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

Bronwyn Myers, Carl J Lombard, Crick Lund, John A Joska, Naomi Levitt, Tracey Naledi, Petal Petersen Williams, Claire van der Westhuizen, Pim Cuijpers, Dan J Stein, Katherine R Sorsdahl

Summary

Background Community health workers (CHWs) are increasingly providing task-shared psychological interventions for depression and alcohol use in primary health care in low-income and middle-income countries. We aimed to compare the effectiveness of CHWs dedicated to deliver care with CHWs designated to deliver care over and above their existing responsibilities and with treatment as usual for patients with a chronic physical disease.

Methods We did a three-arm, cluster randomised, multicentre, open-label trial done in 24 primary health-care clinics (clusters) within the Western Cape province of South Africa. Clinics were randomly assigned (1:1:1) to implement dedicated care, designated care, or treatment as usual, stratified by urban–rural status. Patients with HIV or type 1 or type 2 diabetes were eligible if they were 18 years old or older, taking antiretroviral therapy for HIV or medication to manage their diabetes, had an Alcohol Use Disorders Identification Test (AUDIT) score of eight or more or a Center for Epidemiologic Studies Depression Scale score of 16 or more, and were not receiving mental health treatment. In the intervention arms, all participants were offered three sessions of an evidence-based psychological intervention, based on motivational interviewing and problem-solving therapy, delivered by CHWs. Our primary outcomes were depression symptom severity and alcohol use severity, which we assessed separately for the intention-to-treat populations of people with HIV and people with diabetes cohorts and in a pooled cohort, at 12 months after enrolment. The Benjamini-Hochberg procedure was used to adjust for multiple testing. The trial was prospectively registered with the Pan African Clinical Trials Registry, PACTR201610001825403.

Findings Between May 1, 2017, and March 31, 2019, 1340 participants were recruited: 457 (34·1%) assigned to the dedicated group, 438 (32·7%) assigned to the designated group, and 445 (33·2%) assigned to the treatment as usual group. 1174 (87·6%) participants completed the 12 month assessment. Compared with treatment as usual, the dedicated group (people with HIV adjusted mean difference −5·02 [95% CI −7·51 to −2·54], p<0·0001; people with diabetes −4·20 [−6·68 to −1·72], p<0·0001) and designated group (people with HIV −6·38 [−8·89 to −3·88], p<0·0001; people with diabetes −4·80 [−7·21 to −2·39], p<0·0001) showed greater improvement on depression scores at 12 months. By contrast, reductions in AUDIT scores were similar across study groups, with no intervention effects noted.

Interpretation The dedicated and designated approaches to delivering CHW-led psychological interventions were equally effective for reducing depression, but enhancements are required to support alcohol reduction. This trial extends evidence for CHW-delivered psychological interventions, offering insights into how different delivery approaches affect patient outcomes.

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Curtin enAble Institute, Faculty of Health Sciences, Curtin University, Perth, WA, Australia (Prof B Myers PhD); **Alcohol, Tobacco and Other Drug Research Unit** (Prof B Myers, P Peterson Williams PhD) **and Biostatistics Unit** (Prof C J Lombard PhD), **South African Medical Research Council, Cape Town, South Africa; Department of Psychiatry and Mental Health** (Prof B Myers, Prof C Lund PhD, Prof J A Joska PhD, P Peterson Williams, C van der Westhuizen PhD, Prof D J Stein PhD, Prof K R Sorsdahl), **Department of Medicine, Faculty of Health Science** (Prof N Levitt MD, T Naledi FCPHM), **and Desmond Tutu HIV Centre, Faculty of Health Sciences** (T Naledi), **University of Cape Town, Cape Town, South Africa; Division of Epidemiology and Biostatistics, Department of Global health, Stellenbosch University, Bellville, South Africa** (Prof C J Lombard); **Centre for Global Mental Health, Health Service and Population Research Department, Institute of Psychiatry, Psychology & Neuroscience, King's College London, London, UK** (Prof C Lund); **Department of Clinical, Neuro and Developmental Psychology, Amsterdam Public Health Research Institute, Vrije Universiteit Amsterdam, Netherlands** (Prof P Cuijpers PhD)

Correspondence to: Prof Bronwyn Myers, Curtin enAble Institute, Faculty of Health Sciences, Curtin University, Perth, WA 6845, Australia **bronwyn.myers-franchi@curtin.edu.au**

Introduction

South Africa, like many other low-income and middle-income countries (LMICs), has an underfunded public health system that is challenged by high rates of infectious diseases, like HIV, and non-communicable diseases, such as diabetes.[1] These diseases generate considerable costs to the health system that are amplified by untreated depression and alcohol use disorders.[2]

Depression and alcohol use disorders often co-occur with chronic physical conditions, with two-times to five-times higher prevalence of these disorders in people with chronic physical conditions than the general population.[3,4] Compared with patients with a chronic physical condition alone, patients with comorbid depression or alcohol use disorders are more likely to have suboptimal chronic disease treatment adherence, poorly controlled disease,

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Research in context

Evidence before this study

Task-sharing of psychological interventions from specialist providers to non-specialist providers, like community health workers (CHWs), is recommended to address the substantial treatment gap for common mental disorders in low-income and middle-income countries (LMICs). A Cochrane review searched databases (CINAHL, MEDLINE, WHO's Global Health library, PsycINFO, Cochrane, and Embase), clinical trials registries, and reference lists of selected systematic reviews for randomised trials of CHW-led interventions treating people with mental health symptoms in LMICs published from inception of each database to Aug 24, 2020. We used the search terms "depressi*" or "alcohol*" and "community health worker" and "developing country" or "low and middle income country", and "randomised controlled trial" or "clinical trial". There were no restrictions on language, type of mental health condition, or type of intervention. The review showed that CHW-delivered psychological interventions in LMICs might reduce depression (eight trials; low certainty evidence) and alcohol use (five trials; low certainty evidence) symptom severity. Outcome analysis in 11 of these trials was restricted to no longer than 6 months and none tested whether different approaches to CHW-delivered psychological interventions impact patient outcomes.

Added value of this study

To inform the scale-up of CHW-delivered psychological interventions in LMICs, service planners need to know which option gives the best results: should existing CHWs be designated to provide these interventions in addition to their current responsibilities or should new CHWs be recruited who are dedicated to the provision of these interventions. To the best of our knowledge, this is the first cluster randomised controlled trial evaluating the effectiveness of the dedicated and designated approaches to CHW-delivered psychological interventions for depression and alcohol use symptom severity in patients with a chronic disease, relative to treatment as usual. In this trial, both the dedicated and designated approaches to CHW-delivered psychological interventions resulted in significantly better outcomes for depression compared with treatment as usual at 12 months follow-up, irrespective of type of chronic disease. For depression, intervention gains at 6 months follow-up were maintained for the dedicated group and improved for the designated group at the 12 month endpoint. By contrast, only the dedicated approach led to better alcohol use outcomes at 6 month follow-up, with intervention gains deteriorating between the 6 and 12 month endpoints.

Implications of all the available evidence

Building on existing evidence that CHW-delivered psychological interventions reduce depression and alcohol use symptom severity, this trial provides guidance on how to staff such services for optimal mental health outcomes. Findings from this trial suggest that a dedicated approach to CHW-delivered psychological interventions has the potential to improve a broader range of mental health outcomes than the designated approach.

lower quality of life, and worse health outcomes.[5,6] This evidence has underpinned global calls to integrate psychological interventions into chronic disease care.[7] South Africa's Integrated Chronic Disease Management model, part of a broader primary health-care re-engineering strategy, recognises the importance of addressing mental health as part of chronic disease management in primary health care, yet psychological interventions are rarely available to patients.[8,9] Structural and systemic impediments to the delivery of psychological interventions in this setting include the country's chronic shortage of mental health providers and limited mental health-care proficiencies among other health providers.[9,10,11]

To overcome these barriers, South Africa has endorsed WHO's recommendation of task-sharing psychological interventions between specialist and non-specialist providers, such as community health workers (CHWs).[12] Evidence of the feasibility, acceptability, and effectiveness of CHW-delivered psychological interventions informed this decision.[13,14,15] However, multiple barriers have delayed implementation, including uncertainty about whether to implement a designated or dedicated approach to CHW-led psychological interventions.[12,16] The designated approach involves expanding the duties of CHWs available within primary health care to include psychological interventions. By contrast, the dedicated approach involves employing additional CHWs to provide this new service.[12] Findings from our formative work suggested that it is feasible and acceptable for both designated and dedicated CHWs to deliver structured psychological interventions and showed patient and provider equipoise about the relative merits of the two approaches.[9,17,18] Like previous studies,[14,15] providers who endorsed the designated approach thought CHWs' scope of work could be expanded to include structured psychological interventions given that they provide supportive health counselling to patients with chronic disease. Conversely, those who favoured the dedicated approach thought dedicated CHWs would offer more effective interventions than designated CHWs. Like earlier studies,[19,20] they thought existing CHWs had little additional capacity to deliver psychological interventions.

LMICs require evidence of the relative effectiveness of the dedicated and designated approaches to inform decisions about how to proceed with integrating CHW-delivered psychological interventions into chronic disease care. Yet, to the best of our knowledge, there are no trials comparing the relative effectiveness of these approaches. Project MIND (integrating treatment for mental illness

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into chronic disease) aimed to address this gap by comparing the effectiveness of these two approaches compared with treatment as usual. We aimed to assess examined depression and alcohol outcomes in a cohort of participants with a chronic infectious disease (HIV) and a cohort of participants with a non-communicable disease (diabetes) to enhance the generalisability of findings beyond a single mental health concern and chronic physical condition.

Methods

Study design and participants

Project MIND was a three-arm, cluster randomised, multicentre, open-label trial done in 24 primary health-care clinics (clusters) within the Western Cape province of South Africa. These clinics offered co-located but vertically organised HIV and diabetes services to geographically distinct catchment areas. Because the MIND intervention influenced service provision, we selected a cluster design to reduce risk of contamination.

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. Patients with HIV or type 1 or type 2 diabetes were eligible for inclusion if they were 18 years old or older, taking antiretroviral therapy (ART) for HIV or medication to manage their diabetes, had an Alcohol Use Disorders Identification Test (AUDIT)[21] score of eight or more or a Center for Epidemiologic Studies Depression Scale (CES-D) score of 16 or more,[22] and were not receiving mental health treatment. No exclusion criteria were used.

The methods are described in the published trial protocol.[16] Written informed consent was obtained from each participant, and ethics approval was granted by The South African Medical Research Council, Cape Town, South Africa (EC004–2/2015), the University of Cape Town, Cape Town, South Africa (089/2015), and Oxford University, Oxford, UK (OxTREC_2–17).

Randomisation and masking

The Western Cape Department of Health is divided into a metro (urban) and rural health district. The Department of Health purposively selected 24 clinics (15 from the metro and nine from the rural health district) reflecting the geographic distribution and variability in size and organisation of clinics.[10] Facility Managers consented for their clinic to participate before random assignment. An independent statistician used a computer-generated sequence to centrally randomly assign (1:1:1) clinics, stratified by urban–rural status, to use either a designated care approach (designated group), a dedicated care approach (dedicated group), or treatment as usual (treatment as usual group). Investigators remained masked to the allocation. Masking of participants to their intervention was not possible; they were informed of their clinic's assignment during the consent process. CHWs delivering the intervention and study assessors collecting outcomes data functioned independently of each other. Study assessors were not masked to treatment allocation.

Procedures

Eligible patients were invited to an enrolment appointment in which the study assessor obtained written informed consent for trial participation before a computer-assisted baseline characteristics assessment of chronic disease treatment, depression, and alcohol use was done in English, Afrikaans, or isiXhosa (the official languages of the province). Self-reported information on socio-demographic factors (age, education, employment, relationship status, and frequency of hunger in last month) and perceived health status was also collected during this assessment. Participants provided whole blood samples for HIV viral load or $HbA1_c$ testing that were sent to a South African National Accreditation System-accredited laboratory for analysis.

After completing this assessment, counselling appointments were scheduled for participants at intervention clinics. All participants were asked to return for appointments at 6 months and 12 month after enrolment during which the baseline questionnaire was readministered and blood samples collected for repeated HIV viral load or $HbA1_c$ testing. Participants had a 30-day and 60-day window after their scheduled follow-up appointment dates to complete these assessments. Participants were reimbursed for their transport costs and given grocery vouchers for completion of the baseline (South African R100), 6 month follow-up (R120), and 12 month follow-up (R150) assessments. Activities occurred in private spaces within the clinics.

Participants recruited from the eight treatment as usual 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.[9] With variable implementation of standard care,[10] we offered all participants a list of mental health and substance use services within their health subdistrict and a referral to their choice of service provider.

Patient, provider, and stakeholder consultations informed the development of the designated and dedicated intervention approaches,[9,10,17] which were refined after feasibility testing.[18] Clinics assigned to the dedicated and designated approaches delivered the identical intervention programme, 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 programme in addition to their other chronic disease-associated responsibilities, such as health promotion and adherence support for HIV and non-communicable diseases.[13] In the dedicated group, an additional CHW was

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Delivery agents	Facility-based CHWs who had completed high school and trained to provide HIV adherence counselling
Structure of intervention package	Three sessions of MI and PST, with an optional booster session, to be delivered weekly
Content	
Session 1	• Provide feedback on mental health assessment • Educate about the effect of depression and alcohol use on chronic disease • Use MI techniques to build rapport and develop readiness to change • Develop a change plan • Describe take-home activity 1
Session 2	• Patient check-in using MI • Review activities from session 1 • Build the rationale for PST • Teach the steps of PST • Problem-busting exercises • Describe take-home activity 2
Session 3	• Patient check-in using MI • Review activities from session 2 • Coping with negative thoughts: how to cope with problems that are not important • Advance process of acceptance: how to deal with problems that are important and cannot be solved • Problem-busting exercise
Booster session	• Patient check-in using MI • Review of previous activities • Problem-busting exercise
Facility-based CHW Training	
Trainers	• Two registered psychological counsellors with a 4-year psychology qualification and registered with the Health Professions Council of South Africa • 3 years of experience in delivering MI-PST and training health-care workers • Training oversight and support provided by a psychologist with a doctoral qualification and 10 years previous experience in MI-PST
Training structure and format	• 40 h of formal training designed to align with current Western Cape Department of Health approaches to training facility-based CHWs in new practices and guidelines changes • Mixture of didactic teaching and experiential activities (skills rehearsal exercises and role plays) • Counselling proficiency assessed during role plays using a counselling fidelity checklist • Knowledge, attitudes, beliefs, and practices around counselling assessed pretraining and post-training • Booster training targeting MI-PST skills provided to all CHWs 1 month after formal training
Training content	• Information on depression and alcohol use disorder, diabetes, and HIV • Basic communication skills • Screening patients for depression and alcohol use disorder • MI skills • PST skills • Delivery of the MI-PST intervention • Ethics: managing distressed participants and referral for additional care
Characteristics of supervisor	• 5 years' experience in delivering brief cognitive-behavioural therapy • 3 years' experience in delivering MI-PST and training health-care workers • Registered with the Professional Board for Psychology and the Health Professions Council of South Africa
Structure of supervision and debriefing	• Weekly in-person or telephonic individual supervision and debriefing • Mobile telephone messaging to address challenges in real time between scheduled supervision sessions • CHWs provided with structured feedback on their proficiency using an intervention fidelity checklist • Brief skills rehearsal exercises or role-playing used to improve aspects of intervention delivery with average-to-low scores on the fidelity checklist
Supervisor training and support	• Trained to use a structured approach to supervision • Weekly in-person or telephonic supervision provided by a psychologist who assessed adherence to the supervision approach and discussed ways of overcoming challenges to provision of supervision and debriefing

Figure 1: **Overview of the intervention and CHW training**
More details on the take home activities are available in the protocol. CHWs=community health workers. MI=motivational interviewing. PST=problem-solving therapy.

added to the pool of CHWs in the chronic disease team.[16] The main task of this dedicated CHW was the delivery of the MIND programme. Dedicated and designated CHWs were matched on education level, counselling experience, remuneration, and conditions of service.[13]

Participants recruited from the 16 intervention clinics were offered the MIND programme and additional referrals if required. This manualised programme comprised three intervention sessions based on motivational interviewing and problem-solving therapy with the option of a booster session. Each session was 45–60 min in duration, with sessions scheduled at least a week apart. This intervention was selected because it is transdiagnostic and has effectively reduced risk for a range of disorders, including severity of depression and alcohol use.[23,24] Transdiagnostic interventions are more efficient to implement in busy under-resourced settings than multiple condition-specific interventions.[16]

In brief, the intervention focused on motivating participants to engage in the intervention and teaching strategies for coping with stress and life problems, which are known risk factors for depression, alcohol use disorders, and suboptimal chronic disease management (figure 1).[23,25] The intervention was aided by a participant handbook that summarised each session and included practice activities. Participants had 6 weeks to complete the intervention.

CHWs in both intervention groups received the same amount of training, supervision, and support.[13] To enhance feasibility, our training and supervision model (figure 1) was designed to align with the Western Cape Department of Health's CHW training approach.[10,13] All CHWs had received previous training in chronic disease adherence counselling and generic counselling skills. During Project MIND, CHWs completed 40 h 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 Health Professions Council of South Africa (HPCSA)-registered psychological counsellors with experience in delivering the programme. Role-plays and observations assessed CHWs' proficiency in delivering the programme.

CHWs audio-recorded the intervention sessions of consenting participants. To enable adequate assessment of intervention quality for both depression and alcohol use across both HIV and diabetes cohorts, we planned to randomly select 320 participants from the 888 participants who completed one or more intervention sessions for

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quality assurance of their intervention sessions. The counselling supervisor was an HPCSA-registered psychological counsellor with 5 years of experience in providing motivational interviewing and problem-solving therapy. The supervisor used an intervention delivery checklist to assess treatment-specific competencies (fidelity) including use of motivational interviewing principles and problem-solving therapy techniques. A South African version of the ENhancing Assessment of Common Therapeutic (ENACT) factors checklist assessed general counselling competencies.[26] During weekly individual supervision, the supervisor provided feedback on ways to enhance fidelity and improve counselling quality.

Outcomes

All outcomes were measured at the individual level. Primary outcome were the changes in depression and alcohol use severity from baseline to 12 month follow-up. The primary outcomes were measured separately in people with HIV and those with diabetes. Changes in these primary outcomes were assessed at 6-months follow-upas a prespecified secondary endpoint. Depression severity was assessed via composite scores on the 20-item CES-D:[23] scores ranged from 0 to 60; higher scores indicated more severe depressive symptoms. A score of 16 or more indicated clinically relevant symptoms.[23] Alcohol use severity was assessed using composite scores of the AUDIT.[24] For this 10-item scale, scores ranged from 0 to 40; higher scores indicated more severe alcohol use. An AUDIT score of eight or more indicated hazardous use and a scores of 16 or more indicated a possible alcohol use disorder.[24]

Prespecified secondary outcomes were changes in medication adherence, chronic disease control, and perceived health. A visual analogue scale assessed the self-reported percentage of medication adherence over a 30-day timeframe separately for people with HIV and those with diabetes. Visual analogue scale scores were dichotomised into optimal (≥90%) and suboptimal (<90%) adherence.[27] HIV disease control was assessed through changes in the proportion of participants with a viral load of less than 40 copies per mL (considered an indicator of good control) and of 1000 copies per mL or more (indicating poor control).[28] Diabetes disease control was assessed through changes in the proportion of participants with $HbA1_c$ levels of 7·0% or more, indicating poor glycaemic control.[29] The visual analogue scale associated with the EuroQol 5D-3L assessed perceived health status. Scores range from 0 to 100; higher scores indicated better perceived health. Information on adverse events, including death and hospitalisation were collected at each participant contact point.

Statistical analysis

The study was powered to detect changes in mean AUDIT and CES-D scores at 12 month follow-up. The sample size was calculated to account for two primary outcomes for separate analyses of people with diabetes and those with HIV, showing a difference between the three treatment groups using two-sided tests at an α of 0·05 and 90% power. For the assessment of alcohol use, we were powered to detect a 3-unit difference between the three treatment groups (SD 6·5). For this specification, we calculated requiring eight clinics per group (24 in total) with a cluster size of 20 participants per disease per clinic. For the assessment of depression, we powered the trial to detect a 5-unit difference between the groups (SD 10·1). For this specification, we estimated needing seven clinics per group (21 in total) with a cluster size of 20 participants per disease cohort per clinic. To account for a worst case scenario of 20% attrition, we inflated the cluster size to 25 participants per disease cohort. Consequently, we estimated that a sample size of eight clinics per group, with a cluster size of 25 participants with HIV and 25 with diabetes would meet the inference requirements of the trial.

For each cluster, we examined the number of participants who were eligible based on the CES-D and the AUDIT scores after reaching this recruitment target. Most clusters reached their targets for depression but under-recruited for alcohol use. In the under-recruited clusters, we continued to recruit participants with AUDIT scores of eight or more until we reached the required number of 25 participants.

A statistical analysis plan was finalised before analysis. Participants' baseline characteristics were summarised using mean and standard deviation (SD) for continuous variables and frequency and percentage for binary variables. In post-hoc analyses, we used χ^2 tests to explore whether intervention exposure differed by intervention group. Assessment of the primary and secondary outcomes were conducted according to the intention-to-treat principle. The trial statistician (CJL), masked to the intervention allocation, assessed the extent of missing data before the planned analyses. Missing data were scarce and treated as missing at random, with no imputation of the primary endpoint. Binomial regression models (using the sandwich variance estimator) were done to identify variables associated with attrition at 12 months follow-up.

Mixed-effect linear regression models examined mean differences in the primary outcome profiles separately for each disease cohort and via a pooled analysis of the disease cohorts. Analysis of alcohol use was restricted to participants with a baseline AUDIT score of eight of more and analysis of depression was restricted to participants with baseline CES-D scores of 16 or more. With only 24 clusters, we used the Satterthwaite approach to control for type 1 error. Regression models were fit using maximum likelihood. In all models, clusters and participants were considered as random effects to account for clustering at the clinic level and repeated measures within participants. Fixed effects included time (as a

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categorical variable), an intervention effect with two indicator variables for the intervention groups, and the interaction between the intervention and time variables. Intervention effects and 95% CIs were estimated for three comparisons: the dedicated group versus the treatment as usual group; the designated group versus the treatment as usual group; and the dedicated group versus the designated group. Urban–rural stratification and baseline factors associated with higher attrition at 12 month follow-up (sex, hunger, and poor disease control; appendix p 1) were included as fixed effects to adjust for missing data. We also adjusted for the co-occurrence of HIV and diabetes in analyses of the separate disease cohorts. For secondary outcomes, binomial regression models examined change in the proportion of participants with optimal adherence and poor disease control and mixed-effect linear regression for perceived health. Mixed-effect linear regression models also examined change in mean HIV and diabetes medication adherence scores in post-hoc analyses.

See Online for appendix

Data were analysed using Stata SE (version 16.1). We used the Benjamini-Hochberg procedure to adjust for multiple comparisons (n=24) of the two primary outcomes within the two study populations. An adjusted p value of 0·035 was considered statistically significant, with a false discovery rate of 10%.

The trial is registered with the Pan African Clinical Trials Registry, PACTR201610001825403. A trial steering committee, which included an independent statistician and clinicians, oversaw the study.

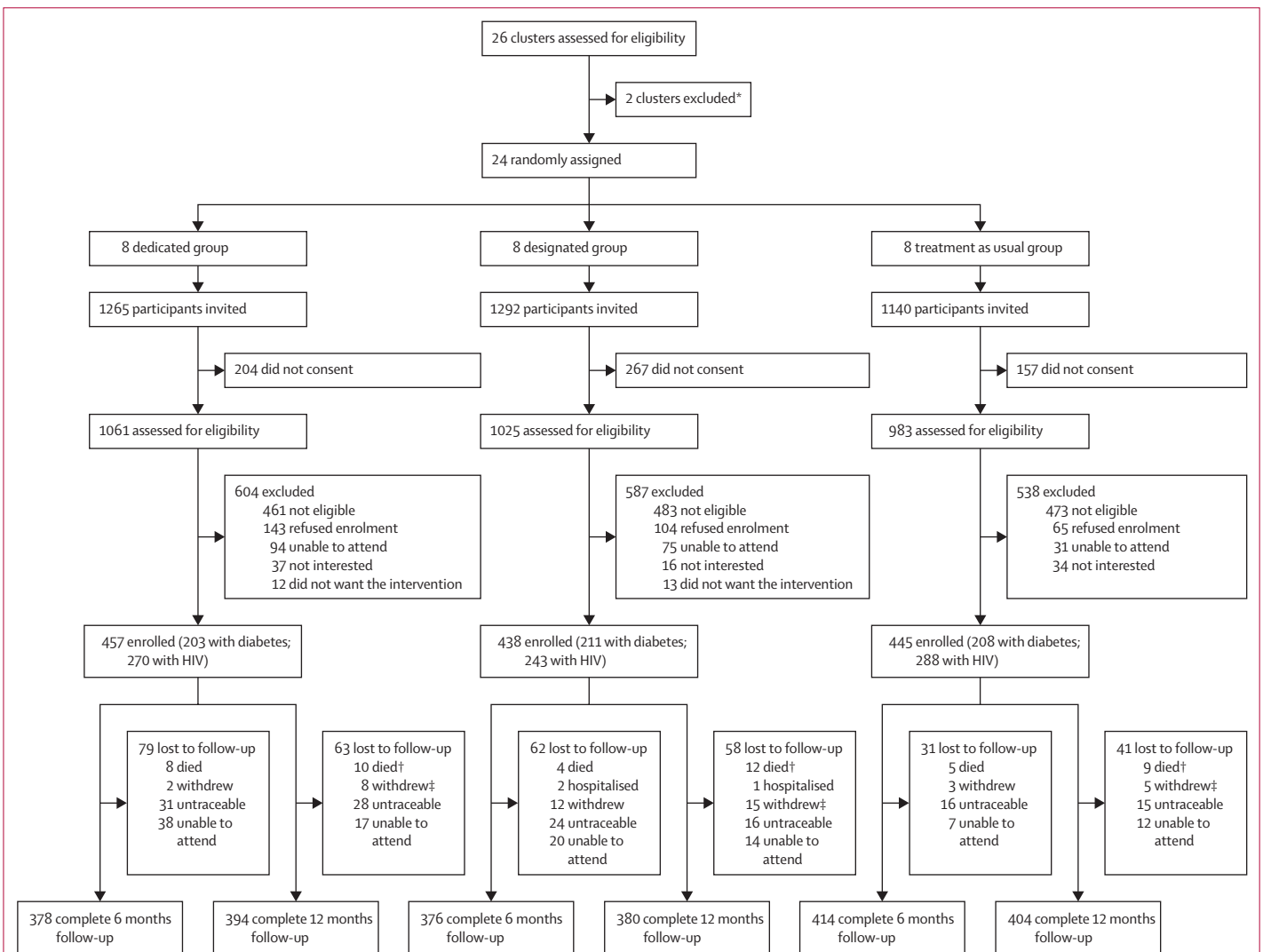

Figure 2: **Trial profile**

*Two clusters were excluded because other mental health interventions were offered at these centres, and they were contamination risks. †Cumulative deaths (ie, the number of people who died before follow-up at 6 months plus those who died between the 6 month and 12 month follow-up visits). ‡Cumulative withdrawals (ie, the number of people who withdrew before follow-up at 6 months plus those who withdrew between the 6 month and 12 month follow-up visits).

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Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, writing of the report, or the decision to submit for publication.

Results

Between May 1, 2017, and March 31, 2019, 3697 individuals were referred for screening of whom 3069 (83·0%) consented to eligibility screening. Of those who consented, 1652 (53·8%) met the eligibility criteria, and 1340 (81·1%; 801 with HIV; 622 with diabetes) were enrolled (457 [34·1%] in the dedicated group, 438 [32·7%] in the designated group, and 445 [33·2%] in the treatment as usual group; figure 2). Participants' mean age was 46·0 years (SD 12·8), 1019 (76·0%) were women and 321 (24·0%) were men, 167 (12·5%) had completed high school, 733 (54·7%) were unemployed, and 441 (32·9%) reported often experiencing hunger in the month before enrolment. 162 (20·2%) of 801 people with HIV had poorly controlled disease; 502 (80·7%) of 622 people with diabetes had poorly controlled disease. Compared with the intervention groups, participants in the treatment as usual group were less likely to be a man or experience hunger often (table 1). During the trial we trained 13 dedicated CHWs and 18 designated CHWs. On average, there were 24·2 (SD 15·9) participants per CHW in the dedicated group and 19·9 (18·3) participants per CHW in the designated group.

Across both intervention groups, 662 (74%) of 895 participants completed the MIND programme (347 [76%] of 457 participants in the dedicated group; 315 [72%] of 438 participants in the designated group). Across both groups, seven (1%) participants had no intervention exposure, 888 (99%) completed one session, and 796 (89%) completed two sessions. Degree of intervention exposure did not differ by intervention group (χ^2 2·41 [degrees of freedom 2]; p=0·44).

Assessment of intervention quality showed that facility-based CHWs had high levels of treatment-specific (89·7%) and general counselling competencies (85·2%).

	Overall study group (n=1340)			People with HIV (n=801)			People with diabetes (n=632)		
	Dedicated group (n=457)	Designated group (n=438)	TAU group (n=445)	Dedicated group (n=270)	Designated group (n=243)	TAU group (n=288)	Dedicated group (n=203)	Designated group (n=221)	TAU group (n=208)
Age (years)	44 (12·4)	47 (13·6)	44 (12·2)	39 (10·2)	39 (10·9)	40 (9·6)	54 (9·9)	55 (10·9)	57 (11·5)
Sex									
Male	95 (21%)	111 (25%)	115 (26%)	48 (18%)	68 (28%)	68 (24%)	49 (24%)	45 (20%)	50 (24%)
Female	362 (79%)	327 (75%)	330 (74%)	222 (82%)	175 (72%)	211 (73%)	154 (76%)	166 (75%)	158 (76%)
Significant other									
Yes	177 (39%)	171 (39%)	172 (39%)	78 (29%)	73 (30%)	97 (34%)	104 (51%)	101 (46%)	97 (47%)
No	280 (61%)	267 (61%)	273 (61%)	192 (71%)	170 (70%)	191 (66%)	99 (49%)	110 (50%)	111 (53%)
Level of education									
Primary school	148 (32%)	166 (38%)	123 (28%)	71 (26%)	74 (30%)	64 (22%)	85 (42%)	93 (42%)	75 (36%)
Some high school	258 (56%)	234 (53%)	244 (55%)	169 (63%)	149 (61%)	168 (58%)	96 (47%)	99 (45%)	101 (49%)
Completed high school	51 (11%)	38 (9%)	78 (18%)	32 (11%)	20 (8%)	56 (19%)	22 (11%)	19 (9%)	32 (15%)
Frequency of hunger in last month									
Seldom	264 (58%)	301 (69%)	334 (75%)	142 (53%)	145 (60%)	206 (72%)	131 (65%)	164 (74%)	168 (81%)
Often	193 (42%)	137 (31%)	111 (25%)	128 (47%)	98 (40%)	82 (28%)	72 (35%)	47 (21%)	40 (19%)
Employed									
No	250 (55%)	249 (57%)	234 (53%)	171 (63%)	168 (69%)	169 (59%)	86 (42%)	94 (43%)	92 (44%)
Yes	207 (45%)	189 (43%)	211 (47%)	99 (37%)	75 (31%)	119 (41%)	117 (58%)	117 (53%)	116 (56%)
CES-D score*	30·9 (8·9)	32·3 (9·8)	27·9 (8·5)	31·4 (9·4)	32·5 (9·9)	28·4 (8·4)	30·2 (8·0)	31·8 (9·7)	27·9 (9·1)
AUDIT score†	19·7 (7·4)	19·6 (7·1)	19·4 (7·0)	20·7 (7·5)	20·1 (7·2)	20·2 (7·0)	13·6 (7·6)	15·3 (8·8)	13·5 (7·1)
Perceived health	77·4 (19·7)	74·9 (20·5)	84·6 (24·3)	78·4 (19·8)	76·7 (21·4)	85·6 (18·4)	75·5 (20·5)	71·8 (20·3)	83·0 (29·6)
Self-reported adherence >90%‡	..	..	..	179 (66%)	171 (70%)	215 (75%)	121 (60%)	150 (68%)	205 (99%)
Poor disease control§									
No	..	..	..	207 (77%)	197 (81%)	235 (82%)	36 (18%)	38 (17%)	46 (22%)
Yes	..	..	..	63 (23%)	46 (19%)	53 (18%)	167 (82%)	173 (78%)	162 (78%)

Data are n (%) or mean (SD). AUDIT=Alcohol Use Disorder Identification Test. CES-D=Centre for Epidemiological Studies Depression Scale. TAU=treatment as usual. *CES-D score calculated for participants with CES-D screening scores ≥16. †AUDIT score calculated for participants with AUDIT screening scores ≥8. ‡Self-reported adherence (%) to either HIV or diabetes medication over last 30 days. §Poor disease control defined as HIV viral load of 1000 copies per mL or more for HIV and HbA1$_c$ levels of 7 or more for diabetes.

Table 1: **Baseline characteristics of participants for the overall sample, for people with HIV, and people with diabetes by study group**

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All clusters and participants were followed up at 6 months and 12 months. 1167 (87%) of 1340 participants were assessed at 6 months follow-up (378 [83%] of 457 participants in the dedicated group; 376 [86%] of 438 participants in the designated group; and 414 [93%] of 445 participants in the treatment as usual group). At 12 months follow-up, 1174 (88%) participants were assessed (394 [86%] in the dedicated group; 380 [87%] in the

	Distribution across study groups			Mixed model analysis					
	Dedicated group* (n=270)	Designated group* (n=243)	TAU group* (n=288)	Dedicated group *vs* TAU group	p value	Designated group *vs* TAU group	p value	Dedicated group *vs* designated group	p value
CES-D (n=640)†‡§¶									
Baseline	29·79 (1·20)	31·75 (1·18)	27·96 (1·20)	..	..	..	..	..	..
6 months	9·57 (1·25)	14·34 (1·22)	14·50 (1·23)	−4·96 (−7·47 to −2·45)	<0·0001	−2·76 (−5·28 to −0·26)	0·031	−2·20 (−0·34 to 4·73)	0·090
12 months	9·46 (1·25)	11·28 (1·21)	12·36 (1·25)	−5·02 (−7·51 to −2·54)	<0·0001	-6·38 (−8·89 to −3·88)	<0·0001	−1·36 (−3·85 to 1·13)	0·29
AUDIT (n=519)†‡§‖									
Baseline	20·38 (0·71)	20·00 (0·73)	20·00 (0·70)	..	..	..	..	..	..
6 months	8·84 (0·78)	10·47 (0·80)	11·58 90·75)	−3·12 (−5·02 to −1·21)	0·0014	−1·10 (−3·05 to 0·86)	0·27	2·00 (−0·04 to 4·05)	0·055
12 months	9·18 (0·76)	8·62 (0·78)	10·24 (0·74)	−1·45 (−3·42 to 0·53)	0·15	−1·60 (−3·62 to 0·42)	0·17	−0·19 (−2·16 to 1·78)	0·85
Perceived health CES-D ≥16†									
Baseline	77·65 (2·00)	75·81 (2·01)	82·70 (2·03)	..	..	..	..	..	..
6 months	86·75 (2·08)	80·11 (2·07)	86·52 (2·05)	5·27 (0·75 to 9·79)	0·022	0·48 (−4·04 to 5·01)	0·84	−4·79 (−9·35 to −0·23)	0·040
12 months	87·79 (2·06)	85·71 (2·07)	87·57 (2·07)	5·26 (0·73 to 9·78)	0·023	5·02 (0·44 to 9·59)	0·031	−0·24 (−4·78 to 4·30)	0·92
Perceived health AUDIT ≥8									
Baseline	78·23 (1·75)	78·38 91·80)	87·37 (1·74)	..	..	..		..	..
6 months	86·52 (1·85)	83·34 (1·89)	89·66 (1·77)	6·00 (1·22 to 10·79)	0·014	2·67 (−2·24 to 7·57)	0·29	−3·34 (−8·37 to 1·70)	0·19
12 months	87·63 (1·84)	87·64 (1·88)	88·69 (1·80)	8·08 (3·28 to 12·89)	0·0012	7·93 (3·02 to 12·85)	0·0022	−0·14 (−5·14 to 4·85)	0·95
Self-reported ART adherence >90%†† **									
Baseline	66·20 (3·74)	70·31 (5·75)	74·92 (4·31)	..	..	..	..	..	..
6 months	66·88 (3·07)	64·06 (5·29)	66·40 (4·91)	−0·48 (−11·90 to 10·94)	0·93	2·34 (−11·91 to 16·60)	0·75	−2·82 (−14·87 to 9·21)	0·65
12 months	79·35 (4·69)	81·83 (1·89)	84·04 (3·49)	4·72 (−6·98 to 16·44)	0·43	2·21 (−5·65 to 10·07)	0·58	2·51 (−7·57 to 12·59)	0·63
Viral load ≤40 copies per mL†††‡‡**									
Baseline	61·48 (4·09)	61·07 (3·40)	65·71 (2·83)	..	..	..	..	..	..
6 months	70·32 (3·67)	62·64 (3·59)	71·50 (3·58)	3·05 (−3·42 to 9·53)	0·36	−4·24 (−12·55 to 4·06)	0·32	7·29 (0·63 to 14·00)	0·032
12 months	64·73 (4·35)	64·21 (3·07)	67·90 (3·37)	0·98 (−5·37 to 7·33)	0·76	0·89 (−5·74 to 7·52)	0·79	−0·09 (−6·84 to 6·67)	0·98
Viral load ≥1000 per mL†††‡‡**									
Baseline	23·32 (2·63)	19·26 (2·54)	18·72 (2·33)	..	..	..	..	..	..
6 months	18·69 (3·11)	28·03 (2·64)	17·08 (2·35)	−3·13 (9·69 to 3·42)	0·35	10·35 (4·41 to 16·29)	0·0011	−13·48 (−19·47 to −7·49)	<0·0001
12 months	23·94 (2·71)	19·36 (2·39)	18·72 (2·48)	−1·08 (−7·42 to 5·25)	0·74	6·39 (−1·47 to 14·26)	0·11	7·48 (−0·31 to 15·27)	0·060

AUDIT=alcohol use disorders identification test. CES-D=Center for Epidemiologic Studies Depression Scale. TAU=treatment as usual group. *Data are mean (SE). †Data are adjusted mean difference (95% CI). ‡Mixed effect linear regression models adjusted for rural or urban location of cluster, sex, hunger, and poor disease control (viral load ≥1000 copies per mL). §The adjusted p value for multiple comparisons is 0·035 based on the Benjamini-Hochberg procedure for a false discovery rate of 10%. ¶CES-D intervention effect calculated for participants with CES-D scores of 16 or more on enrolment. ‖AUDIT intervention effect calculated for participants with AUDIT scores of eight or more on enrolment. **Data are adjusted risk difference (95% CI). ††Intervention effects assessed using generalised linear model (binomial regression) adjusted for rural or urban location of cluster, sex, and hunger; results reported as difference in change in proportions between study groups from baseline to specified endpoint. ‡‡Viral load of 1000 per mL or more indicate poor disease control, viral load of 40 copies per mL or less indicates good control.

Table 2: **Intervention effects in participants with HIV**

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	Distribution across study groups					Mixed model analysis			
	Dedicated group* (n=203)	Designated group* (n=221)	TAU group* (n=208)	Dedicated group *vs* TAU group	p value	Designated group *vs* TAU group	p value	Dedicated group *vs* designated group	p value
CES-D (n=552)†‡§¶									
Baseline	29·55 (1·20)	31·82 (1·18)	28·06 (1·20)	..	..	..	..	..	..
6 months	9·74 (1·24)	14·26 (1·21)	14·42 (1·22)	−6·17 (−8·61 to −3·73)	<0·0001	-3·92 (-6·30 to −1·15)	0·0014	2·27 (−0·24 to 4·71)	0·066
12 months	9·56 (1·24)	11·24 (1·21)	12·27 (1·24)	−4·20 (−6·68 to −1·72)	<0·0001	-4·80 (-7·21 to −2·39)	<0·0001	−0·63 (−3·04 to 1·77)	0·63
AUDIT (n= 170)†‡§‖									
Baseline	16·58 (0·71)	18·58 (0·74)	15·77 (0·72)	..	..	..	..	..	..
6 months	4·60 (0·82)	6·54 (0·84)	6·54 (0·76)	−2·75 (−5·31 to −0·19)	0·035	−2·80 (−5·41 to −0·19)	0·035	−0·05 (−2·71 to 2·60)	0·97
12 months	4·53 (0·85)	6·29 (0·86)	5·45 (0·86)	−1·73 (−4·38 to 0·92)	0·20	−1·97 (−4·65 to 0·71)	0·15	−0·23 (−2·93 to 2·46)	0·87
Perceived health: CES-D ≥16†									
Baseline	74·48 (2·33)	71·08 (2·09)	79·17 (2·33)	..	..	..	..	..	..
6 months	84·22 (2·40)	78·97 (2·34)	85·92 (2·37)	2·99 (−1·82 to 7·79)	0·22	1·14 (−3·53 to 5·82)	0·63	−1·84 (−6·58 to 2·89)	0·45
12 months	84·77 (2·41)	82·95 (2·35)	89·69 (2·41)	−0·23 (−5·14 to 4·67)	0·93	1·35 (−3·42 to 6·12)	0·58	1·58 (−3·16 to 6·33)	0·51
Perceived health: AUDIT ≥8†									
Baseline	79·15 (2·35)	72·54 (2·41)	86·34 (2·40)	..	..	..	..	..	..
6 months	88·75 (2·56)	82·34 (2·60)	91·57 (2·45)	4·38 (−3·24 to 12·01)	0·26	4·58 (−3·20 to 12·35)	0·25	0·20 (−7·71 to 8·11)	0·96
12 months	90·26 (2·54)	86·93 (2·53)	92·39 (2·52)	5·07 (−2·61 to 12·76)	0·20	8·35 (0·57 to 16·13)	0·035	3·28 (−4·53 to 11·08)	0·41
Self-reported adherence >90%†† **									
Baseline	59·61 (4·28)	70·93 (6·07)	73·47 (4·49)	..	..	..	..	..	..
6 months	76·42 (7·39)	81·63 (4·64)	78·81 (6·97)	2·39 (−17·30, 22·07)	0·81	−2·82 (−18·95 to 13·30)	0·73	5·21 (−11·95 to 21·95)	0·54
12 months	79·21 (9·11)	86·54 (3·73)	84·59 (5·82)	5·38 (-15·52, 25·38)	0·61	−1·94 (−15·02 to 11·13)	0·77	7·32 (−11·32 to 25·97)	0·44
HbA1$_c$ level ≥7†††‡‡**									
Baseline	82·27 (2·53)	81·99 (3·47)	77·99 (3·38)	..	..	..	..	..	..
6 months	76·02 (3·04)	80·11 (3·03)	77·08 (4·06)	1·06 (−8·87, 10·99)	0·83	−3·03 (−12·95 to 6·90)	0·55	4·09 (−4·32 to 12·49)	0·34
12 months	78·44 (2·81)	77·90 (2·11)	78·74 (3·81)	0·29 (−8·98, 9·96)	0·95	0·84 (−7·69 to 9·36)	0·85	-0·54 (−7·43 to 6·34)	0·88

AUDIT=alcohol use disorders identification test. CES-D=Center for Epidemiologic Studies Depression Scale. TAU=treatment as usual. *Data are mean (SE). †Data are adjusted mean difference (95% CI). ‡Mixed effect linear regression models adjusted for rural or urban location of cluster, sex, hunger, and poor disease control (viral load ≥1000 copies per mL). §The adjusted p value for multiple comparisons is 0·035 based on the Benjamini-Hochberg procedure for a false discovery rate of 10%. ¶CES-D intervention effect calculated for participants with CES-D scores of 16 or more on enrolment. ‖AUDIT intervention effect calculated for participants with AUDIT scores of eight or more on enrolment. **Data are adjusted risk difference (95% CI). ††Intervention effects assessed using generalised linear model (binomial regression) adjusted for rural or urban location of cluster, sex, and hunger; results reported as difference in change in proportions between study groups from baseline to specified endpoint. ‡‡HbA1$_c$ level of 7% or more indicates poor glycaemic control.

Table 3: **Intervention effects in participants with diabetes**

designated group; and 404 [91%] in the treatment as usual group). Most participants lost to follow-up were untraceable because they had moved. Participants lost to follow-up were more likely to be a man, report often experiencing hunger, and have poor disease control (HbA1$_c$ of ≥7% for people with diabetes and viral load ≥1000 for people with HIV) than those who were retained (appendix p 1).

From baseline to the 12 month follow-up, the dedicated group had greater reductions in mean CES-D scores than did the treatment as usual group for people with HIV (table 2) and people with diabetes (table 3), and the pooled cohort (table 4). The designated group also had greater reductions in CES-D scores than did the treatment as usual group for people with HIV (table 2), people with diabetes (table 3), and the pooled cohort (table 4). 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

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	Distribution across study groups			Mixed model analysis					
	Dedicated group* (n=457)	Designated group* (n=438)	TAU group* (n=445)	Dedicated group *vs* TAU group†	p value	Designated group *vs* TAU group†	p value	Dedicated group *vs* designated group†	p value
CES-D (n=1119)‡									
Baseline	30·25 (1·09)	32·29 (1·08)	27·94 (1·10)	..	..	..	..		..
6 months	11·33 (1·13)	15·61 (1·12)	14·94 (1·14)	−5·92 (−7·73 to −4·91)	<0·0001	−3·92 (−6·30 to −1·15)	<0·0001	−2·24 (−4·01 to −0·48)	0·013
12 months	11·44 (1·12)	12·57 (1·12)	14·68 (1·14)	−5·55 (−7·36 to −3·74)	<0·0001	−6·45 (−8·26 to −4·65)	<0·0001	−0·91 (−2·66 to 0·85)	0·31
AUDIT (n= 663)§									
Baseline	19·50 (0·67)	19·47 (0·69)	19·29 (0·67)	..	..	..	..		..
6 months	7·73 (0·71)	9·64 (0·73)	10·66 (0·70)	−3·14 (−4·74 to −1·53)	<0·0001	−1·19 (−2·84 to 0·46)	0·16	−1·94 (−3·64 to −0·26)	0·025
12 months	7·96 (0·70)	8·12 (0·71)	9·49 (0·69)	−1·75 (−3·41 to −0·09)	0·038	−1·56 (−3·27 to 0·14)	0·072	0·18 (−1·46 to 1·82)	0·83
Perceived health status: CES-D ≥16¶									
Baseline	74·45 (2·32)	71·03 (2·29)	79·20 (2·33)	..	..	..	..		..
6 months	84·19 (2·39)	78·93 (2·34)	85·95 (2·36)	2·99 (−1·80,7·78)	0·22	1·15 (−3·51 to 5·81)	0·63	−1·84 (−6·56 to 2·88)	0·44
12 months	84·59 (2·37)	82·82 (2·33)	88·96 (2·37)	0·29 (−4·47,5·05)	0·91	2·03 (−2·62 to 6·69)	0·39	1·74 (−2·91 to 6·39)	0·46
Perceived health status: AUDIT ≥8‖									
Baseline	79·33 (2·30)	72·07 (2·37)	86·08 (2·35)	..	..	..	..		..
6 months	89·13 (2·57)	91·25 (2·40)	90·52 (2·42)	4·63 (−3·05,12·31)	0·24	4·95 (−2·87 to 12·78)	0·22	0·32 (−7·64 to 8·29)	0·94
12 months	90·52 (2·48)	87·11 (2·48)	91·24 (2·42)	6·03 (−1·52,13·58)	0·12	9·88 (2·14 to 17·61)	0·012	3·85 (−3·87 to 11·56)	0·33

AUDIT=alcohol use disorders identification test. CES-D=Center for Epidemiologic Studies Depression Scale. TAU=treatment as usual. *Data are mean (SE). †Data are adjusted mean difference (95% CI). ‡Mixed effect linear regression models adjusted for rural or urban location of cluster, sex, hunger, and poor disease control (viral load ≥1000 copies per mL). §AUDIT intervention effect calculated for participants with AUDIT scores of eight or more on enrolment.¶CES-D intervention effect calculated for participants with CES-D scores of 16 or more on enrolment. ‖AUDIT intervention effect calculated for participants with AUDIT scores of eight or more on enrolment.

Table 4: **Intervention effects in the pooled cohort**

(table 4). This difference dissipated at 12 months follow-up (table 4).

From baseline to 12 months follow-up, reductions in AUDIT scores were similar across study groups (tables 2, 3, and 4). At 6 months follow-up, mean AUDIT scores reduced more in the dedicated group compared with the treatment as usual group for people with HIV (table 2), people with diabetes (table 3), and the pooled cohort (table 4). In the pooled cohort, greater reductions in mean AUDIT scores were observed in the dedicated group compared with the designated group (table 4).

No intervention effects were observed for the proportion of participants reporting optimal adherence to their ART medication regime in people who had HIV (table 2). As a post-hoc sensitivity analysis, we compared change in mean adherence scores from baseline to 12 month follow-up. No differences were observed between the treatment as usual group and the dedicated group (AMD 2·66 [95% CI −1·63 to 6·96]; p=0·22) or the designated group (−2·17 [−6·59 to 2·25]; p=0·34; appendix p 2). There was no evidence of an intervention effect for HIV disease control: the proportion of participants with viral loads of 40 copies per mL or less and 1000 copies per mL or more remained relatively unchanged in each group (table 2).

Similar findings were found in people with diabetes (table 3). No intervention effects were observed for the proportion of participants reporting optimal diabetes medication adherence. When we compared change in mean adherence scores from baseline to 12 month follow-up, there were no differences between the treatment as usual group and the dedicated group (AMD 2·41 [95% CI −0·97 to 5·81]; p=0·17) or the designated group (0·52 [−2·82 to 3·85]; p=0·76; appendix p 3). Similarly, there was no evidence of an intervention effect for glycaemic control (table 3).

From baseline to 12 month follow-up, perceived health of participants assessed according to their CES-D scores improved more in the dedicated group (AMD 5·26 [95% CI 0·73–9·78]; p=0·023) and designated group (5·02 [0·44–9·59]; p=0·031; table 2) compared with the treatment as usual group for people with HIV. Compared with the treatment as usual group, perceived health of participants assessed according to their AUDIT scores improved more from baseline to

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12 months follow-up in people with HIV in the dedicated group (8·08 [3·28–12·89]; p=0·0012; table 2) and people with HIV in the designated group (7·93 [3·02–12·85]; p=0·0022; table 2), people with diabetes in the designated group (8·35 [0·57–16·13]; p=0·035; table 3), and the pooled cohort (9·88 [2·14–17·61]; p=0·012; table 4).

During the study, 31 (2·3%) of the 1340 participants died across all three groups; these deaths were unrelated to study involvement. No adverse events related to study participation were recorded.

Discussion

Our study compared the effectiveness of dedicated and designated approaches for CHW-delivered psychological interventions compared with treatment as usual for reducing depression and alcohol use symptom severity in people with HIV or diabetes in the Western Cape province of South Africa. The dedicated and designated approaches were equally effective in reducing depression symptom severity to below clinically significant levels, with each group outperforming treatment as usual at the 12 month endpoint in both people with HIV and those with diabetes after accounting for multiple hypothesis testing. Although spontaneous recovery might explain some reduction in depression severity scores, it cannot explain findings in favour of the intervention. By contrast, only the dedicated approach was more effective than treatment as usual at reducing alcohol severity at the 6 month endpoint for the separate disease cohorts.

Trial findings suggest that when adequately trained and supervised CHWs can effectively deliver psychological interventions in clinics with human and infrastructure resource constraints. These findings align with a Cochrane review, which found CHW-delivered interventions to be more effective than usual care for reducing depression (eight trials) and alcohol severity (five trials) in LMICs.[15] Included studies used either existing (designated) or employed additional (dedicated) CHWs to deliver the psychological intervention, but they did not compare the effectiveness of these approaches on patient outcomes. The 13 studies also did not target patient populations with chronic physical diseases and were restricted to short-term outcomes. To our knowledge, Project MIND is the first randomised trial to show that dedicated and designated approaches confer similar benefits for depression symptom severity, but the dedicated approach offers additional benefits for severity of alcohol use in patients receiving care for chronic diseases.

CHW stigma towards patients with alcohol use disorders[9,10] could explain why the dedicated approach leads to better alcohol outcomes. In our formative work, participants did not have confidence in the designated approach due to experiences of alcohol-related stigma from CHWs providing care for chronic diseases.[17] We also previously observed provider stigma towards patients using alcohol, particularly women and people with HIV.[10] Previous stigmatising interactions with designated CHWs could have diminished participants' motivation to change their alcohol use and engage with the MIND intervention. Dedicated CHWs had no shared history with MIND participants. Additional analyses to explore whether anticipated alcohol stigma mediates the effects of the intervention on alcohol use and whether this relationship is modified by sex and HIV status are planned.

Despite its additional benefits, the dedicated approach might need bolstering to sustain intervention gains. This was particularly evident for the alcohol outcome for which, in keeping with the literature,[14,15] intervention gains deteriorated with time. Expansion of the MIND programme to include relapse prevention content might help sustain initial alcohol reductions. Several evidence-based alcohol-focused interventions address relapse prevention, including counselling for alcohol problems.[30] With the normalisation of heavy alcohol use in South African communities,[18] participants are likely to need ongoing support to maintain behaviour change. The need for additional support might be heightened for participants with little family support for alcohol behaviour change. Analyses to explore whether social support and neighbourhood factors moderate the effects of the MIND programme on alcohol outcomes are ongoing.

Our findings on depression underscore the potential benefits of additional support. Although intervention gains were largely maintained in the dedicated approach, they improved over time in the designated approach in which CHWs continued to provide chronic disease support to participants. Together, these findings suggest that additional opportunities for patients to have supportive contact after completion of the initial MIND intervention programme might enhance the effectiveness of the dedicated approach for both depression and alcohol outcomes. Yet the best source of this support remains unclear. Additional research is needed to evaluate whether facility-based CHWs are best placed to provide this long-term support or whether investment in community-based peer support networks yield greater benefits for participants.

Of note, this trial found no direct effects on HIV or diabetes adherence and control. Unlike other interventions that have shown effects on disease adherence and control,[31] this trial was not designed to detect change in these outcomes because the MIND programme does not address medication adherence or disease management. Ceiling effects might also explain the null findings, given the high proportion of people with HIV and those with diabetes reporting optimal medication adherence and the high proportion of people with HIV with undetectable HIV viral load at baseline. Although ceiling effects cannot account for glycaemic control findings, several (unmeasured) factors other than adherence probably

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affected this trial's ability to detect change on $HbA1_c$, including nutrition, anaemia, and dyslipidaemia.[29]

Our trial has some limitations to consider, including the limited number of clusters. We were underpowered to detect change on alcohol outcomes for the separate disease cohorts. This precluded an examination of outcomes for participants with both high depression and alcohol use severity. Future studies should compare the effectiveness of the dedicated and designated approaches for people with comorbid depression and alcohol use disorders. We also did not record or control for the frequency of contact with CHWs between study groups or uptake of referrals for ongoing care, which might have influenced findings. Like similar trials,[14,15] participants and outcome assessors were unmasked, and the primary outcomes relied on self-report questionnaires, both of which are potential sources of bias. Future trials should consider supplementing self-report questionnaires with objective clinical assessments and biomarkers of alcohol consumption. However, our trial has several strengths. Generalisability is enhanced through the assessment of intervention effects for both depression and alcohol use disorders in separate cohorts of people with HIV and people with diabetes. Although most previous trials of CHW-delivered psychological interventions assessed outcomes at 6 months follow-up or less,[15] this trial assessed outcomes at 12 months, offering insights into the longer-term benefits of these approaches. Furthermore, we retained a large number of participants from low-income households despite sporadic community violence that disrupted health services.

Although the dedicated approach offered the broadest range of clinical benefits, understanding the mechanisms through which the MIND intervention changes depression and alcohol use outcomes could drive intervention enhancements. We plan to explore whether treatment readiness, self-efficacy, and problem-solving mediate the intervention's effects. Additional research is needed to guide decisions about whether and how to implement the dedicated approach at scale. Cost-effectiveness analyses (currently underway; expected to be published in 2023) are required to guide the health system in its investment decisions. Of note, the research team provided clinics in both intervention groups with extensive support (eg, support to promote uptake of the service, advocacy for prioritisation of the service, and daily support for staff implementing the service) to overcome implementation barriers (eg, scarcity of space to deliver counselling, mental health stigma, and low mental health literacy in clinics).[10,13] Regardless of whether a dedicated or designated approach is implemented, clinics require support to resolve these barriers. Research that evaluates strategies for optimising implementation could reveal the type and level of support required to scale CHW-delivered psychological interventions in LMICs. Additionally, a clinic-based intervention will not reach patients who disengage from chronic disease care. In 2020 the Western Cape Department of Health invested in community-oriented primary health-care teams of CHWs to enhance health equity.[32] These community-based CHWs could extend the programme's reach to out-of-care populations, but research is needed to establish the relative effectiveness of the dedicated and designated approaches for community contexts. Finally, we acknowledge that the qualifications and support of South African CHWs might differ from those in other LMICs. Additional trials of the dedicated and designated approach to CHW-delivered psychological interventions are needed to establish their relative feasibility, acceptability, and effectiveness in differently resourced health systems.

In conclusion, this trial extends evidence for CHW-delivered psychological interventions, offering insights into how different delivery approaches affect patient outcomes. Our findings should provide policy makers with the impetus to allocate additional resources to task-shared psychological interventions.

For the **projects website** see http://projectmind.mrc.ac.za

Contributors

BM and KRS designed the study with inputs from CJL, CL, DJS, NL, JAJ, and TN. PPW coordinated data collection with support from CJL, CvdW, KRS, and BM. KRS, PC, and BM were responsible for MIND intervention content, with KS supervising the project MIND trainer and supervisor. CJL and CvdW did all statistical analyses and data management. BM, KRS, CvdW, and CJL verified the underlying data. All authors had access to the data. All authors assisted in interpretation of results. BM wrote the first draft of the article. All authors contributed substantially to revising the article and approved submission.

Declaration of interests

JAJ reports payment to attend a Sanofi advisory committee meetings and payment for manuscript writing for Prudential Africa. TM was employed by the Western Cape Department of Health at the time of the study. DJS reports research grants or consultancy honoraria from Discovery Vitality, Johnson & Johnson, Kanna, L'Oréal, Lundbeck, Orion, Sanofi, Servier, Takeda, and Vistagen. All other authors declare no competing interests.

Data sharing

A data dictionary and deidentified participant data will be made available for individual patient data meta-analyses with publication of the trial after approval of a proposal and a signed data access agreement sent to the corresponding author. The project's approved study protocol, statistical analysis plan, data sharing plan, and template for requesting access to the data are available online.

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