

Exploratory cluster randomised controlled trial of shared care development for long-term mental illness

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SUMMARY

Background: Primary care clinicians have a considerable amount of contact with patients suffering from long-term mental illness. The United Kingdom's National Health Service now requires general practices to contribute more systematically to care for this group of patients.

Aims: To determine the effects of Mental Health Link, a facilitation-based quality improvement programme designed to improve communication between the teams and systems of care within general practice.

Design of study: Exploratory cluster randomised controlled trial.

Setting: Twenty-three urban general practices and associated community mental health teams.

Method: Practices were randomised to service development as usual or to the Mental Health Link programme. Questionnaires and an audit of notes assessed 335 patients' satisfaction, unmet need, mental health status, processes of mental and physical care, and general practitioners' satisfaction with services and beliefs about service development. Service use and intervention costs were also measured.

Results: There were no significant differences in patients' perception of their unmet need, satisfaction or general health. Intervention patients had fewer psychiatric relapses than control patients (mean = 0.39 versus 0.71, respectively, $P = 0.02$) but there were no differences in documented processes of care. Intervention practitioners were more satisfied and services improved significantly for intervention practices. There was an additional mean direct cost of £63 per patient with long-term mental illness for the intervention compared with the control.

Conclusion: Significant differences were seen in relapse rates and practitioner satisfaction. Improvements in service development did not translate into documented improvements in care. This could be explained by the intervention working via the improvements in informal shared care developed through better link working. This type of facilitated intervention tailored to context has the potential to improve care and interface working.

Keywords: chronic disease; delivery of health care, integrated; interprofessional relations; mental disorders; mental health services; primary health care; randomised controlled trial.

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Introduction

PATIENTS with long-term mental illness suffer considerable disability, morbidity, and mortality and remain a high priority on national policy agendas. Although there is now an imperative for more primary care input, the extent of change and methods for achieving it have not been clearly outlined.¹ Historically, providing mental health care for this group of patients has not been recognised as core work for general practitioners (GPs) and there has been no consensus among GPs regarding more proactive or structured care.^{2,3} Yet, up to 50% of patients with long-term mental illness have no contact with specialist services and have comparable levels of unmet need to those who do have contact.⁴ A range of recommendations for the development of care, both within practices and across the primary-secondary interface, include developing mental illness registers, systems for patient review and recall, audit of care, payment for primary care-based reviews, consultation-liaison psychiatry, 'link workers' (mental health team members linked to specific practices), practice-based mental health workers, and GPs with a special interest in mental health.^{1,5-7} Apart from mixed results for recall and structured assessments,⁸⁻¹¹ there is little substantive evidence to back up these recommendations, though many have considerable face validity. The contextual diversity of both primary care and specialist services is likely to demand a range of solutions.⁷ Furthermore, components such as systems for recalling patients and placing link workers with practices are potentially interdependent,¹² and a whole-system approach may therefore be needed to ensure maximum benefit for each component.

The complexity of the solutions and the systems involved do not lend themselves to a simple strategy for delivering change; the delivery of any intervention would therefore need to be multifaceted.¹³ In line with Medical Research Council recommendations for developing and evaluating complex interventions (phases I-II),¹⁴ the Mental Health Link project used this complexity as a rationale for an iterative process of development¹⁵ of a conceptual framework and a multifaceted intervention aiming to support the development of shared care.¹⁶

Facilitation, which encourages a flexible approach, rather than academic detailing, which promotes predetermined best practice, was chosen as the vehicle for delivering the programme. Facilitators worked with the individual teams to help them make choices based on their own context, rather than imposing a new system from the outside. Facilitation programmes, as a subtype of organisational interventions, although ultimately aiming to improve the health of patients, work through changing practitioner beliefs and behaviour to

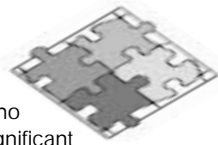
HOW THIS FITS IN

What do we know?

Patients with long-term mental illness who are seen mainly in primary care have significant unmet needs. Few interventions have been shown to have an impact on care in general practice and, although there are many recommendations, there is little agreement about which interventions or components of shared care constitute good practice.

What does this paper add?

A low-cost facilitated general practice and mental health team-based complex intervention improved partnership working between primary and secondary care and was associated with a reduction in recorded relapses. Facilitation programmes, which are sensitive to local conditions, have the potential to bring about significant improvements to neglected areas of primary and community care.



develop systems and improve practice during contact with patients.¹⁷ We therefore used a pragmatic exploratory (phase II) cluster-based randomised controlled trial to evaluate the Mental Health Link intervention by looking at its impact on three levels: practice, practitioner, and patient.

Method

Selection and randomisation of practices

Approval was obtained from Lewisham Ethics Committee. We sent a recruitment advertisement to the 152 general practices within the Lambeth, Southwark and Lewisham Health Authority in Southeast London, and the 26 practices that expressed an interest were sent an information pack outlining the research. Of these, 24 practices agreed to participate. We sent questionnaires to the 96 GPs from the participating practices to assess their interest in long-term mental illness and satisfaction with specialist services.

The practices were randomised to receive the Mental Health Link intervention or to continue with usual service provision. We stratified the practices according to both size of partnership and interest in mental health. These two factors were balanced across intervention and control groups using the randomisation technique of 'minimisation' carried out independently by the statistician.¹⁸

The intervention

The quality improvement intervention was delivered by three researchers, two of whom had experience of the delivery of primary mental health care. Researchers were trained in facilitation methods, and to follow a flexible protocol over three 3-hour sessions.¹⁹ They were allocated the intervention general practices and worked with small joint working groups of professionals and managers drawn from each practice and its associated community mental health team. Each group was given the option of inviting patients to join the group. Box 1 outlines the core components of the intervention. At the first meeting the group considered local needs and considered visions for change. Over two to three subsequent meetings the group worked through a series of

Initial assessment

- Assessing epidemiological needs — numbers of patients
- Obtaining patients' views on needs — local focus groups and national literature
- Sharing visions for change — primary care and mental health team

Developing a shared care agreement

- The role of linked workers and/or psychiatrists — taking direct referrals, providing advice on referrals, screening referrals, providing advice about the trust
- Meetings — linked workers attending GP meetings, joint clinical review meetings
- Formal communication guidelines — written referrals, discharge, significant specialist or GP contacts, GP input to care programme approach
- Detailing responsibilities for groups of patients — for example, for physical health, for mental health if under or not under specialist care

Developing systems

- Constructing a disease register for long-term mental illness
- Setting up paper or electronic databases for patients' clinical details
- Systems for recall
- Training needs assessment
- Audit

Box 1. Facilitating decisions about shared care for long-term mental illness.

options for the configuration of shared care, outlined in a tool kit. It focused on appointing and developing the role of a linked specialist mental health worker and planning the chronic disease management systems within the practice. In particular, the placement of 'aligned caseload' link workers, in which the linked community mental health worker has a majority of cases from one practice, was encouraged. The tool kit gave guidance on setting up registers, databases, audits, and systems of recall. An annual joint review of patients' notes was recommended in order to detect and address unmet mental and physical healthcare needs. The facilitators produced a tailored shared care agreement based on these discussions. They also arranged follow-up at 3 months and 1 year, and assistance with systems development where appropriate. Payments of about £2000 (dependant on practice size) were made to the practices.

Outcome measures

The pilot year was used to develop and test possible outcome measures. The use of health status outcome measures,²⁰ requiring large numbers of long interviews with patients who were difficult to track down owing to intermittent contact with services, was shown to be impractical. No previously validated instruments measured the main domains of interest. Existing outcome measures from across the possible levels of change were therefore chosen and adapted for primary care, or developed *de novo*, as summarised with examples in Table 1.

For the primary outcome measure, patients' satisfaction with care and their perception of unmet need were measured

by adapting two previously validated questionnaires to the context of primary mental health care.^{21,22} Scores, derived from primary care case notes, for the quality of care patients received for different aspects of mental and physical health, were constructed to reflect recommended practice; a 'severity of mental illness score', based on criteria in the global assessment of functioning,²⁰ and relapse rates were also determined from the notes. Service use data were collected from case notes and a patient questionnaire.²³ Logs of the time devoted to the intervention and usual service development were maintained. We used the results of a questionnaire sent to a reference panel of 28 patients and professionals to rank the importance of the areas of outcome in the note audit.

Inclusion criteria, recruitment, and follow-up of patients

We created a sample frame of patients with long-term mental illness in each practice from three sources: the mental health teams' databases, the practices' databases, and GPs' recall from memory. The definition of long-term mental illness was based on the 'three Ds' model of diagnosis, disability, and duration,²⁴ and it included all patients with chronic psychosis

requiring even minimum care, and those with ongoing and significantly disabling neuroses, such as chronic depression or chronic anxiety, but excluded those with predominantly drug and alcohol dependency or personality disorders. A list of patients for each practice was sent to their usual GP and the practice manager, who checked contact details and suitability in terms of risk to others and vulnerability.

Questionnaire data were collected at baseline (T1) and at 18–24 months after the intervention started (T2). Written consent was obtained while requesting the T1 questionnaire in all but one practice, where it was obtained prior to the questionnaire. Non-responders were followed up by telephone calls from care coordinators, and at follow-up by home visits. We gave patients £5 gift vouchers in recognition of their time for each questionnaire completed. Notes were audited for periods covering 1 year before and 1 year after the intervention.

Blinding

Within this cluster trial the 'participants' include the practices, the professionals, the researchers and also the patients. Patients were unaware of the status of their practice. The professionals were aware of their practice's status and the

Table 1. Range of outcome measures used in the exploratory randomised controlled trial before and after intervention.

Outcome	Measure or scale (with examples where applicable)
Patient level	
1. General and mental health	<ul style="list-style-type: none"> • Single 7-point one-dimensional self-rating scale of general health in patient questionnaire. • Ordinal 4-point scale for mental health symptoms and functioning rated by researcher from GP notes (derived from global assessment of functioning²⁰). • Number of relapses (deteriorations in mental state) documented in notes.
2. Met and unmet need	Adapted version of the Camberwell assessment of need ²¹ (nine items examining met and unmet needs for care such as medication, emotional support, financial advice).
3. Patients' satisfaction with services	Nineteen-item satisfaction questionnaire on a scale of 1–5, based on a previously validated format ²² adapted for primary care to examine: <ul style="list-style-type: none"> • physical care (for example, provided by GP or nurse); • mental health care (for example, provided by GP, counsellor or psychiatrist); • interface work (for example, communication and joint working); • information/access to services (for example, written information, access to advice). The format also allowed patients to express their perceived unmet need for services they had not received.
4. Quality of process of care	Presence of 54 key criteria in practice notes ^a for the following areas of care: <ul style="list-style-type: none"> • continuity (percentage of consultations with most commonly seen GP); • physical health care (for example, investigations and referrals made); • health promotion (for example, cervical smears up to date and blood pressure measured); • mental health assessment in primary care (for example, mental state examined, carers needs assessed); • active mental health management (for example, medication changed or referral made); • communication to primary care.
Practitioner level	
5. GPs' satisfaction and attitude	Fourteen-item questionnaire regarding satisfaction with services and interest in mental health on 5-point scales.
Practice community mental health team level	
6. Service development for long-term mental illness	Presence of key service developments for long-term mental illness in primary care (register, patient database, link worker operating, meetings with community mental health team, recall or review of patients for physical and mental health).
Cost	
7. Cost and quantity of care provision at primary and secondary levels. Cost of intervention.	<ul style="list-style-type: none"> • Adapted client service receipt interview.²³ • Staff and research team time to set up Mental Health Link or involvement in service development for long-term mental illness.

^aMaximum of 16 sets per practice.

Table 2. Characteristics of patients in control and intervention groups.

Patient characteristic	Intervention group <i>n</i> (%)	Control group <i>n</i> (%)
Sex (<i>n</i> = 335)		
Male	83 (45)	76 (50)
Female	101 (55)	75 (50)
Diagnostic group (<i>n</i> = 344)		
Chronic psychosis	104 (57)	87 (58)
Bipolar disorder	24 (13)	20 (13)
Chronic depressive or neurotic conditions	56 (30)	44 (29)
Severity of illness		
Well	13 (14)	10 (13)
Mild	32 (34)	23 (30)
Moderate	37 (39)	32 (43)
Severe	13 (14)	10 (13)
Under specialist care	120 (76)	100 (75)
Past harm to self	26 (16)	19 (14)
Past harm to others	12 (8)	22 (16)
Ethnic grouping (<i>n</i> = 142)		
Black	17 (23)	13 (19)
White, British	44 (60)	39 (57)
Other ethnic group	12 (17)	17 (25)
Accommodation (<i>n</i> = 134)		
Own or partner's	10 (14)	12 (19)
Rented	58 (82)	46 (74)
Supported	4 (6)	4 (7)
Main income (<i>n</i> = 139)		
Salary	12 (17)	5 (8)
Benefits	56 (78)	52 (78)
Pension	4 (5)	10 (15)
Employment (<i>n</i> = 137)		
Unemployed	46 (67)	46 (67)
Employed/self-employed	11(16)	7 (11)
Other	16 (12)	20 (17)

facilitators were aware only of the status of the practices they facilitated, with the exception of one researcher who was initially providing blinded mentoring to the facilitators but in time took over the facilitation of all practices. The researchers were responsible for collecting questionnaire data from practices they were not facilitating and were therefore blind to the status of patients from those practices. Eighty-one per cent of note audits were carried out by a new researcher, blind to all but one practice; one researcher carried out 19% of note audits unblinded.

Analysis

It was not possible to calculate an accurate sample size, as the principal outcome measure was a newly adapted questionnaire with unknown properties. A pragmatic estimate of 400 patients was made. Allowing for a 60% return rate at baseline and 80% for follow-up, this would provide nearly 200 patients for analysis, which would be sufficient to detect with 80% power a moderate (0.5) effect size at patient level, assuming a relatively small (0.025) intra-class correlation and about eight patients per practice.

The questionnaire data were recoded as recommended;²² services that were not received but wanted by patients were scored 2/5 for satisfaction, whereas those not received or

wanted scored 4/5. The total number of met and unmet needs were calculated for each patient. Individual 'items of care provided' outcome frequency data, such as the number of times health promotion advice was recorded, were standardised to have unit standard deviation and totalled to form 'area of care' scores, described in Table 1. These area of care scores, standardised by dividing by the upper limit of the range for each area and weighted by multiplying by the panel's mean rating, were added together to give a total score for 'process of care'. At the practice level, assigning a point for each component of service development where an improvement had occurred created a total 'practice development score'. Costs were calculated by multiplying service and implementation data by the relevant unit costs.²⁵

Univariate analyses were performed using χ^2 and Fisher's exact tests or McNemar's test for T2/T1 comparisons (categorical data); Mann-Witney tests were performed for single practice level comparison, and paired *t*-tests for T2/T1 GP comparisons were used for continuous data. The estimated effects of the intervention at patient and GP levels were found from ANCOVAs, comparing the outcomes for the two groups at T2, adjusting for the T1 value. Simes' test was used to adjust for multiple outcomes.²⁶ The analyses were carried out in STATA, using random effects regression with robust variance estimates for the patient data (the random effects being contributed by the practices).²⁷ This allowed for the effect of clustering of patients within practices on standard errors and *P*-values. Cost comparisons were made using regression analysis, clustered for practice. Non-parametric bootstrapped 90% confidence intervals (CIs) were generated in order to deal with the skewness of the cost data.²⁸

Results

The impact of Mental Health Link on practices, practitioners, patients, and costs are described.

Practices

One control practice withdrew from the study, leaving 11, whereas 12 practices received the intervention. Control and intervention practices were similar with respect to staff retention. There was a wide spread in practice size although only one single-handed practice took part. There was an even mix of urban and inner-city practices, and an even balance across community mental health team areas. More control practices had allocated link workers at the start of the study. The majority provided chronic disease care and were involved in teaching. There was increased computerisation in control practices, with nine compared with three intervention practices inputting consultation data (Fisher's exact test *P* = 0.012).

Each intervention practice received the core components of the intervention in the form of a series of three to four facilitated joint working group meetings, payment and a tool kit. There were a number of deviations from the intervention protocol: only two joint working groups actively wanted to involve service users; attendance by psychiatrists, practice managers and practice nurses was variable; and for four practices, there were significant delays in setting up meetings. In three of these practices, systems development continued beyond the study period. The extent to which practices

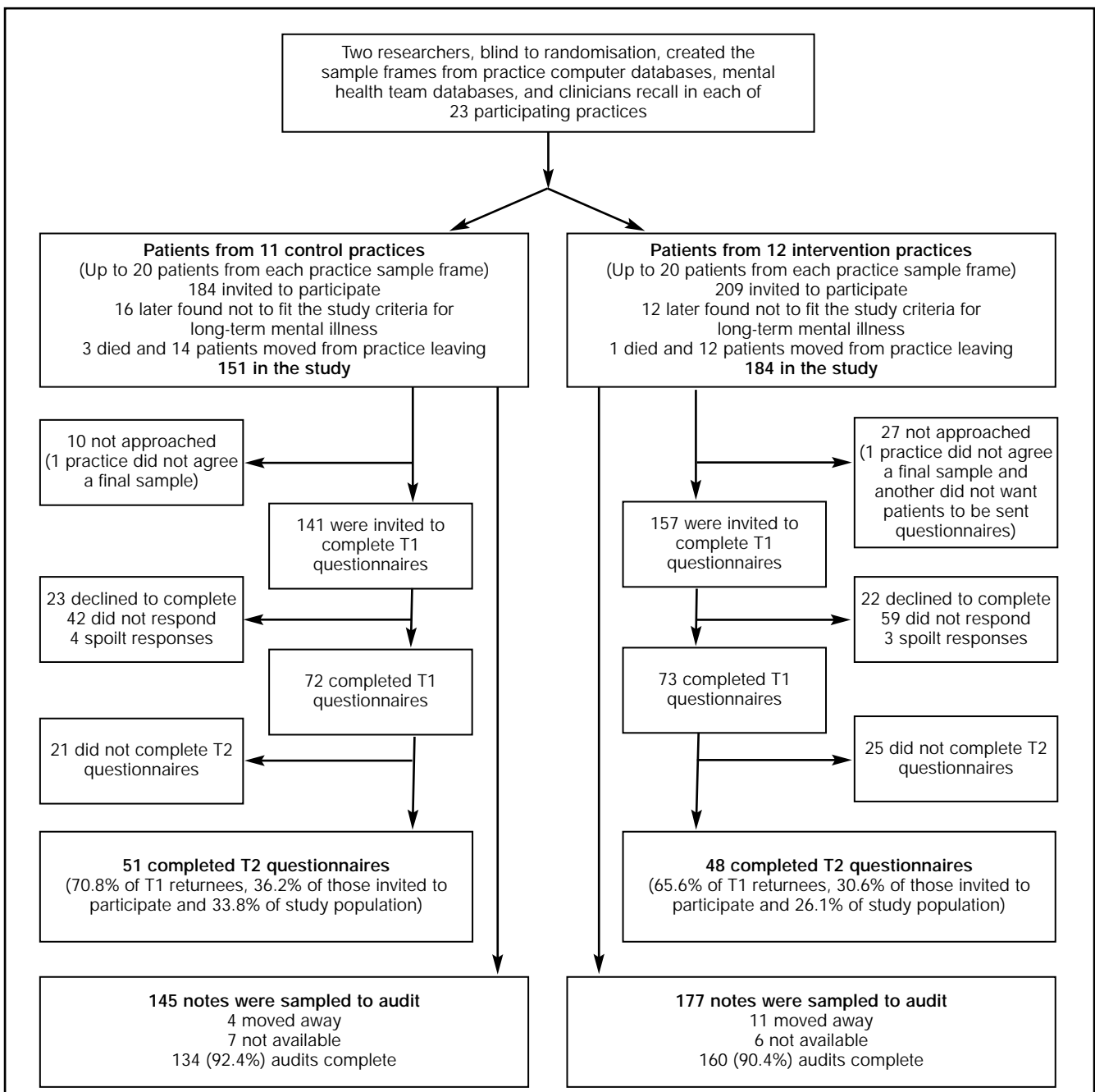


Figure 1. Pathways for patients and data collection in Mental Health Link randomised controlled trial.

both accepted support from the facilitators beyond the joint working group meetings and participated in service development was variable.

Active link working in intervention practices increased (from one to five practices) and declined in control practices (from six to four). Control practices recorded more long-term mental illness registers at the beginning, which declined (from seven to four), whereas intervention practices showed an increase (from five to ten). There were also improvements in systematic review and recall (from nought to seven) for intervention practices; these were intermittent in three, discontinued in two and sustained in only two practices. There

were few changes in other areas such as carers groups and training. The 'practice development score', the number of improvements in key areas per practice, was significantly better for the intervention practices (control mean = 2.9 versus intervention mean = 0.7, Mann-Witney, $P = 0.003$).

General practitioners

The questionnaire return rate was 86% at T1 and, among those who responded at baseline and who were still working as GPs in the same practices at T2 ($n = 71$), the return rate was 92%. Although interest in mental health did not

Table 3. Differences between global scores for health and care derived from note audits and questionnaires: intervention versus control.

Variable	Mean scores at baseline and follow-up ^a		Intervention versus control		
	Mean at baseline	Mean at follow-up	Adjusted difference ^b between control and intervention at follow-up	95% CI for difference	P-value
Patients' views from questionnaires (n = 99)					
Lack of wellbeing (7-point scale)					
Intervention	3.69	3.41			
Control	3.76	3.46	-0.03	-0.79 to 0.73	0.93
Total satisfaction (scale of 1-5)					
Intervention	3.73	3.71			
Control	3.66	3.66	-0.01	-0.21 to 0.18	0.88
Total met need (out of nine needs)					
Intervention	2.12	2.23			
Control	2.22	2.43	-0.27	-0.46 to 1.00	0.46
Total unmet need (out of nine needs)					
Intervention	1.58	1.49			
Control	1.51	1.31	-0.02	-0.56 to 0.51	0.94
Outcomes from note audit (n = 304)					
Severity of illness (4-point scale)					
Intervention	2.53	2.56			
Control	2.34	2.46	0.21	-0.01 to 0.42	0.06
Number of relapses					
Intervention	0.56	0.66			
Control	0.39	0.71	0.28	0.08 to 0.49	0.01
Total score for 'process of care' (observed range of 0-24)					
Intervention	7.04	7.30			
Control	5.69	6.40	0.55	-0.44 to 1.54	0.27

^aFurther standard deviations, intra-class correlation co-efficients and adapted scales are available from authors. ^bControlling for baseline scores and allowing for clustering of patients within practices.

change during the course of the trial or differ between groups, intervention GPs reported greater improvement in satisfaction with specialist services, on a scale of one to five, compared with control GPs, allowing for baseline data and clustering within practices (improvement of 0.67 for intervention versus 0.29 for control, adjusted difference = 0.46, 95% CI = -0.74 to 0.18, $P = 0.001$).

Patients

A total of 335 patients were included in the study and of these, 298 were invited to complete an initial questionnaire. After following up non-responders with a further questionnaire, 145 (49%) valid questionnaires were returned, and of these, after reminders and home visits, valid follow-up questionnaires were completed by 51 control and 48 intervention practice patients (68%). A total of 294 (91%) note audits of the 322 attempted were completed. Figure 1 provides a detailed account of the patients' progress through the trial in line with the CONSORT agreement.

Table 2 shows the sociodemographic characteristics, the mental health-related patient descriptors and the questionnaire responses, comparing intervention with control patients. The mean ages of intervention and control patients were 41 and 42 years, respectively. The broad diagnostic categories were established on the basis of diagnoses used by community mental health teams or, where this was not available, according to medication and clinical details; 70% of patients had a diagnosis of chronic psychosis or bipolar

affective disorder. There were no significant differences between control and intervention patients, with the exception that more control patients were recorded as having harmed others in the past ($\chi^2 = 5.6$, $P = 0.018$). There were no statistically significant differences in characteristics of those responding to both questionnaires compared with others, nor any differences between T2 responders and T1-only responders with respect to baseline outcome measures.

A summary of results for patient level outcomes is shown in Table 3. After controlling for baseline and allowing for clustering of patients within practices, there were no significant differences between control and intervention practices for patients' perception of their general health, unmet need, or satisfaction with services. However, there was a significant difference in the number of relapses with more documented in the control practices compared with the intervention practices (adjusted difference = 0.28, 95% CI = 0.08 to 0.49, $P = 0.01$). The severity of mental illness showed a borderline significant difference between control and intervention adjusted for baseline (adjusted difference = 0.21, 95% CI = -0.01 to 0.42, $P = 0.06$). These two results were very similar when calculated by excluding cases where the observer was not blind ($P = 0.02$ and $P = 0.06$, respectively). Using the Simes' test²⁶ to adjust for multiple outcomes, there was still borderline evidence for improvement in these two measures of mental health. There were no significant differences between the processes of physical and mental health care documented.

Table 4. Service development and service costs 1999/2000 (£).

Cost element	Control group ^a mean (SD)	Intervention group ^b mean (SD)	90% CI of difference ^c
Service development costs			
Practice start-up	30 (84)	63 (36)	-17 to 69
On-going practice development	28 (48)	73 (40)	11 to 72
CMHT service development	56 (98)	39 (37)	-81 to 30
<i>Total development costs</i>	113 (219)	176 (89)	-92 to 151
Service costs			
Inpatient costs			
Baseline	2327 (6297)	2006 (5451)	-2467 to -246
Follow-up	1036 (3514)	778 (4007)	-1776 to 117
Community costs			
Baseline	333 (283)	353 (315)	6 to 160
Follow-up	421 (320)	348 (303)	-105 to 32
Medication costs			
Baseline	370 (610)	674 (1048)	18 to 317
Follow-up	525 (895)	586 (989)	-364 to -14
Total service costs			
Baseline	3030 (6391)	3034 (5904)	-2266 to -73
Follow-up	1982 (3735)	1711 (4246)	-2052 to 11
Total costs	3147 (5923)	1887 (4253)	-1973 to 132

^a(n = 134). ^b(n = 160). ^cEstimated from a bootstrapped clustered regression model. CMHT = community mental health team. SD = standard deviation.

Health economics

Table 4 summarises the costs of the intervention and the associated patient costs. The direct development costs per patient with psychosis (assuming 15 patients with chronic psychosis per 2000 registered in this predominantly inner-city setting) for practices in the Mental Health Link implementation group ranged from £46 to £347 (mean = £176, standard deviation = £95); these were, on average, £63 higher per patient than development costs reported by the control practices and associated community mental health teams. At baseline there was a significant difference in inpatient costs (which were higher for the control group) and controlling for this meant that the inpatient costs difference at follow-up was not significant. Medication costs were significantly higher for the intervention group at baseline whereas this was reversed at follow-up.

Discussion

The study found mixed results with respect to outcomes at different levels. There were significant improvements in link working, practice systems, and GP satisfaction with services. Significant improvements were seen in the relapse rates of intervention compared with control patients; these were of borderline significance after adjusting for multiple comparisons, although some would argue that in an exploratory trial no adjustments should be made.²⁹ However, there were no improvements in processes of care in the notes or reported satisfaction with care or unmet need. The cost of the intervention was low and associated patient care costs were lower for the intervention patients. No clear conclusions

about cost-effectiveness can be made. The use of adapted and newly developed outcome measures, some of which showed changes, adds further difficulties for the interpretation of this combination of results.

Interpretation

Three possible explanations for this pattern of results are discussed. One is that the intervention may have been ineffective for the time and context. The GPs and practices were not blind so the changes in satisfaction and practice development could have been owing to bias; the changes in relapse rates, which were adjusted to account for differences in baseline results, would have to have been owing to chance.

Alternatively, it may have been partially effective, acting mainly through the improvements in joint working, rather than the improved systems in primary care, and leading to earlier intervention and reduced relapse rates. This explanation is supported by increased GP satisfaction with specialist services. We did not measure the number or quality of primary-specialist interface contacts, which would have provided more robust evidence, however, a move from competition to cooperation, facilitated by the intervention, is one potential mechanism for improved inter-professional and cross-boundary working. Although patients did not report improved satisfaction or reduced unmet need, the low percentage of patients completing questionnaires make any conclusions difficult to interpret. The improvements to practice systems were possibly too short lived or took place towards the end of the study period, accounting for the lack of significant changes to the process of individual care. In particular, the development, beyond the construction of registers and databases, of routine systems for review by primary care was not achieved in most intervention practices.

A third possible explanation is that contamination from intervention to control sites prevented us from detecting the full effect of the intervention. This is unlikely as link working declined in control practices and practice systems were at early stages of development, making it unlikely that they would have spread from practice to practice.

In summary it appears likely that link working, attributable to Mental Health Link, brought about changes in patient care in some, but not all practices. Improvements in practice systems, on the other hand, although reported, probably fell short of delivering sustainable change to processes of care. The complementary 'realistic evaluation'³⁰ of the process behind the trial should help shed light on both the interpretation of the results and the mechanisms underpinning the intervention.

Implications for practice and future research

We do not know whether the intervention, designed for the inner-city, would have been more or less successful in more affluent or suburban settings, where teams may be less stretched, but prevalence of long-term mental illness may be lower.

The low cost per patient of the intervention, although partly owing to the limited time committed to service development and joint working, provides a case for continuing to develop and evaluate interventions of this nature. Small improvements

in patient outcomes would make the intervention cost-effective. This study, although substantial, was not powered to detect such small changes, making type 2 errors possible. Another economic evaluation of link working was also unable to draw definitive conclusions about cost-effectiveness.³¹

Further research, to define more clearly the benefits of a Mental Health Link-type facilitated intervention, could involve a more expensive phase III fully-powered randomised controlled trial,¹⁴ capturing more face-to-face data from a higher proportion of this inaccessible community sample. It is worth noting that for future sample size calculations, the intra-class cluster coefficients were significant for baseline data but not for the differences between follow-up and baseline. A more representative sample of practices would also be required, clinicians and managers in both primary and secondary care would need to be more involved, and additional outcome measures would need developing. However, such a study could not deal with the uncertainties and complications associated with working in a changing National Health Service and its unpredictable organisations and patients. The more stringent requirements for obtaining consent would add further complications.

Ironically, although our trial took place in a relatively adverse local policy context, as the external environment becomes more favourable it will become more difficult to identify controls with minimal background service development. We would argue that this is a scenario for preferring a cheaper but theoretically driven pragmatic evaluation, in a variety of settings, concentrating on understanding why intermediate outcomes are or are not achieved, and more qualitative and participative approaches to learning. The value of novel components of shared care developed for this and other projects, such as the adaptable shared care agreement, the core primary-secondary mental health dataset, the system of jointly reviewing notes for unmet need, and the 'aligned' model for link working¹⁹ can be assessed to provide practical and timely guidance for implementation of the *National service framework for mental health*¹ and other policy initiatives across Europe and North America.

Although we were not able to demonstrate substantial and consistent changes, the results give grounds for optimism that relatively small amounts of money and robust facilitated service development, directed at improved partnership working⁵ and ensuring regular proactive review of those patients most in need, could achieve significant gains for this disempowered group of patients.

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