

World Psychiatry

OFFICIAL JOURNAL OF THE WORLD PSYCHIATRIC ASSOCIATION (WPA)

Volume 7, Number 1



February 2008

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Integrating evidence-based treatments for common mental disorders in routine primary care: feasibility and acceptability of the MANAS intervention in Goa, India

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Common mental disorders, such as depression and anxiety, pose a major public health burden in developing countries. Although these disorders are thought to be best managed in primary care settings, there is a dearth of evidence about how this can be achieved in low resource settings. The MANAS project is an attempt to integrate an evidence based package of treatments into routine public and private primary care settings in Goa, India. Before initiating the trial, we carried out extensive preparatory work, over a period of 15 months, to examine the feasibility and acceptability of the planned intervention. This paper describes the systematic development and evaluation of the intervention through this preparatory phase. The preparatory stage, which was implemented in three phases, utilized quantitative and qualitative methods to inform our understanding of the potential problems and possible solutions in implementing the trial and led to critical modifications of the original intervention plan. Investing in systematic formative work prior to conducting expensive trials of the effectiveness of complex interventions is a useful exercise which potentially improves the likelihood of a positive result of such trials.

Key words: Depression, anxiety, low-income countries, primary care, effectiveness of interventions

(World Psychiatry 2008;7:59-46)

Depressive and anxiety disorders, also referred to as common mental disorders (CMD), are widely prevalent in primary care settings in low- and middle-income countries (LAMIC)(1) and are associated with significant levels of disability, increased health care costs and reduced economic productivity (2-4). Although substantial proportions of primary care attenders in LAMIC suffer from a CMD – estimates vary from 10 to 30% (1,5) – the vast majority of patients do not receive effective treatments (6). This treatment gap persists even as a growing evidence base demonstrates that there are efficacious treatments that are feasible in LAMIC settings (7-10). To address this treatment gap, integration of mental health services into primary care is widely acknowledged as the most feasible strategy (11). While we now have encouraging evidence that specific treatments for CMD work in LAMIC, the challenge is to integrate these in a comprehensive intervention package within routine primary care systems. This is one of the key research priorities for CMD in LAMIC (12).

A recent review of evidence from high-income countries highlighted the components that are necessary for the effective integration of services for depression in primary care settings (13). These were the routine screening of patients, ed-

ucation for primary health care staff, skilled mental health providers delivering a stepped-care intervention and the active collaboration of mental health specialists in the programme.

The adaptation of these principles in LAMIC primary care settings presents several challenges. These include limited skilled mental health resources, vastly different social and cultural contexts and an already constrained primary care system (14-16). Other barriers to possible integration include the low recognition rates of CMD by primary care doctors (17), limited primary health care staff and large numbers of patients, infrequent and/or inadequate use of antidepressants (18) and the frequent use of medications such as vitamin injections which are prescribed for their supposedly "restorative" properties (19). Low adherence to medication regimens further minimizes the gains of treatment. In addition, few patients receive psychosocial treatments, typically because of a scarcity of personnel with the time and skills to deliver these (20).

The MANAS project is an effectiveness trial of a multi-component, comprehensive intervention to integrate the treatment of CMD in primary care facilities in Goa, a state on the West coast of India which has been the setting for a

number of studies on the epidemiology and treatment of CMD (21-23). The original intervention plan was based on two principles: first, the treatments selected would be based on evidence from published trials in LAMIC and, thus, include psychoeducation (24,25), antidepressants (7,9) and group interpersonal therapy (IPT) (8,10); and, second, the intervention would address the challenges highlighted earlier and be based on the best global evidence available (13). The intervention would involve a re-configuration of both the human resources and the principles of care delivery in primary care. The personnel would comprise a low cost, skilled mental health care provider working in the clinics (the “health counselor”), who, along with the existing primary care doctor, would detect and provide treatments for CMD with the support and supervision of a visiting psychiatrist. The treatments provided would be matched to the needs of the patient (stepped care) (7), including brief psychoeducation as the first step, with the more intensive treatments (antidepressants and IPT) being available for those with more severe problems (Table 1). We refer to this collaborative, stepped care intervention as the MANAS intervention. As a word, MANAS means “humanity” in the local Konkani language. It is also an acronym for MANAShanty Sudhar shodh (“project to promote mental health”).

Our aim is, ultimately, to evaluate the MANAS intervention in a cluster randomized controlled trial in primary care settings in Goa, India. This trial is now in progress. In this paper, we describe the preparatory stage (October 2005 - December 2006), in which the feasibility and acceptability of the intervention was evaluated systematically, in keeping with the current recommendations for the conduct of complex intervention trials (26). The preparatory stage had three distinct phases: a) consultation with stakeholders; b) formative research to evaluate key components of the intervention; and c) piloting of the entire intervention. Each stage is described sequentially, with a focus on the methods and key findings, and questions which arose which were then addressed in the subsequent stage.

CONSULTATION PHASE

Objectives and methods

The objective of this phase was to consult with local, national and international stakeholders from the public, private and academic sectors about the feasibility of the proposed intervention. A total of 14 consultation meetings were held at primary health care centres and conference venues with the local stakeholders. A total of 145 doctors from the Directorate of Health Services and private practitioners participated, in addition to the primary health care staff. During these meetings, a key member of the team described the MANAS intervention. Group exercises were undertaken to get feedback on the relevance and need of the programme in primary care, on the feasibility of implementing the intervention and on the specific problems and solutions that were likely to occur in these settings. A meeting of national and international collaborators involved with the trial was held in early 2006, during which results of the previous consultations were presented and further inputs of this group were considered.

Results

Doctors suggested that the routine screening results for detection of CMD be presented to them in a simple manner that would also be of assistance in providing feedback to patients. Psychoeducation (Step 1) should be brief, emphasize the connection between the stressors and the symptoms, and be delivered in an empathic manner. The health counselor should avoid using terms that could be stigmatizing.

Public sector doctors wanted the antidepressant to be made available free of cost, in keeping with usual care practices and in order to improve adherence rates. The participants suggested that the group psychological intervention be delivered either in primary health care centres or in community locations (e.g., temple courtyards or local schools),

Table 1 The collaborative stepped care intervention framework for the MANAS project

Steps of care	Objective	Responsible health workers	Intervention
Recognition	Sensitive and specific detection of CMD	Health counselor	Use of screening questionnaire
Step 1	Provision of health promotion advice and education about symptoms	Health counselor	Psychoeducation
Step 2	Provision of evidence-based pharmacotherapy or psychotherapy to patients who do not respond to Step 1	Primary health care centre doctor and health counselor	Antidepressant (fluoxetine 20-40 mg/day for at least 6 months) OR interpersonal psychotherapy
Step 3	Provision of both treatments for patients who do not respond to Step 2	Primary health care centre doctor and health counselor	Antidepressant plus interpersonal psychotherapy; intensive adherence management
Step 4	Management of treatment resistant cases or suicidal patients	Psychiatrist (visiting)	Referral (either through phone discussion or face to face evaluation in primary health care centre)

CMD – common mental disorders

for men and women separately and in the evenings to maximize attendance. Furthermore, concerns were expressed that many patients would not find group sessions acceptable or convenient, and that an individual treatment format should also be offered as a choice.

Many of the participants felt that including yoga as one of the group activities would make the intervention more culturally acceptable. It was agreed that a set of yoga techniques, selected on the basis of their efficacy for anxiety and depression, would be utilized in the MANAS intervention. It was proposed that the yoga sessions be available to all primary health care attendees and staff, in addition to the patients receiving the intervention, so as to destigmatize the overall program.

According to the original formulation of the program, doctors would provide patients with a choice of antidepressants or psychological treatments. However, the stakeholders felt that, in the context of the strong medical model in current care, this would lead to most patients receiving antidepressants. It was recommended that the effectiveness and appropriateness of psychological treatments be emphasized in the training of doctors, to make the process of choice more balanced. Furthermore, doctors felt there should be a distinction in guidelines for mildly ill patients from those who are severely ill (based either on screening questionnaire data or clinical assessment), so that the latter can be moved straight to a higher step on their first presentation. Considering the multiple responsibilities of the health counselor, the decision was made to separate the roles of screening and intervention delivery. Thus, two additional full-time staff would be based in facilities, one to screen and, where needed, to register patients (whom we refer to as the "health assistant") and one to be the case manager for the MANAS intervention (the health counselor). The health counselor was seen as the most important human resource of the program, and most of the participants were of the opinion that she should be a woman, be fluent in the local languages, have excellent communication skills and be available for consultations on a regular basis in the clinics. Many also wanted her to be called the "*salagar*" (advisor), to reflect local understandings and improve her acceptability.

FORMATIVE PHASE

Objectives and methods

The objective of the formative phase was to evaluate the feasibility and acceptability of the specific treatments in the intervention.

The formative research was conducted over 16 weeks (April - July 2006) in four primary health care centres and four private general practice facilities. The primary health care centres, which were staffed by 3-5 doctors backed up by nursing and administrative personnel, offered outpatient

care 6 days a week, as well as limited inpatient facilities. The private general practice clinics were in urban and rural areas and were run by a single doctor with or without inpatient facilities in single rooms or in small hospitals referred to locally as "nursing homes". None of these facilities had counsellors or health educators and specialty mental health care was accessible only through referrals.

In keeping with the recommendations made during the consultation phase, 10 women (4 health counselors and 6 health assistants) were recruited. The health counselors were trained to deliver the various treatments, including counseling skills, psychoeducation, yoga and IPT; their training was based on a draft manual developed for the intervention. The health assistants were trained in the use of the screening instrument chosen for the trial. The final training exercise for the doctors was conducted either individually or in small groups. This focused on the recognition and management of CMD, with a particular emphasis on the rational use of antidepressants and avoidance of non-evidence based medications. A set of materials were developed for patients and program staff, including a "patient card" for the reporting of the screening results to the doctor, handouts for various symptom management strategies and a doctor's guide on the use of antidepressants. The health counselor and health assistant were then placed in facilities where they implemented the specific treatments.

Two types of data were collected for the assessment of the formative phase:

Process indicators. These were the total number of attendees in each facility; the number who were excluded from undergoing screening on the basis of *a priori* exclusion criteria (<18 years old, inability to speak any of the local languages, in need of urgent medical care, attending the clinic within 2 weeks of the initial screening and therefore not eligible for screening at this contact, refusal to answer); the number who screened as having possible CMD; the number who met the health counselor after consulting the doctor during their initial visit; and the number who returned for follow-up sessions. These data were collected on a daily basis by the health counselor and collated weekly; analysis was carried out using the SPSS14 package.

Qualitative data. In-depth, semi-structured interviews with key stakeholders (doctors, facility staff, health counselors and patients) were conducted to document their perspectives about the feasibility, utility and acceptability of various aspects of the intervention. Since we wanted to elicit specific information from each of the groups, different interviews were developed for each group. For example, the interviews for patients focused on their recollection of the process of the intervention and their opinion about the utility of the treatments; the interviews for primary care physicians elicited their perceptions of the feasibility of the intervention and the individual treatments as well as their role in the overall process. The thematic method of analysis of qualitative data was used to generate results.

Results

A total of 7473 patients attended the primary care facilities during the formative phase (Table 2). Of those who were screened, 899 (31.6%) were positive for CMD. Of these cases, 70.6% were women; the average age was 41 years (SD 13.5). Among them, 53% actually received the first session of psychoeducation and only 24.3% of those who had received the initial session returned for further follow-up appointments. IPT was offered (all opted for the individual format) to 16 patients, 11 of whom (68%) attended at least four sessions and only 3 (19%) completed six or more sessions.

A total of 89 interviews were completed with doctors (n=10), patients (n=50), staff in the facilities (n=17) and the intervention team (n=12). Clinic and programme staff spoke of problems in providing counselors with work space that offered an acceptable level of privacy, especially in the smaller general practice clinics. Facility staff and the counselors consistently suggested that a systematic mapping of the physical infrastructure and the personnel in the facility be conducted prior to implementing the intervention. This would orient counselors to the usual care processes in their clinics, and help them identify any potential difficulties in positioning the intervention. Doctors and staff in the facilities also mentioned the need for counselors to be visible members of the facility. Several strategies to achieve this goal were suggested, including meetings between the counselors and the doctors every day before and after the outpatient clinic, regular meetings with other facility staff, and counselors' attendance at the scheduled monthly review meetings with the field staff of the primary health care centres. There was near unanimity in stakeholder groups that women with excellent communication skills were the ideal choice for being effective health counselors.

A majority of patients reported screening to be a useful process, as they were asked about emotional problems, which were not otherwise usually assessed. Most patients felt that the duration of the screening was acceptable, and the clinic staff did not feel that the new procedure adversely impacted on the usual care processes. The 30 minute psychoeducation session was described as useful by most patients, with the majority able to recall the contents of the session. Most endorsed the role of stress in contributing to their health problems, and were practicing the suggested tech-

niques to improve their symptoms. In particular, the breathing exercises, and advice about sleep and diet, were felt to be the most useful components of the psychoeducation session; this was also endorsed by the health counselors. The efforts to deliver IPT met with limited success, as users cited a variety of problems in returning for treatment on a weekly basis, in particular the loss of wages and the cost of repeated travel to the clinic. Another important barrier, specific to the group format, was concerns about confidentiality, given the personal nature of the issues being discussed and that other members of the groups who lived in the same community might gossip about their problems to others.

In conclusion, the formative research suggested that, with the exception of the group IPT component, specific treatments of the MANAS intervention were feasible and acceptable to patients and providers. We were reassured that the locally recruited and trained health counselors (who had no prior mental health experience) could provide the intervention consistently. We agreed that facilities that lacked a private space for the health counselor office could not participate in the program. A "running-in period" before starting service delivery was accepted as an important exercise for the team to become familiar with the physical layout of the clinic, the staff and usual procedures. Though patients felt that the intervention was acceptable, the poor follow-up rates indicated that non-adherence would be a major obstacle to the successful implementation of the intervention. To generate an appropriate and effective adherence management strategy, it was felt that an in depth understanding of the reasons for non-adherence from the service user perspective was essential. Another concern was the large number of patients who did not meet the health counselor after being screened and seen by the doctor, and were lost to the program. Greater attention to minimize this attrition by initiating changes to the care pathway in the clinic became an immediate priority.

PILOTING PHASE

Objectives and methods

The objectives of the pilot phase were to implement and evaluate the intervention, and to understand the reasons for

Table 2 Salient process indicator data in the formative and piloting phases of the MANAS intervention

	Total attenders	Total screened	Reasons for exclusion	Total cases identified	% receiving psycho-education	% returned for follow-up
Formative phase	7473	2846 (38.0%)	530 (41.0%) <18 years 165 (12.8%) acutely ill 214 (17.4%) attending specialist unit	899 (31.6%)	53.0%	24.3%
Pilot phase	7194	2530 (35.1%)	1711 (38.7%) <18 years 497 (11.2%) acutely ill 1167 (26.4%) repeat attenders in <2 weeks	854 (33.7%)	65.8%	43.8%

non-adherence while implementing efforts to improve follow-up rates.

The intervention was piloted in four primary health care centres between August and November 2006. In this phase, the MANAS intervention, as originally proposed, was considerably modified in the following ways: a structured adherence management protocol was developed; the role of the health counselors was broadened so that they would also provide advice for practical social difficulties (e.g., by keeping a referral register of community agencies for social problems); the focus of IPT was switched from group to individual formats; a structured protocol for the supervision of the health counselor by the visiting psychiatrist (clinical specialist) was produced. Finally, a list of process indicators that would enable the clinical specialist to effectively support and monitor the progress of the intervention was developed (Table 3).

Quantitative and qualitative data were collected during this phase by using the above-mentioned process indicators and by administering semi-structured interviews to patients who provided consent to describe their experiences of the intervention and reasons for adherence or non-adherence. Purposive, random sampling generated two groups of participants who were interviewed in their homes: 50 who were adherent and 50 who were not (attended two or less sessions and not following-up). A guide took each participant through the process of the MANAS intervention and explored his/her reasons for adherence or non-adherence. Feedback was also sought on the participants' views about the utility of the adherence management strategies. The qualitative data were compiled and analysed by using thematic analysis techniques.

Results

A total of 7194 patients attended the primary health care centres during the piloting phase and, of these, 854 (33.7%) were identified as possible cases. Of the patients identified

Table 3 Process indicators to monitor progress of MANAS intervention

-
- The number/proportion of patients screened as having CMD who received the first psychoeducation session
 - The number/proportion of patients with moderate/severe CMD (based on screening questionnaire score) who were started on step 2 treatments (antidepressant/interpersonal psychotherapy) on the initial visit
 - The number/proportion of patients in the program who attended scheduled follow-up appointments
 - The number/proportion of patients receiving interpersonal psychotherapy
 - The proportion of patients started on antidepressant who completed 3 months of treatment
 - The proportion of patients started on interpersonal psychotherapy who completed 6 sessions
 - The number/proportion of patients who have been discharged from the program
-

CMD – common mental disorder

by screening, 68.3% were women, and the average age was 40 years (SD 12.8). The adherence management procedures improved both the rates of patients receiving the first psychoeducation session and those attending follow-up for further consultation (Table 2). When reminder letters and telephone calls were feasible, the response was also encouraging and suggested that these would be important adherence management aids during the main trial.

Our attempts to provide IPT in a group format were again not successful. Problems in finding mutually convenient times and inadequate local transportation facilities made it impossible to form ongoing groups of a minimum of 3-4 patients. However, while the health counselors were, with supervision, able to confidently deliver IPT in an individual format, adherence remained a major challenge. Out of 12 patients who were offered IPT, only 7 (58%) attended the first session, of whom only 2 completed all of the sessions.

Health counselors conducted a total of 7 yoga courses (5 daily sessions each) in the selected primary health care centres: four of them were for the staff of the centres, while three were conducted for patients and members of the local community. All yoga courses were well attended and most participants continued for the full 5 days of the course.

Data on the use of antidepressant medication (fluoxetine) were collated across the formative and the pilot phases. Of 1753 patients who had screened positive, 598 (34.1%) were prescribed fluoxetine. Of those who received the medication, only 148 (24.7%) returned for a repeat supply. This is possibly an underestimate, because some patients prescribed antidepressants in the later part of the phase are likely renew their medication supply after the end of the collation of process indicators.

Of the 100 patients selected for the study of reasons for adherence, 77 could be interviewed. The most frequent reasons for not being interviewed were that the user was not at home (61%) and the evaluation team did not have the correct address (22%).

The results of this study are reported in Tables 4 and 5. The most frequently cited reason for not returning to meet the health counselor was economic: patients were daily wage earners and could not come to the clinic during the working week. Other reasons for non-adherence included child care obligations and annoyance with waiting for long periods to see the doctor and health counselor. Feeling better after receiving and practicing treatments like the breathing exercise was a reason for adherence. The importance of proactively reminding patients to return for follow-up emerged as a key factor influencing adherence. In contrast to the patients who were adherent with treatment (three quarters of whom reported the reminder as a reason for adherence), the majority of non-adherent patients (61%) reported that they had not been sent any reminders. Patients who were adherent reported that one of the most important reasons for coming back was that their problems were understood by the intervention team, who talked to them in a sympathetic manner within a confidential relationship. Adherent patients also

Table 4 Commonly cited reasons for adherence with the MANAS intervention (n=41)

- Felt problems were understood by doctor and health counselor	38 (92%)
- Belief in the beneficial effects of treatment	37 (90%)
- Confidence in the ability of doctor and health counselor to handle problems	37 (90%)
- Felt better with treatment	36 (87%)
- Given an active role and hence a sense of control in treatment	33 (80%)
- Treated with empathy and respected by the team	32 (78%)
- Treatment for these problems was being provided in the centre	31 (75%)
- Flexible follow-up appointment given	30 (73%)
- Reminders sent for appointment (postcard/phone)	30 (73%)
- Treatment was provided free of charge	26 (63%)
- Family was supportive about practicing techniques like breathing exercise at home	24 (58%)
- Ease of transport facilities	23 (56%)
- Family encouraged continuation of treatment	22 (53%)
- Family believed that subject has an illness that needs regular consultation at health facilities	14 (34%)
- Short waiting period to meet the doctor and health counselor	13 (31%)

Table 5 Commonly cited reasons for non-adherence with the MANAS intervention (n=36)

- Engaged in work – cannot find time to get to treatment	18 (50%)
- Have become better and saw no need to follow-up	7 (19%)
- Caring for children or other family members	7 (19%)
- Long wait to meet the doctor and health counselor	6 (16%)
- Side effect of medication	3 (8.3%)
- Difficult transport facilities	3 (8.3%)
- Change in health status, i.e. developed other illness	3 (8.3%)
- Distance of home from clinic	2 (5.5%)
- Expense of transportation	2 (5.5%)
- Feeling worse since last consultation and did not feel advice was useful	2 (5.5%)
- Family emergency	2 (5.5%)

reported being supported by the social network of their immediate family, friends and other relatives.

Respondents in both the adherent and non-adherent groups had adequate recall of the process of the program, and there were few differences in the way they perceived the acceptability of the interventions. For example, most respondents identified the screening process as being useful in helping them gain an understanding of their problems, especially endorsing the concept of “tension”. The majority of patients remembered the content of the initial psychoeducation session with the health counselor, and reported that advice on the breathing exercise, improving the quality of sleep and diet problems was the most useful. Most adherent patients appreciated that they had an active role to play in getting better, which reinforced their sense of mastery and control over their symptoms.

In conclusion, the principal outcome of the piloting phase was the confirmation of the feasibility of the MANAS intervention, in general, and of the adherence management and supervision protocols, in particular. However, a number of modifications were still needed: a) the inclusion of an adherence management protocol in the initial assessment of the patient, exploring possible risk factors for non-adherence and guiding the development of a careful plan to

improve adherence at every step of the process of care delivery; b) replacing group IPT with individual IPT; c) confirming the use of yoga, in a course of 5 sessions delivered over consecutive weekdays, as a component of the intervention (since it was a culturally acceptable mental health promotion activity, yoga could also improve the overall acceptability of the intervention); d) the use of structured sentinel indicators to enable supervision and monitoring of the program by the visiting psychiatrist.

DISCUSSION

To the best of our knowledge, this is the first systematic effort in a low-income country to develop a complex intervention for integrating the care of CMD into routine primary care. These studies were carried out prior to testing the effectiveness of the MANAS intervention in a cluster randomized trial. We used a three-phase method for the development of the intervention. This method provided a systematic framework, while at the same time being sufficiently flexible to ensure that outputs from each stage raised questions and informed the design of the subsequent stage. We believe that such preparation is critical in ensuring the feasibility and acceptability of complex interventions, and serves to identify a number of challenges which need to be addressed before conducting an effectiveness trial.

Each of the three phases was a rich learning experience and resulted in incremental improvements in the development of the final intervention. We have been able to demonstrate the need for such an intervention, by confirming that about 12% of all primary care attendees are suffering from a CMD. Although the final intervention protocol continues to use the same specific treatments that we had originally envisaged, there have been a number of key modifications to improve their feasibility and acceptability. Eight examples are considered in this discussion. First, we had initially conceptualized IPT as a group intervention with 8-12 sessions, based on the evidence available from the trial in Uganda (8). However, we discovered that the group format and number of sessions were likely to be impractical in the social context of primary care in Goa; thus, we have had to reformat the IPT to be delivered in an individual format over 6 to 8 sessions. Second, adherence management moved from being a peripheral component of the intervention to becoming a central feature, running across the intervention from the first psychoeducation session onwards, with a proactive set of strategies. Third, we had originally anticipated that the health counselor would carry out both screening and delivery of the intervention. This proved to be unfeasible and we added an additional, low-cost, human resource (the health assistant) to administer the screening instrument. Fourth, the scope of the health counselors' role expanded to include a range of additional activities, such as managing adherence and being a link between the health centre and existing resources in the community. Fifth, we had anticipated no se-

lection criterion for facilities, apart from consent of the facility. However, we accepted that the lack of a minimum private space for the health counselor was a non-negotiable criterion for a facility to be eligible. Sixth, the important role of yoga was affirmed as a means to both promote mental health and possibly destigmatize the MANAS intervention. Seventh, we learnt that the intervention should have a running-in phase, during which the team employs a structured mapping process to familiarize itself with the primary health care centre and, thus, to identify and address potential physical and logistic barriers. Finally, the process indicators allowed us to set realistic and appropriate targets for the delivery and monitoring of the intervention.

The preparatory phase also provided critical feedback regarding the content and structure of the training for the team members, as well as the content and format of the materials used for the intervention. We have not described our findings in detail in this paper due to space considerations, but these are available from the authors.

We wish to re-emphasize the importance of a preparatory phase as a crucial step before conducting clinical trials of complex interventions in mental health. In our experience, the MANAS intervention has been improved significantly, at least in terms of its feasibility and acceptability, as a consequence of this work. We hope that these modifications will help enhance the overall effectiveness of the intervention, currently being conducted in its first phase in 12 primary health care centres in Goa.

In conclusion, complex interventions for CMD are best delivered by teams who are adequately skilled, motivated and have in place structured supervision and strong leadership to improve their practice. This involves a clear delineation of the roles of each member of the team and mechanisms to manage and resolve conflicts. The preparatory phase has given us the opportunity to develop a framework that will streamline the safety, quality and comprehensiveness of the subsequent program.

Acknowledgements

The MANAS project is entirely supported by the Wellcome Trust through a senior clinical research fellowship awarded to Vikram Patel. The project is implemented through a collaboration between the London School of Hygiene and Tropical Medicine and three Goan institutions: Sangath, the Directorate of Health Services (Government of Goa) and the Voluntary Health Association of Goa.

References

- Patel V. The epidemiology of common mental disorders in South Asia. *NIMHANS Journal* 1999;17:307-27.
- Chisholm D, Sekar K, Kumar KK et al. Integration of mental health care into primary care. Demonstration cost-outcome study in India and Pakistan. *Br J Psychiatry* 2000;176:581-8.
- Lopez A, Mathers CD, Ezzati M et al (eds). *Global burden of disease and risk factors*. Washington: Oxford University Press and the World Bank, 2006.
- Ustun TB, Sartorius N (eds). *Mental illness in general health care: an international study*. Chichester: Wiley, 1995.
- Ormel J, Von Korff M, Ustun TB et al. Common mental disorders and disability across cultures. Results from the WHO Collaborative Study on Psychological Problems in General Health Care. *JAMA* 1994;272:1741-8.
- Ustun T, Von Korff M. Primary mental health services: access and provision of care. In: Ustun TB, Sartorius N (eds). *Mental illness in general health care: an international study*. Chichester: Wiley, 1995:347-60.
- Araya R, Rojas G, Fritsch R et al. Treating depression in primary care in low-income women in Santiago, Chile: a randomised controlled trial. *Lancet* 2003;361:995-1000.
- Bolton P, Bass J, Neugebauer R et al. Group interpersonal psychotherapy for depression in rural Uganda: a randomized controlled trial. *JAMA* 2003;289:3117-24.
- Patel V, Chisholm D, Rabe-Hesketh S et al. Efficacy and cost-effectiveness of drug and psychological treatments for common mental disorders in general health care in Goa, India: a randomised, controlled trial. *Lancet* 2003;361:33-9.
- Verdeli H, Clougherty K, Bolton P et al. Adopting group interpersonal psychotherapy for a developing country: experience in rural Uganda. *World Psychiatry* 2003;2:114-20.
- World Health Organization. *Mental health: new understanding, new hope*. The world health report 2001. Geneva: World Health Organization, 2001.
- The Lancet Mental Health Group. Scale up services for mental disorders: a call for action. *Lancet* (in press).
- Bower P, Gilbody S, Richards D et al. Collaborative care for depression in primary care. Making sense of a complex intervention: systematic review and meta-regression. *Br J Psychiatry* 2006;189:484-93.
- Abas M, Baingana F, Broadhead J et al. Common mental disorders and primary health care: current practice in low-income countries. *Harv Rev Psychiatry* 2003;11:166-73.
- Cohen A. *The effectiveness of mental health services in primary care: the view from the developing world*. Geneva: World Health Organization, 2001.
- Petersen I. *From policy to praxis: rethinking comprehensive integrated primary mental health care*. Unpublished PhD thesis, University of Cape Town, 2000.
- Patel V. Recognition of common mental disorders in primary care in African countries: should "mental" be dropped? *Lancet* 1996;347:742-4.
- Patel V, Andrade C. Pharmacological treatment of severe psychiatric disorders in the developing world: lessons from India. *CNS Drugs* 2003;17:1071-80.
- Linden M, Lecrubier Y, Bellantuono C et al. The prescribing of psychotropic drugs by primary care physicians: an international collaborative study. *J Clin Psychopharmacol* 1999;19:132-40.
- Saxena S, Sharan P, Garrido Cumbreira M et al. World Health Organization's Mental Health Atlas 2005: implications for policy development. *World Psychiatry* 2006;5:179-84.
- Patel V, Kirkwood BR, Pednekar S et al. Gender disadvantage and reproductive health risk factors for common mental disorders in women: a community survey in India. *Arch Gen Psychiatry* 2006;63:404-13.
- Patel V, Kirkwood BR, Pednekar S et al. Risk factors for common mental disorders in women. Population-based longitudinal study. *Br J Psychiatry* 2006;189:547-55.
- Patel V, Kirkwood BR, Weiss H et al. Chronic fatigue in developing countries: population based survey of women in India. *BMJ* 2005;330:1190.
- Ali BS, Rahbar MH, Naem S et al. The effectiveness of counsel-

- ing on anxiety and depression by minimally trained counselors: a randomized controlled trial. *Am J Psychother* 2003;57:324-36.
25. Lara MA, Navarro C, Navarrete L et al. Seguimiento a dos años de una intervención psicoeducativa para mujeres con síntomas de depresión, en servicios de salud para población abierta. *Salud Mental* 2003;26:27-36.
26. Campbell NC, Murray E, Darbyshire J et al. Designing and evaluating complex interventions to improve health care. *BMJ* 2007;334:455-9.