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A cluster randomised trial comparing a standardised childbirth preparation education programme versus basic childbirth preparation education programme for primigravid women to alleviate postnatal depression: A study protocol

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Study protocol

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Abstract

Postnatal depression is a significant public health concern that adversely affects maternal well-being, infant development, and family functioning. Although childbirth preparation education programmes (CPEP) have shown promise in enhancing childbirth experiences and maternal psychological outcomes, evidence from South African public healthcare settings remains limited. The study will evaluate the effectiveness of a standardised CPEP against a CPEP based on the maternity case record information (MCRCPEP), through a cluster randomised controlled trial conducted among primigravid women attending public healthcare facilities in the Buffalo City Metropolitan Health District (BCMHD), Eastern Cape, South Africa. Four healthcare facilities will be randomly allocated to either an intervention or a control group. A total of 274 primigravid women aged between 18 and 35 years with singleton pregnancies will be recruited between 28 and 34 weeks' gestation. Participants allocated to the intervention group will receive the standardised CPEP together with routine antenatal care, while those allocated to the control group will receive the MCRCPEP with routine antenatal care. Analyses will follow the intention-to-treat principle. Data will be captured on REDCap and analysed using Stata version 18 and Epi Info™ 7. Descriptive statistics will be used to summarise participant characteristics, and between-group differences will be assessed using appropriate inferential statistical tests that account for cluster allocation. Statistical significance will be set at $p < 0.05$. The primary outcome will be postnatal depression, which will be assessed at six weeks postpartum using the Edinburgh Postnatal Depression Scale. Secondary outcomes will include fear of childbirth, childbirth satisfaction, childbirth experience, maternal self-esteem, labour induction, labour augmentation, analgesia use, assisted birth, caesarean section, preterm birth, and neonatal intensive care unit admission. It is hoped that the evidence regarding the effectiveness of the standardised CPEP will influence postnatal depression among primigravid women. This trial is registered with the Pan African Clinical Trial Registry under the unique identification number PACTR202603665018582. The date of registration is 11 March 2026.

Background

The World Health Organization (WHO) identifies maternal mental health as a global health priority (Rodríguez-Almagro et al., 2019). Postnatal depression (PND), also known as postpartum depression, is one of the most common psychological complications associated with childbirth and has far-reaching effects on mothers, infants, families, and healthcare systems. Globally, the prevalence of PND is estimated at 17.2% (Levis et al., 2020; Wang et al., 2021), while the estimated prevalence among primiparous women ranges between 10% and 20% (Shorey et al., 2018). This burden is considerably greater in low- and middle-income countries, including South Africa, where prevalence estimates range from 20% to 32% (Garman et al., 2019).

Postnatal depression is associated with impaired maternal functioning, reduced breastfeeding success, poor mother-infant bonding, sleep disturbances, and diminished quality of life. In addition, maternal depression can adversely affect infant cognitive, emotional, and behavioural development, with potential long-term consequences for child health and wellbeing.

The development of PND is shaped by a combination of biological, psychological, and social factors. Established risk factors include antenatal depression, post-traumatic stress disorder, inadequate social support, traumatic childbirth experience, and the fear of childbirth (FOC) (Shiva et al., 2021). Fear of childbirth is increasingly recognised as an important determinant of maternal psychological well-being and birth outcomes. Women experiencing severe FOC are more likely to report heightened anxiety, lower childbirth self-efficacy, prolonged labour, increased requests for caesarean birth, and negative birth experiences (Slade et al., 2019). Collectively, these factors can contribute directly or indirectly to the development of postpartum psychological morbidity.

Childbirth preparation education programmes (CPEPs) are widely implemented internationally to improve women's preparedness for labour, birth, and the postpartum period. These programmes are intended to enhance knowledge, coping skills, self-efficacy, informed decision-making, and emotional readiness for childbirth. Evidence suggests that structured childbirth education can improve maternal confidence, reduce FOC, enhance birth satisfaction, and promote psychological well-being (Khresheh et al., 2018; Kuo et al., 2022).

Despite these benefits, the implementation of structured CPEPs remains inconsistent in low- and middle-income countries, limiting equitable access to evidence-based antenatal education (WHO, 2018; Khresheh et al., 2018). In South Africa, antenatal education is frequently constrained by staff shortages, high patient volumes, limited resources, and the absence of standardised educational programmes (WHO, 2018; Okafor & Goon, 2020). Consequently, many primigravid women enter labour with inadequate preparation for childbirth and the postpartum period (Slade et al, 2019; Whitburn et al., 2014). Similar challenges have been reported in other African settings, where inadequate childbirth preparation has been associated with poor birth preparedness, inadequate planning for childbirth, and negative birth experiences (Munkhondya et al., 2020; Konlan et al., 2019).

Although previous studies have demonstrated the benefits of childbirth education on maternal knowledge, self-efficacy, and birth experiences (Khresheh et al., 2018; Kuo et al., 2022), there is limited evidence regarding the effectiveness of a standardised CPEP in reducing postnatal depression (PND) among primigravid women in South Africa (Garman et al., 2019). This evidence gap highlights the need for context-specific research to determine whether a standardised CPEP can improve maternal psychological outcomes and reduce the burden of PND (Levis et al., 2020; WHO, 2018). Furthermore, structured childbirth education remains underutilised within public-sector maternity services despite recommendations for comprehensive antenatal care and the promotion of positive childbirth experiences (WHO, 2018; Mutabazi & Brysiewicz, 2021).

There is a need to evaluate interventions that may improve maternal mental health outcomes, given the high prevalence of PND (Levis et al., 2020; Kuo et al., 2022). In addition, the psychological burden associated with childbirth and its potential impact on maternal mental health and the limited availability of standardised antenatal education programmes (WHO, 2018; Mutabazi & Brysiewicz, 2021,Shiva et al., 2021; Rodríguez-Almagro et al., 2019). This cluster randomised controlled trial (CRCT) will evaluate the

effectiveness of a standardised CPEP compared to the MCRCPEP on PND and childbirth-related outcomes among primigravid women.

Study objectives

The primary objective of the study will be to determine the effectiveness of a standardised CPEP compared with the MCRCPEP on PND in primigravid women, using the Edinburgh Postnatal Depression Scale (EPDS) with a cut-off score of > 10 (Cox et al., 1987; Lawrie et al., 1998; Levis et al., 2020).

The secondary objectives will be to measure the FOC using the revised Wijma Delivery Expectancy/Experience Questionnaire (Wijma, 1998; Massae et al., 2022), childbirth satisfaction using the Birth Satisfaction Scale-Revised Indicator (Martin et al., 2017), childbirth experience using the Childbirth Experience Questionnaire (CEQ) (Dencker et al., 2010), maternal self-esteem using the Rosenberg Self-Esteem Scale (RSES) (Rosenberg, 1965; Orth & Robins, 2022), and birth outcomes, including the induction of labour, the augmentation of labour, the use of analgesia, assisted vaginal birth, caesarean section, preterm birth, and neonatal intensive care unit (NICU) admission (WHO, 2018).

Methods

Study design

The study design is a two-armed CRCT designed to evaluate the effectiveness of the standardised CPEP compared to the MCRCPEP on PND among primigravid women receiving routine antenatal care in public healthcare facilities (Kuo et al., 2022; Khresheh et al., 2018). Participating antenatal care facilities (clusters) will be randomly allocated to either the intervention arm, which will receive the standardised CPEP, or the control arm, which will receive the MCRCPEP. (Kuo et al., 2022; Khresheh et al., 2018).Both groups will receive routine antenatal care.

Cluster randomisation was selected because the intervention is delivered at facility level and there is a high risk of contamination if individual women within the same clinic were allocated to different groups. Women attending the same facility may share information and experiences, thereby reducing the observable difference between study groups and potentially influencing the study findings (Campbell et al., 2012).

Outcomes will be assessed at the participant level and analysed using statistical methods that account for clustering within facilities (Campbell et al., 2012). The protocol has been developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Chan et al., 2013).

Intervention

The intervention is the standardised CPEP developed through a systematic review of the literature and documentary analysis of national and international maternity care guidelines (WHO, 2018; Khresheh et al., 2018). The programme development is underpinned by Dickoff, James and Wiedenbach's (1968) practice-oriented theory, which aligns the agent, recipient, context, procedure, dynamics, and terminus of the intervention (Dickoff, James, & Wiedenbach, 1968).

Both the standardised CPEP and the MCRCPEP consists of six structured educational modules intended for completion between 28 and 34 weeks' gestation. The standardised CPEP covers: (1) understanding pregnancy and labour; (2) emotional preparation for birth; (3) coping skills for labour; (4) birth planning and decision making; (5) life after birth and postnatal mental health; and (6) support & when to seek help. MCRCPEP covers: (1) healthy pregnancy, (2) pregnancy danger signs, (3) labour and delivery, (4) baby care, (5) breastfeeding and (6) care after birth. Content is presented in an illustrated, plain-language pamphlet available in hard-copy and electronic formats to facilitate accessibility and implementation within resource-constrained public healthcare settings (WHO, 2018; Khresheh et al., 2018). The MCRCPEP also consist of six structured modules based solely on what is covered the maternity case record (National Department of Health, 2023).

The content, relevance, clarity, and feasibility of the programme will be evaluated using an e-Delphi process, which is a structured electronic consensus-building method that uses iterative rounds of anonymous online questionnaires and controlled feedback to achieve expert consensus (Hasson, Keeney, & McKenna, 2000). The e-Delphi panel will comprise; maternal and mental health experts, academics and end-users of the intervention. The panelists will be asked to review and rate the programme's content, relevance, clarity, applicability, acceptability, and feasibility over successive online rounds until a predetermined level of consensus is reached (Hasson, Keeney, & McKenna, 2000).

Trained research assistants will explain and obtain informed consent. Baseline data will be collected. Eligible primigravid women allocated to the intervention arm will receive the standardised CPEP pamphlet while the control group will receive the MCRCPEP. The research assistant will explain the use of the pamphlet and participants will be offered clarification where required (Bellg et al., 2004). The programmes are designed as a self-paced educational intervention (Kuo et al., 2022). All facilitators will undergo good clinical practice (GCP) training (Bellg et al., 2004). Both groups will receive standard antenatal care, as provided in routine public sector antenatal care services. This will ensure pragmatic relevance, enhance external validity, and enable the determination of the added benefit of the intervention beyond existing antenatal education services (Zwarenstein et al., 2008).

Setting of the study

The study will be conducted in the BCMHD of the Eastern Cape Province, South Africa. This district provides healthcare services to a large urban and peri-urban population through a network of community health centres and maternity services (Eastern Cape Department of Health, 2024). The participating healthcare facilities will include the Duncan Village Community Health Centre (CHC), the Nontyatyambo

CHC, the Empilweni Gompo CHC, and Gateway Midwifery Obstetric Unit (Eastern Cape Department of Health, 2024). These facilities provide antenatal, intrapartum, and postnatal care services and were selected because of their high antenatal attendance rates and comparable service delivery profiles (Eastern Cape Department of Health, 2024).

Participants

The target population for the study will be primigravid women receiving antenatal care at the selected healthcare facilities (Kuo et al., 2022).

Inclusion criteria

Participants will be eligible if they are between 18 and 35 years of age, have a singleton pregnancy, are between 28 and 34 weeks' gestation at recruitment, plan to receive maternity care and deliver at participating facilities, can communicate in English and/or isiXhosa, and provide written informed consent (Kuo et al., 2022; Khresheh et al., 2018).

HIV positive women with CD4 count higher than 400 cells/μL and undetectable viral load at randomisation may participate.

Exclusion criteria

Participants will be excluded if they have been diagnosed with a psychiatric disorders, are receiving treatment for severe chronic medical conditions, have significant pregnancy complications requiring specialist management, use non-prescribed addictive substances (Kuo et al., 2022; WHO, 2018).

Sampling and sample size

An a priori sample-size analysis will be performed to ensure that the selected sample size provides adequate statistical power to detect a significant difference in PND scores between the intervention and control groups (Rutterford et al., 2015; Esserman et al., 2016). In a CRCT, sample-size calculations account for the intraclass correlation coefficient (ICC) and the design effect to allow for clustering during sample-size estimation (Rutterford et al., 2015).

Parameter estimates

The parameter estimates used for the sample size calculation were a Type I error rate (α) of 0.05, a desired power (1 − β) of 0.80, an expected variance of the primary outcome of 1.00, an ICC of 0.20, and a hypothesised intervention effect (Δ) of − 0.50. The ICC of 0.20 was selected based on published CRCTs in similar primary care and community settings, where ICC estimates for psychological outcome measures typically range from 0.15 to 0.25 (Hemming & Marsh, 2013; Batistatou et al., 2014). A systematic review has informed the 20% attrition allowance of follow-up rates in perinatal mental health

trials, which reported a pooled attrition of 17.8% across 13 studies of psychologically-informed interventions (National Collaborating Centre for Mental Health, 2007).

Sample size calculation

The sample size was calculated using standard formulae for CRCTs. The required sample size will first be estimated for an individually randomised two-group trial and will then be adjusted for clustering using the design effect (Rutterford et al., 2015).

The design effect will be calculated as: Design effect = 1 + (m − 1) × ICC, where m is the average number of participants per cluster. Using m = 5 and ICC = 0.20, the design effect is: 1 + (5 − 1) × 0.20 = 1 + 0.80 = 1.80 (Rutterford et al., 2015). The sample size per group will be calculated using the formula: $N = [2 \times (Z\alpha/2 + Z\beta)^2 \times \sigma^2 \times \text{design effect}] \div \Delta^2$. In this formula, $Z\alpha/2 = 1.96$, $Z\beta = 0.84$, $\sigma^2 = 1.00$, and $\Delta = -0.50$.

Substituting the values gives: $N = [2 \times (1.96 + 0.84)^2 \times 1.00 \times 1.80] \div (-0.50)^2$. This is calculated as: $[2 \times (2.80)^2 \times 1.00 \times 1.80] \div 0.25 = [2 \times 7.84 \times 1.80] \div 0.25 = 28.224 \div 0.25 = 112.90$.

The minimum sample size will therefore be 113 participants per group, giving a minimum total sample size of 226 participants. Allowing for 20% attrition, the sample size will be increased to approximately 137 participants per group, resulting in a final target sample size of 274 participants (Rutterford et al., 2015). All calculations will be cross-verified using Stata/SE 17.0 (StataCorp LLC) with the *clustersampsi* command (Batistatou et al., 2014).

Enrolment

All eligible primigravid women attending routine antenatal visits will be recruited and screened (Schulz et al., 2010). Engagement with clinic managers and healthcare providers will be undertaken before study commencement to facilitate recruitment activities and their integration into routine clinic workflows (WHO, 2018). Trained research assistants will be stationed at antenatal clinics to support participant screening, informed consent, and enrolment (Bellg et al., 2004).

Clear information about the study will be provided to potential participants through participant information sheets and verbal explanations in appropriate local languages to promote understanding and facilitate informed participation (World Medical Association, 2013). Study posters will be displayed on clinic notice boards to increase awareness of the study (WHO, 2018). Participants will be enrolled during routine antenatal clinic visits once eligibility has been confirmed and written informed consent has been obtained (World Medical Association, 2013).

Randomisation and allocation

Because of their geographical location and the anticipated monthly number of primigravid births, the participating sites will be purposefully paired before randomisation (Esserman et al., 2016). Duncan

Village CHC (74 births/month) and Nontyatyambo CHC (60 births/month) will form one pair because of their comparable monthly birth volumes, whereas Empilweni Gompo CHC (48 births/month) and Gateway Midwifery Obstetric Unit (134 births/month) will form the second pair.

Allocation for cluster randomisation will be done by tossing a coin. Heads will be intervention group and tails will be the control group., whereby one facility from each pair will be randomly allocated to the intervention arm and the remaining facility to the control arm (Esserman et al., 2016). The unit of randomisation will be the two groups as explained above (Esserman et al., 2016).

The four participating facilities will first be paired according to monthly birth volume. Within each pair, an independent statistician will allocate one facility to the intervention group and the other to the control group using a coin toss method. The statistician performing the cluster allocation will not be involved in participant recruitment, enrolment, or intervention delivery. Cluster allocation results will be released to the coordinating site only after the randomisation sequence has been generated and finalised. This separation of responsibilities will minimise selection bias and maintain the integrity of the CRCT (Schulz et al., 2010).

The statistician conducting the primary analysis will remain blinded until the statistical analysis plan has been finalised and the dataset has been locked (Moher et al., 2010).

Blinding and unblinding

Participants, outcome assessors and data analysts will remain blinded through the use of de-identified datasets (Campbell et al., 2012). The allocation key will be withheld until completion of the primary analyses and database lock, and statistical analyses will be conducted without knowledge of group identity to minimise detection and analytical bias (Moher et al., 2010).

The intervention and control group are identical in screening, baseline data collection, follow-up questionnaires and analysis. The only difference between the two groups are the intervention pamphlets where the intervention group will get standardised CPEP, and control group will get the MCRPEP pamphlet (WHO, 2018).

Routine unblinding procedures will be highly unlikely because the intervention is based on low-risk participants. Outcome assessors and data analysts will remain blinded until completion of the primary analysis and database lock (Moher et al., 2010). Unblinding of group allocation will occur only after finalisation of the statistical analysis (International Council for Harmonisation, 2016). Any instance of unblinding, because of participants safety or regulatory reasons will be fully documented (International Council for Harmonisation, 2016).

Data collection and study procedure

Information on the primary outcome will be collected at baseline before enrolment and again six weeks postpartum for all participants (Campbell et al., 2012).Trial data will be collected using structured,

standardised data collection tools and the electronic data capture system termed Research Electronic Data Capture (REDCap) managed by North-West University (Harris et al., 2019). Data will be captured electronically to facilitate real-time data storage, quality assurance, and statistical analysis (Harris et al., 2019). Baseline data will be collected at enrolment and will include participants' demographic characteristics, obstetric history, and baseline psychosocial indicators (Kuo et al., 2022). The questionnaire will be repeated at six weeks postnatal.

Participants will receive phone calls every two weeks to enquire about any possible adverse events and to reduce loss to follow up at six weeks postnatal (Kuo et al., 2022). Table 1 explains the study procedure

Table 1
Procedure

Study phase	**Screening**	**Baseline**	**Intervention**	**Delivery**	**6-weeks postpartum**
Eligibility screening	**X**				
Informed consent	**X**				
Baseline questionnaire		**X**			
Delivery of allocated intervention (Standardised CPEP or MCRCPEP)			**X**		
Birth form questionnaire (Childbirth outcomes) (Maternity Case Record)				**X**	
Fear of childbirth (W-DEQ)		**X**			**X**
Maternal self-esteem (Rosenberg scale)		**X**			**X**
Postnatal depression (EPDS)		**X**			**X**
Childbirth experience (CEQ)				**X**	
Childbirth satisfaction (BSS-RI)				**X**	

The schedule in Table 1 is based on the SPIRIT recommendations for clinical trial protocols (Chan et al., 2013). It illustrates the timing of participant screening, informed consent, baseline assessments, intervention delivery, and follow-up outcome assessments throughout the study period. Table 1 demonstrates that eligibility screening and informed consent will be completed before participant enrolment. Baseline assessments, including the Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ) to assess fear of childbirth (Wijma et al., 1998) and the RSES to measure maternal self-esteem (Rosenberg, 1965; Orth & Robins, 2022) and postnatal depression using Edinburgh Postnatal Depression Scale (EPDS), developed by Cox et al. (1987), will be undertaken before commencement of the

intervention. During the antenatal period, participants allocated to the intervention group will receive the standardised CPEP, while those in the control group will receive the MCRCPEP intervention.

Following childbirth, birth outcomes will be extracted from maternity case records, using birth form questionnaire and participants will complete CEQ to assess their childbirth experience (Dencker et al., 2010). As well as childbirth satisfaction using the BSS-RI developed by Martin et al. (2017). At six weeks postpartum, participants will complete the EPDS, which is the primary outcome measure used to assess PND (Cox et al., 1987; Lawrie et al., 1998; Levis et al., 2020), the Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ) to assess fear of childbirth (Wijma et al., 1998) and Self-esteem using the Rosenberg Self-Esteem Scale (Rosenberg, 1965). This schedule ensures that baseline assessments precede intervention delivery and that outcome measures are collected at clinically appropriate time points to determine the effectiveness of the intervention and is consistent with the SPIRIT recommendations for clinical trial protocols (Chan et al., 2013).

Research staff will maintain regular communication with participants to encourage continued engagement, and administering the questionnaires (Bellg et al., 2004).

For participants who discontinue the intervention or deviate from the protocol, outcome data will still be collected where consent permits (Gupta, 2011). Reasons for withdrawal or loss to follow-up will be documented where available (Moher et al., 2010).

Data management and monitoring

All trial data will be captured using the secure electronic data capture system REDCap, managed by North-West University (Harris et al., 2019). Data entry will be performed by trained research assistants (Bellg et al., 2004). Data quality will be ensured through built-in range checks, logical validation rules, automated error prompts within the database, routine data cleaning, consistency checks, and regular audits (Harris et al., 2019). Automated scheduled backups will be performed to prevent data loss (Harris et al., 2019).

All data will be de-identified using unique participant identification numbers (World Medical Association, 2013). Identifiable information will be stored separately from research data in password-protected files accessible only to authorised personnel (World Medical Association, 2013). Electronic data will be stored on secure, encrypted North-West University servers, while physical study documents will be retained in locked storage within restricted-access facilities (World Medical Association, 2013).

The Data and Safety Monitoring Board (DSMB) will comprise the study supervisor, the biostatistician, and an independent member (International Council for Harmonisation, 2016). The DSMB will oversee participant safety, study conduct, data quality, and ethical issues arising during the trial (International Council for Harmonisation, 2016). Reporting and management of adverse events (AEs) and serious adverse events will be undertaken in accordance with good clinical practice guidelines (International Council for Harmonisation, 2016). An interim statistical analysis will be conducted after 50% of the target sample has been enrolled (Pocock, 1977). The results will be submitted to the DSMB, which will

evaluate the accumulated data with respect to participant safety, study conduct, recruitment progress, data completeness, and overall trial progress (International Council for Harmonisation, 2016). Following this interim review, the DSMB will determine whether the study should continue as planned, be modified, or be terminated on the basis of participant safety, ethical considerations, or study integrity (International Council for Harmonisation, 2016).

Ongoing monitoring of recruitment, data quality, protocol compliance, and participant safety will be conducted by the coordinating site and reported to the DSMB (International Council for Harmonisation, 2016). Any serious or unexpected adverse psychological outcomes identified through routine screening will be reviewed promptly and managed in accordance with ethical and institutional requirements (World Medical Association, 2013). The decision to terminate the trial early, should unforeseen safety concerns or major ethical issues arise, will rest with the principal investigator in consultation with the DSMB and the research ethics committee

Data analysis

Data will be analysed using Stata Release 18 and Epi Info™ 7 (StataCorp, 2024; Dean et al., 2011). Statistical significance will be assessed using two-sided tests at the 5% significance level, and results will be reported as effect estimates, 95% confidence intervals, and p-values (Altman et al., 2000; Schulz et al., 2010).

Intention-to-treat analysis

All analyses will follow the intention-to-treat principle (Gupta, 2011). Participants will be analysed according to the group to which their cluster was originally randomised, irrespective of adherence to the intervention (Gupta, 2011; Campbell et al., 2012). All protocol deviations will be documented and reported (Moher et al., 2010).

Accounting for clustering

As this is a CRCT, all analyses will account for the hierarchical structure of the data and the correlation of outcomes within clusters (Campbell et al., 2012; Rutterford et al., 2015). Mixed-effects regression models will be used to adjust for clustering, account for between-cluster variability, and estimate the intervention effects (Campbell et al., 2012; Rutterford et al., 2015).

Descriptive analysis

Baseline participant and cluster characteristics will be summarised using appropriate descriptive statistics (Altman et al., 2001). Continuous variables will be presented as means and standard deviations or, where appropriate, medians and interquartile ranges (Altman et al., 2001). Categorical variables will be summarised using frequencies and percentages (Altman et al., 2001).

Primary outcome analysis

The primary outcome will be PND measured using the EPDS at six weeks postpartum (Cox et al., 1987; Lawrie et al., 1998; Levis et al., 2020). Differences in mean EPDS scores between the intervention and control groups will be analysed using mixed-effects linear regression models, with cluster included as a random effect (Campbell et al., 2012; Rutterford et al., 2015). Baseline covariates identified a priori may be included to improve the precision of the estimated intervention effect (Moher et al., 2010).

If EPDS scores are categorised using established clinical cut-off points, mixed-effects logistic regression models will be used to compare the proportion of participants with probable PND between the intervention and control groups (Levis et al., 2020; Campbell et al., 2012).

Secondary outcome analysis

All secondary outcomes will be analysed according to the intention-to-treat principle using statistical methods that account for the cluster randomised controlled design (Gupta, 2011; Campbell et al., 2012). Continuous outcomes, including FOC, childbirth satisfaction, childbirth experience, and self-esteem, will be compared between the intervention and control groups using mixed-effects linear regression models (Rutterford et al., 2015; Campbell et al., 2012). Binary birth outcomes, including induction of labour, augmentation of labour, use of analgesia, assisted vaginal birth, caesarean section, preterm birth, and NICU, will be analysed using mixed-effects logistic regression models (Rutterford et al., 2015; Campbell et al., 2012). Results will be reported as adjusted effect estimates together with 95% confidence intervals and p-values (Altman et al., 2001; Schulz et al., 2010). Sensitivity analyses will be conducted, where appropriate, to assess the robustness of the findings (Moher et al., 2010).

Data quality and diagnostics

Before analysis, data will undergo comprehensive cleaning procedures, including range checks, consistency checks, assessment of missing values, and evaluation of outliers (Harris et al., 2019). All statistical analyses will be performed according to a pre-specified statistical analysis plan developed before database lock (Moher et al., 2010).

Participants who withdraw or deviate from the protocol will remain in the intention-to-treat analysis, with their data analysed in their assigned group (Gupta, 2011). Missing outcome data will be addressed using appropriate statistical methods as specified in the statistical analysis plan (Little et al., 2012).

The extent and patterns of missing data will be examined (Little et al., 2012). Where appropriate, multiple imputation techniques will be used under the assumption that data are missing at random (Little et al., 2012). Sensitivity analyses will be conducted to assess the impact of missing data on the study findings (Little et al., 2012).

Sensitivity analyses will include complete-case and per-protocol analyses (Moher et al., 2010). Prespecified subgroup analyses may be conducted according to maternal age, baseline psychological status, and gestational age at enrolment (Moher et al., 2010).

Discussion

Maternal mental health is an under-recognised component of maternity care in many low- and middle-income countries (Rodríguez-Almagro et al., 2019). Although substantial progress has been made in reducing maternal mortality and improving access to maternity services, comparatively less attention has been directed towards psychosocial outcomes associated with pregnancy and childbirth (Rodríguez-Almagro et al., 2019). PND affects a significant proportion of women and contributes to adverse consequences extending beyond the immediate postpartum period (Levis et al., 2020; Garman et al., 2019).

The transition to motherhood is characterised by profound physical, emotional, psychological, and social changes (WHO, 2018). For primigravid women, these changes may be accompanied by uncertainty, fear, and anxiety regarding labour, childbirth, parenting responsibilities, and concerns regarding infant wellbeing (Slade et al., 2019; Shiva et al., 2021). Inadequate preparation for childbirth may exacerbate these challenges and contribute to negative childbirth experiences and subsequent psychological distress (Munkhondya et al., 2020; Shiva et al., 2021).

Childbirth preparation education programmes represent a potentially cost-effective strategy for addressing these challenges (Khresheh et al., 2018; WHO, 2018). Previous studies have demonstrated that structured antenatal education improves childbirth preparedness, promotes informed decision-making, enhances maternal confidence, reduces fear of childbirth, and improves satisfaction with care (Khresheh et al., 2018; Kuo et al., 2022). Nevertheless, existing evidence has several limitations (Levis et al., 2020).

Many previous studies have focused primarily on childbirth knowledge, labour pain management, or birth outcomes, while relatively few have specifically examined the impact of childbirth education on PND (Khresheh et al., 2018; Kuo et al., 2022). Furthermore, studies conducted in high-income countries may not be directly transferable to low-resource settings characterised by different healthcare systems, cultural contexts, and service delivery challenges (WHO, 2018).

The present study will address these gaps by evaluating a standardised CPEP specifically designed for implementation within South African public healthcare facilities (Garman et al., 2019). The intervention will incorporate psychological preparation, birth preparedness, respectful maternity care, informed decision-making, postpartum adjustment, and maternal mental health education (WHO, 2018; Khresheh et al., 2018).

The proposed intervention is hypothesised to improve maternal psychological outcomes through several interconnected mechanisms. By providing structured, evidence-based information about pregnancy, labour, childbirth, and the postpartum period, the programme is expected to enhance women's childbirth knowledge, increase childbirth self-efficacy, reduce uncertainty and fear of childbirth, and promote more realistic expectations regarding the birth experience.

Improved preparedness and confidence may contribute to more positive childbirth experiences and greater childbirth satisfaction, both of which have been identified as important protective factors against the development of postnatal depression. Furthermore, the inclusion of information on postpartum adjustment, maternal mental health, and available support services may facilitate early recognition of psychological distress and encourage timely help-seeking behaviours. Collectively, these pathways provide the theoretical basis through which the standardised childbirth preparation education programme is expected to reduce the risk of postnatal depression among primigravid women (Khresheh et al., 2018; Kuo et al., 2022; Slade et al., 2019; Levis et al., 2020; WHO, 2018).

If effective, the intervention could provide a scalable and sustainable approach for strengthening antenatal care services and improving maternal mental health outcomes (WHO, 2018). The findings may also inform national maternity care policies and contribute to the integration of structured childbirth preparation education into routine antenatal care services throughout South Africa (WHO, 2018).

List of abbreviations

AE Adverse Event

BCMHD Buffalo City Metropolitan Health District

BSS-RI Birth Satisfaction Scale-Revised Indicator

CEQ Childbirth Experience Questionnaire

CHC Community Health Centre

CONSORT Consolidated Standards of Reporting Trials

CPEP Childbirth Preparation Education Programme

CRCT Cluster Randomised Controlled Trial

DSMB Data and Safety Monitoring Board

EPDS Edinburgh Postnatal Depression Scale

FOC Fear of childbirth

HREC Health Research Ethics Committee

ICC intraclass correlation coefficient

NICU neonatal intensive care unit

NWU North-West University

PND postnatal depression

REDCap Research Electronic Data Capture

RSES Rosenberg Self-Esteem Scale

SPIRIT Standard Protocol Items: Recommendations for Interventional Trials

W-DEQ Wijma Delivery Expectancy/Experience Questionnaire

WHO World Health Organization

Declarations

Ethical approval and consent to participate

Ethical approval for the study has been obtained from the North-West University Health Research Ethics Committee (NWU-HREC) (Ethics reference number: NWU-00022-24-S1), the Eastern Cape Department of Health (EC_202503_004), and the BCMHD (World Medical Association, 2013). Written informed consent will be obtained from all participants before enrolment in the study (World Medical Association, 2013). Participation will be voluntary, and participants will retain the right to withdraw from the study at any stage without prejudice to their healthcare or future access to healthcare services (World Medical Association, 2013). Participant confidentiality and privacy will be protected throughout the study through the use of de-identified data and secure data management procedures (World Medical Association, 2013; International Council for Harmonisation, 2016).

The study will be conducted in accordance with the ethical principles of the Declaration of Helsinki, the Belmont Report, the South African National Health Research Ethics Guidelines, and good clinical practice guidelines (World Medical Association, 2013; National Department of Health, 2024; International Council for Harmonisation, 2016).

Consent for publication

Not applicable

Availability of data and materials

The dataset analysed during the current study is available from the corresponding author on reasonable request.

Competing interest

The authors declare no competing interests.

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Authors' contributions

X.D is the principal investigator and doctoral candidate responsible for study conception, protocol development, intervention development, trial implementation, data collection, **data** analysis, and manuscript preparation. **G.P.K** serves as **the** principal supervisor and provides scientific and methodological oversight. **M.M** provides methodological and statistical expertise. **C.N** contributes expertise in maternal and neonatal health, intervention development, and protocol review. All authors contributed to the development of the study protocol and approved the final manuscript.

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Trial Status

At the time of manuscript submission, the intervention development phase **will have been** completed, including **the** systematic review **and** the Delphi validation of **the** programme content. Participant recruitment is anticipated to commence following **the** completion of administrative logistics.

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