Effect of collaborative care between traditional and faith healers and primary health-care workers on psychosis outcomes in Nigeria and Ghana (COSIMPO): a cluster randomised controlled trial

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Summary

Background Traditional and faith healers (TFH) provide care to a large number of people with psychosis in many sub-Saharan African countries but they practise outside the formal mental health system. We aimed to assess the effectiveness and cost-effectiveness of a collaborative shared care model for psychosis delivered by TFH and primary health-care providers (PHCW).

Methods In this cluster-randomised trial in Kumasi, Ghana and Ibadan, Nigeria, we randomly allocated clusters (a primary care clinic and neighbouring TFH facilities) 1:1, stratified by size and country, to an intervention group or enhanced care as usual. The intervention included a manualised collaborative shared care delivered by trained TFH and PHCW. Eligible participants were adults (aged ≥18 years) newly admitted to TFH facilities with active psychotic symptoms (positive and negative syndrome scale [PANSS] score ≥60). The primary outcome, by masked assessments at 6 months, was the difference in psychotic symptom improvement as measured with the PANSS in patients in follow-up at 3 and 6 months. Patients exposure to harmful treatment practices, such as shackling, were also assessed at 3 and 6 months. Care costs were assessed at baseline, 3-month and 6-month follow-up, and for the entire 6 months of follow-up. This trial was registered with the National Institutes of Health Clinical Trial registry, NCT02895269.

Findings Between Sept 1, 2016, and May 3, 2017, 51 clusters were randomly allocated (26 intervention, 25 control) with 307 patients enrolled (166 [54%] in the intervention group and 141 [46%] in the control group). 190 (62%) of participants were men. Baseline mean PANSS score was 107·3 (SD 17·5) for the intervention group and 108·9 (18·3) for the control group. 286 (93%) completed the 6-month follow-up at which the mean total PANSS score for intervention group was 53·4 (19·9) compared with 67·6 (23·3) for the control group (adjusted mean difference –15·01 (95% CI –21·17 to –8·84; 0·0001). Harmful practices decreased from 94 (57%) of 166 patients at baseline to 13 (9%) of 152 at 6 months in the intervention group (–0·48 [–0·60 to –0·37] p<0·001) and from 59 (42%) of 141 patients to 13 (10%) of 134 in the control group (–0·33 [–0·45 to –0·21] p<0·001), with no significant difference between the two groups. Greater reductions in overall care costs were seen in the intervention group than in the control group. At the 6 month assessment, greater reductions in total health service and time costs were seen in the intervention group; however, cumulative costs over this period were higher (US $627 per patient *vs* $526 in the control group). Five patients in the intervention group had mild extrapyramidal side effects.

Interpretation A collaborative shared care delivered by TFH and conventional health-care providers for people with psychosis was effective and cost-effective. The model of care offers the prospect of scaling up improved care to this vulnerable population in settings with low resources.

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Introduction

With schizophrenia alone being responsible for about 7% of years lived with disability, psychotic disorders are a major cause of disability as well of considerable burden to families and caregivers globally.[1] In many low-income and middle-income countries as well as in poorly resourced parts of high-income countries, many people with psychotic disorders receive health care from complementary alternative health-care providers, including traditional and faith healers (TFH).[2–4] In much of sub-Saharan Africa, factors such as scarcity of mental health specialists, nearness to the community, and shared belief about the causes and treatment of psychosis make TFH the preferred sources of care.[5–8] These realities have often led to calls for the integration of traditional healers into mainstream health services,[9] with several

Research in context

Evidence before this study

We searched PubMed and PsychINFO from Sept 25, 2012, to Oct 1, 2014, for studies exploring the feasibility, effectiveness, and cost-effectiveness of collaboration between complementary alternative health care providers, specifically traditional and faith healers, and conventional health-care providers in the care of people with psychosis. We imposed no language restrictions. Our search terms included "severe mental disorders", "psychosis", "traditional healers", "faith healers", "mental health providers", "collaboration", "integration", and "low and middle-income countries". We also hand searched reference lists of papers and books identified by this search. Several journal articles provided information about the profile of patients in the care of traditional and faith healers, with evidence that people with psychosis were commonly among these patient groups. There was also information about diagnostic and treatment approaches as well as observation that, even though the care provided often led to improvement in the clinical condition of the patients, some of the treatment practices were potentially harmful and not always in conformity with the human rights of patients. A need to develop approaches to facilitate collaboration between the healers and conventional health care providers was frequently emphasised even though there was also scepticism about whether collaboration could work given discordant views about the nature of psychopathology between healers and conventional providers. Other than collaborative efforts involving the engagement of traditional healers in the provision of care, specifically counselling, to people with HIV, no systematic study had been done to test whether healers and conventional providers can collaborate in the care of people with psychosis and no previous randomised controlled trial of the effectiveness and cost-effectiveness of collaboration between healers and providers has been done.

Added value of this study

To our knowledge, this is the first randomised controlled trial of the effectiveness and cost-effectiveness of a collaborative shared care for psychosis delivered by traditional and faith healers and conventional primary care providers. Prespecified primary and secondary outcomes, assessed at 6 months following trial entry, included psychotic symptoms, disability, self-stigma, course of illness, duration of admission, quality of work performance, living condition, and having harmful or inhumane treatments. Findings show that most outcomes were better with a model of care in which primary care providers worked collaboratively with traditional and faith healers to deliver care to people with psychotic disorders compared to care as usual. Collaborative shared care was successfully implemented between healers and conventional providers and was cost-effective.

Implications of all the available evidence

Our findings suggest that collaboration between healers and conventional providers can be designed and implemented, and that collaboration has the potential for delivering effective and cost-effective care to the large population of people in need of care for psychosis in low-income and middle-income countries. However, more research is needed to examine the factors that might be relevant for scaling up such collaborative shared care model into routine service for people with psychosis.

countries including the idea of integration in their national policies.

Although there is interest in integration,[9] which implies the inclusion of TFH in the formal health system, a more cautious programme of collaboration has been suggested to be tested for its feasibility and effectiveness in promoting better outcomes for patients.[2] One of the main reasons for that caution is the concern that some TFH use treatment approaches that are potentially harmful or that verge on human rights infringements of vulnerable patients with serious mental disorders, such as shackling, use of untested or unknown concoctions, and forced prolonged fasting,[10,11] even though some of these practices also sometimes occur in institutional care. TFH include people whose healing practice is guided by traditional religion, Christianity, or Islam, as well as those who subscribe to no particular faith, and eclecticism is common.

Although there is some evidence that a collaborative care programme with TFH can be feasible, especially in the care of people with HIV,[12,13] no study has examined the clinical effectiveness of such a programme for severe mental health conditions. In a series of formative studies, we had systematically explored strategies that might promote trust and facilitate collaboration between healers and formal health-care providers.[14,15] This trial, Collaborative Shared Care to Improve Psychosis Outcome (COSIMPO), using cluster randomisation to avoid contamination, aims to determine the effectiveness of such collaboration in improving the clinical outcome of people with psychosis.[16] We hypothesised that a collaborative intervention delivered by TFH and conventional primary health-care providers would be more effective and cost-effective than care as usual for people with psychotic disorders. Typically, TFH do not engage with biomedical health providers in their usual or routine practice.

Methods

Study design

The protocol and a full description of the setting and methods of the study have been published.[16] COSIMPO is a single-blind, cluster randomised controlled trial done in the 11 local government areas in and around the city of Ibadan in Nigeria and in the Ashanti region of Ghana.

Following a mapping of all facilities run by TFH providing mental health services and all the public primary health-care clinics in the two locations, a sampling frame of service clusters was constructed. A cluster consisted of one primary care clinic (PHC) and all the TFH facilities in the catchment area served by the PHC. A cluster was eligible if it had at least one TFH facility with active inpatient service and a PHC with full complement of staff to permit the participation of two primary health-care workers (PHCW) in the trial. A cluster was thus composed of one PHC and between one and five TFH facilities, Across the two sites, a total of 71 clusters were formed following this procedure (37 in Ghana and 34 in Nigeria).

In the setting of COSIMPO, Ghana and Nigeria, traditional healers comprise herbalists (those who use plant products for medicinal purposes) or diviners (those who claim to gain insight for healing by occultic or ritualistic processes). Faith healers are those who subscribed to Christian or Islamic faith and rely on prayers and religious rituals, including divination and fasting to provide healing. In practice, an eclectic approach in which both rituals and divination are used as treatment modalities is common between the three groups. In both settings, healers provide care for most people with psychotic disorders[17] and most healers who treat mental disorders offer inpatient services. PHCWs consisted of registered nurses, clinical officers, community health officers, or community health extension workers. In Ghana, a few PHCs have community psychiatric nurses. In both settings, referrals from PHCs can be made to other levels of care such as a general hospital staffed by general physicians or to specialists when available.

The trial was approved by the University of Ibadan–University College Hospital Ethics Committee (UI/EC/12/0219) and the Ethics Committee of the Kwame Nkrumah University of Science and Technology (CHRPE/AP/512/16). The trial was also approved and monitored by the US National Institute of Mental Health Data Safety and Monitoring Board; an independent oversight body established by the funder.

Patients

All patients were recruited into the trial at the TFH facilities where they were admitted for treatment of psychosis. The trained research assistants, all university educated, came to know about potential participants either during the research assistants' routine visits to the facilities or following calls from the TFH to the study team about the presence of potential participants. All patients who were admitted at TFH facilities during recruitment were deemed potentially eligible and were approached by the research assistants and, if they provided consent to be screened, were assessed for eligibility. Eligible patients were those aged 18 years or over, fluent in the study language of Yoruba (Nigeria) or Twi (Ghana), with a confirmed diagnosis of non-organic psychosis as assessed using the structured clinical interview for Diagnostic and Statistical Manual of Mental Disorders version IV,[18] and who were actively symptomatic at the time of recruitment as indicated by a minimum score of 60 on the total positive and negative syndrome scale (PANSS).[19] Designed as a pragmatic trial, the few exclusion criteria were: women who were pregnant or attempting to become pregnant during the study period, serious physical illness in need of urgent medical attention, severe cognitive impairment, and people who would not be in the study area for at least 6 months following recruitment, as detailed in the protocol.[16] A strict consenting procedure, including prior assessment by an independent social worker of capacity to consent, was followed to obtain participants' as well as primary caregivers' consents. Consent was given by a signature or a thumbprint.

Randomisation and masking

The unit of randomisation was eligible and consenting clusters consisting of one PHC and a group of TFH facilities, although the unit of analysis was individual participants. Consent for clusters was obtained from PHC managers and TFH facility owners. Participating clusters were stratified by country and randomly allocated to deliver collaborative shared care or enhanced care as usual. Allocation to the two groups was balanced by site (Ghana versus Nigeria) and by size of the cluster, using the total number of admission beds in each cluster (small versus large). Following the mapping exercise of the facilities and the composition of the clusters, anonymised codes for each cluster were provided by the research team to the statistician, with no other involvement in the implementation of the trial, who used a computer generated allocation sequence to carry out the block randomisation.

Baseline assessments of participants who consented were done within 3 days of enrolment. The 3-month outcome assessments were done by research assistants who recruited the trial participants at baseline and therefore could not be masked. The 6-month outcome assessments were done by masked assessors who had no other involvement in the trial. Patients, caregivers, and care providers (PHCW and TFH) were not masked at any point.

Procedures

The intervention involved the working together of TFH and PHCW to provide care for people with psychotic disorders who were admitted to the facilities of the TFH. In each cluster, two PHCW were engaged in a collaborative care model (described later). The PHCW made two types of visits to the TFH facilities in their cluster: scheduled visits done at least weekly and unscheduled visits initiated by the TFH and done in response to urgent requests for assistance in the management of the trial participants. Such requests might be for acute deterioration in trial participants' mental status, including risks of violence, self-harm, absconding, or emergent or worsening physical illness.

As described in the protocol[16] and specified in a detailed intervention manual of procedures provided to the PHCW, there were two main components in the collaborative shared care. First, clinical support to respond to the medical needs of patients with psychosis, which often meant the administration of medication to manage psychotic symptoms, especially in response to acute psychotic disturbance, or medication for emergent physical illnesses, such as infections or injuries. Second, clinical support to improve service on a continuous basis, which consisted of engagement and interactions with the TFH, the patient, and the caregivers of the patient. During the regular weekly visits, the PHCW provided information on best clinical practice (reinforcing the message provided to the TFH during training before trial commencement, especially on how to avoid the use of potentially harmful treatment practices), provided information on patient rehabilitation, and attended to any other clinical issues raised by TFH. The PHCW also provided psychoeducation to both patients and any available relative during such visits. All inputs from the PHCW were in addition to the treatments routinely provided by the healers, including herbal, ritual, and psychosocial interventions.

In this collaborative shared care arrangement, medication could only be prescribed by the PHCW. If a patient required a prescription of a psychotropic medication, the PHCW would take into account any herbs prescribed for the patient by the TFH and monitor closely for any side-effects. Chlorpromazine (up to 200 mg daily), which the PHCWs are authorised to prescribe, was the antipsychotic of first choice and this was made freely available during the study. In Ghana, primary care providers also had access to and were able to prescribe olanzapine (up to 20 mg daily). Higher doses for both drugs were discussed with the supervising psychiatrists whenever indicated. PHCW at each site were supervised by the psychiatrists in the research teams and were consulted on as-needed basis using closed-user-group mobile telephony. The PHCW could also refer a trial participant to a health facility, as necessary, but always following consultation with and consent of the TFH.

As described in full in the protocol,[16] the PHCW in the intervention group received a manualised, 3-day interactive training on the medical management of psychosis. TFH were trained over 2 days about how to avoid the use of harmful treatment practices, among other topics such as the common symptoms and signs of psychosis and the different courses of the condition. Both were trained on the modalities for implementing collaborative shared care including expectations, roles, and possible barriers and facilitatory factors for effective collaboration.

Participants in the control group received enhanced care as usual. Because the participants were all admitted at TFH facilities, usual care consisted of the usual treatment provided by the TFH, which varied by healer. Typically, this treatment consisted of combinations of herbs, rituals, prayer, fasting, and divination. As indicated earlier, eclectic approaches are common and so is the use of shackling to restrain patients who are acutely disturbed and scarification to drain away so-called bad blood.

Usual care meant that no formal collaboration was fostered between the TFH and PHCW in this group. Nevertheless, care as usual was enhanced through the separate training of both the TFH and PHCW in this group. In particular, and as requested by our ethics committees, detailed discussions were held with the TFH in the control group about ways to reduce inhumane and potentially harmful treatment practices. The PHCW had a 2-day discussion session and the TFH were invited for a 1-day interactive session. The contents of the sessions were essentially similar to those for the collaborative shared care groups except that topics dealing with the features and modality of collaborative shared care were not included. The goal of the trainings was to reduce potential harm to patients who were nonetheless still receiving care as usual.

Outcomes

The primary outcome, assessed at 6 months following enrolment into the trial, was the difference in psychotic symptom improvement (or reduction in symptoms) as measured with the PANSS. Similar to previous observations in the setting of our study,[20] both the internal reliability of PANSS, using screening data of the total trial sample, (307 participants; Cronbach's alpha, 0·82) and the inter-rater reliability, from the independent ratings of ten patients by four assessors (intraclass correlation 0·99) were excellent. Secondary outcomes measured at 3 and 6 months included: disability (using the WHO Disability Assessment Scale 2.0),[21] having self-stigma (using the 29-item Internalised Stigma of Mental Illness),[22] exposure to harmful treatment practices (such as shackling, scarification, prolonged fasting), and to victimisation by relatives, friends or neighbours (such as verbal, physical or sexual abuse, financial exploitation, or neglect) both of which were assessed using locally designed tools as described in the protocol.[16] An overall masked assessment of the course of illness (using the Life Chart Schedule[23]) including duration of admission, symptom course, work performance, and living condition (independent or not) was also done at 6 months.

We also collected information on other serious adverse events (including serious medical emergency, serious suicidal behaviour, and death).

All outcome assessments were done via face-to-face interviews using either the Yoruba (in Nigeria) or Twi (in Ghana) versions of the different instruments, derived by standard protocols of iterative back-translation that take account of language and cultural nuances. The 6-month primary outcome assessment was done in

Nigeria by senior trainee psychiatrists and in Ghana by a mix of senior trainee psychiatrists and pre-doctoral psychology graduates. These assessors had no role in patient recruitment and the assessments were masked to patient group allocation and mostly in patients' homes or, in a few instances, at the TFH facilities. These assessors were trained at each site over 3 days by OG and VM.

See Online for appendix

Costs measures

To assess the cost-effectiveness of collaborative shared care compared with enhanced care as usual over the period of the trial, we administered to all participants an adapted version of the Service Utilization Questionnaire[24] to capture the range of health-related services used by service users over the preceding 2 months (including the care received from TFHs and services delivered by PHCWs and other conventional health providers) as well as any out-of-pocket health-care spending for consultations, medicaments, and other related costs. The adaptation enabled us to collect data on use of herbs and drugs as well as costs incurred on rituals and sacrifices (animals or foodstuff). Also included are the costs of training PHCWs and TFH as well as of incentives to the former PHCWs (appendix p 1). We used simplified costing templates and local data inputs to generate a set of unit costs and prices for inpatient and outpatient service use provided and paid for by government or non-state actors; for health services or goods paid for privately by individuals or households we used the monetary amounts reported in the Service Utilization Questionnaire. Multiplication of unit costs or prices with reported levels of service use enabled us to compute health-service costs per trial participants both for the 3-month periods leading to the baseline and to the follow-up assessment at 3 and 6 months. All costs were collected in the local currency units of the two participating countries and were subsequently converted into US$ for the year 2017–18 using the mean official exchange rate for the period.

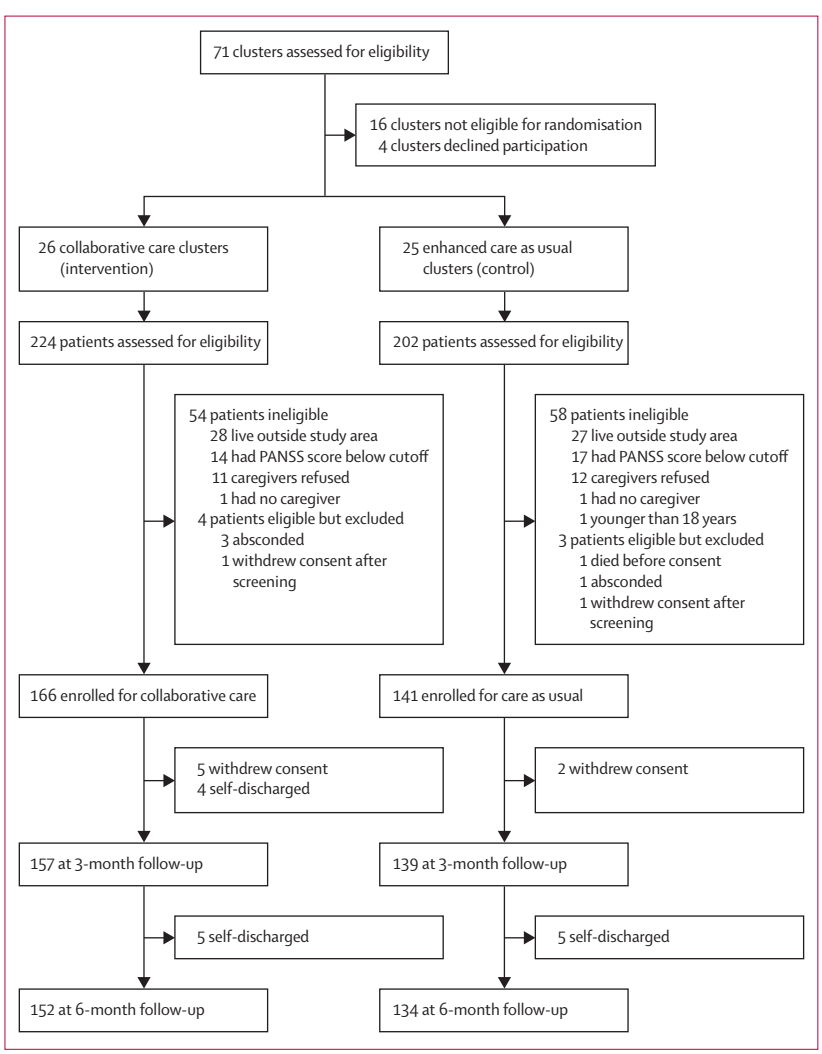

Figure 1: **Trial profile**
PANSS=positive and negative syndrome scale.

Statistical analysis

Using data from a previous naturalistic follow-up study of people with psychosis undergoing treatment conducted by our team,[25] we estimated that a mean difference of 7·5 points on the total PANSS outcome scores between the two groups would represent a clinically significant difference. As detailed in the protocol,[16] we estimated an intra-cluster correlation coefficient of 0·02 based on other studies and we estimated a loss of 20% of participants for the primary analysis. The estimated uninflated sample size required was 112 participants per group, with 80% power and an alpha of 0·05. With a target of six participants per cluster and a design effect of 1·10, the total number required for analysis was 246. With 49 clusters and six participants per cluster, we therefore aimed to recruit a total of 296 participants. Since 51 clusters were eligible and agreed to participate in the trial, we decided to include them all.

Data were analysed using a prespecified analysis plan in accordance with CONSORT guidelines,[26] with between-group comparisons analysed by intention to treat at cluster level. All analyses were done for the total sample, pooled across both country sites and focused primarily on baseline and the masked 6-month outcome data. Descriptive statistics were used to compare the characteristics of participants across groups at baseline. Because the 6-month follow-up rate was found to be high, we decided not to impute for missing data and the analyses also disregarded adherence to the intervention or withdrawal from the trial. We present unadjusted as well as adjusted estimates. For continuous outcomes with normally distributed residuals, the intervention effect was estimated as the difference in mean scores

between collaborative shared care and enhanced care as usual using random effects linear regression, adjusted for sex, marital status baseline PANSS score, country, and cluster. The effect sizes are reported as standardised mean differences with 95% CI. Random-effects logistic regression is used to analyse binary outcomes with the effect sizes reported as relative risks estimated using the marginal standardisation technique with 95% CI of the ratios estimated by the delta method. In both analyses, cluster and country site were accounted for, with the clustering variable included as random effect. For a higher standard of evidence and to take account of multiple comparisons, we set our statistical significance level as p<0·005.[27]

For every service, input and time loss, mean 3-month costs were computed at baseline, 3-month and 6-month follow-ups as well as for the entire 6 months of follow-up. For cost-effectiveness analysis, mean costs were computed for each trial group and these were then linked to the change from baseline of the clinical measure (PANSS total score) as well as functioning (WHO disability assessment scale summary scores) at 3-month and 6-month outcome points. Owing to the non-normal distribution of mean service costs per study participant, the 95% CI around cost and cost-effectiveness estimates were derived using non-parametric bootstrapping techniques (1000 resamples were run). All analyses were done using the STATA, version 15.0.

This trial is registered with ClinicalTrials.gov, NCT02895269.

Role of the funding source

The funder of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author has full access to all data and had final responsibility for the decision to submit for publication.

Results

Of 71 clusters assessed, 16 were found ineligible and four had PHCs that declined to participate. Of the 16 ineligible clusters, ten had TFH that were no longer active and six had PHC with inadequate number of staff, as determined by the facility managers, to guarantee the participation of at least two PHCW in the collaborative activities. The remaining 51 eligible clusters, where all the TFH and PHCW provided consent, were randomly assigned the two groups of the study (figure 1, table 1). The groups were similar in demographic and clinical features at baseline. Recruitment into the trial commenced on Sept 1, 2016 and ended on May 3, 2017. The last 6-month outcome assessment was done on Oct 3, 2017. Follow-up at 6 months was completed for 152 (92%) of 166 patients in the intervention group and for 134 (95%) of 141 patients in the control group. The 14 (8%) of 166 patients in the intervention group and the seven (5%) of 141 patients in the control for whom primary outcome data was not collected exited the trial before completion, with 11 (52%) of the 21 patients doing so before the 3-month outcome assessments.

	Intervention group (n=166)	Control group (n=141)
Sex		
Male	111 (67%)	79 (56%)
Female	55 (33%)	62 (44%)
Religion		
Christianity	101 (60%)	89 (63%)
Islam	64 (39%)	52 (37%)
Traditional	1 (1%)	0
Marital status		
Single	110 (66%)	73 (52%)
Married	31 (19%)	32 (23%)
Divorced	10 (6%)	17 (12%)
Separated or widowed	15 (9%)	19 (13%)
Employment status*		
Unemployed	120 (72%)	106 (75%)
Housewife	6 (4%)	2 (1%)
Unskilled labourer	14 (8%)	15 (11%)
Skilled labourer	19 (11%)	13 (9%)
Middle-level worker	3 (2%)	1 (1%)
Professional	4 (2%)	4 (3%)
Type of psychosis		
Schizophrenia	137 (83%)	122 (87%)
Schizophreniform disorder	13 (8%)	8 (6%)
Schizoaffective disorder	9 (5%)	6 (4%)
Brief psychotic disorder	7 (4%)	5 (4%)
Age, years	33·2 (12·1)	33·4 (10·2)
Years of education	9·6 (3·8)	9·3 (3·6)
Total PANSS score†	107·3 (17·5)	108·9 (18·3)
Total WHO-DAS score‡	94·7 (29·5)	91·5 (28·7)
GAF score§	36·8 (11·2)	35·6 (10·1)
Total ISMI score¶	2·4 (0·6)	2·3 (0·6)

Data are n (%) or mean (SD). PANSS=Positive and Negative Syndrome Scale. WHO-DAS=WHO disability assessment schedule. GAF=Global Assessment of Functioning. ISMI=Internalised Stigma of Mental Disorders. *Unemployed was defined as not currently in paid employment; housewife as a woman who is a homemaker and not seeking employment outside the home; unskilled labourer as a worker who has not learnt any trade; skilled labourer as an artisan; middle-level worker as clerical or secretarial staff, junior administrative worker, or other similar role; and professional as a teacher, nurse, doctor, or senior administrative staff. †PANSS scores range from 30 (best) to 210 (worst). ‡WHO-DAS scores range from 0 (best) to 144 (worst). §GAF scores range from 0 (worst) to 100 (best). ¶ISMI mean scores range from 1 (best) to 4 (worst).

Table 1: **Baseline characteristics**

Trial participants in the intervention group had greater improvements in PNASS total mean scores at 6 months (the primary outcome) than did participants in the control group (107·3 [SD 17·5] at baseline to 53·4 [19·9] at 6 months in the intervention group *vs* 108·9 [18·3] to 67·6 [23·3] in the control group; adjusted mean difference at 6 months –15·01 [95% CI –21·17 to –8·84]; 0·0001; table 2; appendix p 1). This improvement of scores in the intervention group compared with the control group was

	Intervention group (n=152)	Control group (n=134)	Unadjusted analysis		Adjusted analysis	
			Mean difference (95% CI)	p value	Mean difference (95% CI)*	p value
Primary outcomes						
PANSS scales						
Positive scale	14·6 (7·6)	19·3 (7·8)	−5·23 (−7·48 to −2·98)	0·0001	−4·85 (−7·01 to −2·70)	0·0001
Negative scale	12·9 (6·0)	15·8 (6·8)	−3·27 (−5·15 to −1·39)	0·0007	−3·16 (−5·00 to −1·31)	0·0008
General psychopathology scale	25·9 (9·0)	32·4 (11·3)	−7·03 (−9·97 to −4·10)	0·0001	−6·75 (−9·54 to −3·97)	0·0001
Total score	53·4 (19·9)	67·6 (23·3)	−15·70 (−22·18 to −9·22)	0·0001	−15·01 (−21·17 to −8·84)	0·0001
Secondary outcomes						
ISMI scales						
Alienation	1·9 (0·8)	2·2 (0·8)	−0·2 (−0·5 to 0·0)	0·053	−0·3 (−0·4 to −0·1)	0·0092
Stereotype endorsement	2·0 (0·7)	2·1 (0·7)	−0·2 (−0·4 to 0·1)	0·20	−0·2 (−0·4 to 0·0)	0·059
Discrimination experience	1·9 (0·7)	2·1 (0·9)	−0·2 (−0·5 to 0·1)	0·27	−0·2 (−0·4 to 0·0)	0·014
Social withdrawal	1·9 (0·7)	2·0 (0·8)	−0·1 (−0·3 to 0·1)	0·32	−0·1 (−0·3 to 0·0)	0·090
Stigma resistance	2·2 (0·7)	2·2 (0·7)	−0·0 (−0·3 to 0·2)	0·75	0·0 (−0·1 to 0·2)	0·57
Total score	2·0 (0·6)	2·1 (0·6)	−0·1 (−0·4 to 0·1)	0·23	−0·2 (−0·3 to 0·0)	0·013
WHO-DAS scales						
Cognition	10·6 (6·1)	12·6 (6·5)	−2·6 (−4·7 to −0·5)	0·014	−2·2 (−3·8 to −0·6)	0·0062
Mobility	6·8 (3·1)	7·5 (3·8)	−0·9 (−2·1 to 0·3)	0·13	−0·9 (−1·9 to 0·1)	0·065
Self care	5·5 (2·9)	6·4 (3·3)	−1·3 (−2·4 to −0·2)	0·022	−1·0 (−1·7 to −0·3)	0·0046
Getting along with people	7·6 (4·3)	9·2 (5·4)	−2·0 (−3·7 to −0·3)	0·020	−1·8 (−3·2 to −0·4)	0·014
Household life activities	7·1 (4·4)	8·5 (5·2)	−2·2 (−3·9 to −0·5)	0·010	−1·8 (−3·0 to−0·6)	0·0036
Work life activities	8·9 (5·6)	10·2 (5·6)	−1·6 (−4·3 to 1·1)	0·24	−0·7 (−2·9 to 1·6)	0·57
Participation	15·2 (7·1)	17·5 (8·0)	−2·6 (−4·8 to −0·5)	0·016	−2·5 (−4·3 to −0·8)	0·0047
Total score	52·3 (25·0)	61·8 (28·3)	−11·8 (−20·3 to −3·3)	0·0063	−10·5 (−17·0 to −4·0)	0·0015
Course of illness and recovery						
Months on admission	3·7 (2·1)	4·4 (1·9)	−0·7 (−1·3 to 0·0)	0·064	−0·7 (−1·4 to −0·1)	0·029
Course of illness†	93 (61%)	54 (40%)	2·3 (1·3 to 4·1)	0·0033	2·5 (1·4 to 4·8)	0·0032
Engagement in work‡	118 (78%)	77 (57%)	3·0 (1·6 to 5·5)	0·0006	3·3 (1·7 to 6·2)	0·0003
Ever in independent living	92 (61%)	57 (43%)	2·2 (1·0 to 4·7)	0·052	2·4 (1·1 to 5·2)	0·027

Data are n (%) or mean (SD). PANSS=Positive and Negative Syndrome Scale. ISMI=Internalised Stigma of Mental Disorders. WHO-DAS=WHO disability assessment schedule. *Adjusted by baseline total PANSS score, sex, marital status, country, and clusters. Clusters are included as random effects to capture within-cluster correlations and across-cluster variability. †Percentage rated as not continuous. ‡Including housekeeping; percentage rated as good or fair.

Table 2: **Outcomes at 6 months**

also seen in the three subscales (positive, negative, and general psychopathology scale) of PANSS (table 2).

Compared with the control group, the intervention group had greater improvements in functioning (significantly lower scores on the WHO disability assessment [WHO-DAS] scale; table 2; appendix p 1). Assessment with the Life Chart Schedule showed that, compared with participants in the control group, participants in the intervention group were more likely to have episodic rather than continuous illness, and more likely to be rated as good or fair in their engagement with work or housekeeping at follow-up (table 2). There was some evidence for shorter duration of admission and higher likelihood of independent living following discharge in the intervention group (table 2).

Participants in both trial groups had significant reductions in harmful treatment practices. Such practices decreased from 94 (57%) of 166 patients at baseline to 13 (9%) of 152 at 6 months in the intervention group (adjusted mean difference −0·48 [95% CI −0·60 to −0·37] p<0·001) and from 59 (42%) of 141 patients to 13 (10%) of 134 in the control group (−0·33 [−0·45 to −0·21] p<0·001). There was no significant difference in the extent of these reductions between the two groups (−0·15 [−0·32 to 0·01] p=0·071; figure 2; appendix p 2). The proportions of participants reporting having experienced victimisation of any type over the 6-month trial period were also similar in the intervention and control groups (8·6% *vs* 9·7%; adjusted odds ratio 0·80; 95% CI 0·3–2·4; p=0·70).

Five participants, all in the intervention group (three in Ghana and two in Nigeria), were treated for extrapyramidal side effects, all of which resolved. One participant in the intervention group in Ghana, aged 41 years, died of a stroke. This death was not deemed to be related to study procedure by the Ethics Committees as well as the National Institute of Mental Health's Data Safety Monitoring Board.

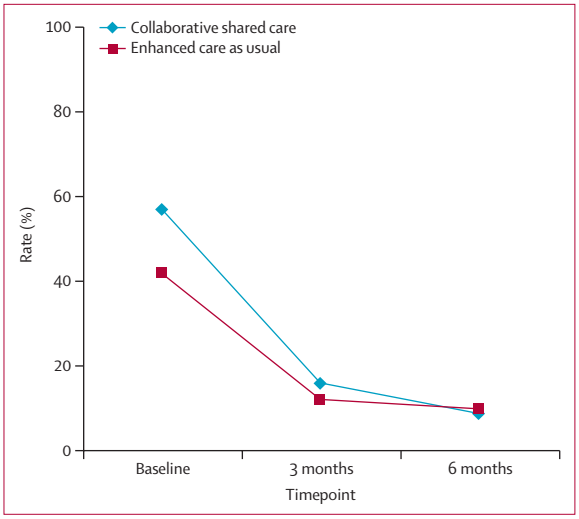

Figure 2: **Rates of harmful practices in the collaborative shared care and the enhanced care as usual groups**

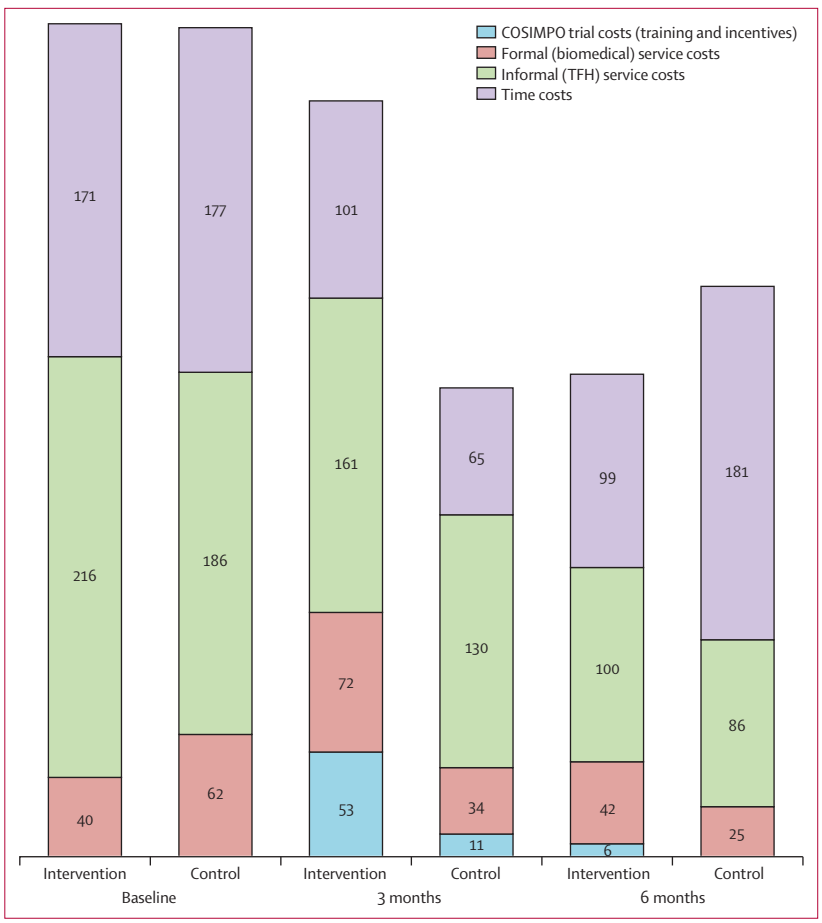

Figure 3: **Breakdown of costs at baseline and follow-up assessments***
TFH=traditional and faith healers. *Costs are in 2017–18 US$ over 3 months.

Estimated quarterly service use and time costs per participant in the intervention group fell from US$425 for the 3 months before baseline to $382 at 3-month follow-up and $247 at 6-month follow-up. Costs per participant in the control group decreased from $425 at baseline to $240 at 3-month follow-up but rose to $292 at 6-month follow-up. Over the full 6-month period from baseline, the estimated total cost for the intervention group was $627 and was $526 for the control group. Health service costs alone (without time costs) followed a broadly similar pattern (figure 3; appendix p 3).

At 3 months and 6 months, symptom and functional status improvements were better in the intervention group than the control group (appendix p 1). However, while reduction in total service and time costs was greater in the intervention group at 6 months, the reverse was observed at 3 months (that is, costs reduced less in the intervention group than control group; table 3). When only service costs were considered (time costs omitted), enhanced care as usual was also associated with a slightly greater cost reduction at both 3-month and 6-month follow-up points. At 6-month follow-up, the total health service and time cost associated with a one-point improvement on the PANSS was –$4 (95% CI, –29 to 15) and –$4 (–29 to 18) with a one-point improvement on WHO-DAS in the intervention group (meaning that the intervention was dominant—ie, both more effective and less costly than control). When only health-service costs were assessed, the cost associated with a one-point improvement on the PANSS at 6 months was $2 (95% CI, –6 to 14) and $2 (–5 to 14) for a one-point improvement on WHO-DAS in the intervention group. These findings indicate that at the primary outcome assessment collaborative shared care was a dominant intervention over enhanced care as usual for total costs (health service plus time), while for service costs alone there is a marginal value of less than $1 per month to pay for a unit improvement on both symptoms and functioning (table 3; appendix p 4).

Across the two study sites, PHCW in the intervention group made a total of 1480 scheduled and 54 unscheduled visits to TFH facilities during the trial. In the intervention group, a total of 103 (64%) of 161 patients (53 in Ghana and 50 in Nigeria), were prescribed oral medication while 28 (17%) of 161 patients (22 in Ghana and six in Nigeria), were prescribed depot medication following reviews by specialists.

Discussion

To our knowledge, this is the first systematic study of the effectiveness and cost-effectiveness of a programme of collaboration between TFH and conventional health care providers (in this case, primary health care providers) in the care of people with psychotic disorders. Many studies have explored the practice and profile of traditional and faith healing as well as the views of the healers about collaboration with or integration into the conventional public health system,[2,28–30] but no study has designed a package for such interventions or tested its effectiveness

	3-month follow-up			6-month follow-up		
	Intervention group	Control group	Adjusted difference (95% CI)	Intervention group	Control group	Adjusted difference (95% CI)
Service costs						
Total service cost per 3 months	$283 (20)	$175 (13)	$108 (63 to 155)	$148 (13)	$111 (10)	$37 (1 to 69)
Change in cost since baseline	$29 (28)	−$73 (59)	$102 (3 to 246)	−$106 (26)	−$137 (54)	$31 (−72 to 167)
Incremental cost-effectiveness ratio (PANSS)†	..	..	9 (−0·5 to 21)	..	..	2 (−6 to 14)
Incremental cost-effectiveness ratio (WHODAS)†	..	..	10 (−0·3 to 22)	..	..	2 (−5 to 14)
Service and time costs						
Total service and time cost over 3 months	$382 (44)	$240 (17)	$142 (61 to 247)	$247 (26)	$292 (105)	−$45 (−288 to 103)
Change in cost since baseline	−$43 (61)	−$185 (81)	$142 (−38 to 351)	−$178 (43)	−$133 (130)	−$45 (−357 to 217)
Incremental cost-effectiveness ratio (PANSS)†	..	..	13 (−4 to 32)	..	..	−4 (−29 to 15)
Incremental cost-effectiveness ratio (WHODAS)†	..	..	14 (−4 to 36)	..	..	−4 (−29 to 18)

Data are mean (SE). PANSS=positive and negative syndrome scale. WHO-DAS=WHO disability assessment scale. *All costs in 2017–18 US$. †Effectiveness measure expressed as the level of positive improvement between intervention and control (eg, a relatively greater reduction in symptoms); therefore, a positive cost-effectiveness ratio refers to the mean additional 3-month cost required to obtain a unit of improved effect, while a negative ratio means that the intervention dominates (less costly but also more effective than control).

Table 3: **Costs and cost-effectiveness of collaborative shared care (intervention) and enhanced care (control) as usual at 3-month and 6-month follow-up assessment***

on patient outcomes. We found that patients in receipt of collaborative shared care had significantly better outcomes than those receiving enhanced care as usual. Better clinical improvements in the intervention group were seen on each of the syndromes (positive, negative, and general psychopathology) as well as overall PANSS score. Participants in the intervention group also had significantly less disability, better course of illness, and better adjustment to work. Although non-significant, we noted a suggestion of shorter admission and greater likelihood of independent living associated with the intervention. Collaborative shared care was also more cost-effective for total costs but marginally less so for health service costs only than enhanced care as usual. In both groups, there was a similar but significant decrease in harmful treatment practices.

Even though rigorously done trials of the practical implementation of collaboration between TFH and conventional providers are not available for comparison, our findings are in keeping with reports suggesting that healers might be willing to collaborate with conventional health providers.[31] It is of particular interest that this collaboration led not only to better symptom remission, but to improved overall functioning and self-appraisal as indicated by suggestive evidence for lower self-stigma Even though relatively small, the difference in self-stigma between the groups seems to be a clinically meaningful difference given its similarity to what has been reported among other clinical groups.[32] It is plausible to speculate that having less self-stigma might reflect the improvement in symptoms and functioning rather than better attitudes of people in close contact with the patients. In view of the strict ethical requirements we implemented, including the training and close monitoring of the practice of TFH in the control group, there was a significant reduction in the use of harmful treatment practices in both groups. Healers can be trained and monitored to substantially reduce the use of such practices, which are a barrier to the integration of their services into mainstream mental health care.[2] This observation contrasts with that of a study in which, apparently, no such training was provided.[33] Nevertheless, work is required to understand what might promote or impede a rights-based service approach by TFH as well as their readiness to collaborate with biomedical service in routine practice. Although our findings provide evidence for the effectiveness of collaboration in improving the outcomes of people with psychosis, research is needed to test the applicability of this approach for other health conditions for which care is sought from healers as well as to explore factors that might enhance the adoption and sustainability of collaboration at scale.

The findings of this trial should be considered within its limitations. First, the participants were not told group allocation but they could have guessed it, and the assessments were based on self-reports. The possibility cannot be excluded that the knowledge of the involvement of conventional providers in their care could have influenced the reporting of the outcomes by participants in the intervention group. However, primary 6-month outcome assessments were done by assessors masked to the intervention type and who were meeting the trial participants for the first time thus reducing the tendency

for desirability bias (ie, participants seeking to please the assessors). Second, the judgement about whether a psychotic episode was organic was based on history and physical signs, such as fever and recent head injuries, and not on laboratory investigations. Third, the 3-month assessments were not done masked and for this reason, we have not placed much emphasis on the findings at that outcome point. Fourth, even though the trial was designed to be pragmatic, there were at least two inputs that are not available in routine patient care at the sites: the providers were given incentives to make the visits to the TFH facilities and medications were provided free for the purpose of the trial. In Nigeria, as opposed to Ghana, patients had to pay for these medications. Fifth, even though our cost estimates were comprehensive, we have not included the minimal costs of supervision, done mainly by mobile phone. Sixth, healers used eclectic treatment approaches which were not systematically studied in this trial. The possibility of significant differences between the groups in treatment approaches that might affect patient outcome cannot be ruled out. One important strength of our study is that, by setting our statistical significance level at $p<0\cdot005$ we have sought to present findings supported by a higher standard of evidence and for which account has been taken of the multiple comparisons we have done.[27]

In conclusion, we have shown that collaboration between traditional and faith healers and conventional health providers in the care of people with psychotic disorders is possible in Nigeria and Ghana and that such collaboration led to improved patient outcomes and greater reductions in overall care costs. We provide the first empirical evidence that collaboration might have the potential to expand evidence-based care to people with psychosis, especially in resource-constrained settings, and that the practice of TFH can be made more humane and in observance of basic human rights.

Contributors

OG drafted the Article with input from RA, DC, and SS. OG, JA-P, CO, and SS obtained funding. All authors reviewed the draft and approved the final version. OG designed the trial with inputs from JA-P, CO, LP, BH, and SS; OG, with input from VM, designed the intervention and both delivered the intervention training and were responsible for the assessment tools; OG, JA-P and LK supervised trial conduct; TB and OE designed and managed the study database and TB did the statistical analyses; TB did the economic analysis and DC provided methodological advice on its design and reporting. LP was a scientific collaborator and was involved in study design as permitted under the funding collaborative agreement.

Declaration of interests

We declare no competing interests.

Data sharing

De-identified participant data on which this report is based will be made available, following publication, upon request to ogureje@com.ui.edu.ng, and after a signed data access agreement with the principal investigator.

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