# User-held personalised information for routine care of people with severe mental illness (Review)

**Farrelly S, Brown GE, Flach C, Barley E, Laugharne R, Henderson C**

THE COCHRANE COLLABORATION®

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2013, Issue 10

http://www.thecochranelibrary.com

WILEY


**Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.**

## TABLE OF CONTENTS





Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

[Intervention Review]

# User-held personalised information for routine care of people with severe mental illness

Simone Farrelly[1], Gill E Brown[2], Clare Flach[3], Elizabeth Barley[4], Richard Laugharne[5], Claire Henderson[6]

[1]Health Service and Population Research Department, Institute of Psychiatry, London, UK. [2]Faculty of Health and Social Care, Edge Hill University, Ormskirk, UK. [3]Biostatistics, Health Sciences-Methodology, University of Manchester, Manchester, UK. [4]Florence Nightingale School of Nursing and Midwifery, King's College London, London, UK. [5]Mental Health Research Group, Cornwall Partnership NHS Foundation Trust and Peninsula College of Medicine and Dentistry, Exeter, UK. [6]Health Service and Population Research Department, Institute of Psychiatry, King's College London, London, UK

Contact address: Simone Farrelly, Health Service and Population Research Department, Institute of Psychiatry, King's College London, De Crespigney Park, London, SE5 8AF, UK. simone.farrelly@kcl.ac.uk.

**Editorial group:** Cochrane Schizophrenia Group.
**Publication status and date:** New search for studies and content updated (conclusions changed), published in Issue 10, 2013.
**Review content assessed as up-to-date:** 2 August 2011.

**Citation:** Farrelly S, Brown GE, Flach C, Barley E, Laugharne R, Henderson C. User-held personalised information for routine care of people with severe mental illness. *Cochrane Database of Systematic Reviews* 2013, Issue 10. Art. No.: CD001711. DOI: 10.1002/14651858.CD001711.pub2.

Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

## ABSTRACT

### Background

It is important to seek cost-effective methods of improving the care and outcome of those with serious mental illnesses. User-held records, where the person with the illness holds all or some personal information relating to the course and care of their illness, are now the norm in some clinical settings. Their value for those with severe mental illnesses is unknown.

### Objectives

To evaluate the effects of personalised, accessible, user-held clinical information for people with a severe mental illness (defined as psychotic illnesses).

### Search methods

We updated previous searches by searching the Cochrane Schizophrenia Group Trials Register in August 2011. This register is compiled by systematic searches of major databases, and handsearches of journals and conference proceedings.

### Selection criteria

We included all relevant randomised controlled trials (RCTs) that:

i. have recruited adult participants with a diagnosis of a severe mental illness (specifically psychotic illnesses and severe mood disorders such as bipolar and depression with psychotic features); and

ii. compared any personalised and accessible clinical information held by the user beyond standard care to standard information routinely held such as appointment cards and generic information on diagnosis, treatment or services available.


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

**Data collection and analysis**

Study selection and data extraction were undertaken independently by two authors and confirmed and checked by a third. We contacted authors of trials for additional and missing data. Where possible, we calculated risk ratios (RR) and 95% confidence intervals (CI). We used a random-effects model. We assessed risk of bias for included studies and created a 'Summary of findings' table using GRADE.

**Main results**

Four RCTs (n = 607) of user-held records versus treatment as usual met the inclusion criteria. When the effect of user-held records on psychiatric hospital admissions was compared with treatment as usual in four studies, the pooled treatment effect showed no significant impact of the intervention and was of very low magnitude (n = 597, 4 RCTs, RR 0.99 CI 0.71 to 1.38, moderate quality evidence). Similarly, there was no significant effect of the intervention in three studies which investigated compulsory psychiatric hospital admissions (n = 507, 4 RCTs, RR 0.64 CI 0.37 to 1.10, moderate quality evidence). Other outcomes including satisfaction and mental state were investigated but pooled estimates were not obtainable due to skewed or poorly reported data, or only being investigated by one study. Two outcomes (violence and death) were not investigated by the included studies. Two important randomised studies are ongoing.

**Authors' conclusions**

The evidence gap remains regarding user-held, personalised, accessible clinical information for people with psychotic illnesses for many of the outcomes of interest. However, based on moderate quality evidence, this review suggests that there is no effect of the intervention on hospital or outpatient appointment use for individuals with psychotic disorders. The number of studies is low, however, and further evidence is required to ascertain whether these results are mediated by the type of intervention, such as involvement of a clinical team or the type of information included.

## PLAIN LANGUAGE SUMMARY

**Patient-held clinical information for people with psychotic illnesses**

User-held information is where the ill person holds personal information about their care. Such records are becoming the norm in many settings and are becoming more popular with patients. This is especially the case where the person concerned is not in hospital and receives care from more than one professional. Providing people with information about their care is thought to increase their feelings of involvement in their treatment and aims to increase people's satisfaction and participation with services, ensure early treatment and prevent hospital admission.

The value of user-held personal information for those with severe mental illnesses is not known however and research evaluating the effectiveness is rare. Some research suggests that while many people decline the offer of a user-held record, the majority of those who carry their records report this to be useful.

Based on a search in 2011, this review includes four trials with a total of 607 people and evaluates the effects of user-held information for people with severe mental illness. In the main, the number of relevant studies is low, with poor reporting of some outcomes. Based on moderate quality evidence, the review found that user-held information did not decrease hospital admissions, and did not decrease compulsory admissions or encourage people with severe mental illness to attend appointments (when compared to treatment as usual). Other important outcomes, such as satisfaction with care, costs and effect on mental health, were not available due to the limited quality of the four studies. There is therefore a gap in knowledge and evidence regarding user-held information for people with severe mental health problems. Further evidence is also required on the different types of user-held information (for example, if it involves the mental health team and what type of information is included in the record). Large-scale, well-conducted and well-reported studies are required to assess the effects of user-held information for people with mental illness. Two important randomised studies are currently taking place. For the present, despite a gap in evidence, user-held information is low cost and acceptable to patients, so its use is likely to grow. However, it cannot be assumed that user-held information is of benefit to people and is cost-effective without further large-scale, well-conducted and well-reported trials.

This plain language summary has been written by a consumer, Benjamin Gray: Rethink Mental Illness. E-mail: ben.gray@rethink.org


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

## SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

**User-held information versus Sstandard Information for routine care of people with severe mental illness**

**Patient or population:** patients with routine care of people with severe mental illness
**Settings:** inpatient and community (UK)
**Intervention:** user-held information versus standard information

| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of Participants (studies) | Quality of the evidence (GRADE) | Comments |
|---|---|---|---|---|---|---|
| | Assumed risk | Corresponding risk | | | | |
| | Control | USER-HELD INFORMATION versus STANDARD INFORMATION | | | | |
| **Psychiatric hospital admission: psychiatric admission**<br>Numbers admitted<br>Follow-up: mean 13 months | **Low**[1] | | **RR 0.99**<br>(0.71 to 1.38) | 597<br>(4 studies) | ⊕⊕⊕◯<br>**moderate**[2] | |
| | **50 per 1000** | **49 per 1000**<br>(35 to 69) | | | | |
| | **High**[1] | | | | | |
| | **440 per 1000** | **436 per 1000**<br>(312 to 607) | | | | |
| **Psychiatric hospital admission: compulsory admission**<br>Numbers admitted<br>Follow-up: mean 13 months | **Low**[1] | | **RR 0.64**<br>(0.37 to 1.1) | 507<br>(3 studies) | ⊕⊕⊕◯<br>**moderate**[3] | |
| | **40 per 1000** | **26 per 1000**<br>(15 to 44) | | | | |
| | **High**[1] | | | | | |
| | **260 per 1000** | **166 per 1000**<br>(96 to 286) | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Death: causes other than suicide** - not reported | See comment | See comment | Not estimable | - | See comment | No study reported this outcome |
| **Violence** - not reported | See comment | See comment | Not estimable | - | See comment | No study reported this outcome |
| **Mental state: psychopathology** | See comment | See comment | Not estimable | 0 (3 studies) | See comment | Data not pooled: studies used inconsistent/incompatible measures of psychopathology and/or data are skewed. No indication of differences between groups |
| **Satisfaction with health care** | See comment | See comment | Not estimable | 0 (3 studies) | See comment | Data not pooled: studies used inconsistent/incompatible measures of satisfaction and/or data are skewed. No indication of differences between groups |

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
**CI:** Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence
**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.
**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
**Very low quality:** We are very uncertain about the estimate.

[1] Assumed risk: the low and high risk values correspond to the lowest and highest rates of admissions in the control groups from the included studies.

[2] Imprecision: rated 'serious' - The 95% confidence interval around the pooled estimate is wide, it contains no effect, appreciable benefit and appreciable harm as defined by the GRADE system as a 25% risk decrease or increase respectively.

User-held personalised information for routine care of people with severe mental illness (Review)
Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

[3] Imprecision: rated 'serious' - The 95% confidence interval around the pooled estimate is wide, containing both no effect and an appreciable benefit as defined by the GRADE system as 25% risk reduction. There were also only 67 events in total.


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

# BACKGROUND

It is important to seek cost-effective methods of improving the care and outcome of those with serious mental illnesses. User-held records, where the person with the illness holds all or some personal information relating to the course and care of their illness, are now the norm in some clinical settings (Kaelber 2008). This is particularly the case where the person concerned is not in hospital and receives care from more than one professional. User-held notes are becoming popular for obstetric care (Brown 2004; Phipps 2001) both in developed and developing countries (Shah 1993). Parent-held records are widely used in paediatric care (Bourgeois 2009; Ghossein 1998; Hampshire 2004). The management of people with chronic disabilities such as stroke or cancer can also involve user-held records (Banet 1997; Finlay 1999; Ko 2010; Williams 2001).

Brief types of user-held information are available for use in emergencies such as anaphylaxis and post-splenectomy infection (Freeman 1998; Wharry 1996; Williams 1996). This type of information tends not to be comprehensive and the aims vary with setting and condition. Nevertheless, as with the full notes, the aim of these truncated personal record systems is to promote patient participation in care, increase consumer satisfaction with services, facilitate early treatment and help avoid hospital admission.

Both long and short forms of user-held information are now being used for people with mental health problems (Backlar 1996; Essex 1990; Henderson 2004; Lester 2003; Pickersgill 1998; Reuler 1991; Stafford 1997; Sutherby 1999; Swanson 2006a; Wolf 1996). In certain countries legislation obligates the provision of a copy of the treatment outline and professionals' contact details to those in receipt of specialist mental health services (DoH 1990). This information is not specifically designed to be something patients might wish to carry, nor to be of use in a crisis, but it may in itself have an effect, so evaluation is justified. Another form of personal information has recently emerged. Advance Statements can be defined as statements regarding service user preferences for future treatment (Henderson 2008). These are typically devised and held by the service user and include such interventions as Psychiatric Advance Directives, Joint Crisis Plans (Sutherby 1999) and Wellness Recovery Actions Plans (Cook 2009).

Attempts at evaluation of the effects of user-held records for those with long term mental illness are rare. There are several audit and case series studies of the use of user-held records (Essex 1990; Pickersgill 1998; Reuler 1991; Stafford 1997; Wolf 1996). These suggest that while many people refuse the offer of a user-held record, the majority of those who carry their records report this activity to be useful (Stafford 1997). In the USA, Psychiatric Advance Directives (PADs) have been shown to be popular with service users and their carers (Backlar 2001) and some professional groups (Atkinson 2004). However, there are some concerns regarding the implementation of wishes contained in PADs during crises from both service users and clinicians (Atkinson 2004; Backlar 2001); the ability of the service user to generate a valid PAD (Amering 2007; Atkinson 2004; Elbogen 2007); and questions regarding their impact on or relationship to outcome (Backlar 2001). Additionally, clinicians often express concern regarding the possibility of service users requesting unreasonable treatments or indeed refusing treatment altogether (Atkinson 2004; Backlar 2001; Elbogen 2006; Swartz 2005; Van Dorn 2006). However, an analysis of the content of PADs developed by 106 outpatients in the US (Srebnik 2005) showed that in 95% of cases the PADs were rated as clinically useful and consistent with clinical practice standards. Another type of advance statement, the Wellness Recovery Action Plan (WRAP) is a structured self-management intervention that assists users both manage symptoms and consider broader life issues. A recent assessment of WRAPs for mental illness (Cook 2009) suggests that it may generate improvements in a range of areas including symptoms, hopefulness and feelings of empowerment. Furthermore, a case series study of the Joint Crisis Plan intervention (Sutherby 1999) in which patients develop their personalised plan for use in a crisis or possible relapse, suggests that hospital use may be reduced in those who develop such a plan. The increased input in determining future treatment was suggested to be an important factor in determining the perceived coerciveness of the treatment experience (Lidz 1995). It certainly seems plausible that those who have little knowledge of the patient or no access to their notes, such as a junior psychiatrist in a hospital emergency department, would find such information useful in making an appropriate disposition, and further that actions carried out which have been previously negotiated are less likely to require compulsory interventions.

## Description of the condition

For the purpose of this review, we defined severe mental illness (SMI) as psychotic disorders and severe mood disorders such as bipolar disorder and depression with psychotic features. Psychosis is a collective term used to describe a range of conditions including schizophrenia, delusional disorder, and schizoaffective disorder. Individuals with psychotic disorders may experience a range of symptoms including unusual thoughts or 'delusions', hallucinations, and mood disturbance such as emotional flatness and withdrawal. Recent studies of schizophrenia globally suggest that about seven individuals per 1000 will be affected and individuals with schizophrenia have a two to threefold increased risk of dying compared to the general population (McGrath 2008). The economic burden associated with schizophrenia is substantial, with recent estimates suggesting it represents between 1.5% and 3% of total healthcare expenditures (Knapp 2004).

## Description of the intervention


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

'User-held records' may be defined as information, held by the individual with the illness, which contains all or some personal information relating to the course and care of his or her illness. User-held records may include notes made by professionals at appointments and kept by the patient, advance directives and crisis cards (personal information held for use in the event of a crisis or relapse).

### How the intervention might work

The main aim of providing individual patients with personalised information about their illness and treatment is to improve the individual's sense of control and empowerment. Providing patients with information is thought to increase their feelings of involvement in their treatment, reducing the perceived coerciveness of the treatment experience (Lidz 1995); it may also facilitate early help-seeking.

### Why it is important to do this review

This is an update of a Cochrane review first published in 1999 (Henderson 1999). The previous review found no studies meeting the criteria for inclusion, but found two ongoing trials (Lester 2003; Papageorgiou 2002). Since the publication of the original Cochrane review, there have been a number of published and relevant clinical trials undertaken. Additionally, current national treatment guidelines in the United Kingdom (NICE 2009) recommend involving mental health service users in decisions about their treatment and providing opportunities for service users to make advance statements and advance decisions to refuse treatment. Valid advance decisions are now legally binding under the UK's Mental Capacity Act 2005. User-held records potentially provide a cost-effective methodology for facilitating such involvement. Several of the authors of this updated review are affiliated with an ongoing trial of user-held records (CRIMSON) (Thornicroft 2010). Another randomised evaluation of user-held records for those with serious mental illnesses (Ruchlewska 2009) is known to be ongoing.

## OBJECTIVES

To evaluate the effects of personalised, accessible, user-held clinical information for people with a severe mental illness (defined as psychotic illnesses).

## METHODS

### Criteria for considering studies for this review

#### Types of studies

All relevant randomised, controlled trials (RCTs).

#### Types of participants

Adults with SMI. For the purposes of the review we defined SMI as a diagnosis of a psychotic illness, including other psychoses such as bipolar disorder and depression with psychotic features. In studies where there was a mixture of diagnostic groups, only those studies where the majority of participants (that is, more than 50%) had psychotic diagnosis were included. We did not include studies where the sole diagnosis was bipolar disorder or depression. People whose main problem and primary diagnosis was one of deliberate self harm were also not the focus of this review.

#### Types of interventions

**1. User-held information: any personalised and accessible clinical information held by the patient beyond standard care.**

This includes both user-held records (notes made by professionals at appointments and kept by the patient) and crisis cards (personal information held for use in the event of a crisis or relapse). Generic information on diagnosis, treatment or services available was excluded.

**2. Standard information: any information routinely held such as appointment cards and generic information on diagnosis, treatment or services available.**

In certain settings standard information may include a copy of the treatment plan with contact details for the key carers (DoH 1990).

#### Types of outcome measures

Outcomes were not part of the criteria for including studies in the review. Outcomes of interest are listed below. We divided outcomes into very short term (less than three months), short term (less than six months), medium term (seven to 12 months) and long term (over one year).

##### Primary outcomes

**1. Psychiatric hospital admission**

1.1 Admitted or not
1.2 Compulsory admission


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

1.3 Number of days spent in hospital
1.4 Discharged or not

**2. Death from causes other than suicide**

**3. Violence**

***3.1 To self***

3.1.1 Non-fatal
3.1.2 Fatal

***3.2 To others***

3.2.1 Major (homicide, sex attacks, attempted or actual serious assault)
3.2.2 Non-major (incidents requiring attendance of police or on-ward seclusion or special civil law admissions to a place of safety)

**Secondary outcomes**

**1. Rates of criminal charges**

**2. Mental state**

2.1 Relapse of psychotic illness
2.2 Mental state score

**3. Satisfaction with health care**

3.1. Patient satisfaction
3.2. Carer satisfaction

**4. Perceived coercion on hospital admission**

**5. Acceptability of management**

5.1 As measured by loss to follow-up within the study

**6. Compliance with treatment other than the intervention**

**7. Social functioning**

7.1 Homelessness
7.2 Employment
7.3 Average change in social functioning

**8. Economic costs of all care and health care**

**9. Other relevant measures**

**10. Summary of findings table**

We used the GRADE approach to interpret findings (Schünemann 2008) and used the GRADE profiler (GRADEPRO) to import data from RevMan 5.1 (Review Manager) to create 'Summary of findings' tables. These tables provided outcome-specific information concerning the overall quality of evidence from each included study in the comparison, the magnitude of effect of the interventions examined, and the sum of available data on all outcomes we rated as important to patient care and decision making. We aimed to select the following main outcomes for inclusion in the 'Summary of findings' table.

- Psychiatric hospital admission: general admission - medium and long term
- Psychiatric hospital admissions: compulsory admission - medium and long term
- Death: causes other than suicide
- Violence
- Mental state: psychopathology - medium and long term
- Satisfaction with health care - medium and long term

## Search methods for identification of studies

### Electronic searches

We searched the Cochrane Schizophrenia Group Trials Register (August 2011) using the phrase:
[((*consumer?h?ld* or *consumer?particip* or *client?h?ld* or *client?particip* or *user?h?ld* or *user?particip? or *patient?h?ld* or *patient particip* or (*Cris?s* AND *plan*) in the title, abstract and index terms in REFERENCE) and ((patient particip* or patient info* or *decision* or medical record* or *crisis plan*) in interventions field in STUDY)]
This register is compiled by systematic searches of major databases, handsearches of journals and conference proceedings (see Group Module). For previous searches please see Appendix 1.

### Searching other resources

#### 1. Reference lists

All references of included articles were searched for further relevant trials.


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

## Data collection and analysis

Methods used in data collection and analysis for this update are below, for previous methods please see Appendix 2.

### Selection of studies

SF and GB independently inspected all citations from the searches and identified relevant abstracts. Where disputes arose, the full report was acquired for more detailed scrutiny and was independently assessed. All included citations were then discussed with CH. Where it was not possible to resolve a disagreement by discussion, we contacted the authors of the study for clarification. If citations met the inclusion criteria, we obtained full reports of the papers for more detailed inspection. Full reports were then inspected by SF and GB, and discussed with CH.

### Data extraction and management

#### 1. Extraction

Review author SF extracted data from all included studies. In addition, to ensure reliability, GB independently extracted data from all studies. Any disagreement was discussed with CF (statistician) and the decisions documented and, if necessary, authors of studies were contacted for clarification. CH provided advice and final decisions were documented. We attempted to contact authors through an open-ended request in order to obtain missing information or for clarification whenever necessary. If studies were multi-centre, where possible, we extracted data relevant to each component centre separately.

#### 2. Management

#### 2.1 Forms

We extracted data onto standard, simple forms.

#### 2.2 Scale-derived data

We included continuous data from rating scales only if:
a. the psychometric properties of the measuring instrument have been described in a peer-reviewed journal (Marshall 2000); and
b. the measuring instrument has not been written or modified by one of the trialists for that particular trial.
Ideally the measuring instrument should either be: i. a self-report, or ii. completed by an independent rater or relative (for example, not the therapist). We acknowledge that this is often not reported clearly and noted if this was the case or not in the 'Description of studies' section.

#### 2.3 Endpoint versus change data

There are advantages of both endpoint and change data. Change data can remove a component of between-person variability from the analysis. On the other hand the calculation of change needs two assessments (baseline and endpoint), which can be problematic in unstable and difficult to measure conditions such as schizophrenia. We decided to primarily use endpoint data, and only use change data if the former were not available. If we had found both, we would have combined endpoint and change data in the analysis and used mean differences (MD) rather than standardised mean differences throughout (Higgins 2011).

#### 2.4 Skewed data

Many of our targeted outcomes tend to be skewed, for example, duration of admission and duration of compulsory admission. For this reason the authors of included studies have provided non-parametric summary measures and tests, that is, the median and range, and tested with the Mann-Whitney U test. Since it is not possible to combine non-parametric data in a meta-analysis, and there were so few studies that met the inclusion criteria and provided these data, we report these data in 'Other data' tables.

#### 2.5 Common measure

To facilitate comparison between trials, we converted variables reported in different metrics, such as days in hospital (mean days per year, per week or per month), to a common metric (for example, mean days per month).

#### 2.6 Conversion of continuous to binary

Where possible we tried to maintain continuous measures to avoid losing information and power in the analyses.

#### 2.7 Direction of graphs

Where possible, we entered data in such a way that the area to the left of the line of no effect indicated a favourable outcome for user-held records. Where keeping to this made it impossible to avoid outcome titles with clumsy double-negatives we reported data where the left of the line indicates an unfavourable outcome. This was noted in the relevant graphs.

### Assessment of risk of bias in included studies

SF and GB worked independently to assess risk of bias by using the criteria described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) to assess trial quality. This set of criteria is based on evidence of associations between overestimation of effect and high risk of bias of the article, such as sequence generation, allocation concealment, blinding, incomplete outcome data and selective reporting.


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

If the raters disagreed, the final rating was made by consensus, with advice from CH. Where inadequate details of randomisation and other characteristics of trials were provided, the authors of the studies were contacted in order to obtain further information. Non-concurrence in quality assessment was reported, but if disputes arose as to which category a trial was to be allocated, again, resolution was be made by discussion.

## Measures of treatment effect

### 1. Binary data

For binary outcomes we calculated a standard estimation of the risk ratio (RR) and its 95% confidence interval (CI). It has been shown that RR is more intuitive (Boissel 1999) than odds ratios and that odds ratios tend to be interpreted as RR by clinicians (Deeks 2000). For statistically significant results we had planned to calculate the number needed to treat to provide benefit/to induce harm statistic (NNTB/H), and its 95% confidence interval (CI) using Visual Rx (http://www.nntonline.net/) taking account of the event rate in the control group. This, however, has been superseded by the Summary of findings for the main comparison and calculations therein.

### 2. Continuous data

We had too few studies to combine continuous outcomes. Furthermore, outcomes common to more than one study were assessed by different measures therefore precluding any combined estimate of effect. However, if we had found sufficient studies we would have estimated the mean difference (MD) between groups. Data from included studies were often skewed, in these circumstances we have presented the data as reported by the original authors in 'Other data' tables.

## Unit of analysis issues

### 1. Cluster trials

Studies increasingly employ 'cluster randomisation' (such as randomisation by clinician or practice) but analysis and pooling of clustered data poses problems. Firstly, authors often fail to account for intra-class correlation in clustered studies, leading to a 'unit of analysis' error (Divine 1992) whereby P values are spuriously low, confidence intervals unduly narrow and statistical significance overestimated. This causes type I errors (Bland 1997; Gulliford 1999).

For relevant cluster trials that did not account for clustering in the primary studies (Warner 2000), we have presented data in a table marked with a (*) symbol to indicate the presence of a probable unit of analysis error. We have sought statistical advice and were advised that the binary data as presented in a report should be divided by a 'design effect'. This is calculated using the mean number of participants per cluster (m) and the intra-class correlation coefficient (ICC) (design effect = 1 + (m - 1)*ICC) (Donner 2002). If the ICC was not reported it was assumed to be 0.1 (Ukoumunne 1999).

Clustering was appropriately incorporated into the analysis of one of the cluster studies (Lester 2003) but not in the second (Warner 2000). Therefore we have reported the original data as if from a non-cluster randomised study (Analysis 1.1) and, in addition, have provided a cluster-adjusted outcome where frequencies have been divided by the design effect (Analysis 1.8).

### 2. Cross-over trials

A major concern of cross-over trials is the carry-over effect. It occurs if an effect (for example, pharmacological, physiological or psychological) of the treatment in the first phase is carried over to the second phase. As a consequence, on entry to the second phase the participants can differ systematically from their initial state despite a wash-out phase. For the same reason cross-over trials are not appropriate if the condition of interest is unstable (Elbourne 2002). We did not find any cross-over trials in our search.

### 3. Studies with multiple treatment groups

We did not find any multiple treatment group studies, but we would have presented the additional treatment arms in comparisons. If data were binary we would have added and combined the data within the two-by-two table. If data were continuous we would have combined data following the formula in section 7.7.3.8 (Combining groups) of the *Cochrane Handbook for Systematic Reviews of Interventions*. Where the additional treatment arms were not relevant, we would not have reproduced these data.

## Dealing with missing data

### 1. Overall loss of credibility

At some degree of loss of follow-up data must lose credibility (Xia 2009). We chose that, for any particular outcome, should more than 50% of data be unaccounted for we would not reproduce these data or use them within analyses. If, however, more than 50% of those in one arm of a study were lost, but the total loss was less than 50%, we would have marked such data with (*) to indicate that such a result may well be prone to bias. However, this did not occur for any of the included studies.

### 2. Binary

The included studies had low attrition on the primary outcomes. However, had we found higher attrition rates we would have followed the following procedure. Where attrition for a binary outcome was between 0% and 50% and where these data were not


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

clearly described, we would have presented data on a 'once randomised always analyse' basis (an intention-to-treat analysis). We would have assumed that data were missing at random, and that those leaving the study early would be similar to those remaining and have the same rates of negative outcome as those who completed the study.

#### 3. Continuous

### 3.1 Attrition

If attrition for a continuous outcome had been between 0% and 50% and completer-only data were reported, we would have reproduced these. However, this was not the case.

### 3.2 Standard deviations

The continuous outcome measures in our studies were skewed and authors reported the median as a summary measure rather than the mean. In the case of skewed data the standard deviation is not a useful measure and so we did not seek to obtain it. Had the mean values been reported but not the standard deviations we would have first tried to obtain the missing values from the authors. If not available, we would have calculated the standard deviation, where possible, from the data provided, that is, from confidence intervals and statistical tests.

### 3.3 Last observation carried forward

We did not find any studies that used the last observation carried forward (LOCF) for missing data. If this had been used in a trial for less than 50% of the data, we would have reproduced these data and indicated that they were the product of LOCF assumptions.

## Assessment of heterogeneity

#### 1. Clinical heterogeneity

We considered all included studies initially, without seeing comparison data, to judge clinical heterogeneity. We simply inspected all studies for clearly outlying people or situations which we had not predicted would arise. When such situations or participant groups arose, these were discussed.

#### 2. Methodological heterogeneity

We considered all included studies initially, without seeing comparison data, to judge methodological heterogeneity. We simply inspected all studies for clearly outlying methods which we had not predicted would arise. When such methodological outliers arose these were fully discussed.

#### 3. Statistical heterogeneity

### 3.1 Visual inspection

We visually inspected graphs to investigate the possibility of statistical heterogeneity.

### 3.2 Employing the $I^2$ statistic

Heterogeneity between studies was investigated by considering the $I^2$ statistic method alongside the $Chi^2$ P value. The $I^2$ provides an estimate of the percentage of total variance due to study heterogeneity (beyond inconsistency thought to be due to chance) (Higgins 2003). The importance of the observed value of $I^2$ depends on: i. magnitude and direction of effects, and ii. strength of evidence for heterogeneity (for example, P value from $Chi^2$ test, or a confidence interval for $I^2$). An $I^2$ estimate greater than or equal to around 50%, accompanied by a statistically significant $Chi^2$ statistic, was interpreted as evidence of substantial levels of heterogeneity (Higgins 2011). When substantial levels of heterogeneity were found in the primary outcome, we explored reasons for heterogeneity (Subgroup analysis and investigation of heterogeneity).

## Assessment of reporting biases

Reporting biases arise when the dissemination of research findings is influenced by the nature and direction of results (Egger 1997). These are described in Section 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We are aware that funnel plots may be useful in investigating reporting biases but are of limited power to detect small-study effects. As we had less than 10 studies, we did not use funnel plots.

## Data synthesis

We understand that there is no closed argument for preference for use of fixed-effect or random-effects models. The random-effects method incorporates an assumption that the different studies are estimating different, yet related, intervention effects. This often seems to be true to us and the random-effects model takes into account differences between studies even if there is no statistically significant heterogeneity. There is, however, a disadvantage to the random-effects model. It adds an extra weight to all studies, making the weights more evenly spread and giving small studies relatively more weight compared to the fixed-effect model analysis. The small studies are often the most biased ones and, depending on the direction of effect, these studies can either inflate or deflate the effect size. We chose the random-effects model for all analyses as the studies were all of similar size. The reader is, however, able to choose to inspect the data using the fixed-effect method.


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

### Subgroup analysis and investigation of heterogeneity

#### 1. Subgroup analyses - only primary outcomes

We proposed to undertake this review and provide an overview of the effects of user-held records for people with schizophrenia, and therefore we did not perform any subgroup analyses.

#### 2. Investigation of heterogeneity

If inconsistency was high, this was reported. First we investigated whether the data had been entered correctly. Second, if data were correct, the graph was visually inspected and studies outside the company of the rest were successively removed to see if homogeneity was restored. For this review we decided that should this occur with data contributing to the summary finding of no more than around 10% of the total weighting, the data were presented. If not, the data were not pooled and issues were discussed. We know of no supporting research for this 10% cut off but are investigating use of prediction intervals as an alternative to this unsatisfactory state.

When unanticipated clinical or methodological heterogeneity was obvious, we simply stated that hypotheses regarding these for future reviews or versions of this review would be generated. We did not undertake analyses relating to these.

### Sensitivity analysis

#### 1. Implication of randomisation

We planned to include trials in a sensitivity analysis if they were described in some way as to imply randomisation. For the primary outcomes we included these studies and if there was no substantive difference when the implied randomised studies were added to those with a better description of randomisation, then all data were employed from these studies.

#### 2. Assumptions for lost binary data

There was low attrition in the included studies and therefore it was not necessary to perform a sensitivity analysis.

#### 3. Risk of bias

We analysed the effects of excluding trials that were judged to be at high risk of bias across one or more of the domains of randomisation (implied as randomised with no further details available), allocation concealment, blinding and outcome reporting for the meta-analysis of the primary outcome. If the exclusion of trials at high risk of bias did not substantially alter the direction of effect or the precision of the effect estimates, then data from these trials were included in the analysis.

#### 4. Imputed values

We also undertook a sensitivity analysis to assess the effects of including data from trials where we used imputed values for ICC in calculating the design effect in cluster randomised trials.

If substantial differences were noted in the direction or precision of effect estimates in any of the sensitivity analyses listed above, we did not pool data from the excluded trials with the other trials contributing to the outcome but presented them separately.

#### 5. Fixed and random effects

We assessed the differences between using a fixed-effect model and a random-effects model on our primary outcomes of interest.

## RESULTS

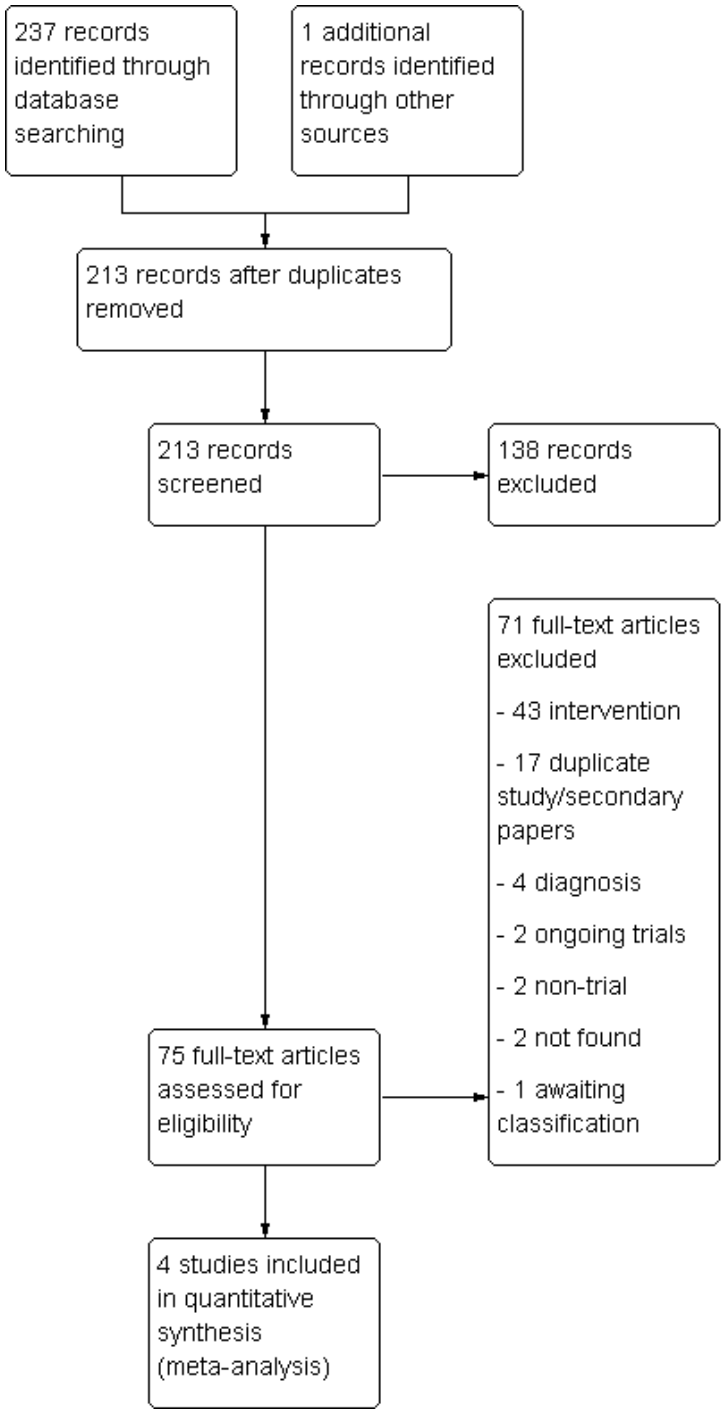
### Description of studies

### Results of the search

Electronic searches identified 237 references. Seventy-five potentially relevant records were obtained and scrutinised, and 70 of these reports did not meet the inclusion criteria (see Characteristics of excluded studies). Two references were protocols for ongoing trials for which no data were available at the time of review (Figure 1).


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

**Figure 1. Study flow diagram.**





Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

## Included studies

Four studies met our inclusion criteria (Henderson 2004; Lester 2003; Papageorgiou 2002; Warner 2000) and are summarised in the 'Characteristics of included studies' table. One study met our inclusion criteria, however we were unable to include it as the required summary statistics and results were not provided in the report. We have classified this study (Swanson 2006) as 'awaiting classification' in the event we should obtain the relevant results from the study authors in the future.

### 1. Study design

All studies were randomised controlled trials. Warner 2000 and Lester 2003 used cluster randomisation and the remaining trials used individual level randomisation. Both cluster trials acknowledged and investigated clustering effects within their reported data. The Lester 2003 study reported that the random-effects model did not alter the results of their analysis and so reported the original figures, which we use in our report. The Warner 2000 study did not specifically report a cluster-adjusted analysis, but provided a design effect based on the intra-class correlation coefficient of 1.53. We have reported the results with the original data and have additionally provided a cluster-adjusted result where the Warner 2000 frequencies have been divided by the design effect.

### 2. Study sizes

The total number of participants included in the four studies was N = 607. The average among the studies was n = 152 and the range was 90 to 201.

### 3. Study setting

All studies were conducted in the United Kingdom. Warner 2000 and Lester 2003 were conducted in a 'shared care' setting, that is, care that was jointly provided by primary and secondary care. Lester 2003 was conducted between six community mental health teams in Birmingham (UK); Papageorgiou 2002 was delivered in an inpatient setting, whereas all other trials involved participants who were treated in community settings. Participants in Henderson 2004 were from eight community mental health teams in South London and Kent (UK).

### 4. Participants

With the exception of Lester 2003, which included only those people with a diagnosis of schizophrenia, all studies had a mixture of diagnoses. Henderson 2004 recruited individuals with psychosis and bipolar disorders (proportions not reported). Papageorgiou 2002 had 63% with psychosis and 28% with depression and bipolar. Warner 2000 had 42% schizophrenia and 12% bipolar (the remaining diagnoses included 22% depression and 14% 'other') and thereby reached our inclusion criterion (at least 50%). In terms of gender profile, there were 338 male participants and 269 female participants across the studies, with the studies having a majority male sample (range 53% to 68%). The average age in the studies was very similar, with inclusion criteria ranging from 18 to 66 years, and a mean age of 39 years.

### 5. Interventions

Two of the studies (Henderson 2004; Papageorgiou 2002) tested a form of advance statement (Henderson 2008); that is, personal information and treatment preferences held for use in the event of a crisis or relapse. In these two studies, the user developed the user-held record with the help of a researcher or 'facilitator', and in the Henderson 2004 study the clinical team involved in delivering routine care was also involved. The content of these interventions was similar and broadly included the users' views on relapse indicators, wishes for future treatment, contact details for themselves, their clinicians and family and carers. They may also have included an indication of treatments that they did not want, that is, a refusal of medication.

The other two studies (Lester 2003; Warner 2000) tested a form of medical record which included aspects such as contact details, clinical notes, future appointments and medication. Lester 2003 also included an indication of relapse indicators and a diary section. For Lester 2003 and Warner 2000, these records were given to the user after randomisation.

All studies compared the active intervention to 'treatment as usual' in primary or secondary care. In addition, Henderson 2004 provided control participants with information leaflets regarding local services, treatments, and relevant legislation and policies (Henderson 2004).

### 6. Outcomes (rating scales)

A range of outcomes were investigated in the included studies. However, only four outcomes were investigated by more than one study: psychiatric hospital admissions; psychopathology; satisfaction; and outpatient attendance. All outcomes investigated by the studies are listed below.

#### 6.1 Psychiatric admissions

Each included study compared the effect of user-held records to treatment as usual on the rate and length of psychiatric admission.


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

### 6.2 Compulsory psychiatric admissions

Henderson 2004, Lester 2003 and Papageorgiou 2002 also examined the rates of compulsory psychiatric hospital admissions under a section of the UK's Mental Health Act. Henderson 2004 and Papageorgiou 2002 additionally looked at number of days spent under a section of the Mental Health Act.

### 6.3 Psychopathology

Psychopathology was examined by three of the four studies (Lester 2003; Papageorgiou 2002; Warner 2000).

*6.3.1 Brief Psychiatric Rating Scale (BPRS)* (Overall 1962)

Warner 2000 used the BPRS, which is a rating scale designed to assess psychopathology across 16 dimensions: somatic concern; anxiety; emotional withdrawal; conceptual disorganisation; guilt feelings; tension; mannerisms and posturing; grandiosity; depressive mood; hostility; suspiciousness; hallucinatory behaviour; motor retardation; uncooperativeness; unusual thought content; and blunted affect. The BPRS is usually rated by an experienced researcher or clinician, with each item rated on a seven-point scale, varying from 0 = 'not present' to 7 = 'extremely severe', with high scores indicating more severe symptoms.

*6.3.2 Behavior and Symptom Identification Scale (BASIS-32)* (Eisen 1994)

Papageorgiou 2002 and Warner 2000 used the BASIS-32 scale, which is a self-report measure completed by patients. The BASIS-32 has five subscales: relation to self and others; daily living and role functioning; depression and anxiety; impulsive and addictive behaviour; and psychosis. Thirty-two items are rated between 0 (= no problem) and 4 (= severe problem).

*6.3.3 Krawiecka and Goldberg (K & G) scale* (Krawiecka 1977)

Additionally, Lester 2003 used the K & G scale, which is a five-point rating scale assessing psychopathology across the following domains: depressed; anxious; coherently expressed delusions; hallucinations; incoherence and irrelevance of speech; poverty of speech; flattened incongruous affect; psychomotor agitation; and side effects of medication (tremor, rigidity, dystonic reactions, akathisia, difficulties with vision, other). A score of 0 represents the absence of an item, where a score of 4 may indicate severe psychopathology.

### 6.4 Satisfaction

*6.4.1 Verona Service Satisfaction Scale (VSSS)* (Ruggieri 1993)

Three studies examined the effect of the intervention on patient satisfaction. Lester 2003 and Papageorgiou 2002 used the Verona Service Satisfaction Scale (VSSS), however Papageorgiou 2002 used an 'adapted brief version'. The full VSSS-54 contains 54 items rating questions over seven dimensions: overall aspects; professionals' skills and behaviour; information; access; efficacy; types of intervention; and relative's involvement. This is a five-point Likert scale, with a score of 1 = 'terrible' and 5 = 'excellent'.

*6.4.2 Client Satisfaction Questionnaire (CSQ)* (Larsen 1979)

Warner 2000 used the Client Satisfaction Questionnaire (CSQ), which is an eight-item self-report measure covering: quality of service; needs addressed; amount of assistance; effect of assistance; recommendable; and overall satisfaction. Each item is rated on a one to four scale, with a lower score indicating a worse outcome.

### 6.5 Outpatient visits

Lester 2003 and Warner 2000 both examined outpatient visits in terms of attendance.

### 6.6 Economic costs

The Henderson 2004 study published a secondary economic evaluation paper comparing the costs of service use between those who received the intervention and the control group over the 15-month study period. They used a modified version of the client service receipt inventory to collect information about use of services. Hospital use was collected from patient medical records and the Mental Health Act office.

### 6.7 Other outcomes

Several other outcomes were investigated by individual studies including: self efficacy (no summary statistics so unable to include) (Papageorgiou 2002); and use of home treatment and non-mental health referrals (Lester 2003).

## Excluded studies

Of the 75 potentially relevant references identified in the updated search, 17 were duplicate studies or secondary references, and 49 were excluded as they did not meet the inclusion criteria described in the 'Types of studies', 'Types of participants', and 'Types of interventions'. The most common reason for exclusion was that the intervention did not involve a user-held information component. Four further references were excluded after contacting the authors (n = 3) or having materials translated (n = 1). Hamann 2006 was a trial of shared decision making compared with standard treatment for 113 individuals with psychotic disorders treated in an inpatient setting in Germany. The intervention involved patients working through a decision aid booklet and noting their preferences for care, and using that as a prompt for discussion with their treating doctor; however, the patients did not hold the a record after this consultation. Similarly, Van Os 2004 examined the effect of patients completing a checklist (2-COM) to identify care needs prior to routine consultations with their doctor, however the patients did not hold a record of the consultation or treatment plan. Likewise, Borell 1995 examined a psycho-education initiative that involved some personalised information, but the patients did not hold the records after the sessions. Finally, Swanson 2008 was excluded as it was a secondary paper from the Swanson 2006 study


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

that examined coercive events within the intervention group who received a Facilitated Psychiatric Advance Directive, that is, there was no comparison group.

Previously excluded studies are discussed below and reasons for exclusion are listed in the 'Characteristics of excluded studies' table. Stafford 1997 was an audit of 45 people with long term mental illness who agreed to carry a small pocket-sized file containing contact details, early warning signs for relapse, and notes made by professionals. Level of use was recorded by checking entries in the professionals' notes against those in the record, and the holders were surveyed on their views of the usefulness of the record as a whole and of its separate components. There was no control group. Two randomised studies concerned the use of 'green cards' to facilitate access to services for patients with a primary diagnosis of deliberate self harm (Cotgrove 1995; Morgan 1993) rather than one of a psychotic illness. Six other studies were already known of by the authors but were not identified by the search strategy. The aims of three (Essex 1990; Pickersgill 1998; Wolf 1996) were to improve shared care between professional primary care givers and specialist mental health services as well as to empower users of mental health services (Essex 1990; Reuler 1991; Wolf 1996). Pickersgill 1998 primarily focused on patient empowerment along with developing partnerships with users and carers. Each of these uncontrolled studies described the development and introduction of a personal record and then surveyed the individuals' views on its usefulness or level of use. (Sutherby 1999) described the use of crisis cards and joint crisis plans for people with severe mental illnesses who were in receipt of specialist care. 'Joint crisis plans' were drawn up once the contents had been agreed by both the team and patient at a meeting between the patient, an advocate if required, team members and a facilitator. Where the team could not agree with the patient's wishes, these were to have been written on a 'crisis card' instead. Participants were then followed up and asked their views on the plans and whether they had affected how they felt about their illness and treatment. There was no control group. The last case series (Backlar 1996) was not an intervention study but a postal survey of members of organisations for relatives of mentally ill people, to assess the level of use of advance directives for mental health treatment.

#### Ongoing

Two ongoing studies were found (Ruchlewska 2009; Thornicroft 2010) and are summarised in the 'Characteristics of ongoing studies' table. Both trials were due to be completed at the end of 2011 and were expected to report results in 2013.

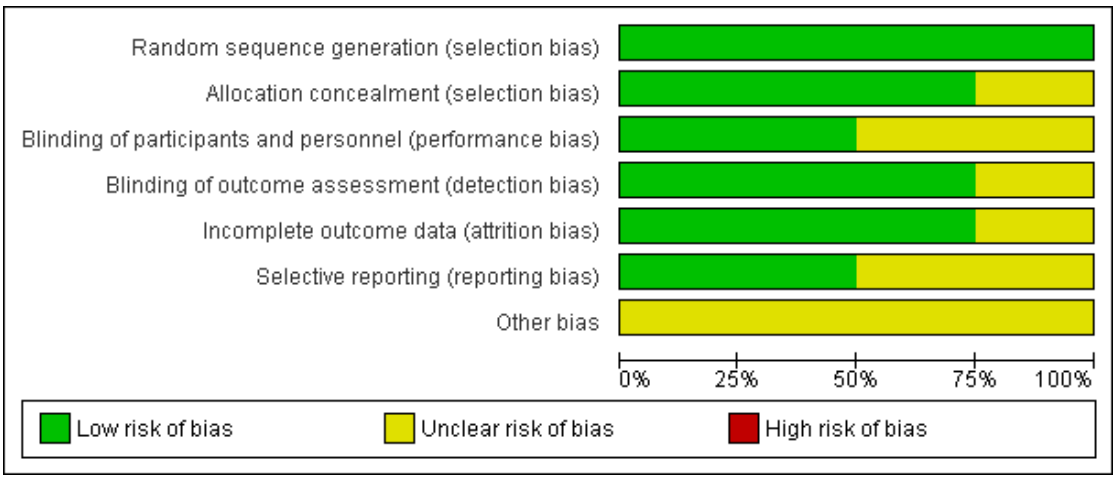
#### Awaiting assessment

Swanson 2006 did not report any summary statistics of potentially relevant outcomes. We were unable to obtain further data from the authors.

### Risk of bias in included studies

For summary and graphical representation of the risk of bias please see Figure 2 and Figure 3.

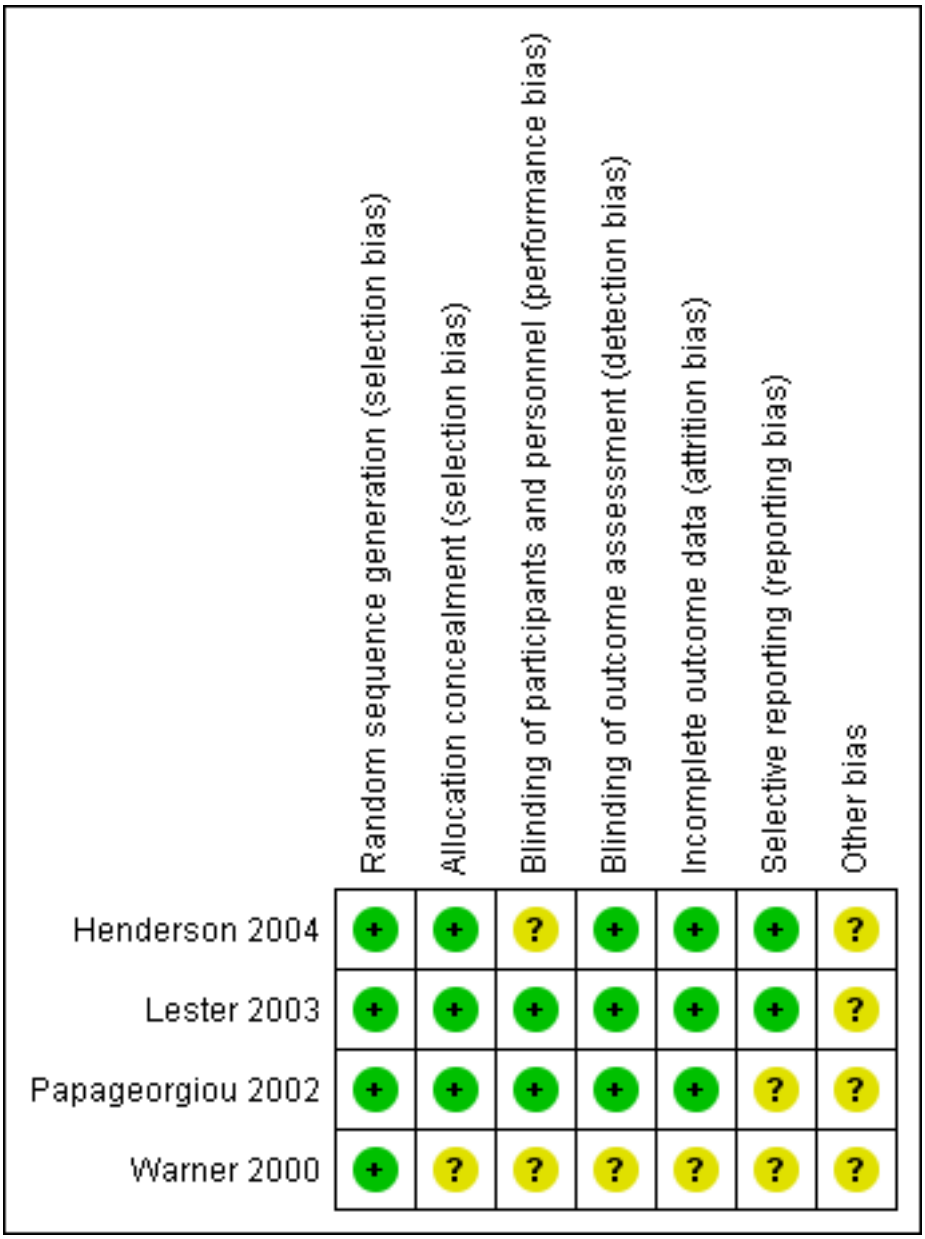
**Figure 2. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.**





Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

**Figure 3. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.**





Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Full assessment of bias was hindered by inadequate reporting in some of the trials. Authors were contacted for further information but either relevant data were not available or we received no reply from the requests for further information.

### Allocation

All trials were randomised, and each provided a detailed description of methods used to reduce problems associated with allocation (Henderson 2004; Lester 2003; Papageorgiou 2002; Warner 2000).

### Blinding

Due to the nature of the intervention, none of the trials were able to use double-blinding procedures. However, three trials (Henderson 2004; Lester 2003; Papageorgiou 2002) attempted to reduce bias by using outcome raters who were blinded to allocation. The remaining study (Warner 2000) did not report on the blinding of outcome raters.

### Incomplete outcome data

One study (Warner 2000) did not report missing data in sufficient detail and was therefore rated as unclear risk. The remaining studies (Henderson 2004; Lester 2003; Papageorgiou 2002) attempted to reduce bias by using outcome raters who were blinded to allocation. The remaining studies had low levels of data attrition, and where present it was spread evenly across the intervention arms. Reasons for data attrition were considered unlikely to be a result of the intervention.

### Selective reporting

All data in this review came from the published reports of the trials. None of the studies had published protocols and therefore we were unable to determine if the published report covered the full range of planned comparisons.

### Other potential sources of bias

We detected no other potential sources of bias.

## Effects of interventions

See: **Summary of findings for the main comparison** User-held information versus standard information for routine care of people with severe mental illness

### Comparison 1: user-held records versus treatment as usual

All pooled data are presented below. For continuous outcomes, where means and standard deviations were unavailable these have been presented in the 'Other data' tables as 'unpooled secondary outcomes', including data that was not suitable for data synthesis.

#### 1.1 Psychiatric hospital admission

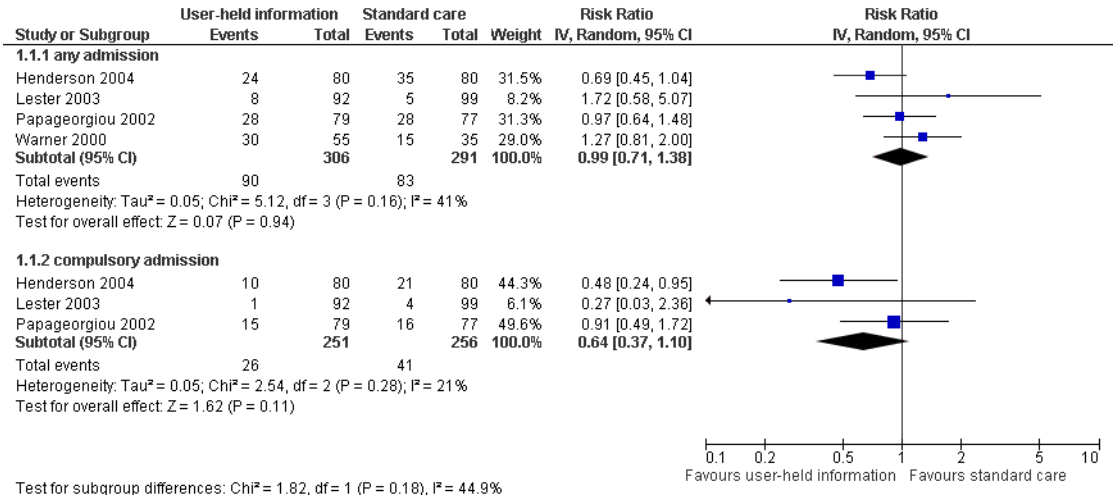
Many of the results were not provided as means and standard deviations. We have, however, presented results in our data and analysis section where other data such as medians or ranges were reported.

#### 1.1.1 Psychiatric admission

Psychiatric hospital admission data were available for four trials involving 597 participants. We found no significant effect of the intervention in any of these studies individually. The pooled treatment effect showed no significant impact of the intervention and was of very low magnitude (n = 597, 4 RCTs, RR 0.99 CI 0.71 to 1.38, Analysis 1.1), see Figure 4 and Summary of findings for the main comparison. There was some heterogeneity between the studies (P = 0.16; $I^2$ = 41%), with the variance explained by between-study differences.


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

**Figure 4. Forest plot of comparison: 1. Psychiatric hospital admission: 1. general admission.**




We adjusted the cluster randomised study for the design effect but found very little effect on the pooled effect estimate (n = 566, 4 RCTs, RR 0.97 CI 0.70 to 1.35, Analysis 1.8).

### 1.1.2 Compulsory admission

Only three studies involving 507 participants provided information on compulsory admissions to hospital. This is a low number of studies for a meta-analysis, though we have provided a pooled estimate (see Figure 5). When pooled there was no significant effect of the intervention (n = 507, RR 0.64 CI 0.37 to 1.10, Analysis 1.1). Heterogeneity was lower in this comparison (P = 0.28; $I^2$ = 21%), though this was very difficult to judge with only three studies considered (see Summary of findings for the main comparison).

### 1.1.3 Psychiatric admission - number of days spent in hospital

Summary data on the length of admissions were provided by three studies, none of which found a significant impact of the intervention. It was not possible to pool this data as the measure was skewed and so non-parametric summary measures were provided (Analysis 1.3). There was evidence of some heterogeneity between the studies in terms of the median length of admissions, and the magnitude and direction of the treatment effect. This would suggest that the studies were not comparable on this outcome.

### 1.1.5 Compulsory admission - number of days spent in hospital under a section of the Mental Health Act

Two trials also provided information on length of compulsory admission (that is, days under a section of the Mental Health Act). A significant effect of the intervention was stated to have been found in one study but not the other (Analysis 1.3); the results generally suggested that people who received user-held personal information spent less time in hospital under compulsory admission. It was not possible to pool this data as the measure was heavily skewed and so non-parametric summary measures were provided. These data should be interpreted with caution.

## 1.2 Mental state

### 1.2.1 Psychopathology

Psychopathology was examined, using three different measures, by three of the four studies (Lester 2003; Papageorgiou 2002; Warner 2000).

#### *1.2.1.1 Brief Psychiatric Rating Scale (BPRS), high = worse, skew*

The one study that reported this outcome found little effect of the user-held information on psychopathology using the BPRS scale. These data were not included in a meta-analysis due to the large standard deviations, and they were considered skewed. These are best inspected by viewing Analysis 1.4.

#### *1.2.1.2 Behaviour and Symptom Identification Scale-32 (BASIS-32), high = worse, skew*

Two trials used the self-report measure of BASIS-32. The Papageorgiou 2002 study presented only the data as median and


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

range, with heavily skewed data, which are therefore presented in additional Table 5. In the Warner 2000 study, there was no effect of the intervention on self-reported psychopathology measured by the BASIS-32; however these data were also heavily skewed and are included in a separate table (Analysis 1.4).

#### *1.2.1.3 Krawiecka and Goldberg (K & G), high = worse, skew*

Lester 2003 reported change scores using the K & G scale rated by blinded keyworkers; there was no effect of the intervention. Because the standard deviations were large, the data were reported separately (Analysis 1.4).

### 1.3 Satisfaction

The three studies (Lester 2003; Papageorgiou 2002; Warner 2000) examining satisfaction found no effect.

#### 1.3.1 Client Satisfaction Questionnaire (CSQ), high = better, skew

One small study used the CSQ and found no effect of intervention (1 RCT, n = 90, MD -0.89 CI -3.35 to 1.15). When entered into data synthesis, the calculated mean difference was different than that reported in the published report. We decided to use the published data and present this in an additional table (Analysis 1.5).

#### 1.3.2 Verona Hospital Service Satisfaction Scale (VSSS), high = better, skew

As above, the data in one study were either skewed or adjusted; we therefore presented these data as reported by the authors in Table 7. Lester 2003 reported change scores on the VSSS scale; there was no effect of the intervention (Analysis 1.5). Using a brief version of the VSSS, Papageorgiou 2002 reported no effect (Analysis 1.5).

### 1.4 Other relevant measures

#### 1.4.1 Service use

#### *1.4.1.1 Outpatient attendance*

Lester 2003 and Warner 2000 both examined the effect of user-held records on outpatient attendance and found no effect (2 RCTs, n = 281, RR 1.09 CI 0.92 to 1.29, Analysis 1.6).

#### *1.4.1.2 Home treatment use*

Lester 2003 examined the use of home treatment teams, and demonstrated no difference (n = 191, 1 RCT, RR 0.72 CI 0.21 to 2.46, Analysis 1.6).

#### *1.4.1.3 Non-mental health referrals*

Lester 2003 also examined the use of non-mental health referrals, which again demonstrated no difference (n = 191, 1 RCT, RR 1.08 CI 0.59 to 1.98, Analysis 1.6).

### 1.5 Economic costs of care

#### 1.5.1 Client service receipt inventory (cost, skew)

A secondary economic analysis (Flood 2006) of the Henderson 2004 trial suggested that while the mean difference in costs between user-held records and treatment as usual was not significantly different, the user-held personal information intervention (JCP) was more likely than not to be cost effective, most likely due to the reduction in compulsory admissions in the intervention group. However, due to very large standard deviations and skewed data, these results were presented in a separate table (Analysis 1.7).

## Sensitivity analysis

### 1. Implication of randomisation

There were no studies that implied randomisation; all included studies provided details as to randomisation.

### 2. Assumptions for lost binary data

There was low attrition in the included studies and therefore it was not necessary to perform a sensitivity analysis.

### 3. Risk of bias

No studies were rated as at 'high' risk across one or more of the domains of risk of bias, therefore a sensitivity analysis was not necessary.

### 4. Imputed values

Adjusting for the reported ICC in the cluster randomised trial made little difference to the pooled estimate and did not change the conclusions of the analysis (Analysis 1.8).


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

#### 5. Fixed-effect and random-effects models

Applying a fixed-effect model analysis made little difference to the pooled effect estimates for both psychiatric admissions (fixed-effect RR 0.96, 95% CI 0.76 to 1.22) and compulsory admissions (fixed-effect RR 0.65, 95% CI 0.41 to 1.03). The conclusions of the analysis remained the same whether a fixed-effect or random-effects model analysis was used.

## DISCUSSION

### Summary of main results

In this updated search, we found four studies involving 607 participants that met our inclusion criteria. As shown in the Summary of findings for the main comparison, four studies involving 597 participants investigated the impact of user-held records on psychiatric hospitalisation and three studies involving 507 participants investigated compulsory psychiatric hospitalisation. The evidence suggests that user-held records do not affect the rate of either voluntary or involuntary psychiatric admissions.

There were too few investigations of other outcomes to estimate an effect size, but there is some preliminary evidence to suggest some beneficial effect on overall costs. There is no evidence of effect for psychological variables such as psychopathology and patient satisfaction.

### Overall completeness and applicability of evidence

#### 1. Completeness

With only four studies investigating the core question of the effect of user-held records on psychiatric hospitalisation, and fewer examining other outcomes, it is too early to determine the effectiveness of user-held records. We note with interest two ongoing trials, due to be completed in 2012, that examine our primary and secondary outcomes of interest including hospitalisation, costs and working alliance (Ruchlewska 2009; Thornicroft 2010).

#### 2. Applicability

The only study to find a significant reduction in compulsory psychiatric admissions (Henderson 2004) investigated a form of advance statement (Henderson 2008), suggesting that both the involvement of the service user in deciding the content and inclusion of future treatment wishes or refusals in the record may have an important effect. However, one other trial (Papageorgiou 2002) also investigated a form of advance statement but found no effect on the outcomes of interest. There were several differences between Papageorgiou 2002 and Henderson 2004; firstly, the Papageorgiou 2002 study was conducted in an inpatient setting with service users who were under a section of the Mental Health Act and due for discharge. It is conceivable that service users may have felt compelled to participate in the trial or that their participation could influence their discharge from the hospital ward. By contrast, the Henderson 2004 study was conducted in the community and thus the potential for perceived pressure to participate was lessened. Secondly, and perhaps more importantly, the Henderson 2004 study had some direct or indirect involvement (see Henderson 2008) of the clinical team. This suggests that the efficacy of this type of user-held record may be increased if clinical teams are also involved in the discussion of the contents and thus may be better placed to facilitate the service user's wishes in the event of a future relapse.

### Quality of the evidence

Four studies involving 607 participants and two different types of interventions were included. The overall quality of the evidence was moderate. Each of the individual studies were methodologically quite strong, notwithstanding some gaps in reporting of randomisation and blinding procedures. However, there were too few studies addressing each outcome of interest to reach a robust conclusion regarding the effectiveness of user-held records.

There was a great deal of heterogeneity in both the outcomes reported and their measurement, which prevented synthesis of most outcomes. Additionally, we believe the between-study variability for the psychiatric hospital admissions and compulsory psychiatric admission outcomes resulted in wide confidence intervals for these estimations. We therefore downgraded the precision rating for these estimations in the Summary of findings for the main comparison. Only one study (Henderson 2004) found a significant reduction in compulsory psychiatric admissions.

### Potential biases in the review process

The search for studies was rigorous, using the Cochrane database, reference chaining, grey literature searching and contact with topic experts. One study was identified in a trial registry entry from the early 2000s, but neither reports of findings nor the authors could be located. It is unlikely that this trial would strongly affect our results as the primary outcomes were only of secondary interest to this review (for example, health behaviours and psychological variables such as locus of control). Study selection and data extraction were conducted separately by two authors and confirmed by a third, and thus the risk of bias in study selection and extraction is limited. Authors of included studies were contacted for information regarding gaps in the reports of methods but the informa-


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

tion was not available. Without this information, the risk of bias is inconclusive and noted as such in the risk of bias tables.

### Agreements and disagreements with other studies or reviews

We know of one other Cochrane Review in this topic area (Campbell 2010), a review of Advance Treatment Directives. This review included two studies that are also included in this review (Henderson 2004; Papageorgiou 2002). The authors shared our conclusion that there is insufficient evidence to make a robust conclusion about the impact of such interventions.

## AUTHORS' CONCLUSIONS

### Implications for practice

#### 1. For clinicians

The current state of the evidence suggests that practitioners should be wary of user-held information systems until their effects have been more thoroughly evaluated with respect to hospital admissions and other outcomes (see 'Implications for research'). In the meantime, any decision about whether to use such systems must be made based on clinical judgement and in the light of current mental health care legislation unsupported by trial-based evidence. This lack of evidence should be made clear to patients (see below). Clinicians interested in this question may wish to participate in clinical trials to test the effects of user-held information systems.

#### 2. For people with psychotic illnesses

If a user of services with a diagnosis of a psychotic illness is offered the choice of holding clinical information regarding their care and treatment, it should be on the understanding that, currently, no evidence exists as to whether this helps or harms, although some patients report finding it useful. It would be understandable if users of services who are interested in establishing whether they and others would be better off or not with such information ask to be included in a randomised controlled trial.

#### 3. For managers and policymakers

A policy that mandates the provision of information to patients on their care plan is not based on evidence from randomised controlled trials; nor is there any evidence for or against promoting the holding of personalised clinical information by patients with a diagnosis of psychotic illness. Managers and policymakers should encourage randomised controlled trials of this potentially inexpensive but potent intervention.

### Implications for research

#### 1. General

Registration of trials before anyone is randomised would ensure that participants could be confident that people would know that the study had at least taken place. Unique study numbers would help researchers identify single studies from multiple publications and reduce the risk of duplicating the reporting of data. Compliance with CONSORT would help clarify methodology and many outcomes. Failure to do this results in both loss of data and confusion in the results. Finally, working with the ALLTRIALS initiative would ensure all data from relevant randomised trials were available.

#### 2. Specific

**2.1 Reviews**

Three excluded studies are of interest to this broad area and would fit into other related relevant systematic reviews

| Proposed title | Excluded study tag |
|---|---|
| Pre-consultation decision aids in the routine care of people with severe mental illness | Van Os 2004; Hamann 2006 |
| Psychoeducation initiatives in the routine care of people with severe mental illness | Borell 1995 |


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

### 2.2 Trials

The findings of this updated review suggest that the evidence gap remains regarding user-held, personalised, accessible clinical information for people with psychotic illnesses. Since the cost of such information systems is low and their use seems acceptable to some patients, it is likely that interest in user-held records will grow. It cannot be assumed, however, that user-held information is beneficial and cost effective without evidence from well planned, conducted and reported randomised trials.

As noted, two large trials are underway and are due to report findings shortly. Both are investigating a form of advance statement. The CRIMSON trial (Thornicroft 2010) is a large effectiveness trial of the Joint Crisis Plan intervention, following on from the Henderson 2004 trial reported in this review. Such a large scale trial is likely to provide important evidence regarding both the effectiveness and acceptability of these types of intervention in a range of treatment settings. Similarly, the Ruchlewska 2009 is underway in the Netherlands and is comparing both service user facilitated and clinician facilitated joint crisis plans with treatment as usual. This important trial is likely to add to the understanding of the mechanism of action of such interventions.

## ACKNOWLEDGEMENTS

This study was carried out in collaboration with the Cochrane Schizophrenia Review Group and the review authors would like to thank Clive Adams, Claire Irving and Samantha Roberts for their advice and support. We would also like to thank Ben Gray for writing the plain language summary. The Cochrane Schizophrenia Group maintains a standard text for the methods and data collection sections, we have used and adapted this in our text.

SF, GB, CF and CH are (all or partly) funded by the CRIMSON trial, an independent research trial funded by the MRC and managed by the NIHR on behalf of the MRC-NIHR partnership. The views expressed in this publication are those of the author(s) and not necessarily those of the MRC, NHS, NIHR or the Department of Health.

## REFERENCES

### References to studies included in this review

**Henderson 2004** *{published data only}*

Flood C, Byford S, Henderson C, Leese M, Thornicroft G, Sutherby K, Szmukler G. Joint crisis plans for people with psychosis: economic evaluation of a randomised controlled trial. *BMJ* 2006;**333**:729–32.

Henderson C, Flood C, Leese M, Thornicroft G, Sutherby K, Szmukler G. Effect of joint crisis plans on use of compulsory treatment in psychiatry: single blind randomised controlled trial. *BMJ* 2004;**329**(7458):136.

**Lester 2003** *{published data only}*

Lester H, Allan T, Wilson S, Jowett S, Roberts L. A cluster randomised controlled trial of patient-held medical records for people with schizophrenia receiving shared care. *British Journal of General Practice* 2003;**53**:197–203.

**Papageorgiou 2002** *{published data only}*

Papageorgiou A, King M, Janmohamed A, Davidson O, Dawson J. Advance directives for patients compulsorily admitted to hospital with serious mental illness. *British Journal of Psychiatry* 2002;**181**:513–9.

**Warner 2000** *{published data only}*

* Warner JP, King M, Blizard R, McClenahan Z, Tang S. Patient-held shared care records for individuals with mental illness. *British Journal of Psychiatry* 2000;**177**:319–24.

### References to studies excluded from this review

**Backlar 1996** *{published data only}*

Backlar P, McFarland BH. A survey on use of advance directives for mental health treatment in Oregon. *Psychiatric Services* 1996;**47**:1387–9.

**Borell 1995** *{published data only}*

Borell P, Orhagen T, d'Elia G. Feasibility and effects of a patient information program in schizophrenia [Sjukdomsrelaterad information vid schizofreni: klinisk tillampning och effekter]. *Scandinavian Journal of Behaviour Therapy* 1995;**24**:75–86.

**Cotgrove 1995** *{published data only}*

Cotgrove A, Zirinszy L, Black D, Weston D. Secondary prevention of attempted suicide in adolescence. *Journal of Adolescence* 1995;**18**:569–77.

**Essex 1990** *{published and unpublished data}*

Essex B, Doig R, Renshaw J. Pilot study of records of shared care for people with mental illness. *BMJ* 1990;**300**:1442–6.

**Hamann 2006** *{published data only}*

Hamann J, Langer B, Winkler V, Busch R, Cohen R, Leucht S, Kissling W. Shared decision making for in-patients with schizophrenia. *Acta Psychiatrica Scandinavica* 2006;**114**:265–73.

**Liaw 1998** *{published data only}*

Liaw ST, Radford AJ, Maddocks I. The impact of a computer generated patient held health record. *Australian Family Physician* 1998;**27 Suppl 1**:39–43.


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

**Morgan 1993** *{published data only}*
Morgan HG, Jones EM, Owen JH. Secondary prevention of non-fatal deliberate self-harm. *British Journal of Psychiatry* 1993;**163**:111–2.

**Pickersgill 1998** *{published data only}*
Pickersgill D. *Patient held information record - Adult Mental Health*. Wakefield and Pontefract Community Health, 1998.

**Reuler 1991** *{published data only}*
Reuler J, Balazs JR. Portable medical record for the homeless mentally ill. *BMJ* 1991;**303**:446.

**Stafford 1997** *{published and unpublished data}*
Stafford A, Laugharne R. Evaluation of a client held record introduced by a community mental health team. *Psychiatric Bulletin* 1997;**21**:757–9.

**Sutherby 1999** *{published and unpublished data}*
* Sutherby K, Szmukler G, Halpern A, Alexander M, Thornicroft G, Johnson C, Wright S. A study of 'crisis cards' in a community psychiatric service. *Acta Psychiatrica Scandinavica* 1999;**100**:56–61.

**Swanson 2008** *{published data only}*
Swanson JW, Swartz MS, Elbogen EB, Van Dorn RA, Wagner HR, Moser LA, et al.Psychiatric advance directives and reduction of coercive crisis interventions. *Journal of Mental Health* 2008;**17**:255–67.

**Van Os 2004** *{published data only}*
Van Os J, Altamura AC, Bobes J, Gerlach J, Hellewell JS, Kasper SND, Robert P. Evaluation of the two-way communication checklist as a clinical intervention. Results of a multinational, randomised controlled trial. *British Journal of Psychiatry* 2004;**184**:79–83.

**Wolf 1996** *{unpublished data only}*
Wolf R. The Paddington Shared Care Project (report summary). Unpublished report 1996.

## References to studies awaiting assessment

**Swanson 2006** *{published data only}*
Elbogen EB, Swanson JW, Appelbaum PS, Swartz, MS, Ferron J, Van-Dorn RA, Wagner HR. Competence to complete psychiatric advance directives: effects of facilitated decision making. *Law and Human Behaviour* 2007;**31**: 275–89.
Swanson JW, Swartz MS, Elbogen EB, Van Dorn RA, Ferron J, Wagner HR, et al.Facilitated Psychiatric Advance Directives: a randomised trial of an intervention to foster advance treatment planning among persons with severe mental illness. *American Journal of Psychiatry* 2006;**163**: 1943–51.

## References to ongoing studies

**Ruchlewska 2009** *{unpublished data only}*
Ruchlewska A, Mulder C, Smulders R, Roosenschoon B, Koopmans G, Wierdsma A. The effects of crisis plans for patients with psychotic and bipolar disorders: a randomised controlled trial. *BMC Psychiatry* 2009;**9**:8.

**Thornicroft 2010** *{unpublished data only}*
Thornicroft G, Farrelly S, Birchwood M, Marshall M, Szmukler G, Waheed W, et al.Crimson crisis plan impact: Subjective and objective coercion and engagement protocol: A randomised controlled trial of joint crisis plans to reduce compulsory treatment of people with psychosis. *Trials* 2010;**11**:102.

## Additional references

**Altman 1996**
Altman DG, Bland JM. Detecting skewness from summary information. *BMJ* 1996;**313**:1200. [: PHR020600]

**Amering 2007**
Amering M, Stastny P, Hopper K. Psychiatric Advance Directives: qualitative study of informed deliberations by mental health service users. *British Journal of Psychiatry* 2005;**186**:247–52.

**Atkinson 2004**
Atkinson JM, Garner HC, Gilmour WH. Models of advance directives in mental health care: stakeholder views. *Social Psychiatry and Psychiatric Epidemiology* 2004;**39**(673): 680.

**Backlar 2001**
Backlar P, McFarland BH, Swanson JW, Mahler J. Consumer, provider and informal caregiver opinions on psychiatric advance directives. *Administration & Policy in Mental Health* 2001;**28**(6):427–41.

**Banet 1997**
Banet GA, Felchlia MA. The potential utility of a shared medical record in a 'first-time' stroke population. *Journal of Vascular Nursing* 1997;**15**:29–33.

**Bland 1997**
Bland JM. Statistics notes. Trials randomised in clusters. *BMJ* 1997;**315**:600.

**Boissel 1999**
Boissel JP, Cucherat M, Li W, Chatellier G, Gueyffier F, Buyse M, et al.The problem of therapeutic efficacy indices. 3. Comparison of the indices and their use [Apercu sur la problematique des indices d'efficacite therapeutique, 3: comparaison des indices et utilisation. Groupe d'Etude des Indices D'efficacite]. *Therapie* 1999;**54**(4):405–11. [PUBMED: 10667106]

**Bourgeois 2009**
Bourgeois FC, Mandl KD, Shaw D, Flemming D, Nigrin DJ. Mychildren's: Integration of a personally controlled health record with a tethered patient portal for pediatric and adolescent population. *AMIA Annual Symposium Proceedings Archive* 2009;**2009**:65–9.

**Brown 2004**
Brown HC, Smith HJ. Giving women their own case notes to carry during pregnancy. *Cochrane Database of Systematic Reviews* 2004, Issue Issue 2. [DOI: 10.1002/ 14651858.CD002856.pub2]

**Campbell 2010**
Campbell LA, Kisely SR. Advance treatment directives for people with severe mental illness. *Cochrane Database*


**Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.**

*of Systematic Reviews* 2010, Issue 3. [DOI: 10.1002/14651858.CD005963.pub2]

**Cook 2009**
Coo, JA, Copeland ME, Hamilton MM, Jonikas JA, Razzano LA, Floyd CB, et al.Initial outcomes of a mental illness self-management program based on Wellness Recovery Action Planning. *Psychiatric Services* 2009;**60**: 246–9.

**Deeks 2000**
Deeks J. Issues in the selection for meta-analyses of binary data. Proceedings of the 8th International Cochrane Colloquium; 2000 Oct 25-28; Cape Town. Cape Town: The Cochrane Collaboration, 2000.

**Divine 1992**
Divine GW, Brown JT, Frazier LM. The unit of analysis error in studies about physicians' patient care behavior. *Journal of General Internal Medicine* 1992;7(6):623–9.

**DoH 1990**
Department of Health. *The Care Programme Approach for people with a mental illness referred to the specialist mental health services - Joint Health/Social Services Circular*. London: HMSO, 1990.

**Donner 2002**
Donner A, Klar N. Issues in the meta-analysis of cluster randomized trials. *Statistics in Medicine* 2002;**21**:2971–80.

**Egger 1997**
Egger M, Davey-Smith G, Schneider M, Minder CSO. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;**13**:629–34.

**Eisen 1994**
Eisen SV, Dill DL, Grob MC. Reliability and validity of a brief patient-report instrument for psychiatric outcome evaluation. *Hospital and Community Psychiatry* 1994;**45**: 242–7.

**Elbogen 2006**
Elbogen EB, Swartz MS, Van Dorn R, Swanson JW, Kim M, Scheyett A. Clinical decision making and views about psychiatric advance directives. *Psychiatric Services* 2006;**57** (3):350–5.

**Elbogen 2007**
Elbogen EB, Swanson JW, Appelbaum PS, Swartz MS, Ferron J, Van Dorn RA, Wagner HR. Competence to complete psychiatric advance directives: effects of facilitated decision making. *Law and Human Behaviour* 2007;**31**: 275–89.

**Elbourne 2002**
Elbourne D, Altman DG, Higgins JPT, Curtina F, Worthingtond HV, Vaile A. Meta-analyses involving cross-over trials: methodological issues. *International Journal of Epidemiology* 2002;**31**(1):140–9.

**Finlay 1999**
Finlay IG, Wyatt P. Randomised cross-over study of patient-held records in oncology and palliative care. *Lancet* 1999; **353**:558–9.

**Flood 2006**
Flood C, Byford S, Henderson C, Leese M, Thornicroft G, Sutherby K, Szmukler G. Joint crisis plans for people with psychosis: economic evaluation of a randomised controlled trial. *BMJ* 2006;**333**(7571):729.

**Freeman 1998**
Freeman TM. Anaphylaxis: diagnosis and treatment. *Primary Care* 1998;**25**:809–17.

**Ghossein 1998**
Ghossein Y, Gibbs C, Cunningham N, McConathy J, Sung T, Hernandez M, et al.The child's personal health record in New York City: which components are used?. *Ambulatory Child Health* 1998;**4**:3–11.

**Gulliford 1999**
Gulliford MC. Components of variance and intraclass correlations for the design of community-based surveys and intervention studies: data from the Health Survey for England 1994. *American Journal of Epidemiology* 1999;**149**: 876–83.

**Hampshire 2004**
Hampshire AJ, Blair ME, Crown NS, Avery AJ, Williams EI. Variation in how mothers, health visitors and general practitioners use the personal child health record. *Child: Care, Health and Development* 2004;**30**(4):307–16.

**Henderson 2008**
Henderson C, Swanson JW, Szmukler G, Thornicroft G, Zinkler M. A typology of advance statements in mental health care. *Psychiatric Services* 2008;**1**:63–71.

**Higgins 2003**
Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;**327**: 557–60.

**Higgins 2011**
Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.2 [updated September 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org..

**Kaelber 2008**
Kaelber DC, Jhan AK, Johnston D, Middleton B, Bates DW. A research agenda for personal health records (PHRs). *Journal of the American Medical Informatics Association* 2008; **15**(6):729–36.

**Knapp 2004**
Knapp M, Mangalore R, Simon J. The global costs of schizophrenia. *Schizophrenia Bulletin* 2004;**30**(2):279–93.

**Ko 2010**
Ko H, Turner T, Jones C, Hill C. Patient-held medical records for patients with chronic disease: a systematic review. *Quality and Safety in Health Care* 2010;**19**:1–7.

**Krawiecka 1977**
Krawiecka M, Goldberg D, Vaughan M. A standardised psychiatric assessment scale for rating chronic psychotic patients. *Acta Psychiatrica Scandinavica* 1977;**55**:299–308.


**Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.**

**Larsen 1979**
Larsen D, Attkisson CC, Hargreaves WA. Assessment of client/patient satisfaction: development of a general scale. *Evaluation and Programme Planning* 1979;**2**:197–207.

**Lidz 1995**
Lidz CW, Hoge SK, Gardner W, Bennett NS, Monahan J, Mulvey EP, Roth LH. Perceived coercion in mental hospital admission. *Archives of General Psychiatry* 1995;**52**:1034–9.

**Marshall 2000**
Marshall M, Lockwood A, Bradley C, Adams C, Joy C, Fenton M. Unpublished rating scales: a major source of bias in randomised controlled trials of treatments for schizophrenia. *British Journal of Psychiatry* 2000;**176**: 249–52.

**McGrath 2008**
McGrath J, Saha S, Chant D, Welham J. Schizophrenia: A concise overview of incidence, prevalence and mortality. *Epidemiologic Reviews* 2008;**30**:67–76.

**Mulrow 1999**
Mulrow CD, Oxman AD. Cochrane Collaboration Handbook [updated 1 March 1999]. Cochrane Database of Systematic Reviews. Oxford: Update Software; 1996–. Updated quarterly.

**NICE 2009**
National Collaborating Centre for Mental Health. Core interventions in the treatment and management of schizophrenia in primary and secondary care (update). *Core interventions in the treatment and management of schizophrenia in adults in primary and secondary care (update)*. National Institute for Clinical Excellence, 2009.

**Overall 1962**
Overall JE, Gorham DR. The brief psychiatric rating scale. *Psychological Reports* 1962;**10**:799–812.

**Phipps 2001**
Phipps, H. Carrying their own medical records: the perspective of pregnant women. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 2001;**41**(2): 398–400.

**Ruggieri 1993**
Ruggeri M, Dall'Agnola R. The development and use of the Verona Expectations for Care Scale and the Verona Service Satisfaction Scale for measuring expectations and satisfaction with community based psychiatric services in patients, relatives and professionals. *Psychological Medicine* 1993;**23**:511–23.

**Schünemann 2008**
Schünemann HJ, Oxman AD, Vist GE, Higgins JPT, Deeks JJ, Glasziou P, et al.Chapter 12: Interpreting results and drawing conclusions. In: Higgins JPT, Green S editor(s). *Cochrane Handbook for Systematic Reviews of Interventions*. The Cochrane Collaboration, 2008:359–83.

**Shah 1993**
Shah PM, Selwyn BJ, Shah K, Kumar V. Evaluation of the home-based maternal record: a WHO collaborative study. *Bulletin of the World Health Organisation* 1993;**71**:525–48.

**Srebnik 2005**
Srebnik DS, Rutherford LT, Peto T, Russo J, Zick E, Jaffe C, et al.The content and clinical utility of psychiatric advance directives. *Psychiatric Services* 2005;**56**(5):592–8.

**Swartz 2005**
Swartz MS, Swanson JW, Ferron J, Elbogen EB, Van Dorn RA, Kim M, et al.Psychiatrists' views and attitudes about psychiatric advance directives. *International Journal of Forensic Mental Health* 2005;**4**(2):107–17.

**Ukoumunne 1999**
Ukoumunne OC, Gulliford MC, Chinn S, Sterne JAC, Burney PGJ. Methods for evaluating area-wide and organistation-based intervention in health and health care: a systematic review. *Health Technology Assessment* 1999;**3**(5): 1–75.

**Van Dorn 2006**
Van Dorn RA, Swartz MS, Elbogen EB, Swanson JW, Kim M, Ferron J. Clinicians' attitudes regarding barriers to the implementation of psychiatric advance directives. *Administration & Policy in Mental Health* 2006;**33**(4): 449–60.

**Wharry 1996**
Wharry S. Medicalert Foundation turns 35, issues warning about lookalike bracelets. *CMAJ* 1996;**154**:919–20.

**Williams 1996**
Williams DN, Kaur B. Postplenectomy care. Strategies to decrease the risk of infection. *Postgraduate Medicine* 1996; **100**:195–8.

**Williams 2001**
Williams JG, Cheung W-Y, Chetwynd N, Cohen DR, El-Sharkawi S, Finlay I, et al.Pragmatic randomised trial to evaluate the use of patient held records for the continuing care of patients with cancer. *Quality in Health Care* 2001; **10**:159–65.

**Xia 2009**
Xia J, Adams CE, Bhagat N, Bhagat V, Bhoopathi P, El-Sayeh H, et al.Loss to outcomes stakeholder survey: the LOSS study. *Psychiatric Bulletin* 2009;**33**(7):254–7.

## References to other published versions of this review

**Henderson 1999**
Henderson C, Laugharne R. User-held personalised information for routine care of people with severe mental illness (Review). *Cochrane Database of Systematic Reviews* 2000, Issue 1. [DOI: 10.1002/14651858.CD001711]

* *Indicates the major publication for the study*


**Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.**

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies *[ordered by study ID]*

**Henderson 2004**

| | |
|---|---|
| Methods | Allocation: randomised.<br>Blindness: single.<br>Duration: 15 months.<br>Raters: independent.<br>Setting: eight community mental health teams, South London and Kent (UK) |
| Participants | Diagnosis: 100% psychosis (including schizophrenia spectrum and bipolar disorders using OPCRIT checklist).<br>N=160.<br>History: at least one previous psychiatric admission.<br>Sex: 94 M, 66 F.<br>Age: over 18 years, mean years (SD) intervention group 39.5 (12.1); control group: 38.6 (10.6)<br>Inclusions: in contact with local community mental health team; admitted to a psychiatric inpatient service at least once in previous two years; diagnosis of psychotic illness or bipolar affective disorder without psychotic symptoms.<br>Exclusions: current inpatients, unable to give informed consent |
| Interventions | 1. The 'Joint Crisis Plan' (JCP) intervention: The JCP is developed by a service user together with their treatment team and facilitated by a member of the research team. The JCP is held by the user and contains his or her choice of information, which can include an advance agreement for treatment preferences for any future psychiatric relapse or crisis, n=80<br>2. Treatment As Usual (as stipulated by the UK's Care Programme Approach) and information leaflets about local services, and relevant policies, n=80 |
| Outcomes | Psychiatric hospital admission.<br>Compulsory hospital admission.<br>Length of psychiatric admission.<br>Length of compulsory admission.<br>Economic costs (collected using modified version of 'client service receipt inventory')* |
| Notes | *Published as separate paper (Flood 2006). |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Randomised - allocation sequence was generated by using minimization, stratified by team and by severity of patients' condition (standard versus enhanced CPA) to ensure even distribution of these features which we expected would influence the production of the plan and its use by staff |


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

**Henderson 2004** (*Continued*)

| | | |
|---|---|---|
| Allocation concealment (selection bias) | Low risk | Predictability of allocation by the minimization process was occasionally a problem (when batches of similar patients were forwarded for allocation). To avoid this, ML reassigned the allocation of one patient, chosen at random, within each batch, before we reverted to minimization. When a patient was recruited, the project worker requested allocation by email, which was returned by a statistician as intervention or control group. Allocation was not revealed to the investigator |
| Blinding of participants and personnel (performance bias)<br>All outcomes | Unclear risk | Single blind - "the investigator was blind to allocation" (p1). The nature of the intervention meant that the participants could not be blinded to allocation |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | One investigator (CH) collected follow-up data and was blinded to treatment group |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | Information on hospital admissions was available for all participants. Bed days was missing from one admission |
| Selective reporting (reporting bias) | Low risk | Yes - all outcomes reported. |
| Other bias | Unclear risk | None detected. |

**Lester 2003**

| | |
|---|---|
| Methods | Allocation: cluster randomisation (at GP practice level).<br>Blindness: single.<br>Duration: 12 months.<br>Raters: independent.<br>Setting: six community mental health localities, Birmingham (UK) |
| Participants | Diagnosis: 100% schizophrenia.<br>N=201.<br>History: receiving shared care (primary and secondary care) in North Birmingham.<br>Sex: 125 M, 76 F.<br>Age: over 18 years, mean years (SD)=46 (11.8).<br>Exclusions: learning disability, organic brain disease, and key worker concerns (e.g., current hospitalisation) |


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

**Lester 2003** (*Continued*)

| | |
|---|---|
| Interventions | 1. "Patient held record" was a loose-leaf record, containing sections for personal details, appointments, medication, basic health information, personal and emergency contact numbers, early warning symptoms and a diary section to record patient, carer and professional comments. The record was given to intervention participants at the time of recruitment, n=100<br>2. Treatment as usual*, n=101. |
| Outcomes | Psychiatric hospital admission.<br>Compulsory hospital admission.<br>Length of psychiatric admission.<br>Outpatient attendance.<br>Non-mental health referrals; home treatment use.<br>Psychopathology (K&G).<br>Satisfaction with community mental health teams (VSSS).<br>Unable to use -<br>Service use: outpatient attendance; home treatment team use; non-mental health referrals |
| Notes | *No description given. |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | "176 general practices… were randomised by one of the authors (TA) to either intervention or control, using a computer generated random number schedule. These practices were stratified by list size and the number of people with schizophrenia, using minimization to adjust for imbalances within the strata." |
| Allocation concealment (selection bias) | Low risk | "To minimize selection bias, recruitment was undertaken on each day of the week over a four to eight week period depending on team caseloads. Within each team, patients were approached consecutively" |
| Blinding of participants and personnel (performance bias)<br>All outcomes | Low risk | Blinding of participants was not possible. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | Outcome assessors of psychopathology were blinded. Satisfaction was a patient self-report and therefore may be subject to bias as patients were not blinded |


**Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.**

**Lester 2003** (*Continued*)

| | | |
|---|---|---|
| Incomplete outcome data (attrition bias) All outcomes | Low risk | Up to 8 from intervention group (2 deaths; 5 refusals; 1 in prison) and 2 from control group. Unlikely to be related to the intervention |
| Selective reporting (reporting bias) | Low risk | No protocol available. |
| Other bias | Unclear risk | None detected. |

**Papageorgiou 2002**

| | |
|---|---|
| Methods | Allocation: randomised.<br>Blindness: none.<br>Duration: 12 months.<br>Raters: independent researchers.<br>Setting: |
| Participants | Diagnosis: 63% psychosis, 28% depression/bipolar; 8% other.<br>N=156.<br>History: receiving compulsory treatment under Section 2, 3, 4 of the Mental Health Act (i.e., formally admitted).<br>Sex: 83 M, 73 F.<br>Age: over 18 years, mean years (SD): Intervention: 35.5 (11.3); control: 36.3 (12.6).<br>Exclusions: specialised sections; pending transfer from hospital; organic brain disease |
| Interventions | 1. Advance Directive (AD) in the form of a booklet entitled *Preferences for Care*. Containing: contact details of patient, treatment team; and seven statements on future preferences for treatment. Patients who did not want to write in the booklet themselves, dictated their preferences to the researcher. A rider printed at the end of the booklet indicated that professionals were not legally bound to comply with preferences for care. Copies given to keyworker and GP, n=80<br>2. Standard community psychiatric care (coordinated care programme delivered by a multi-disciplinary team), n=81 |
| Outcomes | Psychiatric hospital admission.<br>Compulsory hospital admission.<br>Length of compulsory admission.<br>Psychopathology (BASIS-32; skewed, summary data only).<br>Satisfaction (VSSS - adapted brief version).<br>Unable to use -<br>Decision making ability (Self-Efficacy Scale; no summary data) |
| Notes | Participants who were receiving compulsory treatment under a section of the Mental Health Act were recruited from an inpatient setting in London |

***Risk of bias***


**Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.**

**Papageorgiou 2002** (*Continued*)

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | "We allocated patients randomly using a block design, stratified according to whether this was the patient's first ever or subsequent sectioning. Blocks of twelve random combinations (six experimental, six control) were prepared and sealed in envelopes" |
| Allocation concealment (selection bias) | Low risk | Sealed envelopes. Research assistants telephoned an independent colleague to select the next envelope |
| Blinding of participants and personnel (performance bias)<br>All outcomes | Low risk | It was not possible to blind participants. It was also impossible to mask the research assistants to the patient's allocation as they were required to assist patients to make a directive in those allocated to the intervention group. However, systematic bias was unlikely as the primary outcome concerned compulsory hospital admission and was not based on any later assessment by the researcher |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | As above. |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | 75% of intervention group and 71% of the control group were assessed at follow-up. Missing outcome data are balanced across the intervention groups and for similar reasons |
| Selective reporting (reporting bias) | Unclear risk | No protocol available. |
| Other bias | Unclear risk | None detected. |

**Warner 2000**

| | |
|---|---|
| Methods | Allocation: cluster randomised (at GP practice level).<br>Blindness: not reported.<br>Duration: 12 months.<br>Raters: not reported. |
| Participants | Diagnosis: 42% psychosis, 12% bipolar, 22% depression, personality disorder 10%, 13% other. |


**Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.**

| | |
|---|---|
| | N=90.<br>History: long-term mental illness (either psychosis, severe non-psychotic disorder, severe personality disorder, functional impairments), registered with GP and receiving care from mental health professional.<br>Sex: 36 M, 54 F.<br>Age: 18-65 years, mean years (SD): intervention=36 (12.5); control=41(12.6).<br>Exclusions: none reported. |
| Interventions | 1. Given a shared care booklet which contained: contact details of participant, GP and psychiatrist, social workers etc; brief clinical notes and medication details; future appointments, n=55<br>2. Treatment as usual: care from the primary and hospital teams, n=35 |
| Outcomes | *Psychiatric hospital admission.<br>Length of psychiatric admission (days).<br>Psychopathology (BASIS-32 and BPRS, skew).<br>Client satisfaction (CSQ, skew).<br>*Service use: outpatient attendance. |
| Notes | *This study did not account for clustering in results; therefore, outcomes marked with (*) symbol indicate the presence of a probable unit of analysis error |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | "Practices were randomised to shared care or control status using a computer- generated algorithm (practices were number sequentially based on alphabetical order)" |
| Allocation concealment (selection bias) | Unclear risk | Unclear. It was unclear if researchers recruiting participants were aware of which GP practice the participant was registered with |
| Blinding of participants and personnel (performance bias)<br>All outcomes | Unclear risk | Unclear. It was not possible to blind participants. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | It is not clear who rated the outcome measures and if they were blinded |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | Missing data not reported in sufficient detail. |
| Selective reporting (reporting bias) | Unclear risk | No protocol available. |


**Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.**

| | | |
|---|---|---|
| Other bias | Unclear risk | None detected. |

## Characteristics of excluded studies *[ordered by study ID]*

| Study | Reason for exclusion |
|---|---|
| Backlar 1996 | Allocation: not random, case series. |
| Borell 1995 | Allocation: randomised.<br>Participants: adults with serious mental illnesses.<br>Intervention: records not personalised. |
| Cotgrove 1995 | Allocation: randomised.<br>Participants: those with a history of deliberate self harm, not psychosis |
| Essex 1990 | Allocation: not random, case series. |
| Hamann 2006 | Allocation: randomised.<br>Participants:adults with serious mental illnesses.<br>Intervention: records not personalised. |
| Liaw 1998 | Allocation: randomised.<br>Participants: those with chronic health problems, not psychosis |
| Morgan 1993 | Allocation: randomised.<br>Participants: those with a history of deliberate self harm, not psychosis |
| Pickersgill 1998 | Allocation: not random, case series. |
| Reuler 1991 | Allocation: not random, case series. |
| Stafford 1997 | Allocation: not random, case series. |
| Sutherby 1999 | Allocation: not random, case series. |
| Swanson 2008 | Allocation: not random, case series. |
| Van Os 2004 | Allocation: randomised.<br>Participants: adults with serious mental illnesses.<br>Intervention: records not user-held. |
| Wolf 1996 | Allocation: not random, case series. |


**Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.**

## Characteristics of studies awaiting assessment *[ordered by study ID]*

**Swanson 2006**

| | |
|---|---|
| Methods | Allocation: randomised.<br>Blindness: non-reported.<br>Duration: 1 month.<br>Raters: non-reported. |
| Participants | Diagnosis: 59% schizophrenia/psychosis; 27% bipolar disorder; 14% depression with psychotic features.<br>N=469.<br>History: receiving community based treatment through one of two programs in North Carolina.<br>Sex: 40% M, 60% F.<br>Age: 18 to 65 years; mean (sd): 42 years (10.7).<br>Exclusions: unable to give informed consent. |
| Interventions | 1. Facilitated-Psychiatric Advance Directive (F-PAD) which is a semi structured, manualised interview and guided discussion of choices involved in anticipatory mental health treatment planning. The intervention includes orientation to concepts related to psychiatric advance directives, review of past treatment experiences, and documentation of future treatment preferences. The core of the intervention is a semi-structured interview and guided discussion of choices involved in planning for mental health care during periods of incapacity. If the participants wishes to prepare the relevant legal psychiatric advance directive documents, the facilitator helps with the completion of the forms<br>2. Given an introduction to psychiatric advance directives, written materials describing the purpose of advance directives, copies of standard forms for psychiatric advance directives and the toll-free telephone number of the local consumer organisation that provides consultation to persons who wish to prepare psychiatric advance directives |
| Outcomes | Working Alliance at one month (Working Alliance Inventory; unable to use as no means or SDs reported)<br>Needs for treatment (Mental Health Statistic Improvement Program Consumer Survey Index of treatment satisfaction; unable to use as no means or SDs reported)<br>Decisional capacity* (DCAT-PAD; unable to use as no means or SDs reported) |
| Notes | * Published in separate paper Elbogen 2007.<br>We contacted the study authors to obtain summary statistics for each group relevant to our outcomes of interest; however, we received no reply |

## Characteristics of ongoing studies *[ordered by study ID]*

**Ruchlewska 2009**

| | |
|---|---|
| Trial name or title | The effects of crisis plans for patients with psychotic and bipolar disorders: a randomised controlled trial |
| Methods | Randomised controlled trial |
| Participants | Outpatients with psychotic or bipolar disorders |
| Interventions | Crisis plan made with advocate, Crisis plan made with own clinician, no crisis plan |
| Outcomes | Number of emergency visits, (involuntary) admissions and length of stay in hospital |


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

**Ruchlewska 2009** (*Continued*)

| | |
|---|---|
| Starting date | 2006 |
| Contact information | j.ruchlewska@erasmusmc.nl |
| Notes | At analysis stage October 2011 |

**Thornicroft 2010**

| | |
|---|---|
| Trial name or title | CRIMSON: A randomised controlled trial of joint crisis plans to reduce compulsory treatment of people with psychosis |
| Methods | Multi-centre, single-blind, individual level randomised controlled trial |
| Participants | 540 individuals with psychotic disorders |
| Interventions | Joint Crisis Plan compared with treatment as usual |
| Outcomes | Involuntary admissions to hospital |
| Starting date | October 2007 |
| Contact information | Graham.Thornicroft@kcl.ac.uk |
| Notes | Finishing data collection November 2011 |


**Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.**

## DATA AND ANALYSES

### Comparison 1. User-held information versus standard information

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Psychiatric hospital admission: 1. Psychiatric admission | 4 | | Risk Ratio (IV, Random, 95% CI) | Subtotals only |
| 1.1 any admission | 4 | 597 | Risk Ratio (IV, Random, 95% CI) | 0.99 [0.71, 1.38] |
| 1.2 compulsory admission | 3 | 507 | Risk Ratio (IV, Random, 95% CI) | 0.64 [0.37, 1.10] |
| 2 Psychiatric hospital admission: 2a. Days in hospital (compulsory only, by range of days) | 1 | | Risk Ratio (IV, Random, 95% CI) | Subtotals only |
| 2.1 0 days | 1 | 156 | Risk Ratio (IV, Random, 95% CI) | 1.02 [0.87, 1.20] |
| 2.2 1-100 days | 1 | 156 | Risk Ratio (IV, Random, 95% CI) | 0.70 [0.33, 1.47] |
| 2.3 101-365 days | 1 | 156 | Risk Ratio (IV, Random, 95% CI) | 2.44 [0.49, 12.18] |
| 3 Psychiatric hospital admission: 2b. Days in hospital (skewed data) | | | Other data | No numeric data |
| 3.1 any admission | | | Other data | No numeric data |
| 3.2 compulsory admission | | | Other data | No numeric data |
| 4 Mental state: Scores (high=worse, skewed data) | | | Other data | No numeric data |
| 4.1 BPRS | | | Other data | No numeric data |
| 4.2 BASIS-32 | | | Other data | No numeric data |
| 4.3 K&G | | | Other data | No numeric data |
| 5 Satisfaction: Scores (high=better) | | | Other data | No numeric data |
| 5.1 hospital service satisfaction (VSSS, skewed data) | | | Other data | No numeric data |
| 5.2 client satisfaction (CSQ, non skewed but data analysed taking clustering into account) | | | Other data | No numeric data |
| 6 Service use | 2 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 6.1 outpatient attendance | 2 | 281 | Risk Ratio (M-H, Random, 95% CI) | 1.09 [0.92, 1.29] |
| 6.2 home treatment use | 1 | 191 | Risk Ratio (M-H, Random, 95% CI) | 0.72 [0.21, 2.46] |
| 6.3 non-mental health referrals | 1 | 191 | Risk Ratio (M-H, Random, 95% CI) | 1.08 [0.59, 1.98] |
| 7 Economic costs of care (£ - client service receipt inventory, skew) | | | Other data | No numeric data |
| 8 Sensitivity analysis: Psychiatric hospital admission: adjusting for clustering | 4 | | Risk Ratio (IV, Random, 95% CI) | Subtotals only |
| 8.1 adjusted for cluster effects | 4 | 566 | Risk Ratio (IV, Random, 95% CI) | 0.97 [0.70, 1.35] |
| 8.2 not adjusted for cluster effects | 4 | 597 | Risk Ratio (IV, Random, 95% CI) | 0.99 [0.71, 1.38] |

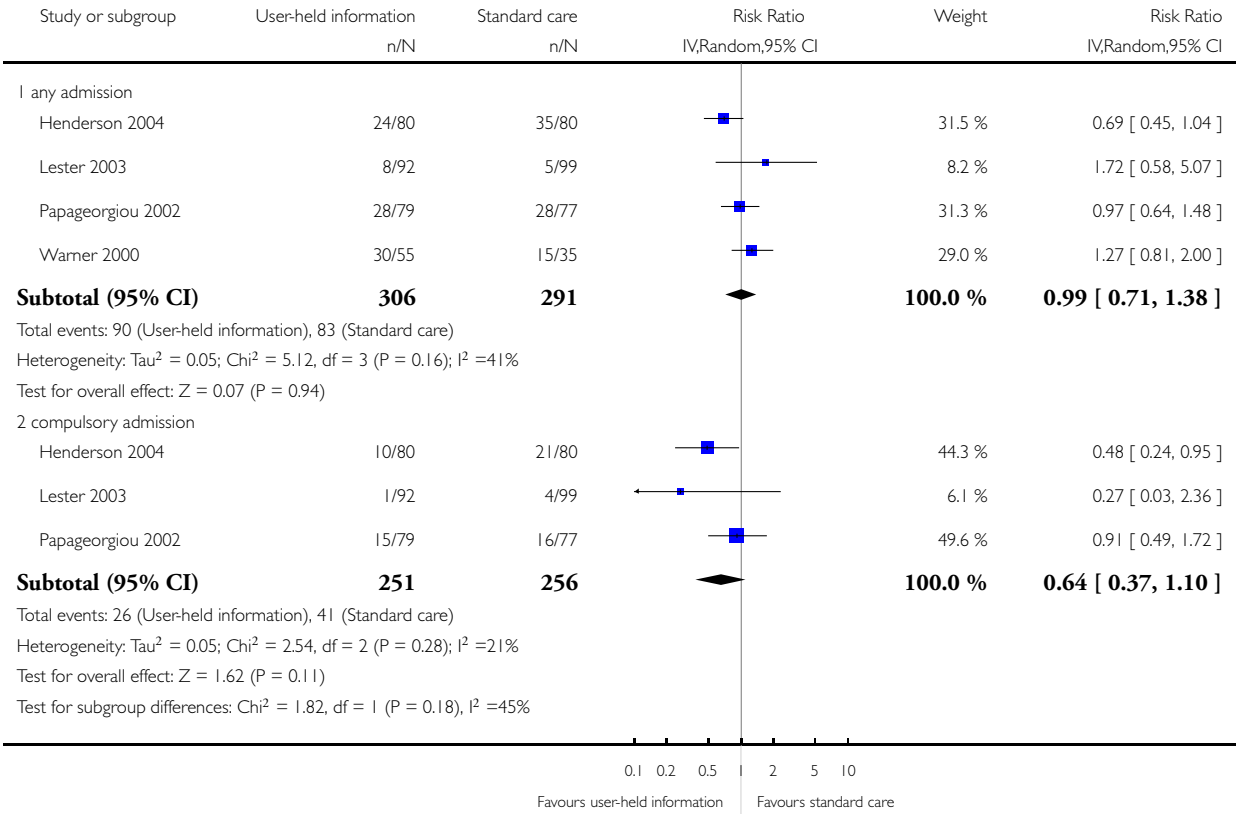

Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

## Analysis 1.1. Comparison 1 User-held information versus standard information, Outcome 1 Psychiatric hospital admission: 1. Psychiatric admission.

Review: User-held personalised information for routine care of people with severe mental illness

Comparison: 1 User-held information versus standard information

Outcome: 1 Psychiatric hospital admission: 1. Psychiatric admission





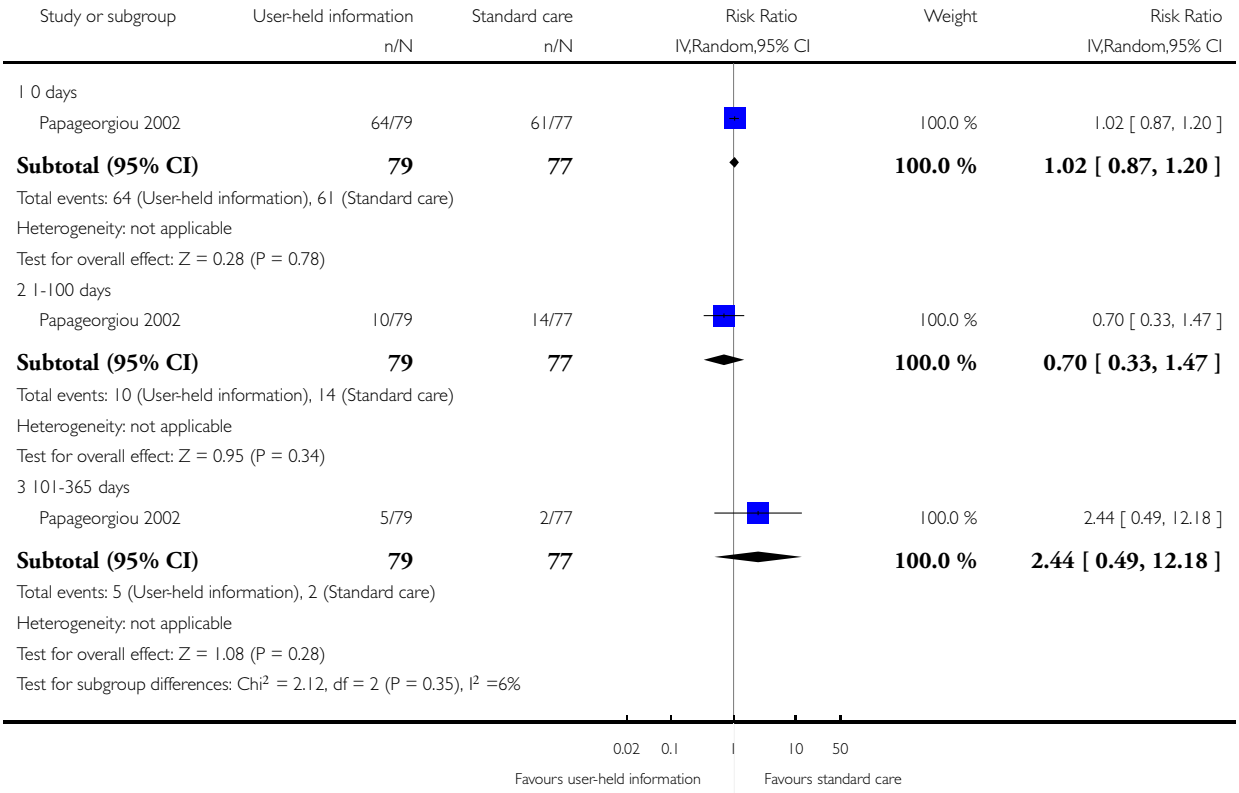
Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

### Analysis 1.2. Comparison 1 User-held information versus standard information, Outcome 2 Psychiatric hospital admission: 2a. Days in hospital (compulsory only, by range of days).

Review: User-held personalised information for routine care of people with severe mental illness

Comparison: 1 User-held information versus standard information

Outcome: 2 Psychiatric hospital admission: 2a. Days in hospital (compulsory only, by range of days)




### Analysis 1.3. Comparison 1 User-held information versus standard information, Outcome 3 Psychiatric hospital admission: 2b. Days in hospital (skewed data).

**Psychiatric hospital admission: 2b. Days in hospital (skewed data)**

| Study | Intervention | Mean | Median | Range | N | Test statistic | Significance |
|---|---|---|---|---|---|---|---|
| **any admission** | | | | | | | |
| Henderson 2004 | User-held information | 32 | 0 | - | 80 | Mann Whitney=1.52 | p=0.15 |
| Henderson 2004 | Standard care | 36 | 0 | - | 80 | | |


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

**Psychiatric hospital admission: 2b. Days in hospital (skewed data)** (*Continued*)

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Lester 2003 | User-held information | - | 16.5 | 11.3 to 59.0 (IQR) | 92 | Mann Whitney= -1.10 | p=0.271 |
| Lester 2003 | Standard care | - | 31.0 | 19.5 to 129.0 (IQR) | 99 | | |
| Warner 2000 | User-held information | - | 7 | 0 to 235 | 55 | Mann Whitney= 0.96 | p=0.33 |
| Warner 2000 | Standard care | - | 0.71 | 0 to 96 | 35 | | |
| **compulsory admission** | | | | | | | |
| Henderson 2004 | User-held information | 14 | 0 | - | 80 | Mann Whitney=4.13 | p=0.04 |
| Henderson 2004 | Standard care | 31 | 0 | - | 80 | | |

**Analysis 1.4. Comparison 1 User-held information versus standard information, Outcome 4 Mental state: Scores (high=worse, skewed data).**

**Mental state: Scores (high=worse, skewed data)**

| Study | Intervention | Mean | SD | Median | Range | N |
|---|---|---|---|---|---|---|
| **BPRS** | | | | | | |
| Warner 2000 | User-held information | 16.9 | 9.8 | - | - | 55 |
| Warner 2000 | Standard care | 13.8 | 8.6 | - | - | 35 |
| **BASIS-32** | | | | | | |
| Papageorgiou 2002 | User-held information | - | - | 0.81 | 0 to 3.34 | 59 |
| Papageorgiou 2002 | Standard care | - | - | 0.62 | 0 to 3.25 | 55 |
| Warner 2000 | User-held information | 1.27 | 0.81 | - | - | 55 |
| Warner 2000 | Standard care | 1.20 | 0.82 | - | - | 35 |
| **K&G** | | | | | | |


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

**Mental state: Scores (high=worse, skewed data)** (*Continued*)

| | | | | | | |
|---|---|---|---|---|---|---|
| Lester 2003 | User-held information | -1.22 | 3.1 | - | - | 91 |
| Lester 2003 | Standard care | -1.69 | 3.0 | - | - | 99 |

### Analysis 1.5. Comparison 1 User-held information versus standard information, Outcome 5 Satisfaction: Scores (high=better).

**Satisfaction: Scores (high=better)**

| Study | Intervention | Mean | SD | Median | Range | N | Notes |
|---|---|---|---|---|---|---|---|
| **hospital service satisfaction (VSSS, skewed data)** | | | | | | | |
| Lester 2003 | User-held information | 0.025 | 0.30 | - | - | 92 | - |
| Lester 2003 | Standard care | 0.008 | 0.30 | - | - | 99 | |
| Papageorgiou 2002 | User-held information | - | - | 29 | 9 to 45 | 59 | - |
| Papageorgiou 2002 | Standard care | - | - | 31 | 9 to 44 | 55 | |
| **client satisfaction (CSQ, non skewed but data analysed taking clustering into account)** | | | | | | | |
| Warner 2000 | User-held information | 22.3 | 6.5 | - | - | 55 | Mean Difference (IV, Fixed, 95% CI) |
| Warner 2000 | Standard care | 23.4 | 4.4 | - | - | 35 | -0.89 [-3.38, 1.59] |

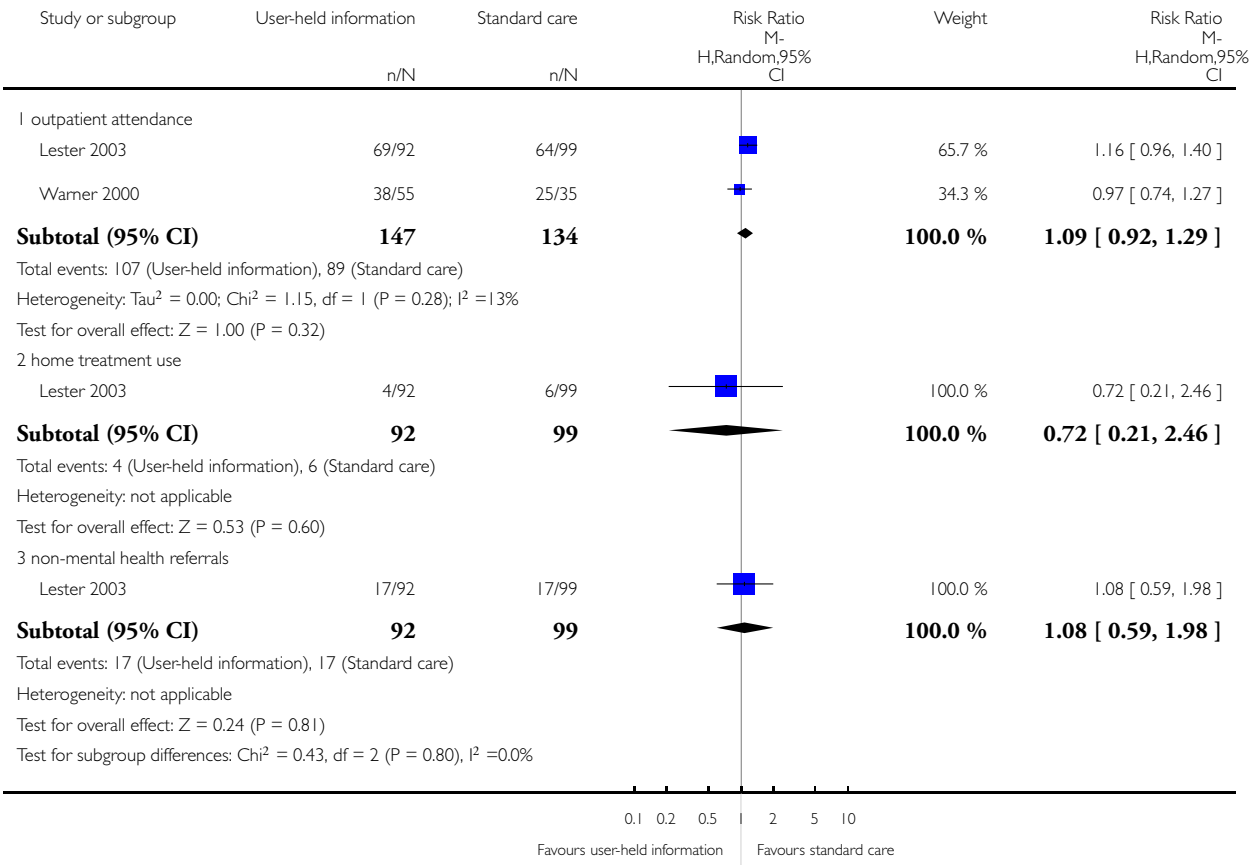

Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

### Analysis 1.6. Comparison 1 User-held information versus standard information, Outcome 6 Service use.

Review: User-held personalised information for routine care of people with severe mental illness

Comparison: 1 User-held information versus standard information

Outcome: 6 Service use




### Analysis 1.7. Comparison 1 User-held information versus standard information, Outcome 7 Economic costs of care (£ - client service receipt inventory, skew).

**Economic costs of care (£ - client service receipt inventory, skew)**

| Study | Intervention | Mean (£) | Standard deviation | N |
|---|---|---|---|---|
| Henderson 2004 | User-held information | 7,264 | 13,045 | 80 |
| Henderson 2004 | Standard care | 8,359 | 12,168 | 80 |

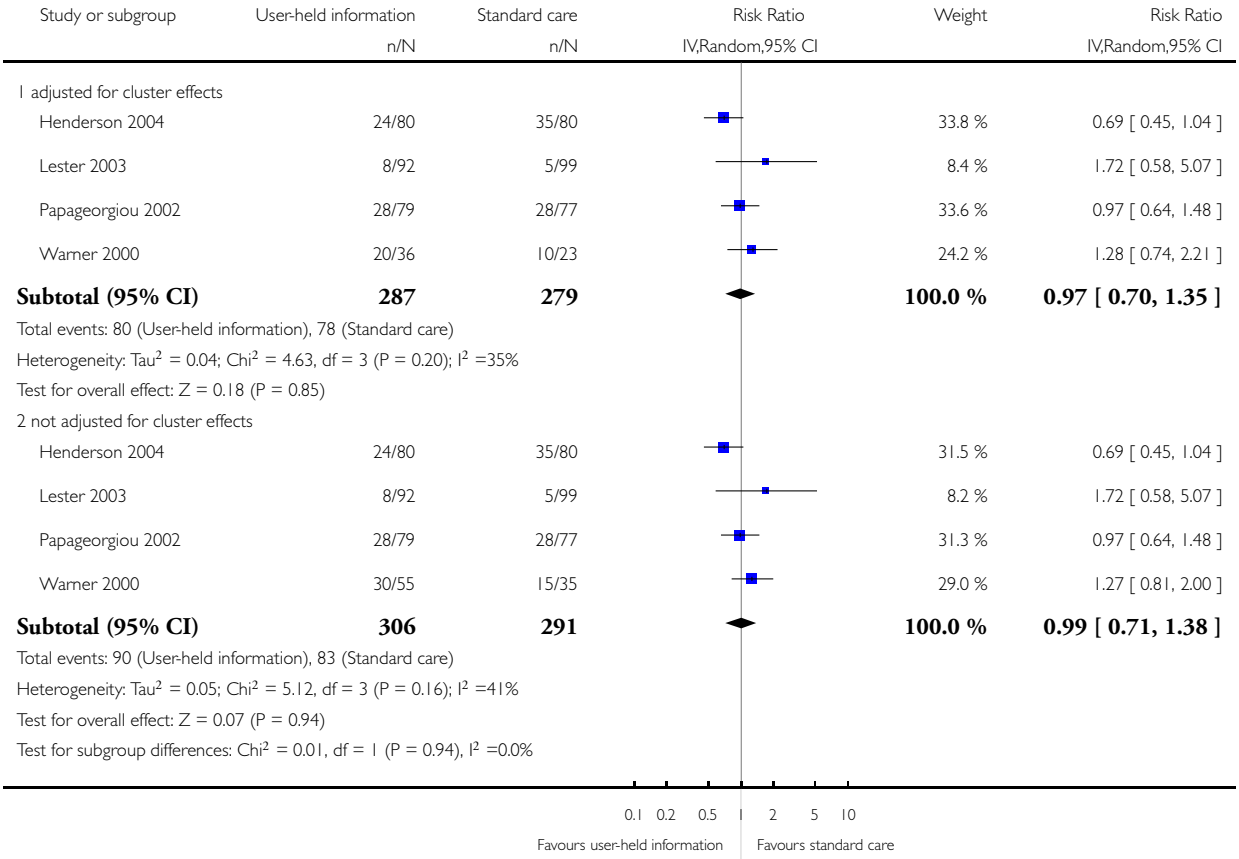

Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

### Analysis 1.8. Comparison 1 User-held information versus standard information, Outcome 8 Sensitivity analysis: Psychiatric hospital admission: adjusting for clustering.

Review: User-held personalised information for routine care of people with severe mental illness

Comparison: 1 User-held information versus standard information

Outcome: 8 Sensitivity analysis: Psychiatric hospital admission: adjusting for clustering





Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

# APPENDICES

## Appendix 1. Previous searches

1. AMED (c.1980 - September 1998) was searched using the Cochrane Schizophrenia Group's phrase for randomised controlled trials (see Group search strategy for Biological Abstracts) combined with the phrase:
[and ((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) near2 (HOLD* or HELD or CARR* or PARTICIPATION)) and ((RECORD* or NOTE* or CARD* or PLAN*) or (CRISIS near2 (CARD* or PLAN)) or (ADVANCE near1 DIRECTIVE*)]
2.Biological abstracts (January 1985 - December 1998) was searched using the Cochrane Schizophrenia Group's phrase for randomised controlled trials (see Group search strategy) combined with the phrase:

[and ((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) near2 (HOLD* or HELD or CARR* or PARTICIPATION)) and ((RECORD* or NOTE* or CARD* or PLAN*) or (CRISIS near2 (CARD* or PLAN)) or (ADVANCE near1 DIRECTIVE*)]
3. British Nursing Index (January 1994 - December 1998) was searched using the Cochrane Schizophrenia Group's phrase for randomised controlled trials (see Group search strategy for Biological Abstracts) combined with the phrase:

[and ((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) near2 (HOLD* or HELD or CARR* or PARTICIPATION)) and ((RECORD* or NOTE* or CARD* or PLAN*) or (CRISIS near2 (CARD* or PLAN)) or (ADVANCE near1 DIRECTIVE*)]
4. CAB (1973-March 1999) was searched using the Cochrane Schizophrenia Group's phrase for randomised controlled trials (see Group search strategy for Biological Abstracts) combined with the phrase:

[and ((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) near2 (HOLD* or HELD or CARR* or PARTICIPATION)) and ((RECORD* or NOTE* or CARD* or PLAN*) or (CRISIS near2 (CARD* or PLAN)) or (ADVANCE near1 DIRECTIVE*)]
5. CINAHL (1982 - February 1999) was searched using the Cochrane Schizophrenia Group's phrase for randomised controlled trials (see Group search strategy) combined with the phrase:
[and (explode "CONSUMER-PARTICIPATION"/ all topical subheadings / all age subheadings and explode "MEDICAL-RECORDS"/ all topical subheadings or ((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) near2 (HOLD* or HELD or CARR* or PARTICIPATION)) and (RECORD* or NOTE* or CARD* or PLAN*)) or (CRISIS near2 (CARD* or PLAN)) or explode "ADVANCE DIRECTIVES" all topical subheadings / all age subheadings or (ADVANCE near1 DIRECTIVE*)]
6. The Cochrane Controlled Trials Register (Issue 1, 1999) was searched using the phrase:
[((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) and (HOLD* or HELD or CARR* or PARTICIPATION)) and ((RECORD* or NOTE* or CARD* or PLAN*) or (CRISIS and (CARD* or PLAN)) or (ADVANCE and DIRECTIVE*)]

7. EMBASE (January 1980 - February 1999) was searched using the Cochrane Schizophrenia Group's phrase for randomised controlled trials (see Group search strategy) combined with the phrase:

[and (((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) near2 (HOLD* or HELD or CARR* or PARTICIPATION)) and (RECORD* or NOTE* or CARD* or PLAN*)) or (CRISIS near2 (CARD* or PLAN)) or ((explode "CONSUMER"/ all subheadings or explode "PATIENT"/ all subheadings) and (explode "MEDICAL-RECORD"/ all subheadings)) or explode "ADVANCE DIRECTIVES" all subheadings or (ADVANCE near1 DIRECTIVE*)]
8. HEALTHSTAR (January 1990 - March 1999) was searched using the phrase:
[((((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) near2 (HOLD* or HELD or CARR* or PARTICIPATION)) and (RECORD* or NOTE* or CARD* or PLAN*)) or (CRISIS near2 (CARD* or PLAN)) or ((explode "CONSUMER"/ all subheadings or explode "PATIENT"/ all subheadings) and ((explode "MEDICAL-RECORD"/ all subheadings) or (explode "FORMS-AND-RECORDS-CONTROL"/ all subheadings )) or and (explode "ADVANCE DIRECTIVES"/ all subheadings) or ADVANCE near1 DIRECTIVE*)]
9. HMIC (King's Fund Database 1979 -1998; HELMIS 1984 - 1998) was searched using the phrase:
[((((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) near2 (HOLD* or HELD or CARR* or PARTICIPATION)) and (RECORD* or NOTE* or CARD* or PLAN*)) or (CRISIS near2 (CARD* or PLAN)) or (ADVANCE near1 DIRECTIVE*)]
10. MEDLINE (1966 - May 1999):was searched using the Cochrane Schizophrenia Group's phrase for randomised controlled trials (see Group search strategy) combined with the phrase:
[and (("CONSUMER-PARTICIPATION"/ all subheadings) and


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

(explode “MEDICAL-RECORDS”/ all subheadings) or (explode FORMS-AND-RECORDS-CONTROL“/ all subheadings) or (RECORD* or NOTE* or CARD* or PLAN*)) or (CRISIS near2 (CARD* or PLAN)) or explode ”ADVANCE DIRECTIVES“/ all subheadings or (ADVANCE near1 DIRECTIVE*)]
11. PsycLIT (1887 - March 1999) was searched using the Cochrane Schizophrenia Group’s phrase for randomised controlled trials (see Group search strategy) combined with the phrase:
[and (((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) near2 (HOLD* or HELD or CARR* or PARTICIPATION)) and (RECORD* or NOTE* or CARD* or PLAN*)) or (CRISIS near2 (CARD* or PLAN)) or ((”CLIENT-RECORDS“ IN DE or explode ”MEDICAL-RECORDS“) and (”CLIENT-PARTICIPATION“ IN DE)) or explode ”ADVANCE DIRECTIVES“/ all subheadings or (ADVANCE near1 DIRECTIVE*)]
12. Royal College of Nursing database (1985-1996) was searched using the Cochrane Schizophrenia Group’s phrase for randomised controlled trials (see Group search strategy) combined with the phrase:
[and ((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) near2 (HOLD* or HELD or CARR* or PARTICIPATION)) and ((RECORD* or NOTE* or CARD* or PLAN*) or (CRISIS near2 (CARD* or PLAN)) or (ADVANCE near1 DIRECTIVE*)]
13. SIGLE (1990- December 1998) was searched using the Cochrane Schizophrenia Group’s phrase for randomised controlled trials (see Group search strategy) combined with the phrase:
[and ((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) near2 (HOLD* or HELD or CARR* or PARTICIPATION)) and ((RECORD* or NOTE* or CARD* or PLAN*) or (CRISIS near2 (CARD* or PLAN)) or (ADVANCE near1 DIRECTIVE*)]
14. Sociological Abstracts (1963-December 1998) was searched using the Cochrane Schizophrenia Group’s phrase for randomised controlled trials (see Group search strategy) combined with the phrase:
[and (explode ”PATIENTS“) and (explode ”RECORDS-(DOCUMENTS)“ or ((CONSUMER* or CLIENT* or USER* or PATIENT* or OWN) near2 (HOLD* or HELD or CARR* or PARTICIPATION)) and (RECORD* or NOTE* or CARD* or PLAN*)) or (CRISIS near2 (CARD* or PLAN)) or (ADVANCE near1 DIRECTIVE*]

## Appendix 2. Previous data collection methods

2. Assessment of quality
Trials were allocated to three quality categories, as described in the Cochrane Collaboration Handbook (Mulrow 1999) by each reviewer, again, working independently.
A. Low risk of bias (all criteria met e.g. adequate allocation concealment)
B. Moderate risk of bias (one or more criteria partly met e.g. some doubt about the results)
C. High risk of bias (one or more criteria not met e.g. inadequate allocation concealment).
When disputes arose as to which category a trial was allocated, resolution was attempted by discussion. When this was not possible, and further information was necessary, data were not entered into the analyses and the study was allocated to the list of those awaiting assessment. Only trials in Category A or B were included in the review.
**Please note that no trials were found that met these criteria in the previous review. The originally proposed method for data management and analysis is included below for completeness.
3. Data management
3.1 Data extraction
This was performed independently by both reviewers and, where further clarification was needed, the authors of trials were contacted to provide missing data.
3.2 Intention to treat analysis
Data were excluded from studies where more than 50% of participants in any group were lost to follow up (this does not include the outcome of ’leaving the study early’). In studies with less than 50% dropout rate, people leaving early were considered to have had the negative outcome, except for the event of death. The impact of including studies with high attrition rates (25-50%) was analysed in a sensitivity analysis. If inclusion of data from this latter group did result in a substantive change in the estimate of effect their data were not added to trials with less attrition, but presented separately.
4. Data analysis
4.1 Binary data
For binary outcomes a standard estimation of the risk ratio (RR) and its 95% confidence interval (CI) was calculated. The number needed to treat statistic (NNT) was also calculated. If heterogeneity was found (see section 5) a random effects model was used.
4.2 Continuous data
4.2.1 Skewed data: Continuous data on clinical and social outcomes are often not normally distributed. To avoid the pitfall of applying parametric tests to non-parametric data the following standards are applied to all data before inclusion: i. standard deviations and means


**Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.**

were reported in the paper or were obtainable from the authors; ii. when a scale starts from a finite number (such as 0), the standard deviation, when multiplied by 2, was less than the mean (as otherwise the mean was unlikely to be an appropriate measure of the centre of the distribution) (Altman 1996). Endpoint scores on scales often have a finite start and end point and this rule can be applied to them. Change data is more problematic, and this rule cannot be applied with confidence. Change data were therefore only presented if no endpoint data were available (see 4.2.4).

4.2.2 Summary statistic: For continuous outcomes a weighted mean difference (WMD) between groups was estimated. Again, if heterogeneity was found (see section 5) a random effects model was used.

4.2.3 Valid scales: Continuous data from rating scales were included only if the measuring instrument had been described in a peer-reviewed journal and the instrument was either a self report or completed by an independent rater or relative (not the therapist).

4.2.4 Endpoint versus change data

Where possible endpoint data were presented and if both endpoint and change data were available for the same outcomes then only the former were reported in this review.

5. Test for heterogeneity

A Chi-square test was used, as well as visual inspection of graphs, to investigate the possibility of heterogeneity. A significance level less than 0.10 was interpreted as evidence of heterogeneity. If this was found the data were re-analysed using a random effects model to see if this made a substantial difference. If it did not the studies responsible for the heterogeneity were not added to the main body of homogeneous trials, but summated and presented separately.

6. Addressing publication bias

Data from all included studies were entered into a funnel graph (trial effect against trial size) in an attempt to investigate the likelihood of overt publication bias (Egger 1997).

7. General

Where possible, reviewers entered data in such a way that the area to the left of the line of no effect indicated a favourable outcome for user-held notes.

8. Sensitivity analysis

The sensitivity of the results from the main outcomes will be tested for change when the assumption that those who did not complete the study had a poor outcome was not employed.

## WHAT'S NEW

Last assessed as up-to-date: 2 August 2011.

| Date | Event | Description |
|---|---|---|
| 10 September 2013 | New citation required and conclusions have changed | Conclusions changed: no evidence of effect with hospitalisations,<br>but evidence gap remains for other outcomes. |
| 2 August 2011 | New search has been performed | New search conducted August 2011. Four trials are now included in this review |


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

## HISTORY

Review first published: Issue 3, 1999

| Date | Event | Description |
|---|---|---|
| 13 April 2011 | Amended | Minor update. |
| 15 February 2010 | Amended | Minor update. |
| 5 November 2008 | Amended | Update. |
| 31 October 2008 | Amended | Converted to new review format. |
| 31 October 2005 | Amended | Minor update. |
| 24 September 2003 | New citation required but conclusions have not changed | Updated. |
| 26 October 1999 | New citation required and conclusions have changed | Review first published. |

## CONTRIBUTIONS OF AUTHORS

Simone Farrelly - study selection, data extraction, data analysis, completion of report.

Gill Brown - study selection, data extraction.

Clare Flach - data analysis, completion of report.

Claire Henderson - original protocol writing, confirmation of trial selection and data extraction, completion of report.

Richard Laugharne and Elizabeth Barley - completion of report.

## DECLARATIONS OF INTEREST

Simone Farrelly, Gill Brown, Clare Flach and Claire Henderson all worked on the ongoing trial CRIMSON (Thornicroft 2010), a trial of Joint Crisis Plans funded by the Medical Research Council (UK). Claire Henderson also worked on one of the studies included in this review (Henderson 2004).


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

## SOURCES OF SUPPORT

### Internal sources

- No sources of support supplied

### External sources

- Medical Research Council, UK.

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We were concerned about splitting outcome data for the results at 12 months; the review authors appreciate that time frames were specified in the protocol, but we made the decision that it does not fairly represent the data by making a distinction between three studies with a 12-month follow-up and one study with a 15-month follow-up. We think that representing the data in this way may lead to misleading messages about time trends that we do not have evidence for.

This review update modified the previous inclusion criteria by specifying a minimum diagnostic threshold for studies with a mixture of diagnoses in their samples.

We have also updated the methods section of this review to reflect advances in Cochrane methodology.

## INDEX TERMS

### Medical Subject Headings (MeSH)

*Medical Records; *Patient Participation; Advance Directives; Psychotic Disorders [*therapy]

### MeSH check words

Adult; Humans


Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.