TITLE: PREVALENCE OF DEPRESSION AMONG POSTPARTUM WOMEN ON ISONIAZID-PREVENTIVE THERAPY AND EFAVIRENZ-BASED TREATMENT FOR HIV— AN EXPLORATORY OBJECTIVE OF THE IMPAACT P1078 RANDOMIZED TRIAL

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CONFLICTS OF INTEREST

No conflicts of interest to disclose



IMPAACT P1078 WAS A PHASE IV, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED NON-INFERIORITY STUDY

956 pregnant women

14-34 weeks gestational age living with HIV at high risk of TB underwent randomization

477 Immediate Isoniazid (INH)

300 mg of INH daily initiated at entry and continued for 28 weeks, followed by Placebo

370 women had at least one PHQ-9 evaluation

479 Deferred Isoniazid (INH)

Placebo until 12 weeks postpartum, followed by 300 mg of INH daily for 28 weeks

379 women had at least one PHQ-9 evaluation

Patient Health Questionnaire 9 (PHQ-9) was added partway through study implementation to systematically evaluate depression symptoms





EXPLORATORY ANALYSIS TO INVESTIGATE POSSIBLE DEPRESSION SYMPTOMS IN POSTPARTUM WOMEN ON

4 HIV TREATMENT

- Summarized percentages of women with depression symptoms at postpartum weeks 4, 12, 24, 36, and 48
- Assessed association of II risk factors of probable depression (PHQ-9 ≥10) at 36 weeks postpartum using exact logistic regression, adjusted for gestational age stratum

 Evaluated the study arm effect modification by EFV use





BASELINE CHARACTERISTICS WERE SIMILAR ACROSS TREATMENT ARMS

Characteristic	Immediate INH (N=370)	Deferred INH (N=379)	Overall (N=749)
Age (years)	29.0	29.0	29.0
Median (Q1, Q3)	(25.0, 33.0)	(24.0, 34.0)	(24.0, 33.0)
Black African/Black of African	344 (93%)	347 (92%)	691 (92%)
origin Gestational age	130 (35%)	136 (36%)	266 (36%)
14 - <24 weeks Cotrimoxazole use	179 (48%)	164 (43%)	343 (46%)
Efavirenz (EFV) regimen	313 (85%)	327 (86%)	640 (85%)
Undetectable HIV viral load	226 (61%)	241 (64%)	467 (62%)

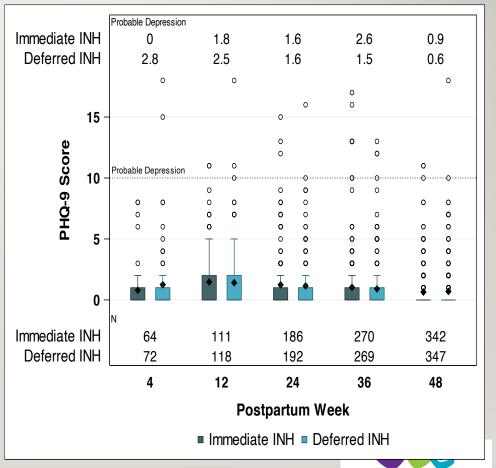


DEPRESSION SYMPTOMS (PHQ-9 ≥5) PEAKED AT 12% DURING WEEK 12, THEN DECREASED TO LESS THAN 6% AT WEEK 48

Postpartum	Number of	Depression Symptoms				
Week	Women	Minimal	Mild	Moderate	Moderately	
	Evaluated	(PHQ-9: 1-4)	(PHQ-9: 5-9)	(PHQ-9: 10-14)	severe, severe	
					(PHQ-9: 15-27)	
4	136	28 (20.6%)	8 (5.9%)	0 (0%)	2 (0.7%)	
12	229	57 (24.9%)	24 (10.5%)	4 (1.7%)	1 (0.4%)	
24	378	91 (24.1%)	29 (7.7%)	3 (0.8%)	3 (0.8%)	
36	539	117 (21.7%)	26 (4.8%)	9 (1.7%)	2 (0.4%)	
48	689	127 (18.4%)	25 (3.6%)	4 (0.6%)	1 (0.1%)	

Cotrimoxazole use was associated with increased odds of probable depression (PHQ-9 ≥10) at Week 36 adjusted odds ratio (95% confidence interval): 9.45 (1.32, 413.68)

There was no evidence of study arm differences in odds of probable depression (PHQ-9 ≥10), nor treatment effect modification by EFV use









EFAVIRENZ VS EFV/INH

There was **no difference** in the frequency of depression symptoms between postpartum women on Efavirenz alone and those on Efavirenz plus Isoniazid

Further study is advised to formally assess associations of risk factors with probable depression



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