An Intervention to Improve Mental Health and HIV Care Engagement Among Perinatal Women in Malawi: A Pilot Randomized Controlled Trial

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Abstract

Perinatal depression (PND) is common and an important barrier to engagement in HIV care for women living with HIV (WLHIV). Accordingly, we adapted and enhanced The Friendship Bench, an evidence-based counseling intervention, for perinatal WLHIV. In a pilot randomized trial (NCT04143009), we evaluated the feasibility, acceptability, fidelity, and preliminary efficacy of the Enhanced Friendship Bench (EFB) intervention to improve PND and engagement in HIV care outcomes. Eighty pregnant WLHIV who screened positive for PND symptoms on the Self-Report Questionnaire (≥ 8) were enrolled, randomized 1:1 to EFB or usual care, and followed through 6 months postpartum. Overall, 100% of intervention participants were satisfied with the intervention and 93% found it beneficial to their overall health. Of 82 counseling sessions assessed for fidelity, 83% met or exceeded the fidelity threshold. At 6 months postpartum, intervention participants had improved depression remission (59% versus 36%, RD 23%, 95% CI 2%, 45%), retention in HIV care (82% versus 69%, RD 13%, -6%, 32%), and viral suppression (96% versus 90%, RD 7%, -7%, 20%) compared to usual care. Adverse events did not differ by arm. These results suggest that EFB intervention should be evaluated in a fully powered randomized trial to evaluate its efficacy to improve PND and engagement in HIV care outcomes for WLHIV.

Keywords HIV · Perinatal depression · Engagement in HIV care · Malawi · Option B+

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Introduction

Access to lifelong antiretroviral therapy (ART) for pregnant and breastfeeding women living with HIV (WLHIV) has rapidly expanded in low and middle-income countries since first being recommended by the WHO in 2016 [1]. The policy of lifelong ART for pregnant women, known as Option B+, has resulted in declines in vertical HIV transmission and maternal and infant mortality and improvements in viral suppression [2–8]. However, engagement in HIV care has emerged as a challenge to sustaining, and building on, the success of Option B+. In Malawi, up to 30% of women in the Option B + program are lost to HIV care within 6 months of starting ART [9, 10]. To continue progress towards UNAIDS 2025 AIDS Targets, [2]. there is an urgent need for interventions that address barriers to sustained engagement in HIV care for pregnant WLHIV.

Perinatal depression (PND) is common among WLHIV and is an important barrier to ongoing engagement in HIV care [11–13]. PND is defined as onset of depression during pregnancy and/or within the first 3–6 months postpartum [14, 15]. WLHIV face unique challenges including, receiving an HIV diagnosis, fear of disclosure, stigma, and concerns over vertical HIV transmission, which place them at an increased risk of PND [16, 17]. Among WLHIV in sub-Saharan Africa, 30–40% experience prenatal depression and 20-30% experience postnatal depression [18–20]. PND among WLHIV has been linked to reduced ART adherence, increased HIV viral load, and postpartum disengagement from HIV care [11, 21–24]. For these reasons, addressing PND is critical to supporting the long-term engagement in HIV care of WLHIV. However, there are currently few evidence-based interventions that address both mental health and HIV care outcomes during the perinatal period [25].

The Friendship Bench is an evidence-based counseling intervention for the general population to address common mood disorders developed in Zimbabwe through over 20 years of community-based research [26–28]. The Friendship Bench uses a task-shifting approach to deliver counseling using lay healthcare workers. Task-shifting refers to shifting the delivery of healthcare services from more highly qualified health workers to those with fewer qualifications in order to more efficiently deliver care in settings with few highly trained healthcare workers [29]. The Friendship Bench intervention effectively reduces depressive symptoms among people living with HIV and pregnant women [27, 30], and was recently adapted to the needs of perinatal populations living with HIV [25]. Herein, we report on a pilot randomized controlled trial to evaluate the feasibility, acceptability, fidelity and preliminary efficacy of the Enhanced Friendship Bench intervention to improve PND and engagement in HIV care outcomes among perinatal WLHIV enrolled in Option B + in Malawi. We hypothesized that a mental health intervention adapted to the needs of WLHIV and enhanced to directly address HIV care engagement would demonstrate feasibility, acceptability, fidelity, and preliminary indicators of effectiveness in improving both HIV and mental health outcomes.

Methods

Trial Design

The study's goal was to conduct a two-arm individually-randomized pilot trial to compare the Friendship Bench intervention, adapted for pregnant WLHIV and enhanced with additional direct support for HIV care engagement, to enhanced usual care. The pilot trial occurred at two large healthcare clinics in Lilongwe District. Both clinics serve the urban Lilongwe area, but differed in catchment area and size, making individual randomization preferable over cluster randomization.

Participants

Recruitment occurred from August 2020-August 2021. Women were eligible for inclusion if they were living with HIV and ≤ 34 weeks pregnant, over 18 years of age, initiating, re-initiating, or on established antiretroviral therapy (ART) during the index pregnancy, and screened positive for PND symptoms with a score ≥ 8 on the Self-Reported Questionnaire (SRQ)-20 [31]. The SRQ-20 is a common mental health disorders and depressive symptom screening tool developed by WHO and validated for use in perinatal populations in Malawi [31–33]. Women provided consent to be screened for depressive symptoms with the SRQ-20 separately from consent to participate in the study. Women who met inclusion criteria and screened positive for depressive symptoms but who chose not to participate were referred to a mental health provider for care. Women with active suicidal ideation or psychotic symptoms requiring immediate psychiatric care were excluded and referred for care. Ethical approval was obtained from the National Health Science Research Committee and the University of North Carolina at Chapel Hill. The trial was registered with Clinicaltrials.gov (clinical trial number: NCT04143009) prior to study start.

Study Settings

The study took place at 2 public health centers in Lilongwe District, Malawi. Each of the health centers provides ART services to WLHIV through the antenatal clinic during

pregnancy and has separate ART clinics serving non-pregnant adults living with HIV co-located on the health center grounds. In Malawi, all pregnant women presenting for care receive opt-out HIV testing at their first antenatal care visit. Women who test positive for HIV undergo adherence counseling and start ART the same day. ART is provided as part of routine antenatal care during the prenatal period. After delivery, WLHIV transition to receiving HIV care at an ART clinic, usually at 6 weeks postpartum. PND screening and assessment are currently not part of standard antenatal care in Malawi.

Intervention

The Friendship Bench is a counseling intervention that uses problem-solving therapy [34, 35] to improve mental health outcomes and is delivered using a task-shifting approach by lay health workers. The original Friendship Bench intervention includes 6 individual sessions, plus an optional 6-session group peer support program [28]. Our Friendship Bench adapted for perinatal WLHIV included 4 prenatal counseling sessions to align with WHO's recommended 4 antenatal care appointments, and 2 postnatal counseling sessions.

All counseling and support sessions were delivered by a trained counselor, with a certificate in psychosocial counseling. Counselors were supervised through weekly meetings by the project manager, who is a certified Friendship Bench Master Trainer experienced in training on, administering, and providing supervision for the Friendship Bench. Additional clinical input was provided by the study psychiatrist as needed. Prior to trial initiation, counselors attended a 2-week training which covered the intervention protocol, presentation, and care for PND, counseling skills, problem solving therapy, and participant self-care. Problem-solving therapy training sessions were audio-recorded and assessed to ensure counselors covered all the critical intervention components.

During counseling sessions, participants were led through a structured 6-step process of problem orientation, problem definition, generation of alternative solutions, decision-making, and solution implementation and verification [36]. The first counseling session included three components called Opening the Mind, Uplifting, and Strengthening, with subsequent sessions building on the first. Opening the Mind refers to the therapeutic process by which clients are encouraged to identify a problem list, choose a priority problem, identify a goal, brainstorm for solutions and choose one, and agree on an action plan through an iterative process guided by the counselor. All counseling sessions were conducted individually to ensure confidentiality. All sessions were conducted by telephone due to the COVID-19 pandemic. Counseling sessions lasted 30–45 min and were conducted in Chichewa, the local language.

In addition to individual counseling sessions, formative work by our team revealed the importance of social support to improve and sustain ART adherence and HIV care engagement for WLHIV experiencing PND [12, 25]. Thus, intervention participants were invited to complete an antenatal social support session with a trusted person. The social support sessions were led by a counselor and followed a guide developed by the study team [37]. The sessions aimed at providing the social support person with accurate information about HIV and depression and discussing ways that the social support person could support the participant in her goals around HIV care engagement and mental health. Intervention participants also received check-in by phone every 2 weeks from study staff in the third trimester and early postpartum period to support ART adherence and mental health.

Usual Care

Usual care for mental health in public facilities in Malawi includes options for basic supportive counseling by a primary provider or nurse, medication management by the primary provider (amitriptyline is the one antidepressant typically available at primary health centers and is rarely prescribed for depression), referral to the clinic psychiatric nurse or mental health clinic, or in more severe cases referral to the psychiatric units at tertiary care hospitals. For this study, usual care was enhanced by providing a mental health evaluation; brief supportive counseling; information, education, and support on common mental disorders; and (if indicated) facilitation of referral for further follow-up at a mental health clinic or psychiatric unit. Study participants receiving referrals for further mental health assessment or treatment were contacted by study staff up to 3 times to assess whether participants had followed up on recommended referrals or treatment plans and to assess whether any further outreach was indicated [28].

Outcomes

At the enrollment visit (baseline), women completed questionnaires about their mental and behavioral health, physical health, HIV, and reproductive health history. Women were followed from enrollment through 6 months postpartum. At 6 months postpartum, research assistants blinded to study arm evaluated mental health status of all participants using the Edinburgh Postnatal Depression Scale (EPDS)[38, 39], a depressive symptom measure specific to PND, and SRQ-20, which was used for screening. HIV RNA viral load was assessed using dried blood spots. Information on HIV

appointment attendance and retention in HIV care was gathered from participants' medical records. A sample of participants in the intervention arm were asked to complete a brief exit interview to assess the feasibility and acceptability of the intervention. Preliminary efficacy of mental health and engagement in HIV care outcomes were evaluated by study arm.

Primary Outcomes

As a pilot study, primary outcomes included the feasibility, acceptability, and fidelity of the intervention to improve PND and engagement in HIV care. We defined feasibility as the ability to successfully enroll and retain participants, assessed as the number of women enrolled, reasons for non-enrollment, and the proportion of women retained in each arm at 6 months postpartum. We defined acceptability as the ability to deliver a culturally and resource-appropriate intervention. We assessed acceptability through 17 questions during brief exit interviews which asked about intervention satisfaction, helpfulness, perceived benefit, and emotional discomfort at 6 months postpartum (Table S2). Acceptability was assessed in a sample of the final 15 intervention participants to complete the study due to delays in ethical approval during the COVID-19 pandemic. Fidelity was assessed using a checklist of 10 core components of Friendship Bench counseling sessions (see Table S1) applied 82 randomly selected sessions (29% of all completed sessions). We defined fidelity to the intervention protocol for a particular session as either meeting or exceeding expectations for at least 80% of checklist items.

Secondary Outcomes

Secondary outcomes for this pilot study included preliminary indicators of effectiveness in improving mental health and HIV care engagement, both separately and jointly, at 6 months' postpartum. Our main mental health outcome measure was the EPDS. We defined depression remission on the EPDS as a score at 6 months postpartum that was below the threshold of 10 for depressive symptoms and was also a $\geq 50\%$ reduction from baseline [38, 39]. We also examined depression remission using the SRQ-20, defined as below a threshold of 8 and a $\geq 50\%$ reduction from baseline [31, 39].

Retained in HIV care was originally defined as at least 1 HIV care appointment in the 30 days preceding the 6-month interview. However, during the COVID-19 pandemic longer supplies of ART were dispensed to reduce clinic visits. Thus, we defined a revised retention in HIV care outcome as having attended at least 2 HIV visits postpartum that were at least 30 days apart between delivery and 6 months postpartum, based on the minimum expected HIV care appointment schedule per Malawi HIV clinical guidelines [40].

Additional preliminary effectiveness outcomes at 6 months postpartum included (1) a composite outcome of retained in HIV care (original and revised definitions) and remission of depression as measured by the EPDS and SRQ-20; (2) SRQ-20 and EPDS scores at 6 months; (3) viral load suppression (HIV RNA level < 1000 copies/mL^3) among 56 (70%) women with viral load data; and (4) infant outcomes, including HIV testing and HIV seroconversion by 6 months postpartum.

Adverse Events

Adverse events were defined as: (1) deaths related to study participation, (2) unexpected serious adverse events related to study participation, (3) unanticipated problems involving risk to self or others or (4) adverse events or unanticipated problems not related to study participation. All reports of suicidal thoughts by participants were evaluated by study staff following a safety protocol and by a clinician prior to leaving the clinic to ensure appropriate action plans and follow-up were in place. Study staff followed up with all participants with suicidal thoughts to ensure care plans were being followed.

Sample Size

A sample size of 80 women (40 per arm) allowed for the estimation of quantitative measures of feasibility and acceptability with reasonable precision (e.g., confidence intervals around proportions of $\pm$ 7–9% points across all arms, and $\pm$ 9–17% points within a given arm). The pilot trial was not designed to have power to detect differences in secondary preliminary efficacy outcomes.

Randomization

In the pilot phase, participants were individually randomized 1:1 to intervention or usual care. Study arm assignments were generated using a random number generator in randomly ordered blocks of sizes 4,6, and 8 by one of the study principal investigators and stored in a password protected excel file on a secure server accessible by the project coordinator. For each participants' enrollment, following the completion of baseline data collection, research assistants would call the project coordinator to receive that participant's study arm assignment.

Statistical Methods

We descriptively compared baseline sociodemographic, mental health, HIV, and reproductive health characteristics of participants using means (SD) for continuous variables and frequencies (percentages) for categorical variables to assess balance across study arms. To evaluate feasibility, we compared the mean number of participants enrolled and the proportion of participants retained across study arms through 6 months postpartum. Acceptability and fidelity were evaluated as the proportion of intervention participants who found the intervention easy to administer and helpful during exit interviews (acceptability) and the proportion of counseling sessions covering at least 80% of checklist items during recorded sessions (fidelity). Since this pilot study was not designed to be powered to detect effects on efficacy outcomes, no statistical testing was performed, but differences in outcomes between arms are reported as mean or risk differences with 95% confidence intervals to communicate precision. Statistical analyses were done in Stata version 15.1 (StataCorp: College Station, TX).

Results

From August 2020 to August 2021, 909 women were assessed for eligibility and 80 (9%) met inclusion criteria and provided informed consent. The primary reason for exclusion was not meeting the threshold for depressive symptoms (Fig. 1/ Figure S1). Very few women (n = 5) who met inclusion criteria declined to enroll. Among the 80 enrolled participants, all (100%) completed a baseline assessment and 78 (98%) completed a 6-month postpartum assessment.

At baseline, women were on average 28 years of age (SD 6.0) and 19 weeks' gestation (SD 5.6; Table 1). Most women had attended standard 6–8 in school or higher, were married, and had at least 2 children. Approximately a quarter of the population was initiating ART during the current pregnancy, including 12% initiating ART at the baseline study visit. Among women already on ART, nearly half had missed an ART dose in the past 30 days. Participants had a mean SRQ-20 score of 11.8 (SD 2.5), with ≥ 8 being the threshold for inclusion. There were no notable differences between participants randomized to the intervention and usual care arms.

Primary Outcomes

Feasibility was assessed through enrollment and retention rates among intervention participants (n = 40). In this group, 83% attended all 4 prenatal sessions, 85% attended the social support session, and 83% attended at least 2 postpartum sessions. Of 82 counseling sessions assessed, 83% of sessions met the definition for fidelity to the intervention protocol by meeting or exceeding expectations for at least 80% of checklist items, including 84% of prenatal sessions and 77% of postnatal sessions.

Acceptability was assessed among a sample of 15 intervention participants. Overall, 100% of participants indicated they were satisfied with the intervention and would recommend it to someone with PND, and 93% found the intervention very beneficial to their overall health (Fig. 2). One intervention participant commented, "It helped me to deal with the depression I had, get back to old friends, brought peace to my family, as well as focusing on my HIV care." Eighty to 100% of participants felt individual intervention components (prenatal counseling sessions, social support session, postnatal counseling sessions) helped a lot, with postpartum sessions being rated as most helpful. In addition, 80% of participants felt the intervention definitely helped to support their engagement in HIV care and to address social stressors.

Preliminary Efficacy

By 6 months postpartum, depression remission was higher in the intervention arm for the EPDS (59% versus 36%, risk difference (RD) 23% [2%, 45%]) and the SRQ-20 (77% versus 59%; RD 18% [95% CI -2%, 38%]), compared to usual care (Table 2). Retention in HIV care (revised definition) was 82% among intervention participants compared to 69% among usual care participants (RD 13% [-6%, 32%]; Table 3). At 6 months postpartum, 49% of women in the intervention arm met the definition for the composite outcome of retained in HIV care and depression remission on the EPDS, compared to 21% in the usual care arm (RD 28% [8%, 48%]). Most women (93%) were virally suppressed, with a trend towards higher viral suppression in the intervention arm (96% in intervention participants versus 90% in usual care participants; RD 7% [-7%, 20%]). Overall, 94% of infants were tested for HIV by 6 months of age, with no differences by study arm. Only one infant seroconverted to HIV (intervention arm).

Adverse Events

Overall, three infant deaths, three stillbirths, and two miscarriages occurred (n = 8). In each instance, the events were evaluated by the study's project coordinator, who spoke with the mothers and consulted medical records to determine cause of death. In all instances, the cause of death was determined to not be related to study participation and were reported to the local ethics board in Malawi. There were

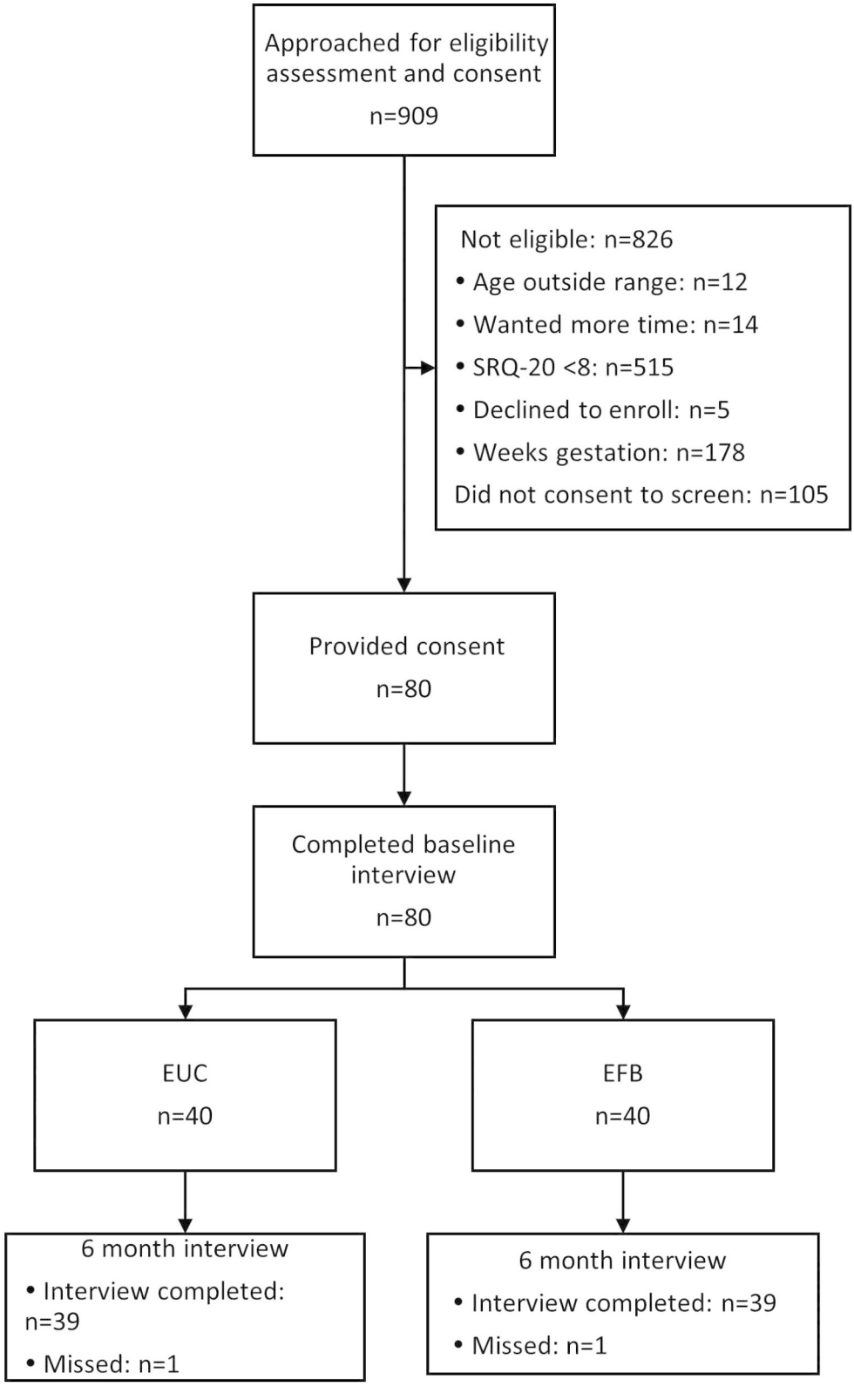

Fig. 1 Study Population CONSORT Diagrams from Revised Pilot Trial Study Phase

no differences in adverse infant outcomes by arm (12.5% in usual care versus 7.5% in the intervention arm, p-value 0.47). Mothers who experienced a pregnancy or child loss were not withdrawn from the study but continued with arm-specific activities to the extent they wished to do so. Mothers in the usual care arm were offered the opportunity

Table 1 Participant Demographics at Baseline Interview

	Overall (N = 80)	Friendship Bench (N = 40)	Usual Care (N = 40)
Age			
Mean (SD)	29.2 (5.7)	29.9 (5.3)	28.4 (6.0)
Gestational Age			
Mean (SD)	19.5 (5.4)	19.1 (5.1)	19.9 (5.8)
Education			
No formal schooling or Standard 1–5	16 (20.0)	9 (22.5)	7 (17.5)
Standard 6–8 or higher	64 (80.0)	31 (77.5)	33 (82.5)
Parity			
0	8 (10.0)	4 (10.0)	4 (10.0)
1	14 (17.5)	5 (12.5)	9 (22.5)
2+	58 (72.5)	31 (77.5)	27 (67.5)
Marital status			
Never married, separated, or widowed	8 (10.0)	5 (12.5)	3 (7.5)
Currently married or cohabitating	72 (90.0)	35 (87.5)	37 (92.5)
First tested positive for HIV			
Before this pregnancy, during another pregnancy	29 (36.3)	16 (40.0)	13 (32.5)
Before this pregnancy, NOT during another pregnancy	38 (47.5)	17 (42.5)	21 (52.5)
During this pregnancy	12 (15.0)	6 (15.0)	6 (15.0)
Perinatally infected	1 (1.3)	1 (2.5)	0 (0.0)
First initiated antiretroviral therapy			
Before this pregnancy, not during a pregnancy	39 (48.8))	18 (45.0)	21 (52.5)
Previous pregnancy	28 (35.0)	15 (37.5)	13 (32.5)
Current pregnancy, previous visit	8 (10.0)	4 (10.0)	4 (10.0)
Current pregnancy, baseline visit	5 (6.3)	3 (7.5)	2 (5.0)
Days missed ART dose (past 30 days)[1]	N = 75	N = 37	N = 38
0 days	41 (54.7)	21 (56.8)	20 (52.6)
Any days	34 (45.3)	16 (43.2)	18 (47.4)
SRQ score, range 0–20, $\geq$ 8 threshold for depression			
Mean (SD)	11.6 (2.4)	11.7 (2.3)	11.6 (2.6)
EPDS score, range 0–30, $\geq$ 10 threshold for depression			
Mean (SD)	11.9 (3.5)	12.2 (3.2)	11.5 (3.7)

[1]Among women on ART at baseline

to speak with a Friendship Bench counselor and to receive referrals for additional support.

Sixteen events of suicidal thoughts were reported (10 in intervention participants, including 5 passive, 1 active-low, 3 active-moderate, 1 active-acute instances and 6 in usual care participants including 5 passives and 1 active moderate instances).). All instances of suicidal thoughts were assessed as passive vs. active, evaluated by a clinician, and followed-up by study staff to ensure participants' follow-up care plans were in place.

Discussion

In this pilot randomized trial of the Friendship Bench counseling intervention adapted for perinatal WLHIV and enhanced with specific support for HIV care engagement, we observed high levels of feasibility, acceptability, and fidelity, that provide strong support for further testing this enhanced intervention in a fully powered trial. Overall, enrollment, intervention delivery, and follow-up were demonstrated to be feasible with 94% of eligible women agreeing to enroll, 83–85% of intervention participants completing each intervention component, and 98% of all participants completing the 6-month follow-up interview. Additionally, 93–100% of participants rated the intervention as acceptable and beneficial, and 83% of counseling sessions reviewed by an experienced Friendship Bench trainer met protocol fidelity criteria.

Although this pilot trial was not powered to detect intervention effects, strong preliminary indicators of intervention effectiveness were observed, including clinically meaningful improvements in both mental health and HIV care engagement outcomes [41]. Compared to enhanced usual care participants, intervention participants were more likely to experience remission of depression symptoms, be retained in HIV care, and achieve a composite outcome of both depressive symptom remission and HIV care retention at 6 months postpartum. Viral suppression at 6 months postpartum and infant HIV testing were high overall, with a trend toward improved viral suppression in the intervention arm. The present pilot trial represents a key innovation by adapting the proven Friendship Bench intervention for perinatal WLHIV and additionally enhancing it with content specifically focused on HIV care engagement. Prior studies have delivered the Friendship Bench separately to pregnant women and to people living with HIV but the two focus areas have not previously been combined.

Our study is among the first intervention trials focused on WLHIV during the perinatal period to demonstrate improvements in both mental health and retention in HIV care outcomes following a counseling-based depression intervention. In a small trial of a psychosocial depression and ART adherence intervention among WLHIV in South Africa, intervention participants experienced improvements in depressive symptoms but there were no differences in ART adherence [42]. Outside the perinatal period, trials focused on cognitive behavioral therapy for depression combined with ART adherence counseling have shown improvements in both mental health and HIV outcomes,[43–45]. while

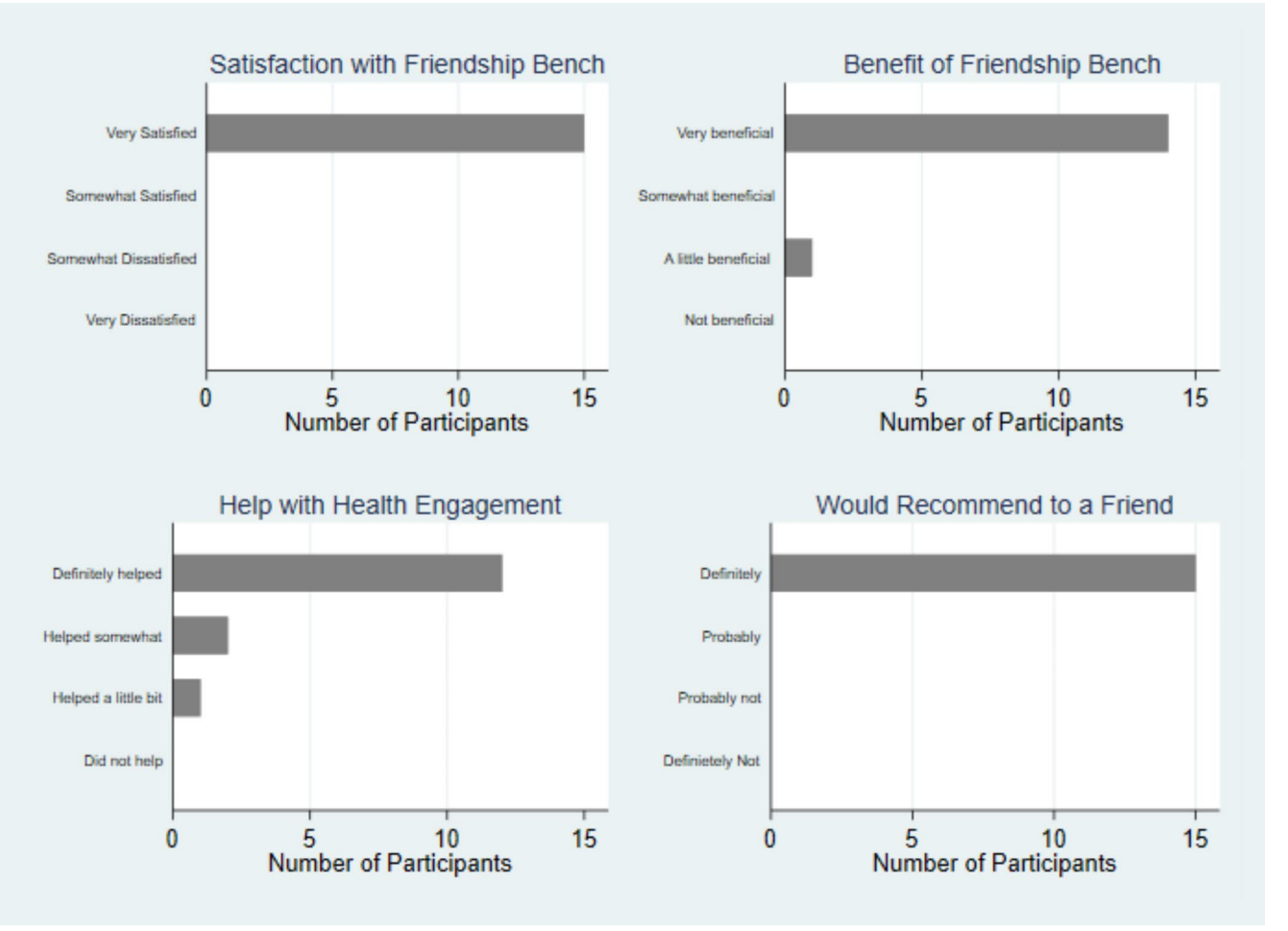

Fig. 2 Feasibility and Acceptability of the Adapted Friendship Bench Intervention among Intervention Participants (n = 15)

Table 2 Mental health outcomes at 6 months postpartum among women living with HIV and experiencing perinatal depression

	Enhanced Friendship Bench N = 39	Usual Care N = 39	Mean or Risk Difference (95% CI)
EPDS Scores[1]			
6 Month, mean (SD)	5.2 (3.8)	7.5 (4.9)	-2.4 (-4.3, -0.4)
Change baseline to 6 months, mean (SD)	-7.1 (4.9)	-3.8 (4.3)	-3.2 (-5.2, -1.2)
Remission, % (n/N)[2]	59.0% (23/39)	35.9% (14/39)	23.1% (1.5, 44.6)
SRQ Scores[3]			
6 Month, mean (SD)	3.9 (4.0)	5.5 (5.0)	-1.5 (-3.5, 0.5)
Change baseline to 6 months, mean (SD)	-7.8 (4.0)	-6.1 (5.8)	-1.7 (-3.9, 0.5)
Remission, % (n/N)[2]	76.9% (30/39)	59.0% (23/39)	17.9% (-2.4, 38.3)

[1]The Edinburgh Postnatal Depression Scale (EPDS) is a series of 10 questions to assess postnatal depression with a score range of 0–30. We used an adapted version which was previously validated in Malawi. Scores ≥ 10 meet the threshold for depression

[2]Remission defined as ≥ 50% decrease in score from baseline to 6-month study visit with a 6-month score < 8 and < 10 for the SRQ and EPDS, respectively

[3]The Self-Reporting Questionnaire (SRQ) is a series of 20 questions to screen for depression with a score range of 0–20. Scores ≥ 8 meet the threshold for depression

trials focused on antidepressant medication management without adjunctive ART adherence counseling have shown improvements in mental health measures but not HIV outcomes [46–48]. The present study lends further support to the importance of enhancing mental health interventions for people with HIV with components focused on improving HIV care engagement to impact both mental health and HIV outcomes.

Table 3 Mothers' and infants' engagement in HIV care and composite outcomes at 6 months postpartum

	Enhanced Friendship Bench Mothers (N = 39)	Usual Care Mothers (N = 39)	Risk Difference (95% CI)
Mother's Viral load at 6 months			
Below limit of detection (< 1000)	96.3% (26/27)	90.0% (26/29)	6.6% (-7.0, 20.3)
Mother Retained in Care			
Original retention definition % (n/N)[1]	51.3% (20/39)	25.6% (10/39)	25.6% (4.8, 46.5)
Revised retention definition % (n/N)[2]	82.1% (32/39)	69.2% (27/39)	12.8% (-6.6, 32.2)
	Infants (N = 36)	**Infants (N = 34)**	
Infant tested for HIV[3]			
% (n/N)	94.4% (34/36)	94.1% (32/34)	0.3% (-0.1, 0.1)
Infant HIV test results[3]			
HIV Negative	96.8% (30/31)	100% (29/29)	-3.2 (-9.8, 3.3)
Composite outcomes4			
EPDS: Original retention + Remission, %(n/N)	33.3% (13/39)	7.7% (3/39)	25.6% (8.6, 42.6)
EPDS: Revised retention + Remission, % (n/N)	48.7% (19/39)	20.5% (8/39)	28.2% (8.0, 48.4)
SRQ: Original retention + Remission, % (n/N)	59.0% (23/39)	38.5% (15/39)	21.0% (-1.2, 42.0)
SRQ: Revised retention + Remission, % (n/N)	43.6% (17/39)	12.8% (5/39)	30.8% (12.0, 49.5)

[1]Retained in care originally defined as at least 1 HIV care appointment in the 30 days preceding the 6-month interview

[2]Retained in care defined as at least 2 HIV care appointments post-delivery spaced 30 + days apart, all prior to the 6-month interview

[3]For n = 1 set of twins, only the first infant was included in infant outcomes

[4]Composite outcome is the combination of retained in care) + Remission (≥ 50% decrease in score from baseline to 6-month study visit with a 6-month score < 8 and < 10 for the SRQ and EPDS)

In the present study, 82% of intervention participants achieved HIV care retention but only 49% achieved both HIV care retention and depression remission, suggesting that for some participants, the intervention was successful in improving HIV care engagement even without fully resolving mental health symptoms. Several larger cluster randomized trials of interventions to address depressive symptoms and engagement in HIV care outcomes for WLHIV are currently being conducted that may help to shed light on the impact of treating depressive symptoms on both mental health and retention in HIV care outcomes [49–51].

Overall, study participants experienced levels of perinatal mortality that were similar (3.8%) to the national average (3%) [52]. No adverse perinatal events were attributable to the intervention and their incidence did not differ by arm. However, these findings may suggest that perinatal WLHIV experiencing PND are at high risk for adverse perinatal outcomes which should be evaluated in future studies within this population. In addition, 20% of women in the study experienced suicidal ideation, including 7.5% who experienced active (rather than passive) suicidal ideation, with no important differences by study arm. These findings are similar to levels of suicidal ideation previously reported among WLHIV [53, 54].

Our findings are relevant to perinatal WLHIV in Malawi and similar resource-constrained settings with a high burden of PND and HIV. The study took place in an urban setting with a higher prevalence of HIV and a slightly older population who were more likely to have initiated ART prior to the current pregnancy, compared to rural areas in Malawi. The Friendship Bench has previously been shown to be efficacious among younger populations with low educational attainment [28]. Thus, findings from the pilot phase may be most applicable to WLHIV on established ART treatment.

Addressing PND among WLHIV in resource-constrained settings is challenging due to the limited number of mental health professionals available [55]. The Enhanced Friendship Bench intervention addresses this concern by using a task-shifting model where trained and supervised psychosocial counselors deliver counseling sessions. Task-shifting has been used effectively in resource-limited settings and populations living with HIV to deliver perinatal mental health services [56]. Within this study, our task shifting approach to delivering a counseling intervention was viewed as highly feasible and acceptable by participants, with high levels of participant attendance at intervention sessions, satisfaction, and perceived benefits of the intervention. In addition, we observed high levels of fidelity to the intervention protocol by psychosocial counselors. Taken together, these

findings suggest that task-shifting interventions may be a scalable approach to delivering perinatal mental health and engagement in HIV care support for WLHIV in resource-constrained settings.

Conclusion

In a pilot randomized trial of a counseling intervention for WLHIV experiencing PND, we observed high levels of feasibility, acceptability, and fidelity of the Enhanced Friendship Bench intervention. Participants randomized to the intervention saw greater improvements in depressive symptom remission and were more likely to engaged in HIV care at 6 months postpartum compared to participants randomized to usual care. The Enhanced Friendship Bench intervention should be scaled up and evaluated in a larger randomized controlled trial to evaluate its efficacy to improve mental health and engagement in HIV care outcomes for WLHIV experiencing PND.

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Authors' contributions AMB, SM, SMB, VFG, and BWP designed the study; AMB, TRF, SM, SMB, VFG, MCH and BWP were involved in acquisition and analysis of the data; all authors contributed to the interpretation of the data; AMB drafted the manuscript, with assistance from SM, TRF, and BWP; all authors critically reviewed and provided feedback on the manuscript and final approval of the version to be published.

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Data availability data are available upon reasonable request from the senior author.

Code availability code is available upon reasonable request from the senior author.

Declarations

Conflicts of interest/Competing interests none declared.

Ethics approval Ethical approval was obtained from the National Health Services Research Committee and the University of North Carolina at Chapel Hill. The trial was registered with Clinicaltrials.gov (clinical trial number: NCT04143009) prior to study start.

Consent to participate all participants provided written informed consent to patriciate in the study.

Consent for publication no individually identifiable data or images are included in the publication. All participants provided written informed consent to participate in the study and have their data included in publications.

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