

A cluster randomised controlled trial of patient-held medical records for people with schizophrenia receiving shared care

Helen Lester, Teresa Allan, Sue Wilson, Sue Jowett and Lesley Roberts

SUMMARY

Background: Patient-held records can improve communication across the primary–secondary interface. There has been no previous rigorous assessment of the utility of patient-held records for people with schizophrenia from a primary care perspective and their value for this population is unclear.

Aim: To evaluate the effectiveness of a patient-held record for patients with schizophrenia receiving shared care.

Design of study: Cluster randomised controlled trial.

Setting: Seventy-four general practices and six community mental health localities in Birmingham, England between June 1998 and June 1999.

Method: A sample of 201 patients with schizophrenia (ICD-10 classification F20) was recruited; of these, 100 were intervention and 101 were control. Patient-held records were given to the intervention patients. At 12-month follow-up, all patients were accounted for and 191 (95%) were revisited. Primary outcomes were the Verona Service Satisfaction Scale-54 (VSSS-54) and the Krawiecka and Goldberg (K & G) rating scale of psychopathology at 12-month follow-up. Secondary outcomes were use of primary and secondary care services.

Results: A total of 63/92 (68.5%) patients still had the patient-held record, 64/92 (69.6%) had used it, and 39 (60.9%) of the 64 who had used it said the patient-held record was regularly used by their keyworker. However the patient-held record had no significant effect on primary outcomes (VSSS-54: $F_{1,116} = 0.06$, $P = 0.801$, K & G: $F_{1,116} = 0.6$, $P = 0.439$) or on use of services. A higher symptom score was associated with not using the patient-held record.

Conclusions: The trial provides no good evidence to suggest that patient-held records should be introduced as part of routine shared care for all patients with schizophrenia. However, the patient-held record was acceptable to patients with schizophrenia and acted as a communication tool, particularly between patients and keyworkers.

Keywords: schizophrenia; satisfaction; patient-held record; primary care.

Introduction

PATIENT-HELD records, where the patient holds all or some information relating to the course and care of their illness, are common in the management of some chronic physical illnesses such as diabetes, are acceptable to both clinicians and patients, and can improve communication across the primary–secondary care interface.¹ Audit and case series of these records for people with long-term mental illness^{2–4} suggest positive patient evaluations, but variable staff participation. However, there has been no previous rigorous assessment of the utility of patient-held records for people with long-term mental illness from a primary care perspective^{5,6} and their value is unclear. Schizophrenia is the most common long-term serious mental illness in the UK with an estimated prevalence of between 0.5% and 1.6%.⁷ Primary care is playing an increasing role in the provision of health care for people with schizophrenia.⁸ This paper reports the largest randomised controlled trial of patient-held records for people with schizophrenia receiving shared care completed to date, and aims to evaluate the effectiveness of a patient-held record on mental health, satisfaction with care, and use of primary and secondary healthcare services.

Method

Study population

Patients with schizophrenia (ICD-10 classification criteria F20) and receiving shared care in contact with secondary care community services between 1998 and 1999 were identified from caseloads of teams in the six North Birmingham Community Mental Health localities. Exclusion criteria were learning disability (ICD 10 = F70), organic brain disease (ICD 10 = F0–9), any keyworker concerns (e.g. current hospitalisation) and being less than 18 years of age. There was no upper age limit. North and West Birmingham ethics committee approval was obtained.

Assignment

Randomisation was undertaken at practice level, as the introduction of a patient-held record could change general practitioner (GP) behaviour and, since several patients were managed by the same practitioner, there was a risk of contamination. The 176 general practices within the North Birmingham Mental Health Trust were randomised by one of the authors (TA) to either intervention or control, using a computer-generated random number schedule. The number of patients with schizophrenia in contact with the Mental Health Trust was available for 108 of these practices from the Trust care programme approach (CPA) returns database. These

H Lester, MD, clinical senior lecturer; T Allan, MSc, lecturer in medical statistics; S Wilson, PhD, senior research fellow; S Jowett, MSc, research fellow; and L Roberts, BSc, research fellow, Department of Primary Care and General Practice, University of Birmingham.

Address for correspondence

Helen Lester, Department of Primary Care, Medical School, University of Birmingham, Edgbaston, Birmingham B15 2TT.
E-mail: H.E.Lester@bham.ac.uk

Submitted: 1 February 2002; Editor's response 23 April 2002; final acceptance: 22 October 2002.

©British Journal of General Practice, 2003, 53, 197–203.

HOW THIS FITS IN

What do we know?

Patient-held records have been shown to improve communication across the primary–secondary interface. There has been no previous rigorous assessment of the utility of patient-held records for people with long-term mental illness from a primary care perspective and their value for this population is unclear.

What does this paper add?

Patient-held records should not be routinely introduced for all patients with schizophrenia receiving shared care. They may be a useful adjunct to treatment for patients with chronic stable schizophrenia.



practices were stratified by list size and the number of people with schizophrenia, using minimisation to adjust for imbalances within the strata.

Patient recruitment

The study aimed to evaluate the utility of a patient-held record in primary care rather than predominantly research-orientated or teaching practices, and therefore a large number of practices were approached to participate. Pilot work demonstrated significant variations between computer- and paper-based practice systems in the completeness of identifying people with a diagnosis of schizophrenia. The original study design therefore aimed to utilise the recently updated Trust care programme approach database as the primary source of the study population. Inaccuracies in the database also required mental health team caseloads to be used as a supplementary source of recruitment. Patients in assertive outreach, continuing needs and depot clinics were recruited to ensure the study population was representative of patients receiving shared care. Diagnosis was established from secondary care records and current keyworker records. If diagnosis was uncertain, patients were excluded from the study. Patients within each keyworker's caseload were approached by one of the authors (HL or LR), either in a secondary care clinic setting or the patient's home during routine visits. To minimise selection bias, recruitment was undertaken on each day of the week over a four- to eight-week period, depending on team caseloads. Within each team, patients were approached consecutively. After informed consent had been obtained, the patient's current GP was ascertained and the patient was classified as being in the intervention or control group, depending on their practice status on the randomisation list. This list was held by the two field researchers who were not blinded to the intervention. Patient and practice recruitment ceased once the proposed sample size had been achieved.

Intervention and protocol design

Focus groups were held with users to discuss the content and format of the patient-held record. The final version was a loose-leaf record, containing sections for personal details, appointments, medication, basic health information, personal

and emergency contact numbers, early warning symptoms, and a diary section to record patient, carer, and professional comments. The record was given to intervention patients at the time of recruitment. Demographic details and baseline assessments using the Verona Service Satisfaction Scale (VSSS-54)⁹ and the Krawiecka and Goldberg (K & G) rating scale¹⁰ were collected at recruitment, and these rating scales were used to measure outcomes.

Practices were sent a letter describing the study prior to recruitment and each senior partner was contacted to gain consent for participation if patients from their practice were subsequently recruited. Patients' primary care notes were flagged to enable prospective recording of service use.

Consultants, whose consent to participate was also obtained prior to recruitment, were notified by letter after recruitment and secondary care notes flagged to signpost involvement. All health professionals received training in the use of the record. At 12-month follow-up, changes in demographic details were recorded and the VSSS-54 and the K & G rating scale were re-administered. A short, structured questionnaire to elicit views on the patient-held record was administered to intervention patients. All patient-held records stated as being still in the patient's possession were examined to confirm possession and utilisation.

Outcome measures

The primary outcome measures were the VSSS-54 and K & G rating scale. The VSSS-54 is a reliable self-completed measure of satisfaction with community mental health services that includes domains relevant to primary care, such as information giving and relatives' involvement.¹¹ Satisfaction was a primary outcome because it is positively related to concordance and clinical outcomes in mental health.¹² The five-point K & G scale has been used to assess psychopathology in trials involving patients with chronic psychosis.^{13,14} Validity has been shown to be greater if the scale is completed by a person with current knowledge of the patient's mental state. Keyworkers, who were blinded to the allocation, were trained by one of the authors (HL or LR) to ensure understanding of the scale, and then completed this form at recruitment and follow-up.

Secondary outcomes were primary care consultation rate, number of mental health and non-mental health referrals, and number and duration of inpatient admissions or episodes of home treatment during the trial.

Sample sizes were calculated to achieve 90% power at 5% significance. For the VSSS-54, assuming a standard deviation of 0.5,¹⁵ a minimum sample size of 84 patients in each arm was required to detect a change of 0.25 on the five-point scale. An average standard deviation of 5 was used for the K & G scale^{14,16} to detect a difference of 2.5. This required a minimum sample size of 84 in each arm. The incorporation of practice level effects required a greater number of patients to power the study adequately.¹⁷ Information on the variation between practices was not available and a typical intracluster correlation coefficient of 0.05 was used.^{18,19} With an average of three patients per cluster, the design effect²⁰ was 1.1, giving a sample size of 93 patients in each arm. The study was not powered for secondary outcomes.

Statistical analysis

Analysis was on an intention-to-treat basis and undertaken at patient level, which accounted for the intracluster correlation. No outcomes data were available for those who had died and these cases were excluded from the analysis. Imputation using either group mean change or overall mean change did not change the results. Missing data were therefore not imputed for those patients who had died. Primary and secondary outcomes were prespecified.

For primary outcomes, the change in score from baseline to 12 months was calculated. Differences were initially compared using the one-way analysis of variance. Practice level variation was accounted for by hierarchical random effects modelling (HRE)^{17,21} with practice treated as a random factor. Although the data for the K & G were non-normal, they were not strongly so and many statistical methods are robust and valid if the sample size is sufficient (central limit theorem), so the raw scores were used in the modelling.²² For secondary outcomes, proportions were compared using χ^2 (or Fisher's exact) test and the test for proportions. Continuous data that were non-normally distributed were compared using the Mann-Whitney *U* test. Backward stepwise logistic regression modelling was used to explore predictors of card use, with a significance level of 10% for variable removal. Publications reporting the importance of intra-practice variability²³ prompted the dichotomisation of practices into single-handed and group. This analysis was not prespecified.

Results

Participant flow and follow-up

Keyworker caseload returns for the North Birmingham Mental Health Trust identified 681 eligible patients and 271 were approached. Thirty-five patients were excluded by keyworkers and a further 35 patients refused to participate. The sex distribution of these 35 was comparable to that of the study population.

The first 201 eligible patients registered in practices willing to participate, and where no keyworker concerns existed, were recruited into the study. One hundred patients were randomised to the intervention and 101 to the control group.

Seventy-eight of the 176 practices were approached; four (5%) declined to participate. One-hundred and eight practices were randomised using minimisation principles and 178 of the 201 patients recruited were in 61 of these practices. The remaining 23 individuals were in 13 practices where stratification data was not available prior to randomisation.

At 12 months, all patients were accounted for and 191 (95%) were followed up (Figure 1). Twenty-six (13.6%) patients had moved, 23 (12.0%) changed GP and 81 (42.4%) changed keyworker.

Baseline characteristics

The study population comprised 125 (62.2%) men and 76 (37.8%) women, ranging in age from 18 to 74 years (mean = 46.0, standard deviation = 11.8). Baseline characteristics are detailed in Table 1.

There appeared to be an imbalance between intervention and control patients with respect to sex, CPA team, and housing status. These variables were added to the models but had

no significant effect and are not reported in the final models.

Intervention and control practices did not differ on Townsend score, number of partners, list size or the percentage of single-handed practices (data not shown). The practices ($n = 13$) where stratification variables were not available prior to randomisation were similar to the remainder ($n = 61$) in terms of Townsend score but had fewer partners per practice (1.0 versus 2.0, $z = -2.44$, $P = 0.015$).

Baseline scores for the primary outcome measures were comparable (Table 1).

Analysis

Primary outcomes: VSSS-54. There was no statistically significant difference between the proportions of patients who had improved scores in the two arms of the trial (adjusted 57.4%, versus 47.6%, $\chi^2 = 1.963$, $P = 0.161$). There was no significant difference between those who changed practice ($n = 23$) and those who did not on the satisfaction score (difference = -0.008 , 95% confidence interval [CI] = -0.65 to 0.67). Hierarchical random effects modelling demonstrated that the effect of the patient-held record on satisfaction was not significant (Table 2). The effect of practice on change in satisfaction scores was greater than the effect of the patient-held record. An adjustment of single-handed/group practices was considered in the hierarchical random effects model. The observed inter-practice variation in change in satisfaction score was predominantly explained by variability among single-handed practices as seen in Table 2 (practice: single-handed $F_{31,31} = 2.218$, $P = 0.015$, group practices $F_{40,85} = 1.25$, $P = 0.198$). Both intervention and control groups showed an overall improvement in satisfaction with mental health services. The mean difference in score from baseline to 12-month follow-up for all patients was 0.016 (SD = 0.33).

Primary outcomes: K & G. Although an improvement in K & G symptom score was observed for both intervention and control groups during the study period, no significant difference in the change in scores between the groups was observed (Table 2).

Secondary outcomes. No differences were observed between intervention and control groups for any of the secondary outcomes. Random effects modelling did not alter the significance of the results, therefore simple tests are reported¹⁸ (Table 3).

Patient use and views on the patient-held record

Sixty-three (68.5%) of the patients in the intervention group still had the patient-held record after 12 months. Sixty-four (69.6%) reported using it at some point, and 51 (79.7%) of these still had the patient-held record at 12 months. Twelve patients had been given the patient-held record but had neither used nor lost it (Table 4).

The main reasons reported for not always using it were forgetting it (27/92 [29.3%]), losing it (19/92 [20.7%]), and feeling unable to ask health professionals to use the card because of perceived differences in status (17/92 [18.5%]). Twenty (31.2%) said the patient-held record acted as a communication channel and helped them to ask their keyworker questions, acting as both reminder and mechanism to write

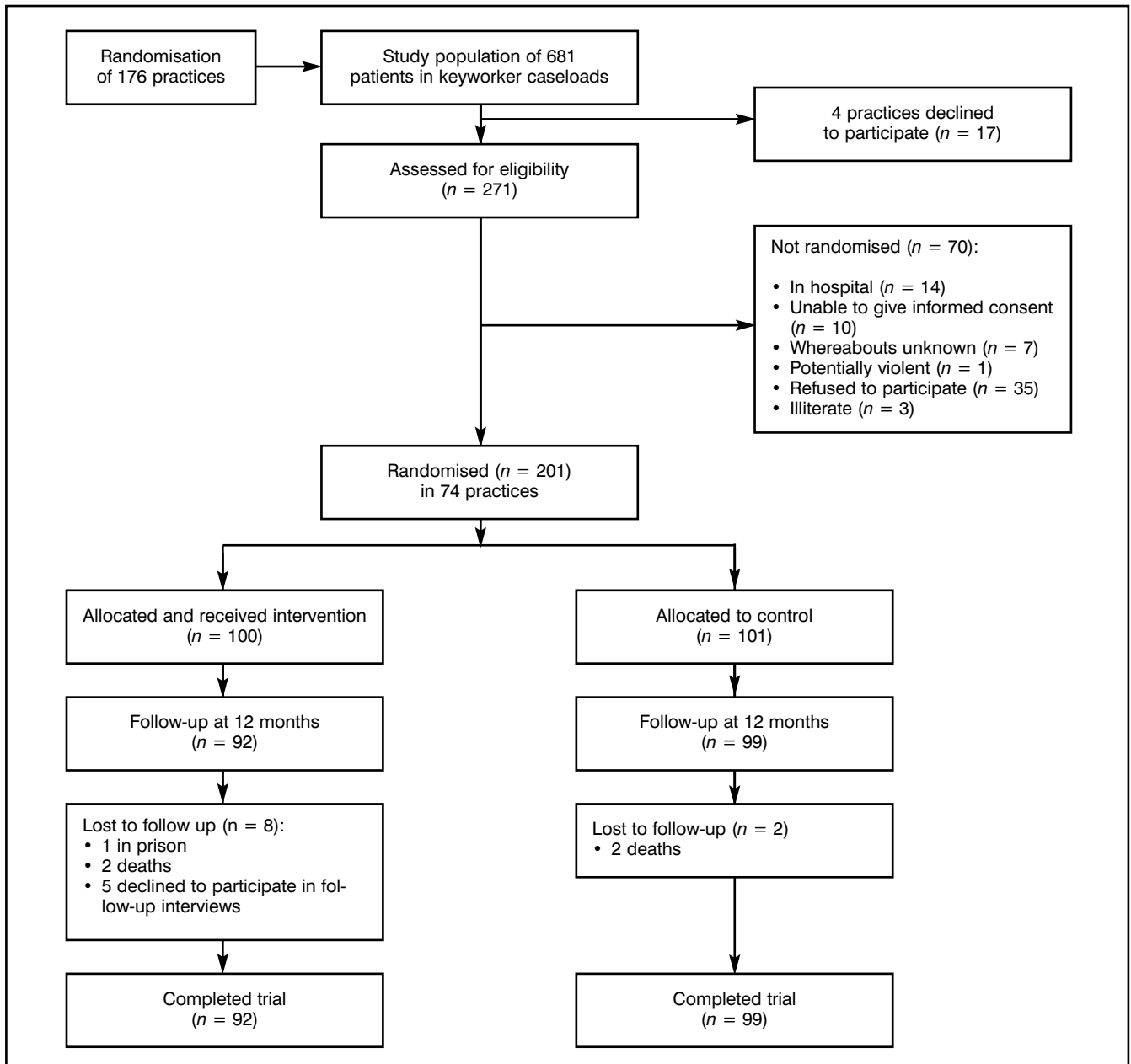


Figure 1: Trial profile

their thoughts down beforehand. Thirty-nine (60.9%) patients reported that their keyworkers used the patient-held record, 21 (32.8%) that their GP had used it, and 20 (31.3%) that their consultant had used it; 49/92 (53.3%) said that they would continue to use the patient-held record.

Logistic regression modelling was used to predict use of the patient-held record. The only identified predictor was K & G score at baseline, with a higher symptom score associated with not using the card (odds ratio [OR] = 0.88, 95% CI = 0.78 to 0.99).

Discussion

This is the first primary care-based randomised controlled trial to examine the value of a patient-held record for people with schizophrenia receiving shared care. The patient-held

record was valued and used as a communication tool, particularly by patients with chronic stable schizophrenia. However, it did not lead to a change in use of services, mental health, or satisfaction with care.

Strengths and limitations

The study population was representative of people with schizophrenia receiving shared care.^{8,24,25} Previous studies have shown an overall male excess in studies that have involved more chronic patients and an increased prevalence in lower socio-economic groups, and there is no reason to believe these findings are not generalisable.

A common reason for trials failing to demonstrate a significant difference is a type II error (i.e. the null hypothesis is not rejected as it should be, because a real difference exists

Table 1. Demographic characteristics and use of services.

	Intervention (n = 100)	Control (n = 101)
Mean age in years (SD)	45.9 (12.2)	46.1 (11.4)
Male (%)	58 (58.0)	67 (66.3)
Ethnicity (%)		
Caucasian	73 (73.0)	72 (71.3)
Afro-Caribbean	20 (20.0)	20 (19.8)
Asian	4 (4.0)	9 (8.9)
Mixed race	3 (3.0)	0
Marital status (%)		
Single	57/99 (57.6)	65 (64.4)
Divorced/separated/widowed	25/99 (25.3)	15 (14.9)
Married/cohabiting	17/99 (17.2)	21 (20.8)
Housing status (%)		
Alone	42/98 (42.8)	45 (44.6)
With relatives	9/98 (9.2)	21 (20.8)
Supported accommodation	47/98 (48.0)	35 (34.7)
Social class (%)		
II	12/97 (12.4)	6/99 (6.1)
III M/N	33/97 (34.0)	40/99 (40.4)
IV, V	21/97 (21.6)	28/99 (28.3)
Long-term unemployed	31/97 (32.0)	25/99 (15.3)
CPA team (%)		
Depot	39 (39.0)	59 (58.4)
Continuing care	43 (43.0)	27 (26.7)
Assertive outreach	18 (18.0)	15 (14.9)
Use of services		
Secondary care		
Mean years of service contact (SD)	17.9 (10.0)	17.4 (9.6)
Psychiatric admissions		
Ever been admitted (%)	93 (93.0)	93 (92.1)
Median number of admissions (IQR)	3 (1–6)	4 (2–6)
Admission in year before project (%)	9 (9.0)	8 (7.9)
Sections		
Ever been sectioned (%)	54 (54.0)	58 (57.4)
Median number of sections (IQR)	1.0 (0–2)	1.0 (0–2)
Sectioned in year before project (%)	3 (3.0)	2 (2.0)
Primary care		
Median annual consultation rate (IQR)	3.5 (2–7)	3.5 (2–8.5)
Baseline scores for outcome measures (unadjusted)		
VSSS-54 overall satisfaction	3.80 (0.39)	3.78 (0.40)
K & G	4.54(3.58)	5.27 (3.47)
Baseline scores for outcome measures (adjusted)		
VSSS-54 overall satisfaction	3.87 (0.38)	3.82 (0.31)
K & G	4.48 (3.29)	5.54 (2.75)

IQR = interquartile range; SD = standard deviation

though it is not detected in the sample). The actual intracluster correlation in this trial was 0.199, which, with an average cluster size of 2.4, gave a design effect of 1.29. However, the standard deviation of the change between baseline and follow-up was lower than anticipated for both primary outcomes (Table 1). The sample size was therefore sufficient to detect a difference of 0.185 for the VSSS-54 and 1.86 points for the K & G at 90% power.

Blinding was not possible; however, measurement bias was limited, since the VSSS-54 is a self-completion scale and trained keyworkers filled in the K & G rating scale.

The mobility of this patient group may have affected the observed changes in satisfaction scores. However, observed improvements in satisfaction scores were not significantly different between those that had, and had not, changed practices during the study. The use of global primary outcome

scores was reported because individual domains showed no significant difference between groups when hierarchical modelling was used.

Both the VSSS-54 and K & G scores improved during the 12-month follow-up period. This may be attributable to either a Hawthorn effect (where behaviour changes as a result of involvement in the study) or regression towards the mean. Since the trial aimed to recruit a representative cohort of patients receiving shared care, the latter explanation is more likely. The generation of robust estimates of mean satisfaction (VSSS-54) and psychopathology (K & G) scores for those receiving shared care will enable the representativeness of future cohorts to be established.

Comparisons with previous literature

Most previous studies involving patients with schizophrenia²⁶

Table 2. Mean change in satisfaction and symptom scores (adjusted) at 12 months.

VSSS-54	Mean (SD) change from baseline at 12 months		Mean (95% CI) difference in change
	Intervention	Control	
All practices	<i>n</i> = 92, 0.025 (0.30)	<i>n</i> = 99, 0.008 (0.30)	-0.017 (-0.86 to 0.82)
Single-handed	<i>n</i> = 19, -0.025 (0.30)	<i>n</i> = 45, -0.008 (0.30)	-0.017 (-0.36 to 0.33)
Group practice	<i>n</i> = 73, 0.056 (0.31)	<i>n</i> = 54, 0.023 (0.31)	-0.033 (-0.88 to 0.81)
HRE model	Degrees of freedom	<i>F</i>	<i>P</i> -value
All practices			
Treatment group	1, 116	0.06	0.801
Practice	73, 116	1.607	0.011
Single-handed			
Treatment group	1, 31	0.02	0.889
Practice	31, 31	2.218	0.015
Group practice			
Treatment group	1, 85	0.17	0.679
Practice	40, 85	1.25	0.198
K & G	Mean (SD) change from baseline at 12 months		Mean (95% CI) difference in change
	Intervention	Control	
All practices	<i>n</i> = 91, -1.22 (3.1)	<i>n</i> = 99, -1.69 (3.0)	-0.47 (-9.06 to 8.11)
HRE model	Degrees of freedom	<i>F</i>	<i>P</i> value
All practices			
Treatment group	1, 116	0.6	0.439
Practice	72, 116	1.062	0.382

Table 3. Secondary outcomes.

	Intervention (<i>n</i> = 92)	Control (<i>n</i> = 99)	Test statistic	<i>P</i> -value
Secondary care				
Total inpatient admissions (%)	8 (8.5)	5 (5.1)	0.65	0.514
Days of inpatient admissions ^a	16.5 (11.3–59.0)	31.0 (19.5–129.0)	-1.10	0.271
Home treatment (%)	4 (4.3)	6 (6.1)		0.748
Days of home treatment ^a	35.5 (7.8–70.0)	22.5 (13.0–29.5)	-0.11	0.915
Sections (%)	1 (1.1)	4 (4.1)		0.369
Outpatient attendance (%)	69 (72.7)	64 (75.8)	0.23	0.635
Number of outpatient attendances ^a	2.0 (1.0–4.0)	2.0 (0.0–3.0)	-0.54	0.592
Non-mental health referrals (%)	17 (18.3)	17 (17.9)	-0.12	0.904
Primary care				
Overall consultation rate (GP + practice nurse) ^a	2.5 (1.0–5.0)	4.0 (1.0–7.0)	-1.32	0.186
Issues raised per consultation ^a	1.0 (1.0–1.4)	1.1 (1.0–1.6)	-1.50	0.135
GP consultation (minutes) ^a	6.0 (5.0–10.0)	7.5 (5.0–8.5)	-0.14	0.889
Nurse consultation (minutes) ^a	10.0 (5.8–10.0)	12.0 (10.0–14.3)	-1.95	0.051

^aMedian (interquartile range). SD = standard deviation.

have been based in a secondary care setting. Studies have been short, (54% under six weeks), small (mean number of patients = 65), and fewer than 20 (1%) addressed the statistical power of the study. In this study, we recruited sufficient patients and practices to adequately power the study and achieved better follow-up rates at 12 months than most previous trials with this population. As in previous studies of the use of patient-held records, the majority of patients used them^{2,4} but the record did not appear to embed into clinical practice, perhaps because of variable health professional use.

Implications for clinical practice

The finding of significant practice variability among single-

handed practices appears to conflict with evidence linking personal list systems with higher satisfaction with primary care.²³ Since GPs hold varying views about their role for patients with schizophrenia,²⁷ it is possible that patients in group practices were able to consult a GP with a particular interest in mental health, a choice not necessarily available to those in single-handed practices. However, this study did not set out to explore health professionals' attitudes and behaviour towards mental health, and further work is needed to explain the greater variability in change in satisfaction score in single-handed compared with group practices.

The study adds a predominantly negative finding to the literature, which may reduce the possibility of unjustified service developments in this area. Although the majority of

Table 4: Use of patient-held record.

	n (%)
Frequency of card use (n = 92)	
Always	15 (16.3)
Usually	13 (14.1)
Sometimes	13 (14.1)
Occasionally	23 (25.0)
Never	28 (30.4)
Mean (SD)	
Usefulness of sections on a scale of 1-6 [1 = best], (number responding)	
Appointment section (61)	2.4 (1.3)
Medication pages (60)	2.3 (1.1)
Diary section (60)	2.5 (1.5)
Useful telephone numbers (58)	3.9 (1.2)
Emergency contact telephone numbers (56)	4.5 (1.5)
Early warning signs section (56)	5.3 (1.1)
n (%)	
Use of card (n = 64)	
Did the card help you to remember:	
GP appointments?	31 (48.4)
Keyworker appointments?	35 (54.7)
Consultant appointments?	36 (56.3)
Take tablets?	27 (42.2)
Go to depot?	30 (46.9)
Ask your GP questions?	15 (23.4)
Ask your keyworker questions?	20 (31.3)
Ask your consultant questions?	16 (25.0)
n (%)	
Number of health professionals using the patient-held record (n = 64)	
Did your keyworker use the card?	39 (60.9)
Did your GP use the card?	21 (32.8)
Did your consultant use the card?	20 (31.3)

patients used and intended to continue using them, the trial provides no evidence to suggest that patient-held records are associated with significant improvement in satisfaction and psychopathology. Based on this evidence, patient-held records should not be introduced as part of routine care for all patients with schizophrenia receiving shared care. However, this trial did not examine alternative outcomes, such as disease-specific quality of life or communication. Since use was predicted by symptom score, it also suggests that if patient-held records are used as an adjunct to shared care, they may be best targeted at patients with chronic stable schizophrenia although their use would need to be encouraged by both GPs and consultants.

References

- Liaw ST. Patient and general practitioner perceptions of patient-held health records. *Fam Pract* 1993; **10**: 406-415.
- Essex B, Doig R, Renshaw J. Pilot study of records of shared care for people with mental illnesses. *BMJ* 1990; **300**: 1442-1446.
- Reuler JB, Balazs J. Portable medical record for the homeless mentally ill. *BMJ* 1991; **303**: 446.
- Stafford A, Laugharne R. Evaluation of a client-held record introduced by a community mental health team. *Psychiatr Bull* 1997; **21**: 757-759.
- Henderson C, Laugharne R. Patient-held clinical information for those with psychotic illnesses. (Cochrane Review). In: Cochrane Collaboration. *Cochrane Library*, Issue 4. Oxford: Update Software,

- 1999.
- Warner JP, King M, Blizard R, *et al*. Patient-held shared care records for individuals with mental illness. *Br J Psychiatr* 2000; **177**: 319-324.
- Jenkins R, Bebbington P, Farrell M, *et al*. The National Psychiatric Morbidity Surveys of Great Britain — initial findings from the Household Survey. *Psychol Med* 1997; **27**: 775-789.
- Kendrick T, Burns T, Garland C, *et al*. Are specialist mental health services being targeted on the most needy patients? The effects of setting up special services in general practice. *Br J Gen Pract* 2000; **50**: 121-126.
- Ruggeri M, Dall'Agnola R. The development and use of the Verona Expectations for Care Scale and the Verona Service Satisfaction Scale for measuring expectations and satisfaction with community based psychiatric services in patients, relatives and professionals. *Psychol Med* 1993; **23**: 511-523.
- Krawiecka M, Goldberg D, Vaughn M. A standardised psychiatric assessment scale for rating chronic psychotic patients. *Acta Psychiatr Scand* 1977; **55**: 299-308.
- Ruggeri M, Lasalvia A, Dall'Agnola R, *et al*. Development, internal consistency and reliability of the Verona Service Satisfaction Scale- European Version. *Br J Psychiatr* 2000; **177**(suppl 39): 41S-48S.
- Birchwood M, Smith J, McMillan F, *et al*. Predicting relapse in schizophrenia. *Psychol Med* 1989; **3**: 649-656.
- Johnstone EC, Crow TJ, Frith CD, Price JS. Mechanism of the antipsychotic effect in the treatment of acute schizophrenia. *Lancet* 1978; **1**: 848-851.
- Kirov GK, Murray RM, Seth RV, Feeney S. Observations on switching patients with schizophrenia to risperidone treatment. Risperidone Switching Study Group. *Acta Psychiatr Scand* 1997; **95**: 439-443.
- Ruggeri M, Biggeri P, Rucci P, Tansella M. Multivariate analysis of outcome of mental health care using graphical chain models. The South-Verona Outcome Project I. *Psychol Med* 1998; **28**: 1421-1431.
- Tarrier N, Barrowclough C, Bamrah JS. Prodromal signs of relapse in schizophrenia. *Soc Psychiatr Psychiatr Epidem* 1991; **26**: 157-161.
- Campbell MK, Mollinson J, Steen N, *et al*. Analysis of cluster randomised trials in primary care: a practical approach. *Fam Pract* 2000; **17**: 192-196.
- Fahey TP, Peters TJ. What constitutes controlled hypertension? Patient-based comparison of hypertension guidelines. *BMJ* 1996; **313**: 93-96.
- Campbell M, Grimshaw J, Steen N. Sample size calculations for cluster randomised trials. *J Health Serv Res Policy* 2000; **5**(1):12-16.
- Donner A, Brown KS, Brasher P. A methodological review of non-therapeutic intervention trials employing cluster randomisation, 1979-1989. *Int J Epidemiol* 1990; **19**: 795-800.
- Donner A, Klar N. *Design and analysis of cluster randomization trials in health research*. London: Arnold, 2000.
- Armitage P, Berry G. *Statistical methods in medical research*. London: Blackwell Scientific Publications, 1994.
- Baker R, Streatfield J. What type of general practice do patients prefer? Exploration of practice characteristics influencing patient satisfaction. *Br J Gen Pract* 1995; **45**: 654-659.
- Castle D, Wessely S, Murray M. Sex and schizophrenia: Effects of diagnostic stringency and associations with pre-morbid variables. *Br J Psychiatry* 1993; **162**: 658-664.
- Hafner H. What is schizophrenia? *Neurol Psychiatry Brain Res* 1993; **2**: 36-52.
- Thornley B, Adams C. Content and quality of 2000 controlled trials in schizophrenia over 50 years. *BMJ* 1998; **317**: 1181-1184.
- Bindman J, Johnson S, Wright S, *et al*. Integration between primary and secondary services in the care of the severely mentally ill: patients' and general practitioners' views. *Br J Psychiatr* 1997; **171**: 169-174.

Acknowledgements

We thank all the keyworkers who were integral to the success of this project and the patients who participated in the focus groups during the development of the patient-held record and in the trial. We would also like to thank the GPs and consultants who participated in this trial. Ms Wendy Cotterill helped coordinate the trial administration and entered patient data. Professor Nick Freemantle provided valuable comments on earlier versions of the manuscript. We also acknowledge the helpful advice of the four anonymous referees.

This project was completed while Dr Helen Lester was in receipt of a Sheldon research fellowship from the West Midlands NHSe and Lesley Roberts was in receipt of a New Blood research fellowship from the West Midlands NHSe.