Effectiveness of an intervention led by lay health counsellors for depressive and anxiety disorders in primary care in Goa, India (MANAS): a cluster randomised controlled trial

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Summary

Background Depression and anxiety disorders are common mental disorders worldwide. The MANAS trial aimed to test the effectiveness of an intervention led by lay health counsellors in primary care settings to improve outcomes of people with these disorders.

Methods In this cluster randomised trial, primary care facilities in Goa, India, were assigned (1:1) by computer-generated randomised sequence to intervention or control (enhanced usual care) groups. All adults who screened positive for common mental disorders were eligible. The collaborative stepped-care intervention offered case management and psychosocial interventions, provided by a trained lay health counsellor, supplemented by antidepressant drugs by the primary care physician and supervision by a mental health specialist. The research assessor was masked. The primary outcome was recovery from common mental disorders as defined by the International Statistical Classification of Diseases and Related Health Problems—10th revision (ICD-10) at 6 months. This study is registered with ClinicalTrials.gov, number NCT00446407.

Findings 24 study clusters, with an equal proportion of public and private facilities, were randomised equally between groups. 1160 of 1360 (85%) patients in the intervention group and 1269 of 1436 (88%) in the control group completed the outcome assessment. Patients with ICD-10-confirmed common mental disorders in the intervention group were more likely to have recovered at 6 months than were those in the control group (n=620 [65·0%] *vs* 553 [52·9%]; risk ratio 1·22, 95% CI 1·00–1·47; risk difference=12·1%, 95% CI 1·6%–22·5%). The intervention had strong evidence of an effect in public facility attenders (369 [65·9%] *vs* 267 [42·5%], risk ratio 1·55, 95% CI 1·02–2·35) but no evidence for an effect in private facility attenders (251 [64·1%] *vs* 286 [65·9%], risk ratio 0·95, 0·74–1·22). There were three deaths and four suicide attempts in the collaborative stepped-care group and six deaths and six suicide attempts in the enhanced usual care group. None of the deaths were from suicide.

Interpretation A trained lay counsellor-led collaborative care intervention can lead to an improvement in recovery from CMD among patients attending public primary care facilities.

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Introduction

Depressive and anxiety disorders (the so-called common mental disorders) are the leading neuropsychiatric cause of the global burden of disease and are associated with an increased risk of suicide, increased health-care costs, and reduced economic productivity.[1–4] The prevalence of these disorders varies substantially between primary care settings with a mean of 20% from a study of 14 countries,[5] but recognition of these disorders is poor, with less than a third of clinically significant cases identified.[6] Although evidence of the efficacy of antidepressant drugs and brief psychological treatments for common mental disorders has long been available,[7–11] there are several obstacles to providing effective interventions to real-world primary care settings in developing countries.[12–14] These obstacles include the low recognition rate of these disorders by primary care doctors, the inadequate use of antidepressant drugs or psychosocial treatments, and

low adherence to treatments. In a systematic review[15] of the constituents of collaborative care interventions for primary care management of these disorders, the use of routine screening, the professional skills of staff, and specialist supervision predicted a favourable outcome. Task shifting is an increasingly advocated method that can alleviate shortages in specialist health human resources.[16,17]

We undertook a cluster randomised controlled trial (MANAS; MANashanti Sudhar Shodh, which means "project to promote mental health" in Konkani) to systematically develop an intervention for common mental disorders that aimed to address these barriers in routine primary health care in Goa, India.[18] More than half of all primary care consultations in India take place in the private sector.[19] We aimed to assess the effectiveness of collaborative stepped-care interventions led by lay health counsellors on patients' recovery from common mental disorders in primary health-care

settings (both public primary health centre [PHC] and private general practitioner [GP] settings) in Goa, India.

Methods

Study design and patients

This cluster randomised controlled trial was done in two consecutive phases from April, 2007, to September, 2009, in 12 PHCs (phase 1) and in 12 GP facilities (phase 2). A randomised design with the health facility as the unit of randomisation was chosen to prevent contamination between individuals.

Adults older than 17 years were screened if: they spoke Konkani, Marathi, Hindi, or English; did not need urgent medical attention; did not have difficulty with hearing, speaking, or cognition, which could make interviewing difficult; had not already been screened in the previous 2 weeks; and were not already receiving the intervention. Those who screened positive for common mental disorders with the 12-item general health questionnaire (GHQ; with a previously validated cutoff score of >5)[20] and who expected to be resident in Goa for the subsequent 12 months were invited to participate in the trial. If the patient gave written consent (or verbal consent for illiterate individuals), a structured clinical diagnostic interview for use by trained lay interviewers (the revised clinical interview schedule [CIS-R])[21] was administered to provide a baseline assessment of severity and diagnostic categorisation.

Details about trial protocol approval and consent have been published previously.[22] The trial was approved by the Institutional Review Boards of the London School of Hygiene and Tropical Medicine and Sangath, the Indian Council of Medical Research, and an independent Trial Steering Committee. In Phase 1, facility consent was obtained from the Government of Goa's Directorate of Health Services. In Phase 2, facility consent was obtained from each GP. Individual participant consent was obtained in two stages: after the screening, those who screened positive were invited to participate in the CIS-R

interview and be enrolled in the trial. Written consent was again obtained by the field researcher at the time of the outcome assessment.

Randomisation and masking

The sampling frames included all facilities with the space and privacy for lay health counsellors, had regular out-patient clinics, and were not involved in preliminary phases of the project. For phase 1, 17 facilities in Goa met these inclusion criteria, of which 12 were randomly selected for inclusion in the trial. PHC facilities were first stratified by the presence or absence of a visiting psychiatrist and then randomised within four strata defined by size. For phase 2, we sent out 400 letters to GPs from a list of all registered medical GPs in the state; eight responded. The research team then visited a purposively selected subsample of GPs who had not responded (n=60). Thus, altogether, 68 GPs were visited and assessed for eligibility; 25 did not meet our a-priori eligibility criteria and 21 declined to participate. 12 of the 22 eligible GP facilities were randomly selected for phase 2 of the trial. The 12 GP facilities were randomised within two strata defined by size. For both phases, facilities were randomly allocated within each stratum to either the intervention or control arm using a 1:1 allocation ratio using a computer-generated random-isation sequence.

Masking of the research assessor was maximised by: undertaking assessments at home; randomly allocating unique identification numbers to patients so that there was no association between their number and the identity of the facility; outcome assessment being done by an independent institution whose team did not know the randomisation allocation; and undertaking the primary outcome assessment before all other assessments.

Interventions

All interventions were implemented at the individual level within clusters. The formative and piloting work leading to the design of the collaborative stepped-care

	Suitable recipient	Timing	Treatment	Health worker contact
Initiation of treatment (step 1)	Patients screened for common mental disorders	At first consultation	Advice about results from screening questionnaire; advice about seeing an LHC; psychoeducation	Primary care physician; LHC
Management of moderate or severe cases (step 2)	Patients who are severely ill at first consultation or whose symptoms persist at follow-up	At first consultation or at follow-up if not responding to step 1	Antidepressant drugs or interpersonal psychotherapy; adherence management	Primary care physician; LHC
Monitoring outcomes (step 3)	Patients who remain unwell or who are not adherent to treatment	Patients who do not respond to step 2 despite taking the treatment	Antidepressant drugs and interpersonal therapy; adherence management	Primary care physician; LHC
Referral to specialists (step 4)	Patients who do not respond despite good adherence or who are judged to be at high risk of suicide	Patients who do not respond to steps 2 or 3 despite taking the treatment and patients who are at high risk of suicide at any time	Continue all existing treatments; referral to clinical specialist	Clinical specialist

LHC=lay health counsellor.

Table 1: Collaborative-stepped care intervention

intervention has been described previously.[18] In brief, the intervention is based on the stepped-care approach, which emphasises the efficient use of scarce resources. The collaborative approach involves three key team members: the lay health counsellor, the primary care physician, and a visiting psychiatrist (the clinical specialist). The locally recruited lay health counsellors did not have health backgrounds and underwent a structured 2-month training course. Lay health counsellors acted as a case-manager for all patients who screened positive for common mental disorders, and took overall responsibility for delivering all the non-drug treatments in close collaboration with the primary care physician and the clinical specialist, with the ultimate goal of a planned discharge on recovery. Table 1 provides the steps of the collaborative stepped-care intervention.

Psychoeducation provided by the lay health counsellor to all patients who screened positive for common mental disorders focused on educating the person about their symptoms, the association of common mental disorders with interpersonal difficulties, and the need to share emotional symptoms with the doctor and to share personal difficulties with family members caring for them or other key people in their social network (derived from the initial phase of interpersonal psychotherapy). Psychoeducation taught patients strategies to alleviate symptoms, such as breathing exercises for anxiety symptoms and scheduling activities for symptoms of depression. Encouraging adherence to treatments for these disorders and providing information about social and welfare organisations when needed were other key components of psychoeducation. Antidepressant drugs were recommended only for moderate or severe common mental disorders (ie, with a GHQ score >7) and for those who did not respond to psychoeducation alone on the basis of routine clinical assessments by the lay health counsellor. The antidepressant used, fluoxetine, was provided by the project to integrate with the existing model of free drugs prescribed by the PHC doctor. In the GP clinics, doctors could prescribe antidepressant drugs of their choice, from recommendations offered in a manual that provided information about commonly available drugs and their side-effects and costs,[23] which were purchased by patients as usual. Once initiated, antidepressant drugs were recommended for a minimum of 90 days at an adequate dose (at least 20 mg per day of fluoxetine or the equivalent, which could be titrated up to 40 mg if clinical response was inadequate). Physicians were given training for half a day and a manual. The other key roles of the physicians were to encourage patients to meet the lay health counsellor, to avoid the use of unnecessary drugs, and to provide usual care for any coexisting physical health problems.

Interpersonal psychotherapy, delivered by the lay health counsellor, was the structured psychological intervention chosen because of its documented feasibility and effectiveness in Uganda, another low-income country,[24] and because of its focus on interpersonal problems such as grief, disputes, and role transitions, which were common in the adverse life experiences of participants in previous research in Goa.[25] A minimum of six sessions, with an optimum of eight and a maximum of 12, were offered. Interpersonal psychotherapy was reserved only for patients who had moderate or severe common mental disorders, and was offered as an alternative to or in addition to antidepressant drugs for those who did not respond to antidepressant treatment.

Referral to the clinical specialist was reserved for patients who were assessed as having a high suicide risk at any stage, were unresponsive to the earlier treatments, posed diagnostic dilemmas (eg, an elderly patient who has notable memory problems along with depressive symptoms or a patient who has hallucinations in addition to depressive symptoms), had substantial comorbidity with alcohol dependence, had other associated substantial medical problems (eg, a patient who has uncontrolled diabetes or hypertension in addition to depression), or for whom the primary care physician requested a consultation. Every facility team was supported by a clinical specialist who visited about once a month and was also available for consultation on the telephone to discuss cases.

Patients' discharge was either planned (eg, if they were deemed to have recovered) or unplanned (eg, if they did not return for reviews despite adherence management procedures).

For the control intervention (enhanced usual care), physicians and patients in usual care practices received screening results and were given the treatment manual prepared for primary care physicians. Physicians were allowed to start treatments of their choice.

Process indicators assessing the fidelity and quality of the intervention were obtained from four sources: the separate clinical records maintained by the lay health counsellor and the clinical specialist, antidepressant use from the clinic records, and quality assessments done for every component of the intervention. Quality assessments for intervention components were made by direct observation or through transcripts of sessions, and were rated by senior clinicians. The only possible process indicator in the enhanced usual care group was antidepressant use.

Primary and secondary outcomes

The primary outcome was the proportion of patients who recovered from common mental disorders as defined by the International Statistical Classification of Diseases and Related Health Problems—10th revision (ICD-10) at 6 months. The secondary outcome was the severity of depression and anxiety symptoms, assessed at 6 months.

The primary and secondary outcomes were assessed with the CIS-R, which generates two outputs: an ICD-10 diagnosis derived from a computer algorithm and a total score indicating the overall severity of symptoms.[21]

Statistical analyses

Our sample size estimates have been described in detail in our protocol.[22] Briefly, we assumed a coefficient of variation of 0·2; prevalence of common mental disorders (as defined by ICD-10) of 66% in participants who screened positive; and a follow-up of 75% at 6 months. The resulting sample size of 100 screen-positive participants in 24 clusters provides more than 90% power to detect a difference in recovery rates of 70% in the intervention group versus 50% in the control group (enhanced usual care). The higher rates of ICD-10 cases and follow-up rates recorded during phase 1 led to a downward re-estimation of the sample sizes in phase 2 to 80 screen-positive participants per cluster.

All analyses were done in Stata (version 11.0). Participants were divided into four a-priori diagnostic groups on the
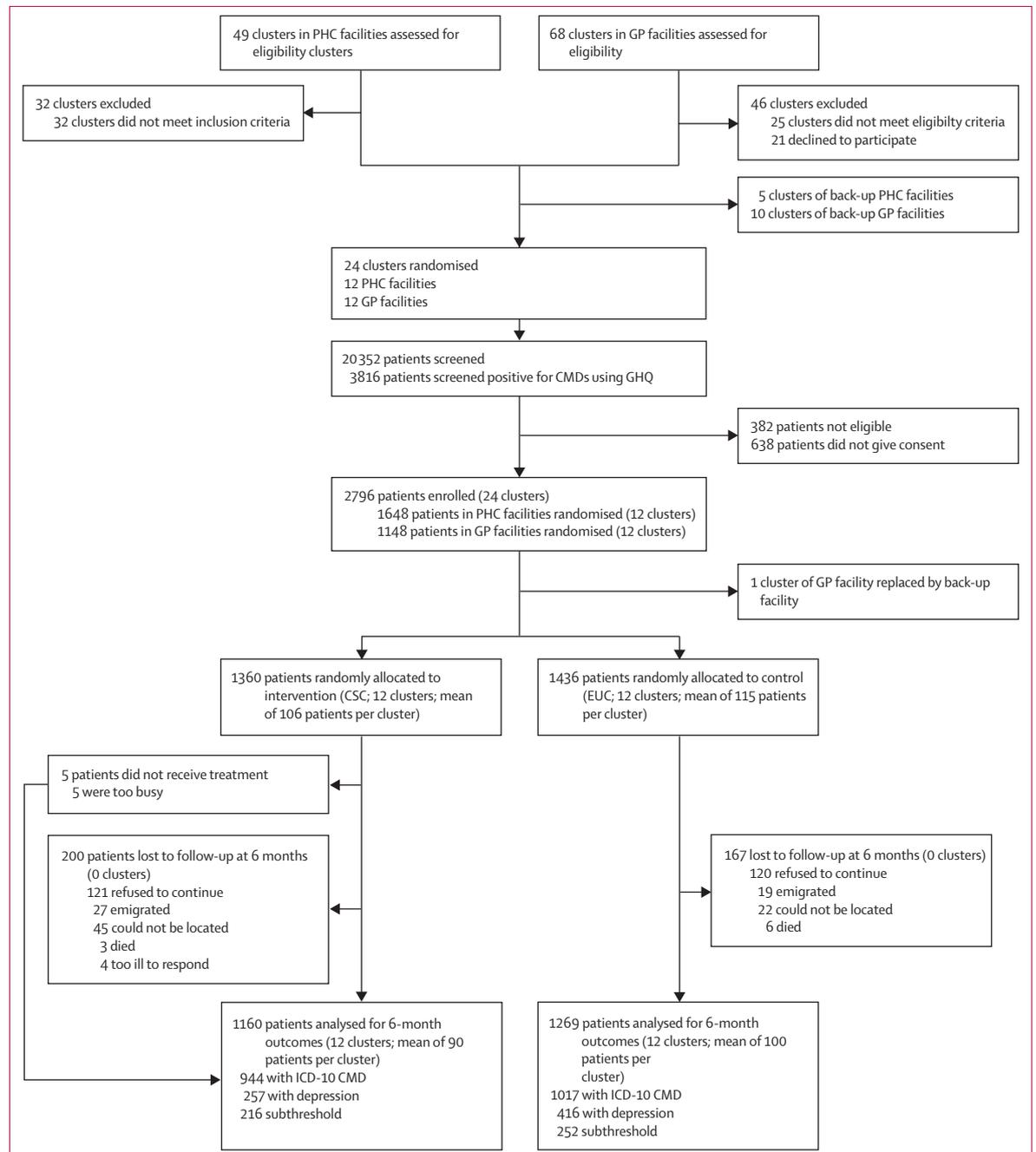
Figure: Trial profile

CSC=collaborative stepped care. EUC=enhanced usual care. PHC=public primary health centre. GP=general practitioner. CMD=common mental disorder. ICD-10=International Statistical Classification of Diseases and Related Health Problems—10th revision.

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basis of their clinical diagnosis at baseline. Screen-positive cases were all participants in the trial—ie, patients who had been assessed with the GHQ-12 and identified to have a probable common mental disorder. For these patients, identification of a common mental disorder could be established through routine screening in primary care; a lengthy diagnostic interview would not be feasible because of the longer duration needed. ICD-10 cases comprised the subgroup of screen-positive patients who had a diagnosable CMD assessed with the CIS-R; these patients were the primary analysis group. Subthreshold cases were the subgroup of screen-positive patients who did not meet ICD-10 diagnostic criteria for CMD on the CIS-R. Depression cases were the subgroup of ICD-10 patients with the specific diagnosis of depression, assessed with the CIS-R; these cases included patients with comorbidity with anxiety.

As per the trial protocol,[22] the primary analysis was the difference across groups in the proportion of patients with these disorders who recovered at 6 months at baseline according to the ICD-10 criteria (ie, are no longer patients). Secondary analyses were also evaluated at 6 months and comprised the differences across groups in: the proportion of depression cases who recovered; the prevalence of patients who met ICD-10 criteria for common mental disorders among screen-positive cases and subthreshold cases; and the mean total CIS-R score in each diagnostic group.

Analyses were based on cluster-level summary measures, because individual-level regression methods are not robust when there are few clusters per group.[26] For binary outcomes, the effect was measured by the risk ratio and risk difference. The stratum-specific RRs were calculated as the ratio of the geometric mean risks between groups for each of the six strata, and the overall risk ratio was estimated as the weighted-average of these stratum-specific RRs. An approximate variance for the log (mean risk) in each group was obtained from the residual mean square from a two-way analysis of variance of community log-risk on strata and study group. A 95% CI for the risk ratio was calculated from this variance with a stratified t test with 12 degrees of freedom.[26] Similarly, a 95% CI for the risk difference was obtained from an analysis of variance of the mean risk on strata and study group. For continuous outcomes (CIS-R score), the measure of effect was the mean difference between groups, and these outcomes were analysed in an analogous method on the basis of mean scores in every facility. Secondary planned analyses assessed the effect of the intervention separately in the two types of facilities, with assessment of effect-modification of the intervention effect by facility type estimated using Welch's t test to compare log risk ratios in the two groups.[27] Predefined sensitivity analyses included adjustment for age, sex education level, and baseline CIS-R score. Finally, we did a sensitivity analysis to investigate the effect of missing data by using multiple imputation with chained equations to create multiple datasets, which were analysed with an individual level Poisson regression model, allowing for within-cluster correlation using generalised estimating equations. Analyses were completed on an intention-to-treat basis (ie, analysis included the 1160 patients randomly assigned to the collaborative stepped-care group who were seen at 6 months and the 1269 patients randomly assigned to the enhanced usual care group who were seen at 6 months). The trial is registered with ClinicalTrials.gov, number NCT00446407.

	CSC (n=1360; 12 clusters)	EUC (n=1436; 12 clusters)
Facility type		
PHC	823 (61%)	825 (57%)
GP	537 (39%)	611 (43%)
Baseline diagnostic category		
Subthreshold case	262 (19%)	292 (20%)
ICD-10 case	1098 (81%)	1144 (80%)
Depression case*	304 (22%)	470 (33%)
CIS-R score	19·9 (9·1)	19·4 (9·1)
Age (years)		
18–29	147 (11%)	147 (10%)
30–39	296 (22%)	275 (19%)
40–49	365 (27%)	368 (26%)
50–59	256 (19%)	278 (19%)
≥60	296 (22%)	368 (26%)
Sex		
Male	246 (18%)	245 (17%)
Female	1114 (82%)	1191 (83%)
Marital status†		
Never married	96 (8%)	63 (5%)
Married	761 (64%)	857 (65%)
Widowed	330 (28%)	378 (29%)
Separated or divorced	8 (1%)	18 (1%)
Ethnic origin†		
Goan	1131 (95%)	1251 (96%)
Non-Goan	55 (5%)	54 (4%)
Language†		
Konkani	1163 (98%)	1292 (99%)
Other	23 (2%)	13 (1%)
Education (years)†		
<1	490 (41%)	657 (50%)
1–4	221 (19%)	198 (15%)
≥5	475 (40%)	450 (34%)

Data are number (%) or mean (SD). CSC=collaborative stepped care. EUC=enhanced usual care. PHC=public primary health centre. GP=general practitioner. ICD-10=International Statistical Classification of Diseases and Related Health Problems—10th revision. CIS-R=revised clinical interview schedule. *Including comorbid anxiety disorders. These depression cases are a subset of ICD-10 cases. †These variables were asked at the interim 2-month follow-up[22] and are based on 2491 (89%) of participants: 1186 (87%) of those in the CSC group and 1305 (91%) in the EUC group.

Table 2: **Baseline characteristics of trial participants, by intervention group**

Role of the funding source

The sponsors of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. HAW and VP had full access to all the data; VP had the final responsibility for decision to submit for publication.

Results

The figure shows the trial profile. One GP cluster was replaced by a back-up within a month of randomisation because of small patient numbers. All 24 clusters were followed to the end of the trial 20 352 patients were screened, of whom 3816 (18·8%) screened positive for common mental disorders and 3434 (16·9%) were eligible to participate (figure). Of these patients, 1360 were enrolled in the collaborative stepped-care group and 1436 in the enhanced usual care group. Participants who did not consent tended to be younger than those who did consent (webappendix p 1). 1160 participants (85%) in the collaborative stepped-care group and 1269 (88%) in the control group completed the 6-month outcome assessment. Participants who were not followed up at 6 months were more likely to be younger and male;

however, we noted no differences in terms of intervention group, facility type, or baseline diagnostic group (webappendix p 2).

1098 patients met ICD-10 criteria for common mental disorders at baseline in the intervention group (81% of patients who screened positive) and 1144 (80%) in the control group. Of these, 944 (86%) in the intervention group and 1017 (89%) in the control group were seen at the 6-month outcome assessment. We recorded little intra-cluster correlation (0·03), and the coefficient of variation (k) for prevalence of these disorders at baseline in all patients who screened positive was 0·08.

Table 2 shows the sociodemographic and clinical characteristics of the two groups. The trial population was mostly female, and the mean age was 46·3 years (SD 13·3). Of the 2242 patients (81%) who met ICD-10 criteria for these disorders at baseline (1098 in the collaborative stepped-care group; 1144 in the enhanced usual care group), 774 (35%) had depression, including comorbid anxiety disorders (304; 470). The most common diagnosis was mixed anxiety-depressive disorder (n=1032; 46% of patients with common mental disorders); the remaining 436 (19%) had a pure anxiety disorder (233; 203). Generally,

	All facilities (primary analysis)	PHC	GPs	p value*
Primary analysis group: patients with ICD-10 CMD (n=1961)				
Collaborative stepped care (n=944)†	620 (65·0%)	369 (65·9%)	251 (64·1%)	..
Enhanced usual care (n=1017)†	553 (52·9%)	267 (42·5%)	286 (65·9%)	..
Risk difference (95% CI)	12·1% (1·6–22·5)	23·4% (5·0–41·7)	−1·8% (−17·7 to 14·1)	0·02
Risk ratio (95% CI); p value	1·22 (1·00–1·47); p=0·05	1·55 (1·02–2·35); p=0·04	0·95 (0·74–1·22); p=0·63	0·02
Secondary analysis group: patients with depression (n=673)				
Collaborative stepped care (n=257)	143 (53·6%)	81 (52·1%)	62 (55·1%)	..
Enhanced usual care (n=416)	216 (50·4%)	114 (38·8%)	102 (65·5%)	..
Risk difference 95% CI	3·2% (−9·4 to 15·7)	13·3% (−10·1 to 36·6)	−10·4% (−29·0 to 8·1)	0·06
Risk ratio (95% CI); p value	1·05 (0·81–1·36); p=0·69	1·34 (0·73–2·45); p=0·25	0·82 (0·60–1·12); p=0·18	0·07

Prevalence of binary outcomes in each arm was estimated as the geometric mean of the cluster-level prevalences within each arm. CMD=common mental disorder. PHC=public primary health centre. GP=general practitioner. ICD-10=International Statistical Classification of Diseases and Related Health Problems—10th revision. *For effect modification by facility type. †Excluding subthreshold cases.

Table 3: Effect of intervention on recovery from ICD-10-confirmed CMDs and depression at 6 months, by diagnostic group at baseline

	All facilities (primary analysis)	PHC	GPs	p value*
Screen-positive cases (n=2429)				
Collaborative stepped care (n=1160)	354 (28·8%)	196 (27·7%)	158 (29·9%)	..
Enhanced usual care (n=1269)	541 (38·6%)	375 (50·8%)	166 (29·4%)	..
Risk difference (95% CI)	−9·9% (−19·4 to 0·03)	−23·1% (−42·1 to 4·2)	−0·05% (−12·9 to 14·0)	0·02
Risk ratio (95% CI); p value	0·76 (0·57 to 1·02); p=0·06	0·54 (0·37 to 0·81); p=0·01	1·07 (0·66 to 1·74); p=0·76	0·02
Subthreshold cases (n=468)				
Collaborative stepped care (n=216)	30 (12·7%)	20 (12·4%)	10 (13·0%)	..
Enhanced usual care (n=252)	77 (25·0%)	49 (31·2%)	28 (19·9%)	..
Risk difference (95% CI)	−12·3% (−23·5 to 1·1)	−18·8% (−46·6 to 9·0)	−6·9% (−19·3 to 5·5)	0·33
Risk ratio (95% CI); p value	0·52 (0·29 to 0·96); p=0·04	0·40 (0·11 to 1·38); p=0·11	0·70 (0·31 to 1·59); p=0·35	0·31

Prevalence of binary outcomes in each arm was estimated as the geometric mean of the cluster-level prevalences within each arm. PHC=public primary health centre. GP=general practitioner. ICD-10=International Statistical Classification of Diseases and Related Health Problems—10th revision. *For effect modification by facility type.

Table 4: Effect of intervention on prevalence of ICD-10-confirmed CMDs at 6 months, by diagnostic group and facility type at baseline (secondary analyses)

	Mean CIS-R score at baseline (SD)	All facilities (primary analysis)	PHC	GPs	p value*
ICD-10-confirmed cases					
Collaborative stepped care	22·93 (7·31)	9·30 (–59%)	9·28 (–58%)	9·33 (–61%)	..
Enhanced usual care	22·56 (7·16)	11·61 (–48%)	14·12 (–38%)	9·10 (–58%)	..
Mean difference (95% CI); p value for difference		–2·14 (–4·32 to 0·04); 0·05	–4·84 (–8·48 to –1·20); 0·02	0·63 (–2·76 to 4·02); 0·68	0·01
Depression cases					
Collaborative stepped care	28·31 (6·90)	11·38 (–60%)	11·30 (–58%)	11·47 (–62%)	..
Enhanced usual care	26·58 (7·06)	12·54 (–53%)	15·59 (–41%)	9·48 –65%)	..
Mean difference (95% CI); p value		–1·01 (–3·63 to 1·61); 0·42	–4·30 (–9·58 to 0·98); 0·09	2·38 (–1·29 to 6·05); 0·17	0·02
Screen-positive cases					
Collaborative stepped care	20·03 (9·05)	8·56 (–57%)	8·39 (–56%)	8·72 (–59%)	..
Enhanced usual care	19·49 (8·99)	10·87 (–44%)	13·14 (–34%)	8·60 (–55%)	..
Mean difference (95% CI); p value		–2·15 (–4·20 to –0·10); 0·04	–4·75 (–8·86 to –0·64); 0·03	0·52 (–2·36 to 3·40); 0·69	0·02
Subthreshold cases					
Collaborative stepped care	7·37 (3·01)	5·63 (–27%)	5·69 (–24%)	5·56 (–31%)	..
Enhanced usual care	7·10 (3·10)	7·62 (5%)	8·57 (–22%)	6·68 (–11%)	..
Mean difference (95% CI); p value		–1·90 (–4·01 to 0·20); 0·07	–2·87 (–8·09 to 2·34); 0·20	–0·91 (–3·25 to 1·44); 0·40	0·38

PHC=public primary health centre. GP=general practitioner. ICD-10=International Statistical Classification of Diseases and Related Health Problems—10th revision. CIS-R=revised clinical interview schedule. *For effect modification by facility type.

Table 5: **Effect of intervention on severity of symptoms (mean CIS-R score at individual level [% difference; SD]) at 6 months, by diagnostic group and facility type at baseline (secondary analyses)**

distribution of these disorders between groups was similar; although participants in the enhanced usual care group were more likely to have depression, the proportion of patients with these disorders according to ICD-10 and mean CIS-R scores were similar (table 2).

The collaborative stepped-care intervention had a small effect on recovery for patients who met ICD-10 criteria for common mental disorders at 6 months (table 3). The effect was larger in PHC participants and not evident in GP participants (table 3). The intervention had no significant effect on recovery from common mental disorders in patients with depression (table 3). The effect on recovery from common mental disorders persisted when missing values were imputed (risk ratio 1·19, 95% CI 1·02–1·40 on imputed analysis *vs* risk ratio 1·22, 95% CI 1·00–1·47 on complete case analysis). The number needed to treat for the overall primary outcome was eight (95% CI 4–63), which was four in the PHC clinics (95% CI 2–20).

There was modest evidence of an effect on the overall prevalence of common mental disorders at 6 months in screen-positive cases, with prevalence halved in PHCs, although there was no effect in GP facilities (table 4). In the subthreshold cases, there was evidence of a protective effect of the intervention overall, which did not differ by facility type (table 4).

For each diagnostic group, the mean CIS-R score was lower in the collaborative stepped-care than in the enhanced usual care group at 6 months (table 5). Furthermore, in the screen-positive cases, the intervention had a positive effect in PHCs for patients who met ICD-10

criteria for common mental disorders, and weak evidence of a positive effect for patients with depression, although it had no effect in GP facilities (table 5).

Adjustment for baseline factors made little difference to all the findings (data not shown).

	Original target	Trial performance		Weighted average (95% CI)
		PHC phase	GP phase	
Proportion of screen-positive patients who meet ICD-10 criteria for common mental health disorders	Minimum 66%	78%	84%	81 (79–83)
Proportion of patients who receive at least first psychoeducation session	Minimum 90%	95%	98%	96 (95–97)
Proportion of moderate to severe cases who receive antidepressant drugs	Minimum 80%	83%	88%	85 (82–88)
Proportion of all patients who receive antidepressant treatment	NA	48%	64%	54 (51–57)
Proportion of patients receiving antidepressant drugs who complete at least 3 months of treatment	Minimum 50%	53%	52%	53 (49–56)
Proportion of moderate to severe cases who receive interpersonal psychotherapy	NA	5%	<1%	..
Proportion of patients receiving interpersonal psychotherapy who complete at least six sessions	Minimum 50%	33%	0%	..
Proportion of patients who had a planned discharge	Minimum 60%	51%	67%	57 (54–60)
Proportion of patients referred to psychiatrist	Maximum 5%	<1%	<1%	0·5 (0·3–1·1)

PHC=public primary health centre. GP=general practitioner. ICD-10=International Statistical Classification of Diseases and Related Health Problems—10th revision. NA=not available/applicable.

Table 6: **Process indicators of fidelity and quality for intervention facilities**

The original target for coverage was reached for most indicators (table 6), although among patients receiving interpersonal psychotherapy the proportion who completed at least six sessions was lower than expected. A major barrier was the indirect and direct costs associated with the requirement for patients to return to the facility for regular sessions. More than half of all patients had a planned discharge from the programme. The number of quality assessments also exceeded the targets set for the trial (data not shown). In the control group, of those on antidepressant drugs, 45 (10·2%) completed 3 months of treatment in the PHC phase and 34 (11·3%) in GP phase.

There were seven serious adverse events (three deaths and four suicide attempts) in the collaborative stepped-care group and 12 in the enhanced usual care group (six deaths and six suicide attempts). None of the deaths were from suicide.

Discussion

Findings from this study have shown that overall there was modest evidence for a beneficial effect of the intervention on recovery from common mental disorders at 6 months according to the ICD-10 criteria, with a statistically significant effect in PHCs but no effect in private facilities. We recorded no effect of the intervention on the smaller subgroup of patients with depression. Secondary analyses showed that the intervention had a consistent effect in PHCs but not in private facilities for all baseline diagnostic groups apart from depression. The intervention also suggested some preventive effect in reducing the prevalence of common mental disorders in subthreshold cases.

The results of the MANAS trial indicate that such a collaborative-stepped care intervention delivered by trained lay health counsellors can improve recovery rates for patients with common mental disorders in public primary care settings, but not in private primary care settings. The recorded effects might underestimate

the true effect because two key components of the intervention (provision of screening results to patients and physicians, and evidence-based guidelines to the physician) were offered in both groups. The recovery rates in the intervention groups in both types of facilities are similar to those reported by other trials (panel) and to our original hypothesis.[22] We recorded similar recovery rates in the private GP control group; thus, private GPs do well irrespective of presence of a lay health counsellor. By contrast, PHCs benefit from the addition of a lay health counsellor, and the intervention appeared effective for the treatment and prevention of common mental disorders.

There are several possible explanations for these results. Although the PHC facilities were indicative of typical centres, having been selected randomly from the eligible sampling frame, the participating GPs were likely to represent a subgroup of physicians who were motivated to improve the quality of care for common mental disorders because of the difficulties in obtaining a representative sampling frame. Other explanations could include the style of GP interactions with patients, which might have similar characteristics to that of the lay health counsellors (eg, better continuity of care with the same physician). By contrast, in the PHCs, larger numbers of patients tend to be seen for shorter periods by a doctor and the privacy needed to discuss interpersonal difficulties is not assured. This difference has also been reported in the WHO international study[3] of common mental disorders in general health-care settings, which categorised primary care facilities into two distinct types: individual, personalised client-centred care model; and a collective clinic-centred care model. The personalised types of health-care settings showed better performance indicators than did the collective model, suggesting that the organisation of health care might directly affect the outcomes. We are investigating these hypotheses through qualitative interviews with GPs to ascertain the extent to which usual care by these GPs approximated the care provided by the lay health counsellors. Finally, characteristics of patients differed by clinic type (webappendix p 3). The absence of an overall effect in the subgroup of patients with depression might be partly attributable to lower power to detect a clinically significant effect in this subgroup, inadequate guidelines to triage depression cases, and inadequate intensity of the treatments, particularly the failure to deliver interpersonal psychotherapy as planned. Future analyses will assess the effect of the intervention at short-term and long-term secondary endpoints.

The strengths of this trial include: large samples from rural and urban populations with inclusion of both public and private facilities; high follow-up rates; high levels of fidelity and quality of the intervention (with the exception of low coverage of interpersonal psycho-therapy); and consistent documentation of effect in PHCs for each diagnostic group apart from depression.

Panel: Research in context

Systematic review

Systematic reviews show that antidepressant drugs and brief psychological treatments are effective for the treatment of common mental disorders[28] and that collaborative stepped-care models are effective for their delivery in primary health care.[15]

Interpretation

The results of the MANAS trial suggest that a collaborative stepped-care intervention provided by trained lay health counsellors can improve recovery rates for patients with common mental disorders in public primary care settings, which are characterised by a collective clinic-centred model of care. However, the results of this trial indicate that this intervention is not effective for private primary care settings, characterised by a personalised client-centred model of care.

Additionally, we were able to confirm the high specificity of our screening procedure in a real-world context. About 13% of patients were not seen at the 6-month outcome, and these patients were more likely to be younger and male. However, separate models by age-group and sex were fitted, and showed no evidence of differential recovery rates by sex or age. Missing data are thus unlikely to affect the results.

We recommend that the collaborative stepped-care intervention should be extended to clinics run by public primary health-care facilities. Screening is feasible because of the high prevalence of common mental disorders in primary care attenders, the brevity of screening instruments[29] and increasing literacy rates in many countries that makes self-completion feasible, and, as we noted, a relatively high specificity of diagnosis of these disorders by ICD-10 criteria. Screening might have been a crucially important component accounting for the good outcomes in the control GP facilities. Lay health counsellors could undertake several health-care roles, are fairly low cost to recruit, and are readily available in most developing countries. However, the fact that the intervention had no effect on the smaller subgroup of patients with depression also indicates the need for feasible methods for its detection and for more intensive treatments for these patients—for example, psychological treatments that are more specific to the needs of the patient or more aggressive pharmaco-therapy.[30] In conclusion, results from the MANAS trial indicate the effectiveness of a lay health counsellor-led collaborative stepped-care intervention for common mental disorders in public primary health-care facility attenders in India. This evidence should be used to improve services for common mental disorders in settings for which mental health professionals are scarce.

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