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Schizophrenia medication adherence in a resource-poor setting: randomised controlled trial of supervised treatment in out-patients for schizophrenia (STOPS)

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Background
Most people with schizophrenia in low- and middle-income (LAMI) countries receive minimal formal care, and there are high rates of non-adherence to medication.

Aims
To evaluate the effectiveness of an intervention that involves a family member in supervising medication administration – supervised treatment in out-patients for schizophrenia (STOPS) – in improving treatment adherence and clinical outcomes.

Method
Individuals ($n = 110$) with schizophrenia or schizoaffective disorders were allocated to STOPS or to treatment as usual (TAU) and followed up for 1 year. The primary outcome was adherence to the treatment regimen. Positive and Negative Syndrome Scale for Schizophrenia and Global Assessment of Functioning scores were also assessed.

Results
Participants in the STOPS group had better adherence (complete adherence: 37 (67.3%) in STOPS *v.* 25 (45.5%) in TAU; $P < 0.02$) and significant improvement in symptoms and functioning.

Conclusions
STOPS may be useful in enhancing adherence to treatment for schizophrenia in LAMI countries.

Declaration of interest
None.

Maintaining long-term treatment in non-communicable diseases is a major public health challenge faced by many low- and middle-income (LAMI) countries, where these disorders are likely to account for more than 40% of the burden of disease by 2040.[1] The situation is particularly alarming for chronic mental disorders. In LAMI countries only 13% of people with bipolar disorders receive treatment compared with 51% and 77% of those with asthma and diabetes.[2] With less than one qualified mental health professional for half to one million people and about 1% of the health budget dedicated to mental health,[3] most people with schizophrenia in LAMI countries probably receive little or no formal care. One manifestation of this is a very long duration of untreated psychosis (DUP) in the first episode in LAMI countries: 125 weeks compared with 62.5 weeks reported in high-income countries.[4] This poses a major public health problem considering that around 41.7 million people with schizophrenia may need care in LAMI countries.[5]

Poverty is a major barrier to adherence to treatment in schizophrenia in these countries.[5] It is estimated that rates of adherence to treatment 1 year after discharge from hospital are only around 50%.[6,7] The actual rate of non-adherence may be even higher, as these estimates do not account for individuals who refuse treatment or drop-out of follow-up studies[8] and are based on studies from health systems where drug treatment is at least partially subsidised. Moreover, there is little evidence to suggest that newer antipsychotics are associated with better rates of adherence compared with first-generation antipsychotics.[9] The result is high relapse rates, spiralling costs and perpetuation of stigma.

We suggested that a framework based on the principles of DOTS (directly observed therapy, short course), devised originally for tuberculosis, could be used to overcome the public health challenge of non-adherence and maintaining long-term treatment in people with schizophrenia in resource-poor settings.[10,11] The strategy promoted by the World Health Organization as DOTS has been the cornerstone of a policy package to provide the complete course of treatment in tuberculosis, which is crucial to avert the emerging challenge of highly dangerous multiple-drug-resistant tuberculosis arising from partially treated cases.[12] We argued that the essential ingredients of the DOTS approach – registration and recording of individuals, free access to essential medication, and monitoring drug adherence by observing and recording the correct medication – could be used to treat schizophrenia in LAMI countries.

These principles of DOTS were incorporated in an intervention entitled STOPS[9,10] (supervised treatment in out-patients for schizophrenia). The intervention was developed after focus group discussions with staff involved in implementation of DOTS in the local tuberculosis control programme in order to learn about the principles of DOTS that could be incorporated into the care of those with schizophrenia. Focus group discussions were also conducted with people with schizophrenia and their families. This revealed that the primary concerns for family members centred on misconceptions about treatment, stigma and supernatural beliefs about the illness. Therefore, we incorporated psychoeducation in the intervention to address these concerns, in addition to techniques for administering and supervising the medication.

The rationale and details of the approach are fully described elsewhere.[9,10] Briefly, STOPS comprises the following components.

(a) Registration and recording of all people presenting with a diagnosis of schizophrenia/schizoaffective disorder from a geographically defined catchment area.

(b) Training a key care supervisor, identified by the patient and usually a close relative, in administering and supervising the medication. The key care supervisor took responsibility for

collecting the medicine from the health facility, administering the correct dosage of all the medication and recording adherence with treatment.

(c) Uninterrupted drug supplies to provide drug treatment following a simple standardised treatment protocol. The treatment protocol was adapted from the American Psychiatric Association guidelines for treatment of schizophrenia.[13] The sequence of treatment was simplified to reflect the services and resources available in a LAMI country setting. Medicines were provided every month at the health facility. Both the patient and the carer reported on adherence with treatment.

(d) Standardised monitoring of therapy and outcome. This consists of adherence with the medication and assessment of functioning using the Global Assessment of Functioning (GAF) scale.[14]

The present study describes a randomised controlled trial (RCT) aimed at testing the effectiveness of STOPS. The primary outcome was to compare the effectiveness of STOPS in improving adherence with a regimen of standard doses of antipsychotic medication in participants with schizophrenia and schizoaffective disorders compared with treatment as usual (TAU). The study design was a two-arm prospective RCT over a 1-year period, with masking of assessors to the status of the intervention. The trial is registered at ClinicalTrials.gov (NCT00392249).

Method

The study protocol was approved by the Research Ethics Committee of the Postgraduate Medical Institute, Lady Reading Hospital, Peshawar, Pakistan. After a complete description of the study was given to the participant and the caregiver, written informed consent was obtained from both. Since a significant proportion of the patient population was illiterate, special care was taken to explain the procedures in Pushto, the language spoken by this population. No monetary incentives were provided to the participants in the trial.

Study settings and participants

The study was conducted at Psychiatry Department of Lady Reading Hospital, Peshawar. This is one of the two major tertiary care mental health centres that serve a large population in Khyber Pukhtunkhwa province (previously known as North West Frontier Province) of Pakistan and adjoining areas of Afghanistan. For the purpose of this study we only recruited people from the Peshawar district, which has a population of about two million. The inclusion criteria were: (a) aged 17 to 60 years; (b) a diagnosis of schizophrenia or schizoaffective disorder based on the ICD-10 Research Diagnostic Criteria (RDC);[15] and (c) residence in Peshawar district. The exclusion criteria were evidence of organic disorder, ICD-10 'mental retardation', and severe drug dependence requiring in-patient treatment and/or detoxification. Recruitment to the study started in November 2006 and the final follow-up of participants was carried out in January 2009.

Based on the literature, an average rate of adherence to medication at 1 year for those with schizophrenia is 50%.[6,7] We expected the rate of medication adherence to be 75% in the intervention group. Thus, a sample size of 45 participants per group would have 80% power to detect a 25% difference in the rate of adherence to medication between the two study groups with a one-sided significance of 5%. To control for non-adherence and losses to follow-up 55 people were recruited in each group.

Procedures

Eligible individuals were identified from the out-patients presenting to the psychiatry department at Lady Reading Hospital. They were first screened by trained psychiatrists working in the out-patients department and subsequently assessed by one of three consultant psychiatrists (S.F., Z.N., J.A.) to satisfy the ICD-10 criteria for the diagnosis of schizophrenia and schizoaffective disorders.[15] After identifying eligible individuals through interview and reviews of previous notes, therapists were asked to approve their recruitment into the study. Individuals who met inclusion criteria were randomly assigned to each treatment group. The random allocations of patients to each group were enclosed in opaque envelopes which were sealed and numbered sequentially. These allocations were placed away from the site of assessment. After assessment and satisfying the inclusion criteria, the staff which were not part of the study were asked to open the sealed envelope and reveal the treatment arm for each patient.

STOPS and control groups

The salient features of the two interventions are shown in the Appendix. Psychiatrists for the TAU (control) group were asked to provide treatments as they would normally deliver in routine out-patient settings. This included prescribing evidence-based pharmacological treatments, out-patient attendance in the psychiatry department as deemed appropriate by the consultant and brief counselling about the treatment and outcome. Participants who could not afford to buy medication had the option to seek free drug treatment from the social welfare department of the hospital, which provided treatment for the participants from the Zakat Fund (a fund established to provide essential medicine for patients who are poor from a charity funding based on Muslim law). The participants in the STOPS arm received the usual care and in addition they each had a key care supervisor, defined as any family member living with the individual for at least 6 months and providing support for the treatment as identified by the participant. Specific education was provided to the key care supervisor about the nature of the illness, misconceptions about treatment, the relationship between supernatural and biological causes of illness and the importance of continuing the medication, as well as basic skills in how to administer and supervise the medication. It was emphasised that participants should not be antagonised and violence should never be used in case of refusal to accept the treatment. Steps involved in collecting medicine from the treatment centre, storage at home, administering tablets and their ingestion by the participant and how to confirm this were demonstrated. The medications required were provided 1 month at a time. The intervention was first implemented in a pilot project over 1.5 years[9] and therefore trainers and assessors were adequately trained and experienced in providing the intervention.

Doses in each group were titrated according to the clinical needs of the individual. All participants received atypical antipsychotics with the exception of those who were already on typical antipsychotics and were stable on these. Treatment teams for both STOPS and TAU participants consisted of two consultant psychiatrists, three postgraduate trainees with a minimum of 2 years training in psychiatry, two qualified psychiatric nurses and a master's level social worker.

Measurements

The baseline assessment included a clinical interview to satisfy the ICD-10 RDC criteria for diagnosis of schizophrenia and schizoaffective disorders, demographic data and illness history, GAF ratings[14] and the Positive and Negative Syndrome Scale (PANSS) for Schizophrenia.[16] The follow-up assessments at 3 months, 6 months and at the end of 1 year included: GAF ratings, PANSS and medication adherence using a scale devised for this purpose.

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Adherence with medication was measured at interview using a questionnaire with a 5-point scale (where 1 is always and 5 is never) adapted from Herz *et al*.[17] The scale was used in the pilot project by the research workers with a high degree of reliability.[9] The assessments for adherence to treatment were done quarterly from baseline with the help of information provided by participants and relatives. The information was supplemented by the tablet counts from previous prescriptions where available. Complete adherence with medication was defined as participants always taking medication as prescribed without any break during the assessment period. Non-adherence was defined as missing drugs completely for more than a week at a time. If a participant took some medication but not on every day of the week, this was defined as partial adherence.

All assessments were carried out by doctors with at least 2 years' training in psychiatry. The same team of psychiatrists carried out all the follow-up assessments. The follow-up assessments were done by researchers who were masked to participant group assignment and instructed not to enquire about a participant's treatment during interviews. To ensure this, the administration of STOPS was kept completely separate from the research team assessing adherence and administering questionnaires for the trial and they were not associated with clinical care of the participants in the trial. The participants and relatives were briefed not to discuss their treatment with the assessors. All the participants remained in the study whether or not they were adherent with treatment, needed hospitalisation or relapsed. Attempts to maintain contact were made by telephone and/or home visits if participants did not appear for clinic visits at follow-up assessments.

Statistical analyses

Data were analysed in accordance with the CONSORT guidelines wherein the between-group comparisons were done using an intention-to-treat analysis.[18] The intention-to-treat analysis was performed with the last observation carried forward. SPSS Version 16 for Windows was used for the analysis. Descriptive statistics were obtained on participants' baseline characteristics and the primary outcome measure was analysed as a categorical variable. Chi-squared tests were used to compare the distribution of baseline variables and adherence scores between the two study groups (95% CIs and *P*-values). The number of participants who had partially adhered to treatment was small in the follow-up assessments. Therefore, we combined the results for those with partial and non-adherence together for the purpose of this analysis. This is also in line with the measurement of adherence, as described originally by Herz *et al*.[17] Parametric variables were then assessed for simple group differences using the *t*-test. A repeated-measures ANCOVA was used to measure the differences between the two groups at four time points (within- and between-group analyses). Baseline scores were used as covariates to take into account the initial differences. The Kolmogrove–Smirnov test was used to assess normality. The number of participants needed to be treated with STOPS to prevent one adverse outcome such as one participant not adhering to treatment in 1 year was calculated.

Results

The details of recruitment and follow-up are shown in Fig. 1. Fifty-five individuals were recruited in each arm and 95 (86.4%) participants completed the study; 49 in STOPS and 46 in the TAU group. The mean age of participants in the STOPS group was 29 years (s.d. = 8.1), which did not differ significantly from the TAU group (mean age 30 years (s.d. = 8.5), $P = 0.699$). The baseline sociodemographic and clinical variables were not significantly different in the two groups (Table 1). Similarly the relationship with the primary caregiver as defined by the participants did not differ significantly between the two groups. Those in the STOPS group had mean durations of illness of 73.6 months, compared with 83.8 months in the TAU group ($P = 0.485$). No statistically significant difference was found between the two groups for PANSS and GAF ratings at baseline.

We compared the two groups at four time points to see whether the mean dosage of antipsychotic drugs was different in the two groups at any stage. The doses of all antipsychotics were converted to chlorpromazine equivalents.[19] The differences were not significant for the time effect (Wilks' lambda 0.94, $F(3,93) = 1.89$, $P = 0.136$), and between-participant effect ($F = 0.24$, d.f. = 1, $P = 0.878$). The number of participants on depot medication also did not differ between the two groups.

Medication adherence, symptoms and functioning outcomes

The two groups showed a statistically significant difference in the primary outcome measure at the end of 1 year. In the intention-to-treat analysis at 1-year follow-up 37 participants (67%) in the STOPS group had complete adherence with medication compared with 25 (45%) in the TAU group ($P < 0.02$) (Table 2). Using relative risks, it is estimated that participants in the STOPS group were 1.59 times more likely to adhere to medication than those in the TAU group (95% CI 1.03–2.53). The number needed to treat to achieve one positive outcome is five for STOPS.

The participants in the STOPS group showed significantly more improvement in symptoms and functioning, as measured by PANSS and GAF in the intention-to-treat analysis. Differences between the STOPS and TAU groups over time were measured using analysis of covariance, with baseline scores being used as covariates to account for the initial differences. Statistically

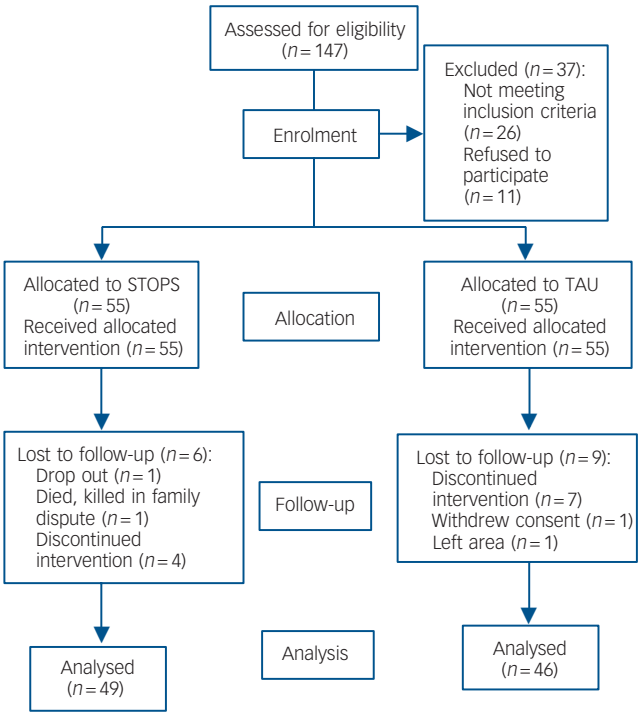

Fig. 1 The CONSORT flow chart for the randomised controlled trial of supervised treatment in out-patients for schizophrenia (STOPS) *v.* treatment as usual (TAU).

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Table 1 Differences between the supervised treatment in out-patients for schizophrenia (STOPS) and treatment as usual (TAU) groups at baseline

	STOPS, *n* (%)	TAU, *n* (%)	*P*[a]
Gender			1.000
Male	47 (85.5)	47 (85.5)	
Female	8 (14.5)	8 (14.5)	
Marital status			0.999
Married	30 (54.5)	31 (56.4)	
Unmarried	22 (40.0)	21 (38.2)	
Divorced, widow/widower	3 (5.4)	3 (5.4)	
Employment status			0.480
Unemployed	40 (72.7)	41 (74.5)	
Employed	8 (14.6)	12 (21.9)	
Retired	1 (1.8)	0 (0)	
Student	6 (10.9)	2 (3.6)	
Education			0.520
No education	23 (41.9)	21 (38.1)	
5–9 years	18 (32.7)	14 (25.5)	
10 years or more	14 (25.4)	20 (29.3)	
Relationship with caregivers			0.286
Mother	6 (10.9)	4 (7.3)	
Father	11 (20.2)	16 (29.1)	
Child	1 (1.8)	4 (7.3)	
Spouse	2 (3.6)	5 (9.1)	
Brother	19 (34.5)	16 (29.1)	
Sister	3 (5.5)	4 (7.3)	
Other	13 (23.6)	6 (10.9)	
Course			0.216
Continuous	41 (74.5)	35 (63.6)	
Episodic	14 (24.5)	20 (36.4)	
Cannabis use			0.425
Current	6 (10.9)	10 (18.2)	
Past	4 (7.3)	2 (3.6)	
Never	45 (81.8)	43 (78.2)	
Diagnosis			1.000
Schizophrenia	45 (81.8)	45 (81.8)	
Schizoaffective disorder	10 (18.2)	10 (18.2)	

a. χ^2-test.

significant differences existed for PANSS total scores, (time effect: Wilks' lambda 0.90, $F(3,105) = 3.54$, $P = 0.017$ and between-participant effect: $F = 9.0$, d.f. = 1, $P = 0.003$) and PANSS positive symptoms (time effect: Wilks' lambda 0.91, $F(3,102) = 3.31$, $P = 0.011$ and between-participant effect: $F = 5.9$, d.f. = 1, $P = 0.003$) in favour of STOPS. However, for PANSS negative symptoms neither time effect (Wilks' lambda 0.94, $F(3,102) = 1.2$, $P = 0.303$) nor between-participant effect ($F = 2.11$, d.f. = 1, $P = 0.149$) was significant. The GAF scores significantly improved over time in the STOPS group compared with the TAU group (time effect: Wilks' lambda 0.90, $F(3,106)$ d.f. = 3.66, $P = 0.036$ and for between-participant effect: $F = 7.3$, d.f. = 1, $P = 0.008$). Table 3 shows the descriptive statistics.

Discussion

Main findings

To our knowledge this is the first study that has attempted to test the effectiveness of a model based on the principles of DOTS in a non-infectious disease. A framework based on the DOTS strategy has been suggested to overcome the problems of non-adherence and continuity of care for non- communicable disorders in LAMI countries[10,20] and has also been used for the delivery and monitoring of antiretroviral therapy for HIV/AIDS in resource-poor countries.[20] However, the effectiveness of the approach has not been tested in an RCT.

Table 2 Differences in medication adherence in the supervised treatment in out-patients for schizophrenia (STOPS) and treatment as usual (TAU) groups at three time points

Adherence	STOPS, *n* (%)	TAU, *n* (%)	*P*[a]
3 months			0.05
Complete	38 (69.1)	28 (50.9)	
Partial or none	17 (30.1)	27 (49.1)	
6 months			0.23
Complete	40 (72.7)	34 (61.8)	
Partial or none	15 (27.3)	21 (38.2)	
12 months			0.02
Complete	37 (67.3)	25 (45.5)	
Partial or none	18 (32.7)	30 (54.5)	

a. χ^2-test.

We found that STOPS, which used an educational intervention for carers to administer and supervise the medication provided free of cost as part of a treatment programme, resulted in a significant improvement in adherence with medication. The trial did not have the statistical power to assess the effects of this experimental intervention on symptoms and functioning but the participants in the STOPS group showed a significant improvement in symptoms and functioning compared with TAU. The mean duration of illness in the two groups was more than 6 years. The improvement in symptoms and functioning in the STOPS group shows that maintaining regular treatment and engaging the family can have a significant impact even in a population with

Table 3 Comparison of the supervised treatment in out-patients for schizophrenia (STOPS) and the treatment as usual (TAU) groups for measures of psychopathology[a]

	STOPS ($n = 55$) mean (s.d.)	TAU ($n = 55$) mean (s.d.)	*P*
Positive and Negative Syndrome Scale total scores			0.003
Baseline	101.80 (21.0)	94.6 (19.4)	
3 months	70.87 (23.18)	77.11 (21.29)	
6 months	67.38 (23.9)	76.96 (20.8)	
12 months	67.35 (24.66)	74.33 (21.58)	
Positive symptoms			0.003
Baseline	21.6 (6.7)	21.5 (6.3)	
3 months	12.6 (7.2)	16.6 (6.5)	
6 months	12.4 (7.0)	16.6 (6.7)	
12 months	13.6 (6.9)	15.3 (5.5)	
Negative symptoms			0.149
Baseline	21.3 (6.1)	19.4 (6.3)	
3 months	17.4 (6.0)	17.1 (7.6)	
6 months	16.3 (6.1)	17.2 (7.2)	
12 months	16.2 (6.8)	17.1 (7.6)	
General symptoms			0.007
Baseline	47.9 (10.6)	44.4 (8.9)	
3 months	33.7 (10.0)	36.6 (10.5)	
6 months	31.4 (10.9)	35.2 (10.2)	
12 months	30.3 (10.3)	33.8 (8.8)	
Global Assessment of Functioning scores			0.008
Baseline	42.56 (13.54)	45.95 (11.92)	
3 months	55.18 (14.5)	52.13 (15.8)	
6 months	58.71 (15.81)	52.67 (16.08)	
12 months	62.0 (16.70)	56.05 (18.12)	

a. Higher scores represent more psychopathology on the Positive and Negative Syndrome Scales, but not on the Global Assessment of Functioning scale where the reverse is the case. Analyses were carried out using repeated-measures ANCOVA (to compare within-participant and between-participant differences), with baseline values used as covariates.

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chronic mental illness. This is consistent with other studies that reported similar improvement in symptoms and functioning at 9 months after discharge in participants receiving family education,[21] and at 12- and 18-months follow-up in participants receiving a family-based intervention.[22]

There is little available information on the effectiveness of strategies for extending care to people with severe mental illness in LAMI countries.[23] The essential components of STOPS (i.e. monitoring drug adherence by observation and recording of the correct medication by a guardian assigned to the patient) has been shown to be effective in a retrospective case–control study in rural China.[24] Broadly similar approaches have been shown to be cost-effective and significantly reduced disability and psychotic symptoms.[25,26] However, these studies employed family or social interventions typically comprising at least one session of 1–2 h every 2 or 4 weeks over the study period, which is more akin to an assertive outreach programme and may be difficult to apply in LAMI countries. The STOPS approach, in contrast, used a brief intervention of initially one session, which was reinforced on subsequent visits, without directly addressing family dynamics or expressed emotion. The better adherence to treatment and improvement in symptoms in this cohort is consistent with the evidence from a systematic review of interventions to improve medication adherence in schizophrenia that showed that relatively brief interventions (both in terms of duration and frequency) that targeted the behaviours related to medication adherence were more effective than longer interventions with a broader focus on psychoeducation.[7]

Most of the key care supervisors were first-degree relatives. Spouses were involved only in 3.6% and 9.1% of STOPS and TAU groups respectively, despite the fact that more than half of the participants in both groups were married. This reflects the routine involvement of the extended family in the care of those with a severe mental illness. Involvement of family members as treatment supervisors to improve treatment adherence could have adverse consequences for the family members and possibly for patients in the form of coercion to take treatment. The latter was specifically addressed during the pilot phase and the development of the intervention.[9,10] Psychoeducational programmes are generally found to decrease the family burden and improve aspects of family functioning such as problem-solving, communication and interpersonal relationships.[21,26] These aspects of care were, however, not evaluated in this RCT and will need to be addressed in future studies.

Limitations

It can be argued that the provision of free drugs could have contributed to the better outcome in the STOPS group. The average cost of medication for a month using atypical drugs is about 900 rupees (£1 is equivalent to approximately 136 rupees), which can be quite costly for patients and families from lower socioeconomic backgrounds presenting in a public hospital such as Lady Reading Hospital. The DOTS is a complex intervention and free access to medication is an essential component of the DOTS programme as applied in tuberculosis control.[12] The participants in the TAU group had the option of accessing free drugs from the social welfare department. Providing free medication as part of the trial would have grossly distorted the TAU condition in these settings. The evidence, however, suggests that even if drugs were free, non-adherence persists. One recent study showed that even among people who have health plans with no cost-sharing for medication, rates of non-adherence were nearly 40%.[27]

Other limitations in evaluating the results of this study should also be recognised. We selected standard out-patient care for comparison, which is most often the only type of mental healthcare available in these settings. Treatment as usual is criticised as a comparator in evaluation of complex interventions as the healthcare system in which the treatment programme is embedded is known to have important consequences for outcome.[28] The drug supply for the TAU group could vary in supply and quality, being dependent upon local pharmacies. It can be argued that the participants in the STOPS group had increased contact with the team to collect medication, which could have contributed to better adherence. However, this should be balanced against the fact that participants in the TAU group received more support for their treatment from the research and social services department of the hospital, being a focus of attention in a research study. Enhanced care associated with regular assessment of adherence and follow-up visits in this RCT was not typical 'treatment as usual'. It is also well known that the measures that rely on subjective reports of pill taking to measure adherence in schizophrenia tend to overestimate adherence and reduces the likelihood of detecting intervention effects.[8] These limitations should, however, minimise the difference between the two groups. The masking of research interviewers to the treatment group could not be completely assured since the study was not placebo-controlled, with the possibility that research interviewers favoured the STOPS group. The contamination of treatments was also possible, i.e. the treatment team providing TAU would act more like the team providing the experimental intervention over time.

Implications for service provision and research

Interventions for people with schizophrenia in LAMI countries should primarily involve the families as more than 90% of patients in these countries live within a family unit.[5] This study provides preliminary evidence that a package of care based on a brief educational intervention for the families, and supervision and easy access to medication as envisaged in the DOTS strategy using a simple treatment regimen can be used to improve services for people with schizophrenia in LAMI countries. Adopting a model of care devised essentially to treat an infectious disorder like tuberculosis for a chronic illness that may run a lifelong course will require certain modifications. Neither health systems in most LAMI countries nor caregivers can be expected to provide the lifelong commitment required for a STOPS programme. However, the initial 2 years in the course of schizophrenia have been described as the 'critical period'. The treatment status during this period is the strongest predictor of long-term outcome and disability.[29] Even a gap as small as 1–10 days in medication adherence over a 1-year period has been found to be significantly associated with an increased risk of hospitalisation with an odds ratio of 1.98.[30] Based on this evidence and recommendations from a systematic review of interventions to address non-adherence in schizophrenia that clinical interventions targeting non-adherence should continue for at least 18 months,[8] we suggest an approach for early intervention for psychosis in LAMI countries. It is proposed that people with schizophrenia should be provided with an uninterrupted drug supply based on a public health programme like STOPS for an initial 2-year period.

The present study sample consisted of participants with a relatively chronic course of illness as recruiting a first-episode sample would have taken much longer and was not feasible within our resources. The approach suggested in this trial now needs to be evaluated in first-episode psychosis, as effective intervention during this period is likely to achieve maximum long-term gains during the entire course of the illness. The effectiveness of this approach in non-specialist health settings in view of the shortage

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of psychiatrists in LAMI countries, and the cost-effectiveness of STOPS, will also need to be evaluated.

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Appendix

Comparison of supervised treatment in out-patients for schizophrenia (STOPS) with treatment as usual (TAU)

	STOPS	TAU
Setting	Community	Community
Therapist's contact with patient/family	Participants and an identified family member (key care supervisor)	Participant, family optional (any family member)
Access to medication	Supplied free by the programme	Had the option of obtaining free drugs provided by social service, may be out of pocket
Supervision for medication	Medicine administered under supervision of key care supervisor	None
Participant and family education	One session at the start to educate the key care supervisor to administer and supervise the drugs	No specific session, some education may be provided by therapist
Frequency	Once a month to collect the drugs	Variable as deemed necessary by therapist
Service provided by	Psychiatrist, social worker, psychiatric nurses	Psychiatrist, social worker, psychiatric nurses

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