ICAP Journal Club

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Article


Study Summary

This multi-center, prospective, comparative cohort study evaluated the effect of the Friendship Bench (FB) psychological intervention on HIV viral suppression after 6 months among people living with HIV (PLWH) with co-morbid common mental disorders (CMD), as compared to enhanced usual care (EUC).

Study Setting

• Eight purposively selected high-volume primary care clinics in Harare, Zimbabwe; six clinics provided the FB intervention and two provided EUC.
• All clinics provided HIV care and other primary care services, including acute primary care, chronic disease management, family planning, and maternity services. None routinely provided specialist mental health care.
• Clinics were typically staffed by up to 50 health care professionals with an average of 20 nurses and two physicians.

Methods

• Every third client attending each clinic was screened for eligibility.
• PLWH were eligible to participate if they were ≥18 years old, had been on antiretroviral therapy (ART) for at least three months, received HIV care at the clinic in person, lived in the clinic catchment area and had co-morbid CMD diagnosed using the Shona Symptom Questionnaire (SSQ-14).
• PLWH were excluded if they were receiving mental health care in a psychiatric unit, or presented with suicidal intent, psychotic symptoms, intoxication, or dementia.
• Participants were interviewed at baseline and at endline (six months post-enrollment) to collect sociodemographic information and mental health outcomes. Participants who did not present for their endline visit were contacted by phone or through significant others using contact information collected at baseline.
• Date of ART initiation and baseline viral load values were obtained from clinical records. Viral load was collected specifically for the study at endline.

• The following validated questionnaires were used for mental health assessment:
  o The Shona Symptom Questionnaire (SSQ-14): a measure of CMD developed and validated in Zimbabwe, which includes locally accepted idioms of distress. It is scored from 0–14, and a cutoff of ≥9 is used to diagnose CMD (i.e. depression and/or general anxiety disorder).
  o The Patient Health Questionnaire (PHQ-9): measures depression based on scores from 0–27, with a cutoff of ≥11 used to classify depression based on a previous validation of the Shona language version in Zimbabwe.
  o The Generalized Anxiety Disorder questionnaire (GAD-7): screens for general anxiety disorder based on scores from 0 to 21, with a cutoff of ≥10 used to classify anxiety based on a previous validation of the Shona language version.

• The FB intervention involved:
  o Six sessions of culturally adapted problem-solving therapy and simple behavioral activation for depression, delivered by a trained lay counsellor on a bench in a discreet area outside the clinic. The first session was delivered on the day of enrollment with subsequent weekly sessions.
  o If a participant missed a session, the counsellor made phone contact to encourage adherence to problem-solving therapy and re-schedule the next session.
  o An invitation to a peer-led support group with an income generation component.

• Twelve trained lay health counsellors delivered the FB intervention, supervised every two weeks by a mental health care professional from the FB team. All counsellors were experienced in delivering the intervention from a previous FB clinical trial.
  o The initial training lasted nine days and included knowledge on CMD, counselling skills, problem-solving therapy, and self-care.
  o All lay counsellors attended a group discussion where lessons from the earlier trial were shared.
  o Lay counsellors also received a five-day refresher training on problem-solving therapy with core modules on counselling PLWH and management of participants with ‘red flags’ (defined as SSQ-14 ≥11 or positive screen for suicidal ideation or psychotic symptoms).

• The comparison group received EUC, which consisted of nurse-led psychoeducation and assessment for any additional mental health care needs based on the Mental Health Gap Action Program (mhGAP) of the World Health Organization.

• Participants in both groups could be referred for further mental health care, which included the prescription of antidepressant medication by the clinic nurse and strengthened referral to existing mental health services for participants with ‘red flag’ symptoms as defined above.

• All participants received standard HIV care. Nurse-led enhanced adherence counselling was provided for those with viral non-suppression, consisting of three sessions on the benefits of ART and an in-depth discussion of reasons for non-adherence with the option to refer to a physician.
The primary outcome was the proportion of participants with viral non-suppression (defined as ≥400 copies/mL) at six months follow-up or death.

Secondary outcomes included mental health symptoms assessed using the SSQ-14, PHQ-9, and GAD-7. These were analyzed as continuous scores and proportions screening positive as defined above.

The primary analysis was a cluster-level difference-in-difference approach assessed using linear regression of cluster-level proportions or means on FB vs. EUC, adjusted for baseline viral non-suppression (aDiD).

Individual-level multivariable logistic regression was used to identify baseline variables that were potential confounders and baseline variables independently associated with loss-to-follow-up. These variables were included in the initial aDiD model if they changed the effect estimate by more than 10%.

**Study Population and Follow-up**

Between August 2017 and July 2018, 2,019 PLWH were screened in the six FB clinics, of whom 543 (26.9%) were eligible, and 500 (92.1%) were enrolled. In the two EUC clinics, 817 PLWH were screened, of whom 212 (25.9%) were eligible, and 200 (94.3%) were enrolled.

The main reason for non-eligibility in both FB and EUC clinics was not having CMD (n = 1,704).

Overall, 579 (82.7%) participants had viral load test results at both baseline and endline (81.4% and 86.0% in the FB and EUC group, respectively). The median duration from enrollment to follow-up viral load test was 6.5 months (interquartile range [IQR] 5.3–7.8) in the FB group and 8.1 months (IQR 6.8–11.7) in the EUC group (p<0.001).

A total of 568 (81.1%) participants had mental health outcome data at follow-up (81.2% and 81.0% in the FB and EUC groups, respectively). The median duration of follow-up for the mental health outcomes was 6.5 months (IQR 5.2–7.2) in the FB group and 9.5 months (IQR 7.0–12.8) in the EUC group (p<0.001).

Among the participants with complete viral load data, the mean age at enrollment was 40.6 years (standard deviation 9.9 years), 82.0% were female and 89.1% reported some form of income.

At baseline, 13.8% of participants had viral non-suppression (14.3% and 12.8% in the FB and EUC groups, respectively). Median duration on ART in both groups was similar, as was severity of CMD.

Prevalence of major depression (PHQ-9 ≥11) was 55.8% and 11.6% were considered to have severe depression (PHQ-9 ≥20). Clinically relevant general anxiety disorder (GAD-7 ≥10) was detected in 47.0%, with 22.8% considered to have severe generalized anxiety disorder (GAD-7 ≥15).

**Primary Outcome**

Overall, 10.1% (41/407) of the participants in the FB group had viral non-suppression at endline as compared to 15.1% (26/172) in the EUC group (aDiD = -7.3%; 95% confidence interval [CI] -14.7% to -0.01%; p = 0.05).
Among the 499 participants who were virally suppressed at baseline, prevalence of viral non-suppression at follow-up was lower in the FB group than in the EUC group (2.9% vs. 9.3%; DiD -6.5%; 95% CI -10.5% to -2.4%; p = 0.002).

Among the 80 participants with viral non-suppression at baseline, there was no evidence of a difference in viral non-suppression at endline between the FB and EUC groups (53.5% vs. 54.5%; p = 0.93).

**Secondary Outcomes**

- Participants in the FB group had a lower prevalence of CMD (SSQ-14 ≥9) at endline (27.6%) than those in the EUC group (52.5%) (aDID = -21.6%; 95% CI -36.5% to -6.7%; p = 0.008).
- There was a similar pattern of reduced prevalence of depression (PHQ-9 ≥11) (20.9% in FB group vs. 31.5% in EUC group) and anxiety (GAD-7 ≥10) (17.2% in FB group vs. 28.4% in EUC group), although the associations were not statistically significant.
- CMD symptom severity, as measured by mean SSQ-14 scores, was also lower in the FB group at endline (aDID = -1.90; 95% CI 3.50 to -0.31; p = 0.02), but no association was found with symptom severity using the other mental health scores.

**Critical Analysis**

This multi-center, prospective, comparative cohort study among PLWH with co-morbid CMD found that those who received the FB psychological intervention were more likely to maintain HIV viral suppression after 6 months than those who received EUC. However, there was no evidence of an intervention effect among participants with viral non-suppression at baseline. There was also evidence that the FB intervention improved CMD symptoms as measured by the SSQ-14.

The following points should be considered when interpreting the study findings:

- The findings suggest that FB helps PLWH maintain good adherence to ART and stay virally suppressed, but not to newly achieve viral suppression. This may indicate that factors beyond mental health remain as barriers to adherence and viral suppression in this population.
- The original enrollment targets were 750 participants in FB clinics and 250 in EUC clinics. However, fewer PLWH attended the clinics per day than expected, which was largely attributed to relatives and friends of PLWH coming to collect prescriptions for them. This led to the study closing after only enrolling a total of 700 participants. The reduction in final sample size may explain the lack of statistically significant associations between treatment group and depression or anxiety scores.
- When the study began (August 2017), scale-up of the FB intervention was taking place in primary care clinics in Harare. The FB clinics in the study already had the FB intervention, which may introduce some selection bias in clinic population.
- The non-randomized study design increased the risk of bias due to confounding. In individual-level analyses, participants at the FB clinics were older, more likely to be female,
more likely to be widowed, less likely to have an income, and had been on ART for a longer period. The authors evaluated potential confounders and found that age and duration since ART initiation were independently associated with both treatment group and viral non-suppression at endline. However, these variables did not change the effect estimate of the intervention on the primary outcome by more than 10%, suggesting little confounding.

- The study assessed CMD using three psychometric tests that were validated in the study setting. Other programs looking to implement similar programs would need to validate these tools in their settings before use.
- Viral non-suppression was less prevalent than anticipated, which limited the power to detect a difference between groups at follow-up. Baseline prevalence of viral non-suppression in both groups was similar to population-based estimates of non-suppression in ZIMPHIA, however the authors expected that viral suppression among participants with CMD symptoms would be twice as high.
- There was a notable difference in follow-up time between treatment groups, which occurred because of logistic challenges with data collection. The median follow-up was two months longer in the EUC group than the FB group, giving the EUC group a longer period at risk in which to develop viral non-suppression. This might have led to an underestimation of the effect of treatment on viral non-suppression using the difference-in-difference approach, which assumes that the treatment groups have parallel trends in viral non-suppression without the intervention.\(^1\)
- Alcohol use did not seem to be a major contributor to mental health outcomes, with only 13% of all participants reporting they drank alcohol and only five participants reporting they consumed alcohol daily. However, it should be noted that the majority of participants (82%) were female, and problematic alcohol use may be more prevalent with men.

**Implications**

This multi-center, prospective, comparative cohort study in Zimbabwe found evidence that the FB psychological intervention helped PLWH with CMD to maintain viral suppression, and to achieve better mental health outcomes. However, more is needed to support PLWH with CMD who are struggling with non-adherence. Nonetheless, this low-cost intervention that is delivered by lay counselors is a promising approach to integrating mental health care into primary care and ultimately improving treatment outcomes for PLWH in similar settings.

\(^1\)More information on the difference-in-difference approach is available here: [publichealth.columbia.edu/research/population-health-methods/difference-difference-estimation](publichealth.columbia.edu/research/population-health-methods/difference-difference-estimation)

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