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# Assessing the effectiveness of a depression-integrated model in adult HIV care in Uganda (the HIV+D trial): a cluster-randomised controlled trial

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## Summary

### Background

Although depression is common in people with HIV, mental health interventions are not available to the vast majority of people with HIV in Africa. We aimed to test the effectiveness of the HIV+D collaborative stepped care depression intervention in adult HIV care in Uganda.

### Methods

A cluster-randomised controlled trial was done at 40 randomly selected primary HIV care centres (clusters) at public health-care facilities in three districts in Uganda. The 40 clusters were randomly allocated (1:1) to enhanced usual care only (EUC arm) or to HIV+D intervention plus EUC, with the randomisation stratified by level of health facility. We recruited adults (aged 18 years or older) with HIV with depression, defined by the locally validated version of the Patient Health Questionnaire 9 (PHQ-9). Participants were consecutively recruited into the study clinics until there was a maximum of 30 participants per cluster. HIV+D was coordinated by a lay counsellor and involved four sequential steps of psychoeducation, behavioural activation, antidepressant medication, and referral. EUC comprised sharing screening results with the HIV clinic physician and training on the WHO guidelines for depression management in routine care. The primary outcome was PHQ-9 scores at 3 months. The trial is registered with the ISRCTN registry (ISRCTN86760765) and is completed.

### Findings

8441 people with HIV were referred to the trial, and 1115 (13%) were enrolled between May 3 and Dec 31, 2021. The mean age was 38 years, 859 (77%) were female, 535 were enrolled in the EUC group, and 580 were enrolled in the HIV+D plus EUC group. Primary outcome data were available for 1097 (98%) participants. We observed high levels of fidelity, with 290 (92%) of 316 participants in the HIV+D plus EUC intervention group receiving the recommended 4–10 sessions of behavioural activation. At 3 months, the mean PHQ-9 scores were lower in the HIV+D plus EUC group, at 3·0 (SD 3·2) compared with the EUC group, at 7·6 (SD 4·2; adjusted mean difference 4·4; 95% CI 3·4–5·5;  $p < 0·0001$ ; effect size  $[d] = 1·34$ ). This effect was sustained, although attenuated, at 12 months (adjusted mean difference 1·9; 95% CI 1·0–2·8;  $p < 0·0001$ ;  $d = 0·81$ ). Baseline depression severity scores moderated the HIV+D plus EUC intervention effect, with the intervention having stronger effects for those with baseline scores in the severe range ( $\geq 20$ ) than for those whose scores were in the moderate range (10–19) both at 3 and 12 months ( $p$  values for effect modification were  $< 0·001$  and  $0·005$ , respectively). There was no evidence of effect modification by sex nor baseline HIV viral load. One participant in the HIV+D plus EUC group was hospitalised because of severe depression.

### Interpretation

The HIV+D plus EUC intervention had a significant and sustained effect on depression compared with EUC. This intervention offers a scalable approach to integrate mental health care for adult HIV care settings.

### Funding



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Outline



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