Patient-held shared care records

for people with mental illness

by

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Abstract

Background
Shared care, the process whereby professionals from different disciplines or settings actively contribute to the management of a patient, has been widely advocated in many branches of medicine. Patient-held records are the most common method of sharing care. Few formalised shared care schemes exist within psychiatry and the evidence-base for sharing psychiatric care is weak.

Objective
To evaluate the effectiveness and acceptability of patient-held shared care records for individuals with long-term mental illness

Design
Cluster-randomised controlled parallel-group trial.

Setting
General practices within the catchment area of a teaching hospital in North London

Subjects
Ninety patients with long-term mental illness who were at the point of discharge following an inpatient-episode on the psychiatric unit. To be included, subjects’ had to be registered with a general practitioner and have follow-up arranged through the local psychiatric service.
Outcome measures

Hospital admissions and outpatient clinic attendance; mental state assessed by the Behaviour and Symptom Identification Scale (BASIS-32) and Brief Psychiatric Rating Scale (BPRS); patient satisfaction assessed by the Client Satisfaction Questionnaire (CSQ); subjects and professionals use of shared care records; attitudes to shared care.

Results

Carrying a shared care booklet had no significant effect on service usage, mental state or satisfaction with psychiatric services. Compared to controls, patients in the shared care group were equally likely to be admitted (RR 1.2, 95% CI 0.86, 1.67), and attend clinic (RR 0.96, 95% CI 0.67, 1.36) over the study period. There was no difference at follow up between groups in terms of BASIS-32 (t=0.73, p=0.38), BPRS (t=2.52 p=0.12) or CSQ (t=0.79, p=0.37) scores.

Uptake of the shared care scheme was low by patients and professionals alike. Subjects with psychotic illness were significantly less likely to use their records (p=0.04). Professionals were more pessimistic about the value of patient-held shared care records at the end of the study.

Conclusions

Patient-held records had no significant impact on patients' use of services, clinical state or wellbeing and are unlikely to be of use in psychiatry.
Conjoint statement.

I developed the original idea, wrote the protocol, obtained ethical approval, designed the shared care booklet and new questionnaires used in this study, and promulgated the study to involved professionals. I undertook the pilot study and part of the data collection. I was also responsible for the data input and analysis and writing up the thesis.

Dr Zara McClanahan and Dr Sylvia Tang helped with recruitment and follow-up of subjects and Ms Angela Thomas undertook data re-entry.
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PART I

Literature review
Chapter 1

Psychiatric illness in the community

1.1 Epidemiology

1.1.1 Introduction

The presence of a mental illness is often stigmatising for the patient and his or her family. Mental illness may also be associated with a lack of insight. Therefore, individuals are often reluctant to seek help and for many years our knowledge of psychiatric illness was based on those who had been assessed by psychiatrists. Although the concept of mental illness has changed over time, and successive editions of diagnostic formularies like the International Classification of Diseases (ICD) (WHO, 1992), and the Diagnostic and Statistical Manual (DSM) (APA, 1994) re-align what constitutes a defined mental illness, an inescapable fact is that at some point in their life many individuals will be affected by symptoms commonly or exclusively arising from disordered mental processes. Deciding exactly how common mental illness is in the community is difficult, not only because of reticence of individuals to admit symptoms, but also because of difficulties of case definition.

1.1.2 Prevalence in the community

Mental illness is common. The Epidemiologic Catchment Area Program was a large community survey in the United States using the Diagnostic Interview
Schedule and Research Diagnostic Criteria for case definition (Regier et al 1984; Robins et al 1984). This study found the six-month prevalence for any axis-I DSM-III (APA 1980) diagnosis in 24,371 adults was 18.0% (Fichter et al 1996). Jenkins et al (1997b) reported the results of a major epidemiological survey of psychiatric morbidity in the UK. This survey of 10,108 adults used robust case finding methods (Jenkins et al 1997a). All subjects were assessed using the revised Clinical Interview Schedule (Goldberg et al, 1970) and the Psychosis Screening Questionnaire (Bebbington and Nayani, 1995). Those who were positive on the psychosis screen were then further assessed using the Present State Examination (Wing et al 1974). The survey found that 12.3% of men and 19.5% of women had a one-week prevalence of neurotic disorder, defined as scoring 12 or above on the revised Clinical Interview Schedule. The one-year prevalence of functional psychosis was 4 per thousand of the population, a figure similar to other surveys (WHO 1973a; Harvey et al 1996a; Harvey et al 1996b; Jeffreys et al 1997). The most common symptoms were fatigue, sleep problems, irritability and worry, symptoms that may accurately be regarded as part of normal human experience rather than formal psychiatric labels. More formal psychiatric symptoms such as depression and anxiety were much less common. The one week prevalence of psychiatric disorders defined by ICD-10 (WHO 1992) included: anxiety disorder 31 per thousand, depressive episode 21 per thousand, obsessive compulsive disorder 12 per thousand and alcohol dependence 75 per thousand population. All disorders except alcohol dependence and functional psychosis were more common in women.
1.1.3 Prevalence in general practice

It has been recognised for some time that a significant proportion of patients in general practice presents with predominantly or exclusively symptoms of mental disorder. Shepherd et al (1966) used primary care records to survey the prevalence of psychiatric morbidity among general practitioner attenders. Approximately 14% of the 15,000 patients who consulted their general practitioner over the period of 1 year had a psychiatric disorder detected at screening. The Morbidity in General Practice survey (McCormick et al 1995) is a comprehensive assessment of general practice consultations covering over 500,000 patients within 60 general practices in England and Wales. Just under 6.5% of the sample consulted for a mental disorder i.e. were explicit about their symptoms and were diagnosed by their general practitioner. Eighty-five percent of patients in this category consulted for “neurotic, personality or other non-psychotic illnesses”. The rate of consultation for non-organic psychosis was 7.7 per thousand; similar to the prevalence of psychosis found in epidemiological surveys in the USA (Kendler et al 1996) and the UK (Jenkins et al, 1997b). However, the rates for general practitioner consultation for anxiety and neurasthenia (3.4%), depression (1.1%), and personality disorders (0.15%) are far lower than community prevalence surveys suggest. This disparity may be explained by Goldberg and Huxley’s model of pathways to care explained below (Goldberg and Huxley 1980). The parity between general practitioner consultation rates for psychosis and the prevalence of psychosis in the community suggests that individuals with psychosis are more visible within primary care, possibly because their symptoms are more overt, or general practitioners are less
likely to mis-diagnose psychosis. Because psychotic individuals are more likely to be diagnosed than those with less severe mental illness, they may not be subject to the same constraints in terms of accessing secondary care. Indeed, they may also bypass primary care altogether by admission via the police or social services.

### 1.1.4 Identification of psychiatric disorder in general practice

Shepherd (1966) found the estimation by general practitioners of psychiatric morbidity among their patients varied considerably, from around 4% to 65% of attendees. Goldberg and Huxley (1980), in a seminal study, drew attention to the vast amount of mental illness that exists in the community but is not recognised by doctors. Epidemiological studies, based on random samples of individuals in the community that have used standardised instruments like the General Health Questionnaire (Goldberg et al 1970) suggest that the point prevalence of psychiatric disorder in the community is between 100 and 200 per thousand of the population. Although the majority of these illnesses are minor mood disorders and anxiety 4% of patients seen by family doctors had a psychotic illness (Goldberg and Huxley 1980).
1.2 Care of mentally ill patients in the community

1.2.1 History

Over the last three decades a significant change in how patients with long term mental illness are cared for has taken place. The closure programme of asylums, started in the 1960s has resulted in the planned closure of over 33 hospitals and an estimated 90,000 beds (Thornicroft 1988, Thornicroft 1992). Although many former long-stay in-patients have been successfully re-integrated into the community, the reduction of acute beds consequent on these closures has resulted in more acutely ill patients living in the community, often without adequate support or treatment (Melzer et al 1991).

Given the relatively high prevalence of psychiatric disorder in the community, it is not surprising that up to 25% of patients who visit their general practitioners have symptoms of mental illness, often in combination with physical symptoms (Goldberg and Huxley 1980). Most are treated solely by their general practitioner. Goldberg and Huxley (1980) reported that only 1 patient in 20 presenting to their general practitioner with psychiatric symptoms was referred on to secondary care. The reasons for non-referral were twofold; 1) non-recognition of the problem either due to the patient shrouding the symptoms or the doctor's bias against making a psychiatric diagnosis; or 2) adequate recognition of the disorder but the decision by the clinician to manage the disorder at the primary care level. General practitioners
manage most of these problems, usually only referring patients with psychosis or severe depressive or anxiety disorders, or those who do not respond to treatment or present diagnostic difficulty.

In the last two decades there has also been a considerable change in the way psychiatric care is delivered. The closure of psychiatric hospitals, and shift towards community provision has resulted in what some would call a chaotic situation characterised by under-provision of resources, poor skill mix and unclear lines of responsibility. Changes have not ended there, with further alterations in service delivery including the introduction of the care programme approach and care management, which have also been widely criticised (Anonymous, 1995). The ethos underpinning these changes is logical and attractive; patients should live in the community where possible, be reviewed regularly and managed effectively using evidence-based practices. Although the notion of assertive outreach is a laudable one, some have suggested that it is not working in practice (Tyrer, 1998a; Tyrer 1998b). Tyrer (1998a) points out that much of the evidence underpinning the shift towards community care and especially the evidence of cost effectiveness is flawed. Furthermore, the poor integration of social and health agencies is expensive and ineffective. Tyrer promotes the ideal; well-trained teams with a common training and philosophy of care with better integration of hospital and primary care.

Not all patients with serious mental illness are in contact with hospital-based services (Burns and Kendrick, 1997). Nazareth et al (1995) in a survey of 13 London-based general practices found only 65% of patients with schizophrenia
were in contact with a psychiatrist. The Hampstead schizophrenia survey (Harvey et al 1996) used key informant case finding to identify 794 community-dwelling patients with a broad definition of schizophrenia. They found 193 (24%) were managed only by their general practitioner. This study would have missed many patients not registered with a general practitioner. A significant minority are not registered with a general practitioner, probably as a result of their chaotic and peripatetic lifestyle. Murray et al (1996) highlighted the unidentified and unmet needs of psychotic patients living in the community. One surprising finding of this study was that the needs of those not under a community team were equally severe as those who were. Overall, 42% of their sample had at least one “clinical need”, defined as a clinical problem requiring an intervention. Although this study does not quantify psychopathology, it does highlight the degree of morbidity in patients with severe mental illness living in the community. Indeed, the problem is probably worse than Murray and colleagues suggested, as their case-finding may have missed a significant number of psychotic individuals (Kendrick and Burns, 1996a).

1.2.2 Prognosis of mental illness in the community

So how do patients fare in the community? Those ill enough to warrant hospital admission probably do not do very well. Melzer et al (1991) found that 55% of 91 patients with schizophrenia interviewed one year after discharge had ongoing psychotic symptoms and most had profound social impairment. In another study designed to compare two methods of care for patients after discharge, Tyrer et al (1998b) followed up a cohort of 133 patients over one year after discharge. They
demonstrated little change in psychopathology measured by the comprehensive psychopathological rating scale (McGuffin et al 1993).

1.2.3 Respective roles of primary and secondary care

At the inception of the National Health Service (NHS), hospital consultants were seen as advisers to GPs, and the GPs retained sole clinical responsibility for day-to-day care of their patients (Stoeckle et al, 1997). This was echoed in 1973 by the World Health Organisation working party on psychiatry in general practice (WHO, 1973b), and the joint Royal Colleges working group (Royal College of General Practitioners, 1993). Recent years have seen this principle overturned, and a concatenation of events initially blurred the margins of clinical responsibility, then placed them firmly in the hospital consultants’ court. These events fall into two groups. Firstly, the realisation that needs of patients with long-term psychiatric illness cannot be met in solely primary care. The principal reasons are the discharge of large numbers of psychiatric patients to the community (Thomicroft, 1992), and the realisation that patients with long-term mental illness have high levels of physical and psychological morbidity that place considerable demand on primary care (Nazareth and King, 1992; King and Nazareth, 1996). Secondly, a series of high profile inquiries resulting from tragic consequences of a breakdown of care (e.g. see Ritchie and Lingham 1994), and a series of recommendations about the care of the seriously mentally ill (Department of Health 1996).

In addition to the shift in the locus of responsibility, there has been a politicisation of mental health care, with government initiatives like the Care Programme
Approach (CPA) (Department of Health, 1990; NHS executive circular 1994) and the supervision register which have placed an administrative burden on clinicians. I would argue that these initiatives, often introduced quickly and with little consultation with the professions, may be intended to divert responsibility for adverse events from the government for deficiencies in funding and provision, to the clinicians. In fact, when these initiatives are critically evaluated, there is no evidence that they work. Holloway and Carson (1998), in a randomised trial of intensive case management or standard management of discharged patients found no changes in clinical outcome among those receiving the intensive package of care, although satisfaction and service contact were better in this group. In a randomised controlled trial of social service case management, Marshall et al (1995) found no improvement in terms of needs fulfilled, quality of life, accommodation, employment status, social behaviour or mental health in those randomised to case-management compared with routine care as delivered before the introduction of case management.

To an extent, the patient is in danger of falling between stools here. The debate about who should provide clinical care and who has overall responsibility is dwarfed by the problems of under-funding of services. Arguments, with increasingly embittered entrenchment, as seen in the General Medical Services Committee (GMSC) statement suggesting responsibility for care of patients with psychiatric illness passes to hospital services after the referral (Beecham, 1996), probably stem from the fact that current needs and expectations outstrip resources. Individuals and groups then move to husband the few resources available to them.
by limiting their clinical remit. Given resources are finite and are unlikely to ever meet current perceived need, something has to shift. Either expectations will be reduced, which is hardly likely in today's climate of litigation-driven health care, or the current services find their level of optimal working.

Co-operation is far more efficient than conflict, as the old Quaker story of the two donkeys illustrates.¹ This is, in my view, a fundamental force driving shared care.

There are many similarities between general practice and psychiatry. Both disciplines tend to have a holistic approach to patients and emphasise the importance of communication between patient and doctor. Many patients with mental illness are treated exclusively by general practitioners. However those referred to secondary care tend to remain the responsibility of hospital-based services, only returning to the general practitioner if discharged from hospital care. Kendrick et al (1991) showed that although most general practitioners were happy to look after the physical needs of their mentally ill patients, most were reluctant to take prime responsibility for psychiatric care.

¹ Two mules are tied together with a length of rope. Each spies a load of hay at opposite corners of the field. Each mule pulls and pulls to try to get to the load of hay it has seen. The mules struggle against each other to the point of exhaustion, neither having so much as a bite to eat. Eventually, they decide that both should visit one load of hay, and then the other consecutively. Both are fulfilled!
Falloon et al (1996) assessed attitudes of GPs in Auckland, New Zealand to their role in the shared management of patients with mental health problems. New Zealand has a health care system that is similar to the UK with well-developed primary health care and specialist mental health services. Interpreting this survey is hampered by a relatively poor response rate (49% of the 287 GPs polled). Ninety-four percent of respondents considered that co-management with specialist services was important. Most GPs felt that there were difficulties in receiving information and in liaising with specialist services. Items particularly relevant to the shared care model included 1) lack of information about changes to treatment, 2) uncertainty about identity of key worker, 3) unsatisfactory communication with specialist care, 4) GPs not included in review process and 5) GPs not recognised as part of the treatment team. A patient-held record could address all of these elements.

The emergence of the psychiatrist and other mental health professionals from hospital to the community does not seem to have been mirrored by an increased wish the joint working between primary and secondary care. The General Medical Services Committee, the body that represents general practitioners issued guidance in 1996 suggesting that responsibility for care of the mentally ill should pass to the hospital team once a referral has been made (Beecham, 1996). The view of this committee was that care of individuals with mental illness that merited hospital input should be delivered solely by the hospital, and that “general practitioners have fulfilled their obligations when they have made a competent assessment and identified the need to refer”. The guidance also indicated that the hospital team should be responsible for prescribing and administering drugs. This advice
appeared to directly oppose the notion of shared care, the recommendations of the joint Royal College working party (Royal College of General Practitioners 1993), and was not universally accepted by general practitioners or psychiatrists (Hillam and Warner 1996, Kendrick and Burns 1996 b). Nevertheless, currently the advice still stands.

The GMSC advice underlines a major question: who is responsible for the care of patients? The debate has become increasingly tendentious. On the one hand, Kendrick and Burns (1996 b) have suggested that family doctors have a pivotal role in ongoing management of stable psychotic patients. Murray et al (1997) argue otherwise; that multidisciplinary community teams are best able to deliver care to this group, although they do admit that psychiatric services often fail to monitor patients and provide adequate recognition of needs.

1.2.4 Integration of primary and secondary care

Two issues dominate the decision about who cares for patients; clinical responsibility and clinical demarcation. Responsibility is a big issue, especially with the move towards a more defensive practice of medicine (Beran 1997). This is particularly the case in mental health care, where adverse incidents like suicide and attacks on others are often assumed to be due to a failure of care, and automatically result in an inquiry. These inquiries are often seen as adversarial. The fact that an inquiry is often seen as axiomatic following an incident means that many clinicians practise a defensive form of medicine, not only with a view to minimising the chance of an adverse incident, but also for protecting themselves should such an
inquiry take place. Clear boundaries of responsibility have therefore become very important to the clinicians. It is an established precept of English law that lack of awareness of an event does not remove responsibility for that event (vicarious liability). Thus clinicians are becoming increasingly aware of the need to know exactly where their responsibilities lie in order that they can acquit themselves of those responsibilities to the best of their ability (Beran, 1997).

Demarcation is also important. Clinical freedom is a holy grail that many clinicians already perceive to be under threat by the introduction of guidelines and evidence-based practices. The reductionist view that medicine can be boiled down to its component parts, like a recipe in a cook book, negates one important element; that clinical judgement, an ability formed over years of experience and practice, is an essential part of the decision-making process within medicine. Clinicians need to feel free to make choices about treatment and management. This includes freedom from constraint by colleagues. For example, two doctors looking after the same patient may have differing views about that patient's management. It is no longer the case that general practitioners will defer to the opinion of a hospital consultant. Consequently the patient's treatment maybe changed in a haphazard way as they move between hospital and the community. Both clinicians in this example may be making sensible treatment choices. The consultant would argue that they have specialist knowledge of the patient's condition and available treatments, the GP would argue that they know that patient and the family better and are ultimately responsible for the cost and prescription of the treatment and thus should have a say
in the decision. This scenario could result in a damaging impasse if lines of demarcation and responsibility were not apparent.

1.2.5 Psychiatrists in the community

The notion that psychiatric care has recently begun to move into the community is misleading. Most delivery of psychiatric care has always been in the community with general practitioners managing 90-95% of all mental illness. From the viewpoint of specialist services however, as psychiatric hospitals have closed and the delivery of psychiatric care has become more community-oriented psychiatrists have been prompted to redefine their role. Some have suggested that psychiatrists decant to general practitioners' surgery to undertake community psychiatry (Mitchell, 1985; Tyrer, 1986). I would argue that there are two problems with the notion: geographical movement alone does not necessarily result in a change of culture of care and; most sector psychiatrists would have too many general practices within their catchment area to make the scheme tenable (Warner 1996). Brown and Tower (1990) undertook a postal questionnaire of all general practitioners in one health district to identify their views about co-operative working with psychiatrists. Ninety general practitioners replied (86% of sample). The authors found that 28% of the sample had postgraduate experience in psychiatry, and 22% had existing links with a psychiatrist, often as satellite outpatient clinics. Of the possible types of co-operative working proposed, most general practitioners preferred joint assessment and treatment or joint treatment after psychiatric assessment. Thirty-one percent of the sample wanted the psychiatrist to undertake sole assessment and treatment. Only 9% wanted no links with a psychiatrist.
Assertive case management by clinicians has also been subject to considerable scrutiny. A meta-analysis of assertive community treatment compared with standard community care or hospital-based rehabilitation has recently been reported by the Cochrane collaboration (Marshall and Lockwood 1999). This meta-analysis found a modest reduction in admissions to hospital in those receiving assertive community treatment compared with standard community care (OR 0.59, 99% CI 0.41-0.85). However, there are two problems in interpretation of this meta-analysis. Firstly, "assertive community treatment" was not defined, so different studies included in the analysis may have had very different approaches to treatment. Secondly, much of the perceived treatment effect is derived from two small studies (Bond et al 1988, Test et al 1991) that took place early in the history of assertive community treatment, and may have had an exaggerated effect size through having highly dedicated teams and charismatic leaders. A later and much larger study (Chandler 1996) found no significant difference in admissions between assertive outreach and standard care.

Even if psychiatrists and their teams move into the community, universal cooperative working with primary care is not assured. Barriers to collaboration include the traditional and thankfully dying notion that hospital practitioners were superior to those in primary care. Time is important. Individuals in both disciplines have increasing claims on their time both from clinical and administrative demands. If collaboration is taken to mean reduplication, neither group is likely to embrace it. Other barriers to closer collaboration between services includes waiting times,
delays in information exchange, lack of rapport and uncertainty about what is offered by specialist services (Mitchell, 1985).

The reticence for full integration between psychiatry and general practice is two-way. Against the backdrop of closure of long-stay facilities, the introduction of community care and the debate about the roles of respective clinicians, Kendrick et al (1991) undertook a postal survey of general practitioners’ views about their involvement in the care of long-term mentally ill. They mailed 507 general practitioners in the South West Thames region in the UK, and received 369 replies. Several interesting findings emerged from this survey. Many (64%) general practitioners accepted the presence of mental illness resulted in communication problems between doctor and patient. Seventy-nine percent felt that patients only came to their attention during a crisis; although the patient has moved into the community, many general practitioners clearly felt their care had not. Most respondents (83%) preferred patients with long-term mental illness to remain the prime clinical responsibility of the psychiatrist, although 90% of respondents agreed to “shared care” between psychiatrist and general practitioner. However, “shared care” was not defined in the article, and the meaning of the term is not likely to be universally agreed by the respondents. A counter-intuitive finding in the survey was that half the respondents agreed that patients should be monitored for relapse by the general practitioner, although this did not mean to the exclusion of the psychiatric team. Therefore, although general practitioners saw the prime responsibility for after-care devolved to the psychiatric team, they were willing to participate in the follow-up process. Likewise, most general practitioners (78%)
agreed that they should screen for physical problems, although 38% also agreed that this was a role of the psychiatric team. In summary, general practitioners in this survey appeared to favour the notion of sharing clinical responsibility for patients with long-term mental illness.

1.2.6 Treating mental illness in primary care

Encouraging general practitioners to undertake management of patients with more severe mental health problems has been assessed in several studies. Kendrick et al (1995) reported a randomised trial of teaching general practitioners to conduct structured assessments. Based in 16 practices, the intervention comprised two teaching sessions. Assessment schedules were placed in the primary care notes of all patients identified as having long term mental illness (defined as psychosis or severe non-psychotic disorder causing defined disability for two years or more). The authors reported a significant increase in referrals to community psychiatric nursing services and changes in antipsychotic drug treatment. There was no difference in referrals to psychiatrists or admission rates between groups. Most of the 31 participating general practitioners felt it was worth doing the structured assessment, at least on some occasions, but it rarely resulted in changes in clinical management. One problem in translating this study to routine practice is the high level of selectivity of practices; only 16 of the 110 practices approached agreed to participate.

Nazareth et al (1996) reported the results of a pilot study of a structured approach to managing patients with non-affective psychosis in general practice. The
intervention consisted of a checklist, a manual and a structured follow-up. This study showed improvement in the Global Assessment Scale (Endicott et al 1976) in the intervention group, but no significant differences in other outcome parameters. The intervention group consulted their general practitioner more. The interpretation of this study is hampered by the fact that allocation of practices to intervention or control was not random.

One method to encourage more general practitioners to monitor the long term mentally ill is to offer a fee-for-service additional payment (Burns and Cohen 1998). This study was based in South London and involved 21 of the 124 practices in the area. Uptake was poor and the scheme did not seem popular; 70 practices failed to express an interest, and 22 practices refused to participate altogether. The follow-up programme included three-monthly structured reviews to be undertaken by the practice nurse (who received training) and a care-plan for each patient. Fifty-eight of the 168 patients recruited (36%) were not in contact with hospital psychiatric services. Cash reward appeared to be a significant motivator; nearly 80% of patients in participating practices had at least one care-plan completed, although the authors suggested that the process was mechanical, and unlikely to lead to improved levels of care.
1.3 Conclusion

A theme is developing here. The closure of psychiatric hospitals has resulted in the movement of large numbers of patients with long-term mental illness into the community. Many are not being looked after by secondary services, and high levels of morbidity exist. Without a substantial change in the culture of delivery of care by hospital services, and acceptance by both primary and secondary care clinicians that mutuality is the best way forward, patients with long-term mental illness will remain at a disadvantage. This utopian view may be achieved by more formalised shared-care.
Chapter 2

Shared care

2.1 Introduction

For this literature review, I attempted to identify all published articles about shared care. Articles were sought from MEDLINE and EMBASE databases regularly throughout the conduct of this study. Efficacy of the search was hampered by difficulty in mapping the term “shared care” to a suitable Medical Subject Heading (MeSH). The MeSH “Patient care management”, “professional practice”, “family practice” and “delivery of health care” were exploded and linked by the Boolean term or. This was then limited to randomised trials and restricted to those articles with the word shared in the title, MeSH or abstract. Review articles were also sought, and further trials identified through these sources. The textword search on “shared care” identified many review articles.

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Table 2.1 Results of last MEDLINE search undertaken for this thesis (dated Feb 1999).
2.2 Models of shared care

Hickman et al (1994a) defined shared care as "joint participation of GPs and hospital consultants in the planned delivery of care for patients with a chronic condition, informed by an enhanced information exchange over and above routine discharge and referral letters." At its most basic level, shared care may merely mean effective communication between hospital and primary care, and vice versa. The quality of communication between hospitals and general practitioners has been subject to scrutiny for some time, and two issues appear important: the content and relevance of the communication and the length of time taken for information to reach general practitioners. General practitioners often complain of delayed discharge correspondence and inadequate or irrelevant information (Penney, 1988). General practitioners prefer specific information, especially about drugs details, management plan, diagnosis, the results of investigations and what the patients and their relatives have been told (Finau, 1986; Bowling et al 1991, Newton et al 1992). However, many of these details are missing in hospital letters (Hampson et al, 1996). In order to circumvent these problems, structured discharge summaries, possibly on a pro forma have been suggested (Bowling 1991). These range from a combined discharged letter and prescription card to an information card which is given to both patients and their GPs (Sandler et al 1989a, Sandler et al 1989b). This latter model may be seen as a forerunner of shared care booklets. The delay in information reaching GPs is often significant. The proportion of discharge letters taking more than seven days to reach the general practitioner varies between studies
from 6% to 72% (Hampson et al 1996). Indeed, between 16% and 53% of patients consulted their general practitioner before the hospital discharge letter arrived. This is a substantial delay, especially if the patient’s clinical condition is volatile, the general practitioner needs to be involved in aftercare or prescribing medication, or has on-going clinical responsibility for the patient. A shared care record that the patient could take to the general practitioner at their first visit could obviate many of the problems this delayed communication may cause. This may prove an effective method of information transfer; Colledge et al (1992) found 93% of discharge pro formas given to elderly patients were hand-delivered to the general practitioner within 4 days, with a median delivery time of one day.

Hickman et al (1994b), described a survey of different models of shared care operating within two health regions. Using a two-stage postal questionnaire sent to 464 representatives of hospital and primary care services, they attempted to identify shared health schemes operating in Scotland and North-West Thames regions. Sixty-five shared-care schemes were identified for 15 different conditions. Nearly half of the schemes (31) were for diabetes, most of the other schemes were for other physical disorders: hypertension (6), rheumatoid arthritis (5), thyroid disease (4) and asthma (5). Two schemes were identified for patients with chronic mental illness. Most schemes (77%) were co-ordinated by an administrator or dedicated nurse; few were operated only by the doctors involved. The authors reported that most shared care schemes were small, the role of the general practitioner was often unclear and the functions of the schemes were disparate.
They concluded that although shared care schemes were uncommon, the number of schemes would increase.

2.2.1 Taxonomy

The taxonomy arising from this study included six distinct types of shared-care scheme, distinguished by the different types of information transfer (Hickman et al 1994a):

- Shared care record card (42%). Usually carried by the patient. This was the most popular type of shared care, accounting for nearly half of all the schemes.
- Computer assisted care (26%). Similar to the basic model, but computerised and dependent on a co-ordinator. The advantage over the basic model is that non-attenders may be flagged rapidly.
- Basic model (19%). Shared communication only, using a standardised record sheet sent from GP to hospital or vice-versa.
- Community clinics (8% of schemes). A hospital specialist attending and running a clinic in a primary care setting.
- Liaison (6%). Hospital team meets with primary care physicians to discuss individual patients.
- Electronic mail (0%). None of the schemes identified used e-mail.

The authors concluded that patient held records were the most prevalent form of shared care, but in general, shared care schemes were not common.
2.2.2 Patient-held records

Patient-held records vary from the simple “co-operation card” widely used in obstetric care to record brief details of the progress of the pregnancy to the patient carrying their full medical record. The evolution of patient-held records may be traced through several stages (Liaw 1993):

- single purpose records eg immunisation records
- travellers medical records
- paper-based general health records
- maternal health records
- computer-based records
- smart cards

In the last two decades, shared obstetric care has been taken up by many hospitals with little critical evaluation of the model prior to introduction. This has led to a spate of post hoc assessments, mainly based around patient, or professional attitudes, hardly cast-iron evidence of efficacy in itself, but a reasonable proxy. The trouble is, these surveys have provided very conflicting conclusions.

The value of assessing utility and acceptability of new models of care before widespread introduction is underlined by the following examples. A state government report on antenatal services in Victoria, Australia in 1989 found that fewer than two percent of women had shared antenatal care between their family doctor and hospital (Health Department, Victoria, 1990). As a result, a high priority
was given to developing, among other strategies, shared obstetric care. By 1993, the proportion of women receiving shared care had risen to 15%, mainly through patient-held records. In a follow-up survey of women’s satisfaction with antenatal care in Victoria, Laslett et al (1997) sought the views of 1336 post-partum mothers. Various models of care were examined, including private obstetric care, state-provided obstetric care, public general practitioner birth centres and shared care. Although most women rated their satisfaction with antenatal care highly (overall 62% rated it “very good”), women were significantly less likely to be satisfied if they received shared care (33% rated “very good”). This well-designed study appeared to have quite damning conclusions about the shared-care model. Women in the shared-care schemes were less happy with their medical care, often had to wait at appointments, and felt their worries were not taken seriously. Empowerment, measured by to what extent women felt encouraged to ask questions was no better than other models of care.

These findings contrast with another antipodean study by Webster et al (1996). In a survey of satisfaction of shared antenatal care, based on patient held records as the sole medical record, Webster et al (1996) sought the views of 200 women, approximately 75% of whom had opted for shared care. Thirty-six percent of the women having shared care forgot to take their record to at least one appointment. This was a significant finding given the record was the sole repository of clinical information. No differences were noted between groups in the satisfaction with hospital visits, but those in the shared care group were much more satisfied with their general practitioners. This is probably not surprising given the women elected
for shared care at the outset; they were unlikely to decide on shared care if they
didn’t have the confidence of their general practitioner. Other results suggested the
shared-care group felt significantly less anxious, more in control (the issue of
control is a recurrent theme in the shared care literature) and better understood their
care. The findings may be spurious in this study because women who are more
assertive, who consider themselves more in control, may be more likely to elect for
a novel method of service delivery i.e. shared care.

Smart cards, plastic credit-card-sized cards with an embedded microchip that is
capable of storing large amounts of information (up to 8000 characters) may replace
hand-written records (Adelhard et al, 1996; Neame 1997). There are several
advantages to smart cards. They are small, information may be downloaded directly
from the computer that holds the clinical record, avoiding duplication, and that
information may be encrypted and password protected. Data held on smart cards
may be stored in different levels of access, thus some information will only be
available to specified authorised readers. Smart cards are already used in many
arenas, including mobile telephones, and, recently credit cards where they are
replacing the magnetic stripped “dumb” cards. Some countries, notably France and
Canada have already introduced them in health care settings, and their widespread
introduction in the UK is likely. Neame (1997) goes so far as to state “Smart cards
are set to play a pivotal role in the future development of computing in general, and
particularly in health care”. However there are potential problems with smart cards,
not least issues of confidentiality, costs and ownership of data (Regan 1991).
Evaluations of health smart cards are apparently underway, but none, yet, in the mental health arena. As patients with mental health problems may have specific differences in their approach to the use of smart cards, such as suspicion of electronically recorded data they are unable to read and problems with compliance the use of these cards should not be introduced without evaluation. My study provides information about the potential utility of smart cards for mentally ill patients.

Liaw (1993) sought views of GPs and patients on the contents of patient-held records. Both groups felt that humdrum data like allergies and immunisations should be logged, and many were in favour of a problem list. However, fewer doctors favoured recording of psychiatric problems, "sensitive information" and social problems. None of the 500 patients recruited wanted these data recorded on the patient-held record. From the patient's perspective, a credit-card size was preferable, with progressively larger records being less popular. Perceived beneficial aspects of patient held records included, from the clinicians' viewpoint, usefulness for sharing information between hospital doctors, and other health care providers. Patients felt the records would be most useful in the emergency situation and to increase their knowledge about their condition.

Preventative services have been the focus of much work on patient-held records. Although attractive because it may, potentially lead to better uptake of screening this model is rather artificial; users are mostly healthy and have a vested interest in compliance. Results from these studies cannot necessarily be extrapolated to other
groups. Dietrich and Duhamel (1989) investigated whether a patient-held checklist improved uptake of three key preventative services; blood pressure measurement, influenza immunisation and cancer screening in people aged over 65. Subjects were randomly assigned to intervention (n=59) or control (n=55) groups and followed up after 12 months. There were no significant differences between the two groups in uptake of influenza vaccine or blood pressure measurement. There was a trend towards better uptake of most cancer screening services (mammography, faecal occult bloods, cervical smear, prostate examination and breast examination) and a significant difference in skin examination in the checklist group. Of those given the checklist, 26 (44%) kept it and said they found it useful.

Dickey and Petitti (1990) reported that despite over a decade of recommendations of immunisation and periodic examination for certain groups, uptake was usually less than 50% (often much less). Most strategies for improving compliance have focused on the service provider, not the patient. Dickey and Petitti (1990), developed and evaluated a patient-held health record in primary care. In an attempt to evaluate clinicians' attitudes to their "health diaries" they mailed samples of these to 250 family physicians in California along with a 15-item questionnaire. Fifty-three percent of the 190 respondents expressed "greater than a moderate interest in the use of these records". Most doctors felt the health diary would improve uptake of "health maintenance procedures", patient knowledge and continuity of care. They argued that for minimal cost (estimated at $0.10 per diary), the health diaries may improve continuity of care and prevent unnecessary duplication.
Patients are not universally accepting of shared care records, especially, it appears, if the records contain sensitive information. Grun and Murray (1995) investigated the acceptability of a shared care scheme for asymptomatic HIV positive individuals. The proposed scheme replaced three-monthly hospital visits with an annual visit and three-monthly visits to the general practitioner. Patient-held record cards were an integral part of this scheme. Only 19 of the 128 eligible patients accepted the shared-care package. The reasons for non-acceptance were varied, but included distrust of the general practitioner and worries about confidentiality.

One issue to consider when instituting a shared-care record system is the amount of information the record should contain. Comprehensive records that provide a useful record to all concerned may be too big to carry and may contain information worrying to the patient. Draper et al (1986) investigated the views of women randomised to carrying their ante-natal co-operation card or their full medical notes. Most women assigned to carry their complete records felt there were advantages in doing so, including feeling they had a more responsible part to play in their pregnancy. Nearly half of these subjects complained about the bulk of the complete record and fewer always carried the notes compared to those given the co-operation card. Many felt the contents were difficult to read or were worrying. Overall there appeared to be few advantages in carrying comprehensive records.

Intuitively, instituting a shared care scheme should improve delivery of care. Patients are likely to receive input from two sources, have regular reviews and there
should be better information exchange between professionals involved. Furthermore, patients may feel a greater sense of responsibility for their health and feel more empowered to ask questions, seek explanations and demand appropriate services. However, Day et al (1987) failed to find any advantages in sharing care of diabetic patients. Day and colleagues began by providing an education package for 164 local general practitioners. These general practitioners were asked their views on how follow-up services should be developed. General practitioners undertook to share care for both insulin dependent and non-insulin dependent diabetic patients, providing an agreed standard of care follow up and data recording. Patients were provided with shared-care booklets for recording follow-up data. There was a significant worsening of diabetic control over the two-year period of the study. Furthermore, only 117 of the 209 patients in the study had anything recorded in their co-operation booklets. Of those that did most had inadequate recording of basic data like weight, urinalysis or blood pressure. A drawback in interpretation of this study is that this did not reflect true “shared care”. Instead, patients appeared to be discharged back to their general practitioner’s care. Nevertheless, the inescapable conclusion of this important study was that general practitioners were reluctant to use patient-held documents, although this may have been better if they had felt there was more joint care.
2.2.3 **patient-held records for individuals with mental illness**

Little has been written about the format and content of patient-held records for individuals with mental illness. Marks and Swindells (1983) suggested a blueprint for a co-operation card for patients with mental illness. This heuristic attempt suggested listing the name and address of the patient, details of the GP, consultant, social worker, community psychiatric nurse and current medication and dose.

There has been little evaluation of patient-held records for patients with mental health problems. Patient-held emergency cards, sometimes known as crisis cards, are the most basic form of this type of record. These were first developed in 1989 by a user group, Survivors Speak Out (Weston and Lawson 1997). The intention of this card was to enable patients to give advance directives about their care, for later use when they were unable to voice their own opinions due to mental illness. Since then the cards have proven controversial. Some have seen this type of record as a way of identifying mentally ill offenders, or as vehicles for recording clinical information that users regard as damaging. Weston and Lawson (1997) highlighted the need for evidence to support the use of these types of cards.

Reuler and Balazs (1991) undertook a pilot study of patient held records for the homeless mentally ill, using a passport-sized booklet. These were distributed to 41 homeless mentally ill individuals through a health project and a Salvation Army hostel. Most subjects had schizophrenia. Twenty-eight (68%) patients were followed up at least once. Of the 67 follow-up interviews conducted, the record was available in 29 (43%) instances. Of those who did use the record, a high proportion
had showed it to another health care worker. Many patients were reported as having enjoyed reading the records. Only eight records had new information recorded in them.

Wolf (1997) reported a pilot of shared care records in mental health in patients with multi-agency input. He used an A4 ring-binder files with 5 sections: basic information, a care plan, hospital discharge details, risk assessment profile and record sheets, which was kept at the patient's home. However there is only the briefest descriptive evaluation of this pilot.

Stafford and Laugharne (1997) reported a survey of patients' opinions of a new client-held record introduced to a community mental health team. A pocket-sized booklet with three main sections; appointment, notes and medication was distributed to 56 patients with chronic mental illness in a community health team. Forty-five patients were followed up by a semi-structured interview. At follow-up the records had been in use for 2-14 months. Eighty-four percent of patients found the record useful although the majority only reported the appointment section as useful. Only two patients (4%) found the clinical notes useful. Surprisingly, a high proportion of contacts with the team (74%) was recorded in the shared-care record although this appears to include logging of appointments. The authors state that "over 50% had at least one entry in the notes section".

As a result of restructuring health care, including closure of all psychiatric beds in the study hospital, a large shared care scheme for users of mental health services
was set up in Toronto (Turner and de Sorkin 1997). This scheme offered prompt secondary care input on diagnosis and treatment recommendations, leaving the referring primary care physician to institute and monitor treatment. The conclusions of this preliminary, descriptive report, were that this model of shared care increased the numbers of patients having (albeit limited) access to secondary care services. Implicit in this type of scheme is a shift of emphasis from comprehensive care of a few very ill patients to superficial care of large numbers of patients. There is something intuitively attractive about this model; it fosters closer working with primary care and may improve diagnosis and treatment of mentally ill patients in the primary care setting. In investigating this further, Evans (1996) undertook a qualitative study of “stakeholders” views of developments at the primary and secondary care interface. Stakeholders were purchasers, general practitioners, hospital staff and trust managers. Key findings included a perceived shift of power from secondary to primary care, improved communication and increased workload in primary care. Whether this increased workload was a consequence of shifting responsibility from secondary care or merely a facet of a wider change in working practices was unclear.

One of the few more extensive evaluations of patient held shared care records for people with mental illness was a pilot study undertaken by Essex et al (1990). Eighty-four patients with severe mental illness in practices in South East London held records for a period of up to 18 months. Severe mental illness was not defined in the study, but recruitment was aimed at patients with schizophrenia (Essex, personal communication). The main outcome measures were satisfaction of patients
and professionals. The record used by Essex included details of the patient's name, address, telephone number, next of kin, general practitioner, psychiatrist, community psychiatric nurse, and social worker. The record also included the psychiatric diagnosis and details of medication. There was a section containing information for the patient about their treatment and when to be worried about their illness. A large part of this record was allocated to follow up observations by both professionals and the patient. Records were A-5 in size and bound in thin card. The project was co-ordinated by a community psychiatric nurse who encouraged participation among the professionals involved. Ten general practices and 25 local psychiatrists were invited to participate. Patients were invited to carry a shared care record by their GPs, community psychiatric nurse or consultant psychiatrist. Patients with a history of repeated brief admissions to hospital were excluded.

Most of the subjects had schizophrenia or other forms of chronic psychotic illness. A psychiatrist initiated the shared care record in 24 patients, the GP in 30 patients and 30 patients were initiated by community nurses or hostel care-workers. Fifty-one patients completed a follow-up questionnaire. Most found the shared care record acceptable. Many patients liked to see what was written about them although legibility of the handwriting was often a problem. Subjects were divided about whether the diagnosis and personal details should be recorded on the record.

One of the most startling findings of this study was that none of the 25 psychiatrists who were invited to participate agreed to do so. Indeed, one of them described the concept of the shared care record as a "Trojan Horse" (Essex, personal
Psychiatrists were unhappy about allowing patients access to their records for a variety of reasons, including misgivings about the general practitioners' ability to manage psychotic illnesses. They also felt that psychiatrists would best be able to meet the needs of this group of patients. The managers of the community psychiatric nursing services were similarly disinterested. Only 12 (30%) of eligible GPs participated in this pilot study. The reticence of professionals to participate in the study by Essex and co-workers contrasts sharply with the findings of Nazareth et al (1995) who found that 88% of a sample of general practitioners (n=26) were enthusiastic about the introduction of shared care records for patients with schizophrenia. The explanation of the difference may lie in the fact that pragmatism takes over from altruism when extra work is involved.

Essex et al (1990) found a high rate of usage of the record among patients; 55% of the 84 patients took their records to more than 75 per cent of follow-up visits, only 12% took them to less than 50% of visits. Individuals with persecutory delusions appeared least likely to comply.

In summary therefore, patients were enthusiastic about carrying a shared care record but there was considerable reticence amongst the professionals. Essex et al (1990) concluded that the shared care record was "practical, effective and acceptable to certain patients". Essex did not attempt to evaluate the impact carrying a shared care record would have on service use or mental health of the patients involved.
2.2.4 Computer-based shared care and electronic mail

Petrie et al (1989) described an open, prospective, evaluation of 3,352 patients attending a hypertension clinic, involving over 250 GP principals. The model of shared care in this study involved facilitating information transfer between primary care and hospital clinicians. At each planned visit, a shared care co-ordinator prepared a "patient profile"; a document for recording key information about the patient including diagnosis, active problems and details of medication. This was completed by the clinician and returned to the co-ordinator. This study was not truly computer-based; the use of computers was restricted to generating standard letters and summarising patient information. The system remained essentially paper-based. There were no robust outcome parameters of this study. Patients in the "general practitioner follow-up" group appeared to have better control of their hypertension. However, allocation to general practitioner or hospital follow-up was not random. The authors did not report on the impact the scheme had on communication.

Few have written on electronic data exchange, a model of shared care that provides the advantage of rapid, and reliable data exchange between professionals, without the need for the patient to carry a record. In some respects, this model is attractive to the mental health arena, as information the patient may find sensitive or distressing is not given to them. Branger et al (1995) reported on a proposal to replace paper documents entirely with computer-based records that may be mailed to recipients electronically. Their system known as MEDEUR, provided an integrated electronic record. So far, it has not been evaluated fully.
One drawback of computer-based schemes is the need to comply with the provisions of the Data Protection Act. This Act gives individuals the right to access of any information about them held on computer. Although similar provisions in the UK allow patients access to their written medical records through the Access to Medical Records Act, the Data Protection Act appears to provide greater scope for access to computerised records. Clinicians therefore have to be very cautious about what information is entered in computer-held records. Jones et al (1988) in a survey of the impact of the Data Protection Act (HMSO 1985) on a diabetic clinic computer-based shared care scheme found that nearly a quarter of all patients had their record censored and information deleted before the record was passed to them. Most of the “censored” information related to organic problems. Although much of the information originally censored was reinstated on review by the clinicians involved, 34 problems pertaining to 19 patients remained unavailable to those patients. Given that patients have easy access to computer-based records, and clinicians may be called to justify what they write about patients there are two concerns here. Firstly, the clinician may be reluctant to record information that he or she considers the patient should not have access to albeit it is information germane to the patient’s care. Thus, there may be inadequate dissemination of information to other professionals who may rely on the record for information. Secondly, if patients do read their record, they may find the information contained therein very distressing. Although openness about diagnosis is commonplace in psychiatry now, some diagnoses, for example Alzheimer’s disease, are often withheld from patients (Clafferty et al 1998).
2.3 Controlled evaluations of shared care

To date there have been no published randomised controlled trials exploring the utility and acceptability of shared care among patients with mental illness, and few studies have been undertaken in other specialities. Two questions need addressing. Are there any differences in treatment outcome between primary and secondary care and does sharing care confer any advantages over treatment in one site? The first question is an important one. The impetus for sharing care may be less if outcome is similar irrespective of the site of delivery. If the site of care delivery (primary or secondary care) results in differential outcomes, sharing care may help to achieve equality of care. If outcomes are similar between sites, although it is possible that sharing care will result in additive benefits, it is less likely to have an impact.

Hayes and Harries (1984) reported a randomised, controlled trial of hospital versus general practice care for non-insulin dependent diabetics. There had been considerable debate about whether diabetics could, or indeed should be managed in general practice. Two hundred patients who were attending hospital based clinic were randomised to either continue in the hospital care or be followed-up by the GP. The general practitioners that took on patients were given an education leaflet detailing the optimal management of diabetic patients and a record card. Patients in the general practitioner's limb fared worse; their diabetes was less well controlled, they had fewer reviews, a non-significant trend towards more
admissions for diabetic and cardiovascular complications and significantly more deaths due to vascular causes.

In another randomised controlled evaluation of uncomplicated diabetes, Hoskins et al (1993) followed-up 206 patients allocated to one of three interventions; GP care, shared care or clinic care. Those assigned to the shared care limb received a copy of their management protocol, and saw a research nurse. The research nurse liaised at specified intervals between the patient, GP and clinic. Patients and GPs were reminded to undertake metabolic and health assessments. In other words, in this study there was a high degree of input in the shared care limb from the research team. These patients did not receive a dedicated shared-care record. The results of this study found no significant differences between the three groups in terms of metabolic control. The clinic care group was the only one to have glycosylated haemoglobin, weight and blood pressure recorded in over 90% of attendance. Attendance rates fell in all three groups, with least attenuation in the shared care group. In this study the shared care limb achieved better patient attendance and documentation than standard GP care but showed no major benefits over standard hospital care, despite the additional manpower of a research co-ordinator. The cost benefit analysis, which seemed to favour shared care over clinic care, appeared to disregard the costs of the research nurse.

In a randomised evaluation of general practitioner-based monitoring, patients with rheumatoid arthritis commenced on gold or penicillamine therapy were instructed to visit their general practitioner for blood and urine monitoring and dose
adjustment according to a protocol (Pullar et al 1982). Results were documented on a patient-held record. The patients were compared with a group monitored solely at hospital. The authors reported no significant differences in efficacy of treatment or frequency of adverse effects between groups, and concluded that gold and penicillamine therapy could be safely supervised under shared care arrangements.

Eighty-seven general practitioners took part and at the end of the study 58 (67%) agreed to participate in further shared care [figures derived indirectly from data]. Perhaps because this is a relatively old study, there is inadequate analysis of the data. A re-evaluation of the article suggests a significantly higher rate of gold overdosing in the general practitioner managed group (p=0.03 Fisher's exact test).

Furthermore, although not amenable to statistical analysis, three patients in the shared care group were given gold injections despite the presence of contraindications; a potentially serious event. The sub-text of this paper, which has a slightly partisan edge, strikes me as giving the message "we propose to shift routine drug monitoring of gold and penicillamine to general practitioners, and here are the data to prove this is acceptable". It is, perhaps, natural for proselytisers to emphasise data that support their points of view. This is a facet of human nature that scientists and clinicians need constantly to guard against, both in their own work, and that of others.

Dickey and Petitti (1992) reported on a study of patient-held mini-records for preventative care. These passport-sized "health diaries" listed desirable preventative health checks to take place annually between the ages of 18 and 80. Health checks included cholesterol estimations, pneumococcal vaccines, faecal occult bloods and
breast examination. The authors distributed these health diaries to patients attending two practices, and used a third practice as a control. Patients' clinical notes were tagged and practice nurses requested the diaries and clinic visits. The diaries were distributed to all practice attenders over a four-month period. Eighty percent of the providers involved, mainly practice nurses and residents, had a positive overall reaction to the health diary. Although compliance for preventative health measures at baseline was similar between groups, by six months the intervention limb demonstrated significantly improved rates of uptake for five of the eight reported preventative services: faecal occult blood, influenza vaccination, breast examination, mammography and cervical smear. By eighteen months, the intervention group had increased uptake of all interventions by 5.4% from baseline, compared to a 3.9% fall in the control sample, but only uptake of mammography was significantly better than controls. It is difficult to disentangle the effects due to improved clinicians' diligence in offering services since they realised their practice was under scrutiny, and to what extent the improvement was patient driven. In reality, this is a specious separation and the result of improved adherence to preventative healthcare could be viewed as important, whatever the cause.

Richman et al (1996) made the point that shared care arrangements should be carefully designed, structured and evaluated, or risk inadequate patient care. They describe an Australian study comparing hospital-based (standard) management of obesity with shared-care between GP and hospital. GPs were given two half-day training sessions in obesity management. Consecutive patients recruited for the
study (n=37) were matched for age and BMI and gender with controls (n=101). The shared-care records held personal and demographic data, appointments and medical history. Although retention rates for the programme were better in the shared care group, weight loss was not significantly different between the shared care group and controls at end point (26 weeks).

One area where shared care is commonly practised is obstetric care (Bull, 1989). Despite the vigour with which shared care has been taken up over the last 20 years, only recently have evaluations of its utility and acceptability been reported. Two studies have investigated devolved obstetric care. Women with uncomplicated pregnancies looked after by midwives and GPs rather than hospital-based consultants had fewer admissions and clinic defaults (Tucker et al, 1996). Both groups were equally satisfied with the care they received. Sikorski et al (1996), in a randomised trial of conventional care versus a reduced schedule of visits found mothers had a greater level of dissatisfaction with frequency of contact, expressed more concern about their pregnancy and had more negative attitudes towards their baby post partum. Neither of these studies reflect true shared care, in that there was no greater co-operation between primary and secondary care. In the most significant study of shared care to date Turnbull et al (1996) compared antenatal care provided solely by midwives with shared care between general practitioners, hospital doctors and midwives. Nearly 1,300 woman with uncomplicated pregnancies were randomly assigned to midwife care or shared care. Few differences were noted between these groups, although the midwife-managed group was more satisfied with antenatal and
postnatal care. One third of women transferred to hospital care, mainly for clinical reasons. It is ironic that the one randomised trial of shared obstetric care should be assessing the utility of an alternative to shared care, given shared care is an unproven method of care delivery.

2.4 Summary

Where does all this lead? One clear problem is that there is little robust evidence underpinning the widespread adoption of shared care in various clinical settings, notably obstetric care, that has taken place. The uncritical adoption of shared care schemes, probably because they are intuitively beneficial, has a hollow ring of history: one example of “bandwagon” clinical practice that lacked an evidence-base, and ultimately proved harmful was extracranial-intracranial bypass operations. This method of treating cerebral ischaemia was introduced in 1967 and adopted uncritically world-wide, resulting in thousands of operations. In 1985 the results of a randomised controlled trial of this intervention found no benefit, and higher morbidity, among the patients receiving the operation. Shared care is unlikely to be positively harmful (although this is possible), but it may certainly be neutral in terms of clinical benefit. An additional problem in tackling questions of evidence base for established interventions is that it is often harder to prove or disprove utility post hoc. The reason for this is that it may be deemed unethical to undertake a randomised placebo controlled trial with an intervention that is thought
useful: withholding that intervention may contravene the ethical pillars of beneficence and non-maleficence. Often the investigator is left clad in statistically less powerful investigations; controlled trials against other established interventions (also potentially of dubious efficacy, and thus poor controls), or trials seeking evidence of harm rather than efficacy, through case-controlled or cohort studies. Therefore, I would argue that even attractive interventions that appear to have good face validity must be subject to scrutiny \textit{a priori}.

Another corollary to this is that the trial that sets out to prove or disprove an intervention should be of a sufficiently robust design and have adequate power to detect significant results. The example I will use here is ECT. Four randomised controlled trials using sham ECT as a control have sought to prove the efficacy of ECT (Freeman \textit{et al} 1978; Taylor and Fleminger 1980; Johnstone \textit{et al} 1980, Brandon \textit{et al} 1984). All had fundamental flaws in design or interpretation of results, often a result of ignoring missing data or through patient selection. However, all showed a statistically significant benefit of real ECT over sham, and are often quoted in support of using ECT (Buchan \textit{et al} 1992). Consequently, ECT is now regarded as an established treatment, and I suspect it would be very difficult to have a further placebo controlled trial passed by an ethical committee, despite the lack of adequate, robust evidence supporting it.

There is a problem. The perfect research study is impossible. Power calculations only offer a guide to the numbers needed, subjects often go missing or die, and those that don’t may be atypical. The best researchers can do then is to strive to
achieve the three foundations of a good trial: the method must be valid, the results analysed and reported accurately and the conclusions of the trial must be translatable to usual clinical practice.
Chapter 3
Clinical trials in psychiatry

3.1 Purpose of clinical trials

The purpose of a clinical trial is to identify whether a hypothesis is accepted or rejected, analogous to possible jury verdicts in an English court of guilty or not-guilty. In Scottish courts of law a middle ground is possible, the “not proven” verdict. This implies some doubt about the guilt or innocence of the defendant, and leaves everyone in confusion. At the end of a properly conducted clinical trial there should, ideally, be no “not-proven” verdict, i.e. no middle ground. The investigators and wider audience should be clear that the hypothesis under scrutiny has been accepted or rejected. Categorical outcomes in clinical trials are desirable, not only because trials are a waste of time, effort and money if the result is “not proven”, but also clinical trials which, at the outset, do not have a chance of accepting or rejecting the hypothesis are probably unethical. In 1998 Richard Smith, the Editor of the BMJ, said at the Royal College of Psychiatrists annual meeting (and subsequently reported in The Guardian) that 98% of medical studies are “rubbish” (Smith, 1998). He was referring to studies that are poorly designed, or underpowered. Rubbish is probably too strong a word; few studies are so bad that the results should be dismissed out of hand and most will advance knowledge to some extent. Rather than a reductionist good/bad approach, I would advocate that validity
of clinical trials is viewed as a continuum, from the excellent to the terrible. It is a matter of judgement of the individual reading the report to decide where on the continuum a particular study lies, and how much cognisance to place on the results. In order to do this, it is incumbent on the authors, and the Journal editor, to ensure enough information is provided to ensure adequate appraisal of the study. A huge step forward in clinical trial reporting came with the CONSORT (Altman 1996). These guidelines, the “uniform requirements for manuscripts submitted to biomedical journals” evolved from a group of journal editors known as the Vancouver group. Now in their 5th edition, the guidelines have had a large impact on many aspects of medical research, well beyond the preparation of manuscripts (www.thelancet.com/). More peripheral issues addressed in the CONSORT guidelines include avoiding redundant or duplicate publication, uniform manuscript layout and presentation and citation of references. However, the greatest impact has been in ensuring that clinical trials are reported in sufficient depth to allow duplication of the study and proper interpretation of the results. Full details of the progress of subjects through the trial and accounting for loss of subjects must be provided. Precise details of how subjects were randomised and how blinding was maintained should also be provided. The implementation of the CONSORT guidelines have enabled readers to judge better where a particular study lies on the continuum.

Research is difficult to do and easy to criticise, especially with hindsight. However, all researchers should strive for the ideal, i.e. a definitive study that clearly and unambiguously answers a question. There are a number of ways to maximise
achieving this, essentially by planning trials in advance so that they meet with the recommendations of the CONSORT guidelines and evidence based medicine working group’s advice on reporting clinical trials (Guyatt et al 1993, Guyatt et al 1994). The recommendations of the working group include the following.

1. Ensuring assignment of patients is truly random
2. Ensuring all patients who enter the trial are properly accounted for at the end
3. Ensuring all patients are analysed in the groups to which they were initially randomised
4. Ensuring, where appropriate or possible, that all patients, clinicians and study personnel are adequately blinded, and that blinding of subjects and study personnel is assessed.
5. Checking whether groups are similar at the start of the trial. There has been some debate about this point. If the groups are truly randomised, then any baseline differences will be random. Randomisation per se does not confer uniformity on known or unknown confounders. Indeed it would be unusual if groups were entirely similar. Furthermore, testing baseline variables does not ensure that unknown confounders are balanced. Some researchers determine the statistical significance of between-group baseline measures of mental health and demography for two reasons. Firstly, if several significant differences emerge, it may indicate bias in the randomisation process, and secondly, significant differences at baseline may indicate the need to control for the factor in subsequent analysis.
6. Ensuring that the groups were treated equally, aside from the intervention.
3.2 Power

Another important element is undertaking a pre-trial sample size calculation. Having adequate power to detect real differences, should they exist, will reduce the possibility of type II error. On the other hand, recruiting too many subjects to a trial may be unethical. There are problems in determining power and sample size. In relatively untested interventions, as in this study, there may be over or under-estimation of the effect size of the intervention *vis a vis* the control. Another complication germane to this study is the effect of clustering. Where patients are from practices, and the practices are the unit of randomisation, homogeneity of subjects within practices may influence outcome (Roberts and Sibbald 1998).

3.3 Pragmatic versus explanatory trials

An important distinction to make at the planning stage of a clinical trial is whether the trial is explanatory or pragmatic (Schwartz and Lellouch, 1967, Roland and Torgerson, 1998). Explanatory trials measure efficacy, and are designed to test outcome differences between interventions under strictly controlled experimental conditions. They assume 100% compliance from a well-defined population. Consequently, explanatory studies have high internal validity, but low external validity and the results do not necessarily translate to the population at large. Outcomes are often measured in physiological or biochemical parameters and specific disease rather than overall health gain. Most phase III drug trials are explanatory. One of the problems with many pharmaceutical trials, especially phase
III studies, is that in order to meet the stringent inclusion/exclusion criteria the subjects are usually very healthy (except for the index condition), with no significant co-morbidity or alcohol and drug use. The subjects also have to be willing to participate in clinical trials, which further reduces how representative they are of the patient population in general. Although a broader range of subjects may be recruited in non-phase III trials, the last point cannot be compensated for, as most trials must be conducted in accordance with the Helsinki agreement and informed consent obtained.

Pragmatic trials measure effectiveness; they seek differences between interventions under “field conditions” and are subject to attrition and the wide variance inherent in heterogeneous populations. The results are usually analysed on an “intention to treat” basis, i.e. all subjects who are randomised are included in the analysis, whether or not they received the allocated intervention. All subjects entering the trial should be included in the final analysis, even if the only data available are from the baseline assessments. Pragmatic trials may reveal other issues such as high levels of attrition or non-compliance that should be considered outcomes in themselves. Pragmatic trials are attractive because they provide information on the likelihood of the intervention being successfully applied (i.e. the process) as well as information on the efficacy of the intervention.
3.4 Validity and precision

Another issue concerning clinical trials in psychiatry is the validity and precision of outcome measures. The practice of psychiatry is hampered by one inescapable fact: the diagnosis of mental illness is almost entirely based on the patient's, or their carer's, report of symptoms, and not on aetiological or pathological substrates. The result is a lack of robustness to the psychiatric diagnoses in use. Symptoms may be ephemeral, or change in intensity over a relatively short time. The impact of symptoms on an individual may also vary. The corollary of this abstract nature of psychopathology is that it is difficult to measure pathology, or change, with as much precision as other systems. This results in two problems. Firstly, a larger sample size is needed to confer adequate power so that true change may be detected above the "noise". Secondly, there is a nagging doubt that we are not really measuring what the instruments purport to measure. Most of the instruments in use have face validity and good inter-rater and test-retest reliability, but they do not measure what the patient is experiencing; only what they report they are experiencing (if we are lucky). This cannot be overcome, and for the moment we are constrained to research using these methods. This is not a problem provided investigators and individuals who read research all maintain a sense of perspective about the results.

Research should be hypothesis led. But a hypothesis is a difficult mistress to serve, and many Sirens call from the shore, beckoning one to steer the analysis in a different direction, (one that usually ends in wreckage). Most readers of medical
literature are now cogniscent of the practice of “data dredging”. Sometimes this practice may help generate new hypotheses but often the practice serves no particular purpose except to find a significant result, albeit one peripheral to the research question. Most results found in this way will be spurious, as the study would not have been designed to generate them. Data dredging is a consequence of the pernicious culture in medical research of undervaluing negative studies, by which I mean studies that show a negative result, rather than no results at all. There is an ethos that a successful researcher is one who regularly rejects his null hypothesis, and an unsuccessful one accepts it, unless the findings are sufficiently challenging to be newsworthy. This overturns one of the fundamental principles of research; that one should have no real prior expectations of the outcome of a study. If there are, counter-intuitive results may be neglected or dismissed, despite being valid and possibly important, and researchers, probably inadvertently, may analyse data in a misleading way. To avoid this pitfall, methods of data analysis should be decided at the protocol stage. This is laudable but not always possible for two reasons. Firstly, we may not get the data we anticipate and secondly, statistical methods and ideas may change over the life span of a study. Nevertheless, the initial proposals should be borne in mind when undertaking analysis.

Using appropriate outcome instruments that are sensitive to change is important. Outcome instruments that appear to have good validity and reliability may fail to show real differences in treatment because they lack responsiveness (Guyatt et al, 1987). Fitzpatrick et al (1992) suggest that sensitivity to change is as important as these other parameters when considering outcome measures.
3.5 Specific issues in research in general practice.

Since most patients are seen in general practice, and those discharged from hospital often come into contact with their general practitioner, undertaking research in general practice is intuitively appropriate. However, until the last decade most research has been conducted in a hospital setting, and the results of studies on hospital inpatients are rarely translatable to the wider population. Patients in hospital are usually more ill, may have more co-morbidity, and may be different to the wider patient population in many ways. The difficulties in undertaking research in general practice have been outlined by Pringle and Churchill (1995). Undertaking research does not necessarily fit well with the other roles of the general practitioner. General practitioners who undertake research may be atypical, and the results not translatable to a broader population. Patients may, because of loyalty to their doctor, feel unable to decline an offer of participation in a trial. General practitioners’ may inadvertently not suggest recruitment to some patients, thereby introducing bias. Randomising patients may compromise the doctor-patient relationship, especially if the patient has clear views on which treatment they would prefer. Finally, because of the risk of contamination of patients within the practice where different management strategies are under scrutiny, it may be desirable to randomise practices rather than patients. This requires a large effort of co-ordination, and has a major impact on sample size and analysis.
3.5.1 Randomising in clusters

Randomising in practices (cluster randomisation) raises specific issues. When undertaking research in primary care, it is often imperative to use the practice as the unit of randomisation (Roberts and Sibbald 1998). There are two principal reasons for this. Firstly, it is difficult to constrain changes of the method of care delivery to individuals within the same practice but randomised to different limbs of the trial. It is likely that control patients would be influenced if general practitioners substantially alter their practice as a result of the intervention (Roberts and Sibbald 1998). Secondly, it is likely to be more difficult to ensure that the subjects receive the allocated intervention.

A good analogy to this situation is experiments on teaching methods in schools. Randomise the pupils and the teachers end up using two methods in the same class, and having to remember to which method each pupil was allocated. Randomise the teachers, and the pupils from different classes will still meet in the playground and discuss the different methods and, just as in general practice, pupils will see different teachers, some in the intervention limb and some controls.

A potential problem with cluster randomisation of this type is the choice of the unit of analysis. Individuals within a practice should not be regarded as independent. As with schools, different practices may attract different types of patient, depending on the population they serve, the attitude and interest of the partners and proximity to facilities where patients congregate (for example a hostel). These issues may be particularly important in mental health, where some practices in areas of high
deprivation may have much higher levels of morbidity than other practices. Alternatively, some practices may have partners with special interest in psychiatry, and will attract larger numbers of patients with mental health problems.

This differential morbidity may have an impact on the results of a study. A corollary to randomising practices is that relatively small numbers of units may be randomised. This may lead to unsystematic errors. For example, if there is considerable variability of morbidity between practices, it is possible, because of the small numbers involved, that the distribution of morbidity will differ across practices to a greater extent than between patients. Therefore, if the two groups (intervention and control) differ substantially at baseline, any real treatment effect may be missed (type II error), or a spurious difference may be found (type I error). It has been suggested that the sample size of a cluster-randomised study be adjusted to take into account the coefficient of the “between cluster” and “within cluster” variation; known as the intra-cluster correlation coefficient (ICC) (Underwood et al 1998, Kerry and Bland 1998a). The value of the ICC in general practice is usually between 0.01 and 0.05 (Underwood et al 1998). A small ICC, around 0.01 has little impact on sample size, whereas an ICC of 0.05 will apparently increase the required sample size by over 3-fold. A problem here is deciding a priori what the ICC for a particular study is. At the moment, while research in primary care is still in its infancy, the data to derive the ICC are not available. As more studies are undertaken, this will be less of a problem.
There are different approaches to this problem in terms of analysis (Kerry and Bland 1998b). Firstly, testing for between practice differences of demographic and baseline scores may identify whether significant differences exist. If they do, greater caution in analysing results is needed. The next level would be to analyse summary statistics of individual practices, although there are two disadvantages to this approach. It will have a major impact on sample size, substantially reducing the power of the study if each practice is given equal weight, despite widely varying numbers of subjects. Weighted analysis, taking into account the number of subjects per practice may circumvent the latter point. A more sophisticated approach still would be to use multi-level statistical modelling. This also has the advantage of dealing in a more satisfactory way with missing data values, providing the missing data are randomly missing (Everitt 1998), an unlikely event in a follow-up study of patients with severe mental health problems.

3.6 Choice of outcome measures

There are several different domains of outcome in psychiatric research including service utilisation, mental health outcome (as assessed by rating scales) and patient satisfaction. Each domain has advantages and disadvantages. Service utilisation data are useful because data can be collected on all subjects. However, interpreting these results may be difficult. For example, does an increase in admission rates mean the subject is more ill, or they have had more contact with services and their morbidity detected? The advantage of measuring outcome using instruments assessing mental health status is that there is less ambiguity about what a change
in scores means but it is unlikely that all subjects will be followed up in order to complete these scales. There is a possibility that more ill subjects (or indeed more well ones) are missed in the follow-up and if the results are analysed on an intention-to-treat basis these may be skewed. A broad mix of outcomes is usually a reasonable compromise.

All research, especially in the psychiatric domain, is a balance between obtaining enough information to make a judgement about outcome and seeking so much information that the subject is alienated. Over-inclusiveness in outcome measures also increases the chance of spuriously statistically significant results. Use too few tools and real differences may be missed, too many and bogus “significant” results may arise by chance. The key attributes sought in the instruments were established reliability, sensitivity to change over time and ease of completion. Self report questionnaires have the advantage of usually being brief and “user friendly”. They may also minimise bias in a study where the raters were not blind to the status of the patient. Observer-rated instruments are useful in defining caseness, but may be more prone to bias when the rater is not blind. Diagnostic questionnaires are not necessarily sensitive to change over time.

A full explanation of the outcomes chosen for this study is provided in the methods section (chapter 5).
3.7 Summary

Mental illness is a common cause of morbidity, irrespective of the way it is defined and classified. Most mental illness is diagnosed and treated in primary care. Although patients with more severe and enduring mental illness tend to be managed in a secondary care setting, many are not. The changes in the method and culture of care delivery over the last 20 years have altered the relationship between general practitioners and hospital staff. Communication between these groups, and the other health care professionals involved with patients with severe mental illness is pivotal to delivery of co-ordinated, effective care.

The concept of shared care has many meanings. At the most basic level it involves enhancing the communication between professional groups. Despite widespread introduction in some healthcare settings, there is little evidence to underpin shared care schemes. The research that has been undertaken often produces counter-intuitive results. Nevertheless, the concept is a popular one and is widely advocated. Consequently, there is a need to define the utility and acceptability of shared care in a psychiatric population. Despite the methodological problems inherent in addressing questions of this nature, I have attempted a randomised controlled evaluation of patient-held shared care records.
Evaluation of patient held shared care records for people with mental illness
Chapter 4

Hypothesis and aims

4.1 Types of shared care

Hickman et al (1994) suggested that there are six models of shared care: patient-held shared care records, computer-assisted care, standardised record sheets for GPs and hospitals, community clinics, shared liaison and electronic mail (see chapter 2). These types of shared care can be reduced to three models depending on the vehicle for shared care; professional-based (liaison and community clinics), media-based (computer-assisted, basic model, e-mail) and patient-based (patient-held records). Each basic model has advantages and drawbacks.

4.1.1 Professional-focused shared care

Professional-focused shared care involves the movement of clinicians, usually from secondary care to a primary care setting. This method is highly valued by general practitioners (Brown and Tower, 1990). The ultimate model for this type of shared care is joint home visits, a concept advocated at the inception of the National Health Service.

The advantages of this model include the opportunity for face-to-face contact between professionals, where particular patients can be discussed at some length. All professionals involved have the opportunity to share information and opinions,
and there is scope for two-way education. The general practitioner often has a unique knowledge of the patient's history and social circumstances and the local facilities (day centres, sheltered workshops etc.). The consultant should be up-to-date about new approaches to diagnosis and treatment and know how best to use the particular skills of his or her team. Patients may find assessments in a general practitioner's surgery more convenient and less daunting than travelling to hospital, especially if visiting psychiatric outpatients. They may also be willing to accept a diagnosis and treatment plan if they see their general practitioner is involved in the formulation. Planning follow-up, which may also be shared, will be easier. The immediacy of the information exchange inherent in this model far outstrips other methods of sharing care.

The main disadvantage to this type of shared care is time. Each sector psychiatrist will have several general practices in their area, and it may not be possible to accommodate them all, unless visits are so infrequent they are ineffective. Tying up two clinicians for one assessment can be inefficient, although may be appropriate in particularly difficult cases. A more efficient method is for clinicians to meet and discuss several patients, perhaps on a monthly basis. Another potential disadvantage is that the relationship between the patient and the general practitioner may be jeopardised if the patient links him or her closely with the psychiatric process.
4.1.2 Media-based shared care

Shared care may be effected through a variety of media that are completed and distributed to all relevant professionals after each evaluation of the patient; standardised record sheets or computer-generated records distributed by post or e-mail. This model may be viewed as one stage beyond the standard current practice of disseminating information through letter, and is a relatively basic form of shared care. There are two principal advantages to this model. Firstly, information may be coded on a standardised form that provides all relevant information, and cuts out irrelevant material. Forms could be designed to meet the local needs of general practitioners and secondary care teams. Information recorded in this way can facilitate audit and activity analysis. The second advantage is that the dissemination of information should be more rapid, than the current practice of letter writing, although this is not guaranteed. This model has few obvious advantages to the patient, who is unlikely to be aware of the process.

The main disadvantage of this model is that it confers little advantage over current systems, and in my view barely constitutes shared care. There is no joint involvement in decision making, or opportunities for educating professionals or patients.
4.1.3 Patient-based shared care

The intervention evaluated in this study is patient-held shared care records. Patient-held records may range from just a vehicle for facilitating information exchange (similar to the media-focused model described above) to a tool that promotes links between professionals similar to the professional-based model. For the latter to occur, the introduction of shared care records would need to be mirrored by, or indeed cause a change in the culture of care; encouraging assessment and treatment decisions by all professionals involved. The degree to which this is achieved is dependent on how the shared care records are introduced, the professionals and patients attitudes and sense of ownership to the scheme.

4.1.3.1 Potential advantages of patient-held shared care records

Participation in a patient-focused shared care programme may result in several advantages for patients and professionals. These may have an impact on the process of care delivery and result in a reduction in morbidity and admission to hospital.

Patient education.

Patients may be encouraged to take a more active role in making decisions about their care. Increasing knowledge about their illness may facilitate this, as they will have automatic access to their shared care record. Patients may feel better able to ask questions about their diagnosis and treatment, or seek information from other sources (libraries, self-help groups etc.). The fact that the patient is being made responsible for the record may also engender a feeling of participation and equality rather than being the passive recipient of services, improving overall satisfaction.
with the service. It is possible that if patients have better understanding of their illness and treatment, adherence with treatment regimens and aftercare will improve, reducing the risk of relapse and readmission.

**Dissemination of information.**

Information may be exchanged more effectively between professionals caring for the patient. One record could be shared between general practitioner, psychiatrist, social worker, community psychiatric nurse, psychologist and occupational therapist. As in other specialities, such as obstetrics, it is unlikely that the record will replace hospital notes or primary care records. Instead it will provide a written summary of assessments and actions taken by each professional and could reduce the need for letter writing.

More effective exchange of information may confer several advantages. Letters may take several days to generate following a consultation, and may not be sent to all interested carers. Thus, clinicians may be better informed about recent changes to treatment and may be alerted to potential difficulties with that patient. Wider dissemination of information than would be possible by letter would ensure that all professionals the patient has contact with have at least some information. For example, a social worker undertaking an assessment may have no prior knowledge of the patient, but the record could prove pivotal in designing an appropriate package of social care. Furthermore the record could be invaluable in an emergency. Knowledge of a patient’s current diagnosis and treatment may help doctors decide on the most appropriate management strategy in emergency
situations. In particular, patients who present in crisis will have a record of their keyworker who may be able to provide a clearer judgement of the current degree of urgency. The record may also facilitate more accurate risk assessment by providing up to date information about risk factors such as suicide attempts.

_Increased professional involvement._

The primary care physician may be strengthened in his or her role. Hospital based services may become less distant and remote. Just as with obstetric care, general practitioners should be able to make decisions regarding treatment and other aspects of management without necessarily referring to the psychiatrist. Their knowledge of psychiatry, and confidence in dealing with patients with mental health problems may increase as they engage more. This may result in a better understanding of principles of diagnosis and treatment as well as the facets of an individual patient.

For the psychiatrist, shared care may result in better liaison with other professionals. This is increasingly important as good communication is a core feature of the Care Programme Approach. If general practitioners take on some follow-up responsibility this may free up time for psychiatrists to see more difficult cases or more new cases (for example the cases of schizophrenia currently looked after solely by GPs). The greater liaison between GP and psychiatrist may result in more rapid detection of problems arising with a particular patient, facilitate earlier intervention and avoid admission.
4.1.3.2 Potential drawbacks of patient-held shared care records

Participation in a patient-held shared care record scheme could result in disadvantages to both the patient and professional. Ultimately this may have an adverse impact on the delivery of care and outcome.

Confidentiality

A significant drawback of shared care cards is the issue of confidentiality. Confidential information from various sources will be entered on the card. If the card is lost, or read by non-professionals it may prove embarrassing to the patient and this may deter some patients from participating. Patients may feel the responsibility for keeping this card safe, and bringing it to appointments is too great. Shared care cards in obstetric care contain little information of a nature that is likely to prove embarrassing to the patient, unlike the cards in psychiatry. One possible method of safeguarding confidentiality will be to have cards numbered instead of named, or just identify the patient by initials and date of birth. Encoding the data on disk (or eventually on a "smart card") will go some way to obviating this problem.

Lost records

Patients will doubtless lose their records or forget to bring them along to some consultations and this will be frustrating to the professionals, (Essex et al (1990) found 55% took their cards to more than 75% of visits). This may reduce patients' engagement with services. For example, a patient who has lost his or her record may be reluctant to attend an appointment for fear of censure.
lack of professional interest

It is essential that involved professionals are aware of which patients carry shared care cards and request to see these at each interaction. If this does not happen, the patient may not perceive their cards as being valued by the professionals and are less likely to continue to carry them.

The shift from records only available to professionals to open records may encourage, or require the practitioner to spend more time explaining and discussing aspects of illness, treatment and general care. This may deter the participation of clinicians, first because of the implications with regard to time and second because they may feel threatened by the more egalitarian relationship with the patient that shared care will confer. Clinicians may also be reluctant to enter sensitive information onto a medium the patient will have access to. Overall, this could have a very detrimental effect, with clinicians becoming antipathetic to a scheme that patients value.

Duplication of information

If completing the shared care card is done in addition to other, established record keeping this will result in duplication and time wasting and is likely to be unpopular with carers. If the record is the only record of information then if it is mislaid, valuable records (of medico-legal significance) will be lost. Furthermore, carers may wish to record data they do not wish the patient to see or which they would not wish to reach a wider forum. For these reasons it is probably unacceptable for the shared care card to be the sole repository of information.
Duplication of information is a significant drawback, especially in primary care where consultation time is so brief. Clinicians could become very dissatisfied with this scheme, especially where they do not perceive any tangible benefits.

**Margins of responsibility**

A further possible drawback is the blurring of the margins of responsibility, both clinical and financial. Clinical responsibility should remain invested in the doctors caring for the patient; if the general practitioner takes on more of the care, more responsibility will be devolved to him or her. The shared care card may be perceived as diffusing clinical responsibility to a wider group although this remains to be seen. With the shift in emphasis of health care delivery to Purchaser/provider model, some general practitioners who are fund holders may be unhappy with, on the one hand purchasing psychiatric services and on the other hand taking back more clinical work as a result of shared care. This may impede the study, but if shared care became commonplace this would be taken into account in setting up contracts.
4.2 Hypothesis

For patients with long-term mental illness (Kendrick et al 1995) (see chapter 5 for definition), the use of a patient-held, shared care record by primary care physicians, psychiatrists and other members of the mental health team will lead to significant changes in the use of services, mental health and satisfaction with services.

4.3 Aims

1. To design, pilot and introduce a shared care booklet for patients with long-term mental illness.

2. By means of a randomised controlled trial, to:

   a) identify whether carrying a shared care record improves patients' mental health outcome as measured by hospital admissions, self-rated and observer-rated global measures of mental health.

   b) identify whether carrying a shared care booklet improves contact with the service as measured by clinic attendance and defaults.

   c) identify whether carrying a shared care record improves patients' satisfaction with the service, measured by the client satisfaction questionnaire.
3. To measure professionals’ and patients’ expectations about patient-held shared care records.

4. To measure how often patient-held records are used by patients and professionals, and to identify predictors of this use.


4.4 Summary

Patient-held records are the most common type of shared care. Given the lack of clarity of the utility of shared care records in other disciplines, and absence of robust evidence for patient-held shared care in mental illness, I undertook a randomised trial to attempt to fulfil the above aims.
Chapter 5

Methods

5.1 Introduction

The methods used in this study are closely linked to the pilot of recruitment. Significant changes were made to the final method as a result of the pilot. This chapter outlines the methods considered, and summarises the final method bearing in mind the pilot results (chapter 6). The stages of the study are shown in the flow diagram overleaf (figure 5.1.1).
**Figure 5.1.1** Stages followed in the evaluation of patient-held shared care records
5.2 Design of the shared care record

The record was designed to be small enough to be convenient, but large enough to take adequate information. Essex et al (1990), in their pilot of shared care records in psychiatric patients used an A5 booklet of paper surrounded by thin card. A5 size is useful but probably too large for most patients; ideally records should be able to fit into a pocket. A6 size may be too small to be of use if significant amounts of clinical information are to be recorded. The trade-off between a size small enough to be acceptable for the patient and large enough to be of clinical utility was eventually overcome by having an A6 record with several pages for recording information. Following comments in the pilot phase, the records were bound in a clear plastic cover.

The record was broken down into sections; section 1 for recording the patient’s initials, the names and addresses of GP, psychiatrist, and social worker and the key worker. At the bottom was a return address if the card was found. Section 2 provided space for recording brief clinical notes and section 3, on the back was for future appointments. As a result of the pilot survey, the space allocated for each visit was increased to the full length of each A6 page. Each page has a space for recording the date, identity of the healthcare worker, comments, intervention and medication. For reasons of confidentiality, the patients’ full name and address were not entered on the record.
5.3 Information sheets

The cooperation of the patients was pivotal in the success of this study. For this reason, great emphasis was placed on educating the patients about the study and the use of the shared care record. In addition to a careful verbal explanation, each recruit was given two information sheets. The first information sheet (appendix 7) gave information about the study in general. The second (appendix 8) was in a question and answer format, explaining in greater detail about shared care and the use of the record. This was only given to those allocated to the shared care limb of the study.

5.4 Outcome instruments

The need to derive meaningful clinical and satisfaction data from this study, and yet maximise the response rate were pivotal issues in deciding the choice of outcome measures.

The questions addressed when choosing outcome measures were:

1. Does participation in shared care improve patient care? This may be measured in terms of admissions to hospital and attendance at clinic appointments, contact with general practitioner and perceived quality of contact with psychiatric services
2. Does participation in shared care improve clinical outcome for the patient? This was measured in several ways; admission rates, length of time in hospital while in the study, and psychiatric symptoms assessed by rating scales.

3. Is shared care acceptable to participating groups? The views of general practitioners, psychiatrists and other health workers was assessed before and after the study. Patients' expectations were assessed at the outset and service satisfaction was assessed before and after the study.

5.4.1 mental health

The outcome measures used in this study were chosen to provide information on a diverse range of parameters, yet allow completion of the assessments in approximately half an hour. A mix of self-completion and observer rated scales was chosen, each providing global scores and sub-scores for the major mental illnesses.

5.4.1.1 Hospital admission rates and service usage

Hospital admission rates were supplemented by data on clinic attendance and defaults. Given the problems assessing outcome using questionnaires and standardised instruments, a robust and clinically useful measure is the amount of contact a patient has with a service. This has the added advantage of being available, even for those subjects who could not be followed up clinically.
However, there are problems with interpreting these data; increased frequency of admissions does not necessarily mean the patient was more ill. It may reflect a greater recognition of his or her illness by the clinical team, or a greater willingness to seek care by the patient.

5.4.1.2. Behaviour and Symptom Identification Scale (BASIS-32)

It was not possible to blind raters to the intervention in this study because much of the follow-up data collection was undertaken by individuals who had also recruited subjects. Furthermore, it was essential that the researcher undertaking the follow-up knew the allocation of the subject so that they could complete the questionnaire and offer a replacement booklet if the subject was in the shared care limb.

For this reason, in order to avoid bias, it was desirable that the main measure of mental health status was a self-report questionnaire. This does not remove the possibility of bias from the patient. Several patient-completed instruments exist but few had been designed to provide a comprehensive assessment of mental state including symptoms of psychosis. Given the need to balance the utility of an outcome measure with a high response rate, I decided to use a brief self report questionnaire that had recently been standardised. This was the 32-item Behaviour and Symptom Identification Scale; the BASIS-32 (Eisen et al 1994). The BASIS-32 provides a global score and five sub-scale scores. The sub-scales were derived by factor analysis and comprised; relation to self and others, daily living, depression and anxiety, impulsive and addictive behaviours and psychosis.
The BASIS-32 was derived from cluster analysis of an heuristically derived list of problems experienced by patients with mental illness. The utility of the BASIS-32 was assessed on a sample of 387 patients with a broad range of diagnoses. Test-retest reliability for the all-item score was 0.85. Discriminant validity using the subscale scores as predictors of clinicians' diagnoses was good. The scale was sensitive to change over time. A multivariate analysis of variance for repeated measures on the time point factor (a six month interval between admission and follow-up) was significant (F=25.3, df= 6,241  p<0.001).

5.4.1.3 Brief Psychiatric Rating Scale (BPRS)

The Brief Psychiatric rating scale (Overall and Gorham 1962) is a well-established global measure of mental health status. It has been widely used as an outcome instrument in mental health research (Hedlund and Vieweg, 1980). Although originally developed for use with inpatients, it is also useful in measuring change in outpatient populations. There are 19 items on the modified version, rated on a scale 0 to 6 from “absent” to “extremely severe”, based on verbal reports and observation of the patient. After interviewing the patient for the assessment, a few specific questions only are necessary to enable completion of the BPRS. There is also a global score; an overall impression of the status of the patient ranging from “normal” to “among the most extremely ill patients”. The BPRS is sensitive to change over time, and the total score is usually used in outcome research. However, significant changes in one domain, for example psychotic phenomena, may be masked by minor changes in other questions. For this reason, some researchers suggest calculating sub-scale scores. For the purposes of this study, the BPRS was
used to provide a global overview of mental health, and total scores were used, in addition to the sub-scale scores. Another potential drawback with the BPRS is rater bias. Ideally the BPRS should be rated by two individuals, or by someone blind to the status of the patient.

Another advantage of using the BPRS was the possibility of checking the validity of the self-report scale, the BASIS-32, in this study sample. Correlation between total BASIS and BPRS scores would provide a measure of validity for the BASIS.

### 5.4.2 Quality of life

The World Health Organisation definition of quality of life is:

> An individual’s perception of their position in life in the context of the cultural and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person’s physical health, psychological state, level of independence, social relationships and their relationships to salient features of their environment.  

(WHO 1993)

Gurland (1992) has tried to define the components of quality of life and has come up with no fewer than 13 different domains. These include distress, discomfort, the loss of role, self-control and will to live, loss of gratification, continuing stress, indignities, service dissatisfaction, discontinuity in lifestyle, relative poverty, narrowing of the social repertoire and perceived shortening of life span. A more reductionist definition is “the achievement of optimum levels of mental, physical,
role and social functioning” includes assessment of health, fitness and of life satisfaction (Bowling 1996).

Quality of life measures are increasingly used as an outcome in clinical trials. One reason for this is that measuring quality of life goes beyond measuring disease, and attempts to measure the impact of a disease and treatment on day-to-day life (Muldoon et al 1998). To this extent quality of life measures appear appropriate adjuncts to disease-specific measures. However, most quality of life measures impose specific pre-conceptions on what is a “good life”. Furthermore, many quality of life measures appear to be quasi disease measures; there are often several disease specific questions in quality of life instruments.

5.4.2.1 Short form-36 (SF-36)

The Short Form 36 (SF-36) (Jenkinson et al 1993; Ware, 1993) is a brief quality of life measure that has been reported to have good validity and reliability and is acceptable to patients in primary care settings (Garratt et al 1993). The SF-36 appeared to combine twin requirements of brevity (taking about 10 minutes to complete) and validity, although evidence of sensitivity to change over time was not established. Another reason for choosing the SF-36 was its popularity as an outcome measure. Using popular measures helps comparison of results between studies. It was clear from the pilot study that patients found longer interviews difficult to complete. The pilot study also predicted significant problems with the completion of the Short Form-36 (SF-36) (Jenkinson et al 1993) (see chapter 6).
5.4.3 patient satisfaction

Patient, or client, satisfaction is used as an outcome measure with increasing frequency. Patient satisfaction is useful in assessing acceptability of services and as such is an indicator of the likelihood that patients will adhere to medication and other management strategies. High levels of satisfaction is also linked to better outcome (Svensson and Hansson, 1994), although it is not clear whether satisfied patients get better, or patients who get better are more satisfied.

A different viewpoint is that patient satisfaction may be a useful outcome because many interventions in psychiatry have, at best, a moderate effect size and the instruments used to measure change are not very sensitive. In psychiatry, almost no interventions are below a number needed to treat of 3. In other words, although antidepressants are arguably one of the most effective interventions available to treat mental illness, three patients will need to be treated for one to get better, in the best conducted trials. The figure for patients in the community is likely to be less, as those enrolled in randomised studies are frequently atypical and subject to the Hawthorn effect (the introduction of extraneous variables through social interaction of experimenters and subjects (Freeman and Tyrer, 1992). Thus, patient satisfaction is a useful additional outcome that may serve as a proxy measure of efficacy, and supplement relatively weak outcome measures.

Patients are likely to express satisfaction, or dissatisfaction for that matter, because of the quality of personal contact they have with the service providers, rather than with the quality of their treatment outcome. For example, in Italy, a person
practised for years as a general practitioner without any medical qualifications. No complaints had been lodged by his patients, some of whom lobbied for him to be allowed to continue to practice after he was exposed (Hooper, 1997). Another example in the United Kingdom, involved an individual who practised for many years as a general practitioner although he had no formal medical training. He gave his patients shocking advice, including painting creosote on tonsils and swallowing shampoo. No complaints had been received about this man, and his patients were reported to be very satisfied. These cases highlight the issue of how important the way care is delivered, not just the type of care. Savage and Armstrong (1990) reported a controlled evaluation of general practitioner’s interviewing styles on patient satisfaction. Patients (n=350) were randomly allocated to one of two consulting methods; “directing” (authoritative and paternalistic) or “sharing” (egalitarian and understanding). Patients in the directing group were more satisfied with many aspects of the consultation. Unfortunately, patients with severe mental illness were excluded from this study, which nevertheless underlines the importance of the style of communication between doctor and patient, and that the style patients seem to prefer is not what many clinicians (especially psychiatrists) advocate.

Despite the above caveat, I chose to include a satisfaction instrument in this study. The main reason for this was that patients in the two limbs of the trial may have been subject to very different interactions with the professionals delivering health care. Satisfaction is also related to the patient’s sense of autonomy and control over their care. These are core facets underpinning the use of the patient-held shared care
A useful proxy measure for these differences could be perceived satisfaction with the service.

There are several satisfaction rating scales, but few are validated for psychiatric patients (Ruggeri 1994). The Verona satisfaction scale (Rugerri et al, 1994) was described at the time this study was being designed. It has been used in psychiatric populations but appeared rather long and relatively untested. As the Client Satisfaction Questionnaire (Larsen et al 1979) is brief, commonly used and well established this was chosen as the satisfaction outcome measure.

5.4.3.1 Client Satisfaction Questionnaire (CSQ-8)

The client satisfaction questionnaire (Larsen et al 1979) is a brief, validated scale developed specifically for patients with mental health problems that has been widely used as a satisfaction scale. This was derived from a larger scale using principal components factor analysis. The final scale has good internal consistency (alpha = 0.93). The eight-item version usually takes less than five minutes to complete.

5.4.4 Attitudes to shared care

The attitude of subjects and professionals to the concept and practice of shared care may have a significant impact on uptake and compliance with the process. For example, if professionals were unconvinced about the usefulness of shared care, they may not request to see the record at consultations. It was also important to evaluate any changes in attitudes over the study period.
5.4.4.1 Subjects’ attitudes

The subjects’ views of the concept of shared care and the degree with which they feel they should be involved in decisions about their care formed an integral part of the baseline assessment. Not only would this provide information about the views of patients with mental illness on the concept of shared care and autonomy, but may be related to later uptake of the shared care record. No validated scales existed for this, so I constructed a brief self report scale (appendix 4). This was piloted on 10 patients prior to adoption to the study (see chapter 6).

5.4.4.2 Professionals attitudes

How health care professionals perceived the concept of shared care was also likely to have a bearing on the outcome. If professionals were antipathetic, to the idea, or felt it had little clinical utility, then they would not fill the booklets in. Because of the precise focus of the study, no existing suitable questionnaire could be identified. A questionnaire intended to assess professionals’ attitudes to shared care was designed.

5.4.4.3 Design of the attitude questionnaires.

At recruitment, those patients assigned to the shared-care group were given a questionnaire designed to assess their attitude to shared care and the amount of input patients should have in decisions about their care (appendix 4). Using a four-point Likert scale, patients were asked to what extent they agreed or disagreed with hospital consultants, general practitioners and social workers being involved with their care. Patients were also asked whether they knew enough about their diagnosis...
and treatment and whether carrying a shared care booklet would help professionals involved. Finally, in an attempt to assess motivation, subjects were asked whether or not they felt they would forget to carry their booklet. The reliability of this questionnaire was assessed by assessing the measure of agreement on test-retest in a sample of 10 patients (see pilot study: chapter 6).

A similar questionnaire was designed for health professionals (appendix 5). There were 9 items in this questionnaire, rated on a four-point Likert Scale from strongly agree to strongly disagree. There were three domains; beliefs about the usefulness of the shared care record to the patient, beliefs about the usefulness of the records for professionals and general questions about shared care.

**Before study**

Questionnaires designed to elicit attitudes to shared care and the shared care record were sent to all professionals (consultant, GP, social worker and CPN) at the time of recruitment of one of their patients (appendix 5). Questionnaires were only sent once to each professional and were not re-mailed when subsequent subjects, for whom the professional had responsibility, were recruited. Answers were on a four point Likert scale, with no possibility of a neutral response.

**After study**

All professionals who had patients enrolled in the study were invited to complete a follow-up questionnaire at the end of the study (appendix 6). This included 7
questions identical to the attitude questionnaire at the beginning of the study. It also sought information about exposure to the shared care record, including whether the health worker had seen, read or written in a record. Professionals known to have retired in the interim were not mailed. Some uncompleted questionnaires were returned because the intended recipient had retired, moved away or died.

5.4.5 Final choice of outcome measures

Following the pilot of the recruitment, the final outcome questionnaires chosen were the Behaviour and Symptom Identification Scale; (BASIS-32) (Eisen et al 1994), the Brief Psychiatric Rating Scale (BPRS) (Overall and Gorham 1962) and the Client Satisfaction Questionnaire (CSQ) (Larsen et al 1979). The SF-36 was not used as an outcome because of anticipated difficulties in completion by this patient group. Other quality of life measures, such as the Lancaster Quality of Life profile were considered but rejected due to their length. In addition, process data and record use would be evaluated. The BASIS-32 and CSQ would be completed by the subject wherever possible, but this could be undertaken by the researchers if necessary, using a prompt card with the possible responses, and asking the subject to indicate the most appropriate response. Although the BPRS may be scored from 1 to 7, for this study I scored 0-6 following the recommendations of Hedlund and Vieweg (1980) to utilise the “0” anchor, if a symptom was not present.
5.5 Promulgation of the study to health professionals

The co-operation of health professionals was sought prior to starting this study. It was important that all involved professionals were aware of the shared-care project, so they could participate if they wished.

5.5.1 Before the study

5.5.1.1 General practitioners

All 216 general practitioners in the Camden and Islington area (covering the catchment area of the Royal Free Hospital) were sent a letter about the study before recruitment commenced (appendix 10), along with a copy of the shared care booklet. This letter gave information about the reasons for the study and role of the general practitioner. Comments about the study were invited. General practitioners were invited to request to see the booklet of patients participating in the study and to peruse this, and add comments if they wished. In addition, the aims of the study and the role of the GP were presented to a monthly meeting of local GPs.

5.5.1.2 Hospital psychiatrists

The junior and consultant psychiatrists were informed about the study prior to the start. A letter was sent to each consultant and junior doctor at the start of the study (appendix 10). In addition, the study was presented to each cohort of junior doctors as they began their post.
5.5.1.3 Other professionals

It was anticipated that social workers and community psychiatric nurses would use the shared-care records. An outline of the study was presented to the team leaders of both disciplines and letters detailing the study were sent to all community nurses and social workers likely to have patients involved.

5.5.2 At recruitment

Each time a patient was recruited, the consultant, general practitioner and if relevant community nurse and/or social worker, were sent a letter explaining the nature of the study and details of the patient recruited. Letters sent to professionals relating to subjects in the shared care limb included an explanation about using the shared care record (appendix 11). This information was omitted from the letters about subjects in the control limb.

5.6 Randomisation

For the purposes of this study, the unit of randomisation was the patient’s general practice. Randomising the patient or individual general practitioner could both result in bias, given that the introduction of the patient held records to some patients, or doctors within a practice may result in a change in the culture of care, and this could have an impact on the controls.

Prior to commencement of the study, a comprehensive list of all the local general practitioners and practices in the hospitals catchment area was assembled. Practices
were sequentially numbered in alphabetical order according to the first line of the address. Practices were randomised to shared care or control status using a computer generated algorithm. Forty-six numbers were derived from a computerised random number generator (SPSS) (Norusis1993), by selecting the first 46 unique numbers between 1 and 91. These numbers were then matched to the practice numbers in order to determine those practices in the shared care limb of the trial. The patient was placed in the limb of the trial dictated by their general practitioners status.

5.7 Recruitment

5.7.1 Identifying potential subjects

Patients were recruited at around the time of discharge (i.e. within a week of anticipated discharge date as supplied by the ward). Posters were displayed prominently on the wards and ward staff were reminded regularly about the study. Wards were visited at least weekly during the recruitment periods in an attempt to identify potential subjects. Discharges were monitored in order to identify patients who had been discharged without seeing a member of the study team. Attempts were made to see at home any individuals who may have met eligibility criteria but who were discharged before recruitment. Patients identified as likely to be discharged were approached directly on the wards.
5.7.2 Recruitment process

In order to minimise the bias during recruitment, the recruitment procedure was sequentially defined. It was particularly important to avoid potential recruits from knowing their randomisation status until after consent and entry into the study. The flow diagram of the recruitment procedure is given overleaf (figure 5.7.1)
Figure 5.7.1 Flow diagram of recruitment procedure
5.7.3 Definition of long-term mental illness

Individuals who had been admitted to the hospital's psychiatric unit and diagnosed as having a mental illness or personality disorder were considered for the study. For patients to be eligible for this study they had to meet clinicians' diagnosis of mental illness. The confirmation of this diagnosis by the Present State Examination (Wing et al 1974), or other similar diagnostic instrument was considered. However, this study was intended to be as pragmatic as possible, and restricting recruitment to individuals who only met strict case definition would hamper the generalisability of the results.

The diagnosis was confirmed by perusal of the casenotes prior to seeing the subject. Subjects had to meet the criteria for long term mental illness (Kendrick et al, 1995) (table 5.7.1), and meet the inclusion criteria for the study (table 5.7.2.).

| 1. Diagnosis of psychosis, severe non-psychotic disorder, severe personality disorder, eating disorder, alcohol or drug misuse. |
| 2. Disability resulting in the patient being unable to fulfil at least one of the following: |
| - Holding down a job |
| - Self care and personal hygiene |
| - Performing necessary domestic chores |
| - Participating in recreational activities |
| 3. Disability must be due to one of the following |
| - Withdrawal or inactivity |
| - Responses to hallucinations |
| - Bizarre or embarrassing behaviour |
| - Violence towards self or others |
| 4. No dementia or organic brain disorder or learning disability |

Table 5.7.1 Criteria for long-term mental illness (after Kendrick et al 1995)
**5.7.4 Inclusion criteria**

Criteria for inclusion in the study, and exclusion are given in Table 5.2. Exclusion criteria were kept to a minimum in order to maximise the generalisability of the study.

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Living in catchment area of the hospital</td>
<td>Unable to complete questionnaires (aided)</td>
</tr>
<tr>
<td>Registered with general practitioner locally</td>
<td>Refusal to consent</td>
</tr>
<tr>
<td>Chronic mental illness (see Table 5.7.1.)</td>
<td></td>
</tr>
<tr>
<td>Able to give informed consent</td>
<td></td>
</tr>
<tr>
<td>Requires follow-up (i.e. aftercare arrangement with healthcare professional other than general practitioner)</td>
<td></td>
</tr>
<tr>
<td>Age 16-65</td>
<td></td>
</tr>
</tbody>
</table>

**Table 5.7.2 Inclusion and exclusion criteria for the study.**

In-patients on the psychiatric unit who appeared to meet eligibility criteria for the study were invited to take part in this trial. Individuals who refused, or were unable to give informed consent were not included in the trial. For ethical reasons, apart from gender and reason for non-participation, data were not collected on non-participants. In order to identify whether the recruited sample was representative of the inpatient population, socio-demographic data and diagnosis of the sample were compared with the whole in-patient population on the psychiatric unit for a six-month epoch during the conduct of the trial.
Those patients who were prepared to participate in the study were given an information sheet and had the opportunity to talk about the study with an investigator. Written informed consent was then obtained from those who agreed to participate.

5.7.5 Baseline assessment

After giving consent subjects were asked to complete the BASIS-32 and the CSQ-8 and the BPRS was completed by the assessor after interviewing the patient. Raters in this study were familiar with the scoring protocol and scale definitions. The assessor was blind to the BASIS-32 and CSQ results at the time of the first BPRS. Socio-demographic data were collected. The subject was then asked who their general practitioner was, and was accordingly allocated to the shared care or standard care group. Thus the investigator and subject should not have known the allocation until towards the end of the recruitment process. Those in the shared care limb were then given a shared care booklet, and an explanation of its use (with reference to the information sheet). They were also asked to complete an attitude questionnaire about shared care and using the booklet (see Chapter 6 for further explanation).

5.7.6 Informing professionals

Once a subject had been recruited to the study, a letter was sent to the patient's consultant psychiatrist and general practitioner giving information about the recruitment [appendix 11]. If the patient was allocated to the shared care intervention, brightly coloured stickers identifying the patient as being in the shared
care study and prompting the health worker to request the record were attached to the patient’s hospital notes. These brightly coloured self-adhesive labels identifying the patient as being in the study were sent to the general practitioner and other health workers to attach to their records.

Each time a patient was recruited to the shared care limb, all health workers involved with that patient were sent the questionnaire assessing professionals’ attitudes to shared care (appendix 5). Non-responders were sent a reminder after three weeks. This questionnaire was sent once to each professional; if other patients under their care were subsequently recruited, no additional questionnaires were sent.

5.7.7 Follow-up procedure

A central register of subjects was maintained. Follow-up was arranged at two time points; six and twelve months after recruitment. Follow-up appointments were arranged by telephone whenever possible. Alternatively, a letter giving details of the visit was mailed a week in advance of the proposed appointment. This letter invited the subject to ring and rearrange the appointment if the time was inconvenient. Patients who could not be contacted at the first follow-up visit were visited at home on two further occasions. In the event of patients not being contactable, checks were made on the hospital Patient Administration System for a change of address and the patient’s key worker was contacted for information about their whereabouts. Some patients were in hospital at the time of follow-up. Hospitalisation did not preclude follow-up interviews. When patients expressed the
wish to have no further contact about the study, they were withdrawn from the follow-up procedure.

5.7.8 assessment schedule

The schedule of assessments at each time point is given below (figure 5.7.2). When seen for follow-up, patients were asked to complete another BASIS-32 and CSQ, and following a further interview, were rated using the BPRS. Patients were also asked about frequency of contact with health professionals (community nurse, hospital doctor, GP and social worker). Those in the shared care group were also asked about the professionals’ use of the record. Those who reported losing their record during the six-month assessment were offered a replacement.

At the end of the study data on subjects’ admissions and clinic activity were collected from the hospital’s patient administration system. This is a computerised database of all outpatient and inpatient activity. The number of admissions to psychiatric wards for the year prior to entry into the study and the year after entry and the total number of in-patient days in the year after admission were recorded. Clinic attendance and the number of defaults from booked appointments were also recorded.

At the end of the study a follow-up attitude questionnaire was mailed to all professionals who had patients enrolled into the shared care limb. (appendix 6) Non-responders were re-mailed after three weeks.
Figure 5.7.2 Assessment schedule at recruitment and follow-up for intervention and control limbs
5.8 Statistical analysis

5.8.1 Sample size and power calculation

The BASIS-32 was used as an outcome measure for the purpose of calculation of the sample size. In studies evaluating the validity and reliability of the BASIS-32, undertaken in the USA (Eisen et al 1994), the mean all-sub-scale score of hospitalised patients was 1.34 (standard deviation = 0.68). A difference of 0.7 standard deviations in the BASIS-32 score is equivalent to a mean difference in global scores of 0.48, similar to the difference observed between admission and follow-up in the original study by Eisen et al (1994). In order to detect such a difference between the intervention and control groups at the end of the study at a significance level (\(\alpha\)) of 5% (2 sided test) and 80% power, (1-\(\beta\)), 33 patients needed to be recruited to each limb of the study.

Because the unit of randomisation was the practice, not the patient, this figure required adjustment to take into account the assumed intra-cluster correlation. When cluster randomisation is used, there may be a difference in the variance between practices and the variance between patients within practices. The variance cannot be assumed to be equal because patients with different characteristics or levels of morbidity may co-segregate to different practices. At the start of this study in 1995 there was little information about the size of the intra-cluster coefficient for mental health parameters in primary care. For this reason, and because a relatively high level of attrition was anticipated due to the peripatetic nature of the subjects, I aimed to recruit 90 subjects.
Given the expected sample size of 90 subjects, a back-calculation of the power to detect changes in admission rates was undertaken. Assuming a readmission rate of 60% over one year in the control group (Owen et al 1997), the sample size was sufficient to detect a 50% reduction in admissions in the experimental group. This is a large (and probably over-optimistic) anticipated effect size.

5.8.2 Data handling

Data entry and data checking were undertaken using the data entry module of Epi-Info (v6.01). The results of each questionnaire for each time period, and the administrative and demographic data was entered onto individual EPI-Info files. Each file was associated with a check file to identify out-of-range data values, and essential missing data. Each EPI-Info file was checked for accuracy by double entry by a different individual. These files were then exported to SPSS (v7.5) data files and were combined to provide a comprehensive database of variables (Norusis, 1993). At this point a second comprehensive check of data was carried out by checking each data bit against the original data record to ensure the database was as error-free as possible. Mean (or median for non-parametric data) total and sub-scale scores were calculated as appropriate for the questionnaires.

5.8.3 Statistical analysis

Data were initially plotted graphically (bar charts, histograms, probability plots or scatter plots as appropriate), to check the distribution and detect outliers.
Non-normally distributed data were log-transformed prior to parametric statistical procedures when these were desirable.

5.8.3.1 Validation of the BASIS-32

One aim of this study was to validate the BASIS-32, a relatively new scale, against the BPRS. Baseline results of all subjects' were used to calculate the correlation coefficient, regression equation and kappa values of the change scores of two instruments.

5.8.3.2 Validation of the attitude questionnaire

The test-retest reliability of the subjects' attitude questionnaire was determined by intra-class correlation coefficient.

5.8.3.3 Main study

Descriptive statistics were analysed using the Chi-square or other non-parametric statistic as appropriate. Parametric data were analysed using Student’s t-tests. Longitudinal data were analysed using analysis of covariance (ANCOVA). Data were analysed by intention to treat. i.e. anyone completing the recruitment procedure was incorporated into the final analysis. A subgroup analysis of those patients completing follow-up was also carried out. Missing data were accounted for in two ways: last observation carried forward and average of the follow-up scores where present. Practice-based analysis was also performed on the main outcome parameters.
In recent years there has been a shift to presenting data in a form that allows a more meaningful calculation of effect size. With randomised controlled trials evaluating new treatment approaches, the Number Needed to Treat (NNT) provides a clinically meaningful measure of efficacy (Sackett, 1997). The NNT is the number of people who would need to be treated with the intervention being evaluated in order for one person to be “improved” compared to if they received the control intervention.

In order to calculate the NNT the outcome data need to be presented in a dichotomous form, i.e. better/not better or; case/not case. When instruments are used which do not have established case cut-off criteria, the NNT may be derived by using a clinically appropriate improvement score as the cut-off. For the purposes of this study, therefore, the results of the primary outcome measures were dichotomised using a priori criteria, and the NNT calculated accordingly.

5.9 Ethical considerations

This study received the approval of the ethical practices sub-committee of the Royal Free Hampstead NHS trust, and was carried out in accordance with the Helsinki declaration on research into human subjects, (including amendments). This included obtaining and documenting informed consent and ensuring archiving of patient identity codes for at least 15 years. All data relating to this project will be archived for 10 years. The shared-care booklets were anonymised to safeguard confidentiality if the subject lost their book. All study records were kept
confidential. In accordance with the data protection act, subjects' names were not entered onto the computer database.

Responsibility for the clinical care of the patients rested with the clinicians involved. The study investigated the application of patient-held records, but did not supplement, or supplant the delivery of clinical care. The term "shared care" has been seen by some as a way of devolving clinical work, responsibility and costs from secondary services to primary care (Stoeckle et al 1997). In the information supplied to the professionals at the start of the study, it was made clear that there was no change in the respective responsibilities of the clinicians involved. Another issue centres on the management of patients found, during the evaluation, to be seriously mentally ill to the extent that they presented a risk of suicide or harm to others. The a priori decision was that the key-worker of such patients, and the general practitioner, be contacted if this situation arose.

An ethical issue that became manifest during the study was that of implicit withdrawal of consent. Subjects were free to withdraw at any time, and a statement of wish to withdraw resulted in cessation of contact. However, a number of patients appeared to frustrate efforts to follow them up, without explicitly withdrawing consent. Often this occurred in the context of a disturbed mental state. The question arose; was it ethical to pursue a subject in these circumstances, wait until the mental state improved or withdraw them on their behalf? In the end, I decided to withdraw the subject from that follow-up point if they failed to keep two follow-up appointments.
5.10 Summary.

The design of this study was complicated by the need to create new instruments to assess attitudes to shared care and adjust the final choice of outcome measures as a result of the pilot. The results of the pilot are presented next (chapter 6).
Chapter 6.

Pilot

6.1 Patient expectation questionnaire

6.1.1 Design

The attitudes and expectations of participants towards their illness, current care and the concept of shared care could be important determinants in the success or failure of introducing shared care. For example, a patient who is antipathetic to hospital care, or the idea of shared care may be less likely to carry their record than patients who are accepting of these concepts. There are no established instruments to seek patients' opinions of shared care. Therefore, I designed a questionnaire intended to elicit these attitudes. The questionnaire was an heuristic attempt to quantify attitudes to shared care (appendix 4). It comprised three sections: attitudes to delivery of care and involvement of various professionals (originally 4 items); knowledge of diagnosis and treatment (2 items); attitudes of the individual about shared care records (originally 6 items).

6.1.2 Method

In order to confirm the reliability of this new instrument, test-retest was attempted on inpatients after the nature of shared care had been explained to them. This questionnaire was completed after the subject had read both information sheets and
discussed the project with the researcher. The test-retest was not performed on the sample who piloted the recruitment process, as those individuals were recruited from diverse sources. To enable a high recapture rate, the test-retest was performed on volunteers from the psychiatric wards at the Royal Free hospital.

6.1.3 Results

Twelve patients on one of the acute inpatient wards were given the questionnaire. After one week, respondents were invited to re-complete the same questionnaire. Two were unable to do this; one had been discharged in the interim, one refused.

Responses were scored on a four-point Likert scale from strongly agree (4), to strongly disagree (1). The mean all-item score was 2.83 (sd = 0.27). The test-retest reliability coefficient (Intraclass correlation) for the whole scale (12 items) between time 1 and time 2 was calculated by one-way ANOVA. The reliability coefficient was calculated by dividing the difference of the between and within group differences by the sum of the differences (Bartko 1976). In this case, the reliability coefficient was 0.73. This is reasonable, and may suggest good test-retest reliability. For individual items Kappa statistic was calculated for dichotomised results. The kappa values for the individual items are shown in table 6.1
6.1.4 Discussion

Following the pilot of this questionnaire, two modifications were made to the final questionnaire; questions about community psychiatric nurses were added to the sections about professionals’ involvement in care and shared care (appendix 4 for modified attitude questionnaire). No further reliability testing was performed.

For an instrument to be useful it should measure something in a reproducible and consistent fashion. The test-retest reliability as measured by the ICC suggests that the respondents answered reasonably consistently over time. The interval between the initial and follow-up questionnaires was one week, and some respondents may have remembered their initial responses when completing their follow-up questionnaire. However, this interval is regarded as a reasonable compromise
between subjects remembering previous responses and the condition of the subject changing, resulting in a real difference in results (Streiner and Norman, 1989). The sample size for this exercise was small, and the precision of the result will be low as a consequence. Furthermore, the relatively small numbers of items on this instrument will reduce reliability.

Test-retest reliability is only one method of assessing the utility of a questionnaire. No attempt was made to test validity of the instrument. This would have involved matching questionnaire results with attitudes derived at interview. However, I felt the questions posed were quite simple and unambiguous and were likely to represent the views of the respondents accurately.

6.2 Pilot of recruitment

Before embarking on the study proper, a pilot trial of recruitment was undertaken. The purpose of a pilot study is to highlight problems with the method and ascertain whether the study is feasible. The aims of the pilot were to:

1. assess whether patients would be willing to be recruited to the study
2. identify likely sources of patients
3. identify problems with the recruitment and randomisation process
4. seek views about the shared care record
6.2.1 Methods

Recruitment of subjects was attempted from a variety of sources, including hospital wards, community hostels and outpatient clinics. Potential recruits were given a verbal explanation of the study and invited to read both information sheets (appendices 7 and 8). Signed consent was obtained and the recruits were then invited to complete the questionnaires (initially the SF-36 (Jenkinson et al 1993) and the CSQ (Larsen, et al 1979)). The rater then completed the BPRS after a brief interview. Subjects were then randomised according to their general practitioner and those in the shared care arm were then shown the shared care booklet and asked to complete the expectation questionnaire.

6.2.2 Results

No patients refused to participate in the pilot. Of the 12 patients recruited in the pilot, eight were male and all had a diagnosis of schizophrenia. Nine were recruited from the hospital wards, two from a local hostel and one from outpatients. Six subjects were randomized to shared care, six to standard care.

Completion rates for these questionnaires are given in table 6.2. Some problems were encountered in completion of the questionnaire battery; several patients requested help in completing the questionnaires, and in some instances, the interviewer was asked to read out the questions and complete the form. This was especially problematic with the SF36, because the responses take the form of phrases that vary from question to question. Other questionnaires, with more simple formats appeared less confusing to the respondents.
Discussion

The pilot was encouraging, although some difficulties were encountered, especially in completion of questionnaires. Some amendments were made to the proposed method as a result of the pilot study.

Recruitment process

Patients recruited \textit{ad hoc} from a variety of sources could result in bias, and it was decided to recruit only those patients who had been admitted to hospital, and were nearing the point of discharge. These patients were likely to be well enough to complete the recruitment process, and the identification of potential recruits would be less prone to bias. The response rates to the study were encouraging, and suggested that most patients would agree to participate in the trial proper. The equal numbers recruited to shared care and standard care indicated the practice-based randomisation should yield similar numbers in each group.
Questionnaires

Patients appeared to get very confused by the SF36 and the results were unreliable in some subjects, especially if the patient had to be read the question and all possible answers. The fact that responses changed from question to question, were often complex and some questions were answered across the page and others down the page were also sources of confusion. For this reason the SF-36 was dropped as an outcome for this study. An additional self-report questionnaire for assessing mental health, the Behaviour and Symptom Identification Scale (BASIS-32) (Eisen et al 1994) which was not open to observer bias, had been considered before the pilot but was initially omitted in an effort to keep the recruitment process simple and acceptable to the subjects. With the abandonment of the SF-36, the BASIS-32, a questionnaire of more simple design was introduced. This was not re-piloted. Two additional questions about involvement with, and benefit of shared care to community psychiatric nurses were added to the expectation questionnaire. As a result of some subjects having difficulty with completion of the questionnaires, a sheet with the five potential answers to the BASIS-32 in large print was constructed.

Shared care booklet.

Following comments from subjects and colleagues, the record was re-designed slightly. Initially, the record had a space for two entries per page. This was felt to be insufficient space, and the record was redesigned with one entry per page. A clear plastic cover was added.
6.3 Conclusions

Some elements were not considered in this pilot, notably the anticipated follow-up rate and the acceptability of the new questionnaire, the BASIS-32. Nevertheless, the results of the pilot were encouraging and I decided to begin the definitive trial at this point.
Chapter 7

Results

Introduction

This section begins with a description of the validation of the BASIS-32 as a self-report questionnaire in the setting of a clinical trial based in the United Kingdom. The characteristics of the sample recruited to the main study, the population from which they were drawn and the practices involved are presented. The main results comparing shared care and standard care in terms of service utilisation, mental health and satisfaction are given in section 8. Data are presented in various ways to take account of missing data and the effect of cluster randomisation. The extent to which shared care records were used and some examples of use are provided. Finally, there is an account of subjects’ and professionals’ attitudes to shared care records.
7.1. Validation of the BASIS-32

Introduction

The BASIS-32 is a relatively new instrument to use as an outcome parameter. It is intuitively attractive because it is a brief self-report measure of mental health that includes questions specific to psychotic phenomena. Although it has face validity and its reliability has been established in a study from the USA, (Eisen et al 1994) there have been no reports to date on the use of this instrument in the UK.

7.1.1 Comparison of BASIS-32 results to other studies

Few other studies have reported use of the BASIS-32. The mean overall BASIS-32 score for the 90 subjects of this study was 1.24, (sd=0.87) and the mean BASIS-32 score reported in the standardisation sample of recently discharged patients from the USA was 1.29 (s.d.= 0.99) (Eisen et al 1994). There was no significant difference between these two scores (t=0.45, p >0.2).

7.1.2 Comparison of BASIS-32 and BPRS

In order to validate the use of the BASIS-32 as an outcome instrument on a sample from the United Kingdom, and to underpin its use as an outcome parameter in the study, the results were compared with the BPRS scores from this study. The BPRS is widely used as a measure of change in studies in mental illness, and as both instruments are designed to produce global assessments of morbidity in patients including those with severe mental illness, it seemed reasonable to compare it to the BASIS-32.
The two instruments were compared in five ways:

a) baseline global scores
b) baseline sub-scale scores
c) relationship of sub-scale scores to subjects' diagnosis
d) comparison of dichotomised change scores
e) comparison of change scores (continuous data)

7.1.2.1 Baseline BASIS-32 score compared with BPRS.

The clinician performing the initial BPRS assessment was blind to the BASIS-32 result. The BASIS-32 showed some positive skew although the BPRS was approximately normally distributed (figures 7.1.1 and 7.1.2). The Pearson correlation coefficient of the global scores of the BPRS and BASIS-32 was 0.51 (p<0.001) (see figure 7.1.3).

![Histogram of baseline BASIS-32 scores](image)

**Figure 7.1.1** Histogram of baseline BASIS-32 score of all subjects (n=90)
Figure 7.1.2 Histogram of baseline BPRS score of all subjects (n=90)

Figure 7.1.3 Sunflower scatterplot with regression line (n=90) of baseline BPRS and BASIS-32 total scores. Sunflowers have a “petal” for each overlapping datapoint, thereby reducing confusion from overlapping points.
The baseline BPRS and BASIS-32 scores were also compared using a linear regression model, utilising the BPRS score as the dependent variable and BASIS-32 as the explanatory variable. The regression coefficient (b) was 3.91 (p<0.001, 95% CI= 2.49, 5.33) with an intercept of 7.71 (95% CI = 5.58, 9.85). Therefore, for a given BASIS-32 score, the corresponding BPRS score would be 7.71 + (3.91 x BASIS-32 score).

In order to assess whether the relationship between the two scales was linear across the range of scores, the residual values, (the difference between the square of the actual scores and the regression line) were plotted against the predicted values. There is no obvious trend or pattern, suggesting a linear relationship between scores (figure 7.1.4) (Altman 1991).

Figure 7.1.4. Scatterplot of residuals and the baseline BASIS-32 scores with regression line. Ideally, the residuals should cluster horizontally about the reference line, with a similar distribution above and below the line, forming no obvious pattern.
7.1.2.2 Comparison of sub-scale scores

The sub-scales of these instruments do not always appear to measure equivalent parameters. Nevertheless, at least at face value, some sub-scales did appear to have common themes and the correlation coefficients of these sub-scales were calculated. These included the BASIS-32 depression and BPRS anxiety-depression sub-scales, and the BASIS-32 psychosis and BPRS thinking disturbance sub-scales. Most sub-scale scores were not normally distributed, and correlation coefficients were determined using Spearman’s test (table 7.1.1).

<table>
<thead>
<tr>
<th>Theme</th>
<th>Basis-32 sub-scale</th>
<th>BPRS sub-scale</th>
<th>Correlation coefficient</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=90</td>
<td>n=90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>depression</td>
<td>anxiety</td>
<td>0.68</td>
<td>0.001</td>
</tr>
<tr>
<td>Psychosis</td>
<td>psychosis</td>
<td>thinking</td>
<td>0.43</td>
<td>0.001</td>
</tr>
<tr>
<td>Interactions</td>
<td>relationships</td>
<td>withdrawal/retardation</td>
<td>0.14</td>
<td>0.18</td>
</tr>
<tr>
<td>Self care</td>
<td>living skills</td>
<td>withdrawal/retardation</td>
<td>0.13</td>
<td>0.225</td>
</tr>
</tbody>
</table>

Table 7.1.1. Correlation coefficients of sub-scale scores on the baseline BPRS and BASIS-32 that appeared to have related themes.

Thus, there is a relatively high correlation between depression sub-scales, reasonable correlation between psychosis sub-scales and no significant correlation between the living skills and relationship sub-scales on the BASIS-32 and the withdrawal-retardation sub-scale on the BPRS.

7.1.2.3 Sub-scale scores compared with diagnosis

The BPRS and BASIS-32 are instruments designed to measure change. Neither provide a case definition. Therefore it was not possible to compare the sensitivity and specificity, or the positive and negative predictive values of the BASIS-32 with
the BPRS in terms of case definition. However, exploring the relationship between these scores and the subject’s diagnostic group was used to assess the utility of the psychosis and depression sub-scales. Two main diagnostic groups were used; schizophrenia and related psychosis and affective disorders. Significance was tested using the Mann-Whitney U test. Higher scores on the BPRS thinking disturbance sub-scale were associated with a diagnostic classification of “psychosis” \((z = 3.77, p = 0.0002)\). This was not the case when the BASIS-32 psychosis sub-scale was compared between the two diagnostic groups \((z = 0.31, p = 0.75)\). There was a significant relationship between those patients with depression and high scores on the BPRS sub-scale for anxiety-depression \((z = 4.6, p = 0.000)\) and the BASIS-32 sub-scale for depression \((z = 3.56, p = 0.004)\).

### 7.1.2.4 Change over time

Looking at the simple direction of change from baseline to follow-up between the two scales may provide some information on how the scales inter-relate. For the 72 patients followed up, the change scores for the BASIS-32 and BPRS were calculated and subjects were divided into two groups; worse or same/better.

<table>
<thead>
<tr>
<th>BASIS-32</th>
<th>BPRS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Worse</td>
</tr>
<tr>
<td>Worse</td>
<td>33</td>
</tr>
<tr>
<td>Same/better</td>
<td>15</td>
</tr>
</tbody>
</table>

**Table 7.1.2** Dichotomised change scores between baseline and follow-up: number of subjects scoring worse or same/better on the BPRS and BASIS-32.
If the BPRS is taken as the “gold standard”, the BASIS-32 appears to under-estimate the number of patients worse at follow-up, but accurately predicts improvement as rated by the BPRS.

The correlation coefficient of the change scores of the BASIS-32 and BPRS from baseline to follow-up (taking an average of the follow-up scores where appropriate) for subjects followed-up at least once was 0.57 ($p<0.001$) (see figure 7.1.5).

**Figure 7.1.5** Scatterplot of change scores of BPRS and BASIS-32 between baseline and follow-up, with regression line.
7.2. Recruitment

The results of this study are reported in accordance with the CONSORT statement on reporting randomised controlled trials (Altman, 1996). The flow diagram below (figure 7.2.1) gives an outline of the attrition during the trial.

**Figure 7.2.1.** Flow diagram of recruitment and attrition.
7.2.1 Exclusions

One-hundred and sixty-two individuals were approached during the study but were not recruited. The reasons for non-recruitment are given below. Of these potential recruits 100 (62%) were male. There was no significant difference in gender between study entrants and those excluded (chi-square = 2.15, p=0.14). For ethical reasons, other data were not collected from individuals withholding consent.

<table>
<thead>
<tr>
<th>Reason for non-recruitment</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not meeting diagnosis criteria</td>
<td>53 (33%)</td>
</tr>
<tr>
<td>Refused consent</td>
<td>26 (16%)</td>
</tr>
<tr>
<td>General practitioner out of area</td>
<td>24 (15%)</td>
</tr>
<tr>
<td>Not registered with general practitioner</td>
<td>20 (12%)</td>
</tr>
<tr>
<td>Living out of study catchment area</td>
<td>18 (11%)</td>
</tr>
<tr>
<td>Transferred to other unit</td>
<td>8 (5%)</td>
</tr>
<tr>
<td>No hospital follow-up</td>
<td>7 (4%)</td>
</tr>
<tr>
<td>Other</td>
<td>6 (4%)</td>
</tr>
</tbody>
</table>

Table 7.2.1 Reasons for non-recruitment of 162 individuals discharged during the recruitment phase, but not enrolled to the study.

The most common reason for exclusion was because 53 potential subjects failed to meet the criteria for long-term mental illness, mainly because they did not meet the time constraints of the diagnosis. This group included; 21 (40%) patients with alcohol related problems and 11 (21%) with drug induced illness thought unlikely to result in long-term morbidity; six (11%) with brief psychotic episodes and two (4%) each with mild depression, dementia or no mental illness. The rest had no confirmed diagnosis or were not subject to follow-up by hospital services. The patients transferred to other units were moved to a rehabilitation facility (3), women-only unit (2), mother and baby unit (1), forensic unit (1) and an army hospital (1). Seven patients did meet the definition of long-term mental illness and
fell within the catchment area, but did not have follow-up arranged with the hospital. The reasons for this lack of follow-up were not explored. "Other" reasons included four patients who were identified as possible recruits, but were discharged before they could be recruited, and were not contactable at home, one who had a severe learning disability impairing consent and one who could not speak English.

7.2.2 Comparison of subjects with usual hospital in-patient population

In order to identify whether the study sample was representative of the population of the psychiatric unit as a whole, the demographic characteristics of subjects in the study were compared with all patients admitted to the psychiatric unit over a six-month period during recruitment to the study (January to July 1997). Data for the hospital population were provided by the unit's patient administration system. There were no significant differences in age, sex or diagnosis between the two groups.

<table>
<thead>
<tr>
<th></th>
<th>Hospital population</th>
<th>Study sample</th>
<th>Test</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n= 400</td>
<td>n=90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>number (%)</td>
<td>male</td>
<td>213 (53%)</td>
<td>47 (52%)</td>
<td>$\chi^2 = 0.03$</td>
</tr>
<tr>
<td></td>
<td>female</td>
<td>187 (47%)</td>
<td>43 (48%)</td>
<td></td>
</tr>
<tr>
<td>Diagnosis*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>number (%)</td>
<td>psychosis</td>
<td>139 (47%)</td>
<td>40 (44%)</td>
<td>$\chi^2 = 0.18$</td>
</tr>
<tr>
<td></td>
<td>non psychosis</td>
<td>157 (53%)</td>
<td>50 (56%)</td>
<td></td>
</tr>
<tr>
<td>Mean Age (SD)</td>
<td></td>
<td>36 (12.2)</td>
<td>38 (12.7)</td>
<td>$T = 1.04$</td>
</tr>
</tbody>
</table>

Table 7.2.2. Comparison of demographics and diagnoses of subjects recruited to the study and the whole population of the psychiatric unit over a six-month period. Diagnostic groups dichotomised to "psychotic" (schizophrenia and delusional disorder) and "non psychotic" (all other diagnoses). *Not all hospital population had an ICD-10 diagnosis recorded. Percentage for hospital population refers to the total with a diagnosis (n=296).
There were no significant differences between the study sample and hospital population for individual diagnostic groups (chi square = 5.95, df 7, p=0.65). The distribution of diagnoses for the two groups is shown in figure 7.2.2.

Figure 7.2.2. Diagnostic groups of patients recruited to the study compared with all those admitted to hospital over a six-month period during the study.
7.3. Characteristics of general practices

Subjects were allocated to the shared care or control group according to the general practice with which they were registered. All practices in the hospital’s catchment area (n=91) were randomly allocated to control or intervention status by computer-generated random numbers. A total of 216 general practitioners worked in these practices. The characteristics of the practices randomised are provided in table 7.3.1.

<table>
<thead>
<tr>
<th></th>
<th>Number of practices (n=91)</th>
<th>Number of general practitioners (n=216)</th>
<th>Mean (range) partners per practice</th>
<th>Number single handed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shared care</td>
<td>46</td>
<td>111</td>
<td>2.4 (1-7)</td>
<td>20</td>
</tr>
<tr>
<td>Standard care</td>
<td>45</td>
<td>105</td>
<td>2.3 (1-7)</td>
<td>17</td>
</tr>
</tbody>
</table>

Table 7.3.1 Practice characteristics. The number of partners in the practices randomised to shared care and standard care

By the end of the study, patients from 28 practices had been recruited. More patients were recruited to the shared care than the control group (Table 7.3.2).

<table>
<thead>
<tr>
<th></th>
<th>Practices randomised</th>
<th>Practices from which subjects recruited</th>
<th>Number of subjects</th>
<th>Mean (range) of subjects per practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shared care</td>
<td>46</td>
<td>15</td>
<td>55</td>
<td>3.7 (1-11)</td>
</tr>
<tr>
<td>Standard care</td>
<td>45</td>
<td>13</td>
<td>35</td>
<td>2.7 (1-12)</td>
</tr>
</tbody>
</table>

Table 7.3.2 Numbers of subjects recruited from practices in shared care and control limbs.
There was a tendency for subjects in shared care limb to come from larger multi-partner practices and for practices randomised to shared care to provide more subjects per practice (Table 7.3.3). These differences may partially explain the inequality of numbers recruited to shared and standard care limbs of the study.

<table>
<thead>
<tr>
<th>number of partners per practice</th>
<th>Mean (range) of GP partners per recruiting practice</th>
<th>Number of practices providing 3 or more subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shared care</td>
<td>5.9 (1-7)</td>
<td>9</td>
</tr>
<tr>
<td>Standard care</td>
<td>2.4 (1-7)</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 7.3.3 Characteristics of practices (n=28) from which subjects were recruited.
7.4. Characteristics of study sample

7.4.1 Demographic data of sample

Forty seven (52%) of the sample were men. The mean age of the sample was 38 (range 17-67, sd= 12.7). The age distribution is shown in figure 7.2.3. Sixty-nine (77%) subjects were white, most subjects were single and living alone. Further socio-demographic data are given in figures 7.4.1 to 7.4.5.

Figure 7.4.1 Histogram of subjects’ ages at entry into the study.
**Figure 7.4.2** Bar chart of ethnicity of subjects as recorded in hospital casenotes. Black includes individuals of African or Caribbean descent.

**Figure 7.4.3** Bar chart of marital status of subjects at entry to trial. Single = never married, married = married or cohabiting and separated = widowed, separated or divorced.
Figure 7.4.4 Occupation of subject at time of entry into the study.

Figure 74.5 primary diagnosis of subjects at entry as given in hospital case-notes. Other diagnoses include anxiety disorders (2) alcohol-related disorders (2) and eating disorder (1). The category “schizophrenia” includes two subjects with delusional disorder.
7.4.2 Baseline mental health

Thirty-three (37%) of the 90 subjects in the study had been admitted in the previous year to the hospitals' psychiatric unit (range 1-4 admissions). The mean BASIS-32 score for the whole sample was 1.24 (sd = 0.87). The mean BPRS score was 12.6 (sd = 6.7). Further details are given in the next section (effectiveness of randomisation).
7.5. Effectiveness of randomisation

Socio-demographic and baseline mental health parameters of subjects randomised to shared care were compared with controls. Socio-demographic characteristics are shown in table 7.5.1.

<table>
<thead>
<tr>
<th></th>
<th>Whole sample n=90</th>
<th>Shared care n=55</th>
<th>Standard care n=35</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (sd)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>47 (52%)</td>
<td>31 (56%)</td>
<td>16 (46%)</td>
</tr>
<tr>
<td>Female</td>
<td>43 (48%)</td>
<td>24 (44%)</td>
<td>19 (54%)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>78 (87%)</td>
<td>49 (89%)</td>
<td>27 (77%)</td>
</tr>
<tr>
<td>Non-white</td>
<td>12 (13%)</td>
<td>6 (11%)</td>
<td>6 (23%)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychosis</td>
<td>40 (44%)</td>
<td>24 (44%)</td>
<td>16 (46%)</td>
</tr>
<tr>
<td>Other</td>
<td>50 (56%)</td>
<td>31 (56%)</td>
<td>19 (54%)</td>
</tr>
<tr>
<td>Social status*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alone</td>
<td>55 (61%)</td>
<td>36 (65%)</td>
<td>19 (54%)</td>
</tr>
<tr>
<td>M/H</td>
<td>15 (17%)</td>
<td>9 (16%)</td>
<td>6 (17%)</td>
</tr>
<tr>
<td>S/W/D</td>
<td>17 (19%)</td>
<td>9 (16%)</td>
<td>8 (23%)</td>
</tr>
</tbody>
</table>

Table 7.5.1 comparing socio-demographic characteristics of subjects' randomised to shared care and standard care. Diagnosis dichotomised to psychosis (schizophrenia and other non-affective psychoses) and non psychosis (other diagnoses) and ethnicity dichotomised to white/non-white. M/H = married/cohabiting, S/W/D = separated/widowed/divorced. * 3 subjects unclassified

Baseline scores of mental health (BASIS-32, BPRS), satisfaction (CSQ) and inpatient admissions in the year prior to entry for the shared care and control groups are shown in table 7.5.2. Baseline sub-scale scores for the BASIS-32 and BPRS for the two groups are shown in tables 7.5.3 and 7.5.4 respectively.
<table>
<thead>
<tr>
<th>Baseline measure</th>
<th>Whole sample n=90</th>
<th>Shared care n=55</th>
<th>Standard care n=35</th>
</tr>
</thead>
<tbody>
<tr>
<td>BASIS-32 mean (sd)</td>
<td>1.24 (0.87)</td>
<td>1.21 (0.88)</td>
<td>1.27 (0.86)</td>
</tr>
<tr>
<td>BPRS mean (sd)</td>
<td>12.57 (6.72)</td>
<td>12.61 (7.02)</td>
<td>12.49 (6.32)</td>
</tr>
<tr>
<td>CSQ mean (sd)</td>
<td>22.18 (4.82)</td>
<td>22.18 (4.83)</td>
<td>22.17 (4.87)</td>
</tr>
<tr>
<td>Inpatient admissions</td>
<td>0</td>
<td>57</td>
<td>35 (64%)</td>
</tr>
<tr>
<td></td>
<td>1+</td>
<td>33</td>
<td>20 (36%)</td>
</tr>
</tbody>
</table>

Table 7.5.2 Comparison of inpatient admissions in year prior to entry and baseline mental health and satisfaction between subjects allocated to shared care and standard care.

<table>
<thead>
<tr>
<th>Sub-scale:</th>
<th>Whole sample n=90</th>
<th>Shared care n=55</th>
<th>Standard care n=35</th>
</tr>
</thead>
<tbody>
<tr>
<td>depression</td>
<td>1.74 (1.22)</td>
<td>1.68 (1.3)</td>
<td>1.84 (1.11)</td>
</tr>
<tr>
<td>impulsive behaviour</td>
<td>0.61 (0.76)</td>
<td>0.58 (0.78)</td>
<td>0.65 (0.74)</td>
</tr>
<tr>
<td>living skills</td>
<td>1.60 (1.11)</td>
<td>1.58 (1.10)</td>
<td>1.62 (1.26)</td>
</tr>
<tr>
<td>psychosis</td>
<td>0.78 (0.89)</td>
<td>0.77 (0.93)</td>
<td>0.81 (0.84)</td>
</tr>
<tr>
<td>relationship to others</td>
<td>1.46 (1.11)</td>
<td>1.47 (1.12)</td>
<td>1.45 (1.11)</td>
</tr>
</tbody>
</table>

Table 7.5.3 Baseline mean (sd) BASIS-32 sub-scale scores.

<table>
<thead>
<tr>
<th>Sub-scale:</th>
<th>Whole sample n=90</th>
<th>Shared care n=55</th>
<th>Standard care n=35</th>
</tr>
</thead>
<tbody>
<tr>
<td>anxiety depression</td>
<td>4.5 (3.2)</td>
<td>4.5 (3.2)</td>
<td>4.7 (3.3)</td>
</tr>
<tr>
<td>hostility/suspiciousness</td>
<td>0.5 (1.3)</td>
<td>0.4 (1.0)</td>
<td>0.7 (1.8)</td>
</tr>
<tr>
<td>withdrawal/retardation</td>
<td>2.2 (2.9)</td>
<td>2.6 (3.2)</td>
<td>1.5 (2.1)</td>
</tr>
<tr>
<td>thinking disturbance</td>
<td>1.8 (2.6)</td>
<td>1.8 (2.6)</td>
<td>1.8 (2.5)</td>
</tr>
</tbody>
</table>

Table 7.5.4 Baseline mean (sd) BPRS sub-scale scores.
7.6. Follow-up rates

7.6.1 Follow-up intervals

Seventy-four patients (82%) were followed up at least once during the study. The median times to follow-up are given in table 7.6.1.

<table>
<thead>
<tr>
<th>Follow-up point</th>
<th>Number (% successfully followed-up (n=90))</th>
<th>median interval in months from recruitment date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim</td>
<td>50 (55%)</td>
<td>6</td>
</tr>
<tr>
<td>Final</td>
<td>62 (68%)</td>
<td>12</td>
</tr>
</tbody>
</table>

Table 7.6.1 Number of subjects followed up at each time-point (intended to be six months and one year after recruitment) and median interval between recruitment and follow-up.

7.6.2 Comparison of subjects according to success at follow-up.

Of the 16 subjects not followed up at either time-point, 6 refused contact with the study personnel, 5 moved out of London, 3 were untraceable and two died. There are four groups of patients defined by their follow-up status; followed up twice, once at first follow-up, once at the second and not followed-up at all. There were no significant differences in demographic and baseline mental health and satisfaction parameters between subjects with different follow-up status (table 7.6.2 and 7.6.3).
Table 7.6.2 baseline demographics of subjects according to follow-up success. Follow-up point 1 is interim (six-month) follow-up, point 2 is final (1 year) follow-up. Diagnosis dichotomised to “psychosis” (schizophrenia and related disorders) and “non-psychosis” (affective disorders, anxiety, eating disorders and personality disorder) Significance levels: for sex, diagnosis, ethnicity and randomisation status determined by chi square test for linear trend (comparing those followed up twice, once or never); for age by one-way analysis of variance f (3,86)

<table>
<thead>
<tr>
<th>Follow-up successful at point:</th>
<th>Test result</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 and 2 n=38</td>
<td>2 only n=25</td>
<td>1 only n=11</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>22</td>
<td>9</td>
</tr>
<tr>
<td>female</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>psychosis</td>
<td>19</td>
<td>11</td>
</tr>
<tr>
<td>non psychosis</td>
<td>19</td>
<td>14</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>white</td>
<td>33</td>
<td>16</td>
</tr>
<tr>
<td>non white</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>shared care</td>
<td>22</td>
<td>17</td>
</tr>
<tr>
<td>standard</td>
<td>16</td>
<td>8</td>
</tr>
<tr>
<td>Age mean (sd)</td>
<td>40.4 (12.8)</td>
<td>39.8 (13.9)</td>
</tr>
</tbody>
</table>

Table 7.6.3 Baseline mental health and satisfaction measures for subjects according to success at follow-up. Significance levels: for categorical variables determined by chi square test for linear trend (comparing those followed up twice, once or never); for continuous variables by one-way analysis of variance.

<table>
<thead>
<tr>
<th>Follow-up successful at point:</th>
<th>Test result</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 and 2 n=38</td>
<td>2 only n=25</td>
<td>1 only n=11</td>
</tr>
<tr>
<td>BASIS-32</td>
<td>1.16 (0.86)</td>
<td>1.14 (0.87)</td>
</tr>
<tr>
<td>BPRS mean (sd)</td>
<td>11.7 (6.02)</td>
<td>13.2 (8.19)</td>
</tr>
<tr>
<td>CSQ mean (sd)</td>
<td>22.7 (4.76)</td>
<td>22.2 (4.86)</td>
</tr>
<tr>
<td>Admissions (year before entry)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>17</td>
<td>10</td>
</tr>
<tr>
<td>No</td>
<td>21</td>
<td>15</td>
</tr>
</tbody>
</table>
Patients lost to clinical follow-up may be missing at random, or may differ from those who were followed-up in terms of their mental state. This is relevant from the point of dealing with the missing data in subsequent analysis, but difficult to do because they are, de facto missing. Proxy measures for mental health status are admission rates and clinic attendance. Patients lost to follow-up were no more likely to be admitted during the study, but were significantly less likely to attend outpatient clinics (see table 7.6.4).

<table>
<thead>
<tr>
<th></th>
<th>Followed up</th>
<th>test</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>yes</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Inpatient admissions</td>
<td>None</td>
<td>37</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>1+</td>
<td>37</td>
<td>8</td>
</tr>
<tr>
<td>Clinic attendance</td>
<td>None</td>
<td>18</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>1+</td>
<td>56</td>
<td>7</td>
</tr>
<tr>
<td>Inpatient days mean</td>
<td>26.2</td>
<td>14.5</td>
<td>$Z = -0.49$</td>
</tr>
</tbody>
</table>

Table 7.6.4. Differences in service use in subjects successfully followed up at least once compared with those lost to follow-up. Significance of categorical variables tested by chi-square, and continuous variables by Mann-Whitney U test.
7.7 Changes in service during the study period

Several events occurred that may have had an impact on the study, but were beyond the control of the study. This included the retirement of two consultants, the presence of locum consultants pending substantive appointments, and several changes of other mental health personnel. Some patients also changed general practitioner, two moving to practices randomised to the other limb of the trial. These patients did not have their treatment allocation changed and were analysed in the groups to which they were first allocated. Although these changes are likely to be random across groups, unbalanced differences may introduce bias. There were no between-group differences in change of general practitioner but there was a trend for those in the shared care limb to be more likely to have a change of consultant (relative risk 1.34, 95% C.I. 0.97, 1.84) (table 7.7.1).

<table>
<thead>
<tr>
<th>Change of general practitioner</th>
<th>Shared care</th>
<th>Standard care</th>
<th>Chi-square</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>7</td>
<td>6</td>
<td>0.34</td>
<td>0.56</td>
</tr>
<tr>
<td>No</td>
<td>48</td>
<td>29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change of consultant</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>24</td>
<td>9</td>
<td>2.96</td>
<td>0.08</td>
</tr>
<tr>
<td>No</td>
<td>31</td>
<td>26</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 7.7.1 Changes in general practitioner and consultant during the study period comparing subjects allocated to shared care or standard care.
7.8. Comparison of shared care and standard care

7.8.1 Adverse events

Two subjects, both from the shared care limb, died during the study. One died of cancer, one from suicide by hanging. The suicide occurred soon after discharge and was unforeseen. No other adverse events were reported during the study.

7.8.2 Service use.

Data on hospitalisations and clinic attendance for the period of the trial were available on all 90 subjects.

7.8.2.1 Admissions to hospital

Forty-five subjects (50%) were admitted during the year of participation in the study, compared with 33 (37%) in the previous year. The distribution of frequency of admissions in the shared care and standard care groups are shown in figure 7.8.1, and the number of inpatient days in figure 7.8.2.

Figure 7.8.1 Bar chart of admissions in year after entry to study, comparing shared and standard care.
During the study, patients in the shared care limb were equally likely as controls to be admitted to hospital (RR 1.2, 95% CI 0.86, 1.67), or attend an outpatient appointment (RR 0.96, 95% CI 0.67, 1.36). The number of in-patient days was similar between groups (Mann-Whitney U test $z=0.96$, $p=0.33$). Subjects with psychotic illness were more likely to be admitted. Twenty-eight of the 40 (70%) subjects with schizophrenia and non-affective psychoses were admitted during the study compared with 17 of 50 (34%) patients with other diagnostic categories (chi-square 11.5, $p<0.001$). The number of inpatient days was also greater in those with psychosis (mean = 41 days compared with 11 days, Mann-Whitney U test $Z=-3.7$, $p<0.001$). Details of numbers of subjects admitted and inpatient days between shared care and standard care are shown below (table 7.8.1).
The proportion of patients admitted in the shared care group increased from 35% in the year before the study to 55% during the study, compared with an increase from 37% to 43% in the control group (chi square 0.3, d.f=3, p=0.58). Seventeen of the 24 patients in the shared care group (70%) who experienced a change of consultant during the study were admitted, compared with 13 of the 31 (41%) who kept their consultant (relative risk 1.69, 95% CI 1.04, 2.75, chi square 4.6, p=0.03). The numbers of patients admitted during the study compared with their admission status in the preceding year is shown in table 7.8.2.

<table>
<thead>
<tr>
<th>Admission status before study</th>
<th>Number (%) admitted during study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shared care (n=55) admitted</td>
<td>20 (65%)</td>
</tr>
<tr>
<td>not admitted</td>
<td>35 (49%)</td>
</tr>
<tr>
<td>Standard care (n=35) admitted</td>
<td>13 (46%)</td>
</tr>
<tr>
<td>not admitted</td>
<td>22 (41%)</td>
</tr>
</tbody>
</table>

Table 7.8.2 admission status of subjects during the year of the study compared with admission status in the previous year.
The rate of admissions in those subjects followed-up who reported using their records was compared with the admissions in the control group, and those in the shared care limb who did not report record use (table 7.8.3).

<table>
<thead>
<tr>
<th></th>
<th>Admitted</th>
<th>$\chi^2$</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>yes</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Shared care record used (n=24)</td>
<td>11 (46%)</td>
<td>13 (54%)</td>
<td>1.16</td>
</tr>
<tr>
<td>Shared care record not used (n=21)</td>
<td>13 (62%)</td>
<td>8 (38%)</td>
<td></td>
</tr>
<tr>
<td>Shared care record used (n=24)</td>
<td>11 (46%)</td>
<td>13 (54%)</td>
<td>0.05</td>
</tr>
<tr>
<td>Control (n=35)</td>
<td>15 (43%)</td>
<td>20 (57%)</td>
<td></td>
</tr>
</tbody>
</table>

Table 7.8.3 number of subjects admitted during the study period, comparing shared care record users with non-users in the shared care limb, and with the control group.

Factors that may predict admission during the study period were explored using logistic regression with the following covariates: age, gender, ethnicity, baseline BPRS scores, diagnosis (dichotomised to psychosis/non psychosis), change of consultant, change of general practitioner, admission in the year prior to the study and allocation to shared care or standard care. Two covariates emerged as significant. Admission was more common in patients with psychotic illness (OR 5.2, 95% CI 1.9, 14.1) and non-white patients (OR 4.1, 95% CI 1.2, 14.2). Treatment allocation (shared or standard care) was not a significant predictor of subsequent admissions (OR 1.5, 95% CI 0.5, 4.0).

7.8.2.2. Outpatient attendance

Seventy-six of the 90 patients (84%) recruited to the study had outpatient appointments during the year of follow-up, 47 (85%) in shared care and 29 (83%) in the control group. The distribution of clinic attendance and defaults is shown in figures 7.8.3 and 7.8.4.
Figure 7.8.3 Number of outpatient clinic appointments attended during the year of study, comparing shared and standard care.

Figure 7.8.4 Comparison of shared care and standard care: number of outpatient clinic appointments defaulted during the study.
The number of subjects attending outpatients and the number of outpatient clinic visits did not differ significantly between groups (table 7.8.4).

<table>
<thead>
<tr>
<th></th>
<th>Shared care (n=55)</th>
<th>Standard care (n=35)</th>
<th>Significance test</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>number (%) attending clinic</td>
<td>38 (69%)</td>
<td>25 (71%)</td>
<td>χ² = 0.06</td>
<td>0.81</td>
</tr>
<tr>
<td>median (range) clinic visits</td>
<td>1.50 (0-17)</td>
<td>1.46 (0-7)</td>
<td>z = 0.48</td>
<td>0.63</td>
</tr>
<tr>
<td>median (range) clinic defaults</td>
<td>0.94 (0-6)</td>
<td>0.90 (0-6)</td>
<td>z = 0.27</td>
<td>0.79</td>
</tr>
</tbody>
</table>

Table 7.8.4 Outpatient clinic attendance and default rates. Grouped median of visits and defaults. Significance of non-normally distributed continuous data tested by Mann-Whitney U test.

Predictors of outpatient attendance and defaults were explored by logistic regression using the co-variates: age, gender, ethnicity, baseline BPRS scores, diagnosis (dichotomised to psychosis/non psychosis), change of consultant, admission in the year prior to the study and allocation to shared care or standard care. No factor was significantly associated with clinic attendance. However, younger age (p=0.02) and experiencing a change of consultant (p=0.05) emerged as predictors of clinic defaults.

7.8.3 Mental health status

7.8.3.1 Changes in BASIS-32 and BPRS

The results of the BASIS-32 and BPRS scores for baseline and both follow-up points for the shared care and control groups are shown in the box and whisker plots below (figure 7.8.5, 7.8.6). The plots show a trend for individuals, especially in the shared care group, to become worse over time, although the changes observed are small.
Figure 7.8.5 Box and whisker plots of baseline, six-month and one year follow-up results of BASIS-32. The central band is the median score, the box represents the inter-quartile range and the horizontal lines at the extremes represent the limits of scores (excluding outliers).

Figure 7.8.6 Box and whisker plots of baseline, six-month and one year follow-up results of the BPRS. The central band is the median score, the box represents the inter-quartile range and the horizontal lines at the extremes represent the limits of scores (excluding outliers). Outliers are shown as small circles outside the whiskers.
7.8.3.2 Individuals' changes from baseline.

Changes in the BASIS-32 and BPRS scores from baseline to follow-up were calculated for those subjects followed up at least once (n=71). Thirty-five subjects (49%) had unchanged or better BASIS-32 scores, 23 (32%) had unchanged or better BPRS scores at follow-up. The range of the change scores is shown in figures 7.8.7 and 7.8.8.

Figure 7.8.7 Changes in BASIS-32 from baseline to follow up for those followed up at least once (n=74). Mean values are calculated in subjects followed up twice. Those above the index line have improved over time, those below have deteriorated.
Figure 7.8.8 Changes in BPRS from baseline to follow up for those followed up at least once \((n=74)\). Those above the index line have improved over time, those below have deteriorated.

Seventy-four \((82\%)\) patients were followed up at least once, and 38 subjects \((42\%)\) were followed up at both time points. The missing data may be dealt with in different ways.

1. Analysis of subjects with complete data \((n=38)\). The disadvantage of this approach is that completers are no longer random, when compared to all controls. Furthermore, small numbers result with consequent loss of power and increased risk of type II error.

2. Average of any data for those subjects followed up at least once \((n=74)\)

3. Last observation carried forward (LOCF) (including baseline) \((n=90)\)
Where follow-up data are available at 1 year, these data are used in the LOCF analysis. If these data are absent, but data from six-months is present these are used. If data from both follow-up periods are missing, the baseline data are carried forward.

The mean results of the BASIS-32, BPRS and CSQ for the three follow-up time points, and the results of these three different approaches to the follow-up data are reported in tables 7.8.5 and 7.8.6.

<table>
<thead>
<tr>
<th></th>
<th>( T_0 ) n=90</th>
<th>( T_1 ) n=49</th>
<th>( T_2 ) n=62</th>
<th>Completers n=38</th>
<th>Mean ( t_1/t_2 ) N=76</th>
<th>LOCF n=90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shared care</td>
<td>1.21 (0.88)</td>
<td>1.22 (0.84)</td>
<td>1.24 (0.9)</td>
<td>1.20 (0.88)</td>
<td>1.25 (0.78)</td>
<td>1.27 (0.81)</td>
</tr>
<tr>
<td>Standard care</td>
<td>1.27 (0.86)</td>
<td>1.23 (0.77)</td>
<td>1.21 (0.91)</td>
<td>1.21 (0.70)</td>
<td>1.23 (0.86)</td>
<td>1.20 (0.82)</td>
</tr>
</tbody>
</table>

**Table 7.8.5** Mean (sd) BASIS-32 scores at baseline \((T_0)\) and both follow-up points \((T_1, T_2)\). Mean results for those followed-up at both time intervals (completers), at least one time interval (mean \(T_1/T_2\)) and all subjects (LOCF) are also given.

<table>
<thead>
<tr>
<th></th>
<th>( T_0 ) n=90</th>
<th>( T_1 ) n=49</th>
<th>( T_2 ) n=62</th>
<th>Completers n=38</th>
<th>Mean ( t_1/t_2 ) N=76</th>
<th>LOCF n=90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shared care</td>
<td>12.6 (7.0)</td>
<td>15.8 (8.8)</td>
<td>18.4 (13.1)</td>
<td>17.5 (10.4)</td>
<td>17.4 (10.3)</td>
<td>16.9 (9.8)</td>
</tr>
<tr>
<td>Standard care</td>
<td>12.5 (6.3)</td>
<td>12.9 (7.5)</td>
<td>15.0 (10.1)</td>
<td>13.1 (6.9)</td>
<td>14.6 (8.8)</td>
<td>13.8 (8.6)</td>
</tr>
</tbody>
</table>

**Table 7.8.6** Mean (sd) BPRS scores at baseline \((T_0)\) and both follow-up points \((T_1, T_2)\). Mean results for those followed-up at both time intervals (completers), at least one time interval (mean \(T_1/T_2\)) and all subjects (LOCF) are also given.
7.8.3.3 Data imputation

Analysis of incomplete data sets using last observation carried forward is usually the most conservative statistical approach. For example, in drug trials, individuals tend to improve over time, so bringing forward a baseline score is likely to underestimate the effect size. However, in this study the trend was for subjects to get worse after discharge (see boxplots), therefore LOCF is likely to overestimate the effect size, particularly since the two groups (shared care and standard care) have trends in different directions. The results were analysed using analysis of covariance with the randomisation status as a fixed variable and the relevant baseline result as a co-factor. Using the baseline as a covariate will reduce the impact of between-practice differences given the practice is the unit of randomisation. In order to determine whether significant differences emerged according to the method of analysis, all follow-up data were analysed using both LOCF and averaged results of those followed up (see tables 7.8.7 below). No differences in significance of the test results were noted using these different methods of analysis.

<table>
<thead>
<tr>
<th>Followed up at least once (n=74)</th>
<th>LOCF (n=90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (sd)</td>
<td>f</td>
</tr>
<tr>
<td>Shared</td>
<td>standard</td>
</tr>
<tr>
<td>BASIS</td>
<td>1.25 (0.78)</td>
</tr>
<tr>
<td>BPRS</td>
<td>17.4 (10.3)</td>
</tr>
</tbody>
</table>

Table 7.8.7 Comparing mean (sd) follow-up scores (n=74) and last observation carried forward (n=90) using analysis of covariance with the randomisation status as a fixed variable and the relevant baseline result as a co-variate.
Analysis of completers

A further method of dealing with missing data is to exclude those subjects who do not have a complete data set. The comparison of subjects in shared and standard care who were followed up at both time points is shown in table 7.8.8.

<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>Shared care (n=22)</th>
<th>Standard care (n=16)</th>
<th>f</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>BASIS-32</td>
<td>1.20 (0.88)</td>
<td>1.21 (0.70)</td>
<td>0.332</td>
<td>0.57</td>
</tr>
<tr>
<td>BPRS</td>
<td>17.5 (10.3)</td>
<td>13.6 (6.9)</td>
<td>2.430</td>
<td>0.13</td>
</tr>
</tbody>
</table>

Table 7.8.8 Comparing mean (sd) follow-up results of completers (n=38) using analysis of covariance with the randomisation status as a fixed variable and the relevant baseline result as a co-variate.

7.8.3.4. Absolute risk reduction and effect size.

An approach to data presentation fostered by evidence-based medicine is to provide results that allow calculation of a clinically meaningful treatment effect, such as the number needed to treat. In order to do this, categorical data must used. Neither the BASIS-32 or the BPRS have case-defining cut-off scores. However, an alternative approach commonly used with the BPRS is to look at those subjects who had a 30% or greater improvement in the scores from baseline, using the mean follow-up scores (n=74).
<table>
<thead>
<tr>
<th></th>
<th>Shared care</th>
<th>Standard care</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved*</td>
<td>6</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Not better</td>
<td>39</td>
<td>22</td>
<td>61</td>
</tr>
<tr>
<td>Total</td>
<td>45</td>
<td>28</td>
<td>73</td>
</tr>
</tbody>
</table>

Table 7.8.9 subjects improving as defined by a 30% or greater improvement in the BPRS score from baseline. (chi square 0.824, p=0.36).

The control event rate (CER) (i.e. proportion of the control group improving by 30%) is 0.21 and the experimental event rate (EER) is 0.13. Thus, the absolute risk reduction is 0.21 - 0.13 = 0.08 (in favour of the control group). The confidence intervals for this are given by:

$$ARR \ = \ 0.08 \ \pm \ 1.96 \times \sqrt{\left(\frac{CER \times (1-CER)}{n(control)}\right) + \left(\frac{EER \times (1-EER)}{n(experimental)}\right)}$$

ie the ARR is 0.08 with 95% confidence intervals of 0.26, -0.10

The NNT is the number of patients who have to be given an intervention, rather than standard treatment (or placebo) in order for one additional person to achieve a defined outcome and is the reciprocal of the absolute risk reduction. In this case the NNT favours the control group and should be considered as a number needed to harm (NNH). The NNH is 13 (95% Confidence intervals = 4 to -10). Therefore there appears to be a non-significant trend to a worse outcome in those given shared care records.
7.8.3.5 Practice-based analysis

Between practice differences at baseline

In any trial with cluster randomisation, cluster effects may affect results. Cluster effects may arise because demographic and clinical characteristics of patients are not similar across all participating practices. For example, some practices may attract a larger number of patients with severe mental illness if the partners in those practices are particularly skilled and understanding about the needs of this patient group.

In order to assess whether there was any cluster effect within practices, between-group and within-group differences in demographic variables and baseline satisfaction, BASIS-32 and BPRS scores were compared. Between practice demographic differences were tested by one-way analysis of variance. There were no significant differences between practices with respect to patients' gender, age, ethnicity or diagnostic grouping. Between practice differences in baseline scores were compared by analysis of variance weighted for numbers of subjects per practice. There were significant differences between practices in baseline mental health and satisfaction measures (table 7.8.10), but not the number of admissions in the year prior to entry to the study. (Kruskal Wallis Chi square 28.5, d.f =27, p=0.38).
Table 7.8.10 Baseline admission data and scores of BASIS-32, BPRS and CSQ-differences between practices determined by general linear model one-way analysis of variance weighted for numbers of subjects per practice (d.f 27,62).

<table>
<thead>
<tr>
<th>BASIS-32</th>
<th>Combined practice mean (sd) (n=28)</th>
<th>Difference between practices (f)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.3 (0.8)</td>
<td>1.91</td>
<td>0.02</td>
</tr>
<tr>
<td>BPRS</td>
<td>13.2 (6.5)</td>
<td>1.61</td>
<td>0.06</td>
</tr>
<tr>
<td>CSQ</td>
<td>21.8 (4.6)</td>
<td>1.73</td>
<td>0.04</td>
</tr>
</tbody>
</table>

**Intracluster correlation coefficient**

The intra cluster correlation coefficient was calculated for baseline values for those practices with more than one recruit (n=17) using the formula:

\[
\rho_{\text{int.}} = \frac{\sigma^2_{\text{between}}}{\sigma^2_{\text{between}}+\sigma^2_{\text{within}}}
\]

where \( \rho_{\text{int.}} \) is the intra cluster correlation, \( \sigma^2 \) between is the between cluster variance and \( \sigma^2 \) within is the within cluster variance (Machin *et al* 1997).

The intracluster correlation coefficient for baseline values for the BASIS-32 was 0.24 and for the BPRS was 0.30. This can be used to calculate the "inflation" needed to correct sample size estimates. This is given by the equation:

\[
1 + (np - 1)\rho_{\text{int}}
\]

Where np is the mean number of patients per practice and \( \rho_{\text{int}} \) is the ICC. Given the mean number of patients per practice in this study was 3.2, the inflation factor is 168.
1.53. In other words, given the *a priori* power calculation based on the BASIS-32 suggested a sample size of 66, using the ICC for the BASIS-32 the sample size should be increased to 101.

*Analysis of practice averages at follow-up*

Given there are some significant baseline differences between practices, analysis of the main findings was repeated using the practice as the unit of analysis, weighted for number of subjects per practice. There were no significant differences in admissions or days spent in hospital, when practices were compared (table 7.8.11).

<table>
<thead>
<tr>
<th></th>
<th>Shared care (n=15)</th>
<th>Standard care (n=13)</th>
<th>z</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median (range) admissions</td>
<td>0.8 (0-3)</td>
<td>0.4 (0-4)</td>
<td>-1.4</td>
<td>0.2</td>
</tr>
<tr>
<td>Median (range) admission days</td>
<td>17 (0-120)</td>
<td>13 (0-92)</td>
<td>-0.5</td>
<td>0.6</td>
</tr>
<tr>
<td>Median (range) clinic attendance</td>
<td>1.8 (0-17)</td>
<td>1.7 (0-4)</td>
<td>-0.3</td>
<td>0.8</td>
</tr>
<tr>
<td>Median (range) clinic default</td>
<td>1.1 (0-5)</td>
<td>1.5 (0-6)</td>
<td>-0.35</td>
<td>0.7</td>
</tr>
</tbody>
</table>

*Table 7.8.11* comparison of mean admission rates and number of days admitted for practices. Significance tested by Mann Whitney-U test.

Practice means for the BASIS-32 and BPRS are shown in table 7.8.12. Both BPRS and BASIS-32 scores were approximately normally distributed. Note the differences in practice means compared with means of individual subject scores (see table 7.8.5 and 7.8.6).
Table 7.8.12 Practice-based values. Minimum, maximum and mean (sd) Follow-up scores of BASIS-32 and BPRS for patients within practices randomised to shared care and standard care. Last observation carried forward.

The practice means of the BPRS and BASIS-32 follow-up results were compared using analysis of covariance weighted for numbers per practice, with relevant baseline score as co-variate. Analysis of the weighted practice averages of the BASIS-32 and BPRS follow-up scores showed that the baseline BASIS-32 and BPRS scores were significant predictors of follow-up results, but practice allocation and treatment allocation had no significant effect on outcome (table 7.8.13). Although significant between-practice differences in baseline scores were found in this study, practice allocation *per se* did not appear to affect the results.

Table 7.8.13 Analysis of practice averages of BASIS-32 and BPRS (LOCF) for practices allocated to shared care (n=16) and standard care (n=13). Weighted general linear ANCOVA, assessing main effects of relevant baseline score, practice allocation and treatment allocation.

7.8.4 Changes of clinician and outcome

The impact of changes of consultant and general practitioner on service use and mental health outcome was explored. Twenty-five (76%) of the 33 subjects who experienced a change of consultant defaulted from clinic appointments, compared
with 31 (54%) of the 57 subjects who kept their consultant throughout (relative risk
1.9 95% C.I. 0.97, 3.72. chi square 4.06, df=1, p=0.04). There was a trend for
subjects who changed consultant to have more outpatient clinic visits and
admissions to hospital. Twenty (61%) subjects who changed consultant were
admitted compared with 25 (44%) of subjects who kept their consultant (RR 1.54,
95% C.I. 0.88, 2.70. chi square 2.3, df=1, p = 0.1). Twenty-seven (81%) of those
who changed consultant attended outpatient clinics compared with 36 (63%) of
those who did not (RR 1.93, 95% C.I. 0.9, 4.13. Chi square 3.46 p = 0.06). Changes
of general practitioner did not affect clinic usage or admission rates. There were no
significant differences in BASIS-32 or BPRS scores between those who changed
consultant or general practitioner and those who did not.

**7.8.5 Satisfaction**

Baseline satisfaction with the service as measured using the CSQ was moderate,
with an overall mean 22.2 (sd = 4.8). Predictors of satisfaction were assessed using
general linear model ANOVA. Diagnosis, sex, ethnicity, an admission in the
preceding year and baseline BASIS-32 and BPRS scores were not related to levels
of satisfaction, although older subjects were more likely to be satisfied (f=7.71, df,
1, 87 p = 0.007)

Small changes in satisfaction with the mental health services were noted over the
study period. Baseline satisfaction did not predict subsequent drop-out from the
study (Mann-Whitney-U Z = -0.6, p=0.55)
The mean baseline and follow-up scores for the CSQ are shown in table 7.8.14. There was no significant difference in service satisfaction at follow-up between the intervention and control groups (baseline score as co-variate $f=0.79$ $p=0.37$). No differences emerged when analysis was restricted to subjects who completed both follow-up questionnaires. Experiencing a change in consultant or general practitioner did not affect satisfaction.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>T1 (n=90)</th>
<th>T2 (n=49)</th>
<th>T3 (n=62)</th>
<th>Completers (n=38)</th>
<th>Mean t2/t3 (N=76)</th>
<th>LOCF (N=90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shared care</td>
<td>22.2 (4.8)</td>
<td>21.4 (6.5)</td>
<td>23.1 (7.0)</td>
<td>22.6 (5.6)</td>
<td>22.4 (6.7)</td>
<td>22.3 (6.5)</td>
</tr>
<tr>
<td>Standard care</td>
<td>22.2 (4.9)</td>
<td>23.5 (5.0)</td>
<td>23.7 (5.0)</td>
<td>23.1 (4.1)</td>
<td>23.9 (3.9)</td>
<td>23.2 (4.4)</td>
</tr>
</tbody>
</table>

**Table 7.8.14** Mean (sd) CSQ scores at baseline (T1) and both follow-up points (T2, T3). Mean results for those followed-up at both time intervals (completers), at least one time interval (mean t2/t3) and all subjects (LOCF) are also given.
7.9. Use of shared care records

7.9.1 Subjects' use of records

Twenty-four (44%) of the 55 individuals given a shared care record said they had used it. Twelve of these records were retrieved at the end of the study.

Reported record use

During the course of the study no records were returned to the investigator after being lost. Data on all reported contacts with professionals and record use (in the shared care group) were collected at six months and one year. Forty-three of the 46 subjects randomised to shared care limb who were followed up clinically reported seeing at least one professional (general practitioner, hospital doctor, social worker or community psychiatric nurse) by the end of the study compared with 27 of the 28 control subjects followed up. However, reported use of the record was uncommon (table 7.9.1).

<table>
<thead>
<tr>
<th>Professional group</th>
<th>Number of subjects reporting seeing professional</th>
<th>Number in shared care reporting use of record by professional</th>
</tr>
</thead>
<tbody>
<tr>
<td>General practitioner</td>
<td>20 (Standard care n=35) 30 (Shared care n=55)</td>
<td>7</td>
</tr>
<tr>
<td>Hospital doctor</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>Social worker</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>Community nurse</td>
<td>15</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 7.9.1. Professionals seen by subjects during the study period, and use of the shared care record by professionals as reported by the subjects in shared care.
**Recorded use of records**

Of the 12 records retrieved at the end of the study, the 11 records returned by individuals who designated themselves as "record users" had been used by professionals at least once. The number of entries in the records varied from two to eight (median = 4). Further details of record use are given in table 7.9.2.

<table>
<thead>
<tr>
<th>Professional group</th>
<th>Number of records used</th>
<th>Total number of entries for all retrieved records (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital doctor</td>
<td>9</td>
<td>19</td>
</tr>
<tr>
<td>General practitioner</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Social worker</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Community nurse</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Unidentified user</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Appointments section</td>
<td>6</td>
<td>26</td>
</tr>
</tbody>
</table>

**Table 7.9.2.** Use of shared care records; number of records used and total number of entries for each professional group, and appointment section.

**7.9.2 Professionals report of record use**

At the end of the study, details of record use were sought from all professionals who had patients allocated to the shared care limb of the study. Thirty-three of the 51 questionnaires (65%) were returned. Fourteen professionals reported remembering having seen a record during the study (5 general practitioners, 3 consultants, 2 community nurses and 4 social workers). Eight professionals recalled having records volunteered by the patient and 5 professionals reported asking the patient for the record. Nine reported writing in a shared care record (3 general
practitioners, 1 consultant, 3 social workers and 2 community nurses). Seven of the fourteen respondents who saw a record felt this was helpful.

*Examples of shared care record use*

An example of record use facilitating inter-agency communication is shown in this series of entries about medication-associated weight gain:

13/8/97 *Community nurse*

*Went to Highgate cemetery with [patient]- to spend time at friend’s grave. Had been problems before in finding grave.*

*Medication remains the same, but needs to be reviewed re concerns about weight gain.*

20/8/97 *Visit to GP* documented in record, but no text.

9/9/97 *Community nurse*

*Has had physical problems recently. Mood appears to be low at present. Focused on cognitive aspects of feelings around illness.*

*Carbamazepine has been reduced by G.P. from 400 b.d. to 200 b.d.*
Other examples of record use included this series of entries highlighting the utility of recording medication:

11/3/97 Outpatients (seen by psychiatry registrar)

Doing well.

No signs of depression or relapse

Has decreased Stelazine [trifluoperazine] from 10mg bd to 10mg nocte

See in 6-8 weeks

Medication

Stelazine 10mg nocte

Dothiepin 150mg nocte

25/3/97 general practitioner

Stopped medication 2 weeks ago - relapse.

Must restart

Medication

Trifluoperazine 10mg bd

Dothiepin 150mg nocte

22/4/97 Registrar

Some residual anxiety/panic

No depression or paranoia

Relapse after stopping medication noted and discussed

See in 2 weeks

Medication

trifluoperazine 10mg bd

dothiepin 150mg nocte

[hospital telephone number added to bottom of record]
Other examples of communication between primary and secondary care about a physical problem follows:

**28/4/97 general practitioner**
- Milk from breasts? cause.
- Full blood screen done
- See with results 10 days
- Depression - quite low

**12/5/98 general practitioner**
- Hyperprolactinaemia
- Refer to hospital

**Medication:**
- Paroxetine 40mg od
- Thioridazine 25mg morning 100mg night

**15/5/98 Hospital consultant**
- Mood remains quite low and regularly distressed by memories of past traumatic events. Trying to cope eg swimming to lose weight and exploring daytime activity. Referral to psychotherapy day hospital.
- Continue same medication. Discussed decrease dose of thioridazine but she cannot contemplate this at present.

One card contained, among other entries, a note from an emergency duty social worker:

**29/5/97 21.00 Emergency duty team**
- Visit regarding ex-partner for info. XX seemed well himself
- Warned not to let [ex-partner] in at present until she has been assessed.
7.9.3 Card users compared with controls
Of the 24 subjects who reported using their shared care record, 11 (46%) were admitted during the study, compared with 15 (43%) of the control group. There was no difference in number of admissions between these groups (z=0.1, p=0.92), number of outpatient visits (z=1.3 p=0.17), or clinic defaults (z= 0.82 p= 0.4).
Analysis of those individuals reporting card use compared with controls showed no significant differences in follow-up BASIS-32, BPRS or CSQ scores (table 7.9.3). Non significant results were also found when record users were compared with non-users in the shared care group.

<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>Shared care subjects reporting record use (n=24) Mean (sd)</th>
<th>Controls (n=28) Mean (sd)</th>
<th>f</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>BASIS-32</td>
<td>1.28 (0.88)</td>
<td>1.22 (0.85)</td>
<td>0.47</td>
<td>0.49</td>
</tr>
<tr>
<td>BPRS</td>
<td>16.4 (9.0)</td>
<td>14.6 (8.8)</td>
<td>0.87</td>
<td>0.35</td>
</tr>
<tr>
<td>CSQ</td>
<td>24.0 (5.6)</td>
<td>23.9 (3.84)</td>
<td>0.05</td>
<td>0.82</td>
</tr>
</tbody>
</table>

Table 7.9.3. Comparing record users and standard-care controls by analysis of covariance. Outcome scores of those subjects followed-up for BASIS-32, BPRS and CSQ, controlling for baseline scores.

7.9.3.1 Predictors of use of shared care record.
Predictors of record use were explored using logistic regression. Age, marital status, ethnicity, change of consultant or general practitioner, baseline admission rate and baseline scores of the BASIS-32, BPRS and CSQ did not emerge as significant predictors of shared care record use. Diagnosis was a predictor of record use; subjects with psychotic illness were significantly less likely to carry their records (OR 0.51 95% CI 0.27, 0.99 p=0.04). Furthermore, record use was not related to
higher scores on the thinking disturbance or hostility/suspiciousness sub-scales on the BPRS or the psychosis sub-scale on the BASIS-32.

7.9.3.2 Lost records

Eighteen (39%) of the subjects in the shared care group who were followed up reported losing their shared care record at least once. All 10 subjects who reported losing their record at the first follow-up were given a replacement. Nine of this group reported losing the record for a second time. Subjects' reported loss of the record was not significantly associated with diagnosis, gender, change of consultant or general practitioner or admission to hospital over the study period. One of the 13 (8%) non-white subjects in shared care lost their shared care record compared with 17 of the 42 (40%) white subjects (chi square 4.84, p=0.04, two-tailed Fisher's exact test). Baseline global and sub-scale scores for the BPRS were not related to loss of the record.
7.10. Subjects' attitudes to shared care

Subjects randomised to shared care were asked to complete a questionnaire assessing attitudes to psychiatric care and shared care at baseline. This attitude questionnaire was developed and piloted before the study (see chapter 6 and appendix 4).

The attitude questionnaire was completed by 53 of the 55 patients in the shared care group. There were three sections to the questionnaire. The first was designed to elicit opinions about the extent various professionals should be involved with the patient, the second section sought views about whether the subject felt they had enough knowledge about their diagnosis and treatment, and the third section sought beliefs about the shared care record. Results are analysed as scores but are dichotomised in tables for clarity.

7.10.1 Professional involvement in care

Most subjects agreed that both their general practitioner and consultant should be involved in the management of their mental illness. Furthermore, when a social worker or community nurse was involved, this was usually welcomed by the respondents (see table 7.10.1). Subjects who were against involvement of their general practitioner were usually also against involvement of their hospital consultant. Subjects with a diagnosis of schizophrenia or other psychotic illness were significantly less likely to want the involvement of their general practitioner
(Mann-Witney U test: $z = 3.01$, $p = 0.003$), a hospital consultant ($z = 2.81$, $p = 0.005$) or social worker ($z = -2.54$, $p = 0.01$) compared with non-psychotic patients.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Agree</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>My general practitioner should be involved in my care</td>
<td>45 (86%)</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>My consultant should be involved in my care</td>
<td>47 (89%)</td>
<td>6 (11%)</td>
</tr>
<tr>
<td>My social worker should be involved in my care</td>
<td>31 (89%)</td>
<td>4 (11%)</td>
</tr>
<tr>
<td>My community nurse should be involved in my care</td>
<td>15 (88%)</td>
<td>2 (12%)</td>
</tr>
</tbody>
</table>

**Table 7.10.1** Subjects' views about professionals involvement in the management of their mental illness. Number (percent) agreeing or disagreeing with the statements shown. Note: not all respondents answered all questions, usually because they did not have a social worker or CPN.

**7.10.2 Subjects' knowledge and involvement**

Many respondents were dissatisfied with the amount of knowledge they had about their diagnosis and treatment, and most wanted more say in decisions about their care (table 7.10.2). Diagnosis was not a significant predictor of dissatisfaction with knowledge level or decision input.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Agree</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I know enough about my diagnosis</td>
<td>21 (40%)</td>
<td>31 (60%)</td>
</tr>
<tr>
<td>I know enough about my treatment</td>
<td>24 (45%)</td>
<td>29 (55%)</td>
</tr>
<tr>
<td>I would like more say in decisions about my care</td>
<td>38 (76%)</td>
<td>12 (24%)</td>
</tr>
</tbody>
</table>

**Table 7.10.2** Subjects' views about their knowledge about their diagnosis and treatment, and their input into decision making about their care. Number (percent) agreeing or disagreeing with the statements shown. Note: not all respondents answered all questions.
7.10.3 Beliefs about the shared care record

Most respondents agreed that a shared care booklet would be of help to the professionals involved in their care, although opinion was more divided about whether carrying a shared care booklet would help their understanding of their illness, or improve their prognosis (table 7.10.3). Twenty-two respondents (42%) indicated that they would forget to carry their shared-care record.

<table>
<thead>
<tr>
<th>Statement: a shared care booklet will:</th>
<th>agree</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>help my general practitioner</td>
<td>45 (90%)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>help my consultant</td>
<td>43 (88%)</td>
<td>7 (12%)</td>
</tr>
<tr>
<td>help my social worker</td>
<td>34 (100%)</td>
<td>0</td>
</tr>
<tr>
<td>help my community nurse</td>
<td>16 (94%)</td>
<td>1 (6%)</td>
</tr>
<tr>
<td>help me stay well</td>
<td>27 (64%)</td>
<td>15 (36%)</td>
</tr>
<tr>
<td>help me understand my illness</td>
<td>36 (78%)</td>
<td>10 (22%)</td>
</tr>
</tbody>
</table>

Table 7.10.3 Subjects’ beliefs about the utility of carrying a shared care record. Number (percent) agreeing or disagreeing with the statements shown. Note: not all respondents answered all questions.

7.10.4 Subjects’ attitudes as predictors of record use.

Forty-four subjects (80%) who were allocated to the shared care limb were followed-up at least once. The results of the attitude questionnaire of these individuals were examined in order to identify possible predictors of card use. Belief at the beginning of the study that the shared care booklet would help the subject stay well was significantly associated with being a shared-care record user by the end of the study ($z = -2.1$, $p=0.04$) (figure 7.10.1). No other responses, including whether the patient believed they would forget to carry their record, appeared to predict record use.
Figure 7.10.1 clustered bar chart of respondents attitudes to whether shared care records will help patients stay well. Clusters defined by whether the subject had used their record by the end of the study.
7.11. Professionals' attitudes to shared care

7.11.1 Baseline assessment

Questionnaires designed to elicit attitudes to shared care and the shared care record were sent to all professionals (consultant, GP, social worker and CPN) at the time of recruitment of one of their patients, and again at the end of the study. The follow-up questionnaire included some questions about shared care record use. Response rates are given in table 7.11.1 below. The overall response rate was lower in the follow-up questionnaire, especially among the community psychiatric nurses.

<table>
<thead>
<tr>
<th></th>
<th>Baseline questionnaires</th>
<th>Follow-up questionnaires</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>sent</td>
<td>returned</td>
</tr>
<tr>
<td>Consultant</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>General practitioner</td>
<td>35</td>
<td>27</td>
</tr>
<tr>
<td>Social worker</td>
<td>13</td>
<td>10</td>
</tr>
<tr>
<td>CPN</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>TOTAL</td>
<td>66</td>
<td>55</td>
</tr>
</tbody>
</table>

Table 7.11.1 Response rates of professionals' attitude questionnaire at baseline and end of study

The pre-study attitudes showed the majority of professionals felt that shared care records would benefit their patients, and no significant differences between professional groups were apparent.
<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly agree / agree</th>
<th>Disagree/ strongly disagree</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients will find shared care booklets helpful</td>
<td>50 (89%)</td>
<td>6 (11%)</td>
<td>0.28</td>
</tr>
<tr>
<td>Patients will usually carry shared care booklets</td>
<td>29 (53%)</td>
<td>26 (47%)</td>
<td>0.52</td>
</tr>
<tr>
<td>Professionals will find shared care booklets helpful</td>
<td>53 (96%)</td>
<td>3 (4%)</td>
<td>0.74</td>
</tr>
<tr>
<td>Professionals will use shared care booklets</td>
<td>51 (93%)</td>
<td>4 (7%)</td>
<td>0.59</td>
</tr>
<tr>
<td>Shared care booklets will improve patient care</td>
<td>48 (87%)</td>
<td>7 (13%)</td>
<td>0.82</td>
</tr>
<tr>
<td>Shared care booklets will improve the mental health of the patient</td>
<td>42 (77%)</td>
<td>11 (23%)</td>
<td>0.87</td>
</tr>
<tr>
<td>Shared care will improve communication between professionals</td>
<td>46 (92%)</td>
<td>4 (8%)</td>
<td>0.34</td>
</tr>
<tr>
<td>Filling in shared care booklets is likely to be a waste of time</td>
<td>3 (6%)</td>
<td>50 (94%)</td>
<td>0.72</td>
</tr>
</tbody>
</table>

Table 7.11.2. Professionals’ attitudes to shared care at beginning of study. Not all of the 56 respondents answered all questions. Number (%) of all respondents to that question is shown. Significance of differences between professional groups determined by Kruskal Wallis test.

On the initial questionnaire some comments were received including the following from a general practitioner:

"In my opinion, patients most at risk from psychiatric illness are chaotic and default there [sic] appointments, therefore they are unlikely to be organised enough to bring their booklet".

A community nurse wrote:

" already great deal of documentation, CPA [ care programme approach], 117 [ requirements of section 117 of the mental health act 1983], care management notes, inter-professional meetings.... This administrative focus is failing to appreciate the need for relevant community reforms, employment, training, accommodation"
7.11.2 Follow-up questionnaires

Significance of differences in professionals' responses between the baseline and follow-up was analysed using Wilcoxon Signed Rank Test. (Table 7.11.3). Fewer respondents believed that patients would carry their cards and more believed that filling in records is likely to be a waste of time (figures 7.11.1, 7.11.2)

<table>
<thead>
<tr>
<th>Question</th>
<th>z</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients will find shared care booklets helpful</td>
<td>-0.881</td>
<td>0.378</td>
</tr>
<tr>
<td>Patients will usually carry shared care booklets</td>
<td>-2.16</td>
<td>0.03</td>
</tr>
<tr>
<td>Professionals will find shared care booklets helpful</td>
<td>-0.847</td>
<td>0.397</td>
</tr>
<tr>
<td>Professionals will use shared care booklets</td>
<td>-0.617</td>
<td>0.537</td>
</tr>
<tr>
<td>Shared care booklets will improve patient care</td>
<td>-1.06</td>
<td>0.289</td>
</tr>
<tr>
<td>Shared care booklets will improve communication</td>
<td>-1.83</td>
<td>0.067</td>
</tr>
<tr>
<td>Filling in booklets is likely to be a waste of time</td>
<td>-1.98</td>
<td>0.047</td>
</tr>
</tbody>
</table>

Table 7.11.3. Changes in attitudes about shared care before and after the study. A negative score indicates a response was perceived as less likely.

Figure 7.11.1 Change in professionals' attitudes before and after study- perceived utility of using shared care records
Figure 7.11.2 Change in professionals’ attitudes before and after study - perception of whether patients will carry their shared care books.
7.12. Summary

In this chapter I have presented results relating to the validation of the BASIS-32 as an outcome instrument in a United Kingdom-based population. The demographic and clinical characteristics of the study sample were described and the effectiveness of randomisation and the representativeness of the sample considered. The differences in service use, clinical outcome, and satisfaction between subjects in the shared care and standard care limbs were reported. Finally, I presented data concerning the use of the shared care records, and the attitudes of the patients and professionals to these records.

In the next section I will outline the main findings, discuss the potential impact of shared care schemes for people with mental health problems and consider the methodological problems encountered in this study.
Chapter 8

Discussion

8.1 Summary of results

Participation in shared care did not significantly affect rates of admission to hospital, or the length of in-patient episodes. A large proportion of subjects, mostly patients with schizophrenia and related psychoses, were admitted during the study, reflecting the fact that the subjects recruited had severe mental illness and were vulnerable to relapse. Subjects in the shared care limb of the trial were no more likely to receive, or to keep outpatient appointments. Only 76 of the 90 patients recruited had outpatient appointments. Since an inclusion criteria was that follow-up by the hospital services had been organised, it appears that not all patients are followed-up in outpatients. This may reflect the increasing shift to community psychiatry, with some patients only followed up in the community.

Mental health, as assessed by the BASIS-32 and BPRS, did not differ significantly between shared and standard care at follow-up. There was a non-significant trend for patients in shared care to have worse BPRS scores than those receiving standard care. Patient satisfaction with the service was moderate, and shared care had no impact on satisfaction at follow-up.

Most patients and professionals were strongly in favour of the proposed shared care scheme at the start of the study, although this was not translated into practice.
Uptake of the shared care record scheme was low. Professionals and patients alike appeared reticent to use the records. Patients with psychotic illness appear to be particularly reluctant to engage, possibly because of their chaotic lifestyle, or paranoid ideation affecting their judgement about the purpose of the record. By the end of the study, professionals' enthusiasm for the scheme had waned; they were significantly more pessimistic about patients carrying their records, and the utility of the scheme.

8.2 Use of BASIS-32

The BASIS-32 (Eisen et al 1994), a relatively new instrument for measuring mental health, was chosen as an outcome measure in this study over other, more established instruments. The BASIS-32 was chosen because it is a self-report instrument, and thus affords patients with psychosis a rare opportunity to complete a questionnaire about serious psychological symptoms. It also overcomes some of the difficulties inherent in observer rated scales where the rater is not blind to the condition of the subject.

There was moderate correlation between the global score of the BASIS-32 and the global score of the BPRS (correlation coefficient of 0.51), and the depression and psychosis domains of the two scales. The BASIS-32 and the BPRS regression residuals demonstrated that the relationship between the two scales was linear across a range of scores. However, the confidence intervals of the regression
coefficient of the BPRS and the BASIS-32 score are wide, suggesting that an individual’s BASIS-32 score does not necessarily predict well the BPRS score.

Ideally, two scales purportedly measuring the same thing should be strongly correlated, although some care is needed when comparing different scales using correlation coefficients alone (Bland and Altman 1996). A significant correlation coefficient merely proves there is a relationship between scores, not that they are measuring the same thing. For example, there is likely to be a positive correlation between weight and height in a population, although these are quite separate entities. Another approach in comparing a new instrument with an established one is to assess criterion validity. This is the ability of the new scale to distinguish case from non-case, compared with an established one, often by plotting receiver operating characteristic (ROC) curves using the sensitivity and specificity for various values. This was not possible in this study, because of the lack of case defining criterion of the BPRS.

One possible explanation for the correlation coefficient not being higher may be that patients completing the BASIS-32 who lack insight may underestimate the impact of their disease. The lack of correlation between the “self-care” and “relationships” sub-scales on the BASIS-32 and the “withdrawal retardation” sub-scale on the BPRS may be due to lack of insight causing an over-estimation of ability and underscoring on questions. For example, difficulties sought in BASIS-32 questions such as “To what extent are you experiencing difficulty managing day-to-day life” or “To what extent are you experiencing difficulty in the area of leisure
time or recreational activities” may be underestimated, resulting in an artificially low score on the BASIS-32.

The BPRS thinking disturbance sub-scale measured at baseline was strongly associated with a diagnosis classed as a “psychotic illness” i.e. schizophrenia and delusional disorder. However, there was no such relationship with the BASIS-32 psychosis sub-scale. The BASIS-32 may not therefore be a good measure of psychotic symptoms. The components on the BASIS-32 that measure psychosis include the following questions:

“To what extent are you experiencing difficulty in the area of disturbing or unreal thoughts or beliefs?”,

“To what extent are you experiencing difficulty in the area of hearing voices or seeing things?”.

Patients lacking insight into their psychotic symptoms and may not think that their psychotic thoughts are “disturbing or unreal”, or that their auditory hallucinations are causing difficulty. Manic patients rarely feel their symptoms are problematic.

Another reason for the difference between the two scales is that respondents are aware of their symptoms, but chose not to admit them. Even if insight is present, patients may not wish to reveal these on a questionnaire. Answering positively to questions like those listed above may not only prove embarrassing to the
respondent, but may also be distressing to admit to. An individual with psychosis and consequently, eroded ego boundaries and the classic defences of denial and regression may be overwhelmed by having to confront the ego-damaging admission that they are experiencing delusions or hallucinations. I view the admission of these phenomena as different to admitting the label of the phenomena, even if the admission is only to self. The label carries with it stigma, prejudice and a sense of self-accountability that the phenomenon does not. This is one of the strengths of observer-rated scales of severe mental illness; the patient may manifest symptoms, but it is left to the clinician, often without the raters knowledge, to label those symptoms.

Another benefit of observer-rated scales is that behaviours are more easily recorded. For example, the BASIS-32 asks the respondent

"To what extent are you experiencing problems in the area of impulsive, illegal or reckless behaviour?"

"To what extent are you experiencing problems in the area of manic, bizarre behaviour?"

"To what extent are you experiencing problems in the area of apathy, lack of interest in things?"
Rating one's own behaviours, especially in the context of an abnormal mental state, possibly without insight, is unlikely to yield a highly accurate response, especially if one of the core questions asks about illegal behaviours. Similar probes exist on the BPRS (excitement, blunted affect), which are rated mainly by the observed behaviour during the interview. This may account for the relatively low correlation between those sub-scales measuring psychosis on the BPRS and the BASIS-32 compared with, say, the depression sub-scales.

I have presented arguments that two of the main domains germane to assessing psychosis; psychotic experiences and abnormal behaviours, are difficult to gauge by self-report. Nevertheless, there is still an argument for retaining self-report scales for severe mental illness. Patients may have experiences that they would not divulge to an interviewer, or may be missed by a superficial assessment, they do not require the presence of an experienced clinician and the responses will not be contaminated by the assessors’ preconceptions of the patient, or their knowledge of the subject’s randomisation status.
8.3 Methodological limitations

Several methodological limitations may have had an impact on the final outcome of this study.

8.3.1 Recruitment

A total of 252 patients were considered for entry into this study. This figure is far lower than the number of inpatient discharges over the study period (estimated to be around 600). One possible reason for this is that recruitment for the study did not proceed over a continuous period of time, mainly because of a lack of time among the study personnel. During periods of recruitment, although the study was widely advertised and wards were visited frequently, it is likely that a number of patients were discharged without coming to the attention of the study personnel. This was a particular problem because of bed shortages. Many patients are precipitously discharged over the weekend or at night in order to create a vacant bed for a new admission. It was also apparent that, despite visits to the wards almost daily, and posters displayed prominently on each ward, planned discharges were not always referred for the study. Efforts to recruit patients who were discharged before being seen by the study team included visiting the newly discharged patient at home. Some subjects were recruited this way, but several potential subjects were lost.

Non-consecutive recruitment may result in bias as it enables patients to be selectively recruited or ignored and may significantly undermine the validity of the study. This is a particular issue in this study where
a) ward staff may have made *a priori* decisions not to refer the patient because they judged them unsuitable, or

b) unplanned discharges (mainly at night) would have been patients deemed particularly well, at low risk or with better social support, or

c) study personnel decided not to recruit an individual. Although this is likely to be an unconscious decision, non-consecutive recruitment does enable bias of this nature

In clinical trials undertaken without external funding it is often important to strike a balance between remaining methodologically pure and getting the data collected. If consecutive recruitment is impossible evidence of how representative the study sample is may provide some reassurance. No differences in gender, diagnostic group or age were observed between those patients recruited to the study and the whole inpatient population of the psychiatric unit over a six-month period. This would suggest that the study population was representative of the in-patient population as a whole.

A large number of potential subjects were excluded from the trial. However this does not necessarily undermine the validity of the sample recruited to the trial. Many potential subjects were excluded because they failed to meet the chosen criterion of severe mental illness (Kendrick *et al*, 1995) and therefore would be less likely to be engaged in a shared care programme in the future if this method of co-operative follow-up is adopted. Another principal reason for non-recruitment was
that the potential subject, or their general practitioner lived outside the catchment area of the hospital. Geographical proximity to the hospital was necessary for two reasons. Firstly, only local general practitioners had been randomised and informed of the study. Secondly, data collection relied entirely on individuals all of whom had significant clinical commitments and were unable to travel long distances in order to follow up subjects.

Twenty potential subjects were excluded because they were not registered with a general practitioner. This is an important finding because patients discharged from a mental health unit are likely to require follow-up. Most people in the United Kingdom are registered with a general practitioner and the proportion of patients discharged from this unit who were not registered is much higher than the UK average. Patients with chronic mental illnesses are likely to place high demands on primary care services (albeit no higher than some with chronic physical illness) and may be less desirable patients in the current climate of prescribing budgets and clinical responsibility. Indeed, five of the 13 patients who left the care of their general practitioner between the start and end of the study did not register with a new one. Four of these patients were likely to need high levels of input: two had schizophrenia and two had bipolar illness. Another reason that may explain the high rate of non-registration with a general practitioner is that patients with certain mental illnesses, notably schizophrenia, may lack the drive to register with a doctor.

If shared care were to become more widely adopted, the finding of relatively low general practitioner registration of patients with long-term mental illness would
have two implications. Firstly, being registered with a general practitioner would become a *sine qua non* of being discharged, obviating the risk of falling through the primary care net. Secondly, and arguably a less attractive consequence, general practitioners would be under pressure to accept, and not remove, patients from their lists, even if the relationship with the patient had broken down.

Only 26 (10%) of subjects considered for recruitment refused to consent to the study. This is a relatively low figure and may indicate that many patients were interested in the shared care scheme. This is reflected in patients' beliefs about their shared care records. The majority of patients who completed the attitude questionnaire at the beginning of the study felt that carrying a booklet would help the professionals involved in their care.

### 8.3.2 Randomisation

Three units of randomisation were possible in this study; the subject, the general practitioner and the general practice. Randomising the subject is problematic because it is difficult to constrain interventions to individuals within the same practice randomised to different limbs of the trial. In particular, control patients may be influenced if general practitioners alter their practice more globally as a result of the intervention (Roberts and Sibbald 1998), and some patients may accidentally receive the wrong intervention at different times. In practice, a study like this one could probably have used the subject as the unit of randomisation as the cross-contamination may be small. However, it is difficult to measure these
effects and if no significant results are found at the conclusion of the study (as in this case) the investigator is left wandering to what extent contamination has minimised the treatment effect. Randomising general practitioners is also a problem, especially since most multi-partner practices operate on the principle that patients can see any of the partners. Thus one day a patient may see a partner in the shared care limb, and a control partner the next time. Therefore, in primary care research it is often desirable to use the practice as the unit of randomisation as this reduces these effects.

The randomisation of practices to shared care or standard care was constrained. Despite almost equal numbers of practices being allocated to each treatment limb, many more patients were recruited to shared care than to standard care. There are several possible explanations for this disparity. By chance, larger practices were allocated to the shared care limb, resulting in more general practitioners allocated to shared care (111) than standard care (105). There were other differences between practices in the two groups; more patients were recruited to the shared care group from large practices (four or more partners) than to the control group, and only four practices accounted for 30 subjects in the shared care limb.

Another possible explanation is that several large practices close to the hospital were randomised to the shared care limb and a larger proportion of patients with chronic mental health problems may be registered with these practices because of their proximity to the hospital. Patients may have been registered in these practices because the partners were known to be accepting of patients with mental illness,
and prepared to accept them onto their list. Alternatively, the proximity of these practices to areas of deprivation, with high levels of mental illness may have had some influence.

Although patients should not have been aware of which treatment they would be randomised to prior to entry into the study, it is possible that some patients refused consent knowing that they would be in the control group. This may happen when patients discussed the study among themselves while on the ward. Patients sharing a general practice with someone who has been recruited to the control limb may have declined to participate knowing they would also be controls.

The differential is probably accounted for by the cumulative effect of a series of small differences: one extra practice in shared care than standard care; more general practitioners in the shared care practices; different characteristics of practices from which subjects were drawn, the geographical proximity of these practices and chance.

An alternative method of randomisation that allows the investigator more control, is block randomisation. This would necessitate randomising practices in, say blocks of 10 (5 to shared care, 5 to standard care) and using these “allocations” before entering the next “block”. The advantage here is that if only one third of all practices are involved in the study (as happened here) the investigator is more certain to have equal numbers of practices allocated to the two limbs. Disadvantages to this method include the risk of accidentally randomising practices
twice, unaware that a particular practice had already been allocated to an arm, particularly if two researchers were recruiting on the same day and not being able to inform partners of a practice of their treatment allocation in advance of the recruitment. This method would not circumvent the problem of patients refusing consent because of advanced knowledge of which limb they would be allocated if they had discussed the study with fellow patients. Block randomisation is unlikely to have reduced the differential recruitment in this study since similar numbers of practices (15 in shared care and 13 in standard care) participated in each limb of the trial.

Another way to circumvent some of these problems would be to stratify randomisation, for example according to practice size. However, it is unlikely that I would have been able to predict all the correct factors for stratification. Furthermore, with around 100 practices randomised, it is reasonable to expect factors will balance out.

A further method that would overcome some of these difficulties is minimisation. Minimisation (Altman 1991) is a technique whereby certain factors that may lead to imbalance are selected *a priori*. The first practice is randomised and subsequent practices (drawn at random) are allocated (or weighted to) limbs in such a way that the selected factors are balanced out. For example, in this study practices could be minimised in such a way as to balance out number of partners, list size and proximity to the hospital. Minimisation has been used successfully in practice-based studies (Kendrick *et al* 1995). There are two problems with minimisation. Firstly, in
a study such as this, with large numbers of practices randomised, one would expect factors to balance out. Secondly it is sometimes impossible to predict a priori which factors would need to be minimised. For example, at the start of the study I would not have predicted proximity of the practice to the hospital to be an important factor.

I did not report tests of significance for baseline differences in socio-demographic, mental health or satisfaction variables between shared and standard care. If randomisation has been truly random, then any differences, significant or not, are irrelevant, as they occur by chance. Furthermore, as differences at baseline in outcome measures are likely to be co-factored out at analysis, significant differences are unlikely to have an impact on the study results. However, differences in socio-demographic details may be important. For example if, by a dint of chance, one group is much older than another, age may be a confounder, since age may be related to levels of psychiatric morbidity. Another reason to test for significance at baseline is that it may reveal the presence of several differences. Several differences are unlikely to be due to chance, and may indicate hitherto unsuspected bias. Testing for significance between groups at baseline therefore does have its merits.

The large disparity in allocation to the two groups in this study, without adequate explanation, raises the possibility of a hidden systematic error (bias) and suggests the results should be viewed with some caution. Another problem with the differential recruitment rate is the power of the study is undermined. A change in
ratio from 1:1 to 3:2 will reduce the power from 80% to 77%, a relatively small change, but nevertheless undesirable.

**8.3.3 Follow-up success**

Fifty-five percent of subjects were followed up at the first time-point and 68% at the final follow-up. The main reason for the low follow-up rate was patients refusing, although some patients were difficult to contact. Two attempts were made to follow-up individuals who were initially non-contactable. Several issues stem from this.

1. It is possible that patients who were not followed up because they refused or "disappeared" were more ill, resulting in suspicion of the study team or a withdrawn or chaotic lifestyle. If this were so, the psychopathology of those who were followed up would under-estimate the true levels of morbidity of the whole sample. This is supported by the trend for patients with non-affective psychoses to be at greater risk of loss to follow-up, but is not supported by the fact that baseline BASIS-32 and BPRS scores were not significantly different in those subsequently followed-up compared with those who were not.

2. By having an open-ended policy to follow-up, patients may avoid follow up when ill and be "captured" for follow-up at a time when they are relatively well. This would also result in an under-estimate of psychopathology. With assertive follow-up, trying on three separate occasions to see the patient at home after an appointment was made, the final rate was 82%, which is reasonable for a study
of this patient group, who may be peripatetic, chaotic or change their mind about participating in research. This was a dilemma that was considered carefully during the study, i.e. whether to maximise the numbers followed-up by extending the time frame, or have rigorous time limits to follow up. I chose the first option, mainly because without maximising the numbers successfully followed-up the study would lack adequate power. In fact, most subjects who were followed up were contacted within a relatively narrow time-frame of the desired date. Subsequent analysis showed there was little evidence to support the theory that patients lost to follow-up had higher levels of morbidity, at least based on baseline results and service use.

3. Another problem with open-ended follow-up epochs is deciding when does someone seen for first follow-up actually become a second follow-up? This was arbitrarily set at beyond nine months. Therefore, some subjects were only followed-up once because their first follow-up actually counted as a final one. The question that arises from this is, "is it better to have one follow-up point, and concentrate on maximising the return on this, or is it preferable to have multiple points. The advantage of having more than one follow-up is that trends in results will become apparent."
8.3.4 Missing data

Missing data are an important, but usually inevitable part of a clinical trial, especially with multiple follow-up points. Missing data may be of three different types (Everitt 1998):

1. **Missing completely at random.** In this case, the probability of drop-out does not depend on the subject's previously observed (usually baseline) measures. The missing values would have the same distribution as the observed values.

2. **Missing at random.** The probability of dropout is related to previous observed measures, but not the unrecorded (missing) values at dropout.

3. **Informative.** The probability of dropout is related to the unobserved values of the response variable. In other words, the missing values are not predictable from the observed values for that time-point.

There are a number of ways of dealing with missing data. These include

1. Ignoring them, and confining the analysis to subjects with a full dataset. There are very good reasons not to do this. Confining analysis to completers doesn’t fit the logic or principles of a pragmatic trial. Data are rarely missing at random, and, as completers represent a unique group of individuals willing to participate in clinical trials, confining the analysis to completers is likely to give spurious results. Also, as is the case in this study, only using those subjects with
complete data would significantly reduce the power, and increases the possibility of not rejecting a false null hypothesis (a type II error).

2. Confining the analysis to those subjects who have been followed up at least once. If a subject has one follow-up dataset, this is considered as the endpoint, if two follow-ups have been completed the average results are used. There is still a risk of reduced power because of the smaller sample size in the analysis, and this is still a form of "completer analysis" subject to the other constraints outlined above.

3. Data imputation by last observation carried forward (LOCF). This is an established method, widely used in clinical trials. The consequence of this method of analysis is that erroneous results will arise if subjects may tend to get better (or in the case of this study, worse) over the trial period. If one intervention is more successful than another, but the follow-up rate is relatively low, the treatment effect will be diluted. Furthermore, if there is bias in the capture of subjects (for example, if subjects randomised to standard care were less assiduously followed-up), then spurious differences between groups would emerge. This is not usually a problem in blinded randomised trials, where blinding should protect against follow-up bias. In this study, where blinding was impossible, follow-up was equally assiduous, and successful, in each limb.

4. Multi-level modelling. This model estimates the missing values, provided they are non-informative (random). The unresolved problem with this technique,
acknowledged by its proponents, is the difficulty in distinguishing whether missing values are informative or not. Multi-level modelling may provide a more accurate way of analysing longitudinal data, but the question of whether missing data are informative or not is an important one. In this study, the missing data may well be informative (non-random), especially given the trend for drop-outs to have psychotic illnesses.

A strategy to overcome the problems posed by missing data is to use process data such as admission rates and clinic attendance rather than patient derived data. Process data are usually derived from the hospital patient administration system. This has the advantages of having a more complete dataset (data for all 90 subjects were available, although only data pertaining to activity at the base hospital are recorded), being devoid of observer bias and providing data which are clinically meaningful. Admissions are often taken to be a meaningful outcome but should be viewed with some circumspection; an increased rate of admissions may reflect increased service contact and thence recognition of need, rather that the mental state of the subject.

The primary outcome measure of this trial (admission rates) was not subject to the constraints of missing data. The supplementary outcomes (BASIS-32, BPRS, satisfaction) were analysed using methods 1, 2 and 3 outlined above. Results were non-significant irrespective of the method used.
8.3.5 Power of the study.

Despite the sample size being set by a pre-trial power calculation, the sample size may have been too small to detect a real clinical difference. This may be so because the estimated difference in treatment effect between the shared care and standard care groups was over-estimated. The pre-trial power calculation assumed a decrease in admission rate of 50% in the shared care limb. This is a large treatment effect, which in retrospect is over optimistic. The BPRS is an established instrument, and has been frequently used as a primary outcome measure. If the sample size calculation had been based on the estimated change in BPRS score, a five-point difference between groups would have been necessary to detect a difference. This is not a particularly large difference in BPRS scores and the sample size calculation would have been similar. Another explanation is that the intra-cluster effect was larger than predicted, and this could have resulted in a significant decrease in power. Post-hoc measures of the intra-cluster correlation coefficient showed this to be around 0.3 for baseline values of the BPRS and 0.23 for the BASIS-32. This ICC is very large, as most values hitherto reported in studies in primary care are 0.01 to 0.05 (Underwood et al 1998). Using the inflation formula suggested by Underwood et al (1998) the actual sample size for this study should be about 150. The “inflation” figure is relatively low for an ICC of this magnitude because of the small number of patients recruited from each practice. Nevertheless, the cluster effect found in this study may significantly undermine the power.
8.3.6 Choice of outcome measures.

One of the limitations of this study is the concentration on outcome data rather than changes in process of care. Outcome data, such as mental health measures and admissions are easy to measure and clinically meaningful. However they are one step beyond changes in the process of care, such as how clinicians interact with patients or how patients regard their medication. These data often require observational measures, interviews or specific questionnaires to collect. A drawback with these data is that observed changes do not necessarily alter the "bottom line", i.e. whether a patient is better or not. It is probably better to collect both; process data can indicate significant changes in practice that will be lost because of the relatively insensitivity of hard outcome variables. A possible explanation for absence of effect is that the BASIS-32 may not be adequately sensitive to change. Sensitivity to change, or responsiveness, is a vital attribute to outcome measures, that some have argued should be as carefully considered as validity and reliability when selecting measures (Guyatt et al 1987, Fitzpatrick et al 1992). An instrument that has a high variability relative to the change scores is said to have a poor responsiveness. Fitzpatrick et al (1992) suggest that the effect size (difference in mean score between time 1 and time 2, divided by the standard deviation at time 1) is an expression of responsiveness. Using the initial data on the BASIS-32 (Eisen 1994) the standard deviation at time 1 (0.68) and the total change score (0.41) give an effect size of 0.60; a moderate to large difference suggesting that the BASIS-32 is useful in measuring changes over time.
Admission to hospital is a commonly used outcome in studies of this nature, but is difficult to interpret. An increase in admissions does not necessarily equate to greater ill health. It is possible that an increase in admissions is a result of greater detection of morbidity, rather than greater morbidity itself. This is particularly germane in studies like this one, where one intervention (shared care) may result in greater scrutiny of the patient during assessment.

8.3.7 Blinding

Blinding of professionals and subjects in randomised trials is important in order to reduce bias in both parties. In this study, subject bias may have resulted in increased adherence to clinical regimens especially if the patient had the *a priori* belief that shared care was a good thing and desirability set when filling in questionnaires. Desirability set occurs when patients answer questionnaires the way they think the investigator would like them answered. In studies of this nature it is not possible to blind the subject; they have to know they are subject to shared care.

Blinding of the assessors in the study is another matter. The Brief Psychiatric Rating Scale was completed by study personnel who knew the randomisation status of the patient. Ideally the BPRS should be rated by someone blind to the status of the patient, as there is a significant risk of bias (albeit unconscious) during completion. Throughout this study I maintained a position of genuine equipoise with regard to the principal question. Nevertheless, although blinding for the BPRS is desirable, it was not possible in this study due to funding constraints, and consequently the BPRS results should be treated with some circumspection. Many
of these issues of blinding are less relevant when administrative data are used as outcomes, one reason for choosing service use as the main outcome of this study.

8.4 Effect of shared care

Intuitively, participation in a shared care scheme should improve outcome but the main finding of this study is that there were no significant differences in service usage, mental health or satisfaction between the shared care and standard care groups. Indeed, there was a non-significant trend for individuals allocated to the shared care limb to do worse in terms of mental health outcome. This lack of an effect may have several explanations.

8.4.1 Lack of patient interest.

Patients may have been reluctant to carry the shared care record at all for a variety of reasons. When recruiting to the study, considerable efforts were made to maintain an impartial position and present the shared care scheme in a neutral light. This was for two reasons. Firstly, I held a personal genuinely dispassionate view about the utility of the intervention. Secondly, a neutral stance is important to reduce the impact of over-enthusiastic (or even evangelistic) presentation of new interventions that has been the source of criticism of other studies, and blurs the capacity of the study to answer the hypothesis. This may account for the much higher uptake of shared care in psychiatric patients found by Essex et al (1990).
In retrospect, this neutrality may have been interpreted as disinterest and resulted in low levels of enthusiasm in the subjects. Getting this balance right is difficult, and future studies may need to take a more positive view, at least in the early stages of introducing shared care.

Patients may have been reluctant to carry records because they may have been perceived as stigmatising or labelling them as ill. Although the records were anonymous, some subjects may have harboured concerns about losing them and the subsequent embarrassment that this would cause. Rendering records anonymous is only partially effective in protecting patients. For example, a record lost in a communal area of a group home or block of flats is likely to be traced back to the owner. If the record contained sensitive clinical information, this would be highly embarrassing for the patient. Some subjects may have been reluctant to take responsibility for the record. Future evaluations of patient-held record schemes should include a qualitative assessment of patients views after the study, to identify factors that may be a disincentive in participation.

Subjects may not have presented their shared care records at interviews. This may be linked to a lack of interest in the concept, or the study, despite the pre-trial questionnaires suggested a high level of support for the shared care record. An interesting finding in this questionnaire was that respondents, although supportive of the concept of shared care records, were not convinced that the records would help them stay well. The transition from process to outcome is not axiomatic,
although some clinicians and politicians appear to believe otherwise. The findings of this survey indicate that patients appreciate the error of the dogma that an intervention leads to a better process, which leads to improved outcome. Without this belief, the impetus for carrying the record is reduced.

Some subjects may have been keen to use their records, but waited to be asked by the professional they were seeing. This may especially be the case when the subject saw the brightly coloured flash on the clinical notes. Subjects and professionals may both have been reticent to mention shared care because this was a new scheme, and both felt unsure of the response the other would give. Future studies could address this issue by having ongoing education about the study and information about its progress. However, this could introduce bias by causing a significant additional treatment effect (akin to a Hawthorne effect) but operating only in the shared care limb.

Subjects may have been initially keen on shared care, as indicated in the pre-trial questionnaire, but may have lost interest as a result of not being asked for their records when in contact with professionals. Apparent disinterest (apparent, because it may have been unintentional, for example because of lack of knowledge of the study; see below) by professionals and lack of positive feedback from them when the record was presented was likely to engender apathy in the patient.

Just over half of the subjects followed-up who were given shared care records used them. This low rate of use may dilute any real treatment effect, although the use of
the record may not have been the sole contributor to any effect. Just having the
record may have empowered patients to a degree and had an impact on outcome.
Analysing the data of those who did use their records did not show any significant
differences, but the relatively low numbers would undermine the power of this
analysis, and real treatment effects may be missed. Again this raises the spectre of
lack of power, although the absence of any trend to differential admission rates
suggests there was no real difference.

When assessing the impact reported use of the record had on admission rates and
other parameters, the choice of the comparison group presents problems. The group
given records who chose to use them are not a random group. Simply comparing
these “users” with all participants in the control group is problematic, because one
group is random, the other is not. In this case the point is academic as no real
differences were found in the completer analysis. However, if significant
differences were apparent, then interpretation would require some caution.

8.4.2 Lack of professional interest.
One of the main causes of failure to find any real treatment effects could be lack of
professional interest. There was an average of four entries in each of the records
returned at the end of the study. Intuitively, patients whose records were not used
are less likely to retain their records and return them, thus returned records are
likely to over-represent record use. At the end of the study, five of the 33 (15%)
professionals in the shared care limb who returned the follow-up questionnaire said
they had asked the patient for a shared care record. Nine reported writing in the
record, so at least some of the time, the record must have been proffered by the patient without prompting.

This rate of record use by the professionals is disappointingly low, especially given the degree of promulgation of the study, and the enthusiasm at the start of the study noted in the attitude questionnaires. Reasons for this low level of professionals' engagement may include;

1. Unwillingness to duplicate information from a clinical record to the shared care booklet. This is a key issue in all shared care record schemes. Duplication means extra work and time, with no guarantee that anyone else will see what has been written. Unless the shared care record is the only repository of information some duplication is necessary. Only using the shared record is unwise medico-legally and practically, since patients often forget to bring their records. Future schemes, which could use encrypted information on a smart card, will obviate the need for duplication if the original clinical record is held electronically. From personal experience, most clinicians are usually reticent form-fillers, and unless they are convinced about the benefit of the extra work the duplication entails, they are unlikely to do it. Unless they do it, the utility will remain unproven; a catch-22.

2. Changes in personnel. One of the striking findings was the large number of changes in staff during the study. Junior doctors change posts every six months, and this was overcome by presenting the study during the induction
programmes. There were also several changes of consultant staff, although new consultants were informed that the study was underway. Nevertheless, coming in half-way is less likely to engender enthusiasm for the study, especially when newly appointed consultants have many new procedures to learn.

Changes in personnel in general practice, social services and the community psychiatric nursing service were more difficult to monitor. Consequently, new staff in other disciplines may not have been aware that the study was ongoing, and be unaware of the need to request the shared care booklet and how to use it. These alterations of staff were not anticipated at the outset; a mechanism for monitoring new appointments and automatically providing information about the study with induction packs could reduce the impact of staff changes.

Many more subjects allocated to the shared care group (44%) experienced a change of consultant compared with the control group (25%). This alone may have had an impact on the outcome, because subjects in the shared care group would have been seen more frequently by locum consultants than subjects in the control group. Locum consultants are less likely to have commitment to research of this nature. Furthermore, any change of personnel is likely to have a more negative impact on the subjects having shared care, even if the changes were distributed equally across groups, as the clinician could be seen as delivering the intervention. As the engagement in shared care diminished, the effect of shared care would approximate to that of the control group.
3. Lack of enthusiasm for shared care records. Initially enthusiastic professionals could have lost motivation because the patients didn’t carry the records. Shared care is relatively untested in the mental health arena. This should engender a wish to engage in inquiry about the usefulness of the concept. It is quite possible that some individuals did not approach the study’s hypothesis from a position of neutrality. Probably on a subconscious level, these individuals may then reject the study. Combined with a sense of exasperation at the additional bureaucracy that the Care Programme Approach and aftercare planning entails this will lead to failure to use the records. A quote by a CPN in the pre-study attitude questionnaire encapsulates this sentiment well:

"already great deal of documentation, CPA, 117, care management notes, inter-professional meetings.... This administrative focus is failing to appreciate the need for relevant community reforms, employment, training, accommodation"

4. Uncertainty about what to write. Even if the professionals had been willing to write in the records, they may have been reticent to do so. This may be due to uncertainty about what information is germane to other readers of the record. Clinicians from different disciplines have different agenda, and differing priorities in terms of the utility of information. For example, a community nurse wrote a long entry about a visit to a cemetery; something unlikely to be of use to many other readers. Another issue here is the possible reluctance to write information that the patient is likely to read. Clinicians will probably feel the
need to exercise some self-censorship to avoid writing information that the patient may find upsetting, although this smacks of paternalism. The result could be an entry that is merely platitudinous. If the clinician does write in the record they may have expected the patient to question them about the entry. One of the potential consequences of shared care records is greater empowerment of the patient, especially if the record is seen as a vehicle for education about their disorder and treatment. This was certainly the case in obstetric shared care records (Webster et al 1996). However, this education will take time, and may provoke discussion that erodes the patient's confidence in their professional. For example, any reference to stigmatising diagnoses or symptoms may be upsetting to the patient, or may result in a debate about whether they (the patient) is really ill. In summary, the two strands to this issue centre on the patient-centred motive vis-à-vis the professional centred one. It is unlikely that both will be achieved in the same record, and many professionals may have been confused about which strand the study centred on.

5. Lack of ownership of the study. Medical research is commonplace in a teaching hospital setting and many professionals may get inured to it. Antipathy to research is probably greater when the participants have no involvement in the conception, design and execution of the study. The high response rate of the pre-trial attitude questionnaires, and the very positive attitudes expressed by professionals suggested that participation should have been higher. But attitudes and practice may differ significantly. Several attempts were made to introduce the study to all professional groups, but with the exception of general
practitioners and hospital consultants this was after the planning phase. Seeking the opinions of all professional groups during the planning phase about shared care and how it could be evaluated may increase uptake of any future schemes.

6. Poor quality of the record. This study received no external funding. Consequently, the shared care record was designed and prepared “in-house”. The records were photocopied and stapled with a clear plastic cover. Although attempts were made to make them look professional, they did not have the feel of an official record. This may have been an important point. Clinicians and subjects alike may have been more inclined to use a record that has an “official” or professional impact.

Another aspect was that the record structure was quite limiting. There was a relatively small space for writing notes, despite the available space being increased after the pilot study. Great care was taken at the start of the trial to achieve a balance between having a record that was useful in terms of capacity and the record being small enough to carry. In their pilot study Essex et al (1990) used a record twice the size of that used in this study, but found much higher levels of compliance; 55% of patients took the records to more than 75% of visits. If future studies concentrate on electronic storage in credit card-sized smart cards, the issue of size will be removed. Any further evaluations using a paper-based system should consider using A5 records.
Many of these points could be addressed in a future study if the focus was not the introduction of a record *per se* but creating a shift in the whole culture of care delivery. For example, a whole hospital, or group of hospitals could introduce patient-held records throughout the service. This would enable all relevant professionals to be consulted prior to the study and adequately trained in the use of the records. If using the records became a requirement to be audited, uptake would be higher. Those providing services for the mentally ill would be saturated with shared care. There would be less scope for forgetting to ask for the record, and clinicians would not have to think whether a patient was, or was not, in shared care. For example, general practitioners who were randomised to shared care in this study knew to ask patients recruited to the study for the shared care booklet. If some patients under their care were having shared care and some were not (because they had not been recruited), the default option of not asking anyone for a record may be more attractive.

There could be a knock-on effect to patients, who would be more likely to carry their records. There would be implied (or explicit) censure of patients who forgot. Shared care records would be as commonplace as appointment cards are now. The problem with this is it would be very difficult to evaluate in a randomised trial. It is almost impossible to change the culture of care, but restrict this to only some patients. This is a catch-22. Left unable to conduct a randomised trial, effects of shared care would have to be measured using less robust methods (for example a before and after design).
Another argument against this type of trial is that the cause of any detected changes is obscure. For example, in any non-randomised study several events which exert influence across all participants will affect the results, but will not be controlled. Taking the above example further, any detected improvement in service use or mental state parameters may be due to the introduction of shared care, but may also be due to any other changes introduced over the study period such as new drugs, new doctors, improved social support, introduction of new procedures etc.

8.4.3 Service changes during study

This study was conducted at a time of considerable change both within the health service, and the hospital. Recruitment began in 1995, around the time the Care Programme Approach (CPA) was being introduced. The CPA was a government initiated policy designed to standardise and formalise aftercare following contact with psychiatric services. Although the CPA became policy in 1991, it did not achieve widespread use until 1995. The locally agreed CPA policy was finally introduced at the centre where the investigation was conducted in 1995. All patients discharged from the hospital had CPA forms completed, detailing treatment, follow-up arrangements and nominating a keyworker. This change would have been unlikely to account for between group differences, but was perceived by many health workers to be a redundant paper exercise. This may have caused antipathy to yet more form filling required by this shared care study.
8.4.4 Effect of diagnosis

Patients with schizophrenia and other non-affective psychoses were significantly less likely to use shared care records than those with non-psychotic disorders. If shared care is to become more widespread in mental health care, these findings suggest that patient-held records are not a suitable vehicle for shared care schemes involving psychotic patients. No data are available to shed light on why psychotic patients might use their records less, but reasons may include a more chaotic or disorganised lifestyle, apathy due to negative symptoms, a lack of insight to being ill, hence no perceived use for the record, or suspicion of the record as a consequence of paranoid ideation. If the latter is the case, the patient-held “smart” cards with embedded microchip, already in use in some countries as a health record, are likely to be regarded with even more suspicion, especially as their contents cannot be read by the card holder. The irony here is that patients who could derive most benefit from shared care, and who need it most in terms of rapidly changing mental state, and multiple social and medical needs, are those who use it least. If shared care is to be introduced to this patient group, an alternative delivery should be considered, possibly using e-mail or local “intranet” for information transfer between interested professionals. Any such methods should still be subject to the scrutiny of a randomised trial.

A significant direction for future research is to more clearly define the utility of shared care records in non-psychotic individuals. Patients with certain diagnoses may derive tangible benefit from shared care, especially individuals with depression anxiety, anorexia nervosa, phobias or those with multiple complaints (“heartsink”
patients). The drawback here is that these patients are less in need of shared care schemes in terms of dissemination of information between agencies, although they may derive more benefit from reading the records. Another group that may benefit is the carers of patients with dementia and mental handicap; these groups have multi-professional input, and the carer could be the guardian of the record.

### 8.4.5 Negative effects of shared care

Much of the discussion so far has focused on the possibility of a type II error due to the methodological limitations of this study. But what interpretation could be placed on the results if they are valid, i.e. shared care records confer no significant treatment effect with a trend, in some domains, to a worse outcome?

It is possible that shared care records do not improve patients’ well-being no matter how diligently they are used. It does take a leap of faith to conclude that better communication will have a positive impact on the outcome parameters measured. Shared care records may enhance communication between professionals. Efficacy of communication *per se* is hard to measure, and probably the best method to assess this would have been to include a qualitative assessment of professionals at the end of the study. All the outcomes chosen are at a level beyond communication and rely on the notion that better communication results in better health or satisfaction or service use. This is a quantum leap and at least patients appear to appreciate it is not automatic (see section 7.7.10).
The reason for the trend to worsening health by those in shared care could be that any benefit arising from the shared care record was off-set by a negative impact of the records. Patients, initially keen on the concept, could have become disillusioned when confronted by disinterested professionals. This disillusionment could have spread to other facets of the service, and could for example, have resulted in poor adherence to medication. Blurring of boundaries of professional responsibility because of the shared care scheme may have operated to reduce the overall clinical care, although this seems unlikely.

8.5 Future directions of research

Throughout this discussion, I have considered how future evaluations could be modified in order to maximise the effect of patient-held shared care records, and how to maximise the chances of success when undertaking studies in this area in the future. There are a number of omissions to this study that, in retrospect, would have enhanced our knowledge.

There should have been more qualitative assessment of both professionals and subjects, before and after the study. The particular focus of these assessments would be what clinicians and patients want from shared care, and how they felt about the scheme afterwards. These data could be gathered by incorporating open-ended questions on the attitude questionnaires although a semi-structured interview with a sub-sample of participants would have been ideal.
Subjects’ specific opinions about using the shared care record should have been sought at the end of the study. A follow-up attitude questionnaire, similar to that sent to the professionals at the end of the study, would have been a relatively easy addition to the final assessment. This was considered during the planning of the study but I chose not to do this, relying on the Client Satisfaction Questionnaire to assess satisfaction. However, this has no questions specific to shared care, and given the changes in attitudes observed among the professionals before and after the study, similar data from the patients would have been helpful.
Chapter 9

Conclusions

The findings of this study suggest two things; firstly, that neither patients nor professionals are keen to use shared care records, and secondly, that even if they do, the records do not have any major impact of outcome. It is difficult to be dogmatic about the utility of these records because of the methodological problems encountered during the study that may have had a significant effect on the power. This does suggest that patient-held records should not be introduced to this patient group, at least in the way attempted here.

For a scheme of this nature to work in the future it is likely that patients targeted for shared care will have to be selected carefully, probably excluding those most severely ill patients who may benefit most from shared care. Furthermore, any future shared care scheme should be introduced wholesale, probably with a dedicated coordinator, thence altering the culture of care throughout the service. Paradoxically this would obviate the opportunity to evaluate future schemes under controlled conditions.
Chapter 10

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Shared-care record survey

CONSENT FORM

I, ________________________________ (name)

of, ________________________________

I have read the information sheet and agree to participate in the survey looking at the use of the shared-care records for patients with mental health problems. I understand that I may be given a booklet into which doctors, nurses social workers and other people involved in my care will write information about my progress and treatment. The record will also have the name and address of my doctor, psychiatrist, and key-worker. The record will not have my name or address on it, but will be identified through my initials and date of birth.

I understand that I may not be given a shared care record.

I also agree to allow Dr Warner and other members of the study team to have access to my medical and primary care notes for the purpose of collecting information for the study.

I understand that the study will last for a year, but I will be able to withdraw from the study at any time.

Signed ________________________________

Name ________________________________

Date ________________________________
THE CLIENT SATISFACTION QUESTIONNAIRE (CSQ)

Name: ___________________________  Date: _______________  Study Number ____________

Please help us improve our service by answering some questions about the services you have received. We are interested in your honest opinion, whether they are positive or negative. Please answer all of the questions. We also welcome your comments and suggestions. Thank you very much, we appreciate your help.

CIRCLE YOUR ANSWER

1. How would you rate the quality of service you receive?

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Did you get the kind of service you wanted?

<table>
<thead>
<tr>
<th>No, definitely not</th>
<th>No, not really</th>
<th>Yes, generally</th>
<th>Yes, definitely</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. To what extent has our service met your needs?

<table>
<thead>
<tr>
<th>Almost all of my needs have been met</th>
<th>Most of my needs have been met</th>
<th>Only a few of my needs have been met</th>
<th>None of my needs have been met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. If a friend were in need of similar help, would you recommend our program to him/her?

<table>
<thead>
<tr>
<th>No, definitely not</th>
<th>No, I don't think so</th>
<th>Yes, I think so</th>
<th>Yes, definitely</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. How satisfied are you with the amount of help you received?

<table>
<thead>
<tr>
<th>Quite dissatisfied</th>
<th>Indifferent or mildly dissatisfied</th>
<th>Mostly satisfied</th>
<th>Very satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. Have the services you received helped you to deal more effectively with your problems?

<table>
<thead>
<tr>
<th>Yes, they helped a great deal</th>
<th>Yes, they helped somewhat</th>
<th>No, they really didn't help</th>
<th>No, they seemed to make things worse</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. In an overall, general sense, how satisfied are you with the service you received?

<table>
<thead>
<tr>
<th>Very satisfied</th>
<th>Mostly satisfied</th>
<th>Indifferent or mildly dissatisfied</th>
<th>Quite dissatisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. If you were to seek help again, would you come back to our service?

<table>
<thead>
<tr>
<th>No, definitely not</th>
<th>No, I don't think so</th>
<th>Yes, I think so</th>
<th>Yes, definitely</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 4:
Subjects’ expectation questionnaire

**EXPECTATION OF SHARED CARE**

<table>
<thead>
<tr>
<th>Study no:</th>
<th>date:</th>
</tr>
</thead>
</table>

For each question, tick the box that most closely fits with your opinion. Thank you.

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>About my psychiatric care:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My GP should be involved in my care:</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>My consultant should be involved in my care:</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>My social worker should be involved in my care:</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>My community nurse should be involved in my care:</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I would like more say in decisions about my care:</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td><strong>About my health:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I know enough about my diagnosis:</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I know enough about my treatment:</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td><strong>About shared care</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I think that carrying a shared care booklet will help my GP:</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>will help my consultant:</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>will help my social worker:</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>will help my CPN</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>will help me to stay well:</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>will help me to understand my illness:</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I may forget to carry the shared care booklet</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>
EXPECTATION OF SHARED CARE

Your patient has been enrolled into the shared care study and will be carrying a shared care booklet for 12 months. I would, at this point, like to ask your views and expectations about shared care. Please complete the few questions below, ticking the most appropriate box for each answer. More of your patients may be enrolled into the study, but you will only be sent this questionnaire once. Please return it now in the envelope provided.

Thank you.

Name:  

Job title:  

Date:  

| Patients will find shared care booklets helpful: | □ | □ | □ | □ |
| Patients will usually carry shared care booklets: | □ | □ | □ | □ |
| Professionals will find shared care booklets helpful: | □ | □ | □ | □ |
| Professionals will use shared care booklets: | □ | □ | □ | □ |
| Shared care booklets will improve the care patients get: | □ | □ | □ | □ |
| Shared care booklets will benefit the mental health of the patient: | □ | □ | □ | □ |
| Shared care booklets will improve communication between professionals: | □ | □ | □ | □ |
| Filling in shared care booklets is likely to be a waste of time: | □ | □ | □ | □ |
Appendix 6:
Second professionals’ questionnaire

Shared care study
Professionals follow-up survey

Name: __________________________
Job title: __________________________
Date: __________________________

1. Exposure to the shared care record

I saw a shared-care record on at least one occasion: yes □ no □
(if no: go to question 3)

2. On at least one occasion:

A patient volunteered their shared-care record: yes □ no □
I asked to see the shared-care record: yes □ no □
I read the contents of a shared-care record: yes □ no □
I wrote in the shared-care record: yes □ no □
I found the shared-care record helpful: yes □ no □

3. About shared care in general
(please complete this section even if you did not use a shared care record)

<table>
<thead>
<tr>
<th>Statement</th>
<th>strongly agree</th>
<th>agree</th>
<th>disagree</th>
<th>strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients will find shared care booklets helpful</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Patients will usually carry shared care booklets</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Professionals will find shared care booklets helpful</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Professionals will use shared care booklets</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Shared care booklets will improve patient care</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Shared care booklets will improve communication between professionals</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Filling in shared care booklets is likely to be a waste of time</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>
CARRYING A SHARED-CARE BOOKLET

Dear

This note explains about a study we are doing in the department of psychiatry.

We are often looking for ways to improve the care that you get from the health service. One thing that may help the doctors and nurses who care you is for you to carry a booklet which has a record of your progress and treatment.

This is already very common in people who are pregnant and have "shared care" during their pregnancy. They carry a card which they show to their GP or hospital consultant whenever they see them.

I want to find out whether carrying a booklet helps people with mental health problems.

If you agree to help, you may be given a small booklet, about the size of a passport, which you should bring with you every time you see your GP, hospital consultant, community nurse, social worker etc. They can then write in this how you are doing, and about your treatment. In this way other people helping to look after you will find out quickly what is happening, by looking at the book.

*Whether you are given a booklet or not is decided by chance, depending on who your general practitioner is.*

If you are given a booklet, you will be able to read the things the doctors and nurses write in it. You may even want to ask them about things they have written in it. This booklet will not have your name on it, so if you lose it you shouldn't be embarrassed.

If you are given a booklet, I would like you to use it for a year.

*Whether you are given a book or not, I would like to have a short chat with you and get you to fill in a couple of questionnaires at the beginning, middle and end of the survey. That is now, then after six months and again after 12 months.*

The only other thing I ask is that you let me have a quick look at your medical notes and the notes that your General Practitioners hold.

**Please remember, you are free to withdraw from this study at any time, and doing so will not affect you care in any way.**

Thank you for reading this. If you have any further questions, please ask me. You can ring me in the hospital on the following number: 0171 794 0500 extension 3950.

Dr James Warner
Appendix 8:
Information sheet for subjects in shared care

SHARED CARE

Some questions and answers:

What is "shared care"?
Shared care means that if you have an illness, for example schizophrenia, the hospital specialist (psychiatrist) and your general practitioner both help to look after you. In other words they share your care.

Doesn't this happen anyway?
Often it does, you probably see both your GP and psychiatrist from time to time about your nerves.

So, what is this study about?
Often, people with mental health problems have several people caring for them. Not only the GP and psychiatrist, but possibly also a social worker, community nurse, psychologist etc. In order to make sure that everyone involved with you knows what is going on, these people may write letters to each other, for example passing on information about a change in your medication, or finding a new flat. Passing information by letter can take a long time, and can get lost "in the system". It would be quicker, and easier if information is entered into a small booklet that you carry with you.

What do I do with this booklet?
You will be given a shared care card; a small booklet which you should bring to all outpatient appointments and appointments with your GP. You could also show it to your community nurse and social worker. In this card, the doctors, nurses and social worker looking after you will write down anything important. They will also write down details of your next appointment and your treatment. This card is yours to keep. You can look at it, and if there is anything you are not sure about, you can ask your doctor. We hope that you will keep the card for a year.

What about confidentiality?
We accept that the card may contain confidential information. For this reason we ask that you try to keep it safe. To protect you from embarrassment, the card will only have your initials and date of birth on it, so if you lose it, it is unlikely to be traced back to you, except by the hospital.

What has all this got to do with me?
We want to find out whether shared care helps the patients we look after. If it does it could be used much more in the future. To help us find this out we will be doing a survey of how shared care helps. We want to know what you think about carrying a card. We also want to find out whether it improves the quality of your care. For this reason, we will ask you to complete a few questionnaires at the beginning of this survey. We will repeat these at six months and then at the end of the survey, after a year.

We hope that you will agree to help.

Thank you

Dr James Warner
Appendix 9
Shared care record

Please see shared care record in pocket at back of thesis.
Dear

Evaluation of patient-held shared care records for individuals with mental illness

I am about to undertake a project designed to investigate the use of shared care booklets in patients with long-term mental health problems. Patients will be allocated, according to their General Practitioner, to one of two groups: carriers of shared care booklets or non-carriers. Those allocated to the shared care group will be given a booklet similar to the one enclosed. This should be presented by the patient at each contact with a health care professional, who may then enter a brief synopsis of the interview into the book. Potential advantages include more rapid communication between agencies and improved care (whatever that is). The advent of smart card technology, with computer encoded health data held by the patient make it essential to determine whether this type of data record is useful in the mentally ill.

From your point of view, I would be grateful if you would spend a few seconds to write something in the booklet when you see patients, especially if you alter their medication or management plan. Anyone involved with the patient's care (consultants, general practitioners, social workers and community psychiatric nurses etc.) are invited to use the booklet. Patients will no doubt need some prompting to produce the card and their case notes will be annotated if they are booklet carriers.

Patients will be asked to continue carrying the booklet for one year, although they may withdraw from the study at any time. If you have any reservations about this study, please let me know.

I am enclosing, for your information, a copy of the patient information sheets.

One final point, I will be assessing the expectation, and satisfaction of the health professionals and I would be grateful if you would complete the enclosed questionnaire and return it to me.

Thank you for your help,

Yours sincerely,

James Warner
Lecturer/Senior Registrar
Appendix 11
Professional's information letter after recruitment

To:

Date:

Dear

re: ____________________________________________

This patient has agreed to participate in our study of shared care and has been given a shared care booklet to carry for the following year. The aim of this booklet is to facilitate communication between different professionals and agencies that care for the patient. This is a passport-sized booklet in 3 sections. The first contains information about personnel involved with that patient's care, and the initials and date of birth of the patient. The centre pages are for you, and other health professionals, to write anything you feel is important for people involved in the care of the patient to know. Please feel free to use it.

The patient should present this book to you at every consultation. Please ask to see it; it may keep you better updated as to what is happening to the patient. At the back is a multidisciplinary appointment section. The patient will be free to read the contents of the booklet, and may as a result become a more active participant in decisions about his/her care.

I am enclosing a self-adhesive label which you may wish to attach to the patients notes.

This study is being conducted in order to evaluate the usefulness of this approach to patient care. Patient held records for people with mental health problems have not been adequately assessed up to now and we wish to find out whether these booklets will help patient's mental health, social wellbeing and use of health services.

If you have any comments or wish to know more, please contact me.

Thank you for helping with this study,

Yours sincerely,

Dr James Warner