Comparison of intensive and standard case management for patients with psychosis

Rationale of the trial

UK700 GROUP

Background Case management, particularly in intensive form, has been widely introduced for the treatment of severe mental illness. However, the optimal intensity of case management has not been determined.

Aims We aimed to assess whether intensive case management (small case load) reduces hospitalisation and costs compared with standard case management.

Method Development and rationale of a large randomised controlled trial comparing intensive case management (case load per worker ≤ 15 patients) with standard case management (case load 30–35 patients).

Results Two-year outcome data will be obtained on patients representative of the seriously mentally ill in inner-city mental health services.

Conclusions The study planned with 700 patients should be sufficient to detect small differences in the readmission of patients to hospital (10%), the number of days spent in hospital over a two-year period (10 days) and the average weekly cost of care per patient. The sample is large enough to compare the cost-effectiveness of intensive and standard case management in mild and severe disability and in people of African–Caribbean origin and White Caucasians.

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This paper describes the rationale and design of the largest study to evaluate intensive case management in the UK. It aims to put the study in context, assist in designing future studies, and indicate which patients are best served by which forms of case management.

The severely mentally ill are at particular risk of neglect in large cities; not only is the prevalence of psychosis high, but the services are often fragmented and poorly coordinated. As a result, many patients fail to make satisfactory use of available resources, drop out of treatment, and show poor clinical and social outcome (Meltzer et al, 1991; Merson et al, 1992). Coordination and continuity of care are therefore of particular importance in the care of people with severe mental illness in cities; indeed, this is a priority in British government policy (Department of Health, 1997). The prime objective of case management is the improvement of these aspects of care (Bachrach, 1993). In this paper, case management is taken to cover both the care programme approach, used in the health service, and care management, used by social services, for those with severe mental illness.

PREVIOUS EVIDENCE OF EFFICACY OF CASE MANAGEMENT

Much of the research into the effectiveness of case management has been performed in the USA. Reviews of this work come to conflicting conclusions regarding the efficacy of case management; the problems highlighted (Baker & Intagliata, 1992; Rubin, 1992; Solomon, 1992; Clark & Fox, 1993; Burns & Santos, 1995) are outlined here.

Defining the model of case management

Case management v. assertive community treatment

A recent systematic review has compared 'case management' and 'assertive community

treatment' (ACT) and attempted to define these (Marshall et al, 1996). Both case management and ACT share the same goals: (a) maintain contact with patients, (b) reduce the frequency and duration of hospital admissions, and (c) improve clinical and social outcome. A case manager is expected to: (a) assess the person's needs, (b) develop a care plan, (c) arrange for suitable care, (d) monitor the quality of care provided and (e) maintain contact with the person (Holloway, 1995). The ACT team, in addition: (a) provides rather than arranges interventions, (b) practices 'assertive outreach', (c) emphasises medication compliance, and (d) offers emergency cover. Assertive community treatment teams invariably work with small case loads of no more than 15 patients each, with the emphasis being on the relationship between the patient and the multi-disciplinary team, so several members may work with the same individual.

Brokerage v. clinical models

One overview compares the 'brokerage' model with the 'clinical' model; the latter is becoming more popular than the former in the USA (Bachrach, 1993). There may be overlap between these two, however, and it is sometimes impossible to discern which model has been used in a particular research project as descriptions of the services are too limited (Burns, 1997).

In the 'brokerage' model, the case manager increases the patient's access to a variety of community services, helps patients to keep appointments, to organise housing placements, and to link in with appropriate social and rehabilitative programmes. However, to some extent, in practice, the case manager accompanies the patient to the appointments thereby increasing the chance of engagement with the service – this is where the brokerage model may become the clinical one.

In the 'clinical' model, the case manager will in addition often become involved in symptom monitoring, rationalising pharmacotherapy, encouraging treatment compliance, and advising on means of ameliorating side-effects of medications. In some studies, the case manager may use psychological techniques for specific problems including medication-unresponsive psychotic symptoms and lack of insight; alternatively, the case manager may refer the patient to a psychologist or other specialist for such treatment.

Evaluation of efficacy

Measures of outcome and costs

Outcomes have traditionally been measured in terms of clinical outcome, that is symptomatic improvement and social outcome (e.g. quality of life) but there is little difference between experimental and control groups on these measures in most studies. Greater attention is now paid to service utilisation and costs of all services as the primary outcomes.

A meta-analysis of case management studies (Marshall et al, 1996) found that both case management and ACT achieve the stated goal of maintaining contact with patients (and both were significantly superior to control) but subjects receiving case management were more likely to be admitted to hospital, whereas the opposite was true for the ACT services. The main difference between these types of service probably lies in health care costs.

Factors influencing outcome

It is not clear what factors are required ingredients of successful case management. The following have been suggested: (a) a single point of accountability (i.e. a keyworker), (b) the case manager–patient relationship, which leads to continuity of care, (c) adherence to pharmacotherapy, (d) good multi-disciplinary team, (e) a psychiatrist as an integrated member of the team, and (f) adherence to the ACT model. However, there is little evidence on which to verify or reject these claims.

Size of case load

The 'clinical' model of case management, in which the case manager provides direct care, requires a small case load to be effective, at least for severely disabled clients. Although it has been asserted that one case manager to 10–15 clients is the optimal ratio (Rubin, 1992) there is no clear evidence to support this view.

Two studies demonstrated that increasing the case load size from 15 patients per case manager to 30–50 patients led to the case managers becoming reactive (to crises) rather than proactive. Case managers were always 'on the run', and unable fully to assess the patient's needs; to save time the case managers did things for patients rather than helping them to become more independent (Baker & Intagliata, 1992; Muijen et al, 1994). Nevertheless, in the UK as a whole, the mean current community psychiatric nurse (CPN) case load is 36 clients; for one-sixth of CPNs it is greater than 50.

A small case load has been a central part of the three main studies evaluating case management in the UK (Ryan et al, 1991; Muijen et al, 1992, 1994); only one showed a definite advantage of intensive case management over standard care in terms of reduced hospitalisation. A small case load allows the case manager to arrange and execute early discharge from hospital, thereby reducing costs (Muijen et al, 1992). A small case load was associated with improved compliance with medication in all three studies.

Nature of the clients

Case management may have greatest impact in certain groups of patients, such as those who are frequently hospitalised and who refuse other after-care services (Bond et al, 1988). However, in their overview, Clark & Fox (1993) conclude that little is known about which clients benefit most from different types of case management. Baker & Intagliata (1992) recommend further studies using large samples that will allow analysis of patient outcome by subgroups (e.g. homeless patients or patients who use illicit substances). In the UK, African–Caribbeans are at increased risk of psychotic illness compared with their White neighbours and have been identified as a group who do not benefit substantially from standard management and, in particular, have poor compliance with medication and a high readmission rate (Thomas et al, 1993; Sellwood & Tarrier, 1994). Research is needed to demonstrate which categories of patients respond to intensive input and those categories whose outcome is independent of type of case management (Muijen et al, 1994).

Access to support facilities

Local resources available to people with serious mental illness vary a great deal between centres. If local resources are poor or scarce, then the potential for case managers linking clients with them and improving outcome is severely limited. If local resources are available but poorly accessed, there is considerable scope for the case manager to be effective (Meltzer et al, 1991; Solomon, 1992); if they are already accessed, then case management may add little. A successful outcome has been related to widespread use of vocational services and poor outcome linked to failure to use day care facilities.

Aspects of the research design

Factors relevant to the present design include the failure of previous studies to include a major proportion of the patients in a district service (casting doubts upon the generalisability of the results), lack of measures of unmet need and quality of life (which may vary independently of symptomatology and social functioning), lack of specific training for all case managers, problems with differences between experimental and control groups in baseline measures of severity of disability arising through the absence of random allocation, and lack of measures of compliance to assess whether this is related to outcome.

Comparison between the case management service and standard treatment

Some earlier comparisons of case management teams with services which were known to be substandard mean that differences in outcome may have derived more from the inadequacies of the control service than from strengths of the case management service (Marshall et al, 1996).

Duration of case management

When the advantage of case management over standard care has been demonstrated, this has usually not become apparent for at least one year; shorter studies may therefore miss an effect (Baker & Intagliata, 1992).

Cost and clinical/social outcome

Few studies have examined cost and outcome. Although cost savings (through reduced hospitalisation) may be the clearest advantage of case management (Clark & Fox, 1993), this needs to be related to outcome measures to ensure that relative therapeutic neglect is not registered as a treatment advantage.

Patient characteristics predict response

Previous studies of case management have paid little attention to potential predictors of outcome. Such factors include duration of illness prior to the study, nature of premorbid adjustment, level of social relationships, presence of affective symptoms, and level of cognitive functioning.

THE STUDY

In 1993, four centres, three in London – St Mary's and St Charles' Hospital; St George's; the Maudsley and King's College Hospital; and the School of Psychiatry and Behavioural Sciences, University of Manchester – obtained National Health Service (NHS) research and development funding for a randomised controlled trial of intensive case management. All four sites are inner-city areas.

Aspects of overall design

The study is designed as a randomised controlled trial, in which one key variable (case load size) was different between the experimental and the control groups, while all other important variables which might determine outcome (e.g. access to other services and training offered to the intensive and standard case managers) were the same for the two groups. This stringent condition, so common in trials in other areas of medicine, is not easy to meet in mental health service research.

By creating teams with small case loads, coupled with appropriate training, we intended to encourage assertive outreach. In practice, however, the establishment of intensive case management teams at four centres across the UK, where no such teams had previously existed, was, in itself, an enormous task. To insist on adherence to a particular model of case management was beyond the scope of this study, whose primary aim was to assess the effect of case load size rather than to test a particular model of case management.

Inclusion of a large number of subjects would allow analysis by subgroups of patients of sufficient size to test subsidiary hypotheses, for example concerning African–Caribbean patients and those with more severe forms of disability. It would also allow the evaluation of predictors of outcome and the investigation of adverse events.

Aims of the study

The following hypotheses are to be tested:

(a) Intensive case management by mental health workers carrying a small case load leads to less hospitalisation of patients and reduced costs compared with case management by those carrying a standard case load.

(b) Intensive case management leads to better outcome and lower costs in severely, but not moderately, disabled psychotic patients.

(c) The differences in outcome between intensive and standard case management are greater in African–Caribbean patients than other ethnic groups (mainly Caucasians).

The two forms of case management are being compared using a parallel design over two years in approximately 700 patients with psychosis (aged 18–65 years) from four centres.

Inclusion criteria

Each of the four centres attempted to recruit 200 patients with psychosis into the study using the following inclusion criteria:

(1) Psychosis, defined as the presence, according to the Research Diagnostic Criteria, of delusions, hallucinations or thought disorder (Spitzer et al, 1978).

(2) At least one-third of patients should be of African–Caribbean ethnicity, using the Office of Population Censuses and Surveys (1993) classification of ethnicity.

(3) Aged 16–65 years.

(4) Hospitalised for psychotic symptoms at least twice, with the most recent admission within the previous two years.

(5) Absence of organic brain damage or a primary diagnosis of substance abuse.

(6) Patient not already involved in some form of case management (such as a specific rehabilitation programme), but permitting 'routine' care programme approach.

Patient recruitment

Patients were either recruited at the point of discharge from hospital (when the symptomatology and social functioning may be optimal) or in the community (when engagement may be more difficult and clinical and social functioning and quality of life may be considerably impaired).

Randomisation

Patients were individually randomised to assertive case management (case loads 10–15) or standard case management (case loads of 30 or more) independently by statisticians at the London School of Hygiene and Tropical Medicine by telephone contact.

The randomisation process was stratified by (a) centre, (b) source of patient at point of randomisation – either at discharge from hospital or in the community, and (c) ethnic origin (30% of patients will be African–Caribbean), except at St George's where randomisation was by minimisation (Pocock, 1983) to achieve a balance by gender, ethnic origin and community mental health team. All patients gave informed consent prior to randomisation.

It was impractical to randomise mental health workers as well as patients at all study centres.

Follow-up and outcomes

Data were collected at baseline, year one follow-up and year two follow-up from interviews with patients, relatives or carers and from case notes. The researchers could not be blind to treatment group as additional information from case managers was required, for example, to ensure safety of researchers.

The primary outcome measure will be duration of hospitalisation over two years. In addition, we shall compare outcome in terms of symptomatology, quality of life, unmet needs for care, disability, satisfaction with services and service costs (Comprehensive Psychopathological Rating Scale (Jacobsson et al, 1978), Montgomery–Åsberg Depression Rating Scale (Montgomery & Åsberg, 1979), Lancashire Quality of Life Profile (Oliver, 1991), and the Camberwell Assessment of Need (Brewin et al, 1987)).

Treatment fidelity

Information about contact with services is particularly detailed. It includes continuous case management records, time sampling observation studies and retrospective researcher interviews. Particular attention is being paid to urgent contacts with case managers, general practitioners, other members of the psychiatric services, accident and emergency departments, forensic contacts, etc., to determine whether intensive case management leads to more contacts in the community and involves other services to a greater or lesser extent.

Although other local services may change during the course of the project due to external pressures such as budget and policy decisions, the key variable under scrutiny, case load size, will not change.

Generalisability

The multi-site study and large sample size increases the generalisability of the study's results. However, since the study is being

performed in inner-city locations with similar NHS resources the results may not be generalisable to all other locations.

Sample size

The power calculations were based on the results of the Daily Living Programme study (Muijen *et al*, 1992), but with a greatly reduced duration of standard length of hospitalisation, and the Greenwich results (Muijen *et al*, 1994). We used the costs from the Daily Living Programme study (Knapp, 1995), and assumed a drop-out rate over two years of 15%. With 350 patients randomised to each case management strategy, we will be able to detect any of the following differences (or larger) as statistically significant at the 5% level with 80% power:

(a) A 10-day mean difference in the number of days spent in hospital over two years (e.g. a reduction from 45 to 35 days).

(b) A 10% difference in two-year hospitalisation rates (e.g. a reduction from 80% to 70% associated with intensive case management).

(c) A difference of £45 in the average weekly cost per patient (e.g. a reduction from £200 to £155).

In the subgroup of African–Caribbean patients (about 100 patients in each group), the corresponding differences that will be detected with the same power are: (a) a 17-day mean difference in hospital stay, (b) an 18% difference in hospitalisation rates, and (c) an £80 average weekly cost difference.

Statistical analysis

The principal analysis will compare average time in hospital over two years between the intensive and standard groups (as randomised). Adjustment will be made for centre, source of patient (hospital v. community) ethnic group, and initial level of disability. The following treatment variables will also be examined in relation to outcome: duration of contact with case manager, and compliance with medication. The symptomatology, disability, unmet needs for care, quality of life and patient satisfaction scores at two years will be summarised and compared using analysis of covariance, adjusting for baseline levels. The one-year data will be used to describe the time course of any difference observed.

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Economic analysis

The primary objective of the economic analysis is to determine the relative costs and cost-effectiveness of intensive v. standard case management. Therefore, the focus of the economic component of the analysis will be a comparison of the direct health and social care costs associated with intensive and standard case management. Data on the utilisation of health and social care resources will be collected prospectively for both groups over the study period and the unit costs of these resources will be estimated. Where possible, unit costs will be locally determined and collected directly from service providers. For some services, particularly those which add little to the total cost of care, national published cost data may be employed. Relevant costs will include case manager contacts, hospital services, primary care services and social services. The use and cost of staffed accommodation, voluntary sector services and police and legal services will also be evaluated.

Data on service utilisation for each client in the trial will be multiplied by the unit cost of those services to provide a total cost per client. From this, an average cost per client will be calculated for both the intensive and standard case management groups. Cost variations within and between the experimental and control groups, and within and between the four sites will be analysed.

If there are significant differences in the costs of the experimental and control groups, it will be appropriate to relate the net costs of the two intensities of case management to patient outcomes. A descriptive comparison of the costs and outcomes of intensive and standard case management will be undertaken (cost-consequences analysis) and a cost-effectiveness analysis carried out. The primary outcome measure in the trial is duration of hospitalisation for psychiatric problems and cost-effectiveness will be calculated as the cost per day in hospital for psychiatric problems.

Patients recruited

A total of 708 patients were recruited into the study. Approximately half were recruited at the point of discharge from hospital and half were resident in the community. Fifty-seven per cent of the sample are male, average age 38 years (s.d.=12 years); 52% are White Caucasians, 28% Black Caribbean, 10% Black African/Black other and 10% other ethnicity.

Eighty-seven per cent have schizophrenia or schizoaffective disorder, 5% bipolar disorder, 2% major depression and 6% unspecified functional psychosis. The median duration of symptoms is 14 years. Only 12% of patients were living as married and 20% were in full- or part-time work. Approximately one-third of patients were living with a family member.

Results

This study will provide two-year outcome data on 708 patients who are representative of the seriously mentally ill in inner-city mental health services. It will demonstrate any differences in the readmission rates, social and clinical outcomes and health care costs between those managed with intensive case management and those managed with standard care.

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