

Cochrane Database of Systematic Reviews

Communication skills training for mental health professionals working with people with severe mental illness (Review)

Papageorgiou A, Loke YK, Fromage M

Papageorgiou A, Loke YK, Fromage M. Communication skills training for mental health professionals working with people with severe mental illness. *Cochrane Database of Systematic Reviews* 2017, Issue 6. Art. No.: CD010006. DOI: 10.1002/14651858.CD010006.pub2.

www.cochranelibrary.com



TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
SUMMARY OF FINDINGS FOR THE MAIN COMPARISON	4
BACKGROUND	6
OBJECTIVES	7
METHODS	7
Figure 1	10
Figure 2	11
RESULTS	13
Figure 3	14
DISCUSSION	17
AUTHORS' CONCLUSIONS	18
ACKNOWLEDGEMENTS	18
REFERENCES	19
CHARACTERISTICS OF STUDIES	21
DATA AND ANALYSES	25
Analysis 1.1. Comparison 1 Communication skills training versus no specific training, Outcome 1 Patient satisfaction: 1.	
Satisfaction with treatment: average endpoint score (CSQ-8, high = good, medium term).	26
Analysis 1.2. Comparison 1 Communication skills training versus no specific training, Outcome 2 Patient satisfaction: 2.	
Satisfaction with therapeutic relationship: average endpoint score (STAR-P, high = good, medium term)	26
Analysis 1.3. Comparison 1 Communication skills training versus no specific training, Outcome 3 Mental state: 1. General	
Symptom: Average endpoint score (PANSS General, high = poor, medium term)	27
Analysis 1.4. Comparison 1 Communication skills training versus no specific training, Outcome 4 Mental state: 2. Positive	
Symptom; Average endpoint score (PANSS Positive, high = poor, medium term).	27
Analysis 1.5. Comparison 1 Communication skills training versus no specific training, Outcome 5 Mental state: 3. Negative	
Symptom: Average endpoint score (PANSS Negative, high = poor, medium term)	28
Analysis 1.6. Comparison 1 Communication skills training versus no specific training, Outcome 6 Leaving the study early	
(patient)	28
ADDITIONAL TABLES	28
APPENDICES	30
CONTRIBUTIONS OF AUTHORS	30
DECLARATIONS OF INTEREST	31
SOURCES OF SUPPORT	31
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	31

[Intervention Review]

Communication skills training for mental health professionals working with people with severe mental illness

Alexia Papageorgiou¹, Yoon K Loke², Michelle Fromage³

¹St George's University of London Medical School, University of Nicosia, Nicosia, Cyprus. ²Norwich Medical School, University of East Anglia, Norwich, UK. ³School of Medicine, University of East Anglia, Norwich, UK

Contact address: Alexia Papageorgiou, St George's University of London Medical School, University of Nicosia, 93 Agiou Nikolaou Street, Engomi, Nicosia, 2408, Cyprus. papageorgiou.a@unic.ac.cy.

Editorial group: Cochrane Schizophrenia Group. Publication status and date: New, published in Issue 6, 2017.

Citation: Papageorgiou A, Loke YK, Fromage M. Communication skills training for mental health professionals working with people with severe mental illness. *Cochrane Database of Systematic Reviews* 2017, Issue 6. Art. No.: CD010006. DOI: 10.1002/14651858.CD010006.pub2.

Copyright © 2017 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ABSTRACT

Background

Research evidence suggests that both mental health professionals and people with severe mental health illness such as schizophrenia or schizoaffective disorder find it difficult to communicate with each other effectively about symptoms, treatments and their side effects so that they reach a shared understanding about diagnosis, prognosis and treatment. Effective use of communication skills in mental health interactions could be associated with increased patient satisfaction and adherence to treatment.

Objectives

To review the effectiveness of communication skills training for mental health professionals who work with people with severe mental illness.

Search methods

We searched the Cochrane Schizophrenia Trials Register (latest search 17 February, 2016) which is compiled by systematic searches of major resources (including AMED, BIOSIS, CINAHL, Embase, MEDLINE, PsycINFO, PubMed, and registries of clinical trials) and their monthly updates, handsearches, grey literature, and conference proceedings. There are no language, date, document type, or publication status limitations for inclusion of records into the register.

Selection criteria

All relevant randomised clinical trials (RCTs) that focused on communication skills training (CST) for mental health professionals who work with people with severe mental illness compared with those who received standard or no training. We sought a number of primary (patient adherence to treatment and attendance at scheduled appointments as well as mental health professionals' satisfaction with the training programme) and secondary outcomes (patients' global state, service use, mental state, patient satisfaction, social functioning, quality of life). RCTs where the unit of randomisation was by cluster (e.g. healthcare facility) were also eligible for inclusion. We included one trial that met our inclusion criteria and reported useable data.

Communication skills training for mental health professionals working with people with severe mental illness (Review) Copyright © 2017 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Data collection and analysis

We independently selected studies, quality assessed them and extracted data. For binary outcomes, we planned to calculate standard estimates of the risk ratio (RR) and their 95% confidence intervals (CI) using a fixed-effect model. For continuous outcomes, we planned to estimate the mean difference (MD) between groups, or obtain the adjusted mean difference (aMD) where available for cluster-randomised trials. If heterogeneity had been identified, we would have explored this using a random-effects model. We used GRADE to create a 'Summary of findings' table and we assessed risk of bias for the one included study.

Main results

We included one pilot cluster-RCT that recruited a total of 21 psychiatrists and 97 patients. The psychiatrists were randomised to a training programme in communication skills, compared to a no specific training (NST) programme. The trial provided useable data for only one of our prestated outcomes of interest, patient satisfaction. The trial did not report global state but did report mental state and, as global state data were not available, we included these mental state data in the 'Summary of findings' table. There was high risk of bias from attrition because of substantial losses to follow-up and incomplete outcome data.

Patient satisfaction was measured as satisfaction with treatment and 'experience of therapeutic relationship' at medium term (five months). Satisfaction with treatment was similar between the CST and NST group using the Client Satisfaction Questionnaire (CSQ-8) (1 RCT, $n = 66/97^*$, aMD 1.77 95% CI - 0.13 to 3.68, *low-quality evidence*). When comparing patient experience of the therapeutic relationship using the STAR-P scale, participants in the CST group rated the therapeutic relationship more positively than participants in the NST group (1 RCT, n = 63/97, aMD 0.21 95% CI 0.01 to 0.41, *low-quality evidence*).

Mental state scores on the Positive and Negative Syndrome Scale (PANSS) were similar between treatment groups for general symptoms (1 RCT, n = 59/97, aMD 4.48 95% CI -2.10 to 11.06, *low-quality evidence*), positive symptoms (1 RCT, n = 59/97, aMD -0.23, 95% CI -2.91 to 2.45, *low-quality evidence*) and negative symptoms (1 RCT, n = 59/97, aMD 3.42, 95% CI -0.24 to 7.09, *low-quality evidence*).

No data were available for adherence to treatment, service use or quality of life.

* Of the total of 97 randomised participants, 66 provided data.

Authors' conclusions

The evidence available is from one pilot cluster-randomised controlled trial, it is not adequate enough to draw any robust conclusions. There were relatively few good quality data and the trial is too small to highlight differences in most outcome measures. Adding a CST programme appears to have a modest positive effect on patients' experiences of the therapeutic relationship. More high-quality research is needed in this area.

PLAIN LANGUAGE SUMMARY

Communication skills training for mental health professionals working with people with severe mental illness

Question

Does communication skills training for mental health professionals benefit their patients with severe mental illness?

Background

Severe mental illness (such as schizophrenia or schizoaffective disorder) is a mental, behavioural or emotional disorder which severely interferes with, or limits a person's life activities for a prolonged time (e.g. from a few months to a few years).

People with severe mental health problems do not always follow their treatment plans. Effective communication between health professionals and their patients is an essential part of ensuring that vital information about treatment options and maintaining contact with services is understood and followed to by the patient. For patients with severe mental health problems, and their carers, this interaction can be challenging. There are many negative outcomes for patients with severe mental health problems who experience ineffective communication with health professionals, which include alienation, increase of symptoms and possible compulsory hospitalisation. It is thought that when effective communication skills are used by mental health professionals, their patients are more satisfied and adhere to their treatment plans. Moreover, professional-patient rapport is a necessary part of giving the patient the confidence to be pro-active in their treatment regimens. However, there is a lack of evidence from randomised controlled trials (RCTs) to guide practice in this area for people with severe mental illness.

Searches

We ran a search for RCTs using Cochrane Schizophrenia's register of trials, latest search date was in February 2016. Only five possible studies were found and from these only one pilot study could be included. It measured the effect on patients of communication skills training for psychiatrists ability to identify and clarify misunderstandings during communication with patients.

Results

We were interested in the effect communication skills training had on patient adherence to treatment, satisfaction, mental state, service use and quality of life. We could only use data reported for the patient's satisfaction with the treatment, with the therapeutic relationship and mental state (psychiatric symptoms). Five months after treatment, patients who were treated by psychiatrists who received communication training had a modest increase in satisfaction with the therapeutic relationship compared with patients treated by psychiatrists who did not receive the training. Satisfaction with treatment and mental state of the patient were similar between the two treatment groups.

Conclusions

These results are based on low-quality evidence are not conclusive; the available evidence is from one small pilot trial, which is not adequate enough to draw any meaningful conclusions. Much more high-quality research is needed in this area.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Communication skills training programme compared with no specific training programme for psychiatrists who treat patients with severe mental illness

Patient or population: psychiatrists and people with schizoaffective disorder or schizophrenia

Settings: outpatient or community

Intervention: communication skills training programme (CST)

Comparison: no specific communication skills training programme (NST)

Outcomes	Illustrative comparative risks* (SD)		Relative effect (95% Cl)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Experimental				
Adherence to Adher- ence to treatment: tak- ing of medication, at- tending appointments	See comments	See comments	Not estimable	See comments	See comments	no data available
1. Patient satisfac- tion: 1. Satisfaction with treatment: average endpoint score (CSQ-8, high = good, medium term)	The mean patient satis- faction with treatment in NST group was 26.6 ± 4.6 at 5 months	The mean patient satis- faction with treatment in the CST group was 28.3 ± 3.6 at 5 months	Adjusted mean differ- ence 1.77 (95%CI - 0.13 to 3. 68)	1 RCT, n = 66/97	⊕⊕⊖⊖ low ¹	This was based on unpublished data ob- tained from the author. Intracluster correlation coefficient was 0.65
Patient satisfaction: 2. Satisfaction with thera- peutic relationship: av- erage endpoint score (STAR-P, high = good, medium term)	The mean therapeutic relationship (as judged by the patient) in the NST group was $2.6 \pm 0.$ 3	The mean value for therapeutic relation- ship (as judged by the patient) in the CST group was 2.8 ± 0.4	Adjusted mean differ- ence 0.21 (95% Cl 0.01 to 0. 41, P = 0.043)	1 RCT, n = 63/97)	⊕⊕⊖⊖ low¹	Patients in the inter- vention group judged the therapeutic rela- tionship to be more favourable. There was a negative intracluster correlation coefficient

Mental state: General, Positive and Nega- tive Symptoms: Av- erage endpoint score (PANSS General, Pos- itive, Negative, high = poor, medium term)	In the NST group, the mean severity scores at follow-up were: General symptoms 34. 1 ± 7.9 ; Positive symptoms 14. 5 ± 5.9 Negative symptoms 14. 1 ± 5.5	In the CST group, the mean severity scores at follow-up were: General symptoms 34. 3 ± 12.3 Positive symptoms 14. 9 ± 6.9 Negative symptoms 16. 3 ± 7.3	Adjusted mean differ- ence General 4.48 (95%Cl - 2.10 to 11.06) Positive -0.23 (95% Cl - 2.91 to 2.45) Negative 3.42 (95% Cl - 0.24 to 7.09)	1 RCT, n = 59/97	⊕⊕⊖⊖ low¹	No significant differ- ence in endpoint dis- ease severity scores between intervention and control. This was based on unpublished data obtained from the author. Intracluster cor- relation coefficient was zero
Global State: clini- cally important im- provement	See comments	See comments	Not estimable	See comments	See comments	no data available
Service Use: hospital admission, days in hos- pital	See comments	See comments	Not estimable	See comments	See comments	no data available
Quality of Life: clin- ically important im- provement	See comments	See comments	Not estimable	See comments	See comments	no data available
*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; SD: Standard deviation						
GRADE Working Group g	grades of evidence	abanga aur confidence in	the estimate of offect			

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. Very serious: Downgraded by 2. The downgrading is because of the small pilot nature of the trial, imprecision and substantial losses to follow-up amounting to >30%.

BACKGROUND

Description of the condition

Schizophrenia, bipolar affective disorder, schizoaffective disorder and clinical depression are some of the severe mental illnesses which form a small proportion of the larger umbrella of mental illnesses. According to World Health Organization (WHO), severe mental illness (including drug and alcohol misuse) accounted for about 11% of the global burden of disease in 1990 and was expected to rise to 15% by 2020 (Murray 1996). Evidence also suggests that mortality and morbidity are much higher among people with severe mental illness than the general population (Harris 1998).

People with severe mental illness may be treated with drugs and psychological therapies in primary care, they may be treated in the community or they may be treated by specialist mental health services in secondary care or the community. All of these interventions require mental health professionals to interact with patients in a competent manner so that patients can engage with and maintain contact with the services.

Interactions between mental health professionals and patients with severe mental health illness present significant communication challenges as patients may experience severe and sustained disturbance of mood accompanied by feelings of worthlessness, loss of interest, suspiciousness and paranoia (Silverman 2005). Mental health workers may lack the training in effective communication skills and may find it difficult to establish common ground with their patients. Ineffective communication skills during such interactions may lead to alienation and disengagement from services, deterioration in mental health and the possibility of compulsory admission to hospital, and risk to self and others (Priebe 2005). Research evidence suggests that both mental health professionals and patients with severe mental health illness find it difficult to communicate effectively about symptoms, drug treatments and their side effects and to reach a shared understanding about diagnosis, prognosis and treatment (Poole 2006). However, effective use of communication skills in mental health interactions could be associated with increased patient satisfaction and adherence to treatment (McCabe 2002).

Description of the intervention

Communication skills training (CST) in mental health can be defined as any form of structured didactic, e-learning, and experiential (e.g. using simulated patients and role-playing) training for mental health professionals to develop proficiency in efficient, effective and satisfactory mental health consultations with patients (Kurtz 2005). A number of mental health professionals have traditionally been trained according to a wide range of basic communication and psychotherapy skills but currently they receive little structured teaching in how to communicate meaningfully with patients with severe mental health illness. In recent years, attempts have been made to design succinct and comprehensive CST packages tailored for mental health professionals and people with severe mental illness such as psychosis (Kemp 1996). These packages aim to promote patient-centredness, patient and professional satisfaction with the consultation as well as to improve concordance with antipsychotic medication, insight into illness and change of attitudes to treatment. The most recent textbooks on communication skills teaching in undergraduate medical education describe CST for mental health professionals in terms of different models (e.g. Three Functions Model (Cole 2000), Calgary/Cambridge model (Silverman 2005). These models divide the mental health consultation into a number of tasks (e.g. introductions, information gathering, explanation and planning, closing the consultation) and processes (e.g. building a patient-centred relationship, structuring the consultation) that have to be achieved by the mental health professional and the patient jointly. In order for these tasks and processes to be carried out successfully, the mental health professional has to use a number of skills (e.g. active listening, using open and closed questions appropriately, summarising, signposting, chunking and checking, recognising, acknowledging and validating patient's ideas, concerns and expectations).

The training of undergraduate and graduate students to use the above skills requires detailed scenarios of patients with severe mental health conditions which are acted out by simulated patients. The trainees practice the skills in role-plays in groups or in one-toone sessions and receive feedback from experienced consultation skills tutors on their performance. In some training environments the trainees are video-taped and their video-recordings are used for feedback purposes.

Within the last 10 years a number of e-learning resources has been developed with on-line communication skills modules that also include model consultations, which can reinforce trainees' learning (www.doc.com). However, there is very limited evidence on the effectiveness of these training programmes.

How the intervention might work

There is a paucity of research evidence in terms of which communication skills are useful in mental health interactions between mental health professionals and patients with severe mental illness which empower patients to become adherent. Two variables have been found to play an important role in this process: good therapeutic alliance and good communication skills (Julius 2009). To achieve a strong therapeutic alliance good communication skills are a prerequisite. Research evidence from undergraduate and graduate medical training suggests that teaching communication skills to healthcare professionals can lead to improved patient outcomes such as:

- 1. patient satisfaction,
- 2. patient recall and understanding,

3. adherence,

4. symptom resolution,

5. psychological outcomes (e.g. decreased need for analgesia after mental illness),

6. reduced costs in terms of length of stay in intensive care units (ICU) and hospital,

7. reduced malpractice litigations (Kurtz 2005).

Hassan and colleagues review on professional-patient communication in mental illness, identified a number of qualitative studies which suggest that "in the treatment of schizophrenia, about onethird of therapists had a negative communication style, characterised by criticism, hostility, and over-involvement, which may be associated with more patient relapses." (p. 149) Hassan 2007.

Why it is important to do this review

Unfortunately there is very little evidence in this area from wellconducted randomised controlled trials which link CST of mental health professionals in the treatment of severe mental illness with outcomes of treatment (Hassan 2007). A Cochrane review on this topic will identify the research gaps and pave the way for the design of new studies in this area. Hopefully, future study results will inform the training of mental health professionals, the education of users of mental health services and the education of a range of primary care professionals and professionals in other treatment settings.

OBJECTIVES

To review the effectiveness of communication skills training (CST) for mental health professionals who work with people with severe mental illness.

METHODS

Criteria for considering studies for this review

Types of studies

All relevant randomised controlled trials. If we had found trials described as 'double-blind' but had implied randomisation, we would have included such trials in a Sensitivity analysis .We would have excluded quasi-randomised studies, such as those allocating by alternate days of the week.

Types of participants

1. Mental health workers: mental health nurses, trainee psychiatrists, consultant psychiatrists.

2. Adults, however defined, with severe mental illness, or related serious mental disorders, including schizophreniform disorder, schizoaffective disorder and delusional disorder, again by any means of diagnosis. We would have included trials where participants had diagnosis of bipolar or affective disorder, but only if within these trials the majority of participants had schizophrenia or related disorders, i.e. we would not have included trials where bipolar or affective disorder were the sole diagnosis.

We are interested in making sure that information was as relevant to the current care of people with severe mental illness as possible so proposed to clearly highlight the current clinical state (acute, early post-acute, partial remission, remission) as well as the stage (prodromal, first episode, early illness, persistent) and as to whether the studies primarily focused on people with particular problems (for example, negative symptoms, treatment-resistant illnesses).

Types of interventions

1. Communication skills training (in the form of didactic training, looking at video-footage, role-play with simulated or volunteer patients).

2. Standard or no training.

Types of outcome measures

We divided outcomes into short term (less than three months), medium term (three to 12 months), and long term (over one year).

Primary outcomes

With relation to the patients treated by the mental health professional.

1. Adherence to treatment

1.1 Taking of medication
 1.2 Attendance at scheduled appointments.
 With relation to the mental health professional.

2. Satisfaction with the training programme

Secondary outcomes

With relation to the patients treated by the mental health professional.

1. Global state

1.1 Clinically important improvement

1.2 Any improvement

1.3 Average change or endpoint scores on global state scales

2. Service Use

2.1 Number of hospital admissions2.2 Days spent in hospital

3. Mental state

3.1 Positive symptoms (delusions, hallucinations, disordered thinking)

3.2 Negative symptoms (avolition, poor self-care, blunted affect)3.3 Average change or endpoint scores on mental state scales

4. Patient satisfaction

4.1 Average change or endpoint scores on satisfaction scales

5. Social functioning

5.1 Average change or endpoint scores on social functioning scales5.2 Employment status (employed/unemployed)

5.3 Work-related activities

5.4 Able to live independently

5.5 Imprisonment

6. Quality of life

6.1 Clinically important change in general quality of life6.2 Average change or endpoint scores on quality of life scales

7. Leaving the study early

8. 'Summary of findings' table

We used the GRADE approach to interpret findings (Schünemann 2011) and used GRADEpro to export data from our review to create a 'Summary of findings' table. This table provided outcomespecific 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. Where available, we aimed to select the following main outcomes for inclusion in the 'Summary of findings' table.

1. Adherence to treatment - taking of medication, attending appointments

2. Satisfaction with the training programme *

3. Global state - Clinically important improvement *

4. Service Use - hospital admission, days in hospital

5. Quality of life - Clinically important improvement

(all with relation to the patients treated by the mental health professional)

* see Differences between protocol and review

Search methods for identification of studies

Electronic searches

Cochrane Schizophrenia Trials Register

On 29 January, 2014 and 17 February, 2016, the information specialist searched the Cochrane Schizophrenia Trials Register using the following search strategy, which has been developed based on literature review and consulting with the authors of the review: ((*didactic* OR *video* OR (*role NEXT play*) OR (*e NEXT learning*) OR (*active NEXT learning*) OR (*consultation NEXT skill*) OR (*communication NEXT skill*)):ti,ab) in REF-ERENCE or ((*didactic* OR *video* OR (*role NEXT play*) OR (*e NEXT learning*) OR (*active NEXT learning*) OR (*consultation NEXT skill*) OR (*communication NEXT skill*)):sin) in STUDY

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

The Cochrane Schizophrenia's Register of Trials is compiled by systematic searches of major resources (including AMED, BIOSIS, CINAHL, Embase, MEDLINE, PsycINFO, PubMed, and registries of clinical trials) and their monthly updates, handsearches, grey literature, and conference proceedings (see Group's Module). There are no language, date, document type, or publication status limitations for inclusion of records into the register. For previous searches, please see Appendix 1.

Searching other resources

I. Reference searching

We inspected references of all identified studies for further relevant studies.

2. Personal contact

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

Data collection and analysis

Selection of studies

Due to the small amount of studies that were identified (four studies in total) by the Information Specialist of the Cochrane Schizophrenia Group, all three authors AP, YL, MF inspected all four studies and unanimously agreed that only one of the studies should be included in the review. We obtained both abstracts and full study reports and thoroughly assessed all of them.

Data extraction and management

I. Extraction

Review authors AP and YL independently extracted data from the included study. We discussed any disagreements and documented decisions. We contacted authors of the included study through an open-ended request in order to obtain missing information or for clarification. If the study had been multi-centre, where possible, we would have 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);

b) the measuring instrument has not been written or modified by one of the trialists for that particular trial; and

c) the instrument should be a global assessment of an area of functioning and not sub-scores which are not, in themselves, validated or shown to be reliable. However there are exceptions, we would have included sub-scores from mental state scales measuring positive and negative symptoms of schizophrenia.

Ideally, the measuring instrument should either be i. a self-report or ii. completed by an independent rater or relative (not the therapist). We realise that this may not often been reported clearly. In Description of studies we noted if this was 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), which can be difficult in unstable and difficult to measure conditions such as schizophrenia. We decided primarily to use endpoint data, and only use change data if the former were not available. We would have combined endpoint and change data in the analysis as we preferred to us mean differences (MD) rather than standardised mean differences (SMD) throughout (Deeks 2011).

2.4 Skewed data

Continuous data on clinical and social outcomes are often not normally distributed. If our included trial had not been a cluster-randomised controlled trial (RCT) that reported on adjusted difference in means, we would have aimed to apply the following standards to relevant continuous data before inclusion.

We planned to enter all relevant data from studies of more than 200 participants in the analysis irrespective of the following 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 tell whether data are skewed or not.

For endpoint data from studies of less than 200 participants, we planned to use the following methods:

(a) if a scale started 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 is lower than 1, it strongly suggests a skew, and we would have excluded these data. If this ratio is higher than 1 but below 2, there is suggestion of skew. We would have entered these data to test whether their inclusion or exclusion changed the results substantially. Finally, if the ratio was larger than 2, we planned to include these data, because skew is less likely (Altman 1996; Higgins 2011);

(b) if a scale starts from a positive value (such as the Positive and Negative Syndrome Scale (PANSS), which can have values from 30 to 210) (Kay 1986), we planned to modify the calculation described above to take the scale starting point into account. In these cases skew is present if 2 SD > (S - S min), where S is the mean score and 'S min' is the minimum score.

2.5 Common measure

In the future, in order to facilitate comparison between trials, we intend to convert variables that can be 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 to binary

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

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 indicates a favourable outcome for CST. Where keeping to this makes it impossible to avoid outcome titles with clumsy double-negatives (e.g. 'Not improved') we would have reported data where the left of the line indicates an unfavourable outcome. This would have been noted in the relevant graphs.

Assessment of risk of bias in included studies

Review authors AP, YL and MF aimed to work independently to assess risk of bias by using criteria described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a) to assess trial quality. 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, we would have made the final rating by consensus. Where inadequate details of randomisation and other characteristics of trials were provided, we contacted the authors of the study in order to obtain further information. Non-concurrence in quality assessment would have been reported, but if disputes had arisen as to which category the trial was to be allocated, again, we would have resolved these by discussion.

We noted the level of risk of bias in the Risk of bias in included studies, Summary of findings for the main comparison and Figure 1, Figure 2.

Figure 1. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.





Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

Measures of treatment effect

I. 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 continuous outcomes, we planned to evaluate mean difference (MD) between groups. We preferred 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 we would have calculated the effect size and transformed the effect back to the units of one or more of the specific instruments.

Unit of analysis issues

2. Continuous data

I. 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.

Where clustering has been incorporated into the analysis of the primary study, we presented the adjusted data obtained from the investigators. We extracted the adjusted difference in means (aMD) of the endpoint and a measure of variation (such as a confidence intervals or standard error).

If clustering had not been accounted for in the primary study, we would have presented the data in a table, with a (*) symbol to indicate the presence of a probable unit of analysis error. We contacted the first author of the included study to obtain intra class correlation coefficients (ICCs) of their clustered data and adjusted for this by using accepted methods Gulliford 1999. If binary data had been presented in a report, we would have divided this by a 'design effect' Raj 2005, calculated using the mean number of participants per cluster (m) and the ICC [Design effect = 1 + (m-1) *ICC] Donner 2002. If the ICC had not been reported we would assume it to be 0.1 (Ukoumunne 1999).

2. Studies with multiple treatment groups

If a study involved more than two treatment groups, if relevant, we would have presented the additional treatment groups in additional relevant comparisons. We would not have double-counted data. We would not have presented data where the additional treatment groups were not relevant.

Dealing with missing data

I. Overall loss of credibility

At some degree of loss of follow-up, data must lose credibility Xia 2009. If more than 40% of data were unaccounted for, we would not have reproduced these data or used them within the analyses.

2. Binary

In the case where attrition for a binary outcome is between 0% and 40% and where these data are not clearly described, we would have presented data on a 'once-randomised-always-analyse' basis (an intention-to-treat (ITT) analysis). Those leaving the study early would have been all assumed to have the same rates of negative outcome as those who completed, with the exception of the outcome of death and adverse effects. For these outcomes, the rate of those who stayed in the study - in that particular arm of the trial - would have been used for those who did not. We would

have undertaken a sensitivity analysis to test how prone the primary outcomes were to change when data only from people who completed the study to that point were compared with the ITT analysis using the above assumptions.

3. Continuous

3.1 Attrition

In the case where attrition for a continuous outcome was between 0% and 40%, and data only from people who completed the study to that point were reported, we have presented and used these data.

4. Intention-to-treat (ITT)

Intention-to-treat would have been used when available. We anticipate that in some studies, in order to perform an ITT analysis, we would employ the method of last observation carried forward (LOCF) within the study report. For instance, we would have taken the last recorded value on the depression severity scale. LOCF introduces uncertainty about the reliability of the results. Therefore,we would have indicated where LOCF data were used in the analysis.

Assessment of heterogeneity

I. Clinical heterogeneity

If more than one study had been included, we would have considered all included studies, hoping to combine all studies together. Had clear unforeseen issues become apparent that may have added obvious clinical heterogeneity, we would have noted these issues, considered them in analyses and undertaken sensitivity analyses for the primary outcome.

2. Statistical

2.1 Visual inspection

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

2.2 Employing the I² statistic

We would have investigated heterogeneity between studies by using the I² method Higgins 2003 and the Chi² 'P' value. The former provides an estimate of the percentage of variation in observed results thought unlikely to be due to chance. A value equal to or greater than 50% would have been taken to indicate heterogeneity and reasons for heterogeneity would have been explored. If the

inconsistency was high and clear reasons were found, we would have presented the data separately.

Assessment of reporting biases

If more than one study had been included, data from all identified and selected trials would have been entered into a funnel graph (trial effect versus trial size) in an attempt to investigate overt publication bias. The possible existence of small-study effects would have been examined by Egger's regression method Egger 1997, as well as by visual inspection of the graph.

Data synthesis

In the absence of significant heterogeneity, a fixed-effect model is an appropriate option. However, if more studies ha been included and significant heterogeneity had been demonstrated, we would have then used a random-effects model for analysis. Where available, the analyses would have been based on ITT data from the individual studies. We would have combined the data from included trials in a meta-analysis if they were sufficiently homogeneous, both clinically and statistically.

Subgroup analysis and investigation of heterogeneity

I. Pre-planned subgroup analyses

Subgroup analyses would have been performed and interpreted with caution because multiple analyses would have lead to false positive conclusions Oxman 1992.

We would have considered type of intervention and duration of intervention as well as gender of psychiatrist and patient, education in the UK versus non-UK trained psychiatrists. In addition, we would have noted patient diagnosis, duration of illness, and education and ethnicity.

Sensitivity analysis

We would have examined the robustness of our findings by excluding (i) studies with less than 20% follow-up on the variable at the time point (ii) skewed data (iii) trials with a high risk of bias or where the overall risk of bias was unclear.

For the primary outcomes if inclusion had not resulted in a substantive difference, data would have remained in the analyses. If their inclusion had resulted 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 trials, but would have presented such data within a subcategory.

RESULTS

Description of studies

See also Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Results of the search

Electronic searching found five references to five studies. We obtained full-text citations for four studies and the research protocol for the fifth study and we assessed them for eligibility. We excluded four studies with reasons. Only one randomised controlled trial (RCT) met the inclusion criteria for our systematic review and this was the research protocol. This trial has been completed and we contacted the author to obtain study characteristics, preliminary findings, and the accepted version of a journal manuscript for inclusion in our review (Figure 3)



Figure 3. Study flow diagram.

Included studies

We included one study (McCabe 2016).

I. Duration

The length of trial was five months.

2. Size

Twenty one professionals and 97 patients entered into the trial.

3. Setting

The study was carried out at a university-affiliated, state-supported, outpatient psychiatric clinic in an urban area (East London, UK). Study sites were the East London NHS Foundation Trust and North East London NHS Foundation Trust.

4. Participants

The participants were higher or advanced trainees in psychiatry working in outpatient or community settings and their adult patients.

4.1 Higher or advanced trainees in psychiatry

In total, 26 psychiatrists agreed to participate in the study. Of those, five subsequently withdrew, thus leaving 21 randomised (10 to intervention, 11 to control group). Eighty per cent of the psychiatrists in the intervention group were male. Psychiatrists' mean age in the intervention group was 42.4 years (SD = 9.8). Of the 11 participants who were randomised in the control group, 64% were male. Psychiatrists' mean age in the control group was 41.5 years (SD = 10.4)

4.2 Patients

All the patients fulfilled the International Classification of Diseases 10th revision (ICD-10) criteria for a diagnosis of schizoaffective disorder or schizophrenia; 68% of the patients in the CST group were male. Mean age of participants was 43.8 years (SD = 10). Again, 68% of the patients in the no specific training (NST) group were male. Mean age of patients in the NST group was 42.8 years (SD = 10.4).

The total number of previous hospital admissions for patients in the intervention group was 3.3 (SD = 4.2), while the compulsory admissions for this group was 1.2 (SD = 1.4).

The total number of previous hospital admissions for patients in the control group was 3.6 (SD = 7.5), while the compulsory admissions for this group was 2 (SD = 2.4).

5. Interventions

5.1. Communication skills training (CST)

The psychiatrists in the intervention group received a training programme which consisted of four training sessions four hours each at weekly intervals. The training was delivered in small groups. There were two refresher sessions, one at eight weeks and the other at 12 weeks. During the training sessions, the psychiatrist and the patient were video-recorded during the consultation; the researchers then provided feedback. Each psychiatrist saw between one to seven patients.

5.2 No specific training (NST)

The psychiatrists in the control arm did not receive any specific training sessions in communication skills. Each psychiatrist in the control group saw between one to seven patients.

6. Methods

This study was described as a cluster-randomised controlled trial, where the unit of randomisation was by cluster (e.g. healthcare facility). The psychiatrists were randomised to a training programme in the intervention arm, as compared to no training (control arm). Patients, but not psychiatrists, were blinded.

7. Outcome scales

The following scales provided continuous data for analysis. 7.1 Mental state: Positive and Negative Symptoms Scale (PANSS) (Kay 1987)

A 30-item rating scale used to assess positive and negative symptoms in schizophrenia and measure their relationship to one another and to global psychopathology. Each item is defined on a seven-point scale varying from "absent" to "extreme", scoring from one to seven. The PANSS is scored by summation of ratings across times, such that the potential ranges are seven to 49 for the positive and negative scales and 16 to 112 for the General Psychopathology scale. The composite scale is derived by subtracting the negative from positive score, thus yielding a bipolar index that ranges from -42 to +42.

7.2 Client Satisfaction Questionnaire CSQ-8 (Nguyen 1983) A brief, global index rating scale used to measure service satisfaction. There are different versions of the scale but the one used for

this study has eight items. Each item is defined on a four-point scale varying from "poor" to "excellent" or "quite dissatisfied" to "very satisfied", scoring from one to four. Scores can range from eight to 32 with higher scores indicating more satisfaction with services.

7.3 Scale To Assess the Therapeutic Relationship in community mental health care (STAR) (McGuire-Snieckus 2007)

This scale is used to measure patient satisfaction with the therapeutic relationship.

A brief rating scale used to measure the clinician-patient therapeutic relationship in community psychiatry. The STAR scale has two versions, one for patients (STAR-P) and one for clinicians (STAR-C). Each scale has 12 items comprising three subscales: positive collaboration and positive clinician input in both versions, nonsupportive clinician input in the patient version, and emotional difficulties in the clinician version. Each item is defined on a fivepoint scale varying from "never" to "always", scoring from zero to four. Scores can range from zero to 48 with high scores indicating a higher satisfaction with the therapeutic relationship.

7.4 Missing outcomes

Through contact with the author, we were able to obtain data on some of the unpublished outcomes, but data were not available for adherence to treatment, global state, service use, quality of life, social functioning. Leaving the study data were not provided, we calculated loss from a flow chart.

Studies awaiting assessment

No studies are awaiting assessment.

Ongoing studies

We are not aware of any ongoing studies.

Excluded studies

We excluded four of the five studies identified by the Cochrane Schizophrenia Group Trials Register. One study was a stratified RCT and recruited general practitioners with the aim to train them to detect a first episode of psychosis. One study did not provide any intervention, one study aimed at training patients to raise their concerns during their psychiatric consultations and the final study randomised "regressed" patients to remotivation, psychodrama and no-treatment groups. None of the excluded studies met the inclusion criteria for our review.

Risk of bias in included studies

This was a pilot RCT.

Allocation

Overall unclear. Although the randomisation sequence generation was appropriate and low risk, there was no allocation concealment.

Blinding

Low for patient outcomes because patients were blinded, but high for practitioner reported outcomes because of lack of blinding. Overall, the risk of bias here is unclear because we are not certain the extent to which lack of practitioner blinding might have influenced outcomes.

Incomplete outcome data

High due to the substantial losses (> 30%) to follow-up.

Selective reporting

Low as we were able to obtain data after contacting the authors. We contacted the lead investigator and we were able to obtain data on all the outcomes of interest to us. We also received additional data on outcomes that were pre-specified by the investigators, but not of relevance to our review.

Other potential sources of bias

Unclear. The trial was designed to have a further follow-up point six months later, but this could not be carried out as psychiatrists had moved away. The extent and direction to which this could have biased the results is unclear.

Effects of interventions

See: Summary of findings for the main comparison Communication skills training compared with no specific training As there was only one included study, we did not conduct a metaanalysis. The comparisons here are from the single cluster study reporting on communication skills training (CST) versus no specific training (NST) according to clusters. We present both the unadjusted and adjusted data.

COMPARISON 1: Communication skills training (CST) versus no specific training (NST)

I.I Patient satisfaction

1.1.1 with treatment

Patient satisfaction did not significantly differ between treatment groups at medium-term follow-up. The adjusted mean difference

between groups was (aMD 1.77 95% confidence interval (CI) - 0.13 to 3.68, low-quality evidence); Analysis 1.1 with an intracluster correlation coefficient of 0.65.

1.1.2 with therapeutic relationship

At follow-up, the patient-reported experience of the therapeutic relationship (STAR) was higher in the CST group as compared to the NST group at medium-term follow-up. The adjusted difference in means was (aMD 0.21 95% CI 0.01 to 0.41, low-quality evidence); Analysis 1.2, with a negative intracluster correlation coefficient. The authors reported that they detected a medium effect size for patient ratings of the relationship, d = 0.36.

1.2 Mental state

Mental state was measured using the PANSS.

1.2.1 Mental state: general symptoms - average endpoint score PANSS general (high = poor) medium term

No significant difference in general symptom scores was found at medium term (1 RCT, n = 59, aMD 4.48 95% CI - 2.10 to 11.06, low-quality evidence); Analysis 1.3.

1.2.2 Mental state: positive symptoms - average endpoint score PANSS positive (high = poor) medium term

No significant difference in positive symptom scores was found at medium term (1 RCT, n = 59, aMD - 0.23 95% CI -2.91 to 2.45); Analysis 1.4.

1.2.3 Mental state: negative symptoms - average endpoint score PANNS negative (high = poor) medium term

No significant difference in negative symptom scores was found at medium term (1 RCT, n = 59, aMD 3.42 95% CI - 0.24 to 7.09, low-quality evidence); Analysis 1.5.

1.3 Leaving the study early (patient)

According to a flow chart, 15 patients were lost to follow-up in the CST group and 18 patients were lost to follow-up in the NST group. Using these data, there was no difference between groups for number of patients leaving the study early (RR 0.89, 95% CI 0.51 to 1.55); Analysis 1.6; .

1.4 Other data

1.4.1 Psychiatrist satisfaction

As there was no sham intervention, data on psychiatrist's satisfaction with the educational intervention was reported only for one arm of the trial, and we were unable to conduct a comparative analysis. Here, psychiatrists in the CST group (n = 10) rated the training as highly beneficial (mean score 8.9 on a zero to 10 scale).

DISCUSSION

Summary of main results

COMPARISON 1: Communication skills training (CST) versus no specific training (NST)

Main outcomes (assessed at medium term)

Patient satisfaction with treatment as reported by the patients did not differ between the intervention and control groups at mediumterm follow-up, although there was a modest improvement in patients' satisfaction with the therapeutic relationship in the intervention group as compared to control. Equally, there was no significant difference in the mental state scores of the patients when comparing the CST group and NST group at medium-term follow-up, nor any difference in numbers leaving early.

Due to the small sample size and the exploratory nature of this randomised controlled trial (RCT), it is difficult to draw robust conclusions on the treatment effect. More, and larger scale studies in psychiatry are needed in order to collect evidence on the effectiveness of clinical communication training on the above outcomes.

Overall completeness and applicability of evidence

Applicability

The one study included in this version of the review recruited specialist psychiatric trainees working in outpatient clinics or community mental health teams that would be recognisable in every day practice. Psychiatrists working at this level have basic knowledge and experience in psychiatry gained through at least three years core psychiatric training and practice without direct supervision. The participants who were included in the study were: adults aged 18 to 65; met ICD-10 criteria for a diagnosis of schizophrenia or schizoaffective disorder; were attending psychiatric outpatients or being cared for by community mental health teams; and were capable of giving informed consent.

The outcomes that have been used in this review are accessible to both clinicians and patients in outpatient clinics or community mental health teams and the intervention could be used for larger scale RCTs to train psychiatrists with the aim to identify treatment effects.

Quality of the evidence

The only included randomised trial was designed as an exploratory pilot study, and not as a hypothesis-testing, adequately-powered trial. Thus, we cannot draw robust conclusions from the available data.

There were a number of limitations to the study design, namely lack of allocation concealment and losses to follow-up exceeding 30% of participants. In addition, a planned follow-up point was not able to be carried out because some of the psychiatrists had moved away. This reduces the validity of the available data.

Potential biases in the review process

The only data available at the time of writing this review are unpublished data as supplied by the investigators conducting the single included study.

Agreements and disagreements with other studies or reviews

There are no other relevant studies available for us to compare against.

AUTHORS' CONCLUSIONS

Implications for practice

I. For people with severe mental illness

As there is only one small pilot RCT in this topic, the results are inconclusive due to the small sample size. However, it is encouraging that the intervention suggests an increase in patient satisfaction at 12 weeks follow-up.

2. For clinicians

Due to the small sample size, it is difficult to draw conclusions about the effect of the training on psychiatrists. However, it is encouraging that the psychiatrists who received the training reported more satisfaction with the therapeutic relationship at five months in comparison to their colleagues in the control group.

3. For decision makers

There is weak evidence for mental health communication skills training (CST) on which to base decisions on provision of such educational interventions.

Implications for research

I. General

There is a lack of RCTs on the effect of CST for mental health professionals working with people with severe mental illness.

2. Specific

More well-designed, conducted and reported RCTs (see Table 1 for suggested design) are needed in order to draw meaningful conclusions about the effectiveness of CST for mental health professionals working with people with severe mental illness. However, a cluster-randomised controlled trial such as the included study is an appropriate method for testing the latter. Single blinding is a more realistic allocation for this type of study which should aim to blind trainees and patients to primary and secondary outcomes. Three-, six- and 12-month follow-ups would be desirable in order to assess whether the impact of CST is enduring. Future studies could follow the current study and target both trainee psychiatrists and more experienced ones and patients diagnosed with specific mental health conditions (e.g. psychosis, bipolar, anxiety), but recruit inpatients or patients near discharge from hospital in addition to outpatients. In order to avoid loss to follow-up and increase the power of the study, a larger sample needs to be recruited with multiple psychiatric hospitals/trusts. The interventions could be expanded to include on-line CST, written feedback, a reflective written report and a control condition. Video-taping of face-toface consultations with patients could be done before the intervention starts in order to obtain baseline data and allow post-intervention comparisons. Text messaging and access to computerised GP records could be employed to limit loss to follow-up and improve data quality. Outcome measures could be expanded to include the ones suggested in this review.

ACKNOWLEDGEMENTS

The Cochrane Schizophrenia Group Editorial Base in Nottingham produces and maintains standard text for use in the Methods sections of their reviews. We have used this text as the basis of what appears here and adapted it as required. We also used the protocol by Kinoshita 2010 and the review by Lewin 2001 as guides for our protocol.

We thank Katherine Deane for her help with developing the protocol of this review.

The search terms have been developed by the Information Specialist of the Cochrane Schizophrenia Group, Samantha Roberts and the review authors.

We would like to acknowledge and thank Rose McCabe, Professor of Clinical Communication at the University of Exeter Medical School for her willingness to share the data from her unpublished study. Without her data this review would be incomplete. We would also like to thank Victoria Bird and Katie Tyrell for peer reviewing this version of the review.

Last but not least, we would like to express our special thanks to Claire Irving the Managing Editor of the Cochrane Schizophrenia Group for her continuous support and guidance throughout this process.

REFERENCES

References to studies included in this review

McCabe 2016 {published and unpublished data}

McCabe R, John P, Dooley J, Healey P, Cushing A, Kingdon D, et al. Training to enhance psychiatrist communication with patients with psychosis (TEMPO): cluster randomised controlled trial. British Journal of Psychiatry 2016; Vol. 209, issue 6:517–24.

References to studies excluded from this review

Lester 2006 {published data only}

Lester HE, Birchwood M, Tait L, Freemantle N. Redirect: evaluating the effectiveness of an educational intervention about first episode psychosis in primary care. *Schizophrenia Research* 2006;**86**(Suppl 1):S39–40.

Mooney 1984 {published data only}

Mooney K. The impact of interviewer style in initial interviews with schizophrenic patients an analysis of warmth and structure. PhD dissertation submitted to Duke University 1984:104.

Steinwachs 2011 {published data only}

Steinwachs DM, Roter DL, Skinner EA, Lehman AF, Fahey M, Cullen B, et al. A web-based program to empower patients who have schizophrenia to discuss quality of care with mental health providers. *Psychiatric Services* 2011;**62** (11):1296–302. MEDLINE: 22211208

Sturm 1974 {published data only}

Sturm IE, Stuart BR. Effects of remotivation and role re training on inpatient interview presentableness. *Newsletter for Research in Mental Health and Behavioral Sciences* 1974; **16**(1):15–9.

Additional references

Altman 1996

Altman DG, Bland JM. Detecting skewness from summary information. *BMJ* 1996;**313**(7066):1200.

Bland 1997

Bland JM, Kerry SM. Statistics notes. Trials randomised in clusters. *BMJ* 1997;**315**(7108):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]

Cole 2000

Cole SA, Bird J. *The Medical Interview: The Three-function Approach*. Missuri, USA: Mosby Inc, 2000.

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.

Deeks 2011

Deeks JJ, Higgins JPT, Altman DG (editors). Chapter 9: Analysing data and undertaking meta-analyses. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from www.handbook.cochrane.org.

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.

Donner 2002

Donner A, Klar N. Issues in the meta-analysis of cluster randomized trials. *Statistics in Medicine* 2002;**21**(19): 2971–80.

Dwamena 2012

Dwamena F, Holmes-Rovner M, Gaulden CM, Jorgenson S, Sadigh G, Sikorskii A, et al. Interventions for providers to promote a patient-centred approach in clinical consultations. *Cochrane Database of Systematic Reviews* 2012, Issue 12. [DOI: 10.1002/14651858.CD003267.pub2]

Egger 1997

Egger M, Davey SG, Schneider M, Minder C. Bias in metaanalysis detected by a simple, graphical test. *BMJ* 1997;**315** (7109):629–34.

Gulliford 1999

Gulliford MC, Ukoumunne OC, Chinn S. 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**(9):876–83.

Harris 1998

Harris EC, Barraclough B. Excess mortality of mental disorder. *British Journal of Psychiatry* 1998;**173**:11–53.

Hassan 2007

Hassan I, McCabe R, Priebe S. Professional-patient communication in the treatment of mental illness: A review. *Communication and Medicine* 2007;4(2):141–52.

Higgins 2003

Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;**327** (7414):557–60.

Higgins 2011

Higgins JPT, Green S (editors). Chapter 7: Selecting studies and collecting data. In: Higgins JPT, Green S (editors), Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from www.handbook.cochrane.org.

Higgins 2011a

Higgins JPT, Altman DG, Sterne JAC (editors). Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from www.handbook.cochrane.org.

Julius 2009

Julius RJ, Novitsky MA, Dubin WR. Medication adherence: a review of the literature and implications for clinical practice. *Journal of Psychiatric Practice* 2009;**15**:34–44.

Kay 1986

Kay SR, Opler LA, Fiszbein A. *Positive and Negative Syndrome Scale (PANSS) Manual.* North Tonawanda, NY: Multi-Health Systems, 1986.

Kay 1987

Kay SR, Fisbein A, Opler LA. The positive and negative syndrome scale (PANSS) for Schizophrenia. *Schizophrenia Bulletin* 1987;**13**(2):261–76.

Kemp 1996

Kemp R, Hayward P, Applewhaite G, Everitt B, David A. Compliance therapy in psychotic patients: randomised controlled trial. *BMJ* 1996;**312**:345–9.

Kinoshita 2010

Kinoshita Y, Furukawa TA, Omori IM, Watanabe N, Marshall M, Bond GR, et al. Supported employment for adults with severe mental illness. *Cochrane Database of Systematic Reviews* 2010, Issue 1. [DOI: 10.1002/ 14651858.CD008297]

Kurtz 2005

Kurtz S, Silverman J, Draper J. *Teaching and Learning Communication Skills in Medicine*. 2nd Edition. Oxford: Radcliffe Publishing, 2005.

Leucht 2005

Leucht S, Kane JM, Kissling W, Hamann J, Etschel E, Engel R. Clinical implications of brief psychiatric rating scale scores. *British Journal of Psychiatry* 2005;**187**:366–71. [PUBMED: 16199797]

Leucht 2005a

Leucht S, Kane JM, Kissling W, Hamann J, Etschel E, Engel RR. What does the PANSS mean?. *Schizophrenia Research* 2005;**79**(2-3):231–8. [PUBMED: 15982856]

Lewin 2001

Lewin SA, Skea ZC, Entwistle V, Zwarenstein M, Dick J. Interventions for providers to promote a patient-centred approach in clinical consultations. *Cochrane Database* of *Systematic Reviews* 2001, Issue 4. [DOI: 10.1002/ 14651858.CD003267]

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.

McCabe 2002

McCabe R, Heath C, Burns T, Priebe S. Engagement of patients with psychosis in the medical consultation: a conversation analytic study. *BMJ* 2002;**325**:1148–51.

McGuire-Snieckus 2007

McGuire-Snieckus R, McCabe R, Catty J, Hansson L, Priebe S. A new scale to assess the therapeutic relationship in community mental health care: STAR. *Psychological Medicine* 2007;**6**:299–314.

Murray 1996

Murray C, Lopez A. *The Global Burden of Disease*. Harvard CT: Harvard University Press, 1996.

Nguyen 1983

Nguyen TD, Attkisson CC, Stegner BL. Assessment of patient satisfaction: development and refinement of a service evaluation questionnaire. *Evaluation and Program Planning* 1983;**6**:299–314.

Overall 1962

Overall JE, Gorham DR. The brief psychiatric rating scale. *Psychological Reports* 1962;**10**:799–12.

Oxman 1992

Oxman AD, Guyatt GH. A consumer's guide to subgroup analyses. *Annals of Internal Medicine* 1992;**116**(1):78–84.

Poole 2006

Poole R, Higgo R. *Psychiatric Interviewing and Assessment*. Cambridge: Cambridge University Press, 2006.

Priebe 2005

Priebe S, Watts J, Chase M, Matanov A. Processes of disengagement and engagement in assertive outreach patients: qualitative study. *British Journal of Psychiatry* 2005;**187**:438–43.

Raj 2005

Raj M, Farooq S. Interventions for obsessive compulsive symptoms in people with schizophrenia. *Cochrane Database* of *Systematic Reviews* 2005, Issue 2. [DOI: 10.1002/ 14651858.CD005236]

Schünemann 2011

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 (editors), Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Silverman 2005

Silverman J, Kurtz S, Draper J. *Skills for Communicating with Patients*. 2nd Edition. Abingdon: Radcliffe Medical Press, 2005.

Ukoumunne 1999

Ukoumunne OC, Gulliford MC, Chinn S, Sterne JA, Burney PG. Methods for evaluating area-wide and organisation-based interventions in health and health care: a systematic review. Health Technology Assessment 1999; Vol. 3, issue 5:iii–92.

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

Papageorgiou 2012

Papageorgiou A, Loke Y, Deane KHO, Fromage M. Communication skills training for mental health professionals working with people with severe mental illness. *Cochrane Database of Systematic Reviews* 2012, Issue 8. [DOI: 10.1002/14651858.CD010006]

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

McCabe 2016

Methods	Allocation: random, cluster. Blindness: single. Duration: 5 months (152 days). Setting: outpatient - university-affiliated, state-supported, outpatient psychiatric clinic in an urban area (East London, UK). Study sites were the East London NHS Foundation Trust and North East London NHS Foundation Trust
Participants	Practitioners Higher or advanced trainees working in outpatient or community settings. N = 21. Age = mean ~ 43 years. Sex: 15M, 11F. Patients Diagnosis: ICD-10 criteria for a diagnosis of schizoaffective disorder or schizophrenia N = 97. Age: mean ~ 43 years. Sex: 66 M, 31F. Exclusions: patients who had organic impairment or required an interpreter
Interventions	1. Communication skills training: A training programme:, comprised of 4 training sessions of 4 hours each, at weekly intervals to small groups of psychiatrists, followed by two refresher sessions (one at 8 weeks and the other at 12 weeks). During the training sessions, the psychiatrist and the patient were video-recorded during the consultation; the researchers then provided feedback. N = 10 (psychiatrists), N = 47 (patients) 2. No specific communication skills training: N = 11 (psychiatrists), N = 50 (patients)
Outcomes	Mental state: endpoint score PANSS (positive, negative, and general symptoms) Patient satisfaction: with treatment- endpoint (CSQ-8), with therapeutic relationship - endpoint score (STAR-P) Leaving the study early Unable to use Self-repair frequency: STAR - psychiatrist (data on psychiatrist's satisfaction with the educational intervention was reported only for one arm of the trial, and we were unable to conduct a comparative analysis)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated allocation: sequence generated in Excel with the RAND func- tion

McCabe 2016 (Continued)

Allocation concealment (selection bias)	High risk	The trial report states "There was no allo- cation concealment"		
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were blinded for primary and secondary outcomes as they did not know whether the psychiatrists had undergone communication skills training or not. It was not possible to blind the psychiatrists in- volved in the study		
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessors: primary outcome, self-repair, was masked but for the secondary outcome, the therapeutic re- lationship, it was not possible to mask		
Incomplete outcome data (attrition bias) All outcomes	High risk	Only 64/97 patients were followed up as 33 had left the trial early		
Selective reporting (reporting bias)	Low risk	We contacted the investigators and ob- tained data on all the outcomes that were relevant to our review, even if the data had not been reported in the published version. We also received additional data on out- comes that were pre-specified by the inves- tigators, but not of relevance to our review		
Other bias	Unclear risk	Originally. the trial planned to have a fur- ther follow-up point six months later, but this could not be carried out as psychiatrists had rotated away to different posts. The ex- tent to which this could have biased the re- sults is unclear		

CSQ - 8: Client Satisfaction Questionnaire

ICD 10: International Classification of Diseases 10th revision

N = number

PANSS: Positive and Negative Symptom Scale

STAR - P: Scale To Assess the Therapeutic Relationship in community mental health care

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Lester 2006	Allocation; randomised Participants:General Practitioners (GPs) Intervention: not directed at communication skills of healthcare professionals. The aim was to train general practitioners in detecting first episode of psychosis
Mooney 1984	Allocation: unclear Participants: people with schizophrenia Intervention: not reported.
Steinwachs 2011	Allocation; randomised Participants: people with schizophrenia Intervention: Interactive Web-based intervention featuring actors simulating a patient discussing treatment con- cerns. The study was not directed at healthcare professionals, but was aimed at training patients to raise concerns during consultations
Sturm 1974	Allocation: randomised Participants: people with schizophrenia Intervention: Psychodrama-based Role Re-Training. The study was not directed at healthcare professionals but at "regressed schizophrenic inpatients" with the aim to improve their "interpersonal presentableness."

DATA AND ANALYSES

^ · ·	O 1 1 1 1	• •	
Comparison 1.	Communication skills	fraining versus no s	necific fraining
Companioon II	Communication signi	training versus no s	peeme training

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patient satisfaction: 1. Satisfaction with treatment: average endpoint score (CSQ-8, high = good, medium term)	1		Mean Difference (Fixed, 95% CI)	1.77 [-0.13, 3.68]
2 Patient satisfaction: 2. Satisfaction with therapeutic relationship: average endpoint score (STAR-P, high = good, medium term)	1		Mean Difference (Fixed, 95% CI)	0.21 [0.01, 0.41]
3 Mental state: 1. General Symptom: Average endpoint score (PANSS General, high = poor, medium term)	1		Mean Difference (Fixed, 95% CI)	4.48 [-2.10, 11.06]
4 Mental state: 2. Positive Symptom; Average endpoint score (PANSS Positive, high = poor, medium term)	1		Mean Difference (Fixed, 95% CI)	-0.23 [-2.91, 2.45]
5 Mental state: 3. Negative Symptom: Average endpoint score (PANSS Negative, high = poor, medium term)	1		Mean Difference (Fixed, 95% CI)	3.42 [-0.24, 7.09]
6 Leaving the study early (patient)	1	97	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.51, 1.55]

Analysis I.I. Comparison I Communication skills training versus no specific training, Outcome I Patient satisfaction: I. Satisfaction with treatment: average endpoint score (CSQ-8, high = good, medium term).

Review: Communication skills training for mental health professionals working with people with severe mental illness

Comparison: I Communication skills training versus no specific training

Outcome: I Patient satisfaction: I. Satisfaction with treatment: average endpoint score (CSQ-8, high = good, medium term)

Study or subgroup	Mean Difference (SE)		Diffe	Mean erence		Weight	Mean Difference
			IV,Fixe	d,95% Cl			IV,Fixed,95% CI
McCabe 2016	1.771 (0.9724)				_	100.0 %	1.77 [-0.13, 3.68]
Total (95% CI)					-	100.0 %	1.77 [-0.13, 3.68]
Heterogeneity: not applical	ble						
Test for overall effect: $Z =$	I.82 (P = 0.069)						
Test for subgroup difference	es: Not applicable						
		-4	-2 () 2	4		
	Favours No	specific tr	aining	Favours	CS training		

Analysis 1.2. Comparison I Communication skills training versus no specific training, Outcome 2 Patient satisfaction: 2. Satisfaction with therapeutic relationship: average endpoint score (STAR-P, high = good, medium term).

Review: Communication skills training for mental health professionals working with people with severe mental illness

Comparison: I Communication skills training versus no specific training

Outcome: 2 Patient satisfaction: 2. Satisfaction with therapeutic relationship: average endpoint score (STAR-P, high = good, medium term)

Study or subgroup	Mean Difference (SE)		Mean Difference		Weight	Mean Difference
		IV,	Fixed,95% CI			IV,Fixed,95% CI
McCabe 2016	0.21 (0.102)			_	100.0 %	0.21 [0.01, 0.41]
Total (95% CI)				-	100.0 %	0.21 [0.01, 0.41]
Heterogeneity: not applical	ble					
Test for overall effect: $Z =$	2.06 (P = 0.040)					
Test for subgroup difference	es: Not applicable					
				1		
		-0.5 -0.25	0 0.25	0.5		
	Favours	No specific training	g Favour	s CS training		

Analysis 1.3. Comparison I Communication skills training versus no specific training, Outcome 3 Mental state: I. General Symptom: Average endpoint score (PANSS General, high = poor, medium term).

Review: Communication skills training for mental health professionals working with people with severe mental illness

Comparison: I Communication skills training versus no specific training

Outcome: 3 Mental state: I. General Symptom: Average endpoint score (PANSS General, high = poor; medium term)



Analysis I.4. Comparison I Communication skills training versus no specific training, Outcome 4 Mental state: 2. Positive Symptom; Average endpoint score (PANSS Positive, high = poor, medium term).

Review: Communication skills training for mental health professionals working with people with severe mental illness

Comparison: I Communication skills training versus no specific training

Outcome: 4 Mental state: 2. Positive Symptom; Average endpoint score (PANSS Positive, high = poor; medium term)

Study or subgroup	Mean Difference (SE)		Mean Difference		Weight	Mean Difference
		I\	/,Fixed,95% CI			IV,Fixed,95% CI
McCabe 2016	-0.2349 (1.3674)		-		100.0 %	-0.23 [-2.91, 2.45]
Total (95% CI)					100.0 %	-0.23 [-2.91, 2.45]
Heterogeneity: not applic	able					
Test for overall effect: Z =	= 0.17 (P = 0.86)					
Test for subgroup differen	ices: Not applicable					
				i.		
		-4 -2	0 2	4		
		Favours CS trainin	ng Favours	s No specific tr	raining	

Analysis 1.5. Comparison I Communication skills training versus no specific training, Outcome 5 Mental state: 3. Negative Symptom: Average endpoint score (PANSS Negative, high = poor, medium term).

Review: Communication skills training for mental health professionals working with people with severe mental illness

Comparison: I Communication skills training versus no specific training

Outcome: 5 Mental state: 3. Negative Symptom: Average endpoint score (PANSS Negative, high = poor, medium term)



Analysis 1.6. Comparison I Communication skills training versus no specific training, Outcome 6 Leaving the study early (patient).

Review: Communication skills training for mental health professionals working with people with severe mental illness

Comparison: I Communication skills training versus no specific training

Outcome: 6 Leaving the study early (patient)

Study or subgroup	CS training	No specific training		Risk Ratio			Weight	Risk Ratio
	n/N	n/N		M-H,Fixe	ed,95% CI			M-H,Fixed,95% Cl
McCabe 2016	15/47	18/50			ł		100.0 %	0.89 [0.51, 1.55]
Total (95% CI)	47	50		•	•		100.0 %	0.89 [0.51, 1.55]
Total events: 15 (CS training), 18 (No specific training)								
Heterogeneity: not applie	able							
Test for overall effect: Z	= 0.42 (P = 0.67)							
Test for subgroup differer	nces: Not applicable							
			0.01	0.1 1	10	100		
Favou				training	Favours	No speci	fic training	

ADDITIONAL TABLES

Table 1. Suggested future trial design

Method	Cluster-randomised controlled study with the allocation clearly described Blinding: single-blinded, described and tested Single-blinding is a more realistic allocation for this type of study which should aim to blind trainees and patients to primary and secondary outcomes Three-, six- and 12-month follow-ups would be desirable in order to assess whether the impact of communication skills training is enduring					
Participants	Future studies target both trainee psychiatrists and more experienced psychiatrists. Patients diagnosed with specific mental health conditions (e.g. psychosis, bipolar, anxiety), but recruit inpatients or patients near discharge from hospital. In order to avoid loss to follow-up and increase the power of the study a larger sample needs to be recruited with multiple psychiatric hospitals/trusts					
Intervention	The interventions could be expanded to include on-line communication skills training, written feedback, a reflective written report and a control condition. Video-taping of face-to-face consultations with patients could be done before the intervention starts in order to obtain baseline data and allow post-intervention comparisons. Text messaging and access to computerised GP records could be employed to limit loss to follow-up and improve data quality					
Outcomes	Primary outcomes With relation to the patients treated by the mental health professional. 1. Adherence to treatment 1.1 Taking of medication 1.2 Attendance at scheduled appointments. With relation to the mental health professional. 2.1 Statisfaction with the training programme 2.2 Integration of key communication skills into clinical practice post-intervention 2.3 Reason for leaving the study early Secondary outcomes With relation to the patients treated by the mental health professional 1.1 Clinically important improvement 1.2 Any improvement 1.3 Average change or endpoint scores on global state scales 2.4 Departing the synthesis (delusions, hallucinations, disordered thinking) 3.2 Negative symptoms (delusions, hallucinations, disordered thinking) 3.2 Negative symptoms (avolition, poor self-care, blunted affect) 3.3 Average change or endpoint scores on mental state scales 4. Patient satisfaction 4.1 Average change or endpoint scores on social functioning scales 5. Social functioning 5.1 Average change or endpoint scores on social functioning scales 5. Social functioning 5.3 Work-related activities 5.4 Able to live independently 5.5 Imprisonment </td					

Table 1. Suggested future trial design (Continued)

	 6. Quality of life 6.1 Clinically important change in general quality of life 6.2 Average change or endpoint scores on quality of life scales 7. Reason for leaving the study early
Notes	A future study should be powered to be able to identify a difference of ~10% between groups for primary outcomes with adequate degree of certainty

APPENDICES

Appendix I. Previous searches

1.1 Search in 2012

I.I.I Electronic searches

1.1.1.1 Cochrane Schizophrenia Trials Register

In July 2012, we searched the register using the phrase: [*didactic* OR *video* OR *role?play* OR *e?learning* OR *active?learning* OR *consultation skill* OR *communication skill* in title, abstract and index terms of REFERENCE or interventions of STUDY] This register is compiled by systematic searches of major databases, handsearches and conference proceedings (see group module).

I.I.2 Searching other resources

1.1.2.1 Reference searching

We inspected references of all identified studies for further relevant studies.

1.1.2.2 Personal contact

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

CONTRIBUTIONS OF AUTHORS

Alexia Papageorgiou: Protocol development, personal contact with author of unpublished studies, screening of studies, writing the report.

Yoon Loke : Protocol development, personal contact with author of unpublished studies, screening of studies, data analysis, writing the report.

Michelle Fromage :Protocol development, screening of studies, lay summary, writing the report.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

• George's University of London Medical School, University of Nicosia, Nicosia, Cyprus. Employs lead review author Alexia Papageorgiou

• Norwich Medical School, University of East Anglia, Norwich, UK.

Employs review author Yoon Loke and Michelle Fromage is a PhD student with this University.

External sources

• None, Other.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

1. Change of authors

Catherine Deane is no longer an author of the review.

2. Selection of studies

The text in the protocol reads as follows: "Review authors AP and KD will independently inspect citations from the searches and identify relevant abstracts. A random 20% sample will be independently re-inspected by YL to ensure reliability. Where disputes arise, we will acquire the full report for more detailed scrutiny. Full reports of the abstracts meeting the review criteria will be obtained and inspected by AP and KD. Again, a random 20% of reports will be re-inspected by YL in order to ensure reliable selection. Where it is not possible to resolve disagreement by discussion, we will attempt to contact the authors of the study for clarification."

This now reads: "Due to the small amount of studies that were identified (four studies in total) by the Information Specialist of the Cochrane Schizophrenia Group, all three authors AP, YL, MF inspected all four studies and unanimously agreed that only one of studies should be included in the review. We obtained both abstracts and full study reports and thoroughly assessed all of them."

3. Change to 'Summary of findings' outcomes

Satisfaction with training programme was not reported in trials so we used the reported outcomes for satisfaction (with treatment and with 'therapeutic relationship').

Mental state was not a prestated outcome of interest in our protocol, however, as other data were not available, we included mental state data, reported in our included study, in the 'Summary of findings' table.

4. Assessment of risk of bias in included studies

The text in the protocol reads as follows: "Again, review authors AP and KD will work independently to assess risk of bias by using criteria described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) to assess trial quality."

This now reads:

"Review authors AP, YL and MF aimed to work independently to assess risk of bias by using criteria described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) to assess trial quality."

5. Data extraction and management

The text in the protocol reads as follows: "Review authors AP and YL will independently extract data from all included studies. Again, any disagreement will be discussed, decisions documented and, if necessary, we will contact the authors of studies for clarification. With remaining problems KD will help clarify issues and these final decisions will be documented."

This now reads:

Review authors AP and YL independently extracted data from the included study. We discussed any disagreements and documented decisions. We contacted authors of the included study through an open-ended request in order to obtain missing information or for clarification. If the study had been multi-centre, where possible, we would have extracted data relevant to each component centre separately.

For cluster randomised trials, we extracted the adjusted difference in means (aMD) of the endpoint and a measure of variation (such as a confidence intervals or standard error).

6. References

Four more references were added to 'Additional references' (Dwamena 2012; Kay 1987; McGuire-Snieckus 2007; Nguyen 1983).