ICAP Journal Club

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Article

Myers B, Lombard CJ, Lund C, et al. **Comparing dedicated and designated approaches to integrating task-shared psychological interventions into chronic disease care in South Africa: a three-arm, cluster randomised, multicentre, open-label trial**. *Lancet*. 2022; 400 (10360):1321-1333. https://doi.org/10.1016/S0140-6736(22)01641-5

Study Summary

Project MIND (integrating treatment for mental illness into chronic disease) was a three-arm, cluster randomized, multi-center, open-label trial that compared the effectiveness of two approaches to integrating task-shared psychological interventions for depression and alcohol use in primary care, compared with treatment as usual (TAU), for people living with HIV or diabetes.

Study Setting

- Twenty-four primary health-care clinics (15 urban and nine rural) in the Western Cape province of South Africa.
- Clinics offered co-located, vertically organized HIV and diabetes services and were purposively selected for geographic distribution and variability in size and organization of clinics.
- Facility-based community health workers (CHWs) are part of the chronic disease team, and their responsibilities include health promotion and medication adherence support for HIV and non-communicable diseases.

Methods

- Health providers screened potential participants during routine HIV or diabetes care visits for recent alcohol use and low mood. Individuals reporting any alcohol use in the past year or low mood in the past 2 weeks were referred for eligibility screening.
- Individuals with HIV or type 1 or type 2 diabetes were eligible for inclusion if they were ≥18 years old, taking antiretroviral therapy (ART) for HIV or medication for diabetes, had an Alcohol Use Disorders Identification Test (AUDIT) score of ≥8 or a Center for Epidemiologic Studies Depression Scale (CES-D) score of ≥16, and were not receiving mental health treatment. No exclusion criteria were used.

- Clinics were randomly assigned (1:1:1), stratified by urban–rural status, to use either a designated care approach (designated group), a dedicated care approach (dedicated group), or TAU (TAU group).
- All participants completed a computer-assisted baseline self-assessment on chronic disease treatment, depression, alcohol use, socio-demographic factors and perceived health status. Participants also provided whole blood samples for HIV viral load (VL) or HbA1c testing.
- All participants were asked to return at 6 months and 12 months, when the baseline questionnaire was readministered and blood samples were collected for repeated HIV VL or HbA1c testing.
- Participants recruited from the eight TAU clinics received standard care for mental health concerns. This involved monitoring mood and alcohol use, providing lifestyle advice, and offering referrals to an on-site or off-site mental health nurse or social worker for additional services as required.
- Participants recruited from the 16 intervention clinics were offered the transdiagnostic MIND program and additional referrals if required. This manualized program included:
    - Three 45–60-minute intervention sessions based on motivational interviewing and problem-solving therapy, with the option of a booster session. Each session was scheduled at least a week apart and participants had 6 weeks to complete the intervention.
    - Sessions focused on motivating participants to engage in the intervention and teaching strategies for coping with stress and life problems.
    - A participant handbook summarized each session and included practice activities.
- Clinics assigned to the dedicated and designated approaches delivered the identical intervention program, but the job scope of the CHW differed.
    - In the designated group, a facility-based CHW from the chronic disease team was assigned to provide the MIND program in addition to their other chronic disease-associated responsibilities.
    - In the dedicated group, an additional CHW was added to the pool of CHWs in the chronic disease team. The main task of this dedicated CHW was to deliver the MIND program.
- Dedicated and designated CHWs were matched on education level and counseling experience, and received the same amount of training, supervision, and support.
    - All CHWs had received previous training in chronic disease adherence counseling and generic counseling skills.
    - During Project MIND, CHWs completed 40 hours of didactic and experiential training that addressed understanding depression and alcohol use, principles of motivational interviewing, problem-solving therapy techniques, intervention content and content delivery, providing referrals for other services, and managing distressed participants and risk of harm.

- Trainers were registered psychological counselors with experience in delivering the program. Role-plays and observations assessed CHWs' proficiency in delivering the program.

- To assess intervention quality, 320 participants were randomly selected for quality assurance of their intervention sessions.
  - CHWs audio-recorded the intervention sessions of consenting participants and a counseling supervisor used checklists to assess treatment-specific competencies (fidelity) and general counseling competencies.
  - During weekly individual supervision, the supervisor provided feedback to CHWs on ways to enhance fidelity and improve counseling quality.
- The primary outcomes were changes in depression and alcohol use severity from baseline at 12-month follow-up, measured separately in people with HIV and those with diabetes.
  - Depression severity was assessed via composite scores on the 20-item CES-D. Scores ranged from 0 to 60, with higher scores indicating more severe depressive symptoms and a score ≥16 indicating clinically relevant symptoms.
  - Alcohol use severity was assessed using composite scores of the 10-item AUDIT. Scores ranged from 0 to 40, with higher scores indicating more severe alcohol use. A score of ≥8 or more indicated hazardous use and ≥16 indicated a possible alcohol use disorder.
- Pre-specified secondary outcomes were changes in symptom severity at 6 months, self-reported medication adherence and chronic disease control.
  - HIV disease control was assessed through changes in the proportion of participants with a VL <40 copies/mL (indicating good control) and ≥1000 copies/mL (indicating poor control).
  - Diabetes disease control was assessed through changes in the proportion of participants with HbA1c levels of ≥7.0%, indicating poor glycemic control.
- Assessment of the primary and secondary outcomes were conducted according to the intention-to-treat principle. Mixed-effect linear regression models were used for the primary outcomes, adjusted for rural or urban location and baseline factors associated with higher attrition at 12 months (sex, hunger, and poor disease control) to account for missing data.

<u>Study Population and Follow-up</u>

- Between May 2017 and March 2019, 3,069 individuals underwent eligibility screening and 1,652 (54%) met the eligibility criteria.
- Of these, 1,340 (81%) were enrolled (801 with HIV and 622 with diabetes); 457 (34%) in the dedicated group, 438 (33%) in the designated group, and 445 (33%) in the TAU group.
- Participants' mean age was 46.0 years (standard deviation [SD] 12.8), 76% were women, 13% had completed high school, 55% were unemployed, and 33% reported often experiencing hunger in the previous month.

- Of the people living with HIV, 20% had poorly controlled disease (VL ≥1000 copies/mL) and 81% of people with diabetes had poorly controlled disease (HbA1c of ≥7%).
- Compared with the intervention groups, participants in the TAU group were less likely to be male or report experiencing hunger often.
- During the trial 13 dedicated CHWs and 18 designated CHWs were trained. On average, there were 24.2 (SD 15.9) participants per CHW in the dedicated group and 19.9 (SD 18.3) participants per CHW in the designated group.
- Across both intervention groups, 74% of participants completed the MIND program (76% in the dedicated group; 72% in the designated group); 99% completed one session, and 89% completed two sessions with no difference by intervention group.
- Assessment of intervention quality showed that facility-based CHWs had high levels of treatment-specific (90%) and general counseling competencies (85%).
- At 6 months follow-up, 87% of participants were assessed (83% in the dedicated group; 86% in the designated group; and 93% in the TAU group).
- At 12 months follow-up, 88% of participants were assessed (86% in the dedicated group; 87% in the designated group; and 91% in the TAU group).
- Participants lost to follow-up were more likely to be male, report often experiencing hunger, and have poor disease control than those who were retained.

Primary Outcome

- At 12 months follow-up, the dedicated group had greater reductions in mean CES-D scores than did the TAU group for people with HIV (adjusted mean difference –5.02; 95% confidence interval [CI] –7.51 to –2.54; p <0.0001) and people with diabetes (adjusted mean difference –4.20; 95% CI –6.68 to –1.72; p <0.0001), and the pooled cohort (adjusted mean difference –5.55; 95% CI –7.36 to –3.74; p <0.0001).
- The designated group also had greater reductions in CES-D scores than did the TAU group for people with HIV (adjusted mean difference –6.38; 95% CI –8.89 to –3.88; p <0.0001), people with diabetes (adjusted mean difference –4.80; 95% CI –7.21 to –2.39; p <0.0001) and the pooled cohort (adjusted mean difference –6·45; 95% CI –8.26 to –4.65; p<0.0001).
- Mean CES-D scores for the people living with HIV at 12 months were 9.46 (standard error [SE] 1.25) in the dedicated group, 11.38 (SE 1.21) in the designated group and 12.36 (SE 1.25) in the TAU group. Similarly for people with diabetes, mean CES-D scores at 12 months were 9.56 (SE 1.24) in the dedicated group, 11.24 (SE 1.21) in the designated group and 12.27 (SE 1.24) in the TAU group
- From baseline to 12 months follow-up, reductions in AUDIT scores were similar across all study groups, with no intervention effects noted.

Secondary Outcomes

- At 6 months follow-up, the dedicated group had greater reductions in mean CES-D scores than did the designated group in the pooled cohort (adjusted mean difference –2.24; 95% CI –4.01 to –0.48; p=0.013). However, this difference dissipated at 12 months follow-up.
- At 6 months follow-up, mean AUDIT scores reduced more in the dedicated group compared with the TAU group for people with HIV (adjusted mean difference –3.12; 95% CI –5.02 to –

1.21; p=0.0014), people with diabetes (adjusted mean difference –2.75; 95% CI –5.31 to –0.19; p= 0.035), and the pooled cohort (adjusted mean difference –3.14; 95% CI –4.74 to –1.53; p <0·0001).

- In the pooled cohort, greater reductions in mean AUDIT scores were observed in the dedicated group compared with the designated group (adjusted mean difference –1.94; 95% CI –3.64 to –0.26; p= 0.025) at 6 months.
- There were no intervention effects observed on the proportion of participants living with HIV reporting optimal adherence to their ART medication and there was no evidence of an intervention effect for HIV disease control; the proportion of participants with VL <40 copies/mL and ≥1000 copies/mL remained relatively unchanged in each group.
- Similar findings were found in people with diabetes, with no intervention effects observed for the proportion of participants reporting optimal diabetes medication adherence and no evidence of an intervention effect for glycemic control.

Critical Analysis

The three-arm, cluster randomized, multi-center, open-label Project MIND trial found dedicated and designated approaches to CHW-delivered psychological interventions were equally effective in reducing depression symptom severity to below clinically significant levels in people with HIV and people with diabetes at 12 months, with both groups outperforming TAU. However, only the dedicated approach led to better alcohol use outcomes at 6 months follow-up, with no intervention gains after 12 months.

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

- Participants, CHW and study outcome assessors were unmasked, and the primary outcomes relied on self-report questionnaires, both of which are potential sources of bias. However, CHWs and study assessors functioned independently of each other and study investigators remained masked to group allocation.
- Intervention reductions in depression symptoms were largely maintained in the dedicated approach, whereas they improved over time in the designated approach in which CHWs continued to provide chronic disease support to participants. The authors believe this suggests that additional supportive contact after completion of the initial MIND intervention program could enhance the effectiveness of the dedicated approach.
- The trial found no direct effects on HIV or diabetes medication adherence or control; however, this trial was not designed to detect change in these outcomes because the MIND program does not directly address medication adherence or disease management.
- Task-sharing in the intervention groups included extensive training of CHW and quality assurance, with ongoing feedback from counseling supervisors. This may limit the feasibility of implementing a similar intervention in more resource constrained settings. No data on cost were reported, but cost-effectiveness analyses are planned.
- While the intervention groups had greater improvement in their mean CES-D scores, it should be noted that participants in the TAU group also had improvements in their scores,

with all groups achieving a mean score that was below the cut off for clinically significant symptoms (<16) at 12 months.

- The authors hypothesize that CHW stigma towards patients with alcohol use disorders could explain why the dedicated approach led to better alcohol outcomes, as previous stigmatizing interactions with designated CHWs could have diminished participants' motivation to engage with the MIND intervention. By contrast, dedicated CHWs had no shared history with MIND participants.
- The study was underpowered to detect change in alcohol outcomes for the separate disease cohorts and was unable to assess outcomes for participants with comorbid depression and alcohol use disorders.
- The study evaluated task sharing among CHWs based at health facilities and in populations attending facilities for chronic care services, thus findings may not be generalizable to people who are lost to care or who are receiving community-based care.

Implications

The three-arm, cluster randomized, multi-center, open-label Project MIND trial findings suggest that when adequately trained and supervised, CHWs can effectively deliver psychological interventions in clinics with human resource constraints. Project MIND is the first randomized trial to show that dedicated and designated approaches confer similar benefits for depression symptom severity, but that the dedicated approach offers additional short-term benefits for severity of alcohol use in individuals receiving care for chronic diseases. This trial contributes to the evidence for CHW-delivered, task-shared psychological interventions, which is an essential approach for offering mental health services in resource limited settings.

This article synopsis was written by Dr. Cassia Wells. Share your thoughts on this article or suggest an article for Journal Club by emailing her at caw2208@columbia.edu.