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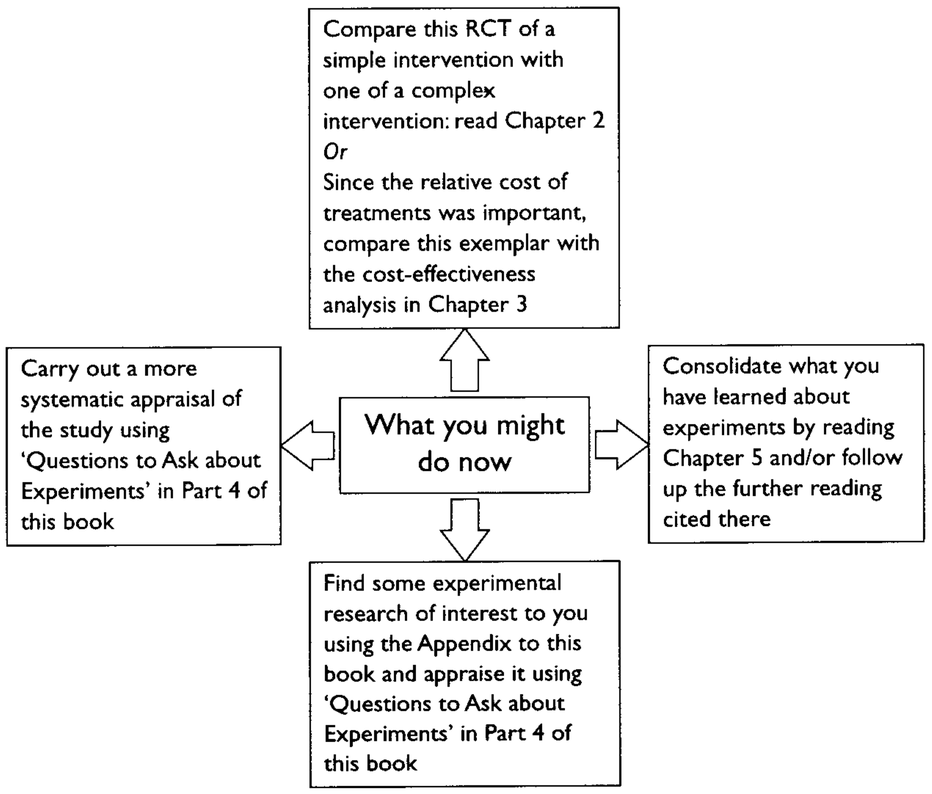
What you might do now



CHAPTER 2

EXPERIMENTAL METHODS AND COMPLEX INTERVENTIONS: CASE MANAGEMENT IN MENTAL HEALTH CARE

Marshall, M., Lockwood, A. and Gath, D. (1995) 'Social Services case-management for long-term mental disorders: a randomised controlled trial', *The Lancet*, 345: 409–12

EXEMPLAR

What you need to understand in order to understand the exemplar
The basics of experimental design. *See Chapter 5, throughout but particularly sections 1 to 3, 5 to 9 and 12*
'the data were first evaluated to ensure normality of sampling distributions, linearity and homogeneity of variance' *See Chapter 7, section 6*
The table of results (Table 3). *See Chapter 7, section 10.1*
Why the researchers used 'off-the-peg' instruments rather than inventing their own. *See Chapter 6, section 1*
The problems caused by subjects dropping out of experiments. *See Chapter 5, section 8*
That given the extreme scores of all subjects on entry, some of the improvement shown may be due to regression to the mean. *See Chapter 5, section 6*
The difficulties arising from non-standardised treatment of subjects within arms of an experiment. *See Chapter 5, section 7; Chapter 7, section 7*
The problem of conducting experiments about complex interventions. *See Introduction to this Chapter; Chapter 5, section 9*

The way most of the instruments used generated interval level data or better, which is analysed with parametric statistics (ANCOVA, *F*-test) though measures in days were treated as ordinal data and analysed with the non-parametric Mann-Whitney *U* test. *See Chapter 6, sections 3 and 4; Chapter 7, section 6*
You do *not* need to understand how to do the statistical calculations in this research but you do need to understand the meaning of statistical significance and the interpretation of confidence intervals. *See Chapter 7, sections 1, 2 and 4*

Introduction

The exemplar for this chapter is a study of case (or care) management in social work for people living in the community and diagnosed as suffering from severe mental illness. The idea of case management for mental health emanated in the USA, and in the UK became a constituent of community care for mentally ill people with the introduction of the 'Care Programme Approach', first in England and Wales from 1990 and later in Scotland. But neither in the USA, nor in the UK was there much sound evidence from research to show that case management for people with severe mental health problems would have better outcomes than alternative ways of organising care in the community.

The study takes a randomised controlled trial format, without blinding (see Chapter 5). Blinding practitioners would have been impracticable in this situation and the fact that practitioners knew what treatment subjects were receiving creates room for practitioner bias to influence the results (Chapter 5, section 5). However, such bias, if it occurred, would be most likely to create differences in outcomes, while the result of this trial was of similar outcomes for subjects dealt with differently.

There is a case for saying that the topic of case management is at or beyond the limits of what can be investigated using randomised controlled trials, or other experimental structures, at least with the kinds of sample size they usually have. This is because of the complexity of the interventions concerned (Chapter 5, section 9). Community mental health care is supposed to involve practitioners customising the care to the particular needs of individual clients and there is no reason to suppose that practitioners involved in this trial did otherwise. Thus while the researchers behave as if they were conducting a trial with two arms – treatment and control – it can be suggested that

in reality this was a trial with a large but undetermined number of arms; many different modalities of treatment; many different modalities of alternatives (see Chapter 7, section 7). In this trial there are also likely to be differences *within* arms of the trial between practitioners; their levels of skill, their congeniality to particular clients, and so on. These comments would be more important if this experiment had shown significant differences in improvement in mental health between the two groups, because failures to create and maintain similar groups and failures to standardise treatments within arms of a trial are more likely to produce outcome differences than outcome similarities. In fact, the trial showed little difference in mental health outcomes for two groups on most of a number of different measures.

There is no reason not to accept the researchers' conclusion that *in this case*, with the exception of deviant behaviour measurement, there were no significant differences in the outcomes measured between the group subjected to case management and the group dealt with otherwise. The authors, quite rightly, do not claim that either treatment actually caused the improvements made. These might have been due to the fact that those selected for the experiment were in a severe condition, and for that reason were more likely to get better than worse (see Chapter 5, section 6) in both arms of the experiment. Or it may be that those least likely to improve were those most likely to drop out of either arm of the experiment. A weakness of this study is that at the end there are no data for 24 per cent of the subjects who were entered into the experiment at the beginning (Chapter 5, section 8).

There are problems in this experiment about the extent to which its results can be generalised (Chapter 5, section 12). The generalisability question is 'how far can the results of this study serve as a confident judgement on "case management" elsewhere?'. The research report gives very little information as to what case management meant in the experiment. Nor does it describe the way in which the controls were treated. Readers have no way of judging how different these two interventions were from each other, or how similar the case management of one client was to the case management of another (Chapter 5, section 7). To add to this difficulty, the term 'case management' has no fixed meaning, and what is called case management in one place may be very different from what is called case management in another, particularly in terms of face-to-face relations between client and practitioner. Thus readers do not really know what was done, and do not know how it compares to what happens in their own practice. This makes it extremely difficult to base generalisations on this study. However, most other studies in the same field give similar results. This suggests that even though there is a wide variety of practices going under the name of case management,

none of them has much effect, and the result of this study strengthens this conclusion.

The analysis of experimental and quasi-experimental research tends to concentrate on differences *between* arms of a trial. Restricting comparisons to those between means (averages) for groups leads prematurely to the conclusion that had the case managed and the control groups been reversed, then the outcomes would have been much the same, not only group score on group score, but individual by individual. This may be a cogent assumption where interventions are simple and standardised and the important mechanisms are physiological, but it seems unlikely where relationships and interpretations are the important mechanisms for change. Almost certainly there will be some people who made more improvement under the alternative treatment, who would have made less if case managed, and some people who made less improvement under case management and who would have made more under the alternative regime. The bald question 'does case management work?' around which this study is framed is less interesting than the questions 'is case management the best option for anyone, and if so, for whom and under what circumstances and why?' This is a question which is amenable to experimental research but would require a very large sample indeed in order to pursue it; large enough to distinguish distinctive sub-groups within arms of the trial and to analyse the factors associated with more improvement under one regime than another (see Chapter 7, section 7).

SOCIAL SERVICES CASE-MANAGEMENT FOR LONG-TERM MENTAL DISORDERS: A RANDOMISED CONTROLLED TRIAL

M. Marshall, A. Lockwood, D. Gath

Summary

Case-management arose in the USA as a solution to the difficulties of providing community care to people with severe mental disorders. The basic principle of the approach is that a case-manager takes responsibility for a client; arranges an assessment of need, a comprehensive service plan, delivery of suitable services, and monitoring and assessment of services delivered. The case-management approach has been widely accepted, to the extent that recent legislation has made case-management the cornerstone of community care in the UK.

We did a randomised controlled trial to evaluate a social services case-management team for people with long-term mental disorders. Subjects were referred from hostels for the homeless, night shelters, a general practitioner clinic for the homeless, the Oxford City Council homelessness unit, and local voluntary-sector group homes. Of 103 subjects referred, 80 consented to be randomised to treatment or control groups. At 14-month follow-up, as assessed by standardised interviews, there were no significant differences between groups in number of needs, quality of life, employment status, quality of accommodation, social behaviour, or severity of psychiatric symptoms. In the case-management group there was a significant reduction in deviant behaviour on a standardised behaviour rating scale (REHAB) (mean = 0.79; 95% confidence interval (CI) 0.26–1.32).

It is unfortunate, in view of the limited effectiveness we have shown, that social services case-management was not evaluated in randomised controlled trials before its implementation in the UK.

Introduction

People with long-term mental disorders have many social and psychiatric needs.[1] Since the closure of psychiatric hospitals in the UK, services required to meet these needs have become dispersed among different sites and providing authorities,[2] with the consequence that many people with mental disorders are unable to obtain the care they need.[3] In the USA, case-management arose as a solution to this problem of dispersion; this approach has been widely accepted[4,5] and recently became the cornerstone of community care in the UK.

In the UK, as elsewhere, the practice, composition, and organisation of case-management teams vary. Some UK teams work entirely within social services departments; others are jointly managed by social services and mental health services, or by mental health services alone.[6] Nevertheless, teams share basic principles of the case-management approach: a case-manager, who takes responsibility for a client, arranges an assessment of need, a comprehensive service plan, delivery of suitable services, monitoring and assessment of services delivered, and also evaluates results.[2,7] The expectation was that, by working alongside existing services, case-management teams would improve the quality and efficiency of care for patients with long-term mental disorders.[8]

The case-management approach has been described as 'intuitively appealing',[9] but there is little evidence that it is efficacious. The only randomised trial of an approach comparable to that practised by UK case-management teams was carried out in the USA and showed that the case-management group received more services than the control group and were more often admitted to mental hospitals, but showed no improvements in quality of life.[9] We report the findings of a randomised controlled trial of the effectiveness of a social services case-management team set up by Oxford Social Services in September 1991.

Subjects and methods

The study was a randomised controlled trial. Subjects were assessed before allocation to treatment or control groups and at 7 and 14 months after entering the study.

Entry and randomisation

Before the study, researchers and the case-management team approached two local night shelters, three hostels for the homeless (two of which also provided sheltered accommodation), a general practice clinic for the homeless, the city council homelessness unit, housing associations providing sheltered care, a local voluntary organisation providing group homes, and a health authority employment rehabilitation service in contact with people living in poor-quality bedsits. These organisations were asked to refer subjects to the study over a 6-month recruitment period.

Subjects were considered for inclusion if they were judged by the referrer to have a severe, persistent, psychiatric disorder; were homeless (roofless, or living in a night shelter or hostel for the homeless); at risk of homelessness (i.e., facing a threat of eviction, or having a recent history of homelessness, or frequent changes of accommodation); living in accommodation which was temporary, or supported (such as a group home), or of poor quality; were coping badly, experiencing social isolation, or causing disturbances; and were not clients of another case-management service.

Subjects who had a well-documented psychiatric history were assessed either by a trained research nurse or a research psychiatrist; others were assessed by a research psychiatrist. One of the authors (M.M.) then allocated an ICD-10 diagnosis.

After initial assessment, subjects were randomly allocated to case-management or control groups. Randomisation was by sealed envelop. Random permuted blocks were used to keep the numbers of subjects balanced in both groups. Once a subject had been allocated to the case-management team, the senior case-manager was notified of the subject's name, address and principal carer.

Case-management

Case-managers chose how much time to offer each subject. As a minimum, each was offered an assessment of need from a case-manager, a discussion of the findings of this assessment with the subject's carer, intervention from the case-manager to meet needs that were identified, monitoring of the subject's progress by the case-manager, and further assistance should needs arise. In addition, case-managers were free to choose how far they would personally assist the subject with transport, counselling, organisation of activity programmes, assistance with completion of forms, crisis intervention, help with finding accommodation, assistance with benefits, finding work or places on training courses, and help with obtaining furnishings and domestic appliances. The extent to which case-managers should act as advocates was likewise an individual choice.

Control

Subjects continued to receive any assistance that they had been receiving before the study. Staff working with subjects were at liberty to obtain any further care they saw fit. However, no control subjects were taken on by the study case-management team, or by any other case-management team.

Rating scales

The needs of subjects for psychiatric and social care were assessed with a modified version of the MRC Needs for Care Schedule,[10] as described elsewhere.[11,12] Ratings of need were made by a psychiatrist and a psychiatric nurse, both experienced in psychiatric rehabilitation. Quality of life was assessed in terms of accommodation, employment status, and subjects' own ratings of their quality of life on the Quality of Life Interview.[13]

Social behaviour was measured by observer ratings and subjects' own ratings. The observer rating of social behaviour was made with a standardised behaviour scale (REHAB), which rates the frequency of items of embarrassing or disruptive behaviour, such as violence, self harm, shouting and swearing, and sexual offensiveness (deviant behaviour); and lack of general skills (general behaviour).[14] REHAB ratings were made by an observer trained by the researchers (e.g., a member of staff in a hostel, a voluntary worker, or a primary-care worker). The subject's perception of his or her own social behaviour was rated with the Social Integration Questionnaire.[15] Severity of psychiatric symptoms was assessed with the Manchester Scale.[16]

Analysis

The data were first evaluated to ensure normality of sampling distributions, linearity and homogeneity of variance. One-way repeated measures analyses of variance were used to compare scores at the start, and at 7 and 14 months. Two by two repeated measures analyses of covariance (incorporating experimental grouping as a between-subjects factor) were used to examine differences between groups in ratings of psychopathology, social functioning, quality of life and numbers of needs. In each of these analyses the scores on the dependent variable at baseline were used as the covariates.

Changes in the accommodation status of the subjects were analysed with non-parametric statistics. Control and treatment groups were compared in terms of the number of days in accommodation better than their baseline accommodation, days in accommodation worse than baseline, and days in hospital. Employment status was compared with non-parametric statistics, after adjustment for baseline differences between the groups. Comparisons were made of total days in employment, and of weighted days (paid employment receiving greater weight than voluntary work). (Details available from authors.)

Results

During the 6-month recruitment period, 103 subjects were referred to the study, of whom 14 declined to participate and 4 were unable to give informed consent. Mean age of these 18 subjects was 53.2 years; 2 were female. Case-notes indicated that 11 (61%) had a previous diagnosis of schizophrenia or a related disorder. Five subjects were excluded from the study before randomisation because they were involved with another case-management service. Eighty subjects entered the study.

After baseline assessment, they were randomly allocated to case-management (40) or control groups (40).

Baseline characteristics

There were no significant differences between the groups in terms of age, sex, housing status, previous psychiatric history, diagnosis (Table 1), or psychiatric symptoms (Table 2). At baseline, mean REHAB general behaviour score of the 80 subjects was high (43.5; SD 24.3; 95% CI 38.6–48.9). 36 (45.6%) were mildly socially disabled; 27 (34.2%) were moderately disabled; and 16 (20.3%) were severely disabled. The sample had high measures of deviant behaviour (mean 1.25; 0.89–1.61). At baseline, subjects had a mean of 1.0 psychiatric/medical needs, and 2.6 social needs (total 3.6 needs, SD 2.2).

Table 1 Characteristics of subjects

	Contol group (n = 40)		Case-management (n = 40)	
	No.	**%**	**No.**	**%**
Age grouping				
20–29	4	10.0	4	10.0
30–39	6	15.4	11	28.2
40–49	16	40.0	6	15.4
50–59	5	12.5	9	22.5
60+	9	22.5	9	22.5
Sex				
Male	34	85.0	34	85.0
Female	6	15.0	6	15.0
History				
Illness > 1 year	40	100	40	100
Previous psychiatric admission	34	85.0	34	85.0
In contact with psychiatric services	25	62.5	21	52.5
ICD 10 diagnosis				
Schizophrenia and related disorders	32	80.0	27	67.5
Mood disorders	3	7.5	6	15.0
Personality disorder	2	5.0	3	7.5
Neurotic disorders	1	2.5	3	7.5
Organic disorders	2	5.0	1	2.5
Housing status				
Hostels for the homeless	18	45.0	20	50.0
Staffed group homes	7	17.5	4	10.0
Unstaffed group home	5	12.5	5	12.5
Night shelter or sleeping rough	4	10.0	3	7.5
Supported flat	3	7.5	3	7.5
Own flat	2	5.0	3	7.5
Poor quality bedsit	0	0.0	2	5.0
With family	1	2.5	0	0.0

Table 2 Symptoms among study subjects

Subjects	Symptoms no. (%)				
	Psychotic*	**Mood†**	**Negative§**	**Any**	**None**
Control	21 (52.5)	21 (52.5)	14 (35)	32 (80)	8 (20.0)
Case-management	19 (47.5)	18 (45)	11 (27.5)	31 (77.5)	9 (22.5)
All	40 (50)	39 (48.8)	25 (31.3)	63 (78.8)	17 (22.2)

* Rating of two or more points on any of the following Manchester scale items: hallucinations, delusions, or incoherence of thought. † Rating of two or more points on any of the following Manchester scale items: depression, anxiety. § Rating of two or more points on any of the following Manchester scale items: psychomotor retardation, blunting of affect, or poverty of speech.

Outcome

Of the 80 subjects assessed at baseline, 61 were reassessed at 7 and 14 months after entering the study, and 8 at 7 but not at 14 months. Of 11 who dropped out, 6 were in the case-management and 5 were in the control group. Reasons for drop out were: moved to another town (6); refused further contact (2); died (2); and moved locally without leaving contact address (1). The 2 who died were in the case-management group.

The sample as a whole showed significant improvements in social behaviour (REHAB general behaviour, $F = 5.01$, $p < 0.01$) and social integration ($F = 4.28$, $p < 0.05$) over 14 months. Table 3 shows the results of the repeated measures analyses of covariance, which were used to compare measures of quality of life, social behaviour, deviant behaviour, social integration, and mental state at 7 and 14 months. Outcome was better for the case-management group on three of the five variables (REHAB general and deviant behaviour and mental state), but only deviant behaviour differed significantly between the two groups. Subjects in the case-management group had a mean of 44.3 days in better accommodation as against a mean of 32.3 for the control group; and a mean of 15.1 days in worse accommodation as against a mean of 33.4 for the control group. These differences were not significant (days in better accommodation, Mann–Whitney $U = 470$; $p = 0.17$; days in worse accommodation, $U = 515$; $p = 0.67$). Subjects in the control group spent a mean of 21.8 (SD 62.3) days in hospital during the study whereas subjects in the case-management group spent a mean of 14.6 (30.5) days in hospital. There was no significant difference between the groups in terms of days in hospital, after adjustment for days in hospital during the baseline period (mean of observed days − expected days [control group] = 5.3; mean of observed days − expected days [case-management] = 5.6; $U = -1.6$; $p = 0.1$).

Subjects in the case-management group spent slightly more days in employment than expected, whereas subjects in the control group spent slightly fewer days than expected; this difference between the groups is not statistically significant either for days in any kind of employment ($U = 726$; $p = 0.40$) or for days in employment weighted in favour of paid employment or training ($U = 733$; $p = 0.45$). There were significant falls in the numbers of needs for psychiatric/medical care and social care in both groups ($F = 18.7$; $p < 0.001$), but there were no significant differences between the groups (Table 3).

Throughout the study, case-managers kept a record of the time spent working with, or for, each subject. 4 subjects received no input from the case-management

Table 3 Outcome of control and case-management groups

Measure	Group	Baseline scores (n)	Change at 7 mth (n)	Change at 14 mth (n)	Mean diff at 14 mth (95% CI)*	F	Clinically relevant difference†
REHAB GB	Control	44.7 (40)	4.3 (35)	4.9 (30)	4.3 (−4.9 to 13.4)	0.87	15
	Case-management	42.2 (40)	5.3 (34)	7.5 (31)			
REHAB DB	Control	1.56 (40)	0.15 (35)	0.19 (30)	0.3 (0.15 to 0.46)	8.42§	0.5
	Case-management	0.98 (40)	0.26 (34)	0.42 (31)			
Manchester scale	Control	6.73 (40)	0.1 (35)	−0.8 (30)	0.75 (−1.0 to 2.5)	0.26	2.0
	Case-management	6.88 (40)	0.1 (34)	0.1 (31)			
Quality of life	Control	3.54 (38)	0.0 (32)	0.2 (27)	0.0 (−0.42 to 0.42)	0.19	1.0
	Case-management	3.59 (40)	0.2 (33)	0.2 (31)			
Social interactions	Control	1.77 (40)	0.0 (35)	0.2 (29)	−0.07 (−0.27 to 0.13)	1.36	0.5
	Case-management	1.80 (40)	0.1 (34)	0.2 (31)			
Needs	Control	3.60 (40)	1.2 (35)	1.3 (30)	−0.07 (−0.97 to 0.84)	0.02	1.0
	Case-management	3.68 (40)	1.7 (34)	1.3 (31)			

* Mean difference between the groups at 14 months and the 95% CIs were calculated with a linear regression model in which baseline scores were the independent variable. A negative score indicates a difference in favour of the control group. † Estimate of the change in score that would represent a clinically recognisable improvement.
§ $p < 0.01$. GB = general behaviour, DB = deviant behaviour.

team; of these, 1 left Oxford within 2 days of being recruited, 2 refused to be seen, and 1 was admitted to hospital. Case-managers gave a mean of 21.6 h (SD 32.4) to the remaining 36 subjects.

Discussion

The aim of the study was to determine the effectiveness of social services case-management in addition to services already provided in the community. After 14 months of case-management, case-management subjects showed no significant differences from controls on measures of need, quality of life, quality of accommodation, employment status, social behaviour, or psychopathology; they showed significantly less deviant behaviour. This limited effectiveness is in keeping with other findings.[5,9]

Our findings cannot be generalised to all case-management teams in the UK; variability between teams means that an overall judgement on the effectiveness of case-management has to be based on the accumulated findings of several trials. However, our results challenge the orthodoxy that case-management is effective. The case-managers we studied may not have spent enough time with subjects to bring about improvement, although case-managers decided how much time to spend with a subject, as happens in everyday practice.

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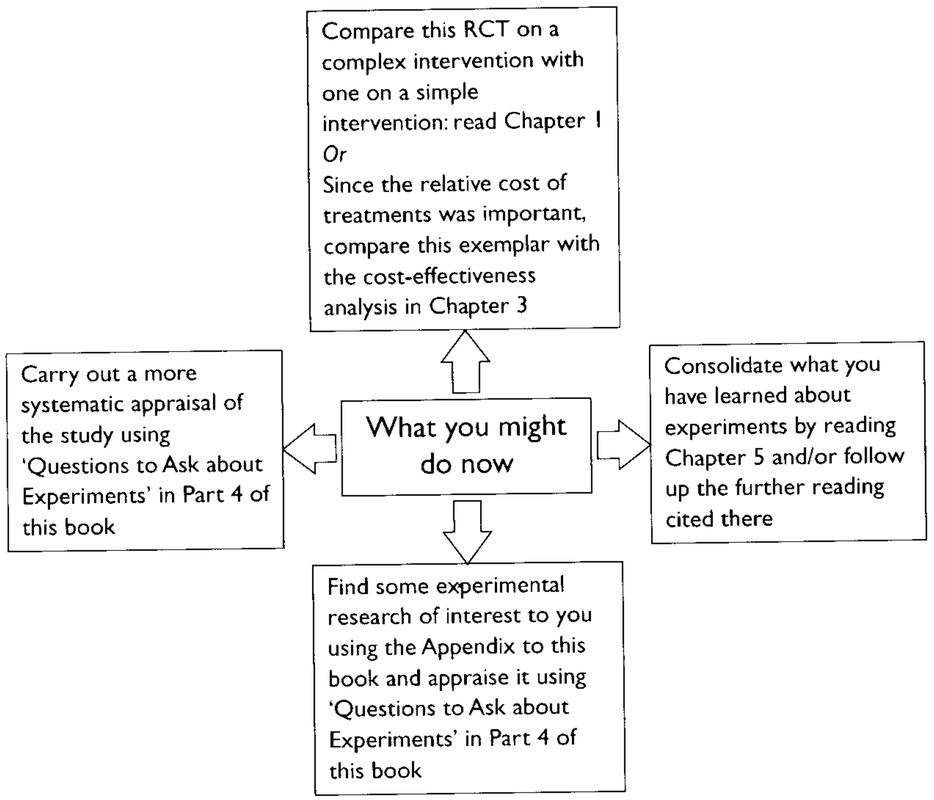
What you might do now



CHAPTER 3

FROM EFFECTIVENESS TO COST-EFFECTIVENESS: A TRIAL OF A HOSPITAL AT HOME SCHEME

Shepperd, S., Harwood, D., Gray, A., Vessey, M. and Morgan, P. (1998) 'Randomised controlled trial comparing hospital at home care with inpatient hospital care. II: cost minimisation analysis', *British Medical Journal*, 316: 1791–6

EXEMPLAR

What you need to understand in order to understand the exemplar
You can accept that the RCT establishing the similar effectiveness of the two interventions was well-designed and well-conducted, but if you want to investigate experimental design for research on effectiveness, see the *Introduction to this chapter and Chapter 5*
'analysis was done on an intention to treat basis' *See Chapter 5, section 8*
'When appropriate, data with a non-normal distribution was log transformed before further parametric analysis was done.' (The use of the geometric mean is for the same reason.) *See Chapter 6, section 4 (data transformations); Chapter 7, section 6*
What the figures for standard deviation (SD) tell you. *See Chapter 7, section 9*
P values and how to interpret them (where no *p* values are cited the results are not statistically significant at the 0.05 (5%) level). *See Chapter 7, section 2 (especially Table 7.2)*
Confidence intervals and how to interpret them. *See Chapter 7, sections 4 and 5*
Sensitivity analysis. *See Chapter 7, section 12*
The problems of generalising from a cost-effectiveness study done in one locale to cost-effectiveness elsewhere. *See Chapter 5, section 12*