Economic evaluation of a task-shifting intervention for common mental disorders in India

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Objective To carry out an economic evaluation of a task-shifting intervention for the treatment of depressive and anxiety disorders in primary-care settings in Goa, India.

Methods Cost–utility and cost–effectiveness analyses based on generalized linear models were performed within a trial set in 24 public and private primary-care facilities. Subjects were randomly assigned to an intervention or a control arm. Eligible subjects in the intervention arm were given psycho-education, case management, interpersonal psychotherapy and/or antidepressants by lay health workers. Subjects in the control arm were treated by physicians. The use of health-care resources, the disability of each subject and degree of psychiatric morbidity, as measured by the Revised Clinical Interview Schedule, were determined at 2, 6 and 12 months.

Findings Complete data, from all three follow-ups, were collected from 1243 (75.4%) and 938 (81.7%) of the subjects enrolled in the study facilities from the public and private sectors, respectively. Within the public facilities, subjects in the intervention arm showed greater improvement in all the health outcomes investigated than those in the control arm. Time costs were also significantly lower in the intervention arm than in the control arm, whereas health system costs in the two arms were similar. Within the private facilities, however, the effectiveness and costs recorded in the two arms were similar.

Conclusion Within public primary-care facilities in Goa, the use of lay health workers in the care of subjects with common mental disorders was not only cost–effective but also cost-saving.

Introduction

Non-communicable diseases account for a growing burden on the health systems of developing countries. The effective management of these diseases typically requires a collaborative effort across the health workforce as well as continuing care for months or even years. In resource-poor areas, a “task-shifting” strategy can be beneficial, in which community or lay health workers (with oversight from primary-health-care practitioners and specialists) provide “front-line” care, instead of physicians and trained nurses. There is growing evidence of the effectiveness of such task-shifting in the management of some chronic conditions, including infection with the human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS), diabetes and some mental disorders.

Although the strategy appears particularly attractive in the many low-income countries with inadequate numbers of physicians and trained nurses, there is considerable institutional resistance to the widespread implementation of the strategy and also concern that the quality of care will deteriorate.

There is a clear need for more studies in which the cost–effectiveness of patients attended by physicians and trained nurses. There are various “steps” or levels of treatment, with the most intensive treatments reserved for the most severe cases. Used together, the collaborative-care and stepped-care components of this strategy can maximize the efficient use of scarce resources, especially in those public health facilities where case management has previously been relatively poor.

In several studies, collaborative stepped care led by lay health workers has been found to be successful in the primary care of depression and/or anxiety in low- or middle-income countries. This approach encourages the most effective sharing of tasks between medical, specialist and non-medical staff. There are various “steps” or levels of treatment, with the most intensive treatments reserved for the most severe cases. Used together, the collaborative-care and stepped-care components of this strategy can maximize the efficient use of scarce resources, especially in those public health facilities where case management has previously been relatively poor.

In the MANAS trial, the effectiveness of this approach in the primary care of patients with depression and/or anxiety was investigated in Goa, India. The design, implementation and general effectiveness of this cluster-randomized controlled trial have been described in detail elsewhere. Both public and private facilities were included in the trial because in India’s private facilities, the quality and costs of care are both gener-
ally higher than in public facilities. For example, private facilities offer repeated consultations with the same physician and are primarily financed with out-of-pocket payments from the patients. In contrast, many patients attending a public facility may see a different physician on each visit but will not pay for any of the consultations.

The present study evaluates the cost–effectiveness and cost–utility of the MANAS trial. We hoped that the additional resources needed to train, pay and supervise the lay health workers used in the “task-shifting” approach to the primary care of common mental disorders would promote recovery and reduced disability in a more cost–effective manner than more conventional care. In any particular country, the CHOICE programme of the World Health Organization (WHO) deems an intervention to be highly cost–effective if it generates an extra year of healthy life for an amount no greater than the country’s per capita gross domestic product.22

Methods

Study site

The present study formed part of the MANAS trial, which has been registered with Clinicaltrials.gov (NCT00446407) and previously described in detail.18,19,21 In brief, the trial was carried out in the state of Goa, in western India. Participants who met the initial eligibility criteria (e.g. aged >17 years and spoke one of the four study languages) were screened for depression and/or anxiety by means of a pre-tested General Health Questionnaire.25 Subjects found positive for either of these common mental disorders were invited to participate. The trial comprised two consecutive phases: an evaluation of the task-shifting intervention in 12 public centres for primary health care that were operated by the government of Goa (Phase 1), and an evaluation of the same intervention in 12 private general practitioner clinics (Phase 2). In each phase, health-care facilities were randomized to the intervention arm (i.e. collaborative and stepped care) or the control arm (i.e. enhanced usual care, described later).

Intervention arm

Subjects with depression and/or anxiety in the intervention arm received both collaborative care and stepped care. The collaborative care of each eligible subject was provided by three key health-care providers: the existing, full-time physician at the facility, a full-time lay health worker (or “health counsellor”) trained to provide psycho-social interventions, and a mental health specialist who visited each study facility once or twice a month. For stepped care, the intensity of the care offered to a subject was matched with the severity of that subject’s disorder, to optimize the use of scarce resources. Consenting subjects in the intervention arm were educated about their symptoms and the link between depression, anxiety and interpersonal difficulties. They were also taught strategies to reduce their symptoms (e.g. relaxation breathing exercises and scheduling activities) and provided with tailored information about the relevant social and welfare organizations. Subjects with mild depression and/or anxiety who did not respond well to such psycho-education were offered antidepressants and/or interpersonal therapy, as were subjects with moderate to severe depression and/or anxiety. The interpersonal therapy focused on the subject’s relationships with other people and their coping with events such as role transitions, conflict and grief. Case management, with proactive monitoring of outcomes and adherence support, formed the backbone of the intervention.

Control arm

Eligible subjects in the control arm received “enhanced usual care”. For this, the existing, primary-care physician in the facility was provided with the results of the initial screening and a treatment manual. Physicians were permitted to administer the treatments of their choice but did not have access to any additional (i.e. trial-related) human resources.

Health outcomes

The outcomes recorded for each subject 2, 6 and 12 months after recruitment were a psychiatric symptom score, presence/absence of either depression or anxiety and days of lost or reduced work. Quality-adjusted life years (QALYs) over the 12 months of follow-up were generated from disability scores.

For each subject, at enrolment and at each follow-up, a psychiatric symptom score between 0 and 49 was estimated using the Revised Clinical Interview Schedule, which measures 14 symptom groups of common mental disorder, including depression and anxiety. Although this schedule was developed in the United Kingdom of Great Britain and Northern Ireland,24 it has been used in several studies in India.25–27 The PROSQY software package – a diagnostic algorithm based on the ICD-10 criteria for the diagnoses of common mental disorders28 – was used to determine whether a subject had a common mental disorder at each follow-up.

The 12-item short-form version of WHO’s Disability Assessment Schedule29 was used to assess disability outcomes. Standardized summary scores were converted to a preference-weighted utility index,30 which was then used to compute the additional number of QALYs generated by the intervention over the 12-month follow-up.

The answers to two questions in WHO’s Disability Assessment Schedule29 can be used to estimate the number of days in the previous month that someone was completely unable to work or able to work only part time because of a health condition. For the present study, these two numbers were summed to give the number of days in which working hours were reduced because of poor health. As decreases in psychiatric symptom scores or in the number of days of lost work would both be favourable outcomes, the reciprocals of these scores and numbers were used for the regression analyses, so that the resultant incremental cost–effectiveness ratios would be easier to interpret.

Costs

At each of the three follow-ups, subjects self-reported their health-care utilization, medication use and out-of-pocket payments on the same type of cost-of-illness inventory used in several earlier studies in India.25,29,31 Two key categories of costs were estimated: health-system costs (including those related to the intervention itself, comprising the costs of inpatient and outpatient care, medical and clinical investigations) and the “time costs” for the subjects and their families (i.e. the opportunity costs of time spent travelling to, waiting for or receiving care, plus the wages from any days of work lost).

The additional human resource use associated with the lay health workers employed in the intervention was evaluated using the clinical process indicator

records listed in Appendix A (available at: http://sangath.com/images/file/MANASCEA_AppendixA.pdf). Some of the costs of the intervention were estimated by multiplying the total number of minutes a subject in the intervention arm had contact with a lay health worker by the per-minute cost of the health worker (Appendix A). All costs were calculated in Indian rupees (INR) for 2009 but are reported in United States dollars (exchange rate: INR 46.5 = US$ 1). As costs (and effects) for each subject were only followed for 1 year, no annual discounting was required.13

Analysis

Costs, scores and days-of-work data from each follow-up were summed to give totals for the full year post-recruitment. Descriptive means and standard deviations (SDs) for the cost data are presented. To assess the differences between the treatment and control groups and to allow for the skewed nature of the data on costs and outcomes, generalized linear models were used, with gamma distributions and log transformations.34–36 Estimates were adjusted for baseline depression scores and are presented with confidence intervals (CIs). The data analyses used in earlier studies on the MANAS trial were based on cluster-level summaries37 but there were too few clusters to use this approach in the present study. Furthermore, the approach has been deemed inappropriate for analyses of cost–effectiveness. 38 The analysis of resource use was based only on the data from subjects who were available for each of the scheduled follow-ups.39 In terms of subject age, gender and the other variables recorded, loss to follow-up appeared to be a random process. The substitution of missing data on costs with the corresponding mean, minimum or maximum values13 was reported in Indian rupees (INR) for 2009 but are reported in United States dollars (exchange rate: INR 46.5 = US$ 1). As costs (and effects) for each subject were only followed for 1 year, no annual discounting was required.13

Table 1. Average annual costs, per subject, in the intervention and control arms in public facilities, Goa, India, 2009

<table>
<thead>
<tr>
<th>Type of expenditure</th>
<th>Mean cost in US$ (SD)</th>
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<tbody>
<tr>
<td></td>
<td>Control (n = 825)</td>
</tr>
<tr>
<td>Health system</td>
<td></td>
</tr>
<tr>
<td>Outpatient</td>
<td>42 (61)</td>
</tr>
<tr>
<td>Inpatient</td>
<td>24 (102)</td>
</tr>
<tr>
<td>Investigations</td>
<td>5 (14)</td>
</tr>
<tr>
<td>Medication</td>
<td>17 (29)</td>
</tr>
<tr>
<td>Additional human resource costs</td>
<td>0</td>
</tr>
<tr>
<td>Subtotal</td>
<td>88 (140)</td>
</tr>
<tr>
<td>Time</td>
<td></td>
</tr>
<tr>
<td>Time costs of visiting outpatient facilities</td>
<td>17 (20)</td>
</tr>
<tr>
<td>Lost wages</td>
<td>108 (20)</td>
</tr>
<tr>
<td>Costs of time lost by family caregivers</td>
<td>12 (24)</td>
</tr>
<tr>
<td>Retreat costs</td>
<td>3 (13)</td>
</tr>
<tr>
<td>Subtotal</td>
<td>141 (198)</td>
</tr>
<tr>
<td>Total</td>
<td>229 (274)</td>
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</tbody>
</table>

SD, standard deviation; US$, United States dollars.

* Exchange rate: 46.5 Indian rupees = US$ 1. Note: The standard deviations in this table are unusually large because of the skew often found in cost data.

Results

Overall, 20,352 subjects were screened for depression and/or anxiety in the 24 study facilities. Of these, 3816 were found positive and 3434 met the criteria for eligibility; 2796 (81%) of the eligible subjects (1436 and 1360 subsequently assigned to the control and intervention arms, respectively) agreed to participate. In public facilities, 1437, 1416 and 1386 subjects were available at the first, second and last follow-ups. In private facilities, the corresponding numbers were 1054, 1013 and 981, respectively. Complete data were recorded for 1243 (75.4%) of the subjects recruited in public facilities and for 938 (81.7%) of those recruited in private facilities.

Public facilities

Costs

The descriptive means for costs are presented in Table 1. The mean total cost of the human resources associated with the intervention was INR 93 (US$ 2; SD: 1.53) per participant, or 2% of the unadjusted total health system cost incurred in the intervention arm. Subjects in the intervention arm had contact with the lay health workers, either in person or over the telephone, on a mean of 6.9 occasions (SD: 3.80) and for a mean total of 70.8 min (SD: 54.2).

The regression-adjusted cost differences between the intervention and control arms are presented, for those with complete data, in Table 2. Total health system costs were marginally higher in the intervention arm than in the control arm but this difference was not statistically significant. However, overall time costs for subjects and their families and total costs were significantly lower in the intervention arm than in the control arm (P < 0.001 and < 0.01, respectively).

Health outcomes

Over the 12 months of follow-up, mean psychiatric symptom scores improved by 3.84 points (95% CI: 3.29 to 4.38) more in the intervention arm than in the control arm (Table 2). Furthermore, compared with their counterparts in the control arm, subjects in the intervention arm gained significantly more QALYs and achieved significantly more days of work (Table 2).

Cost–effectiveness and cost–utility

Although negative incremental cost–effectiveness ratios can be difficult to interpret,34,36,42 the ratios calculated in the present study indicate that the intervention was both less costly and more effective than enhanced usual care in terms of all the health outcomes investigated. The between-arm difference in QALYs gained appeared small (0.02), partly because it only relates to a single year, but this difference represents a mean of 7.3 additional days free of depression and/or anxiety for each subject in the intervention arm. The mean health system cost per case recovered at the end of
follow-up (Appendix A) was INR 5959 (US$ 128; 95% CI: 105 to 157) in the intervention arm and INR 6933 (US$ 149; 95% CI: 131 to 169) in the control arm. The between-arm difference in the total costs per case recovered was even more striking, with such costs in the public and private facilities about INR 5600 (US$ 120) and INR 4000 (US$ 86) lower, respectively, in the intervention arm than in the control arm.

**Sensitivity analysis**

Uncertainty analyses can provide a range of conditions over which an intervention is plausibly cost–effective.33,43 In the public facilities, incremental cost–effectiveness ratios indicate that the intervention would be cost-saving under about half of the conditions illustrated in Fig. 1. Although the intervention would be more effective under the other conditions, it would also be more costly.

Uncertainty in the cost–effectiveness of an intervention can also be illustrated as a cost–effectiveness acceptability curve (Fig. 2).44 There are no accepted threshold values to indicate willingness-to-pay for improvement in depression measures such as the psychiatric symptom score, but the probability that the intervention will be cost–effective at very low threshold values of < INR 400 (US$ 8.60; i.e. less than the amount earned by an individual working for 3 days for the legal minimum wage in Goa)13 is very high (nearly 1.00). When the only outcome considered is the number of days of work gained, the intervention always appears to be cost–effective. When time costs are included, the intervention appears to be cost-saving, since it improves health outcomes while lowering costs.

The results of other sensitivity analyses indicated that the cost data were sensitive to the missing observations (Appendix A). However, the cost differences between the intervention and control arms were found to be consistently statistically significant, in favour of the intervention arm, under all conditions except the worst-case scenario.

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**Table 2. Between-arm difference in annual costs, per subject in public facilities, and health outcomes, Goa, India, 2009**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Control arm</th>
<th>Intervention arm</th>
<th>Difference^a</th>
</tr>
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<tbody>
<tr>
<td><strong>Mean cost in US$^b (95% CI)</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Health system</td>
<td>88 (78 to 100)</td>
<td>88 (73 to 109)</td>
<td>0.5 (−19 to 22)</td>
</tr>
<tr>
<td>Time</td>
<td>136 (122 to 151)</td>
<td>91 (79 to 104)</td>
<td>−45 (−65 to −27)</td>
</tr>
<tr>
<td>Total</td>
<td>225 (204 to 247)</td>
<td>179 (154 to 208)</td>
<td>−46 (−79 to −12)</td>
</tr>
<tr>
<td><strong>Mean outcome (95% CI)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychiatric symptom score^c</td>
<td>32.03 (31.63 to 32.45)</td>
<td>35.87 (35.49 to 36.23)</td>
<td>3.84 (3.29 to 4.38)</td>
</tr>
<tr>
<td>Quality-adjusted life years</td>
<td>0.82 (0.81 to 0.83)</td>
<td>0.84 (0.84 to 0.85)</td>
<td>0.02 (0.01 to 0.03)</td>
</tr>
<tr>
<td>Complete or partial days worked</td>
<td>197 (187.7 to 206.8)</td>
<td>259.54 (251.75 to 267.28)</td>
<td>62.2 (49.6 to 75.0)</td>
</tr>
</tbody>
</table>

**Incremental cost–effectiveness**

<table>
<thead>
<tr>
<th></th>
<th>Control arm</th>
<th>Intervention arm</th>
<th>Difference^d</th>
</tr>
</thead>
<tbody>
<tr>
<td>In terms of health system costs</td>
<td>–</td>
<td>More costly, more effective</td>
<td>–</td>
</tr>
<tr>
<td>In terms of total costs</td>
<td>–</td>
<td>Less costly, more effective</td>
<td>–</td>
</tr>
</tbody>
</table>

CI, confidence interval; US$, United States dollars.

^a The value for the control arm subtracted from the corresponding value for the intervention arm.

^b Exchange rate: 46.5 Indian rupees = US$ 1.

^c Adjusted for baseline symptom scores.

^d Evaluated using the Revised Clinical Interview Schedule, the scale of which was inverted for ease of inference for the incremental cost effectiveness ratios.

^e The same trends were seen when each of the three outcomes was considered separately.


**Discussion**

Despite the additional resources required for the intervention led by lay health workers, the health system costs incurred over the 12 months of follow-up were similar across the two arms. In the public (but not the private) facilities investigated, time costs were lower and health outcomes were significantly better in the intervention arm than in the control arm. In the public primary-care facilities, therefore, the intervention appeared to be not only cost-effective but also cost-saving: the subjects in the intervention arm used and/or lost less cash and showed greater improvement in their mental state than the control subjects. There were no statistically significant between-arm differences in any of the health outcomes investigated in private facilities, probably because the standard of routine care in such facilities (i.e. the basic level of care experienced in the control arm) was relatively high. In these facilities, however, the care of the subjects with depression and/or anxiety was cheaper in the intervention arm than in the control arm and therefore the intervention still appeared advantageous from a cost-minimization perspective.

The use of task-shifting to reduce the barriers posed by shortages of mental health professionals is becoming increasingly common. One study has already shown it to be an effective approach. The present results indicate that such task-shifting can reduce the total costs of the care of patients with depression and/or anxiety and improve health outcomes in public facilities. In such facilities the intervention was cost–effective by WHO’s CHOICE programme criteria.

Our study adds to the little that is known about the cost–effectiveness of task-shifting interventions for non-communicable or chronic diseases in developing countries. There is a clear need for more studies on this topic. A task-shifting pharmaceutical intervention for HIV/AIDS patients in South Africa was found to be cost–effective. There appears to have been only one previous investigation of the cost–effectiveness of a task-shifting intervention for the treatment of mental disorders in a developing country: in Chile, an intervention based on the stepped care model of depression in women was found to increase health-system costs but provided an extra depression-free day for a small incremental cost of about US$ 1 per woman.

The present study has several limitations. All the data on service utilization were participant-reported and therefore subject to recall bias. A recent review of self-reported service utilization in 42 studies identified several key factors that can influence the quality and accuracy of self-reported data, such as the sample population and cognitive ability, the recall time frame, the type of utilization, questionnaire design, the mode of data collection and the use of memory aids and probes. Most of these issues were addressed and mitigated in the present study, whose design was based on the Client Socio-Demographic and Service Receipt Inventory – European Version. A second limitation of the present study is that no baseline data on resource use were collected, although there were no significant between-arm differences in any baseline outcome measures. A third limitation is that detailed results are only presented for the public facilities, since the results from the private facilities did not show that the intervention was more effective. The full results from the private facilities are, however, available in Appendix A and other articles. Finally, our use of the minimum wage as a measure of the economic value of lost time was designed to be conservative but is subject to uncertainty. For example, there are some highly skilled workers in the study population who, presumably, earn much more than the minimum wage. There are also variable ways in which households cope with illness. A more detailed microeconomic analysis of household impacts is needed to provide better estimates of the associated costs.

In conclusion, for practitioners and policy-makers concerned about invest-
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ing in lay health workers for improving the care of patients with non-communicable diseases, our findings demonstrate that the additional investments needed to scale up the MANAS intervention via task-shifting to lay health workers would probably be offset by reduced overall costs. Such an intervention could also provide significant clinical and functional benefits to people with depression and/or anxiety who attend public primary-care facilities. There may be a compelling economic case for investing in lay health workers for the care of other chronic and non-communicable diseases in India. Future studies should be conducted to assess the cost-effectiveness of such an intervention in other settings.

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Competing interests: None declared.

Résumé
Évaluation économique d’une intervention de transfert de tâches dans le cadre du traitement des troubles mentaux communs en Inde
Objectif Réaliser une évaluation économique d’une intervention de transfert de tâches dans le cadre du traitement des troubles dépressifs et anxieux dans les établissements de soins primaires à Goa, en Inde.
Méthodes Des analyses de coût-utilité et coût-efficacité basées sur des modèles linéaires généralisés ont été effectuées dans le cadre d’un essai organisé dans 24 établissements publics et privés de soins primaires. Les sujets ont été répartis de manière aléatoire entre groupe d’intervention ou groupe témoin. Les sujets du groupe d’intervention ont bénéficié d’une psychoéducation, de la gestion de cas, d’une psychothérapie interpersonnelle et/ou d’antidépresseurs de la part d’agents de santé professionnels. Les sujets du groupe témoin ont été traités par des médecins. L’utilisation des ressources de santé, le handicap de chaque sujet et le degré de morbidité psychiatrique, tel que mesuré par le Programme d’entretien clinique révisé, ont été déterminés à 2, 6 et 12 mois.
Résultats Les données complètes de chacun des trois suivis ont
Étude recueillies pour 1243 (75,4%) et 938 (81,7%) des sujets inscrits dans les établissements publics et privés, respectivement. Dans les établissements publics, les sujets du groupe d’intervention connaissaient une amélioration plus importante de tous les résultats sanitaires étudiés que les sujets du groupe témoin. Les coûts en termes de temps étaient également significativement plus faibles dans le groupe d’intervention que dans le groupe témoin, alors que les coûts du système de santé dans les deux groupes étaient similaires. Dans les établissements privés, cependant, l’efficacité et les coûts enregistrés dans les deux groupes étaient similaires.

Conclusion Dans les établissements publics de soins primaires à Goa, le recours à des agents de santé non professionnels pour la prise en charge des sujets atteints de troubles mentaux communs était non seulement efficace en termes de coût, mais aussi plus économique.

Resumen

Evaluación económica de una intervención de delegación de funciones para trastornos mentales comunes en India

Objetivo Realizar una evaluación económica de una intervención de delegación de tareas para el tratamiento de trastornos depresivos y de ansiedad en entornos de atención primaria en Goa, India.

Métodos Se llevaron a cabo análisis de la relación coste-utilidad y coste-eficacia basados en modelos lineales generalizados en un ensayo realizado en 24 centros de atención primaria tanto públicos como privados. De manera aleatoria, se asignó a los sujetos un brazo de intervención o otro de control. Empleados sanitarios no profesionales proporcionaron psicoeducación, tratamiento del caso, psicoterapia interpersonal y/o antidepresivos a los sujetos que reunían los requisitos necesarios en el brazo de intervención. Los sujetos en el brazo de control fueron tratados por médicos. Se determinó el uso de recursos para la atención sanitaria, la discapacidad de cada sujeto y el grado de morbilidad psiquiátrica, según lo evaluado por el Perfil de funcionamiento clínico (CIS-R), a los 2, 6 y 12 meses.

Resultados De los tres seguimientos, se recogieron los datos completos de 1243 (75,4%) y 938 (81,7%) de los sujetos inscritos, respectivamente, en los centros de estudio públicos y privados. En los centros públicos, los sujetos en el brazo de intervención mostraron una mejora superior que los del brazo de control en todos los resultados sanitarios que se investigaron. Los costes de mantenimiento también fueron notablemente inferiores en el brazo de intervención que en el de control, mientras que los costes para el sistema de salud fueron similares en los dos brazos. En los centros privados, sin embargo, la eficacia y los costes registrados fueron similares para los dos brazos.

Conclusión El uso de empleados sanitarios no profesionales en los centros de atención primaria públicos en Goa para el cuidado de sujetos con trastornos mentales comunes no sólo fue efectivo en relación con los costes sino que también supuso un ahorro.


