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Adapting a brief psychological intervention for pregnant women experiencing depressive symptoms and intimate partnerviolence in rural Ethiopia

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Adapting a brief psychological
intervention for pregnant women
experiencing depressive symptoms
and intimate partner violence in
rural Ethiopia

Thesis submitted for the degree of
Doctor of Philosophy in
Health Services and Population Research

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Dissemination of findings

Peer-reviewed publications

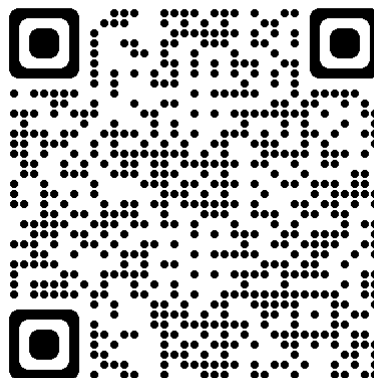
Keynejad, R. C., Hanlon, C., & Howard, L. M. (2020). Psychological interventions for common mental disorders in women experiencing intimate partner violence in low-income and middle-income countries: a systematic review and meta-analysis. *The Lancet Psychiatry*, 7(2), 173-190.

Keynejad, R. C., Bitew, T., Sorsdahl, K., Myers, B., Honikman, S., Medhin, G., Deyessa, N., Sevdalis, N., Tol, W. A., Howard, L. (2020). Problem solving therapy (PST) tailored for intimate partner violence (IPV) versus standard PST and enhanced usual care for pregnant women experiencing IPV in rural Ethiopia: protocol for a randomised controlled feasibility trial. *Trials*, 21, 1-15.

Open access research documents

Where referenced throughout this thesis, PDF files of study documents, including information sheets, consent forms and standard operating procedures, have been uploaded to a dedicated open access repository on the open science framework (OSF) website:

Keynejad, R.C. (2021). PhD open access documents. Available from: <https://osf.io/762zq/> or the following QR code:



Cross-references to other sections of this thesis are hyperlinked and can be followed by clicking on the link.

Table of abbreviations

AAU	Addis Ababa University
AE	Adverse event
AIDS	Acquired immunodeficiency syndrome
ANC	Antenatal care
aOR	Adjusted odds ratio
aRR	Adjusted relative risk
ASSET	Health system strengthening in sub-Saharan Africa study
BA	Behavioural activation
BATD	BA treatment for depression
CAP	Counselling for alcohol problems
CAPS	Clinician-administered PTSD scale
CBT	Cognitive behavioural therapy
CDT-Africa	Centre for innovative drug development and therapeutic trials for Africa
CETA	Common elements treatment approach
CIDI	Composite individual diagnostic interview
DC-HOPE	Washington DC healthy outcomes of pregnancy expectations
DSM	Diagnostic and statistical manual of mental disorders
dSMD	Difference between standardised mean differences
CHAMP	Checklist for the appraisal of moderators and predictors
CHW	Community health worker
CI	Confidence interval
CIA	Central intelligence agency
CICI	Context and implementation of complex interventions framework

CMD	Common mental disorder
CMHW	Community mental health worker
CONSORT	Consolidated standards of reporting trials
COVID-19	Coronavirus disease caused by the SARS-CoV-2 virus. Also refers to the global pandemic time period, which began in 2019 and is continuing at the time of submission.
CPA	Community psychosocial assistant
CPT	Cognitive processing therapy
CRC	Caring, respectful and compassionate (care)
CSRI	Client service receipt inventory
CTS	Conflict tactics scale
EMDR	Eye movement desensitisation reprogramming
ENACT	Enhancing assessment of common therapeutic factors scale
EPDS	Edinburgh postnatal depression scale
EUC	Enhanced usual care
FB	Friendship bench
FRAME	Framework for reporting adaptations and modifications – expanded
GAD-7	Generalised anxiety disorder scale
GCP	Good clinical practice
GHQ-12	General health questionnaire
GII	Gender inequality index
GNI	Gross national income
HAP	Healthy activity program
HEW	Health extension worker
HDI	Human development index
HICs	High-income countries

HIV	Human immunodeficiency virus
HSCL-25	Hopkins symptom checklist
HTQ	Harvard trauma questionnaire
HW	Health worker
HW _x , where <i>x</i> is an integer	An antenatal care health worker participant in Study Two
IAPT	Improving access to psychological therapies
IPT	Interpersonal psychotherapy
IPV	Intimate partner violence
IQR	Interquartile range
KCL	King's College London
LEC	Life events checklist
LHW	Lady health worker
LMICs	Low and middle-income countries
LTE	List of threatening experiences
MCC	Motivated, competent and compassionate (health workforce)
mhGAP	Mental health gap action programme
mhGAP-HIG	mhGAP humanitarian intervention guide
mhGAP-IG	mhGAP intervention guide
MI	Motivational interviewing
MI-PST	Motivational interviewing combined with problem-solving therapy
MINI	Mini international neuropsychiatric interview
MNS	Mental, neurological and substance use (disorders)
MRC	Medical Research Council
N/A	Not applicable
NET	Narrative exposure therapy

NGL	Non-graphic language (IPV questions)
NHS	National health service
NGO	Non-governmental organisation
NIHR	National Institute for Health Research
ODK	Open data kit
OR	Odds ratio
OSSS	Oslo social support scale
PACK	Practical approach to care kit
PACTR	Pan-African clinical trials registry
PCL-5	PTSD checklist for DSM-5
PCL-C	PTSD checklist – civilian version
PHC	Primary healthcare
PHCG	PHC clinical guidelines
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
P_x , where x is an integer	A pregnant woman participant in Study Two
RCI	Reliable change index
RR	Relative risk
SAE	Serious adverse event
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SH+	Self-help plus
SMD	Standardised mean difference
SMI	Severe mental illness
PTSD	Post-traumatic stress disorder
RA	Research assistant
SNNPR	Southern Nations, Nationalities and People's Region

SOP	Standard operating procedure
SPIRIT	Standard protocol items: recommendations for interventional trials
SRQ-20	Self-reporting questionnaire
SSQ-14	Shona symptom questionnaire
STARI	Standards for reporting implementation studies
TAU	Treatment as usual
TC	Trial coordinator
THP	Thinking healthy program
THPP	THP – peers
TIDieR	Template for intervention description and replication
TM	Teachable moment (intervention)
ToC	Theory of change
TPLF	Tigray people’s liberation front
UK	United Kingdom
UN	United nations
UNDP	United nations development programme
USA	United States of America
VAW	Violence against women
WDA	Women’s development army
WHO	World health organization
WHODAS	WHO disability assessment schedule

Lay summary

Mental health problems are common in pregnancy and linked to worse health and even death among women and babies. It is known that people experiencing mental health problems are at higher risk of abuse by their partner or ex-partner, and that people experiencing partner or ex-partner abuse are at a higher risk of mental health problems. In Ethiopia, more than two thirds of women who have ever had a partner, have experienced abuse by them, and abuse may be even more common in pregnancy. Studies have shown that short talking therapies can work to improve depression and anxiety in low and middle-income countries. However, studies often do not consider the effects on pregnant women or women being abused by their partner or ex-partner. Pregnancy care is a good time to study mental health treatments for women experiencing abuse, because it can be some women's only chance of getting healthcare.

This PhD reviewed previous research to find out if women in low and middle-income countries who were experiencing abuse by their partner responded differently to women not experiencing abuse, to short talking therapies. Detailed interviews were then done with 16 pregnant women and 12 pregnancy care workers in Ethiopia, to find out their views. A type of talking therapy called problem-solving therapy was then carefully modified to meet the needs of pregnant women experiencing partner abuse in Ethiopia. Finally, this treatment was provided to 25 pregnant women (allocated at random) experiencing partner abuse in Ethiopia, and compared with the same talking therapy, which had not been modified for women experiencing partner abuse (provided to 12 women), and a leaflet and information about available support (provided to 15 women).

The first study found that in previous research, women experiencing partner abuse in low and middle-income countries benefitted at least as much as women not experiencing abuse from short talking therapies. In particular, their anxiety got even better than it did in women not reporting partner abuse. The second study found that pregnant women and health workers in this part of Ethiopia had experience of partner abuse and the way it affects pregnant women's mental health. The people interviewed said that although people often try to help women experiencing partner abuse, they usually encourage women to go back to their abusive partner, making them feel powerless to change their

situation, and making their mental health worse. Pregnant women and health workers said that it would be helpful if short talking therapies were provided as part of pregnancy care, so long as their privacy was always maintained. The third study showed how involving interested people and experts in Ethiopia with a range of views and following guidelines can be used to modify problem-solving therapy to meet the needs of pregnant women experiencing partner abuse. The third study developed a map to explain how this treatment was expected to improve pregnant women's mental health, and also looked at any possible ways that the treatment could cause harm without meaning to. The fourth study showed that problem-solving therapy modified for women experiencing partner abuse could be provided in Ethiopian pregnancy care. Pregnant women accepted the treatment and pregnancy care workers found it possible to provide. The research study approach, which allocated women to different treatments at random, was also accepted by women, pregnancy care workers and researchers, who found it possible to carry out. This study found that research and antenatal care staff needed more training and guidance, to make sure that all planned actions were followed, and that women were spoken to kindly and supportively. Higher than expected numbers of women were identified for this study, showing the need to only enrol small numbers at a time. Attending research appointments after their baby was born was difficult for women, so future studies should organise these before and several month after women give birth.

Overall, this PhD showed that although people often expect it to be difficult to talk about partner abuse and mental health problems, women experiencing them benefit from short talking therapies. Pregnant women and pregnancy care workers think partner abuse and mental health problems are important and think the best treatment should focus on women's problems. Short talking therapies like problem-solving therapy can be modified for the needs of pregnant women experiencing partner abuse in Ethiopia, and a study that randomly allocates them to different treatments can be carried out safely. This PhD identified important changes that should be made to the research design, so that a bigger, future study, is carried out in an even more effective way.

Abstract

Mental health conditions are common during the perinatal period, and associated with maternal, foetal, and neonatal morbidity and mortality. The prevalence of antenatal depressive symptoms in rural Ethiopia is estimated to be 12-29%. There is an established bidirectional relationship between mental ill-health and intimate partner violence (IPV), including during and after pregnancy. The lifetime prevalence of IPV exposure among women in rural Ethiopia is as high as 72% and may be even higher during the perinatal period. Although a growing literature demonstrates the efficacy of brief psychological interventions for the treatment of common mental disorders (CMDs), including clinically relevant depressive, anxiety, and post-traumatic stress disorder (PTSD) symptoms, in low and middle-income countries (LMICs), few measure or examine the impact on pregnant women, or women experiencing IPV, especially in rural, low-income country settings. Pregnancy is the commonest time for Ethiopian women to access healthcare, making antenatal care (ANC) an important opportunity for interventions that address the mental health impacts of IPV.

The aims of this PhD were as follows. (1) To test the hypothesis that IPV exposure moderates the efficacy of psychological interventions for CMDs in LMICs, with IPV exposure associated with lower treatment effects (Study One). (2) To explore the perspectives of women and ANC staff on perinatal emotional difficulties, IPV, and features of an acceptable intervention in rural Ethiopia (Study Two). (3) To adapt a brief psychological intervention for the perinatal emotional difficulties of women experiencing IPV in rural Ethiopia (Study Three). (4) To evaluate the feasibility of the adapted intervention and a randomised, controlled study design (Studies Four and Five).

In Study One, I conducted a systematic review and meta-analysis of randomised controlled trials of psychological interventions conducted in LMICs, which measured IPV exposure among women participants. Study Two comprised in-depth qualitative interviews with 16 pregnant women and 12 members of ANC staff in Sodo, Ethiopia, analysed using thematic analysis. Interviews explored participants' experiences of perinatal emotional difficulties and IPV, to inform the adaptation of a brief psychological intervention and its implementation strategies, for this context. In Study Three, I

identified the psychological intervention model best suited to addressing the findings of Studies One and Two. I then followed the latest guidance to adapt problem-solving therapy (PST) for the perinatal emotional difficulties of women experiencing IPV in Sodo (PST-IPV), including devising a theory of change and corresponding ‘dark logic model’, to capture potential unintended adverse impacts. In Study Four, I developed the protocol for a randomised, controlled feasibility trial, comparing PST-IPV with standard PST (not adapted for women experiencing IPV), and enhanced usual care (EUC). In Study Five, I analysed the results for the 52 participants randomised to PST-IPV (n=25), standard PST (n=12), and EUC (n=15).

Study One found, contrary to my hypothesis, that women disclosing IPV benefitted more from psychological interventions for CMDs than women who did not, in LMICs. This effect was particularly evident for anxiety symptoms (difference between standardised mean differences (dSMD)=0.31, CI: 0.04, 0.57), with a similar but non-significant effect of IPV exposure on reductions in PTSD (dSMD=0.14, CI: -0.06, 0.33), depressive symptoms (dSMD=0.10, CI: -0.04, 0.25), and psychological distress (dSMD=0.07, CI: -0.05, 0.18). Study Two found that abusive treatment, emotional and bodily distress were widespread in Sodo, and that women and health workers were familiar with the relationship between them. Participants contextualised IPV as the primary form of abusive treatment women experienced, connected by multiple pathways to emotional and bodily distress. Patriarchal norms explained how the actions of neighbours, family, community leaders, law enforcement, and government agents in response to IPV often reinforced women’s experiences of abuse. This created a sense of powerlessness, exacerbated by the tension between high cultural expectations of reciprocal generosity and severe deprivation. Participants advocated an ANC intervention with a problem-solving focus, addressing women’s powerlessness, but they also identified intrinsic benefits of unburdening oneself and being listened to. Women and health workers made a range of recommendations, including prioritising confidentiality, building women’s trust in ANC staff, and raising community awareness about the adverse effects of IPV. Study Three found that a model of brief PST developed in South Africa was best suited to the findings of Studies One and Two. I adapted the delivery format in line with women’s prioritisation of confidentiality and brevity. I adapted the ‘surface’ of treatment delivery via translation, culturally congruent examples, locally relevant illustrations,

conceptual simplification, removal of incongruent elements, developing an in-session flip-chart resource, and accommodation of non-biomedical explanatory models of distress. Adaptations for pregnant women in this context included integration into routine ANC appointments and adding relaxation techniques. Adaptations for the needs of women experiencing IPV comprised basic training on responding to IPV disclosures, based on international guidance, incorporating anonymised local women's IPV testimonies from Study Two, practice applying the PST model to IPV-related problems, clear guidance on how to manage IPV-related problems throughout the manual and training course, and safeguards for responding to IPV-related risks. The theory of change identified short, medium, and long-term outcomes required to achieve PST-IPV's desired impact, and the evidence and experience-informed actions required to achieve each step. It also articulated underlying assumptions and progress markers. Studies Four and Five found that attending four sessions of PST-IPV, and implementing a randomised, controlled study design, comparing PST-IPV with active and inactive arms, was acceptable to women and health workers, and feasible in Sodo. Evidence included a recruitment rate of 10 participants per week across two sites, 76% of participants randomised to PST-IPV completing four sessions, and 24% dropping out, usually due to moving away or postnatal confinement. Staggering recruitment in line with therapist availability to address the high recruitment rate, focusing therapist training on communication skills, automating randomisation decisions, training supervisors using a cascade model, and conducting immediate and longer-term outcome assessments were recommended adjustments.

This PhD concluded that: (1) IPV exposure does not reduce the efficacy of psychological interventions for CMDs in LMICs. (2) Women and ANC staff in rural Ethiopia perceive multiple, interconnected pathways between perinatal emotional difficulties and IPV, for which brief psychological interventions are acceptable. (3) Brief PST can be adapted for pregnant women experiencing IPV by reviewing the context in depth, following recent adaptation guidance, and developing a theory of change with stakeholders. (4) PST-IPV and the randomised, controlled study design are acceptable to women and ANC staff, and feasible to implement. (5) Study Four's design requires adjustment for a future, fully-powered RCT. Limitations included the lack of available data from 29% of eligible papers in Study One, the inability to conduct member checking for Studies Two and Three,

weakening of statistical power to detect between-arms differences in Study Four, due to a protocol deviation, and delays to qualitative interviews with Study Four stakeholders, caused by the coronavirus pandemic.

COVID-19 impact statement

The global pandemic of SARS-CoV-2 infection impacted the conduct of Studies Four and Five of this PhD. The start of the randomised, controlled feasibility trial of the brief psychological intervention adapted in Study Three, informed by the results of Studies One and Two, was delayed by the pandemic. Intervention training, recruitment of participants, and the timely delivery of all components of the standard operating procedure were disrupted by the need to follow COVID-19 precautions in Ethiopia. International travel restrictions and university travel policies prevented my in-person attendance at training courses and my planned delivery of dissemination events in rural Sodo. Delayed initiation of Studies Four and Five meant that full process evaluation data (qualitative interviews requiring translation from Amharic into English) could not be analysed and presented in this thesis, within the timeframe of this PhD. These data will be analysed and written up in the future publication of Studies Four and Five.

Personal contribution to the research

I conducted Study One, with input from two independent reviewers, as described in the methods section of Chapter 3, and statistics advice from two professional statisticians.

I devised and led all components of Study Two, but in-depth qualitative interviews were conducted in Amharic, by research assistants based at Addis Ababa University.

I devised and led all components of Studies Three and Four, but aspects of this work included collaborative activities (such as theory of change workshops) with a post-doctoral researcher colleague based at Addis Ababa University, as described in Chapters 6 and 7.

I conducted Study Five, with input from a professional statistician.

I conducted all five studies with the support and guidance of my first supervisor, Dr Charlotte Hanlon, and second supervisor, Professor Louise Howard. My research assistant (Adiyam Mulushoa) and trial coordinator (Eshcolewyine Fekadu) played important roles in the conduct of Studies Four and Five, as described in Chapters 6 and 7. Individuals who contributed to specific studies are named in the Acknowledgements section.

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1 THESIS OVERVIEW

This PhD followed the first two phases of the new Medical Research Council (MRC) and National Institute for Health Research (NIHR) framework for developing and evaluating complex interventions (Skivington et al., 2021; see Figure 2.3). First, during intervention development (Studies One, Two, and Three), I identified existing evidence, identified and developed theory, and adapted a brief psychological intervention in light of these steps. Second, I assessed the feasibility and acceptability of the intervention and evaluation design (Studies Four and Five), to inform decisions about progression to the third, post-doctoral, phase (evaluation).

The first and second phases followed the core MRC/NIHR framework elements of considering context, developing and refining programme theory, engaging stakeholders, identifying key uncertainties, and refining the intervention. I collected data pertaining to the final core element (economic considerations), but formal economic analysis was beyond the scope of this PhD. This thesis is divided into five studies and a description of the research study context, preceded by the introduction chapter, and followed by the overall discussion chapter.

1.1 Introduction

The introduction (chapter 2) is divided into three sections. Section One reviews the research background to this PhD, encompassing Ethiopia, perinatal mental health conditions, intimate partner violence (IPV), and mental healthcare in low and middle-income countries (LMICs). Section Two reviews the theoretical frameworks relevant to the PhD's structure and methods. Section Three presents the rationale for study, aims, and research questions.

1.2 Study One

In chapter 3, I report my systematic review and meta-analysis of randomised controlled trials (RCTs) of 14 psychological interventions for common mental disorders (CMDs) in

LMICs, which measured IPV exposure among female participants. Study One synthesises the existing evidence.

1.3 Research study context

In chapter 4, I describe key contextual factors relevant to the research study site of Sodo in rural Ethiopia, addressing the domains prioritised by recent NIHR guidance (Craig et al., 2018).

1.4 Study Two

In chapter 5, I explore women’s experiences of perinatal emotional difficulties and IPV in rural Ethiopia, through in-depth interviews with 16 pregnant women and 12 antenatal care (ANC) staff living in Sodo district, in the Southern Nations, Nationalities and People’s Region. Study Two captures stakeholder perspectives, and identifies barriers to and facilitators of intervention, and suitable implementation strategies.

1.5 Study Three

In chapter 6, I review candidate intervention models, before adapting a brief psychological intervention for this context, following the latest (ADAPT) guidance (Moore et al., 2021), and developing a theory of change.

1.6 Study Four

In chapter 7, I present the protocol of a randomised, controlled feasibility trial and process evaluation, to determine the feasibility and acceptability of the intervention adapted in Study Three. Study Four describes the methods used to test procedures, estimate recruitment and retention, to inform a future, definitive, RCT.

1.7 Study Five

In chapter 8, I present the results of Study Four, and discuss their implications for the third phase of the MRC/NIHR framework (Skivington et al., 2021): evaluation.

1.8 Overall discussion

In the overall discussion (chapter 9), I summarise the key findings of this PhD in relation to my aims and research questions, before synthesising and interpreting the results in terms of the literature. I review the strengths and limitations of this PhD, its implications for theory, research, and practice, before drawing final conclusions.

2 INTRODUCTION

Section One: research background

2.1 Ethiopia

Ethiopia is a landlocked country in the horn of Africa, bordered by Somalia, Kenya, South Sudan, Sudan, Eritrea, and Djibouti (Figure 2.1). At 115 million people, Ethiopia is the second most populous country in the African region (The World Bank, 2020a). Fifty-nine percent of the population is aged under 25 years, and a further 33% are 25 to 54 years old (CIA, 2021).



Figure 2.1 The location of Ethiopia (Google Earth, 2021)

Google Earth images can be used for research, education and non-profit use, under principles of fair use.

Ethiopia is an ethnically and religiously diverse nation. Oromo (35%), Amhara (28%) and Tigray (7%) are the most populous ethnic groups, with the remaining population comprising Sidama (4%), Welaita (3%), Gurage (3%), Somali (3%), Hadiya (2%), Afar

(0.6%), and other ethnic groups (CIA, 2021). The population is 44% Ethiopian Orthodox Christian, 31% Muslim, 23% Protestant, and 0.7% Catholic, with the remaining population observing traditional or other faiths (CIA, 2021).

Ethiopia is classified as a low-income country, having a gross national income (GNI) of \$1,035 or less per capita (The World Bank, 2021a). Although 70% of the population works in agriculture, the service sector contributes a higher proportion of the country's gross domestic product (CIA, 2021). Ethiopia relies on the port of Djibouti for international trade, but there are plans to start trading through two Eritrean ports, following a peace agreement in 2018. Low road coverage and poor road conditions present particular problems for rural populations, whose primary source of income is agriculture (The World Bank, 2021b).

The human development index (HDI) combines life expectancy at birth, mean years of education received by adults aged over 24 years, expected years of education for children starting school, and GNI per person, adjusted for increasing GNI (UNDP, 2021a). Ethiopia ranked 173rd out of 189 countries providing data on the HDI in 2020, influenced by especially low expected and mean years of education (UNDP, 2020a).

The gender inequality index (GII) combines maternal mortality and adolescent birth rates, proportions of women occupying parliamentary seats, relative proportions of male and female adults aged over 24 years with some secondary education, and individuals aged over 14 years participating in the workforce (UNDP, 2020b). Ethiopia also ranked 173rd out of 189 countries providing data on the GII in 2020, influenced by especially low female education and high maternal mortality rates (UNDP, 2021b).

Ethiopia's fertility rate (total births per woman) in 2019 was 4.15, lower than the recorded peak of 7.44 in 1984 (The World Bank, 2021c), and lower than the highest global rate in 2019, of 6.82 in Niger (The World Bank, 2021d). From 2002, the Young Lives longitudinal cohort study researched the experiences of 3,000 Ethiopian young people living in 20 communities (Crivello, Boyden, & Pankhurst, 2019). A nested cohort of 60 children born in 1994 participated in qualitative interviews and group discussions between 12 and 20 years of age, across five localities. The authors described 'ambiguous

agency’: that concerted government efforts to expand girls’ education and eradicate child marriage had not prevented poverty, restrictive gender norms, and “vested familial interests in women’s reproductive capacity” (p. 10) from constraining their life choices.

2.2 Perinatal mental health conditions

Common mental disorders (CMDs) are usually defined as mild to moderate depression, anxiety disorders (such as generalised anxiety disorder), and post-traumatic stress disorder (PTSD). Depression refers to a diagnosis made by a qualified clinician, with reference to diagnostic criteria, such as the World Health Organization’s international classification of diseases (WHO, 2021), or a comprehensive diagnostic interview, such as the mini international neuropsychiatric interview (Sheehan et al., 1998). Depressive symptoms refer to meeting a threshold on a screening instrument, which has been validated against a gold standard assessment in a given population (Hanlon et al., 2015). However, there is considerable heterogeneity in how depression and depressive symptoms are measured and defined, across the literature (Wang et al., 2017). Similar distinctions and methodological differences apply to anxiety disorders and symptoms, clinically diagnosed PTSD and PTSD symptoms. In this thesis, I use terms such as CMD, depression, and depressive symptoms to reflect the terminology used by the referenced authors. CMDs are often distinguished from severe mental illness (SMI), defined as disorders which severely impair the person’s ability to work and function in their daily life, including schizophrenia and bipolar affective disorder (Public Health England, 2018).

Common and severe perinatal mental health conditions are a common complication of pregnancy, associated with maternal, foetal, and neonatal morbidity and mortality (Howard et al., 2014). Psychotic episodes of both established and new-onset bipolar affective disorder and schizophrenia increase during the postpartum period, relative to the antenatal period (Jones, Chandra, Dazzan, & Howard, 2014). Perinatal mental health conditions are directly associated with maternal mortality from suicide and complications of substance use, and indirectly, via higher rates of obstetric complications (Howard & Khalifeh, 2020; WHO, 2008c). An umbrella review found that the pooled odds ratio (OR) of preterm birth was 1.49 (confidence interval (CI): 1.32-1.68; three reviews) and the OR

of low birthweight was 1.39 (CI: 1.22-1.58; three reviews) among women with, compared to women without, antenatal depression (Dadi, Miller, Bisetegn, & Mwanri, 2020). Perinatal depression and prenatal alcohol excess, especially, are associated with future adverse mental health outcomes in children, although drawing conclusions about causality is complicated by reliance on observational studies and potential confounding (Howard & Khalifeh, 2020).

A meta-analysis of the prevalence of perinatal CMDs in low and lower-middle-income countries identified 13 papers (Fisher et al., 2012). Antenatal data were available from nine countries and postnatal data from 17 countries in Africa and Asia. The weighted mean prevalence of any CMD was 15.6% (CI: 15.4-15.9) antenatally and 19.8% (CI: 19.5-20) postnatally. Risk factors for perinatal CMDs included experiencing intimate partner violence (IPV; ORs ranged between 2.11-6.75). These prevalence estimates for CMDs were higher than the 10% reported antenatally (Hendrick, Altshuler, Cohen, & Stowe, 1998) and 13% (CI: 12.3-13.4; 59 studies, n=12,810) postnatally in high-income countries (HICs; O'Hara & Swain, 1996).

A recent meta-analysis of postnatal depression in low and middle-income countries (LMICs) reviewed 58 prevalence studies (63,293 women) and 17 studies of child outcomes (32,454 infants; Dadi, Miller, & Mwanri, 2020). The authors found a higher pooled prevalence of postnatal depression in low-income countries (25.8%; CI: 17.9-33.8) than in middle-income countries (20.8%; CI: 18.4-23.1). The pooled relative risk (RR) of adverse infant health outcomes was 1.31 (CI: 1.17-1.48) among children of women with depression, compared to those women without depression. Common infant illnesses (RR=2.55), malnutrition (RR=1.39), and non-exclusive breastfeeding (RR=1.55) were associated with postnatal depression.

A meta-analysis of 28 studies of antenatal depression in Africa enrolling 17,938 women across ten countries found a pooled prevalence of 26.3% (CI: 22.2-30.4; Dadi, Wolde, Baraki, & Akalu, 2020). Antenatal depression was associated with “unfavourable marital condition” (p. 8), including marital conflict (OR: 4.17, CI: 1.75-9.94). A meta-analysis of postnatal depression in Africa identified 19 studies enrolling 40,953 women across ten countries (Dadi, Akalu, Baraki, & Wolde, 2020). The pooled prevalence was 16.8% (CI:

14.5-19.2) and postnatal depression was associated with IPV exposure (OR: 2.9, CI: 1.6-5.2).

2.2.1 Perinatal depression in Ethiopia

The prevalence of depression in Ethiopia may be higher in pregnant women, compared to the general population. A review which included eight general population studies found a pooled depression prevalence of 11% (CI: 10.4-11.5; Bitew, 2014) in Ethiopia. Depression prevalence was highest among pregnant women, higher among female participants and those with experience of IPV, gender-based violence, or parental violence in childhood. A meta-analysis of eight observational studies conducted in Ethiopia found a pooled prevalence of perinatal depression of 26% (CI: 24.6-27.1; Mersha, Abebe, Sori, & Abegaz, 2018). However, included studies were conducted in both community and healthcare settings, and not all used validated outcome measures.

Two population-based studies have investigated perinatal depression in the Southern Nations, Nationalities and People's Region (SNNPR) of Ethiopia, where my PhD was conducted. Most recently, a population-based prospective study followed up pregnant women living in my study site (Sodo district) at different time points (Bitew, Hanlon, Medhin, & Fekadu, 2019). Using the locally-validated patient health questionnaire (PHQ-9), 356 out of 1240 women (28.7%) screened positive for antenatal depressive symptoms (scoring five or more). Antenatal depressive symptoms persisted into the postpartum period in 138 (38.8%) of these women, while 136 (15.4%) women reported new-onset postnatal depressive symptoms. Symptoms were rated as severe in 274 women (22.1%). Incident depression was associated with IPV during pregnancy (adjusted RR (aRR): 1.06, CI: 1.00-1.12).

Among 1,267 women enrolled in the same study, antenatal depression was associated with higher rates of unscheduled antenatal care (ANC) visits (aRR: 1.41), contacts with traditional practitioners (aRR: 1.64, CI: 1.17-2.31) and health services (aRR: 1.31, CI: 1.04-1.69) for pregnancy-related emergencies (Bitew, Hanlon, Kebede, Medhin, & Fekadu, 2016). In 1,251 women enrolled in this study, antenatal depression was associated with assisted delivery (adjusted OR (aOR): 1.72, CI: 1.10-2.69) and use of

emergency care for delivery (aOR=1.62, CI: 1.09-2.42; Bitew, Hanlon, Kebede, Honikman, Onah, et al., 2017).

An earlier population-based cohort study of 1,065 pregnant women living in Butajira, neighbouring Sodo, found that higher antenatal CMD symptoms (scoring six or more on the self-reporting questionnaire: SRQ-20; n=128: 12.0%) were associated with prolonged labour (RR=1.6; CI: 1.0-2.6) and delayed initiation of breast-feeding (RR=2.8; CI: 1.3-6.1), in a dose-response relationship, compared to no CMD symptoms (Hanlon, Medhin, et al., 2009). Low CMD symptoms (SRQ-20 scores of 1-5) were reported by 634 women (59.5%). Finally, a cross-sectional study of 1,319 women up to two years postpartum, living in the Amhara region, found that 19.8% of women had probable CMD when an SRQ-20 cut-off score of eight or more was used, and 32.8% when a score of five or more was used (Baumgartner et al., 2014).

2.2.2 Perinatal depression in Ethiopia: qualitative evidence

Several qualitative studies have explored women's experiences of antenatal and postnatal distress and depression in the SNNPR, Ethiopia. In the Butajira health and demographic surveillance site, 25 in-depth interviews were conducted with perinatal women, health workers, traditional birth attendants, religious, community, government and non-governmental organisation staff (Hanlon, Whitley, Wondimagegn, Alem, & Prince, 2010). Five focus group discussions were also conducted with perinatal women, their mothers, partners, and traditional birth attendants (n=53). Participants described concerns about childbirth and survival, which they managed with dietary restriction, prayer, rituals, and continuing physical labour during pregnancy. Economic and marital difficulties, short birth intervals and pregnancies outside marriage meant that many pregnancies were unwanted. IPV was commonly discussed; some women attributed worsening IPV during pregnancy to their increased dependence on their partner.

The same study also explored postnatal distress (Hanlon, Whitley, Wondimagegn, Alem, & Prince, 2009). Participants described a shared sociocultural pattern of postnatal confinement, rest and recovery. For between 40 days and three months postpartum, women engaged in a range of traditional practices, and received attention and special

treatment. Participants linked postnatal distress to pressures and expectations of the postpartum period, worsening financial or marital difficulties, and inability to access help due to postnatal confinement. Inability to earn money rendered postpartum women more dependent on partners, increasing the risk of IPV, resulting in distress and suicidal thoughts. Participants also described concerns about ‘spirit attack,’ such as harm or possession by an evil spirit, manifesting as cognitive and behavioural disturbances. Women used postnatal confinement to protect themselves from spirit attack.

In a linked study, 22 perinatal women in the same setting were interviewed (Molenaar et al., 2020). Perinatal mental distress was conceptualised as a non-pathological response to difficulties such as isolation, hopelessness, food poverty and relative poverty in comparison to peers. Five women described being beaten, hit or kicked, of whom several normalised physical IPV in terms of women’s disempowerment. Most women asserted that only a trusted person should be informed about IPV.

Qualitative interviews have also explored antenatal depression in Sodo, with eight pregnant women experiencing depressive symptoms, eight ANC staff (nurses, midwives and health officers), and eight community-based health extension workers (HEWs; Bitew et al., 2020). Pregnant women described somatic manifestations of depression during pregnancy, in terms of exhaustion and headaches. Women and health workers conceptualised depression as “thinking too much” (p. 4) about life difficulties (such as poverty), reproductive health problems (such as miscarriage), uncompassionate care in labour, and marital conflict (including over partners’ alcohol use). Women often coped through spirituality and religion, but social interaction and seeking support from health workers were less common.

In the same study (Bitew et al., 2020), participants identified cultural barriers to attending sessions of a psychological intervention. These included fears of being branded “shameless” (p. 6) for leaving their home late in pregnancy, concern about diseases and spirits encountered outdoors, and being prevented from attending by relatives. Health workers admitted that, despite being trained to use the World Health Organization (WHO)’s mental health gap action programme intervention guide (mhGAP-IG; WHO, 2016a) for detection, assessment and first line management of depression, they did not

routinely assess women for depression. For some, this was because they perceived assessment as burdensome. Most participants advocated delivering sessions individually, to maintain privacy, and integrating interventions into the existing ANC framework. However, Bitew et al. (2020) did not explore the needs and perspectives of women experiencing IPV.

2.2.3 Perinatal mental healthcare in Ethiopia

Ethiopian primary care, including ANC, is delivered through satellite ‘health posts’ staffed by community HEWs, health centres staffed by nurses, midwives and health officers, and primary hospitals. Secondary care is delivered through more centralised hospitals. At the national level, the availability of and investment in mental health services in Ethiopia were previously described as poor (WHO, 2006). Subsequent national mental health strategies (Ministry of Health, 2012, 2021a) have focused on task-shared mental healthcare delivery by non-specialist staff, and integrating mental health into primary care services. In line with ministerial objectives, efforts have been made to scale up the mhGAP-IG (WHO, 2016a). As of 2020, an estimated 26% of health services (including 25% of hospitals) in Ethiopia were providing some form of mental healthcare (p. 17; Ministry of Health, 2021a). However, there was limited integration of the mhGAP-IG into maternal, new-born, and child healthcare services. As part of an effort to address this, the Ministry of Health adapted the South African practical approach to care kit (PACK) for Ethiopia, as the primary healthcare clinical guidelines (PHCG; Feyissa et al., 2019). The Ethiopian PHCG seeks to horizontally integrate mental healthcare, consideration of violence exposure, and risk assessment into primary care-based maternal care.

The second objective of the latest Ethiopian national mental health strategy for 2020-25 is to empower the population to promote mental health (Ministry of Health, 2021a). A sub-objective (2.7, p. 34) is to create favourable maternal, social, economic and environmental conditions for the mental health of children and adolescents. This sub-objective includes key interventions (2.7, p. 34) to integrate mental health into ANC, delivery services, postnatal care, immunisation clinics, and sexual and reproductive health units. Intervention goals include providing counselling for CMDs, increasing detection and improving the response to IPV, promoting safe and secure environments

for women, children and adolescents, ensuring effective responses to IPV and maltreatment, and building the primary care staff capacity to deliver mental healthcare.

2.3 Intimate Partner Violence

WHO recognises violence against women as a major public health concern, of which the majority is IPV (WHO, 2017a).

2.3.1 Definition and prevalence

IPV is behaviour by an intimate partner or ex-partner, which causes physical, sexual or psychological harm. IPV includes physical aggression, sexual coercion, psychological, emotional, financial abuse, and controlling behaviours. Given the expansion of digital technology (Woodlock, 2017), IPV is increasingly perpetrated online, as well as in person. The United Kingdom's (UK) broader definition of domestic violence and abuse also includes abusive behaviour perpetrated by other members of the family, aged 16 years or older (Home Office, 2013). Most research on the perinatal period focuses on IPV. In this thesis, I refer to IPV unless studies specifically reported data pertaining to people experiencing domestic violence and abuse.

Global estimates suggest that around 30% of women who have ever had an intimate partner have experienced IPV (WHO, 2013a). Twenty-nine percent of women and 14% of men living in England and Wales have experienced domestic violence and abuse (Office for National Statistics, 2019). Thirty-six percent of women and 33% of men in a national survey in the United States had experienced IPV during their lifetime (Smith et al., 2018). In Australia, women's lifetime prevalence of physical and/or sexual IPV is 23% (UN Women, 2017). Lifetime IPV prevalence in LMICs appears to be higher than in HICs. The WHO multi-country study of women's health applied standardised instruments and research methods to survey populations across 10 low, middle, and high-income countries (García-Moreno, Jansen, Ellsberg, Heise, & Watts, 2006). This survey of 24,000 women found high prevalence estimates of physical (13-61%), sexual (6-59%), and psychological (20-75%) IPV.

Between March and June 2020, the number of domestic violence and abuse-related police reports in England and Wales increased by seven percent, compared with the same period in 2019 (Office for National Statistics, 2020). The UK national domestic abuse helpline website also received a 700% increase in visits in the second quarter of 2020, compared with the first quarter (Office for National Statistics, 2020). A meta-analysis of 18 empirical studies and 37 estimates (Piquero, Jennings, Jemison, Kaukinen, & Knaul, 2021) found evidence of increased domestic violence during lockdowns (overall mean effect size: 0.66, confidence interval: 0.08-1.24), with stronger effects when only American studies were analysed. Violence against women and girls during COVID-19 (UN Women, 2020) has been described as a “shadow pandemic” (p. 1; Mlambo-Ngcuka, 2020). A UK report stated that the pandemic had been “weaponised” by perpetrators as a new tool of control, and used as an excuse for domestic abuse, and even femicide (p. 8; Bates, Hoeger, Stoneman, & Whitaker, 2021).

2.3.2 Frameworks of IPV

A range of causal explanations has been offered for the occurrence and continuation of IPV (Rothman, 2018). Biological accounts link IPV perpetration to behavioural disinhibition and increased aggression resulting from genetic, hormonal, neurotransmitter and cognitive differences (Ali & Naylor, 2013a). Psychological perspectives propose aetiological roles for mental, personality, substance use and attachment disorders, and individual differences in hostility, self-esteem, assertiveness, and communication skills (Ali & Naylor, 2013a). However, such individual-focused accounts struggle, in isolation, to explain the diversity of people, relationships, and circumstances in which IPV arises and persists, including why some individuals with a given disorder or personality trait do and some do not perpetrate IPV. Feminist theories suggest ways that gender inequality inhibits women’s ability to leave abusive relationships, such as the cycle of violence, learned helplessness, so-called “battered women syndrome”, power and control, and patriarchy (Ali & Naylor, 2013b). Sociological perspectives, such as social learning theory and resource theory, explain IPV by reference to the social contexts and dynamics in which it occurs (Ali & Naylor, 2013b).

While each of these approaches contributed insights into IPV as a phenomenon, a framework was required to capture the multi-level forces driving the widespread occurrence and continuation of IPV in diverse contexts. The integrated ecological framework (Heise, 1998) gained prominence for its ability to capture the real-world interplay between individual, situational, and sociocultural factors. Conveying the complexity of violence with intuitive simplicity, the integrated ecological model was adopted by the WHO (Krug, Dahlberg, Mercy, Zwi, & Lozano, 2002).

Labels describing the levels of the integrated ecological framework varied, but different versions shared recognition of distinct personal, microsystem (immediate contextual), exosystem (institutional, social structural), and macrosystem (wider cultural) levels (Heise, 1998). As shown in Figure 2.2, the framework was revised to reflect evidence-based risk factors for IPV victimisation and perpetration in LMICs (Heise, 2011). The levels were divided into conflict arena, relationship, male partner, woman, community, and macrosocial levels, reflecting the evidence base. Identified risk factors for women experiencing IPV were childhood violence, attitudes (such as tolerance of IPV), and low social support. Risk factors for men perpetrating IPV were violence in childhood, attitudes (such as acceptance of IPV), excess alcohol use, conflict about gender roles, association with delinquent peers, and sociodemographic factors. Relationship risk factors pertained to the nature of partners' interactions (such as unequal decision making). Established triggers associated with the conflict arena were divided into situational triggers (such as men's alcohol use), and patriarchal triggers (such as (perceived) challenges to men's authority by women). Evidence-based community risk factors comprised norms, lack of sanctions, and neighbourhood factors. Macrosocial factors were gender order, cultural factors, and economic factors.

Heise (2011) identified childhood violence exposure, patriarchal norms and structures, alcohol use, poverty-related stress, and poor relationship communication as having the most robust evidence as risk factors for IPV perpetration. Macrosocial factors of societal militarisation, active conflict, war or displacement, and instability of nation states (p. 9) were not included in the model, due to insufficient evidence. Women's employment, participation in credit or development schemes, and ownership of assets were associated with both increased and decreased IPV in different settings.

Some researchers argued that the revised ecological model should go further, to incorporate the influence of globalisation on IPV. Drawing on research in the Maldives and Cambodia, Fulu and Miedema (2015) suggested that global ideologies, economic integration, religious fundamentalism, and global cultural exchange are candidate global risk factors for IPV, which should be included in the revised model. They raised women's rights and democracy as global ideologies which may foster gender equality or entrench patriarchal norms, depending on the context. They highlighted differential impacts of financially-motivated migration and changes in financial decision-making power as examples of economic integration influencing IPV. Fulu and Miedema (2015) pointed to increasing adoption of veiling in the Maldives as evidence of growth in religious fundamentalism, potentially affecting women's roles in public life, access to divorce, and male dominance in families. Finally, they raised cultural globalisation by television, film and online media as sources which may simultaneously glorify "violent masculinities" (p. 1447) and promote gender equality, with the potential to provoke reactionary IPV.

A recent review of the drivers of IPV perpetration (Gibbs et al., 2020) was informed by the six year 'what works to prevent violence against women and girls?' global programme. It found that structural factors (poverty, gender inequality, and normalisation of violence in social relationships) interact with individual and relationship factors (poor communication, poor mental health, substance abuse, child maltreatment, and disability) to drive IPV, exacerbated by armed conflict and post-conflict conditions.

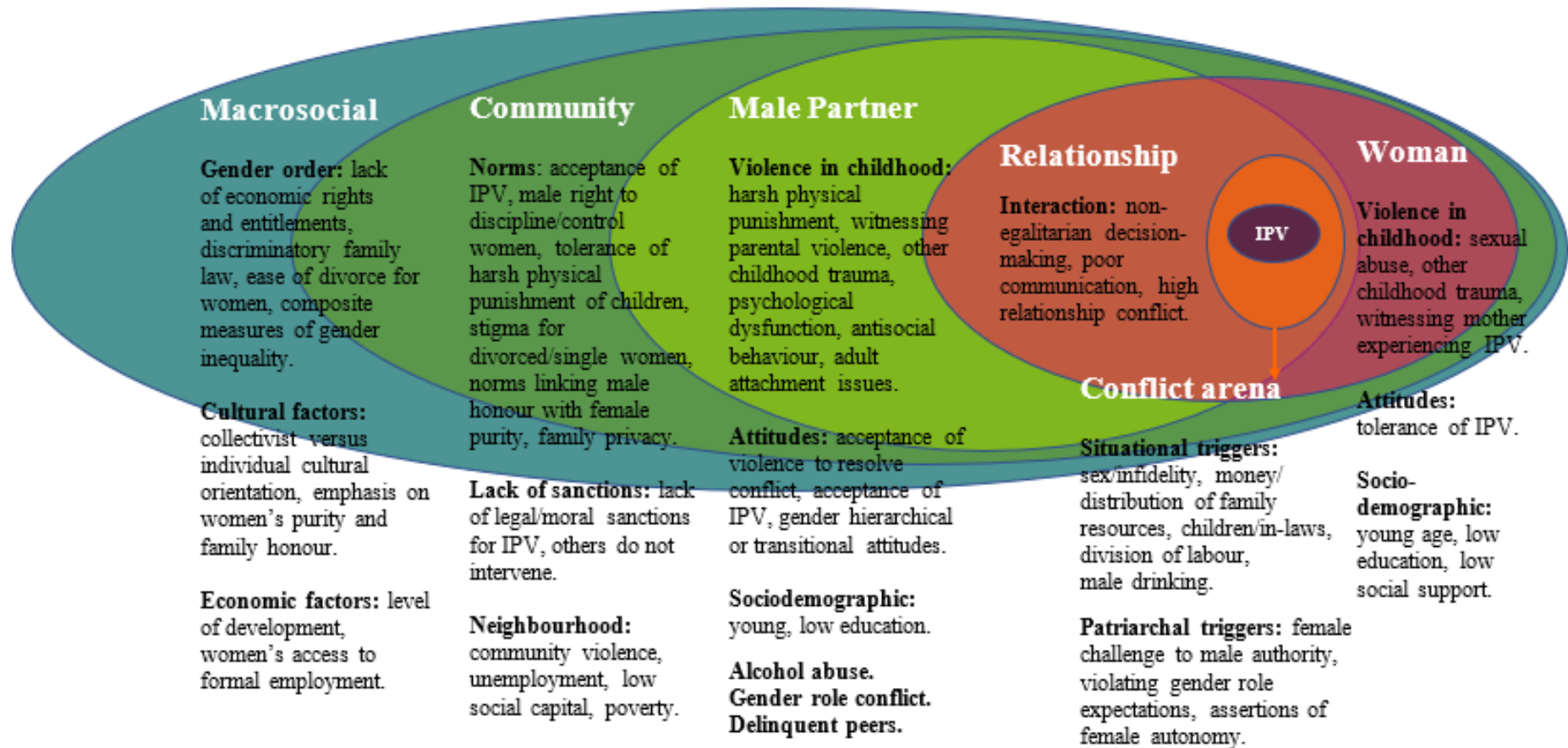


Figure 2.2 The revised ecological framework for IPV, adapted from Heise (2011)

The original integrated ecological framework (Heise, 1998) was revised in line with new evidence from LMICs. Women's employment, participation in credit schemes and development programmes, and asset ownership were noted to act as both risk and protective factors in different settings.

2.3.3 IPV in Ethiopia

The lifetime prevalence of IPV exposure among women in rural Ethiopia is as high as 72% (Deyessa et al., 2009). A systematic review of 10 studies found a mean lifetime prevalence of any IPV in Ethiopia of 61% (Semahegn & Mengistie, 2015). Mean lifetime prevalence of IPV sub-types was 48% for physical IPV, 40% for sexual IPV, and 52% for emotional IPV. IPV perpetration was associated with alcohol and khat¹ use, a family history of violence, women's educational and occupational status, and rural residence.

A cross-sectional study of 510 women living in the Oromia region who had ever had a partner found that 48% had experienced IPV in their lifetime (Tadegge, 2008). A lifetime history of physical (OR: 3.8, CI: 2.2-5.3) or sexual IPV (OR: 3.8, CI: 2.5-5.9) was associated with current mental distress. Additionally, lifetime IPV was associated with depression (OR: 2.8, CI: 1.3-5.9), after adjusting for age, education and excess alcohol use. Suicidal ideation was also associated with sexual (OR: 3.1, CI: 1.1-8.8) and emotional abuse (OR: 3.4, CI: 1.1-10.7).

A prospective cohort study followed up the children of women in Butajira, born within one year of their mothers participating in the WHO multi-country study on women's health and life events (Deyessa et al., 2010). Meeting criteria for diagnosis of maternal depression on the Composite International Diagnostic Interview (CIDI), but not IPV alone, was associated with an increased risk of child mortality (RR=2.3, CI: 1.0-4.9). The children of women experiencing both depression and physical IPV (RR=4.0, CI: 1.6-10.1) or emotional IPV (RR=3.7, CI: 1.3-10.4) had even higher child mortality. The use of CIDI to formally diagnose depression meant that participants in this study were likely to have experienced more severe symptoms than in studies which used screening questionnaires.

A global literature review, which included 23 studies, found that justification of IPV by members of the public was widespread (Waltermaurer, 2012). Considering IPV to be justifiable in certain circumstances was associated with younger age, female gender,

¹ *Catha edulis*, a plant whose leaves are chewed as a stimulant in countries bordering the Red Sea (Cox & Ramples, 2003).

lower education, poverty and rural residence, across 17 sub-Saharan African countries, including Ethiopia (Uthman, Lawoko, & Moradi, 2009). However, a study examining data from 16,515 Ethiopian women who participated in the 2011 demographic and health survey found that they were more likely to report that IPV was justifiable when women were present during the interview, than when men were present (Trott, Harman, & Kaufman, 2017). The authors highlighted unanswered questions about whether women were describing reality: that IPV was justified by their community, or whether strong patriarchal norms prevented women from condemning IPV.

A recent study analysed data collected by the 2016 demographic and health survey from 4,469 Ethiopian women (Ebrahim & Atteraya, 2021). The authors found that particularly low proportions of women sought formal help for IPV: 3.8% for physical IPV, and 4.4% for sexual IPV. Informal help-seeking from family was associated with emotional (OR: 2.42, CI: 1.29-4.55), but not physical or sexual violence exposure. These results were surprising, given the evidence that IPV is often normalised (Uthman et al., 2009). The authors hypothesised that emotional abuse might be perceived as less shameful to disclose than physical or sexual IPV. However, attention is needed to participants' comprehension and data collectors' sensitivity when asking about IPV in large-scale surveys (Trott et al., 2017).

Efforts to achieve the millennium development goals led to some improvements in gender equality in Ethiopia, in terms of girls' attendance at primary education, women's formal employment, and representation in parliament (Gebru & Demeke, 2014). However, patriarchal sociocultural norms, attitudes and practices are persistent barriers to gender equality. A recent qualitative study reviewed legal frameworks protecting Ethiopian women and girls from gender-based violence (Salemot & Birhanu, 2021). The authors concluded that existing gender-relevant legislation provides inadequate civil remedies to protect women, with no specific domestic violence act. In addition, Ethiopian criminal law lacks sufficient criminal liability for IPV perpetration, with no definition of violence against women or recognition of economic abuse (Fite, 2014). Fite (2014) also noted that no national bodies or authorities hold responsibility to protect women, report or respond to incidents of IPV.

2.3.4 IPV in Ethiopia: qualitative evidence

Three qualitative studies have explored IPV in Ethiopia with community stakeholders, predominantly members of the community involved in responding to IPV. In Gondar, northwest Ethiopia, a qualitative study conducted five in-depth interviews and six focus group discussions with 46 participants (Yigzaw, Berhane, Deyessa, & Kaba, 2010). Participants included two women with experience of IPV and one male perpetrator, family arbitrators, religious leaders, health workers, police officers, and researchers. They were familiar with IPV, characterising it as “an expression of male dominance” (p. 41). Some participants described severe violence, such as burning, breaking a woman’s teeth with a stone, and deliberately infecting a woman with human immunodeficiency virus (HIV). Withholding of money was experienced by women as “tormenting” (p. 41) and raised by a judge as a commoner reason for divorce, in addition to men selling property without discussion, than physical IPV. Infidelity and abandonment by partners, even when violent, was a source of distress. Participants justified men finding a new partner because of women ageing, which they perceived to be exacerbated by motherhood and domestic labour. Participants stated that IPV is unacceptable, but on probing legitimised it, because disagreements were considered to be normal. Some male and female participants spoke positively about IPV: “if he hated me, he would not talk to me, let alone beat me” (p. 42) or justified it: “he is expected to beat, punish, correct, and put his wife on the right track” (p. 42). Male participants questioned the notion of marital rape. Some female participants felt that rape was not the right word or thought that not wanting to have sex was not a good reason to refuse. Christian and Muslim teachings were used to discourage women from declining sex with their husbands. The impact of psychological IPV was minimised by some participants, as “words would not hurt a woman” (p. 43). “Psychological trauma” (p. 43) and harm to “a woman’s psyche” (p. 43) by IPV were raised once, without elaboration. A perpetrator admitted to selecting insults “that he knew would wound his wife’s morale” (p. 43). Divorce was discouraged because of stigma, the difficulty of remarrying, women’s economic dependence, and the welfare of children. Yigzaw et al. (2010) highlighted the fine line drawn by participants between acceptable marital conflict and IPV, depending on perceived severity (evidenced by injuries or use of weapons) and reasonableness (association with a verifiable cause).

A second qualitative study (Abeya, Afework, & Yalew, 2012) conducted 12 focus group discussions with 60 women and 55 men in one urban and four rural districts of East Wollega zone, western Ethiopia. Extra-marital sex, suspected infidelity, “failure to give birth” (p. 4), disobedience, recurrent disagreement with her partner or neighbours, and assertive “controlling and non-domestic” behaviour (p. 4) were reasons for which IPV was considered justifiable. Scriptural passages and idiomatic expressions were used to emphasise women’s inferiority and reinforce dehumanising gender norms. For example, “we do not find wise women” (p. 7), “a stick breaks only a clay pot” (p. 4) and “mothers’ womb is like a container” (p. 4) were used to justify controlling women through IPV. Participants considered IPV in the context of recurrent alcohol use, adultery, or minor grievances to be unacceptable. Excluding men from the cultural practice of *idir*² was one community action proposed for punishing abusive men. This would only be pursued, however, if the woman was confirmed to have “fulfilled the expectations of the husband/partner and the community” (p. 5). Four options available to women were tolerance, leaving home (usually, temporarily), and, rarely, self-defence and seeking help. However, sources of help were themselves subject to unequal gender norms, with all-male arbitration panels encouraging women to withdraw legal cases, and courts requiring three witness accounts and a medical certificate to convict men accused of IPV.

The third qualitative study conducted 10 in-depth interviews and three focus group discussions in Debre Tabor, northwest Ethiopia (Muche, Adekunle, & Arowojolu, 2017). Thirty participants comprised married women with experience of IPV, relatives of women experiencing IPV, female family arbitrators, including religious leaders, health workers, women’s affairs officials, a judge, and a police officer. Many participants expressed that IPV is a private matter indicating love between partners, and most questioned the concept of marital rape. They also described sexual coercion within households, such as by step-fathers and step-sons. Women expressed the need to tolerate IPV because they perceived marriage as a means to overcome poverty. The view that physical IPV is an expression of love was also stated. One woman described how her husband began asking her for oral and anal sex after starting to watch pornography, before starting to spit on and beat her.

² Neighbourhood associations raising funds for emergency expenses, such as funerals (Bekerie, 2003).

A former commercial sex worker described often being beaten after sex, demonstrating a common link between sex and violence within and outside relationships. This link may have related to the expressed view that men should initiate sex, because women do not openly express desire. The authors themselves attributed the severity of IPV to women's "failure" (p.107) to disclose it, suggesting a cycle of blame which sites responsibility for IPV within women.

Two further qualitative interview studies explored IPV, specifically during pregnancy, in Jimma, western Ethiopia. The first conducted in-depth interviews with 16 community stakeholders, of whom six (38%) were female (Gashaw, Magnus, Scheib, & Solbraekken, 2019). Participants comprised seven police officers, judges and prosecutors, seven religious leaders, and two women's affairs office staff. The study was limited by the fact that most participants declined to be audio-recorded, so content analysis was based on translations of handwritten notes. Themes were reconciliation, reluctance to involve the police, limited awareness of the consequences of IPV during pregnancy, and the lack of a coordinated response. Participants interacted with dozens of women experiencing IPV each month. Adverse consequences of divorce were regularly cited, to justify reconciliation and discourage reporting IPV to the police. Consequences of divorce for women included poverty, loss of community respect, and stigmatisation of her children. Participants concurred that there was no network for supporting women experiencing IPV. Two women's affairs office representatives cited male infidelity during pregnancy as a factor causing IPV. These staff reported obstruction from performing their roles by court authorities and being threatened by abusive partners. Religious leaders did not refer women for support, but focused on reconciliation, with reference to scripture.

The second qualitative study of IPV during pregnancy in Ethiopia conducted 10 semi-structured interviews with ANC health workers in Jimma (Gashaw, Schei, Solbraekke, & Magnus, 2020). Again, analysis relied on written notes, because most participants did not wish to be audio-recorded. ANC staff were familiar with adverse physical health and obstetric complications of IPV during pregnancy, including miscarriage, stillbirth, and maternal death. However, they did not discuss psychological abuse or the perinatal mental health impacts of IPV. Health workers did not ask women about IPV due to their perceived lack of knowledge, skills, and guidelines for responding appropriately, and

managing the emotional difficulties associated with disclosure. They also considered IPV to be outside the remit of their healthcare roles. ANC staff encouraged women to reconcile with abusive partners, and offered to mediate between them, due to women being financially dependent. They noted the absence of direct referral pathways between ANC and organisations that could support pregnant women experiencing IPV. Reporting IPV to the authorities was perceived as unhelpful, with police encouraging reconciliation, and health workers concerned about exacerbating abuse. Health workers recommended government prioritisation, IPV screening tools and guidelines, health worker training, public awareness raising, women's empowerment, education, employment, and income generating activities.

One study interviewed 15 women experiencing IPV alongside the disabling lymphoedematous disorder, podoconiosis, in Gojjam, northwest Ethiopia (Girmay Tsegay et al., 2018). Women reported that worsening of their symptoms and disability was associated with more frequent and severe IPV, or a transition from physical to psychological and financial abuse. IPV was in turn associated with worsening of podoconiosis, reinforcing women's entrapment by abusive partners.

2.3.5 Prevalence of IPV in pregnancy

The WHO multi-country study found that physical IPV prevalence during pregnancy ranged from 1% in urban Japan to 28% in provincial Peru, but ranged from 4 to 12% in most sites (García-Moreno, Jansen, Ellsberg, Heise, & Watts, 2005). A meta-analysis of 92 studies conducted during pregnancy found an average reported prevalence of 28% for emotional IPV, 14% for physical IPV and 8% for sexual IPV (James, Brody, Hamilton, & victims, 2013). A meta-analysis of studies from African countries found high heterogeneity of reported IPV prevalence during pregnancy (Shamu, Abrahams, Temmerman, Musekiwa, & Zarowsky, 2011). Prevalence ranged between two and 49% in Nigerian studies, for example, but the overall prevalence was 15% across 13 studies. A meta-analysis of IPV during pregnancy in Ethiopia identified eight studies enrolling 2,691 women (Alebel et al., 2018). The pooled prevalence of IPV during pregnancy was 26% (CI: 20-32).

In the 55 studies reporting risk factors in James et al. (2013)'s meta-analysis, abuse preceding pregnancy and lower education of women strongly predicted IPV during pregnancy. Lower socio-economic status, being unmarried and 'unintended' abuse moderately predicted IPV during pregnancy. In Shamu et al. (2011)'s meta-analysis, five studies found a significant association between testing positive for HIV and experiencing IPV during pregnancy (OR: 1.48-3.10), after adjusting for confounders; two studies reported no association. Alcohol use by partners (OR: 2.52-4.10) and women (OR: 4.59-11.60) was significantly associated with IPV during pregnancy in the five Nigerian, South African and Rwandan studies examining this relationship. Seven studies reported associations between IPV during pregnancy and prior abuse. In Alebel et al. (2018)'s meta-analysis, low education of the woman (OR: 2.1, CI: 1.1-3.7) and partner (OR: 3.5, CI: 1.4-8.5), and partner alcohol use (OR: 11.4, CI: 2.3-56.6) were risk factors for IPV during pregnancy in Ethiopia.

2.3.6 Health impacts of IPV in pregnancy

IPV during pregnancy is associated with a range of adverse health outcomes (WHO, 2011). Non-fatal outcomes include physical and mental disorders, injuries, reproductive and sexual health problems, and adverse health behaviours. Fatal outcomes of IPV during pregnancy are femicide/homicide and suicide.

IPV causes non-fatal injuries and illnesses, directly and indirectly. The WHO multi-country study found significant associations between lifetime IPV and self-reported poor health (OR: 1.6), emotional distress, suicidal thoughts (OR: 2.9), and suicide attempts (Ellsberg, Jansen, Heise, Watts, & García-Moreno, 2008). Lifetime experience of IPV was associated with pain (OR: 1.6), dizziness (OR: 1.7), memory loss (OR: 1.8), vaginal discharge (OR: 1.8), difficulty walking (OR: 1.6), and difficulty with daily activities (OR: 1.6) in the past month.

IPV during pregnancy is also a risk factor for femicide (Campbell et al., 2003). A USA national violent death reporting system study of women of reproductive age between 2003 and 2007 found suicide and femicide rates during pregnancy of 2.0 and 2.9 per 100,000 live births, respectively (Palladino, Singh, Campbell, Flynn, & Gold, 2011). Fifty-four

percent of perinatal suicides were associated with intimate partner conflict, and 45% of perinatal femicides were associated with IPV.

Large observational studies (Cheng, Salimi, Terplan, & Chisolm, 2015) and meta-analyses (Crane, Hawes, & Weinberger, 2013) have shown that the risk of smoking during pregnancy is greater for women experiencing IPV than women not experiencing IPV. Smaller studies suggest elevated alcohol (Flynn, Walton, Chermack, Cunningham, & Marcus, 2007) and other substance use (Udo, Lewis, Tobin, & Ickovics, 2016) among pregnant women experiencing IPV. A literature review of the health consequences of prenatal IPV proposed intersecting pathways between maternal stress, mental disorders, attachment, substance use, nutritional intake, antenatal care and infection, and long-term child development (Murray, Kaiser, et al., 2020). The authors highlighted the need for more research in LMICs, studies designed to overcome confounding, and development of interventions addressing these pathways.

2.3.7 Obstetric and neonatal impacts of IPV in pregnancy

Studies in low (Rahman, Nakamura, Seino, & Kizuki, 2012) and high-income countries (Goodwin et al., 2000) have identified an association between IPV exposure and late presentation to ANC. A review of demographic and health surveys in 10 LMICs found that women experiencing IPV in the Dominican Republic and Zambia were less likely to access ANC in their first trimester, after multivariate adjustment (Hindin, Kishor, & Ansara, 2008). In Rwanda, women experiencing IPV were less likely to give birth at a health facility, after multivariate adjustment.

WHO multi-country study data for over 17,500 women across 10 countries found increased odds of abortion (aOR: 2.68) and unplanned pregnancy (aOR: 1.69) among women experiencing physical or sexual IPV, or both, after adjusting for confounders (Pallitto et al., 2013). Physical assault during pregnancy is associated with immediate and long-term harm to the woman and foetus, such as uterine rupture and premature delivery (El Kady, Gilbert, Xing, & Smith, 2005). Meta-analyses have found associations between IPV and low birthweight (aOR: 1.53), and preterm delivery (aOR: 1.46; Shah & Shah, 2010).

A cohort study of 4,750 pregnant women in Canada found elevated odds of antepartum haemorrhage (aOR: 3.79), intrauterine growth restriction (aOR: 3.06), and perinatal death (aOR: 8.06; Janssen et al., 2003) among women experiencing IPV. A Swedish longitudinal cohort study found that among nearly 1,700 pregnant women, a history of childhood or adulthood abuse, including domestic violence, was associated with premature delivery and Caesarean section (OR:1.33; Finnbogadóttir, Baird, & Thies-Lagergren, 2020). A history of emotional abuse was also associated with both planned and emergency Caesarean section (OR: 1.5).

A systematic review found some evidence that IPV may be associated with shorter breastfeeding duration (four out of seven studies), and early cessation of exclusive breastfeeding (five out of ten studies; Normann et al., 2020). Evidence for an association between IPV and reduced initiation of breastfeeding was mixed. One study of 1,200 Chinese women in Hong Kong found that women not reporting IPV during pregnancy were more likely to initiate breastfeeding (aOR: 1.84) than women who did, after adjusting for potential demographic, socioeconomic and obstetric confounders (Lau & Chan, 2007). Mechanisms which may underlie the relationship between IPV and worse obstetric and neonatal outcomes include physical trauma, poor maternal nutrition, inadequate ANC, elevated stress levels, and substance use (Alhusen, Ray, Sharps, & Bullock, 2015).

2.3.8 IPV and mental health

There is an established bidirectional relationship between IPV and mental health: IPV increases the risk of mental health conditions, and mental health conditions increase vulnerability to IPV. A meta-analysis of six longitudinal studies found that IPV was associated with incident depressive symptoms (OR: 1.97, CI: 1.56-2.48), and that depressive symptoms were associated with incident IPV (four studies: OR: 1.93, CI: 1.51-2.48; Devries et al., 2013). Two included studies also reported increased suicide attempts among participants experiencing IPV. A second meta-analysis of 15 prevalence estimates from nine longitudinal studies found that IPV was associated with subsequent alcohol use disorders (OR=1.25, CI: 1.02-1.52), and that alcohol use disorders were associated with subsequent IPV (12 estimates from seven studies: OR: 1.27, CI: 1.07-1.52; Devries et al.,

2014). Devries et al. (2014) noted that across both reviews, few studies controlled for confounders.

An earlier meta-analysis identified associations between the severity of IPV and the severity of depression and PTSD, and that rates of depression reduced with time since IPV had stopped (Golding, 1999). A systematic review suggested that the frequency with which IPV was experienced was associated with the risk of depression and PTSD, and that IPV severity was associated with anxiety symptoms (Lagdon, Armour, & Stringer, 2014).

Experiencing IPV appears to be even commoner among people with, compared to those without, mental health conditions. The adult psychiatric morbidity survey of over 7,400 people in England found elevated odds (aOR: 4.4) of lifetime IPV among women with CMDs (Jonas et al., 2014). A UK survey also found higher odds (aOR: 2.7) of IPV among women accessing mental health services, than the general population (Khalifeh et al., 2015). A literature review found that lifetime prevalence of severe domestic violence and abuse among people admitted to psychiatric inpatient wards ranged from 30 to 60% (Howard et al., 2010). The authors found that domestic violence and abuse were infrequently detected in routine clinical practice in mental health settings.

A WHO multi-country study analysis of data for nearly 21,000 women across 13 rural and urban sites found that after adjusting for CMDs, the most consistent risk factors for suicide attempts were IPV, non-partner physical violence, relationship separation, childhood sexual abuse, and maternal history of IPV (Devries et al., 2011). Twenty-five to 50% of women with suicidal thoughts in the preceding four weeks had seen a health worker during that period, highlighting the role of health services in supporting the mental health of people experiencing IPV.

The relationship between IPV and mental health has been conceptualised as a “vicious cycle” (p. 4), in which violence and mental ill-health reinforce each other, while also influencing and being influenced by wider contextual factors (Tol, 2020). Tol argued that a social justice framework, which considers health to be one of six elements of well-being (Powers & Faden, 2019), would encourage exploration of how social determinants of

health (such as IPV) are influenced by other determinants of other aspects of well-being. Other aspects of well-being beyond health are personal security, knowledge and understanding, equal respect, personal attachments, and self-determination, all of which are influenced by patriarchal norms and gender inequality. Tol therefore argued that research should examine intersections of adverse social determinants and disrupt them. He advocated collaborative, interdisciplinary approaches which embrace complexity and context, using mixed methods.

When disease states interact detrimentally, increasing community vulnerability, a synergistic epidemic, or 'syndemic' can occur (Sharma, 2017). Syndemics show how social, economic, environmental and political conditions, interacting with each other and exacerbated by inequality, can influence health. Recently, the results of a survey of 2,454 men living in an informal settlement outside Johannesburg, South Africa, were analysed using structural equation modelling (Hatcher et al., 2019). The authors found that unequal gender norms predicted IPV perpetration, which predicted alcohol excess, leading to further IPV, and sexual practices increasing the risk of HIV infection. Although focused on perpetration, this syndemic model demonstrated how the complex relationship between IPV and mental ill-health can be illuminated by exploring wider aspects of social justice and well-being.

2.3.9 IPV and perinatal mental health

The bidirectional relationship between IPV and mental health conditions has also been identified during pregnancy. A meta-analysis of 67 studies found increased odds of postpartum depressive symptoms (OR: 3.1) in women who experienced IPV during pregnancy (Howard, Oram, Galley, Trevillion, & Feder, 2013). Those women with high perinatal depressive, anxiety, and PTSD symptoms also had higher odds of having experienced IPV. A large UK birth cohort study of over 13,500 child-mother dyads found that after adjusting for potential confounders, antenatal domestic violence and abuse were associated with antenatal (OR: 4.02) and postnatal (OR: 1.29) depressive symptoms (Flach et al., 2011). Antenatal abuse predicted future behavioural problems in children at the age of 42 months (OR: 1.87), but the association was not significant after adjusting

for maternal antenatal or postnatal depressive symptoms, or postpartum domestic violence.

A prospective cohort study of over 1,500 nulliparous women in Australia also found associations between postpartum depressive symptoms and emotional abuse (aOR: 2.72), physical abuse (aOR: 3.94), and antenatal depressive symptoms (aOR: 2.89; Woolhouse, Gartland, Hegarty, Donath, & Brown, 2012). In terms of evidence from LMICs, a systematic review included 24 studies conducted in 10 low and lower-middle-income countries (Halim et al., 2018). Women reporting IPV had 1.69-3.76 times higher odds of antenatal depression and 1.46-7.04 times higher odds of postnatal depression than women not reporting IPV. The aforementioned Swedish longitudinal cohort study of nearly 1,700 pregnant women also found that a history of childhood or adulthood abuse (including domestic violence) was associated with depressive symptoms and lower stress management scores (Finnbogadóttir et al., 2020). Smaller studies have found associations between domestic violence during pregnancy and maternal attachment (Pires de Almeida, Sá, Cunha, & Pires, 2013), and maternal-rated infant temperament (Quinlivan & Evans, 2005).

2.4 Mental healthcare in LMICs

There is an established global gap between the need for and provision of services to prevent, diagnose and treat mental, neurological and substance use (MNS) disorders. In response, the WHO (2001) world mental health report recommended that MNS disorders should be assessed and managed in primary healthcare and community settings, with high quality staff training, supervision, and support.

2.4.1 The mental health gap action programme

The WHO mental health gap action programme (mhGAP) was launched to address the gap between the need for and availability of mental healthcare (WHO, 2008a). In 2010, the mhGAP intervention guide (IG) was released, providing evidence-based guidance and tools to enable assessment and integrated management of priority MNS disorders in LMICs (WHO, 2010). The mhGAP-IG provides clear protocols for clinical decision-

making, aimed at non-specialist primary care staff, but has also been used by governments, non-governmental organisations (NGOs), and researchers.

The WHO (2013b) mental health action plan 2013-2020 set out an approach to integrating mental healthcare into primary care, using the mhGAP-IG. The action plan has been extended to 2030 (WHO, 2021a), in alignment with the 2030 agenda for sustainable development (UN, 2015a). A key target of the mental health action plan is sustainable development goal target 3.4, to reduce premature deaths from non-communicable diseases by a third, by 2030, and promote mental health and well-being.

A version of the mhGAP-IG for humanitarian settings was subsequently published (WHO, 2015a), before a revision of the intervention guide, which incorporated updated evidence and user feedback (WHO, 2016a). An e-mhGAP mobile device app (WHO, 2017b), operations manual (WHO, 2018), and community toolkit (WHO, 2019a) have been launched, and a growing evidence base documents uses, applications, and evaluations of mhGAP tools (Keynejad, Dua, Barbui, & Thornicroft, 2017; Keynejad, Spagnolo, & Thornicroft, 2021).

The mhGAP-IG recommends stepped care, in which the nature and intensity of treatment is personalised to meet the needs of each individual (Patel & Thornicroft, 2009). For example, the essential care and practice module (p.p. 12-14; WHO, 2016a) outlines a biopsychosocial model of treatment planning, starting with psychosocial interventions (including strengthening social supports and addressing social stressors), building up to pharmacological interventions (when indicated and available), and referral to a specialist or hospital (if needed), with regular follow-up.

2.4.2 **Task-sharing**

WHO (2008b) described the chronic shortage of trained clinicians as a crisis of the global health workforce. Aging populations, increasingly prevalent chronic disease and the HIV pandemic meant there were insufficient numbers of trained health workers to meet worldwide demand. WHO (2008b) therefore recommended task-shifting, or task-sharing: the rational redistribution of tasks to staff with less training and qualifications, where appropriate. Recommendations included monitoring the quality of task-shared care, clear

role definition, training, supportive supervision, clinical mentoring, efficient referral systems, adequate remuneration, sustainable financing, and incentives to retain and improve the performance of staff allocated new or increased responsibilities.

A systematic review of MNS interventions delivered in primary and community healthcare settings in LMICs by non-specialist health workers and other professionals, such as teachers, included 38 studies using a range of designs (Van Ginneken et al., 2013). The authors identified promising benefits of task-sharing for depression, PTSD, alcohol use disorders, dementia, and the well-being of carers. The available evidence was of low or very low quality, and few studies reported adverse effects. A recent update of this review (van Ginneken et al., 2021) found a further 72 studies: a total of 95 randomised controlled trials (RCTs) from 30 LMICs. The majority of evidence was of low certainty, due to the heterogeneity of settings, health workers, intervention models, target participants, and diagnoses. The authors concluded that for women with perinatal depression, lay health worker-led interventions probably slightly reduce symptoms (standardised mean difference (SMD): -0.26, CI: -0.37, -0.14; five trials, 1,989 participants), may increase recovery (RR: 1.29; four trials, 1,243 participants), and may slightly reduce functional impairment (SMD: -0.23, CI: -0.41, -0.04; four trials, 1,856 participants).

A second systematic review included 21 studies reporting the acceptability and feasibility of mental health task-sharing in LMICs (Padmanathan & De Silva, 2013). The authors identified distress experienced by the task-shared workforce, perceived competence, acceptance by colleagues, and incentivisation to retain staff as key determinants of success and sustainability. Padmanathan and De Silva (2013) concluded that effective task-sharing requires adequate investment in mental health services and personnel. A third systematic review identified 24 qualitative studies describing the implementation of nine primary care mental health programmes in LMICs (Esponda et al., 2020). The authors found that healthcare provider-perceived advantages of interventions, access to training, knowledge, and information influenced implementation success. Insufficient specialists to supervise non-specialists was a key barrier. Personal attributes, such as respectfulness, receptivity, discretion, cooperation, and commitment were noted

facilitators. Esponda et al. (2020) recommended capacity building activities to optimise task-sharing.

2.4.3 Cultural relativist critiques

The field of global mental health seeks to achieve worldwide mental health equity by addressing the gap between the need for mental healthcare and its provision (WHO, 2013b). However, global mental health has been criticised from cultural relativist perspectives (Bemme & D'souza, 2012). For example, diagnostic categories conceptualised in HICs have been accused of lacking validity in LMICs, and their clinical application of being a form of imperialism (Summerfield, 2012). Patel (2014) countered that CMDs such as depression show historical validity across time, face validity (across non-biomedical health practitioners, who recognise symptom clusters as denoting health problems), predictive validity (for example, of suicide attempts) and concurrent validity (such as the association of depressive symptoms with help seeking). Accusations of neo-colonialist importing of 'Western' diagnoses have been countered with evidence of leadership of the field by professionals based in LMICs, its focus on multidisciplinary, psychosocial task-sharing, rather than exclusively biomedical approaches, collaboration with community organisations and people with lived experience, cultural and contextual adaptation and development of instruments and interventions (Patel, 2014).

Debates about cultural relativism contribute important considerations to the design and conduct of global mental health research, especially studies led by individuals based in HICs. To avoid medicalisation of healthy expressions of distress or suffering, it is essential to understand the perceptions and experiences of individuals living in a given context. Relatedly, to avoid importing inappropriate treatments for CMDs, it is vital to explore the acceptability of interventions to prospective health professionals and service users. Where deemed potentially acceptable, in-depth understanding of the needs and perspectives of women and clinicians is required, to tailor interventions for that context.

International organisations, such as the UN (2015b) and WHO (2013c), approach gender equality from the position of human rights universalism, which gained traction following the genocides of World War II (Zechenter, 1997). This perspective presumes that a shared

humanity affords all individuals a set of basic human rights, irrespective of their culture, religion, nationality, and other personal characteristics. Human rights universalism has also been subject to cultural relativist critiques.

Normative relativism contends that cultures cannot be judged against supposedly extra-cultural standards because these are themselves culture-specific (Zechenter, 1997). However, this group-centred perspective can be used to condone persecution of individuals and minorities, and to selectively promote practices furthering unequal power dynamics. Zechenter (1997) argued that cultural relativism characterises culture as static, discounting the evidence that environmental shifts are often associated with social changes. Relativism also disregards the diversity within each cultural group, and the fact that traditions perceived as dominant are commonly those practised by the most powerful, or the majority. Finally, Zechenter (1997) countered the criticism of gender equality movements as neo-colonial Western ideologies, by pointing to the breadth of self-organised women's movements in LMICs. Zechenter (1997) argued that practices being defended as 'cultural' should be scrutinised in terms of whose interests are served, and whose are infringed.

The qualitative literature from Ethiopia (section 2.3.4) confirms the pervasiveness of IPV and its association with a range of physical, psychological and societal harms. Qualitative studies of IPV from a range of other sub-Saharan African countries also describe underlying patriarchal social norms (Balogun & John-Akinola, 2015; Ilika, 2005; Okeke-Ihejirika, Salami, & Amodu, 2019). Ambivalent community and institutional responses to IPV, which both condone and condemn its perpetration, are also widely reported by sub-Saharan African studies (Balogun & John-Akinola, 2015; Ilika, 2005; Odero et al., 2014; Okeke-Ihejirika et al., 2019; Sedziafa, Tenkorang, & Owusu, 2018), alongside gendered power dynamics entrenched across multiple sectors of society (Gillum, Doucette, Mwanza, & Munala, 2018; Odero et al., 2014; Sedziafa et al., 2018). An unequal status quo, in which women's needs and views are infringed, serves the interests of men: the more powerful group.

The evidence from Ethiopian and other sub-Saharan African research therefore confirms that IPV and the gender inequality behind it are far from being an accepted fact of non-

Western cultures. Rather, a range of women and men, relatives, community members, healthcare, governmental and criminal justice stakeholders in diverse rural and urban settings have identified IPV as an important concern. Therefore, adopting a human rights universalist perspective (UN, 2015b; WHO, 2013c) that women's shared humanity affords them basic rights to live free from violence is supported by the evidence base. Similar arguments can be made for the basic rights of individuals experiencing mental health conditions, to access evidence-based care and treatment (Patel, 2014; WHO, 2019).

2.4.4 Brief psychological interventions

Brief psychological interventions are condensed, simplified versions of talking therapies, which were often originally developed to be delivered over several months. The mhGAP-IG recommends a range of evidence-based brief psychological interventions, such as problem management plus (PM+), cognitive behavioural therapy (CBT), and interpersonal therapy (IPT; p. 27, WHO, 2016a). PM+ combines techniques of problem-solving, behavioural activation (such as activity scheduling), stress management (such as relaxation techniques), and strengthening social support (WHO, 2020b). CBT targets cycles of negative thoughts (cognitions) that provoke unhelpful feelings, leading to counter-productive actions (behaviours); CBT-based interventions include the thinking healthy program (WHO, 2015b). IPT focuses on addressing four interpersonal difficulties associated with depression: grief, disputes, life changes, and loneliness (WHO, 2020a).

Task-shared brief psychological interventions have been shown to be effective for treating CMDs in LMICs. For example, an umbrella review of meta-analyses of LMIC studies identified 123 primary RCTs (Barbui et al., 2020). Highly suggestive evidence of moderate credibility supported the efficacy of psychosocial interventions in adults with depression in humanitarian settings (SMD: 0.87, CI: 0.67-1.07), and adults with CMDs in general settings (SMD: 0.49, CI: 0.36-0.62). One included study, which meta-analysed 27 studies of interventions delivered by non-specialists (SMD: 0.49, CI: 0.36-0.62; Singla et al., 2017) noted that studies rarely reported moderators of effectiveness, and often lacked statistical power to detect them.

The Lancet Psychiatry commission on psychological treatments research identified ten priority areas requiring investigation (Holmes et al., 2018). These included establishing the mechanisms by which interventions work, developing brief, flexible treatments which can be adapted across cultures and implemented sustainably, evaluating them using high quality RCT methods, training interdisciplinary therapists, and exploring personalisation, to address complexity and comorbidity.

2.4.5 Components of evidence-based psychological interventions in LMICs

A systematic review and meta-analysis of 27 RCTs of psychological interventions delivered by non-specialist providers in LMICs differentiated between specific elements, non-specific elements, and in-session techniques (Singla et al., 2017). Specific elements were rooted in individual psychological processes, non-specific elements were strategies used by therapists to engage participants, and techniques were skills used by therapists to implement an element. The authors divided specific elements into four domains: behavioural (e.g. problem-solving, activation, relaxation), cognitive (e.g. identifying thoughts, restructuring, mindfulness), interpersonal (e.g. identifying or eliciting support, assessing relationships, communication skills), and emotional (e.g. identifying or eliciting affect, linking affect to events, emotional processing). Examples of non-specific elements to engage participants included collaboration, empathy, active listening, and normalisation. In-session techniques included psychoeducation, assigning homework, role playing, and goal setting (Singla et al., 2017, p. 156). Regression models showed significant associations between trial effect size and interpersonal ($\beta=0.442$, $p=0.029$) and emotional ($\beta=0.415$, $p=0.046$) specific elements, and non-specific engagement elements ($\beta=0.409$, $p=0.052$). Singla et al. (2017) therefore recommended simplified treatment protocols, implemented by a broader range of non-specialist providers. They advocated more emphasis on competence to deliver non-specific elements (such as empathy and active listening), and more attention to interpersonal and emotional mediators of effectiveness. However, the variable detail with which intervention elements were described in published accounts limited the ability to draw definitive conclusions.

A recent review of 16 psychological interventions which were effective in LMICs found that competence in 15 common factors was shared across models (Pedersen et al., 2020).

For example, promoting hope and realistic expectation of change, confidentiality, giving praise, psychoeducation, and rapport building were common elements of most interventions. Shared features among evidence-based interventions raised the possibility that therapist competence, session quality, acceptability and feasibility for the target population and context might be more important than the specific model, in determining effectiveness.

2.4.6 Cultural adaptation

In HICs, culturally adapted versions of psychological interventions are more effective than non-adapted versions of the same intervention (nine studies, SMD: 0.52), another manualised intervention (10 studies, SMD: 0.45), or another active intervention (25 studies, SMD: 0.60; Hall, Ibaraki, Huang, Marti, & Stice, 2016). A meta-analysis of eight RCTs of minimally-guided online or book-based treatments (Shehadeh, Heim, Chowdhary, Maercker, & Albanese, 2016) also found that greater cultural adaptation was associated with greater efficacy ($p=0.04$). The literature on cultural adaptations of brief psychological interventions in LMICs is smaller than from HICs. A meta-analysis of 32 psychotherapy RCTs conducted in LMICs found higher effect sizes than in HICs (Cuijpers, Karyotaki, Reijnders, Purgato, & Barbui, 2018), even after controlling for publication bias (SMD: 0.73). Adaptation for the setting did not appear to be a moderator of treatment efficacy, but this finding was limited by the brevity of intervention descriptions in included studies.

Cultural adaptation of psychological interventions raises a number of challenges (Heim & Kohrt, 2019). These include the difficulty of separating adaptations to intervention language and metaphors (Bernal, Jiménez-Chafey, & Domenech Rodríguez, 2009), which often overlap, and distinguishing peripheral from core intervention components (Chu & Leino, 2017). Heim and Kohrt (2019) therefore proposed a new framework for cultural adaptation of psychological interventions, addressing (1) cultural concepts of distress (a: explanatory models and b: idioms of distress), (2) treatment components (a: specific elements, b: non-specific elements, and c: in-session techniques), and (3) treatment delivery (a: format, b: surface).

Heim and Kohrt (2019) argued, based on literature, that intervention explanatory models (1a) should be congruent with participants' intuitions, while being sufficiently different to offer new perspectives, and propose a treatment rationale. Idioms of distress (1b) targeted by adapted interventions should capture stakeholders' understandings of symptoms in a non-stigmatising manner, without assuming direct connections to latent culture-bound diagnostic constructs such as 'depression'. Based on the taxonomy proposed by Singla et al. (2017), Heim and Kohrt (2019) proposed that specific elements of treatment (2a) should be founded in participants' "core assumptions about human suffering and healing" (p. 10), and their idioms of distress. Non-specific elements (2b): common factors which enhance engagement, such as active listening, may only be adaptable in terms of culturally appropriate ways of demonstrating listening. Heim and Kohrt (2019) proposed that the acceptability and need for adaptation of in-session techniques (2c), such as goal setting or homework tasks, should be investigated through formative, qualitative research. The treatment delivery format (3a) should be adapted in line with cultural preferences and acceptability (for example, of individual versus group sessions). Finally, Heim and Kohrt (2019) considered the 'surface' of treatment delivery (3b) akin to Chu and Leino (2017)'s peripheral aspects: language, metaphor, illustrations, simplified text. They highlighted how, despite the intuitive appeal of surface adaptations, there is a lack of evidence for their impact on intervention acceptability and effectiveness.

2.4.7 Psychological interventions for women experiencing IPV

There is a limited literature on brief psychological interventions for women experiencing IPV, most of which comes from HICs. Most studies of psychological interventions do not analyse sex and gender differences in outcomes, or the effects of gendered risk factors on outcomes (Howard, Ehrlich, Gamlen, & Oram, 2017). RCTs of psychological interventions also rarely measure exposure to IPV (Oram, Khalifeh, & Howard, 2017). One study conducted secondary data analysis on a sub-sample of 211 married women who completed all stages of follow-up in an RCT of the healthy activity program (HAP): a behavioural activation intervention in Goa, India (Patel, Weobong, Patel, & Singla, 2019). Women reporting IPV at three and 12 months' follow-up had lower levels of behavioural activation and higher levels of depressive symptoms than women who did not report IPV. However, higher activation responses were associated with improved

depressive symptoms, irrespective of IPV exposure, suggesting that the intervention was still beneficial for women experiencing IPV. The study was limited by the lack of baseline IPV measurement.

A rapid evidence review identified 33 studies (all from HICs) reporting mental health interventions for women experiencing IPV (Yapp, Keynejad, & Oram, 2020). Most described group-delivered CBT-informed or mind-body interventions (such as mindfulness-based stress reduction, yogic techniques, and biofeedback), or individually-delivered, trauma-focused psychotherapeutic treatments. A recent Cochrane review identified 33 randomised and quasi-randomised trials of psychological therapies delivered to women with recent or lifetime experience of IPV (Hameed et al., 2020). Studies were conducted in HICs (n=25) and middle-income countries (n=8), only. Interventions were classified as integrative (e.g. IPT, motivational interviewing; n=11), humanistic (e.g. non-directive therapy; n=9), CBT (e.g. problem-solving therapy; n=6), third-wave CBT (e.g. mindfulness; n=4), and others (e.g. music therapy; n=3). No psychodynamic (e.g. psychoanalytic therapy) interventions were identified; systemic therapies (e.g. couple or family therapy) were excluded for involving individuals other than the woman. Meta-analyses found a probable benefit of interventions for depression (SMD: -0.24, 95% CI: -0.47, -0.01, four studies, n=600), and a possible benefit for anxiety (SMD: -0.96, 95% CI: -1.29, -0.63, four studies, n=158). There was no evidence of between-groups differences in PTSD (four trials), safety planning (one trial), or subsequent IPV (two trials). Hameed et al. (2020) recommended future research into interventions which address the safety, support, and holistic needs of women experiencing complex trauma associated with IPV, using rigorous RCT methods.

2.4.8 Psychological interventions for women experiencing IPV in LMICs

The literature on brief psychological interventions for women experiencing IPV in LMICs is even smaller. The paucity of intervention research targeting the mental health needs of people experiencing and perpetrating IPV in low-income countries, and lack of replication studies, was highlighted by a recent systematic review (Tol et al., 2019). Recommendations included strengthening the theoretical underpinnings of therapies for IPV survivors and perpetrators' mental health, testing interventions' impact on

hypothesised mediators, and improving IPV detection, using continuous outcome measures and fully-powered samples.

Generic psychological interventions can neglect the role played by trauma in the mental ill-health of women experiencing IPV. Traumatic experiences (such as IPV) have lasting physical and psychological impacts, which influence a person's relations to the world, self and others (Van der Kolk, 2014). People with lived experience of IPV have cautioned against 'pathologising' IPV-related difficulties, by considering mental disorders in isolation, without addressing the emotional impact of IPV (Tsai, Tomlinson, Comulada, & Rotheram-Borus, 2016). Researchers have highlighted the risk of reducing the therapeutic potential of psychological interventions, by neglecting the wider needs of people experiencing IPV (Tol et al., 2017).

Acknowledging the impact of IPV (Humphreys & Thiara, 2003) and meeting complex needs (Simmel, Postmus, & Lee, 2016) are clear priorities for people with lived experience. Trauma-informed care prioritises trauma awareness, safety, trustworthiness, choice, collaboration, strength, and skill-building (Holly, 2017). A Cochrane realist review of advocacy interventions for women experiencing IPV included 98 studies, most of which were conducted in HICs (Rivas, Vigurs, Cameron, & Yeo, 2019). The authors concluded that therapeutic alliance, empowerment, woman-centredness, and trauma-informed approaches were central to the effectiveness of individualised advocacy interventions (p. 49).

Few RCTs have evaluated psychological interventions for CMDs, tailored for women's experiences of IPV in LMICs. One study randomised 100 women attending IPV services in Pakistan to attend 10 twice-weekly 90 minute sessions of IPV-adapted group CBT, and 100 women to CBT-based group self-help (Latif & Khanam, 2017). Depressive and anxiety symptoms improved significantly among women attending IPV-adapted group CBT, relative to women attending CBT-based group self-help, post-intervention. In Iran, investigators randomised 24 women living with IPV to attend 10-12 sessions of IPV-tailored narrative exposure therapy (NET), and 21 women to attend life skills and supportive counselling sessions, some of which involved abusive husbands (Orang et al., 2018). Women in both arms received psychoeducation on trauma reactions. PTSD and

depressive symptoms improved significantly more in the 17 women receiving IPV-tailored NET who attended follow-up, than the 17 women receiving life skills and supportive counselling, who attended three and six-month follow-up. These two studies suggested that tailoring psychological interventions for CMDs for women experiencing IPV in LMICs may enhance their effectiveness. However, both were conducted in middle-income countries with small to moderate sample sizes, and neither used task-sharing methods. Latif and Khanam (2017)'s intervention was particularly intensive and Orang et al. (2018)'s model exposed women to traumatic memories while they continued to live with abusive partners. These factors limited these interventions' applicability to rural Ethiopia.

Recently, a brief psychological intervention was developed for the mental health of women experiencing IPV in a low-income African setting. Nguvu adapted brief cognitive processing therapy (CPT) and advocacy counselling, for a Congolese refugee camp in Tanzania (Greene et al., 2019). One individual advocacy session, six group CPT sessions and a group advocacy session (each lasting two hours) were delivered by trained, supervised, lay refugee facilitators (Greene et al., 2021). Women with psychological distress and past-year IPV were randomised to the intervention group (n=158) or usual care (n=153), which included access to a gender-based violence response programme. Psychological distress but not functioning or IPV improved significantly among Nguvu participants, relative to usual care participants, at nine weeks' follow-up. However, these differences reduced after adjusting for mental health symptoms and violence frequency at baseline. Mean session attendance was 66%, although half the participants attended at least 75% of sessions (Greene et al., 2021). Nguvu was deemed relevant to women's needs, acceptable and feasible to implement, although several participants mentioned safety concerns related to abusive partners learning about their attendance. Those completing exit interviews recommended more advanced notice of session dates, food and other incentives, and provision of mobile telephones, to optimise attendance. Participants recommended organising groups according to age, as the presence of elders inhibited younger women from discussing relationship problems.

2.4.9 Perinatal psychological interventions in LMICs

Brief psychological interventions for pregnant women in LMICs are gaining research attention. In recognition of women's vulnerability during pregnancy, and the variable quality of obstetric care worldwide, eight standards of maternal and new-born healthcare have been advocated at the international level (WHO, 2016b). The sixth standard is that every woman and her family or chosen companion receives emotional support sensitive to their needs, which strengthens the woman's capability. Under this standard, quality statement 6.2 (p. 52) highlights the need to identify and support women with complex emotional needs, including those arising from gender-based violence and mental health conditions.

The impact of the perinatal period means that generic interventions may not be optimal to meet women's needs. A systematic review of interventions delivered by non-specialist health workers for perinatal depressive symptoms in LMICs identified nine studies (Chowdhary et al., 2014). Five studies employed psychological interventions such as IPT, CBT, problem-solving therapy (PST), psychoeducation, and peer befriending. However, 'peers' were usually defined as fellow women or mothers, rather than individuals with lived experience of mental health problems (Ryan et al., 2019). Woman-focused techniques included cognitive restructuring and behavioural activation, alongside empowerment and attending to social problems. Common implementation strategies were integration into ANC or child healthcare, starting sessions prenatally and continuing postnatally, including children in session content and other family members in session delivery. Chowdhary et al. (2014) found that included studies adapted intervention language (using translation and idiomatic changes), metaphor, and content elements for the cultural context. Method adaptations included reducing written tasks for low-literacy populations. Challenges to implementation included low attendance, transport costs, lack of private space, low staff motivation, competing responsibilities, low acceptability of talking therapy and social problems taking precedence. Quality of delivery and therapist competence were rarely evaluated.

After Chowdhary et al. (2014)'s review was published, the perinatal Thinking Healthy Programme (THP) was adapted for delivery by 'peers' (fellow mothers from a similar

background) in Pakistan and India (Atif et al., 2017). Seven focus group discussions and 61 in-depth interviews informed initial adaptations, before piloting with 20 pregnant women with depressive symptoms in Pakistan and 24 in India, followed by 41 in-depth interviews and eight focus group discussions. THP for peers (THPP) was simplified, using vignettes, pictures, and household objects. A key simplification was to focus intervention content on behavioural activation rather than cognitive restructuring, which participants considered a more difficult skill. THPP used narrative vignettes for CBT education, via progressive story-telling, centred around culturally appropriate illustrations. The number of sessions was reduced to a (still substantial) maximum of 14 in India and 10 in Pakistan. Cascade training enabled specialist master trainers to train and supervise a group of non-specialist graduate trainers, who trained and supervised peers, in groups. Peer competence was assessed through direct observation in Pakistan and audio-recording in India, with feedback given during supervision. In-session ‘job aids’ were developed, with illustrations and captions conveying key messages. Participants considered having experiences and characteristics in common with peers to be a benefit. Concerns included confidentiality and stigma, while some peers found the therapist role emotionally challenging. The voluntary peer therapist role appeared to be acceptable in Pakistan, but financial incentives were required in India.

In Cape Town, a task-shared, manualised counselling intervention for perinatal depressive symptoms was informed by semi-structured interviews with 26 service users and providers, an expert evidence review workshop, and a document review of South African community counselling manuals (Nyatsanza, Schneider, Davies, & Lund, 2016). Stakeholders considered intervention acceptable and feasible, if occurring within ANC, in Xhosa, by female counsellors from the community. Psychoeducation, problem solving, healthy thinking and behavioural activation were included in the six session intervention, based on expert and stakeholder perspectives. The fifth session focused on birth preparation, to address anxiety about labour, bonding, and childcare. However, an RCT found no significant difference between this intervention and ANC plus three monthly telephone calls (Lund et al., 2020). The authors hypothesised that intervention brevity, complexity (problem solving, behavioural activation, cognitive reframing), and adverse social and economic conditions, including IPV, contributed to the lack of measured

efficacy. Other suggestions were low intervention dose (53% of participants completed all six sessions), moderate manual fidelity (55-70%), floor effects caused by participants with only moderate symptoms, and potential efficacy of enhanced usual care.

Recently, a brief, task-shared psychological intervention was developed for mild to moderate perinatal anxiety and depressive symptoms in South Africa (Boisits et al., 2021). The authors reviewed the manuals of seven relevant interventions from LMICs and two local training programmes. They also interviewed 20 health workers and 37 pregnant women attending ANC in Cape Town. Boisits et al. (2021) identified problem-solving, psychoeducation, basic counselling, and behavioural activation as components of existing interventions suitable for this setting. Stakeholders understood depression and anxiety in behavioural rather than biomedical terms and attributed them to conflict with partners or family members, violence or abuse, lack of partner support, and difficult social circumstances. A three session intervention delivered by community health workers was identified as the most acceptable model, with ‘adjunct treatments’ including mindfulness, relaxation breathing techniques, and a component on managing conflict. The efficacy of this intervention model is yet to be evaluated.

2.4.10 Perinatal psychological interventions for women experiencing IPV

Many of the studies summarised in section 2.4.9 identified the relevance of IPV to pregnant women’s experiences of CMDs, and their ability to engage with interventions. However, there is limited evidence for mental health interventions tailored to the needs of pregnant women experiencing IPV (Warshaw, Sullivan, & Rivera, 2013). One systematic review identified only two studies targeting the mental health of pregnant women experiencing IPV; a further three interventions addressed both mental health and violence (Howell, Miller-Graff, Hasselle, & Scrafford, 2017).

The first mental health-focused intervention was a randomised feasibility study of interpersonal psychotherapy (IPT) between pregnancy and two weeks postpartum for women with low incomes experiencing IPV in Rhode Island, USA (Zlotnick, Capezza, & Parker, 2011). Attending up to five sessions of IPT was associated with reduced PTSD symptoms three months postpartum, but not fewer depressive episodes. The second

mental health-focused intervention was an uncontrolled pilot study of women experiencing IPV in San Francisco, USA, between their third trimester and six months postpartum (Lavi, Gard, Hagan, Van Horn, & Lieberman, 2015). Weekly child-parent psychotherapy was associated with improved depressive and PTSD symptoms, but drop-out rates (44%) were high.

One of the three interventions for mental health and IPV identified by the systematic review (Howell et al., 2017) was a cluster RCT of at-home befriending, advocacy, parenting support, and referral, delivered by English and Vietnamese-speaking women in Melbourne, Australia (Taft et al., 2011). One year of weekly sessions was associated with significant reductions in IPV compared with the control group, but only non-significant improvements in depressive symptoms and well-being. The second intervention for mental health and IPV was an RCT of a single ANC empowerment session in Hong Kong (Tiwari et al., 2005). Postnatal depressive symptoms, physical functioning, and role limitation improved, women reported less psychological and ‘minor’ physical abuse, but unchanged sexual and severe physical abuse. Unexpectedly, intervention group women reported more body pain than control group participants, post-participation, requiring further investigation in future studies.

The same systematic review (Howell et al., 2017) also identified four studies of the Washington DC healthy outcomes of pregnancy expectations (DC-HOPE) integrated education and counselling intervention. DC-HOPE comprised 4-8 sessions delivered to African American women experiencing at least one of smoking, environmental smoke exposure, depressive symptoms, and IPV. The RCT found no differences between intervention and control group women’s depressive symptoms, post-participation (El-Mohandes et al., 2008), but did find reduced frequency of ‘minor’ IPV during pregnancy and severe IPV postpartum (Kiely, El-Mohandes, El-Khorazaty, & Gantz, 2010). Obstetric findings were lower rates of very preterm birth in the intervention group (El-Mohandes, Kiely, Gantz, & El-Khorazaty, 2011), but no difference in a range of other adverse pregnancy and neonatal outcomes (Subramanian et al., 2012).

A systematic review of interventions for pregnant women experiencing domestic violence in LMICs identified only six studies (Daley, McCauley, & van den Broek, 2020). Of

these, just one quasi-experimental study in Kenya measured depressive symptoms. This three-session empowerment intervention focused on safety assessment, explaining gender-based violence, and linking women to support services, was associated with lower depressive symptoms than the control arm (Mutisya, Ngure, & Mwachari, 2018).

Recently, a pilot RCT was conducted with 140 pregnant women experiencing domestic and family violence in Nepal (Sapkota, Baird, Saito, Rijal, & Anderson, 2020). Seventy women randomised to the intervention arm attended a single in-person session of motivational interviewing-informed counselling, focused on self-directed decision-making. They also received the counsellor's telephone number and a booklet describing the mental health impacts of domestic and family violence, staying safe, and sources of support. Seventy women randomised to the enhanced usual care (EUC) arm received a booklet listing local sources of support. Relative to the EUC group, the intervention group showed greater reductions in anxiety and depressive symptoms, greater increases in self-efficacy scores, and use of safety behaviours, four to six weeks post-enrolment, and six weeks postpartum (all $p < .001$).

Reviewing the evidence demonstrates the striking paucity of perinatal mental health interventions for women experiencing IPV. The few published studies conducted in HICs and middle-income countries have shown promise, but research conducted in low-income countries is a clear priority.

Section Two: theoretical frameworks

2.5 The MRC framework for developing and evaluating complex interventions

The first edition of the influential Medical Research Council (MRC) framework described a linear approach to developing and evaluating complex interventions, akin to pharmaceutical research (Campbell et al., 2000). This linear approach, the lack of detail on intervention development, and insufficient attention to context, implementation, and process evaluation, were criticised. The second edition (Craig et al., 2006; Craig et al., 2008) instead proposed a cyclical process of complex intervention development, feasibility and piloting, evaluation, and implementation (p. 980).

Craig et al. (2008) sub-divided the development stage into identifying existing evidence (including systematic reviews), identifying and developing theory (of the intervention's anticipated processes of change), and modelling processes and outcomes (for example, consulting prior economic evaluations of related studies). The guidance then sub-divided feasibility and piloting into testing procedures, estimating recruitment and retention, and determining sample size. The authors recommended only proceeding to full-scale evaluation (such as a definitive RCT) and implementation, once development, feasibility, and piloting stages had completed.

In September 2021, a third edition of the MRC guidance was published, in collaboration with the UK National Institute for Health Research (NIHR; Skivington et al., 2021). A gap analysis, expert workshop, open consultation, expert review, and stakeholder engagement contributed to the updated guidance. A key addition was the acknowledgement that intervention complexity arises from both intervention components and interactions between those components and the implementation context. A second addition was the explicit recognition that theory-based and systems perspectives are required in addition to efficacy and effectiveness-focused complex intervention research.

The new MRC/NIHR guidance retained the four phase framework (Figure 2.3) of intervention development (or identification), feasibility assessment, evaluation, and implementation outlined by Craig et al. (2008). However, Skivington et al. (2021) positioned consideration of context, development, refinement and (re)testing of programme theory, stakeholder engagement, identification of uncertainties, intervention refinement, and economic considerations as 'core elements' integral to each of these four phases. A final difference from previous guidance was a new recognition that the evaluation phase should answer questions beyond whether an intervention 'works' (achieves its intended outcome). Skivington et al. (2021) characterised evaluation as also measuring other intervention impacts, theorising mechanisms of change, identifying contextual interactions and system changes, and determining the relevance of findings to real-world decision-making.

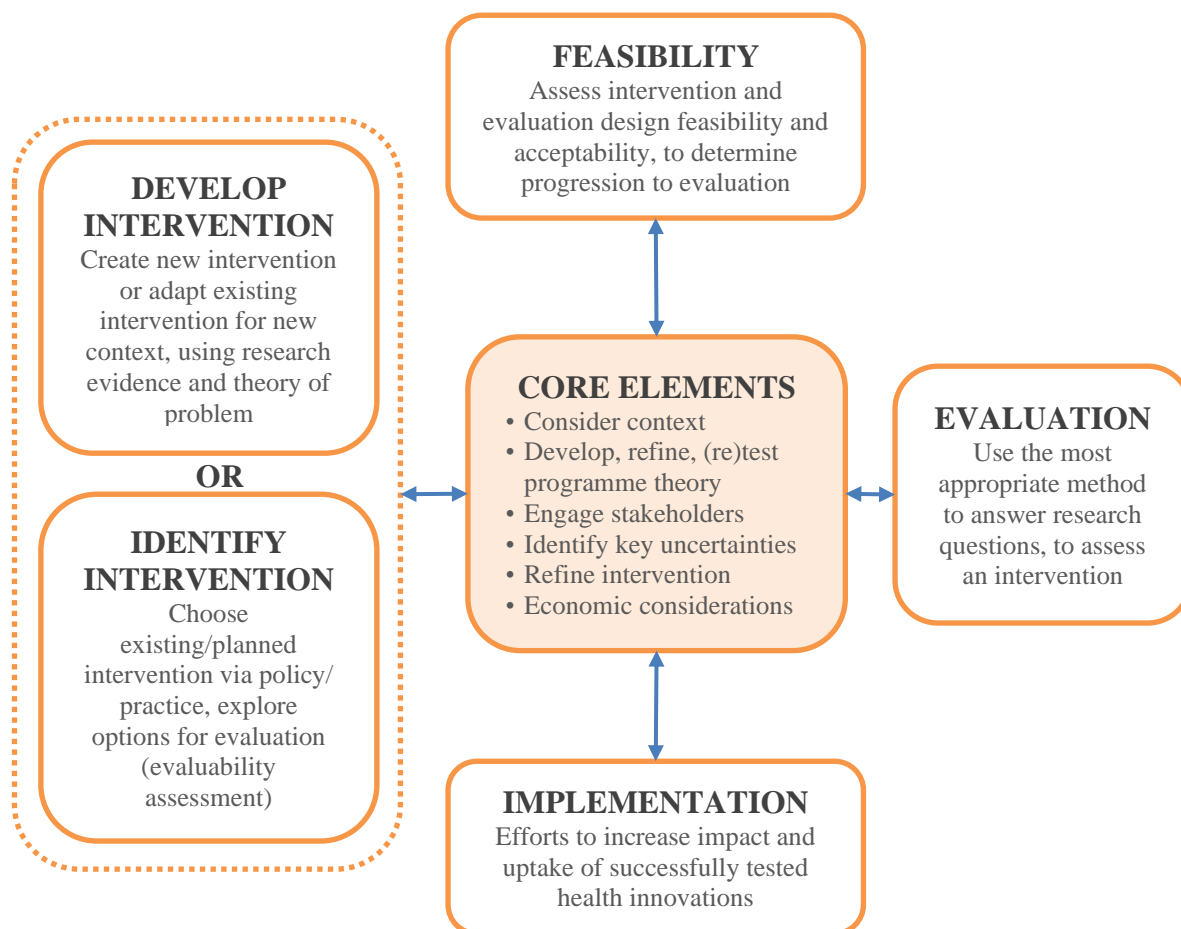


Figure 2.3 The new MRC/NIHR framework for developing and evaluating complex interventions (Skivington et al., 2021; p. 4)

2.6 Complexity and context

The first MRC guidance (Campbell et al., 2000) defined complex interventions as those having several components. The second edition (Craig et al., 2008) added the number and difficulty of behaviours addressed, the number of groups targeted, the number and variability of outcomes, and the degree of permitted flexibility to the definition of intervention complexity. Shiell, Hawe, and Gold (2008) argued that these definitions effectively mean ‘complicated’, rather than complex, which is a property of a system, not an intervention. Complicated systems are difficult to understand, but predictable, whereas complex systems feature uncertainty, and their component parts cannot be readily isolated (Glouberman & Zimmerman, 2002). Hawe, Shiell, and Riley (2009) proposed that interventions should be considered ‘events’ occurring in complex ecological systems, a perspective incorporated into the latest MRC/NIHR framework (Skivington et al., 2021).

Researchers might consider the complex system of interest to be the health service, but the woman's life could also be considered a 'complex system' within which an event (the intervention) occurs. Using social network analysis and complex systems theory, Hawe et al. (2009) drew attention to the self-organising nature of systems, whose dynamic properties must be harnessed for an intervention to make an impact. This perspective was also incorporated into the new MRC/NIHR framework. Skivington et al. (2021) highlighted emergence, feedback, adaptation, and self-organisation as key properties of complex adaptive systems, which require consideration during intervention development and evaluation.

Hawe et al. (2009) argued that interventions affect evolving networks of interaction between people, places and time, making attention to the wider systemic context, and any activities displaced by an intervention, particularly important. Consideration of context is one of the core elements of each phase in the new MRC/NIHR framework (Skivington et al., 2021); see Figure 2.3. Howarth, Devers, Moore, O'Cathain, and Dixon-Woods (2016) recommended using mixed methods to integrate contextual understanding into the design and evaluation of complex interventions, as early as possible. Dedicated NIHR guidance (Craig et al., 2018) recommended that context should be considered at every stage of developing and evaluating health interventions, from defining the research question, to reporting findings.

2.7 Applied qualitative research

The first MRC framework for complex interventions emphasised the need for qualitative methods, to canvas the views of potential service users, define intervention components, identify barriers to change and, later, to evaluate the resulting intervention (Campbell et al., 2000). Qualitative methods contribute to the identification and development of theory (Craig et al., 2006), illuminating the process of change by which the intervention is hypothesised to work. The value of qualitative methods is also asserted by the new MRC/NIHR complex interventions framework, in which stakeholder engagement is a core element of each of the four phases (Skivington et al., 2021); see Figure 2.3.

Qualitative research may have theoretical aims, such as generating theory, or applied aims, such as addressing a specific concern (Ritchie & Ormston, 2014). The functions of theoretical and applied qualitative research can be contextual, explanatory, evaluative, or generative (Ritchie & Ormston, 2014). The contextual function refers to research which describes the ways that phenomena manifest, are experienced, and understood in the social world. The explanatory function refers to research into the forces and influences which drive phenomena to occur, including associations between thoughts and actions, and the meanings they hold. The evaluative function studies how well practices and systems work, including operational dynamics, by exploring processes and outcomes. Evaluation research can be formative (informing changes to an intervention or service that improve its organisation or delivery), or summative (identifying the impact, effectiveness, or outcomes of an intervention or service (Ritchie & Ormston, 2014)). The generative function contributes new ideas to social theory, or policy solutions.

Applied qualitative research therefore has a role in adapting a psychological intervention for the perinatal emotional difficulties of women experiencing IPV in rural Ethiopia. The functions of such research are contextual (exploring how perinatal emotional difficulties and IPV manifest, are experienced, and understood), explanatory (identifying forces and influences perceived to drive perinatal emotional difficulties and IPV), and evaluative (understanding the processes and outcomes of currently available responses to perinatal emotional difficulties and IPV). Such formative evaluation can inform changes made to current practice by adapting a complex intervention.

The contextual, explanatory, and evaluative functions of applied qualitative research all serve to illuminate aspects of context. Applied qualitative research exploring perinatal emotional difficulties and IPV in rural Ethiopia is especially suited to illuminating the cultural context: the attitudes, perspectives, and practices of practitioners and prospective intervention recipients that will interact with an intervention. Applied qualitative research can also be used to identify which implementation strategies may optimise intervention acceptability and feasibility in a given context.

2.8 Intervention development and adaptation

Despite recommending that interventions should be carefully developed and adapted with reference to literature, stakeholder perspectives, and theory, the first and second MRC complex interventions frameworks (Campbell et al., 2000; Craig et al., 2008) did not provide instructions on how interventions should be developed or adapted.

Later guidance on intervention development was informed by reviews of existing recommendations, primary research, qualitative interviews, e-Delphi consensus exercises, and input from an (exclusively HIC-based) expert panel (O'Cathain et al., 2019). This guidance identified five guiding principles of intervention development: to be dynamic, iterative, creative, open to change, and forward looking to future evaluation and implementation. The authors' first recommended action out of 11 was to plan the development process, including understanding the problem, considering whether effective interventions already exist, and whether the cost of developing a new intervention outweighs its potential benefits.

Healthcare interventions are often adapted from others with an existing evidence base, rather than developed anew. However, the effectiveness and implementation strategies of successful interventions may be specific to the contexts in which they were developed and evaluated. Recently, guidance focused specifically on adapting existing interventions was published, based on a systematic review, scoping review, qualitative interviews with stakeholders and a three-round e-Delphi exercise (Moore et al., 2021). The authors of 'ADAPT' acknowledged that the distinction between intervention adaptation and development can be subtle and change as a project progresses. They emphasised that for changes to an intervention to constitute adaptation, its mechanisms of action should be unaltered, although they did not specify how this could be assured.

2.9 Articulating programme theory

Articulating programme theory is another core element of the four phases of the new MRC/NIHR complex interventions framework (Skivington et al., 2021); see Figure 2.3. In their guidance on intervention development, O'Cathain et al. (2019) described programme theory as a description of how the intervention is expected to result in

anticipated effects, under stated circumstances, showing causal pathways between intervention components, intermediate and long-term outcomes, and interactions with the context.

Programme theory can be articulated through a range of different approaches, often as part of theory-driven evaluation (Coryn, Noakes, Westine, & Schröter, 2011). For example, logic models link short and long-term outcomes to programme activities and processes, and express underlying theoretical principles and assumptions (p. III; WK Kellogg Foundation, 2004). However, logic models have been criticised for linearity and rigidity, while logical frameworks (log frames), often used for programme monitoring, do not articulate underlying causal pathways (De Silva et al., 2014).

2.9.1 Theory of change

The theory of change (ToC) approach, by contrast, describes prospectively how a complex intervention is envisaged to achieve its goals, by articulating the steps of a theory-informed, hypothesised causal pathway, towards a particular vision (Breuer et al., 2016). The ToC process entails identifying short, medium, and long-term outcomes to achieve a desired impact, agreeing evidence and experience-informed actions required to achieve each step, underlying assumptions, and markers of progress. One advantage of ToC is the generation of a visual map of the overall programme theory, which is iteratively developed as new evidence and experience are obtained. ToC maps can be a valuable tool to facilitate discussion and attain shared understanding of complex interventions. Another advantage is that the ToC process entails participatory workshops with stakeholders, which integrate the perspectives of contextual experts into the map at key stages of planning, development, and evaluation. Furthermore, ToC workshops offer natural opportunities to engage stakeholders throughout the process of programme implementation. ToC has therefore been recommended for articulating the programme theory of complex interventions developed and evaluated under the MRC framework (De Silva et al., 2014). The ToC process has been used successfully in Ethiopia, including my PhD study site of Sodo (Abayneh et al., 2020; Hailemariam et al., 2015), and other LMICs (Breuer et al., 2014).

2.9.2 Mid-range theory

The ToC approach to articulating an over-arching programme theory is compatible with a range of theoretical conceptualisations of the processes that it describes. Identifying the most appropriate ‘mid-range’ theory to explain the mechanisms by which a ToC is expected to work presents challenges. First, the dominance of behavioural theories such as the transtheoretical ‘stages of change’ model (Prochaska et al., 1994) has been criticised as a “security blanket” (p. 1038) for researchers (West, 2005). Reliance on intuitively appealing theories may distract developers from important mechanisms outside the chosen theory, diminishing the effectiveness of resultant interventions (West, 2005). Second, theories selected “off the shelf” (p. 133) often focus simplistically on the individual level, neglecting the other levels of the ecological framework (Moore & Evans, 2017), limiting their ability to capture and respond to real-world complexity.

Moore and Evans (2017) built on Hawe et al. (2009)’s characterisation of interventions as events occurring in unpredictable, self-organising, complex systems. They contended that individual-level behavioural theories cannot account for ways that putative intervention mechanisms function in a given context at a given time. They argued that the inherent uncertainty associated with complex systems means that the ToC must be informed by the intimate knowledge of stakeholders. Moore and Evans (2017) emphasised the need for theories of change tailored to temporal and place contexts. They recommended that (1) the ToC should be informed by clarity on how problems are created and sustained in the context. Moore and Evans (2017) also advocated (2) broad theories of change which extend beyond the individual level, and (3) understanding of the systems within which the ToC is contextualised, privileging the perspectives of stakeholders.

However, there is a lack of evidence for which contextual adaptations make interventions more effective, and which are “nice-to-have” (p. 13; Heim & Kohrt, 2019). The authors recommended that cultural adaptation studies formulate and test theory-driven hypotheses about which components make interventions more acceptable and effective. ToC ensures that theory-driven hypotheses are articulated from the outset, facilitating theory-driven evaluation (Coryn et al., 2011).

2.9.3 Dark logic models

When articulating pathways to intended outcomes through a ToC, pathways to potential unintended consequences, including harms, require consideration (Bonell, Jamal, Melendez-Torres, & Cummins, 2015). Bonell et al. (2015) recommended developing a ‘dark logic model’ by first considering possible unintentional interactions between intervention stakeholders and broad aspects of social structure, such as gender norms. Second, they proposed building comparative understanding across similar interventions, by consulting relevant logic models, descriptions, and process evaluations, where available. Third, Bonell et al. (2015) recommended consulting stakeholders on foreseeable harms, based on their intimate knowledge of the systemic context.

2.10 Implementation science

Despite strong evidence for the efficacy of many healthcare interventions, their successful uptake into clinical practice is often hindered by implementation difficulties (Peters, Tran, & Adam, 2013). Implementation research³ is a key part of adapting evidence-based complex interventions for a specific setting. Capturing implementation outcomes, such as acceptability, feasibility, and fidelity can illuminate clinical outcomes and inform future applications in different contexts (Proctor et al., 2011). The new MRC/NIHR complex interventions framework explicitly advocates research perspectives beyond efficacy and effectiveness, emphasising the need for information that is useful for decision-making, including through process evaluation (Skivington et al., 2021).

2.10.1 Feasibility studies and process evaluations

MRC (Campbell et al., 2000; Craig et al., 2008) and MRC/NIHR frameworks (Skivington et al., 2021), and growing consensus (Hallingberg et al., 2018), support the need to determine the feasibility of complex interventions and their associated research designs, before conducting definitive RCTs. However, a binary focus on whether interventions are

³ Implementation research has been defined as “the scientific study of methods to promote the systematic uptake of proven clinical treatments, practices, organizational, and management interventions into routine practice, and hence to improve health” (Implementation Science, 2021).

or are not feasible or acceptable, and the use of RCT progression criteria, have been criticised. Fletcher et al. (2016) argued that realist evaluation principles would answer questions about interventions' feasibility "for whom and under what circumstances" (p. 294). They proposed that feasibility studies should refine mechanistic hypotheses in light of how an intervention appears to work in different contexts, in order to finesse programme theory, and pilot optimal measurement tools. They recommended purposively sampling diverse participants (for example, women who did and who did not engage with the intervention), exploration in different contexts (such as multiple study sites), collecting rich qualitative data, and using multiple study arms to compare the feasibility and acceptability of different interventions.

The second MRC framework (Craig et al., 2008) and new MRC/NIHR guidance (Skivington et al., 2021) also highlighted the importance of process evaluations for identifying causal mechanisms of and contextual barriers to intervention implementation. Process evaluations of feasibility studies can enhance the safety, efficiency, and validity of subsequent RCTs (Moore et al., 2015), by identifying barriers to implementation at the earliest possible stage.

2.10.2 Implementation science in LMICs

Explaining why and how patient, therapist, and psychological intervention variables influence clinical outcomes in LMICs is a key priority (Singla & Hollon, 2020). A systematic review of nine primary care mental health programmes conducted in 11 LMICs found that implementation success was influenced by the extent of organisation readiness, intervention planning, and adaptation processes (Esponda et al., 2020). The complexity of service user needs was the most commonly cited barrier, leading the authors to recommend social support interventions to address complex needs, such as poverty and IPV, alongside mental health conditions.

A systematic review of process evaluations of task-shared interventions for perinatal depressive symptoms in LMICs identified only three eligible studies, from Pakistan, India, and China (Munodawafa, Mall, Lund, & Schneider, 2018). A qualitative meta-synthesis found that the location and accessibility of the intervention setting, and

upholding of cultural norms, were important contextual factors. Intervention acceptability was influenced by session content and duration, and therapist training, supervision, and personal characteristics (such as being respected women from the community). Facilitators included therapist engagement and motivation to deliver sessions, efforts to build trusting therapeutic relationships, use of accessible visual aids, and perceived utility of the intervention. This limited evidence base, exclusively from middle-income Asian countries, demonstrated the contribution that process evaluations of perinatal mental health interventions conducted in sub-Saharan Africa would make to the literature.

The available evidence supports the need for high quality feasibility studies of psychological interventions in LMICs. Studies are required which pilot RCT methods and evaluate implementation, while considering contextual, setting, and intervention parameters (Pfadenhauer et al., 2017).

Section Three: PhD rationale, aims, and research questions

2.11 Rationale for study

No interventions have been developed to meet the needs of women experiencing perinatal mental health conditions and IPV in Ethiopia, despite the high prevalence of both, and their adverse health impacts. The evidence base from other LMICs is also sparse. There is a stronger evidence base for brief psychological interventions (not tailored for pregnant women or women experiencing IPV) from other LMICs. However, there is a range of contextual differences between rural Ethiopia and the peri-urban and/or middle-income country settings in which most published RCTs were conducted.

Concerted efforts to meet the millennium development goals in Ethiopia (Assefa, Van Damme, Williams, & Hill, 2017) mean that pregnancy is the commonest time for Ethiopian women to access healthcare. ANC is an important opportunity to provide interventions that address women's experiences of IPV. Given the adverse health impacts of perinatal IPV, described in sections 2.3.6, 2.3.7, and 2.3.9, ANC offers an opportunity to integrate support, services and interventions. Regular appointments, the ability to see the same health worker, and postpartum follow-up, make ANC well-suited to develop the trusting relationship required to explore sensitive subjects (WHO, 2011). My PhD therefore aimed to review the evidence base and consult stakeholders, before adapting and evaluating the feasibility of a brief psychological intervention for pregnant women experiencing IPV, in rural Ethiopian ANC.

2.12 Aims and Research Questions

This PhD aimed to:

- 1) Investigate the impact of IPV exposure on the efficacy of psychological interventions for CMDs in LMICs (Study One).
- 2) Explore the perspectives of pregnant women and antenatal care staff on perinatal emotional difficulties, IPV, and features of an acceptable intervention in rural Ethiopia (Study Two).

- 3) Adapt a brief psychological intervention for pregnant women experiencing depressive symptoms, functional impact, and IPV in rural Ethiopia (Study Three).
- 4) Evaluate the feasibility of the adapted intervention and a randomised, controlled study design (Studies Four and Five).

My research questions were:

- (i) Does IPV exposure reduce the efficacy of psychological interventions for CMDs in LMICs (Study One)?
- (ii) What are women's experiences of and health workers' perspectives on perinatal emotional difficulties and IPV in rural Ethiopia (Study Two)?
- (iii) What are women and health workers' perspectives on a brief intervention for the emotional difficulties of pregnant women experiencing IPV in rural Ethiopia (Study Two)?
- (iv) How can a brief psychological intervention be adapted for pregnant women experiencing depressive symptoms, functional impact, and IPV in this context (Study Three)?
- (v) Are the brief psychological intervention adapted for this context and a randomised, controlled feasibility study design acceptable to women and antenatal care staff, and feasible to implement (Studies Four and Five)?
- (vi) How should the intervention and randomised, controlled feasibility study be improved, to optimise the implementation of a future RCT (Studies Four and Five)?

3 STUDY ONE: DOES EXPERIENCING INTIMATE PARTNER VIOLENCE MODERATE THE EFFICACY OF PSYCHOLOGICAL INTERVENTIONS FOR COMMON MENTAL DISORDERS IN LOW AND MIDDLE-INCOME COUNTRIES?

This chapter presents the aims (3.1), hypothesis (3.2), methods (3.3), results (3.4), and discussion (3.5) of Study One.

3.1 Aims

The evidence base for the efficacy of psychological interventions for women experiencing common mental disorders (CMDs) and intimate partner violence (IPV) in low and middle-income countries (LMICs) is scarce, both outside (2.4.8) and during (2.4.10) pregnancy. Given the very limited evidence for interventions tailored for women experiencing IPV, I aimed to determine whether exposure to IPV moderates the efficacy of generic (untailored) psychological interventions in LMICs. I aimed:

- 1) To synthesise the available literature on the relative treatment responses of women who did and women who did not report experiencing IPV, to psychological interventions evaluated using randomised controlled trial (RCT) methods in LMICs.
- 2) To investigate the hypothesis that exposure to IPV is an effect modifier of psychological interventions for CMDs in LMICs, with greater IPV frequency and severity associated with a lesser treatment response.

3.2 Hypothesis

I hypothesised that exposure to IPV moderates the efficacy of psychological interventions for CMDs in LMICs, with treatment effects being smaller in women reporting IPV than in women not reporting IPV.

3.3 Methods

I registered Study One on the PROSPERO database (Ref: CRD42017078611; Keynejad, Hanlon, & Howard, 2017) and followed PRISMA guidelines for its reporting (Page et al., 2021).

3.3.1 Inclusion criteria

A paper was eligible for inclusion in Study One if it described an RCT, which evaluated a psychological intervention delivered to at least some adolescent or adult female participants in a LMIC, for the purpose of improving symptoms of a CMD, and measured exposure to IPV.

3.3.1.1 Population

IPV is defined as behaviour occurring between intimate partners or ex-partners (WHO, 2017a); in the UK, domestic violence and abuse are specified as occurring between those aged 16 years and over (Home Office, 2013). Child marriage (under 18 years of age) affects one in five girls worldwide (UNICEF, 2021), blurring the boundaries between IPV and child abuse. In order to focus Study One on exposure to IPV rather than child abuse, I restricted eligibility to studies which included adolescent female (aged 13 years or over) or adult participants, with no upper age limit.

I included studies of both female and male participants, if the paper or authors could provide data disaggregated by gender. I defined countries as LMICs according to their economic classification at the time of that study's data collection (The World Bank, 2021a). In 2021, a low-income country was defined as having a gross national income (GNI) of \$1,035 or less per capita, and a middle-income country was defined as having a GNI of between \$1,036 and \$12,535 per capita, according to figures from 2019 (The World Bank, 2021a). I excluded studies conducted in HICs (with a GNI of \$12,536 or more per capita), due to their anticipated contextual heterogeneity in comparison to studies conducted in LMICs. For example, I expected that the type of intervention offered, women's access to education, and the provision of services assisting women to respond to IPV and its mental health consequences, would differ substantially between HIC and

STUDY ONE: DOES EXPERIENCING INTIMATE PARTNER VIOLENCE MODERATE THE EFFICACY OF PSYCHOLOGICAL INTERVENTIONS FOR COMMON MENTAL DISORDERS IN LOW AND MIDDLE-INCOME COUNTRIES?

LMIC settings. For inclusion, I required studies to have clinically diagnosed or screened participants for depressive, anxiety, PTSD, or psychological distress symptoms, at baseline.

3.3.1.2 Intervention

I adopted a broad definition of ‘psychological intervention’ to mean any talking-based therapeutic treatment delivered with the stated aim of improving the primary outcome of a CMD, or psychological distress. I defined CMDs as symptoms or diagnoses of mild to moderate depression, anxiety disorders, and PTSD. I distinguished CMDs from severe mental illness (SMI), adopting the Public Health England (2018) definition of disorders which severely impair work and functioning on a daily basis, such as schizophrenia, bipolar affective disorder, and severe depression. I included psychological distress as an additional outcome measure, which is often employed in LMIC settings (Getanda, Papadopoulos, & Evans, 2015), in order to capture emotional difficulties falling outside a biomedical diagnostic model (Andrews & Slade, 2001). Given my hypothesis, that IPV moderates the efficacy of psychological interventions for CMDs in LMICs, I excluded studies targeting psychotic, cognitive (dementia, traumatic brain injury, intellectual disability), neurodevelopmental, substance use, and personality disorders.

3.3.1.3 Comparator

I required included studies to compare sessions of a psychological intervention with any comparator, including treatment as usual.

3.3.1.4 Outcome

I required included studies to measure symptoms of one or more CMD, or psychological distress, as outcomes.

3.3.2 Exclusion criteria

I excluded any studies which were not RCTs; that is, if they did not allocate participants with similar characteristics to one of at least two study arms, at random (NICE, 2021). I excluded any RCT of a psychological intervention delivered to at least some adolescent

or adult female participants for CMDs in a LMIC, unless outcome data could be separated into results for women who did and women who did not report exposure to IPV, as defined by WHO (2017a). I therefore excluded studies which did not measure IPV exposure, or which only included participants who were experiencing IPV (and so could not compare their outcomes with those of women not experiencing IPV). I did not apply language or date exclusions, to maximise the breadth of literature eligible for inclusion.

3.3.3 Search strategy

3.3.3.1 Sources

I performed the search on 12th February 2018 and repeated it to check for more recent publications on 16th August 2019. I searched Medline, Embase, PsycInfo and Global Health databases via the Ovid platform (Wolters Kluwer, 2019) and 3ie, CINAHL, Cochrane Central, LILACS, PILOTS, SciELO, Scopus, and Web of Science Core Collection databases, via their respective websites. Each platform required slightly different search terms, but each search comprised a comprehensive set of terms pertaining to the four constructs of “RCT”, “psychological intervention”, “CMD”, and “LMIC”. Each synonym within each of these four sub-searches was combined using the Boolean operator “OR”. The results of each of these four sub-searches were then combined using the Boolean operator “AND” (search terms used in Medline are shown in Appendix 10.1.1). I performed supplementary searches of trials registries and backward and forward citation tracking of included studies. Given my focus on RCTs, I only searched for peer-reviewed papers published in academic journals.

3.3.3.2 Screening

I imported all references from online databases into Endnote X8 (The EndNote Team, 2016). After removing duplicates electronically, I imported the remaining references into Covidence online software (Veritas Health Innovation, 2016), for screening. I screened the titles and abstracts of all references, using a hierarchical approach to exclusions. That is, I excluded studies first if they did not use an eligible study design (RCT), second if they did not use an eligible intervention (psychological), third, if they were not conducted in an eligible setting (LMIC), fourth, if they were not conducted for an eligible indication

(CMDs), and fifth, if they did not study an eligible population (adolescent or adult females).

Due to the likelihood of IPV being measured by some studies but not mentioned in titles and abstracts, I first screened the search results to identify RCTs of psychological interventions for CMDs in LMICs, which included at least some adolescent or adult female participants. I then hand-searched the full texts of otherwise eligible studies to determine whether exposure to IPV had been measured.

An independent reviewer (KS) screened 5% (278/5452) of unduplicated records at title and abstract level; I single-screened full text articles. I resolved any disagreements about exclusion and implications for other exclusions through discussion with KS.

3.3.3.3 Data extraction

I obtained anonymised aggregate, sub-group data from eligible records through individual approaches to authors, by email. I extracted the following pre- and post-intervention data for meta-analysis: N, mean outcome measure scores and standard deviations, for female participants, separated into those who did and did not report IPV exposure, in both intervention and control groups. An independent reviewer (SP) repeated the data extraction and cross-checked it for quality control purposes. I used a piloted table to extract study design and implementation details, and evaluated all included studies using the Cochrane risk of bias tool (Higgins & Green, 2011).

3.3.4 Data analysis

I performed independent samples t-tests to compare mean baseline CMD and psychological distress scores between groups reporting and not reporting IPV in each included study. I performed random-effects meta-analyses using Stata 15 (StataCorp, 2017) for any CMD or psychological distress outcome measured by at least four studies (Guolo & Varin, 2017), estimating heterogeneity using I^2 , and visually inspecting the funnel plot for meta-analyses including at least 10 studies.

Because authors provided disaggregated data, I first separately calculated the standardised mean difference (SMD) in treatment effect, and the standard error between

participants with and without IPV exposure, for each intervention group and for each control group, before conducting a second random-effects meta-analysis of the difference between SMDs (dSMD) between intervention and control groups.

I anticipated that in settings where IPV was sufficiently prevalent to be measured, female therapists may have been considered more culturally acceptable to female participants. In fact, a lower than anticipated number of interventions was delivered by female therapists (five), and no study matched participants and therapists by gender. Conversely, a higher than anticipated number of included studies evaluated interventions featuring components explicitly designed to address traumatic experiences (four). I therefore conducted post-hoc sub-group analyses, to compare the dSMDs of female-delivered versus mixed staff-delivered interventions, and trauma-focused versus generic psychological interventions. I performed sensitivity analyses by reviewing changes to pooled dSMD estimates when one study was removed from each meta-analysis at a time.

3.4 Results

The PRISMA checklist for Study One is presented in Appendix 10.1.8.

3.4.1 Flow of records

After excluding 2670 duplicates, I screened 5452 records at title and abstract level, excluding 4961 (Figure 3.1). I screened the remaining 491 records at the level of full text, yielding 21 eligible records. Agreement between me and KS on screening decisions was 98.6% (274/278). I resolved all disagreements following discussion, and noted the reasons for initial differences, to inform subsequent decisions. Of the 470 records excluded at the level of full text, 395 (84%) were RCTs of psychological interventions in LMICs which did not measure whether participants were experiencing IPV. Other reasons for exclusion are shown in Figure 3.1. Data were not provided for six of the 21 eligible records; the authors of 15 records shared data for meta-analysis pertaining to 12 studies. The data provided described 14 interventions because two studies reported three-arm trials (Bolton et al., 2014; Ertl, Pfeiffer, Schauer, Elbert, & Neuner, 2011), enabling meta-analysis of four symptom groups: anxiety, PTSD, depression and psychological distress.

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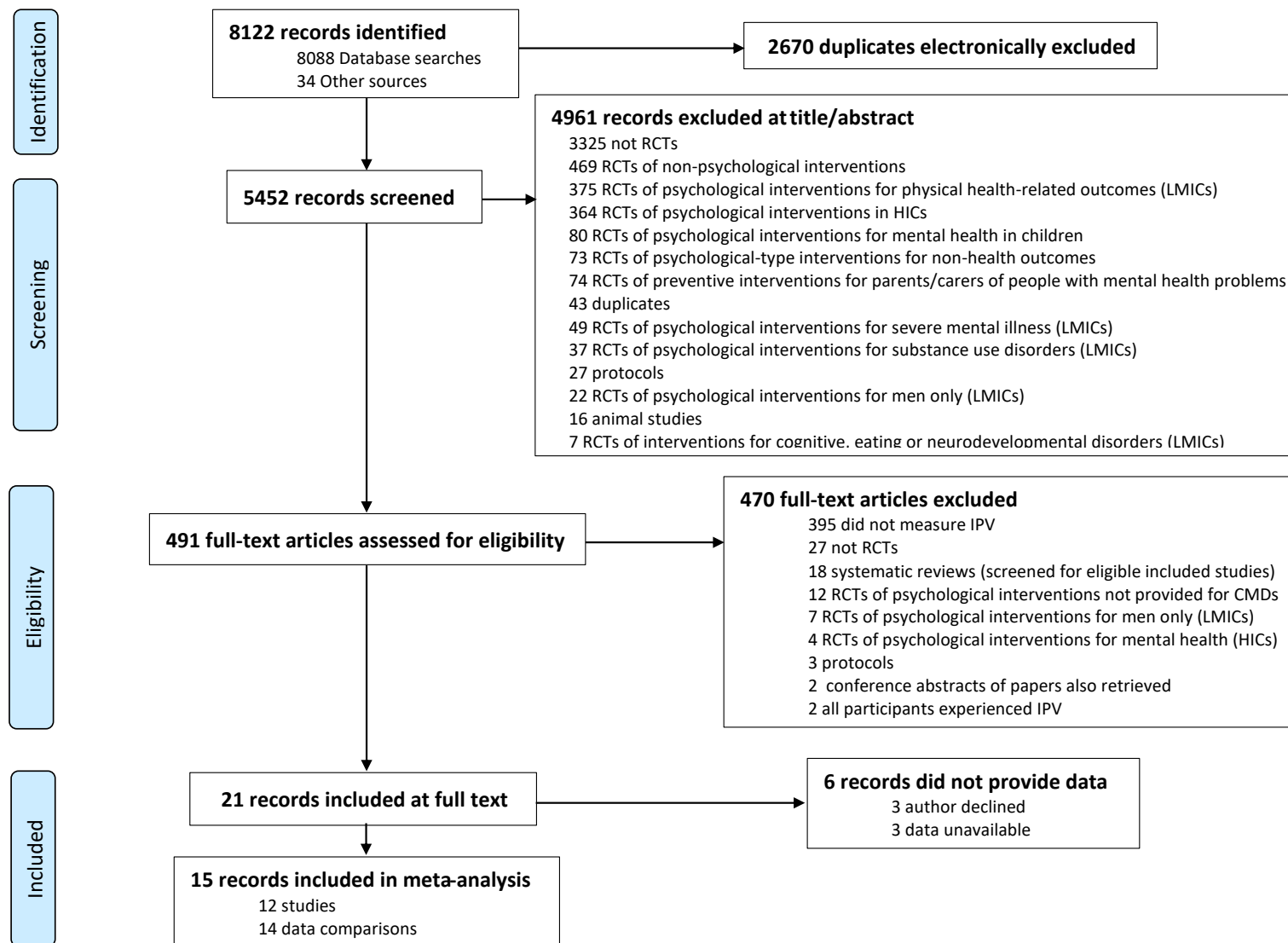


Figure 3.1 PRISMA diagram: identification, screening, eligibility, and inclusion

3.4.2 Characteristics of included studies

Table 3.1 summarises the study designs and implementation details of included records. Seven of the 14 interventions were implemented in the (WHO-designated) African region (four in Uganda and one each in Kenya, Zimbabwe, and South Africa). Four interventions were implemented in the Eastern Mediterranean region (three in Iraq, one in Pakistan), two in the South-East Asia region (both in India), and one in the Western Pacific region (Cambodia). Six of the interventions were implemented in post-conflict regions of Iraq (Bass et al., 2016; Bolton et al., 2014), Uganda (Ertl et al., 2011), and Cambodia (Steinert et al., 2017), and one was implemented in a settlement for South Sudanese refugees in Uganda (Tol et al., 2020). The remaining interventions were implemented in areas unaffected by recent conflict. All studies had been published after 2010 and none included participants aged under 13 years. Three studies employed cluster randomisation (Chibanda, Weiss, et al., 2016; Sikander et al., 2019; Tol et al., 2020) and the remainder randomised participants individually.

The 14 interventions described by included studies were delivered by a range of professionals. These comprised a public health professional and researcher (Grundlingh, Knight, Naker, & Devries, 2017), psychology master's-educated therapists (Steinert et al., 2017), community mental health (Bass et al., 2016; Bolton et al., 2014), general health (Bryant et al., 2017; Lund et al., 2014), and other community workers (Tol et al., 2020), and lay persons (Chibanda, Weiss, et al., 2016; Ertl et al., 2011; Fuhr et al., 2019; Patel et al., 2017; Sikander et al., 2019). Five studies compared the control intervention (enhanced usual care: EUC) to the intervention plus EUC (Chibanda, Weiss, et al., 2016; Fuhr et al., 2019; Patel et al., 2017; Sikander et al., 2019; Tol et al., 2020). Control conditions comprised face-to-face or telephone-delivered basic counselling (Bryant et al., 2017; Lund et al., 2014), diagnosis and WHO mental health gap action programme intervention guide (mhGAP-IG)-led treatment (Fuhr et al., 2019; Patel et al., 2017; Sikander et al., 2019), a home visit (Tol et al., 2020), film screenings (Grundlingh et al., 2017), and a waiting list (Bass et al., 2016; Bolton et al., 2014; Ertl et al., 2011; Steinert et al., 2017).

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The number of psychological intervention sessions delivered ranged from three (Grundlingh et al., 2017) to 14 (Fuhr et al., 2019). Sessions were delivered at clinics (Bass et al., 2016; Bolton et al., 2014), in community settings (Chibanda, Weiss, et al., 2016; Grundlingh et al., 2017; Tol et al., 2020), at home (Bryant et al., 2017; Ertl et al., 2011; Fuhr et al., 2019), or a mixture of locations (Lund et al., 2014; Patel et al., 2017; Sikander et al., 2019). Two interventions were delivered in groups (Grundlingh et al., 2017; Tol et al., 2020), one study delivered both group and individual sessions (Sikander et al., 2019), and the remainder were fully individualised. All but two studies reported statistically significant improvements in at least one CMD in the intervention group, compared with the control group. These were Grundlingh et al. (2017) and Lund et al. (2014), whose results were later published as Lund et al. (2020). Mean baseline CMD scores differed significantly between women who did and did not report IPV in none of the five interventions reporting anxiety symptoms, two out of eight interventions reporting PTSD symptoms, five out of 12 interventions reporting depressive symptoms, and one of the four interventions reporting psychological distress symptoms (see Appendix 10.1.2).

3.4.3 Risk of bias

Cochrane risk of bias assessments (see Appendix 10.1.3) indicated moderate risk of bias in 67% (8/12) of studies, and low risk in 33% (4/12). All studies shared the inability to mask participants and professionals to the psychological or control intervention which they received or delivered. Only PTSD symptom results comprised studies exclusively rated as being at moderate risk of bias. The funnel plot for the 12 studies included in the depression meta-analysis was asymmetrical, suggesting potential publication bias (see Appendix 10.1.4).

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Table 3.1 Characteristics of included records

AIDS=Acquired Immunodeficiency Syndrome, ANC=Antenatal Care. BA=Behavioural Activation. BATD=Behavioural Activation Treatment For Depression. CAP=Counselling for Alcohol Problems. CAPS=Clinician-Administered PTSD Scale. CAS=Composite Abuse Scale. CMD=Common Mental Disorder. CHW=Community Health Worker. CMHW=Community Mental Health Worker. CPA=Community Psychosocial Assistant. CPT=Cognitive Processing Therapy. DSM=Diagnostic and Statistical Manual of Mental Disorders. EMDR=Eye Movement Desensitisation Reprogramming. EPDS=Edinburgh Postnatal Depression Scale. ENACT=Enhancing Assessment of Common Therapeutic factors assessment. EUC=Enhanced Usual Care. FB=Friendship Bench. GAD-7=Generalised Anxiety Disorder Assessment. GHQ-12=General Health Questionnaire. HAP=Healthy Activity Program. HIV=Human Immunodeficiency Virus. HSCL-25=Hopkins Symptom Checklist. HTQ=Harvard Trauma Questionnaire. IPV=Intimate Partner Violence. LEC=Life Events Checklist. LHW=Lady Health Worker. mhGAP=WHO Mental Health Gap Action Programme. MINI=Mini-International Neuropsychiatric Interview. NET=Narrative Exposure Therapy. NGO=Non-Governmental Organisation. PCL-5=PTSD checklist for DSM-5. PCL-C=PTSD Checklist-Civilian version. PHC=Primary Health Care. PHQ-9=Patient Health Questionnaire 9. PM+=Problem Management Plus. PSS-I=Post-traumatic Stress Symptom scale – Interview. PTSD=Post-Traumatic Stress Disorder. RCT=Randomised Controlled Trial. ROTATE=Resource-Oriented Trauma therapy and EMDR resource installation. SH+=Self-Help Plus. SRQ-20=Self-Reporting Questionnaire-20. SSQ-14=Shona Symptom Questionnaire. TAU=Treatment As Usual. THPP=Thinking Healthy Programme-Peers. VAW= Violence Against Women. WHO=World Health Organization. WHODAS=WHO Disability Assessment Schedule.

First author, Year	Site	Timing	Design, Population	Inclusion, Exclusion, IPV measure(s)	Intervention (N), Control arms (N)	Intervention training, delivery	Supervision and quality control	Intervention content	Session format, #, duration	Safety aspects
Bass et al. 2016	Dohuk, Kurdistan, northern Iraq.	<u>Screening:</u> June 2009 to June 2010.	Individual RCT of 18+ year-old adults referred by clinic doctors and former prisoner organisations.	<u>Inclusion:</u> HSCL-25 depression score 20+, 2x DSM-IV depression symptoms, experienced or witnessed torture, imprisonment or military attacks. <u>Exclusion:</u> psychosis, suicidality, unable to consent. <u>IPV:</u> Asked about domestic violence (no time limit).	<u>Intervention:</u> A trauma-informed support, skills, and psychoeducation intervention. (N=54). <u>Control:</u> waiting list: CMHWs telephoned to briefly check if substantially greater distress or new risks to self or others. (N=15).	11 CMHWs attended 2 weeks' training on social work model of support using locally-informed training materials, then more advanced and refresher training over 2 years.	Weekly phone check-ins, monthly on-site field supervision groups led by psychiatrist. Supervisor reviewed notes for CMHW responses, checklists of activities could have provided.	Time limited trauma-informed support, skills and psycho-education sessions on depression, anxiety, and grief strategies.	6-12 individual sessions at Ministry of Health clinics.	CMHWs adhered to ethical standards. Advised to self-care, monitor own feelings, access professional support, maintain work-life balance. Control participants advised to contact CMHWs if worsened. Staff could refer to psychiatrist/ trauma rehabilitation centre.

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First author, Year	Site	Timing	Design, Population	Inclusion, Exclusion, IPV measure(s)	Intervention, (N), Control arm (N)	Intervention training, delivery	Supervision and quality control	Intervention content	Session format, #, duration	Safety aspects
Bolton et al. 2014	Rural areas of Erbil and Sulaimaniyah, Kurdistan, northern Iraq.	<u>Recruited:</u> June 2009 to June 2010	Individual RCT of 18+ year-old adults referred by doctors and nurses at 14 Ministry of Health PHC centres, 1 outpatient clinic, and publicity by former prisoner groups.	<u>Inclusion:</u> HSCL-25 depression 20+, DSM-IV depression symptoms, experienced or witnessed torture, imprisonment or military attacks. <u>Exclusion:</u> Sorani Kurdish non-fluent, psychosis, suicidality, lacking capacity to consent. <u>IPV:</u> experienced domestic violence? (No time limit).	<u>Interventions:</u> (a) behavioural activation treatment for depression (BATD; N=65) (b) cognitive processing therapy (CPT; N=58). <u>Control:</u> waiting list: monthly inquiry about symptoms, risks to self or others (a: N=16: b: N=23).	20 CMHWs: local PHC staff with experience of rural work with torture and trauma survivors, trained in supportive counselling. Training (a) or (b) for 2 weeks by American trainers then local supervisor.	Local supervisors received remote online weekly training and oversight from American trainers.	(a) BATD strategies encourage healthy and positive values-based behaviours. (b) CPT cognitive restructuring and emotional processing of traumatic events.	12 individual sessions delivered in private spaces provided by clinics.	Control participants were advised to contact CMHWs at any time if their symptoms worsened substantially. Such participants were assessed for consideration of referral and transfer to a psychiatrist or torture treatment centre.
Bryant et al. 2017	Peri-urban Nairobi, Kenya.	<u>Screening:</u> 15/04/2015 to 20/08/2015. <u>Final follow-up:</u> 16/01/2016.	Individual RCT of women residing in every 10 th household with a history of gender-based violence (GBV).	<u>Inclusion:</u> GHQ-12 >2, WHODAS 2.0 >16 <u>Exclusion:</u> Imminent suicide, psychotic disorders, severe cognitive impairment. <u>IPV:</u> Any prior/current experience of interpersonal violence on either LEC or WHO VAW Instrument (past 12 months).	<u>Intervention:</u> 5 week course of PM+. N=209. <u>Control:</u> referral to PHC centre for non-specific counselling by 6 experienced, unsupervised nurses who received 3 days' manualised and Psychological First Aid training (N=208).	23 lay CHWs received 8 days' (64 hours) training on CMDs, counselling, PM+, self-care, GBV, ethics, confidentiality. 1 day Psychological First Aid on managing people needing immediate attention and referral.	Each CHW supervised to deliver PM+ to ~3 clients then competency assessed. 2 psychologists supervised CHWs for 2 hours/week in 4 groups of 5. Supervisors received 1.5 hours' weekly online training. 10% sessions checked by supervisor.	<u>1:</u> psycho-education, motivational interviewing, stress management <u>2:</u> problem-solving strategies <u>3:</u> behavioural activation <u>4:</u> strengthening social support <u>5:</u> reinforcement, relapse prevention.	5x weekly 90 minute individual sessions at home unless safety/privacy reasons. Each CHW provided PM+ to 8-12 women.	Threats of harm/self-harm referred to local services. Psychiatric crises (imminent suicidal plan)/need for acute protection referred to local advisory board and participant referred to appropriate services, including local hospitals providing psychiatric care. Adverse reactions monitored and recorded.

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First author, Year	Site	Timing	Design, Population	Inclusion, Exclusion, IPV measure(s)	Intervention, (N), Control arm (N)	Intervention training, delivery	Supervision and quality control	Intervention content	Session format, #, duration	Safety aspects
Ertl et al. 2011	Anaka, Awer and Padibe, northern Uganda.	November 2007 to October 2009.	Individual RCT of former child soldiers with DSM-IV PTSD, screening >15 on PTSD scale, in survey of 1113 people aged 13-25 years.	<u>Inclusion:</u> PTSD on CAPS. Suicidal ideation, substance abuse or depression were <u>not</u> reasons for exclusion. <u>Exclusion:</u> Psychotic symptoms. <u>IPV:</u> Items on the Violence, War and Abduction Exposure Scale (no time limit).	<u>Intervention:</u> (a) Narrative exposure therapy (NET; N=16). (b) Academic catch-up programme with supportive counselling elements (N=19). <u>Control:</u> Waiting list (N=12).	14 (50% female) intensively-trained local lay counsellors	Fidelity and competence monitored by supervision, observation, and video evaluation of sessions, and review of treatment notes. NET testimonies reviewed for trauma focus and detail.	<u>1:</u> (both active arms): PTSD education. Then: (a) biography to reconstruct, habituate traumatic memories. (b) symptom, problem counselling, academic training.	8x 90-120 minute at-home individual sessions scheduled 3x per week in internally displaced persons' camp.	Waiting list participants who reported very high suicidal ideation received suicide intervention. Waiting list and academic catch-up participants still exhibiting PTSD at 12 months' follow-up were offered NET.
Grundlingh et al. 2017	Rural and urban Luwero district, Uganda.	<u>Recruited:</u> 15-16/06/2014. <u>Baseline to endline assessment:</u> 17/06/2014 to 11/07/2014.	Individual RCT of Ugandan university-qualified research assistants employed to interview children about interpersonal violence.	<u>Inclusion:</u> Any research assistant employed by the Good Schools Study. <u>Exclusion:</u> None. <u>IPV:</u> WHO Multi Country Study items, including physical, sexual and emotional violence from partners (past 12 months).	<u>Intervention:</u> 3x weekly Group Debriefings for Secondary Distress, including 'Critical Incident Stress Debriefing' (N=15). <u>Control:</u> Weekly light-hearted, uplifting film screenings presented as fun and relaxing. Intervention provided after study (N=19).	Debriefings delivered by intervention designer and study first author, a healthcare professional with training and experience of facilitating health promotion activities in small groups.	None mentioned.	Storytelling, identifying responses, psycho-education, normalising reactions. <u>Session 1:</u> discussing experiences. <u>Session 2:</u> linking study experiences with life experiences. <u>Session 3:</u> societal and community responses.	3x 90-120 minute face-to-face group sessions after work at staff hotel. Each session started with ice-breaker for relaxed atmosphere/cohesion.	All participants received contact details for external support services and were referred to additional counselling if severe secondary trauma or vicarious trauma detected. Care taken not to pressure individuals to disclose personal experiences; option to write experiences on paper.

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First author, Year	Site	Timing	Design, Population	Inclusion, Exclusion, IPV measure(s)	Intervention, (N), Control arm (N)	Intervention training, delivery	Supervision and quality control	Intervention content	Session format, #, duration	Safety aspects
Brown et al. 2018. Tol et al. 2018. Tol et al. 2020.	14 refugee settlements in northern Uganda.	Recruited: March to April 2017.	Superiority cluster RCT, stratified by locality, of 18+ year-old women from South Sudan screened through random household sampling.	<u>Inclusion:</u> Psychological distress: Juba Arabic Kessler 6 score > 5 <u>Exclusion:</u> Imminent suicide or life-threatening risk, severe mental disorder, unable to understand study materials or speak Juba Arabic. <u>IPV:</u> 3 items from WHO VAW measure (past 12 months).	<u>Intervention:</u> Guided, adapted acceptance and commitment therapy-based SH+ plus EUC (N=331). <u>Control:</u> 10-15 minute CPA home visit with village health team member and a refugee, on distress, overthinking, support (N=363).	2 Arabic and English-speaking secondary educated facilitators with community experience attended 2x 4 day training stages, 1 led by WHO master trainer.	Social worker, clinical supervisor, and team leader supervision, remote access to master trainer, 2x competency checks, written facilitator guide.	Present moment awareness skills and grounding, defusion, acceptance of difficult thoughts and feelings, identifying valued life directions, taking action, compassion towards self and others.	5x 2 hour group facilitator-led workshops with audio-recorded materials and pictorial guide.	Group peer review after each session covering difficulties in delivery, concerns, adverse events, serious adverse events reported to a data safety and monitoring board to act if needed.
Chibanda et al. 2016	24 PHC centres in accessible sites in Harare, Zimbabwe.	01/09/2014 to 25/05/2015.	Cluster RCT, stratified by HIV status, housing density, clinic size, sex, of 18+ year-old adults randomly selected until 24 participants enrolled per clinic.	<u>Inclusion:</u> SSQ-14 score > 8 <u>Exclusion:</u> Pregnant/ up to 3 months post-partum, non-fluent in English/Shona, suicidal intent, end-stage AIDS, acute psychosis, intoxication or dementia, receiving psychiatric care. <u>IPV:</u> any 'domestic upheaval' in the last six months.	<u>Intervention:</u> Friendship Bench (FB): problem-solving therapy + EUC (N=230). <u>Control:</u> nurse-led evaluation, counselling, education, CMD support, antidepressant review, 2-3 messages/ calls, reminder to attend follow-up (N=216).	Female Lay Health Workers (mean age: 53 years, mean education: 10 years), able to use a mobile phone, living in the study area, who attended 9 days' training.	Supervision, support from trained senior health promotion officers. Groups facilitated by trained previous FB recipients. All sessions audio-recorded and assessed with checklist.	<u>1:</u> Guided problem identification and action planning, uplifting, strengthening; later sessions built on #1. Therapists promoted positivity, coping, sense of life control.	6x FB sessions (0:30-1 hour), 6 messages / calls, optional 6x peer-led group support after 4 sessions with crochet.	Excluded individuals referred to tertiary facility. Trained, supervised staff referred worsening/suicidal participants to mental health trained supervisor. Intervention group participants assessed by psychiatrist if worsened SSQ-14 score after 3 sessions.

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Lund et al. 2014	2 ante-natal clinics in a low-income township of Cape Town, South Africa.	October 2013 to June 2016.	Individual RCT of 18+ year-old pregnant women no more than 26 weeks' gestation, living in the study area.	<u>Inclusion:</u> EPDS>12, isiXhosa-speaking. <u>Exclusion:</u> Requiring urgent medical attention, schizophrenia, bipolar mood disorder, psychosis, inability to consent. <u>IPV:</u> Experience of physical or sexual violence by a partner in the past 3 months.	<u>Intervention:</u> Structured, manualised counselling by 6 trained CHWs (N=205). <u>Control:</u> 3x monthly calls by 2 CHWs. Brief conversation about feelings, life changes, support, perinatal services, suicidality (N=214).	12 CHWs employed by local NGO attended 5 days' training (refresher available) by Clinical Social Worker. 6 chosen for intervention (based on motivation, understanding, empathy, interpersonal style).	Weekly group supervision by social worker, including case reviews, managing emergencies. Monthly individual supervision. 1 st session observed, all recorded, random review.	Aspects of psycho-education, problem-solving therapy, behavioural activation, cognitive reframing (healthy thinking) and relaxation training.	6x fortnightly counselling (1 hour) in 3-4 months; phone calls if missed. Sessions in clinic/home, aligned with routine ANC.	Women scoring >16 on MINI referred to health centre psychiatric nurses and District Hospital if needed. Control participants given health service and NGO details if abuse/ other social difficulties. Data safety monitoring board monitored with response protocol. Training covered burnout; staff counselling available.
Sikander et al. 2018	10 village clusters in rural sub-district of Rawalpindi, Pakistan	Randomisation: 15/10/2014 to 25/02/2016.	Cluster RCT of 18+ year-old women in 3 rd trimester of pregnancy registered for village-based healthcare from local lady health workers (LHWs).	<u>Inclusion:</u> PHQ-9 >10 <u>Exclusion:</u> Not staying in area for at least 1 year, non-fluent in Urdu, Punjabi or Potohari, need for immediate medical/ psychiatric inpatient care. <u>IPV:</u> Query about any domestic violence in the last 3 months.	<u>Intervention:</u> THPP + EUC (N=275). <u>Control:</u> LHWs informed of depression screening, given mhGAP perinatal depression guide. Participant given information on how to seek help (N=282).	3 volunteer LHWs per village cluster: married women aged 30-35 years, with children, selected for communication skills. Received brief classroom training and regular group training.	Field supervision by local non-specialist THPP trainers supervised by specialist therapist. ENACT-based competence ratings.	Behavioural activation, narratives and pictures challenging unhelpful thinking and behaviour.	10 individual at-home sessions + 4 group sessions at LHW's home lasting 30-45 minutes; sessions more frequent before delivery.	Overseen by data safety and monitoring board. Data collected on serious adverse events. mhGAP EUC contained guidelines about referral of women at risk of suicide.

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First author, Year	Site	Timing	Design, Population	Inclusion, Exclusion, IPV measure(s)	Intervention, (N), Control arm (N)	Intervention training, delivery	Supervision and quality control	Intervention content	Session format, #, duration	Safety aspects
Patel et al. 2017 Weobong et al. 2017	10 PHC centres in Goa, India.	28/10/2013 to 29/07/2015 (enrolment and randomisation).	Individual RCT, stratified by PHC centre and sex, of 18-65 year-old adults.	<u>Inclusion:</u> PHQ-9 score > 14. <u>Exclusion:</u> Pregnant, requiring urgent medical attention or unable to communicate clearly. <u>IPV:</u> Experience of physical or psychological IPV (no time limit).	<u>Intervention:</u> Healthy Activity Program (HAP): manualised treatment + EUC (N=103). <u>Control:</u> informed of depression screening results, mhGAP manual provided to physician with referral details (N=116).	3 week participatory workshop for lay counsellors on HAP+CAP: Counselling for Alcohol Problems, followed by 6 month internship phase: delivery with peer-led group supervision.	5 trained local specialists supervised by international BA expert supervised 11 trained lay counsellors. Random 10% recordings expert-rated, fortnightly supervision, weekly peer supervision.	Psycho-education, behavioural assessment, activity monitoring, structuring, scheduling, social networking, problem solving, communication, sleep, relaxation.	6-8x individual sessions lasting 30-40 minutes. Sessions delivered at PHC centre or home, by telephone when needed.	Participants who did not respond could be referred for specialist care. EUC included information about referral. Study overseen by data and safety monitoring committee. Serious adverse event data collected.
Fuhr et al. 2019	North district of Goa, India.	<u>Assessed for eligibility:</u> 24/10/2014 to 24/06/2016 <u>Final treatment:</u> 27/05/2017	Individual RCT of 18+ year-old pregnant women (second or third trimester) attending 1 of 2 antenatal clinics and 2 primary healthcare centres.	<u>Inclusion:</u> scoring 10+ on PHQ-9 <u>Exclusion:</u> Not intending to remain in study area for next year, not speaking Konkani, Hindi or Marathi, needing immediate psychiatric or medical inpatient care. <u>IPV:</u> 'Any domestic violence in the last three months?'	<u>Intervention:</u> THPP: Thinking Healthy Program (Peers) + EUC (N=140). <u>Control:</u> women + gynaecologist informed of depression, given adapted mhGAP guide for perinatal depression including on referring suicidality. Women informed about perinatal care (N=140).	26 <i>Sakhi</i> : middle-aged lay mothers interested in supporting women, selected for communication skills. Received 25-40 hours' interactive training on intervention, relationship-building skills. Training incorporated discussion and role plays.	Role play competence assessment. Fortnightly peer-led supervision in groups of 4-5; 50% attended by supervisor. Supervision discussed recorded sessions, rated on Therapy Quality Scale. Monitored by independent audio ratings of random 5%.	THP model adapted to focus on BA. 4 phases: <u>Prenatal:</u> 1-6 sessions <u>Early Infancy:</u> 1-4 sessions in 2 postnatal months, <u>Middle Infancy:</u> 2 sessions 3-4 months postpartum, <u>Late Infancy:</u> 2 sessions 5-6 months postpartum.	6-14x 30-45 minute individual sessions delivered over 7-12 months at home, unless requested.	Sakhi training included dealing with difficult situations, recognising worsening symptoms, and serious adverse events. Sakhis had a maximum caseload of 4 women at any one time.

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First author, Year	Site	Timing	Design, Population	Inclusion, Exclusion, IPV measure(s)	Intervention, (N), Control arm (N)	Intervention training, delivery	Supervision and quality control	Intervention content	Session format, #, duration	Safety aspects
Steinert et al. 2017	Phnom Penh City and nearby Kandal province, Cambodia.	Recruited: May 2012 to June 2014.	Individual RCT of 18+ year-old adults seeking help from 'Mekong Project', which provided free psychological help to traumatised civilians.	<u>Inclusion:</u> 44+ on PCL-C. <u>Exclusion:</u> Psychosis, brain disorder, cognitive impairment, suicidality, acute illness, communication difficulties, therapy in past 2 years. <u>IPV:</u> trauma for which therapy sought, including domestic violence (no time limit).	<u>Intervention:</u> Resource-oriented trauma therapy combined with EMDR resource installation (ROTATE; N=34). <u>Control:</u> Waiting list (N=17).	6 psychology master's educated local psychologists who had completed 3 year course in trauma therapy led by experienced therapist.	Not mentioned.	Manualised resource activation to enhance emotion regulation, grounding techniques, EMDR resource development and installation.	5 hours in weekly individual sessions.	Not mentioned.

3.4.4 Meta-analyses

Data were available for random-effects meta-analysis of five interventions which measured anxiety symptoms in a total of 728 participants (Figure 3.2A). The interventions comprised problem-solving therapy (the Friendship Bench) in Zimbabwe (Chibanda, Weiss, et al., 2016), trauma-informed support, skills, and psychoeducation in Iraq (Bass et al., 2016), behavioural activation treatment for depression (BATD; Bolton et al., 2014a), cognitive processing therapy (CPT) in Iraq (Bolton et al., 2014b), and resource-oriented trauma therapy and eye movement desensitisation and reprocessing (EMDR) resource installation (ROTATE) in Cambodia (Steinert et al., 2017). Meta-analysis showed a greater overall treatment effect on anxiety symptoms among women who reported IPV exposure, than among women who did not (difference in standardised mean differences: dSMD: 0.31, 95% CI: 0.04, 0.57, I^2 : 49.4%).

Data were available for random-effects meta-analysis of eight interventions which measured PTSD symptoms in a total of 1,436 participants (Figure 3.2B). The interventions comprised problem-solving therapy (Problem Management Plus: PM+) in Kenya (Bryant et al., 2017), guided self-help based on acceptance and commitment therapy (Self Help Plus: SH+) for South Sudanese refugees in Uganda (Tol et al., 2020), narrative exposure therapy (NET; Ertl et al., 2011a) and supportive counselling in Uganda (Ertl et al., 2011b), support, skills and psychoeducation (Bass et al., 2016), BATD (Bolton et al., 2014a), and CPT (Bolton et al., 2014b), all in Iraq, and ROTATE in Cambodia (Steinert et al., 2017). Meta-analysis showed a consistent but non-significant overall effect, for greater PTSD symptom reduction among women who reported IPV exposure, than those who did not (dSMD: 0.14, CI: -0.06, 0.33, I^2 : 42.6%).

Data were available for random-effects meta-analysis of 12 interventions which measured depressive symptoms in a total of 2,940 participants (Figure 3.2C). The interventions comprised structured basic counselling in South Africa (Lund et al., 2014), NET (Ertl et al., 2011a), supportive counselling (Ertl et al., 2011b), and SH+ (Tol et al., 2020), all in Uganda, Friendship Bench problem-solving therapy in Zimbabwe (Chibanda, Weiss, et al., 2016), healthy activity program behavioural activation in India (HAP; Patel et al., 2017), thinking healthy programme – peers in India (THPP; Fuhr et al., 2019) and

Pakistan (Sikander et al., 2019), ROTATE in Cambodia (Steinert et al., 2017), support, skills and psychoeducation (Bass et al., 2016), BATD (Bolton et al., 2014a), and CPT (Bolton et al., 2014b), all in Iraq. Meta-analysis also showed a consistent but non-significant effect for greater depressive symptom reduction among women who reported IPV exposure, than those who did not (dSMD: 0.10, CI: -0.04, 0.25, I^2 : 49.3%).

Finally, data were available for random-effects meta-analysis of four interventions which measured psychological distress in a total of 1,591 participants (Figure 3.2D). The interventions comprised Friendship Bench problem-solving therapy in Zimbabwe (Chibanda, Weiss, et al., 2016), SH+ (Tol et al., 2020) and stress debriefing in Uganda (Grundlingh et al., 2017), and PM+ in Kenya (Bryant et al., 2017). Meta-analysis also showed a consistent but non-significant effect for greater reduction in psychological distress among women who reported IPV exposure, than those who did not (dSMD: 0.07, CI: -0.05, 0.18, I^2 : 0.0%).

Sensitivity analyses showed that removing any one study from each meta-analysis did not disproportionately alter the pooled dSMD estimate (see Appendix 10.1.5).

3.4.5 Sub-group analyses

Due to low numbers of participants in one or more sub-groups, I did not conduct several planned sub-group analyses. I had intended to compare the results of studies in which mental health specialists versus laypersons had been trained to deliver interventions, studies in which a group versus an individual model was adopted, and studies in which a stand-alone intervention versus one embedded within a wider programme was employed. These were not possible due to the majority of included studies training laypersons to deliver individual, stand-alone interventions.

Based on common features of included studies, I conducted post-hoc sub-group comparisons to explore whether the difference in SMDs (dSMDs) between women who did and did not disclose IPV was driven by key intervention design features. Comparing explicitly trauma-focused interventions with more generic behavioural activation and CBT-focused interventions did not demonstrate statistically significant differences in the moderation effect of IPV (see Appendix 10.1.6). Sub-group comparisons between

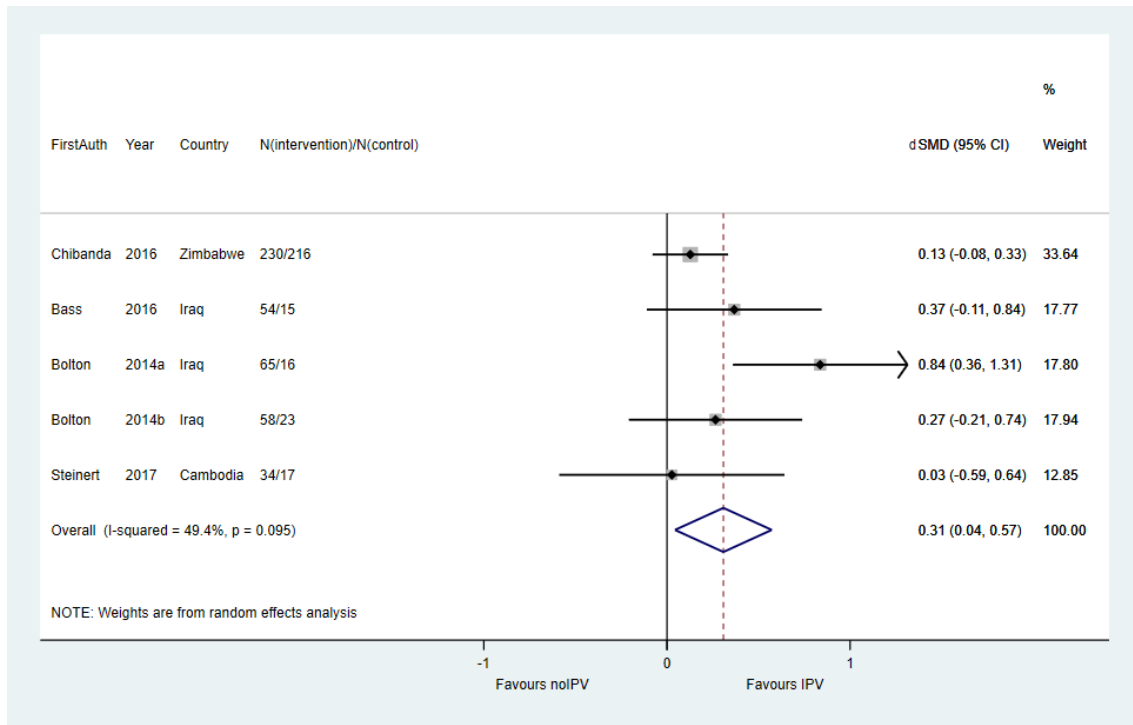
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interventions conducted in rural and urban locations indicated greater but non-significant improvements in depressive symptoms in women reporting IPV relative to women not reporting IPV in urban (dSMD: 0.23; CI: 0.07, 0.36) versus rural locations (dSMD: 0.04; CI: -0.17, 0.25; Figure 3.3).

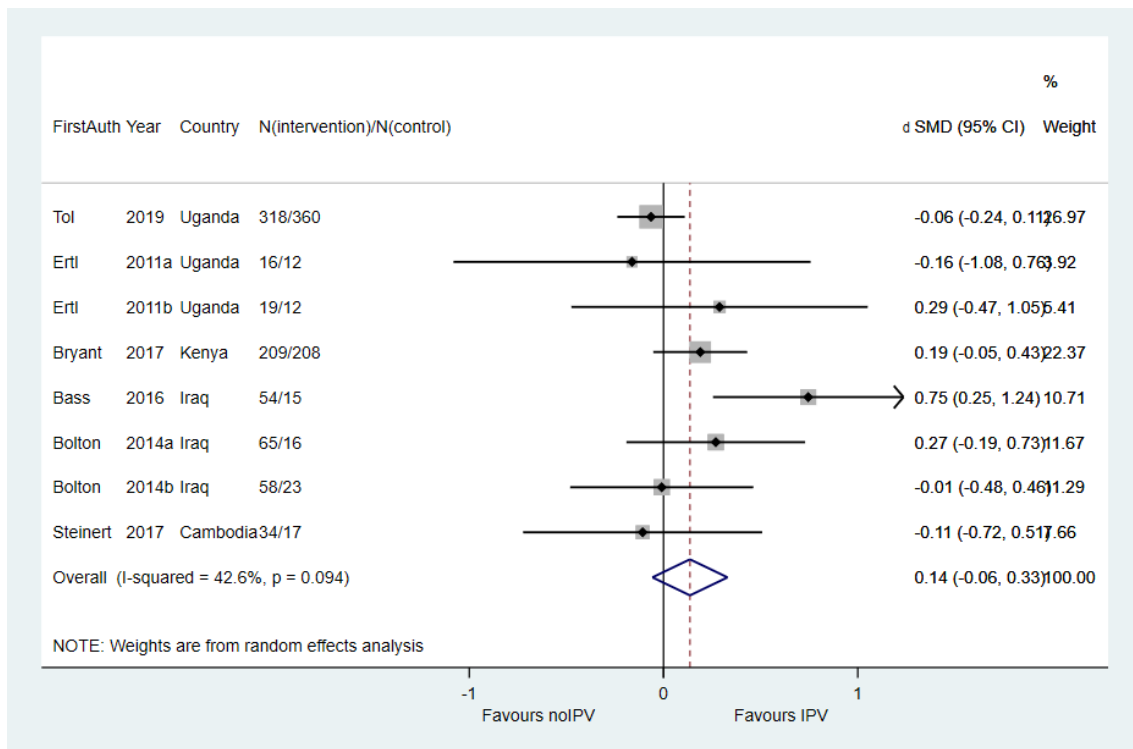
Stratifying interventions by the maximum number of sessions offered indicated a dose-dependent but non-significant relationship with PTSD symptoms in women reporting IPV (up to six sessions: dSMD: 0.03, CI: -0.16, 0.22 versus 7-10 sessions: dSMD: 0.10, CI: 0.48, 0.69 versus 12-14 sessions: dSMD: 0.33, CI: -0.09, 0.75; Figure 3.4A) relative to women not reporting IPV. Similarly, sub-group comparisons suggested a possible dose-dependent, but non-significant relationship with anxiety symptoms in women reporting IPV relative to those who did not (up to six sessions: dSMD: 0.12, CI: -0.08, 0.31; 12-14 sessions: dSMD: 0.49, CI: 0.14, 0.83; Figure 3.4B). However, this association was confounded by the fact that studies measuring anxiety symptoms and offering up to six sessions also took place in urban settings unaffected by recent conflict, while studies offering 12-14 sessions took place in rural settings, with populations affected by recent conflict.

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A

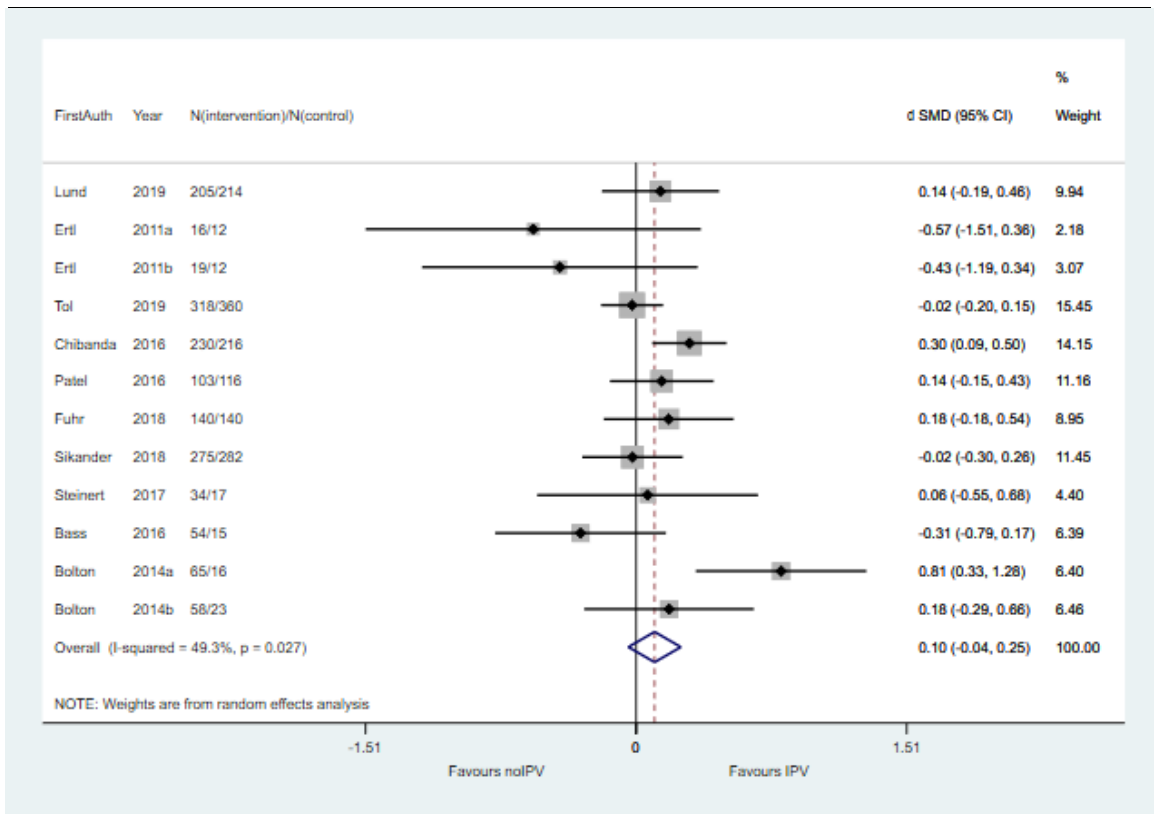


B



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C



D

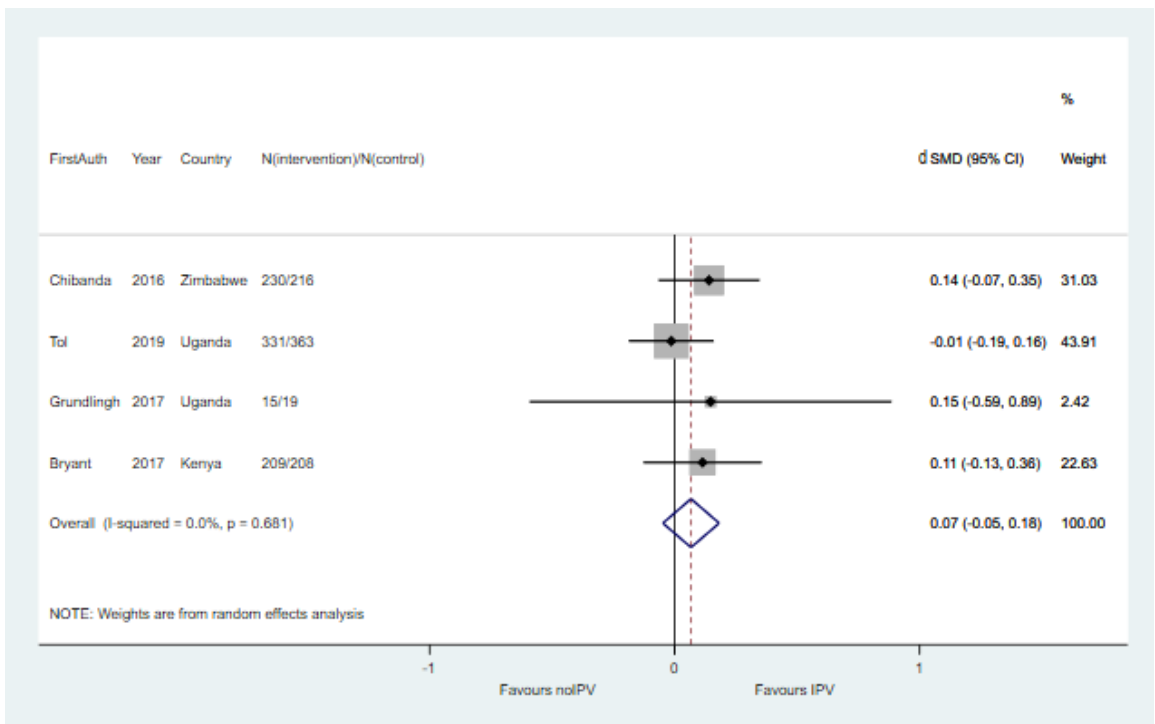


Figure 3.2 Random-effects meta-analyses: differences in effect size (dSMD) between women with and without IPV, for anxiety (A), PTSD (B), depressive (C) symptoms, and psychological distress (D)

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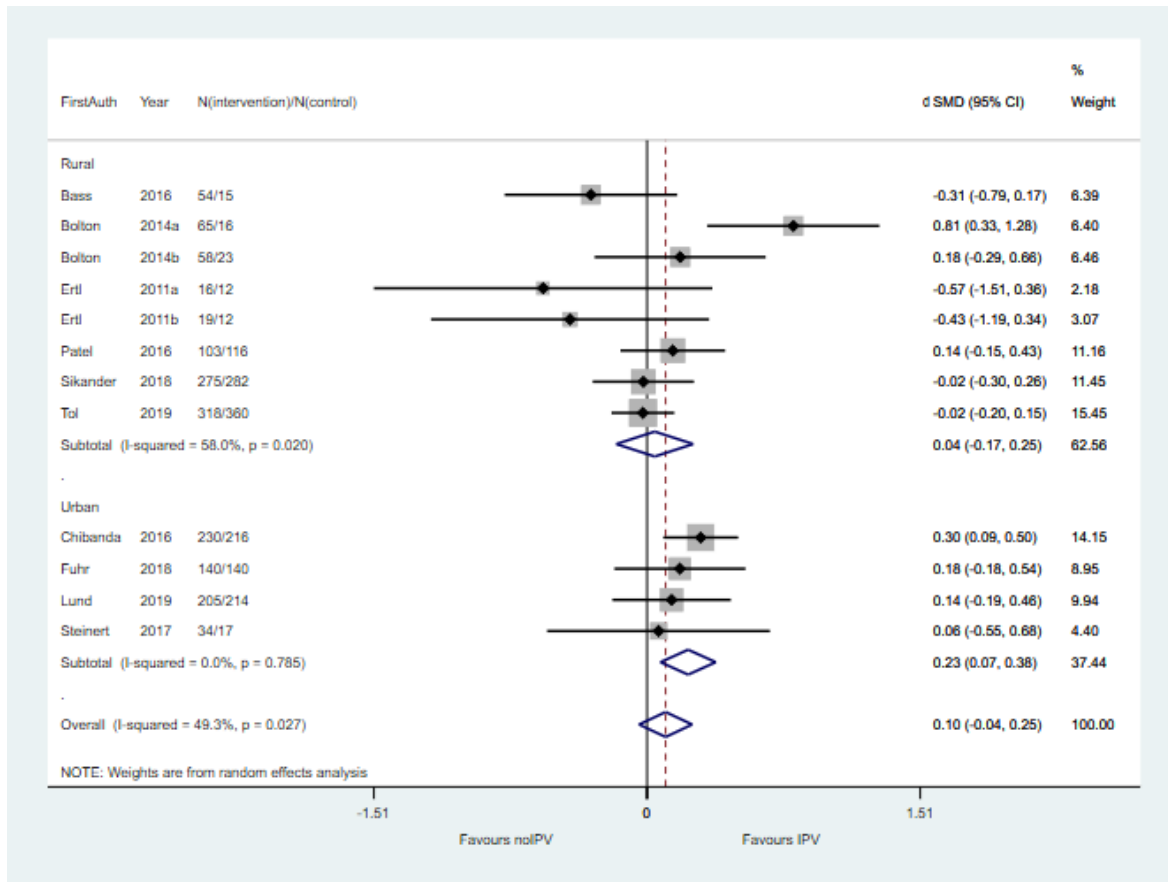


Figure 3.3 Random-effects meta-analyses: differences in effect sizes (dSMD) for depressive symptoms, comparing women with and without IPV exposure, in rural versus urban settings

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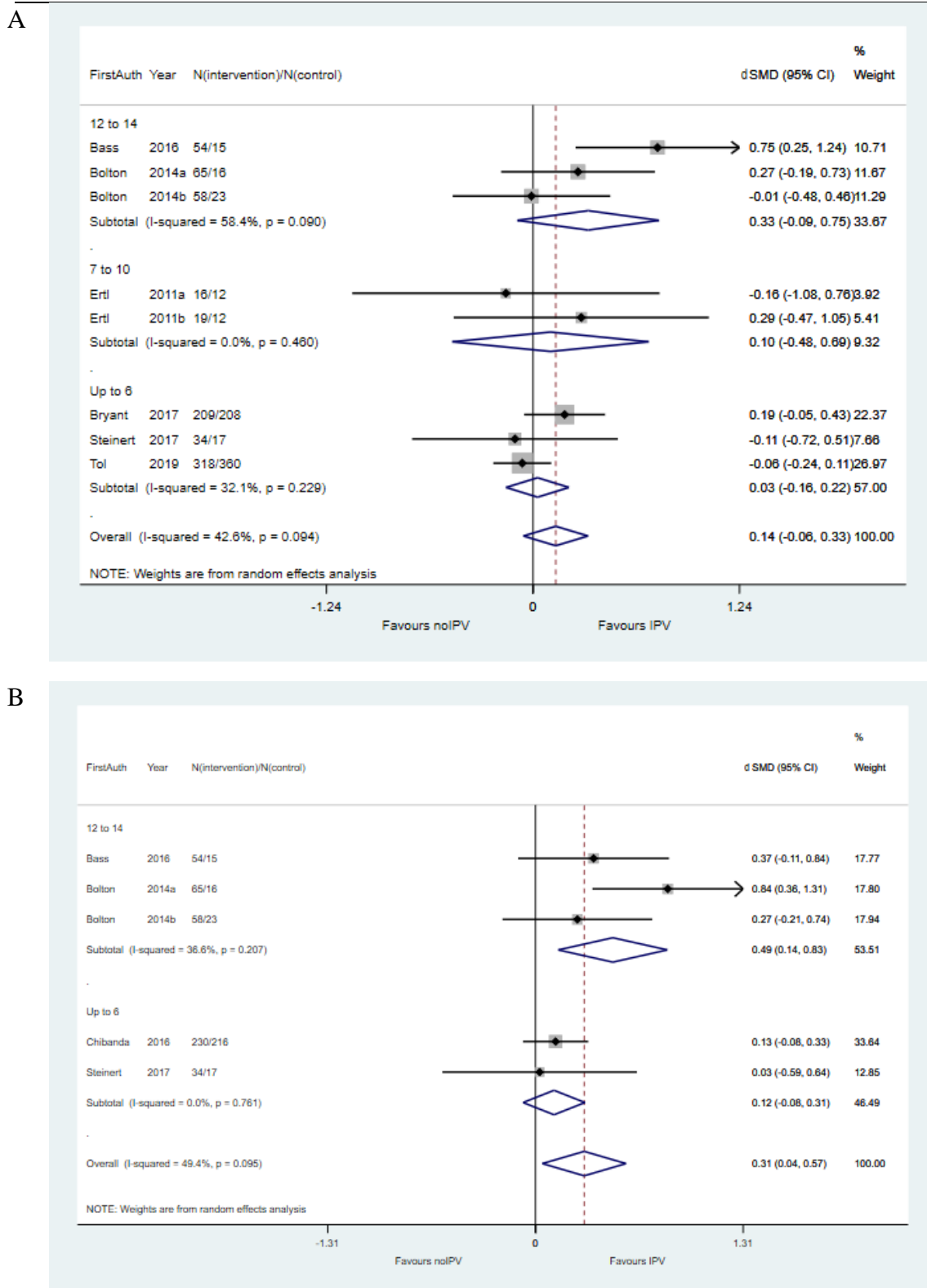


Figure 3.4 Random-effects meta-analyses: differences in effect sizes (dSMD) for PTSD (A) and anxiety symptoms (B) between women with and without IPV exposure, receiving up to six, 7-10 and 12-14 treatment sessions.

Anxiety symptom (B) differences were confounded by location (more sessions in rural locations) and conflict (more sessions in conflict-exposed populations).

3.5 Discussion

Contrary to my hypothesis, Study One showed that women disclosing IPV benefitted more from psychological interventions for CMDs than women who did not, in LMICs. This effect was particularly evident for anxiety, with significant differences between the SMDs of women who did and did not report IPV. There was a similar but non-significant effect of IPV exposure on reductions in PTSD and depressive symptoms, and, to a lesser extent, psychological distress. Although the bidirectional relationship between IPV and mental ill-health is well-established, these results are the first to suggest that IPV exposure moderates treatment efficacy, using unpublished sub-group data from 71% (15/21) of eligible studies.

3.5.1 IPV as a moderator

The checklist for the appraisal of moderators and predictors (CHAMP) is a set of 17 criteria grounded in the literature, selected through piloting and three rounds of Delphi expert consultation (Van Hoorn et al., 2017). CHAMP addresses the design, analysis, results, and transferability of predictor and moderator analyses. Considering the relevant CHAMP criteria, numbered in brackets, IPV is a plausible moderator *a priori* (#1), which I pre-specified (#2), and which was measured pre-allocation, in all but one study (#3). I tested IPV (#5) as a single candidate moderator (#6), using adequate sample sizes (#7: between 728 and 2,940 participants per meta-analysis), and presented all results (#8). The moderating effect of IPV was consistent across related outcomes and settings (#13), and study populations were similar to settings where these results may be informative (#14). Whilst the moderator effect of IPV was not homogeneous across studies (#16), this may result from heterogeneity of study designs, interventions, target groups and contexts, which was moderate.

Although the proportion of participants reporting IPV in included studies was higher than the national prevalence estimate (see Appendix 10.1.7), IPV could still have been under-detected, because its prevalence among women with CMDs is not routinely reported. Several studies asked a single question about IPV, or asked about general relationship dynamics, rather than specific behaviours. These studies were more likely to have

underestimated IPV, including forms which require careful explanation and particularly sensitive inquiry, such as psychological abuse, coercive control, and sexual violence. If included studies under-estimated IPV prevalence among participants, the moderating effect of IPV may have been under-estimated.

3.5.2 Trauma-informed interventions

My hypothesis that traumatic IPV experiences would reduce women's ability to benefit from psychological interventions for CMDs in LMICs was not supported by Study One. None of the included interventions addressed IPV specifically, or symptoms arising from experiencing IPV. However, several interventions were trauma-informed, focusing on cognitive processing of traumatic experiences (Bolton et al., 2014), habituating traumatic memories (Ertl et al., 2011), activating resources following traumatic experiences (Steinert et al., 2017), or debriefing (Grundlingh et al., 2017). Other interventions taught practical skills, which may have met needs of women disclosing IPV, for support with problem-solving (Chibanda, Weiss, et al., 2016), behavioural activation (Bolton et al., 2014; Bryant et al., 2017; Fuhr et al., 2019; Patel et al., 2017; Sikander et al., 2019), coping (Bass et al., 2016; Tol et al., 2020), or a mixture (Lund et al., 2014) of strategies and skills.

Since anxiety symptoms are an important response to trauma, more trauma-focused interventions might be anticipated to be more effective than generic interventions for women experiencing IPV (Hameed et al., 2020). However, sub-group analyses (Appendix 10.1.6) did not demonstrate differences between IPV's moderating effect on the outcomes of trauma-focused versus more generic psychological interventions. One explanation could be the small sample sizes of trauma-focused intervention studies, with limited power to detect sub-group differences. Of note, the two included studies which used three-arm designs drew contrasting conclusions about the benefits of trauma-focused versus generic interventions for participants with a history of trauma. Ertl et al. (2011) found that eight sessions of narrative exposure therapy were more effective for PTSD in Ugandan former child soldiers than supportive counselling or a waiting list control. Bolton et al. (2014) found that twelve sessions of behavioural activation therapy were more effective for depression in Iraqi survivors of systematic violence than cognitive processing therapy or a waiting list control. RCTs conducted in HICs have reported improvements in CMDs

in women experiencing IPV following a range of CBT-informed, mind-body, and trauma-focused psychological interventions (Yapp et al., 2020). No RCTs to date have directly compared generic and trauma-focused psychological interventions for CMDs in a sample of women experiencing IPV in the same LMIC setting.

Unlike most forms of adulthood trauma, IPV is likely to be an active and continuing stressor, even after an abusive relationship has ended. Estrangement and leaving for a new partner are risk factors for intimate partner femicide (Campbell et al., 2003), for example. Problem-solving therapy, behavioural activation, CBT, and strategies to manage trauma symptoms may have been more effective in women disclosing IPV because of their relevance to that specific, continuing stressor, affording a sense of mastery (Warmerdam, van Straten, Jongasma, Twisk, & Cuijpers, 2010).

3.5.3 Selection bias

Since not all women experiencing IPV are likely to have disclosed it to researchers, those who did disclose IPV may not have constituted a representative sample. Severe coercive control and fear of inciting further or more severe abuse could have inhibited some women from disclosing IPV or participating in RCTs. Furthermore, women experiencing the most severe IPV may be the least likely to access the routine healthcare settings in which most included studies recruited participants. The results of Study One may therefore not be generalisable to the population of women experiencing IPV, or the subgroup for whom IPV is most severe.

Several studies included in Study One targeted populations exposed to traumatic experiences beyond IPV. Participants included survivors of torture (Bass et al., 2016) and systematic violence (Bolton et al., 2014) in Iraq, South Sudanese refugees (Tol et al., 2020), Ugandan former child soldiers (Ertl et al., 2011), and individuals experiencing wider gender-based violence in Kenya (Bryant et al., 2017), and trauma in Cambodia (Steinert et al., 2017). Other studies, though not recruiting traumatised participants explicitly, were conducted in settings affected by deprivation, poverty, crime or HIV infection. In these contexts of widespread trauma or adversity, it is possible that women who felt able to disclose IPV to researchers might have differed from women who did

not, in their capacity to benefit from psychological interventions and apply techniques learned from therapy sessions to their daily lives.

3.5.4 Readiness for change

One manner in which women prepared to disclose IPV may have differed from those not reporting IPV is their readiness for change. The trans-theoretical model (Prochaska et al., 1994) outlines five stages of behaviour change: pre-contemplation, contemplation, preparation, action, and maintenance. The model has been applied to clinicians (Zink, Levin, Putnam, & Beckstrom, 2007), people experiencing (Brown, 1997) and perpetrating (Daniels & Murphy, 1997) IPV. For example, a longitudinal study of 225 women enrolled in an RCT found that preparation, action, and maintenance stages of change by the end of the two year study were associated with greater self-efficacy and no longer living with the abusive partner at follow-up (Reisenhofer et al., 2019).

However, qualitative evidence suggests that women experiencing IPV consider multiple actions (not just leaving their partner), and may inhabit different stages of change in relation to each behaviour at the same time (Cluss et al., 2006). A continuum proposed in motivational interviewing between non-readiness and behaviour change (Rollnick, Heather, & Bell, 1992) has therefore been explored for IPV. Cluss et al. (2006) proposed a psychosocial readiness model, in which survivors' readiness to change their relationship is influenced by internal factors (awareness of abuse, perceived support and self-efficacy) and external factors (interpersonal interactions (such as conversations with health workers) and situational factors (such as finances)). Under this model, women included in Study One who were prepared to disclose IPV to researchers may have felt greater psychosocial readiness for change, which could have mediated their ability to benefit from psychological interventions.

3.5.5 Strengths and limitations

Study One synthesised unpublished sub-group data on the moderating effect of IPV on the efficacy of psychological interventions for CMDs in women in LMICs. The provision of higher quality within-study information enabled meta-analysis of the difference between study SMDs: the first analysis of its kind in this field. My strategy of hand-searching otherwise eligible RCTs for IPV measurement reduced the likelihood of

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missing studies. Although a small proportion of titles and abstracts were screened by a second researcher, our agreement about inclusion decisions was high, and discussions informed subsequent decisions. Study One demonstrated the benefits of data sharing for analysing sub-group effects among studies with relatively small sample sizes.

Unfortunately, sub-group data from six studies could not be provided, limiting the completeness of analysis. Three-hundred and ninety-five otherwise eligible studies were excluded because participants' exposure to IPV had not been measured, despite recommendations that all women with mental health problems should be asked about IPV in a safe environment by trained staff (WHO, 2013c). As a result of limited IPV measurement and variable measurement of other CMDs, only the meta-analysis of depressive symptoms included more than 10 studies. The inherent heterogeneity of included interventions, study contexts, and evaluation designs limits the interpretation of Study One's results. However, previous meta-analyses of psychological interventions in LMICs have demonstrated consistent efficacy, despite such variation (Singla et al., 2017).

Higher mean baseline depressive symptoms among women reporting IPV than women not reporting IPV in 42% (5/12) of included studies mean that in these studies, there was greater scope for improvement following intervention among women experiencing IPV. This difference could have confounded some of the IPV moderation effect of treatment efficacy. As data were not collected on other moderator variables, I cannot rule out the possibility that IPV is correlated with another causative moderator variable.

Although all included studies were at low or moderate risk of bias, differences in research methods may have limited their comparability. For example, studies measured post-intervention outcomes at variable times: immediately (Bass et al., 2016; Grundlingh et al., 2017; Steinert et al., 2017), three (Bryant et al., 2017; Ertl et al., 2011; Patel et al., 2017; Tol et al., 2020) or six months post-participation (Bolton et al., 2014; Chibanda, Weiss, et al., 2016), three (Lund et al., 2014) or six months postpartum (Fuhr et al., 2019; Sikander et al., 2019).

The range of ways that IPV was measured across studies (CHAMP criterion #17) contributed to the heterogeneity of Study One's findings. Some studies used validated IPV measures: items from the WHO violence against women instrument (Bryant et al.,

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2017; Grundlingh et al., 2017; Tol et al., 2020) or the violence, war, abduction and exposure scale (Ertl et al., 2011). Most studies asked a single question about IPV (Lund et al., 2014; Patel et al., 2017) or domestic violence (Bass et al., 2016; Bolton et al., 2014; Fuhr et al., 2019; Sikander et al., 2019; Steinert et al., 2017) exposure. ‘Domestic violence’ could have been interpreted by participants to include abuse by non-partner family members. Some studies asked women about IPV exposure in the past three months, only (Fuhr et al., 2019; Lund et al., 2014; Sikander et al., 2019), perhaps underestimating IPV prevalence. One study asked about ‘domestic upheaval’ in the past six months (Chibanda, Weiss, et al., 2016), potentially over-estimating IPV prevalence. One study only measured IPV exposure at 3 months’ follow-up (Patel et al., 2017).

No included studies distinguished between IPV which was continuing, and IPV which had ended at the time of participation. Specifying exposure to past, current, or both forms of IPV would enhance the interpretation of results, since HIC studies suggest cumulative impacts of IPV on women’s mental health (Romito, Turan, & De Marchi, 2005). Many studies incorporated safety protocols to manage adverse events arising from mental health conditions, but none described procedures for responding to IPV-related risks occurring during participation.

3.5.6 Future research

Study One confirmed how rarely the gendered risk factor of IPV is measured by RCTs of psychological interventions in LMICs (Howard et al., 2017; Oram et al., 2017). Future intervention research should measure evidence-based moderators of treatment efficacy, such as IPV exposure. This requires quantifying the type, severity, frequency and timescale of IPV, using validated measures. Agreement on a minimum reported outcome dataset for women experiencing IPV would facilitate the comparison of results between studies.

Three included studies targeted perinatal participants (Fuhr et al., 2019; Lund et al., 2014; Sikander et al., 2019), but two studies excluded pregnant (Patel et al., 2017) and perinatal (Chibanda, Weiss, et al., 2016) women. RCTs should actively recruit women at risk of experiencing IPV, including during pregnancy, to overcome barriers to their participation and expand the evidence base for their CMD treatment. Clinical and research staff should

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be trained to ask about and respond to IPV safely (WHO, 2013c), including in antenatal care settings. Future research must follow international guidance addressing the ethics, design, and safety of research with women experiencing IPV (Ellsberg & Heise, 2005), including incorporation of safety protocols into study designs.

No RCTs directly compared generic and trauma-focused psychological interventions for CMDs in women experiencing IPV in the same LMIC setting. Such study designs would be particularly informative, given the sparse literature. The possibility that the moderation effect of IPV disclosure could have been mediated by psychosocial readiness for change and other factors requires investigation by future studies. Further research is also required to determine whether adapting generic intervention designs to meet the needs of women experiencing IPV in LMICs can enhance their acceptability and feasibility, before investigating their efficacy, relative to standard models. This was the focus of Studies Two, Three, Four, and Five of my PhD.

4 RESEARCH STUDY CONTEXT

The need to consider context at every stage of the development and evaluation of complex interventions, from defining the research question, to reporting findings, is widely acknowledged, including by new MRC/NIHR guidance (Skivington et al., 2021). In this chapter, I summarise aspects of context relevant to the four research chapters of this thesis conducted in Ethiopia: Studies Two, Three, Four, and Five.

Consideration of context is a core element of every phase of complex intervention development and evaluation (Skivington et al., 2021). Context is defined as “features of the circumstances in which an intervention is conceived, developed, implemented and evaluated” (p. 1; Craig et al., 2018). As well as informing an intervention’s adaptation, understanding the study context is vital to explain the success or failure of its implementation, how and why it does or does not make an impact, and its potential to be scaled up or translated to a different context.

Dedicated NIHR guidance (Craig et al., 2018) and the context and implementation of complex interventions (CICI) framework (Pfadenhauer et al., 2017) have recommended considering similar features of context. Craig et al. (2018)’s more extensive list comprised epidemiological, social and economic, cultural, geographical or environmental, service and organisational, ethical, policy, legal, financial, political, and historical context, as well as external shocks and catalytic events (p.p. 7-8).

‘Desk reviews’ pragmatically collate available literature without applying systematic review methods. They have been advocated to inform cultural and contextual adaptation of mental health and psychosocial support interventions (Greene et al., 2017). I conducted a desk review of verified information about Ethiopia in general, and the Southern Nations, Nationalities and People’s Region (SNNPR) in particular, considering each aspect of the study context (Craig et al., 2018). I discussed the relevance of articles from national websites, international websites, and peer-reviewed publications of research conducted in the SNNPR, with my first supervisor (based in Addis Ababa), and Ethiopian research colleagues, throughout my PhD.

4.1 Epidemiological context

Craig et al. (2018) recommended identifying the baseline incidence, prevalence, and distribution of the relevant health problem and its determinants in the target population. Estimates of perinatal depression prevalence in Ethiopia vary, as discussed in section 2.2.1. However, a population-based study in my PhD site of Sodo found that 28.7% of pregnant women met criteria for antenatal depression, that symptoms persisted in 38.8% of women, and that a further 15.4% developed new-onset postnatal depressive symptoms (Bitew et al., 2019). As outlined in section 2.3.3, estimates of women's lifetime IPV prevalence in rural Ethiopia have been as high as 72% (Deyessa et al., 2010). Some studies have found higher reports of IPV during pregnancy than outside pregnancy in Ethiopia (Gossaye et al., 2003). In Bitew et al. (2019)'s study, incident depression was associated with IPV during pregnancy (aRR: 1.06, CI: 1.00-1.12).

4.2 Social and economic context

The social and economic context refers to the distribution of resources among communities affected by the intervention. The most recent mini demographic and health survey was conducted in Ethiopia between March and June 2019, with a nationally representative sample of 8,663 households (Ethiopian Public Health Institute & ICF, 2019). The survey found that 29% of SNNPR households only had access to unimproved drinking water, such as an unprotected dug well, spring or surface water, with clean water access associated with wealth quintile (p. 15).

The same study found that in SNNPR, 77% of households had unimproved sanitation facilities, such as an open pit latrine, or no facilities (p. 17). Sixteen percent of the population was in Ethiopia's lowest wealth quintile, 20% in the second, 24% in the middle, 32% in the fourth and 8% in the highest wealth quintile (compared to Addis Ababa, where 99% of the population was in the highest wealth quintile; p. 17). The educational attainment of women in SNNPR showed that 41% had no education, 42% attended some primary schooling, 4% completed primary school, 9% attended some secondary schooling, 1% completed secondary school and 4% completed more than secondary education. Women had a median of two years' total education (p. 27). The

proportion of women aged 15 to 49 years who were literate in SNNPR was 42% (p. 28). Across Ethiopia, 20% of women were married by 19 years of age (p. 28).

4.3 Cultural context

Craig et al. (2018) recommended identifying beliefs, attitudes, and practices of policy makers, practitioners, and prospective service users of the intervention. The last Ethiopian census found that the Sodo district population was 67% Protestant, 27% Orthodox Christian, 5% Catholic, 0.2% Muslim, and 1% other religions (p. 204; Central Statistics Agency, 2007a).

I summarised the wider qualitative literature on perinatal mental health and IPV in Ethiopia, in sections 2.2.2 and 2.3.4. A local study found that neither screening pregnant women for depressive symptoms, nor delivering WHO mhGAP-IG refresher training to staff, improved detection or diagnosis of depressive symptoms in ANC (Girma, 2020). Qualitative interviews with nine pregnant women identified not expecting to receive help from ANC staff as a client-side barrier to disclosing depressive symptoms. Two focus group discussions with 12 local ANC staff identified inadequate mental health training as a provider-level barrier. Health workers recommended integrating mental healthcare into ANC, to improve detection of perinatal depression.

A recent study conducted 13 qualitative interviews with maternal and mental health service leaders in the Amhara region, about implementing perinatal depression services (Dadi, Miller, Azale, & Mwanri, 2021). Structural barriers included a lack of relevant perinatal mental health policies, strategies, and systems. At the organisational level, there was a lack of government capacity, readiness, and prioritisation of perinatal mental health. At the socio-cultural level, low awareness of perinatal depression, low health-seeking behaviour, and cultural norms were barriers to implementing services. Finally, the authors identified low literacy about perinatal depression at the individual health administrator level. Facilitators of perinatal mental health service implementation included the roll-out of mhGAP-IG training, health workers' commitment, and the feasibility of screening for perinatal depressive symptoms in ANC.

4.4 Geographical or environmental context

The geographical and environmental context of an intervention refers to features of the immediate, regional or national, natural or built physical environment. SNNPR is one of ten regions of Ethiopia, south-west of Addis Ababa (see Figure 4.1). Sixty-five percent of the region is over 1,500 metres above sea level, where crops, including maize and sweet potatoes, are grown (UNICEF, 2019). An inadequate or late rainy season delays planting and harvesting, leading to insufficient food. In a situation analysis, UNICEF (2019) identified a range of factors increasing the vulnerability of people living in SNNPR to climate change. These included population growth and density, distance between homes and marketplaces, competition for land, ethnic tensions and conflicts, rural to urban migration, poverty, weak infrastructure, degraded environments, low-technology farming methods and low education levels (p. 29). In particular, UNICEF highlighted the disproportionate threat to women from climate change (CEDAW, 2018).

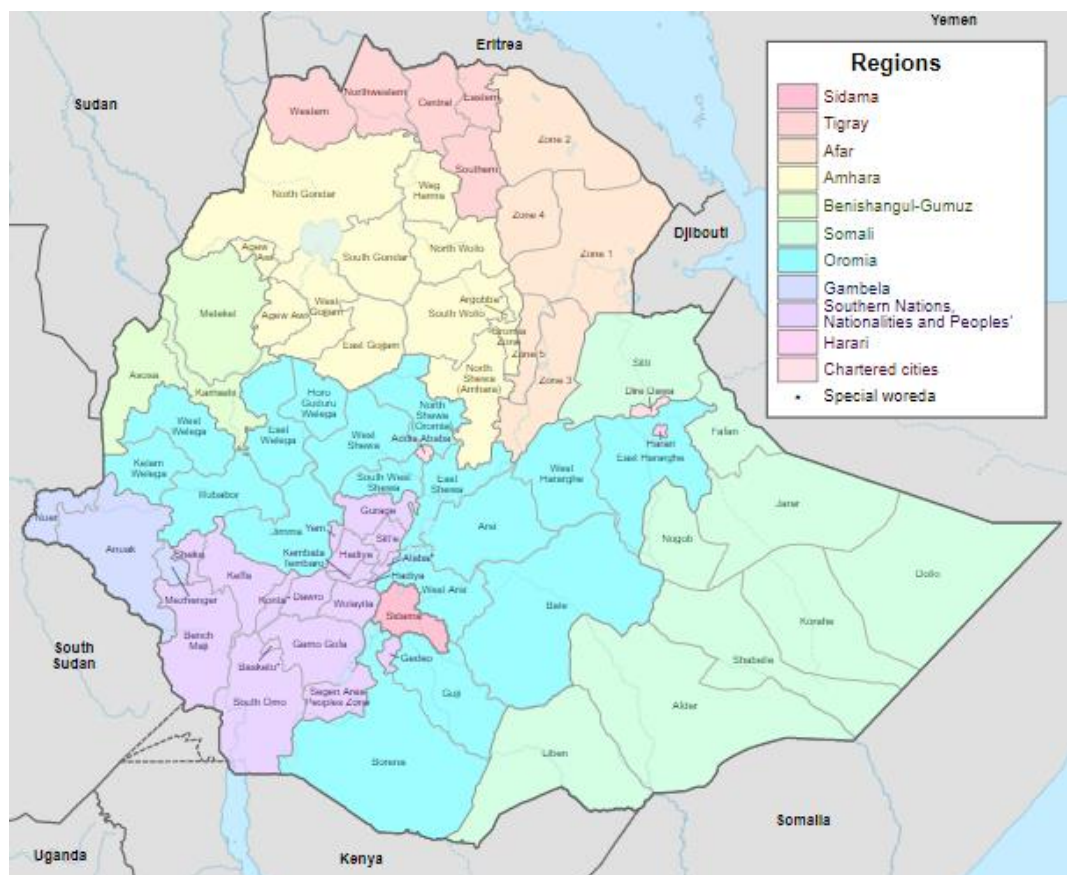


Figure 4.1 Gurage zone, SNNPR, Ethiopia (Wikipedia, 2017)

SNNPR (Southern Nations, Nationalities and People's Region) is shaded in lilac in the south-west of Ethiopia. Gurage zone is labelled; it is the northernmost zone of SNNPR. This map was licensed under a Creative Commons Attribution-Share Alike 4.0 International license.

The northernmost zone of SNNPR, the Gurage zone, was projected to have a population of 17,837,005 by 2017, of which 161,097 were expected to reside in Sodo⁴ *woreda*⁵ (Central Statistics Agency, 2007b). The administrative centre of Sodo *woreda* is Bu'i⁶, where a primary hospital is located. Smaller towns along the main road from Addis Ababa include Kela⁷, where a health centre is located.

4.5 Service and organisational context

Craig et al. (2018) recommended considering characteristics of the individuals delivering the intervention, the organisations where they work, and the wider health service environment. They also suggested identifying any co-interventions which target the same outcomes in the same population. The most recent mini demographic and health survey found that 69% of women aged 15 to 49 years in SNNPR, who had had a live birth in the preceding five years, had received ANC from a skilled provider (Ethiopian Public Health Institute & ICF, 2019). However, only 34% of women had attended the recommended four (or more) ANC visits. Fifty percent of births were delivered by a skilled provider and 48% were delivered in a health facility (p. 65). Five percent of births in SNNPR in the preceding five years were delivered by Caesarean section, compared to 24% in Addis Ababa (p. 68). Postnatal checks were performed within the first two days after birth for only 32% of live births, in the two years preceding the survey, in SNNPR (p. 65). Sixty-seven percent of women (p. 69) and 69% of babies (p. 71) received no postnatal checks.

In primary care in Ethiopia, staff working in health centres and health posts (satellite clinics) refer patients to a single primary hospital (serving 60,000-100,000 people), if specialist care is required. Health centre and primary hospital staff can rotate through different services, so may or may not be members of the local community. Outside of pastoralist areas of Ethiopia, Health extension workers (HEWs) are exclusively female high school graduates who have received one year's undergraduate-level training, and are usually members of the local community (Medhanyie et al., 2012). HEWs deliver

⁴ Transliterated into English as Soddo in some references.

⁵ A district (Feyissa, Midega, & Wakjira, 2018).

⁶ Transliterated as Bue in some references.

⁷ Transliterated as Kella in some references.

women's first antenatal contact, refer them for ANC at a health centre or primary hospital, and maintain contact during pregnancy.

The perspectives of HEWs contributing to ANC in Ethiopia have received more attention than those of midwives and other ANC providers (Kok et al., 2015). A qualitative study conducted 45 in-depth interviews with midwives, midwifery students and postpartum women in Debre Markos, in the Amhara region (Burrowes, Holcombe, Jara, Carter, & Smith, 2017). The authors identified regular physical and verbal abuse by health workers towards women, and non-consensual care during labour and delivery. Clinicians stated that most abuse was unintentional and attributed it to medical necessity and health system weaknesses. Most had received no training on counselling skills or responsive and respectful care, but supported this suggestion.

A resource mapping exercise conducted in Sodo district identified community assets which could support integration of mental health into primary care across 58 sub-districts (Selamu et al., 2015). Government-funded primary care comprised eight health centres (serving 15,000-25,000 people) and 58 health posts (serving 3,000-5,000 people), staffed by one to two HEWs each. Community volunteers (then the 'health development army', now known as the 'women's development army') supported health promotion and prevention messaging. Selamu et al. (2015) found that religious community resources included more than 150 traditional healers, 164 churches and mosques, and 401 religious groups. Fifty-one microfinance organisations were identified in addition to 67 government-directed women's associations and 58 youth associations, led by HEWs. Each sub-district of around 5,000 people had around five *idir*⁸ groups, four non-religious social associations (*mahabers*), and two traditional bars serving home-brewed beer (*tela*), honey wine (*tej*), and spirits (*araki*). No formal community mental health services were identified.

Recently, a cluster RCT was conducted in Sodo and three neighbouring districts, evaluating a 14 session 'gender-transformative' intervention. The 'unite for a better life' intervention, centred around the traditional Ethiopian coffee ceremony, focused on IPV and HIV, and was delivered to separate groups of women, men, and couples, by trained

⁸ Neighbourhood associations raising funds for emergency expenses, such as funerals (Bekerie, 2003).

facilitators. ‘Unite for a better life’ had mixed effects on IPV perpetration (Sharma, Leight, Verani, Tewolde, & Deyessa, 2020), substance use, and depression (Leight, Deyessa, Verani, Tewolde, & Sharma, 2020). The men-only intervention was associated with reductions in self-reported sexual IPV perpetration (aOR: 0.73, CI: 0.56-0.94) and women’s reports of past-year physical and/or sexual IPV (aOR: 0.81, CI: 0.66-0.99), but no intervention reduced men’s self-reported physical IPV perpetration (Sharma et al., 2020). In terms of mental health outcomes at 24 months’ follow-up, men’s self-reported past-year alcohol intoxication reduced (aOR: 0.56, CI:0.36-0.85), but khat use increased (aOR: 3.09, CI:1.37-6.96), after attending the couples’ intervention (Leight et al., 2020). Women who attended the women-only intervention reported significantly higher symptoms of depression (aOR: 1.65, CI:1.13-2.41) at 24 months’ follow-up, relative to control arm women. However, ‘unite for a better life’ did not incorporate mental health components or address perinatal CMDs. No interventions have been adapted to address perinatal emotional difficulties or depressive symptoms in SNNPR, either in the presence or absence of IPV.

4.6 Ethical context

The ethical context refers to the balance between benefits and harms of the intervention, and the ability of participants to give informed consent to take part. Potential benefits include affording women access to an evidence-based, brief psychological intervention adapted for their context and needs. Attending sessions could improve women’s well-being and mental health, improve their experience of ANC, and increase their engagement with healthcare services. Speaking to ANC staff trained to respond to disclosures of IPV might improve pregnant women’s well-being and mental health, their safety and that of their children. Potential harms of the intervention include abusive partners learning about women’s participation, provoking aggression.

A range of previous studies conducted in Sodo has confirmed that pregnant women (Bitew et al., 2020; Hanlon et al., 2010), women experiencing IPV (Deyessa et al., 2009), and other vulnerable groups, such as adults with schizophrenia (Asher et al., 2018), are willing and able to give informed consent to participate in research. A local study also confirmed that women experiencing IPV could give informed consent to participate in intervention research (Sharma et al., 2020).

4.7 Policy context

The policy context refers to the wider policy framework in which the adapted intervention will be embedded. Although there are no policy frameworks specific to Sodo, the Ethiopian national mental health strategy for 2020-25 (Ministry of Health, 2021), and the roll-out of mental health-integrated primary healthcare clinical guidelines (PHCG; Feyissa et al., 2019) provide a supportive policy context (see section 2.2.3).

4.8 Legal context

Study Four followed a government directive to prevent and control the spread of the coronavirus pandemic (Ethiopian Public Health Institute, 2020). This document outlined actions required to protect research staff and participants, such as maintaining a distance of two strides wherever possible, thorough, regular hand washing, wearing of masks, action to take if developing symptoms, testing positive for COVID-19 or having close contact with someone testing positive.

4.9 Financial context

The financial context refers to intervention funding and wider payment, reward, incentive, or charging structures. Despite a fee waiver programme, household out-of-pocket expenditure comprises one third of total health expenditure in Ethiopia (Hailemichael et al., 2019). Perinatal healthcare is free at the point of access, but out-of-pocket expenses are still incurred (Tsegaye & Ayalew, 2020).

My PhD was funded through a research grant, as a ‘proof-of-concept’ study. Because Study Four entailed training health workers to deliver care additional to their usual job descriptions, the grant included funds to pay ANC staff to attend training and supervision, to deliver intervention sessions, and to pay mental health specialists to deliver training and supervision. In keeping with usual research practice, my PhD budget included funds to reimburse women for travel costs incurred to attend research and intervention appointments, and small incentive payments to compensate women for their time at research appointments.

4.10 Political context

Craig et al. (2018) recommended considering the distribution of power among stakeholders, and others interested in promoting or obstructing the intervention's optimum design or implementation. My PhD built on decades of collaborative research investment in the study site, by AAU clinical researchers (Asher et al., 2016; Fekadu et al., 2016; Seward et al., 2021).

Given the decision to use a task-sharing model, of training existing ANC staff to deliver intervention sessions, I recognised that health workers' primary obligations were to their ANC duties. It was therefore important to secure support from health centre managers prior to proceeding with intervention training. This was achieved by discussing proposals for Study Four with health centre managers and other stakeholders through an engagement meeting (see section 6.4.3.4).

4.11 Historical context

The historical context refers to the continuing influence of past conditions, socio-political relationships, policies, and legal frameworks. The principal historical factor relevant to the study context is the long-term investment of time, resources, and research attention in the study site by the PRIME project (Fekadu et al., 2016). Over eight years of inception, implementation, scale-up and extension, PRIME developed an integrated mental healthcare plan, implemented it in Sodo district, scaled up to other health facilities, and evaluated outcomes. Results included enabling 81% of people with severe mental illness to access care (Hailemariam, Fekadu, Medhin, Prince, & Hanlon, 2019), reduced clinical symptoms (SMD: 0.28; CI: 0.13-0.44) and disability (SMD: 0.50; CI: 0.35-0.65), and a 15% reduction in past-year restraint (Hanlon et al., 2020).

Funded by NIHR, ASSET is a four year global health research unit focused on health system strengthening in sub-Saharan Africa (Seward et al., 2021). It aims to develop and evaluate effective, sustainable health system strengthening interventions to improve primary care, maternal, neonatal, and surgical care in Ethiopia, Sierra Leone, South Africa, and Zimbabwe. In Ethiopia, ASSET activities are building on the work of PRIME by improving the quality and person-centredness of maternal and new-born care.

4.12 External shocks and catalytic events

Craig et al. (2018) listed extreme weather events, economic crises, regime changes and armed conflicts as examples of events that may impact the implementation, sustainability or uptake of an intervention or directly influence the outcomes of interest. Each of these eventualities arose during my PhD.

4.12.1 Desert locusts

Since January 2020, the worst desert locust invasion in over 25 years damaged a projected 2.4 million hectares of farmland, threatening food security and economic growth in SNNPR and other regions of Ethiopia and the horn of Africa (United Nations Ethiopia, 2020).

4.12.2 Inflation

Between 2005 and 2019, inflation averaged 16% per year in Ethiopia. This grew to 20% in the year 2019-20 due to food inflation, government measures to expand money supply and devalue the birr, and economic slowing during the coronavirus pandemic (United Nations Ethiopia, 2020). High inflation impacts agricultural communities' financial security, with corresponding effects on well-being, health, and quality of life. Inflation also influences the value of payments made to research staff and study participants, influencing their readiness to participate.

4.12.3 Armed conflicts

Between April and June 2018, a period of inter-ethnic conflict arose between communities in the Gedeo zone of SNNPR and West Guji zone of the Oromia region, which have a history of tension (UNICEF, 2019). The violence displaced almost one million civilians, leading 800,000 internally displaced persons to be urgently accommodated in communities and refugee camps. UNICEF (2019) highlighted health impacts on children, pregnant and breast-feeding women (p. 32). Closer to Sodo, two episodes of inter-ethnic violence in September and November 2018 in Meskan and Mareko districts caused at least 24 deaths, 167 injuries, and the displacement of thousands of people (Addis Standard, 2018).

On 4th November 2020, an attack on a military base by the regional Tigray people's liberation front (TPLF) led to a violent conflict in north-eastern Ethiopia, in which rockets were fired into bordering Eritrea (BBC News, 2021a). The ensuing conflict displaced hundreds of thousands of civilians into neighbouring Sudan, and international agencies raised concerns about ethnically motivated atrocities. Although these events occurred far from the study site, inflamed national tensions raised concerns about further inter-group conflict associated with the national election. Ultimately, however, this did not occur.

During the conduct of my randomised, controlled feasibility trial (Studies Four and Five), national tensions escalated further. On 28th June 2021, TPLF forces took control of Mekelle, the capital of the Tigray region (The Guardian, 2021), after which the government agreed a temporary ceasefire to allow the planting season to take place. In August, the TPLF agreed an alliance with the insurgent Oromo Liberation Army (Bloomberg, 2021). Ground offensives and air strikes by government forces in Tigray resumed in October (Reuters, 2021b). On 2nd November 2021, a six month national state of emergency was declared, after TPLF forces captured two strategic towns (Dessie and Kombolcha) in the neighbouring Amhara region.

TPLF forces took control of the Amhara town of Nifas Mewcha between 12th and 21st August 2021. Rapes of 73 women in the town, including gang rapes at gunpoint, looting of medical facilities and rape survivors' homes, physical and verbal assaults by TPLF fighters were recently reported (Amnesty International, 2021). A comprehensive investigation was conducted by the Ethiopian Human Rights Commission and Office of the United Nations High Commissioner for Human Rights between 16th May and 30th August, and published on 3rd November 2021 (EHRC and OHCHR, 2021). It found that "serious abuses and violations of human rights, humanitarian, and refugee law... [which] may amount to crimes against humanity and war crimes" were perpetrated by Ethiopian, Eritrean, Tigray, and Amhara forces, and allied militias, and other parties (p. 5).

Despite disruption on a national level, day-to-day life was not apparently impacted in Sodo, so these events did not affect the timing of outcome assessments for Studies Four and Five. However, study participants are likely to have been exposed to reports of armed conflict and gender-based violence in Tigray and Amhara, during Studies Four and Five.

The accuracy with which the conflict was reported by international media was questioned, with accusations of the government restricting local and national media, and accusations by the government of deliberate misrepresentation (BBC News, 2021b). Perceived interference in the conflict by external parties led to some anti-Western sentiment, expressed at rallies, and leading some nations to instruct non-emergency staff to leave the country (Al Jazeera, 2021b). However, the majority of data collection had been completed by November 2021.

4.12.4 Election

The national election was deferred from 20th August 2020 to 5th June 2021 because of the coronavirus pandemic, and then to 21st June 2021, due to logistical difficulties (Al Jazeera, 2021a). The election proceeded peacefully, but necessary precautions limited the ability to conduct research fieldwork to support intervention implementation around this time.

4.12.5 COVID-19

The coronavirus pandemic caused disruption, illness and death, worldwide. Ethiopia announced a state of emergency between April and October 2020, which limited the movement of people between geographical regions. At the time of writing (22nd October 2021), Ethiopia had reported 360,503 confirmed cases of COVID-19 infection and 6,287 deaths (WHO, 2021b). By 20th October 2021, 4,102,954 doses of COVID-19 vaccinations had been administered in Ethiopia. The peak of confirmed cases to date was reported on 29th March 2021 (14,517 in one week), and the peak of deaths to date was reported on 27th September 2021 (306 in one week). In 2020, lockdown measures instituted by the Ethiopian government included school closures, some workplace closures, recommendations that citizens avoid leaving their homes, and banning of arrivals from some regions (Reuters, 2021a). By October 2021, the only measures in place were alternate day school attendance and Saturday opening, to limit children's contacts, and quarantining of arrivals from some regions.

5 STUDY TWO: WHAT ARE WOMEN'S EXPERIENCES OF PERINATAL EMOTIONAL DIFFICULTIES AND INTIMATE PARTNER VIOLENCE IN RURAL ETHIOPIA?

This chapter presents the introduction (5.1), aim (5.2), research questions (5.3), methods (5.4), results (5.5), and discussion (5.6) of Study Two. Since women usually characterise experiences during the perinatal period in terms of distress, worry, and sadness, rather than mental health conditions, I refer to biomedical diagnostic categories in this chapter, only where these terms were employed by participants.

5.1 Introduction

As outlined in section 2.3.4, there is a rich qualitative literature exploring IPV in Ethiopia, through focus group discussions and some in-depth or semi-structured interviews. However, the perspectives of community stakeholders, health workers, and other professionals predominate, with few interview studies focused on women's experiences. The existing literature highlights the pervasiveness of IPV in Ethiopia, its relationship to patriarchal social norms, and community responses encouraging reconciliation and discouraging separation. In previous studies, community stakeholders lacked awareness of the impacts of IPV on pregnant women, and health workers focused on IPV's physical, obstetric and neonatal impacts. Emotional, psychological, and psychiatric impacts of IPV were rarely acknowledged. No existing qualitative studies have explored the relationship between IPV and women's mental health in Ethiopia, or between IPV and perinatal emotional difficulties.

5.2 Aim

To explore women and health workers' experiences of perinatal emotional difficulties and IPV, to inform the adaptation of a brief psychological intervention and its implementation strategies in rural Ethiopian antenatal care (ANC).

5.3 Research questions

1. What are women's experiences of emotional difficulties and IPV during the perinatal period, in this context?
2. How should a brief psychological intervention for the emotional difficulties of women experiencing IPV be adapted for Ethiopian ANC?
3. What are the barriers and facilitators to implementing a brief psychological intervention for the perinatal emotional difficulties of women experiencing IPV in rural Ethiopia?
4. Which implementation strategies would optimise the acceptability and feasibility of a brief psychological intervention from the perspectives of pregnant women experiencing IPV and health workers in this context?

5.4 Methods

5.4.1 Study design

Study Two comprised qualitative in-depth interviews with key stakeholders. I selected in-depth interviews for their ability to explore participants' perspectives on and experiences of the potentially sensitive subjects of IPV and emotional difficulties. Advantages of interviews include interactivity, combining structure with flexibility, and their potential to obtain deep understanding, generate new knowledge, and focus on the language used (Yeo et al., 2014).

In this rural Ethiopian setting, the utility of alternative methods, such as questionnaires, would have been limited by participants' level of education, and their ability and readiness to express their perspectives in writing. Limitations of focus groups include garnering socially acceptable responses or the views of dominant participants at the expense of dissonant perspectives (Finch, Lewis, & Turley, 2014), and capturing individual experiences of sensitive subjects in insufficient depth (Lewis & McNaughton Nicholls, 2014). In-depth interviews have been successfully used in this and nearby settings to explore the sociocultural context of antenatal distress (Hanlon et al., 2010), and to identify stakeholder perspectives on psychological interventions for antenatal depression (Bitew et al., 2020).

5.4.2 Methodological orientation

I approached Study Two from the interpretivist perspective that both participants and researchers make subjective interpretations of the social world through their lived experience (Ormston, Spencer, Barnard, & Snape, 2014). The constructionist view that knowledge is actively constructed, rather than passively received by participants and researchers, was consistent with my clinical experience as a psychiatrist. I therefore considered Study Two to be an inductive process, grounded in the data, albeit one influenced by my theoretical orientations. I sought to apply a 'substantive' approach concerned with identifying and interpreting meanings within the data, rather than a 'structural' approach focused on the construction and language employed (Spencer, Ritchie, Ormston, O'Connor, & Barnard, 2014).

5.4.3 Context

The rural Ethiopian study context is described in depth, in chapter 4.

5.4.4 Sample

In Study Two, interviews were conducted with a sample of ANC health workers and pregnant women attending ANC in rural Ethiopia, to explore their perspectives on perinatal emotional difficulties, IPV, and interventions for women experiencing both. The roles of health workers in ANC in Ethiopia are described in section 4.5. I opted to interview pregnant women and multidisciplinary health workers, in order to ascertain diverse perspectives, under-represented in existing literature, including those of potential intervention providers, to triangulate different sources (Lewis, Ritchie, Ormston, & Morrell, 2014).

A purposive sample was interviewed in Study Two, to capture the views of pregnant women of diverse age, religion, and educational levels, and of health workers of diverse age, religion, specialism, qualifications, and years of experience. The study research assistant (RA) asked health workers based in Sodo and neighbouring Butajira to identify ANC attendees who had reported symptoms of emotional distress, or whom they suspected could be experiencing IPV. The RA then reviewed with health workers whether

those women met the other inclusion criteria (section 5.4.6), before approaching them to explain the study.

Potentially eligible pregnant women were also identified, from participants in an ANC survey who had reported depressive symptoms on the locally-validated (Gelaye et al., 2013) PHQ-9 patient health questionnaire (Kroenke, Spitzer, & Williams, 2001), and current relationship difficulties on a five-item 'non-graphic language' screen previously found to be a valid measure of IPV in this and other LMIC settings (Zink et al., 2007). Women's eligibility to take part was then discussed with their ANC provider, before approaching them. To identify health workers who met the inclusion criteria (section 5.4.6), the RA spoke to ANC staff.

Once identified, the RA approached potentially eligible pregnant women and health workers to explain the study. Sampling continued until theoretical saturation was attained. I identified the point of theoretical saturation by reading translated interview transcripts as soon as they were available, and discussing them with the RA, who conducted the interviews in Amharic. To determine theoretical saturation, I regularly discussed the depth and breadth of perspectives ascertained with the RA, reviewing new transcripts for recurring themes, and noting the point at which new perspectives were infrequently expressed. I terminated sampling when, based on the literature (sections 2.2 and 2.3) and available transcripts, I anticipated few new or divergent perspectives on the research questions, which had not yet been captured by the sample (Saunders et al., 2018).

5.4.5 Recruitment

The RA approached eligible women and health workers in ANC settings, and provided them with written and verbal information (uploaded to the open access repository; see Keynejad (2021)) about the study, before inviting them to participate and give written, informed consent.

5.4.6 Inclusion criteria

Women eligible to participate in Study Two were required to be:

- Female.
- Aged 16 years or over.

- Pregnant.
- Able to converse in Amharic.
- Able to understand the study information provided.
- Able and willing to provide informed consent.

I considered the age of eligible women carefully. A large local cohort study suggested that first marriage and pregnancy often occur before 18 years of age in this setting (Hanlon, Medhin, et al., 2009), so I included women aged 16 years and over. I did not formally screen women for current depressive symptoms or IPV exposure, to keep recruitment for Study Two as inclusive as possible and avoid excluding women who might not feel comfortable disclosing symptoms or IPV.

Health workers eligible to participate in Study Two were required to be:

- Working in an ANC setting.
- Able to converse in Amharic.
- Able and willing to provide informed consent.

5.4.7 Exclusion criteria

Women were excluded from participation if they were:

- Acutely unwell.
- Requiring emergency treatment.
- Deemed by their ANC health worker or the RA to be unable to understand, remember, weigh up, or communicate their views about the study information. This accorded with the UK definition of lacking mental capacity to consent (Department for Constitutional Affairs, 2007).

5.4.8 Informed consent

All participants were required to provide informed consent prior to being interviewed, usually by signing the consent form (uploaded to the open access repository; see Keynejad (2021)). If the participant was unable to read, the information sheet and consent form were read aloud in the presence of a secondary school-educated, independent witness, to confirm that this took place. If the participant was unable to write, they indicated their

informed consent by making a thumbprint in the presence of the witness, who signed to confirm that this took place. Witnesses were drawn from individuals present at the health centre; their role was confined to observing and confirming that informed consent was obtained and provided appropriately.

Due to difficulties women might experience returning to the health centre on a different day, interested participants were permitted to be interviewed on the day of recruitment, after taking at least 30 minutes to consider taking part. The RA was trained to identify verbal and non-verbal cues suggesting that a woman might not feel comfortable with or interested in participating, and to politely cease providing study information to such women.

5.4.9 Ethical concerns

I considered pregnant women, some of whom had low incomes, had received limited education or were experiencing IPV, to be particularly vulnerable when being invited to take part in research. Additional care was therefore taken at every stage of recruitment and participation, to ensure that women understood the information provided, felt comfortable to proceed, and did not feel coerced.

Information was provided using simple language. ANC attendees were not informed about the study by their health worker, to avoid giving the impression that they were obliged to participate, or that their clinical care would be impacted by participation. The RA emphasised this point, which was stated on the information sheet, when explaining the study. The RA was not a personal colleague of health workers and took care to emphasise the lack of obligation to participate, when explaining the study to staff members. The RA also emphasised the point on the information sheet that participants could withdraw from the study at any time before the end of the interview, without needing to give a reason, and that this would not affect their healthcare or working relationships. Participants were advised that their data could be withdrawn from the study at any time before the writing up of pseudonymised responses took place.

Study Two received ethical approval from the King's College London Psychiatry, Nursing and Midwifery Research Ethics Subcommittee (reference number: HR-17/18-

6063), and the Addis Ababa University (AAU) College of Health Sciences Institutional Review Board (protocol number: 026/18/Psy).

5.4.10 Risk management

Qualitative interviews were conducted in accordance with a standard operating procedure (SOP), uploaded to the open access repository (Keynejad, 2021), informed by relevant internal documents (Deyessa, 2017; Hanlon, 2017; Trevillion, 2015). The Study Two SOP addressed conduct for (1) the safety of researchers, (2) face-to-face contact with participants, (3) managing participant distress, (4) supporting participants experiencing IPV, (5) managing potential risks to children, and (6) managing risks of abuse, harm, or neglect of adults. Each of these SOP sections guided the RA to avoid abusive partners learning about a woman's participation in the study, maintain confidentiality, seek consent to break confidentiality if required, and urgently discuss any concerns with a nominated clinical contact person, or the project mental health professional. The SOP included up-to-date contact details for sources of support in the local community, which were given to women only after discussing the risk of abusive partners discovering them.

5.4.11 Interviewer recruitment

Recruitment, informed consent, and interviewing were carried out in a private room by female, master's degree-qualified RAs, in Amharic. I chose to recruit a female RA for Study Two, because of evidence that the interviewer's gender influences women's readiness to disclose IPV (Ellsberg, Heise, Pena, Agurto, & Winkvist, 2001). I also prioritised empathetic and non-judgemental communication skills, and experience of communicating about sensitive subjects, when recruiting the RA. These attributes were used as standard by the WHO multi-country study on women's health and domestic violence, when recruiting research staff (Jansen, Watts, Ellsberg, Heise, & García-Moreno, 2004).

5.4.12 Interviewer training and supervision

I trained the RA using clinical and policy guidelines (WHO, 2013c), and guidance on researching violence against women (Ellsberg & Heise, 2005). I provided the RA with regular written and verbal (in-person and online) feedback on early interviews, based on

reviews of English-translated transcripts, focused on responding to participants' verbal cues, and exploring any unclear points. I provided the RA with weekly to fortnightly supervision, including discussion of challenging interactions and risk incidents. I read English-translated interview transcripts as soon as possible, to inform iterative development of the topic guide, sampling decisions, and supervision discussions. The RA kept field notes about her experiences of interview interactions, which I read alongside translated transcripts during analysis, to inform my interpretations.

5.4.13 Data collection and procedure

The following sociodemographic information was collected from pregnant women: age, level of schooling attained, and religion. The following information was collected from health worker participants: age, sex, religion, specialism, and years of clinical experience. I did not include ethnicity in sociodemographic data collection because of political sensitivities surrounding this question. Since the 1995 constitution incorporated ethnicity and culture into the restructuring of Ethiopian domestic politics (Meckelburg & Abbink, 2020), questions about ethnicity are not received in a neutral manner. Because prospective participants might interpret being asked about their ethnicity in political terms, this practice has been discouraged by AAU, unless of key relevance to the research question.

In-depth interviews were conducted with pregnant women and health workers at a private location (a private clinic room at the health centre). Interviews followed topic guides (see Appendices 10.2.1 and 10.2.2), which were employed flexibly. Not all question stems were asked, and the conversation was allowed to flow as naturally as possible.

The topic guide for pregnant women comprised 14 stem questions, with associated probes. For example, the stem, "some women have problems in their relationships with their husbands. Has that been a problem for you? [If not, has that been a problem for someone you know?]" was followed by the probes, "please can you tell me about that? How does it affect you [or the person you know]? How do you [or the person you know] try to manage that problem?"

The topic guide for health workers comprised 13 stem questions, with associated probes. For example, the stem, "how would you feel about asking all women about relationship problems and violence in the home as part of antenatal care?" was followed by the probes,

“what would be the best way to ask them? What would stop them from telling you about relationship problems and violence in the home? How do you think health workers could best help women with these problems?”

The topic guide for pregnant women (Appendix 10.2.1) addressed topics of health and well-being during their current pregnancy, relationship problems and violence (personal experience or knowledge of others' experience), perspectives on health worker questioning and intervention, and acceptability of attending intervention sessions. The topic guide for health workers (Appendix 10.2.2) addressed topics of women's health and well-being in pregnancy, relationship problems and violence experienced by pregnant women, perspectives on asking women about mental health and violence, and perceived acceptability of intervention from the perspectives of women and staff.

5.4.14 Reimbursement

Pregnant women and health workers were reimbursed 100 Ethiopian birr (around £2.68 (ExchangeRates.org.uk, 2019)) in compensation for their time. This payment was determined to be locally appropriate, in relation to other studies conducted by AAU.

5.4.15 Data handling and protection

All interviews were digitally audio-recorded and downloaded onto a computer, before being emailed to professional transcribers. Transcribed Amharic interviews were then emailed to translators, who emailed de-identified English-translated interviews to the RA. Samples of new translators' work were reviewed by the fluent Amharic and English-speaking RA before full transcripts were translated. Transcribers noted the timing in the interview of any inaudible statements. Translators noted conceptually difficult translations, retaining the original Amharic word for later discussion, and aspects of language implied by the participant's choice of words, in square brackets. I uploaded English-translated interview transcripts to NVIVO for Windows (QSR International, 2020), for analysis.

Study documents, such as signed consent forms, were transferred to the main research office in AAU, where they were locked in a research cupboard, in a locked office. All electronic files containing interview data (audio-recorded interviews, Amharic language

interview transcripts, English-translated interview transcripts) were password-protected prior to sharing via email and saved onto password-protected computers. No personally identifiable information, such as names or dates of birth, were recorded, and transcripts were each assigned an alphanumeric identifier.

5.4.16 **Data management**

During data analysis (see section 5.4.17), I created a matrix for each theme using NVIVO (QSR International, 2020), to summarise and display the data (Spencer, Ritchie, Ormston, et al., 2014). I exported each matrix into a single Excel (Microsoft Corporation, 2008a) spreadsheet, with each overarching theme occupying a different worksheet. In each thematic worksheet, I allocated a horizontal row to each participant's interview transcript and a column to each sub-theme. I used each matrix to summarise my overall interpretations of lengthy excerpts, and to visualise the frequency and extent of each sub-theme's contribution to the overall theme. In this way, I was able to move between abstract thematic levels and the raw data, to select the quotations that responded most compellingly to my research questions and the literature.

5.4.17 **Analysis**

I calculated medians and interquartile ranges of participants' ages, durations of interviews, and health workers' years of experience, using Excel software (Microsoft Corporation, 2008a). I then tabulated participants' ages and health workers' years of experience using ranges, to preserve confidentiality.

I selected thematic analysis (Braun & Clarke, 2006), as an intuitive means of identifying and interpreting patterns within the data. I followed the six phase approach, first familiarising myself with the data by reading and re-reading translated interview transcripts alongside the RA's field notes, noting down initial ideas. Second, I used NVIVO software (QSR International, 2020) to systematically code the entire dataset, generating initial codes of interest as I went, and collating quotations relevant to each code. Third, I reviewed my initial codes in NVIVO and gathered those relevant to each other into potential themes. Fourth, I reviewed themes in relation to their constituent, coded quotations, and across the dataset using a matrix (see section 5.4.16). Fifth, I refined each theme, clarifying their names and definitions through further abstraction and

interpretation. For the sixth phase (Braun & Clarke, 2006), I engaged in a final process of explanation, referring back to my research questions while writing the final report.

In phase five of Braun and Clarke (2006)'s thematic analysis, I engaged in abstraction and interpretation (Spencer, Ritchie, Ormston, et al., 2014), using the contents of each matrix to describe an initial thematic framework in Word software (Microsoft Corporation, 2008c), selecting illustrative quotations. I then engaged in categorisation, moving from superficial commonalities between perspectives to more analytic aspects (Spencer, Ritchie, O'Connor, Morrell, & Ormston, 2014). For example, after initially grouping quotations about women's experiences of poverty, I re-categorised some of them into perspectives on social expectations of reciprocity. I also engaged in linkage mapping, searching for connections between different elements of the data, and considering whether any complex typologies were present across the data set, linking different phenomena. For example, I explored whether different perspectives on abuse intersected with views on deprivations women experienced. In phase six of Braun and Clarke (2006)'s thematic analysis, I engaged in explanation of the data, seeking to unify patterns within the data by understanding its explicit and implicit logic, via expressed and implied intentions, social norms, expectations, and contextual factors (Spencer, Ritchie, Ormston, et al., 2014).

5.4.18 **Validation and reflexivity**

During phase two of my thematic analysis, I selected two interview transcripts: one with a pregnant woman attending ANC and one with a health worker, which I considered particularly rich in relevant content. I asked the study RA (AMu, who conducted the interview), the trial coordinator (EF), and my post-doctoral researcher colleague (TB) to independently engage in phases one: familiarise themselves with the data, and two: generate initial codes (Braun & Clarke, 2006). I then reviewed their codes alongside my own during phase three (gathering codes into potential themes), to determine whether my codes should be altered or elaborated. I remained reflexive of potential differences in the lived experiences of my Ethiopian research colleagues and research participants, which might also influence their interpretations of the data. After completing phase six, I shared my analysis with these colleagues and my first supervisor, a UK researcher living permanently in Ethiopia (CH), before holding coding discussion meetings.

I used reflexivity to identify my personal biases, influenced by intersectional aspects of my personal circumstances (Patton, 1999). For example, I used self-reflexivity of my position as an English-speaking, female researcher working in a high-income country where gender equality is advocated but not always achieved, to strive for 'empathic neutrality' in my interpretations (Ormston et al., 2014). In order to attain triangulation through multiple analysis (Lewis et al., 2014), I worked closely with Amharic-speaking Ethiopian research colleagues in the analysis, for cross-cultural, collaborative 'sense-making' (Easterby-Smith & Malina, 1999).

Due to the diversity of perspectives expressed by multidisciplinary health workers and pregnant women who did and did not report personal experience of IPV, I did not pursue respondent validation ('member checking') of my interpretations. Interviews explored sensitive subjects and there was potential for a power imbalance between some participants (for example, non-literate women and experienced health workers). I therefore shared concerns described in the literature that respondent validation could have led some more vocal respondents to challenge uncomfortable interpretations, which accurately represented some, if not all, individuals' lived realities (Lewis et al., 2014).

Throughout the analysis, I sought to remain mindful of the fact that interview transcripts were English translations of conversations in Amharic. I regularly recalled that meaning conveyed through spoken language incorporates cultural experiences and understandings which cannot always be captured, even by the most expert translation (Temple & Young, 2004). Furthermore, my own readings of translated texts were inevitably coloured by my own conceptual understandings and personal experiences.

5.5 Results

Participant and interview characteristics

The characteristics of participants in Study Two are shown in Table 5.1. Sixteen ANC attendees and 12 health workers took part. Nine pregnant women were recruited after being identified through caseload reviews with ANC providers. The remaining seven women were recruited after approaching participants in an ANC survey, who had endorsed past-fortnight depressive symptoms and current relationship difficulties.

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The median age of participating pregnant women was 26.5 years (range: 19 to 35, interquartile range: IQR: 22.5 to 30). The median age of participating health workers was 25 years (range: 22 to 34, IQR: 24-28.3). The median duration of interviews was 33 minutes for ANC attendees (range: 13 to 73, IQR: 30-38) and 35 minutes (range: 26 to 65, IQR: 28-52) for health workers. Pregnant women had a range of educational levels, from no formal education (n=3) to secondary schooling (n=3), and religions (Orthodox Christian, Protestant, and Muslim), while the majority of health workers (11 out of 12) were Orthodox Christian.

The structure of the Ethiopian ANC system is described in section 4.5. Health worker participants comprised six community-based health extension workers (HEWs) and six midwives, with a median of 6.5 years' experience (range: 1 to 12, IQR: 3-10.5).

Modifications

The information sheet was read aloud, and the content explained in further simplified language, to three participants, who indicated their consent to participate by a thumb print in the presence of an independent, secondary school-educated witness.

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Table 5.1 Participant and interview characteristics

Characteristic	ANC attendees: n (%)		ANC staff: n (%)
	N=16		
Recruitment method	ANC caseload review	9 (56)	
	ANC survey purposive sampling	7 (44)	
Duration (minutes)	Median (interquartile range)	33 (30-38)	35 (28-52)
Date conducted	December 2018	0	1 (9)
	January to March 2019	0	3 (25)
	April to June 2019	3 (19)	4 (33)
	July to September 2019	6 (37)	4 (33)
	October to December 2019	7 (44)	0
Age (years)	16-19	1 (6)	0
	20-24	4 (25)	5 (42)
	25-29	6 (38)	4 (33)
	30-34	4 (25)	3 (25)
	35-39	1 (6)	0
Education level	No formal education	3 (19)	
	Elementary	10 (62)	
	Secondary	3 (19)	
Religion	Christian (Orthodox)	10 (63)	11 (91)
	Christian (Protestant)	1 (6)	0
	Muslim	5 (31)	1 (9)
Specialism	Health extension worker		6 (50)
	Midwife		6 (50)
Clinical experience (years)	0-4		6 (50)
	5-9		0
	10-14		6 (50)

ANC: antenatal care

Themes

In this section, I describe the themes identified by thematic analysis, alongside representative quotations. Themes were deprivation (5.5.1), pressures and expectations (5.5.2), abusive treatment (5.5.3), patriarchal norms (5.5.4), powerlessness (5.5.5), emotional and bodily distress (5.5.6), and psychological intervention (5.5.7).

perceived from both deprivation and pressures and expectations, to emotional and bodily distress (blue and brown arrows). Psychological interventions were perceived by participants to influence women's powerlessness, and emotional and bodily distress, with potential to indirectly reduce abusive treatment (dashed arrow), via mechanisms such as empowerment.

In quotations, 'P' followed by a number indicates a pregnant woman participant and 'HW' followed by a number indicates a health worker participant. Where participants referred to a quantity of Ethiopian currency (birr), its pound sterling value is shown in square brackets, based on the average 2019 exchange rate (37.3 birr to the British pound (ExchangeRates.org.uk, 2019)).

5.5.1 "I have no-one to help me" – deprivation

Participants described material, health, and social deprivations, which they characterised as causing and prolonging emotional difficulties, and exacerbating IPV. Sub-themes of deprivation were poverty (5.5.1.1), lack of education (5.5.1.2), and lack of support (5.5.1.3).

5.5.1.1 "Low economic condition" – poverty

Poverty was prominent in participant accounts, and often linked to stress and anxiety. Participants frequently described hunger and malnutrition as stressors, such as rarely having milk to drink (P5), struggling to eat once per day (P9, P10, HW6, HW11), lack of nutritious food in rural areas (P9), and difficulties preparing food.

Women and health workers described anxiety associated with long-term and short-term financial hardship during pregnancy:

Mothers with low income raise their children the same as the [other] children at the community. This creates a burden...[they] may worry how their child grows up after they gave birth.

HW1: HEW, 10-14 years' experience.

Women linked financial anxieties to their inability to influence family finances, exacerbated by their husbands' alcohol (P2, P9) and khat (P7) use:

When he gets money, he spends it extravagantly. He chews khat... His wastefulness is causing me a mental problem... the bank book doesn't have my name and picture on it.

P7, 30-34 years old.

I have already finished the money I have on my account. I used this money to feed our children because he drinks every day. I feel bad about that... I can't criticise him because I am currently dependent on him.

P9, 30-34 years old.

Costs associated with healthcare were a commonly raised source of anxiety. Costs included transportation to access emergency care following postpartum haemorrhage (HW6), investigations for ill children (P2), and medications (P16).

5.5.1.2 “If she is illiterate... he will disrespect her” – lack of education

Several participants raised lack of education as a factor in relationship conflicts (P3). Less educated women were described as lacking awareness of their options (P5, P8, HW1) and “illiterate” men were characterised as not listening to their partners (P16), or not knowing how to treat them (P13):

If he is educated and if she is illiterate... he will disrespect her.

P3, 35-40 years old.

Most of the people in this area are uneducated... They don't think that they can divorce their husbands.

P5, 25-29 years old.

Some men are not wise. They physically abuse their wives because they don't know how to treat them properly. Some illiterate people feel conceited and have the wrong perception of themselves.

P13, 25-29 years old.

5.5.1.3 “There is no-one there where I live” – lack of support

In the third sub-theme of deprivation, participants highlighted women's lack of practical, economic, and emotional support from their partners, relatives, partners'

relatives, and communities. Some women described feeling unsupported by their partners without describing abuse, while others also reported IPV at other points in their interviews. I coded women's lack of partner and other support separately from IPV, as a sub-theme of deprivation, to reflect a distinction which they conceptualised.

Women and health workers described distress caused by partners not working or sharing their earnings (P2), not helping women more when pregnant (P2, P11, HW8, HW10), and not helping women to access antenatal or other healthcare (P7, P11, HW6). Some participants described supportive husbands (P10, HW8):

There are some husbands who take care of their pregnant wives and come to the hospital with them to get the prenatal care services and when they give birth.

HW8, Midwife, 0-4 years' experience.

One participant described a husband whom she considered both supportive and abusive (P16). In common with several pregnant women, she remarked that her emotional difficulties began after marriage:

I always feel anxious about life. I was never like this before I got married... Though he beats me and treats me unfairly when we have disagreements, he is usually helpful for me... he just berates me when he is disappointed... [He] becomes disappointed for no reason.

P16, 20-24 years old.

Women also described feeling unsupported by other family members (P2, P4, P5, P13). They implied feeling abandoned and ashamed:

They say that [women] shouldn't do anything at the ninth month. But I have no one to help me with my work, before and after childbirth... My mother is dead. My mother-in-law is also dead. My sister will not come here.

P5, 25-29 years old.

In one case (P2), prior disputes between a woman and her family (refusing to leave school to get married), and between her abusive partner and her family (who tried to deter him from IPV) meant they had no contact during the perinatal period. Pregnant women (P5, P7) also highlighted a lack of practical and economic support from their wider community:

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The people are not friendly. They will not give food to my kids if I face any problem... the relationship between the people in this area doesn't go beyond greetings... Only God and my husband help me.

P5, 25-29 years old.

Despite wanting support, women expressed social norms of self-sufficiency, reticence to expose their difficulties, and inhibitions about seeking help from other women:

I worry about what they might say when I leave the group and go home... I don't feel comfortable to talk... Because it is my first pregnancy, I hold back in case the older women in my neighbourhood could think less of me.

P10, 25-29 years old.

Pregnant women (P1, P4, P5, P13) and health workers (HW10) raised isolation from social and emotional support as a source of particular distress:

I don't have relatives to drink coffee with. I don't know my husband's relatives. I am lonely... [My mother] died after I gave birth to my second child. I have no one else but him.

P5, 25-29 years old.

People learn many things through interactions with other people. I think a woman could become reticent if her husband isolates her from her friends or other people and if he restricts her access to information.

HW10, HEW, 10-14 years' experience.

Some women commented that not having grown up in the area, having recently moved, and discouragement by family members prevented them from building social connections:

The neighbours are also a bit far... my friends live far away... [my husband] comes home after a month or two months of stay [in the city]... I do not meet with people.

P4, 20-24 years old.

I don't know anyone in the neighbourhood... I didn't want to make many friends, but [my sister-in-law] didn't want me to mix with people.

P16, 20-24 years old.

Several women (P10, P14, P16) described self-imposed social isolation in response to guilt, shame, and low mood:

I feel sad and depressed sometimes. I go home and lay down in bed because I worry that I could affect other people's moods... I feel ashamed, and I isolate myself from other people.

P10, 25-29 years old.

I draw negative meanings of what [people] say. I make it all about me and go somewhere and cry. I feel that everybody is talking about me... I isolate myself from other people.

P14, 16-19 years old.

5.5.2 “I feared that they would judge me” – pressures and expectations

The second theme showed that “there is a lot of pressure on women” (P2) to meet high expectations, despite straitened economic circumstances (as outlined in the deprivation theme in section 5.5.1), and other factors beyond their control. Participants did not express that this mismatch (for example, between poverty and costly reciprocal obligations) made some expectations unrealistic. They described high community standards of propriety, and shame in response to deviating, or being suspected of deviating, from social norms. Sub-themes of pressures and expectations were reciprocal obligations (5.5.2.1), unplanned pregnancies (5.5.2.2), fitness to work (5.5.2.3), responsibility for the unborn (5.5.2.4), and community judgement (5.5.2.5).

5.5.2.1 “I can't give them gifts when I go to their houses” – reciprocal obligations.

Despite the impact of poverty (section 5.5.1.1) on women's ability to pay for basic daily living costs (P2), participants described social and cultural expectations of reciprocal expenditure. For example, women described struggling to meet cultural expectations around childbirth and the Christian Orthodox holidays of Meskel⁹ and Easter (P7):

⁹ Commemoration of the discovery of the true cross on which Jesus was crucified (e-Visa Ethiopia, 2021).

If, after you give birth to your child, you don't have any food in your house [for visitors], people will gossip that you didn't make any preparation to welcome the new baby.

P5, 25-29 years old.

Participants linked inability to fulfil such expectations with social isolation and relationship conflicts:

His family... don't like me because I am poor... I don't visit my family because... I can't give them gifts when I go to their houses. They don't visit me because I don't visit them.

P9, 30-34 years old.

In our culture, we have to go to our parents' houses for Meskel. You don't go... without buying gold rings, new shoes ... When I told him that I couldn't go... if he didn't buy these things for me, he told me to get away from him.

P14, 16-19 years old.

Women described a tension between the collective culture of community support, for example through *idir*¹⁰, and the rejection experienced by those unable to honour these obligations (“there is a lot of pressure on women”: P2).

5.5.2.2 “He would not be happy with the new child” – unplanned pregnancies

Avoiding and managing unplanned pregnancies were commonly described expectations of both married and unmarried women. Unplanned pregnancies were attributed to inconsistent or non-use of contraception (HW1, HW2, HW4, P2), due to lack of understanding (HW4), or discouragement by men (HW5). For married women, participants linked frequent pregnancies (“giving birth one on top of the other:” HW1) to practical difficulties (P5) and anxiety about finances. The option to terminate unplanned pregnancies was mentioned (HW2, HW5, P2), but often described as difficult to arrange:

¹⁰ Neighbourhood associations raising funds for emergency expenses, such as funerals (Bekerie, 2003).

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This health professional told me that it was not possible to abort in their facility because it was more than three months... Up to now I feel bad towards the expert [who did not administer the contraceptive injection beforehand].

P2, 30-34 years old.

Health worker participants described how women felt pressurised to avoid closely timed pregnancies (HW1), and to conceal contraception use from partners (HW4). It was unclear whether partner conflict arose more from the economic implications of close birth spacing, or community disapproval:

Maybe if he already told her to use birth control and if they were in agreement not to have a baby at the time... he would not be happy with the new child... They may also worry... that they would be a centre of discussion because they gave birth to too many children without interval.

HW1, HEW, 10-14 years' experience.

The shame of pregnancy outside marriage was a source of significant distress (P14, HW1, HW2, HW5):

I feared that they would judge me for being bad-mannered, as I became pregnant out of wedlock.

P14, 16-19 years old.

Despite high expectations of propriety, women and health workers gave examples of pregnancy outside the social norm of marriage. Their descriptions evoked experiences of pregnancy that were not widely acknowledged, and seemed to be occurring out of sight:

One day I was getting home... There is a... door where nobody lives. A pregnant lady comes ... I followed her into the house, [asked] her if she has antenatal follow up... when I got back [from a meeting] I went straight to her house, since her condition was very sad... Another pregnant lady was there, behind a curtain... It's like they rented a house just to have a baby... They stayed for one month and they left, we could not find them.

HW11, HEW, 10-14 years' experience.

The shame of women being pregnant outside marriage was more evident than condemnation of men's actions. One pregnant woman diagnosed with depression described how after travelling away from home to continue her education, she had been

abducted by a man who forced her into a relationship. She later learned that he was married with children:

He told me that he would make me submit to him... He wanted me to sit in the house and not mingle with other people... he is around fifty... He said that he wouldn't leave me, and I wouldn't marry another person or have a stable life until I have more than three children with him.

P14, 16-19 years old.

5.5.2.3 “I don't want to be idle for more than five days” – fitness to work

Participants described pressure to work and complete household tasks (P2) during pregnancy and soon after delivery. Women commonly described working while pregnant to make and sell *injera*¹¹ (P9), or traditional alcoholic beverages, such as *areki*¹² (P2, P9), also known as *katikala*¹³ (P4). Aspects of daily life, such as preparing *kocho*¹⁴ to eat, were considered particularly laborious (HW8). Women often described continuing to work during pregnancy, despite having been advised to stop (P12), and struggling to manage household chores (P5, P12, P13). Some participants described specific demands of agricultural life, such as needing to take cows to graze (P6), and cook for all the farm labourers, while feeling ill (P13). The pressure to continue manual labour during pregnancy was associated by some participants with adverse obstetric outcomes (P4, HW12), and difficulty attending ANC appointments (HW10). Some women described pressure to return to work soon after childbirth:

I will start doing work shortly after I give birth to my baby. I don't want to be idle for more than five days. We will distil areki and sell the atella¹⁵ and we will get money to buy our food and coffee.

P9, 30-34 years old.

¹¹ The Ethiopian national bread, usually made from teff (*eragostis tef*) flour (Stewart & Getachew, 1962).

¹² A distilled alcoholic drink produced from fermentation products (Lee, Regu, & Seleshe, 2015).

¹³ Another term for *areki* (Yohannes, Melak, & Siraj, 2013).

¹⁴ A local root crop (*enset ventricosum*), known as ‘false banana’ (Abebe, Stoecker, Hinds, & Gates, 2006).

¹⁵ A livestock feed produced as a by-product of *tella* (beer) or *katikala* production (Heuzé et al., 2016).

Women also described pressure to continue working despite headaches (P5, P13, P14), dizziness (P5, HW3), back pain (P15), poor sleep (P13, P15, P16), exhaustion (P5, P7, P10, P13, P16), and nausea (P5, P7, P13, P16). One pregnant woman linked work and household tasks to symptoms of tiredness, demotivation, and anxiety:

I have racing thoughts and I feel stressed... I have lost my interest to wash my clothes and clean the house. I don't want to bathe, and my skin has become darker. All I want to do is sleep. I can't do any work.

P16, 20-24 years old.

Some participants linked high blood pressure with “thinking too much” (P7, P14, HW1). Two women linked household concerns with anxiety and physical symptoms during pregnancy:

I am feeling very stressed and my nose is bleeding because of that... I also want to ask them if I have high blood pressure. I feel very anxious... I worry about my household problems and I hold my feelings to myself.

P7, 30-34 years old.

I just feel anxious without any reason, and I have racing thoughts... I just worry about the ups and downs in life.

P13, 25-29 years old.

5.5.2.4 “Sadness has an impact on the baby” – responsibility for the unborn

Women's perceived responsibility for adverse obstetric and neonatal outcomes was a clear sub-theme of pressures and expectations. Several participants described specific anxieties about miscarriage (P10, P14, HW1, HW12), and dying in childbirth (P5). Other worries included coping with a new baby (P1, HW9), and how difficulties during pregnancy would impact their unborn child:

I worry about the baby so much... A mother's happiness or sadness has an impact on the baby... The baby is very small... I feel that the baby is suffering from my stress and grief. I just hold my stress and grief to myself.

P14, 16-19 years old.

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In this pregnancy, I spent the day by sitting in the market, in the sun and in the rain. I feel very weak because of that. So, I tell him that we should prepare because we have no one to take care of our children if I die at childbirth.

P5, 25-29 years old.

Participants also described anxiety about the physical (P1, P13) and obstetric (P1, P2, HW3, HW11) consequences of physical IPV:

Mostly, when I am pregnant there is a terror. Because if I were not pregnant... I will handle it. I do not have a choice if he hits the foetus... if the foetus is injured, I will also get a problem.

P2, 30-34 years old.

The obligation is there in pregnancy times... especially hitting, with husbands... it is advised for it not to occur... since a little thing is enough... on the foetus, there might be development decrease.

HW3, HEW, 10-14 years' experience.

Participants additionally attributed adverse obstetric outcomes to women's distress in response to IPV (P4, HW7, HW8), creating a cycle whereby women felt anxious about the impact of their anxiety on their unborn child:

A mother's stress is detrimental for foetal growth... She could face APH [antepartum haemorrhage] because of stress... She might lose her appetite. I don't think she will give birth to a normal baby.

HW7, Midwife, 0-4 years' experience.

She could face miscarriage if she gets upset and becomes stressed.

HW8, Midwife, 0-4 years' experience.

Women and health workers alluded, without elaboration, to potential impacts of women's mental states in response to IPV on foetal well-being:

She could also get very angry. She could get disappointed. Since she is pregnant, her child also will get irritated in her womb.

P4, 23 years old.

If she feels disturbed, the foetus will also feel disturbed, because they share many things with each other.

HW10, HEW, 10 years' experience.

5.5.2.5 "Rumours in the village" – community judgement

Participants often anticipated judgement by their community (P1, P5, P8, P10, P14, HW1, HW9, HW12), and health workers (P9, HW5), for violating social norms. Women expressed shame about people knowing they were experiencing IPV (P8), or admitting emotional difficulties (P10) and IPV (HW9) to others:

Almost all of them don't want talk to other people about the violence their husbands perform against them... They keep silent lest people should belittle them... So they keep to themselves and suffer.

P8, 25-29 years old.

They might say... she made her husband's secret public and made him look bad, she did that to destroy his name... so... she has to tolerate it and live with him... The culture holds them back.

HW9, Midwife, 10-14 years' experience.

I hold back in case the older women in my neighbourhood could think less of me for talking about it... I listen to their advice, but I feel ashamed to talk about this issue... I respect them... I just worry about what they might say when I leave.

P10, 25-29 years old.

It was commonly remarked by women (P1, P2, P3, P4, P9, P14) and health workers (HW1, HW10, HW12) that, because of anticipated judgement, women do not wish to "divulge secrets," compounding their shame and isolation:

Most people do not talk about the things that are happening in their house... Since the secret is about their house, they do not speak out.

P4, 20-24 years old.

I didn't want to be [pregnant]. I didn't share my problem with my family and friends, and I kept my secret to myself because I feared that they would judge me.

P14, 16-19 years old.

With respect to accessing support through ANC, participants emphasised concerns about confidentiality (P3, P8, P9 HW1, HW4, HW6, HW8, HW9, HW11), especially in relation to being gossiped about:

If the discussion is one-to one with the health professional, they will tell freely... [whereas] if there is a meeting among pregnant mothers... there will be rumours in the village if she discloses such things.

HW6, Midwife, 0-4 years' experience.

If I know her husband, or if we [live] close [by], she might be scared, thinking that I might tell on her... it might be an obstacle for her to tell you freely.

HW9, Midwife, 10-14 years' experience.

5.5.3 “He told me that no-one would help me” – abusive treatment

Experiences of IPV were widely discussed, alongside abuse and reinforcement of abuse by non-partners. Sub-themes of abusive treatment were IPV (5.5.3.1), family involvement (5.5.3.2), ineffectual responses (5.5.3.3), coerced reconciliation (5.5.3.4), and disrespectful ANC (5.5.3.5).

5.5.3.1 “He threatened to cut me into pieces” – intimate partner violence

IPV was the most extensively elaborated subject across interviews. Participants described all forms of IPV during pregnancy, from first or second-hand experience. Experiences included physical (P2, P11, P16, HW5), sexual (P2, P14, HW7), psychological abuse (P2, P3, P11, P14, P16), and coercive control (P2, P11, P14):

One mother... once, her husband was drunk... he found her sitting without taking the cattle to their cattle pen. They started fighting... she fell to the ground and started bleeding when her husband beat her up.

HW5, Midwife, 0-4 years' experience.

We fought... and he hanged me up from my leg while I was sleeping... I was six months pregnant or so... He did [sexual intercourse] by force... When we are arguing he insults me, saying 'prostitute'... after he gets drunk.

P2, 30-34 years old.

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Once, he... [left] for about a week without buying food for me... I had to be careful when I go... for coffee because he always came home from the market unexpectedly... to see whom I spent my time with. I didn't mingle with people because I feared for my life.

P14, 16-19 years old.

Although asked explicitly about IPV and perinatal emotional difficulties, women mentioned the emotional impact of IPV infrequently, usually as a passing comment that "I feel bad" (P7, P9), "I feel anxious" (P11), or "I feel stressed" (P7, P16):

I feel stressed because he insults me the whole night. [People] tell me to ignore [it]... and to stop worrying. But I can't... ignore my problems and move on easily like other people.

P7, 30-34 years old.

I feel anxious every time... We fight about every little thing... he scolds me if I go out somewhere, without giving me the chance to tell him the reason... I feel nervous when I hear his voice... he used to physically attack me.

P11, 25-29 years old.

Some health workers linked IPV with depression (HW5, HW7), but characterised it as mild or transient (HW5):

Most of the time, depression due to conflict would be acute... She might come bleeding and tell you her husband beat her. Even though she became depressed for the time being, her condition will not reach a severe level.

HW5, Midwife, 0-4 years' experience.

One of the most experienced health worker participants highlighted inter-relationships between partners' substance use, poverty, and women's depression:

In addition to her being physically abused by her drunk husband, she has financial constraints... she faces... household problems and she is responsible to raise the children too, and he doesn't support her... His abuse added to the economic problem is what caused the depression.

HW1, HEW, 10-14 years' experience.

Pregnant women (P2, P8, P9, P12, P14) and health worker (HW9) participants acknowledged the risk of domestic femicide, but did not describe the emotional impact of life-threatening violence:

He threatens to cut my neck and kill me when he comes home drunk. When he drinks, it looks like he is possessed by Satan... Last time, he threatened to stab me with a knife.

P9, 30-34 years old.

He could have killed me... Once... he told me that no one would help me if I cried for help, and he left me [in a field]. There were many hyenas in that area and no one lived close to where he left me.

P14, 16-19 years old.

I heard a story... I think [a woman] didn't listen to [her husband] and she fed the [maize] stalks to the cows. He hit her neck with the sickle in his hand and he killed her. She was pregnant and she was carrying a baby on her back. He killed three people in a moment.

P8, 25-29 years old.

One woman described police attitudes condoning IPV and even femicide, in cases where infidelity was proven. This was one of several descriptions of IPV being rationalised:

When he is drunk... he does not know anything, if he injured or killed you. There was something like sword, konchera¹⁶: I hid it... [the police] said [to him], 'you are [in the] right, even if you kill her, if she is married and sees another man. Otherwise, if you are talking [of infidelity] without evidence, it is nonsense'.

P2, 30-34 years old.

5.5.3.2 “They burned the hut down” – family involvement

Several participants experiencing IPV also described aggressive interactions with their partners' family members (P7, P16, HW6), and actions exacerbating or perpetuating abusive relationships by their own relatives (P7, P9, P11, P16):

¹⁶ Machete (Inkermann, 2015).

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I have suffered a lot because of [his] family... They told me to leave [their] house and they burned [our] hut down. They threatened me and tried to attack me several times... His father attacked me... he has a large family and [my family] can't compete with them... My father loves him. So I don't tell anyone.

P7, 30-34 years old.

His brother's wife is a difficult person... she comes to our house and picks a fight with me... He warned me that he would beat both of us if I let her take the fence-wood again... She misled him... he beat me... I was unhappy that he listened to what she told him about me.

P16, 20-24 years old.

One woman described how her mother-in-law enabled IPV by giving her husband money for alcohol:

His mother is a very difficult person... She calls him and gives him money for drinks. We fight when he comes home drunk. I feel bad and cry when they do this to me. My children cry when I cry.

P9, 30-34 years old.

Participants often linked abuse perpetrated by family members with emotional difficulties. Some described improvements after separation from the extended family:

Her mother-in-law insults her... she was disturbed, she was even crying... We advised [her husband] to change their living place... She was even on her way to be psychotic but now she is fine... When she went to her family's [home] she got better.

HW6, Midwife, 0-4 years' experience.

5.5.3.3 “He will feel that there is no law” – ineffectual responses

Participants described a hierarchy of community responses to IPV, starting with their own (P6, P12, P13, HW2) and their partner's (P2, HW2, HW6) family members. When family were unable to help, participants suggested informal help-seeking from neighbours (P5, P6, P9, P10, P13, P15) and then village elders (P6, P13, HW2), or religious leaders

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(HW6). Formal sources of support were the local (*kebele*¹⁷) authorities (P2, P5, P6, P16, HW2), then the *woreda*¹⁸ women and child affairs office (P2, P8, P9, P16), followed by legal court proceedings (P2, P9, P13, P16, HW2):

The people in this local community hold family meetings and have a lot of respect for their culture... people resolve their conflicts through discussions with village elders... A pregnant woman could take the case to court or the kebele management if... the couple's families can't help them.

HW2, HEW, 10-14 years' experience.

If there is anyone in the family that he can respect and listen, for example... We tell her to tell those religious leaders because he can listen to them.

HW6, Midwife, 0-4 years' experience.

Women (P2, P3, P6) described how the requirement to incrementally pursue each step of a hierarchical response to IPV was enforced by authorities, but created a sense of impunity among abusive partners (P2, P3):

I talked to his family... They took the issue to the kebele and told him very well... I went to the court... they told me to go to 'female and youth affairs'[office]... she told me that they will... first give him advice. It is [later] that they will take him to court... If he gets advice... he will feel there is no law... [it] will not help at all.

P2, 30-34 years old.

The kebele armed man will give warning to her husband and then she will go back to her home... He will return to his... behaviour even though he is arrested for a while. She cannot do anything... unless God surrender him.

P3, 35-39 years old.

Police involvement was reported as a last resort (P2, P5, P9), but only provided brief separation without further consequences for the abusive partner (P2, P9):

¹⁷ The smallest administrative unit in Ethiopia, similar to a UK ward (Feyissa et al., 2018). The term here refers to local government authorities at the kebele level, with powers to resolve community disputes.

¹⁸ A district, comprising multiple *kebeles* (Feyissa et al., 2018).

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Even police had arrived twice during our argument. He was drunk... [They] took him to the police station and made him spend a night there. When they asked him to testify in the morning, he... claimed he had no idea what happened.

P2, 30-34 years old.

When he threatens to kill me... they take him to the police station and he spends the night there... the next day, he promises that he will stop drinking... They say that he could attack me while I am sleeping... but they detain him for 24 hours and they release him.

P9, 30-34 years old.

Women's lack of financial independence made criminal prosecution unfeasible, reinforcing the implied futility of seeking help for IPV:

[The police] told me that they can't do anything to him if I don't take the case to court. I consulted lawyers and they told me that I needed money... so I stopped thinking about suing him as I would rather use the money to feed my children.

P9, 30-34 years old.

In addition to community and legal responses to IPV, health workers (HW1, HW2, HW7, HW8, HW9, HW11) described mediating between partners, but it was unclear how often this occurred in practice:

If a pregnant mother... shares her marital problems with us, we will do everything possible to discuss the issue with the couple and help them resolve their conflict... [She] will be relieved of her stress if we could make her partner understand the causes of her worries... but no one contacted me for advice on this issue.

HW2, HEW, 10-14 years' experience.

Health worker participants (HW1, HW2, HW3, HW5, HW6, HW9, HW11) and one pregnant woman (P9) also described men being instructed in ANC on how to treat their partners, sometimes referring to foetal impacts (HW5, HW6, HW11). However, some health workers acknowledged not having experienced such situations (HW5, HW6):

We say to them, if they want a healthy baby, they need to take care of their wives... I will contact the health extension workers... we will go to his house... I did not have experience of counselling them regarding these issues.

HW6, Midwife, 0-4 years' experience.

Some participants proposed targeted but impersonal means of discouraging men from IPV (P2, HW11):

During a meeting... there were people whose secrets I knew. So when I looked at the men, I changed the topic... and then talked about how some men take care of the mothers... By pretending to tell the others, he will hear it.

HW11, HEW, 10-14 years' experience.

Health workers proposing to mediate between partners acknowledged cultural (HW9) and attitudinal (HW9, HW11) barriers to lasting change:

We will get her permission to sit and talk with him, but if she said 'no'... then we can't do anything other than advise her... She is never the problem maker... if she is not willing to admit that, I will go over and over again and try to convince her.

HW11, HEW, 10-14 years' experience.

Both recently qualified and experienced health workers expressed their powerlessness to safely respond to IPV:

In rural areas like this one, women usually have forced sex with their husbands... We usually advise them to use family planning service. I find it challenging. I think it will be another problem in their marriage if they refuse... It is difficult for me to propose a solution... They do that even when they are sober.

HW7, Midwife, 0-4 years' experience.

What you say... might cause divorce or even death, so the beating might worsen... he might throw her out... you don't know what he would do to her at home, so to avoid her getting hurt you have to call them both and try to make them agree.

HW9, Midwife, 10-14 years' experience.

5.5.3.4 “Village elders... bring me back to his house” – coerced reconciliation

The option for women to leave abusive partners permanently (P10, HW4) and to obtain a divorce (P3, P8, P13, P16, HW3) was mentioned as a final option, usually in hypothetical language:

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A woman should divorce her husband if he nags her or doesn't have any respect for her... and physically attacks her. She should divorce him if she wants to live long.

P13, 25-29 years old.

Women (P3, P7, P9, P13, P14) described barriers to leaving abusive relationships, which often involved third parties. For example, village elders (P3, P11, P12, P13), mediators (P7), neighbours and friends (P14) were described as encouraging women to stay or return to abusive partners, often against women's wishes:

When I go to my sister's or my mother's house, they discuss the problem with village elders and bring me back to his house... My mother tells me that everything will improve in the future if I am patient... I just listen to them and don't say anything.

P11, 25-29 years old.

Village elders bring them back to their husbands' houses... If a woman sues her husband, these people mediate the conflict and make her interrupt the [court] case.

P12, 30-34 years old.

5.5.3.5 "I didn't want to go there because she treated me badly" – disrespectful ANC

In some cases, abusive intimate relationships were mirrored by disrespectful or abusive ANC experiences:

She didn't even look at me properly... She just examined me with something and went back to her chair... she told me to go away... I asked her if they can refer me to [a closer hospital], but she refused... I come here because [otherwise my husband] would yell at me... he could get upset with me and lose his mind if I don't.

P7, 30-34 years old.

Some women described concerns that conflict with health workers could negatively impact their ANC, impacting on their ability to trust staff:

I don't like it when they keep us waiting in the health centre without any reason. They get upset when you ask them why they are not efficient in their service. They hold grudges with you and don't help you when you are in need.

P16, 20-24 years old.

They [health workers] were talking and laughing in the ward... [my husband] told them not to watch and laugh when people die... [Other] people advised him not to scold them... [they] could inject a patient with poison and kill them... I don't want to say anything to them after that happened.

P7, 30-34 years old.

5.5.4 **“It will not be the end of the world if a husband beats his wife” – patriarchal norms**

The theme of patriarchal norms showed how perpetration of IPV and other abuse was implicitly reinforced across society. Sub-themes were inequality (5.5.4.1), victim blaming (5.5.4.2), attribution (5.5.4.3), accommodation (5.5.4.4), and looking the other way (5.5.4.5).

5.5.4.1 **“They are dominated” – inequality**

In addition to educational inequality described under deprivation (section 5.5.1), participants suggested underlying reasons for IPV perpetration, such as occupational inequality (P1, HW9, HW12) and gender unequal attitudes (P2, HW11, HW12), including among women (P2, P10):

What I would call the toughest [problem] is the economic dependency. Those mothers are dependent on their husbands, so they are dominated... I can't say it's 100% that they are deciding [things] for themselves.

HW9, Midwife, 10-14 years' experience.

The guys feel superior. Because of that they might come home drunk... They make the wife do things only in the way they want.

HW12, Midwife, 0-4 years' experience.

As for me, I will not confront my husband if he beats me. Men are not like women: they shouldn't be beaten.

P10, 25-29 years old.

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They see their husbands above everything... in the rural [areas] they say, 'the foreign gov[ernment], they taught us about gender equality and put us in trouble with our husbands.'

P2, 30-34 years old.

One health worker linked poverty and healthcare costs to gender inequality:

When she is ill, she still can't even decide to sell her cattle or hen and go get treated for it: he's the one who makes the decision. He might not even agree.

HW9, Midwife, 10-14 years' experience.

One participant described her lack of control over marital decisions:

He said 'we don't need any wedding ceremonies', saying he has nothing... Then everything was done. I didn't even stay for a day with his Mum and Dad [after we got married]... I will just leave it to God and eat what he gives me.

P1, 20-24 years old.

Several respondents remarked on men's emasculation, suggesting that IPV is a response to feeling undermined in their patriarchal role:

Women pick fights when they face a shortage. What can he do if he doesn't have money?

P10, 25-29 years old.

He works in the night-time because he doesn't want anyone to see him when he does the household chores... We don't fight because he is older than me, and he loves children. He advises them or beats them up. He flogs them with his belt.

P5, 25-29 years old.

5.5.4.2 "Her husband should teach her to behave properly" – victim blaming

The patriarchal view that women's behaviour may provoke their partners to act violently was commonly expressed by participants. Some suggested that women could prevent IPV by not criticising their partners (P1, P4, P10, HW8). Accusations of suspected infidelity were considered provocations for IPV (P1, HW8):

When she... feels dejected she might start the fight... [asking] with whom he's cheating on her... What she should do at that time is maybe waiting... [He] might

raise something and hit her... he might be drunk or not, so [she could speak] to him in the morning with a clear mind... and tell him calmly.

P1, 20-24 years old.

Conflicts between couples arise when the wife hides something from her husband and the husband learns about it from other people.

P5, 25-29 years old.

Some women characterised IPV as a justifiable response to women described as “idle” (P10) or “lazy” (P13). Reciprocal obligations were one source of relationship conflict:

A husband should be very nice to his wife. But it will not be the end of the world if a husband beats his wife... [She] shouldn't nag him about money... it is usually women who [instigate] family conflicts... It is easy for women to make plans for fights when they are idle. They, including myself, start planning for fights when they don't have salt, coffee in the house. Women worry about what to serve for guests who come to their houses.

P10, 25-29 years old.

If a woman is lazy... her husband should teach her to behave properly. Some women... don't manage their houses properly... such wives should be reprimanded... In our culture, a husband would scold his wife if she can't manage... with the money he gives her... if she doesn't respect him.

P13, 25-29 years old.

5.5.4.3 “They are not conscious when they drink” – attribution

IPV perpetration was commonly attributed to situational factors, such as men's substance use (almost always alcohol), rather than dispositional factors. Health workers reported that men typically drank alcohol after selling crops at market (HW6, HW10), and that spending more than the family could afford provoked arguments (HW2, HW6):

Some of them will say... 'he did not do anything for a living, yet he will spend time drinking with his friend and disturb the kids and beat me'... He will come home drunk after he sells the crops... she will start complaining when she saw him selling what is for the children.

HW6, Midwife, 0-4 years' experience.

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Marital conflicts usually arise from drinking. Couples usually have disagreements when the husbands drink with their friends and come home late. Women will be forced to extra work... [if] husbands...live beyond their means.

HW2, HEW, 10-14 years' experience.

Some participants minimised men's personal responsibility for IPV perpetrated while intoxicated. No participant explicitly linked a man's decision to drink alcohol with their responsibility for IPV:

Most guys speak, act differently when they drink katikala. They are not conscious when they drink. They are not aware of what they speak and do.

P4, 20-24 years old.

There are men who act like crazy when they drink. They get upset very quickly and physically attack their wives and children. They might also physically attack their neighbours when they come to their houses to mediate the conflict.

P5, 25-29 years old.

Participants described but did not question the imperative for men to drink alcohol while socialising with each other, or the role this might play in IPV:

His friends call him and invite him to drink beer... Once, [when I was pregnant, he] started playing a music tape at maximum volume. I was very sick and I crawled on all fours and opened the door and left the house. I told him to reduce the volume... but he said he wouldn't... There are times when he doesn't want to drink. We are peaceful when he is not drunk.

P7, 30-34 years old.

He doesn't want to stop drinking. He said he doesn't want to distance himself from his friends... He acts disruptively only when he comes home drunk... he drinks whether he has money or not. Drinking is like his routine of work.

P9, 30-34 years old.

Possibilities that some men may have a violent disposition, or be replicating behaviour observed during their own childhood, were not raised by any participant.

5.5.4.4 “*She should be able to handle the situation wisely*” – accommodation

The perceived responsibility of women to manage their partners' desire to fight with them (P4, HW8, HW10) was commonly articulated:

It is usually the women's responsibility to manage marital conflicts... If her husband wants to start a fight, she should be able to handle the situation wisely. It is usually women who start conflicts... She could have trust issues with her husband... Wives might... openly criticise their husbands when they make mistakes.

HW8, Midwife, 0-4 years' experience.

Women could exacerbate the problem when they fail to ignore their husbands... If a wife ignores her husband by sleeping in the house or going somewhere else, he will stop doing the things after some time. I think this will help her to avoid [conflict].

HW10, HEW, 10-14 years' experience.

A common recommendation was for women to physically separate themselves (HW5) from abusive partners' immediate vicinity, either for a period of hours (P4, P7, P15, HW10), or days to weeks (P2, HW2, HW6), before returning. Participants suggested staying with family (P4, P13, HW2, HW6, HW10), neighbours (HW10), moving into a different room (P2, P4, P15), or leaving the home temporarily (P7, P10, HW10):

If this thing happens repeatedly, I will advise her to stay with her parents because for her to give birth to a healthy baby she needs to be safe... she needs to calm herself and her mind.

HW6, Midwife, 0-4 years' experience.

When the women in the neighbourhood gather... we will advise her not to confront him when he comes home drunk and scolds her... We tell them to keep quiet... We advise them to...move on when they come home drunk.

P15, 20-24 years old.

Some participants implied that IPV would cease without further intervention, if women separated from their partners temporarily:

He could improve his behaviour if she goes to her parents' house. He could regret what he did... he could say that it was Satan or heat of the moment.

P10, 25-29 years old.

If a wife ignores her husband by sleeping in the house or going somewhere else, he will stop doing the things after some time. I think this will help her to avoid [conflict].

HW10, HEW, 10-14 years' experience.

The emotional impact of regularly accommodating IPV was implied in some women's accounts (P7), but not overtly expressed.

5.5.4.5 "I usually don't ask them about that" – looking the other way

The final sub-theme of patriarchal norms encapsulated the ways in which community members, health services, and authorities routinely looked the other way, rather than identifying and addressing IPV. Some participants stated that IPV is less acceptable (P10, HW5) or less likely (P11, P14, HW4) during pregnancy, because men do not wish to harm their unborn child, or because women are more vulnerable during the perinatal period:

It is difficult to hear such type of thing. It is not proper to beat up pregnant women, even, it is not appropriate to let pregnant women do hard work.

HW5, Midwife, 0-4 years' experience.

He has attacked me physically in the past. But he doesn't do that anymore because I am pregnant. I can't take a physical attack now.

P11, 25-29 years old.

Some HEWs and midwives, including several with 10 or more years' experience, reported never (HW2, HW8, HW10), or infrequently (HW1), treating women experiencing emotional difficulties or relationship problems, alongside idealistic statements about pregnancy and ANC. One said:

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Pregnant mothers get the best care, both in the hospital and in the house. We don't encounter women who have psychiatric disorders in pregnancy because they will be taken care of by many people at that time... I didn't encounter pregnant mothers who have relationship problems with their husbands.

HW2, HEW, 10-14 years' experience.

Several ANC attendees (P10, P11, P12, P13, P14, P16) affirmed that asking pregnant women about emotional difficulties and IPV was acceptable. Some participants indicated, however, that it does not happen (P11, P12, HW7):

[The health worker] who follows up my health condition doesn't ask me that kind of question. I would be pleased if she asks me questions about that... I wouldn't be reluctant to share my secrets with her because I want to get solutions.

P12, 30-34 years old.

Health professionals don't usually give them advice on this issue [sexual IPV]. I think it is our problem... Had it been given enough attention and had professionals raised the issue for discussion, the women would have talked about it openly.

HW7, Midwife, 0-4 years' experience.

Some health worker participants acknowledged that pregnant women feel comfortable discussing mental health and IPV (HW1), and that inquiring about them would be acceptable (HW2, HW4, HW10):

Had we been better developed, and if we asked the mothers about [IPV and emotional difficulties], it would have been better, because the mothers are always frank.

HW1, HEW, 10-14 years' experience.

Health workers' expectation that women would not share their secrets seemed to influence their likelihood of asking about emotional difficulties and IPV:

They think their secrets will be revealed so they may not tell you openly, but you can give them general advice. All of the women will not tell you when you ask them... that is the issue.

HW11, HEW, 10-14 years' experience.

One midwife highlighted how lack of training meant that staff did not ask about emotional difficulties and IPV, or identify them when present:

Participant: They don't usually talk about [emotions]. And I usually don't ask them about that... They usually have fatigue.... They don't usually tell us that they feel anxious... But one woman told me that she had pain after she had consensual sex with her husband during pregnancy...

Interviewer: Did she want to have sex? Or, she was forced to have sex?

Participant: I think it was consensual sex... I told her to stop having sexual intercourse if she had pain.

Interviewer: What was her response?

Participant: ... I think she told me that she had no choice... she had sex with him against her will.

HW7, Midwife, 0-4 years' experience.

5.5.5 “She cannot do anything to protect herself” – powerlessness

Women's experiences of abusive treatment and its reinforcement by patriarchal norms, in the context of deprivation, pressures and expectations created a sense of powerlessness. Sub-themes were entrapment (5.5.5.1), silencing (5.5.5.2), and hopelessness (5.5.5.3).

5.5.5.1 “If I take my children... it will be very difficult for me” – entrapment

Some women (P3, P9) described feeling trapped in abusive relationships because of concern for their children, while others described children mediating between partners (P5, P9):

The children are afraid of him... They don't speak to him [or] they... tell him to stay away from me... [My family] will tell me to leave the children with him and go to their house... The children say they will go with me if I leave [but] it will be very difficult... to pay for transportation... I and my oldest daughter sit up late... She comforts me when I cry.

P9, 30-34 years old.

The impact of IPV on existing children was mentioned infrequently, without discussion of long-term consequences. Pregnancy and children's welfare posed barriers to leaving (P3, P7, P9, P13):

In the past, I ran away to escape him and worried about what he could do to the children... now that I am pregnant, I can't do that anymore.

P9, 30-34 years old.

Although some participants suggested that IPV would resolve if women ignored abusive partners, others described it worsening abuse (P16, HW12). This form of entrapment highlighted contradictions between messages of empowerment and discouraging confrontation (P6):

[People] advise us not to be subservient and fearful in our relationships with our husbands. And they tell us not to confront them when we are upset.

P6, 25-29 years old.

I pretend as if I didn't see or hear what he did or said to me... He feels belittled when I don't confront him when he berates me. He will not stop lashing out at me if I don't confront him.

P16, 20-24 years old.

If she keeps quiet... he could also consider it as if she disrespected him. He could beat her for not responding.

HW12, Midwife, 0-4 years' experience.

Participants did not describe the emotional impact of women's pervasive experience of entrapment.

5.5.5.2 "His pressure is there in the house" – silencing

Women's narratives of emotional difficulties and IPV were silenced by a range of factors. Participants raised shame (P6, P10, P13, P15, HW2, HW4) and difficulty verbalising problems (P2, P6, P13) as barriers to disclosure:

There are still some things that I find difficult to share with health professionals... I feel ashamed to speak to you because I am not educated like you... I just feel suffocated with fear.

P13, 25-29 years old.

Pregnant women (P2, P4, P7) and health worker (HW1, HW5, HW8, HW9, HW11) participants highlighted how fear of provoking further or worse IPV prevented women from disclosing their experiences:

Once they were going door to door to do interviews... [One woman said] 'If my husband hears this from somewhere else, he is going to slaughter me... they don't do anything to [help] us...' His pressure is there in the house. It is from a mentality of 'if I tell on him, he will hear that and... force me and... abuse me.'

P2, 30-34 years old.

5.5.5.3 “There is no way to escape” – hopelessness

Participants often conveyed a sense of hopelessness (HW9), the inevitability of death (P2, P3), and a lack of meaningful options (P2, P12) for addressing IPV. A common remark was that IPV “has no solution” (P1, P2, P4, HW7), or that there is nothing that women can do (P8, P12):

The so-called leaders, they show up after you died, with the community... They don't show up... 'we don't want to be part of the conflict'... they don't come, even when we shout.

P2, 30-34 years old.

Even her child might be dead due to their conflict... She cannot do anything to protect herself. Nobody will protect her life. There is no way to escape... That woman will preserve her and [her unborn] child's life by leaving the home and hiding in their family... Since it is her destiny, she will live with him 'til the end of her life.

P3, 35-39 years old.

Some participants expressed a sense of fatalism: the inevitability of their suffering, sometimes in de-humanising terms:

I just said to him, 'as you wish, it doesn't matter, God gave me you, so you can do whatever you like with me. I can't do anything, it's not my command.'

P1, 20-24 years old.

Being a woman, anything may happen. If you leave and become a prostitute... [it] is the same as with [my] current situation. Rather, I decided to live with the person that I know, dealing with his behaviour.

P2, 30-34 years old.

Occasionally, women described verbally retaliating against IPV in a more assertive manner than their other descriptions suggested was culturally acceptable, conveying a sense of recklessness for their safety:

During our last conflict when he threatened to cut me into pieces... I requested with an official letter not to return [his machete] back home. Sometimes... he says that I am responsible for the [machete being] taken. I reply... 'buy a new one'.

P2, 30-34 years old.

I said, 'may your mother eat mud' to him. He loves his mother. That is why he beat me. I was sick for many days because of that.

P16, 20-24 years old.

One woman described resignation to the risks of physically fighting back, including death:

When he tackled me, I grabbed his neck and took him to the wall... I decided either he kills me or I kill him... I told him I just don't need him anymore... 'Go and see how married life is with another woman...' One time he locked the door on me... and asked 'where did you spend the day?' I responded... 'I am the one doing everything'... I am not fearing him, but God. I live for my later life.

P2, 30-34 years old.

Although participants' descriptions of IPV deviated from socio-cultural norms of propriety and decorum which they had described, they did not link women's hopelessness with emotional difficulties or distress.

5.5.6 "I don't always feel happy because I feel sick" – emotional and bodily distress

Women's experiences of perinatal emotional difficulties were much less extensively elaborated than IPV, and often characterised in terms of, or alongside, physical symptoms. Sub-themes of emotional and bodily distress were emotional difficulties

(5.5.6.1) and physical symptoms (5.5.6.2), as well as responses of spiritual coping (5.5.6.3), traditional practices (5.5.6.4), and talking to others (5.5.6.5).

5.5.6.1 “I don’t see any hope in my life” – emotional difficulties

Some participants (HW1, HW10) raised lack of knowledge about perinatal emotional difficulties as a barrier to women discussing their symptoms:

They might not consider the problem itself as a problem... She might not think that what is happening to her... is affecting her mentally. She might not know how to talk about it. The mothers... might think that their problem will not be solved even if they talk... about it.

HW1, HEW, 10-14 years’ experience.

However, several women and some health workers (HW1, HW3, HW8, HW10) described perinatal emotional difficulties. Women reported anxiety (P7, P10, P11, P13, P14, P15, P16), stress (P14, P16), and depression (P14), which they attributed to exhaustion (P10), relationship conflict (P11, P15), unwanted pregnancies (P14, P16), or no reason (P13). They described tearfulness (P7, P14), reduced motivation (P16), poor or excessive sleep and nightmares (P7, P14, P16), feeling numb (P16), irritability (P16), poor concentration (P14), and rumination on past trauma (P14):

I have nightmares... that crazy people chase me... I dreamed that I died and my mother cried in a tent in front of [mourners]. Then I dreamed of them carrying me to a pit and burying me.

P7, 30-34 years old.

I don’t see any hope... I don’t want to meet my friends... I feel sad when I see them... I feel anxious because I don’t share my problems... I talk to myself when I am alone... I think about what I lost in life... I lose my focus.

P14, 16-19 years old.

I am always irritable... I always feel anxious... I feel like I am possessed by the spirit...I have tried to abort the baby several times.

P16, 20-24 years old.

Women’s vulnerability to substance use disorder was mentioned only once, although it was commonly described among men:

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Most of the stress and anxiety on pregnant mothers is related to economic issue... We collect donations for them. However, the help is not sustainable... they stop the medication and go back to drinking.

HW11, HEW, 10-14 years' experience.

Suicidal ideation was mentioned infrequently. Two women described suicidal thoughts associated with shame or despair about current (P11) or past (P14) IPV:

I think that life is not worth living and want to end my life when I face these kinds of problems.

P11, 25-29 years old.

I sometimes want to strangle myself to death because I think that life is not worth living... When I think that I am left behind [by my friends]... I have this idea of hurting myself... I was hoping to die [before] because I didn't know anyone who could help me... I didn't try [to hurt myself] after I came here.

P14, 16-19 years old.

One health worker (HW4) expressed the view that “you can't communicate” with women experiencing emotional difficulties. This health worker and others (HW1, HW2, HW4, HW5, HW9) described benefitting from mental health training and referral pathways:

Participant: We identified a few pregnant women who have depression and referred them to the... outpatient department... they got counselling [or] started medication... there is an mhGAP [WHO mental health gap action programme] focal person...

Interviewer: Did you get [mental health] training?

Participant: Yes... Sometimes [when] they... reach to the level of psychosis... the training helped me a lot. I have better knowledge about depression [now].

HW5, Midwife, 0-4 years' experience.

5.5.6.2 “I go to the health facility every day” – physical symptoms

Participants associated perinatal emotional difficulties with adverse obstetric outcomes, such as intrauterine growth restriction (P7, P8, HW5), delivery complications (P8, HW5, HW9), and stillbirth (P7, HW8). One of the most experienced health worker participants described how acute distress and emotional difficulties can influence childbirth:

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If a mother is psychologically disturbed... in labour, she brings something with her... If there was something [wrong, labour will] immediately stop... there is even this thing of holding back labour... We have to be cautious... we have seen complications here.

HW9, Midwife, 10-14 years' experience.

Participants did not describe non-obstetric impacts of perinatal emotional difficulties. However, persistent perinatal physical symptoms without identified causes were common (P5, P7, P10, P13, P16). One health worker attributed these symptoms to stress and anxiety, managing them with reassurance after ruling out physical pathology (HW1). Another described a woman with “a tendency to feel dizzy and fall down, losing her consciousness... sitting down on wherever she finds a space, sleeping” only when pregnant, which was attributed to “getting stressed out” (HW3). Some women were preoccupied with physical symptoms but had limited understanding of their underlying mechanisms:

I feel tired and there is a swelling around here, where my heart is... My neighbours... said that the umbilical cord will wrap around the baby's neck and choke it to death if I sleep like this.

P7, 30-34 years old.

I feel exhausted and sleepy when it is sunny. I was not like that before I became pregnant. They tell me it is common... I don't know anything about that... I feel ashamed to talk about this issue.

P10, 25-29 years old.

Some women managed emotional difficulties by regularly buying over-the-counter medication or attending the health centre and private clinics:

I come here very often... I was normal before I became pregnant. I don't feel healthy now... I go to the health facility every day. I also visit private clinics.

P16, 20-24 years old.

They have told me not to take medications other than paracetamol. But... my body is adapted to it... There is this medication whose tablets are bigger... I buy that from the village shops... The illness will not leave me if I don't I take four [paracetamol] at once and sleep... It burns me.

P13, 26 years old.

Participants did not describe links between persistent perinatal physical symptoms and women's experiences of IPV.

5.5.6.3 “I pour the holy water over my head” – spiritual coping

Several participants (P2, P5, P6, P13, HW1, HW2) described coping with emotional and bodily distress by seeking religious or spiritual remedies:

[A woman] may also think that she is not sick. So instead of going and sharing her problem, she may think to visit a church for a holy water and things like that, to solve her problem.

HW1, HEW, 10-14 years' experience.

[Some women] believe they can solve their problems through prayers... As a religious person, I believe that praying could help [her] cope with her stress.

HW2, HEW, 10-14 years' experience.

Religious coping included combining biomedical treatment (such as medication) with spiritual remedies, such as holy water:

I go to the church and drink holy water when I feel ill. I pour the holy water over my head and I sprinkle the house with it, and I take the tablets until the headache leaves me... Though it is not very helpful, I use holy water to treat my anxiety.

P13, 25-29 years old.

5.5.6.4 “She put the foetus back in place” – traditional practices

Participants reported that some pregnant women access traditional birth attendants (HW2), practitioners (P16, HW2), and remedies (P7, P13, HW2) for persistent perinatal physical symptoms:

I was sick earlier in this pregnancy... People... thought that I was dead. I had a piercing pain on my side and a burning sensation... people told me to... boil wheat and garden peas and make coffee... when the day is sunny... This is a strange thing for me. My family doesn't do this... I told them that I don't want to depend on Satan to solve my problem.

P7, 30-34 years old.

People tell me that it is the herbal medicine that is causing me the problem... I sit up the whole night because I have a piercing pain when I lie down in bed. It pierces me all over my body... My headache is so serious.

P13, 25-29 years old.

One health worker highlighted a lack of trust in biomedical approaches, such as vaccines (HW2). A woman described how her husband and his family organised a traditional practitioner to assess obstetric complications of physical IPV:

He beat me. I was sick for many days... because the foetus changed its position. As the health centre is far away... it is wogeshas¹⁹ who fix these kinds of problems for us... They [my husband and his family] brought the woman to the house and she put the foetus back in place. He never touched me after that.

P16, 20-24 years old.

5.5.6.5 “I tell my problems to this neighbour of mine” – talking to others

Health workers (HW2, HW6) suggested that women's development groups and monthly 'conferences' for disseminating health information were opportunities for women to support each other, although pregnant women did not raise this point:

There is a conference: they can also learn from each other there... [some] can talk and share their experiences... those who are shy can listen and learn... they talk to each other with a sisterly manner and others can see and join... when they meet every month.

HW6, Midwife, 0-4 years' experience.

Some participants described talking to friends or neighbours:

I tell my problems to this neighbour of mine who is close to me. This woman helps me solve my problems. She advises me about dealing with my problems peacefully.

P8, 26 years old.

¹⁹ Traditional practitioners (Kassaye, Amberbir, Getachew, & Mussema, 2006).

If people who live in my neighbourhood ask me about my feelings and my problems, I will tell them... [others] could... develop negative attitudes towards me. I fear that they will gossip about my pregnancy if I share my secrets with them.

P9, 30-34 years old.

5.5.7 “Psychological support is like a medication” – psychological intervention

Participants supported the suggestion of a brief psychological intervention for pregnant women experiencing IPV: the final theme. Sub-themes comprised the therapeutic relationship (5.5.7.1), intervention content (5.5.7.2), therapists (5.5.7.3), organisation (5.5.7.4), outcomes (5.5.7.5), access (5.5.7.6), practicalities (5.5.7.7), and raising awareness (5.5.7.8).

5.5.7.1 “They will think... that there is a future” – the therapeutic relationship

To gauge the acceptability of intervention, the topic guide asked about additional sessions during ANC, for women experiencing perinatal emotional difficulties and IPV. Health workers (HW1, HW3, HW4, HW5, HW6, HW8, HW9, HW10, HW12) and some women (P8, P10) replied that sharing thoughts and problems reduces stressors, distress, and provides symptomatic relief. One participant (HW6) also proposed health benefits for women's partners and children. Unburdening and being listened to were often characterised as intrinsically therapeutic: “like a medication” (HW9):

A woman whose husband is abusive will suffer a lot if she doesn't share her problems with other people. She will be relieved of her stress... like getting treatment.

P10, 25-29 years old.

If you give them time... they say they feel better... when you teach them something, they will think... that there is a future, they would think to reach there, and that there is someone who can help them.

HW9, Midwife, 10-14 years' experience.

When somebody feels depressed, they will exaggerate small things as a big issue. When you counsel her... she will understand that it is not her problem only... it could happen to any other person too... She will show improvement... when you give attention and listen... even without taking any medication.

HW5, Midwife, 0-4 years' experience.

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Participants singled out communication skills as crucial for brief psychological interventions. Health workers prioritised behaving welcomingly (HW3, HW12), listening attentively (HW3, HW8, HW9, HW12), allowing women to speak (HW3) and share information at their own pace (HW5, HW8), showing empathy (HW8, HW10) and respect (HW10), developing rapport (HW10, HW12), responding calmly (HW9, HW12), normalising difficulties (HW5, HW8, HW12), and building up to more sensitive questions (HW2, HW6). One midwife referenced learning from mhGAP training (HW5) and another, an undergraduate psychiatry course (HW9):

You have to tell them that this will happen in anyone's life and people face many challenges... initially we will inform why we are asking and... explain mental health problems [are] like other health conditions [such] as headache.

HW5, Midwife, 0-4 years' experience.

Health workers (HW1, HW2, HW3, HW5, HW8, HW9, HW11) recognised the need to build women's trust over time, "like my mother or sister" (HW8, HW9), to facilitate constructive and therapeutic communication:

We should give time for that mother... if you listen to me telling you about my problems as if it's your own... the number one thing when you're working on health: you must keep secrets... approaching her like a friend, a sister, a mother.

HW9, Midwife, 10-14 years' experience.

Some women affirmed that they would be comfortable sharing their feelings and experiences with health workers, provided that they were asked about them in an empathetic (P3, P7, P8), calm (P14) manner, that trust (P9) and rapport (P15) had been built, and they were offered support (P8) in a private setting (P14). One participant highlighted how intimidated women might feel:

These women are illiterate, and they could be scared to talk to older or educated people... [she] could feel awkward if you don't smile and try to understand her feelings.

P14, 16-19 years old.

Some pregnant women (P3, P16) and one health worker (HW11) described how previous ANC experiences influence women's readiness to trust staff:

I like these two [health workers] because they ask me if I have a shortage of food or I do too much work, and they advise me to take care of myself. I tell them my problems, and I stop what they tell me to stop doing... I usually come here and face hassle. I lash out at the other [staff] because they make me wait... it would be better if they could treat us with love and give us the service quickly so that we can go back to our house and do our work.

P16, 20-24 years old.

5.5.7.2 “Problems can be solved, step by step” – content

Women and health worker participants affirmed that integrating an intervention for the emotional difficulties of women experiencing IPV into ANC was acceptable:

We can tell a mother to relax and be free to tell us everything. We can incorporate that together with the antenatal care follow up.

HW1, HEW, 10-14 years' experience.

Participants regularly characterised suitable psychological interventions in terms of problem-solving (P2, P3, P16, HW1, HW5, HW6, HW9, HW12). The notion that a woman's problems cannot be solved was considered a barrier to engagement with intervention sessions (P2, P8, HW5):

When these mothers encounter psychological problems, if they can go and discuss with the health professionals, it would get easier for them... we can have them understand that there is a way and a counselling to solve their problem.

HW1, HEW, 10-14 years' experience.

I might consider [sessions] as simple talking and going home... The change comes only when the people talk about the problem and take the solutions. Otherwise if they hold it, everything might remain the same.

P2, 30-34 years old.

Several participants linked the need for support with problem solving to some women's limited education (P3, P10, HW9):

Illiterate woman will keep her problem to herself... Education is a ladder that will take you from many things... Knowing how to solve problems first, she will be able to solve her problems on her own.

P3, 35-39 years old.

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Because she didn't get formal education... [she] could be taught... how... to discuss and find a solution with her husband... that problems can be solved, step by step.

HW9, Midwife, 10-14 years' experience.

Women (P2) and health worker (HW7, HW12) participants proposed that brief psychological interventions for women experiencing IPV could include skills for promoting dialogue between partners:

They could start talking with their husband. They might start to communicate and get into an agreement on things. It is very uncommon in this society for a wife to sit with husband and discuss things... I think it would solve many problems.

HW12, Midwife, 0-4 years' experience.

Some mothers think they can't say no [to sex during pregnancy]. If we teach them, I think that they will go home and discuss the issue with their husbands.

HW7, Midwife, 0-4 years' experience.

Participants (P14, P16, HW9) suggested that women could be supported to manage their safety in abusive relationships:

She could leave the house before things get worse... Getting advice... would save one's life.

P14, 16-19 years old.

I will go and get the therapy because I believe that your advice will help me to protect myself from danger.

P16, 20-24 years old.

However, some suggestions implied that psychological interventions should change women's behaviour to accommodate abusive relationship dynamics:

[A health worker] can tell her ways she can correct her behaviour and also that she shouldn't reply to him right at the moment... when he's starting a fight she will say, '...I should wait for him to cool off.'

P1, 20-24 years old.

Other suggestions had the potential to dismiss women's suffering:

[We should tell her] how they should agree and live as one, how she has to pass today, and that tomorrow is another day.

HW9, Midwife, 10-14 years' experience.

Other participants suggested that abusive partners' behaviour can be changed by women:

*First, the skill she gets... will help her modify her husband's abusive behaviour.
... she will be peaceful with her husband if she applies what she learned.*

HW10, HEW, 10-14 years' experience.

5.5.7.3 "I will think about her when I am sleeping" – therapists

Health worker participants expressed clear views about which staff should deliver brief psychological intervention sessions in ANC. They emphasised the need for training, supervision, and onward referral pathways (HW1, HW5, HW12):

I have never obtained any training regarding this topic... [training] will help us to do more counselling... there should be professionals who have competence.

HW12, Midwife, 0-4 years' experience.

Some reported receiving no training on mental health (HW2, HW7, HW8). A health worker who had received mhGAP training supported its benefits:

I [did not know about] depression before. I perceived that she is bored... or she did not want to receive the medical services when I saw her unhappy. Now I know there is a problem called depression that can occur [during] pregnancy... and even reaches to the level of psychosis... the training helped me a lot.

HW5, Midwife, 0-4 years' experience.

Some health workers (HW5, HW10, HW11, HW12) anticipated deriving personal and professional satisfaction from mental health training:

After she tells me her problems and discusses them, there [will be] a satisfaction for myself... It would help me know what problems mothers are facing out there. It would help me understand how most mothers are living.

HW12, Midwife, 0-4 years' experience.

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I will be stressed if I didn't do what I was supposed to do [provide mental health support], I will think about her when I am sleeping and working.

HW11, HEW, 10-14 years' experience.

Some health workers (HW1, HW2, HW3, HW5) recommended a stepped care model, whereby women with more severe or intractable symptoms would be referred from primary care to a mental health "focal person":

If they get the chance and seek help from us... we [can] provide them with psychological support and even if that is not enough, we will send them to the higher health institutions... if it is beyond our capacity.

HW1, HEW, 10-14 years' experience.

Some participants perceived benefits of female clinicians' shared experience with women (P11, HW9, HW12), but therapists' communication skills were often considered more important than their gender (P16, HW12):

The profession itself has taught us a lot; your age is also a learning experience... Being a mother too, it teaches you many things... After I gave birth, I gave greater value for motherhood, you understand the stress after you gave birth.

HW9, Midwife, 10-14 years' experience.

Some participants (P9, HW10), including two midwives (HW7, HW8), thought that HEWs were best-suited to delivering interventions. Reasons included regularly visiting women's homes (HW7, HW8) and living in the same community (P9, HW10):

Those who live close to you understand your problems and they will be available to help you when you face problems... It would be difficult to confide in a person who doesn't live close to you.

P9, 30-34 years old.

5.5.7.4 "They will not talk openly if there are other people" – organisation

Health workers proposed that intervention sessions should be aligned to the four sessions of ANC follow-up that women typically receive every 15 days (HW1, HW3), over a four to eight week period (HW2). Offering five or six sessions was also suggested (HW3). Several participants considered health centres their preferred intervention setting.

Satellite 'health posts' within communities offered insufficient space (HW1), while homes afforded insufficient privacy (P4, P10, P11, HW1, HW2, HW11). Some participants preferred home visits, due to women's childcare and other commitments (P8, P13, HW4, HW6, HW8). Others (HW5, HW7, HW12) recognised advantages and disadvantages of both settings:

If they came to the health centre... the health professionals... can use references and they can also consult other health professionals when they got something difficult. For the mothers, their confidentiality will be more secured... [but] if she has feelings of stress or if she is depressed, she might not come to the health centre.

HW5, Midwife, 0-4 years' experience.

Some health workers suggested group sessions for efficiency (HW10) and mutual support (HW12) reasons, while others highlighted the benefits of individual sessions for efficacy (HW3) and privacy (HW11) reasons:

It is better if they come here... they will not talk openly if there are other people. Most of the time the mothers tell us their secret when they are alone with us.

HW11, HEW, 10-14 years' experience.

5.5.7.5 "It could help her have a stable and better life" – outcomes

Participants' responses to questions about what should improve following intervention were often vague, or not specific to women's emotional difficulties (P7, P13). A pregnant woman with personal experience of emotional difficulties associated with IPV identified more specific outcomes:

She will not show improvements if she is hopeless... it would help me raise my baby properly... it could help her have a stable and better life if she learns from her past... if I had someone to share my problem, I wouldn't have suffered this much. I just prayed to God to help me because I was alone.

P14, 16-19 years old.

Participants suggested positive obstetric (HW2), neonatal (P1, HW2), and child (P3) outcomes of intervention, and non-specific improvements, such as "they can make themselves stronger" (P2). Some health workers raised more specific perinatal emotional outcomes, such as relief from stress or anxiety (HW3, HW4, HW5, HW10):

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Your stressors would decrease... [Without support] she won't separate from her problems... by sharing her thoughts... she will get relief.

HW3, HEW, 10-14 years' experience.

Some pregnant women (P2, P3, P9, P16) raised cognitive benefits of intervention, such as thinking difficulties through and planning for the future:

They could start thinking about changing their lives after they get the therapy... I would use the advice I get in the therapy to improve my life situation.

P16, 20-24 years old.

Some women (P14) and health workers (HW11) suggested that sessions would enable women to disclose IPV, leading their emotional difficulties to improve following clinical mediation. These comments suggested limited recognition of factors perpetuating IPV:

If the man... applied my advice... it will benefit her in everything. Because if she has peace in her marriage, her mind will also be at peace... they will talk about how they should raise their kids and improve their life. Their children will not be scared when they fight and her mind wouldn't also be hurt.

HW11, HEW, 10-14 years' experience.

5.5.7.6 "People need time to understand it" – access

Participants described barriers to women accessing intervention sessions integrated into ANC. These included lack of knowledge of the benefits (P2, P3, P4, P13, P15, HW2, HW4), men preventing women from attending (HW2, HW6, HW8, HW9, HW12), and expecting that they would need to pay (P3):

If the husband is not supportive, he will not let his wife attend the [sessions]... If they had a fight, the husbands fear that their wives will leave them... if they let them leave the house.

HW8, Midwife, 0-4 years' experience.

Lack of available transport (P13, P14, HW2, HW6, HW8, HW9), transport costs (P2, P6, P11, P14, HW9), and distance between women's homes and health services (HW2, HW6, HW7, HW8, HW9) were key barriers to delivering sessions. However, some participants

considered transport an “excuse” (P2), and that attitudinal factors impacted attendance more (P2, P4, P13, HW2):

They don't see [sessions] as something very important... They might consider transportation as an excuse, but in my opinion this shouldn't be a reason at all. If I want to come, I can borrow money for transportation and come. The main thing is my interest, that I believe this is going to help me.

P2, 30-34 years old.

Participants highlighted competing demands on women's time, such as farming (P10, P14, HW8, HW9, HW12), household chores (P3, P10, P2, P4, P15), funerals (P1, P4, HW10), and childcare (P4, P6, P13, HW6, HW9). They anticipated that once women understood sessions' benefits, attendance would improve (P1, P2, HW8):

They might be difficult first, until they come out. But once they start it... they would say... 'if I miss out today, I might lose something tomorrow.' And if [she needs to attend a] funeral in the morning, she would reschedule [the session].

P1, 20-24 years old.

She might complain, 'they are just calling to nag us, not give a solution.' [She] might accept the education if she saw the result... in her life, through time. So... people need time to understand it, it is not easy for them to grasp it all at once.

P2, 30-34 years old.

5.5.7.7 “We can take time and talk to them” – practicalities

Some participants raised workloads as a barrier to intervention. Community HEWs stated that delivering sessions would “affect our productivity at work” (HW2, HW10), but also that health centre staff “don't have time. Now there is too much queue” (HW4). One HEW explained how their cadre was often allocated multiple health education tasks, leading to de-prioritisation:

If there is overlapped work, we tend to postpone some programmes. It is our job, but sometimes when things overlap, we tend to delay those which can wait... This is the challenge... There might be a shortage of staff there.

HW11, HEW, 10-14 years' experience.

Health centre midwives reported that provided they adjusted their schedules (HW6) or planned ahead (HW8, HW9), they could deliver sessions (HW5, HW7, HW8). One considered home visits impractical due to the distance they would need to cover (HW7). Midwives emphasised that obstetric emergencies and busy ANC clinics would be prioritised (HW5, HW8, HW9, HW12), but that certain mental health presentations should also be prioritised (HW5, HW9):

There could be many pregnant mothers who need medical follow-up and there could be emergency cases... But we can take time and talk to them when there aren't many patients.

HW8, Midwife, 0-4 years' experience.

Regarding the workload, there is no manpower here... but if I sense something that makes me stop and see, like if she is emotional... I would tell her to call me and talk to me, you might have to appoint her tomorrow or after a week, and if it's beyond your capacity... you would consult others.

HW9, Midwife, 10-14 years' experience.

5.5.7.8 "It is important to keep educating" – raising awareness

In addition to the proposed brief psychological intervention, women (P2) and health worker (HW7, HW9) participants recommended sensitising the community through widespread awareness raising about IPV, not just targeted at women known to be experiencing it:

Sometimes no-one knows about my house issue, but the problems might happen. So, the professional needs to teach [women] what are the ways of passing those problems. So, it is important to keep educating because a woman might use it when she is in need of help.

P2, 30-34 years old.

Those who we teach are those who have reached here, but if you go to the community you would find a lot of problems in their home... the awareness [should be] raised... in the community and we can repeat it when they come to us... I don't think there would be much change if we focus only on those mothers [reporting IPV]. In my opinion, this can knock every door; those mothers might have spoken but there might be those who kept silent.

HW9, Midwife, 10-14 years' experience.

5.6 Discussion

5.6.1 Key findings

Study Two showed that abusive treatment, emotional and bodily distress were widespread in this context, and that women and health workers were familiar with the relationship between them. Contrary to expectations of sensitivity, participants elaborated extensively on IPV: the primary form of abusive treatment that women experienced. Emotional and bodily distress were commonly discussed, but in more restricted terms than IPV. Key contextual factors were severe deprivation and high cultural expectations, which were often impossible to meet under the circumstances. Participants recommended brief intervention within ANC to combat women's experiences of powerlessness, and provided a range of suggestions for implementation, to optimise feasibility.

5.6.2 What are women's experiences of emotional difficulties and IPV during the perinatal period in this context?

Study Two showed that all forms of IPV were pervasive in this setting, and reinforced by factors at the conflict arena, relationship, male partner, female partner, community, and macrosocial levels of the revised ecological framework (Heise, 2011). Women and health workers were familiar with the ways that IPV and other forms of abusive treatment led to emotional and bodily distress, including emotional difficulties and physical symptoms. Abusive treatment and its reinforcement by patriarchal norms left women feeling powerless, exacerbated by deprivation, pressures and expectations.

5.6.2.1 Perinatal IPV

In Study Two, women and health workers described and contextualised physical, sexual, and psychological IPV, coercive control, and the risk of femicide, alongside other forms of abusive treatment. At the conflict arena level (Heise, 2011), participants reported that money, conflicts with in-laws, and male alcohol use were situational triggers for IPV. Participants did not explicitly link 'patriarchal triggers' (such as assertions of female autonomy) to IPV. However, several women described avoiding triggers which might emasculate men, and actions which could have been experienced as challenges to male

authority, such as independently selling produce at market, collectively saving, and expressing views about household finances.

At the relationship level (Heise, 2011), women described aspects of marital interaction, such as non-egalitarian decision making and poor communication, leading to IPV. Several women described limited decision-making about entering into the relationship or marriage itself; one had been abducted and forced into a relationship. This phenomenon, known as *telefa*, is associated with an increased risk of IPV (Getahun, 2001). Some women described fluctuant IPV (often associated with men's alcohol intoxication), interspersed with periods of positive interaction. This process of intermittent reinforcement within power-imbalanced relationships has been proposed to foster 'traumatic bonding' (Dutton & Painter, 1981). The authors proposed that traumatic bonding predisposes people experiencing IPV to return to abusive partners after leaving, because the economic and legal difficulties of separation are compounded by deprivation of the abusive attachment object.

At the male partner level, participants minimised men's responsibility for their actions, by reference to intoxication and the social norm of consuming alcohol. Alcohol use, peer influence, low education and gender hierarchical attitudes were the only male factors mentioned by participants. Childhood factors included in the revised ecological model (Heise, 2011), such as witnessing parental IPV, were not mentioned, despite evidence of their role in Ethiopia (Philpart, Goshu, Gelaye, Williams, & Berhane, 2009). Reviews of the literature suggest that responsibility for IPV is often evaded and dismissed through attribution. For example, perpetrators may justify abuse as an unavoidable response to provocation or intoxication, or to further cultural norms, such as so-called 'honour-based' violence (Wallach & Sela, 2008). Such situational (rather than dispositional) attributions of violence prevent men from considering their need to take responsibility and preventative action. Survivors may then internalise their attributions of IPV towards themselves, or externalise attributions to situations experienced by their abusive partner (Overholser & Moll, 1990).

At the female partner level (Heise, 2011), women participants were comparatively young (median age: 26.5 years), with relatively limited education (75% had no education or elementary level, only), and low social support from friends, neighbours, and family

members. Women linked financial dependence on their partners with IPV, in keeping with the findings of other qualitative studies conducted in sub-Saharan Africa (Balogun & John-Akinola, 2015; Sedziafa et al., 2018). As with the male partner level, participants did not discuss childhood risk factors for experiencing IPV, such as witnessing parental IPV, despite evidence for these from Ethiopia (Arnold, Gelaye, Goshu, Berhane, & Williams, 2008).

A range of norms, lack of sanctions, and neighbourhood factors were identified at the community level (Heise, 2011). In terms of norms, IPV was often justified through external attribution (Overholser & Moll, 1990), as an appropriate male response to perceived female provocation. This is consistent with evidence of victim blaming in diverse Ethiopian contexts (Kaufman et al., 2019; Muche et al., 2017). Studies from Ethiopia and other sub-Saharan African countries also support Study Two's findings that IPV was reinforced by a lack of community sanctions (Odero et al., 2014; Okeke-Ihejirika et al., 2019; Yigzaw et al., 2010), unequal gender norms (Balogun & John-Akinola, 2015; Hanlon, Whitley, et al., 2009; Ilika, 2005; Molenaar et al., 2020; Murray et al., 2021; Okeke-Ihejirika et al., 2019; Yigzaw et al., 2010), and treatment of women as property (Balogun & John-Akinola, 2015; Okeke-Ihejirika et al., 2019; Sedziafa et al., 2018).

Community norms meant that women were expected to adjust their behaviour to accommodate IPV, consistent with findings from Ethiopia (Muche et al., 2017) and other sub-Saharan African countries (Balogun & John-Akinola, 2015; Gillum et al., 2018; Murray et al., 2021; Okeke-Ihejirika et al., 2019; Sedziafa et al., 2018). Unlike some focus group studies including small numbers of survivors (Yigzaw et al., 2010), no participants in Study Two suggested that IPV was an expression of love (Muche et al., 2017), quoted scriptural passages justifying abuse (Abeya et al., 2012; Gashaw et al., 2019), or questioned the concept of marital rape (Yigzaw et al., 2010). This finding may have resulted from the one-to-one interview format, and efforts made by the female Ethiopian interviewers to build rapport, and safeguard participants' privacy. However, Study Two also did not conduct interviews with religious or community leaders, who may have been most likely to express these views.

The lack of meaningful community sanctions for IPV perpetration was clear during interviews, with women prevented from pursuing legal action by prohibitive costs.

Another Ethiopian study found that one community response to IPV was to exclude the perpetrator from the *idir* social support system, provided that the woman was proven to have fulfilled all community and partner-dictated expectations, such as bearing children (Abeya et al., 2012). However, this response would negatively impact the financial security of the entire family, including the survivor, and was not raised in Study Two. Participants also did not report institutional corruption obstructing the community response to IPV, as raised in other sub-Saharan African studies (Gillum et al., 2018; Odero et al., 2014; Sedziafa et al., 2018). However, staff delivering services with the potential to support women disregarded signs of harm, and women experienced formal sources of support as unhelpful. These findings echoed the literature from other Ethiopian settings (Abeya et al., 2012; Gashaw et al., 2019; Gashaw et al., 2020), where patriarchal norms obstructed women from contributing to arbitration panels and prevented women and child affairs officers from fulfilling their roles.

In terms of neighbourhood factors, poverty and low social capital were widespread. Family involvement and disrespectful ANC mirrored abusive intimate relationship dynamics, compounded by ineffectual responses, and coerced reconciliation by community leaders, as found in other studies (Abeya et al., 2012; Gashaw et al., 2019; Gashaw et al., 2020).

At the macrosocial level (Heise, 2011), participants described pervasive gender inequality, consistent with Ethiopia's low gender inequality index ranking (UNDP, 2021b). Low economic development is a further risk factor at the macrosocial level (Heise, 2011); Ethiopia also ranks low on the human development index (UNDP, 2020a). Study Two showed that pervasive deprivation in the form of poverty, limited education, and lack of support exacerbated abusive treatment, patriarchal norms, women's sense of powerlessness, and their emotional and bodily distress. This was in keeping with studies from Ethiopia (Hanlon, Whitley, et al., 2009; Molenaar et al., 2020) and other sub-Saharan African countries (Dako-Gyeke, Aikins, Aryeetey, Mccough, & Adongo, 2013; DUBY et al., 2021; Gillum et al., 2018; Laisser, Nyström, Lugina, & Emmelin, 2011; Mootz et al., 2019; Murray et al., 2021; Mwape, McGuinness, & Dixey, 2012; Osok, Kigamwa, Huang, Grote, & Kumar, 2018; Sedziafa et al., 2018; Stewart, Umar, Gleadow-Ware, Creed, & Bristow, 2015) supporting a relationship between economic and social deprivation, IPV, and emotional difficulties.

Consistent with the revised ecological model, participants mentioned divorce, but did not perceive it as a meaningful option. The difficulty of separation was compounded by community action to return women to abusive partners, as reported by other Ethiopian (Gashaw et al., 2019; Yigzaw et al., 2010) and sub-Saharan African studies (Balogun & John-Akinola, 2015; Ilika, 2005; Laisser et al., 2011; Odero et al., 2014; Okeke-Ihejirika et al., 2019; Sedziafa et al., 2018). These findings support evidence that more collectivist societies may respond differently to IPV than individualistic societies, conserving community cohesion at the expense of the individual (Haj-Yahia & Sadan, 2008; Heise, 2011).

5.6.2.2 Perinatal emotional difficulties

As reported by a study of ANC staff in a different Ethiopian setting (Gashaw et al., 2020), Study Two found that the impact of abusive treatment on women's mental well-being was identified infrequently. Emotional difficulties were often characterised as mild or transient, although their relationship with IPV is established in this setting (Bitew et al., 2020; Hanlon, Whitley, et al., 2009), other regions of Ethiopia (Yigzaw et al., 2010), and other sub-Saharan African countries (Balogun & John-Akinola, 2015; Gillum et al., 2018; Odero et al., 2014). Health workers primarily expressed concerns about the impact of emotional and bodily distress on the foetus and pregnancy. This was in keeping with Ethiopian evidence that ANC staff considered IPV-related difficulties beyond their remit (Gashaw et al., 2020), required training on IPV's health impacts, and referral pathways to specialist support.

Women's experiences of emotional difficulties and distress associated with IPV were less extensively elaborated than their experiences of IPV itself. This supports evidence that both experiencing and discussing emotions are often avoided in Ethiopian culture. For example, one ethnographic study found that the relatives of terminally ill people in urban Addis Ababa withheld information about prognosis because of "not wanting to upset" them (p. 21; Ayers, 2015). A study which interviewed 100 key informants in rural Ethiopia found that participants were familiar with mental disorders, such as schizophrenia, when manifesting with overtly disruptive behaviour (Alem, Jacobsson, Araya, Kebede, & Kullgren, 1999). However, informants were much less familiar with depression and subjective descriptions of emotional states, and favoured traditional

treatments over biomedical care. A study conducting semi-structured interviews with 106 Ethiopian refugees and asylum seekers in the UK (Papadopoulos, Lees, Lay, & Gebrehiwot, 2004) found that they drew little distinction between physical health, mental health, and prosperity. Participants considered “happiness” (p. 15) to be the most important requirement for health, with problems with housing, finances or isolation perceived to be as likely to cause ill-health as pathogens or unhealthy behaviours.

Study Two showed that in this rural Ethiopian context, high community standards combined with deprivation meant that women frequently felt pressurised or ashamed of disappointing their own and others' expectations. Perceived failure to fulfil cultural obligations and comply with social norms led women to feel judged by their community, compounding their sense of powerlessness, emotional and bodily distress. This was consistent with evidence that inability to follow a culturally mandated pattern of postnatal confinement is associated with postnatal distress in this setting (Hanlon, Whitley, et al., 2009), and of the role of shame in women's experiences of IPV in sub-Saharan Africa (Gillum et al., 2018; Laisser et al., 2011; Odero et al., 2014; Okeke-Ihejirika et al., 2019). Focus groups with 19 female Ethiopian former Middle East domestic workers, two thirds of whom developed a severe mental illness, identified disappointed expectations as a key theme (Anbesse, Hanlon, Alem, Packer, & Whitley, 2009). Participants described feeling trapped by physical confinement to their workplace, lack of control, and inability to leave, due to high aspirations and obligation to support family members.

Study Two also identified feelings of entrapment (wanting but unable to leave abusive partners), silencing (wanting, but unable to disclose IPV), and hopelessness (resignation to the worst possible outcome) among pregnant women. UK studies of depression and stressful life events have identified stronger temporal associations between humiliation (feeling devalued) or entrapment (severe, continuing difficulties, expected to persist or worsen) and depression, than other event types (such as loss alone; Brown, Harris, & Hepworth, 1995). In particular, lack of control over such situations can provoke hopeless, helpless, and powerless cognitions, which are central to depression (Brown & Harris, 1978). In Ethiopia, studies have examined the psychological effects of extreme poverty and food insecurity (Hanlon, Medhin, Kortmann, & van Uffelen, 2013). The authors found associations with shame, humiliation, defeat or entrapment, a fatalistic sense of helplessness, and low self-efficacy, in relation to an external locus of control. Hanlon et

al. (2013) hypothesised that these processes may mediate psychological distress. In Study Two, women and health workers often expressed powerlessness to influence IPV, amid pervasive reinforcement by patriarchal norms.

Several participants with personal experience of perinatal emotional difficulties or suicidal ideation associated them with IPV, consistent with studies from Ethiopia (Bitew et al., 2020; Hanlon, Whitley, et al., 2009) and other sub-Saharan African countries (Duby et al., 2021; Osok et al., 2018). Persistent physical symptoms were more commonly described than emotional difficulties, as found by other studies (Bitew et al., 2020). While women engaged in spiritual coping and traditional practices more often than talking to others (Bitew et al., 2020; Dako-Gyeke et al., 2013; Hanlon, Whitley, et al., 2009; Nakku et al., 2016; Rosario, Premji, Nyanza, Bouchal, & Este, 2017), they did not explain emotional difficulties in terms of spiritual attacks, as in other local (Hanlon, Whitley, et al., 2009) and sub-Saharan African (Dako-Gyeke et al., 2013; Nakku et al., 2016; Stewart et al., 2015) research.

Despite linking emotional distress to experiencing IPV, the pattern of intermittent reinforcement by partners and the community suggested traumatic bonding (Dutton & Painter, 1981), compounding women's powerlessness. Furthermore, community expectations that women should accommodate IPV placed women at risk of self-blame, low self-esteem, and depression, exacerbating powerlessness further (Dutton & Painter, 1981). Victim blaming, by attributing responsibility for IPV to women's perceived deficiencies, may also induce internal attribution and self-blame (Overholser & Moll, 1990). Internal attribution to unstable factors (such as having 'provoked' IPV) is associated with self-blame, tolerance of abuse, and reduced likelihood of leaving, while internal attribution to stable factors (such as one's character) is associated with low self-esteem, hopelessness and helplessness (Overholser & Moll, 1990), increasing women's risk of depression. The links made in Study Two between deprivation, patriarchal norms, abusive treatment, and emotional difficulties, and the findings of cyclical reinforcement were also consistent with the findings of the global 'what works' programme (Gibbs et al., 2020). Notably, however, Study Two participants did not mention the impact of armed conflict, despite intermittent regional unrest. Reasons may have included the sense that national and regional armed conflicts were not of direct personal relevance to

women's lives, the chronic nature of episodic unrest in this context or, perhaps, failure to inquire about conflict outside the home in the topic guide.

5.6.3 How should a brief psychological intervention for the emotional difficulties of women experiencing IPV be adapted for Ethiopian ANC?

Powerlessness emerged as a key target for brief psychological intervention, with women and health workers emphasising the need to give women hope, and the ability to solve their problems. Such interventions would be expected to work by reducing feelings of entrapment and shame, associated with depression and anxiety disorders (Brown & Harris, 1978; Hanlon et al., 2013). Lack of support and isolation were common, and participants emphasised the therapeutic benefits of unburdening oneself and being listened to. Any intervention should therefore afford women the opportunity to describe and address their problems, which may relate to deprivation, pressures and expectations, abusive treatment, emotional and bodily distress.

Without prompting, participants recommended that interventions should adopt a problem-solving focus. This supported local findings that emotional difficulties were frequently attributed to "thinking too much" (Kaiser et al., 2015) about concrete problems, such as pregnancy, poverty, marital strife, physical ill-health (Bitew et al., 2020), and the general stresses of life (Tekola et al., 2020). Furthermore, a study of 385 women with postpartum depressive symptoms living in Sodo found that problem-focused and emotion-focused coping were commonest among women with formal education, who attributed symptoms to a physical cause, suggesting external attribution (Azale, Fekadu, Medhin, & Hanlon, 2018). Dysfunctional coping was commonest among women reporting marital difficulties. Study Two therefore supported local evidence for the potential suitability of problem-solving techniques within brief psychological interventions adapted for this context.

Such an intervention should take a holistic view of well-being, focusing on women's priorities, including non-health problems and physical symptoms, rather than focusing narrowly on biomedical constructs of mental health conditions. This may include supporting women to access non-medical coping strategies, such as spiritual coping, poverty reduction initiatives, or social support, where appropriate. Where IPV is raised as a problem, therapists need to be trained to avoid inadvertently reinforcing abusive

treatment, colluding in victim blaming or compounding self-blame. This could be achieved by supporting therapists to reframe internal attributions of IPV (Overholser & Moll, 1990) and focus on women's self-efficacy. Given the severity of IPV, including severe and life-threatening harm, any intervention must prioritise the safety of women and any children, above all. Key safeguards should include training therapists to respond empathetically to IPV disclosures, clear protocols for acting on any incidents of IPV or harm to a child, and regular supervision by experienced mental health specialists. Given the prevalence of IPV, health workers are themselves at risk of experiencing IPV. Training should therefore ensure to address health workers' own needs, vulnerabilities, and well-being, and destigmatise help-seeking for emotional difficulties resulting from IPV.

5.6.4 What are the barriers and facilitators to implementing a brief psychological intervention for the perinatal emotional difficulties of women experiencing IPV in rural Ethiopia?

The ineffectual nature of existing responses to IPV, limited mental health literacy, problems with caring, respectful and compassionate ANC, and the deprived context increase the risk of poor engagement with brief intervention sessions. Logistical barriers to implementation include competing demands on women's time, distance of their homes from health centres, and the costs of transport. Unequal gender norms, the high prevalence and widespread reinforcement of IPV, and the likelihood of some health workers themselves experiencing IPV, may be barriers to training staff to ask about IPV and respond empathetically. Women's concerns about community judgement and confidentiality are potential barriers to engagement and disclosure. However, women and health workers' recognition of pervasive problems associated with IPV and emotional difficulties, including impacts on the unborn child, their support for intervention, and acceptance of regular ANC follow-up, are key facilitators.

The proposal of a brief psychological intervention integrated into ANC received broad support, as in a recent qualitative study in the same community (Bitew et al., 2020). In Study Two, some participants also recommended a programme of community awareness raising. A five year cluster RCT of a violence and HIV prevention community mobilisation intervention (SASA!) in Kampala, Uganda, was associated with reduced

social acceptance of IPV among men and women, lower past-year experience of physical and sexual IPV among women, and more supportive community responses to women experiencing IPV (Abramsky et al., 2014). However, a local cluster RCT of a 14 session 'gender-transformative' intervention focused on IPV and HIV delivered to women only, men only, and couples together, through the Ethiopian coffee ceremony, had mixed effects on IPV perpetration (Sharma et al., 2020). The revised ecological framework of IPV (Heise, 2011) clearly shows the forces perpetuating IPV at a range of levels. Cluster RCTs by Abramsky et al. (2014) and Sharma et al. (2020) therefore highlight that while community-level interventions require investigation, interventions targeting the emotional and mental health impacts of continuing IPV are also required.

Women and health workers emphasised the intrinsically therapeutic nature of confiding in a trusted individual, although they were often vague about their anticipated outcomes of intervention. In a study in Sodo, lay health workers trained to deliver community-based rehabilitation for schizophrenia characterised therapeutic interactions as "like a brotherly sisterly relationship" (p. 16, Asher et al., 2021). In Study Two, one more experienced and one less experienced health worker independently characterised their envisaged relationships with women attending intervention sessions as "like a friend, a sister, a mother". However, uncompassionate and disrespectful maternity care is commonly reported in Ethiopia, especially among women from rural areas and those experiencing complications in labour (Wassihun & Zeleke, 2018). Caring, respectful and compassionate (CRC) care had been prioritised in the national health sector transformation plan (p.p. 117-119; Ministry of Health, 2015), which may have sensitised health worker participants to the importance of therapeutic relationships. CRC continues to be prioritised, with a new national transformation agenda for a motivated, competent and compassionate (MCC) health workforce (p.66; Ministry of Health, 2021b), indicating the relevance of an adapted ANC intervention.

Superstitions and community judgement for leaving the house late in pregnancy, raised in another local study, were not mentioned in Study Two (Bitew et al., 2020). However, participants raised practical barriers to women's engagement with an intervention, such as competing demands on their time and distance from their homes to health centres. Retention rates were high in the local cluster RCT of a gender-transformative intervention for IPV and HIV (72% attended 12 or more out of 14 sessions; Sharma et al., 2020).

However, the community setting of this intervention is likely to have reduced barriers of distance and transportation that might influence women's attendance at sessions delivered within centralised health centres.

5.6.5 Which implementation strategies would optimise the acceptability and feasibility of a brief psychological intervention from the perspectives of pregnant women experiencing IPV and health workers in this context?

The barriers to women's engagement with sessions mean that intervention training should focus on therapists' communication skills and building a therapeutic relationship in the first session. Reimbursing women for out of pocket expenses such as transport costs, as highlighted by a local study (Asher et al., 2018), and coinciding sessions with routine ANC appointments, may overcome logistical barriers to attendance. Sessions should be brief and limited in number, with a pragmatic focus, to accommodate practical, educational, and attitudinal barriers to more in-depth psychological interventions. Health workers require training about IPV and emotional difficulties, alongside regular supervision and clear processes for responding to risk disclosures and safety concerns. The importance of confidentiality means that group interventions and home visits would not be appropriate in this setting. Beyond this woman-focused intervention, the potential for community awareness raising, as shown to be effective in another sub-Saharan African context (Abramsky et al., 2014), to address the community level of the revised ecological framework (Heise, 2011), should be explored, for example during activities to disseminate the study findings.

Participants emphasised the importance of session confidentiality. This was consistent with a systematic review which included 21 studies evaluating the acceptability and feasibility of task-shared mental healthcare in LMICs (Padmanathan & De Silva, 2013). Service users and providers expressed concerns about confidentiality, time, and travel constraints in India. Studies from Bangladesh, India, and Nepal highlighted the importance of personal characteristics and communication skills. Padmanathan and De Silva (2013) found that some participants expressed a preference for female therapists, as did some but not all in Study Two. Although women recognised the practical benefits of home visits to deliver sessions in rural Ethiopia, confidentiality meant that health centres were ultimately preferred.

Participants considered advantages and disadvantages of different therapists and organisational features. HEWs were appreciated for their close community links, in keeping with consensus on the value of local therapists in India, South Africa, Uganda, and Zimbabwe (Padmanathan & De Silva, 2013). However, HEWs' workload and variable clinical priorities, often being allocated additional tasks at short notice, limited their suitability to deliver regular sessions, consistent with a systematic review of the Ethiopian HEW programme (Assefa, Gelaw, Hill, Taye, & Van Damme, 2019). However, a key disadvantage of training health centre staff to deliver intervention sessions was their lack of community outreach work, preventing them from following pregnant women up postpartum. In Study Two, health centre staff were ultimately preferred, due to HEWs' workload. Research conducted in India, Nepal, Pakistan, and South Africa has also highlighted the risk of over-burdening community health workers (Padmanathan & De Silva, 2013). Finally, ANC staff emphasised the importance of training and supervision. The optimal duration and frequency of these to ensure staff confidence and competence requires investigation, given varied findings across contexts, interventions, and professional cadres (Padmanathan & De Silva, 2013).

5.6.6 Strengths

No previous studies have used qualitative methods to explore the relationship between pregnant women's experiences of IPV and emotional difficulties in Ethiopia in depth, including the roles played by patriarchal norms, powerlessness, deprivation, and cultural expectations. Study Two also reports the first qualitative research exploring women and health workers' perspectives on perinatal emotional difficulties associated with IPV; two Ethiopian studies focused on professionals' perspectives on perinatal IPV (Gashaw et al., 2019; Gashaw et al., 2020), and one Kenyan study focused on general impacts of IPV on pregnant women (Odero et al., 2014). A further strength was the identification of potential participants with a history of depressive symptoms and relationship difficulties, from among respondents to a local ANC survey. This sampling strategy was preferable to recruiting women (who might not have been typical of the wider ANC population) from specialist mental health or IPV services.

The existing qualitative literature on perinatal mental health in Ethiopia (section 2.2.2) predominantly used focus group discussion methods. Study Two's comparatively large

sample of in-depth qualitative interviews with pregnant women and health workers overcame focus groups' limitations, such as capturing socially desirable responses, neglecting individuals' personal perspectives, and divergent viewpoints (Finch et al., 2014; Lewis & McNaughton Nicholls, 2014). Study Two also benefitted from audio-recording, professional transcription and translation of in-depth interviews, rather than reliance on hand-written notes (Gashaw et al., 2019; Gashaw et al., 2020).

5.6.7 Limitations

A key limitation of Study Two is that interview transcripts were analysed in the form of English translations. This was mitigated by attention to my own positionality through reflexivity, the conducting of interviews in Amharic by female Ethiopian research assistants, and their and other Ethiopian academics' contributions to thematic analysis. However, the social circumstances of academics living in urban areas differ from those of women and health workers based in rural areas. Respondent validation could have addressed this issue, but I did not pursue it due to concerns about the impact of unequal power dynamics on the breadth of perspectives captured (Lewis et al., 2014).

Study Two focused on the perspectives of women and health workers and did not interview men or other community stakeholders. I made this decision due to the relative paucity of studies focused on women's perspectives, but exploring the experiences of a sub-sample of their partners could have enhanced interpretation of the findings.

5.6.8 Future research

After completing Study Two, I used the findings to inform the adaptation of a brief psychological intervention for the perinatal emotional difficulties of women experiencing IPV in this context (Study Three).

6 STUDY THREE: HOW CAN A BRIEF PSYCHOLOGICAL INTERVENTION BE ADAPTED FOR THE PERINATAL EMOTIONAL DIFFICULTIES OF WOMEN EXPERIENCING INTIMATE PARTNER VIOLENCE IN RURAL ETHIOPIA?

This chapter presents the introduction (6.1), aims (6.2), research questions (6.3), intervention adaptation (6.4), programme theory (6.5), and discussion (6.6) of Study Three.

6.1 Introduction

Study Three was focused on adapting an existing, evidence-based, brief psychological intervention, seeking to retain its mechanisms of action while tailoring the design and implementation strategies to optimise its relevance for pregnant women experiencing IPV in rural Ethiopia. I therefore structured Study Three using the MRC-affiliated ADAPT guidance (Moore et al., 2021), which was designed to be used in a non-sequential manner and applied flexibly, allowing for iterative movement between stages.

The context and implementation of complex interventions (CICI) framework (Pfadenhauer et al., 2017) advocates integrated consideration of context and implementation, in relation to the study setting. In Study Three, I followed recommendations to compare the context for which the individual intervention was developed with my study context, and address those aspects which differed most markedly, during adaptation (Craig et al., 2018). In Study Three, I integrated my findings on the study context (chapter 4) and stakeholder perspectives from Study Two (chapter 5) into the adaptation process. In Studies Four and Five, I related these findings to intervention implementation, using CICI (sections 7.1.1 and 8.1.6).

6.2 Aims of Study Three

To adapt a brief psychological intervention for the perinatal emotional difficulties of women experiencing IPV in rural Ethiopia, including a theory of change (ToC) and corresponding ‘dark logic model’.

6.3 Research questions

1. What brief psychological intervention model best addresses the findings of Studies One and Two?
2. What adaptations best tailor this intervention for the perinatal emotional difficulties of pregnant women experiencing IPV in rural Ethiopia?
3. What ToC and dark logic model best capture stakeholder perspectives on perinatal emotional difficulties (the problem), health services (the system), rural Ethiopia (the context), and unintended harms?

6.4 Intervention adaptation

Figure 6.1 displays the process by which I followed ADAPT guidance (Moore et al., 2021), first forming an adaptation team of diverse stakeholders, before (step 1) assessing the rationale for intervention and considering the context fit of existing interventions, and (step 2) planning and undertaking adaptation. In Study Four (chapter 7), I used ADAPT guidance to (step 3) plan and undertake piloting and evaluation. In Study Five (chapter 8), I reported the results of my randomised feasibility study of the adapted intervention. Step 4 of ADAPT (implementing and maintaining the adapted intervention at scale) was beyond the scope of this PhD. Figure 6.1 also shows how I used ToC workshops and other sources of stakeholder feedback to iteratively refine the programme theory of the adapted intervention, throughout Study Three (Breuer et al., 2014; De Silva et al., 2014).

STUDY THREE: HOW CAN A BRIEF PSYCHOLOGICAL INTERVENTION BE ADAPTED FOR THE PERINATAL EMOTIONAL DIFFICULTIES OF WOMEN EXPERIENCING INTIMATE PARTNER VIOLENCE IN RURAL ETHIOPIA?

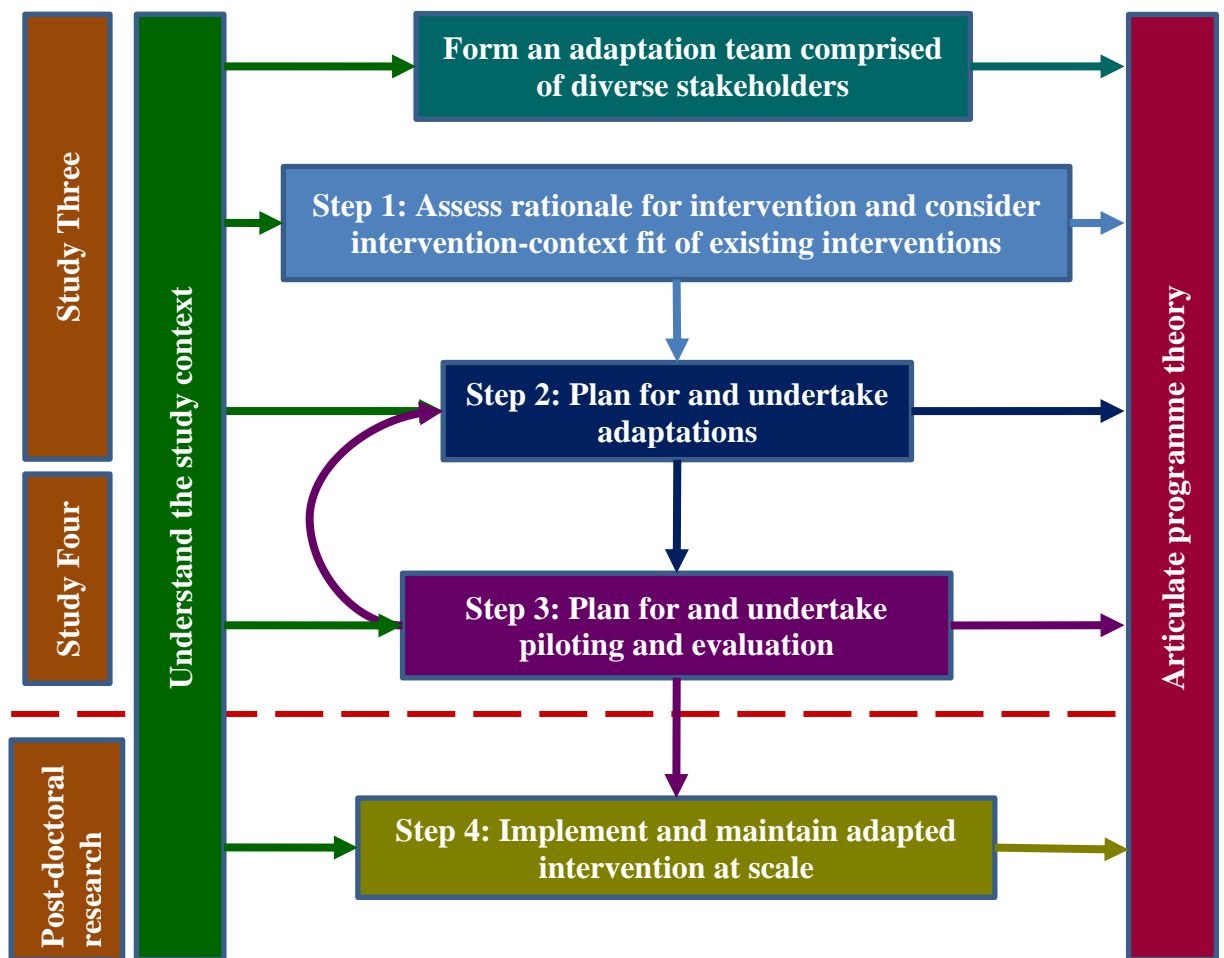


Figure 6.1 Stages of intervention adaptation (Moore et al., 2021)

Figure 6.1 shows how all stages of adaptation incorporated continued efforts to understand the study context, outlined in chapter 4, and derived from Study Two (chapter 5). As recommended by the new MRC/NIHR framework for complex intervention development and evaluation (Skivington et al., 2021) and Craig et al. (2018), I incorporated my growing understanding of the study context into every stage of adaptation. In the following sections, I describe the adaptation process, of assessing intervention rationale and selection (Step 1; section 6.4.1), forming a diverse adaptation team (section 6.4.2), and planning and undertaking adaptations (Step 2; section 6.4.3), before describing the ToC process of articulating the intervention’s programme theory (section 6.5).

6.4.1 Intervention rationale and selection

Following ADAPT guidance (Moore et al., 2021), I moved from defining the problem in the target population (section 6.4.1.1) to identifying candidate interventions (section 6.4.1.2), reviewing the evidence for the selected intervention (section 6.4.1.3), and the robustness of effectiveness claims (section 6.4.1.4), comparing the original context to my study setting (section 6.4.1.5), and considering intellectual property issues (section 6.4.1.6).

6.4.1.1 Problem definition

Study Two defined the problem in the target population, from the perspectives of women and ANC staff. These stakeholders described the relationship between pervasive IPV and other forms of abusive treatment, and women's emotional and bodily distress, including emotional difficulties and persistent physical symptoms. Stakeholders identified powerlessness as a priority target for brief psychological intervention, emphasising women's need for hope and skills to solve their problems. Although stakeholders debated the optimal delivery model, all supported ANC as an access point for intervention.

6.4.1.2 Candidate interventions

My selection of the most suitable intervention model was informed by the perspectives of local experts, who attended a consensus meeting at Addis Ababa University (AAU) on 3rd July 2017, led by the PRIME study (Fekadu et al., 2016). Attendees comprised 14 specialist clinicians and researchers.²⁰ After reviewing interventions with an evidence base in LMICs, attendees highlighted interpersonal psychotherapy (Bolton et al., 2003; Negash et al., 2021; Ravitz et al., 2014; Verdeli et al., 2003), the common elements treatment approach (Hammett, 2020; Kane et al., 2021; Murray et al., 2018; Murray, Kane, et al., 2020), and problem-solving therapy (Bryant et al., 2017; Chibanda, Weiss, et al., 2016; Gureje et al., 2019; Jacobs, Myers, van der Westhuizen, Brooke-Sumner, &

²⁰ Five psychiatrists, two non-psychiatrist doctors interested in perinatal mental health, four public health specialists and three mental health researchers.

Sorsdahl, 2020; Malouff, Thorsteinsson, & Schutte, 2007; Myers et al., 2019; Sorsdahl, Myers, et al., 2015; Sorsdahl, Stein, et al., 2015; Spedding et al., 2020; Van't Hof, Stein, Marks, Tomlinson, & Cuijpers, 2011; van der Westhuizen et al., 2021) as most promising for this setting. I therefore considered each of these models in relation to my PhD study context, and stakeholder engagement findings.

Interpersonal psychotherapy (IPT)

A systematic review identified 17 treatment trials of IPT during the perinatal period (Sockol, 2018). Meta-analyses excluding one outlier showed improved depressive symptoms (SMD: 1.05, CI: 0.07-2.04) among perinatal women receiving IPT, relative to control women. However, no studies were conducted in low-income countries, and only one was conducted in a middle-income country.

IPT has been contextualised for Ethiopia, with training cascaded from psychiatrists to psychiatric nurses and primary care staff (Ravitz et al., 2014), but no RCTs have been reported. An uncontrolled, non-randomised pilot study retained 29 out of 31 participants in all eight sessions of peer-delivered group IPT (Asrat, Lund, Ambaw, & Schneider, 2021), adapted to reflect the explanatory models of depression of people living with HIV in Ethiopia (Asrat, Lund, Ambaw, & Schneider, 2020). Qualitative interviews and focus group discussions suggested that IPT was feasible to deliver and acceptable to participants, despite prior concerns about stigma, transport, and confidentiality. The authors acknowledged that social desirability bias could have impacted participant feedback, although data collectors were independent of the intervention. A model of eight individual IPT sessions was found to be acceptable and feasible for university students in Sodo (Negash et al., 2021), but there is no evidence of IPT's suitability for participants with lower levels of education, in Ethiopia.

Although attending and delivering 16 intervention sessions was acceptable and feasible in Uganda (Verdeli et al., 2003), concerns were raised in Study Two about competing demands on women's time, and distance between their homes and the health centre. Given the difficulty of postnatal continuation of intervention sessions, an extensive intervention might prove unfeasible in my context. The group delivery of Bolton et al. (2003)'s IPT

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model (see Study One: Table 3.1) would also be incompatible with women's concerns in Study Two about confidentiality and community judgement.

The common elements treatment approach (CETA)

CETA is a flexible, modular, transdiagnostic psychological intervention previously evaluated using RCTs in Ukraine, Iraq, Zambia, and Thailand (Murray, Haroz, et al., 2020). The eight CETA elements include psychoeducation and engagement, relaxation strategies, behavioural activation, cognitive restructuring, gradual exposure (talking about traumatic memories), problem solving, risk assessment and planning, and CBT for substance use. Examining results from Iraq and Thailand, Murray, Haroz, et al. (2020) found that 50% of CETA participants showed some improvement after 4-6 sessions, and large improvements after 7-10 sessions. They found that gradual exposure was an 'active ingredient' associated with symptom improvement. Limited application of relaxation and problem solving techniques meant that the analysis lacked power to detect whether these also constituted active ingredients.

An RCT found that lay counsellor-delivered CETA significantly reduced women's self-reports of IPV exposure and men's hazardous alcohol use in Zambia at one (Murray, Kane, et al., 2020) and two years' follow-up (Kane et al., 2021). A qualitative study conducted 50 in-depth interviews and four focus group discussions with participants to explore these results (Murray et al., 2021). Mechanisms of change included safety strategies to avoid or prevent conflict and control anger, improved trust and understanding, and reduced alcohol intake. However, patriarchal norms influenced participants' perceptions of safety strategies. For example, behavioural modifications taught by CETA, such as women "walking away" and "staying quiet" were linked by participants to showing respect for their husbands. These findings demonstrated the importance of sensitivity to inadvertent reinforcement of gender inequality and abuse by brief psychological interventions.

Uncontrolled studies of CETA have reported improved CMD symptoms, suicidality, and antiretroviral medication initiation in Mozambique (Hammett, 2020), and reduced internalising, externalising, and post-traumatic stress symptoms in Somali refugee camps

(Murray et al., 2018). However, women and health workers participating in Study Two prioritised a problem-solving focus for a brief psychological intervention integrated into ANC, to address women's powerlessness, instil hope, and reduce feelings of entrapment and shame.

Problem-solving therapy (PST)

PST is a brief psychological intervention, which teaches problem-solving skills to enhance coping. A meta-analysis of 31 RCTs, all from HICs, which evaluated PST for any mental or physical health problem, found that it was significantly more effective than no treatment, treatment as usual, and 'attention placebo' (controlling for non-specific effects of contact; Malouff et al., 2007). The efficacy of PST was moderated by use of problem-orientation training and homework assignments. A network meta-analysis of (92% HIC) RCTs of psychological interventions for depression (Barth et al., 2016) found significant effect sizes (all >0.46) for PST, IPT, and CBT, compared to waiting list controls, when analyses were restricted to moderate to large samples.

PST has been used to treat depression, anxiety, and psychological distress in LMICs. Both RCTs in Study One which focused on PST alone found that it was effective. In Zimbabwe, an 86% female sample attending six sessions of individual, lay health worker-delivered Friendship Bench PST had significantly lower CMD symptoms (adjusted risk ratio: 0.21) at 6 months' follow-up, compared to enhanced usual care (EUC; Chibanda, Weiss, et al., 2016). In Kenya, women with a history of gender-based violence attending five sessions of PM+ showed improved psychological distress (difference in GHQ-12 scores: 3.33) at three months' follow-up, compared with EUC (Bryant et al., 2017).

A more recent RCT of eight 30-45 minute weekly PST sessions for antenatal depression, followed by four to eight postnatal top-up sessions for higher symptoms in Nigeria, found no significant difference in remission compared to EUC (brief mhGAP-IG training for ANC staff; Gureje et al., 2019). However, PST was more effective than EUC among women with severe depression (OR: 2.29), and associated with higher rates of exclusive breastfeeding (OR: 2.17).

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The evidence base for the acceptability, feasibility and efficacy of variations of PST in LMICs supports its potential suitability as a brief psychological intervention in rural Ethiopia. However, attendance at and delivery of five 90 minute (Bryant et al., 2017), six (Chibanda, Weiss, et al., 2016) or twelve (Gureje et al., 2019) 30 to 45 minute sessions may not be acceptable or feasible in all settings.

6.4.1.3 *Intervention review*

After the identification of PST as the most suitable intervention type for my study context, I reviewed published articles describing its implementation and efficacy in a brief or simplified format, in other LMIC contexts. I consulted relevant feasibility studies and efficacy trials, to identify potential mechanisms of action and how these might change in a different context. I mapped similarities and differences between the two contexts by comparing published descriptions with my own contextual review of the study site (chapter 4).

A Dutch model ('Taking Control'), first developed from self-examination therapy (Bowman, Scogin, & Lyrene, 1995), was translated into English, Xhosa and Afrikaans, with case examples adapted for HIV, unemployment, and violent trauma-related difficulties relevant to a South African township (Van't Hof et al., 2011). Following low uptake of the online version, the authors adapted Taking Control into a booklet, intended for self-directed use with weekly telephone support. Due to drop-outs, the model was adjusted to offer participants five weekly 45-60 minute group sessions, to guide self-help. The study was uncontrolled, but intention-to-treat analyses found significant improvements in psychological distress, CMD symptoms, and perceived empowerment among 103 participants, all of whom were enrolled because they felt they had mental health problems.

Due to difficulties with self-help, Taking Control was reformulated for delivery by peer counsellors, with an initial motivational interviewing (MI) session (Sorsdahl, Myers, et al., 2015). An RCT was conducted of five individual sessions of MI-PST in three Cape Town emergency departments, enrolling 335 adults at moderate to high risk of substance use problems (Sorsdahl, Stein, et al., 2015). Intention-to-treat analyses showed that

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substance use (primary outcome) reduced significantly in the MI-PST group at three months' follow up, compared with one session of MI or a leaflet. Of the participants at risk of depression at baseline, depressive symptoms (secondary outcome) reduced significantly in the MI-PST group after three months, compared to MI only and leaflet groups. However, only 42% of MI-PST participants attended all five sessions and follow-up. The authors recommended reducing the number of sessions and matching the 'dose' of MI in both active arms, to make efficacy more comparable.

MI-PST was later adapted for three sessions, delivered by community health workers (CHWs) to 40 participants with diabetes or HIV, with probable depression, harmful or hazardous drinking, or both, in Cape Town (Myers et al., 2019). This version was feasible and acceptable, whether provided by dedicated CHWs, or by existing ('designated') CHWs, in addition to their other roles. CHWs identified support from colleagues, including managers, as critical to implementation success. For example, building a therapeutic alliance was obstructed by frequent interruptions, and designated CHWs struggled to deliver MI-PST unless colleagues assisted them with other duties. CHWs recommended involving supervisors and employers in discussions about training and implementation, to facilitate team members' buy-in. A subsequent study interviewed 18 health workers who delivered MI-PST (Jacobs et al., 2020). High quality training, including role plays and skill rehearsal, and supervision by an experienced counsellor, were key to building staff competence and confidence. Designated counsellors expressed concerns about 'task dumping': having additional counselling responsibilities added to their workload without additional pay.

Recently, three sessions of MI-PST were integrated into 'Teachable Moment' (TM), a screening, brief intervention, and referral programme for substance use in three Cape Town emergency departments (van der Westhuizen et al., 2021). In an uncontrolled, non-randomised study, 273 recipients praised the non-judgemental, respectful, and caring approach of counsellors, but 97% accessed only one session. In an uncontrolled evaluation, 4,023 participants received TM: 83% of eligible patients screened (van der Westhuizen et al., 2019). TM was acceptable to emergency department clinicians, although some stakeholders considered weekly supervision excessive. Task-sharing and behaviour change aspects of TM were less acceptable to stakeholders with less experience

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of these elements. The adoption of TM was encouraged by senior support from provincial government departments but hindered by confusion about differences between TM counsellors and sexual health counsellors. Stakeholders also expressed confusion about whether TM was “just another research project” (p. 11), or a new service.

Finally, three sessions of PST (without MI) were adapted to include information about pregnancy and piloted with 38 women screening positive for depression in ANC in Cape Town (Spedding et al., 2020). This uncontrolled study identified significant improvements in psychological distress (primary outcome) and depressive symptoms, functional impairment, and perceived social support (secondary outcomes) among participants attending three months’ follow-up. Thirty-nine percent of participants attended all three sessions, 24% attended two and 37% attended one; 42% were lost to follow-up. Brief interviews with 22 participants identified opportunities to confide in a non-judgemental person, hear alternative perspectives, talk about past experiences, and take time for themselves as perceived benefits. However, none of these aspects was central to the PST model. Some but not all participants valued the problem-solving approach itself, citing its pragmatism and coping strategies. Others reported feeling stronger and more able to have difficult conversations after attending PST, which improved their relationships. Some women copied the booklet for their friends or taught them PST techniques. One participant said, “there wasn’t really space for me to talk, we were just reading out of the booklet” (p. 6). ANC staff valued having a service to which they could refer distressed women. Some admitted that they had not always asked women about their problems, to avoid needing to manage their distress alongside heavy workloads.

In their feasibility study, Spedding et al. (2020) found that the commonest barriers to attending sessions were finances, transport, work, childcare and, to a lesser extent, stigma. As referrals for PST increased, the dedicated counsellor was unable to assess all potentially eligible women on the same day, leading to reduced referrals. Delivery of sessions by a single, trained counsellor meant that existing ANC staff did not feel able to support women adequately on days when she was absent. Workloads meant that staff found even simple referral processes using coloured labels burdensome. One stakeholder mentioned lack of space for sessions; another considered this an excuse, to limit the

additional work associated with new programmes. Several women recommended offering group sessions at a separate location, to address stigma and distance from women's homes. Others suggested longer sessions, or more.

6.4.1.4 Effectiveness review

My review of the evidence base for brief PST in South Africa showed that its feasibility and acceptability have been widely investigated (Myers et al., 2019; Sorsdahl, Myers, et al., 2015; Spedding et al., 2020; Van't Hof et al., 2011; van der Westhuizen et al., 2021), employing a range of implementation strategies (Sorsdahl, Stein, et al., 2015). As a task-shared approach that is shorter than PM+ or Friendship Bench, and integrated into wider healthcare services, the MI-PST model showed promise in a range of Cape Town settings. Since the available evidence could not be generalised to my rural Ethiopian context, MI-PST required adaptation and piloting, to investigate its suitability.

6.4.1.5 Context comparison

Considering the different features of context (Craig et al., 2018), the Cape Town settings in which MI-PST was developed shared epidemiological context with Sodo. Prevalence rates of depression (Hartley et al., 2011) and IPV (Malan, Spedding, & Sorsdahl, 2018) during pregnancy were similar in Cape Town and Sodo. The social and economic contexts differed: South Africa is an upper middle-income country and Ethiopia is a low-income country (The World Bank, 2021a). The percentage of literate females aged 15 years and over is 86% in South Africa and 44% in Ethiopia (The World Bank, 2020b). MI-PST's urban setting meant that my intervention needed to be adapted for women from rural areas, with lower literacy, education, and access to income-generating work. The geographical and environmental contexts differed, with Sodo more reliant on agricultural work, although climatic events such as droughts also impact Cape Town (Chersich et al., 2018). The task-shared ANC service and organisational context of brief PST (Spedding et al., 2020), was similar to Sodo. However, domestic general government health expenditure per capita is \$284 in South Africa and \$6 in Ethiopia, compared to \$3392 in the UK (The World Bank, 2020a). The ethical, policy, legal, financial, and (healthcare) political contexts of the two settings were broadly similar in terms of implementing a

brief psychological intervention in ANC, although salary costs were lower in Ethiopia. Both settings shared a history of prior investment by the PRIME programme, where mental health task-sharing was considered acceptable and feasible, provided sufficient resources, supervision, training, and compensation (Mendenhall et al., 2014). Although the specific external shocks and catalytic events facing South Africa and Ethiopia differed, weather events, economic crises, and political upheaval were shared.

6.4.1.6 Intellectual property

My first supervisor and I approached the original developers of MI-PST (Sorsdahl, Stein, et al., 2015), to discuss the possibility of adapting their intervention model. We discussed intellectual property issues and agreed to collaborate, basing the adapted intervention materials on the original content developed for use in Cape Town. Because the original developers (KS and BM) joined the adaptation team, no formal intellectual property agreements were made. We agreed not to share the English language adapted intervention manual beyond the study, until the original developers' materials had been publicly shared, at which time the adapted manual would be made available, with appropriate acknowledgements.

6.4.2 Adaptation team

As recommended by ADAPT guidance (Moore et al., 2021), I involved stakeholders early and throughout the adaptation process (section 6.4.2.1), agreed principles for decision-making and involvement (section 6.4.2.2), considered the advantages and disadvantages of working with the original intervention developers (section 6.4.2.3), and reviewed and updated team membership as the process progressed (section 6.4.2.4).

I co-led the adaptation process in collaboration with a male Ethiopian post-doctoral researcher (TB). We jointly adapted the MI-PST model for pregnant women in rural Ethiopia, informed by stakeholder input and findings from qualitative interviews with pregnant women in Sodo district (Bitew et al., 2020). I then further adapted 'standard PST' to meet the needs of women experiencing IPV, in a version of the intervention called PST-IPV. We then collaborated on Study Four by evaluating the two interventions through a single, three-arm randomised feasibility study design.

Following discussion with my first and second PhD supervisors, I identified potential collaborators with expertise relevant to my PhD research, before approaching them by email.²¹ The trial coordinator and research assistant²² contributed their perspectives to the intervention adaptation, remaining reflexive of their differing socio-economic circumstances to those of women participating in Studies Two and Four.

6.4.2.1 Stakeholder involvement

I involved stakeholders early and throughout the intervention adaptation. Fourteen local primary care staff contributed their perspectives on the adapted intervention's objectives, outcomes, mechanisms, format, challenges, and opportunities through a ToC workshop held on 17th October 2018 (see section 6.5.2). Study Two explored the perspectives of 12 ANC staff and 16 pregnant women, in depth.

After identifying the most suitable intervention model, an MI-PST training course was delivered at AAU by an experienced counsellor (MM) from the original developers' team, between 22nd and 24th October 2018. Attendees comprised 16 Ethiopian mental health professionals and researchers.²³ I kept written notes of stakeholders' perspectives on the intervention design, and elements they identified for adaptation.

On 26th October 2018, a workshop was facilitated by TB and my first supervisor (CH) with a sub-group of these stakeholders. Attendees explored how MI-PST should be adapted for the needs of pregnant women in rural Ethiopia.²⁴ I reviewed the minutes of this workshop to inform the adaptation process.

²¹ My collaborators were a male Ethiopian doctor and IPV researcher (ND), a female South African doctor and perinatal mental health researcher (SH), a male Dutch mental health researcher with extensive experience of intervention development in LMICs (WT), and a male Greek psychologist and professor of implementation science (NS).

²² I set examination and interview questions for the competitive recruitment of both staff members, and co-interviewed candidates for the role of trial coordinator, in person. Appointed staff were both Ethiopian women with master's degrees (in public health and medical microbiology).

²³ Attendees included four female psychiatrists, four male and one female psychologist, and seven mental health researchers (four female, three male), including PhD students.

²⁴ Attendees comprised three female psychiatrists, three male and female clinical psychologists, one male PhD student, and one male post-doctoral researcher; one female psychiatrist contributed detailed comments in writing.

The ‘standard’ version of adapted PST was pre-tested with stakeholders via a ‘theatre testing’ session (Wingood & DiClemente, 2008) on 10th November 2019.²⁵ After each of the four intervention sessions had been demonstrated to attendees,²⁶ stakeholders engaged in focus group discussions.²⁷ I reviewed the English theatre testing notes and collaborated with TB to incorporate the findings into the intervention adaptation.

6.4.2.2 Decision-making

Ultimate decision-making authority was held by me for PST-IPV and by TB for standard PST. All applicable comments from the adaptation team were incorporated into the two intervention manuals, unless they contradicted other agreed priorities.

6.4.2.3 Original intervention developers

As recommended by Moore et al. (2021), I considered the advantages and disadvantages of working on the adaptation with the original intervention developers. As brief psychological interventions often emerge in parallel and are frequently adapted for different contexts, their definitive original source can often be unclear. However, I interpreted the original team to be the researchers who had developed and evaluated the MI-PST model in Cape Town, which I adapted in Study Three. Disadvantages of collaborating with original developers can include power imbalances, conflicts of interest, and different perspectives on the scope of alterations. Advantages include benefitting from original developers’ experience in other contexts, and basing the adapted intervention on the original materials, which were not publicly available.

With my Ethiopian collaborator (TB) and first supervisor (CH), I agreed an adaptation plan with the developers of MI-PST (KS and BM). The first stage of adaptation, for

²⁵ Attendees comprised six pregnant or postnatal women, two women volunteers in the local women’s development army (WDA), one psychiatrist, one psychologist, two psychiatric nurses, and two midwives.

²⁶ A male Ethiopian psychologist (AMi) acted the role of therapist and a female mental health PhD student (MD) acted the role of a pregnant woman.

²⁷ Focus group discussions with women were facilitated by the female research assistant (AMu) and discussions with healthcare professionals were facilitated by TB. Facilitators made written notes of stakeholders’ feedback and recommendations.

pregnant women in Ethiopia, was led by TB, with my contributions. KS and BM provided feedback and suggestions in response to our amendments,²⁸ as did my supervisors (CH and LH²⁹), before feedback from my PhD collaborators.

6.4.2.4 Adaptation team review

In keeping with recommended guiding principles of intervention development (O'Cathain et al., 2019) to be iterative, open to change, and forward looking, I reviewed adaptation team membership flexibly.³⁰

6.4.3 Adaptations

As recommended in Step 2 of ADAPT guidance (Moore et al., 2021), I identified and responded to constraints and facilitators (section 6.4.3.1), adapted the intervention materials (section 6.4.3.2), considered the potential for unintended consequences (section 6.4.3.3), and recruited individuals to deliver the intervention (section 6.4.3.4). I did not assess the costs required for intervention implementation at scale, but planned a full economic analysis of Study Four, as an early post-doctoral project.

6.4.3.1 Constraints and facilitators

In order to adapt MI-PST for the needs of pregnant women in Ethiopia, and standard PST for the needs of women experiencing IPV, I identified constraints and facilitators on PST-IPV. I did so via Study Two, stakeholder engagement activities, and by reviewing published evidence. I incorporated adaptations to PST-IPV implementation strategies into the Study Four standard operating procedure (SOP; uploaded to the open access repository at Keynejad (2021)), to optimise feasibility.

²⁸ Once I had adapted standard PST for women experiencing IPV, KS and BM read and commented on the draft English manual. They also collaborated on the randomised feasibility trial (Study Four).

²⁹ CH is a female, British psychiatrist based in Ethiopia, with expertise in perinatal mental health and local intervention adaptation. LH is a female, British professor of women's mental health and perinatal psychiatrist, with expertise in perinatal intervention development.

³⁰ For example, I involved the five Ethiopian psychiatrists and psychologists appointed to train and supervise health workers during Study Four, in iterative adaptation of PST-IPV, after identifying the important contribution made by their familiarity with the Amharic-language materials.

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Six key facilitators identified in Study Two (section 5.5.7) were, first, that women and health workers considered perinatal emotional difficulties, IPV, and their impacts on unborn children, as problems requiring intervention. Second, women considered existing responses to IPV ineffectual, increasing their likelihood of engagement. Third, women already accepted at least four ANC appointments, raising their potential readiness to attend coinciding sessions. Fourth, women and health workers expressed support for a brief psychological intervention integrated into ANC. Fifth, adaptation workshop and theatre testing attendees considered the problem-solving focus and potential of PST to empower women to be strengths. Finally, adaptation workshop stakeholders highlighted prior sensitisation to integrating mental health into primary care by the PRIME study (Mendenhall et al., 2014) as a facilitator.

Table 6.1 outlines constraints on PST-IPV, sources through which I identified them and adaptations to address them, agreed collaboratively with the adaptation team.

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Table 6.1 PST-IPV constraints, sources, adaptations and impacts

ANC: antenatal care, GCP: good clinical practice, HEW: health extension worker, IPV: intimate partner violence, MI: motivational interviewing, PST: problem-solving therapy, SMI: severe mental illness, ToC: theory of change.

<i>Sources</i>	<i>Constraint</i>	<i>Potential impact</i>	<i>Adaptation in PST-IPV</i>	<i>Difference from standard PST</i>	<i>Intended impact</i>
Staff constraints					
Adaptation workshop Theatre testing Evidence review	ANC staff may struggle to identify depression or find screening laborious.	Recruitment could be impacted (Girma, 2020).	Identification of eligible women was led by research staff rather than health workers.	None.	Save time, so health workers can focus on delivering sessions.
Study Two ToC workshop	ANC staff had received limited prior mental health training.	The quality of brief psychological intervention sessions might be reduced.	Training included perinatal mental health and IPV content. Flip-chart, manual, and session record forms devised to standardise intervention quality and fidelity. Research staff visited health centres prior to selection, to gauge interest and build working relationships with staff. Regular supervision included feedback on session recordings. Pathways to refer women with severe symptoms or requiring specialist support were integrated into the trial design	IPV content not included in standard PST training or manual. Both interventions used the same flip-chart and session record forms, which did not mention IPV.	Standardise session quality and fidelity to the model.
Study Two Theatre testing ToC workshop Evidence review	Problems with caring, respectful, compassionate care (Bitew et al., 2020; WHO, 2016b).	Women might disengage from sessions or distrust staff.	Training focused on communication skills and building a therapeutic relationship, including role plays to practise skills. Staff were supervised by the specialists who had delivered their training throughout Study Four, who provided personalised feedback on audio-recorded sessions.	None.	Engage women by developing staff clinical communication skills.
PST training course feedback	Staff may advise women rather than follow the manual.	Reduced intervention fidelity.	Following the manual/flip-chart emphasised throughout training. Fidelity to the manual was monitored via supervision.	None.	Focus sessions on problem-solving skills.
Study Two ToC workshop	Some staff may be too busy or have other priorities.	Reduced intervention quality or fidelity.	Only health centre staff trained to deliver sessions. HEWs involved in following up women who missed sessions.	None.	Staff selected if able to safely take on role.

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<i>Sources</i>	<i>Constraint</i>	<i>Potential impact</i>	<i>Adaptation in PST-IPV</i>	<i>Difference from standard PST</i>	<i>Intended impact</i>
PST training course feedback Adaptation workshop	Selecting a sub-set of health workers to deliver sessions may be challenging.	Staff not selected for training might be unhappy, impacting health centre buy-in and staff readiness to facilitate session delivery.	After considering selection based on personal attributes, random selection of staff was agreed to be fairest. Staff could opt out of consideration if they did not wish, or were unable, to attend training or deliver sessions. All health centre staff were required to attend GCP training, for which they were compensated for their time. All interested control arm staff offered training, post-trial.	None.	Whole health centre support/ buy-in for the intervention and trial. Range of staff trained, not just those with interest.
Participant constraints					
Study Two Theatre testing ToC workshop Evidence review	Limited mental health awareness, non-biomedical understanding of symptoms, stigma.	Risk of poor engagement due to limited understanding or stigma.	Sessions focused pragmatically on women's self-identified problems. Session content did not discuss depression but focused on well-being during pregnancy.	None.	Accessible content, tailored to women's understanding.
Study Two Theatre testing ToC workshop	Women's concerns about community judgement and confidentiality.	Women's engagement or disclosure of IPV and other difficulties could be reduced.	Confidentiality was reiterated at enrolment and Session 1. Sessions were delivered individually by the same health worker (not in groups), in private health centre rooms (not at home). Support groups to help women to maintain PST skills were discussed in theatre testing but not pursued (confidentiality).	None.	Participants reassured that sessions were confidential and health workers could be trusted.
PST training course feedback Theatre testing	Women may expect to be substantially reimbursed for participation.	Women might expect material support as compensation.	Written and verbal information, including the information sheet, clearly explained that women would be compensated for their time to attend baseline and outcome assessments, and travel costs to and from all appointments would be reimbursed.	None.	Avoid setting a precedent. Sessions aimed to be intrinsically valuable.
Adaptation workshop	Some women may not be comfortable receiving sessions from male staff.	Sensitivity could impact women's engagement with sessions.	This point was raised in the adaptation workshop but not Study Two. As women were familiar with male ANC staff in this context, it was agreed to evaluate the feasibility of sessions delivered by both male and female staff.	None.	Naturalistic evaluation (usual ANC staff genders).

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Sources	Constraint	Potential impact	Adaptation in PST-IPV	Difference from standard PST	Intended impact
Attendance constraints					
Study Two Adaptation workshop Theatre testing Evidence review	Competing demands on participants' time. Distance between home and health centres.	May limit women's attendance at sessions.	Based on PST attendance in South Africa (Sorsdahl, Stein, et al., 2015; Spedding et al., 2020; van der Westhuizen et al., 2021), PST-IPV was designed to be four sessions long. Health workers coincided PST-IPV sessions with routine ANC appointments wherever possible. Session timings were flexible and accommodated women's priorities (e.g. needing to attend market days).	None.	Avoid attendance becoming burdensome for busy women.
Adaptation workshop ToC workshop	Women might miss sessions and be difficult to reach afterwards.	Not all women can be reached via mobile phone.	Three attempts were made to reach women missing sessions, either by telephone or a home visit by their local HEW (the usual system for following up missed ANC appointments).	None.	Follow women up without pressurising them.
Study Two Adaptation workshop ToC workshop	Costs of transport to and from the health centre.	May limit women's attendance at sessions.	Women were reimbursed for out-of-pocket expenses incurred by attending sessions, such as transport costs.	None.	Avoid financial penalties for attending sessions.
Intervention constraints					
PST training course feedback	MI difficult to understand, readiness to change, 'rolling with resistance' culturally discordant.	An overly complicated intervention could impede women's comprehension and engagement.	Following discussion of the purpose MI would serve in this context, and consideration of alternatives (such as simplifying the MI component), the adaptation team agreed to remove the MI component from MI-PST.	None.	Simplify intervention content and focus all content on women's needs.
PST training course feedback	PST phases (identifying the most important things in life, listing problems) could be difficult to separate.	A mental health PhD researcher suggested that goals and problems could be easily conflated.	The manual, flip-chart and session record forms emphasised the separation between phases. Training devoted time for health workers to practise guiding women through phases, under supervision. Supervisors monitored difficulties with separation of phases by monitoring audio-recorded sessions.	None.	Ensure that session content and structure are clear to health workers and women.

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<i>Sources</i>	<i>Constraint</i>	<i>Potential impact</i>	<i>Adaptation in PST-IPV</i>	<i>Difference from standard PST</i>	<i>Intended impact</i>
PST training course feedback	MI-PST classified ‘group A’ problems as ‘unimportant’ or ‘irrelevant’. This was considered unsympathetic by stakeholders (feelings often in this category).	Staff describing some problems (including emotions) as ‘unimportant’ or ‘irrelevant’ may alienate women or dismiss their distress.	Following discussion of the most appropriate Amharic terminology to differentiate ‘group A’ problems, the term ‘lower priority problems’ was selected. The letters A, B, and C were removed from the manual, not being culturally congruent. Care was taken to consider appropriate translations into Amharic, such as <i>chinket</i> (stress) or “thinking too much”, rather than “depression”.	None.	Intervention language tailored to cultural preferences, to be empathetic and supportive.
PST training course feedback Theatre testing	‘B’ and ‘C’ problems called ‘important/cannot be solved’ and ‘important, can be solved’ in MI-PST.	‘Solvable’ was considered problematic, as many problems may not be solved by PST-IPV.	Following discussion of terminology to differentiate ‘group B’, ‘important but cannot be changed’ was selected. ‘Group C’ became ‘important and <i>can</i> be changed,’ to avoid implying that all problems would be solved. A, B, and C were removed from the manual.	None.	Intervention language aimed to be culturally appropriate and clear.
PST training course feedback Supervisor feedback from intervention training	‘Worry Time’ and ‘Thinking Stop’ may not be culturally valid approaches to lower priority problems.	Health workers may struggle to explain/women may struggle to implement these coping strategies.	The adaptation team agreed to trial simple versions of these coping strategies through the randomised feasibility study (Study Four).	A standard PST supervisor suggested that Worry Time sitting beside the river might be more culturally congruent.	Content was tailored to the cultural context but retained the core elements of problem-solving therapy.
PST training course feedback Theatre testing Evidence review	Literacy barriers to writing thoughts out (The World Bank, 2020b).	Writing positive thoughts might be an impractical coping strategy.	This coping strategy for ‘lower priority problems’ was altered to making a mental list of five positive thoughts to be counted off on one hand.	None.	Coping strategies tailored for the social context.
PST training course feedback Adaptation workshop Evidence review	The MI-PST model lacks a coping strategy for emotional distress.	Such techniques may be especially needed by women with trauma symptoms, which are common here.	Slow breathing and progressive muscle relaxation (p.p. 70-71; WHO, 2014) were added to both interventions. Similar techniques were being investigated among people with SMI and a history of trauma in this setting, suggesting their relevance to women experiencing emotional distress and IPV (Ng, Serba, Dubale, Fekadu, & Hanlon, 2021).	Added to standard PST and PST-IPV, to standardise the psychological elements across both trial arms.	Standard PST and PST-IPV offer culturally acceptable strategies for acute distress.

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<i>Sources</i>	<i>Constraint</i>	<i>Potential impact</i>	<i>Adaptation in PST-IPV</i>	<i>Difference from standard PST</i>	<i>Intended impact</i>
PST training course feedback Evidence review	'Group B' problems (important but cannot be changed) may include traumatic losses (Spedding et al., 2020).	Health workers may experience vicarious trauma or feel inhibited about discussing trauma.	Regular supervision by consistent specialists who delivered training courses facilitated sharing of distressing content and identified missed opportunities within sessions for health workers to encourage women's disclosure. Health workers were supported by their supervisors to access mental health or IPV support for themselves, if needed.	None.	Staff supported to safely deliver sessions without compromising well-being.
Adaptation workshop	'Problem busting session' term for 'group C' problems considered unclear.	This terminology was considered Western.	Following discussion, 'problem busting sessions' were translated as <i>cigeren derja bedereja mefetate</i> , meaning 'step by step resolution of problems'.	None.	Accessible terminology.
Implementation constraints					
PST training course feedback Theatre testing Evidence review	Complexity of MI-PST materials was incompatible with literacy and education levels.	Complicated content could detract from therapeutic interactions.	The manual and intervention materials were simplified in line with literacy (The World Bank, 2020b) and education (Ethiopian Public Health Institute & ICF, 2019) levels. Training and intervention materials included local illustrations. Training emphasised pacing for women's needs/understanding.	None.	Simple, accessible intervention content.
PST training course feedback Theatre testing	Unfamiliarity requires health workers to read some standardised content aloud.	Staff may struggle to communicate empathetically while adhering to the manual.	A desktop flip-chart resource was developed, with a culturally congruent image facing the woman and key Amharic text facing the health worker, as an in-session prompt or 'job aid'.	None: flipchart standardised so the same resource could be used by both interventions.	Standardised content, enabling staff to focus on communication.
Theatre testing	Excessive content in Session 2 compared to 3	Women might disengage from excessive detail.	The balance of content between sessions was re-organised in line with stakeholder feedback, by moving some material from Session 2 into Session 3.	None.	Content spread across sessions for even pace.
Study Two PST training course feedback Evidence review	The MI-PST training model should be adapted for the Ethiopian context.	Unfamiliar context or style could reduce effectiveness and session engagement.	Contextual references were adapted throughout (Craig et al., 2018). A fictional case (Belaynesh) gave examples throughout the manual, e.g. problems, most important things in her life. Introductory information about perinatal mental health in Ethiopia, culturally adapted references, and local illustrations.	Only the PST-IPV manual included IPV-related problem examples and information about IPV in Ethiopia.	Content tailored to needs and experiences of pregnant women in this setting.

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<i>Sources</i>	<i>Constraint</i>	<i>Potential impact</i>	<i>Adaptation in PST-IPV</i>	<i>Difference from standard PST</i>	<i>Intended impact</i>
PST training course feedback Evidence review	MI-PST model of self-filled paper booklets brought to sessions incompatible with literacy and education levels.	Paper booklets could alienate women with limited education and pose confidentiality risks.	The MI-PST booklet was adapted into a session record form, completed and securely retained (for confidentiality reasons) by health workers, and referred back to in subsequent sessions. Each session ended with a summary of content and take-home activities for the next session. The next session began with a review of progress on implementing skills and techniques.	None.	Acceptability and feasibility of PST-IPV were optimised. (Take-home activities may be affected).
PST training course feedback Theatre testing	Women may struggle to complete take-home activities without paper booklets.	MI-PST permitted participants to be aided with reading and writing take-home activities by a trusted person.	Reading booklets aloud was considered by stakeholders to violate confidentiality, given women's concerns about this and community judgement in Study Two. Abusive partners might also learn about women's participation from paper booklets. Take-home activity completion without self-filled paper booklets was therefore a focus for process evaluation.	None.	Study Four was designed to evaluate whether take-home activities practicable without booklets.
IPV-related constraints					
Adaptation workshop	Abusive partners and other relatives may prevent women from attending (Bitew et al., 2020).	Women may be prevented from attending sessions in addition to ANC by abusive partners.	Sessions were organised to coincide with routine ANC appointments, as far as possible. A leaflet about general perinatal well-being was prepared, explaining that women were being offered additional sessions during ANC for their well-being, without specific details.	None.	Interventions were integrated into usual ANC as much as possible, to optimise their accessibility.
Study Two Theatre testing ToC workshops Evidence review	Some stakeholders proposed that partners should be involved in sessions.	Some stakeholders proposed that problem-solving between partners could be facilitated by them attending sessions.	This suggestion was not followed due to risks (WHO, 2014) of involving partners in therapeutic sessions (Study Two, ToC workshops), and evidence that a local couples' intervention did not reduce IPV perpetration (Sharma et al., 2020). Requests to involve partners were noted for process evaluation.	None.	Partners were not involved, to maintain safety and focus sessions on women's needs.

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<i>Sources</i>	<i>Constraint</i>	<i>Potential impact</i>	<i>Adaptation in PST-IPV</i>	<i>Difference from standard PST</i>	<i>Intended impact</i>
Study Two PST training course feedback Evidence review	ANC staff have not received prior training on IPV. Widespread IPV, unequal gender norms and reinforcement of IPV. Some health workers may themselves be experiencing IPV.	May prevent health workers from asking about IPV and responding empathetically.	The PST-IPV manual was adapted in line with international curricula (Stewart & Chandra, 2017; WHO, 2019b), addressing IPV, its prevalence in Ethiopia, impact on pregnancy, children, and mental health, with six anonymised quotations (Study two). Staff were trained to use 'LIVES': listen, inquire, validate, enhance safety, and support the woman (WHO, 2014). The PST-IPV training course included tailored activities using: <ul style="list-style-type: none"> Adapted role plays (p.p. 48-49; Stewart & Chandra, 2017). Role plays on responding to IPV-related problems in PST. An adapted list of common questions about IPV (p.p. 14-15; WHO, 2019b). An adapted 'myths versus facts' resource prepared for a 'DoVES' training course delivered to UK clinicians (2019). Translated 'power and control wheel' (DAIP, 2008) resources (one for pregnancy). Power and control were addressed by <i>Nguvu</i>, for Congolese refugees experiencing IPV (Greene et al., 2021; Tol et al., 2017) A 'losses and gains' exercise to help health workers consider why women may not leave abusive partners. An anonymised transcript of a survivor's experience from Study Two for small-group discussion. 	The standard PST manual and training course did not explicitly discuss IPV at all.	PST-IPV were adapted from standard PST to meet the needs of women experiencing IPV, by training ANC staff to empathetically inquire and respond to IPV-related problems.
Study Two Evidence review	Ineffectual existing responses to IPV.	May prevent women from disclosing IPV or stop health workers from asking about or responding to IPV.	Training incorporated content on IPV, as outlined above. Health workers received regular supervision from the psychiatrist and psychologist who trained them to deliver PST-IPV sessions, in which they discussed IPV and any risks. The trial standard operating procedure included clear processes for responding to risk disclosures and safety concerns (see Study Four).	The standard PST manual and training course did not explicitly discuss IPV at all. Standard PST trainers were not sensitised to IPV by the study.	PST-IPV and Study Four were designed to safely support women experiencing IPV and respond to risk/safety concerns.

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Sources	Constraint	Potential impact	Adaptation in PST-IPV	Difference from standard PST	Intended impact
PST training course feedback ToC workshop Evidence review	Exploring IPV requires sensitivity and safeguards.	Unintended harms could arise from unhelpful/unsafe discussions of IPV.	Training incorporated content on IPV, as outlined above. The PST-IPV manual, training, and standard operating procedure were adapted to follow international guidelines for IPV research and interventions (Ellsberg & Heise, 2005; WHO, 2013c, 2014, 2016c, 2019b). Safeguards were integral to the feasibility study of PST-IPV, including adherence to GCP principles and clear processes for responding to risk and safety concerns (see Study Four).	Uniform conduct of Study Four (such as ensuring privacy when screening women for IPV exposure in ANC). IPV-specific training confined to PST-IPV arm health workers.	PST-IPV and Study Four were designed to prioritise women's safety and prevent unintended harms.
PST training course feedback	Adapting standard PST for women experiencing IPV by adding a training module or day covering IPV would be insufficient to address IPV-related difficulties.	Stakeholders thought that IPV adaptations should be integrated into the PST model, rather than comprising stand-alone training.	To ensure that health workers were adequately trained to deliver PST-IPV, and that IPV's relevance to women's emotional difficulties was integrated into intervention sessions, IPV-related concerns were woven throughout the intervention manual and training model, as described above. Modular IPV training would also raise methodological difficulties of comparing the effects of shorter health worker training (standard PST) with longer training (PST-IPV).	The standard PST training course was the same length (5 days) as the PST-IPV course, but included more PST discussion and practice, in place of IPV content.	Adaptations for women experiencing IPV were integrated into the standard PST model, rather than a stand-alone module.
Study Two PST training course feedback Adaptation workshop Evidence review	Women might categorise IPV as 'group A' (lower priority problems) or 'group B' (problems that cannot be changed).	If IPV was categorised as being of lower priority or incapable of change during sessions, women could feel blamed or responsible for IPV, that their distress was dismissed, or that their situation was hopeless.	The adaptation team agreed that IPV-related problems must always be categorised as 'group C' (important and <i>can</i> be changed). A section explaining the importance of this issue was included in the PST-IPV manual. This point was reiterated during training and supervision.	IPV was not explicitly addressed in training or materials for health workers delivering standard PST. Whether IPV was discussed during sessions of both interventions, and for how long, were noted during process evaluation.	Health workers trained to deliver PST-IPV sessions were trained to ensure that IPV-related problems were not categorised as being of a lower priority or incapable of being changed.

6.4.3.2 Materials

When adapting the standard PST manual for the needs of women experiencing IPV, I consulted international clinical and policy guidelines (WHO, 2013c), a recent international clinical curriculum for health workers caring for women subjected to violence (WHO, 2019b), and the associated clinical handbook (WHO, 2014). I also consulted an international guide for researchers investigating violence against women (Ellsberg & Heise, 2005), and ethical and safety recommendations (WHO, 2016c).

Once both manuals were finalised, TB and I collaboratively developed a single desktop flip-chart resource, with a culturally-appropriate illustration facing the pregnant woman, and brief Amharic prompts facing the health worker. We opted to share this resource between both interventions, because the core session content of both interventions was shared. We also designed an illustrated Amharic language leaflet on well-being in pregnancy, which was provided to all participants, to assist recruitment of eligible women into Study Four.

To design the content of PST-IPV training, I reviewed the World Psychiatric Association curriculum on IPV and sexual violence against women (Stewart & Chandra, 2017), and resources used in a domestic abuse simulation course ('DoVES') delivered to UK mental health professionals by Maudsley Learning and the voluntary sector organisation, Standing Together, in December 2019. I additionally reviewed the content of psychological interventions adapted for women experiencing IPV in LMICs (Greene et al., 2019; Latif & Khanam, 2017; Orang et al., 2018), and a local Ethiopian IPV and HIV transmission prevention intervention (Leight et al., 2020; Leight, Deyessa, Verani, Tewolde, & Sharma, 2021; Sharma et al., 2020). I gave particular consideration to potential unintended harms caused by both standard PST and PST-IPV to women experiencing IPV, which informed the 'dark logic model' (see section 6.5.2.14).

To standardise PST-IPV training, I wrote an English language facilitator manual and training plan for a five day health worker course, with key documents, including role play scenarios, translated into Amharic (Appendix 10.3.1 and uploaded to the open-access repository at Keynejad (2021)), which was adapted by TB for the standard PST course.

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With input from Amharic-speaking team members, I prepared Amharic-language lecture slides incorporating translated content from key sections of the PST-IPV manual, using PowerPoint software (Microsoft Corporation, 2008b), for use during training.

The final English versions of the adapted intervention manual (version PST-IPV_1.0) and flip-chart resource were translated into Amharic by an experienced translator who had worked on Study Two (KK). They were then proof-read and reviewed for clarity and cultural appropriateness by the female trial coordinator and research assistant, who suggested amendments.³¹

I sought to visually enhance the manuals and flip-chart (Figure 6.2, Figure 6.3, and Figure 6.4), lecture slides (Figure 6.5), and leaflet (Figure 6.6), emphasise the relevance of training to health workers' clinical practice, and enhance trainees' engagement with visual learning. I therefore recruited an Ethiopian artist (NK) with experience of illustrating health intervention materials in this setting,³² and obtained permission from a Dutch artist (NM) to reproduce several locally-inspired drawings of Ethiopian women experiencing perinatal depression.

Finally, the English PST-IPV manual was professionally formatted.³³ I applied this formatting to the Amharic version of the manual, the Amharic-language lecture slides, and the training manual and facilitator guide, to further standardise the visual branding of intervention materials. The final versions of PST-IPV training and intervention materials are uploaded to the open access repository (Keynejad, 2021). The English language manual will be made open access once the original intervention (Sorsdahl, Myers, et al., 2015) has been shared publicly.

³¹ Ethiopian psychiatrists and psychologists delivering standard PST and PST-IPV training courses requested a copy of their manual in English, as they were unaccustomed to reading clinical texts in Amharic.

³² TB and I described the images required to illustrate the flip chart, the standard PST and PST-IPV manuals, and the coronavirus standard operating procedure, in English. NK then prepared bespoke images, which were reviewed for clarity and cultural appropriateness by EF, AMu and TB, before being iteratively revised.

³³ By a female South African communications and research uptake officer for the ASSET study (MM).

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1. የምንቀት ጊዜ



- አንድ ቤት ሁል ጊዜ አሰራጻ ገልጿል። ገዳማዎች ላይ የምትገኙት ከሆነ በቀን ውስጥ የተወሰነ 'የምንቀት ጊዜ' መመዘን ትችላለች። ይህም ዝቅተኛ ትኩረት ለሌሎች ስሜቶች ማድረግ ያስፈልጋል። አንድ ገንዘብ የሚጠይቀው ጥቅም ይቆያል። ለምሳሌ ያህል፡- 'ባለቤት ጭስ በልጥ ወደ ሥራ ከጸና በኋላ አንድ ሰኔ በሩ ለመጠጣት የሚወስድበትን ጊዜ ያህል የምገልግልበት ጊዜ አለኝ'። ማለት ትችላለች።
- ከዚህ የምንቀት ጊዜ ውጭ ለሌሎች ጉዳዮች ነገሮች አንድ ገንዘብ ላይ ይቆያል። 'አሁን ገንዘብ አሁን ለማግኘት አስተዳደራዊ ነገሮች የምንቀት ጊዜዎ አስከፊ ለመሆን አይችልም' ብለው ለሌሎች ማንን ትችላለች። በምንቀት ጊዜ ውስጥ የተወሰነ ጊዜ መቆየት እና ሌላ ሥራ ስሜት ስለ ችግሮች ብቻ ማሰብ ይገባል። በዚህ ማንን ከሁሉም የምንቀት ጊዜዎች ገለጻል። በአካሉ ላይ ማቆየት ያለው ጊዜ ለማሰብ አንድም ትኩረት ይወስዳል። ይህ በአካሉ ላይ የተሻለ ጭጥር አንድም ያደርጋል።

2. ማሰብ ማቆየት



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Coping with negative thoughts (A: Lower Priority Problems)

If the woman is worrying about something that does not affect the things that are important to her, then this probably has to do with her thoughts. What she is thinking has a major effect on her feelings. For example, one woman may think that coffee ceremony is a pleasant gathering of friendly people, so when she considers attending she feels excited or happy and goes along. Another woman may think that coffee ceremony is a chance for people to gossip and say negative things, so when she considers attending she feels anxious and afraid, and decides not to go. In this example, each woman's thoughts affect her emotions (excitement or anxiety) and her behaviour (attending or not attending).

Likewise, Belaynesh feels upset because her coffee pot is broken. Still, the coffee pot itself is nothing to get upset about. The thing that is really upsetting her is the idea that 'if only I had put it somewhere safer, it wouldn't be broken and my husband would not have got so angry and beaten me. It's all my fault'. In this case, the real problem is the way that Belaynesh's husband responds to problems (getting very angry) and expresses his feelings (beating her). This problem (IPV) is one that can be changed. We will discuss how to address problems that can be changed later.

Some people struggle to stop thinking too much (for example, thinking over and over about the broken coffee pot). They know that negative thoughts may be wrong, or not good for their mood, but they simply cannot get rid of them. There are ways to get this sort of thinking under control. These include: 1) Worry time, 2) The Thinking stop, and 3) Keeping a list of positive thoughts:

1. Worry Time

- If a woman is always worrying about things that don't really matter, she could set aside some 'worry time' in her day. This could be a few minutes during which she allows herself to think about her lower priority problems. She could say, for instance: 'After my husband has eaten breakfast and gone out into the field, I will have my worry time for as long as it takes to drink a cup of coffee.'
- Outside of this worry time, she is not allowed to think about the things that are bothering her. She could say to herself: 'I'm not allowed to think about this now, I will wait until'

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- ምናልባት አሁንም ማሰብ ማቆየት ማድረግ ስሜት ለማግኘት አስፈላጊ ሊሆን ይችላል።
- አሁንም የምንቀት ጊዜ ማሰብ ማቆየት ብቻ ለሌሎች ስሜት ለማግኘት ማድረግ ሊያቅድ ይችላል። በዚህ ሁኔታ ውስጥ 'የማሰብ ማቆየት' ዘዴን ልትጠቀሙ ትችላለች።
- አሁንም የምንቀት ጊዜ ወደ ምንቀት ጊዜ ይሆን የምንቀት ጊዜ ለማድረግ ትችላለች። ለሌሎች 'አሁን ገንዘብ ማሰብ አቅጣጫ' ትኩረት ለማድረግ ይህም የምንቀት ጊዜ ለማሰብ ትችላለች።
- አንዳንድ ሰዎች ለምንቀት ጊዜ ወደ ምንቀት ጊዜ ይሆን ማሰብ ማቆየት ማድረግ ይችላሉ።
- ወደ ሌሎች ምንቀት ጊዜ የሚሉ አሁንም የምንቀት ጊዜ ለማድረግ ሌሎች ማንን በእጅ ከገንዘብ አካሉ ወይንም ሌላን ነገር ማሰብ ማድረግ ነው። ይህ የምንቀት ጊዜ ለማሰብ አንድም ያደርጋል።
- በተጨማሪም ሌሎች ለምንቀት ጊዜ ለማሰብ በአካሉ ላይ ማሰብ ማቆየት አስፈላጊ ነው። ቀጣይ ስትራቴጂዎች ለምንቀት ጊዜ ለማሰብ አንድም ያደርጋል።

3. የምንቀት ጊዜ ማሰብ ማቆየት



66

- ቀን አስተሳሰብ አንድም ለማሰብ ማቆየት አስፈላጊ ነው።
- ይህ ጭጥር ሌሎች ለምንቀት ጊዜ ማሰብ ማቆየት ይችላሉ። ማንን የሚሰጡ ሌሎች ለምንቀት ጊዜ ማሰብ ማቆየት ይችላሉ። ማንን የሚሰጡ ሌሎች የእጃቸውን ጥቅም ለማግኘት ለምንቀት ጊዜ ማሰብ ማቆየት ይችላሉ።

worry time. During her worry time, she should sit in a specific place and think about her worries and do nothing else. In this way, she is not escaping her negative thoughts, but she decides when and how much time to spend on them. This gives her better control over these thoughts.



2. The Thinking Stop

- It may be that negative thoughts continue to come up, and the woman is struggling to find a solution.
- The negative thoughts may pop into her head and she may not be able to do anything about it. In this situation, she might try the 'thinking stop' method.
- As soon as a negative thought comes up, she forces herself to interrupt this thought. She says to herself, 'I'm going to stop thinking about this' and then she returns to the non-negative thoughts she had earlier.
- Some people find it helps if they say STOP to themselves in their head.
- Another way to cope with negative thoughts popping into the woman's head is for her to practise tapping her hand on her arm, leg or a surface. This can help to stop the thought while she imagines it exploding or breaking into pieces.
- It is also important to encourage the woman to replace negative thoughts with a positive thought. The next strategy is a tool for helping her to identify a positive thought.



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Figure 6.2 PST-IPV manual pages
 Pages are reproduced in Amharic (top) and English (bottom).
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6ሀ ደረጃ 2፡- ጭንቀቶችን ወይም ችግሮችን ምንድናቸው?

- አሁን እንኛን በሚያስጨንቁበት ሁሉም ነገሮች ላይ ለመወያየት ጥቂት ጊዜ እንወስዳለን። እንዳንረሳቸው እኔ እጽፋቸዋለሁ።
- እነዚህ ጭንቀቶችን፣ ሀዘን፣ ውጥረት፣ ጭንቀት፣ ገዴት ወይም መጥፎ ስሜት እንዲለማቸው የሚያደርጉ ነገሮች ናቸው። የሚያስጨንቁበት ነገሮች ምንድን ናቸው? በሕይወትሽ ውስጥ ከሁሉም ነገር በላይ አስፈላጊ የሆኑ ነገሮች እንዳይላኩ የሚያደርገው ነገር ምንድን ነው? [ጋ.የስድስትኛው ደረጃ 1]
- ሁሉንም ችግሮች በአንድ ጊዜ መቆታት አይቻልም። በመጀመሪያ ችግሮቹ ምን ዓይነት ችግሮች እንደሆኑ ማለብ አለብን። ሦስት ዓይነት ችግሮች አሉ።

ሀ፡- ዝቅተኛ ትኩረትን የሚሹ ችግሮች፡- እነዚህ ችግሮች የሚረብሩ ችግሮች ናቸው። ነገር ግን በሀይወትሽ ውስጥ ከሁሉም በላይ አስፈላጊ የሆኑ ነገሮች ላይ ተሳታፊ እያደርገንም።

ለምሳሌ፤ የቡናው ጀብና ተሰብሯል፣ አንድ ስህተት ሰርቻለሁ፣ ዛሬ ጤፍ መግዛት ረሳሁ፣ እንደሌሎች ሰዎች ጥሩ ሁኔታ ላይ አይደለሁም እያልኩ አስባለሁ፣ ነገሮችን ማስተካከል በጥቅራቄ እንደማልችል አስባለሁ።


በስድስት ደረጃ 2 ውስጥ እነዚህን የሚረብሩ ወይም የሚያበሳጩ ችግሮች እና ጭንቀቶች እንዴት በቁጥጥር ስር ማዋል እንደምንችል እንማራለን።




6A Phase 2: What are your worries or problems?

- Now, we will take some time to discuss everything that bothers you. I will write them down so that we don't forget what they are.
- These are your worries and the things that make you sad, tense, anxious, angry or feel bad. What are the things that make you worry? What gets in the way of the most important things in your life? [ጋ. Session record 1]
- It is impossible to address all problems at once. We need to think about what types of problems they are first. There are three types of problems.

A: Lower Priority Problems. These are problems that are upsetting but do not affect the most important things in your life. For example, the coffee pot is broken, I made a mistake, I forgot to buy teff today, I keep thinking that I'm not as good as other people, I keep thinking that I will never get things right. In Session 2, we will learn how to get these irritating or upsetting problems and worries under control.



6ለ፡- የሚያስጨንቁበት ጉዳዮች ወይም ችግሮችን ምንድናቸው?



6B: What are your Worries or Problems?




Figure 6.3 Flip-chart resource pages
 Pages are reproduced in Amharic (top) and English (bottom). The right-sided page faces the pregnant woman and the left-sided page faces the health worker. Illustration credits: Kidanemariam (2020).

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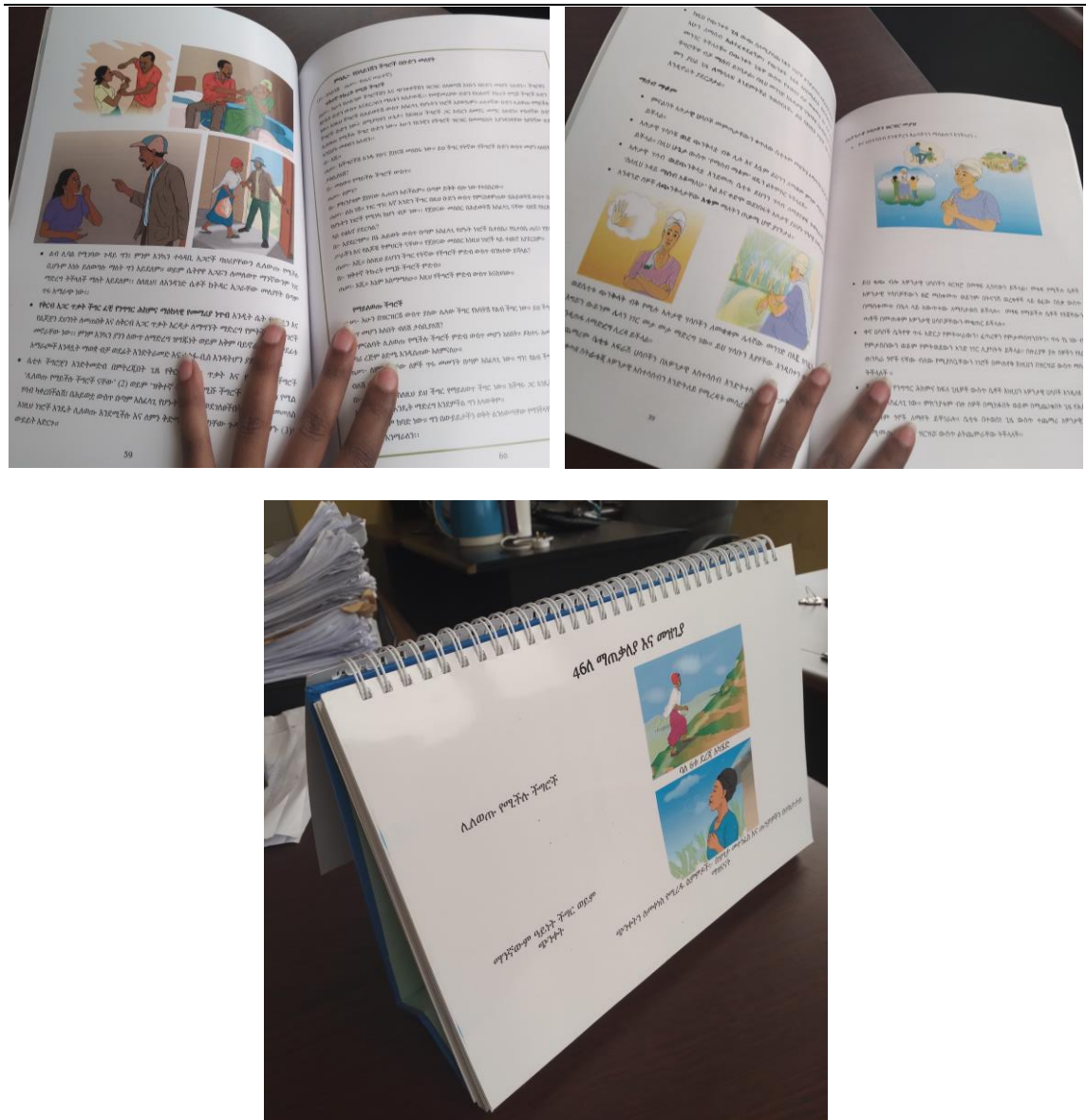


Figure 6.4 PST-IPV manual (top) and flip-chart (bottom) images
Illustration credits: Kidanemariam (2020).

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The figure displays 12 Amharic lecture slides from a PST-IPV training course. Each slide includes text, illustrations, and bullet points. The slides are numbered 1 through 42. The content covers topics like 'Perinatal Loss', 'Pregnancy and Birth', 'Partner Violence', 'Prenatal Loss', 'Postnatal Loss', 'Prenatal Loss', 'Postnatal Loss', 'Prenatal Loss', 'Postnatal Loss', 'Prenatal Loss', 'Postnatal Loss', and 'Prenatal Loss'.

Figure 6.5 PST-IPV training course lecture slide examples, in Amharic

Top two illustrations shared with kind permission of Mathijsen (2019).
All other illustration credits: Kidanemariam (2020).

6.4.3.3 *Unintended consequences*

At every stage, I considered adaptations which could optimise women and staff members' safety and well-being. I explicitly considered unintended consequences under the dark logic model (section 6.5.2.14). I mitigated for these as far as possible, through adaptations and implementation strategies in the Study Four standard operating procedure (SOP), which is uploaded to the open access repository (Keynejad, 2021).

6.4.3.4 *Delivery*

Pregnant women and health workers identified health centre midwives and other ANC staff as best-suited to deliver intervention sessions in Study Two. The trial coordinator and research assistant had worked on a large-scale ANC survey in Sodo, during which they had built relationships with local health centres.³⁴ With my first supervisor, I monitored contextual developments potentially impacting intervention delivery closely, prioritising the safety of women, health workers and researchers at all times.

With my supervisor (CH) and Ethiopian collaborator (TB), I identified Bu'i primary hospital and Kela health centre as potential pilot sites, due to their previous engagement with ASSET research (Seward et al., 2021), but not being enrolled in other intervention studies. Both are conveniently located on the road from Addis Ababa (Figure 6.7), ensuring accessibility to women and research staff during the summer rainy season. The trial coordinator and research assistant approached health centre managers to discuss the acceptability of training health workers to deliver sessions and accommodating those sessions within their working hours.

³⁴ Previously eligible health centres in Meskan and Mareko districts became unsuitable, following an episode of inter-ethnic violence reported on 15th November 2018, due to risks posed to researchers, health workers, and pregnant women (Addis Standard, 2018).

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Figure 6.7 Study site locations in relation to Addis Ababa

Orange: Bu'i primary hospital, green: Kela health centre (Google My Maps, 2021).

Following managers' agreement, Good Clinical Practice (GCP; European Medicines Agency, 2016) training was delivered to all health workers from both participating sites by an experienced master trainer on 31st January 2021. Information about Study Four and the adapted intervention was then provided to ANC staff and district health officials at a wider ASSET meeting on 15th February 2021. Health workers' interest in attending training and delivering sessions was gauged, and the most acceptable method for allocating staff to study arms was collaboratively discussed.

6.4.4 Reporting

Interventions are often poorly reported, in insufficient detail, despite this being crucial for their transfer to different contexts. The 12 item TIDieR (template for intervention description and replication) checklist (Hoffmann et al., 2014) was devised to address this

problem. Given its clarity and intuitive simplicity, I used TIDieR to document PST-IPV, with three recommended modifications (Cotterill et al., 2018). Table 10.5 in Appendix 10.3.2 reports the format, structure and content of PST-IPV, using the modified TIDieR checklist. Appendix 10.3.3 describes session content and Appendix 10.3.4 summarises training, competence assessment, and supervision arrangements.

6.4.5 Piloting and evaluation

Step 3 of ADAPT guidance (Moore et al., 2021) is to plan for and undertake piloting and evaluation. This step comprises considering the extent and type of evaluation warranted, and evaluating feasibility, which are described in Study Four. Step 3 also includes considering the value of new information to stakeholders (section 6.4.5.1), and documenting and classifying responsive adaptations (section 6.4.5.2). I consider these stages below.

6.4.5.1 Information value

My intervention review of evidence (section 2.10.2) confirmed the paucity of studies reporting process evaluations of brief psychological interventions for women experiencing IPV in LMICs, including during pregnancy. This suggested that the potential value of new information on this subject to policy makers, practitioners and other stakeholders would be high, justifying the investment of time and resources.

6.4.5.2 Document and classify responsive adaptations

New MRC/NIHR complex interventions guidance (Skivington et al., 2021) and ADAPT guidance outlined how interventions introduced into complex systems often self-organise, through the actions of involved stakeholders (Moore et al., 2021). Feedback from the complex system also causes those delivering the intervention to adjust their practice, informed by local expertise. Thus, intervention delivery entails responsive adaptation, which must be captured to determine whether it threatens the intervention's theoretical principles or underlying mechanisms (p. 46). Moore et al. (2021) proposed that decisions about retaining responsive adaptations in future intervention iterations could be made by considering whether they enhanced intervention-context fit, maintained fidelity to the

intervention's intended functions and processes, or influenced wider factors, such as engagement (p. 47).

The framework for reporting adaptations and modifications – expanded (FRAME; Stirman, Baumann, & Miller, 2019) recommended noting when responsive adaptation occurred, whether it was planned, who decided to adapt, why, what was changed and what type of content was adapted. The iterative decision-making for evaluation of adaptations (IDEA; Miller, Wiltsey-Stirman, & Baumann, 2020) decision tree built on FRAME to facilitate retention or rejection of iterative modifications. I therefore planned to record responsive adaptations during Study Four, using FRAME, and review their retention or rejection using IDEA.

6.4.6 Implementation and maintenance

Step 4 of ADAPT guidance: implementing and maintaining the adapted intervention at scale (Moore et al., 2021) was beyond the scope of this PhD. However, in keeping with the principle of intervention development as future-looking to ultimate implementation (O'Cathain et al., 2019), I sought to build on the substantial engagement of stakeholders in Study Three by developing sustainable partnerships with health centre managers and ANC staff. To obtain meaningful buy-in, I sought to time the training course and intervention implementation to suit staff needs and availability. I planned to disseminate the findings of Study Three through post-trial engagement events, where possible, given coronavirus restrictions. In terms of establishing data monitoring systems for a future trial, Study Four piloted the use of a digital platform enabling data to be entered using a smartphone (section 7.4.17). I reviewed the use of this system during the process evaluation.

6.5 Articulating programme theory

Throughout the adaptation process, I sought to articulate the programme theory for PST-IPV, as recommended by the new MRC/NIHR framework for complex intervention development and adaptation (Skivington et al., 2021). Following ADAPT guidance, I reviewed existing relevant theory (section 6.5.1), conducted a ToC workshop with stakeholders (section 6.5.2), and documented the results on a ToC map (section 6.5.3).

6.5.1 Theory review

I identified literature on intervention mechanisms, mid-range theories, barriers and facilitators to implementation success, and contextually relevant theories of change, which informed my own ToC.

6.5.1.1 *Intervention Mechanisms*

It has been recommended that RCTs of psychological interventions evaluate mediators of treatment and mechanisms of change (Kazdin, 2007), to determine ‘what works for whom’ (Norcross & Wampold, 2011). Hypothesised core (rather than peripheral) intervention components (Chu & Leino, 2017) of PST have included improving mastery, self-control and the accuracy of perceived problem severity (Mynors-Wallis, 2002), problem-solving skills (Alexopoulos, Raue, & Areán, 2003), ‘life integration’ (Arean et al., 1993), and locus of control (attribution of experiences to internal or external factors; Nezu, 1986).

An RCT comparing PST for depression with online CBT and a waiting list control found that the efficacy of both interventions was mediated by reduced dysfunctional attitudes, worry, negativity towards problems, and increased mastery (Warmerdam et al., 2010). There was no difference in effect sizes between PST and online CBT. The authors proposed that both interventions increased participants’ anticipated self-efficacy, leading to greater initiation and continuation of coping behaviours (Bandura, 1977).

Improving self-efficacy and coping behaviours might also benefit women experiencing IPV. A systematic review of mental health interventions for people experiencing and perpetrating IPV in LMICs suggested that treating depression and PTSD could reduce self-blame, low self-esteem, hopelessness and emotional numbing, and improve communication, stress coping, and anger management skills in both groups (Tol et al., 2019). Multiple mediation analysis of the Thinking Healthy Program delivered by peers found that perceived social support mediated improvements in perinatal depression at six months’ follow-up, in both India and Pakistan (Singla et al., 2021).

Study heterogeneity, methodological quality and, perhaps, complexity of impact, mean that demonstrating a causal link between change in a hypothesised mediator and change in depressive symptoms remains elusive (Lemmens, Müller, Arntz, & Huibers, 2016). Furthermore, no common or specific features of psychological interventions have a demonstrated dose-response relationship with symptom improvement, unaffected by a third variable, alongside a strong theoretical basis and supportive experimental research (Cuijpers, Reijnders, & Huibers, 2019).

6.5.1.2 Mid-range theories

One theory of how PST-IPV could improve the perinatal emotional difficulties of women experiencing IPV is through empowerment. Revollo and Portela (2019) characterised empowerment as active participation in a process of change. They considered agency (“the ability to formulate strategic and purposeful choices, control resources and make decisions that affect important life outcomes”; p. 7) to be central. Revollo and Portela (2019) acknowledged that resources are often required to exercise agency, but that access to resources does not necessarily ensure choice or control.

Although access to resources has been used as an indirect measure of empowerment, directly measuring psychological feelings of power and competence may be more informative (Revollo & Portela, 2019). The authors therefore compared agency, measured using a locus of control scale, and self-efficacy, among 3,000 Ethiopian adolescents enrolled in the Young Lives longitudinal cohort study, at 12, 15, 19 and 22 years of age (1,000 born in 1994-5 and 2,000 born in 2001-2). They found that boys and young men had higher self-efficacy than girls and young women at all ages. Boys also showed mostly higher agency than girls, but differences were not always statistically significant. Gender differences in agency were smaller in the younger than the older birth cohort, suggesting that the parental generation might experience still larger gender differences in agency.

The trans-theoretical model (Prochaska et al., 1994) is a commonly-referenced mid-range theory of how behaviour change interventions may work. However, as discussed in Study One (section 3.5.4), its application to people experiencing IPV (Brown, 1997) has been

challenged, using qualitative evidence. Cluss et al. (2006) instead proposed a psychosocial readiness model, whereby readiness to change an abusive relationship is influenced by internal factors, external factors, and interpersonal interactions. Internal factors included perceived support and self-efficacy, while external factors comprised situational factors and interpersonal interactions, such as conversations with health workers. Under Cluss et al. (2006)'s model, alterations in women's psychosocial readiness for change could mediate the effectiveness of psychological interventions.

A recent meta-analysis of psychological interventions for women experiencing IPV (Hameed et al., 2020) found only four RCTs which measured self-efficacy as an outcome, of which one conducted medium-term follow-up. The authors concluded that there may be no evidence of self-efficacy benefits of psychological interventions for women experiencing IPV, but the available evidence was of low certainty (p. 26). There is mixed evidence that mental health interventions delivered in LMICs reduce IPV victimisation (Tol et al., 2019), but such an association could be mediated by self-efficacy.

Given the evidence that self-efficacy, perceived support and mastery or locus of control may mediate the efficacy of PST, and their theoretical relevance to empowering women experiencing IPV in Ethiopia, I incorporated these constructs into my ToC as hypothesised mediators.

6.5.1.3 Barriers and facilitators

I identified and addressed specific constraints and facilitators of PST-IPV implementation during the intervention adaptation (section 6.4.3.1) and incorporated these into the ToC map. I also considered wider aspects of the study context, which might pose barriers or act as facilitators of implementation success.

The consolidated framework for implementation research (Damschroder et al., 2009) distinguishes between implementation climate and readiness for implementation. Implementation climate refers to the service's ability to change, receptiveness of actors to the intervention, and the degree of encouragement for participation. Readiness for implementation refers to more concrete evidence of organisational commitment, through leadership engagement, resource dedication, and provision of information about the

intervention. Considering necessary requirements for intervention engagement, training and set-up, I included implementation readiness within the ToC, given stakeholders' agreed prioritisation of health manager engagement and endorsement of the intervention. I also included the implementation climate in the ToC, but anticipated that aspects such as tension for change, relative priority and organisational rewards would be more of a focus for a future RCT, and would be enhanced by subsequent dissemination of the findings of Study Four.

6.5.1.4 Theories of change

Previous theories of change for complex interventions developed in Sodo have included an intervention to increase service user and caregiver involvement in mental health system strengthening (Abayneh et al., 2020), and expanding access to mental healthcare through integration in primary care (Hailemariam et al., 2015). The ToC maps highlighted the need for key actors to be sensitised and capable of delivering intervention components, for stakeholders to feel confident to advocate for improvements, for service users to feel satisfied with their care (Abayneh et al., 2020), and for detection, referral, and treatment in primary care (Hailemariam et al., 2015).

A ToC of community interventions to prevent domestic violence in Mumbai highlighted key assumptions (such as the presence of functioning, accessible IPV services) required to achieve outcomes, such as survivors feeling comfortable to disclose abuse (Daruwalla et al., 2019). In considering the intervention's dark logic model, Daruwalla et al. (2019) identified potential unintended harms, such as retaliation to women's empowerment, vigilantism towards perpetrators, adjustment of the types of perpetration to evade sanctions, curtailing of women's liberty by concerned relatives, and hostility towards intervention providers.

6.5.2 Theory of change: methods

I conducted a ToC workshop to develop a visual map of the programme theory, consult local experts, and engage stakeholders.

6.5.2.1 Sample

I worked with two master's degree-qualified female AAU research assistants (SH and HN) to identify a purposive sample of healthcare professionals working in Sodo, with interest, experience, or expertise in maternal and child health, mental healthcare, or supporting women experiencing IPV. I sought the perspectives of different cadres of health professionals due to their pivotal roles in identifying women who were potentially eligible to receive an intervention and engaging them with attending ANC appointments. Research staff approached a balance of male and female stakeholders, reflecting the gender profile of ANC staff. Although I planned to include representatives of local voluntary sector IPV support groups or organisations, none were identified.

I was interested in pregnant women's own theories of change for an adapted psychological intervention. However, several participants in Study Two raised concerns about the confidentiality of discussing emotional difficulties and IPV in group settings. Due to the lack of voluntary sector organisations representing women experiencing IPV in Ethiopia, there were no safe means of identifying women happy to discuss their experiences of IPV in a group setting, without the risk of perceived coercion. I therefore captured women's individual theories of change, through Study Two.

6.5.2.2 Recruitment

The research assistants informed local health centres verbally and by telephone that a ToC workshop on the subject of perinatal mental health and IPV would be taking place and invited interested staff members to consider attending.

6.5.2.3 Inclusion criteria

Any health worker, mental health, perinatal health or IPV stakeholder aged 16 years or older, who was available to attend the workshop, able to converse in Amharic, and able and willing to provide informed consent, was eligible to participate.

6.5.2.4 Exclusion criteria

Individuals aged under 16 years old, those unable to speak Amharic, and those unwilling or unable to provide informed consent were excluded from taking part.

6.5.2.5 Informed consent

On the day of the workshop, one research assistant and a senior female project coordinator (TE) provided prospective participants with a written information sheet (uploaded to the open access repository (Keynejad, 2021)) and a verbal explanation, allowing time for questions. All consenting participants were required to provide written, informed consent, usually by signing the consent form (Keynejad, 2021).

Non-literate participants were not anticipated, due to the requirements of professional roles. However, provisions were made so that the information sheet and consent form would be read aloud in the presence of a secondary school-educated, independent witness, to confirm that this took place, for any non-literate participants. In the case of any participant being unable to write, plans were made for them to indicate their informed consent by making a thumbprint in the presence of the witness, who would sign to confirm that this occurred.

6.5.2.6 Ethical concerns

Care was taken when explaining the ToC workshop study, to avoid any impression of coercion or expectation of participation. The research assistant was not a personal colleague of health workers and took care to emphasise that there was no obligation to participate, when explaining the study to staff members. The research assistant also emphasised the point on the information sheet that due to the interactive nature of ToC workshops, it would not be possible for their individual data to be withdrawn after taking part.

The ToC workshops component of Study Three received ethical approval from the King's College London Psychiatry, Nursing and Midwifery Research Ethics Subcommittee

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(reference number: HR-17/18-6063), and the Addis Ababa University College of Health Sciences Institutional Review Board (protocol number: 026/18/Psy).

6.5.2.7 Risk management

Staff leading the ToC workshop remained mindful throughout that the prevalence of psychological distress and IPV in the study site meant that health worker participants might have relevant personal, as well as professional, experience. They followed those principles of the Study Two standard operating procedure (SOP; see Keynejad (2021)) relevant to managing participant distress, supporting participants experiencing IPV, managing potential risks to children, and managing risks of abuse, harm, or neglect of adults. These included guidelines on maintaining confidentiality, seeking consent to break confidentiality if required, and urgently discussing any concerns with a nominated clinical contact person or the project mental health professional. The SOP included up-to-date contact details for sources of support in the local community, which could be provided to affected health workers after discussing the risk of abusive partners discovering them, where relevant.

6.5.2.8 Facilitators

Recruitment, informed consent, and ToC facilitation were performed in a room of a private research building in Butajira, neighbouring Sodo, by SH, together with a similarly-qualified female mental health PhD student (MD), in Amharic. TB also contributed to the ToC facilitation process.

6.5.2.9 Procedure

The workshop began by introducing all participants and summarising the purpose of the meeting. TB explained the findings of his qualitative interview study (Bitew et al., 2020), which identified women's experiences of psychological distress in pregnancy and the role played by IPV. MD then asked participants about their priority outcomes of an adapted intervention, and how success should be determined. Next, participants were guided to work back, to identify intermediate outcomes which needed to occur, to achieve the final, intended outcome. Participants were invited to suggest actions which might be required

at each step in the envisaged pathway, from their experience of the study context. Facilitators asked participants to articulate any assumptions, on which the steps along the pathway to change were based, including any questions needing to be answered by future research.

6.5.2.10 Recording

The clinical role or health service in which each participant worked, and their geographical work location were recorded for each participant. Amharic notes taken by the research assistant and facilitators during the workshop were later translated into English.

6.5.2.11 Reimbursement

Health workers were reimbursed the prevailing rate of 300 Ethiopian birr (around £8.12; ExchangeRates.org.uk, 2018) in compensation for their time.

6.5.2.12 Data handling and protection

Study documents, such as signed consent forms, were transferred directly to the main research office in Addis Ababa, where they were locked in a research cupboard, in a locked office. All electronic files containing ToC workshop data were fully anonymised. No personally identifiable information, such as names or dates of birth, were recorded during Study Three.

6.5.2.13 Analysis

Following the ToC workshop, I reviewed the English-translated notes and drafted a provisional map, specifying the necessary elements of the adapted intervention, implementation strategies, and indicators which needed to be evaluated. I sought to capture the shared understanding of what the intervention would achieve, and how, generated during the workshop. I then consulted the findings of Study Two, in order to harmonise the ToC generated by health worker stakeholders within the workshop, with the perspectives expressed by pregnant women and ANC staff during in-depth interviews.

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I iteratively adapted the ToC in line with additional insights obtained from other stakeholder activities (the training course, adaptation workshop, and theatre testing), my theory review (section 6.5.1), and exploration of the study context (chapter 4). I then shared my draft ToC map with members of the adaptation team, in order to gain their perspectives and make further, iterative adaptations. I continued to refine the ToC map as I obtained new insights from each PhD study.

Due to the timescale of Study Three, ToC workshop participants could not be consulted on the current version of the map. I plan to share the ToC map during events to disseminate the findings of Study Four, and iteratively adapt it in response to stakeholder feedback.

6.5.2.14 Dark logic model

Before commencing Study Four, I followed the process recommended by Bonell et al. (2015), of examining the assumptions of my ToC map and the potential harms of the adapted intervention's inputs, processes, mechanisms, and contextual interactions. I used the results of Study Two and the ToC workshop to consider unintended interactions between individual agency and social structures. I compared my ToC map with logic models, intervention descriptions, and process evaluations of similar interventions. I focused on corroborations and contradictions between successful and harmful interventions' logic models during my theory review (section 6.5.1). Finally, I consulted individuals with local contextual expertise on unintended harms, including an Ethiopian doctor and IPV researcher collaborator (ND), who had led an RCT of an IPV and HIV prevention intervention in Sodo, which entailed careful risk mitigation (Leight et al., 2020, 2021; Sharma et al., 2020). I then drafted a dark logic model, which I shared with the adaptation team, to make iterative changes as my PhD progressed.

6.5.2.15 Reporting

Although widely used in public health, description of ToC development and application to intervention design and evaluation has been variable, prompting the creation of a reporting checklist (Breuer, Lee, De Silva, & Lund, 2015). The checklist recommended

demonstrating a clear understanding of the problem, developing a broad ToC beyond the individual level, and understanding the functioning of the system which the intervention aims to change. I followed this checklist when reporting my ToC, to optimise its relevance and utility to researchers in similar contexts.

6.5.3 Theory of change: results

In this section, I summarise the results of the ToC workshop, and present the PST-IPV ToC map and dark logic model.

6.5.3.1 ToC workshop

The ToC workshop took place on 17th October 2018 (see Appendix 10.3.5). The 14 participants comprised five maternal care staff, five HEWs, and four health workers based in other community outpatient services. These stakeholders worked in 11 health centres and primary hospitals across Sodo district.³⁵ A balance of male and female health workers took part, although individual participants' genders were not recorded.

6.5.3.2 ToC map

The ToC map (Figure 6.8) shows how the long-term outcomes (ANC staff skilled in detecting and responding to emotional difficulties and IPV, women receiving mental health and IPV support, and women's perinatal emotional difficulties improving) were hypothesised to occur. Intermediate outcomes pertaining to ANC staff were developing a trusting, therapeutic relationship with women, increased awareness of, and confidence to ask about and respond to, emotional difficulties and IPV, and referring severe difficulties for specialist support. Intermediate outcomes pertaining to pregnant women were feeling listened to and supported by ANC staff, feeling comfortable disclosing emotional difficulties and IPV, gaining problem-solving skills, leading to increased self-efficacy, mastery and perceived social support, and feeling less isolated.

³⁵ Three participants worked at Butajira health centre and two at Kela health centre.

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Key aspects of the engagement, training, and set-up of PST-IPV to foster these intermediate outcomes were health service climate and readiness for implementation, identification of women experiencing emotional difficulties and IPV, training and supervision delivery and attendance, acceptability of sessions, competence of intervention providers, attendance at sessions, implementation of empathetic communication skills, and delivery of sessions as designed. Beyond the ceiling of accountability, potential impacts were improved detection of emotional difficulties and IPV in routine ANC, reduced IPV, more compassionate, respectful maternal care, better engagement with and attendance at ANC, and improved obstetric and neonatal outcomes.

The map makes explicit the assumptions that health centre leaders and ANC staff support all aspects of the study, skilled supervisors are available, women are able and motivated to attend sessions, rooms are available in which sessions can be delivered privately, women acquire problem-solving skills after four sessions, ANC staff continue to apply intervention skills, effective IPV and mental health support are available and provided, and IPV incidence can be reduced by support services.

Potential barriers are unexpectedly low disclosure of IPV or emotional difficulties, impairing the identification of eligible women, barriers to engagement with or attendance at sessions (such as stigma towards emotional difficulties), ANC staff requiring more training or supervision than is provided, conflicting clinical priorities preventing session delivery, understaffing or attrition of trained staff, barriers to women acquiring problem-solving and coping skills (such as limited education or literacy), wider factors maintaining IPV, and unavailability or non-provision of IPV and mental health services.

6.5.3.3 Dark logic model

Potential unintended consequences of PST-IPV pertained to the vulnerability of pregnant women experiencing emotional difficulties and IPV. Providing basic psychological intervention training to ANC staff could mean that complex mental health problems requiring specialist input are not referred onwards or adequately addressed. Training ANC staff to be aware of IPV and to respond appropriately could lead to women discussing IPV risks during sessions but not receiving assistance in cases of severe abuse.

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Inappropriate health worker responses to IPV might inadvertently reinforce abuse or disempower women further. If confidentiality is not maintained and abusive partners learn about their partner disclosing IPV, abuse could escalate. If sessions are delivered with poor communication skills, women may be deterred from engaging with and attending routine ANC or accepting hospital delivery of their baby, posing obstetric and neonatal risks. Finally, if women experiencing emotional difficulties and IPV are not identified, this could lead health policy makers and planners to conclude that these problems are a low priority for action.

6.5.3.4 Reporting

I completed the checklist for reporting ToC processes (Breuer et al., 2015) in Table 10.6, in Appendix 10.3.6.

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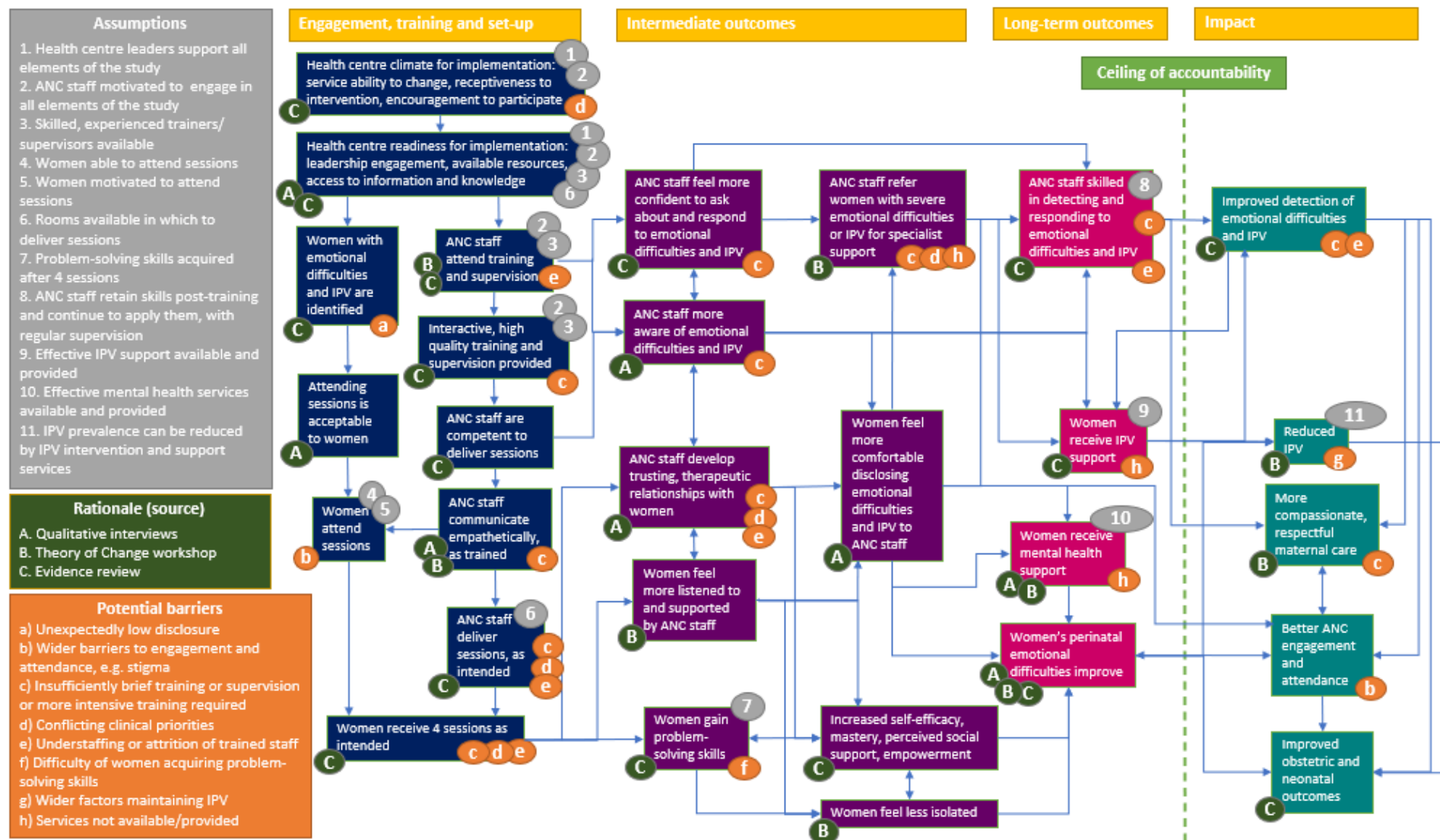


Figure 6.8 Theory of change map

6.6 Discussion

6.6.1 Key findings

Study Three identified a model of brief PST developed for use in South Africa as the most suitable intervention for this rural Ethiopian setting. I collaboratively adapted the intervention materials and developed a desktop flip-chart resource, before adapting standard PST for women experiencing IPV. Finally, Study Three articulated the programme theory and associated dark logic model of PST-IPV.

A range of frameworks has been published, to optimise the development (O'Cathain et al., 2019), adaptation (Moore et al., 2021) and theoretical explication (De Silva et al., 2014) of complex interventions for different contexts (Craig et al., 2018), in line with the MRC/NIHR framework (Skivington et al., 2021). The mechanisms which underlie intervention effectiveness (Singla et al., 2017), informing which components must be retained and which adapted for different contexts (Heim & Kohrt, 2019), are gaining research attention. The roles played by implementation factors in intervention effectiveness (Damschroder et al., 2009; Powell et al., 2015), and how these interact with the study context (Pfadenhauer et al., 2017), are also receiving interest. Adapting PST-IPV by following these frameworks ensured that each adaptation decision was considered, evidence-based, and carefully recorded. Contextualising the adaptation process within a wider intervention development and evaluation framework ensured that both standard PST and PST-IPV were adapted with piloting and feasibility assessment (Step 3 of ADAPT guidance), and a future RCT in mind.

6.6.2 What brief psychological intervention model best addresses the findings of Studies One and Two?

Brief PST, developed as part of MI-PST in Cape Town (Myers et al., 2019; Sorsdahl, Myers, et al., 2015; Sorsdahl, Stein, et al., 2015; van der Westhuizen et al., 2021; van der Westhuizen et al., 2019), was the most suitable intervention model for this context. The existing evidence base demonstrated potential for integrating PST into existing primary care, including ANC, services (Jacobs et al., 2020; Spedding et al., 2020). A context

comparison confirmed that while distinct, Ethiopian and South African study settings shared sufficient commonalities to justify adaptation.

Following Heim and Kohrt (2019)'s framework, the PST-IPV explanatory model (1a) aligns with women's expressed focus on their problems in Study Two, while offering a sufficiently different treatment rationale, incorporating coping strategies, problem-solving skills, and relaxation techniques. Although health worker training included some content about the biomedical concept of perinatal depression, session materials only discussed idioms of distress (1b) expressed by women in Study Two: sadness, stress, and problems. Specific elements of PST-IPV were founded in women's idioms of distress (which focused on life problems), and non-specific (engagement) elements (2b) accorded with women and health workers' identification of the need for trusting, therapeutic relationships in ANC care. The feasibility of in-session techniques (2c), such as take-home activities, was evaluated in Study Four.

6.6.3 What adaptations best tailor this brief psychological intervention for the perinatal emotional difficulties of pregnant women experiencing IPV in rural Ethiopia?

Cultural adaptation of psychological interventions has been shown to improve their efficacy in HICs (Benish, Quintana, & Wampold, 2011; Griner & Smith, 2006; Hall et al., 2016; Shehadeh et al., 2016) and LMICs (Cuijpers et al., 2018). Following Heim and Kohrt (2019)'s framework, the delivery format (3a) of MI-PST was adapted in line with women's prioritisation of confidentiality and brevity. The surface of treatment delivery (3b) was adapted via translation, culturally congruent examples, locally relevant illustrations, conceptual simplification (Chu & Leino, 2017), removal of incongruent elements (Verdeli et al., 2003), and accommodation of non-biomedical explanatory models of distress (Asrat et al., 2020). Adaptations for pregnant women in this context included integration into ANC, reducing written tasks (Chowdhary et al., 2014), simplifying content, incorporating locally-prepared illustrations, developing a 'job aid' flip-chart resource (Atif et al., 2017), and adding relaxation techniques recommended by WHO (2014).

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Adaptations for the needs of women experiencing IPV comprised basic training on responding to IPV disclosures, based on international guidance (Stewart & Chandra, 2017; WHO, 2019b), anonymised local women's IPV testimonies from Study Two, practice applying the PST model to IPV-related problems, clear guidance on how to manage them throughout the manual and training course, plus safeguards for responding to IPV-related risks (Ellsberg et al., 2001). Potential barriers to implementation success included difficulties attending sessions, transport costs, lack of private space, competing responsibilities (Chowdhary et al., 2014; Spedding et al., 2020), concerns about confidentiality, and stigma (Atif et al., 2017).

The resulting PST-IPV intervention features specific and non-specific elements, and techniques, in keeping with Singla et al. (2017)'s meta-analysis. The specific elements are behavioural (problem-solving, relaxation), interpersonal (identifying and eliciting support, communication skills), and emotional (linking affect to events). The non-specific (engagement) elements are collaboration, empathy, and active listening. In-session techniques are take-home activities, behavioural experiments (action plans for problem solving), and reviewing take-home activities. These components, implemented by non-specialist providers, have been demonstrated to effectively treat CMDs in a range of LMICs. Consistent with Pedersen et al. (2020)'s finding of 15 common factors across effective interventions in LMICs, PST-IPV aims to promote hope and realistic expectation of change, preserve confidentiality, give praise, and build rapport.

Considering PST-IPV as an event in the complex ecological system of ANC (Hawe et al., 2009) highlighted the self-organising nature of healthcare systems (Skivington et al., 2021). Study Three therefore engaged a range of diverse stakeholders, including clinical psychiatrists and psychologists, mental health researchers, ANC staff and women, through a PST training course, adaptation workshop, theatre testing demonstration and a ToC workshop. Their perspectives, combined with those captured by Study Two, clarified the wider systemic context. For example, PST-IPV was adapted in the context of mental health gap action programme intervention guide (mhGAP-IG; WHO, 2016a) training of some but not all primary care staff, building on previous mental health research investment (Mendenhall et al., 2014), and growing recognition of the need for

compassionate, respectful ANC (WHO, 2016b) in Ethiopia (Ministry of Health, 2015, 2021b; Wassihun & Zeleke, 2018).

Another aspect of the systemic context was that health extension workers were considered over-burdened with competing priorities (Assefa et al., 2019; Kok et al., 2015; Medhanyie et al., 2012), and so less available to attend training and supervision, and deliver sessions, than other staff. This finding accorded with intervention research with other cadres of health worker in South Africa (Jacobs et al., 2020; Spedding et al., 2020).

6.6.4 What theory of change and dark logic model best capture stakeholder perspectives on perinatal emotional difficulties, health services, rural Ethiopia, and unintended harms?

New MRC/NIHR guidance (Skivington et al., 2021) incorporates development, refinement, and (re)testing of programme theory as a core element of all four phases of complex intervention research. Study Three used theory of change (Breuer et al., 2016) to identify short, medium, and long-term outcomes required to achieve PST-IPV's desired impact. The ToC also identified evidence and experience-informed actions required to achieve each step and articulated underlying assumptions and progress markers. No single 'mid-range' behavioural theory captured stakeholders' understanding of PST-IPV's underlying programme theory (Moore & Evans, 2017; West, 2005). However, the ToC was informed by evidence that PST may work to improve CMDs through mechanisms of increased mastery (Mynors-Wallis, 2002; Revollo & Portela, 2019), self-efficacy (Cluss et al., 2006; Revollo & Portela, 2019; Warmerdam et al., 2010), and perceived social support (Cluss et al., 2006; Singla et al., 2021).

Study Three followed Moore and Evans (2017)'s recommendations for a broad ToC extending beyond the individual level, which understands the systems within which it operates. A theory review identified organisation readiness (Esponda et al., 2020), training and supervision quality (Jacobs et al., 2020), shame about IPV, health worker discomfort and workload (Abrahams, Boisits, Schneider, Honikman, & Lund, 2021), intervention complexity (Lund et al., 2020), and IPV itself (Esponda et al., 2020; Lund et al., 2020) as potential barriers. PST-IPV's dark logic model (Bonell et al., 2015) of

unintended harms included risks of disengagement from ANC and escalation of abuse (Daruwalla et al., 2019), underscoring the importance of safety protocols.

6.6.5 Strengths

The adaptation of PST-IPV and its reporting were structured using the latest guidance (Moore et al., 2021), informed by evidence-based frameworks on cultural adaptation (Heim & Kohrt, 2019), programme theory articulation (De Silva et al., 2014), implementation science (Damschroder et al., 2009), and contextual understanding (Craig et al., 2018). This ensured that the adaptation process and its outcomes can be readily compared with studies conducted in other contexts.

The processes by which some psychological interventions, such as those included in Study One, were developed, have been described in the literature (Chibanda, Verhey, Munetsi, Cowan, & Lund, 2016; Dawson et al., 2015; Epping-Jordan et al., 2016; Kaysen et al., 2013; Rahman, 2007; Singla et al., 2014; Vellakkal & Patel, 2015). Many of these reports describe stakeholder consultation activities which informed implementation decisions, such as the intervention delivery format. However, descriptions of how in-depth understanding of the context translated to individual adaptation decisions is less consistently reported, and rarely evaluated in outcome studies. Study Three contributed to the literature by presenting the process by which a detailed understanding of the study context and stakeholder consultation can inform the adaptation of a brief psychological intervention for a different setting.

Study Three captured the perspectives of diverse stakeholders with personal experience of perinatal emotional difficulties, IPV and ANC in the study setting, and integrated them into a comprehensive intervention adaptation. Collaboration within a diverse adaptation team, including the original intervention developers, meant that PST-IPV benefitted from a range of expertise. A theatre testing event enabled the standard intervention model to be demonstrated to stakeholders and iteratively adjusted, to better suit the study context. Incorporating the anonymised, lived experiences of local women experiencing perinatal emotional difficulties and IPV into PST-IPV training ensured that intervention materials were closely tailored to the needs of the target population.

6.6.6 Limitations

In Study Three, I followed Moore et al. (2021)'s comprehensive framework for intervention adaptation, closely aligned to the new MRC/NIHR complex intervention guidance (Skivington et al., 2021), informed by other approaches (Heim & Kohrt, 2019). However, my post-doctoral researcher colleague followed the assessment, decision, administration, production, topical experts, integration, training, testing (ADAPT-ITT) model (Wingood & DiClemente, 2008). Although in practice, these frameworks had much in common, the variety of approaches to intervention adaptation shows that there is no one 'right' model.

Economic analysis of the cost-effectiveness of PST-IPV was beyond the scope of this PhD. Moore et al. (2021) acknowledged that some steps of ADAPT might not always be relevant. However, the difficulty of fulfilling all stages within an extended period of doctoral study highlights the need for guidance to be pragmatic about the feasibility of recommendations in practice.

Despite adaptation being relatively straightforward in practice, adaptation frameworks' somewhat artificial deconstruction can make the process more complicated to describe and explain, than to conduct. Adaptation frameworks are less successful at fostering the equally important systems-level perspective on adaptation, than at guiding researchers through atomised stages. Although suited to the in-depth study of a PhD thesis, the level of explanation required may not be suited to most research studies, or the word counts of most peer-reviewed journals.

Although their perspectives were incorporated into the ToC via their responses to Study Two, pregnant women did not participate in the ToC workshop. I anticipated that power imbalances would prevent women from feeling able to contribute meaningfully alongside health workers, and that health workers might give more socially desirable answers in their presence. I considered holding a second ToC workshop with pregnant women experiencing IPV alone but concerns about community judgement and confidentiality expressed during Study Two raised ethical concerns.

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The current version of the ToC map was not presented to stakeholders for their validation, which would have enabled them to be “owners of the final product” (Breuer et al. (2015) checklist, item 2d). This did not happen due to all but essential research field work ceasing during the coronavirus pandemic. The map will be shared with stakeholders as part of dissemination activities for Study Four, at which time their proposed amendments will be recorded and incorporated into the iteratively developing ToC map.

Given the focus of PST-IPV on the emotional difficulties of pregnant women experiencing IPV, intervention training did not address the needs of health workers who might themselves be affected. However, the prevalence of IPV in Ethiopia means that ANC staff were themselves at risk. Future updates to the PST-IPV manual and training course should include resources to support health workers experiencing emotional difficulties, IPV, or both.

6.6.7 Future research

The evidence base describing brief psychological interventions adapted for the perinatal emotional difficulties of women experiencing IPV in LMICs is limited. The next step from Study Three was to pilot and evaluate the PST-IPV model, to assess its acceptability and feasibility, using randomised methods, in this context.

7 STUDY FOUR: RANDOMISED FEASIBILITY TRIAL AND PROCESS EVALUATION – PROTOCOL

This chapter presents the introduction (7.1), aims (7.2), research questions (7.3), and methods (7.4) of a randomised feasibility trial, comparing PST-IPV with standard PST and enhanced usual care.

7.1 Introduction

The second phase of the new MRC/NIHR complex interventions framework (Skivington et al., 2021) and step 3 of ADAPT guidance is to plan for and undertake feasibility assessment or piloting. Within this step of ADAPT, Moore et al. (2021)'s recommendations included considering the extent and type of evaluation warranted, considering resources available, evaluating feasibility and considering further adaptations based on feedback, and conducting process evaluation. The methods by which I followed this guidance are described in Study Four, and the results in Study Five. The final part of step 3 of ADAPT, to evaluate the effectiveness and cost-effectiveness of the adapted intervention, is beyond the scope of this PhD.

7.1.1 Implementation in context

The context and implementation of complex interventions (CICI) framework (Pfadenhauer et al., 2017) was developed to enhance consideration of how context and implementation influence the success and effectiveness of complex interventions. The authors proposed that the context, implementation and setting interact with each other and with the intervention, highlighting sub-domains of each. The domains of context highlighted by CICI overlap with those raised by Craig et al. (2018), which I described in chapter 4. I reported aspects of the setting: the physical location in which sessions were delivered, and the intervention itself, in the modified TIDieR checklist (Appendix 10.3.2) and Appendix 10.3.3, in Study Three. With respect to implementation, CICI highlighted five domains which require consideration alongside context, setting, and intervention elements. These were implementation theory, process, strategies, agents, and outcomes.

Pfadenhauer et al. (2017) considered implementation theory analogous to programme theory, which is outlined in the PST-IPV ToC (section 6.5.3.2). They described implementation process as a non-linear, multi-stage, social process, which operationalises an intervention within an organisation. The implementation process begins with exploring organisational needs (Study Two), intervention-organisational fit and capacity, and readiness of the setting (Study Three). Planning and preparation then occur, before initial implementation, in which staff are trained, information is disseminated, interventions are pilot tested and adapted (Study Four). This is followed by full implementation, which integrates the intervention into practice, which is beyond the scope of this PhD. Pfadenhauer et al. (2017) recommended that evaluation and reflection on the implementation process should occur as early as possible.

Implementation strategies are actions taken to enhance the adoption and sustained use of the intervention. A modified Delphi study identified 73 distinct implantation strategies at different levels, including staffing (such as shifting professional roles), training (such as developing educational materials), leadership (such as providing clinical supervision), and evaluation (such as organising quality monitoring systems; Powell et al., 2015).

Implementation agents are the persons and groups involved in an intervention's inception, delivery and receipt. Pfadenhauer et al. (2017) highlighted that their personal attributes, skills, knowledge, perspectives, and attitudes all influence implementation success, via their 'buy-in' as stakeholders. These aspects are described in Study Five, which reports the results of Study Four. Finally, the implementation outcomes, such as intervention adoption, uptake, and acceptability, are described in Study Four and reported in Study Five.

7.2 Aims

Study Four aimed to assess the feasibility and acceptability of PST-IPV and a randomised, controlled study design, to inform a future, fully-powered RCT.

7.3 Research questions

1. Are PST-IPV and the processes of recruitment, randomisation, follow-up, and evaluation feasible and acceptable to pregnant women and health workers, in rural Ethiopia?
2. What changes should be made to PST-IPV and the randomised, controlled study design, to optimise feasibility, acceptability, fidelity, and quality?
3. What contextual factors and causal mechanisms may influence the outcomes of a fully-powered RCT of PST-IPV?

7.4 Methods

7.4.1 Trial design

Study Four was a three-arm feasibility study, which randomised women screening positive for depressive symptoms, functional impact, and past-year IPV, to (1) PST-IPV, (2) standard PST, or (3) enhanced usual care (EUC): information about sources of support).

7.4.2 Relationship to two-arm trial

Study Four (Keynejad, Bitew, et al., 2020) was linked to a two-arm feasibility trial (Bitew et al., 2021), led by my post-doctoral researcher collaborator (TB), which randomised women screening positive for depressive symptoms and functional impact to (1) standard PST or (2) EUC. The relationship between the two studies is shown in Figure 7.1.

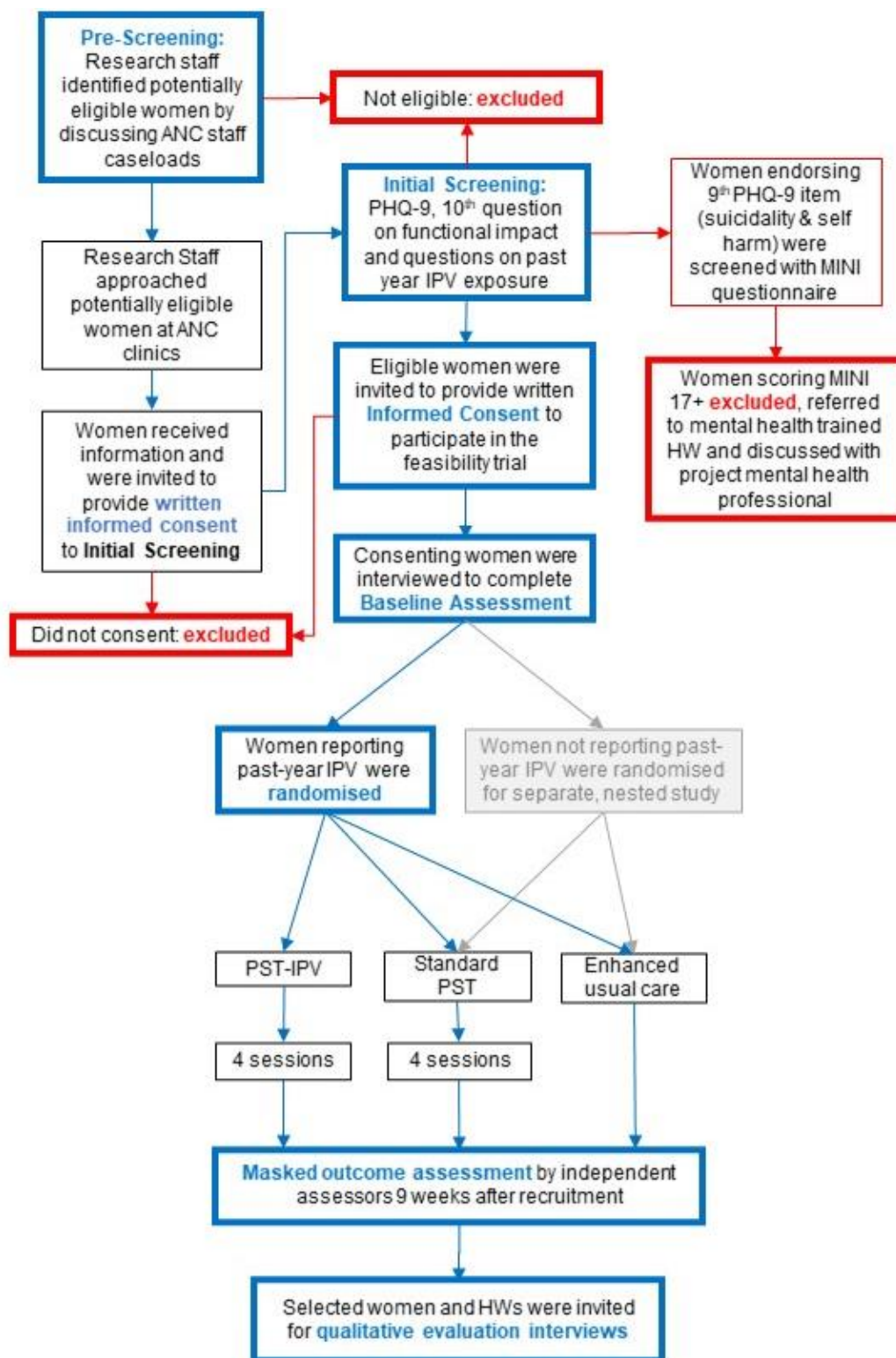


Figure 7.1 PST-IPV feasibility trial flow diagram

The relationship to the nested feasibility trial of standard PST is indicated by the box and arrows shaded in grey (Bitew et al., 2021).

ANC: antenatal care, HW: health worker, PHQ: patient health questionnaire, MINI: mini international neuropsychiatric interview, IPV: intimate partner violence, PST: problem-solving therapy, PST-IPV: PST adapted for women experiencing IPV.

7.4.3 Sample size

As a feasibility trial, I did not intend that Study Four would be powered to detect intervention efficacy, but instead to estimate feasibility parameters to inform a future RCT, and test the intervention and research protocols. I used NIHR guidance (Hopper, 2019) to calculate the percentage confidence interval of the proportion of participants that I estimated would drop out of Study Four. The percentage confidence interval with which Study Four could be used to estimate the actual drop-out rate from a future RCT was: $1.96 \times \sqrt{(p(1-p)/n)}$, where p equalled the anticipated proportion of participants dropping out of the study and n was the intended sample size. Using this calculation, I determined that a total sample size of 75 across the entire trial, including the nested study (25 participants randomised to PST-IPV, 25 to standard PST and 25 to EUC) would enable me to estimate a drop-out rate of 30%, within a 95% confidence interval of +/- 10%. That is, $0.1037 = 1.96 \times \sqrt{(0.3 \times 0.7 / 75)}$. This sample size aligned with recommendations that to inform sample size calculations for a future RCT, studies estimating the standard deviation of the primary feasibility outcome measure should recruit between 12 and 25 participants per arm (Julious, 2005; Sim & Lewis, 2012).

7.4.4 Recruitment

Data collectors with a minimum post-high school diploma level of education were employed by the trial. As outlined in Figure 7.1, data collectors ‘pre-screened’ patient caseloads by consulting ANC staff at Bu’i primary hospital and Kela health centres, supervised by field supervisors with an undergraduate psychology degree. They identified potentially eligible women meeting those inclusion criteria about which information was held, for initial screening.

7.4.5 Informed consent

Potentially eligible women were approached through ANC clinics by data collectors, and provided with written and verbal information in Amharic, before being invited to give written, informed consent to initial screening. Non-literate women signified their consent by thumb-printing. A literate witness drawn from individuals present at the health centre

signed to confirm that the information sheet had been read aloud correctly to non-literate women; their role was confined to observing and confirming that informed consent was obtained and provided appropriately. Women identified through initial screening as eligible to participate in the randomised feasibility trial were then invited to give written, informed consent to participate. As with initial screening, non-literate women signified their consent to participate in the trial by witnessed thumb-printing.

English versions of the initial screening and main trial information sheets and consent forms are uploaded to the open access repository (Keynejad, 2021). Information sheets included details of how participants could access compensation, if required. Due to potential risks of abusive partners learning of women’s involvement in Study Four, information sheets, consent forms, and other study paperwork were kept in the locked research office after being read and signed. It was explained to women that they could be accessed at their request. Due to competing commitments and the distance of women’s homes from ANC, it was not feasible to wait 24 hours before allowing prospective participants to decide whether to take part. A minimum of 30 minutes was allowed for women to make this decision.

7.4.6 Initial screening

Consecutive, potentially eligible women who provided informed consent were initially screened for depressive symptoms and past-year IPV exposure. Depressive symptoms were screened for using the locally-validated (Gelaye et al., 2013) PHQ-9 patient health questionnaire (Kroenke et al., 2001), plus a tenth question asking about the functional impact of symptoms. Eligible women were invited to participate in the overall research study if they scored five or more on PHQ-9 (Girma, 2013; Hanlon et al., 2015), and answered the tenth question, “over the last two weeks, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?” with “somewhat”, “very” or “extremely difficult”.

Data collectors then read the introductory paragraph of the Amharic-translated (Abeya, Afework, & Yalew, 2011) CTS2 conflict tactics scale (Straus, Hamby, Boney-McCoy, & Sugarman, 1996) aloud, to destigmatise IPV. The paragraph begins, “No matter how well

a couple gets along, there are times when they disagree.” Thereafter, data collectors administered the same five-item ‘non-graphic language’ screen, previously found to be a valid measure of IPV in this and other LMIC settings (Zink et al., 2007), used to identify potentially eligible interviewees in Study Two. Finally, items from the WHO multi-country study of women’s health and domestic violence (García-Moreno et al., 2005), previously used in this setting, were used to measure past-year IPV exposure.

Consenting women who endorsed depressive symptoms, functional impact, and disclosed any past-year IPV at initial screening were eligible to participate in my three-arm study comparing PST-IPV, standard PST, and EUC. Consenting women who endorsed depressive symptoms, functional impact, and reported no IPV exposure at initial screening, were eligible to participate in the nested two-arm study, comparing standard PST with EUC, led by my post-doctoral researcher collaborator (TB; see Figure 7.1).

7.4.7 Inclusion criteria

Women were eligible to participate in my three-arm study if they:

- Spoke Amharic: the official regional language, so that they could communicate with the therapist and data collectors, and understand the study materials.
- Were 16 years old, or over.
- Were between 12 and 34 weeks’ gestation of pregnancy.
- Intended to live in Sodo for the duration of the study.
- Scored five or more on the PHQ-9, with functional impact (tenth question).
- Reported any past-year IPV (in a current or previous relationship), during initial screening. I defined a relationship as any romantic or sexual interaction, within or outside marriage.
- Consented to participate, including accepting EUC, or attending four sessions of PST-IPV or standard PST (if randomised to a treatment arm).

PHQ-9 has been validated in Sodo, in primary care (Hanlon et al., 2015) and ANC, where the area under the receiver operating characteristic curve was 0.91 (CI: 0.86, 0.96; Girma, 2013). A score of five or more was the optimal cut-off for identifying possible depressive disorder in primary care, and four or more in ANC. However, at optimal cut-offs, the

positive predictive value was less than 50%. For inclusion in Study Four, women therefore needed to score above the cut-off (five or more), and to report difficulty in their day-to-day activities (tenth item).

7.4.8 Exclusion criteria

Women were excluded from participating in my three-arm study if they:

- Were acutely, physically ill.
- Required emergency treatment of any kind.
- Were unable to understand the interview (e.g. were diagnosed with severe intellectual disability or dementia, or unable to speak Amharic).
- Expected to move away from Sodo before the study completed (within nine weeks of recruitment).
- Were identified by their ANC provider during pre-screening as experiencing possible psychotic symptoms.

All women endorsing question nine of PHQ-9, about suicidal thoughts and self-harm behaviours, were screened using the Amharic-translated (Hanlon et al., 2015) mini international neuropsychiatric interview (MINI) suicidality scale (Sheehan et al., 1998). Women scoring 17 or above, indicating high suicide risk, were excluded from participation, as part of a stepped-care model (Fekadu et al., 2016). They were referred instead to a member of primary care staff trained to use mhGAP (WHO, 2016a) criteria to assess for imminent risk of self-harm or suicide. Women assessed as being at imminent risk were referred to a psychiatric nurse at the primary hospital, for escalation of their care; any transportation costs incurred when accessing off-site services were funded by the study.

Any psychotic symptoms and other risks identified during the trial were discussed with the project mental health professional, and women were referred for specialist mental healthcare, if required. Women who were assessed as eligible to participate at the time of screening but did not consent to take part received the same stepped mental healthcare model, according to their symptoms and risks. Otherwise eligible women who reported

no past-year IPV exposure were invited to participate in the nested two-arm feasibility trial, but were not eligible to take part in my three-arm trial.

7.4.9 Reimbursement

All participants were reimbursed for their time to attend baseline assessments and outcome assessments, and for transport costs and any additional expenses incurred by attending these appointments. Transport payments were 70 birr (£1.18; ExchangeRates.org.uk, 2021) for women who lived comparatively close to the ANC service and 140 birr (£2.36) for women who lived further away, as determined by the field supervisor. Women randomised to the control arm received 140 birr (including transport allowance) for each baseline and outcome assessment, to compensate for not attending sessions. Women randomised to intervention arms received 70 birr for attending each baseline and outcome assessment, in addition to transport allowances for these appointments and intervention sessions. All payment fees were set by the Addis Ababa University (AAU) CDT-Africa finance department, in alignment with government compensation scales. Participants were also reimbursed for any transport costs which they incurred by attending sessions of standard PST or PST-IPV, as these additional costs might preclude women with low incomes from attending. A fund was available to assist participants disclosing IPV, severe mental health symptoms, or suicidal ideation to access support services, such as transportation to a government social support office, police station, or secondary mental health service.

7.4.10 Randomisation

The trial statistician (GM) based at the College of Health Sciences, AAU, who was not otherwise involved in data collection processes, used a random number list to generate a three-arm randomisation table for Study Four. This table was used to proportionately allocate eligible women in the ratio of 2:1:1 to PST-IPV, standard PST, and EUC arms. A second randomisation table allocated women not reporting IPV in a ratio of 1:1, to the standard PST and EUC arms, for the nested study. Eligible women were randomised using these tables until 25 women had been randomised to each arm, at which point enrolment into that arm was closed, and recruitment continued for the remaining, unfilled arms.

The randomisation tables were retained by the trial coordinator (TC) and research assistant (RA), who were telephoned by the field supervisor (FS) following each baseline assessment, to allocate participants to an arm (PST-IPV, standard PST, or EUC) for that participant, who was not named or otherwise identified to the TC or RA. FSs were unmasked and proceeded with the appropriate procedure, depending on which arm was allocated. FSs provided participants randomised to active arms with an unmarked, coloured card, indicating their enrolment in a trial arm. FSs informed participants of the date and time at which their first session of PST-IPV or standard PST would take place, after agreeing this with their allocated health worker. FSs arranged nine week follow-up appointments on the day of randomisation, for women randomised to EUC.

7.4.11 Masking

Given qualitative differences between PST-IPV, standard PST, and EUC, ANC staff delivering intervention sessions could not be masked to participant allocation. To avoid contamination, PST-IPV and standard PST were delivered by two different groups of health workers, who had attended either a PST-IPV or a standard PST training course. EUC comprised a leaflet on well-being during pregnancy and information about sources of support, provided by the FS at the time of randomisation.

Data collectors who had recruited participants at Bu'i primary hospital conducted post-intervention outcome assessments of women recruited at Kela health centre, and vice versa. Data collectors were masked to intervention allocation at the time of outcome assessment, and documented any incidents of un-masking. Data analysts were also masked to intervention allocation, using the anonymised arm identifiers, X, Y, and Z.

7.4.12 Therapist recruitment and retention

Health workers at the two study sites were invited to express their interest in being trained to deliver sessions of problem-solving therapy as part of Study Four, after attending a presentation delivered by the TC and RA. A requirement for eligibility was having attended the good clinical practice training course delivered on 31st January 2021. Health workers were ineligible to deliver sessions if they expected to leave their roles (for example, for maternity leave) during the course of the trial. The names of volunteering

health workers were drawn at random, at a public event held at each workplace, to allocate them to PST-IPV, standard PST, or no role in the trial. Health workers were permitted to swap their allocated trial arm if they wished (including to swap out of delivering an intervention, if they had changed their mind), to accommodate those with a particular interest in or preference against an IPV-related intervention. Health workers who were not randomised to an intervention arm, but who were interested in receiving problem-solving therapy training, were advised that this would be offered to them once the trial had ended.

Government-employed health workers trained to deliver intervention sessions were paid 2,000 birr (£33.70; ExchangeRates.org.uk, 2021) net (after deducting tax), per case, for their time. This fee included their attendance at a five day training course and regular supervision sessions, as well as delivering up to four sessions of PST-IPV or standard PST. This fee was negotiated as being acceptable to staff.

7.4.13 Therapist training and supervision

Six ANC staff members (four from Bu'i primary hospital and two from Kela health centre) received five days' PST-IPV training, delivered by a local psychiatrist (LM) and psychologist (IA) with experience of training primary care staff on mental health subjects. A separate group of six ANC staff members (four from Bu'i primary hospital and two from Kela health centre) received standard PST training, delivered by a different psychiatrist (RS) and psychologist (AMi) to PST-IPV, using the same five day structure. Twelve ANC staff were therefore trained in total, across two active study arms. Both courses were divided into a block of three days, followed by two days' training, on consecutive weeks. This was considered to be less disruptive to health workers' clinical commitments, less tiring for health workers to attend, and more feasible for trainers, who needed to travel to the study site from Addis Ababa.

Standard PST training was delivered on 14th, 15th, 16th, 22nd and 23rd April and PST-IPV training was delivered on 19th, 20th, 21st, 26th and 27th April 2021. At the end of each training day, health workers were asked to complete a brief feedback form, containing questions about the course and trainers, answered using a Likert scale from one ("not at

all”) to five (“completely”). The questionnaire also included qualitative questions about what trainees liked, would do differently following the course, and their recommendations for improvement. Further details about therapist training and supervision arrangements for PST-IPV are described in Appendix 10.3.4.

Both PST-IPV and standard PST training courses combined brief sessions using PowerPoint (Microsoft Corporation, 2008b) presentations to guide health workers through paper copies of the intervention manual and flip-chart, with small group discussions, activities, and role play tasks incorporating peer feedback. Role play is increasingly used to deliver mental health training in LMICs (Keynejad, Dua, et al., 2017; Keynejad et al., 2021), and is an important tool for assessing therapist competence (Ottman, Kohrt, Pedersen, & Schafer, 2020).

With participants’ agreement, health workers audio-recorded each session of PST-IPV or standard PST. Anonymous session recordings were then uploaded to the study computer and securely shared with their supervisor, to inform the content of supervision sessions. After the five day training course, PST-IPV and standard PST-trained health workers were required to be approved by their supervisor (either the psychiatrist or psychologist who trained them) as competent, based on audio recordings of them delivering an ‘accelerated case’ of four sessions within a two week period. Supervisors assessed accelerated cases using a structured form, including items on the fidelity of session content and quality of communication skills (available in the standard operating procedure (SOP) uploaded to the open access repository; Keynejad (2021)).

ANC staff members delivering intervention sessions had access to a project mental health professional, with whom they could raise any immediate clinical concerns. Any clinical concerns or risk incidents identified during the trial were responded to by following the trial SOP (Keynejad, 2021).

After completing a first, accelerated, case of PST-IPV or standard PST and being assessed as competent to continue delivering sessions, health workers received regular supervision. The feasibility of delivering between two and four-weekly supervision, either in-person or by telephone, was assessed as part of the process evaluation. I remained in weekly

email or videoconferencing contact with all four supervisors, to monitor the progress of supervision and discuss any concerns. Supervisors were asked to complete a structured form indicating the content of supervision sessions (available in the SOP uploaded to the open access repository; Keynejad (2021)).

7.4.14 **Active intervention arms**

All arms represented additions to standard clinical care, where no routine interventions were provided for perinatal depression or IPV. Participants randomised to PST-IPV or standard PST (25 per arm) were offered four intervention sessions within a maximum of eight weeks.

Both PST-IPV and standard PST intervention arms followed the four session structure described in Study Three (see Appendix 10.3.3). Women randomised to intervention arms therefore attended a total of six research contacts: one baseline assessment, four intervention sessions, and one outcome assessment.

7.4.15 **Enhanced usual care (EUC) arm**

Twenty-five participants were randomised to EUC. Research staff provided these participants with information about local sources of support, in addition to the trial leaflet about well-being in pregnancy (see Keynejad (2021)). Women randomised to EUC therefore attended two research contacts: one baseline assessment and one outcome assessment, nine weeks later.

In Study One, I found that randomisation of control group participants with depressive, anxiety, PTSD or psychological distress symptoms and IPV exposure to waiting list, treatment as usual, or EUC arms was widespread (Keynejad, Hanlon, & Howard, 2020). This practice, the lack of any existing services for perinatal depression or IPV in this setting, and the provision of safeguards in the study design, justified the use of an EUC arm.

7.4.16 **Loss to follow-up**

Participants who did not attend the health centre for an intervention session or outcome assessment on the appointed date and time were contacted using the telephone number which they provided at trial enrolment, where applicable. Participants who did not provide a telephone number were contacted through their allocated health extension worker (HEW). In both cases, their allocated health worker or data collector attempted to reach missing participants up to a maximum of three times, before recording them as lost to follow-up. Women reporting that they wished to withdraw from the study were not contacted again. Women who did not wish to attend further sessions were offered the opportunity to attend the outcome assessment, if they wished, or not contacted again if they declined. Women who gave birth prior to completing the study were offered the chance to receive their remaining sessions and/or outcome assessment, postpartum, or to withdraw from the study.

7.4.17 **Measurement**

The standard protocol items: recommendations for interventional trials (SPIRIT) schedule (Chan et al., 2013) of participant enrolment, interventions, and assessment is shown in Table 7.1 and the SPIRIT checklist is shown in Appendix 10.4.2. Women consenting to participate first received their routine ANC and then participated in a baseline assessment. This was conducted in a private room of Bu'i primary hospital or Kela health centre, and administered by trained data collectors, using fully structured questionnaires. All participants were then invited to attend an outcome assessment nine weeks post-randomisation, administered by masked data collectors who had enrolled participants at the other healthcare facility.

Data collectors were trained to administer baseline and outcome assessment instruments in Amharic by the TC and RA, prior to commencing recruitment. This training was used to review the time taken to administer questionnaires, confirming that baseline and outcome assessments lasted no more than one hour each, and were not experienced as unduly burdensome. Any items that were poorly understood or completed were

highlighted and their wording was reviewed. Data collectors were supervised by the field supervisor, who was supervised by the TC.

Amharic-language instruments were first prepared using Word software (Microsoft Corporation, 2008c), before an application was prepared, using the open data kit (ODK) electronic system (Bokonda, Ouazzani-Touhami, & Souissi, 2019). ODK creates offline data collection tools for use with smartphones and has been used for effective data collection in Sodo (Bitew Workie et al., 2021).

7.4.17.1 Demographic variables

At baseline, data collectors recorded the following demographic information, obtained from participants' medical records kept by their HEW:

- Gestation.
- Gestation at first ANC attendance.
- Number of ANC appointments attended.
- Proportion of recommended ANC appointments attended.
- Physical or mental health medications prescribed.
- Any documented past psychiatric history.
- Any documented current mental health problems.
- Pregnancy complications.

After women had given birth, data collectors obtained information from their HEW on:

- Obstetric complications.
- Neonatal complications.

Data collectors additionally obtained the following information at baseline, by asking participants directly:

- Age.
- Religious affiliation.
- District of residence.
- Highest education level attended.
- Highest completed grade, if any formal education.
- Occupation.
- Marital status.
- If married, age at marriage.
- Partner’s highest education level attended.
- Partner’s occupation.
- Gravidity.
- Parity.
- Whether pregnancy was planned.
- If planned, whether the pregnancy occurred at the woman’s preferred time.
- Total number of family members living in the household.

Data collectors also administered the Amharic-translated list of threatening experiences (Brugha, Bebbington, Tennant, & Hurry, 1985) at baseline, to capture past-year exposure to stressors other than IPV.

7.4.17.2 Primary outcome

At baseline and outcome assessments, symptoms of depression were measured using the Amharic-translated PHQ-9 (Kroenke et al., 2001), comprising nine questions about depressive symptoms. Participants were asked to rate each symptom according to frequency in the preceding two weeks (0=not at all, 1=several days, 2=more than half of the days, 3=nearly every day). I planned to compare PHQ-9 scores pre- and post-participation, to calculate the mean or median difference (in depressive symptoms) within PST-IPV, standard PST and EUC arms.

I planned to calculate the proportion of participants showing a treatment response (defined as a 50% reduction in PHQ-9 score) in each arm. As a feasibility trial, Study Four was not powered to detect treatment efficacy, so I did not expect these proportions to be significantly different, and did not compare them using statistical tests.

7.4.17.3 Secondary outcomes

At baseline and outcome assessments, the following constructs were also measured, using Amharic-translated scales. I also planned to calculate within-arm mean or median differences between baseline and outcome assessments.

- *Post-traumatic stress* symptoms using the post-traumatic stress disorder checklist for DSM-5 (PCL-5; Blevins, Weathers, Davis, Witte, & Domino, 2015), which has been adapted for a rural Ethiopian context.
- *Anxiety* symptoms using the generalised anxiety disorder scale (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006).
- *Functional impact* using the 12-item Ethiopian adaptation (Habtamu et al., 2017) of the WHO disability assessment schedule (WHODAS 2.0; Gold, 2014).
- *IPV*: the same questions used for initial screening (section 7.4.6) were used to inquire about IPV exposure at baseline and outcome assessments.
- *Attitudes towards gender roles* using the WHO attitudes towards gender roles questionnaire (García-Moreno et al., 2005).
- *Self-efficacy* using an adapted self-efficacy scale validated in Ethiopia for sexual health research (Shaweno & Tekletsadik, 2013).
- *Mastery*: the extent to which the participant considered herself in control of forces affecting her life (Pearlin, Menaghan, Lieberman, & Mullan, 1981) was measured using a 15-item multicultural mastery scale (Fok, Allen, Henry, & Mohatt, 2012) adapted for rural, non-Western communities.
- *Perceived social support* using the OSSS-3 Oslo social support scale (Dalgard et al., 2006), previously used in a study of antenatal depressive symptoms in Sodo (Bitew et al., 2016).

- *Obstetric and neonatal outcomes:* As they are not reliably self-reported (Bitew, Hanlon, Kebede, Honikman, & Fekadu, 2017), field supervisors requested that HEWs, who maintain maternal care records, report stillbirths, early neonatal deaths, delivery site, attendance at subsequent ANC appointments, and physical and mental health prescriptions for each participant. Where women attended ANC at a combination of sites, antenatal contacts at all relevant services were recorded.
- *Healthcare-seeking behaviour,* using the CSRI client service receipt inventory (Beecham & Knapp, 2001), adapted for Ethiopia (Mogga et al., 2006) and modified to focus on the past three months, except for inpatient care at baseline, which was asked for the past 12 months.

7.4.17.4 Process evaluation

MRC guidance (Moore et al., 2015) on process evaluations recommends focusing on an intervention’s implementation, mechanisms, and context. Mixed methods have the potential to illuminate how complexity impacts on interventions in different contexts (Noyes et al., 2019). I therefore triangulated quantitative and qualitative data to evaluate the implementation process of Study Four.

I used secondary outcome measures and qualitative interviews to explore the mechanisms by which the ToC had hypothesised that PST-IPV would work. I kept a weekly implementation log of notes from online supervision meetings with the TC, RA, intervention trainer/clinical supervisors, and co-primary investigators, and key emails, in order to record aspects of the context relevant to intervention implementation. To evaluate implementation outcomes, I gathered quantitative and qualitative data, as follows.

Recommended implementation outcome measures include acceptability, appropriateness, feasibility, fidelity, adoption, and sustainability (Pfadenhauer et al., 2017; Proctor et al., 2011). In this feasibility trial, I focused on evaluating the following aspects of PST-IPV and Study Four’s design:

- Acceptability to women and health workers.
- Appropriateness to the context.

- Feasibility.
- Fidelity to the PST-IPV manual and trial SOP.
- ‘Dose’ of PST-IPV administered.
- Safety.

I did not measure reach, adoption, penetration, or sustainability of PST-IPV, due to the small scale of this feasibility study, and the fact that Study Four did not aim to extend PST-IPV beyond the research team and participants. The TC and RA kept careful records of all costs associated with the trial, to inform a planned post-doctoral economic analysis, which was beyond the scope of this PhD.

Quantitative data

I collected the following administrative data, which informed my assessment of the feasibility outcomes in brackets:

- Number of women screened, proportion eligible (feasibility).
- Number of eligible women identified at each clinical site per week (appropriateness).
- Proportion of eligible women consenting to participate (acceptability).
- Drop-out rates (acceptability, feasibility).
- Numbers of sessions attended (dose).
- Session duration (dose, appropriateness, feasibility, fidelity).
- Follow-up rates (feasibility).
- Number of adverse and serious adverse events and relatedness to trial participation (safety).

A sample of anonymous session audio recordings was evaluated by two independent psychologists not otherwise involved in the study (ED and MY), using relevant items from the enhancing assessment of common therapeutic factors (ENACT) rating scale (Kohrt et al., 2015). ENACT was previously adapted for the Ethiopian context and shown to be reliably administered by trained clinicians (Asher et al., 2016). The psychologists had received prior training in applying ENACT.

The first set of recordings evaluated were the first session of the first case commenced after the health worker's accelerated case. The second set of recordings independently assessed were the second session from a randomly selected case: one for each health worker. The same psychologists evaluated the same health workers' recordings each time. Session audio recordings were also evaluated for session fidelity and completion, using a checklist of expected session components (available in the SOP uploaded to the open access repository; Keynejad (2021)). I used these assessments, together with supervisor observations, to evaluate the quality of intervention sessions. The quality of therapist-client rapport was assessed using the Amharic-translated HAQ helping alliance questionnaire (Luborsky et al., 1996) during post-participation qualitative interviews. The HAQ has been tested in this setting (Mayston et al., 2017).

The frequency and duration of IPV-specific content during audio-recorded sessions of both PST-IPV and standard PST were noted by independent psychologists on the fidelity and completion checklist, to determine the extent to which participants raised and explored IPV-related problems during the two intervention types.

Qualitative data

Research staff documented key features of both clinical sites, to enable comparison of process data, and kept field journals noting:

- Participants' comprehension of randomisation and willingness to be randomised (acceptability).
- Staff willingness to participate at each site and retention in the study (acceptability, appropriateness, feasibility).
- Optimal participant recruitment procedures (feasibility).
- Contextual factors and events influencing trial conduct and processes (appropriateness).
- Adherence of research staff to the study SOP (feasibility).

I aimed to note the degree of take-home activity completion (acceptability, fidelity, appropriateness) and any instances of contamination between trial arms (Sorsdahl, Stein, et al., 2015) recorded in supervisor reports and fidelity and completion checklists. I

planned to use the FRAME structure (Stirman et al., 2019) outlined in Study Three (section 6.4.5.2) to document any iterative adaptations that took place during Study Four.

I planned to evaluate the acceptability of the intervention, study design, recruitment, randomisation, outcome assessment processes and SOP through qualitative interviews with a purposive sample of eight women and six health workers. I planned to interview four women from each study site (two randomised to PST-IPV and two randomised to standard PST) and three health workers trained to deliver PST-IPV and three trained in standard PST. The six participant interviews were planned to recruit a balance of participants who completed all or a proportion of intervention sessions, were recruited at each healthcare setting, were pregnant with their first child or not, and a balance of ages. The six health worker interviews were planned to recruit a balance of specialisms, such as nurses, midwives, and health officers, genders, and health centres of employment.

I identified potential interviewees, who were approached by research staff working in the field. They were provided with written and verbal information about the interview study (uploaded to the open access repository; Keynejad (2021)) and invited to give informed consent. The same procedure as in the main study (section 7.4.5) was used, enabling non-literate participants to consent using a witnessed thumbprint. In-depth interviews were organised to take place at a time convenient to the participant and followed topic guides (see Appendix 10.4.3). They were conducted in Amharic by research staff without extended contact with participants during the trial, in a private location convenient to them. Interview participants were compensated 140 birr (£2.36; ExchangeRates.org.uk, 2021) for their time, a fee set by the CDT-Africa finance department. Interviews were audio-recorded, transcribed, and translated into English.

7.4.18 Analysis and reporting

I followed the consolidated standards of reporting trials (CONSORT) extension to randomised pilot and feasibility trials (Eldridge et al., 2016); see Table 10.8 in Appendix 10.5.1.

7.4.18.1 Statistical analysis

I planned to review process evaluation data for indications of sub-group differences in uptake, recruitment, and retention of participants by clinical site, health worker, recruitment method, participant (age, education, religion, parity), and health worker characteristics (profession). I calculated descriptive statistics of quantitative scale scores using STATA (StataCorp, 2017). I determined whether to calculate means and standard deviations, or medians and interquartile ranges, based on visual inspection of histograms for evidence of normal distribution or skew.

As a feasibility study, Study Four was not powered to calculate effect size. However, I calculated appropriate measures of the central tendency of outcome measures, recruitment and drop-out rates for the intention-to-treat sample (all participants who were randomised, regardless of their uptake of intervention sessions). I planned to use these results to inform future sample size calculations for a post-doctoral RCT. I used quantitative process data to identify improvements to the study design, for a future RCT. I did not impute missing data for clinical outcome measures but calculated appropriate measures of central tendency using data from participants for whom outcome measures were available.

I calculated quantitative fidelity and completion checklist and ENACT scores as percentages out of the maximum score available (reducing the denominator for items marked ‘not applicable’), before calculating appropriate measures of central tendency, of quantitative scale scores at different time points.

7.4.18.2 Qualitative analysis

I planned to use the same six phase approach to thematic analysis (Braun & Clarke, 2006) which I employed in Study Two (section 5.4.16) to analyse translated qualitative interview transcripts, including coding of selected transcripts by members of the Ethiopian research team. I aimed to adopt the same practice of reflexivity, and to triangulate the results of interviews with quantitative process data, through regular meetings with research staff in Ethiopia. I kept detailed notes of weekly trial meetings and triangulated these with researchers’ field journals and the context log kept by the

research team, to identify contextual barriers and facilitators which appeared to influence study progress.

7.4.19 Ethical considerations

Study Four recruited potentially vulnerable women and had the potential to entail IPV disclosure and depressive, anxiety, and PTSD symptom detection. The SOP (uploaded to the open access repository; Keynejad (2021)) therefore outlined systems to mitigate potential risks to participants.

7.4.19.1 Ethical approval

I obtained ethical approval for Study Four from the Psychiatry, Nursing & Midwifery subcommittee of King's College London's (KCL) Research Ethics Subcommittee (Reference: HR-18/19-9230; Appendix 10.4.4.1) and the Institutional Review Board of the College of Health Sciences, AAU (Protocol number: 032/19/CDT; Appendix 10.4.4.2).

Minor amendments to the protocol were approved by KCL (MOD-20/21-9230) on 20/11/2020 and AAU (AAUMF-01-008) on 19/03/2021. These changes comprised increasing the originally planned sample size of 20 per arm to 25 participants per arm, extending the study timescale due to the coronavirus pandemic, adjusting the qualitative interview topic guide, adding a consent process for initial screening, and a COVID-19 SOP.

7.4.19.2 Sensitivity

Research staff were trained to listen non-judgementally, offer privacy, confidentiality and information about sources of support to women disclosing IPV, in keeping with WHO guidelines (Ellsberg & Heise, 2005). Female data collectors were carefully selected, considering the sensitivity of discussing IPV and mental health. Once recruited, they were trained on locally-relevant aspects of IPV by the TC and RA (Gossaye et al., 2003). When approaching women, data collectors exercised sensitivity and ensured that women did not

feel pressurised to participate. Care was taken to ensure the anonymity of interview transcripts and any quotations used in publications or reports.

7.4.19.3 Safety

The SOP (see the open access repository; Keynejad (2021)) outlined measures to mitigate potential risks to participants, including abusive partners learning about their involvement. These included a protocol for responding to concerns or disclosures of risk, emergency contact information, conduct when communicating with vulnerable participants, documenting and responding to serious adverse events, and reporting them to KCL and AAU institutional review boards. Numbers of adverse and serious adverse events were calculated per trial arm. A data monitoring committee was not established, due to Study Four's small sample size, which was not powered for interim analyses.

7.4.19.4 Risk of harm

The risk of harm to participants was minimised by providing full information about the study prior to women's voluntary participation. Participants were free to withdraw from taking part at any time, without needing to give a reason. Their individual data could be withdrawn from Study Four until the final outcome assessment.

Questions about IPV and mental health were asked and worded sensitively, to minimise distress to participants. However, the opportunity to express emotion about problems and difficulties during sessions of PST-IPV and standard PST was potentially therapeutic. ANC staff were trained to respond empathetically to women's distress. Data collectors were trained to be sensitive to signs of distress, and when to suggest rescheduling or discontinuing an interview. If participants remained distressed, data collectors contacted the field supervisor. If needed, participants' ANC providers were informed and the case was discussed with the project mental health professional, a female Ethiopian psychiatrist (BM).

7.4.19.5 Registration

I registered the trial prospectively, on the pan African clinical trials registry (reference: PACTR202002513482084) on 13/12/2019, and published the protocol (Keynejad, Bitew, et al., 2020) on 01/06/2020.

8 STUDY FIVE: RANDOMISED FEASIBILITY TRIAL AND PROCESS EVALUATION – RESULTS

This chapter presents the results (8.1) and discussion (8.2) of the randomised feasibility trial described in Study Four (7.4).

8.1 Results

8.1.1 Timeline

Table 8.1 shows the timeline of key trial activities: administrative tasks, training courses, data collection, intervention delivery, supervision, and relevant events. After a delayed start due to the coronavirus pandemic, COVID-19 did not impact trial progress. Fifty-two eligible participants from Bu'i and Kela were recruited over 35 days (from 27th April to 31st May 2021), a rate of 10 participants per week (see Figure 8.1). A further 23 participants with depressive symptoms and functional impact but not past-year IPV exposure were recruited by the nested study, which compared standard PST with EUC.

In a deviation from the protocol, 17 out of the 52 women meeting inclusion criteria were inappropriately randomised. Research staff used the two-arm randomisation table reserved for women not reporting past-year IPV exposure, instead of the three-arm table, for these participants. This occurred because, despite clear protocols and training, some research staff members interpreted IPV exposure to mean physical and/or sexual IPV and not psychological or emotional IPV. Therefore, although these 17 participants were randomised into one of two appropriate arms (standard PST or EUC), they were denied the opportunity of being randomised into the third trial arm (PST-IPV), as planned. This protocol breach was reported to KCL and AAU institutional review boards on 23/11/2021, after the precise number of mis-randomised participants had been confirmed by an independent data clerk. Figure 8.1 therefore displays participant recruitment, separated into the 35 women correctly randomised using the three-arm table and the 17 women incorrectly randomised using the two-arm table.

Table 8.1 Timeline of trial processes during 2021

Activities ↓		Months →	Jan	Feb	Mar	April	May	June	July	August	Sept	Oct	Nov
Administration	Manual printing												
	Randomisation list												
	Field staff employment												
Training	Good Clinical Practice												
	Trainer orientation												
	PST-IPV for HWs												
	Standard PST for HWs												
Evaluation	Communication skill top-up												
	Baseline assessments												
	Fidelity/completion checks												
	Outcome assessments												
Intervention	Qualitative interviews												
	Recruitment/randomisation												
	Accelerated cases												
Supervision	Session delivery												
	HWs by trainers: in-person												
	HWs by trainers: telephone												
	Field supervisors by TC/RA												
	TC and RA by PI												
	Trainers by PI												
	RK by PhD supervisor												
Key date	April/May: Ramadan, Easter, June: election, July: fiscal year end, Sept: new year												

HW: health worker, IPV: intimate partner violence, PI: principal investigator, PST: problem-solving therapy, RA: research assistant, TC: trial coordinator

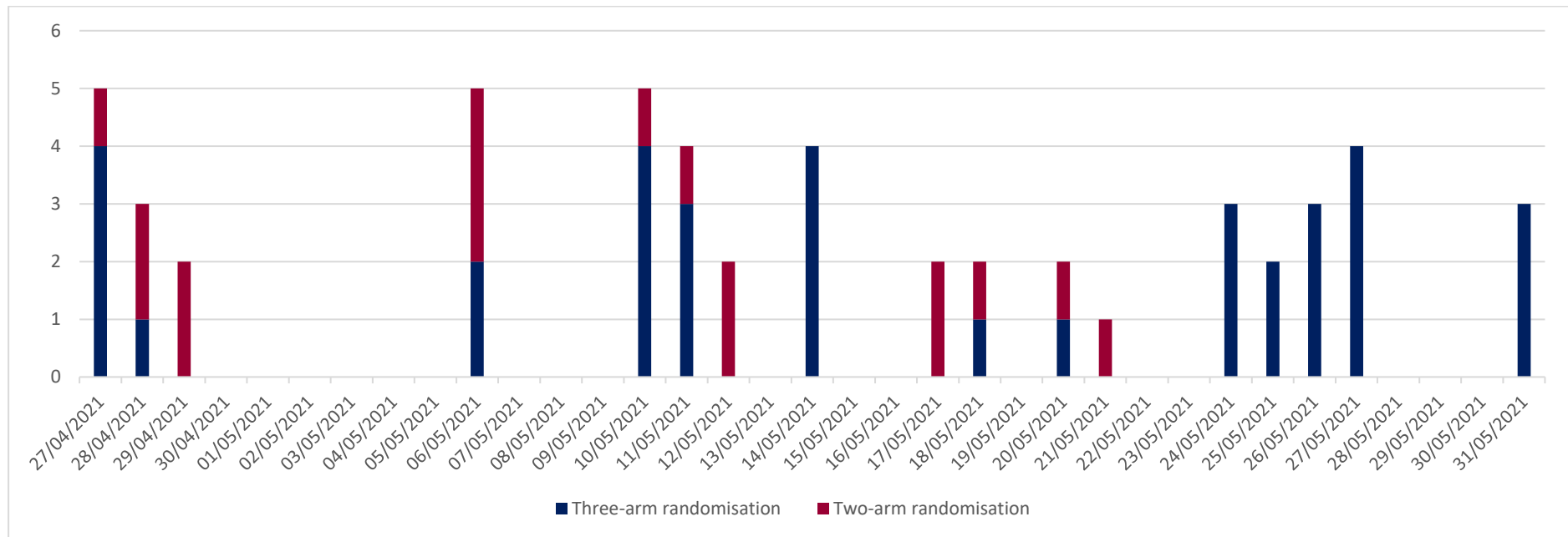


Figure 8.1 Participant recruitment, by date

8.1.2 Participant flow

Figure 8.2 shows the flow of participants through the study. Out of 335 ANC attendees pre-screened prior to being approached by research staff, 193 (58%) were excluded for not meeting basic eligibility criteria, including 12 (4%) who declined initial screening. Of the remaining 142 pregnant women, a further 67 (47%) were excluded following initial screening, as they did not meet eligibility criteria, including 11 with depressive symptoms and functional impact but not IPV, after recruitment for the nested study had completed. Of the remaining 75 pregnant women, 52 (69%) met inclusion criteria for Study Four and were randomised to either PST-IPV, standard PST or EUC. A further 23 pregnant women, who did not report IPV, were randomised to standard PST or EUC for the nested trial (shaded grey in Figure 8.2).

Of the 25 participants randomised to PST-IPV, 19 (76%) attended all four sessions and 19 (76%; not all the same 19 participants) completed the outcome assessment. Of the 12 participants randomised to standard PST (using both the three-arm and the two-arm randomisation tables – outlined in black and blue, respectively, in Figure 8.2), eight (67%) completed the outcome assessment. Of the 15 participants randomised to EUC, 12 (80%) completed the outcome assessment. Of the 13 participants (25%) who did not complete an outcome assessment, five (38%) had moved away from the study area, four (31%) could not be traced, having not attended their appointment and not having a (working) mobile telephone, and four (31%) declined, usually due to postnatal confinement.

In a second protocol deviation, 12 out of 39 outcome assessments were conducted before 9 weeks (between 37 and 61 days, rather than the target 63 days) had elapsed since the participant's enrolment in the trial (two out of 12 women incorrectly randomised using the two-arm table and 10 out of 27 correctly randomised using the three-arm table). This decision was taken by the two field supervisors at both sites, in order to expedite data collection, despite clear training and research protocols, and without knowledge of the investigators. Overall, the median time between enrolment and outcome assessment was lower in participants reporting physical or sexual IPV (between 60 and 69 days), than participants reporting psychological or emotional IPV (between 76 and 86 days).

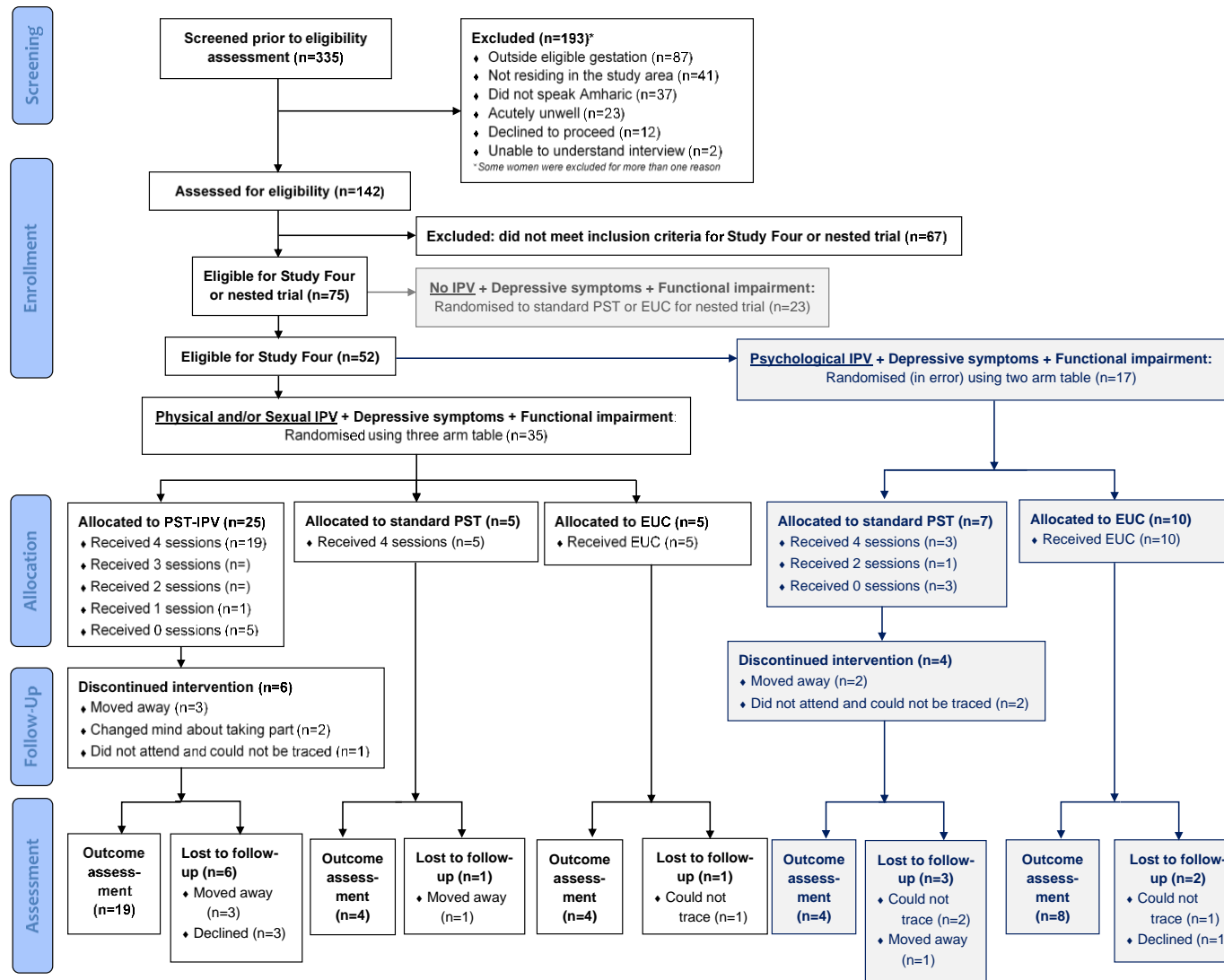


Figure 8.2 CONSORT diagram

8.1.3 Participant characteristics

Demographic characteristics of the 52 participants in Study Four are shown in Table 8.2, separated into those randomised using three-arm and two-arm tables. Demographic information was unavailable for one participant randomised to PST-IPV, as that page of the assessment was omitted in error, and the participant could not be reached afterwards.

Table 8.2 shows that the median ages of participants ranged between 20 and 29 years across all study arms. The majority of participants was of Orthodox Christian faith, primary school educated, and gave their occupation as home-maker. Ninety-two percent of participants (n=47) were in monogamous marriages, and 72% were married by 20 years of age (n=36). Thirty percent of participants' partners worked as farmers (n=15), and a further 26% as government or private sector employees (n=13). Forty-six percent of partners were educated to primary school level (n=23), and the median number of household members ranged between three and six persons. Participants' median gravidity was between two and three pregnancies, and median parity was between zero and two previous deliveries. Fifty-seven percent of participants reported that their pregnancy was planned (n=29), including its timing (86%, n=25). Median list of threatening experiences scores were between 25 and 27 across all arms (indicating experiences of between three and five threatening experiences).

No medical records for any participant mentioned past or current mental health conditions, or IPV. Although the only documented medical comorbidity was one case of dyspepsia, physical health medications were prescribed for 12 (23%) participants. No participant was prescribed psychiatric medication.

Table 8.2 Demographic characteristics of participants at baseline

Characteristic	Randomised using three-arm table			Randomised using two-arm table	
	PST-IPV (n=25)	Standard PST (n=5)	EUC (n=5)	Standard PST (n=7)	EUC (n=10)
Age in years	(n=24)				
Median, IQR	25.5 (23-28.5)	20 (20-26)	29 (28-29)	28 (24-35)	23.5 (19-25)
Religion (n, %)	(n=24)				
Orthodox Christian	22 (92)	4 (80)	5 (100)	5 (71)	6 (60)
Protestant	1 (4)	1 (20)		2 (29)	3 (30)
Muslim	1 (4)				1 (10)
Other					
Highest education (n, %)	(n=24)				
Non-literate	3 (13)	1 (20)	2 (40)	1 (14)	
No formal education	4 (17)	1 (20)			2 (20)
Primary school	9 (38)	3 (60)	2 (40)	5 (72)	4 (40)
Secondary school	6 (25)		1 (20)	1 (14)	2 (20)
Higher education	2 (8)				2 (20)
Occupation (n, %)	(n=24)				
Home-maker	18 (75)	2 (40)	1 (20)	6 (86)	5 (50)
Farmer	1 (4)	1 (20)	1 (20)		1 (10)
Daily labourer	2 (9)	1 (20)	1 (20)		
Merchant/market seller	1 (4)	1 (20)	1 (20)		1 (10)
Teacher	1 (4)				
Self-employed/business	1 (4)				
Brewer/tella vendor			1 (20)	1 (14)	
Government employee					2 (20)
Waitress					1 (10)
Marital status (n, %)	(n=24)				
Married (monogamous)	21 (88)	5 (100)	4 (80)	7 (100)	10 (100)
Married (polygamous)	2 (8)		1 (20)		
Cohabiting					
Single	1 (4)				
Age at marriage (n, %)	(n=23)				
14 years old or younger	1 (4)		1 (20)		
15-16 years old	4 (17)	2 (40)	2 (40)		2 (20)
17-18 years old	8 (35)			2 (28.6)	1 (10)
19-20 years old	5 (22)	3 (60)	1 (20)	2 (28.6)	2 (20)
21-25 years old	5 (22)		1 (20)	1 (14.2)	5 (50)
26-29 years old				2 (28.6)	
Partner occupation (n, %)	(n=23)				
Farmer	12 (52)	2 (40)	3 (60)	3 (43.2)	5 (50)

Daily labourer	5 (22)				1 (10)
Merchant/market seller				1 (14.2)	
Government employee	6 (26)	2 (40)	1 (20)	1 (14.2)	3 (30)
Factory worker			1 (20)		
Construction worker				1 (14.2)	1 (10)
Priest				1 (14.2)	
Unemployed		1 (20)			
Partner's highest education level attended (n, %)	(n=23)				
Non-literate	3 (13)		1 (20)	3 (43)	1 (10)
No formal education	13 (57)	1 (80)	3 (60)	1 (14)	5 (50)
Primary school	6 (26)			3 (43)	2 (20)
Secondary school	1 (4)	1 (20)	1 (20)		2 (20)
Higher education					
Total household family members (median, IQR)	(n=24) 3 (3-5)	3 (2-5)	6 (4-6)	4 (3-9)	3 (2-5)
Gestation in weeks at first ANC attendance	(n=25)				
Median (IQR)	20 (20-28)	20 (20-28)	28 (28-34)	18 (18-28)	22 (20-26)
ANC attendance (n, %)	(n=25)				
All appointments	17 (68)	3 (60)	4 (80)	4 (57)	7 (70)
Some appointments	8 (32)	2 (40)	1 (20)	3 (43)	3 (30)
Gravidity	(n=24)				
Median (IQR)	2.5 (2-4)	2 (1-4)	3 (2-5)	3 (2-4)	2 (1-2)
Range	1-6	1-4	2-7	1-6	1-5
Parity	(n=24)				
Median (IQR)	1 (1-3)	0 (0-1)	2 (2-4)	1 (0-2)	0 (0-1)
Range	1-5	1-3	1-6	0-5	0-4
Pregnancy planned (n, %)	(n=24)				
Yes	11 (46)	3 (60)	2 (40)	5 (71)	8 (80)
No	13 (54)	2 (40)	3 (60)	2 (29)	2 (20)
Timing planned (n, %)	(n=11)	(n=3)	(n=2)	(n=5)	(n=8)
Yes	8 (73)	3 (100)	2 (100)	5 (100)	7 (87.5)
No	3 (27)				1 (12.5)
Medications (n, %)					
None prescribed	20 (80)	4 (80)	4 (80)	7 (100)	5 (50)
Physical health	5 (20)	1 (20)	1 (20)		5 (50)
Mental health					
LTE total score	(n=25)				
Median (IQR)	25 (23-26)	25 (25-26)	25 (25-27)	25 (24-27)	27 (25-27)

ANC: antenatal care, EUC: enhanced usual care, IPV: intimate partner violence, IQR: inter-quartile range, LTE: list of threatening experiences, PST: problem-solving therapy.

8.1.4 Primary outcome

Table 8.3 presents participants' clinical scores and outcomes at baseline and follow-up, separated into those randomised using three-arm and two-arm tables. The small sample sizes of participants randomised to standard PST and EUC using three-arm and two-arm tables limits interpretation of changes in these arms.

Table 8.3 shows that the median PHQ-9 score reduced from 8 (IQR: 7-11) to 6 (3-9), post PST-IPV (n=19). Reductions were also observed among the smaller number of women randomised to EUC using the three-arm table (who experienced physical or sexual IPV; from 11 to 5.5, n=4), and the two-arm table (who experienced psychological IPV; from 7.5 to 4, n=8), as well as among women randomised to standard PST using the two-arm table (from 10 to 5.5, n=4), who completed an outcome assessment.

PHQ-9 score reduced by more than 50% in six (32%) of the 19 participants randomised to PST-IPV who completed both baseline and outcome assessments. However, PHQ-9 score also reduced by more than 50% in six (50%) women randomised to EUC and three (38%) women randomised to standard PST, who completed an outcome assessment.

The proportion of participants endorsing PHQ-9 question nine (on suicidality) reduced across all arms. Among PST-IPV participants, women endorsing question nine reduced from six (24%) to three (16%), post-intervention. The median MINI suicidality score for PST-IPV participants reduced from 9 (IQR: 1-10) to 1 (0-11), post-intervention. The median MINI suicidality score increased, post-participation, among the two participants randomised to EUC who continued to endorse suicidality at outcome assessment.

Table 8.3 Participant clinical scores and outcomes at baseline and follow-up

Clinical score	Randomised using three-arm table			Two-arm randomisation	
	PST-IPV (Baseline n=25, Outcome n=19)	Standard PST (Baseline n=5, Outcome n=4)	EUC (Baseline n=5, Outcome n=4)	Standard PST (Baseline n=7, Outcome n=4)	EUC (Baseline n=10, Outcome n=8)
Days between enrolment and outcome assessment (median, IQR)	69 (44-99)	60 (49-74)	63 (60-81)	76 (68-111)	86 (62-90)
Depressive symptoms					
Median total PHQ-9 score (IQR)					
Baseline	8 (7-11)	7 (7-10)	11 (9-11)	10 (7-11)	7.5 (6-9)
Outcome Assessment	6 (3-9)	7 (4-8)	5.5 (0-16)	5.5 (3-14)	4 (2-7.5)
Recovery					
≥50% reduction in total PHQ-9 (n, %)					
Yes	6 (32)	1 (25)	2 (50)	2 (50)	4 (50)
No	13 (68)	3 (75)	2 (50)	2 (50)	4 (50)
Suicidality					
Endorsing PHQ-9 Question 9 (n, %)					
Baseline	6 (24)	2 (40)	4 (80)	2 (29)	3 (30)
Outcome Assessment	3 (16)	0 (0)	1 (25)	1 (25)	1 (12.5)
Median MINI suicidality score (IQR) if endorsing PHQ-9 Question 9					
Baseline	9 (1-10), n=6	3 (3-3), n=2	5.5 (2.5-8), n=4	3.5 (1-6), n=2	1 (1-2), n=3
Outcome Assessment	1 (0-11), n=3	N/A, n=0	15 (15-15), n=1	2 (2-2), n=1	7 (7-7), n=1
Post-traumatic stress symptoms					
Median total PCL-5 score (IQR)					
Baseline	9 (4-13)	5 (5-6)	9 (4-16)	13 (4-21)	2.5 (0-6)
Outcome Assessment	4 (1-8)	4 (2-5.5)	9 (0-34.5)	2.5 (0-12.5)	4.5 (0.5-7)
Anxiety symptoms					
Median total GAD-7 score (IQR)					
Baseline	11 (8-12)	10 (8-10)	13 (13-14)	11 (8-13)	7 (7-8)
Outcome Assessment	9 (7-12)	8.5 (7.5-11)	8.5 (7-16.5)	10 (8.5-12)	8 (7-10.5)
Functional impact					
Median PHQ-9 Question 10 score (IQR)					
Baseline	1 (1-2)	1 (1-2)	1 (1-2)	2 (1-2)	1 (1-1)
Outcome Assessment	1 (0-1)	1 (0.5-1.5)	2 (2-2)	1 (0.5-1.5)	1 (0-1)
Median total WHODAS 2.0 score (IQR)					
Baseline	17 (11-25)	8 (6-11)	31 (8-36)	22 (17-33)	17 (11-19)
Outcome Assessment	17 (3-25)	22 (22-24)	19 (6-42)	12.5 (4-49)	14 (4-26)
Median days' difficulties in past 30					
Baseline	15 (4-30)	6 (5-7)	7 (4-10)	15 (7-17)	11.5 (5-15)

Outcome Assessment	4 (0-15)	13.5 (9.5-15)	5 (1.5-18.5)	3.5 (1-7.5)	15 (5-30)
Median days' total inactivity in past 30					
Baseline	0 (0-2)	2 (0-3)	0 (0-0)	0 (0-3)	0 (0-0)
Outcome Assessment	0 (0-0)	0 (0-0)	1 (0-16)	0 (0-1.5)	0 (0-4)
Median days' reduced activity in past 30					
Baseline	0 (0-4)	0 (0-0)	3 (0-10)	7 (0-15)	0 (0-7)
Outcome Assessment	0 (0-5)	6 (0-13.5)	3 (1.5-16.5)	0 (0-13.5)	0 (0-6)
Past-year IPV					
Median total NGL question score (IQR)					
Baseline	5 (4-8)	4 (4-4)	5 (3-8)	3 (2-5)	2.5 (2-4)
Outcome Assessment	1 (0-8)	1 (0-5)	5 (1.5-9)	1.5 (0.5-6)	0 (0-2)
Median total WHO question score (IQR)					
Baseline	9.5 (5-11)	6 (4-9)	10 (9-10)	2 (1-3)	3 (1-4)
Outcome Assessment	3 (2-9)	3 (1.5-4.5)	2.5 (1-12)	2.5 (1-12.5)	2.5 (0.5-3.5)
Attitudes towards gender roles					
Median WHO question score (IQR)					
Baseline	27 (24-30)	25 (23-25)	26 (26-30)	25 (22-27)	24 (24-28)
Outcome Assessment	27.5 (26-29)	27 (25-28)	28 (26-29)	26 (24-29)	31.5 (30-32)
Self-efficacy					
Median total adapted scale score (IQR)					
Baseline	15 (10-18)	15 (15-18)	5 (0-10)	15 (10-15)	15 (15-15)
Outcome Assessment	15 (5-17)	15 (10-17)	15 (15-18)	17.5 (10-20)	17 (15-20)
Mastery					
Median total adapted scale score (IQR)					
Baseline	33 (30-34)	30 (25-32)	35 (24-36)	31 (30-40)	33.5 (27-35)
Outcome Assessment	31 (30-36)	32 (28-38)	32 (23.5-41)	33 (29-37)	31.5 (30-35)
Perceived social support					
Median total OSSS-3 score (IQR)					
Baseline	10 (9-11)	11 (11-12)	12 (10-12)	12 (11-12)	11 (10-12)
Outcome Assessment	10 (8-12)	8.5 (8-11)	12 (9-13)	10.5 (8-14)	11 (8-12)
Obstetric complications (n, %)					
Obstructed or prolonged labour	(n=9)	(n=4)	(n=2)	(n=4)	(n=10)
None documented	9 (100)	3 (75)	2 (100)	4 (100)	9 (90)
Neonatal outcomes (n, %)					
Live birth without complications	(n=9)	(n=4)	(n=2)	(n=4)	(n=10)
None documented	8 (89)	3 (75)	1 (50)	3 (75)	8 (80)
None documented	1 (11)	1 (25)	1 (50)	1 (25)	2 (20)

GAD-7: generalised anxiety disorder questionnaire, IPV: intimate partner violence, MINI: mini neuropsychiatric inventory, NGL: non-graphic language questions, OSSS-3: Oslo social support scale, N/A: not applicable, PCL-5: PTSD symptom checklist for DSM-5, PHQ: patient health questionnaire, PST: problem-solving therapy, PST-IPV: PST adapted for women experiencing IPV, WHO: world health organization, WHODAS: WHO disability assessment schedule.

8.1.5 Secondary outcomes

8.1.5.1 *Post-traumatic stress*

Table 8.3 shows that the median PCL-5 score reduced from 9 (4-13) to 4 (1-8), post-PST-IPV (n=19). Reductions in PCL-5 scores were also noted among the smaller sample of participants randomised to standard PST (from 5 to 4 in women experiencing physical and sexual IPV (n=4) and from 13 to 2.5 among women experiencing psychological IPV (n=4)). Notably, median PCL-5 scores were unchanged or increased among women randomised to EUC, who had reported physical or sexual IPV (from 9 to 9, n=4) and psychological IPV (from 2.5 to 4.5, n=8).

8.1.5.2 *Anxiety*

The median GAD-7 score reduced from 11 (8-12) to 9 (7-12), post-PST-IPV (n=19). Median GAD-7 scores also reduced post-standard PST: from 10 (8-10) to 8.5 (7.5-11), among women experiencing physical or sexual IPV (n=4) and from 11 (8-13) to 10 (8.5-12), among women experiencing psychological IPV (n=4). However, anxiety symptoms also reduced from 13 (13-14) to 8.5 (7-16.5) among women experiencing physical or sexual IPV who were randomised to EUC, and who completed outcome assessment (n=4).

8.1.5.3 *Functional impact*

Median responses to the tenth PHQ-9 question on functional impact were similar at baseline and outcome assessment across all arms.

The median total WHODAS 2.0 score among participants randomised to PST-IPV was 17 at both baseline and outcome assessment (n=19). Median WHODAS scores increased from 8 (6-11) to 22 (22-24) among participants experiencing physical or sexual IPV and randomised to standard PST, who completed an outcome assessment (n=4), but decreased in all other arms, post-participation.

Median days' difficulties in the past 30 days reduced from 15 (4-30) at baseline to 4 (0-15) at outcome assessment, among participants randomised to PST-IPV (n=19), but there was no consistent trend in the direction of effect on WHODAS scores, in intervention arms, relative to EUC.

Median days' total inactivity and reduced activity out of the past 30 days remained zero at baseline and follow-up among participants randomised to PST-IPV (n=19) and EUC (total n=12), with no consistent direction of effect in intervention arms, relative to EUC.

8.1.5.4 IPV

Median scores on the 'non-graphic language' (NGL) IPV questionnaire reduced from 5 (4-8) to 1 (0-8), post-PST-IPV (n=19). Median NGL scores also reduced among women randomised to standard PST, experiencing physical or sexual IPV (from 4 to 1, n=4), or psychological IPV (from 3 to 1.5, n=4).

Median WHO IPV questionnaire scores reduced from 9.5 (5-11) to 3 (2-9), among participants randomised to PST-IPV (n=19), and among participants randomised to standard PST, reporting physical or sexual IPV, and completing an outcome assessment (from 6 to 3, n=4). However, WHO IPV scores also reduced among participants randomised to EUC and experiencing physical or sexual IPV (from 10 to 2.5, n=4), or psychological IPV (from 3 to 2.5, n=8).

8.1.5.5 Attitudes towards gender roles

Median scores on the WHO attitudes towards gender roles questionnaire were 27 (24-30) at baseline and 27.5 (26-29) at outcome assessment among participants randomised to PST-IPV (n=19). Higher scores indicate more gender equal attitudes. Increases of 1-2 in attitudes towards gender role scores were recorded in all other arms, except among women experiencing psychological IPV and randomised to EUC (increased from 24 to 31.5, n=8).

8.1.5.6 Self-efficacy

The median adapted self-efficacy scale score was 15 at baseline (10-18) and outcome assessment (5-17) among participants experiencing physical or sexual IPV and randomised to PST-IPV (n=19), or standard PST (n=4). Self-efficacy scores increased among participants experiencing physical or sexual IPV (from 5 to 15, n=4) and psychological IPV (from 15 to 17, n=8), who were randomised to EUC. Self-efficacy also increased among participants experiencing psychological IPV and randomised to standard PST (from 15 to 17.5, n=4).

8.1.5.7 Mastery

The median adapted mastery scale score reduced from 33 (30-34) to 31 (30-36) among participants randomised to PST-IPV (n=19), and among participants experiencing physical or sexual IPV (from 35 to 32, n=4), or psychological IPV (from 33.5 to 31.5, n=8), randomised to EUC. However, median mastery scores increased slightly among participants experiencing physical or sexual IPV (from 30 to 32, n=4) or psychological IPV (from 31 to 33, n=4), randomised to standard PST and completing an outcome assessment.

8.1.5.8 Perceived social support

Median OSSS-3 scores were 10 (9-11) at baseline and 10 (8-12) at outcome assessment, among participants randomised to PST-IPV (n=19). Perceived social support scores were also unchanged among participants experiencing physical or sexual IPV (from 12 to 12, n=4), or psychological IPV (from 11 to 11, n=8), randomised to EUC. However, perceived social support reduced among participants experiencing physical or sexual IPV (from 11 to 8.5, n=4), or psychological IPV (from 12 to 10.5, n=4), randomised to standard PST and completing an outcome assessment.

8.1.5.9 Obstetric and neonatal outcomes

Among the 29 participants who had given birth by the time the trial had completed data collection (56%), two cases of obstructed or prolonged labour (7%) were recorded. No other obstetric or neonatal complications were recorded.

8.1.5.10 Healthcare-seeking behaviour

I plan to analyse CSRI scores as part of a post-doctoral economic evaluation of Study Four.

8.1.6 Process evaluation

In this section, I summarise the evaluations of the two active intervention arm training courses (section 8.1.6.1). I then present the process evaluation of Study Four, according to the CICI framework's five domains of implementation (Pfadenhauer et al., 2017). These are the implementation theory (section 8.1.6.2), process (section 8.1.6.3), strategies (section 8.1.6.4), agents (section 8.1.6.5), and outcomes (section 8.1.6.6). I then present findings regarding safety (section 8.1.6.7) and iterative adaptations (section 8.1.6.8).

Due to delays to the start of Study Four caused by the coronavirus pandemic, the results of qualitative interviews with pregnant women and health worker participants (described in section 7.4.17.4) were not available for inclusion in this thesis. They will be analysed and written up as an early post-doctoral study.

8.1.6.1 Training

Table 8.4 summarises advantages and disadvantages of the training design, identified through my supervision discussions with the trial coordinator (TC) and research assistant (RA), with reference to their field notes and feedback summaries.

Table 8.4 PST-IPV and standard PST training course features

<i>Feature</i>	<i>Advantages</i>	<i>Disadvantages</i>	<i>Recommendation</i>
Five day courses divided into three and two day blocks.	<p>Health workers and trainers only missed up to three days' work at a time.</p> <p>Trainers only spent two nights or fewer at the field site (relevant to Ramadan).</p> <p>Health workers could reflect on and revise content between training blocks.</p>	<p>Potential loss of continuity of a single week course.</p> <p>Potential confusion about which trainees should attend on which days.</p> <p>Some health workers might attend one block and not another.</p>	<p>Divide training courses into two blocks in future.</p> <p>Five days considered by trainers, research staff, and most health workers to be appropriate to introduce the intervention.</p>
Large, well-ventilated venue.	Facilitated adherence to COVID-19 precautions.	Combined with background noise and masks, audibility was compromised.	Provide a battery-operated microphone for future courses.
Training delivered in the study site (Sodo) rather than a centralised site (such as Addis Ababa University).	<p>Close to health workers' usual workplace, making attendance easier and contextualising content to the intervention context.</p> <p>Reduced cost compared to transporting health workers to Addis Ababa, accommodating them in the capital for one week, and organising a training venue.</p>	<p>Trainers and research staff required to travel between Addis Ababa and Sodo, associated with logistical challenges.</p> <p>Health workers could be recalled to their clinical duties (two trainees) or attend another event (three trainees) on one day.</p> <p>Power outages, poor internet connections, and rainy days impacted smooth delivery.</p>	<p>Deliver training in Sodo, as this minimised missed training. For example, one health worker left early to attend a funeral but still obtained some of the day's training. Two trainees were tired because of night shifts, but still attended.</p> <p>Agree clear attendance requirements at the outset and support clinicians to catch up missed content.</p> <p>Ensure that paper handouts are available in case of power outages and poor internet connectivity.</p>
Small group format (six staff per course).	Enabled trainers to observe health workers closely and provide personalised feedback.	Higher cost per trainee than larger group training.	Research staff thought that more than ten learners per course would make training quality and COVID-19 precautions difficult to maintain.
Clinician trainers made reference to their experience.	Increased engagement of trainees.	Requires trainers to be practising mental health professionals.	Ensure that trainers are practising clinicians and refer to their experience during training.

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<i>Feature</i>	<i>Advantages</i>	<i>Disadvantages</i>	<i>Recommendation</i>
Interactive role play exercises.	Increased the relevance of training to health worker trainees. Health workers acted out challenging cases they had encountered, making PST-IPV role plays more realistic.	In the first block of standard PST training, health workers were initially reticent to practise skills in front of the group, leading trainers to demonstrate these.	Devote longer to energising activities, to build confidence among trainees, maintain engagement, and encourage them to volunteer. Pre-recorded role play videos could allow health workers to re-watch content after the course.
Recapping at the start and end of each training day.	Enhanced trainees' memory of intervention content.	Potentially repetitive.	Recap material throughout the course, especially given that the course is divided into two blocks.
Trial protocols detailed on day 5.	Trainees focused on clinical skill acquisition rather than the research.	More details about Study Four's organisation at the start would contextualise training.	Begin the course with an overview of the trial, before giving detailed information on the final day.
Payments dictated by fixed university rates.	Ensured parity of reimbursement across research studies, avoiding variability.	Trainees were disappointed that the attendance fee was lower than expected, impacting their engagement with training.	Agree rates acceptable to health workers with the finance department in advance. Incorporate training fees into the overall fee trainees receive.
ANC staff approved to deliver sessions after accelerated clinical case.	Ensured a minimum standard of intervention quality prior to further sessions being delivered.	Due to unanticipatedly high numbers of eligible participants, some women were required to wait until their allocated health worker had been 'signed off' for their sessions to begin.	Employ one data collector to recruit participants for accelerated cases during the training course week. Employ more data collectors to recruit for the main trial, once staff have completed an accelerated case/are approaching 'sign-off' as competent.
Half day courses recapping training and managing emotions.	After accelerated cases, sessions were added, addressing supervision-identified training requirements. Ensured training was responsive to identified staff needs.	Health workers had delivered some intervention sessions before this training was provided, in which communication skill limitations were noted by supervisors.	More extensive communication skills and managing emotions training, with formative assessment and feedback, should be delivered prior to intervention training. Top-up after accelerated cases should target session quality and staff communication.

ANC: antenatal care, COVID-19: SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) infection, PST: problem-solving therapy.

Trainee feedback

Feedback for the PST-IPV and standard PST courses could not be disaggregated, because few trainees noted the date and course name on their forms. Fifty-three end-of-day feedback forms were collected, completed by the 12 health workers attending the two five day courses. Course feedback was consistently positive, with mean scores of 4.04 (standard deviation (SD): 0.78) to 4.32 (SD: 0.87) out of five for quality, relevance, usefulness, organisation, and meeting expectations. Similarly, feedback about trainers ranged from 4.17 (SD: 1.21) to 4.43 (SD: 0.67) out of five for explanation clarity, participation encouragement, helpfulness of feedback, and making content relevant.

Free-text responses to open questions highlighted role plays and interactive teaching, skilled trainers, learning about anxiety, depression, and IPV, and relevance to the health worker's career as positive aspects. Two health workers praised PST itself, saying "I like the detail about how to break down problems and deal [with them] one by one", and "I like the six steps [approach to problems classified as important and can be changed]".

Suggested improvements were adding more group activities, increasing the *per diem* fee paid to attend training, delivering the course over a single week, organising a generator in case of a power cut, addressing acoustic issues at the training venue, avoiding misunderstandings about the start time of training spread over two weeks, and improving the catering. The lower *per diem* payments than previous training courses arose because of restrictions imposed by the university's clinical trials unit. Health workers' disappointment with this amount was addressed by negotiating that their fee for delivering intervention sessions would be net of tax deductions, rather than a gross payment.

Responses to the question "what might you do differently because of this course?" showed themes of listening to women during ANC, helping women, delivering therapy sessions, gaining knowledge, and sharing learning with their community. For example, "I will ask mothers about their feelings", "it taught me to be more listener than talker", and "I have learned how it is important to give time listening to mothers while delivering [ANC] service".

Materials

Health workers who attended PST-IPV training reported that some role play cases were too straightforward to adequately prepare them to deliver sessions in practice. They thought that it was unrealistic for the pregnant women in role play cases to readily understand the content and concepts of problem-solving therapy the first time they were explained. Trainees recommended more challenging role plays, in which women struggled to follow instructions.

In a spontaneous adaptation initiated by the psychiatrist and psychologist PST-IPV trainers, three English language videos were screened during their course, to aid health workers' understanding of relaxation exercises. Two videos prepared for the UK national health service (NHS) focused on relaxation (Coventry and Warwickshire Partnership NHS Trust, 2013a) and breathing techniques (Coventry and Warwickshire Partnership NHS Trust, 2013b). Having been prepared for people with an intellectual disability, they used simple English language. The third video, on progressive muscle relaxation (Johns Hopkins Rheumatology, 2018), had been prepared by a psychologist for patients experiencing painful musculoskeletal disorders. The content (delivered slowly in English, with subtitles), was therefore grounded in bodily experiences of distress, rather than a mental health-related explanatory model. Trainers and trainees engaged in these three exercises while the videos played, to gain personal experience of how they might benefit pregnant women.

PST-IPV course trainers reported that health workers wanted to watch more role plays at the end of the course and recommended the preparation of locally tailored video resources that could be shown during training. They also proposed that trainees could re-watch these videos before delivering sessions. Standard PST course trainers supported this idea, but also emphasised the value of participatory role plays. They noted the risk of health workers being deterred from practising with their peers, if they felt intimidated by the standard of delivery shown on a video.

Although the intervention training manual and flip chart were translated into Amharic by an experienced translator, trainers fed back that some language required adjustment. For

example, terms such as “intimate”, “control”, “victim”, and “privacy” were not widely used in Amharic and required explanation to ensure clarity.

One item of cultural adaptation feedback referred to an example given of a ‘lower priority problem’ in the manual: the woman’s coffee pot was broken. A health worker highlighted that without a coffee pot, a pregnant woman would be unable to invite her neighbours to her home for the traditional coffee ceremony: a key social activity. They recommended changing this example to the accidental damage of a less culturally significant item. Finally, the first two pages of the flip chart had been bound back-to-front in error, showing the importance of emphasising specific requirements to the printing company.

8.1.6.2 Implementation theory

One addition to the theory of change map (section 6.5.3.2) raised by the available findings was the assumption that women experiencing all forms of IPV are appropriately identified and have the opportunity to be randomised to PST-IPV. Qualitative interviews with pregnant women and health workers may raise further adjustments. However, definitively evaluating the theory of how intermediate outcomes lead to long-term outcomes and impacts requires a larger-scale study and longer-term follow-up.

8.1.6.3 Implementation process

The process of Study Four ran smoothly, once it commenced. Faster than anticipated recruitment of eligible participants meant, however, that some women needed to wait for their sessions to begin until a trained health worker was available. This also meant that eligible participants were referred for sessions as soon as health workers had completed their accelerated cases, limiting the time available for in-depth supervision and reflection on learning from those cases.

At the end of Study Four, giving birth sometimes prevented participants from completing all four sessions of the intervention, or attending an outcome assessment at the planned time of nine weeks post-enrolment. Where women expressed interest in completing an outcome assessment, data collectors performed these at home, provided that there was a private space outdoors, where they would not be overheard, including by abusive partners.

8.1.6.4 Implementation strategies

Table 8.5 summarises the effects of key implementation strategies targeting the retention of participants and health workers, and improving health worker skills, using a typology derived from expert consensus (Powell et al., 2015).

Table 8.5 Implementation strategies and their effects

<i>Focus</i>	<i>Strategy type</i>	<i>Details</i>	<i>Effect</i>	<i>Recommendation</i>
Health worker skills.	Develop educational materials.	Health workers were provided with printed PST-IPV manuals and flip-charts, to deliver the intervention.	Health workers trained to deliver a new intervention for pregnant women experiencing IPV.	For a future trial, develop role play demonstration videos.
	Make training dynamic.	Interactive training focused on small group activities and role play tasks.	Training was positively rated by trainees, with no drop-outs.	Expand: show videos and share for post-course revision.
	Provide clinical supervision.	Health workers received regular supervision from a psychiatrist or psychologist who trained them, discussing audio-recorded sessions.	Health workers received regular feedback and opportunities to discuss challenging cases.	Focus more on regularity of supervision than in-person delivery.
	Conduct ongoing training.	Top-up and refresher training was provided to health workers in response to needs identified during supervision.	Enhanced health worker skills. Improved session quality and intervention fidelity.	Expand in a future trial, with a programme of regular training throughout the study.
Health worker retention.	Alter incentive/allowance structures. Use capitated payments.	Health workers paid 2000 birr net per case, including training and supervision attendance.	Health workers motivated to fulfil their roles as per the standard operating procedure.	Continue in a future trial.
Participant retention.	Intervene with patients/consumers to enhance uptake and adherence.	Pregnant women were reimbursed 70-140 birr for travel expenses incurred by attending sessions.	Drop-outs for reasons other than moving away from the study site were infrequent.	Explore in a future trial: if scaled-up, travel costs would not be reimbursed.

8.1.6.5 Implementation agents

Pfadenhauer et al. (2017) recommended evaluating factors such as the attributes, skills, knowledge, attitudes, and buy-in of all individuals deciding to implement, implementing, and receiving an intervention. In Study Four, implementation agents comprised researchers, supervisors, health workers, and participants (see Table 8.6).

8.1.6.6 Implementation outcomes

Acceptability

As indicated in Figure 8.2, out of 335 women screened prior to eligibility assessment, 12 who were potentially eligible to participate in Study Four declined initial screening (4%). Of the 142 women who underwent initial screening, none who were invited to participate in the randomised feasibility trial (n=75) declined. Participants accepted randomisation and no concerns were raised about their comprehension of randomisation. Once a payment fee had been agreed, training, supervision, and delivery of sessions were acceptable to ANC staff, with no staff dropping out of Study Four. The system of randomly allocating ANC staff to different arms was acceptable. The commonest reason for ANC staff not taking part in Study Four was being pregnant, or not expecting to remain in Sodo.

PST-IPV was acceptable to pregnant women experiencing depressive symptoms and IPV, with 19 out of 25 randomised to this arm attending all four sessions (76%). Reasons for the remaining six participants attending one (n=1) or no sessions (n=5) were moving away (n=3), changing their mind about taking part (n=2), or not attending and not being traceable by telephone or home visit (n=1). Standard PST was also acceptable to participants, with all five participants reporting physical and/or sexual IPV completing four sessions. Three out of seven participants reporting psychological or emotional IPV completed four sessions of standard PST (43%). The remaining four participants attended two (n=1) or no sessions (n=3) because they moved away (n=2) or did not attend and could not be reached (n=2). No concerns were raised about the acceptability of the EUC arm, or of take-home activities.

Table 8.6 Implementation agents

<i>Group</i>	<i>Agents</i>	<i>Facilitators</i>	<i>Barriers</i>	<i>Recommendation</i>
Research staff	Data collectors.	Data collectors with experience of conducting research studies were available in Sodo.	Recruitment was unpredictable and feasibility study was short-term, complicating employment. Data collectors lacked experience of entering data from paper forms into ODK. Errors in baseline data entry led to paper form data needing to be re-entered by an independent data clerk.	Process the contractual employment of data collectors far in advance of an RCT. Ensure ODK electronic data recording system ready prior to commencing the trial. Employ independent clerks for data entry.
	Field supervisors.	Field supervisors with experience of conducting research studies were available in Sodo. They provided an effective interface between field research and study organisation in Addis Ababa.	Despite training and study protocols, field supervisors misunderstood inclusion criteria, and categorised 17 women reporting psychological or emotional IPV as not reporting IPV. Despite training and study protocols, field supervisors opted to organise 12/39 (31%) outcome assessments prior to 9 weeks post-enrolment, to expedite data collection.	Processes determining randomisation decisions should be as automated as possible, to avoid human error. Definitions of IPV require concerted attention during training, given entrenched preconceptions. Field Supervisors should be more closely supervised, and more experienced.
	Research assistant and trial coordinator.	Skilled postgraduate-qualified staff were available in Addis Ababa. They maintained oversight of study conduct and provided an effective interface between field research and the principal investigators.	Being based in Addis Ababa sometimes limited their degree of oversight of fieldwork Restrictions on travel due to coronavirus and periodic episodes of political unrest sometimes prevented visits to the field site as often as needed.	For a full RCT, basing one research assistant or trial coordinator in the study site and one in Addis Ababa could maximise the benefits of both settings.
	Principal investigators.	Online technology enabled me to maintain weekly contact with the trial coordinator, research assistant, my post-doctoral researcher collaborator (TB), and my first supervisor, throughout the trial.	Being unable to travel to Sodo due to coronavirus restrictions and TB being based in another region of Ethiopia limited our ability to be as physically involved in trial conduct as would have been preferable.	Ensure weekly online meetings between principal investigators and the trial coordinator, during a full RCT. Aim for in-person presence by principal investigators at the study site at key times,

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<i>Group</i>	<i>Agents</i>	<i>Facilitators</i>	<i>Barriers</i>	<i>Recommendation</i>
Trainers/ supervisors	Psychiatrists and psychologists.	Experienced mental health professionals with experience of delivering mental health training to health workers. Training and supervision by the same staff enhanced health workers' openness to feedback on audio-recorded sessions. Some supervision was successfully provided in groups, due to logistical barriers to individual supervision.	Competing commitments made lengthy field training and regular in-person supervision difficult. Supervisors did not always have easy access to email or videoconferencing. A personnel change was required due to coronavirus infection. One supervisor moved away prior to the end of the trial. One supervisor was uncomfortable using her personal mobile phone for supervision.	A train-the-trainers model would enable training and supervision to be conducted by trained staff living in the study site, with specialist supervision for challenging cases. Ensure weekly health worker supervision by telephone, where in-person attendance cannot be facilitated. Consider whether some supervision sessions can be delivered in a group format, addressing common challenges. Provide sim cards and fund internet access.
Clinical staff	ANC staff.	Staff were motivated to attend training and supervision, and deliver sessions, once payment was agreed. Male and female ANC staff delivering sessions was acceptable to pregnant women. ANC staff informed supervisors that they valued their new skills and used them during other ANC contacts.	During training, ANC staff raised concerns that the trial could lead women to expect routine ANC to be longer; this was not reported during the trial. During training, ANC staff proposed that sessions could be delivered by a dedicated therapist, if scaled up. However, benefits of ANC staff delivery included improving clinical communication skills and integrating mental healthcare into ANC.	Continue to train ANC providers based at health centres and primary hospitals during a full RCT.
	Health extension workers.	HEWs aided data collectors to conduct outcome assessments for postpartum women confined to home.	A fee was agreed, to compensate HEWs for this additional activity.	Continue to involve HEWs in the conduct of the study, during a full RCT.
Participants	Pregnant women.	Adherence to four sessions was high, with few drop-outs other than for reasons of moving away from Sodo.	Recruitment was unexpectedly swift, with higher numbers of eligible women identified and recruited than expected.	Stagger recruitment for a full RCT, to avoid women needing to wait to start sessions. Prioritise third trimester women for sessions.

ANC: antenatal care, COVID-19: SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), HEW: health extension worker, ODK: open data kit, PST: problem-solving therapy, PST-IPV: PST adapted for women experiencing IPV, RCT: randomised controlled trial.

A small number of women and health workers reported feeling uncomfortable with sessions being audio-recorded but could be reassured about their confidentiality and the reasons for recording. Some women mentioned that they would prefer sessions to be delivered in their local dialect. Some women and health workers expected greater remuneration from the study, but accepted clarification from research staff.

Appropriateness

The appropriateness of PST-IPV and the methods of Study Four to the context was supported by the recruitment of an average of 10 participants per week (see section 8.1.1) across two sites, and the retention of all ANC staff. The appropriateness of take-home activities will be evaluated through qualitative interviews.

The appropriateness of problem-solving therapy was supported by mean session durations of more than 30 minutes for all sessions, of both interventions (see Table 8.7). I did not statistically compare session durations between arms, due to small sample sizes attending standard PST. However, there was a suggestion that the first two sessions of PST-IPV may have lasted longer than the first two sessions of standard PST, and that sessions delivered to women reporting physical and/or sexual IPV lasted longer, on average, than sessions delivered to women reporting psychological or emotional IPV.

Table 8.7 Mean session duration

<i>Intervention →</i>	<i>PST-IPV (minutes: seconds)</i>	<i>Standard PST (women reporting physical and/or sexual IPV)</i>	<i>Standard PST (women reporting psychological or emotional IPV)</i>
<i>Session number ↓</i>			
1	50:37 (n=20)	44:35 (n=4)	32:45 (n=4)
2	51:22 (n=19)	45:09 (n=4)	35:59 (n=4)
3	45:48 (n=19)	47:50 (n=4)	34:08 (n=3)
4	31:50 (n=19)	41:17 (n=4)	42:45 (n=3)

IPV: intimate partner violence, PST: problem-solving therapy, PST-IPV: problem-solving therapy for women experiencing IPV.

This finding was notable, because independent assessments of session fidelity and quality found that IPV was infrequently discussed during sessions of both interventions, and

when it was, it was only discussed for between one and four minutes. Indeed, PST-IPV supervisors noted several instances during audio-recorded sessions, in which women mentioned IPV, but health workers did not respond. When asked, one health worker had explained their concern that the session could become ‘derailed’ by discussing traumatic events.

Health workers delivering both interventions informed their supervisors that several participants reported that techniques such as ‘worry time’ and relaxation exercises were beneficial, supporting the appropriateness of the problem-solving therapy model. During training, a health worker suggested that walking by the river might be more culturally appropriate than sitting down for ‘worry time’.

A key factor in the appropriateness of the intervention was the ability of women to attend intervention sessions and research appointments while pregnant, and the difficulty of doing so postpartum, due to the cultural practice of postnatal confinement.

Feasibility

The feasibility of recruiting eligible participants was demonstrated by the enrolment of 52 participants over 35 days (see section 8.1.1). To enrol 52 participants, 335 women were pre-screened and 142 women underwent initial screening: recruitment rates of 16% and 37%, respectively.

The feasibility of Study Four’s methods were impacted by women struggling to attend outcome assessments postpartum. Among 52 participants randomised, 19 out of 25 (76%) completed outcome assessments for PST-IPV, nine out of 12 (75%) for standard PST, and 12 out of 15 (80%) for EUC.

The feasibility of prompt supervision was influenced by delays in session audio recordings being transferred to supervisors. As files proved too large to be emailed, they were manually transferred to Addis Ababa using hard drives.

The regularity of supervision sessions was impeded in July 2021, after a back-log of tasks at end of the fiscal year at Addis Ababa University caused delays to the release of funds to pay for supervisors’ transport.

Dose

The four session dose of PST-IPV and standard PST proved to be acceptable to participants and health workers, and feasible to deliver. As outlined in Figure 8.2, out of the 37 participants randomised to an intervention arm, one attended one session, one attended two sessions, 27 (73%) attended four sessions, and the remainder dropped out before commencing sessions. Due to Study Four not being powered to detect treatment efficacy, a formal determination of the therapeutic dose of PST-IPV will form part of a future RCT.

Fidelity

Table 8.8 shows the medians and interquartile ranges (IQRs) of intervention fidelity and completion checklist results and ENACT scores. Independent assessors noted that IPV was mentioned in three of the six PST-IPV first sessions and two of the PST-IPV second sessions. The median ENACT score was one ('needs improvement') for asking about harms and risks, across all three sessions that were independently reviewed. The median ENACT score was also 'needs improvement' for assessing potential community or social networks in session one and discussing confidentiality in sessions two and three. Asking about risks, discussing confidentiality, and assessing social networks were not explicit parts of the intervention manual, but were reviewed by assessors, to identify whether health workers addressed these subjects spontaneously.

During my own supervision sessions with intervention trainer-supervisors, they reported that health workers' use of the flipchart resource varied. Some health workers adhered to the flipchart rigidly, sometimes at the expense of a more natural flow to the clinical interaction. Others did not follow the flipchart at all; supervisors used supervision sessions to encourage health workers to use the resource in a more balanced manner.

Both independent fidelity assessors and supervisors noted that some aspects of intervention content were not adhered to, if participants responded that they had no problems. Supervisors noted that this usually occurred when the health worker's initial explanations and inquiries had been brief; they encouraged health workers to explore women's lives further in such situations. Supervisors also noted that some health workers

repeated some intervention content more than once, for example, addressing ‘lower priority problems’ repeatedly. In some early sessions, supervisors noted that health workers did not distinguish between asking women about the most important things in their life and asking them to list their problems. This was addressed during supervision. In other cases, health workers did not follow the recommended order of content, bringing content from later sessions into earlier ones.

During supervision of health workers’ accelerated cases of PST-IPV and standard PST, supervisors noted that health workers often spoke at length and offered women unsolicited advice, rather than following the intervention manual and flipchart. They acknowledged that this is standard practice within ANC and used supervision to reassure health workers that pausing was not a sign of limited competence. One health worker disclosed during supervision that she had waited until the audio recording had stopped to give a pregnant woman advice. A top-up training session was used to emphasise the fact that therapists were not required to solve women’s problems for them. Supervisors noted that health workers struggled with basic communication skills, which were addressed with a refresher training session on active listening, counselling, showing empathy, and intervention components.

Supervisors recommended that health workers needed to be more familiar with the content of the flipchart, and to develop a habit of practising and preparing before sessions. They recommended more refresher training sessions to offer health workers more time to practice, and to require some health workers to complete a second accelerated case before certification as competent. The four supervisors noted that the quality of sessions and fidelity to the intervention increased as health workers gained more experience. In some cases, health workers asked their peers for clarification about aspects of the intervention.

Table 8.8 Independent fidelity and completion checklist and ENACT results

<i>Intervention, time point</i>	<i>Median duration, IQR (minutes: seconds),</i>	<i>Median adherence score, IQR (%)</i>	<i>Median quality score, IQR (%)</i>	<i>Median responsiveness score, IQR (%)</i>	<i>Median ENACT score (%)</i>
Standard PST: Accelerated case, Session 1 (n=2)	47:15 (42:49-51:40)	90 (90-90)	100 (100-100)	100 (100-100)	85 (76-80)
PST-IPV: Accelerated case, Session 1 (n=6)	47:19 (27:08-52:14)	90 (86-98)	92 (83-100)	100 (100-100)	76 (69-81)
Standard PST: random case, Session 2 (n=3)	45:12 (42:14-46:16)	100 (94-100)	100 (100-100)	100 (100-100)	79 (78-82)
PST-IPV: random case, Session 2 (n=5)	53:19 (43:03-53:55)	89 (89-94)	92 (83-100)	75 (75-100)	73 (73-79)
Standard PST: random case, Session 3 (n=2)	38:07 (36:38-39:36)	86 (85-88)	100 (100-100)	100 (100-100)	81 (78-83)
PST-IPV: random case, Session 3 (n=6)	47:55 (41:05-52:08)	86 (67-89)	100 (100-100)	100 (100-100)	84 (77-86)

ENACT: ENhancing Assessment of Common Therapeutic factors rating scale, IPV: intimate partner violence, IQR: interquartile range, PST: problem-solving therapy.

Minimum possible ENACT score: 33% (as 'needs improvement' is scored as 1 out of a maximum 3).

8.1.6.7 Safety

A single serious adverse event (SAE) and no adverse events occurred during the trial. A trial participant telephoned the study field supervisor on 08/07/2021, reporting that she had had an argument with her husband, during which he kicked her in the abdomen. An appointment was offered at the health centre for a clinical review on 12/07/2021, which she did not attend. She was telephoned the following day and attended Bu'i primary hospital, where she was assessed and received an ultrasound scan. No obstetric problems were identified. She informed the ANC staff member that she was experiencing suicidal thoughts, associated with arguments with her husband's parents, with whom she lived. She reported prior plans to kill her father-in-law, for which she reported procuring poison. A mental health review was arranged with the local psychiatric nurse, who identified no symptoms of mental disorder and no acute risks to herself or others. The woman reported plans to stay with her parents, to avoid conflict with her husband's parents. A psychiatrist then reviewed the participant at the next available opportunity (25/08/2021), at her home, due to its rural location, far from the health centre. The psychiatrist's assessment was that the woman (who had now completed her involvement in the trial) had continuing depression and stressors, requiring follow-up from a health worker trained in use of the mhGAP intervention guide. This assessment was communicated to the woman's ANC worker.

The SAE was reported to both KCL and AAU institutional review boards. The report was reviewed by the KCL research governance ethics and integrity team and the chairs of the psychiatry, nursing and midwifery research ethics subcommittee, who considered the event "anticipated", due to trial recruitment criteria. They stated that an appropriate distress protocol was in place and that it had been followed. Due to inability to ascertain the relatedness of the event to participation in the trial, the board deemed the event "possibly related". The committee recommended reviewing procedures to determine whether any modifications would be required, in light of the event, considering the safety of participants and research staff. This took place and modifications to the trial SOP were not proposed.

8.1.6.8 Iterative adaptations

I had planned to use the FRAME (Stirman et al., 2019) structure to describe iterative adaptations and the IDEA (Miller et al., 2020) decision tree to determine whether to retain them. However, no adaptations were made to the intervention itself. Several iterative changes to the Study Four protocol took place; these are summarised in Table 8.9.

Table 8.9 Deviations from the Study Four protocol

<i>Aspect</i>	<i>Deviation</i>	<i>Details</i>	<i>Effect</i>	<i>Recommendation</i>
Staff training	ANC staff had not received mhGAP-IG (WHO, 2016a) training.	mhGAP-IG training had only been offered to one health worker per site.	Health workers had no prior counselling and listening skills training. They required feedback, refresher and top-up training.	Require all staff trained to deliver sessions to complete an mhGAP-IG course, to standardise baselines.
Randomisation	It proved difficult for the field supervisor to reach the CDT Africa data manager.	Field supervisors telephoned the TC or RA, who told them the arm of the latest participant.	This did not meaningfully alter the randomisation process. The field supervisor remained the only member of research staff unmasked to allocations.	For a full RCT, an independent research staff member based in the study site may be more easily reached than staff in Addis Ababa.
	Field supervisors mis-randomised 17/52 (33%) participants.	Field supervisors misunderstood definitions of IPV in inclusion criteria, leading to selection bias.	Women reporting psychological/emotional IPV only were randomised as if they had not reported IPV, preventing randomisation to PST-IPV and weakening statistical power of between-arm comparisons.	Randomisation decisions should be automated. Field supervisors require closer supervision and more experience.
Supervision	Fortnightly supervision was not always provided.	Logistical challenges of travel to Sodo from Addis Ababa prevented consistent fortnightly supervision.	Although telephone supervision was provided, health workers did not have as much regular contact with their supervisor as planned.	Ensure weekly in-person or telephone supervision in the first month, then fortnightly. Base supervisors (trained by trainers) in Sodo.
Data collection	ODK electronic system was not ready in time for baseline assessments.	Baseline assessments were conducted using paper forms, to avoid delaying the start of the trial further.	Data had to be inputted into the ODK system afterwards. This was first done by data collectors but errors were identified, so was repeated by an independent data clerk.	Ensure that all data collection is entered into the ODK system at the time, to avoid data entry errors and inconsistency.
	An un-adapted version of PHQ-9 was used at baseline.	Due to use of paper instruments, an older version was used in error.	This version grouped sleeping too little and sleeping too much, and under-eating and over-eating into single questions. This was known to be confusing in Amharic.	Ensure that all data collection is conducted using ODK, to ensure that identical instruments are used at baseline and outcome assessments.

STUDY FIVE: RANDOMISED FEASIBILITY TRIAL AND PROCESS EVALUATION – RESULTS

	Participants were asked about past-year IPV at baseline and follow-up.	I planned to ask about past-month IPV at follow-up, to assess post-trial changes.	The time periods about which IPV exposure was asked overlapped, complicating interpretation of outcome assessments.	For a full RCT, ensure that IPV time points do not overlap, such as asking about past three months' IPV.
	The HAQ was not incorporated into the ODK system.	All participants were not administered this instrument.	The HAQ was therefore only administered to pregnant women participating in qualitative interviews.	Include HAQ in outcome assessments. Apply these questions to routine ANC for participants who received EUC.
	Field supervisors expedited 12/39 (31%) outcome assessments.	They did so despite clear training and protocols, and did not inform the TC/RA.	Some outcome assessments were conducted sooner than nine weeks post-enrolment into Study Four, introducing heterogeneity.	Field supervisors require closer supervision and more experience.
Analysis	The published protocol proposed to compare means using t-tests or non-parametric tests.	Upon reflection, I did not consider hypothesis testing to be valid, given the Study Four sample size.	Following the literature (Lee, Whitehead, Jacques, & Julious, 2014), I did not conduct hypothesis testing, but reviewed the directions of any changes in median scores.	Prior to a full RCT, prepare a complete analysis plan for all fully-powered statistical tests.
Process evaluation	Health workers received one copy of the session record form at training.	Session record forms were not collected from health workers.	Although all sessions were audio-recorded, written documentation of sessions could not be analysed by the process evaluation.	Provide all staff with one copy of the session record form per case and collect forms for process evaluation.
	The published protocol planned to evaluate adoption but not dose.	I considered adoption more relevant to a larger-scale implementation study.	Preliminary considerations surrounding intervention dose were added as an implementation outcome.	Evaluate adoption and dose in the process evaluation of a full trial.
	Ten, rather than six, women took part in post-trial interviews.	A sample of ten ensured a balance of women across arms, sites and IPV types.	A larger sample than anticipated was recruited for qualitative interviews.	Recruit a balanced sample of participants for post-trial interviews, in a full RCT.

ANC: antenatal care, CDT Africa: centre for innovative drug development and therapeutic trials for Africa, EUC: enhanced usual care, HAQ: helping alliance questionnaire, IPV: intimate partner violence, mhGAP-IG: mental health gap action programme intervention guide, PHQ-9: patient health questionnaire, PST: problem-solving therapy, PST-IPV: PST for women experiencing IPV, RA: research assistant, RCT: randomised controlled trial, TC: trial coordinator, WHO: world health organization.

8.2 Discussion

8.2.1 Key findings

Study Five demonstrated the feasibility and acceptability of implementing four sessions of PST-IPV, and of a randomised, controlled study design, comparing PST-IPV with active and inactive arms. The findings justify a future, fully-powered RCT, and highlight key modifications. Rapid recruitment, high proportions of participants completing four sessions of both PST-IPV and standard PST, and low proportions dropping out of the study, supported the appropriateness, acceptability, and feasibility of the intervention model and study design.

Incorrect randomisation of women reporting psychological or emotional IPV as if they had not reported IPV highlighted an important focus for training and scrutiny in a future RCT. Organising some outcome assessments earlier than the planned nine weeks post-enrolment showed the importance of close scrutiny of field work and recruiting experienced staff for these roles. A technological delay (the unavailability of the ODK electronic interface at the start of recruitment) caused several deviations from the protocol, highlighting the benefits of such systems. Difficulties conducting outcome assessments with participants postpartum raised the need for a future trial to conduct immediate post-intervention and longer-term (rather than medium-term) follow-up, to accommodate cultural practices of postnatal confinement.

More extensive training on basic counselling and active listening skills prior to intervention training, completing two supervised accelerated cases prior to formal study recruitment, and cascade training to enable more responsive supervision mechanisms are required, to optimise a future RCT.

Although the coronavirus pandemic caused some delays, Study Four could still be safely conducted in a manner acceptable to pregnant women, health workers, and research staff. A single SAE occurred, which was deemed to be anticipated, and possibly related to participation. This event enabled safety protocols to be tested prior to a fully-powered RCT.

8.2.2 Primary and secondary outcomes

Outcome assessments measuring primary and secondary outcome measures post-participation were completed by 77% of participants across the three trial arms. Primary and secondary outcomes of depressive and anxiety symptoms showed modest reductions among participants randomised to PST-IPV, post-participation, although one third of PST-IPV participants completing an outcome assessment showed a fifty percent or greater reduction in depressive symptoms. This finding is consistent with evidence of early response or sudden gains among a sub-set of participants in RCTs of brief, task-shared psychological interventions in LMICs (Singla, Hollon, Fairburn, Dimidjian, & Patel, 2019). Similar reductions among the smaller sample of participants randomised to standard PST and EUC complicated interpretation of these findings. However, evidence of reduced anxiety and depressive symptoms, and increased self-efficacy and safety behaviours, following a single perinatal intervention session in Nepal (Sapkota et al., 2020) suggests that PST-IPV could have similar effects in a fully-powered sample.

Secondary outcomes of PTSD symptoms and severity of suicidality among the small number of participants endorsing suicidal ideation improved among participants randomised to PST-IPV, post-participation, and worsened or were unchanged among participants randomised to EUC. This preliminary, underpowered, finding is of interest, given arguments that neglecting the wider needs of people experiencing IPV may reduce the therapeutic potential of psychological interventions in LMICs (Tol et al., 2017). Trauma-informed approaches, woman-centredness, and therapeutic alliance were central to the effectiveness of individualised advocacy interventions for women experiencing IPV in a realist review (Rivas et al., 2019). The trauma-focused design of PST-IPV training may have sensitised health workers to respond to trauma symptoms, addressing hopeless, helpless, and powerless cognitions that may contribute to suicidality (Brown & Harris, 1978). This hypothesis requires investigation by a fully-powered RCT.

As a feasibility study, Study Four was not powered to identify differences in efficacy between arms (Julious, 2005; Sim & Lewis, 2012). Sub-dividing the results of standard PST and EUC arms into participants correctly randomised using the three-arm table and incorrectly randomised using the two-arm table weakened statistical power to detect

between-arm differences further. An important objective of a future RCT will therefore be to compare trajectories of recovery among participants randomised to active treatment with those of participants randomised to the control arm. Researchers conducting an RCT of brief PST for adolescents in India proposed that improvements in mental health symptoms may lag behind changes in mediators, such as self-defined problem severity (Michelson et al., 2020). The authors proposed that follow-up beyond three months might detect delayed improvements in mental health outcomes, after the practice and consolidation of new coping skills over time.

Hypothesised mediators of self-efficacy and perceived social support were unchanged, and mastery slightly reduced, among participants randomised to PST-IPV, at follow-up. Counter-intuitively, among the small number of participants randomised to EUC, self-efficacy scores (among participants experiencing all types of IPV) and attitudes towards gender roles (among participants experiencing psychological IPV only) showed small to moderate increases, not seen among participants randomised to PST-IPV. Interpretation of these findings was again complicated by small sample sizes.

Perceived social support showed small reductions among the small number of participants randomised to standard PST, but not among those randomised to PST-IPV or EUC. The lack of change in perceived social support suggests that even if PST-IPV sessions did offer support not available elsewhere, they did not alter women's perceptions of how supportive their wider social network might be. It is possible that the lack of a trauma focus within standard PST training may have left health workers less equipped than those delivering PST-IPV to respond to women's needs, leaving some participants feeling less supported. This hypothesis requires investigation by a fully-powered RCT.

Reductions in reported IPV post-PST-IPV were also seen among participants randomised to standard PST and EUC, and the time periods asked about overlapped. An RCT of lay counsellor-delivered CETA in Zambia found significant reductions in self-reported IPV exposure at one (Murray, Kane, et al., 2020) and two years' follow-up (Kane et al., 2021). A qualitative study (Murray et al., 2021) identified safety strategies to avoid or prevent conflict and control anger, improved trust and understanding, as mediators. A future RCT

should measure hypothesised interpersonal mediators of change, as well as psychological constructs, such as self-efficacy.

Equivocal findings regarding the impact on functioning may have resulted from the small change in clinical symptoms post-IPV, or outcome assessments may have been timed too early to detect such changes, which may take longer to occur. Alternatively, the four session format may have been insufficiently intense to meaningfully impact functional impairment associated with depressive symptoms.

Improvements to intervention training, supervision, and delivery identified by the process evaluation (section 8.2.3) may increase the clinical utility of PST-IPV, in a future RCT.

8.2.3 Process data

Consistent with MRC (Campbell et al., 2000; Craig et al., 2008) and MRC/NIHR guidance (Skivington et al., 2021), and growing consensus (Hallingberg et al., 2018), Study Five demonstrated the benefits of conducting a feasibility study of a complex intervention, prior to a definitive RCT.

Studies Four and Five report one of few randomised, controlled studies of brief psychological interventions for CMDs, tailored for women's experiences of IPV in LMICs. Unlike ten to twelve session interventions in Pakistan (Latif & Khanam, 2017) and Iran (Orang et al., 2018), Study Five evaluated a four session, task-shared intervention in a rural setting, in a low-income country. Unlike a recent pilot RCT of a single antenatal session in Nepal (Sapkota et al., 2020), Studies Four and Five demonstrated the feasibility and acceptability of building a trusting, therapeutic relationship through recurring clinical encounters, integrated into ANC.

In keeping with a range of guidance (Craig et al., 2008; Moore et al., 2015; Skivington et al., 2021) Study Five also supported the benefits of conducting process evaluations of complex interventions. Identifying barriers and facilitators to intervention and trial implementation will enhance the safety, efficiency, and validity of a future RCT.

8.2.3.1 Protocol deviation

The inappropriate randomisation of 33% of eligible participants, who reported psychological or emotional IPV at baseline, as if they had not reported IPV, was an important protocol deviation. However, recruitment, randomisation, and treatment errors are known to occur in trials. A systematic review of 82 RCTs found such errors in 39% of studies, with a median of eight errors (Yelland et al., 2018). The authors highlighted inadequate reporting and recommended transparent descriptions of errors and how they are handled. In terms of responding to randomisation errors based on incorrect baseline data, Yelland et al. (2015) advocated accepting the randomisation, but recording the correct baseline data. In Study Five, I therefore presented the results for this sub-group of participants, distinct but alongside those for participants who had been correctly randomised. This error had the effect of inadvertently creating a sub-group comparison, albeit lacking in statistical power to detect differences in outcomes.

A recent literature review of perceptions of emotional IPV (Novak, 2020) found evidence that laypersons, university students, survivors and perpetrators in HICs all considered emotional IPV less severe or blameworthy than physical or sexual IPV. Contrary to these perceptions, the impact of psychological and emotional IPV on women's mental health is well-established. A survey of 1,293 ever-partnered women participating in a cluster RCT of an HIV behavioural intervention in South Africa examined relationships between mental health and different types of IPV, controlling for childhood adversity (Jina et al., 2012). Emotional abuse alone was associated with increased risk of suicidality. Furthermore, emotional abuse combined with physical and/or sexual abuse was associated with significantly higher risks of psychological distress, depressive symptoms, suicidality, hazardous drinking, and drug use, compared to physical and/or sexual abuse alone.

A prospective cohort study of 1,045 pregnant women in Brazil found that psychological IPV during pregnancy was associated with postnatal depression, even after adjusting for physical and sexual IPV (OR: 2.29, CI: 1.15-4.57; Ludermir, Lewis, Valongueiro, de Araújo, & Araya, 2010). A longitudinal study evaluated the mental health of 91 women experiencing IPV in Spain, three years after participating in a cross-sectional study

(Blasco-Ros, Sánchez-Lorente, & Martinez, 2010). The authors found significant improvements in depressive, anxiety, and PTSD symptoms among women experiencing physical and psychological IPV, but not among those experiencing psychological IPV alone at baseline. Psychological IPV continued over three years in 65% of cases, whereas physical IPV continued in 12% of cases. Women experiencing psychological IPV alone therefore had poorer prognoses for their mental health and continuation of abuse, than women also experiencing physical IPV.

Evidence therefore confirms that, as per the Study Four protocol, women reporting psychological or emotional IPV alone should have been randomised in the three-arm trial. The fact that they were not, despite training and close supervision, highlights the entrenched nature of preconceptions surrounding what ‘counts’ as IPV. A future RCT must devote greater time to training data collectors and field supervisors about IPV, and ensure that randomisation decisions are fully automated by electronic systems, such as the ODK platform.

8.2.3.2 *Implementation domains*

Study Five evaluated key implementation domains of the CICI framework (Pfadenhauer et al., 2017): implementation theory, process, strategies, agents, and outcomes.

The engagement, training, and set-up components of the implementation theory (section 6.5.3.2) were supported by the safe conduct and completion of Study Four. Anticipated improvements in hypothesised mediators were not detected in the PST-IPV arm (section 8.2.2), but this may have resulted from inadequate statistical power. Further evidence for or against the implementation theory will be provided by qualitative interviews with women and health workers (section 7.4.17.4). The deviation from the randomisation protocol (section 8.2.3.1) highlighted a key assumption to be added to the theory of change: that women experiencing all forms of IPV (including psychological and emotional IPV) are appropriately identified and have the opportunity to be randomised to PST-IPV.

Study Four entailed the planning, preparation, and initial implementation stages of the implementation process. (Pfadenhauer et al., 2017). These stages proceeded in a timely

manner, with recruitment considerably faster than anticipated. However, this created difficulties whereby some women enrolled in Study Four needed to wait for their health worker to be available to commence sessions. For a future RCT, recruitment should be staggered according to the availability of health workers certified by supervisors as competent to deliver sessions. Attending a minimum number of supervision sessions should be required, before health workers are allocated more cases.

Key implementation strategies (Powell et al., 2015) addressed staffing (by shifting professional roles and using incentives), training (developing educational materials and delivering interactive, ongoing training), leadership (providing clinical supervision), and evaluation (recording sessions to monitor fidelity). These were found to be feasible to organise and acceptable to women and health workers, evidenced by the lack of any staff drop-outs and prompt session delivery. As found for MI-PST in Cape Town (Jacobs et al., 2020), implementation strategies of high quality training and specialist supervision were critical for building competence and confidence.

Paying ANC staff to deliver sessions in Study Four avoided accusations of ‘task dumping’ (Jacobs et al., 2020) or concerns about the suitability of task-sharing (Lund et al., 2020), reported by South African studies. The absence of financial compensation was a key barrier to successful implementation of task-shared mental health interventions in LMICs in a recent systematic review (Esponda et al., 2020). Comparisons between the ‘peer’-delivered thinking healthy programme in urban Goa, India and rural Rawalpindi, Pakistan (Singla et al., 2014) highlighted the need to financially reimburse lay therapists in India. In Pakistan, however, altruistic roles were conceptualised as a form of social investment, with future, unspecified rewards expected from the community (Sikander et al., 2019). The authors also suggested that, with limited opportunities for women available, lay therapist roles were valued as a means for increasing community respect. In Nepal, lack of financial rewards for female community health volunteers was a major challenge to continued service (Panday, Bissell, Van Teijlingen, & Simkhada, 2017). These studies and others (Singh, Negin, Otim, Orach, & Cumming, 2015) highlighted the context-dependent nature of acceptable rewards and the importance of distinguishing paid health service staff from otherwise-rewarded volunteers. However, compelling arguments have been made that not paying female volunteers to deliver services reinforces gender

inequality (Panday et al., 2017). Indeed, there is evidence that volunteer community health workers in Ethiopia’s ‘women’s development army’ are themselves at risk of psychological distress, relative to paid health extension workers (Maes, Closser, Tesfaye, & Abesha, 2019).

In Study Four, remuneration was regularly negotiated, for health workers delivering sessions, for data collectors conducting baseline and outcome assessments, and for psychiatrists and psychologists delivering training and supervision. High inflation in Ethiopia (United Nations Ethiopia, 2020) and the impact of tax and other deductions on take-home pay made it particularly important to negotiate remuneration for Study Four, close to the time of the work being conducted. On one hand, payments in addition to regular salaries might make the intervention difficult to integrate into the wider health system, long-term. On the other hand, engaging all implementation agents in professionalised roles may have enhanced the intervention’s potential to be sustainably delivered, given the limitations of a volunteer model (Maes et al., 2019; Panday et al., 2017). Furthermore, as a proof-of-concept study, delivering sessions of problem-solving therapy was not in health workers’ job descriptions, or required by their managers.

Support from key implementation agents (section 8.1.6.5) provided evidence of early implementation readiness (Damschroder et al., 2009), which will be explored further in forthcoming qualitative interviews (section 7.4.17.4). Similar to a feasibility study of MI-PST in Cape Town (Myers et al., 2019), support from managers and ANC staff colleagues facilitated the successful implementation of Study Four. However, several protocol deviations highlighted the importance of sufficient oversight of field work, supervision of field supervisors, and recruitment of adequately experienced individuals to these pivotal roles.

8.2.3.3 *Implementation outcomes*

Studies Four and Five contribute to the literature on perinatal mental health interventions in LMICs (Chowdhary et al., 2014). In particular, they add evidence regarding the quality of intervention delivery and independent evaluations of therapist competence, which were absent from most previous studies. Fletcher et al. (2016) argued for realist evaluations

which determine feasibility “for whom and under what circumstances (p.294). Study Five showed that, in the rural Sodo context, PST-IPV and standard PST were acceptable and feasible for those participants who continued to live in the area for at least three months, and who were able to complete the intervention prior to giving birth. Forthcoming qualitative interviews with pregnant women and health workers will explore diverse perspectives, including those of women whose depressive symptoms did, and did not improve.

Similar to the recent study of cognitive processing therapy adapted for women experiencing IPV (Nguvu) in a Congolese refugee camp in Tanzania (Greene et al., 2021), PST-IPV was acceptable to women and health workers, and feasible to implement and evaluate. A higher proportion of participants randomised to PST-IPV attended all four sessions than attended all sessions in Greene et al. (2021), Lund et al. (2020), and Spedding et al. (2020)’s studies. “Protocol adherence and enthusiasm” during feasibility studies may lead to better outcomes than larger-scale trials (p. 2; Lee et al., 2014), so the acceptability of PST-IPV in a fully-powered RCT must also be determined. Unlike the Nguvu study, participants in Study Four did not request additional incentives to encourage attendance, but this may reflect participants’ needs and expectations in a refugee camp context.

Greene et al. (2021) found that some women had safety concerns about their partners learning about their attendance, and younger women felt inhibited by the presence of older women in groups. Study Four overcame these barriers and confidentiality concerns raised in Study Two, by delivering intervention sessions individually, at the health centre or primary hospital. This arrangement proved acceptable and feasible to women and health workers, consistent with a previous review (Padmanathan & De Silva, 2013).

A systematic review of implementation outcomes of non-specialist-delivered CBT in LMICs for CMDs and substance use disorders synthesised the findings of 18 studies (Verhey, Ryan, Scherer, & Magidson, 2020). The authors identified feedback and support through training and weekly supervision, the preparation of simplified interventions with clear manuals, using culturally appropriate language, as crucial for intervention fidelity. Consistent with Study Five, Verhey et al. (2020) noted that attention to fidelity was

especially important for interventions delivered by staff accustomed to health promotion roles, in which a shift was required from giving advice to non-directive listening and supportive counselling. This aspect of delivering PST-IPV requires more attention in training and supervision in a future RCT.

Spedding et al. (2020) found that intervention delivery by a designated counsellor left ANC staff feeling they could not support women themselves. In Study Five, health workers informed supervisors that PST-IPV training improved the quality of care they delivered to intervention participants and other women. Unlike in Cape Town, ANC staff in Sodo did not report struggling to accommodate PST-IPV sessions alongside their existing workload, and participants did not recommend adjustments to the individual session model. A future RCT should measure potential mediators of efficacy among health workers, such as confidence, motivation, and satisfaction (Nguyen et al., 2015).

The timing of outcome assessments is a common problem in research studies enrolling pregnant participants. In Study Four, offering outcome assessments at home (subject to appropriate risk assessment to ensure absolute privacy) enabled a proportion of postpartum women to complete an outcome assessment, as has been found in other randomised trials of brief psychological interventions in LMICs (Jordans et al., 2019). Some participants who stopped attending sessions due to giving birth expressed interest in receiving more sessions postpartum, raising the potential acceptability of a perinatal, rather than purely antenatal, intervention design, such as that employed by the thinking healthy programme (Fuhr et al., 2019; Sikander et al., 2019). The decision by field supervisors to organise some outcome assessments early, in a protocol deviation, highlighted the difficulty of organising medium-term follow-up, as well as the importance of close supervision of field work and recruitment of particularly experienced individuals to these roles.

8.2.4 Considerations for a future RCT

In addition to the 75 women recruited into Study Four and the nested trial, a further 11 were excluded, as recruitment for the nested study had completed. Of these 86 women meeting inclusion criteria for Study Four or the nested trial, 52 (61%) reported

experiencing IPV. It is likely that a proportion of the remaining 34 women may also have experienced IPV, given barriers to disclosure identified in Study Two. A future RCT might therefore measure IPV exposure but not use it to determine eligibility, similar to a study of PM+ in a region of high gender-based violence prevalence in Kenya (Bryant et al., 2017). This approach would ensure that women experiencing but not disclosing IPV could still participate in the study. In practice, sessions of PST-IPV and standard PST followed the same structure and content. The key difference between the interventions was the provision of a trauma and IPV-informed training course, attention to IPV and risks during supervision sessions, education about IPV in the intervention manual, and emphasis on how to avoid inadvertent collusion with abuse or victim blaming during sessions. The PST-IPV training and intervention structure could therefore be evaluated among a sample of pregnant women both reporting and not reporting IPV, with planned sub-group analyses to evaluate its efficacy among both groups.

Despite no prior training in clinical communication skills and limitations in the quality of intervention delivery identified by supervisors, most women randomised to PST-IPV or standard PST completed four sessions. The acceptability of intervention may relate to the very limited opportunities women have in this context to be listened to, encouraged, and emotionally supported: the sixth international standard of maternal and new-born healthcare (WHO, 2016b). This hypothesis will be explored in forthcoming qualitative interviews. An uncontrolled study of three sessions of antenatal PST in Cape Town (Spedding et al., 2020) found that non-specific elements such as non-judgemental listening, discussion, and time for themselves were key benefits, with more variable perspectives on problem-solving itself. There is therefore a balance to be struck between fidelity to the intervention manual and flexibility, to enable sessions to meet women's needs and address their priorities: a tension between prioritising specific and non-specific (engagement) elements (Singla et al., 2017). In a future RCT, in which health workers receive clinical communication skills and mhGAP intervention guide training prior to intervention training, the optimum balance between specific and non-specific elements should be explored.

Although Study Four was not powered to detect treatment efficacy, the findings raised questions about the most informative statistical test of clinical outcomes, where symptom

scores may fluctuate between repeated measures. The reliable change index (RCI; Jacobson & Truax, 1992) uses locally relevant measures of test-retest reliability to calculate the percentage of a sample with an RCI above the minimal threshold, and has been used in pilot trials of psychological interventions in LMICs (Murray et al., 2014). For example, an analysis of the UK improving access to psychological therapies (IAPT) programme for CMDs found that ‘reliable change’ in that context equated to an eight point reduction in PHQ-9 score and a five point reduction in GAD-7 score (Griffiths & Griffiths, 2015). Calculating the RCI for primary and secondary outcome measures in a fully-powered RCT of PST-IPV in Sodo could be more informative than solely comparing means between arms.

Suicidality was measured in Study Four as part of PHQ-9 and to exclude pregnant women deemed at significant risk of self-harm or suicide but was not a planned secondary outcome. However, there is an established relationship between IPV and suicidal ideation (Devries et al., 2013; Devries et al., 2011; Palladino et al., 2011). Suicidality is often associated with hopelessness (Brown et al., 1995), which is relevant to the power and control exerted over women experiencing IPV, and the powerlessness described in Study Two. A recent mapping review of suicide in vulnerable populations in LMICs (Vijayakumar, Ray, Fernandes, & Pathare, 2021) identified the need for gender-specific interventions for women addressing abuse, violence, gender-based discrimination, and access to healthcare. Suicidal ideation should therefore be investigated as a secondary outcome measure in a future RCT, as its responsiveness to change may be different to CMD symptoms. Similarly, given the findings of Study Two that emotional difficulties often manifested as persistent somatic symptoms in this context, changes on a scale such as the bodily distress syndrome checklist (Budtz-Lilly et al., 2015), once validated in Ethiopia, could also be informative.

Study Four was not powered to detect significant differences in IPV post-participation. However, research from Zambia supports the potential of psychological interventions to impact IPV (Kane et al., 2021; Murray, Kane, et al., 2020; Murray et al., 2021); this hypothesis requires investigation in Ethiopia, by measuring hypothesised interpersonal mediators of change (such as use of safety strategies or improved trust and

understanding), as well as psychological constructs (such as self-efficacy), as part of a fully-powered RCT.

To address the challenges of perinatal follow-up, a future RCT could enrol participants earlier in pregnancy, although in this context, women often do not present to ANC in the first trimester (Tesfaye, Loxton, Chojenta, Semahegn, & Smith, 2017). Conducting an immediate outcome assessment as soon as sessions have ended, followed by a follow-up assessment three months postpartum, or six months post-enrolment (as conducted by several papers included in Study One: Bolton et al. (2014), Sikander et al. (2019), Chibanda, Weiss, et al. (2016), Fuhr et al. (2019)), may be more appropriate to the cultural practices associated with childbirth in this context.

The implementation strategy of psychiatrists and psychologists based in Addis Ababa supervising health workers in rural areas was limited by logistical barriers to regular field site visits. Other studies conducted in LMICs have adopted apprenticeship models (Murray et al., 2011) or cascade training, in which specialist master trainers train and supervise less experienced trainers (Atif et al., 2017; Rahman et al., 2019). In Sodo, this approach could enable rural health workers to be supervised by trainer-supervisors based in the study site, who receive online or telephone supervision from mental health specialists based in Addis Ababa. Basing supervisors in Sodo would increase the responsiveness of observations (as session audio recordings would not need to be electronically or physically transferred to the city), and overcome logistical barriers to regular, in-person supervision.

An important consideration for a future RCT, if the efficacy of PST-IPV is demonstrated, will be to investigate parameters of scalability, relevant to the implementation phase of the new MRC/NIHR complex interventions framework (Skivington et al., 2021). Barker, Reid, and Schall (2015)'s framework for scalability advocates four phases, of set-up (preparing to test the intervention), developing the scalable unit (capturing all features of the smallest representative microsystem that could be scaled up), testing scale-up in a variety of contexts, and scaling up. A future RCT could therefore expand on Study Four's two site model, to set up and develop the scalable unit in multiple rural and urban clinical sites in the Gurage zone.

8.2.5 Strengths

Study Four was the first of its kind in this rural Ethiopian setting. Most research into psychological interventions for CMDs in LMICs comes from urban or peri-urban areas of middle-income countries and only four RCTs to date have evaluated treatments adapted for women experiencing IPV (Greene et al., 2021; Latif & Khanam, 2017; Orang et al., 2018; Sapkota et al., 2020).

As a three-arm randomised feasibility trial, Study Four benefitted from a shared control group with a separate, nested study of standard PST. The efficiency of shared control groups is well-documented (Howard, Brown, Todd, & Gregory, 2018), and multi-arm trials have been recommended for their simplicity, speed and reduced cost, relative to two-arm trials (Parmar, Carpenter, & Sydes, 2014). Furthermore, comparing different adaptations to the same core intervention has been recommended, to explore their relative impacts on outcomes (Heim & Kohrt, 2019). Study Four's focus on evaluating and refining the feasibility of both PST-IPV and the study design using a mixed method process evaluation will enhance the future, definitive RCT.

Sensitivity to discussing emotional difficulties and IPV, logistical challenges to women's participation in research, limited education and literacy, and competing priorities on ANC staff time were potential barriers to successful implementation. These barriers were mitigated for by focusing on confidentiality, supporting participants to access intervention arms, adapting recruitment and intervention procedures to accommodate variable education, and providing comprehensive training and supervision to health workers, including clear safety protocols for responding to risk concerns.

8.2.6 Limitations

Delays caused by COVID-19 meant that the results of qualitative interviews with women and health workers were not available at the time of thesis submission. The forthcoming findings will serve to elucidate quantitative process outcome results further.

The experimental use of secondary outcome measures for hypothesised mediators which had not been validated in this setting or among women experiencing IPV complicated interpretation of the lack of change in these constructs.

Although a crucial learning point prior to a full-scale RCT, the protocol deviation of mis-randomising women reporting psychological IPV using the two-arm table introduced selection bias. This weakened the statistical power of quantitative comparisons between trial arms and limited the ability to identify potential (non-significant) differences between arms. The second protocol deviation, of field supervisors organising a proportion of outcome assessments to take place before the planned nine weeks post-enrolment introduced heterogeneity into the results. However, it provided important learning about the need to recruit even more experienced staff to these crucial roles, and for even closer supervision of field work.

9 OVERALL DISCUSSION

The purpose of this PhD was to adapt a brief psychological intervention for pregnant women experiencing depressive symptoms, functional impact, and IPV in rural Ethiopia. My literature review (section 2.4) found that despite substantial evidence of the efficacy of brief interventions for CMDs in LMICs, very few have been tailored for the needs of pregnant women experiencing IPV in low-income countries. This PhD therefore aimed to:

- 1) Investigate the impact of IPV exposure on the efficacy of brief psychological interventions in LMICs (Study One).
- 2) Explore the perspectives of pregnant women and ANC staff on perinatal emotional difficulties, IPV, and features of an acceptable intervention in rural Ethiopia (Study Two).
- 3) Adapt a brief psychological intervention for the perinatal emotional difficulties of women experiencing IPV in rural Ethiopia (Study Three).
- 4) Evaluate the feasibility of the adapted intervention and a randomised, controlled study design (Studies Four and Five).

To address these aims, this PhD conducted the following studies:

1. For Study One, I systematically reviewed the literature and conducted random-effects meta-analyses of the 15 out of 21 RCTs of psychological interventions for women with CMDs, which measured exposure to IPV, for which data were available.
2. In Study Two, I explored the perspectives of 16 pregnant women and 12 ANC staff members on the relationship between perinatal emotional difficulties and IPV, and on brief psychological interventions, in rural Ethiopia, using thematic analysis of in-depth qualitative interviews.
3. For Study Three, I reviewed the evidence, to identify the most suitable brief psychological intervention model, based on in-depth consideration of the study context. I then adapted MI-PST, developed for South Africa, for pregnant women

experiencing IPV in rural Ethiopia (PST-IPV), following ADAPT guidance. I iteratively developed a theory of change and dark logic model, through stakeholder consultation, which articulated the programme theory of PST-IPV.

4. In Study Four, I developed the protocol of a randomised, controlled feasibility study and process evaluation, comparing PST-IPV with standard PST and EUC, in a three-arm design. Study Four presented the methods by which the feasibility and acceptability of both PST-IPV and the randomised, controlled study design would be evaluated, to inform a future, fully-powered RCT.
5. For Study Five, I analysed the results of Study Four and identified improvements to optimise a future RCT.

This final chapter synthesises the findings of each study in relation to the literature, in order to answer the following research questions:

- (i) Does IPV exposure reduce the efficacy of psychological interventions for CMDs in LMICs (Study One)?
- (ii) What are women and health workers' perspectives on perinatal emotional difficulties, IPV, and brief psychological interventions, in rural Ethiopia (Study Two)?
- (iii) How can a brief psychological intervention be adapted for the perinatal emotional difficulties of women experiencing IPV in this context (Study Three)?
- (iv) Are PST-IPV and a randomised, controlled study design acceptable to women and ANC staff, and feasible to implement (Studies Four and Five)?
- (v) How should PST-IPV and the randomised, controlled feasibility study be improved, to optimise the implementation of a future RCT (Studies Four and Five)?

In the following sections, I summarise my key findings in relation to each research question.

9.1 IPV exposure does not reduce the efficacy of psychological interventions for CMDs in LMICs (Research Question 1)

Contrary to my hypothesis, Study One showed that women reporting IPV benefitted at least as much from psychological interventions for CMDs as women not reporting IPV, in LMICs. This effect was particularly evident for anxiety (difference between standardised mean differences (dSMD)=0.31, CI: 0.04-0.57), with a similar but non-significant effect of IPV exposure on reductions in PTSD (dSMD=0.14, CI: -0.06-0.33), depressive symptoms (dSMD=0.10, CI: -0.04-0.25), and psychological distress (dSMD=0.07, CI:-0.05-0.18. This is the first evidence suggesting that IPV exposure may moderate the efficacy of psychological interventions in LMICs (Keynejad, Hanlon, et al., 2020).

9.2 Women and ANC staff in rural Ethiopia perceive multiple, interconnected pathways between perinatal emotional difficulties and IPV, for which brief psychological interventions are acceptable (Research Question 2)

Although IPV is often considered a sensitive subject, it was discussed in depth by the majority of women and ANC staff participating in Study Two. Emotional difficulties were often conceptualised as part of wider bodily distress. Participants contextualised IPV as the primary form of abusive treatment women experienced, connected by multiple pathways to emotional and bodily distress. Patriarchal norms were a key theme, explaining how community responses to IPV often reinforced abuse. This in turn created a sense of powerlessness, exacerbated by an irreconcilable tension between severe deprivation and high cultural expectations. Participants supported the need for a brief psychological intervention delivered within ANC. They advocated interventions with a problem-solving focus, addressing women's powerlessness, but also identified intrinsic benefits of being listened to. Participants emphasised the need to ensure confidentiality, build women's trust in ANC staff, and raise community awareness about the adverse effects of IPV.

9.3 Brief problem-solving therapy can be adapted for pregnant women experiencing IPV by reviewing the context in depth, following ADAPT guidance, and capturing stakeholders' theory of change (Research Question 3)

In Study Three, I identified the South African MI-PST model as best-suited to this rural Ethiopian context. Following ADAPT, I worked with a diverse team to make a range of adaptations to MI-PST's specific and non-specific (engagement) elements and in-session techniques. These included removing culturally incongruent components, adding relaxation exercises, adapting terminology, simplifying content, reducing take-home activities, and moving away from biomedical explanatory models of depression. Further adaptations for the needs of women experiencing IPV included integrating IPV-related problems throughout the manual, training health workers to respond to disclosures appropriately, sharing anonymised local women's testimonies, providing guidance on how IPV-related problems should be categorised during sessions, and safeguards for risk concerns. The PST-IPV theory of change (ToC) map depicted how long-term outcomes were hypothesised to occur, and identified key intermediate outcomes, including hypothesised mechanisms of action, alongside required engagement, training, and set-up activities. PST-IPV's 'dark logic' model highlighted risks that abusive partners learning of women's disclosure could provoke more IPV, that poor quality sessions could reduce women's engagement with routine ANC and institutional delivery, that therapists could inadvertently reinforce abuse, and that insufficiently empathetic communication could leave women feeling even more disempowered.

9.4 Problem-solving therapy adapted for women experiencing IPV and the randomised, controlled study design are acceptable to women and ANC staff, and feasible to implement (Research Question 4)

Studies Four and Five presented the methods and results of a three-arm randomised, controlled feasibility study and process evaluation, comparing PST-IPV with standard PST and EUC. Recruitment of women experiencing depressive symptoms, functional impact, and past-year IPV was feasible, evidenced by swift recruitment at both clinical sites. Randomisation and attendance at four intervention sessions were acceptable, as

shown by the lack of any eligible women declining to enrol, and a modest drop-out rate, often due to moving away or postnatal confinement. Acceptability and appropriateness were supported by a high proportion attending all four sessions of PST-IPV, and high median session durations. Feasibility of the trial design was supported by high rates of follow-up across all study arms. Safety of the design was supported by only one serious adverse event, which was deemed to have arisen from the presence of depressive symptoms and IPV exposure at baseline, and the trial protocol providing a safe response. Acceptability to staff was shown by the lack of any staff members dropping out of the study. Forthcoming qualitative interviews with women and stakeholders will elucidate these findings further. A deviation from the randomisation protocol introduced selection bias and weakened statistical power to detect differences between trial arms. However, longer median durations of PST-IPV sessions than standard PST sessions suggested that PST-IPV may have been a more appropriate model, for women experiencing IPV.

9.5 Key adaptations to Study Four would optimise its design for a future RCT (Research Question 5)

Although independent ratings of session adherence, quality, responsiveness, and communication were moderate to high, supervisors identified the need for improved clinical communication skills. They recommended staggering recruitment, to facilitate more frequent supervision of early clinical cases, to avoid eligible women needing to wait to receive sessions, and providing more communication skills and mental health training prior to intervention training. The protocol deviation highlighted the importance of automating randomisation decisions. Logistical difficulties, distance between Addis Ababa and the study site, and COVID-19 precautions impeded the regularity of supervision, demonstrating the benefits of cascade training models. The difficulty of conducting outcome assessments in a perinatal population showed that immediate post-intervention follow-up before a longer-term assessment might be more feasible.

In the following section, I synthesise the findings of this PhD and present my interpretations in relation to the literature.

9.6 Synthesis and interpretations

Women experiencing IPV face a range of barriers to accessing mental healthcare, at personal, clinician, health system, and community levels (Rodríguez, Valentine, Son, & Muhammad, 2009). Given concerns that generic psychological interventions may ‘pathologise’ IPV-related distress (Tsai et al., 2016) or neglect women’s complex needs (Humphreys & Thiara, 2003; Simmel et al., 2016; Tol et al., 2017), I hypothesised that they require tailoring, to effectively treat women experiencing IPV. In fact, Study One suggested that in resource-restricted contexts, women experiencing IPV may benefit as much as women not experiencing IPV from generic psychological interventions.

Beyond differences in efficacy, adapting brief psychological interventions to meet the needs of women experiencing IPV may have other advantages. For example, tailoring intervention training and content to enable health workers to respond to IPV might enhance women’s safety, and the acceptability and feasibility of sessions. However, I identified just four RCTs of psychological interventions adapted for women experiencing IPV in LMICs (Greene et al., 2021; Latif & Khanam, 2017; Orang et al., 2018), of which only one pilot, single-session intervention targeted the perinatal period (Sapkota et al., 2020), and all were conducted in middle-income countries. In Study One, I therefore identified the need for randomised trials which directly compare generic and trauma-focused interventions for women experiencing IPV in low-income country settings. Studies Four and Five demonstrated that a randomised feasibility study comparing problem-solving therapy adapted for women experiencing IPV with generic problem-solving therapy, adapted for the rural Ethiopian context, was acceptable to women and health workers, and feasible to implement.

Complex intervention development, adaptation, and evaluation require in-depth understanding of the context (Pfadenhauer et al., 2017; Skivington et al., 2021). Study Two built on my review of diverse aspects of context (Craig et al., 2018) affecting the study site of Sodo. Women and health workers’ perspectives on IPV in Ethiopia in Study Two conformed to the revised ecological framework for the occurrence of IPV (Heise, 2011), and the findings of the ‘what works’ review of the drivers of IPV perpetration (Gibbs et al., 2020). As in Study Two, Gibbs et al. (2020) identified poverty, gender

inequality, and normalisation of violence in social relationships as key structural drivers of IPV, which interact with individual and relationship factors, including poor mental health and substance abuse. Although PST-IPV focused on the level of the female partner (Heise, 2011), Study Three addressed relationship and conflict arena levels of the revised ecological framework, by integrating safe responses to IPV-related problems into the intervention manual. I addressed the community level by engaging stakeholders to develop a theory of change; the resulting ToC map acknowledged potential barriers to implementation arising from wider factors maintaining IPV. Study Four addressed the pervasiveness of IPV by incorporating clear protocols for responding to risks to participants. Study Five showed that despite barriers to engaging with PST-IPV, including poverty (which required women to work throughout pregnancy), limited education and, at times, coercive control by abusive partners, the majority of participants attended all four sessions.

Like other Ethiopian studies (Alem et al., 1999; Ayers, 2015; Gashaw et al., 2020; Papadopoulos et al., 2004), Study Two found that mental health impacts on women experiencing IPV were infrequently acknowledged, with emotional and bodily distress, such as persistent physical symptoms, more commonly identified. These findings suggest that somatic symptoms may be a relevant outcome measure for a future RCT, using a metric such as the bodily distress syndrome checklist (Budtz-Lilly et al., 2015), once validated for Ethiopia. Bodily distress may be a particularly salient outcome measure, given systematic review evidence that IPV exposure is associated with chronic pain (Stubbs & Szoeki, 2021; Walker et al., 2020) and functional gastrointestinal symptoms (Banjar, Ford-Gilboe, Wong, Befus, & Alilyyani, 2021). Study Four did not measure somatic symptoms, but Study Five showed reductions in PTSD symptoms following PST-IPV, suggesting that outcome measures other than depression require further investigation in this context.

Although Study Four was not powered to detect significant differences, modest reductions in depressive and PTSD symptoms at outcome assessment showed the potential for clinical efficacy, when evaluated in a fully-powered, optimised RCT. The absence of larger reductions in clinical symptoms in participants randomised to PST-IPV

may reflect the persistence of perinatal emotional difficulties in women experiencing IPV alongside other forms of social adversity, such as poverty, consistent with Study Two and the evidence base (Gibbs et al., 2020; Heise, 2011).

Also consistent with the literature, Study Two found that women's powerlessness to influence their economic circumstances (Hanlon et al., 2013) reinforced their lack of control over IPV, compounded by pervasive patriarchal norms (Dutton & Painter, 1981). External attribution of blame for IPV to alcohol use, and internal attribution to women's behaviour or personal attributes, led to hopelessness, helplessness (Brown & Harris, 1978; Brown et al., 1995), and self-blame (Overholser & Moll, 1990), further increasing women's risk of depression. Indeed, the powerful effects of patriarchal norms were a cross-cutting theme of this PhD.

For example, the protocol deviation in which women experiencing psychological or emotional IPV were incorrectly randomised highlighted the entrenched nature of preconceptions about what 'counts' as IPV among research staff (Novak, 2020), despite evidence (Blasco-Ros et al., 2010; Jina et al., 2012; Ludermir et al., 2010), training, study materials, and protocols. Although randomisation errors are not uncommon (Yelland et al., 2018; Yelland et al., 2015), this error indicated the need to emphasise in researcher training that IPV includes psychological and emotional abuse, and coercive control, not just physical and sexual violence. It also showed the importance of automating randomisation processes as much as possible, to eliminate selection bias. Prevailing norms were also evidenced by the fact that, although participants freely discussed IPV in Study Two, and clinicians had received intensive training, IPV was infrequently, or only briefly, discussed during PST-IPV sessions, in spite of lengthy median durations. This suggests that even women known to be experiencing IPV require proactive prompting to begin discussing relationship-related difficulties, and that health workers need more extensive training, to have the confidence to do so. These barriers to research staff recognising IPV, despite using validated metrics, and to ANC staff discussing IPV, despite intensive clinical training, underscore the scale of the challenge to routine identification of IPV in clinical practice.

As previously found in Sodo (Azale et al., 2018; Bitew et al., 2020) and other Ethiopian regions (Kaiser et al., 2015), participants in Study Two expressed the need for an antenatal intervention focused specifically on women's problems. This was supported by the acceptability of the problem-solving therapy model in Study Five. Perhaps because of negative experiences of ANC (Wassihun & Zeleke, 2018), Study Two participants considered therapists' personal characteristics and communication skills to be particular priorities (Asher et al., 2021; Padmanathan & De Silva, 2013).

Assessment and education in non-technical skills for health workers in LMICs is acknowledged to be a neglected area, requiring high quality research (Scott et al., 2016). In Ethiopia, the adaptation of the South African practical approach to care kit (PACK) as the primary health care clinical guidelines (PHCG) has included communication skills training (Feyissa et al., 2019), in keeping with national priorities (Ministry of Health, 2015, 2021b). A future RCT must implement basic communication skills and mhGAP intervention guide training (WHO, 2016a), to familiarise ANC staff with basic mental health subjects and listening skills, prior to PST-IPV training. Given women and health workers' emphasis in Study Two on the intrinsic benefits of being listened to, it would also be of interest to evaluate the mental health impact of optimising ANC with communication skills and mhGAP-IG training. A future RCT should compare the clinical outcomes of participants randomised to enhanced ANC, with those of participants randomised to PST-IPV and enhanced ANC. Such a comparison would enable evaluation of the relative contributions of specific and non-specific elements of PST-IPV for pregnant women experiencing IPV in this context (Heim & Kohrt, 2019; Singla et al., 2017).

Study Three is the first study to prospectively articulate a programme theory for a psychological intervention adapted for women experiencing IPV, enabling exploration of how PST-IPV may work, or not, in this context. As shown by Study One, no published studies considered potential unintended harms of generic psychological intervention models delivered to women experiencing IPV in LMICs. The prevalence of patriarchal norms identified in Study Two raised the risk that intervention sessions could inadvertently compound women's sense of powerlessness, reinforce abuse, or 'victim

blame' (Overholser & Moll, 1990). By considering PST-IPV's dark logic model (Bonell et al., 2015), Study Three prioritised women's safety and well-being, by articulating potential unintended harms, and adapting the problem-solving therapy model accordingly. Taken together, Studies One, Two, and Three highlighted the importance of all interventions (not just those targeting women experiencing IPV directly) prioritising the safety of women and any children (WHO, 2016c). Therapists should be trained to respond to IPV disclosures (WHO, 2014, 2019b), receive regular, specialist supervision, and studies should follow safety protocols for any identified risks.

As well as the ANC intervention addressing perinatal emotional difficulties adapted in Study Three and piloted in Studies Four and Five, Study Two also identified a need for interventions at other levels of the revised ecological framework (Heise, 2011), to directly address IPV, and its widespread reinforcement. Hawe et al. (2009) conceptualised interventions as events occurring in complex ecological systems, in which evolving networks of interaction between people, places, and time lead to dynamic self-organisation. Shiell et al. (2008) argued that emergent properties of complex systems, such as community empowerment (Zimmerman, 1990), can be missed by studies focused on individual and short-term outcome measurement. They proposed that numerous episodes of advocacy (for example, activities discouraging IPV) may take place without discernible impact, before a 'tipping point', phase transition (a rapid shift from one state to another), and, finally, measurable change. The intractable nature of IPV and its consequences may therefore require particularly sustained attention and investment, before reductions can be detected. Studies in Sodo which found mixed effects on IPV perpetration (Sharma et al., 2020), substance use, and depression (Leight et al., 2020) of a gender transformative intervention could be complemented by anti-IPV community mobilisation activities (Abramsky et al., 2014), as well as interventions addressing the mental health impacts of IPV on women.

9.7 Strengths

This PhD achieved its purpose of adapting a brief psychological intervention for pregnant women experiencing depressive symptoms, functional impact, and IPV in rural Ethiopia.

Each of the five studies contributed knowledge to the limited literature on interventions tailored for the needs of pregnant women experiencing IPV in LMICs, following the latest guidance on the development and evaluation of complex interventions.

The moderation analysis conducted for Study One was the first of its kind in this field. The in-depth qualitative methods employed in Study Two explored the perspectives of stakeholders in detail, ensuring that subsequent studies were as allied as possible to their experiences and priorities. Study Two also informed an in-depth understanding of the study context, optimising the tailoring of the subsequent intervention and feasibility study. Study Three used participatory approaches to attain as much consensus among diverse stakeholders as possible, followed best evidence on intervention adaptation, and yielded tangible resources for research and clinical practice. Study Three contributed a clear and replicable description of the adaptation process, which could facilitate translation to other contexts and cross-contextual comparisons with other research settings. Clarity about how and why PST-IPV was adapted could also enhance appraisal of any future outcome studies, in terms of whether its efficacy or inefficacy are attributable to treatment mechanisms, adaptation decisions, implementation, or evidence quality (Moore et al., 2021).

By clearly articulating PST-IPV's programme theory (O'Cathain et al., 2019; Skivington et al., 2021), Study Three set out a hypothesised process of change, including testable mediators of anticipated outcomes (Breuer et al., 2014; De Silva et al., 2014; Kazdin, 2007). This enabled Study Four to pilot outcome measures to explore 'what works for whom' (Norcross & Wampold, 2011), with potential future relevance to policy decisions and implementation in practice. The non-linear nature of change in complex systems, characterised by tipping points and phase transitions (Shiell et al., 2008), makes piloting intermediate outcome measures particularly important.

Study Three complemented barriers to and facilitators of implementation success identified in Study Two, by integrating the perspectives of stakeholders from the inception of PST-IPV onwards. This is valuable, given evidence that concerns about 'task dumping' (Jacobs et al., 2020), workload, discomfort with discussing IPV (Abrahams et al., 2021) and health worker buy-in (Myers et al., 2019) were key barriers, in South

African settings. These factors were not identified in Studies Four and Five but will be explored during forthcoming qualitative interviews with study participants.

As recommended by Fletcher et al. (2016), Howard et al. (2018) and Parmar et al. (2014), Studies Four and Five used a three-arm design to compare PST-IPV with standard PST and EUC, benefitting from sharing a control group with the nested trial (Bitew et al., 2021). The three-arm design also enabled comparisons between two adaptations of the same core intervention (Heim & Kohrt, 2019).

Although several studies have evaluated the feasibility of brief perinatal psychological interventions in LMICs, most were uncontrolled (Notiar et al., 2021; Spedding et al., 2020), and so did not evaluate the feasibility of randomisation processes. Studies Four and Five identified a range of improvements to training, supervision, recruitment, randomisation, and outcome assessment, to optimise a future, fully-powered, evaluation of PST-IPV using an RCT design.

A key strength of this PhD is the attention paid to the lived experience of pregnant women affected by IPV, and to the perspectives of health workers practising in resource-limited settings. Stakeholder engagement is an increasingly-acknowledged requirement of health research in LMICs (Cook, Siddiqi, Twiddy, & Kenyon, 2019), with potential to influence subsequent intervention buy-in (Breuer et al., 2014).

Another strength was the effort made in each experimental study to consider the needs and facilitate the inclusion of under-represented and potentially vulnerable women within the research. Studies Two and Four incorporated provision for non-literate women to consent to participate, and were conducted in a rural region several hours' travel from the capital. The Study Four standard operating procedure included protocols to optimise the ability of interested women to participate in the study, maximising inclusivity.

This PhD contributed evidence and experience of complex intervention adaptation and piloting, of relevance to research colleagues based elsewhere in Ethiopia, and in other LMICs. The findings may also be of relevance to researchers in HICs, considering ways to integrate brief psychological therapies into primary, including antenatal, care.

9.8 Limitations

Study One was limited by conducting aggregate data meta-analysis. With greater resources, an individual participant data meta-analysis would have afforded statistical and methodological advantages, such as the ability to adjust for potential confounding (Riley, Lambert, & Abo-Zaid, 2010).

Although this PhD research sought to maximise stakeholder engagement, member checking of Study Two's findings and conducting a dedicated theory of change workshop with pregnant women in Study Three would have enhanced the results. I plan to present Study Three's theory of change map to stakeholders and adjust it to accommodate their feedback, once overseas field work can safely resume.

Deviation from the Study Four protocol by incorrectly randomising women reporting psychological or emotional IPV weakened statistical power to detect differences between trial arms, albeit within a study not powered to detect efficacy. Field supervisors' decision to expedite a proportion of outcome assessments also introduced heterogeneity to the results.

Delays to conducting qualitative interviews caused by the coronavirus pandemic mean that Study Five's process evaluation is incomplete. Once interviews have been transcribed and translated, thematic analysis, triangulated with the comprehensive implementation log, will elucidate the role of key aspects of the study context on the delivery of PST-IPV, its mechanisms and impact, enhancing interpretation of the quantitative findings. Exploring stakeholder-perceived barriers to and facilitators of implementation will further enhance the safety, efficiency, and validity of a future RCT.

9.9 Implications

9.9.1 Theory

This PhD highlighted the importance of understanding the mechanisms by which brief psychological interventions work. A future study could explore context-mechanism-

outcome configurations across settings (Abayneh, Lempp, Manthorpe, & Hanlon, 2018), using realist approaches to move from programme theory to mid-range theory.

This PhD benefitted from a range of theoretical frameworks, including over-arching MRC/NIHR guidance on developing and evaluating complex interventions (Skivington et al., 2021), specific guidance on attending to context (Craig et al., 2018), adapting interventions (Moore et al., 2021), and conducting process evaluations (Moore et al., 2015), as well as implementation science frameworks (Damschroder et al., 2009; Pfadenhauer et al., 2017). However, breaking down each of these aspects of intervention development and evaluation using separate frameworks can risk omitting a more holistic understanding of the intervention within the complex system. Although the new MRC/NIHR complex interventions guidance (Skivington et al., 2021) explicitly references complex systems literature, how to best reconcile this more overarching perspective with the granular approaches taken by individual frameworks remains unclear.

Similar to the difficulty of separating core from peripheral elements of psychological interventions (Chu & Leino, 2017) is the difficulty of separating aspects of the intervention's implementation designed to enhance its feasibility, from aspects of the research study designed to evaluate it. For example, women living far from the health centre were reimbursed with small payments for their transport costs, to facilitate Study Four. Payments also, however, enhanced the acceptability and feasibility of attending four sessions, for women with low incomes. Thus, although theoretical frameworks enhanced the clarity and transparency of this PhD, objective distinctions could not always be made between their many sub-components.

Reporting of this PhD also followed guidance for systematic reviews and meta-analyses (Page et al., 2021), interventions (Hoffmann et al., 2014), theories of change (Breuer et al., 2015), protocols (Chan et al., 2013), and feasibility studies (Eldridge et al., 2016). Although these frameworks and checklists provided valuable structure, some researchers have argued that overly complex reporting guidelines focus attention away from the quality of trial conduct and design (Howick, Webster, Knottnerus, & Moher, 2021).

9.9.2 Research

This PhD contributes evidence and experience of following the new MRC/NIHR complex interventions guidance (Skivington et al., 2021) to adapt and pilot a brief psychological intervention for pregnant women experiencing depressive symptoms, functional impact, and IPV in rural Ethiopia. Given the dearth of psychological intervention research conducted in low income, rural contexts, with perinatal populations and with women experiencing IPV, this PhD contributes detailed descriptions of methods, results, barriers and facilitators to adapting complex interventions in such settings, with such populations.

Study One demonstrated the need for RCTs of psychological interventions not targeting IPV directly, to measure IPV exposure as standard. Although many otherwise eligible RCTs used instruments such as the Harvard trauma questionnaire (Mollica et al., 1992) to capture exposure to traumatic events, they did not specify the identity of the perpetrator, preventing their inclusion in Study One. Given the high prevalence of IPV in LMICs and worldwide (WHO, 2013a), mental health researchers, including principal investigators and field workers, should be trained to ask about and respond to IPV safely and sensitively (WHO, 2013c), including in ANC settings. Additionally, research is required to determine whether other forms of gender-based violence, such as non-partner sexual violence, also moderate the efficacy of psychological interventions for CMDs in LMICs, and whether generic treatments for severe mental illness are also as effective among participants reporting IPV, as among those not reporting IPV.

Entrenched preconceptions that psychological or emotional abuse do not ‘count’ as IPV led to a deviation from the trial protocol, contributing important learning to the field about additional considerations for studies involving IPV. The study was safely conducted, and a single SAE enabled the safety protocol to be assessed. These findings support calls for more research that evaluates the effects of gendered risk factors on outcomes (Howard et al., 2017), and RCTs of psychological interventions that measure exposure to IPV (Oram et al., 2017).

Stakeholder perspectives in Study Two emphasised the importance of addressing IPV more broadly, beyond the individual woman, or couple. Future research should address

how different levels of Heise (2011)'s revised ecological framework and Gibbs et al. (2020)'s drivers of IPV reinforce each other in this context, taking a complex systems perspective. Adapting community mobilisation interventions which have been effective in other sub-Saharan African settings (Abramsky et al., 2014) to address patriarchal norms and pervasive reinforcement of IPV in this context is an important area for future research. Such approaches may have particular potential, given the evidence of substantial demographic changes in Ethiopia's young population (Revollo & Portela, 2019).

A key finding of this PhD was the (potentially, synergistic) impact of other social determinants of mental health, such as poverty, alongside IPV, on pregnant women's mental health. Authors in South Africa have suggested combining psychological interventions with other components directly addressing poverty (such as cash transfer programmes), and interventions targeting IPV directly (Lund et al., 2020). However, when reviewing the literature, Heise (2011) noted that employment, participation in credit or development schemes, and ownership of assets were associated with both increased and decreased IPV in different settings. Multi-component interventions could enable the relative effects of different elements to be compared between the arms of a multi-arm trial, but careful consideration of the 'dark logic' model (Bonell et al., 2015) of unintended harms would be required.

9.9.3 Practice

Despite the anticipated sensitivity of discussing IPV at all, in-depth qualitative research and a randomised, controlled feasibility trial for women experiencing IPV proved acceptable to stakeholders and feasible to implement. This PhD demonstrated the potential of training ANC staff to use WHO (2013c) guidelines on asking about and responding to IPV, in this rural, low-income setting.

A single SAE during Study Four enabled the trial safety protocol to be tested, and highlighted challenges of supporting women in rural areas who do not have a mobile phone but are identified to be at risk. Plans to scale up mental health training (WHO, 2016a) for primary care staff should be enhanced by training on IPV (WHO, 2019b), to sensitise primary care staff to risks and appropriate responses. Such training should also

incorporate support structures for health workers, a proportion of whom are themselves likely to be experiencing IPV.

Health workers informed supervisors that they valued having tools (such as relaxation exercises and ‘worry time’) to teach women, and that they used them in other ANC encounters. In keeping with national prioritisation of caring, respectful and compassionate care (Ministry of Health, 2015), and now motivated, competent and compassionate care (Ministry of Health, 2021b), interventions like PST-IPV could support the prioritisation of health worker communication skills training in settings where women receive little emotional support beyond their neighbours and families (Feyissa et al., 2019).

Although delivering regular supervision faced logistical challenges, it provided ANC staff with a greater frequency and consistency of feedback on their interactions with pregnant women than is possible within routine clinical practice. The ‘state of the world’s midwifery’ report found that midwifery was recognised in law as an independent profession in less than half of the 73 participating LMICs, and that the median number of supervised births before graduation was 33 (Lopes et al., 2016). ANC staff therefore receive limited formative feedback on their skills, even during training. This highlights the potential of regular observation, feedback, and supervision to enhance the provision of compassionate antenatal care, which could improve women’s engagement and obstetric outcomes in Ethiopia (Wassihun & Zeleke, 2018), and beyond.

9.10 Final conclusions

Despite being bidirectionally associated and highly prevalent causes of morbidity and mortality, perinatal mental health conditions and IPV remain neglected worldwide, and especially in LMICs. This PhD showed that IPV does not reduce the efficacy of psychological interventions for CMDs in LMICs, and that women and health workers in rural Ethiopia would prioritise perinatal mental health and IPV for intervention. Brief problem-solving therapy can be readily adapted for the needs of pregnant women experiencing IPV in this context, and its randomised, controlled piloting was acceptable to stakeholders and feasible to implement. Growing national and international

prioritisation of perinatal mental health and the role played by IPV means that research is urgently needed, evaluating the efficacy and potential scalability of task-shared, adapted interventions like PST-IPV, integrated into primary care services in the most resource-limited contexts.

10 APPENDICES

10.1 Study One

10.1.1 Search terms applied in Medline

- 1 exp psychotherapy/ or exp psychotherapy, brief/ or psychotherapy, group/ or psychotherapy, multiple/ or psychotherapy, psychodynamic/
- 2 (psychosocial or psycho-social).ti,ab,kf,hw.
- 3 psychotherap*.ti,ab,kf,hw.
- 4 ((psychosocial or psycho-social or psycholog\$ or behavio?r* or cognitive) adj3 (intervent\$ or therap\$ or treat\$ or manag\$)).ti,ab,kf.
- 5 talking therap*.ti,ab,kf.
- 6 problem sol*.ti,ab,kf,sh.
- 7 talking therapy.mp.
- 8 exp *Family Therapy/
- 9 ((psychosocial or psycho-social or psycholog\$ or behavio?r* or cognitive) adj3 (intervent\$ or therap\$ or treat\$ or manag\$)).tw.
- 10 ((acceptance and commitment) or activity scheduling or analytical therap\$ or art therap\$ or aversion therap\$ or balint group or behavio?r activation or behavio\$ contrac\$ or behavio?r modification or behavio?r therap\$ or bibliotherap\$ or biofeedback or body therap\$ or brief therapy or client cent\$ therapy or cognitive behavio?r therap\$ or cognitive therap\$ or CBT or cCBT or iCBT or cognitive behavio?ral stress management or cognitive restructur\$ or colo?r therap\$ or compassion focus\$ or compassionate therap\$ or contingency management or conversion therap\$ or conversational therap\$ or couples therap\$).mp.
- 11 (((dance therap\$ or dialectic\$) adj2 therap\$) or diffusion therap\$ or distraction therap\$ or (dream\$ adj3 analys\$) or eclectic therap\$ or emotion\$ focus\$ therap\$ or emotional freedom technique or encounter group therap\$ or existential or experiential or exposure therap\$ or expressive therap\$ or eye movement desensiti#ation or family therap\$ or feminist therap\$ or focus oriented or free association or

- freudian or functional analysis or gestalt or griefwork or group therap\$ or guided image\$ or holistic therap\$ or humanistic or hypnosis or hypnotherapy or hypnoti#zability or implosive therap\$ or insight therap\$ or integrative therap\$ or integrative therap\$ or interpersonal therap\$ or Jungian or kleinian).mp.
- 12 (logotherap\$ or logo therap\$ or marathon group therap\$ or marital therap\$ or meditation or metacognitive or meta-cognitive or milieu or mind train\$ or mindfulness or morita or multimodal therap\$ or music therap\$ or narrative therap\$ or nondirective therap\$ or non-directive therap\$ or nondirective therap\$ or non-specific therap\$ or nonspecific therap\$ or personal construct therap\$ or person cent\$ therap\$ or pet therap\$ or play therap\$ or present cent\$ therap\$ or primal therap\$ or problem focus\$ therap\$ or process experiential or psychoanaly\$ or psychodrama or psychodynamic or psychotherap\$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 13 (rational emotive therap\$ or reality therap\$ or relationship therap\$ or relaxation stress management or relaxation technique\$ or relaxation therap\$ or relaxation training or self analys\$ or sensitivity training therap\$ or sleep phase chronotherap\$ or socioenvironment\$ therap\$ or social skill\$ or sociotherap\$ or solution focused therap\$ or stress management or support group\$ or (support adj3 psycho\$) or supportive therap\$ or systematic desensiti#ation or therapeutic techniqu\$ or time limited therap\$ or transference therap\$ or validation therap\$).mp.
- 14 Desensitization, Psychologic/
 15 "Imagery (Psychotherapy)"/
 16 randomi#ed controlled trial.pt.
 17 controlled clinical trial.pt.
 18 randomi#ed.ab.
 19 trial.ti,ab.
 20 (control adj group?).ab.
 21 exp Pragmatic Clinical Trial/ or exp Clinical Trial/ or exp Randomized Controlled Trial/ or exp Controlled Clinical Trial/
 22 exp Random Allocation/

- 23 (clin\$ adj5 trial\$).ti,ab.
- 24 ((waitlist* or wait\$ list* or treatment as usual or TAU) adj3 (control or group)).ab.
- 25 iCBT.mp.
- 26 iCBT.tw.
- 27 ((developing or less developed or under developed or underdeveloped or middle income or low income or lower income) adj (countr* or nation* or world)).mp.
- 28 ((transitional or developing or less developed or lesser developed or under developed or underdeveloped or middle income or low income or lower income) adj (economy or economies)).mp.
- 29 ((low* adj (gdp or gnp or gross domestic or gross national)) or (Imic or Imics or lamics or lamic or third world or lami countries or lami country) or (transitional country or transitional countries)).mp.
- 30 exp Developing Countries/
- 31 (Afghanistan or Albania or Algeria or Angola or Argentina or Armenia or Armenian or Azerbaijan or Bangladesh or Benin or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Botswana or Brazil or Bulgaria or Burkina Faso or Burkina Fasso or Upper Volta or Burundi or Urundi or Cambodia or Khmer Republic or Kampuchea or Cameroon or Camerons or Cameroon or Camerons or Cape Verde or Cabo Verde or Central African Republic or Chad or China or Colombia or Comoros or Comoro Islands or Comoros or Mayotte or Congo or Zaire or Costa Rica or Cote d'Ivoire or Cote d'Ivoire or Ivory Coast or Croatia or Cuba or Djibouti or French Somaliland or Dominica or Dominican Republic or East Timor or East Timur or Timor Leste or Timor-Leste or Ecuador or Egypt or El Salvador or Equatorial Guinea or Eritrea or Ethiopia or Fiji or Gabon or Gabonese Republic or Gambia or Gaza or Georgia or Georgian Republic or Ghana or Gold Coast or Grenada or Guatemala or Guinea or Guinea-Bisseau or Guiana or Guyana or Haiti or Honduras or India or Indonesia or Iran or Iraq or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kyrgyz Republic or Kirghizia or Kyrgyz or Kirghiz or Kirgizstan or Lao or Lao PDR or Laos or Lebanon or Lesotho or Basutoland or Liberia or Libya or Macedonia or Madagascar or Malagasy or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Marshall Islands or Mauritania or Mauritius or Agalega Islands or (Mexico not New Mexico) or Micronesia or Middle East or Maldives or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanmar or Myanma or Burma or Namibia or Nauru or Nepal or Netherlands Antilles or New Caledonia or Nicaragua or Niger or Nigeria or Mariana Islands or Pakistan or Palestine or Panama or Papua New Guinea or Paraguay or Peru or Philippines or Philipines or Phillipines or Phillippines

- or Romania or Rumania or Roumania or Russia or Russian or Rwanda or Ruanda or Saint Lucia or St Lucia or Saint Vincent or St Vincent or Grenadines or Samoa or Samoan Islands or Navigator Island or Navigator Islands or Sao Tome or Senegal or Serbia or Montenegro or Sierra Leone or South Africa or Sri Lanka or Ceylon or Solomon Islands or Somalia or Somaliland or South Africa or Sudan or South Sudan or Suriname or Surinam or Swaziland or Syria or Syrian Republic or Tajikistan or Tadzhikistan or Tadjikistan or Tadzhik or Tanzania or Thailand or Togo or Togolese or Tonga or Tunisia or Turkey or Turkmenistan or Turkmen or Tuvalu or Venezuela or Uganda or Ukraine or USSR or Soviet Union or Union of Soviet Socialist Republics or Uzbekistan or Uzbek or Vanuatu or New Hebrides or Venezuela or Vietnam or Viet Nam or West Bank or Yemen or Yugoslavia or Zambia or Zimbabwe or Rhodesia).mp.
- 32 27 or 28 or 29 or 30 or 31
- 33 exp Mental Disorders/ or exp Mental illness/
- 34 exp Mental Health/
- 35 exp Mentally Ill Persons/ or exp Community Mental Health Services/
- 36 exp Depression/ or exp Depression, Postpartum/
- 37 exp Neurotic Disorders/
- 38 exp Depressive Disorder/ or exp Stress Disorders, Traumatic/ or exp Stress Disorders, Post-Traumatic/ or exp Stress Disorders, Traumatic, Acute/ or exp Stress, Psychological/
- 39 exp Obsessive-Compulsive Disorder/ or exp Obsessive Behavior/ or exp Anxiety/ or exp Anxiety Disorders/ or exp somatoform disorder/
- 40 ((common adj mental adj disorders) or anxiety or depression or distress or (panic adj disorder) or (depressive adj disorder) or (depressive adj symptoms) or (anxious adj symptoms) or (somatization adj symptoms) or (somatisation adj symptoms) or (somatization adj disorder) or (somatisation adj disorder) or (somatoform adj symptoms)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 41 (obsessive or compulsive).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 42 (Neurosis or psychoneurosis).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

-
- 43 ((mood or neurotic or stress or reactive or somatoform or somatization or somatisation or anxiety or phobic or obsessive-compulsive or adjustment or dissociat\$) adj2 disorder\$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 44 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
- 45 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43
- 46 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 25 or 26
- 47 32 AND 44 AND 45 AND 46

10.1.2 Baseline CMD scores: participants reporting versus not reporting IPV

Table 10.1 Independent samples t-tests comparing baseline mean CMD scores for included studies in meta-analyses of anxiety (A), PTSD (B), depression (C) and psychological distress (D).

A

First author, Year	Measure	Participants reporting no IPV			Participants reporting IPV			t	p
		N	Mean	Standard deviation	N	Mean	Standard deviation		
Chibanda 2016	GAD7	69	9.9	5.3	161	11.3	5	-1.91	0.057
Bass 2016	HSCL-25anx	27	12.85	5.22	27	15.44	4.37	-1.98	0.053
Bolton 2014a	HSCL-25anx	43	14.44	5.97	22	16	4.32	-1.09	0.28
Bolton 2014b	HSCL-25anx	40	13.78	5.54	18	16.5	4.19	-1.86	0.068
Steinert 2017	HSCL-25anx	25	2.96	0.7	9	3.02	0.61	-0.23	0.82

B

First author, Year	Measure	Participants reporting no IPV			Participants reporting IPV			t	p
		N	Mean	Standard deviation	N	Mean	Standard deviation		
Tol 2019	PCL-6	219	21.82	4.82	99	22.39	4.32	-1.01	0.31
Ertl 2011a	CAPS	1	84	0	15	68	15	N/A	N/A
Ertl 2011b	CAPS	8	66	11.87	11	60.18	15.38	0.89	0.39
Bryant 2017	PCL-5	59	26.73	20.42	150	36.23	19.11	-3.17	0.0017*
Bass 2016	HTQptsd	27	34.30	12.73	27	43.44	9.79	-2.96	0.0046*
Bolton 2014a	HTQptsd	43	40.23	14.24	22	43.59	13.80	-0.91	0.37
Bolton 2014b	HTQptsd	40	42.58	13.46	18	46.33	10.57	-1.05	0.30
Steinert 2017	HTQptsd	25	3.37	0.45	9	3.4	0.38	-0.18	0.86

C

First author, Year	Measure	Participants reporting no IPV			Participants reporting IPV			t	p
		N	Mean	Standard deviation	N	Mean	Standard deviation		
Lund 2014	HDRS	174	15.19	4.54	31	18	5.93	-3.02	0.0028*
Ertl 2011a	MINI	1	6	0	15	3	3.14	N/A	N/A
Ertl 2011b	MINI	8	3.38	2.45	11	2.73	3.07	0.49	0.63
Tol 2019	PHQ9	219	14.93	4.75	99	15.6	4.65	-1.17	0.24
Chibanda 2016	PHQ9	69	11.1	5.5	161	13.8	5.5	-3.41	0.0008*
Patel 2016	PHQ9	75	17.6	2.69	28	18.43	3.08	-1.34	0.18
Fuhr 2019	PHQ9	124	13.44	3.42	16	15.38	3.79	-2.11	0.037*
Sikander 2018	PHQ9	245	14.73	3.64	30	16.6	4.17	-2.61	0.0095*
Steinert 2017	HSCL-25dep	25	3.04	0.66	9	3.34	0.39	-1.28	0.21
Bass 2016	HSCL-25dep	27	31.04	6.95	27	33.37	8.19	-1.13	0.26
Bolton 2014a	HSCL-25dep	43	33.61	8.19	22	39.09	10.20	-2.35	0.022*
Bolton 2014b	HSCL-25dep	40	35.23	7.75	18	36.33	7.11	-0.52	0.61

D

First author, Year	Measure	Participants reporting no IPV			Participants reporting IPV			t	p
		N	Mean	Standard deviation	N	Mean	Standard deviation		
Chibanda 2016	SSQ-14	69	10.1	1.1	161	10.8	1.4	-3.69	0.0003*
Tol 2019	Kessler 6	232	16.44	4.09	99	16.73	4.21	-0.59	0.56
Grundlingh 2017	SRQ-20	12	2.5	1.09	3	2.33	2.31	0.19	0.85
Bryant 2017	GHQ-12	59	18.24	6.29	150	10.67	5.82	-1.56	0.12

CAPS: clinical-administered PTSD scale, CMD: common mental disorder, GAD: generalised anxiety disorder (questionnaire), GHQ: general health questionnaire, HDRS: Hamilton depression rating scale, HSCL: Hopkins symptom checklist, HTQ: Harvard trauma questionnaire, IPV: intimate partner violence, PHQ: patient health questionnaire, MINI: mini international neuropsychiatry inventory, PCL: PTSD checklist, PTSD: post-traumatic stress disorder, SRQ: self-reporting questionnaire, SSQ: Shona symptom questionnaire.

10.1.3 Risk of bias assessments

Table 10.2 Study One Cochrane risk of bias tool assessments

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Participant/personnel blinding (performance bias)	Primary outcome assessment blinding (detection bias)	Secondary outcome assessment blinding (detection bias)	Incomplete primary outcome data (attrition bias)	Incomplete secondary outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias	Overall risk of bias
Bass et al. 2016	Low risk of bias	Low risk of bias	High risk of bias	High risk of bias	High risk of bias	Low risk of bias	Low risk of bias	Unclear	High risk of bias	Moderate risk of bias
Bolton et al. 2014	Low risk of bias	Unclear	High risk of bias	High risk of bias	High risk of bias	Low risk of bias	Low risk of bias	Unclear	High risk of bias	Moderate risk of bias
Tol et al. 2020	Low risk of bias	Unclear	High risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	High risk of bias	Moderate risk of bias
Bryant et al. 2017	Low risk of bias	Low risk of bias	High risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	High risk of bias	Moderate risk of bias
Chibanda et al. 2016	Low risk of bias	Low risk of bias	High risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias
Ertl et al. 2011	Unclear	Unclear	High risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Moderate risk of bias
Fuhr et al. 2019	Low risk of bias	Low risk of bias	High risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	High risk of bias	Low risk of bias	Moderate risk of bias
Grundlingh et al. 2017	Low risk of bias	Low risk of bias	High risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias
Lund et al. 2014	Low risk of bias	Low risk of bias	High risk of bias	Low risk of bias	Low risk of bias	Unclear	Unclear	Unclear	Unclear	Moderate risk of bias
Patel et al. 2017	Low risk of bias	Low risk of bias	High risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias
Sikander et al. 2018	Low risk of bias	Low risk of bias	High risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias
Steinert et al. 2017	High risk of bias	Low risk of bias	High risk of bias	Low risk of bias	Low risk of bias	High risk of bias	High risk of bias	Unclear	Low risk of bias	Moderate risk of bias

Key			
High risk of bias	Moderate risk of bias	Low risk of bias	Unclear

10.1.4 Funnel Plot

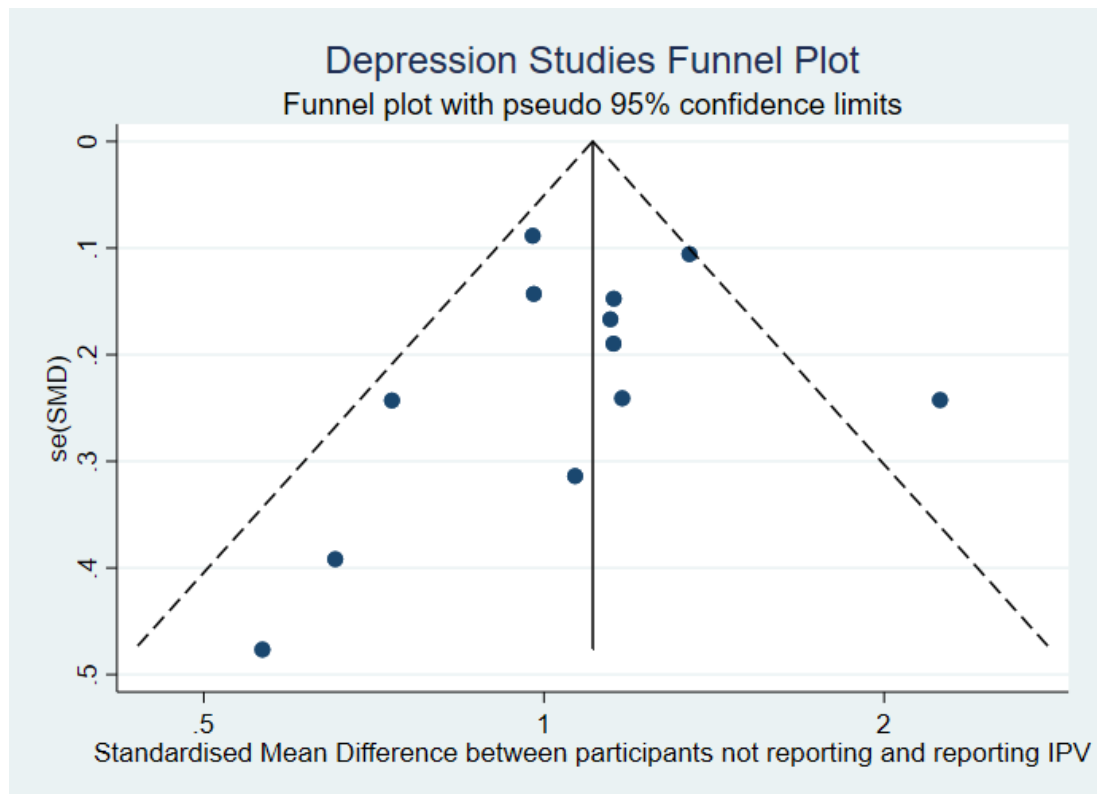
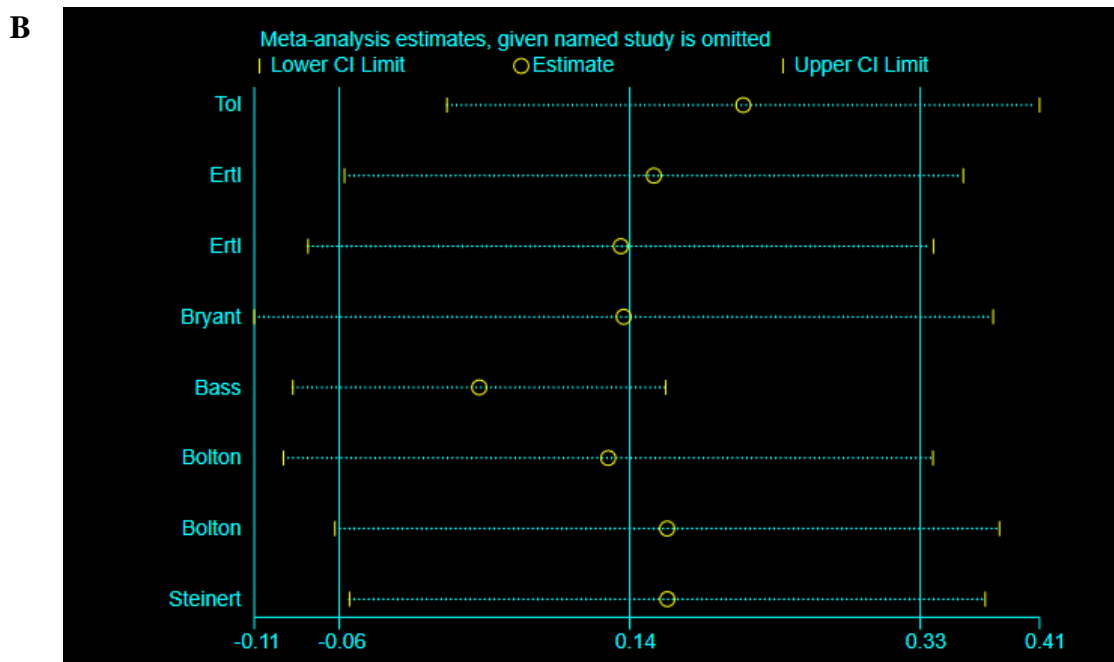
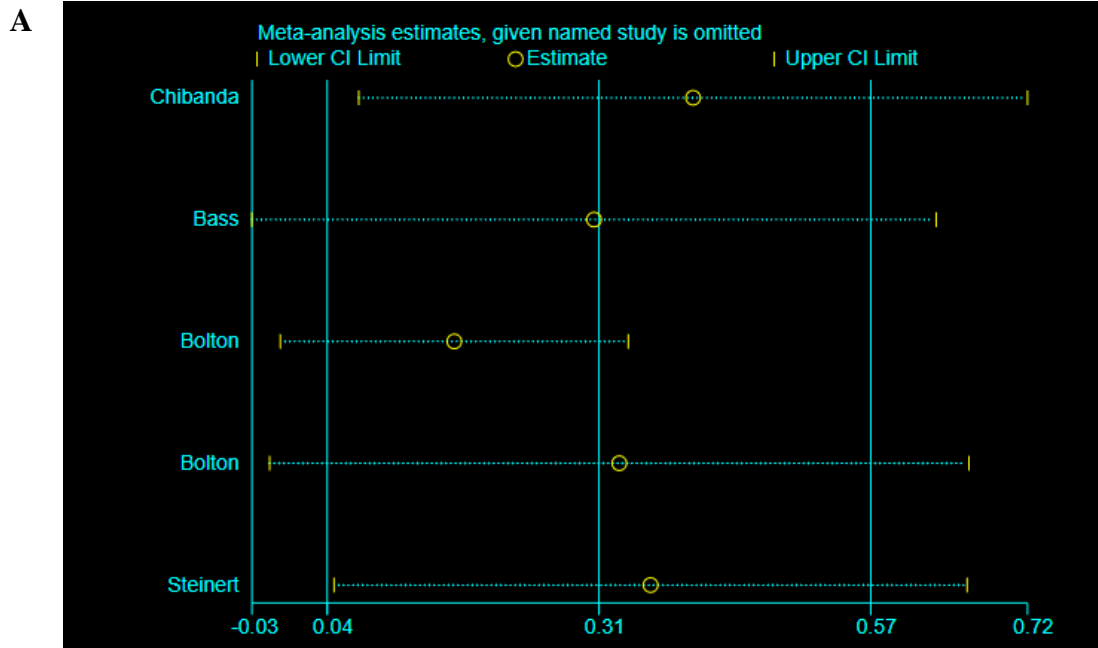


Figure 10.1 Funnel plot of depression meta-analysis studies

IPV: intimate partner violence.

10.1.5 Sensitivity analyses



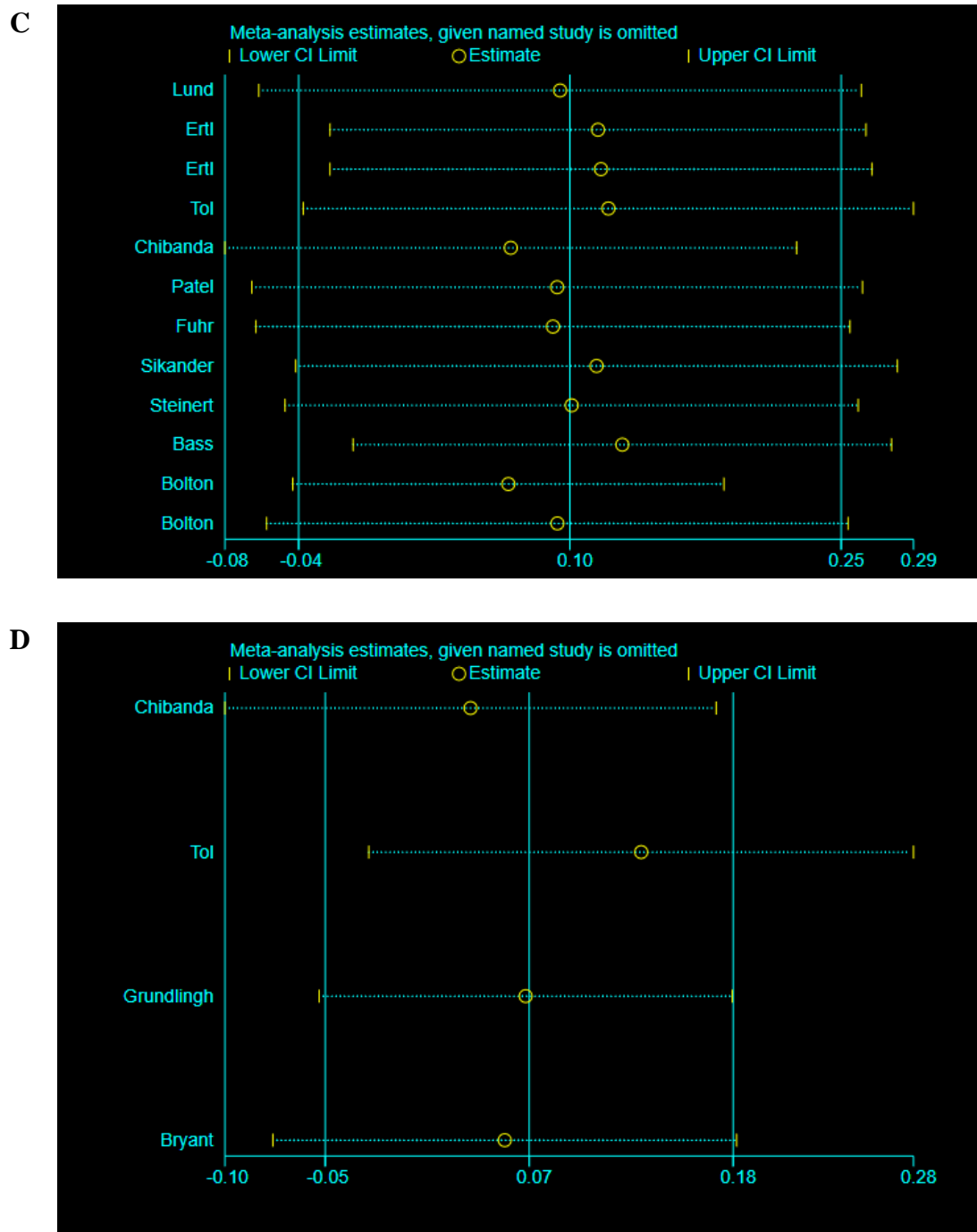
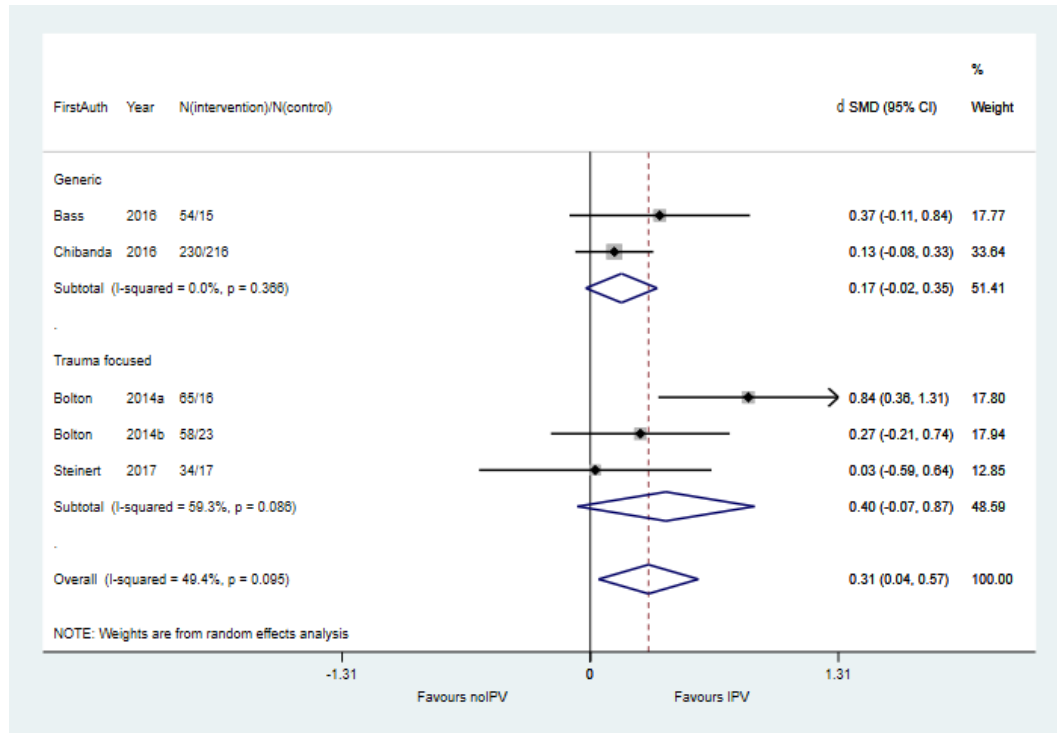


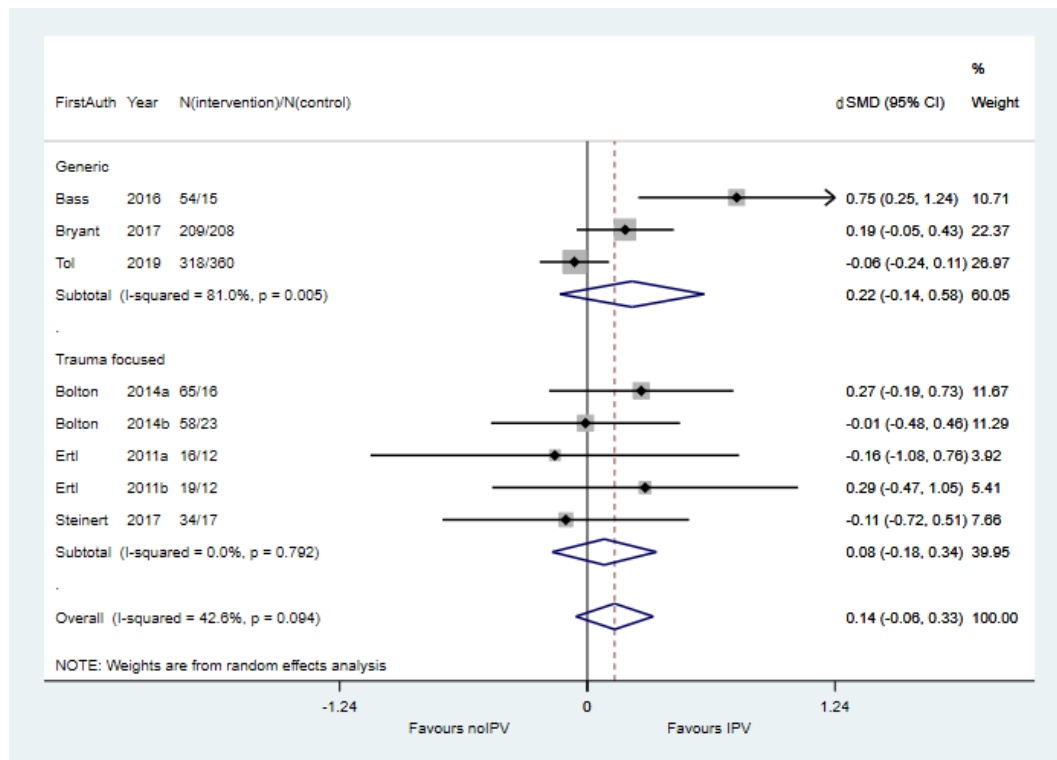
Figure 10.2 Sensitivity analyses: changes to pooled dSMD estimates when one study was removed from each meta-analysis at a time, for anxiety (A), PTSD (B), depression (C) and psychological distress (D) symptoms

10.1.6 Meta-analyses: generic versus trauma-focused interventions

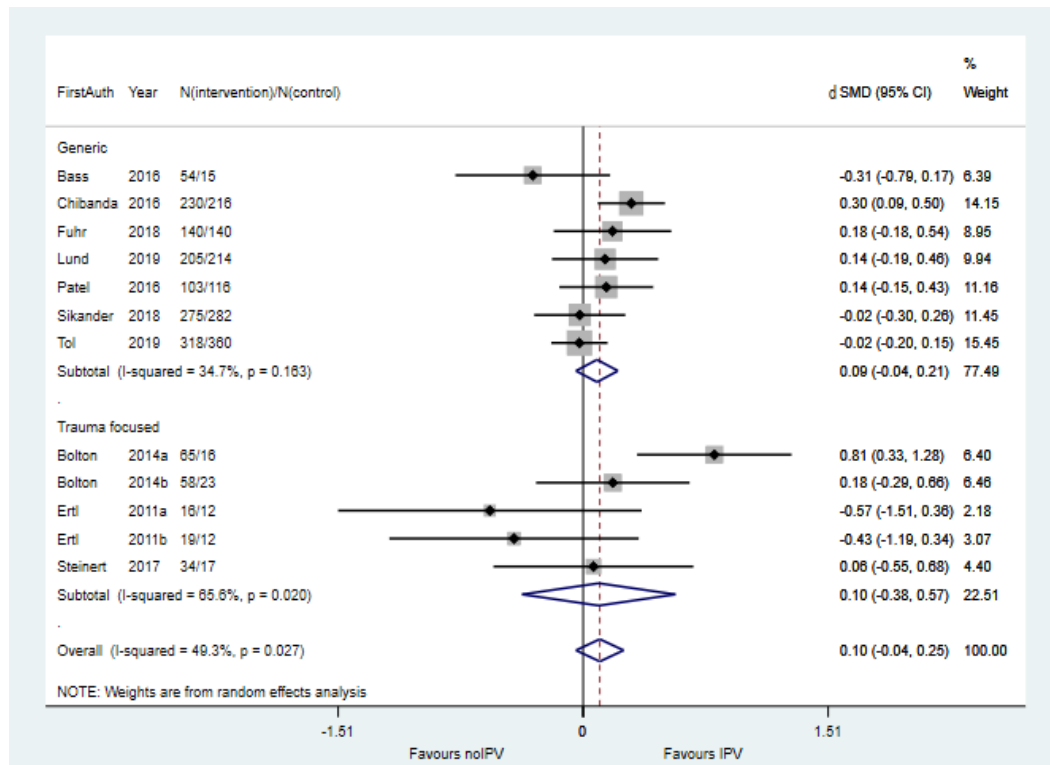
A



B



C



D

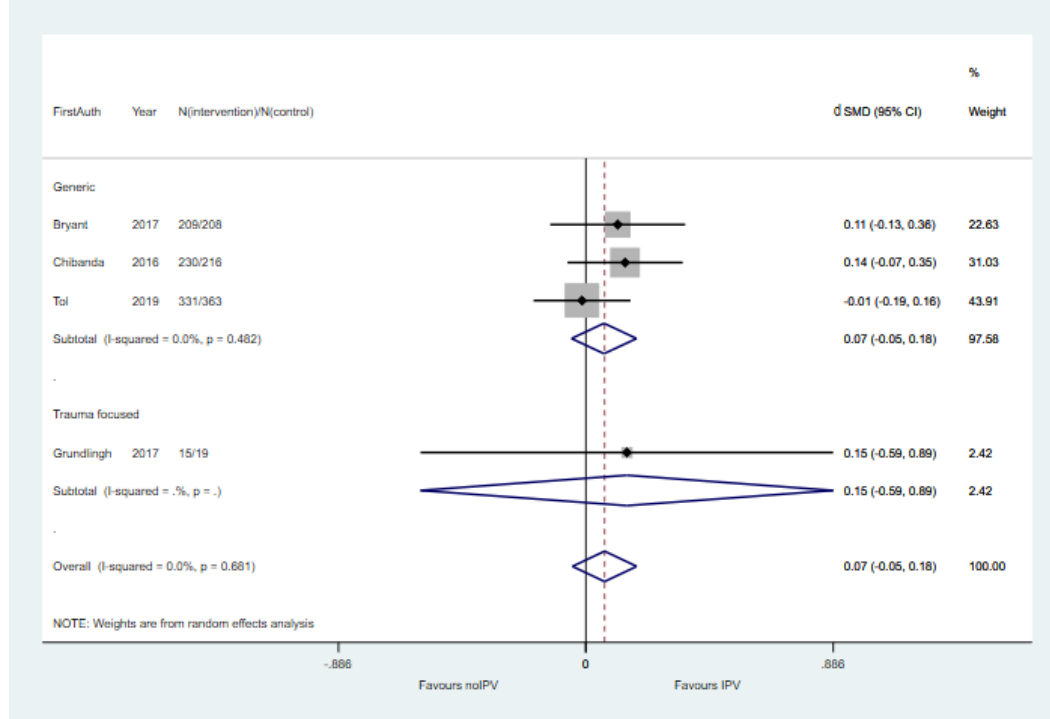


Figure 10.3 Random-effects meta-analyses: differences in effect sizes (dSMD) between women with and without IPV exposure, for anxiety (A), depression (B), PTSD (C) and psychological distress (D), comparing generic and trauma-focused interventions.

10.1.7 Country and regional versus study IPV prevalence or incidence

Table 10.3 National, regional, and study estimates of IPV prevalence/incidence

Country	Relevant studies	% national lifetime physical/sexual IPV prevalence (UN Women, 2017)	% national past-year physical/sexual IPV incidence (UN Women, 2017)	% regional lifetime physical/sexual IPV among ever-partnered women (WHO, 2013a)	% study IPV prevalence or incidence
Cambodia	Steinert et al. 2017	21	8	37.7 (South-East Asia)	27.5 (prevalence)
India	Fuhr et al. 2019 Patel et al. 2017	29	22		13.2 (3 month incidence)
					31.5 (prevalence)
Pakistan	Sikander et al. 2018	Not available	Not available	12.8 (3 month incidence)	
Iraq	Bass et al. 2016 Bolton et al. 2014a Bolton et al. 2014b	Not available	Not available	37 (Eastern Mediterranean)	46.4 (prevalence)
					34.6 (prevalence)
					30.9 (prevalence)
Kenya	Bryant et al. 2017	39	26	36.6 (Africa)	71.0 (prevalence)
South Africa	Lund et al. 2014	Not available	Not available		13.8 (3 month incidence)
Uganda	Tol et al. 2020 Ertl et al. 2011a Ertl et al. 2011b Grundlingh et al. 2017	50	30		29.9 (12 month incidence)
					78.6 (prevalence)
Zimbabwe	Chibanda et al. 2016	35	20	58.1 (prevalence)	
					29.4 (12 month incidence)
					71.7 (6 month incidence)

10.1.8 PRISMA Checklist

Table 10.4 Study One PRISMA Checklist (Page et al., 2021)

Section/topic	#	Checklist item	Page
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	89
ABSTRACT			
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.	366
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	60
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	89
METHODS			
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.	90
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.	90
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	92
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	351
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).	92
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.	93
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	93
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.	93
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	93
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.	93

Section/topic	#	Checklist item	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).	93
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	93
RESULTS			
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.	94
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.	96
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).	97
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.	105
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	105
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	97
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	106
DISCUSSION			
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).	112
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).	115
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	112
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.	366

10.1.9 Published meta-analysis (Keynejad, Hanlon, et al., 2020)

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Articles

Psychological interventions for common mental disorders in women experiencing intimate partner violence in low-income and middle-income countries: a systematic review and meta-analysis

Roxanne C Keynejad, Charlotte Hanlon, Louise M Howard

Summary

Background Evidence on the effectiveness of psychological interventions for women with common mental disorders (CMDs) who also experience intimate partner violence is scarce. We aimed to test our hypothesis that exposure to intimate partner violence would reduce intervention effectiveness for CMDs in low-income and middle-income countries (LMICs).

Methods For this systematic review and meta-analysis, we searched MEDLINE, Embase, PsycINFO, Web of Knowledge, Scopus, CINAHL, LILACS, ScieELO, Cochrane, PubMed databases, trials registries, 3iL, Google Scholar, and forward and backward citations for studies published between database inception and Aug 16, 2019. All randomised controlled trials (RCTs) of psychological interventions for CMDs in LMICs which measured intimate partner violence were included, without language or date restrictions. We approached study authors to obtain unpublished aggregate subgroup data for women who did and did not report intimate partner violence. We did separate random-effects meta-analyses for anxiety, depression, post-traumatic stress disorder (PTSD), and psychological distress outcomes. Evidence from randomised controlled trials was synthesised as differences between standardised mean differences (SMDs) for change in symptoms, comparing women who did and who did not report intimate partner violence via random-effects meta-analysis. The quality of the evidence was assessed with the Cochrane risk of bias tool. This study is registered on PROSPERO, number CRD42017078611.

Findings Of 8122 records identified, 21 were eligible and data were available for 15 RCTs, all of which had a low to moderate risk of overall bias. Anxiety (five interventions, 728 participants) showed a greater response to intervention among women reporting intimate partner violence than among those who did not (difference in standardised mean differences [dSMD] 0.31, 95% CI 0.04 to 0.57, $I^2=49-49\%$). No differences in response to intervention were seen in women reporting intimate partner violence for PTSD (eight interventions, $n=1436$; dSMD 0.14, 95% CI -0.06 to 0.33, $I^2=42-69\%$), depression (12 interventions, $n=2940$; 0.10, -0.04 to 0.25, $I^2=49-39\%$), and psychological distress (four interventions, $n=1591$; 0.07, -0.05 to 0.18, $I^2=0-09\%$, $p=0.481$).

Interpretation Psychological interventions treat anxiety effectively in women with current or recent intimate partner violence exposure in LMICs when delivered by appropriately trained and supervised health-care staff, even when not tailored for this population or targeting intimate partner violence directly. Future research should investigate whether adapting evidence-based psychological interventions for CMDs to address intimate partner violence enhances their acceptability, feasibility, and effectiveness in LMICs.

Funding UK National Institute for Health Research ASSET and King's IoPPN Clinician Investigator Scholarship.

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Introduction

The fifth UN sustainable development goal, which is to achieve gender equality and empower all women and girls, emphasises the need to address intimate partner violence.¹ Intimate partner violence is behaviour by a partner or ex-partner that causes physical, sexual, or psychological harm and includes physical aggression, sexual coercion, psychological abuse, and controlling activity.² It is highly prevalent in low-income and middle-income countries (LMICs); a multi-country study of more than 24000 women found that lifetime prevalence of

physical or sexual intimate partner violence ranged from 24% in urban Serbia and Montenegro to 71% in rural Ethiopia.³ Although the availability of national statistics from high-income countries (HICs) is variable, lifetime prevalence of intimate partner violence in LMICs appears to be higher than countries such as Australia (17%) and the UK (29%).⁴

Intimate partner violence is an important social determinant of health.⁵ The association between intimate partner violence and mental health is bidirectional, such that intimate partner violence increases the risk of mental



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7: 367-380

See Comment page 11-4

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10.2 Study Two

10.2.1 Qualitative interview topic guide: pregnant women

Before we start the interview, I would like to ask you a few details about yourself:

1	Age	___ __ years	
2	Educational level	No formal education	
		Primary only	
		Secondary only	
		Beyond secondary	
3	Educational grade completed	___ __ grade	
4	Religion	Muslim	
		Orthodox Christian	
		Protestant Christian	
		Catholic	
		Other (specify):	

Can you tell me about any problems that you have experienced in your pregnancy so far?

What types of problems?

Health problems?

Emotional problems?

Relationship problems?

Financial problems?

Please can you tell me more about these problems and how they have affected you?

Have you been experiencing stress?

Or worrying a lot?

Please tell me how you have been feeling.

How has that affected you?

How have you tried to cope?

Who have you spoken to about your problems?

What help have they given you?

How helpful has that been?

What else do you need to cope?

Some women have problems in their relationships with their husbands. Has that been a problem for you? If not, has that been a problem for someone you know?

Please can you tell me about that?

How does it affect you (or the person you know)?

How do you (or the person you know) try to manage that problem?

Has your husband ever been violent towards you or hurt you in any way? Please tell me about what happens. If not, has it happened to someone you know?

How often does it happen?

How frequent has it been since you got pregnant?

What is the worst that happened?

What does your husband do to you?

Have you ever felt worried that the violence would injure you?

Or harm the baby?

Tell me about those times.

Why do you think your husband is violent towards you (or someone you know)?

Who have you (or the person you know) talked to about the violence?

Who do you think could help you (or the person you know)?

What have you (or the person you know) tried to do?

How has the violence affected you/the person you know's emotional health or the way you/they feel? Please tell me about that.

How about sleep?

Worrying?

Tearful/distressed?

On edge?

Not able to focus and get things done?

Ever felt like giving up?

Ever thought of harming yourself/themselves?

Please tell me more about what happened.

[NOTE: if 'yes', then refer back to the health worker for further assessment]

How would you feel if the health worker asked you about relationship problems and violence in the home when you come for antenatal care?

What would be the best way for them to ask you?

What would stop you from telling them about relationship problems and violence in the home?

How do you think the health worker could best help you/other women with this?

How would you feel if the health worker asked you about your emotional health?

What would be the best way for them to ask about that?

What would stop you from telling them about your emotional health?

How do you think the health care worker could best help you/other women with that?

What do you think about talking through your problems with a health worker?

How helpful would that be?

What would stop you/other women from telling a health worker about your/their problems?

Would you/they be worried about other people knowing your/their private business?

Could you come to the health centre for 2 or 3 talking sessions?

If you (or someone you know) came to the health centre (or were visited at home) for 2 or 3 talking sessions, what would you like to get better after the sessions?

Physical health?
Emotional health/distress?
Parenting?
Marital relationship?
Violence at home?
Others?

If you (or someone you know) came to the health centre (or were visited at home) for 2 or 3 talking sessions, what problems could there be?

Transport?
Costs of transport or loss of earnings?
Childcare?
Not wanting to attend?
Husband's response?
Confidentiality?
Others?

What would stop you (or someone you know) from coming to the health centre (or accepting visits at home) for 2 or 3 talking sessions?

Is there anything else you would like to say about this subject?

Thank you very much for taking part.

These issues are very common. If you would like any support to talk about these issues, we have this contact information. If you need support for any of these issues, you can talk to your health worker, Prognists or tell us.

10.2.2 Qualitative interview topic guide: health workers

Before we start the interview, I would like to ask you a few details about yourself:

1	Age	___ ___ years	
2	Gender	Male	
		Female	
3	Place of work	Health post	
		Health centre	
		Public hospital	
		Private hospital	
		Other (specify):	
4	Profession	Health extension worker	
		Midwife	
		Nurse	
		Health officer	
		Doctor	
		Other (specify):	
5	Number of years working in current facility	___ ___ years	

What types of problems do you see affecting pregnant women in this area?

- Health problems?
- Financial problems?
- Emotional problems?
- Relationship problems?

In your experience, how much of a problem is stress or distress in pregnant women?

What types of worries do pregnant women have?

In your experience, what do pregnant women do to cope with their worries and distress?

What else do you think they need to cope better?

Can you tell me of any examples when a woman wanted advice from you about emotional problems?

What emotional problems did they have?

How did you advise them?

How has your training prepared you to speak to women about emotional problems?

How comfortable do you feel talking to women about emotional problems?

Some women have problems in their relationships with their husbands. Have you treated women with this problem?

Please can you tell me (generally) about that?

How does it affect women's emotional health?

How does it affect women's pregnancies?

How do you respond?

How would you feel about asking all women about relationship problems and violence in the home as part of antenatal care?

What would be the best way to ask them?

What would stop them from telling you about relationship problems and violence in the home?

How do you think health workers could best help women with these problems?

How would you feel about asking women about their emotional health as part of antenatal care?

What would be the best way to ask them?

What would stop them from telling you about their emotional health?

How do you think health workers could best help with these problems?

What do you think about having time for women to talk through their problems with their health worker?

How helpful would that be for women?

How useful would it be in your role?

How challenging would it be in your role?

What would stop women from telling you about their problems?

Should they come to the health centre for 2 or 3 talking sessions?

Would you prefer to visit them at home for 2 or 3 talking sessions?

If you could offer women 2 or 3 talking sessions as part of antenatal care, what should get better afterwards?

Physical health?
Emotional health/distress?
Parenting?
Marital relationship?
Violence at home?
Others?

If you could offer women 2 or 3 talking sessions as part of their antenatal care, what problems could there be?

Transport?
Costs of transport or loss of earnings?
Childcare?
Not wanting to attend?
Husband's response?
Confidentiality?
Others?

What would stop women from coming to the health centre (or accepting visits at home) for 2 or 3 talking sessions?

What would stop health workers from offering or providing 2 or 3 talking sessions in the health centre (or at home)?

Is there anything else you would like to say about this subject?

Thank you very much for taking part. These issues are very common. If you would like any support to talk about these issues, we have this contact information. If you need support for any of these issues, you can talk to Progynists or tell us.

10.3 Study Three

10.3.1 Example pages of the PST-IPV trainer manual

Problem-solving therapy for women experiencing intimate partner violence and depressive symptoms attending antenatal care: Training Manual and Facilitator Guide

Abbreviations

AAU – Addis Ababa University	KCL – King’s College London
ANC – antenatal care	PST – problem solving therapy
GCP – good clinical practice	PST-IPV – PST adapted for women experiencing IPV
IPV – intimate partner violence	
HWs – health workers	

Rationale

This manual will enable you to train antenatal care (ANC) health workers (HWs), such as nurses, midwives and health officers, to deliver Problem Solving Therapy adapted for women experiencing intimate partner violence (PST-IPV). This manual will cover the key skills and elements of PST-IPV and how to teach them to HWs.

Course Syllabus

Target audience

ANC HWs, such as nurses, midwives and health officers.

Suggested course composition

10-14 HWs, 2-3 facilitators and 1-2 research staff

Training approach

A physically distanced classroom-based course comprising:

- Large-group interactive lectures and discussion.
- Small-group discussion and sharing with the large group afterwards.
- Simulated patient encounters, where facilitators and/or learners act the roles of patients and health workers while other learners observe and provide feedback.
- Role plays.
- Independent reading of the manual.
- Case studies.
- Anonymous comments (via Post-it notes).
- Reflection and feedback.
- Accelerated, supervised cases after the course.

Course description

5 day course followed by accelerated cases in the community.

Each course day starts at 10:00 and finishes at 16:00 (international time).

Reimbursement

HWs will be reimbursed for their time, via contractual arrangements with Addis Ababa University (AAU). HWs who pass this course and go on to deliver PST-IPV to women will be paid for each

Day 1

Arrival and Registration

Health workers sign an attendance sheet and receive:

- A mask
- Alcohol hand gel
- A copy of the training PowerPoint presentations (bound together)
- A copy of the PST-IPV manual
- A copy of the Flip Chart
- Pre-course questionnaire on IPV – asked to complete this before the day begins and return to the Research Staff in attendance
- Paperwork to register for a contract with Addis Ababa University for payment (if not already completed)

Learners are encouraged to sit two adult strides apart for COVID safety and to wear their masks at all times.

Introductions

- Facilitators introduce themselves and share their background in the field of mental health and IPV (e.g. experience of having met women who have experienced mental health problems or who have talked about the impact of IPV on their wellbeing)
- Each health worker introduces themselves and says their clinical role, where they work and why they wanted to be trained in Problem Solving Therapy.
- Brief outline of how the course will work, including timing, practical arrangements, breaks, refreshments, where the bathroom is.
- Explain how the Ministry of Health’s COVID-19 Directorate will be followed throughout the course.
- Group brainstorming activity of ground rules (see Training Techniques above).
- Emphasise that mental health problems and intimate partner violence (IPV) are **very common**. Talking about them can be difficult because we ourselves or people we care about may suffer from mental health problems or have a previous or current experience of IPV. Emphasise that the course is a ‘safe space’ where everyone should feel free to express themselves and for comments shared in the group to remain confidential. If any learner feels personally affected or upset by any discussion, they can speak to a Facilitator or member of Research Staff at any time. They are free to take a moment for themselves if they need to.
- Explain that to be trained in PST, each HW must attend every day of the course in full.

Expectations and Outcome

Research staff carefully explain that the course is being delivered as part of a research study:

- We are trying to find out if this therapy can be delivered well through ANC.
- Their role as trained HWs delivering PST will therefore be very important.
- The role includes completing documentation and attending supervision.
- These are important elements of finding out if PST is effective.
- After the training, each HW will be assessed delivering 4 sessions of PST closer together than they usually will – this is an ‘Accelerated Case’ to help them to be observed and to receive feedback on their skills.

session via contractual arrangements with AAU. This includes their attendance at regular sessions (weekly for the first month and every two weeks thereafter).

Learning Objectives

At the end of the course, learners will:

1. Understand depression, its prevalence, impacts and treatment options.
2. Know about IPV and how it impacts on the health of women, children and family
3. Have basic counselling skills and effective communication skills for compassionate respectful care.
4. Be familiar with the three phases of PST-IPV, the three categories of problems and strategies for dealing with each category.
5. Be ready to deliver four sessions of PST-IPV to women experiencing depression in eight weeks or less.
6. Understand the process by which they will document each session of PST-IPV, the importance of regular supervision and how to respond to risks or concerns.

Learning Materials

- Training Manual and Facilitator Guide (one per Facilitator).
- Participant’s Manual (one per HW).
- Copies of the PowerPoint presentation slides (one copy per HW)
- In-Session PST-IPV small Flip Chart (one per HW).
- Study Standard Operating Procedure (one per Research Staff member).
- Large blank flip charts and (new) marker pens for small-group activities.
- Laptop, speaker and overhead projector for large group lectures.
- Audio recorders (one per HW) to practise recording sessions.
- Notebook and pen (one each, per HW).
- Printed Session Records for practising PST-IPV sessions (one per HW, per practice)
- Adhesive tack or tape to stick group discussion notes to classroom walls.
- Post-it notes
- Refreshments
- Masks and alcohol hand gel

Formative and Summative Assessments

- Daily participation in and contribution to the course, noting and sharing of reflect end of each day.
- Pre- and post-course brief IPV knowledge test.
- Attendance.
- Direct observation of performance during role play exercises.
- Completion of a supervised, accelerated case.
- Completion of daily course evaluation feedback surveys.

Course Evaluation Methods

- Daily facilitators’ meeting, documenting impressions and decisions made.
- Daily course evaluation feedback surveys.
- Pre- and post-course brief IPV knowledge test scores.
- Outcomes of supervised accelerated cases (learners’ pass rate).

- After receiving feedback, HWs who are assessed as competent to deliver PST will start the trial. Pregnant women who meet the study eligibility criteria will be randomly allocated to receive 4 Sessions of PST with them.
- They will deliver 4 Sessions to each woman over a period of 8 weeks. This could be two weeks or another pattern that is most convenient to the woman.
- They will be reimbursed for their time per case, which includes delivering 4 sessions attending all required Supervision) through contractual arrangements with Addis Ababa University. This is the same way they will receive reimbursement for their time to week’s training course.
- HWs will receive weekly Supervision from a psychologist for the first month of the then every two weeks after that.
- Ask HWs if they have any questions

Morning break – time this when it feels appropriate

Section 1: Introduction to Depression

At the end of this section, health workers (HWs) will be able to:

1. Understand what is meant by ‘depression’.
2. Recognise symptoms and signs of depression in women attending antenatal care
3. Describe potential consequences of depression.
4. Discuss treatment options for depression.

Perinatal Depression in Ethiopia

- Small group discussion (talking in pairs about their clinical experience and then sit they discussed with the larger group):
How do women with depression present in antenatal care (ANC)?
- PowerPoint presentation: Depression
- Small group discussion:
How does depression affect the woman, her pregnancy and her baby?
- PowerPoint presentation: Depression in pregnancy and its impact on the woman
- Small group discussion:
Why is it important to offer women with depression treatment and support?
- PowerPoint presentation on treatment for depression and the role of Problem Solving Therapy.

Lunch break – aim for learners to eat outside if possible, for COVID safety

Section 2: Intimate Partner Violence (IPV)

At the end of this section, health workers (HWs) will be able to:

1. Understand what is meant by IPV.
2. Describe potential health consequences of IPV.
3. Know what to do if a woman discloses IPV.
4. Respond to women whose mental health is affected by IPV.

IPV in Ethiopia and its impact on Pregnancy

- PowerPoint presentation: IPV
- Small group discussion:

Figure 10.4 Trainer manual example pages

10.3.2 PST-IPV TIDieR checklist

Table 10.5 TIDieR checklist

Template for intervention description and replication (Cotterill et al., 2018; Hoffmann et al., 2014).

1. Brief Name	Problem-Solving Therapy (PST) for women experiencing IPV (PST-IPV).
2. Why?	<p>As outlined in the evidence review (section 6.4.1.3) and ToC (section 6.5.3.2), the specific elements of PST are hypothesised to improve pregnant women’s mental health by increasing their sense of mastery, self-efficacy and perceived social support.</p> <p>The non-specific elements are hypothesised to foster trusting, therapeutic relationships between pregnant women and ANC care staff, making them feel more listened to, supported, and less isolated.</p> <p>Adaptations to meet the needs of women experiencing IPV are hypothesised to enhance intervention safety (enabling staff to identify and respond to IPV-related problems) and effectiveness, through empowerment (by ensuring that IPV-related problems are always categorised as ‘problems that can be changed’).</p>
3. What (materials)?	<p>Open access intervention materials are available from the open access repository (see Keynejad (2021)).</p> <p>Provided to participants:</p> <ul style="list-style-type: none"> • Information about local sources of support. • Leaflet about well-being in pregnancy. <p>Used during training:</p> <ul style="list-style-type: none"> • Health worker training manual. • Trainer manual and facilitation guide. • Amharic language training slides. <p>Used during sessions:</p> <ul style="list-style-type: none"> • Desktop flip-chart resource. • Session record forms.
4. What (procedure)?	<p><u>At enrolment:</u> All participants screened for depressive symptoms (PHQ-9) and past-year IPV (WHO questions) and completed baseline assessment.</p> <p><u>At randomisation:</u> All participants received a well-being in pregnancy leaflet.</p> <p>Enabling or support activities:</p> <ul style="list-style-type: none"> • Women who missed appointments were contacted up to three times to rearrange their appointment (unless they wished to withdraw from the trial), by telephone (if available) or her community health extension worker, if not. • Women whose health worker raised concerns about their mental health, risk of suicide or self-harm were referred for specialist assessment by a psychiatric

	<p>nurse or mental health gap action programme intervention guide (mhGAP-IG) trained clinician.</p> <ul style="list-style-type: none"> • Women wishing to access support for IPV were assisted to attend the appropriate service, e.g. Women and Child Affairs office, with transport funds provided by the trial budget. <p>Intervention session content is described in Appendix 10.3.3.</p> <p><u>Post-participation:</u> All participants (including those who did not attend four sessions) invited to complete masked outcome assessment.</p>
5. Who provided?	<p>Intervention providers</p> <ul style="list-style-type: none"> • PST-IPV sessions were delivered by ANC staff of Bu'i Primary Hospital and Kela Health Centre. ANC staff are usually midwives, nurses or health officers. <p>Training, competence assessment and supervision arrangements are described in Appendix 10.3.4.</p>
6. How?	Each participant was invited to attend four PST-IPV sessions, which were delivered to each woman face-to-face, individually, by the same health worker.
7. Where?	<ul style="list-style-type: none"> • PST-IPV sessions were delivered in the primary hospital or health centre where the participant was recruited and where she received routine ANC. • Women were reimbursed for their travel expenses to attend sessions.
8. When and how much?	<ul style="list-style-type: none"> • PST-IPV was delivered via four sessions. • Scheduling sessions was at the discretion of the woman and health worker. A minimum gap of two days between sessions was suggested. • Accelerated cases aimed to complete four sessions within four weeks. • Non-accelerated cases aimed to complete four sessions within eight weeks. • Each session was expected to last about 30 minutes, but the precise duration was assessed by the process evaluation.
9. Tailoring	<ul style="list-style-type: none"> • Standard PST was adapted from MI-PST (Sorsdahl, Myers, et al., 2015) for the rural Ethiopian setting. Standard PST was then further adapted to meet the needs of women experiencing IPV, as PST-IPV (section 6.4.3). • The sessions themselves were not personalised or titrated; health workers followed a manual and the 'script' of a desktop flip-chart resource, from which they were not expected to deviate.
11. How well (planned)?	<ul style="list-style-type: none"> • Supervisors (a female psychiatrist and psychologist who delivered PST-IPV training) completed a fidelity and completion checklist, including ENACT scale items, for each of their allocated health workers' accelerated cases, to determine the health worker's competence to continue delivering sessions. • Supervision sessions focused on session fidelity and quality; supervisors provided health workers with feedback and reminders to follow the intervention manual and desktop flip-chart resource.

	<ul style="list-style-type: none"> • Audio recordings of a random sample of sessions were evaluated using the fidelity and completion checklist by two independent psychologists (MY and ED), trained to use the ENACT rating scale. • Completion of session record forms, participant retention within the trial and duration of audio-recorded sessions were assessed during process evaluation.
12. How well (actual)?	This point was evaluated during the process evaluation.
13. Voice	<ul style="list-style-type: none"> • This modified TIDieR checklist was completed by the UK-based principal investigator of PST-IPV (RK), in collaboration with the Ethiopia-based principal investigator of standard PST (TB) and the first supervisor (CH). • The voices of stakeholders were captured through a previous qualitative study with pregnant women and ANC staff (Bitew et al., 2020), Study Two (pregnant women and ANC staff), a PST training course and adaptation workshop (psychiatrists, psychologists and mental health researchers), a theory of change workshop (primary care staff) and theatre testing workshop (pregnant women, ANC staff and mental health professionals).
14. Stage	This modified TIDieR checklist was completed during the early stages of the randomised feasibility study and was revised from a previous version completed during the intervention adaptation stage.

10.3.3 PST-IPV session content

Session 1: Welcome to problem-solving therapy (PST)³⁶

1. Brief summary of intervention rationale.³⁷
2. Starting PST. Brief summary of what to expect.
3. Summary of the overall process of PST.
4. Phase 1: what are the most important things in your life?
5. Guided discussion of the most important things in the woman's life.
6. Phase 2: What are your worries or problems? Guided discussion of the woman's worries or problems. Explanation of (A) Lower Priority Problems.
7. Explanation of (B) Problems that Cannot be Changed and (C) Problems that Can be Changed. Guided categorisation of the woman's worries and problems into different types. Attention paid that any IPV-related problems are listed under (C): Problems that Can be Changed.
8. Phase 3: Planning for the most important things in your life: 'Problem Busting Session' 1: applying the 6 step approach to a (C): Problem that Can be Changed. Step 1: name her problem in detail.
9. Step 2: think of as many solutions as you can, Step 3: choose the best approach, Step 4: make a plan.
10. Step 5: take action, Step 6: see if the plan worked, in Session 2. Explanation of what happens if the plan does not work.
11. Summary of Take-Home Activity 1:
 - i. Put her plan into action and discuss how it went in Session 2.
 - ii. Keep thinking about the most important things in her life.
 - iii. Review her list of problems and worries each day and think about whether they are Lower Priority Problems, Problems that Cannot be Changed or Problems that Can be Changed.

Agree the date and time of Session 2.

Session 2: Coping with different types of problems

12. Review: of well-being and any progress since Session 1. Summary of the three stages of PST.
13. Recap of the three types of problems and the woman's examples of each type.
14. Review Take-Home Activity 1: review the most important things in her life and list of problems and worries. Review Problem Busting Session 1.
15. Review progress since Session 1. If her plan did not solve her problem, identifying the next best approach and making a new plan to approach her problem.
16. Coping with Lower Priority Problems: reviewing her Lower Priority Problems and brief explanation about coping.
17. Worry Time: explanation and discussion of how she might use it.
18. Thinking Stop: explanation and discussion of how she might use it.
19. Positive Thoughts: explanation and discussion of how she might use them.
20. Coping with Problems that Can be Changed: Problem Busting Session 2: applying the 6 step approach to a different Problem that Can be Changed.

³⁶ No abbreviations were used in Amharic.

³⁷ Numbering refers to pages of the flipchart used to guide intervention sessions.

21. Summary of Take-Home Activity 2:
 - i. Put her plan(s) for Problems that Can be Changed into action and discuss how they went in Session 3.
 - ii. Put her plans into action for Lower Priority Problems.
 Agree the date and time of Session 3.

Session 3: Developing your Problem Solving Skills

22. Review: of well-being and any progress since Session 2. Summary of the three coping techniques for Lower Priority Problems.
23. Review whether she tried any of these (if not, why not, if so, whether they were helpful, if so, why, if not, why not), and discuss how they could be more helpful.
24. Review Take-Home Activity 2: Review progress made since Session 2 on Problem Busting Session 1 (if a new plan was made in Session 2) and Problem Busting Session 2.
25. Review whether her plan(s) solved her problem(s), identify the next best approach(es) if they did not, and make new plan(s) to approach these problem(s).
26. Coping with Problems that Cannot be Changed: summarise this type of problem and review which problems identified in Session 1 fell into this category.
27. Identify any new Problems that Cannot be Changed which she has identified since Session 1. Summary of loss and coping.
28. The Stages of Acceptance: summary of denial, anger, bargaining, depression.
29. Summary of acceptance.
30. Accepting your feelings and Talking with Others: summary of these coping strategies.
31. Contact with people who share your experience: summary and discussion of how she could use these strategies.
32. Exercises to Reduce Stress 1: Slow Breathing: guided relaxation exercise
33. Continuation of slow breathing exercise.
34. Exercises to Reduce Stress 2: Progressive Muscle Relaxation: guided relaxation exercise.
35. Continuation of progressive muscle relaxation exercise.
36. Coping with Problems that Can be Changed: Problem Busting Session 3: applying the 6 step approach to a different problem that can be changed.
37. Summary of Take-Home Activity 3:
 - i. Put her plan(s) for Problems that Can be Changed into action and discuss how they went in Session 4.
 - ii. Put her plans into action for Problems that Cannot be Changed.
 - iii. Try the Slow Breathing and Progressive Muscle Relaxation Exercises at home.
 - iv. Try a Problem Busting Session on her own, using the 6 step model.
 Agree the date and time of Session 4.

Session 4: Ending Problem-Solving Therapy and using it in Future

38. Review: of well-being and any progress since Session 3. Summary of the three coping techniques for Problems that Cannot be Changed and the two Exercises to Reduce Stress.
39. Review whether she tried any of these (if not, why not, if so, whether they were helpful, if so, why, if not, why not) and discuss how they could be more helpful.
40. Review Take-Home Activity 3: Review progress made since Session 3 on Problem Busting Sessions 1 and 2 (if new plans were made in Session 3) and Problem Busting Session 3.
41. Review whether her plans solved her problems, identify the next best approaches if they did not and make new plan(s) to approach these problem(s).
42. Review her self-directed 6 Step Approach: review how it went, if she completed this activity.
43. Final Problem Busting Session: for a new Problem that Can be Changed.
44. Using these skills in the future: Summarise what she has learned (Problems that Can be Changed, Lower Priority Problems).
45. Summarise what she has learned (Problems that Cannot be Changed, Exercises to Reduce Stress).
46. Summary and ending: Final summary of how she can apply these techniques to future problems.
47. Discussion about applying these techniques in the future, ways of practising them regularly and who she can talk to if she finds this difficult.

10.3.4 PST-IPV training, competence assessment and supervision

Training

- Although mhGAP-IG training had been provided to some local primary care staff, participating clinicians had not received this, or training in communication skills.
- All health workers delivering PST-IPV sessions were required to attend a five day training course, spread over an initial two days and then a further three days the following week.
- The course was delivered by a female psychiatrist (LM) and a female psychologist (IA) with experience of training primary care staff on mental health.

Competence assessment

- All health workers completed an ‘accelerated case’, delivering four PST-IPV sessions to their first allocated participant in a shorter time frame than usual (e.g. weekly), to enable their competence to continue delivering sessions to be assessed by their supervisor.
- Supervisors completed a fidelity and completion checklist, including ENACT scale (Kohrt et al., 2015) items, for each of their allocated health workers’ accelerated cases, to determine whether the health worker was competent to continue delivering sessions.
- Health workers not deemed competent were asked to complete a second accelerated case unless safety concerns were identified.

Supervision

- Health workers received regular supervision from the psychiatrist (LM) and psychologist (IA) who delivered the PST-IPV course, who listened to audio recordings of their sessions.
- Telephone supervision was conducted where logistical difficulties prevented travel to the study site.
- Group supervision was conducted where logistical difficulties prevented individual supervision.

10.3.5 Theory of change workshop photographs

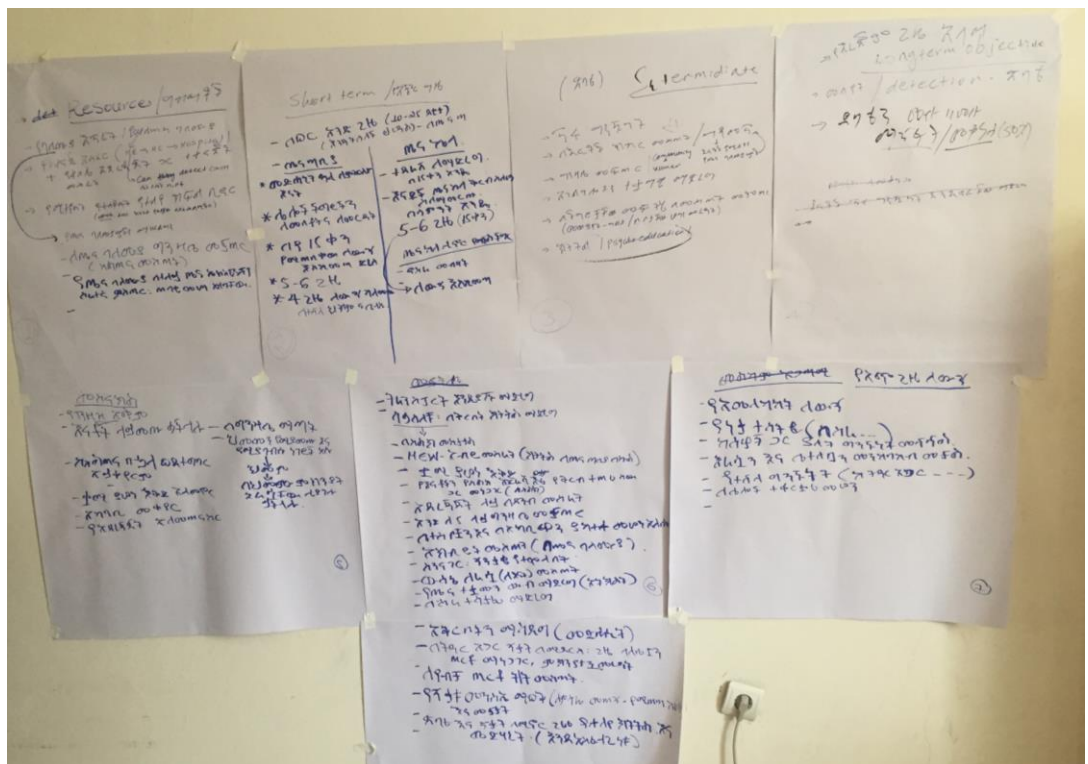


Figure 10.5 Theory of Change workshop and map in Amharic (17/10/2018)
 Participants and staff gave verbal consent for photographs to be taken.

10.3.6 Theory of change checklist

Table 10.6 ToC checklist (Breuer et al., 2015)

<i>Checklist item</i>	<i>Where addressed</i>
1. Is the ToC approach defined?	
a. Is a definition of ToC given by the authors?	Section 2.9.1
b. Do the authors explain their reasons for using a ToC approach?	Section 2.9.1
2. Is the ToC development process described?	
a. Are the methods used to develop the ToC, such as stakeholder meetings and interviews, document reviews, programme observation, existing conceptual frameworks or published research, described?	Section 6.5.2
b. Where stakeholders are involved, is it clear how many stakeholders participated, what their role is in relation to the intervention, how they were consulted (e.g. number of interviews, focus groups, ToC workshops) and the extent to which the consultations were participatory?	Sections 6.5.2 and 6.5.3.1
c. Is the method used to compile the data into a ToC described? (including how disagreements between stakeholders were resolved)	Sections 6.5.2.15 and 6.5.3.4
d. Is the extent to which stakeholders were able to validate the resultant ToC and were owners of the final product described?	Sections 6.5.2.15 and 6.5.3.4
3. Is the resultant ToC (or a summary thereof) depicted in a diagrammatic form and does it include?	
a. The long-term outcome or impact of the intervention	Section 6.5.3.2
b. The anticipated short and medium term outcomes and the process of change	Section 6.5.3.2

c. The intervention components which happen at different stages of the pathway	Section 6.5.3.2
d. The context of the intervention	Chapter 4
e. Assumptions about how change would occur	Section 6.5.3.2
f. Additional ToC elements such as indicators, supporting research evidence, beneficiaries, actors in the context, sphere of influence and timelines where relevant.	Section 6.5.3.2
4. Is the process of intervention development from the ToC described?	
a. Are the methods of how interventions were refined from the ToC to something which can be implemented described? (For example, further stakeholder workshops, interviews, systematic literature reviews)	Section 6.4.3
5. Is the way in which the ToC was used to develop and implement the evaluation described?	
a. Are evaluation research questions generated from the ToC?	Section 7.3
b. Is the role of ToC in the design, plan or conduct of the evaluation clear?	Section 7.4.17.4
c. Does the paper describe the extent to which the key elements described in the ToC were measured in the evaluation (i.e. impact, short and medium term outcomes and the process of change, context, assumptions and the intervention)?	Section 7.4.17
d. Does the paper describe whether and how process indicators were used to improve the quality of the intervention?	Section 7.4.17.4
e. Is the role of the ToC in the analysis of the results of the evaluation clear?	Section 7.4.18
f. Is the role of ToC in the interpretation of the results of the evaluation described? (including the breakdown of programme theory, unanticipated outcomes and causation including the strength and direction of causal relationships)	Section 8.1

10.4 Study Four

10.4.1 Published trial protocol (Keynejad, Bitew, et al., 2020)

This paper was published Open Access and licensed under a Creative Commons Attribution 4.0 International License. An electronic copy is uploaded to the open access repository (Keynejad, 2021).

Keynejad et al. *Trials* (2020) 21:454
<https://doi.org/10.1186/s13063-020-04331-0>

Trials

STUDY PROTOCOL

Open Access

Problem solving therapy (PST) tailored for intimate partner violence (IPV) versus standard PST and enhanced usual care for pregnant women experiencing IPV in rural Ethiopia: protocol for a randomised controlled feasibility trial



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Abstract

Background: In rural Ethiopia, 72% of women are exposed to lifetime intimate partner violence (IPV); IPV is most prevalent during pregnancy. As well as adversely affecting women's physical and mental health, IPV also increases the risk of child morbidity and mortality associated with maternal depression, thus making antenatal care an important opportunity for intervention. Adapting generic, task-shared, brief psychological interventions for perinatal depression and anxiety to address the needs and experiences of women affected by IPV may improve acceptability to women and feasibility for health workers. This randomised controlled feasibility trial will compare brief problem solving therapy (PST) specifically adapted for pregnant women experiencing IPV (PST-IPV) with standard PST and enhanced usual care to determine the feasibility of a future fully powered randomised controlled trial.

(Continued on next page)

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10.4.2 SPIRIT checklist

Table 10.7 Study Four SPIRIT checklist: recommended items to address in a clinical trial protocol and related documents (Chan et al., 2013)

Section/item	Item	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	259
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	284
	2b	All items from the World Health Organization Trial Registration Data Set	See trial Registration
Protocol version	3	Date and version identifier	386 (see protocol paper)
Funding	4	Sources and types of financial, material, and other support	386
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	386
	5b	Name and contact information for the trial sponsor	386
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	386
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A: feasibility study

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	60, 84, 87, 87, 261
	6b	Explanation for choice of comparators	84
Objectives	7	Specific objectives or hypotheses	260
Trial design	8	Description of trial design including type of trial (e.g., parallel group, crossover, factorial, single group), allocation ratio, and framework (e.g., superiority, equivalence, noninferiority, exploratory)	261
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	119
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (e.g., surgeons, psychotherapists)	265, 266, 268
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	271
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving/worsening disease)	N/A: no adverse effects of concern.
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests)	N/A: no strategies
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A: none in this setting

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	275, 276
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended.	272
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	263
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	267
Methods: Assignment of interventions (for controlled trials)			
Allocation sequence generation	16a	Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	267
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	267, 268
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	267
Blinding (masking)	17a	Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how	268
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A: field supervisors unblinded

Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	272
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	272
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	263
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	280
	20b	Methods for any additional analyses (e.g., subgroup and adjusted analyses)	N/A: feasibility study
	20c	Definition of analysis population relating to protocol non-adherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation)	280
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A: feasibility study
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A: feasibility study

Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	283
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A: feasibility study
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	282
Protocol amendments	25	Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	282
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	263
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A: none collected
Confidentiality	27	What a personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	263
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	386 (see protocol paper)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	386
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	263

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	386 (see protocol paper)
	31b	Authorship eligibility guidelines and any intended use of professional writers	386
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	386

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	See open access repository
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A: none collected

10.4.3 Process evaluation qualitative interview topic guides

10.4.3.1 Intervention Arm Participant

Eth_Date_Int	Date (Ethiopian)	
HCID	Health Centre or Hospital	
PIN	Participant ID Number (PIN)	
RWID	Research Staff ID (Conducting Interview)	
Int	Intervention received (Standard PST or PST-IPV) (may need to determine this from records – participant may not know)	
Sess_Total	Number of Sessions attended in total	

Before we start the interview, I would like to ask you a few details about yourself:

Age_Int	How old are you?	___ ___ years	
Edu	Have you received any education?	No formal education	1
		Primary education only	2
		Secondary education only	3
		Beyond secondary education	4
Edu_Grd	What is the highest educational grade that you have reached?	___ ___ grade	
Rel	What is your religious affiliation?	Muslim	1
		Orthodox Christian	2
		Protestant Christian	3
		Catholic	4
		None	5
		Other (please specify which):	6
Dist_HC	How far is your home from this health centre (in terms of time)?	___ ___ hours ___ ___ minutes	
Dist_Hosp	How far is your home from the nearest hospital (in terms of time)?	___ ___ hours ___ ___ minutes	

Answers to the following questions will be audio-recorded.

- 1) This study involved you being asked about relationship problems and violence at home when you came for antenatal care.

-
- How did you find that?
 - Did anything stop you from telling staff about relationship problems and violence in your home?
 - If so, how could staff have helped you to talk about problems?
- 2) This study also involved you being asked about your emotional health and depression.
- How did you find that?
 - Did anything stop you from telling staff about your emotional health, depression, anxiety or trauma?
 - If so, how could staff have helped you to talk about it?
- 3) This study involved you attending sessions of brief talking therapy.
- How did you find the sessions?
 - Were they helpful?
 - Why/why not?
 - Did anything change after you attended the sessions?
 - What could have made them better for you?
 - Did you have any problems attending the sessions?
 - If you did not attend all sessions, why was that?
 - If the sessions were delivered to you in a group with other pregnant women instead of one-to-one, would that be better or worse?
- 4) This study was testing out a design to compare two types of talking therapy.
- Do you think we should continue this study with a larger group?
 - Why/why not?
 - Should anything change about the way the research was organised?
- 5) Would you recommend the talking therapy that you received to a friend?
- Why/why not?
- 6) Would you recommend taking part in this study to a friend?
- Why/why not?
- 7) This study involved you being randomly allocated to one type of talking therapy.
- Was this acceptable to you?
 - Why/why not?
 - Could this have been done better? How?
- 8) This study involved you answering a lot of questions at the beginning and at the end, to help us to understand how the talking therapy affected you.

- Was answering the questions at the beginning and the end of the study acceptable to you?
- Why/why not?
- Could this have been done better? How?

9) Is there anything else you would like to say about this study?

10.4.3.2 Intervention Arm Health Worker

Eth_Date_Int	Date (Ethiopian)	___ / ___ / _____
HCID	Health Centre or Hospital	
HWID	Health Worker ID Number	
RWID	Research Staff ID (Conducting Interview)	
Int	Intervention delivered (Standard PST or PST-IPV)	
Pt_Total	Number of Women for whom the Health Worker delivered Problem-Solving Therapy	
Sess_Total	Total Number of Problem-Solving Therapy Sessions delivered, if known	

Before we start the interview, I would like to ask you a few details about yourself:

Age_Int	How old are you?	___ ___ years	
Gender	What is your gender?	Male	1
		Female	2
Work	What is your primary place of work?	Health post	1
		Health centre	2
		Public hospital	3
		Private hospital	4
		Other (please specify):	5
Prof	What is your professional role?	Health extension worker	1
		Midwife	2
		Nurse	3
		Health officer	4
		Doctor	5
		Other (specify):	6
Exp	How many years have you worked in your current role?	___ ___ years	

Answers to the following questions will be audio-recorded.

- 1) This study involved Research Staff asking women about relationship problems and violence in the home when they came for antenatal care.
 - Was this acceptable? Why/why not?
 - Were there any problems with Research Staff screening antenatal care women for this study?
 - If so, how could we improve the process of identifying women experiencing relationship problems and violence in their homes?

-
- 2) This study also involved Research Staff asking women about their emotional health, including depression.
 - Was this acceptable? Why/why not?
 - Were there any problems with Research Staff asking women about their emotional health for this study?
 - If so, how could we improve the process of identifying women experiencing emotional difficulties, depression, anxiety or trauma?

 - 3) This study involved you receiving training in one type of Problem-Solving Therapy.
 - Did the training prepare you to deliver Problem-Solving Therapy?
 - What aspects of the training were helpful?
 - How could we make the training better?
 - You were advised not to talk about the training you received to your colleagues, so that only Health Workers trained in that type of Problem-Solving Therapy would use its techniques. Was this difficult for you to do?
 - How could we make it easier?

 - 4) This study involved you receiving Supervision while you were delivering Problem-Solving Therapy.
 - Did the Supervision help you to deliver Problem-Solving Therapy?
 - What aspects of Supervision were helpful?
 - How could we make the Supervision better?

 - 5) Now that you have delivered Problem-Solving Therapy to pregnant women, we would like to ask you:
 - What is your opinion of Problem-Solving Therapy?
 - Were the Sessions helpful for women? Why/why not?
 - Did being trained to deliver Problem-Solving Therapy help you to do your job? Why/why not?
 - Did you face any barriers to implementing Problem-Solving Therapy? How did you address them?
 - Do you think that anything changed after women attended Sessions with you?
 - What could have made Problem-Solving Therapy better for women?
 - What could have made Problem-Solving Therapy better for you as a staff member delivering Sessions?
 - Did women have any problems attending your Sessions?
 - If women did not attend all of your Sessions, why do you think that was?
 - Did you have any problems delivering the Sessions?

-
- Did the training or delivering the Sessions affect you personally in any way? (E.g. did it cause you any personal distress or lead you to access support for yourself?)
 - You delivered Sessions from your workplace. In your opinion, where is the best place for these Sessions to be delivered?
 - In your opinion, which staff are the best people to deliver Problem-Solving Therapy?
 - If Problem-Solving Therapy was delivered to a group of pregnant women, would that be better or worse?
- 6) During this study, care was taken to avoid placing women or staff at any risk.
- Was your safety as a member of staff effectively managed during this study?
 - Can you tell me more about that?
 - Was women's safety effectively managed during this study?
 - Can you tell me more about that?
 - Was confidentiality maintained during this study?
 - Can you tell me more about that?
 - Did you have any ethical concerns about this study?
 - Can you tell me more about that?
 - Did you (or a colleague) ever need to respond to risks disclosed by women during the study period? This could be risks to the woman's health or safety from another person (such as her partner) or from herself (for example, thoughts of self-harm or suicide) or risks to her children or unborn child.
 - Can you tell me more about that?
- 7) This study was testing out a design to compare two types of Problem-Solving Therapy.
- Do you think we should continue this study with a larger group of women?
 - Why/why not?
 - Should anything change about the way the research study was organised?
- 8) Would you recommend Problem-Solving Therapy to a pregnant woman experiencing emotional distress or depression?
- Why/why not?
- 9) Would you recommend taking part in this study?
- Why/why not?

10) Would you recommend taking part in this study to a colleague?

- Why/why not?

11) Is there anything else you would like to say about this study or its focus on women's mental health in pregnancy and intimate partner violence?

10.4.4 Ethical approval documents

10.4.4.1 King's College London

Research Ethics
Office

Franklin Wilkins Building
33 Waterloo Bridge Wing
Waterloo Road
London SE1 8WA
Telephone 020 7848 4020/4070/4077
reo@kcl.ac.uk



Dr Roxanne Keynejad

25 January 2019

Dear Roxanne,

Reference Number: HR-18-19-9230

Study Title: Brief problem-solving therapy for perinatal common mental disorders and intimate partner violence: a randomised feasibility study in rural Ethiopia

Review Outcome: Approval with Proviso

Thank you for submitting your application for the above project. I am pleased to inform you that your application has now been approved with the provisos indicated at the end of this letter. All changes must be made before data collection commences. The Committee does not need to see evidence of these changes, however supervisors are responsible for ensuring that students implement any requested changes before data collection commences.

Please ensure that you follow all relevant guidance as laid out in the King's College London Guidelines on Good Practice in Academic Research (<http://www.kcl.ac.uk/college/policyzone/index.php?id=247>).

For your information, ethical approval has been granted for 3 years from 25 January 2019. If you need approval beyond this point, you will need to apply for an extension at least two weeks before this. You will be required to explain the reasons for the extension. However, you will not need to submit a full re-application unless the protocol has changed. If you have been granted approval for only 12 months, you will not be sent a reminder when it is due to lapse.

Ethical approval is required to cover the data-collection phase of the study. This will be until the date specified in this letter. However, you do not need ethical approval to cover subsequent data analysis or publication of the results.

For secondary data-analysis, ethical approval is applicable to the data that is sensitive or identifies participants. Approval is applicable to period in which such data is accessed or evaluated.

Please note you are required to adhere to all research data/records management and storage procedures agreed to as part of your application. This will be expected even after the completion of the study.

If you do not start the project within three months of this letter please contact the Research Ethics Office.

Please note that you will be required to obtain approval to modify the study. This also encompasses extensions to periods of approval. Please refer to the URL below for further guidance about the process:

<https://internal.kcl.ac.uk/innovation/research/ethics/applications/modifications.aspx>

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.

If you have any query about any aspect of this ethical approval, please contact your panel/committee administrator in the first instance (<https://internal.kcl.ac.uk/innovation/research/ethics/contact.aspx>)

We wish you every success with this work.

Yours sincerely,

Mr James Patterson
Senior Research Ethics Officer

For and on behalf of

Mr Chris Webb, Joint Chair
PNM Research Ethics Subcommittee

Major Issues (will require substantial consideration by the applicant before approval can be granted)

Minor Issues related to application (the reviewer should identify the relevant section number before each comment)


1. Section H6: Please note that it is your responsibility to secure all of the legal and ethical permissions required to conduct the study in Ethiopia.

Minor issues related to recruitment documents

2. All recruitment documents: Please note that you are responsible for the accuracy of translations.
3. Information Sheets:
 - i. Please ensure that the sheets are written in sufficiently lay language that is easily understandable to the intended participants.
 - ii. Provide more information about the questions to be posed to participants.
 - iii. Include a departmental postal address within the contact details provided.
 - iv. As this is a student project, the paragraph beginning with 'If this study has harmed you in any way...' should appear before the contact details for your academic supervisor. It should be clear that you, or a local contact, are to be contacted by those with general queries about the study.

Advice and Comments (do not have to be adhered to, but may help to improve the research)

10.4.4.2 Addis Ababa University



ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCES (IRB)
አዲስ አበባ ዩኒቨርሲቲ፣ ጤና ሳይንስ ኮሌጅ
Institutional Review Board

ANNEX 3
Form AAUMF 03-008

IRB's Decision

Meeting No: 05/2019 Date: 27/05/2019
 Protocol number: 032/19/CDT

Protocol Title: Is intimate partner violence an effect modifier for psychosocial interventions for women's mental health in Ethiopia? a randomised feasibility study	
Principal Investigator:	Dr Charlotte Hanlon
Institute:	College of Health Sciences, AAU
Elements Reviewed (AAUMF 01-008)	<input checked="" type="checkbox"/> Attached <input type="checkbox"/> Not attached
Review of Revised Application <input type="checkbox"/> Yes <input type="checkbox"/> No	Date of Previous review:
Decision of the meeting:	<input checked="" type="checkbox"/> Approved <input type="checkbox"/> Approved with Recommendation <input type="checkbox"/> Resubmission <input type="checkbox"/> Disapproved

I. Elements approved- 1. Protocol Version No: 02
2. Protocol Version Date:
3. Informed consent Version No: 02
4. Informed Consent Version Date:

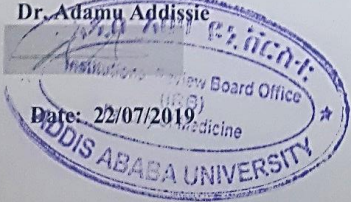
II. Obligations of the PI-

1. Should comply with the standard international & national scientific and ethical guidelines
2. All amendments and changes made in protocol and consent form needs IRB approval
3. The PI should report SAE within 10 days of the event
4. End of the study, including manuscripts and thesis works should be reported to the IRB
5. The PI should report non-compliance and unanticipated events

III. TO NERC

Institution Review Board (IRB) Approval: Period from: July 22, 2019 to July 21, 2020
 Follow up report expected in
 3 Months ___ 6 months ___ 9 months one year ___

Chairperson, IRB
Dr. Adamu Addissie



(Signature)
 Institution Review Board Office
 (IRB)
 Medicine
 ADDIS ABABA UNIVERSITY
 Date: 22/07/2019

10.5 Study Five

10.5.1 CONSORT checklist

Table 10.8 Study Five CONSORT checklist of information to include when reporting a pilot or feasibility trial (Eldridge et al., 2016).

Section/Topic	Item	Checklist item	Page
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	285
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	xiii, 386
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	60, 87
	2b	Specific objectives or research questions for pilot trial	260, 261
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	261
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	315
Participants	4a	Eligibility criteria for participants	265
	4b	Settings and locations where the data were collected	119
	4c	How participants were identified and consented	263
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	271
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	272
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	315
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	263
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A

Randomisation			
Sequence generation	8a	Method used to generate the random allocation sequence	267
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	267
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	268
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	267
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	268
	11b	If relevant, description of the similarity of interventions	271
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	280
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	288
	13b	For each group, losses and exclusions after randomisation, together with reasons	288
Recruitment	14a	Dates defining the periods of recruitment and follow-up	285
	14b	Why the pilot trial ended or was stopped	285
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	290
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	293
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	293, 296
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	299
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	314
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	331
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	327
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	318, 336
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	327, 337

Other information			
Registration	23	Registration number for pilot trial and name of trial registry	284
Protocol	24	Where the pilot trial protocol can be accessed, if available	386
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	386 (see protocol paper)
	26	Ethical approval or approval by research review committee, confirmed with reference number	282

11 Reference list

- Abayneh, S., Lempp, H., Alem, A., Kohrt, B. A., Fekadu, A., & Hanlon, C. (2020). Developing a theory of change model of service user and caregiver involvement in mental health system strengthening in primary health care in rural Ethiopia. *International Journal of Mental Health Systems*, *14*(1), 1-17.
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