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Different communication strategies for disclosing a diagnosis of schizophrenia and related disorders (Review)

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[Intervention Review]

Different communication strategies for disclosing a diagnosis of schizophrenia and related disorders

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ABSTRACT

Background

Delivering the diagnosis of a serious illness is an important skill in most fields of medicine, including mental health. Research has found that communication skills can impact on a person's recall and understanding of the diagnosis, treatment options and prognosis. People may feel confused and perplexed when information about their illness is not communicated properly. Sharing information about diagnosis of a serious mental illness is particularly challenging. The nature of mental illness is often difficult to explain since there may be no clear aetiology, and the treatment options and prognosis may vary enormously. In addition, newly diagnosed psychiatric patients, who are actively ill, often may not accept their diagnosis due to lack of insight or stigma attached to the condition. There are several interventions that aim to help clinicians to communicate life changing medical diagnoses to people; however, little is known specifically for delivering a diagnosis of schizophrenia.

Objectives

To evaluate evidence from randomised controlled trials (RCTs) for the efficacy of different communication strategies used by clinicians to inform people about the diagnosis and outcome of schizophrenia compared with treatment as usual and to compare efficacy between different communication strategies.

Search methods

On 22 June 2015 and 29 June 2016, we searched the Cochrane Schizophrenia Group's Study-Based Register of Trials. We also searched sources of grey literature (e.g., dissertations, theses, clinical reports, evaluations published on websites, clinical guidelines and reports from regulatory agencies).

Selection criteria

We planned to include all relevant RCTs that included adults with schizophrenia or related disorders, including schizophreniform disorder, schizoaffective disorder and delusional disorder. The trials would have investigated the effects of communication strategy or strategies that helped clinicians deliver information specifically about a diagnosis of schizophrenia (which can also include communication regarding the treatment options available and prognosis).

Data collection and analysis

Review authors independently examined all reports from the searches for any relevant studies. We planned to extract data independently. For binary outcomes, we would have calculated risk ratio (RR) and its 95% confidence interval (CI), on an intention-to-treat basis. For continuous data, we would have estimated the mean difference (MD) between groups and its 95% CI. We would have employed a random-effects model for analyses. We planned to assess risk of bias for included studies. We created a 'Summary of findings' table using GRADE.

Main results

The searches identified 44 records which appeared to be relevant to the aims of the review. We obtained full reports for seven potential studies; however, after close inspection none of these studies met the inclusion criteria.

Authors' conclusions

Good communication of diagnosis can affect treatment planning, compliance and patient outcomes, especially in the case of conditions such as schizophrenia, which has the potential to cause serious life disruption for both people with schizophrenia and their carers. Currently, there is no evidence based on findings from RCTs assessing the effects of communication strategies for disclosing the diagnosis of schizophrenia and related disorders. Research is required.

PLAIN LANGUAGE SUMMARY

Sharing information about the diagnosis and outcomes of schizophrenia: evidence from well-designed clinical trials

Background

Health professionals have a duty to give information to their patients in a way that is understandable, especially when the condition is severe and life altering. Schizophrenia and similar related disorders are serious mental illnesses that can have long term, disruptive effects on the lives of both patients and their carers. The way a person is told they have a serious illness and what having this illness will mean for them can affect how they accept their diagnosis and treatment plans which then ultimately can affect their recovery and long-term outlook. At the moment, there is no information or evidence regarding how best to disclose a diagnosis of schizophrenia.

Searching for evidence

In June 2015 and June 2016, we explored the medical literature and the Cochrane Schizophrenia Group's study-based register using appropriate keywords to find any studies which evaluated a method that guided or helped health professionals with how to deliver the news about the diagnosis of schizophrenia. We specifically searched for randomised controlled trials as these are considered the best way (gold standard) to evaluate the effects of treatments. We identified 44 publications and inspected these. From these, we obtained seven full reports of trials and that we thought could be relevant; however, none of these studies could be included in the review.

Conclusions

Currently health professionals can use good quality, evidence based information to guide them in the sharing of news about diagnosis of a serious physical illnesses; however, there is no such evidence available concerning the sharing of news about the diagnosis of schizophrenia. This is a serious gap in knowledge which needs attention and studies are needed in this area.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Communication strategies for compared with treatment as usual for disclosing a diagnosis of schizophrenia or related disorders

Patient or population: people with schizophrenia and their carers
Settings: hospital or community
Intervention: communication strategy to impart information about diagnosis of schizophrenia
Comparison: treatment as usual

Outcomes	No of participants (studies)	Quality of the evidence (GRADE)	Comments
Engagement with services: clinically important change in engagement with services, as defined by individual studies	-	-	No evidence from randomised trials.
Treatment adherence: clinically important change in treatment adherence, as defined by individual studies	-	-	
Understanding: clinically important change in understanding the nature of illness and its outcome, as defined by individual studies	-	-	
Quality of life: clinically important change in general quality of life or well-being, as defined by individual studies	-	-	
Mental state: clinically important change in mental state, as defined by individual studies	-	-	
Satisfaction communication of diagnosis: clinically important change (patient or carer's), as defined by individual studies	-	-	

Adverse effect: clinically important adverse effect of intervention - as defined by individual studies	-	-	

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.

BACKGROUND

Description of the condition

Schizophrenia and related disorders are a group of serious mental illnesses typically characterised by the presence of delusions, hallucinations, disorganised speech, disorganised behaviour and negative symptoms (avolition, apathy, anhedonia, alogia, affective blunting). Schizophrenia typically presents for males in early adulthood or late adolescence (for females the age of onset is slightly later) and affects around 0.30% to 0.66% of people at some point in their life (McGrath 2008). Schizophrenia impairs quality of life and severely impacts the ability of a person to live and work (Krupa 2004).

Diagnosing schizophrenia is not straightforward. The validity of the concept and even the term schizophrenia is fiercely debated and it can be profoundly stigmatising (Lieberman 2007). Most early intervention and prodromal services prefer the term psychosis instead of schizophrenia, although the effects of using the term psychosis or any other alternative to schizophrenia is also currently not evidence based. The two major classification systems, the Diagnostic and Statistical Manual of Mental Disorders (DSM) and International Classification of Diseases (ICD-10), have different requirements of symptom duration for the diagnosis of schizophrenia. While the DSM requires presence of symptoms for a minimum of six months, the ICD-10 warrants a minimum duration of one month. The DSM-IV has a requirement for social/occupational dysfunction; the ICD-10 had no such requisite (APA 2013). Once diagnosed, delivering the diagnosis and sharing information about the treatment options and prognosis of schizophrenia with the person can be very challenging for clinicians. The nature of the condition is often difficult to explain since there is no clear aetiology and outcome is variable. Unlike most physical illnesses, people may not accept a mental health diagnosis due to lack of insight or stigma. Feelings of alienation, devaluation by others, worry about being viewed unfavourably and avoidance of self-disclosure about mental illness are among the most common reported stigma experiences for people with schizophrenia (Dickerson 2002).

Description of the intervention

A communication strategy is defined as any intervention aimed at improving communication between mental health professionals and patients or carers, or both. Effective medical communication strategies take into account the nature and stage of illness, a person's view of the illness, their help-seeking behaviour and their prior knowledge.

A number of different models for breaking bad news regarding health have been published in other branches of medicine. The most commonly reported model is SPIKES (Buckman 1992). This model has six steps for breaking news of a serious diagnosis: 1. start off well, 2. find out how much the patient/family knows, 3. find out how much the patient/family want to know, 4. share the information, 5. respond to patient's/family feelings and 6. plan and follow through (Buckman 1992). These steps have been modified for different conditions, including, in mental health, dementia (Carpenter 2004) and learning disability (Tuffrey-Wijne 2013), but not specifically for schizophrenia. Seeman 2010 suggested that the SPIKES model could be applied to schizophrenia; however, this suggestion is based on qualitative information.

It should be noted that the communication strategy we are discussing here is different to general communication skills between clinicians and patients. These communication skills are related to discussions of the condtions and treatment options for that and is the focus of another Cochrane Review (Papageorgiou 2017). Similarly psychoeducation which is designed to inform and help people learn about their illness is also covered by another review (Xia 2011). The intervention for this review is a strategy or set of communication strategies specifically for delivery of the diagnosis and outcome of schizophrenia.

How the intervention might work

The diagnosis of a severe mental illness such as schizophrenia can cause anxiety and despair when delivered without consideration of the person's views about mental illness and the potential effects of the diagnosis on their mental health. Carers can also be affected by receiving such news. Good initial delivery of information about having a severe mental illness aids informed decision-making about treatment and empowers people and their families. Such interventions in the form of different communication strategies can help to reduce anxiety, fear and stigma. They may help to foster better engagement with mental health services, which can lead to better compliance with treatment.

Why it is important to do this review

Doctors have a duty to provide information to people in a way that is understandable to them (General Medical Council 2009). Delivering information about a serious diagnosis or life-threatening outcomes is an important skill in most fields of medicine, such as oncology, paediatrics and obstetrics (Fallowfield 2004). Given the plethora of research in other medical disciplines, it is surprising that in psychiatry, research on communicating information about a serious illness is mostly limited to dementia (Cleary 2009; Mitchell 2007).

The National Institute for Health and Care Excellence (NICE) guidelines recommend that information about the causes and treatment options for schizophrenia be discussed with the patient and their carers, but does not offer advice on how to communicate to a person the news that he or she has been diagnosed with schizophrenia (NICE 2009). Currently there is no clear strat-

egy available and people with schizophrenia have varied experiences. One literature review on disclosure of mental health diagnosis found that of service users with schizophrenia, 45% received no information regarding their diagnosis compared to a mean of 20% for other mental health diagnoses. There were similar findings in psychiatrist surveys (Clafferty 2001; Luderer 1993; McDonald-Scott 1992; Shergill 1998), except when episodes were recurrent (Clafferty 2001). McDonald-Scott found providing a substitute diagnosis in place of a schizophrenia diagnosis is reported as common practice, and this remained the case even when exact diagnostic information was sought by service-users (McDonald-Scott 1992).

In a multicultural society, cross-cultural issues can pose another challenge. One cross-cultural study revealed that 30% of North Americans and more than 70% of Japanese psychiatrists would not inform people about their diagnosis of schizophrenia (McDonald-Scott 1992). In addition, there are some Chinese-American psychiatrists who believe that not disclosing a diagnosis of schizophrenia to be one of the most effective treatment approaches when working with Chinese-American people (Hwang 2008).

Psychiatric literature on sharing news about serious mental illness is, at the moment, mostly limited to questionnaire-based surveys of psychiatrist and other mental health professionals about their practice (Clafferty 2001; Cleary 2009; Green 1984; Marzanski 2000; Üçok 2004), family members (Lauber 2003), and semi-structured interviews with patients (Gallagher 2010).

Therefore, we feel it is important to evaluate the available evidence and determine if more research is needed. The present review aims to help to identify available interventions and evaluate their effectiveness. This will assist in providing an evidence base and developing guidelines for best practice in this area. It can also identify gaps in the knowledge so we can gather information that leads to better design and implementation of future randomised controlled trials (RCT).

OBJECTIVES

To evaluate evidence from randomised controlled trials (RCTs) for the efficacy of different communication strategies used by clinicians to inform people about the diagnosis and outcome of schizophrenia compared with treatment as usual and to compare efficacy between different communication strategies.

METHODS

Criteria for considering studies for this review

Types of studies

All relevant RCTs. If a trial was described as 'double blind' but implied randomisation, we would have included such trials in a sensitivity analysis (see Sensitivity analysis). We would have excluded quasi-randomised studies, such as those allocating by alternate days of the week. Where participants are given additional interventions within an information-sharing strategy, we would only have included data if the adjunct treatment was evenly distributed between groups and only the information-sharing strategy was randomised.

Types of participants

Adults and adolescents (aged more than 16 years) however defined, with schizophrenia or related disorders, including schizophreniform disorder, schizoaffective disorder and delusional disorder, by any means of diagnosis. The communication strategies may also have involved carers and relatives. Communication strategies involving relatives would have needed to be described as such. We would have reported outcomes about carers separately. We would have only included trials where over 50% of the participants had schizophrenia.

To ensure that information was as relevant to the current care of people with schizophrenia we planned to clearly highlight the current clinical state (acute, early postacute, partial remission, remission) and the stage (prodromal, first episode, early illness, persistent) and as to whether the studies primarily focused on people with particular problems (e.g. subtypes of schizophrenia).

Types of interventions

1. Communication strategies

Information-sharing strategies designed to help clinicians communicate the diagnosis of schizophrenia to people with schizophrenia and their carers.

We defined these as any intervention aimed at improving communication between mental health professionals and patients or carers, or both about the diagnosis of schizophrenia. This communication could also have involved discussion regarding treatment options and prognosis.

We hypothesised that a communication strategy should address the following areas:

1. when to communicate the diagnosis;
2. what information should (and should not) be communicated;
3. how to communicate this information.

Communication strategies may have included different components such as cultural, medical, legal and ethical considerations. They may also have included communication with carers or with patients who may have limited or no insight into their condition.

2. Treatment as usual

The controls may have included no particular strategy (usually described as treatment as usual)
We aimed, if possible, to also compare different communication strategies with each other.

Types of outcome measures

We planned to divide all outcomes into short term (less than six months), medium term (six to 12 months) and long term (over one year). Primary outcomes were engagement with services and treatment adherence. We also aimed to evaluate strategies in terms of improvement in understanding the nature of the illness and its outcome, psychopathology, disability and satisfaction with health care. We would have only used scale data measured using validated scales (see Data extraction and management).

Primary outcomes

1. Engagement with services

1.1. Clinically important change in engagement with services, as defined by individual studies.

2. Treatment adherence

2.1. Clinically important change in treatment adherence, as defined by individual studies.

Secondary outcomes

1. Engagement with services

1.1. Any change in engagement with services, as defined by individual studies.

2. Treatment adherence

2.1. Any change in treatment adherence, as defined by individual studies.

3. Understanding

3.1. Clinically important change in understanding the nature of illness and its outcome, as defined by individual studies.
3.2. Any change in understanding the nature of illness and its outcome, as defined by individual studies.
3.3. Change in insight.
3.4. Change in patients' beliefs about illness.

4. Quality of life or well-being

4.1. Clinically important change in general quality of life or well-being, as defined by individual studies.
4.2. Any change in quality of life or well-being, as defined by individual studies.
4.3. Mean endpoint/change score in general quality of life score or well-being scales.

5. Mental state

5.1. Clinically important change in mental state, as defined by individual studies.
5.2. Any change in mental state, as defined by individual studies.
5.3. Mean endpoint/change score in mental state scales.

6. General functioning

6.1. Clinically important change in general functioning, as defined by individual studies.
6.2. Any change in general functioning, as defined by individual studies.
6.3. Mean endpoint/change score on general functioning scales.

7. Behaviour

7.1. Clinically important change in behaviour (e.g. self-harm), as defined by individual studies.
7.2. Any change in behaviour, as defined by individual studies.
7.3. Mean endpoint/change score behaviour scales.

8. Satisfaction with communication of diagnosis

8.1. Clinically important change in patient satisfaction, as defined by individual studies.
8.2. Clinically important change in carer satisfaction, as defined by individual studies.
8.3. Clinically important change in health professional satisfaction, as defined by individual studies.
8.4. Mean endpoint/change score on satisfaction scales.
8.5. Leaving the study early.

9. Adverse effects from disclosure of diagnosis for patient or carers

9.1. Clinically important adverse effect, as defined by individual studies.

10. Economic

10.1. Direct costs.
10.2. Indirect costs.

'Summary of findings' table

We planned to use the GRADE approach to interpret findings (Schünemann 2011) as well as GRADEpro to import data from Review Manager 5 to create 'Summary of findings' tables. These tables provide 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 rate as important to patient-care and decision making. We aimed to select the following main outcomes for inclusion in the 'Summary of findings' table:

1. engagement with services: clinically important change in engagement with services, as defined by individual studies;
2. treatment adherence: clinically important change in treatment adherence, as defined by individual studies;
3. understanding: clinically important change in understanding the nature of illness and its outcome, as defined by individual studies;
4. quality of life: clinically important change in general quality of life or well-being, as defined by individual studies;
5. mental state: clinically important change in mental state, as defined by individual studies.
6. satisfaction communication of diagnosis: clinically important change (patient or carer's), as defined by individual studies;
7. adverse effects: clinically important adverse effect of intervention, as defined by individual studies.

In future versions, if data are not available for these prespecified outcomes but are available for ones that are similar, we will present the closest outcome to the prespecified one in the table but take this into account when grading the finding.

Search methods for identification of studies

Electronic searches

Cochrane Schizophrenia Group's Study-Based Register of Trials

On 22 June 2015 and 29 June 2016, the information specialist of the Cochrane Schizophrenia Group searched the register using the following search strategy:

Communication in Intervention Field of STUDY

In such a study-based register, searching the major concept retrieves all the synonyms and relevant studies because all the studies have already been organised based on their interventions and linked to the relevant topics.

This register is compiled by systematic searches of major resources (including MEDLINE, Embase, AMED, BIOSIS, CINAHL, PsycINFO, PubMed and registries of clinical trials) and their monthly updates, handsearches, grey literature and conference proceedings (see Group's Module). There is no language, date, document type or publication status limitations for inclusion of records into the register.

For other searches, see Appendix 1.

Searching other resources

1. Reference searching

We would have inspected references of all included studies for further relevant studies.

2. Personal contact

We would have contacted the first author of each included study for information regarding unpublished trials.

3. Handsearching

We also searched sources of grey literature (such as dissertations and theses, clinical reports, evaluations published on websites, clinical guidelines and reports from regulatory agencies).

Data collection and analysis

Selection of studies

Two review authors (FN and RJ) independently inspected citations from the searches to identify relevant abstracts. A third review author (SF) independently re-inspected a random 20% sample to ensure reliability. If disputes had occurred, we would have acquired the full report for more detailed scrutiny.

Data extraction and management

1. Extraction

Two review authors (FN and SF) would have extracted data from all included studies. To ensure reliability, RJ would have independently extracted data from a random sample of these studies, comprising 10% of the total. Any disagreement would have been discussed, decisions documented and, if necessary, authors of studies contacted for clarification. We would have extracted data presented only in graphs and figures wherever possible, but include only if two review authors independently reached the same conclusion. Where necessary to obtain missing information or for clarification, we would have attempted to contact authors through an open-ended request. If studies had been multicentre, we would have extracted data relevant to each component centre separately where possible.

2. Management

2.1. Forms

We would have extracted data on to standard data extraction forms.

2.2. Scale-derived data

We would include continuous data from rating scales only if:

1. the psychometric properties of the measuring instrument had been described in a peer-reviewed journal (Marshall 2000);
2. the measuring instrument had not been written or modified by one of the trialists for that particular trial and
3. the instrument was a global assessment of an area of functioning and not subscores which are not, in themselves, validated or shown to be reliable. However, there are exceptions, we would have included subscores from mental state scales measuring positive and negative symptoms of schizophrenia. Ideally the measuring instrument should have been either be a self-report or completed by an independent rater or relative (not the therapist). We realise that this is not often reported clearly; in 'Description of studies' we would have noted if this is the case or not.

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; however, calculation of change needs two assessments (baseline and endpoint) that can be difficult to obtain in unstable and difficult-to-measure conditions such as schizophrenia. We decided primarily to use endpoint data, and only use change data if endpoint were not available. If necessary, we would have combined endpoint and change data in the analysis, as we prefer to use mean differences (MDs) rather than standardised mean differences (SMDs) throughout (Deeks 2011).

2.4. 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, we would have applied the following standards to relevant continuous data before inclusion.

For endpoint data from studies including fewer than 200 participants:

1. when a scale starts from the finite number zero, we would have subtracted the lowest possible value from the mean, and divided this by the standard deviation (SD). If this value was lower than one, it would strongly suggest that the data were skewed and we would have excluded these data. If this ratio was higher than one but less than two, there would have been suggestion that the data were skewed: we would have entered these data and tested whether their inclusion or exclusion would have changed the results substantially. If such data changed results, we would have entered them as 'other data.' Finally, if the ratio was larger than two we would have included these data, because it was less likely that they were skewed (Altman 1996; Higgins 2011a);
2. if a scale started from a positive value (such as the Positive and Negative Syndrome Scale (PANSS), which can have values from 30 to 210 (Kay 1986)), we would have modified the calculation described above to take the scale starting point into account. In these cases, skewed data were present if 2 SD > (S - S_{min}), where S was the mean score and S_{min} was the minimum score.

Note: we would have entered all relevant data from studies of more than 200 participants in the analysis irrespective of the above rules, because skewed data pose less of a problem in large studies. We would also have entered all relevant change data, as when continuous data are presented on a scale that includes a possibility of negative values (such as change data), it is difficult to determine whether or not data are skewed.

2.5. Common measure

To facilitate comparison between trials, we intended to convert variables that could have been reported in different metrics, such as days in hospital (mean days per year, per week or per month) to a common metric (e.g. mean days per month).

2.6. Conversion of continuous data to binary data

Where possible, we planned to convert continuous outcome measures to dichotomous data. This can be done by identifying cutoff points on rating scales and dividing participants accordingly into 'clinically improved' or 'not clinically improved' groups. It is generally assumed that if there is a 50% reduction in a scale-derived score such as the Brief Psychiatric Rating Scale or the PANSS (Kay 1986; Overall 1962), this could be considered to be a clinically significant response (Leucht 2005a; Leucht 2005b). If data based on these thresholds were not available, we would have used the primary cutoff presented by the original authors.

2.7. Direction of graphs

We intended, where possible, to enter data in such a way that the area to the left of the line of no effect indicated a favourable outcome for 'strategies to share the information' compared to no strategy or treatment as usual. Where doing this made it impossible to avoid outcome titles with clumsy double-negatives (e.g. 'not unimproved'), we would have reported data where the left of the line indicated an unfavourable outcome.

Assessment of risk of bias in included studies

Two review authors (SF and ZC) would have worked independently to assess risk of bias using criteria described in the *Cochrane*

Handbook for Systematic Reviews of Interventions (Higgins 2011b). This set of criteria is based on evidence of associations between overestimate of effect and high risk of bias of the article such as sequence generation, allocation concealment, blinding, incomplete outcome data and selective reporting.

If the raters had disagreed, the final rating was to be made by consensus involving all review authors. If details of randomisation and other characteristics of trials had been inadequate, we would have contacted authors of the studies to obtain further information. We would have reported non-concurrence in quality assessment, but if disputes arose as to which category a trial was to be allocated, again, we would have resolved them by discussion.

We would have noted the level of risk of bias in both the text of the review and in the 'Summary of findings' table.

Measures of treatment effect

1. Binary data

For binary outcomes, we planned to calculate a standard estimation of the risk ratio (RR) and its 95% confidence interval (CI). It has been shown that RR is more intuitive than odds ratios and that odds ratios tend to be interpreted as RR by clinicians (Boissel 1999; Deeks 2000). The number needed to treat for an additional harmful outcome statistic with its CIs is intuitively attractive to clinicians, but is problematic both in its accurate calculation in meta-analyses and interpretation (Hutton 2009). Where possible, for binary data presented in the 'Summary of findings' table, we planned to calculate illustrative comparative risks.

2. Continuous data

For continuous outcomes, we planned to estimate the MD between groups. We prefer not to calculate effect size measures (SMD). However, if scales of very considerable similarity had been used, we would have presumed there was a small difference in measurement, and would have calculated effect size and transform the effect back to the units of one or more of the specific instruments.

Unit of analysis issues

1. Cluster trials

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

Where clustering is not accounted for in primary studies, we would have presented data in a table with an asterisk symbol to indicate the presence of a probable unit of analysis error.

We have sought statistical advice and have been 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 intraclass correlation coefficient (ICC) (design effect = 1 + (m - 1) × ICC) (Donner 2002). If the ICC was not reported, we decided to assume it to be 0.1 (Ukoumunne 1999).

2. Cross-over trials

A major concern of cross-over trials is the carry-over effect, which occurs if an effect (e.g. 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 washout phase. For the same reason, cross-over trials are not appropriate if the condition of interest is unstable (Elbourne 2002). As both effects are very likely in severe mental illness, we would have only used data of the first phase of cross-over studies.

3. Studies with multiple treatment groups

Where a study involved more than two treatment arms, we planned to present the additional treatment arms, if relevant, in comparisons. If data were binary, we would have combined these within the two-by-two table. If data were continuous, we would have combined data following the formula in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a).

Dealing with missing data

1. Overall loss of credibility

At a certain degree of loss to follow-up data loses 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. However, if more than 50% of data in one arm of a study were lost, but the total loss was less than 50%, we would have addressed this within the 'Summary of findings' table by downgrading quality. We would also downgrade quality if the loss was 25% to 50% in total.

2. Binary

In the case where attrition for a binary outcome was between 0% and 50% and where these data were not clearly described, we would have presented data on a 'once-randomised-always-analyse' basis (an intention-to-treat analysis (ITT)). Participants leaving the study early were all assumed to have the same rates of negative outcome as those who completed. We would have used the rate of those who stayed in the study, in that particular arm of the trial, and apply this also to those who did not. We would have undertaken a sensitivity analysis testing how prone the primary outcomes were

to change when data only from people who completed the study to that point were compared to the ITT analysis using the above assumptions.

3. Continuous

3.1. Attrition

In cases where attrition for a continuous outcome was between 0% and 50%, and data from only participants who completed the study to that point were reported, we would have reproduced these.

3.2. Standard deviations

If the SDs were not reported, we would have tried to obtain the missing values from the authors. If this was not possible, where there were missing measures of variance for continuous data, but an exact standard error and CIs were available for group means, and either P value or t value was available for differences in mean, we would have calculated them according to the rules described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011). When only the standard error was reported, we would have calculated SDs by using the formula SD = SE × square root (n). The *Cochrane Handbook for Systematic Reviews of Interventions* presents detailed formulae for estimating SDs from P values, t or F values, CIs, ranges or other statistics (Deeks 2011). If these formulae did not apply, we would have calculated the SDs according to a validated imputation method that was based on the SDs of the other included studies (Furukawa 2006). Although some of these imputation strategies can introduce error, the alternative would be to exclude a given study's outcome and thus to lose information. Nevertheless, we would have examined the validity of the imputations in a sensitivity analysis excluding imputed values.

3.3. Assumptions about participants who left the trials early or were lost to follow-up

Various methods are available to account for participants who left the trials early or were lost to follow-up. Some trials present only the results of study completed, while other trials use the method of last observation carried forward (LOCF). More recently, methods such as multiple imputation or mixed-effects models for repeated measurements (MMRM) have become a standard. While the latter methods seem somewhat better than LOCF (Leon 2006), we feel that a higher percentage of participants leaving the studies early and differences in the reasons for leaving the studies early between groups are often the core problem in randomised schizophrenia trials, and therefore would not exclude studies based on the statistical approach used. However, we would have preferred the use of more sophisticated approaches, for example MMRM or multiple-imputation over LOCF, and we would have only presented completer analyses if no ITT data were available. Moreover, we would have addressed this issue in the item 'incomplete outcome data' of the 'Risk of bias' tool.

Assessment of heterogeneity

1. Clinical heterogeneity

We planned to consider all included studies initially without seeing comparison data to judge clinical heterogeneity. We would have simply inspected all studies for clearly outlying participants or situations that we had not predicted. We would have discussed fully such situations or participant groups.

2. Methodological heterogeneity

We planned to consider all included studies initially without seeing comparison data to judge methodological heterogeneity. We would have simply inspected all studies for clearly outlying methods that we had not predicted and discussed such methodological outliers.

3. Statistical heterogeneity

3.1. Visual inspection

We planned to visually inspect graphs to investigate the possibility of statistical heterogeneity.

3.2. Employing the I^2 statistic

We planned to investigate heterogeneity between studies by considering the I^2 method alongside the Chi^2 P value. The I^2 statistic provides an estimate of the percentage of inconsistency thought to be due to chance (Higgins 2003). The importance of the observed value of the I^2 statistic depends on the magnitude and direction of the effects and the strength of evidence for heterogeneity (e.g. P value from the Chi^2 test or a CI for the I^2 statistic). Values of 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity and 75% to 100% represents considerable heterogeneity (Deeks 2011).

Assessment of reporting biases

1. Protocol versus full study

Reporting biases arise when the dissemination of research findings is influenced by the nature and direction of the results. These are described in Section 10.1 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Sterne 2011). We would have tried to

locate protocols of included RCTs. If the protocol was available, we would have compared the outcomes in the protocol and those in the published report. If the protocol was not available, we would have compared the outcomes listed in the methods section of the trial report with actually reported results.

2. Funnel plot

Reporting biases arise when the dissemination of research findings is influenced by the nature and direction of the results (Egger 1997). These are described in Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Sterne 2011). We are aware that funnel plots may be useful in investigating reporting biases, but are of limited power to detect small-study effects. We decided not to use funnel plots for outcomes where there were 10 or fewer studies, or where all studies were of a similar size. In other cases, where funnel plots were possible, we would have sought statistical advice in their interpretation.

Data synthesis

We understand that there is no closed argument for preference for the 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. However, there is a disadvantage to the random-effects model. It puts added weight on small studies, which often are the most biased ones. Depending on the direction of effect, these studies can either inflate or deflate the effect size. We planned to use the random-effects model for all analyses.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses

1.1. Primary outcomes

We did not plan any subgroup analysis.

1.2. Clinical state, stage or problem

We proposed to undertake this review and to provide an overview of the effects of information strategies to share the diagnosis of schizophrenia in general. In addition, we planned to report data on subgroups of people in the same clinical state, stage and with similar problems.

2. Investigation of heterogeneity

If inconsistency was high, we would have reported this. First, we would have investigated whether the data had been entered correctly. Second, if data were correct, we would have visually inspected the graph and successively removed outlier studies to see if homogeneity was restored. We decided that should this have occurred with data contributing to the summary finding of no more than around 10% of the total weighting, data would have been presented. If not, we would have not pooled data and would have discussed issues. We know of no supporting research for this 10% cutoff, but are investigating the use of prediction intervals as an alternative to this unsatisfactory state.
When unanticipated clinical or methodological heterogeneity was obvious, we would have simply stated hypotheses regarding these for future reviews or versions of this review. We did not anticipate undertaking analyses relating to these.

Sensitivity analysis

1. Implication of randomisation

We aimed to include trials in a sensitivity analysis if they were described in such a way as to imply randomisation. For the primary outcomes, if inclusion of data from these trials did not result in a substantive difference, they would have remained in the analyses. If their inclusion did result in important clinically significant but not necessarily statistically significant differences, we would not have added the data from these lower-quality studies to the results of the better-quality trials, but would have presented such data within a subcategory.

2. Assumptions for lost binary data

Where we had to make assumptions regarding participants lost to follow-up (see Dealing with missing data), we would have compared the findings of the primary outcomes when we used our assumptions and when we used data only from participants who complete the study to that point. If there was a substantial difference, we would have reported results and discussed them but would have continued to employ our assumption.
Where we had to make assumptions regarding missing SDs (see Dealing with missing data), we would have compared the findings of the primary outcomes when we used our assumptions and when we used data only from participants who completed the study to that point. We planned to undertake a sensitivity analysis, testing how prone results were to change when completer-only data were compared to the imputed data using the above assumption. If there was a substantial difference, we would have reported and discuss it but would have continued to employ our assumption.

3. Risk of bias

For the primary outcomes, we planned to analyse the effects of excluding trials that were judged 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). If excluding trials at high risk of bias did not substantially alter the direction of effect or the precision of the effect estimates, then we would have included data from these trials in the analysis.

4. Imputed values

For the primary outcomes, we also planned to undertake a sensitivity analysis to assess the effects of including data from trials where we used imputed values for the ICC in calculating the design effect in cluster randomised trials.

5. Fixed-effect and random-effects models

We planned to synthesise all data using a random-effects model; however, we would have also synthesised data for the primary outcomes using a fixed-effect model to evaluate whether this altered the significance of the results.

RESULTS

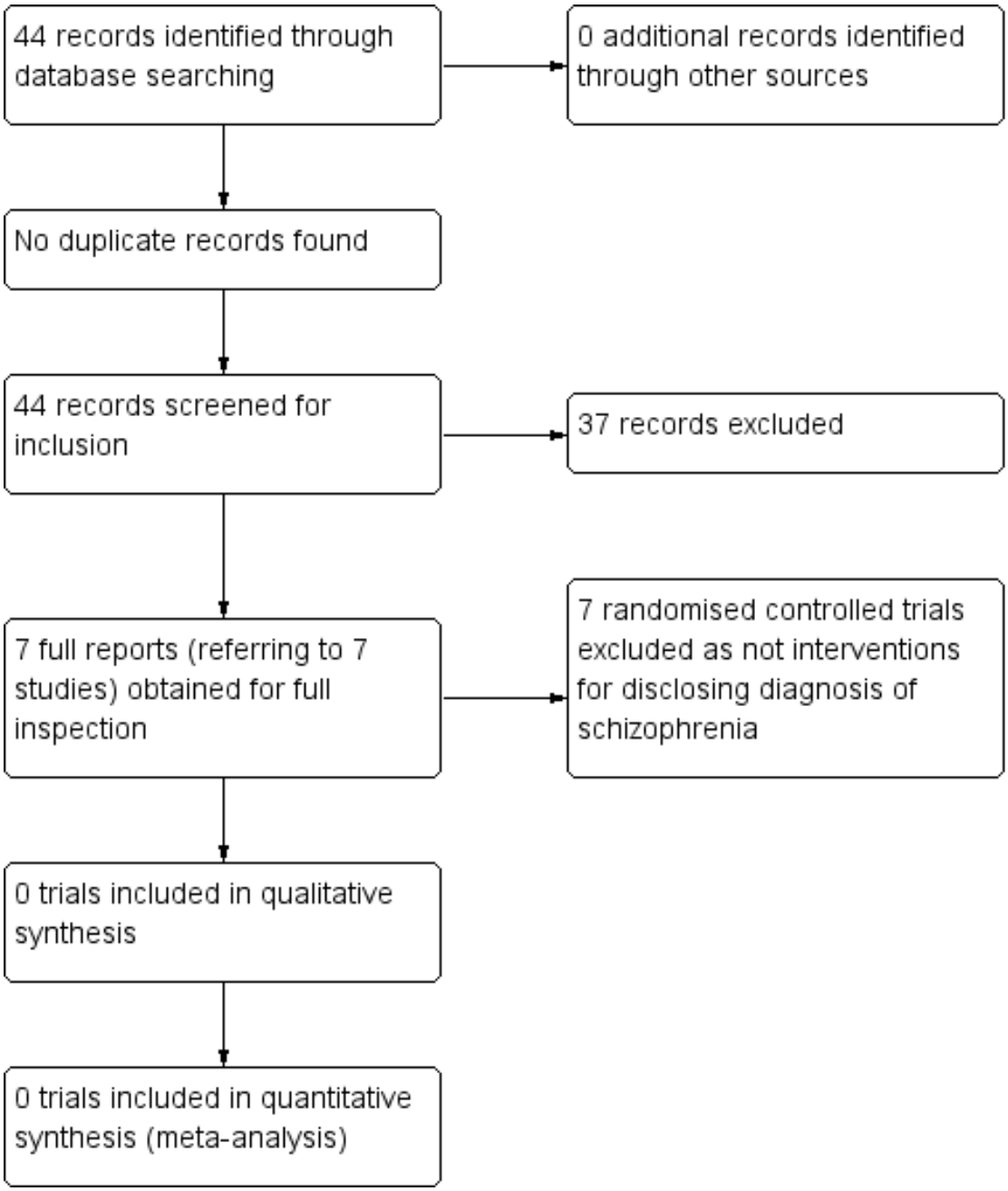
Description of studies

We found no studies that met our inclusion criteria.

Results of the search

We identified 44 records through database searches. No additional records were identified through other sources. We screened these 44 records. Seven records referring to seven studies appeared to be relevant but were excluded after further inspection. See Figure 1.

Figure 1. Flow diagram trial selection from search results.



Included studies

We found no studies that met our inclusion criteria.

Excluded studies

The search found seven potential RCTs (Arvidsson 2014; Haggarty 2008; Hamann 2006; Sousa 2013; Van Os 2004; Weisman 2014; Wirshing 2005). None of these seven trials assessed the effectiveness of a communication strategy or any other intervention to discuss the diagnosis of schizophrenia and we excluded them.

The excluded studies tested a variety of interventions, mostly communication skills post diagnosis. Arvidsson 2014 and Van Os 2004 evaluated a two-way Communication Checklist (2-COM) as a communication tool to provide an opportunity for patients to voice their needs and problem to minimise the discrepancy and miscommunication between patient and professional carer. None of these communication tools aimed to address the communication of the diagnosis. Hamann 2006 and Haggarty 2008 investigated a decision aid to facilitate shared decision making for inpatients. Wirshing 2005 evaluated a videotape intervention to enhance the informed consent process for research. Sousa 2013 described an RCT of a collaborative intervention to promote recovery. Weisman 2014 conducted an RCT to test efficacy of a family-focused culturally adapted therapy for schizophrenia.

These trials may be relevant for a systematic review on shared decision making or strategies to enhance communication between patients and professionals.

Risk of bias in included studies

We found no studies that met our inclusion criteria.

Effects of interventions

See: **Summary of findings for the main comparison** Different communication strategies versus treatment as usual

We found no studies that met our inclusion criteria.

DISCUSSION

For this review, we defined the intervention as any communication strategy or model used specifically for initial sharing of information about the diagnosis of schizophrenia or related disorders. We hypothesised that such a communication strategy would help the clinician to inform the patient about the nature of the condition in a manner that would help patients and their carers process the information, which would lead to better outcomes.

Summary of main results

We found no studies that compared an intervention to communicate the diagnosis of schizophrenia to patients and their carers with treatment as usual. We primarily searched intervention studies but also reviewed other relevant literature, which showed that delivery of diagnosis to psychiatric patients is not researched well (Cleary 2009).

Overall completeness and applicability of evidence

Currently, there is no randomised controlled evidence. It is unlikely that we have missed any RCTs in view of the comprehensive literature search strategy. The lack of studies means that, presently, there is no evidence from RCTs to guide practice and psychiatrists.

Quality of the evidence

We found no studies that met our inclusion criteria.

Potential biases in the review process

There are few potential biases in the review process. The search for trials was thorough with no language, date, document type or publication status limitations and it is unlikely it missed any studies; however, publication bias cannot be entirely ruled out as a possible bias.

Agreements and disagreements with other studies or reviews

In view of the lack of studies, co-comparisons were difficult. One review of the literature also found no communication strategies available for diagnosis of schizophrenia and suggested that the SPIKES (S: **s**etting up; P: assessing the patient's **p**erception; I: obtaining the patient's **i**nvitation; K: giving **k**nowledge and information to the patient; E: addressing the patient's **e**motions with empathic responses; S: **s**trategy and summary) model could be applied to schizophrenia (Seeman 2010). However, this was a qualitative review of the literature, and as in our review, no evidence from RCTs was available.

We found studies that discussed the general communication needs of patients and how these could be met with communication needs related to the information about medication, adverse effects of medication, problems experienced by carers and their communication needs. However, none of the studies examined the communication needs specific to delivery of diagnosis (Dott 2001; Priebe 2007).

Some non-randomised studies suggested that a substitute diagnosis in place of a schizophrenia diagnosis is often provided (Luderer 1993; McDonald-Scott 1992), even when the service users asked for exact diagnosis (McDonald-Scott 1992). There is still, today, a general lack of guidance on how the news about the diagnosis of schizophrenia is communicated to patients and their carers. In one qualitative study from Australia, carers described the "long and difficult pathway" to being given a diagnosis and haphazard means of finding a diagnosis (Outram 2015). This may be due to a number of challenges related to the nomenclature, uncertainties surrounding the diagnosis of schizophrenia, its variable outcome and the stigma associated with having a serious mental illness.

AUTHORS' CONCLUSIONS

Implications for practice

1. For people with schizophrenia

Currently there is no evidence from randomised controlled trials (RCTs) on how disclosure of diagnosis is best done for schizophrenia. However, service users should be encouraged to ask basic questions about the diagnosis and how this was reached.

2. For clinicians

Clinicians need to be aware of the lack of evidence-base in this area and there is a need for further research. For now, developing skills based on best practice in the communication of bad news in other branches of medicine or in other psychiatric conditions such as dementia or learning disability is the only available option. However, in view of the unique nature of schizophrenia considerable modifications would be needed.

3. For funders and managers

National Institute for Health and Care Excellence guidelines recommend that the information about both the causes and treatment options for schizophrenia are discussed with the patients and carers. However, there is little guidance, if any, on how the diagnosis is delivered (NICE 2009).

There is a need to evaluate how current practice affects patients, how much they want to know and the impact of disclosure of the diagnosis. Limited literature suggests that the communication priorities of service users and providers differ considerably and this communication gap can have serious implications and the source of distress for service users (McCabe 2008). In most high-income countries people with first episode psychosis are under the care of Early Intervention in Psychosis services and are likely to receive the diagnosis of schizophrenia from these services so the managers and commissioners for these services need to be aware of the lack of evidence base in relation to the delivery of diagnosis. There is an urgent need to fund the studies which explore this specific area.

Implications for research

1. General

There is an enormous gap in the knowledge in this area. As described above, some studies suggest that almost half of service users with schizophrenia had not received any detailed information about their diagnosis, and the practice of psychiatrists varied considerably. The anecdotal evidence seems to suggest that people with schizophrenia 'learn' the diagnosis, as they 'experience' the psychiatric services (Farooq 2015). RCTs are needed to evaluate the effectiveness of models which help the clinicians to deliver diagnosis.

Further research is needed to develop models for communicating the diagnosis of schizophrenia. Research to understand the perception and communication needs of people with schizophrenia will help to develop the theoretical underpinning for the relevant interventions in this area. It should be possible, for example, to design a communication checklist which will help to complete of all the necessary steps in sharing the information about the diagnosis of schizophrenia. Such communication checklists have been developed and evaluated in RCTS to help communication post diagnosis (Dott 2001; van Os 2004).

2. Specific

Therefore, three priority areas for research in this area are identified.

1. To understand the views and experiences of people with schizophrenia, carers and clinicians receiving and giving information related to diagnosis treatment options and prognosis of schizophrenia.
2. To design interventions that improve the communication skills of mental health professionals to share the information about the diagnosis treatment options and prognosis of schizophrenia.
3. To evaluate these interventions in RCTs.

The literature on communication skills training for other serious illnesses such as cancer can provide some insights into designing the trials in this area (Moore 2013). First, there is need to develop core study outcomes, both for clinicians and patients that can

be used in these trials. Second, the validated scales to measure the communication skills of clinicians in communicating the bad news will need to be developed. A common technique used in the literature in oncology is to use simulated patients for assessing the effectiveness of communication skills training, which will be helpful in the field of schizophrenia, as there is no experience at present in structured patient communication with patients to share the bad news about the diagnosis of the illness. A possible design for future trial is described. It must be noted that any trial in the present state of knowledge will be exploratory in nature, which will help to inform the suitable outcome measures, the scale to measure these outcomes and possible power calculations. See also Table 1 and Table 2.

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The Cochrane Schizophrenia Group Editorial Base in Nottingham, UK produces and maintains standard text for use in the Methods section of their reviews. We used this text as the basis of what appears here and adapted it as required.

The Trials Search Co-ordinator of the Cochrane Schizophrenia Group and the contact author of this review developed the search terms.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Study	Reason for exclusion
Arvidsson 2014	Allocation: cluster randomised controlled trial. Participants: people with schizophrenia or schizoaffective syndromes Intervention: communication tool to enhance the sense of empowerment, satisfaction with care, therapeutic alliance and unmet needs post diagnosis Reason for exclusion: not specifically interventions regarding the delivery of diagnosis of schizophrenia
Haggarty 2008	Allocation: cluster randomised controlled trial. Participants: people with schizophrenia and related disorders Intervention: a shared care model of Transition into Primary care Psychiatry Reason for exclusion: not specifically interventions regarding the delivery of diagnosis of schizophrenia
Hamann 2006	Allocation: randomised controlled trial. Participants: inpatients with schizophrenia. Intervention: shared decision-making programme post diagnosis Reason for exclusion: not specifically interventions regarding the delivery of diagnosis of schizophrenia
Sousa 2013	Allocation: randomised controlled trial. Participants: people with psychotic disorders (schizophrenia, bipolar and depression with psychotic features) Intervention: levels of recovery from Psychotic Disorders Scale enabled dialogue to reduce discrepancy between patient and clinician in assessing symptoms, adherence and functionality post diagnosis Reason for exclusion: not specifically interventions regarding the delivery of diagnosis of schizophrenia
Van Os 2004	Allocation: randomised controlled trial. Participants: schizophrenia. Intervention: a 2-way communication checklist as a clinical intervention to improve communication between patients and the professionals post diagnosis Reason for exclusion: not specifically interventions regarding the delivery of diagnosis of schizophrenia
Weisman 2014	Allocation: randomised controlled trial. Participants: people with schizophrenia and related disorders Intervention: family-focused, culturally informed therapy. Reason for exclusion: not specifically interventions regarding the delivery of diagnosis of schizophrenia
Wirshing 2005	Allocation: randomised controlled trial. Participants: people with schizophrenia. Intervention: a videotape intervention to enhance the informed consent process for medical and psychiatric treatment research Reason for exclusion: not specifically interventions regarding the delivery of diagnosis of schizophrenia

DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Suggested future trial

Methods	Procedure	Comments
Randomisation and allocation	Randomisation using computer-generated numbers. Allocation using sealed envelopes.	It may not be possible to have a double-blind design in these trials. It will be important that the assessors of the outcome measures are blind to the allocation of participants
Participants	Resident psychiatrists who have been in training for at least 3 years and treating patients who are willing to participate in the communication skill training programme aimed at disclosing the diagnosis of schizophrenia and its assessment procedure. They will be randomised to an intervention and a waiting list control	-
Interventions	**Intervention:** a communication strategy to disclose the diagnosis and outcome of schizophrenia consisting of a standard training programme. The training programme would consist of 1. standard content regarding knowledge about the diagnosis of schizophrenia, nature of illness and possible outcomes and 2. necessary communication skills to deliver the bad news The training package will be delivered using the following teaching methodologies: 1. 1-hour theoretical session; 2. role play of predefined cases in sharing information about diagnosis and outcome of schizophrenia and detailed feedback about the performance in role play; 3. small groups discussion (maximum 5 participants) about the practical problems in communicating with patients and stress management techniques to overcome the emotional distress when sharing the bad news **Control:** a group of resident psychiatrists on waiting list.	The training methods vary immensely in the present literature on communicating bad news. This may consist of face-to-face individual or group training sessions. The training will depend upon the guidance developed in sharing information about the diagnosis and outcome and underlying theoretical framework
Outcome measures	Physicians in each group will communicate the news about the diagnosis and outcome of schizophrenia for a standardised patient (SP) encounter. The skills of trainee psychiatrists in both groups will be analysed using the records	We suggest the scoring for communication skills rated on the video-taped interviews. They can also be rated 'live' when the actual interview is taking place. Simulated patient consultations are routinely used in assessing the interviewing

Table 1. Suggested future trial (*Continued*)

	of the patient encounter recorded earlier. Outcome measures will consist of scores by independent assessor and the report of SP involved in the interview. The assessors will be blind to the status of trainees, as to which group they belong. Each encounter will be recorded using a predetermined scoring sheet on the following aspects 1. Understanding the nature of illness and its outcome, defined by SP 2. Satisfaction with interview as reported by assessor and SP 3. Communication skills of the resident psychiatrists using the content analysis, verbal and non-verbal communications checklist 4. Any distressing experience by the SP.	and communication skills and are useful in providing the insight initially. After initial studies, real patients could be recruited

Table 2. Comparisons relevant to other reviews suggested by excluded studies

Intervention	Control	Participants	Reference tag	Potential Cochrane title
Communication checklist	Psychoeducation or treatment as usual	People recently diagnosed with schizophrenia based on a standard diagnostic criteria or carers, or both	Arvidsson 2014; Van Os 2004	Communication checklists for discussing the diagnosis, treatment options and prognosis of schizophrenia
Shared decision making	Treatment as usual or psychoeducation	People recently diagnosed with schizophrenia based on a standard diagnostic criteria or carers, or both	Hamann 2006	Shared decision making for treatment planning in schizophrenia and related disorders

CONTRIBUTIONS OF AUTHORS

SF: developed the protocol, is the guarantor for the review and supervised the overall process of selection of studies, and completed the final draft.

RJ: helped with the protocol and in screening the literature search.

CZ: helped in screening the literature search, selected studies for further examination and assisted SF in writing the final draft.

FN: developed the protocol, selected studies for further examination and assisted SF in writing the final draft.

DECLARATIONS OF INTEREST

SF: none known.

RJ: none known.

CZ: none known.

FN: none known.

SOURCES OF SUPPORT

Internal sources

- Research Institute for Primary Care and Health Science, Keele University, UK.

Employs lead author Saeed Farooq.

- Queen's University, Kingston, Canada.

Employs review authors Rupinder K Johal and Farooq Naeem.

- New Cross Hospital, Wolverhampton, UK.

Employs review author Charlotte Ziff.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We have expanded the background substantially to clarify our intervention in that delivery of diagnosis not only involves revealing the diagnosis but also involves communication regarding treatment options and prognosis for the patient. We wanted to distinguish this from general communication between clinicians and patients during treatment, which is the focus of another Cochrane review (Papageorgiou 2017).

We have extended the age of participants to greater than 16 years, as the age of onset of schizophrenia, particularly for males, and therefore when diagnosis is most likely to be given is late adolescence, early adulthood. This expansion and clarification of the definition did not change our inclusion criteria or objectives of the original protocol. We have also expanded our 'Why it is important to do this review' section. We have reordered and reworded the outcomes to help categorise data collection into continuous or binary but not changed the type of outcomes required. We have specified that all 'Summary of findings' table outcomes should be clinically important.