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# Counselling for mental health and psychosocial problems in primary care (Review)

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[Intervention Review]

# Counselling for mental health and psychosocial problems in primary care

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## A B S T R A C T

**Background**

The prevalence of mental health and psychosocial problems in primary care is high. Counselling is a potential treatment for these patients, but there is a lack of consensus over the effectiveness of this treatment in primary care.

**Objectives**

To assess the effectiveness and cost effectiveness of counselling for patients with mental health and psychosocial problems in primary care.

**Search methods**

To update the review, the following electronic databases were searched: the Cochrane Collaboration Depression, Anxiety and Neurosis (CCDAN) trials registers (to December 2010), MEDLINE, EMBASE, PsycINFO and the Cochrane Central Register of Controlled Trials (to May 2011).

**Selection criteria**

Randomised controlled trials of counselling for mental health and psychosocial problems in primary care.

**Data collection and analysis**

Data were extracted using a standardised data extraction sheet by two reviewers. Trials were rated for quality by two reviewers using Cochrane risk of bias criteria, to assess the extent to which their design and conduct were likely to have prevented systematic error. Continuous measures of outcome were combined using standardised mean differences. An overall effect size was calculated for each outcome with 95% confidence intervals (CI). Continuous data from different measuring instruments were transformed into a standard effect size by dividing mean values by standard deviations. Sensitivity analyses were undertaken to test the robustness of the results. Economic analyses were summarised in narrative form. There was no assessment of adverse events.

**Main results**

Nine trials were included in the review, involving 1384 randomised participants. Studies varied in risk of bias, although two studies were identified as being at high risk of selection bias because of problems with concealment of allocation. All studies were from primary care in the United Kingdom and thus comparability was high. The analysis found significantly greater clinical effectiveness in the counselling group compared with usual care in terms of mental health outcomes in the short-term (standardised mean difference -0.28, 95% CI -0.43 to -0.13, n = 772, 6 trials) but not in the long-term (standardised mean difference -0.09, 95% CI -0.27 to 0.10, n = 475, 4 trials), nor on measures of social function (standardised mean difference -0.09, 95% CI -0.29 to 0.11, n = 386, 3 trials). Levels of satisfaction with counselling were

high. There was some evidence that the overall costs of counselling and usual care were similar. There were limited comparisons between counselling and other psychological therapies, medication, or other psychosocial interventions.

## Authors' conclusions

Counselling is associated with significantly greater clinical effectiveness in short-term mental health outcomes compared to usual care, but provides no additional advantages in the long-term. Participants were satisfied with counselling. Although some types of health care utilisation may be reduced, counselling does not seem to reduce overall healthcare costs. The generalisability of these findings to settings outside the United Kingdom is unclear.

## PLAIN LANGUAGE SUMMARY

### Counselling for mental health and psychosocial problems in primary care

Many patients in primary care suffer from mental health and psychosocial problems. These problems often involve feelings of sadness, nerves or stress. Many of these problems may be due to personal and social problems or reactions to life events such as physical illness or unemployment.

'Counselling' is a recognised psychological therapy that is often provided to such patients. In the United Kingdom, counsellors have often been employed to deliver psychological therapy to patients in primary care settings. Providing counselling alongside other treatments such as cognitive behaviour therapy means that patients have greater choice, and that alternatives can be found for patients who either do not benefit from standard treatments or who do not find them acceptable.

However, recent clinical guidelines in the United Kingdom have highlighted the lack of evidence for counselling compared to other treatments such as cognitive behaviour therapy, and have not been able to clearly recommend the use of counselling in primary care.

In this review we found nine studies involving counselling in primary care for 1384 participants. There were some problems with the methods in some studies. The evidence suggested that counselling is better than usual general practitioner care in improving mental health outcomes in the short term, although the advantages are modest. People who receive counselling in primary care from a trained counsellor are more likely to feel better immediately after treatment and be more satisfied than those who receive care from their general practitioner. However, in the long term, counselling does not seem to be any better than GP care. Although some types of healthcare utilisation may be reduced, counselling does not seem to reduce overall healthcare costs. There is very limited evidence comparing counselling with other psychological therapies (2 studies with 272 participants) or with antidepressant medication (1 study with 83 participants).

# BACKGROUND

## Description of the condition

The prevalence of mental health and psychosocial problems in primary care is high (Goldberg 1992, Singleton 2001). These problems include diagnosed mental health problems such as depression and anxiety, through to less well defined psychosocial difficulties or 'problems in living' which may be associated with depression and anxiety symptoms, but may be linked to financial, domestic or interpersonal pressures.

In the United Kingdom, surveys indicate that around 2.6% of adult patients in the community would meet diagnostic criteria for a 'depressive episode' but the broader category of 'mixed depression and anxiety' would apply to 11.4% (Singleton 2001). When all 'common mental health disorders' are included (NICE 2011), surveys indicate that one in six adults may meet diagnostic criteria (McManus 2009). 'Common mental health disorders' include a range of conditions, such as depression, anxiety, panic, PTSD and antenatal and postnatal mental health (NICE 2011). Many of these disorders are associated with significant impact on health related quality of life (Murray 1996), social function and economic outcomes within and outside health care (NICE 2010).

## Description of the intervention

The World Health Organisation has outlined reasons why treatment for mental health and psychosocial problems should be based in primary care, including the overall burden, the link between mental and physical health, and the potential for primary care services to offer accessible, effective and efficient management (WHO 2008).

Despite this potential, there are concerns that service provision by general practitioners (GPs) and the primary care team for patients with mental health and psychosocial problems is variable, sometimes unresponsive to the needs of patients, and not always achieving the best outcomes for patients (Katon 2000; Mitchell 2009; Ustun 1995). This may reflect a lack of focus on the development of primary care mental health services or limitations in the training of and resources available to primary care practitioners (Thompson 2000; WHO 2001; WHO 2008).

There are many different ways of delivering services for mental health and psychosocial problems (Bower 2005; Cape 2010; Gask 1997). One model involves mental health specialists working directly in primary care to provide psychological therapies. In the United Kingdom, developing evidence of clinical effectiveness (Churchill 2002) and economic benefits (Layard 2006) and patient preferences for psychological therapies over medication (Priest 1996) has led to this model receiving significant support in health policy. This in turn has led to the introduction of the Improving Access to Psychological Therapies (IAPT) initiative (Clark 2009), which provided funding to develop psychological therapy services along a stepped care model (NICE 2010). Stepped care provides a range of treatments of different intensity and cost, designed to maximise access to care and ensure treatment is commensurate with severity and capacity for benefit (Bower 2005a). This can include 'low intensity' interventions such as guided self help (Gellatly 2007), computerised interventions (Kaltenthaler 2006), exercise, and group psychological therapies. More severely ill patients or those who fail to benefit from these treatments may receive medication and conventional 'high intensity' psychological therapies (NICE 2010; NICE 2011).

Evidence for the effectiveness of psychological therapy is generally focused on cognitive behaviour models, which dominate current guidelines for the delivery of IAPT and stepped care (NICE 2010). Nevertheless, a variety of mental health specialists work in primary care settings to deliver psychological therapy, and this includes counsellors. The first reports of counsellors working in primary care in the United Kingdom were published in the 1970s (Anderson 1979; Cohen 1979; Harray 1975). In England and Wales, at one point between one third and one half of general practices reported on-site counselling services (Mellor-Clark 2001; Sibbald 1993). Counsellors come from different professional backgrounds and use a variety of treatments on a wide range of clients (Bolger 1989). Counselling in primary care is often associated with brief treatments (6 to 12 sessions) provided for a wide range of psychosocial problems, and can involve a range of different theoretical approaches, including 'person-centred' and 'psychodynamic and psychoanalytic' therapies, as well as 'integrative' (involving a mixture of therapeutic strategies, including cognitive behaviour therapy), 'systemic', and 'supportive' therapies (Stiles 2006; Stiles 2008).

## How the intervention might work

There is an extensive body of literature on the effectiveness of psychological therapies in a range of mental health disorders (Chambless 1998; Roth 1996; Weston 2004) although there is less consensus over the relative effectiveness of different psychological therapies and the exact mechanisms by which these interventions achieve their effects (Holmes 2002; Luborsky 1975). Non-directive, experiential or person-centred approaches share a number of assumptions about curative mechanisms, including a focus on enhancing subjective experience during treatment, and the crucial role of the therapeutic relationship as a platform for change (Greenberg 1994). Psychodynamic and psychoanalytic counselling may focus on a range of issues and conflicts, including needs, drives, relationships and attachments, while cognitive behaviour counselling considers maladaptive beliefs and behaviours and may use more structured and directive methods to encourage change (Churchill 2002; NICE 2010; Roth 1996; Simpson 2000). It has been suggested that providing such treatments in primary care will enhance their effectiveness because the primary care setting enhances access and minimises stigma (WHO 2008).

## Why it is important to do this review

Concerns remain as to whether counselling in primary care represents a cost-effective use of resources, both compared to usual general practitioner care, and compared to other psychological therapies such as cognitive-behaviour therapy. Initial uncontrolled studies (e.g. Anderson 1979; Baker 1998; Booth 1997; Coe 1996; Harray 1975; Keithley 1995; Waydenfeld 1980) reporting reductions in consultation and prescription rates and high levels of patient and professional satisfaction were important in the early development of counselling in primary care. However, the methodological limitations of these early studies meant that concerns about the efficacy of counselling in primary care began to be expressed (Roth 1996). The place of counselling in stepped care models of treatment delivery is currently unclear. Providing counselling alongside other treatments such as cognitive behaviour therapy means that patients potentially have greater

choice, and that alternatives can be found for patients who either do not benefit from cognitive behaviour therapy or who do not find that therapy acceptable. Making services 'patient-centred' is an increasing focus of health policy (Gilbody 2010), and there is evidence that a significant proportion of patients will choose psychological therapies such as counselling if provided a choice (King 2000).

In the United Kingdom, the recent clinical guidelines for depression published by the National Institute for Health and Clinical Excellence suggested that professionals should 'consider counselling for people with persistent subthreshold depressive symptoms or mild to moderate depression' but should 'discuss with the person the uncertainty of the effectiveness of counselling...in treating depression' (NICE 2010). Such uncertainty is unhelpful for patients, professionals and commissioners, highlighting the need for regular and comprehensive summaries of current evidence.

# O B J E C T I V E S

1. To assess the clinical effectiveness of counselling for patients with mental health and psychosocial problems in primary care, compared with usual care, other psychological and psychosocial interventions, and medication

2. To assess current evidence for the resource use, costs and cost-effectiveness of counselling for patients with mental health and psychosocial problems in primary care, compared with usual care, other psychological and psychosocial interventions, and medication

# M E T H O D S

## Criteria for considering studies for this review

### Types of studies

All randomised controlled trials (RCTs) were considered for inclusion in the review, including cluster trials, but excluding quasi-RCTs without randomisation. Many trials of counselling in primary care are 'pragmatic' RCTs, which seek to determine the relative 'value' of treatments as they would be provided in routine care settings, and seek to increase external validity without significantly compromising internal validity (Roland 1998). In primary care, this means that interventions are not highly standardised, so as to reflect the clinical variation that exists in routine care contexts. The control group ('usual general practitioner care') is the mix of interventions that patients would usually receive, and may include interventions similar to counselling (such as referral to NHS psychological therapy services). Although lack of control over these aspects of the trial can make interpretation of findings complicated, the external validity of study findings is increased and such studies provide a relevant comparison group for estimates of cost-effectiveness.

### Types of participants

Males and females of all ages, consulting a primary care practitioner with mental health or psychosocial problems considered suitable for counselling were eligible for the review.

Traditionally, counsellors have worked with people with situational or life-adjustment problems rather than mental health problems per se, although referrals will vary depending upon counsellor expertise, doctor and patient choice and the availability of alternative mental health services. The review included patients with a defined diagnosis of a mental health problem (such as depression or anxiety), those who were defined on the basis of symptom severity (such as a score on a depression scale) and those who were referred on the basis of clinician judgment that the patient had a problem that would benefit from counselling in primary care. This might include acute or chronic presentations.

### Types of setting

Counselling has to be provided in primary care settings in order to be included in the review. Primary healthcare was defined by the Alma Ata declaration as 'essential healthcare based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination' (www.who.int/hpr/NPH/docs/declaration_almaata.pdf).

Descriptions of the core content of primary care vary (Fry 1994; Starfield 1992), but key aspects include (a) first contact care, with direct patient access; (b) care characterised by patient-centeredness, family orientation, and continuity; (c) a role in the co-ordination of care; and (d) a gatekeeping function in relation to access to specialist care.

Counselling interventions in which the counselling was offered in the patient's own home were included in the review, if the referral was from a primary care practitioner.

### Types of interventions

#### Experimental conditions

As noted above, counselling is a generic term that can be used to describe a range of mental health and psychosocial interventions provided in primary care. The precise boundaries of counselling interventions for the present review are described below. For the purposes of the review, counselling was not an integral component of other mental health care activities (e.g. nursing, medical care) but constitutes a distinct and separate treatment intervention, offered as a series of sessions, following an assessment which generates a therapeutic plan. The definition of counselling used was derived from the British Association of Counselling and Psychotherapy (BACP 1992): "Counselling is the skilled and principled use of relationships which develop self-knowledge, emotional acceptance and growth, and personal resources. The overall aim is to live more fully and satisfyingly. Counselling may be concerned with addressing and resolving specific problems, making decisions, coping with crises, working through feelings and inner conflict, or improving relationships with others. The counsellor's role is to facilitate the client's work in ways that respect the client's values, personal resources and capacity for self determination".

Counselling may be described using a number of specific terms and may involve a number of different therapeutic techniques, including non-directive, person-centred and process-experiential methods, as well as cognitive behavioural and psychodynamic approaches (DOH 2001; Elliott 2003).

Counselling may be offered by a variety of professionals (e.g. counsellors, community nurses, social workers, clinical psychologists, and primary care professionals). In this review, there were no specific inclusion or exclusion criteria related to professional background. However, formal counselling training was considered essential, to standardise expertise and practice. Only practitioners with a formal counselling qualification equivalent to BACP accreditation levels (http://www.bacp.co.uk/accreditation/) were included in the review.

### Comparators

Any relevant comparator was included in the review, categorised as follows:

(a)  usual GP care, which may include 'no treatment' or 'waiting list' comparators where it is assumed that patients will have access to usual GP or primary care services;

(b)  medication, which may involve any appropriate medication for use with mental health or psychosocial problems, but most likely to include antidepressants or anxiolytic medications;

(c)  other psychological therapies, including cognitive behaviour therapy, interpersonal therapy, psychoanalytic or psychodynamic therapy, problem solving therapy, provided in individual, group or self help and computerised formats; and

(d)  other psychosocial interventions, including exercise, alternative therapies (such as acupuncture or yoga) and organisational interventions such as collaborative care.

### Types of outcome measures

Three main types of outcome measure were eligible for inclusion in the review:

1. mental health symptoms such as depression and anxiety (primary outcome). Examples of relevant scales include the Beck Depression Inventory (Beck 1988) and the Symptom Checklist (Derogatis 1983).
2. social functioning. Examples of relevant scales include the Social Adjustment Scale (Cooper 1982)
3. patient satisfaction. There is less consensus concerning the appropriate measures of patient satisfaction, which means that scales may not be standardised or fully validated.

Both self-report and interviewer-rated measures were eligible for the review, and measures could use continuous scales or dichotomous categories. Adverse outcomes and treatment drop outs were not used as outcome measures.

Health care utilisation and cost data included (a) referrals within health and social care settings; (b) referrals to external agencies; (c) medication prescribed; (d) consultations in primary care settings; (e) costs of lost production (i.e. time lost from work due to illness); and (f) patient costs (such as travel and child care costs associated with attending treatment).

### Search methods for identification of studies

#### CCDAN's Specialised Register (CCDANCTR)

The Cochrane Depression, Anxiety and Neurosis Group (CCDAN) maintain two clinical trials registers at their editorial base in Bristol, UK, a references register and a studies based register. The CCDANCTR-References Register contains over 27,000 reports of trials in depression, anxiety and neurosis. Approximately 65% of these references have been tagged to individual, coded trials. The coded trials are held in the CCDANCTR-Studies Register and records are linked between the two registers through the use of unique Study ID tags. Coding of trials is based on the EU-Psi coding manual. Reports of trials for inclusion in the Group's registers are collated from routine (weekly), generic searches of MEDLINE, EMBASE and PsycINFO; quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) and review specific searches of additional databases. Reports of trials are also sourced from international trials registers c/o the World Health Organisation's trials portal (ICTRP), drug companies, the hand-searching of key journals, conference proceedings and other (non-Cochrane) systematic reviews and meta-analyses. Details of CCDAN's generic search strategies can be found on the Group's website.

Due to the broad nature of the counselling interventions and the psychological and psychosocial conditions included in the review, additional searches were performed on MEDLINE, EMBASE, PsycINFO and CENTRAL.

#### Electronic searches

The CCDANCTR-Studies and References Registers were searched (all years) using the following terms:

(counsel* or (supportive and *therap*) or humanistic or "client cent*" or non-directive or "non directive" or nondirective or experiential or process-experiential or focus-orient* or "focus orient*" or "insight orient*" or insight-orient* or "client orient*" or client-orient* or "person cent*" or person-cent* or "person orient*" or person-orient* or nonprescriptive or "non prescriptive" or non-prescriptive or rogerian or (("non specific" or non-specific) and *therap*))
AND
("general practice" or GP or "primary care" or "primary health" or "family practice" or "family health*" or "private practice" or ((family or community or district or practice*) and (doctor or physician or practitioner* or nurse)) or "health cent*" or clinic or ambula* or community or home or rural or ante-natal or antenatal)

Additional, update searches of MEDLINE, EMBASE, PsycINFO and CENTRAL (2005 to May 2011) can be found in Appendix 1. A summary of the original search strategies (to 2005) is found in Appendix 2.

#### Searching other resources

A published Cochrane review dealing with mental health workers in primary care (Harkness 2009) and the United Kingdom National Institute for Health and Clinical Excellence Depression guidelines (NICE 2010) were also used as sources. All the included and excluded studies listed in the first review were checked for additional records, together with the included and excluded studies dealing with counselling in the clinical guidelines. An additional cited reference search was conducted on the Web of Science using all reports of included studies cited in the earlier version of this review (Dec 2010).

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## Data collection and analysis

### Selection of studies

One reviewer (PB) screened the abstracts of all publications obtained by the updated searches, and a second reviewer (PC or SK) provided an independent judgment of eligibility from the abstract or the full paper as required. Disagreement about whether a study should be included was resolved by discussion between the reviewers. Where required, trial authors were contacted for further information.

### Data extraction and management

Data were entered on specially designed data extraction forms by two reviewers independently (PB, PC and SK). The data on the forms were collated onto a third form; disagreements were discussed by the reviewers. The collated data were then entered into the RevMan software. Missing information was obtained from trial authors wherever possible. Trials excluded from the review were listed in the 'excluded studies' section together with their reason for exclusion.

### Assessment of risk of bias in included studies

Methodological quality was assessed according to The Cochrane Collaboration's Risk of Bias tool (Higgins 2008). Assessments were conducted by two reviewers (PB and either PC or SK) working independently. Disagreements were dealt with by discussion. Risk of bias data is presented graphically and described in the following section: Risk of bias in included studies.

The following six domains were considered:

1. Sequence generation: was the allocation sequence adequately generated?
2. Allocation concealment: was allocation adequately concealed?
3. Blinding of participants, personnel and outcome assessors for each main outcome or class of outcomes: was knowledge of the allocated treatment adequately prevented during the study? We assessed blinding of outcome assessors separately for patient reported measures, observer measures, and measures of health care utilisation.
4. Incomplete outcome data for each main outcome or class of outcomes: were incomplete outcome data adequately addressed?
5. Selective outcome reporting: are reports of the study free of suggestion of selective outcome reporting?
6. Other sources of bias: was the study apparently free of other problems that could put it at a high risk of bias?

A judgement was made for each domain based on the following three categories:

- low risk of bias
- unclear risk of bias
- high risk of bias

### Measures of treatment effect

Most outcomes used were measured on continuous scales, but different studies used different outcome measures. In order to provide an overall measure of treatment effect, all data (even from identical outcome measures) were translated to a standardised mean difference by dividing the difference in mean values between treatment and control group by the pooled standard deviation. Short-term (one to six months), long-term (7-12 months) and very long-term data (> 12 months) were analysed separately.

Clinical effectiveness data were analysed using RevMan software. Generally trials reported multiple outcomes, so the analysis either used the identified primary outcome measure within each trial, or the reviewers selected the optimal (i.e. most widely used and validated) measure of anxiety and depression symptoms, which make up the bulk of symptoms in patients in primary care (Goldberg 1987; Goldberg 1992). An overall estimate of treatment effect was calculated for each outcome with 95% confidence intervals (negative estimates represent results favouring counselling).

### Unit of analysis issues

As counselling is an individual level intervention aimed at psychological and behavioural change, non standard designs (such as cluster randomised and cross-over trials) are not generally applicable, but would be included if identified. If results of cluster trials were reported without correction for clustering, they were adjusted to an effective sample size as outlined in the Handbook. Studies including multiple treatment groups were analysed including each pair-wise comparison separately, but with shared intervention groups divided out approximately evenly among the comparisons.

### Dealing with missing data

Few trials imputed values for missing data and thus the data used in the review were the scores of participants who successfully completed follow-up. Where data were missing, contact with authors would be used initially, followed by imputation of data where reasonable estimates could be derived from other studies in the review, or from the wider literature. The effects of any data imputation would be assessed through sensitivity analysis.

### Assessment of heterogeneity

Heterogeneity was assessed to examine whether the variation in treatment effect between trials was greater than that expected by sampling variation alone (Sutton 1998). The assessment included the chi$^2$ test for heterogeneity (with its degrees of freedom and P-value) and the I$^2$ statistic measuring the extent of inconsistency among results. I$^2$ results were interpreted in line with the current guidelines in the Cochrane Handbook (Higgins 2008) but there was no expectation of high levels of heterogeneity and no pre-specified threshold was set in terms of levels of heterogeneity that would preclude meta-analysis. Data were analysed by PB.

### Assessment of reporting biases

Where sufficient trials were available (ten or more), publication bias was assessed via funnel plots (Sutton 2000). However, it should be noted that asymmetric funnel plots are not necessarily caused by publication bias, so any conclusions drawn were interpreted with caution.

### Data synthesis

The primary analysis used a fixed-effect model, but the data were also analysed using random-effects models as a sensitivity analysis.

*Economic analysis*

Each economic analysis was described narratively using a structured format which detailed analysis type (e.g. descriptive, cost minimisation, cost effectiveness, cost utility), utilisation data, outcome data, duration of follow up, and the main results. In this section, analyses by the study authors are described in the text as originally reported. The first author has completed an economic analysis using individual patient data from some of the included studies. However, this was an exploratory analysis. The published results of that individual patient data analysis were reported along with the individual study results.

**Subgroup analysis and investigation of heterogeneity**

No subgroup analyses were planned.

**Sensitivity analysis**

Sensitivity analyses were undertaken to test the robustness of the results. We explored the following:

- the impact of adopting a fixed effect by comparing it with a random effects meta-analysis;
- the impact of excluding trials with different types of populations and comparisons, identified post hoc through data extraction; and
- the impact of excluding trials judged at 'high risk of bias'.

**R E S U L T S**

**Description of studies**

**Results of the search**

After removal of duplicates, 1719 references were identified by the searches. Assessment led to the checking of 87 full texts, and one new study was included in the review (see flow diagram in Figure 1).

**Figure 1. Study flow diagram for 2011 update of searches**



1: **CCDAN's SPECIALIZED REGISTER**
(all years)

a. CCDANCTR-Studies = **94 studies**

b. CCDANCTR-Refs = **217 references**

*(unique records)*

2: **BIBLIOGRAPHIC DATABASES**
(2005 - )

Medline (570); EMBASE (581);
PsycINFO (425); CENTRAL (308)

= **1,884 references**

3: **ADDITIONAL RECORDS**
identified through other
sources

n = **16**

*(unique records)*

**Number records after DUPLICATES REMOVED**

Search 1a = **75 studies**
(18 already included/excluded) ≡ 115 references

Search 1b = **216 references**

Search 2 = **1372 references**
(duplicates removed: 108 CCDANCTR, 512 other)

Search 3 = **16 references**

**Number records SCREENED**

Search 1a = **75 studies**
≡ 115 references

Search 1b = **216 references**

Search 2 = **1372 references**

Search 3 = **16 references**

**Number records EXCLUDED**

Search 1a = **63 studies**
≡ 100 references

Search 1b = **193 references**

Search 2 = **1339 references**

Search 3 = **0 references**

**ELIGIBILITY: Number
full-text articles assessed**

Search 1a = **15 references**
(12 studies)

Search 1b = **23 references**

Search 2 = **33 references**

Search 3 = **16 references**

**Number full-text articles
EXCLUDED**

Search 1a = **15 references**
(12 studies)

Search 1b = **22 references**

Search 2 = **33 references**

Search 3 = **16 references**

**Number STUDIES INCLUDED in
qualitative synthesis**

Search 1a = **0 studies**

Search 1b = **1 study**

Search 2 = **0 studies**

Search 3 = **0 studies**

## Figure 1. (Continued)

```
Search 3 = 0 studies
        |
        v
Number STUDIES included in
Meta-analysis
Search 1a = 0 studies
Search 1b = 0 studies
Search 2 = 0 studies
Search 3 = 0 studies
```

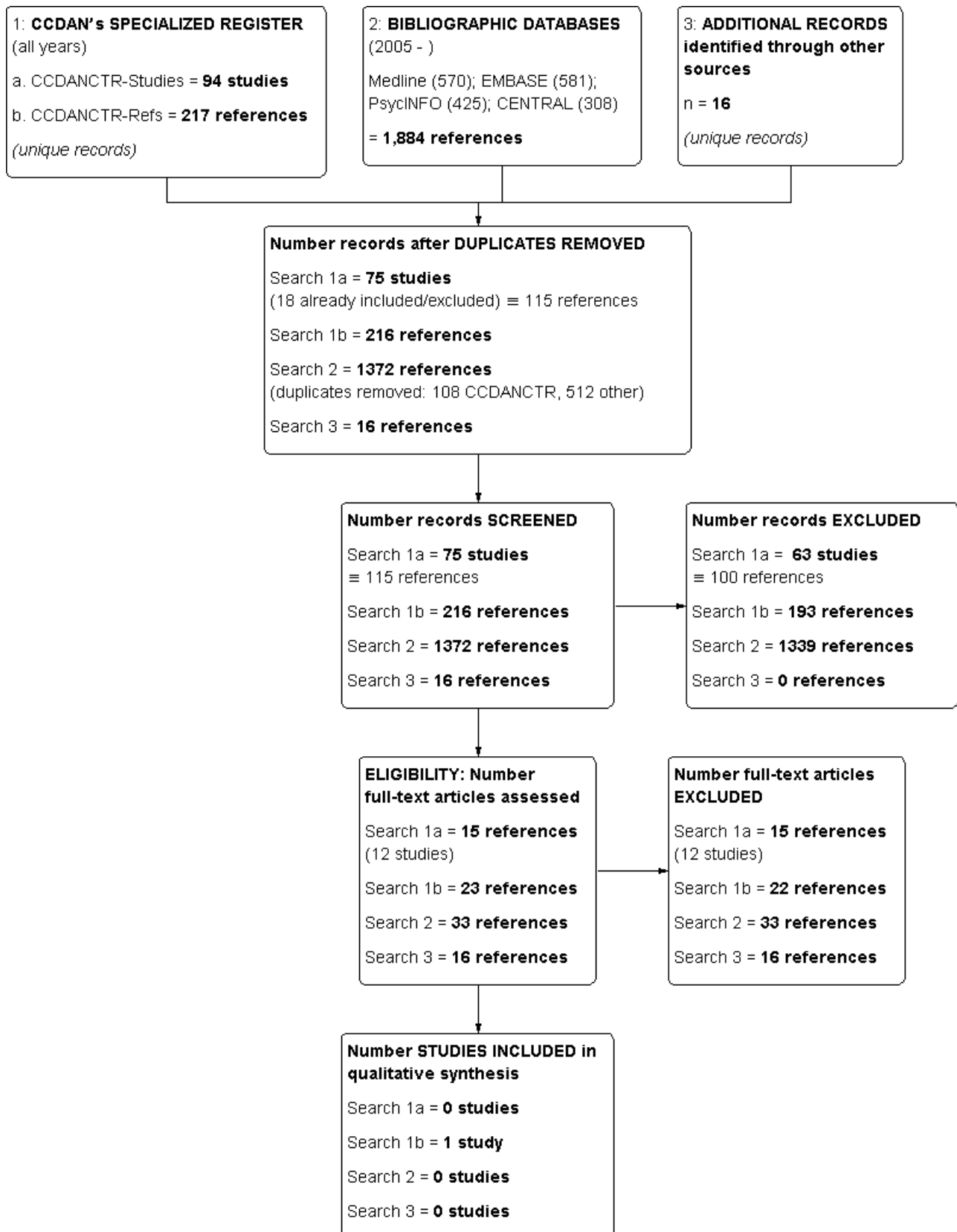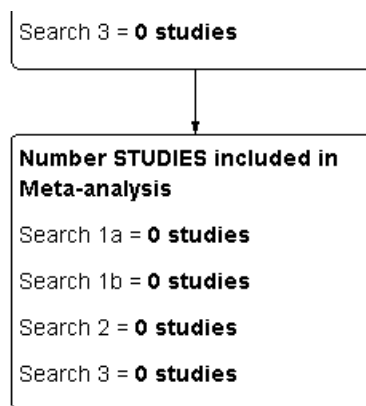### Included studies

Nine trials were included in the review (Barrowclough 2001; Boot 1994; Chilvers 2001; Friedli 1997; Harvey 1998; Hemmings 1997; King 2000; Schroer 2009; Simpson 2000) which were described in 16 separate publications.

The 'Characteristics of included studies' table details the characteristics of the trials, including methodological quality, the characteristics of participants, the characteristics of interventions and outcome measures.

### Types of practitioner

A range of practitioners offered a range of counselling interventions. In eight of the trials, all the professionals had the necessary qualifications and experience to be accredited by the BACP (Barrowclough 2001; Boot 1994; Friedli 1997; Harvey 1998; Hemmings 1997; King 2000; Schroer 2009; Simpson 2000). In one trial, it was not clear whether all the included counsellors met the criteria for BACP accreditation (Chilvers 2001), although correspondence with the authors indicated that a significant proportion did, and all were highly experienced. This trial also included a comparison group other than usual care (see below), and this trial was initially excluded from the analysis of counselling versus 'usual care' and the effect of its inclusion examined in sensitivity analysis.

### Types of intervention

The interventions offered were broadly compatible with the BACP definition of counselling. All trials described therapeutic interventions with individual clients involving face to face contact between patient and counsellor. Although there were differences in the therapeutic models used (e.g. non-directive counselling, psychodynamic counselling, cognitive-behavioural counselling), the interventions were considered homogenous for the purposes of analysis. Planned treatment duration in the studies were as follows: 8 to 12 sessions (Barrowclough 2001), 6 sessions (Boot 1994), approximately 6 sessions (Chilvers 2001), 6 to 12 sessions (Friedli 1997), up to 6 sessions (Harvey 1998), 6 sessions (Hemmings 1997), 6 to 12 sessions (King 2000), 12 or 24 sessions (Schroer 2009) and 6 to 12 sessions (Simpson 2000). Most treatments were delivered weekly and the session length was usually around one hour.

### Types of participants

Criteria for inclusion in terms of disorders were as follows: a diagnosis of anxiety (Barrowclough 2001), 'recent stress, crisis, relationship or family problems, anxiety, depression, bereavement, sexual difficulties, employment and financial problems' (Boot 1994), meeting Research Diagnostic Criteria for major depression (Chilvers 2001), 'patients with emotional difficulties' (Friedli 1997), 'emotional or relationship problems' (Harvey 1998), 'anxiety disorders (including phobic anxiety and obsessive compulsive disorder); depressive disorders, with the exception of very severe depression; undifferentiated somatoform disorder, psychosexual problems, relationship and family problems, bereavement and substance misuse problems' (Hemmings 1997), depression or mixed depression and anxiety (King 2000), depression (Schroer 2009) and chronic depression (Simpson 2000). Two trials restricted entry to participants meeting a certain level of severity on the Beck Depression Inventory (King 2000; Simpson 2000), one to participants meeting a certain level of severity on the Patient Health Questionnaire (Schroer 2009) and one to participants outside the normal range on the Beck Anxiety Inventory (Barrowclough 2001). Most trials were limited to adult participants, but one trial was further restricted to anxious older adults aged 55 or over (Barrowclough 2001).

In one trial (Simpson 2000), poor recruitment meant that participants were screened in surgery waiting rooms rather than referred by the GP. It is possible that these participants would differ from those in the other trials, possibly having lower levels of distress (although this was one of the trials that used a severity criterion) and lower motivation for treatment. In addition, this trial specifically recruited participants with chronic problems, defined as problems of six months or more. Some of the other trials included a mix of acute and chronic problems, although two specifically excluded chronic patients (Boot 1994, Friedli 1997) As no data were available on the exact mix of acute and chronic patients in each trial, it was impossible to determine if the participants in the Simpson trial were qualitatively different. Nevertheless, the effect of the exclusion of this trial was examined in sensitivity analysis.

### Types of comparison group

The comparison group in one trial was GP antidepressant treatment, as opposed to usual care (Chilvers 2001). GPs were given guidelines concerning appropriate antidepressant treatment.

There were no data available concerning the magnitude of the differences between GP management of participants in this group and 'usual care' in the other trials, although correspondence with the authors suggested that the former involved higher rates of antidepressant use than usual care, and also involved the expectation of antidepressants on the part of both participants and GPs. As stated above, this trial was initially excluded from the analysis of counselling versus 'usual care' and the effect of its inclusion examined in sensitivity analysis.

Two trials reported comparisons of counselling with cognitive-behavioural therapy (Barrowclough 2001; King 2000). One trial compared counselling with acupuncture as well as with usual care (Schroer 2009).

**Excluded studies**

The 'Characteristics of excluded studies' table lists those trials that met some but not all of the selection criteria for the review, together with the criteria on which they were excluded.

An author of one study (Schroer 2008) was contacted to discuss data from that study, and an ongoing follow up study. The ongoing study is listed in the 'Characteristics of ongoing studies' table.

**Risk of bias in included studies**

A graphical representation of the risk of bias in included studies is presented in Figure 2 and Figure 3. All studies were at risk of bias, especially in terms of performance, detection and attrition bias.

**Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**
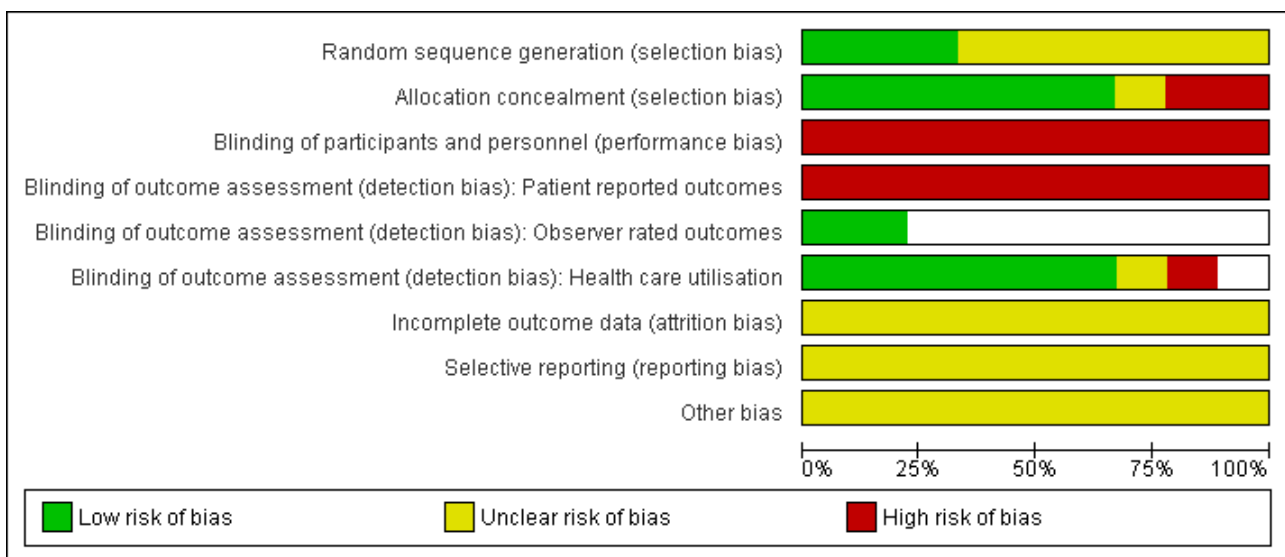
**Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**

**Figure 3.  (Continued)**



## Allocation

*Generation of random sequence*

In three studies (Barrowclough 2001; Boot 1994; Simpson 2000) there was an adequate description of random sequence generation and the studies were rated as 'low risk of bias'. In six studies (Chilvers 2001; Friedli 1997; Harvey 1998; Hemmings 1997; King 2000; Schroer 2009) there was no explicit mention of how the sequence was generated and the studies were rated as 'unclear risk of bias'.

*Allocation*

In six studies (Barrowclough 2001; Chilvers 2001; Harvey 1998; King 2000; Schroer 2009; Simpson 2000) there was an adequate description of allocation concealment (such as use of 'sealed, opaque, numbered envelopes' or central randomisation by telephone) and the studies were rated as 'low risk of bias'. One study reported 'sealed opaque envelopes' only and was rated 'unclear risk of bias' (Friedli 1997). In two studies, problems with the allocation were identified by the authors in terms of clinician allocation behaviour and both studies were rated as 'high risk of bias' (Boot 1994; Hemmings 1997).

## Blinding

In all studies there was no blinding of participants and personnel, and outcome was judged to have likely been influenced by lack of blinding. All studies were therefore rated as 'high risk of bias' (Barrowclough 2001; Boot 1994; Chilvers 2001; Friedli 1997; Harvey 1998; Hemmings 1997; King 2000; Schroer 2009; Simpson 2000).

In blinding of outcome assessment, all studies used patient reported measures, and given the lack of blinding of patients, these self-reports were judged as 'high risk of bias' (Barrowclough 2001; Boot 1994; Chilvers 2001; Friedli 1997; Harvey 1998; Hemmings 1997; King 2000; Schroer 2009; Simpson 2000).

Two studies used observer measures (Barrowclough 2001; Chilvers 2001) and reported that the assessors for these measures were blinded, although only one made an attempt to check the adequacy of the blinding (Chilvers 2001). Both were rated as 'low risk of bias' and all other studies received no rating.

Eight studies reported measures of health care utilisation. Six studies reported either data extraction from medical records, or a combination of medical records and patient self report, and were judged as 'low risk of bias' (Boot 1994; Chilvers 2001; Harvey 1998; Hemmings 1997; King 2000; Simpson 2000). One study reported using patient report only and was judged as 'high risk of bias' (Friedli 1997). One study did not report the source of data and was judged as 'unclear risk of bias' (Schroer 2009).

## Incomplete outcome data

All studies reported follow up rates, which varied between studies, and across different follow up points: 56% at six weeks (Boot 1994), 75% at four months (Harvey 1998), 82% and 53% at four and eight months (Hemmings 1997), 81% and 86% at three and nine months (Friedli 1997), 91% and 84% at 4 and 12 months and 85% and 78% at 4 and 12 months (King 2000), 89%, 79% and 60% at 6, 12 and 36 months (Simpson 2000), 83% and 63% at 8 weeks and 12 months (Chilvers 2001), 71%, 71% and 73% at 3, 6 and 12 months (Barrowclough 2001) and 75%, 63% and  45% at 3, 6 and 9 months (Schroer 2009). However, no studies reported reasons for missing data by group, and therefore all were judged as 'unclear risk of bias'.

## Selective reporting

Eight studies did not have a protocol available and insufficient information was available to judge selective reporting, and studies were judged as 'unclear risk of bias' (Barrowclough 2001; Boot 1994; Chilvers 2001; Friedli 1997; Harvey 1998; Hemmings 1997; King 2000; Simpson 2000). One study was reported in a protocol paper only, but no outcomes were reported at all as the study was not designed to test effectiveness, and this study was also judged as 'unclear risk of bias'.

## Other potential sources of bias

We found no clear evidence of other sources of bias in the nine studies.

In the previous version of the review, the CCDAN Quality Rating Scale (QRS) was used to assess study quality. Although study quality according to the QRS varied on many items, given the importance of quality of the randomisation, it was considered crucial that the randomisation procedure may have been compromised in two trials (Boot 1994; Hemmings 1997). Therefore the effects of the inclusion and exclusion of these trials were examined in sensitivity analysis.  Those sensitivity analyses have been retained in the updated review, on the basis that these trials have been identified as 'high risk of bias' in terms of allocation using the 'risk of bias' tool.

## Effects of interventions

### Counselling compared with usual GP care

Six studies reported data comparing counselling with usual GP care (Boot 1994; Friedli 1997; Harvey 1998; Hemmings 1997; King 2000; Simpson 2000).

#### Mental health outcomes

There were six trials reporting short-term outcomes and utilising 'usual care' as a comparison (Boot 1994; Friedli 1997; Harvey 1998; Hemmings 1997; King 2000; Simpson 2000). Participants receiving counselling had significantly better mental health scores than participants receiving 'usual care' (overall standardised mean difference (SMD) -0.28, 95% CI -0.43 to -0.13, n = 772, heterogeneity chi$^2$ = 9.46, df = 5, p = 0.09, I$^2$ =47%) (Analysis 1.1).

There were four trials reporting long-term outcomes and utilising 'usual care' as a comparison (Friedli 1997; Hemmings 1997; King 2000; Simpson 2000). Participants receiving counselling did not differ in mental health outcomes compared to participants receiving 'usual care' (overall SMD -0.09, 95% CI -0.27 to 0.10, n = 475, heterogeneity chi$^2$ = 3.93, df = 3, p = 0.27, I$^2$ =24%) (Analysis 2.1).

There was one trial reporting very long term outcomes (Simpson 2000). This trial included chronic participants only. Participants receiving counselling did not differ in terms of mental health than patients receiving 'usual care' (overall SMD -0.03, 95% CI -0.41 to 0.34, n = 109, heterogeneity not applicable) (Analysis 3.1).

#### Sensitivity analyses

The sensitivity analyses are all outlined in Table 1. The short-term results were similar when the two trials with inadequate allocation procedures were excluded (overall SMD -0.27, 95% CI -0.45 to -0.09, n = 510, heterogeneity chi$^2$ = 6.31, df = 3, p = 0.10, I$^2$ =52%) (sensitivity analysis 1.1.1, Table 1). The effect size was slightly reduced when the study using GP antidepressant treatment was included as 'usual GP care' (overall SMD -0.24, 95% CI -0.38 to -0.10, n = 855, heterogeneity chi$^2$ = 11.29, df = 6, p = 0.08, I$^2$ =47%) (sensitivity analysis 1.1.2, Table 1). The superiority of counselling rose in magnitude when the one study examining chronic participants only was excluded (overall SMD -0.36, 95% CI -0.53 to -0.19, n = 611, heterogeneity chi$^2$ = 5.45, df = 4, p = 0.24, I$^2$ =27%) (sensitivity analysis 1.1.3, Table 1) and when the inadequate allocation and chronic participant trials were all excluded (overall SMD -0.41, 95% CI -0.62 to -0.19, n = 349, heterogeneity chi$^2$ = 1.87, df = 2, p = 0.39, I$^2$ =0.0%) (sensitivity analysis 1.1.4, Table 1). When the trial with chronic participants was considered alone, counselling was no more effective than usual care (overall SMD 0.00, 95% CI -0.31 to 0.31, n = 161, heterogeneity not applicable) (sensitivity analysis 1.1.5, Table 1).

The long-term results were similar when the trial with inadequate allocation was excluded (overall SMD -0.10, 95% CI -0.31 to 0.10, n = 375, heterogeneity chi$^2$ = 3.78, df = 2, p = 0.15, I$^2$ =47%) (sensitivity analysis 2.1.1, Table 1), when the study using GP antidepressant treatment was included as 'usual GP care' (overall SMD -0.05, 95% CI -0.23 to 0.12, n = 540, heterogeneity chi$^2$ = 4.84, df = 4, p = 0.30, I$^2$ =17%) (sensitivity analysis 2.1.2, Table 1), and when the study examining chronic patients only was excluded (overall SMD -0.11, 95% CI -0.34 to 0.11, n = 332, heterogeneity chi$^2$ = 3.79,

df = 2, p = 0.15, I$^2$ =47%) (sensitivity analysis 2.1.3, Table 1) and when the inadequate allocation and chronic participant trials were both excluded (overall SMD -0.15, 95% CI -0.40 to 0.11, n = 232, heterogeneity chi$^2$ = 3.49, df = 1, p = 0.06, I$^2$ =71%) (sensitivity analysis 2.1.4, Table 1). When the trial with chronic participants was considered alone, counselling was no more effective than usual care (overall SMD -0.03, 95% CI -0.36 to 0.30, n = 143, heterogeneity not applicable) (sensitivity analysis 2.1.5, Table 1).

The results of the random-effects models were similar to the fixed-effects analyses in terms of the magnitude of the treatment effect and statistical significance.

There were insufficient trials to assess publication bias via funnel plots (Sutton 2000).

#### Social function outcomes

Three trials reported social function outcomes (Friedli 1997; King 2000; Simpson 2000). Participants receiving counselling did not differ in overall social function compared to participants receiving 'usual care' at either short-term (overall SMD -0.09, 95% CI -0.29 to 0.11, n = 386, heterogeneity chi squared = 0.58, df = 2, p = 0.75, I$^2$ =0.0%) (Analysis 1.2), long-term (overall SMD -0.12, 95% CI -0.33 to 0.08, n = 369, heterogeneity chi$^2$ = 5.49, df = 2, p = 0.06, I$^2$ =64%) (Analysis 2.2) or very long term (overall SMD -0.18, 95% CI -0.56 to 0.20, n = 109, heterogeneity not applicable) (Analysis 3.2).

#### Satisfaction outcomes

Six trials included measures of participant satisfaction (Boot 1994; Chilvers 2001; Friedli 1997; Hemmings 1997; King 2000; Schroer 2009), although one only compared satisfaction between randomised and preference participants (Chilvers 2001) and one did not report the data collected in the pilot project (Schroer 2009). Two trials reported generally high levels of satisfaction with counselling treatments but did not compare satisfaction with 'usual care' directly. The first (Hemmings 1997) used the Counselling Satisfaction Questionnaire (Corney 1984) to assess levels of satisfaction for counselled participants. A total of 132 participants received counselling and 96 completed questionnaires. The majority (82%) felt that counselling had been helpful; that they had been understood (80%); been given enough time (83%) and that the counsellor had been easy to talk to (75%). The second trial (Boot 1994) found that 67 out of 124 participants in the counselling group and 32 out of 68 participants in the 'usual care' group completed questionnaires at six weeks post intervention, soliciting their views of treatment. Significantly more participants in the counselled group reported that they were satisfied with their treatment and had enough time to talk. Two trials (Friedli 1997; King 2000) used a multi-item questionnaire to compare participant satisfaction with counselling and 'usual care' directly, and both found higher levels of satisfaction in the counselling group at short and long-term follow-up.

### Counselling compared with medication

One study reported a comparison of counselling with GP antidepressant treatment (Chilvers 2001).

#### Mental health outcomes

In the single trial comparing counselling with GP antidepressant treatment, there were no significant differences in outcome in either the short (SMD 0.04, 95% CI -0.39 to 0.47, n = 83,

heterogeneity not applicable) (Analysis 4.1) or long-term (SMD 0.17, 95% CI -0.32 to 0.66, n = 65, heterogeneity not applicable) (Analysis 5.1).

### Counselling compared with other psychological therapies

Two trials reported a comparison of counselling with other psychological therapies, both using cognitive behaviour therapy (Barrowclough 2001; King 2000)

#### Mental health outcomes

One trial compared counselling with cognitive behaviour therapy in depressed participants (King 2000). There were no significant differences in outcome either in the short (SMD -0.02 95% CI -0.28 to 0.24, n = 229, heterogeneity not applicable) (Analysis 6.1) or long-term (SMD 0.13, 95% CI -0.14 to 0.41, n = 209, heterogeneity not applicable) (Analysis 7.1).

One trial compared counselling with cognitive-behaviour therapy in anxious older participants (Barrowclough 2001). There were no significant differences in outcome in the short term (SMD 0.53 95% CI -0.09 to 1.14, n = 43, heterogeneity not applicable) (Analysis 8.1), long term (SMD 0.47 95% CI -0.18 to 1.12, n = 39, heterogeneity not applicable) (Analysis 9.1) or very long term (SMD 0.49, 95% CI -0.16 to 1.14, n = 39, heterogeneity not applicable) (Analysis 10.1).

### Counselling compared with other psychosocial interventions

One trial compared counselling and acupuncture but no outcome data were reported (Schroer 2009).

### Tests for heterogeneity

None of the tests for heterogeneity were significant at the p < 0.05 level. The test for heterogeneity approached significance for two of the main comparisons: the analysis of short-term mental health outcomes in studies comparing counselling and 'usual care' (p=0.09, $I^2$ 47.2%, moderate heterogeneity, Analysis 1.1) and analysis of long term social function in studies comparing counselling and 'usual care' (p = 0.06, $I^2$=63.6%, substantial heterogeneity, Analysis 2.2).

The test for heterogeneity approached significance in some of the sensitivity analyses: for the short-term effects on mental health after the exclusion of the studies at high risk of bias (p = 0.10, $I^2$=52.4%, moderate heterogeneity, sensitivity analysis 1.1.1, Table 1); for the sensitivity analysis of short-term mental health outcomes in studies comparing counselling and 'usual care' including the GP antidepressant trial (p=0.08, $I^2$ 46.8%, moderate heterogeneity, sensitivity analysis 1.1.2, Table 1); and in the analysis of long-term effects on mental health excluding the trials with inadequate allocation and chronic patients (p = 0.06, $I^2$=71.4%, substantial heterogeneity, sensitivity analysis 2.1.4, Table 1).

The low power of tests of heterogeneity (Sutton 1998) suggests some caution in the interpretation of the aggregated results, although it should be noted that the variation concerns the size of the treatment effect rather than its direction.

### Economic outcomes

Each economic analysis is described according to the following criteria: analysis type (e.g. utilisation data only, costing, cost effectiveness, cost utility); the type of utilisation data collected; outcome measures; duration of follow up; and results (including sensitivity analyses).

#### Boot 1994

Analysis type: Health service utilisation only

Utilisation data: Psychotropic drugs, antidepressants, anxiolytics, referrals to outside agencies for psychiatric or psychological help, GP consultation rates.

Outcome data: Not applicable.

Duration of follow up: Six weeks.

Results: The counselled group were prescribed significantly fewer psychotropic drugs during the six week trial period than the usual care group (counselled patients, n = 17/107 (16%); usual care, n = 19/60 (32%); chi$^2$ = 4.8; df = 1, P = 0.029). The counselled group were prescribed less antidepressants (counselled patients, n = 10/107 (9%); usual care n = 14/60 (23%); chi$^2$ = 5; df = 1; P = 0.02). No difference was found between groups in the prescription of anxiolytic drugs (counselled patients, n = 6 (9%); usual care n = 3 (8%); Fisher's exact test, P = 0.28). The usual care group received more referrals to outside agencies for psychiatric or psychological help (counselled group n = 4/107 (4%); GP advice group n = 38/60 (63%); chi$^2$ = 69.4; df = 1; P = 0.000). No difference was found between groups in GP consultation rates (counselled group 54/107 (51%); usual care 39/60 (65%); chi$^2$ = 2.7, df = 1; P = 0.1).

#### Hemmings 1997

Analysis type: Health service utilisation only

Utilisation data: psychotropic drugs, referrals to outside agencies for psychiatric or psychological help

Outcome data: Not applicable

Duration of follow up: Four months

Results: 34/116 (25%) of the counselled group received psychotropic medication, compared with 17 (33%) of the usual care group. Half the counselled group either stopped or reduced their medication at four month follow up. In the usual care group, 18/52 (34%) patients had one consultation, 17 (33%) were referred to external agencies, and six (35%) of whom had been referred to psychiatric services.

#### Harvey 1998

Analysis type: Cost minimisation

Utilisation data: medication, primary care and counsellor staff time, and referral to other health care services (cost years 1992 to 1994).

Outcome data: As there were no differences in outcomes, cost data were not linked to outcomes

Duration of follow up: Four months

Results: Excluding referral data, costs in the counselled group were £67.09 and in the usual care group £57.87. When all referrals were included, costs were £71.21 to £81.23 in the counselled

group and £89.67 to £109.51 in the usual care group. Sensitivity analysis examined different methods of estimating referral costs (e.g. inclusion and exclusion of private referrals). When only mental health referrals were included, costs were £68.15 to £74.43 in the counselled group and £67.32 to £83.91 in the usual care group. No tests of statistical significance.

## Friedli 1997

Analysis type: Cost minimisation

Utilisation data: primary care and counsellor staff time, referral to other health care services, days lost from work, travel and childcare. Medication costs were included in the estimates of GP consultation costs (cost years 1995 to 1996).

Outcome data: As there were no differences in outcomes, cost data were not linked to outcomes.

Duration of follow up: Three months and nine months.

Results: At three months, patients in the usual care group tended to increase their visits, whereas the counselled group decreased their visits to the doctor (P = 0.053). At nine months, there were no differences between groups. No differences were found between the groups in the prescription of antidepressants at three months (counselled group 10, usual care group 12). At nine months, there were no significant differences in total direct costs (counselled group were £308.63, usual care group £474.30). At nine months, there were no significant differences in total indirect costs (counselled group £808.70, usual care group £468.50). At nine months, there were no significant differences in total overall costs (counselled group £1191.27, usual care group £963.33). Sensitivity analysis examined the effects of variation in GP and counsellor unit costs. Using the patient self-reported number of counselling sessions made no difference to the results. Use of revised counsellor unit costs increased the direct costs of the intervention group by £15.61 per patient, but GP cost sensitivity analyses not reported.

## King 2000

Analysis type: Cost effectiveness and cost minimisation.

Utilisation data: primary care and counsellor staff time, medication costs, referral to other health care services, days lost from work, travel and childcare (cost years 1997 to 1998).

Outcome data: BDI.

Duration of follow up: Four and twelve months.

Results: At four months, total direct costs for the counselled group were £257.5 (standard deviation (SD) 356.7), for the cognitive-behaviour therapy group £215.5 (SD 108.6) and for the usual care group £244.0 (SD 597.5). At four months, indirect costs were £444.4 (SD 1127.2), £286.1 (SD 701.3) and £383.7 (SD £1194.3) respectively. At four months, there were no significant differences in total overall costs (counselled group £701.9 (SD 1228.4); cognitive-behaviour therapy group £501.6 (SD 715.3), usual care group £627.7 (SD 1359.8)). At 12 months, total direct costs for the counselled group £501.4 (SD 614.8), for the cognitive-behaviour therapy group £448.9 (SD 471.6) and for the usual care group £472.9 (SD 779.3). At 12 months, indirect costs were £897.2 (SD 2336.1),

£1060.5 (SD 1471.1) and £1217.6 (SD 2013.0) respectively. At 12 months, there were no significant differences in total overall costs (counselled group £1398.6 (SD 2474.1); cognitive-behaviour therapy group £1060.5 (SD 1471.1), usual care group £1217.6 (SD 2013.0)). Sensitivity analysis examined the effects of variation in costs of psychological therapy, inclusion of non-attendances at appointments, use of a national wage rate in the calculation of indirect costs, and restriction of the analysis to patients with complete data. It was reported that none of the sensitivity analyses influenced the main conclusions of the study.

## Simpson 2000

Analysis type: Cost minimisation.

Utilisation data: primary care and counsellor staff time, medication costs, referral to other healthcare services, social care and criminal justice services (cost years 1997 to 1998).

Outcome data: As there were no differences in outcomes, cost data were not linked to outcomes.

Duration of follow up: Six and twelve months.

Results: At six months, total service costs in the counselled group were £633 (SD 1152) and in the usual care group £513 (SD 867), mean difference £121, 95% CI -428 to 198. In the period between 6 and 12 months, costs in the counselled group were £384 (SD 520) and in the usual care group £469 (SD 836), mean difference £86, 95% CI -149 to 352.

## Chilvers 2001

Analysis type: Cost effectiveness, using net mean benefit statistics and cost effectiveness acceptability curves.

Utilisation data: depression-related health services resources, including all GP consultations, drugs, use of GP-arranged counselling, and hospital psychiatric outpatient and inpatient visits (cost years 1995 to 1996).

Outcome data: psychiatrists blind rating of global outcome (as a dichotomy), based on Research Diagnostic Criteria, BDI and data in the GP notes. Duration of follow up: 12 months.

At 12 months, there were no significant differences in total depression related health services costs (counselled group £301.63 standard error (SE) 37.72, antidepressant group £343.64, SE 61.87). The probability that antidepressants were more cost effective was 0.75 when one good outcome was valued at £500, and 0.9 when one good outcome was valued over £2000. Sensitivity analysis examined the effects of imputing values for randomised patients with missing outcome data. Assuming good outcomes for patients with missing data lowered the probability that medication was cost –effective, whereas assuming poor outcomes in patients with missing data reduced the cost-effectiveness of medication when willingness to pay for improved outcomes was lower, but increased the probability when willingness to pay for improved outcomes was higher.

## Bower 2003a

Analysis type: Cost effectiveness, based on individual patient data meta-analysis (Friedli 1997; Harvey 1998; King 2000; and Simpson

2000) using net mean benefit statistics and cost effectiveness acceptability curves .

Utilisation data: GP consultations, psychotropic medication, referrals (inpatient psychiatry, outpatient psychiatry, practice-based psychological therapy, community and voluntary psychological therapy providers) (cost years 1999 to 2000).

Outcome data: BDI.

Duration of follow up: short term and long term (variable in the included trials, but adjusted to represent 6 month and 12 month periods).

In the short term, the mean difference in total direct costs between counselled patients and those in 'usual care' was £92, 95% CI 57 to 126. In the long term, the mean difference in total direct costs between counselled patients and those in 'usual care' was £110, 95% CI 38 to 182. The incremental cost-effectiveness ratio for counselling compared to 'usual care' in the short-term was £50 per one point improvement on the BDI. The probability that counselling was cost effective in the long term was over 50% when a reduction of one point on the BDI was valued at £196, and was 69% when a reduction of one point on the BDI was valued at £2000. Sensitivity analysis examined duration of GP consultations and costs of psychological therapy. Differences in total costs were sensitive to the estimate of consultation length in usual GP care and estimates of the costs of counselling.

[Schroer 2009](#)

Analysis type: Not reported

Utilisation data: Primary and secondary healthcare services, private sector health services, additional complementary therapies, all contacts with acupuncture practitioners, counsellors, medications (prescribed and over-the-counter), herbs and remedies.

Outcome data: BDI.

Duration of follow up: short term and long term.

Data not reported

# DISCUSSION

## Summary of main results

The updated review added only one study ([Schroer 2009](#)), which was a pilot study prior to a fuller trial (listed in the 'Characteristics of ongoing studies' table). Although outcome data were collected as part of this pilot, they were not included in the published paper, and correspondence with one of the authors suggested that the study was not designed as an assessment of effectiveness and thus the outcomes from the pilot should not be included in the meta-analysis. There were therefore no major changes to the overall conclusions of the review.

In summary, there is evidence that counselling is more effective than usual care in terms of mental health outcomes in the short term (standardised mean difference (SMD) -0.28, 95% CI -0.43 to -0.13, n = 772, 6 trials). However, these advantages do not endure in the longer term (SMD -0.09, 95% CI -0.27 to 0.10, n = 475, 4 trials). Counselling may not differ in effectiveness from medication

and cognitive-behavioural therapy, although the precision of these estimates (especially differences in outcomes between cognitive-behavioural therapy and counselling in older patients with anxiety) are necessarily limited. Counselling may be associated with some reductions in aspects of health service utilisation in the United Kingdom, but overall costs did not seem to be reduced, and may be increased, based on the individual patient data analysis across several of the included studies, conducted outside the Cochrane review ([Bower 2003a](#)). Participants were generally satisfied with counselling in primary care, but any benefits of counselling did not seem to extend to measures of social function.

Issues of relevance to the interpretation of the review are considered below.

## Types of participants

Clinical diagnosis was not a factor in selecting and recruiting participants in a number of trials included in this review. It has been argued that studies lacking confirmation of caseness or diagnosis are limited, since outcomes cannot be divorced from the natural history of a condition ([Hughes 1998](#)). Lack of diagnostic assessment has meant that some studies included in the review have been excluded by clinical guidelines, because not all participants have a confirmed diagnosis ([NICE 2010](#)). While it is possible that interventions targeted to a specific diagnostic group may be more likely to demonstrate positive outcomes ([Roth 1996](#)), such trials may not accurately reflect how psychological therapies such as counselling are delivered in routine primary care, where GPs may be more likely to consider the frequency and severity of symptoms or problems than diagnosis (King 1998).

In terms of severity at baseline, the most frequently used measure in the included studies was the Beck Depression Inventory, and the baseline scores in trials using that measure were around 20 ([Friedli 1997](#).[Simpson 2000](#)), 26 ([King 2000](#)) and 27 ([Chilvers 2001](#)). An examination of baseline scores found in studies of cognitive behaviour therapy for diagnosed major depression found in the United Kingdom NICE depression guidelines ([NICE 2010](#)) and other sources found baseline scores that were not dissimilar: 24 ([Blackburn 1981](#)), 27 ([Elkin 1989](#)), 29 ([Scott 1997](#)). However, it was more difficult to compare other studies included in the review which used different outcomes, and there may be other differences between patients with similar symptom scores but different rates of diagnosed disorder (e.g. duration of disorder).

Generally GPs were encouraged to recruit all participants they considered suitable for counselling, but they may have been reluctant to recruit some participants to the study, and some authors reported that gathering information on such participants from GPs is difficult ([Friedli 1997](#); [Harvey 1998](#); [King 2000](#)). While it is inappropriate to assume that patients participating in these trials were representative of eligible patients generally, all the included trials used similar procedures, so they can reasonably be combined. Nevertheless, caution must be exercised when generalising the results to the wider population of patients in primary care. The new study included in the updated review used referral from primary care practitioners and recruitment of cases through computerised primary care databases ([Schroer 2009](#)). Such searches are increasingly used to recruit depressed patients in primary care and can be more efficient. However, such methods potentially access a different population of patients from those recruited by the GP.

## Types of interventions

There is a tension in the present review between the international nature of a Cochrane review, and the topic of 'counselling in primary care', which has developed largely within the context of health care in the United Kingdom. The use of definitions of counselling and accreditation criteria based on a single national organisation creates a number of difficulties. First, the results of the review may not be generalisable to other healthcare contexts. Second, it is not clear whether the inclusion criteria developed for the review will be appropriate if trials are identified from other countries. Finally, the inclusion or exclusion of particular therapies has not been made on the basis of empirically justified criteria. For example, a therapist in one trial (Hemmings 1997) was reported as having trained in cognitive analytic therapy, which is not generally seen as a mainstream form of counselling. However, the counsellors in this trial did meet the BACP criteria and the author confirmed that the interventions offered were consistent with the BACP definition of counselling.

At present, the literature on counselling in primary care is largely restricted to the United Kingdom, as studies in the United States have tended to focus more on defined therapies such as cognitive behaviour therapy and interpersonal therapy. At present, the results of the review are more clearly applicable to the United Kingdom health care system.

None of the trials attempted to standardise 'usual care', and the GP interventions were monitored only from the perspective of gathering health service utilisation data. While some information about medication and referrals was available, there are no other details of the therapeutic encounter between GPs and their patients. Again, it is possible GPs were offering a sympathetic listening approach and that the interventions of counsellors and GPs were somewhat similar (Tylee 1998).

The practices and GPs recruited to the studies were volunteers rather than a random sample. The doctors who participated may have been particularly interested in the research question and may have used therapeutic techniques to a greater extent than is usual, thus reducing the additional effect of counselling (Friedli 1997). In addition, in one trial (Hemmings 1997), GPs participated in an Action Learning programme, in which they learned about counselling and counselling skills. This may have influenced their consultation style and referral practices.

## Types of outcomes

Almost all the outcomes were reported in terms of continuous scales, which may provide a more accurate and sensitive assessment of outcomes than dichotomising outcomes, but can make interpretation more difficult. The current study used the standardised effect size as a useful summary measure, which has also been used in major meta-analyses in the general psychological therapy literature. There are a number of ways of interpreting such an effect. Assuming that the scores of the treatment and control groups correspond to a normal distribution, effect sizes can be converted into percentiles (Roth 1996). The effect size of -0.28 found in the main short term comparison (Analysis 1.1) is relatively modest, and indicates that the average treated patient had a score approximately at the 60th percentile of scores for the untreated group. If the treatment had no effect, the scores of the average treated patient would be at the 50th percentile of scores (Roth 1996). A standardised mean difference can also be converted to an

estimate of number needed to treat (NNT) if certain assumptions are upheld, and the present estimate would represent an NNT of around 6 (Kraemer 2006). Finally, of those studies in the review which used the Beck Depression Inventory, the pooled standard deviations of scores at short term follow up was 9.3, and an effect size of -0.28 would represent a reduction of around 2.6 on that scale associated with the provision of counselling.

Comparisons with the effects of alternative treatments in other reviews is problematic, as differences may relate to variation in study settings, patient populations and study quality. However, it should be noted that the effect size reported in the current review is not markedly different from those reported in other published meta-analyses of psychological and organisational interventions for depression, where they have been restricted to primary care settings (Bortolotti 2008; Cape 2010; Gilbody 2006).

Participants allocated to counselling tended to be satisfied with the help they received from counsellors, and more satisfied than those who remained under 'usual care'. However, satisfaction is not necessarily related to outcome, and satisfaction measures are open to response bias associated with the trial, such as a desire to please the therapist, and to be seen as a polite and courteous person (Hemmings 1997). The comparison of counsellors and GPs is also confounded with the time available to the two types of professionals: differences in satisfaction may be reduced or disappear entirely if both professionals were able to provide 50 minute sessions. Although patient satisfaction is increasingly seen as an important outcome in its own right, its status as a factor in decision-making about treatment provision in clinical guidelines is more ambiguous.

The analysis of economic outcomes was complicated by the range of different analytic techniques used, ranging from simple analyses of health service utilisation through more sophisticated net mean benefit calculations and cost-effectiveness acceptability curves. Given the difficulty of synthesising results across all the included studies, the included individual patient data analysis (Bower 2003a) may represent the best current estimate of the effects of counselling on costs. The data would suggest that counselling is associated with an increase in costs, although that finding is sensitive to assumptions made in the analysis. Whether those cost increases are justified is dependent on the value placed on the significant though modest benefits in patient outcomes.

## Overall completeness and applicability of evidence

Although the review was concerned with mental health and psychosocial problems, and the studies included participants considered relevant for counselling by general practitioners, the primary outcome assessed was usually depression, and the impact of counselling on other outcomes is less well understood. As highlighted above, the topic of 'counselling in primary care' has developed largely within the context of health care in the United Kingdom and the evidence available is restricted to this setting.

## Quality of the evidence

The review included nine studies and 1384 randomised patients, allowing estimates of the short term effects of counselling on mental health with a reasonable degree of precision, although the confidence intervals included effects which may not represent a clinically significant impact. There is clearly scope for further

studies to improve the precision of estimates, allow estimation of the long-term benefits of counselling, and to explore effectiveness in different patient populations and against different comparator treatments. The review has identified methodological limitations in the studies, although some of these (i.e. blinding) reflect difficulties in applying methodological safeguards in the context of psychological therapy generally, rather than weaknesses of the studies included in the review. Patient self-reported measures used with patients who are unblinded to their treatment were judged as being at high risk of bias in the current review, although some researchers question whether such measures are as vulnerable to bias as unblinded observer measures (Friedli 1997). However, given the consistency of the rating across studies, this would be unlikely to have a substantive effect on the results of the review.

### Potential biases in the review process

The definitions of counselling adopted in the review represent the United Kingdom context which means that relevant international evidence may have been excluded, although the list of excluded studies did not appear to include studies that were excluded arbitrarily. Sensitivity analyses on types of interventions, populations and on quality were based on issues identified during the review, rather than being pre-specified, which may have introduced bias. The identified economic analyses were not subject to formal critical appraisal and, as such, it is important to consider that in drawing conclusions about relative resource use, costs or efficiency of counselling in primary care compared with usual care.

### Agreements and disagreements with other studies or reviews

As noted previously, the short term effects of counselling reported in the current review are not markedly dissimilar to those reported in other published meta-analyses of psychological and organisational interventions for depression, where they have been restricted to primary care settings. For example, cognitive behaviour therapy demonstrates an effect size of -0.33 (95% CI -0.60 to -0.06, 4 studies) in depression and -0.26 (95% CI -0.44 to -0.08, 2 studies) in mixed anxiety and depression, while problem solving treatment demonstrates an effect of -0.26 (95% CI -0.49 to -0.03, 6 studies) in depression and -0.17 (95% CI -0.41 to 0.07, 6 studies) in mixed anxiety and depression (Cape 2010). A large review of collaborative care interventions in primary care (Gilbody 2006) demonstrated an effect size of -0.25 (95% CI -0.18 to -0.32, 35 studies). Another review of psychological treatments in primary care reported an effect size of -0.42 (95% CI -0.59 to -0.26, 6 studies) for major depression (Bortolotti 2008).

It has been suggested that counsellors working in primary care can lead to a reduction in health service utilisation, including fewer referrals to psychiatric services, fewer prescriptions and fewer GP consultations. Another Cochrane review which included some of the studies from the present review among a larger data set suggested that this may occur for mental health professionals generally, but that the effects are limited in scope and consistency (Harkness 2009). The current data reflected the findings of the wider review, as there was some evidence that modest reductions in health service utilisation did take place. Some studies suggested that the provision of counselling was not associated with increased costs, but such analyses are hampered by small sample sizes (Briggs 2000) and the finding of no differences in costs must be interpreted cautiously, particularly since the exploratory individual

patient data meta analysis indicated that the costs associated with counselling may be higher, which supports the argument that previous analyses were underpowered (Bower 2003a).

## AUTHORS' CONCLUSIONS

### Implications for practice

Although the exact estimate of effect size depends on the trials included in the analysis, the results demonstrate some consistency in suggesting that counselling is significantly more effective in reducing mental health symptoms in the short-term, but appears to provide no additional advantage in the long-term.

The implication of this finding for the provision of counselling in current stepped care models depends fundamentally on the importance attached the size of the short-term effect, and the comparison with the effects found in relation to alternative treatments, especially cognitive behaviour therapy. Although some reviews suggest that the overall effects of different therapies are similar in primary care settings (Cape 2010), evidence reviews undertaken for clinical guidelines in the United Kingdom are not generally restricted to a single setting such as primary care (NICE 2010). There is some evidence that treatments provided in primary care may demonstrate smaller effects than those in secondary settings (Raine 2002) although it is not clear whether this represents differences in patients, treatments or study quality (Churchill 2002).

The results can only be generalised to similar patients and counsellors. This means that the evidence is restricted to counsellors with BACP accreditation or equivalent. Some of the trials have been restricted to patients with a certain level of disorder, such as a threshold score on the Beck Depression Inventory or Patient Health Questionnaire (King 2000; Schroer 2009; Simpson 2000). Although such severity scores may not be generally available to practitioners in all contexts, such measures are incentivised for use in some primary care settings such as the United Kingdom (Kendrick 2009).

Factors predicting which patients benefit most from counselling and other psychological therapies in primary care are not well understood at present. The United Kingdom Department of Health guidelines suggest that age, sex, social class and ethnicity should not determine access to psychological therapies such as counselling (DOH 2001).

The current evidence suggests that provision of counselling may make a useful addition to primary care services alongside other mental health treatments. Commissioners of services can use the information contained in this review to assist in decision-making about current and future service provision.

The ongoing trial identified in this updated review will add significantly to the evidence base for counselling when it reports in the next 18 to 24 months. The trial has randomised 755 participants between counselling, acupuncture and usual care.

### Implications for research

Although pragmatic trials do not attempt to instigate the highest levels of experimental control, it is important that studies adequately describe the participants, treatments and other factors that are involved in the trial. For example, although 'patients

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suitable for counselling' is a pragmatic criterion for entry to a trial, it would still be helpful to provide information on all types of problems that were eventually referred (e.g. diagnoses). Equally, although treatments may not be highly standardised, it is important to know that treatments were distinct, which may require more extensive descriptive work (especially of the content of GP care) or use of validated rating scales of therapy content (King 2000). Data extraction and quality ratings in the review would be improved if sufficient information on key methodological details were always provided, and the importance of concealment of allocation suggests that routine use of an external randomisation agency is justified.

Although the review provides information on comparisons between counselling and three other treatments (usual care, GP antidepressant treatment and cognitive behaviour therapy), the evidence is limited with respect to two of those treatments. Given the importance of cognitive behaviour therapy in current delivery of care for depression and other mental health problems, there is clearly a need to further assess the comparative effectiveness of counselling and cognitive behaviour therapy to increase the precision of the current estimate, and there is scope to compare counselling with other psychological therapy treatments, such as problem-solving (Mynors-Wallis 1997) or interpersonal therapy (Schulberg 1996) and the new generation of guided self-help treatments (Gellatly 2007). The ongoing trial identified in this updated review is assessing the effectiveness of counselling against both usual general practitioner care and acupuncture (Schroer 2009). As outlined in the introduction, extending the evidence base in this way would have the potential to increase patient choice about psychological therapies, if other interventions are demonstrated to be effective. Questions about the importance of patient preferences as determinants of outcome also remain (King 2005), although there are significant methodological barriers to the assessment of the effects of preferences (Torgerson 1996).

Research into the long-term outcome of patients treated with psychological therapies is a key priority. Although one trial included outcomes at 36 months (Simpson 2000), this was in a population of chronically ill patients who did not demonstrate gains in the short term. More research is required into the long-term clinical and economic impacts of psychological therapies such as counselling, although the methodological and logistical challenges are significant.

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* Indicates the major publication for the study

# CHARACTERISTICS OF STUDIES

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

### Barrowclough 2001

| Methods | RCT |
|---|---|
| | Recruitment: Patients referred from primary care and community services, and self referrals were also accepted following advertisements in local newspapers. The majority of referrals came from primary care. |
| | Randomisation: Patients randomly allocated using minimisation stratified on severity of symptoms, co-morbid psychiatric disorder and diagnosed anxiety disorder. Randomisation conducted by means of a computer program operated by an independent third party. |
| | Follow up: 16 weeks (post treatment) and 3, 6 and 12 months |
| | Attrition: Nine participants lost in baseline period before access to treatment (six declined to enter therapy or complete follow up, three patients excluded because of serious physical illness), three dropped out within first four sessions and were lost to follow up. Forty three participants completed treatment and retention at follow up was 39/43 (91%) at three months, 39/43 (91%) at six months and 40/43 (93%) at 12 months. |
| Participants | Treatment = 24 Control = 19 (n=43 excluding those lost in six week baseline period, total n=55, Treatment=28, Control=27) |
| | Included: Patients, aged 55 and over, diagnosed with anxiety disorder by SCID (panic disorder with and without agoraphobia, social phobia, GAD and anxiety disorder not otherwise specified, Beck Anxiety score outside the normal range and assessed by the GP as not suffering from medical conditions that produces anxiety symptoms. |
| | Excluded: Patients with evidence of significant cognitive impairment, patients on medication which was constant for three months before entry and planned to remain constant for the duration of the study. |
| | Age: Mean 72.0 (SD 6.2) |
| | Gender: Male 10 (23%); Female 33 (77%). |
| | Martial status: 21 (49%) married, 17 (39%) widowed, three (7%) divorced, two (5%) single |
| | Education: 41 (95%) left school between 14 and 16, two (5%) completed college/university |
| | Medication: 100% prescribed medication, 25 (58%) anxiolytics, 22 (51%) antidepressants, four (9%) both |
| | Accommodation: 42 (98%) own accommodation, one (2%) sheltered |
| | Health: eight (19%) had no current physical health problem |
| | Anxiety: 22 (51%) panic disorders with and without agoraphobia, one (2%) social phobia, eight (19%) GAD and 12 (28%) anxiety disorder not otherwise specified, mean duration 20 years (SD 20) |
| | Comorbidity: 10 (23%) had comorbid psychiatric disorders, seven (16%) concurrent mood disorder secondary to anxiety, two (5%) panic as secondary to primary anxiety disorder, one (2%) GAD secondary to primary anxiety disorder |
| | Setting: Not clear |
| | Region: Manchester, England. |
| Interventions | Treatment: Supportive counselling by BACP accredited counsellor and psychology graduate (n = 1), detailed in a treatment manual, involving verbal and nonverbal attending, active listening, open questioning, reflecting back, paraphrasing and summation. Monthly peer supervision to ensure treatment fidelity, audiotaping for fidelity check. |
| | Control: CBT from doctoral level clinical psychologists with specialist training in cognitive therapy (n=2), detailed in manuals, particular CBT models based on particular diagnoses. Monthly peer supervision to ensure treatment fidelity, audiotaping for fidelity check. |
| | Duration: Treatment: 8-12 sessions of 1 hour over 16 weeks, majority delivered in patient's home |

**Barrowclough 2001** *(Continued)*

Control: 8-12 sessions of 1 hour over 16 weeks, majority delivered in patient's home

Mean 10.7 sessions SD 1.2 for both therapies, no difference between therapies

| | |
|---|---|
| Outcomes | Instruments: Beck Anxiety Inventory (BAI), State-Trait Anxiety Inventory (STAI) Trait form, Hamilton Rating Scale for Anxiety (HRSA), Beck Depression Inventory, Geriatric Depression Scale (GDS), Credibility of Treatment questionnaire. |
| Notes | |

*Risk of bias*

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Minimisation by computer programme |
| Allocation concealment (selection bias) | Low risk | Computer program used by independent third party |
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Participants and personnel could not be blinded, outcome likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias) Patient reported outcomes | High risk | Self report and likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias) Observer rated outcomes | Low risk | Assessor not aware of treatment allocation |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | Follow up was 71% at three months (treatment 23/28, control 16/27) 71% at six months (treatment 23/28, control 16/27) and 73% at 12 months (treatment 23/28, control 17/27), no reasons for missing data provided by group |
| Selective reporting (reporting bias) | Unclear risk | No protocol available |
| Other bias | Unclear risk | Insuficient information available to assess |

**Boot 1994**

| | |
|---|---|
| Methods | RCT |
| | Recruitment: Patients identified by GPs during routine consultations. Criteria for trial eligibility were agreed by GPs and counsellors prior to the study. |
| | Randomisation: Random allocation made using a card where concealed experimental and control options were prepared in advance by computer. With consent, patients entered into study and then randomly allocated to treatment or control by GP by peeling sticker from patient allocation card to reveal allocation. |
| | Follow up: six weeks (post-treatment) |

**Boot 1994**  *(Continued)*

|  | Attrition: 12/204 (6%) patients refused entry to trial. 67/124 (54%) Treatment patients followed up and 41/68 (60%) Control patients followed up. Health care utilisation data from GPs for 88% Treatment and 86% Control groups. |
|---|---|
| Participants | Treatment = 124 Control = 68 |
|  | Included: Patients, aged 16 and over, presenting with recent rather than chronic psychological and emotional problems (e.g., stress, crisis, relationship or family problems, anxiety, depression, bereavement, sexual difficulties, employment and financial problems). |
|  | Excluded: Patients with severe psychiatric problems (not specified). |
|  | Age: Mean 38.7<br>Gender: Male 66 (35%); Female 126 (65%).<br>Class: I/II 57 (30%); III 43 (22%); IV 33 (17%); V 33 (18%); Student/NK 23 (12%) |
|  | Setting: seven General Practices<br>Region: Northamptonshire, England. |
| Interventions | Treatment: One to one counselling by BACP accredited or accreditable counsellors (n = 5), using BACP definition of counselling. |
|  | Control: Usual GP care (n = 28). |
|  | Duration: Treatment: Usually a single one hour session per week for six weeks. 107 received 54 GP consultations in 6 weeks.<br>Control: 60 patients received 39 GP consultations over 6 weeks. |
| Outcomes | Instruments: General Health Questionnaire (GHQ); Health service usage (GP consultation rates, prescribing and referrals to external agencies) extracted from medical records; Patient evaluation of treatment (4 item measure). |
| Notes |  |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Prepared by computer |
| Allocation concealment (selection bias) | High risk | Identified problems with allocation procedure in one GP, although corrected at an early stage, may refer to unconcealed allocation |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Participants and personnel could not be blinded, outcome likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias)<br>Patient reported outcomes | High risk | Self report and likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias)<br>Health care utilisation | Low risk | Extracted by GP from patient records |
| Incomplete outcome data (attrition bias) | Unclear risk | Follow up at six weeks was 56% (67/124 in treatment and 41/68 in controls) for primary GHQ outcome, no reasons for missing data provided by group |

**Boot 1994**  *(Continued)*
　　All outcomes

| | | |
|---|---|---|
| Selective reporting (reporting bias) | Unclear risk | No protocol available |
| Other bias | Unclear risk | Insuficient information available to assess |

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**Chilvers 2001**

| | |
|---|---|
| Methods | Patient preference RCT |
| | Recruitment: GPs assessed patients using checklist (Research Diagnostic Criteria for Major depression). Those with mild to moderate depression recruited. |
| | Randomisation: Blocks of four stratified by practice. Allocation by telephone. Patients who refused randomisation received treatment of choice. |
| | Follow-up: eight weeks and 12 months |
| | Attrition: For randomised patients, 85/103 (83%) completed eight week questionnaire; 78/103 (76%) attended eight week visit with GP; 65/103 (63%) completed 12 months questionnaire, 46/103 (45%) attended for 12 month visit with GP; 99/103 (96%) had 12 month case note review. For preference patients, 164/220 (75%) completed 8 week questionnaire; 142/220 (65%) completed 12 months questionnaire, 80/220 (36%) attended for 12 month visit with GP; 212/220 (96%) had 12 month case note review. Significant difference (p = 0.01) in attendance at 12 months follow up appointment - attendance ranged between 25% for patients choosing antidepressants to 53% for those randomised to antidepressants. |
| Participants | Randomised:<br>Treatment = 52 |
| | Medication =51<br>Preference:<br>Treatment = 140<br>Medication = 80 |
| | Included: Aged 18 to 70, met Research Diagnostic Criteria. |
| | Excluded: Suicidal; psychotic; post natal depression; recent bereavement; drug or alcohol misuse. |
| | Age: Mean 37.8<br>Gender: Male 23%<br>Class: I/II 30%; III 38%; IV or V 33%<br>Ethnicity: not reported. |
| | Setting: 31 practices<br>Region: Trent health region, UK |
| Interventions | Intervention: Treatment: Generic counselling provided by trained counsellor |
| | Medication: Antidepressant treatment from GP |
| | Duration: Treatment: Six session guideline - actual number not clear<br>Medication: Not clear |
| Outcomes | Instruments: Beck Depression Inventory (BDI); Research Diagnostic Criteria (RDC); GP rating: SF - 36; global outcome. |
| Notes | |

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**Chilvers 2001**  *(Continued)*

### Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Stated 'random' only |
| Allocation concealment (selection bias) | Low risk | Central randomisation by telephone |
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Participants and personnel could not be blinded, outcome likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias) Patient reported outcomes | High risk | Self report and likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias) Observer rated outcomes | Low risk | RDC criteria and psychiatrist ratings blinded, adequacy of blind checked |
| Blinding of outcome assessment (detection bias) Health care utilisation | Low risk | Extracted from GP and hospital case notes |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | Follow up at 8 weeks was 83% (40/52 in treatment and 45/51 in controls), 12 month case note review was 96% (50/52 in treatment and 49/51 in controls) 12 month questionnaire was 63% (31/52 in treatment and 34/51 in controls), no reasons for missing data provided by group |
| Selective reporting (reporting bias) | Unclear risk | No protocol available |
| Other bias | Unclear risk | Insuficient information available to assess |

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**Friedli 1997**

| Methods | RCT |
|---|---|
| | Recruitment: Patients presenting with emotional difficulties identified and referred for entry into study, with patient consent, by GP. |
| | Randomisation: Block randomisation was carried out. Two sets of blocks of six (three therapist and three GP) random combinations were sealed in consecutive envelopes. Patients were randomly assigned to therapist or GP at the end of the baseline assessment by researcher. |
| | Follow up: three months and nine months |
| | Attrition: 35/171 patients identified by GPs as eligible for trial, were excluded, of whom 20 refused entry. Of 35 non participants, 80% female. 110 (81%) followed up at three months and 117 (86%) at nine months. At nine months 62 (89%) Treatment and 55 (83%) Control followed up. No significant differences in baseline scores between those followed up and those lost to follow up. |
| Participants | Treatment = 70 Control = 66 |

**Friedli 1997** *(Continued)*

| | |
|---|---|
| | Included: Patients aged 18 years or over, with recent onset (last six months) of emotional difficulties deemed by GP to require brief psychotherapy. No consultation for emotional illness for 12 months before index episode. |
| | Excluded: Receiving psychological treatment; psychotic or chronic mental illness; actively suicidal; severe drug or alcohol dependency; physical illness such that unable to attend surgery; language difficulties, illiteracy; learning disability. |
| | Age: Mean age 39<br>Gender:<br>M: 26 (19%); F: 110 (81%)<br>Class: I - IIIa 102 (81%); IIIb - V 24 (19%)<br>Ethnicity: White 125 (92%); Non white 11 (8%) |
| | Setting: 14 general practices<br>Region: N.W. London, UK. |
| Interventions | Treatment: Brief non-directive (Rogerian) one-to-one psychotherapy by four BACP accredited or accreditable counsellors. |
| | Control: Standard GP care. Fourteen practices in London, UK; number of GPs who referred or participated is unclear. GPs discouraged from referring patients to therapist during trial unless essential. |
| | Duration: Treatment: 6 to 12 sessions of 50 mins. Mean 7.7 sessions (SD 3.8, range 1 to 12).<br>Control: Not reported. |
| Outcomes | Instruments: Beck Depression Inventory (BDI); Brief Symptom Inventory (BSI); Modified Social Adjustment Scale (SAS); Revised Clinical Interview Schedule (CIS). Patient satisfaction with treatment measured using Brief Structured Recall for Satisfaction. |
| Notes | |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Stated random combinations in envelopes only |
| Allocation concealment (selection bias) | Unclear risk | Sealed, consecutive envelopes |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Participants and personnel could not be blinded, outcome likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias)<br>Patient reported outcomes | High risk | Self report and likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias)<br>Health care utilisation | High risk | Self report and likely to be influenced by lack of blinding |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | Follow up at three months was 81% (59/70 in treatment and 51/66 in controls), at nine months was 86% (62/70 in treatment and 55/66 in controls), no reasons for missing data provided by group |

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**Friedli 1997**  (Continued)

| | | |
|---|---|---|
| Selective reporting (reporting bias) | Unclear risk | No protocol available |
| Other bias | Unclear risk | Insuficient information available to assess |

### Harvey 1998

| | |
|---|---|
| Methods | RCT |
| | Recruitment: GPs identified suitable patients; requested consent; recorded baseline data; completed scales and then randomised patient. |
| | Randomisation: Subjects randomly allocated using sealed opaque envelopes prepared outside the practices by the research team. Regular checks made to ensure envelopes being opened in strict number order. Block randomisation (six block size) was used, with a 2:1 ratio in favour of counselling to avoid waiting lists for counselling. |
| | Follow up: 4 months. |
| | Attrition: 122/162 (75%) patients followed up at four months, 24% and 26% from each arm (not clear which, presumably Treatment and Control respectively). |
| Participants | Treatment = 111 Control = 51 |
| | Included: Patients aged 16 and over with minor mental health problems, irrespective of previous mental health history. |
| | Excluded: Patients with phobic conditions or psychoses. |
| | Age: 37.0 (median)<br>Gender: Male 42 (26%); Female 120 (74%)<br>Class: Non manual 54 (36%); Manual 18 (12%); Economically inactive 80 (53%) |
| | Setting: GP surgeries and health centres.<br>Region: Cardiff and Swansea, Wales. |
| Interventions | Treatment: Brief non-standardised person centered one to one counselling (including solution focused, cognitive behavioural) by nine different professionals. Counsellors were BACP accredited or trained to diploma standard. |
| | Control: Routine GP care (GPs from nine practices) including drug treatment, referral to secondary care or other agencies. |
| | Duration: Treatment: Treatment offered up to six weekly sessions of 50 mins, median attended three (mean 4.2), 3.67 hours, IQR of 5.3, 3.6% (n = 3 ) DNA. Control: Mean 1.5 hrs GP time, 0.22 referrals. |
| Outcomes | Instruments: Hospital Anxiety and Depression Scale (HAD); COOP/WONCA functional health assessment scales; Duke Functional Social Support Scale (DFSS); Delighted-Terrible Faces overall assessment of quality of life (DT); Short Form 36 (Swansea practices only). Cost of counsellor time £11 (actual costs) or £15 per hour (from recent survey). GP time cost £25 per hour. Cost of medication and referrals to other agencies (latter based on mean prices set by NHS Trusts in Avon). Sensitivity analysis used three approaches to referral costs 1) assumed NHS costs only and that number of Out Patient appointments consistent with specialty follow up patterns observed 2) As above, but included costs of private referrals 3) assumed that each out patient referral resulted in only one appointment and included costs of private referrals. |
| Notes | |

**Harvey 1998**  *(Continued)*

### Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Stated block randomisation only |
| Allocation concealment (selection bias) | Low risk | Opaque, sealed envelopes, but checks made to make sure they were opened in strict number order |
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Participants and personnel could not be blinded, outcome likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias) Patient reported outcomes | High risk | Self report and likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias) Health care utilisation | Low risk | Data from clinical notes |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | Follow up at four months was 75% (24% and 26% lost per group, but not clear which), no reasons for missing data provided by group |
| Selective reporting (reporting bias) | Unclear risk | No protocol available |
| Other bias | Unclear risk | Insuficient information available to assess |

**Hemmings 1997**

| Methods | RCT |
|---|---|
| | Recruitment: Identification, request for consent and randomisation by GPs. |
| | Randomisation: GP opened a sealed random selection envelope containing either a Counselling or Control slip, in a ratio of 2:1. Actual ratio at end of study was 2.85:1. One GP's patients were excluded from the study after referring nine subjects to Counselling group and only one to routine treatment (a chance referral ratio of more than 6:1 was considered unlikely). |
| | Follow up: four months and eight months |
| | Attrition: 154 (82%) patients followed up at four months and 100 (53%) at eight months. 114/136 (84%) Treatment and 40/52 Control (77%) followed up at four months. Figures given identical for eight months but from percentages would be 76 Treatment (56%) and 24 Control (46%). |
| Participants | Treatment = 136 Control = 52 |
| | Included: GPs and counsellors agreed criteria taking into account counsellors' training and skills. Included patients with anxiety disorders, including phobic anxiety and obsessive compulsive disorder; depressive disorder; undifferentiated somatoform disorders; psychosexual problems; relationship and family problems; bereavement and substance misuse problems. |
| | Excluded: Patients with very severe depression. |

**Hemmings 1997** *(Continued)*

Age: Mean age 36.8
Gender:
Male 52 (28%); Female 136 (72%)
Class: I/II 11 (6%); IIINM 44 (23%); IIIM 31 (17%); IV 47 (25%); Housewife 55 (29%)

Setting: one urban, two semi rural general practices.
Region: Sussex, England.

| | |
|---|---|
| Interventions | Treatment: One to one generic counselling by three different professionals who met minimum requirement for BACP accreditation. Consistent with BACP definition of counselling (personal communication, 2000). Cognitive analytic and psychosynthesis used by two counsellors. |
| | Control: Routine care including reassurance and advice. |
| | Duration: Treatment: Mean 5.7 sessions per patient (range 0 to 14); no description of length of sessions, assumed therapeutic hour (50 mins). No details of GP consultations. |
| | Control: 18 (34%) had one consultation only, 17 (33%) referred to external counselling and psychology services; 17 (33%) prescribed psychotropic medication; six of whom were referred to psychiatric services. No details of GP consultations. |
| Outcomes | Instruments: Symptom Index; Inventory of Interpersonal Problems; Eyesenck Personality Questionnaire: Repertory Grids; Counselling Satisfaction Questionnaire. Medical notes for details of external referrals and medication. No cost effectiveness analysis undertaken. |
| Notes | |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Stated random only |
| Allocation concealment (selection bias) | High risk | Sealed envelopes only, patients removed because of irregularities in randomisation process which lead to randomisation ratio of 2.85 to 1, rather than expected 2 to 1 |
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Participants and personnel could not be blinded, outcome likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias) Patient reported outcomes | High risk | Self report and likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias) Health care utilisation | Low risk | Data extracted from GP notes |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | Follow up at four months was 82% (114/136 treatment and 40/52 control), at eight months 53% (76/136 treatment and 24/52 control), no reasons for missing data provided by group |
| Selective reporting (reporting bias) | Unclear risk | No protocol available |
| Other bias | Unclear risk | Insuficient information available to assess |

## King 2000

| | |
|---|---|
| Methods | Patient preference RCT |
| | Recruitment: Identification by GP. |
| | Randomisation: By numbered, sealed, opaque envelopes. Allocation was blocked and stratified for BDI score. Patients either randomised between all three treatments, between two psychological therapies, or allocated by preference. Separate randomisation schedules for randomisation between three treatments and randomisation between the two psychological therapies, and for each assessor. |
| | Follow-up: 4 and 12 months. |
| | Attrition: 180/197 (91%) of patients randomised between the three treatments at four months; 165/197 (84%) at 12 months. 111/130 (85%) of patients randomised between two treatments at four months; 101/130 (78%) at 12 months. 120/137 (88%) of patients with preferences at four months; 106/137 (77%) at 12 months. |
| Participants | Randomised between three therapies (NDC 67, CBT 63, GP 67). Randomised between two therapies (NDC 59, CBT =71). Preference allocation (NDC 54, CBT 81, GP = 2) |
| | Included: Patients with depression or mixed anxiety/depression. |
| | Excluded: Suicidal; therapy in last 6 months; on anti-depressants; restricted mobility; organic brain syndrome; language or learning difficulties. |
| | Age: Mean 39 in NDC, mean 36 in CBT, mean 37 in GP Gender: 53 (79%) F in NDC, 49 (78%) in CBT, 50 (75%) in GP. Class: I -III: 46 (69%) in NDC, 40 (66%) in CBT, 45 (67%) in GP. Ethnicity: 61 (92%) white in NDC, 57 (91%) in CBT, 59 (89%) white in GP. |
| | Setting: 24 practices Region: London and Greater Manchester, although some patients seen in hospital and community setting. |
| Interventions | Treatment 1 = Non directive counselling from BACP accreditable therapists Treatment 2 = cognitive-behavioural therapy from BABCP accreditable therapists Control = Routine GP care. |
| | Duration: Treatment 1 = mean of 6.4 sessions plus 7.7 surgery contacts over 12 months Treatment 2 = mean of 5.0 sessions plus mean of 6.5 surgery contacts over 12 months Control = mean of 9.1 surgery contacts over 12 months |
| Outcomes | Instruments: Beck Depression Inventory; Brief Symptom Index, Social Adjustment Scale, Euroqol; Computerised revised clinical interview schedule; satisfaction scale. Cost effectiveness analysis. |
| Notes | |

### *Risk of bias*

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Stated random schedule only |
| Allocation concealment (selection bias) | Low risk | Numbered, sealed, opaque envelopes |

**King 2000**  *(Continued)*

| | | |
|---|---|---|
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Participants and personnel could not be blinded, outcome likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias)<br>Patient reported outcomes | High risk | Self report and likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias)<br>Health care utilisation | Low risk | Data extracted from medical records and self report |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | Randomised between three groups, follow up at four months was 91% (62/67 treatment 1, 56/63 treatment two, 62/67 control) at 12 months was 84% (58/67 treatment one, 50/63 treatment two, 57/67 control), randomised between two groups, follow up at four months was 85% (50/59 treatment one, 61/71 treatment two) at 12 months was 78% (44/59 treatment one, 57/71 treatment two), no reasons for missing data provided by group |
| Selective reporting (reporting bias) | Unclear risk | No protocol available |
| Other bias | Unclear risk | Insuficient information available to assess |

**Schroer 2009**

| | |
|---|---|
| Methods | Pilot RCT<br><br>Recruitment: Identification by GP and mental health workers, and recruitment via practice databases.<br><br>Randomisation: Patients allocated randomly by trials unit. Researchers and clinicians have no influence on allocation. Allocated to acupuncture, counselling or usual care, patients in acupuncture or counselling randomised to either 12 or 24 sessions of treatment<br><br>Follow-up: 3, 6 and 9 months.<br><br>Attrition: 30/40 (75%) at 3 months, 25/40 (63%) at 6 months, 18/40 (45%) at 9 months |
| Participants | Treatment 1 Randomised to counselling 12 sessions n=6<br><br>Treatment 2 Randomised to counselling 24 sessions n=6<br><br>Treatment 3 Randomised to acupuncture 12 sessions n=6<br><br>Treatment 4 Randomised to acupuncture 24 sessions n=6<br><br>Control 1 Randomised to usual care n=16<br><br>Included: Patients (18+) who are being managed in primary care who have consulted their GP and have been diagnosed with depression with a depression score of 10+ on the PHQ9<br>Excluded: Diagnosed with terminal illness, mobility issues who cannot travel to appointments, involved with other research projects, dementia, learning difficulties, and communication problems, currently receiving acupuncture or counselling, cannot speak sufficient English to communicate with a counsellor or acupuncture practitioner, alcohol or substance abuse problems, diagnosis of bipolar disorder,<br>psychosis, or personality disorder. |

**Schroer 2009**  *(Continued)*

|  |  |
|---|---|
|  | No data on participants (pilot study only) |
| Interventions | Treatment 1 Counselling 12 sessions |
|  | Treatment 2 Counselling 24 sessions |
|  | Treatment 3 Acupuncture 12 sessions |
|  | Treatment 4 Acupuncture 24 sessions |
|  | Control 1 Usual care |
| Outcomes | Instruments: Beck Depression Inventory, PHQ-9, CORE 34, SF-36 Bodily Pain, EQ5D, W-BQ12, cost effectiveness analysis (pilot) |
| Notes |  |

*Risk of bias*

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Stated random only |
| Allocation concealment (selection bias) | Low risk | By trials unit, researchers and clinicians have no influence on allocation |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Participants and personnel could not be blinded, outcome likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias)<br>Patient reported outcomes | High risk | Self report and likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias)<br>Health care utilisation | Unclear risk | Source of data not clear |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | Follow up at three months was 75% (2/6 treatment one, 5/6 treatment 2, 5/6 treatment three, 4/6 treatment four, 14/16 control), at six months was 63% (1/6 treatment one, 4/6 treatment two, 4/6 treatment three, 3/6 treatment four, 13/16 control), at nine months 45% (1/6 treatment one, 3/6 treatment two, 4/6 treatment three, 3/6 treatment four, 7/16 control), no reasons for missing data provided by group |
| Selective reporting (reporting bias) | Unclear risk | Protocol of pilot available, data on outcomes not reported as designed as a pilot only |
| Other bias | Unclear risk | Insuficient information available to assess |

**Simpson 2000**

| Methods | RCT |
|---|---|

**Simpson 2000**  *(Continued)*

Recruitment: Originally identified by GPs; then changed to screening waiting surgery patients using BDI.

Randomisation: Health Authority undertook randomisation using random number tables.

Follow-up: 6 and 12 months.

Attrition: Treatment = 82/92 (89%) at six months, 75/92 (82%) at 12 months, 54/92 (59%) at 36 months. Control = 79/89 (89%) at six months, 68/89 (76%) at 12 months, 55/89 (62%) at 36 months.

| | |
|---|---|
| Participants | Treatment = 92<br>Control = 89.<br><br>Included: Aged 18 to 70 with mild to moderate symptoms of depression from six months or more; depression or anxiety/ depression as main symptom; score 14+ on BDI.<br><br>Excluded: Severe depression or anxiety; anxiety only; drug or alcohol problems; psychotic or suicidal; chronic depression (five years+); heartsink; therapy in last six months.<br><br>Age: Treatment = mean 42; Control = mean 44<br>Gender: Treatment = 78/92 (85%) F<br>Control = 67/89 (75%) Female<br>Class: Treatment = 20% manual; 34% non manual; 20% retired; 26% unemployed Control = 19% manual; 36% non manual; 19% retired; 26% unemployed.<br>Ethnicity: not reported<br><br>Setting: nine practices<br>Region: Derbyshire, UK. |
| Interventions | Treatment = Psychodynamic or non-directive counselling<br><br>Control = Routine GP care<br><br>Duration:<br>Treatment = Mean 6 sessions of 55 mins (range 1 - 16).<br>Control = 4 GP consultations |
| Outcomes | Beck Depression Inventory; Social Adjustment Schedule; Inventory of interpersonal problems; Social Adjustment Scale; Duke Social Support scale. Cost effectiveness analysis. |
| Notes | |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Random number tables |
| Allocation concealment (selection bias) | Low risk | Details given to health authority personnel who undertook randomisation |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Participants and personnel could not be blinded, outcome likely to be influenced by lack of blinding |
| Blinding of outcome assessment (detection bias)<br>Patient reported outcomes | High risk | Self report and likely to be influenced by lack of blinding, assessor potentially blind at first follow up, but blinding not always possible at subsequent follow up |

**Simpson 2000**  *(Continued)*

| | | |
|---|---|---|
| Blinding of outcome assessment (detection bias) Health care utilisation | Low risk | Data extracted from medical records and self report |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | Follow up at 6 months was 89% (82/92 treatment and 79/89 control), at 12 months 79% (75/92 treatment and 68/89 control), 60% (54/92 treatment and 55/89 control), no reasons for missing data provided |
| Selective reporting (reporting bias) | Unclear risk | No protocol available |
| Other bias | Unclear risk | Insuficient information available to assess |

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

| Study | Reason for exclusion |
|---|---|
| Ali 2003 | Training did not meet requirements of the review |
| Ali 2010 | Training did not meet requirements of the review |
| Anderson 1979 | No random allocation |
| Appleby 1997 | Cognitive-behavioural therapy |
| Appleby 2003 | Training did not meet requirements of the review |
| Arn 1989 | Population with psychosomatic disorders |
| Asarnow 2005 | Cognitive-behavioural therapy and collaborative care intervention |
| Ashurst 1983 | Training did not meet requirements of the review |
| Baas 2010 | Cognitive-behavioural therapy |
| Bakker 2006 | Training did not meet requirements of the review |
| Barrett 1999 | Problem solving therapy |
| Barsky 2004 | Cognitive-behavioural therapy |
| Bellamy 2000 | No random allocation |
| Bennun 1984 | Not primary care based |
| Benson 1988 | Group therapy |
| Berardi 2009 | Interpersonal counselling. Training did not meet requirements of the review |
| Blakey 1986 | Cognitive-behavioural therapy. No random allocation |
| Blanchard 1995 | Nurse intervention involving counselling. Training did not meet requirements of the review |
| Blay 2002 | Psychodynamic therapy. Not primary care based |

| Study | Reason for exclusion |
|---|---|
| Blomhoff 2001 | Cognitive-behavioural therapy |
| Bolton 2001 | Cognitive-behavioural therapy |
| Booth 1997 | No random allocation |
| Brantley 1986 | Cognitive-behavioural therapy |
| Brodaty 1983 | Psychodynamic therapy |
| Brody 1990 | GP counselling. Training did not meet requirements of the review |
| Brouwers 2006 | Education and problem solving |
| Brown 2004 | Psychoeducational therapy. Not primary care based. |
| Browne 2002 | Interpersonal therapy |
| Catalan 1984 | Problem solving therapy |
| Catalan 1991 | Problem solving therapy |
| Chabrol 2002 | Counselling included supportive therapy, education and cognitive-behavioral therapy |
| Conradi 2007 | Psychoeducational therapy and cognitive-behavioural therapy |
| Cooper 1975 | Social work counselling |
| Cooper 1997 | Training did not meet requirements of the review |
| Cooper 2003 | Generic mental health intervention. Training did not meet requirements of the review |
| Corney 1984 | Social work counselling. Training did not meet requirements of the review |
| Crowe 1978 | Not primary care based |
| de Groot 2007 | Cognitive-behavioural counselling. Training did not meet requirements of the review |
| de Klerk 2005 | Experiential psychosocial therapy. Not primary care based |
| Dowling 2006 | Not primary care based |
| Dowrick 2000 | Problem solving therapy |
| Driessen 2007 | Not primary care based |
| Earll 1982 | Cognitive-behavioural therapy |
| Escobar 2007 | Cognitive-behavioural counselling. Population with medically unexplained symptoms |
| Finney 1989 | Cognitive-behavioural therapy |
| Finney 1991 | Cognitive-behavioural therapy |
| Freeman 2008 | Individual supportive psychotherapy for all patients. Not primary care based |

| Study | Reason for exclusion |
|-------|----------------------|
| Garcia 2007 | Primary bereavement care by family physicians |
| Gath 1986 | Problem solving therapy |
| Glavin 2010 | Training did not meet requirements of the review |
| Goldman 2006 | Not primary care based |
| Gournay 1994 | Community psychiatric nurse counselling. Training did not meet requirements of the review |
| Greasley 2005 | No random allocation |
| Greenberg 1998 | Not primary care based |
| Guthrie 2004 | No random allocation |
| Hansson 2008 | Group based patient education and support |
| Hawton 1987 | Not primary care based |
| Hebert 1994 | Not primary care based |
| Hellman 1990 | Cognitive-behavioural therapy. Population with psychosomatic complaints |
| Holden 1989 | Nurse counselling. Training did not meet requirements of the review |
| Honey 2002 | Psychoeducational therapy |
| Huibers 2004 | Cognitive-behavioural therapy. Training did not meet requirements of the review. Population with fatigue |
| Hunt 2001 | Structured problem solving therapy |
| Hunter 1995 | Problem solving therapy |
| Huygen 1983 | No random allocation |
| Judd 2001 | Interpersonal counselling and cognitive-behavioural therapy |
| Karlberg 1998 | Population with psychosomatic disorders |
| Kashner 1995 | Consultation-liaison intervention |
| Katon 1992 | Consultation-liaison intervention |
| Katon 1995 | Consultation-liaison intervention |
| Katon 1996 | Consultation-liaison intervention, cognitive-behavioural therapy |
| Kendrick 2005 | Problem solving and generic nurse care |
| Kessler 2009 | Cognitive-behavioural therapy |
| Kilfedder 2010 | Occupational medicine. Not primary care based |

| Study | Reason for exclusion |
|---|---|
| King 1994 | Training did not meet requirements of the review |
| King 2002 | Cognitive-behavioural therapy |
| Kiossis 2010 | Cognitively impaired population. Not primary care based |
| Klerman 1996 | Interpersonal counselling. Training did not meet requirements of the review |
| Kocken 2008 | Health education. Population with psychosomatic complaints |
| Kolk 2004 | Population with medically unexplained physical symptoms |
| Konzag 2006 | Not primary care based |
| Kool 2003 | Not primary care based |
| Kupshik 1999 | Guided bibliotherapy |
| Kuyken 2008 | Cognitive-behavioural therapy |
| Lang 2003 | Cognitive-behavioural therapy |
| Lang 2006 | Problem-solving therapy |
| le Grange 2007 | Not primary care based |
| Lidbeck 1997 | Cognitive-behavioural therapy |
| Liu 2007 | Problem-solving therapy, consultation liaison |
| Lofvander 1997 | Population with pain for rehabilitation |
| Lynch 1997 | Problem solving therapy |
| Lyon 1993 | No random allocation |
| MacCarthy 1989 | Not primary care based. Training did not meet requirements of the review |
| Machado 2007 | Population with pain. Not primary care based. |
| Maina 2005 | Not primary care based |
| Maisiak 1996 | Population with psychosomatic disorders. Not primary care based |
| Malt 1999 | GP counselling. Training did not meet requirements of the review |
| Mann 1998 | Consultation-liaison intervention |
| Manne 2007 | Not primary care based |
| Marks 1985 | Cognitive-behavioural therapy |
| McLeod 1997 | Cognitive-behavioural therapy |
| Menchetti 2010 | Interpersonal counselling. Training did not meet requirements of the review |

| Study | Reason for exclusion |
|---|---|
| Milgrom 2005 | Postnatal population. Unclear if training met requirements of the review |
| Miranda 1994 | Cognitive-behavioural therapy |
| Mohr 2005 | Cognitive-behavioural therapy |
| Moldenhauer 2004 | Cognitive-behavioural therapy |
| Molenaar 2007 | Not primary care based |
| Morrell 2009 | Training did not meet requirements of the review |
| Mossey 1996 | Interpersonal counselling. Not primary care based |
| Munoz 1995 | Cognitive-behavioural therapy |
| Mynors-Wallis 1995 | Problem solving therapy |
| Mynors-Wallis 1997 | Problem solving therapy |
| Mynors-Wallis 2000 | Problem solving therapy |
| Nettleton 2000 | No random allocation |
| O'Leary 2003 | Not primary care based. Unclear if training met requirements of the review |
| Oxman 2008 | Problem solving therapy |
| Padfield 1975 | Not primary care based. Unclear if training met requirements of the review |
| Patel 2010 | Collaborative care intervention |
| Pauntat 1990 | Not primary care based |
| Paykel 1982 | Not primary care based |
| Power 1989 | Cognitive-behavioural therapy |
| Power 1990 | Cognitive-behavioural therapy |
| Power 2000 | Cognitive-behavioural therapy |
| Raphael 1977 | Not primary care based |
| Richards 2003 | Guided bibliotherapy |
| Ridsdale 2001 | Population with chronic fatigue. Training did not meet requirements of the review |
| Ridsdale 2004 | Population with chronic fatigue. Cognitive-behavioural therapy |
| Robson 1984 | Cognitive-behavioural therapy |
| Ross 1985 | Cognitive-behavioural therapy |
| Ryan 2005 | Psychoeducation. Not primary care based |

| Study | Reason for exclusion |
|-------|---------------------|
| Saarijarvi 1991 | Population with chronic pain |
| Schilte 2001 | Training did not meet requirements of the review |
| Schmaling 2002 | Problem solving therapy |
| Schreuders 2007 | Problem solving therapy |
| Schulberg 1996 | Interpersonal therapy |
| Schützmann 2010 | Not primary care based |
| Scott 1992 | Social case work and cognitive-behavioural therapy. Training did not meet requirements of the review |
| Scott 1997 | Cognitive-behavioural therapy |
| Serfaty 2009 | Talking control |
| Sharp 1997 | Cognitive-behavioural therapy |
| Sharp 2000 | Cognitive-behavioural therapy |
| Sharp 2004 | Cognitive-behavioural therapy |
| Sharp 2010 | Training did not meet requirements of the review |
| Simon 2004 | Cognitive-behavioural therapy |
| Simons 2001 | Listening visits. Training did not meet requirements of the review |
| Simpson 2003 | No random allocation. No patient outcomes |
| Spurgeon 2005 | No random allocation. Cognitive-behavioural counselling. |
| Stanley 1996 | Not primary care based. Training did not meet requirements of the review |
| Stanley 2003 | Cognitive-behavioural therapy |
| Stanton 1998 | Nurse counselling. Training did not meet requirements of the review |
| Sumathipala 2000 | Cognitive-behavioural therapy |
| Sutcliffe 1988 | Carers of patients with dementia. Counselling involved CBT. Unclear if training met requirements of the review |
| Teasdale 1984 | Cognitive-behavioural therapy |
| Tutty 2000 | Cognitive-behavioural therapy |
| van Boeijen 2005 | Cognitive-behavioural therapy and guided self help |
| van Eijk 2004 | COPD and diabetes population. Training did not meet requirements of the review |
| Viney 1995 | Not primary care based. Training did not meet requirements of the review |

| Study | Reason for exclusion |
|---|---|
| Vinnars 2005 | Dynamic psychotherapy. Not primary care based |
| Walsh 2004 | Cognitive-behavioural therapy |
| Watson 2003 | Not primary care based. |
| Wells 2001 | Cognitive-behavioural therapy |
| Wickberg 1996 | Nurse counselling. Training did not meet requirements of the review |
| Willemse 2004 | Guided bibliotherapy |

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

### MacPherson 2009

| | |
|---|---|
| Trial name or title | ACUDEP |
| Methods | RCT |
| Participants | Patients with depression |
| Interventions | Acupuncture, counselling and usual care |
| Outcomes | Depression and other self report outcomes, costs |
| Starting date | 2009 |
| Contact information | hm18@york.ac.uk |
| Notes | |

## DATA AND ANALYSES

### Comparison 1. Counselling compared with usual GP care (short term)

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Mental health | 6 | 772 | Std. Mean Difference (IV, Fixed, 95% CI) | -0.28 [-0.43, -0.13] |
| 2 Social function | 3 | 386 | Std. Mean Difference (IV, Fixed, 95% CI) | -0.09 [-0.29, 0.11] |

### Analysis 1.1. Comparison 1 Counselling compared with usual GP care (short term), Outcome 1 Mental health.

| Study or subgroup | Counselling N | Counselling Mean(SD) | GP Care N | GP Care Mean(SD) | Std. Mean Difference Fixed, 95% CI | Weight | Std. Mean Difference Fixed, 95% CI |
|---|---|---|---|---|---|---|---|
| Boot 1994 | 67 | 6.2 (7) | 41 | 10.6 (9) | | 13.91% | -0.55[-0.95,-0.16] |
| Friedli 1997 | 59 | 11.7 (7.7) | 51 | 15.6 (10.5) | | 15.17% | -0.43[-0.8,-0.05] |
| Harvey 1998 | 77 | 7.3 (4.6) | 38 | 8.2 (5.1) | | 14.38% | -0.2[-0.59,0.19] |
| Hemmings 1997 | 114 | 1 (0.7) | 40 | 1 (0.8) | | 16.8% | -0.07[-0.43,0.29] |
| King 2000 | 62 | 11.5 (7.7) | 62 | 17.2 (11.9) | | 16.9% | -0.57[-0.92,-0.21] |
| Simpson 2000 | 82 | 16 (9.3) | 79 | 16 (8.1) | | 22.84% | 0[-0.31,0.31] |
| | | | | | | | |
| **Total \*\*\*** | **461** | | **311** | | | **100%** | **-0.28[-0.43,-0.13]** |

Heterogeneity: Tau²=0; Chi²=9.46, df=5(P=0.09); I²=47.16%

Test for overall effect: Z=3.68(P=0)

Counselling  -1  -0.5  0  0.5  1  GP Care

### Analysis 1.2. Comparison 1 Counselling compared with usual GP care (short term), Outcome 2 Social function.

| Study or subgroup | Counselling N | Counselling Mean(SD) | GP Care N | GP Care Mean(SD) | Std. Mean Difference Fixed, 95% CI | Weight | Std. Mean Difference Fixed, 95% CI |
|---|---|---|---|---|---|---|---|
| Friedli 1997 | 59 | 2.2 (0.5) | 51 | 2.3 (0.6) | | 28.36% | -0.18[-0.56,0.19] |
| King 2000 | 61 | 2.2 (0.5) | 54 | 2.2 (0.7) | | 29.76% | -0.12[-0.49,0.24] |
| Simpson 2000 | 82 | 2.4 (0.6) | 79 | 2.4 (0.5) | | 41.89% | 0[-0.31,0.31] |
| | | | | | | | |
| **Total \*\*\*** | **202** | | **184** | | | **100%** | **-0.09[-0.29,0.11]** |

Heterogeneity: Tau²=0; Chi²=0.58, df=2(P=0.75); I²=0%

Test for overall effect: Z=0.86(P=0.39)

Counselling  -1  -0.5  0  0.5  1  GP Care

### Comparison 2. Counselling compared with usual GP care (long term)

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Mental health | 4 | 475 | Std. Mean Difference (IV, Fixed, 95% CI) | -0.09 [-0.27, 0.10] |
| 2 Social function | 3 | 369 | Std. Mean Difference (IV, Fixed, 95% CI) | -0.12 [-0.33, 0.08] |

### Analysis 2.1. Comparison 2 Counselling compared with usual GP care (long term), Outcome 1 Mental health.

| Study or subgroup | Counselling N | Counselling Mean(SD) | GP Care N | GP Care Mean(SD) | Std. Mean Difference Fixed, 95% CI | Weight | Std. Mean Difference Fixed, 95% CI |
|---|---|---|---|---|---|---|---|
| Friedli 1997 | 62 | 9.7 (8.5) | 55 | 13.5 (10.7) | | 25.7% | -0.39[-0.76,-0.03] |
| Hemmings 1997 | 76 | 1 (0.8) | 24 | 1 (0.8) | | 16.41% | 0[-0.46,0.46] |
| King 2000 | 58 | 11.1 (9.3) | 57 | 10.2 (8.5) | | 25.82% | 0.1[-0.27,0.47] |
| Simpson 2000 | 75 | 15 (9.8) | 68 | 15.3 (8.6) | | 32.07% | -0.03[-0.36,0.3] |

Counselling  -1  -0.5  0  0.5  1  GP Care

| Study or subgroup | Counselling | | GP Care | | Std. Mean Difference | Weight | Std. Mean Difference |
|---|---|---|---|---|---|---|---|
| | N | Mean(SD) | N | Mean(SD) | Fixed, 95% CI | | Fixed, 95% CI |
| **Total \*\*\*** | **271** | | **204** | | | **100%** | **-0.09[-0.27,0.1]** |
| Heterogeneity: Tau²=0; Chi²=3.93, df=3(P=0.27); I²=23.76% | | | | | | | |
| Test for overall effect: Z=0.9(P=0.37) | | | | | | | |

Counselling  -1  -0.5  0  0.5  1  GP Care

### Analysis 2.2. Comparison 2 Counselling compared with usual GP care (long term), Outcome 2 Social function.
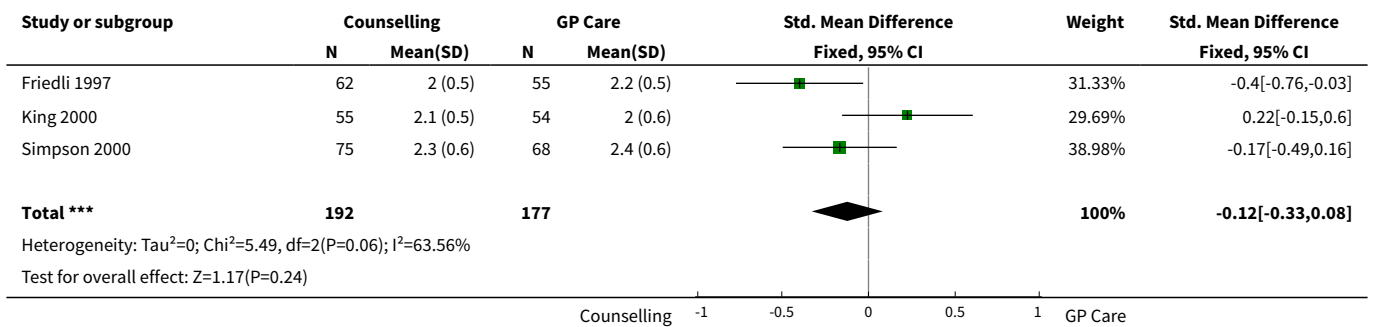
| Study or subgroup | Counselling | | GP Care | | Std. Mean Difference | Weight | Std. Mean Difference |
|---|---|---|---|---|---|---|---|
| | N | Mean(SD) | N | Mean(SD) | Fixed, 95% CI | | Fixed, 95% CI |
| Friedli 1997 | 62 | 2 (0.5) | 55 | 2.2 (0.5) | | 31.33% | -0.4[-0.76,-0.03] |
| King 2000 | 55 | 2.1 (0.5) | 54 | 2 (0.6) | | 29.69% | 0.22[-0.15,0.6] |
| Simpson 2000 | 75 | 2.3 (0.6) | 68 | 2.4 (0.6) | | 38.98% | -0.17[-0.49,0.16] |
| **Total \*\*\*** | **192** | | **177** | | | **100%** | **-0.12[-0.33,0.08]** |
| Heterogeneity: Tau²=0; Chi²=5.49, df=2(P=0.06); I²=63.56% | | | | | | | |
| Test for overall effect: Z=1.17(P=0.24) | | | | | | | |

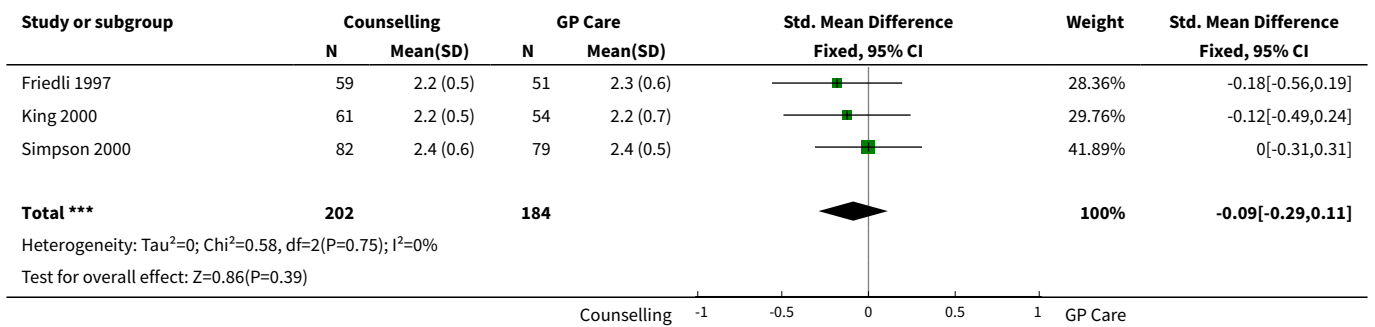Counselling  -1  -0.5  0  0.5  1  GP Care

### Comparison 3. Counselling compared with usual GP care (very long term)

| Outcome or subgroup title | No. of studies | No. of partici-pants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Mental health | 1 | | Std. Mean Difference (IV, Fixed, 95% CI) | Subtotals only |
| 2 Social function | 1 | | Std. Mean Difference (IV, Fixed, 95% CI) | Subtotals only |

### Analysis 3.1. Comparison 3 Counselling compared with usual GP care (very long term), Outcome 1 Mental health.

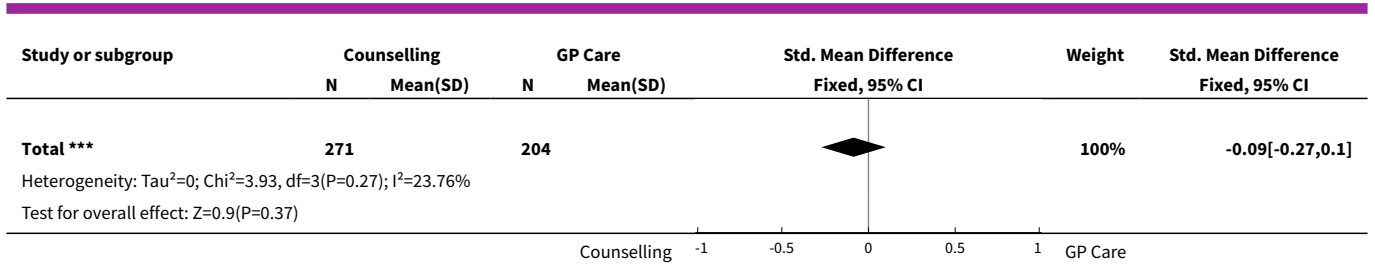| Study or subgroup | Counselling | | GP Care | | Std. Mean Difference | Weight | Std. Mean Difference |
|---|---|---|---|---|---|---|---|
| | N | Mean(SD) | N | Mean(SD) | Fixed, 95% CI | | Fixed, 95% CI |
| Simpson 2000 | 54 | 13.5 (8.8) | 55 | 13.8 (8.4) | | 0% | -0.03[-0.41,0.34] |

Counselling  -1  -0.5  0  0.5  1  GP Care
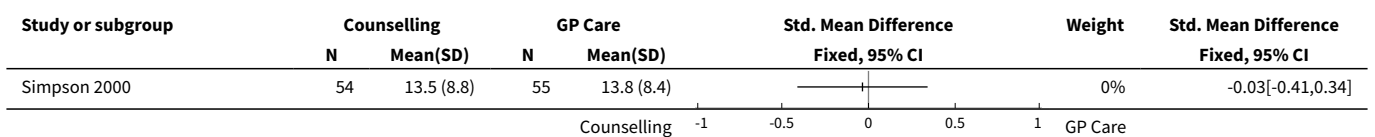
### Analysis 3.2. Comparison 3 Counselling compared with usual GP care (very long term), Outcome 2 Social function.

| Study or subgroup | Counselling | | GP Care | | Std. Mean Difference | Weight | Std. Mean Difference |
|---|---|---|---|---|---|---|---|
| | N | Mean(SD) | N | Mean(SD) | Fixed, 95% CI | | Fixed, 95% CI |
| Simpson 2000 | 54 | 2.3 (0.6) | 55 | 2.4 (0.5) | | 0% | -0.18[-0.56,0.2] |

Counselling  -1  -0.5  0  0.5  1  GP Care
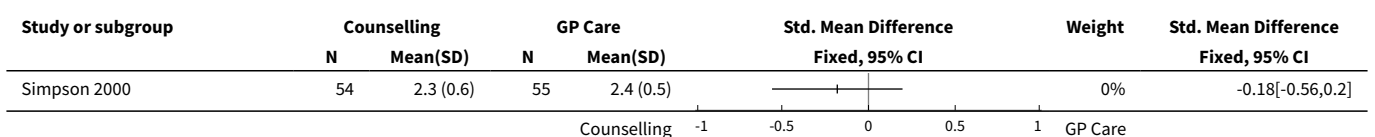
## Comparison 4. Counselling compared with GP antidepressant treatment (short term)

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Mental health | 1 | | Std. Mean Difference (IV, Fixed, 95% CI) | Subtotals only |

### Analysis 4.1.  Comparison 4 Counselling compared with GP antidepressant treatment (short term), Outcome 1 Mental health.

| Study or subgroup | Counselling | | GP antidepressant treatment | | Std. Mean Difference | Weight | Std. Mean Difference |
|---|---|---|---|---|---|---|---|
| | N | Mean(SD) | N | Mean(SD) | Fixed, 95% CI | | Fixed, 95% CI |
| Chilvers 2001 | 39 | 15.2 (11.6) | 44 | 14.8 (10.1) | | 0% | 0.04[-0.39,0.47] |

Counselling  -1  -0.5  0  0.5  1  GP antidepressant treatment

## Comparison 5. Counselling compared with GP antidepressant treatment (long term)

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Mental health | 1 | | Std. Mean Difference (IV, Fixed, 95% CI) | Subtotals only |

### Analysis 5.1.  Comparison 5 Counselling compared with GP antidepressant treatment (long term), Outcome 1 Mental health.

| Study or subgroup | Counselling | | GP antidepressant treatment | | Std. Mean Difference | Weight | Std. Mean Difference |
|---|---|---|---|---|---|---|---|
| | N | Mean(SD) | N | Mean(SD) | Fixed, 95% CI | | Fixed, 95% CI |
| Chilvers 2001 | 31 | 16.7 (11.5) | 34 | 14.6 (13.1) | | 0% | 0.17[-0.32,0.66] |

Counselling  -1  -0.5  0  0.5  1  GP antidepressant treatment

## Comparison 6. Counselling compared with CBT (short term, depressed patients)

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Mental health | 1 | | Std. Mean Difference (IV, Fixed, 95% CI) | Subtotals only |

### Analysis 6.1. Comparison 6 Counselling compared with CBT (short term, depressed patients), Outcome 1 Mental health.

| Study or subgroup | Counselling | | CBT | | Std. Mean Difference | Weight | Std. Mean Difference |
|---|---|---|---|---|---|---|---|
| | N | Mean(SD) | N | Mean(SD) | Fixed, 95% CI | | Fixed, 95% CI |
| King 2000 | 112 | 12.3 (8.5) | 117 | 12.5 (10) | | 0% | -0.02[-0.28,0.24] |
| | | | | | Counselling -0.5 -0.25 0 0.25 0.5 CBT | | |
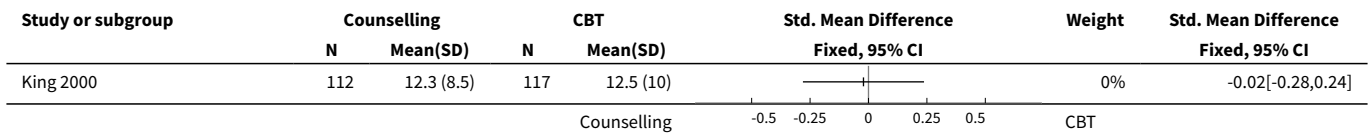
## Comparison 7. Counselling compared with CBT (long term, depressed patients)

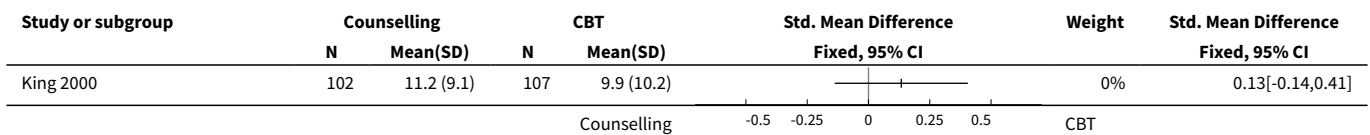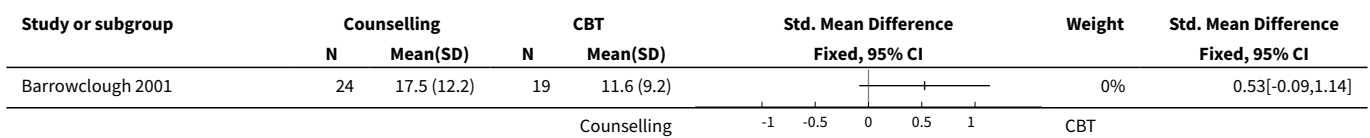| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Mental health | 1 | | Std. Mean Difference (IV, Fixed, 95% CI) | Subtotals only |

### Analysis 7.1. Comparison 7 Counselling compared with CBT (long term, depressed patients), Outcome 1 Mental health.

| Study or subgroup | Counselling | | CBT | | Std. Mean Difference | Weight | Std. Mean Difference |
|---|---|---|---|---|---|---|---|
| | N | Mean(SD) | N | Mean(SD) | Fixed, 95% CI | | Fixed, 95% CI |
| King 2000 | 102 | 11.2 (9.1) | 107 | 9.9 (10.2) | | 0% | 0.13[-0.14,0.41] |
| | | | | | Counselling -0.5 -0.25 0 0.25 0.5 CBT | | |

## Comparison 8. Counselling compared with CBT (short term, anxious patients)

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Mental health | 1 | | Std. Mean Difference (IV, Fixed, 95% CI) | Subtotals only |
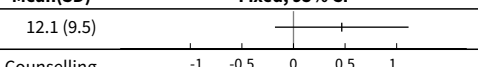
### Analysis 8.1. Comparison 8 Counselling compared with CBT (short term, anxious patients), Outcome 1 Mental health.

| Study or subgroup | Counselling | | CBT | | Std. Mean Difference | Weight | Std. Mean Difference |
|---|---|---|---|---|---|---|---|
| | N | Mean(SD) | N | Mean(SD) | Fixed, 95% CI | | Fixed, 95% CI |
| Barrowclough 2001 | 24 | 17.5 (12.2) | 19 | 11.6 (9.2) | | 0% | 0.53[-0.09,1.14] |
| | | | | | Counselling -1 -0.5 0 0.5 1 CBT | | |

## Comparison 9. Counselling compared with CBT (long term, anxious patients)

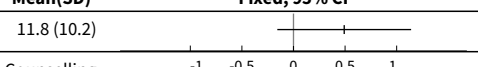| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Mental health | 1 | | Std. Mean Difference (IV, Fixed, 95% CI) | Subtotals only |

### Analysis 9.1. Comparison 9 Counselling compared with CBT (long term, anxious patients), Outcome 1 Mental health.

| Study or subgroup | Counselling N | Mean(SD) | CBT N | Mean(SD) | Std. Mean Difference Fixed, 95% CI | Weight | Std. Mean Difference Fixed, 95% CI |
|---|---|---|---|---|---|---|---|
| Barrowclough 2001 | 23 | 17 (10.9) | 16 | 12.1 (9.5) | | 0% | 0.47[-0.18,1.12] |

Counselling   -1  -0.5  0  0.5  1   CBT

## Comparison 10. Counselling compared with CBT (very long term, anxious patients)

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Mental health | 1 | | Std. Mean Difference (IV, Fixed, 95% CI) | Subtotals only |

### Analysis 10.1. Comparison 10 Counselling compared with CBT (very long term, anxious patients), Outcome 1 Mental health.

| Study or subgroup | Counselling N | Mean(SD) | CBT N | Mean(SD) | Std. Mean Difference Fixed, 95% CI | Weight | Std. Mean Difference Fixed, 95% CI |
|---|---|---|---|---|---|---|---|
| Barrowclough 2001 | 23 | 17.6 (12.4) | 16 | 11.8 (10.2) | | 0% | 0.49[-0.16,1.14] |

Counselling   -1  -0.5  0  0.5  1   CBT

## ADDITIONAL TABLES

### Table 1. Sensitivity analyses

| Comparison number | Comparison | Sensititivity analysis | Outcome | Studies | Participants | Effect estimate [95% CI]  Test for heterogeneity, $I^2$ |
|---|---|---|---|---|---|---|
| 1.1.1 | Counselling compared with usual GP care (short term) | Quality – removing studies with inadequate | Mental health | 4 | 510 | -0.27 [-0.45, -0.09]  Chi$^2$=6.31 df=3 p=0.10 $I^2$ =52.4% |

**Table 1.  Sensitivity analyses**  *(Continued)*

| | | conceal-ment | | | | |
|---|---|---|---|---|---|---|
| 1.1.2 | Counselling compared with all GP care (short term) | Usual care – includ-ing study with GP antide-pressant arm | Mental health | 7 | 855 | -0.24 [-0.38, -0.10] <br><br> Chi2=11.29 df=6 p=0.08 I2 =46.8% |
| 1.1.3 | Counselling compared with usu-al GP care (short term) | Chronic-ity – re-mov-ing the study with pa-tients with chron-ic condi-tions | Mental health | 5 | 611 | -0.36 [-0.53, -0.19] <br><br> Chi2=5.45 df=4 p=0.24 I2 =26.6% |
| 1.1.4 | Counselling compared with usu-al GP care (short term) | Quali-ty and chronic-ity – re-moving stud-ies with inade-quate conceal-ment and study with pa-tients with chron-ic condi-tions | Mental health | 3 | 349 | -0.41 [-0.62, -0.19] <br><br> Chi2=1.87 df=2 p=0.39 I2 =0.0% |
| 1.1.5 | Counselling compared with usu-al GP care (short term) | Chronic-ity – in-cluding study with pa-tients with chron-ic condi-tions on-ly | Mental health | 1 | 161 | 0.00 [-0.31 to 0.31] <br><br> NA |
| 2.1.1 | Counselling compared with usu-al GP care (long term) | Quality – remov-ing stud-ies with | Mental health | 3 | 375 | -0.10 [-0.31, 0.10] |

**Table 1.  Sensitivity analyses**  *(Continued)*

| | | | | | | |
|---|---|---|---|---|---|---|
| | | inade-quate conceal-ment | | | | Chi²=3.78 df=2 p=0.15 I² =47.0% |
| 2.1.2 | Counselling compared with all GP care (long term) | Usual care – includ-ing study with GP antide-pressant arm | Mental health | 5 | 540 | -0.05 [-0.23, 0.12]<br><br>Chi²=4.84 df=4 p=0.30 I² =17.4% |
| 2.1.3 | Counselling compared with usu-al GP care (long term) | Chronic-ity – re-mov-ing the study with pa-tients with chron-ic condi-tions | Mental health | 3 | 332 | -0.11 [-0.34, 0.11]<br><br>Chi²=3.79 df=2 p=0.15 I² =47.2% |
| 2.1.4 | Counselling compared with usu-al GP care (long term) | Quali-ty and chronic-ity – re-moving stud-ies with inade-quate conceal-ment and study with pa-tients with chron-ic condi-tions | Mental health | 2 | 232 | -0.15 [-0.40, 0.11]<br><br>Chi²=3.49 df=1 p=0.06 I² =71.4% |
| 2.1.5 | Counselling compared with usu-al GP care (long term) | Chronic-ity – in-cluding study with pa-tients with chron-ic condi-tions on-ly | Mental health | 1 | 143 | -0.03 [-0.36 to 0.30]<br><br>NA |

# APPENDICES

## Appendix 1. Update search strategies: MEDLINE, EMBASE, PsycINFO, CENTRAL (May 2011)

**OVID MEDLINE** was searched (2005 to May 2011) using the following terms:

*[Condition]*

1. mental disorders/ or exp adjustment disorders/ or exp anxiety disorders/ or exp mood disorders/ or neurotic disorders/

2. (anxi* or depress* or melancholi* or neuros* or neurotic or psychoneuro* or stress* or distress* or emotion*).tw.

3. affective symptom*.mp.

4. or/1-3

*[Intervention]*

5. counseling/

6. counsel*.tw.

7. supportive adj2 (therap* or psychotherap*).tw.

8. humanistic.tw.

9. client adj (cent* or orient*).tw.

10. (non-directive or non directive).tw.

11. experiental.tw.

12. (insight or client) adj orient*.tw.

13. person adj (cent* or orient*).tw.

14. (nonprescriptive or non prescriptive).tw.

15. rogerian.tw.

16. or/5-15

*[Setting]*

17. exp primary health care/

18. physicians, family/

19. family practice/

20. general practice/ *[New MeSH Term 2011]*

21. general practitioners/ *[New MeSH Term 2011]*

22. (primary adj2 (care or health*)).tw.

23. ((general or family) adj (practice* or practitioner*)).tw.

24. (GP or GP's).ab.

25. nurse practitioners/

26. primary care nursing/ *[New MeSH Term 2011]*

27. family nursing/

28. home nursing/

29. community mental health services/

30. community health nursing/

31. exp community health centers/

32. ((family or community or practice*) adj (medic* or doctor* or physician* or health* or nurs*)).tw.

33. ((in or at or based or own) adj2 (home or homes)).ab.

34. exp private practice/

35. private practice*.tw.

36. ambulatory care/

37. (ambulatory adj2 care).tw.

38. ((antenatal or ante-natal) adj2 (care or clinic)).tw.

39. or/17-38

[RCT Filter]

40. randomized controlled trial.pt.

41. controlled clinical trial.pt.

42. randomi#ed.ti,ab.

43.  randomly.ab.

44. placebo.ab.

45. trial.ab.

46. groups.ab

47. (control* adj3 (trial or study)).ab,ti.

48. ((singl* or doubl* or tripl* or trebl*) adj3 (blind* or mask* or dummy)).mp.

49. (animals not (humans and animals)).sh.

50. or/40-48

51. 50 not 49

[Update Search 2005 to 2011]

52. (2005* or 2006* or 2007 or 2008* or 2009* or 2010* or 2011*).ed,yr.

[Combine Sets]

53. (4 and 16 and 39 and 51 and 52)

**OVID EMBASE** was searched (2005 to May 2011) using the following terms:

[Condition]

1. mental disease/ or adjustment disorder/ or exp anxiety disorder/ or exp neurosis/

2. exp "psychological and psychiatric procedures, techniques and concepts"/

3. exp mood disorder/

4. exp stress/

5. exp emotion/

6. emotional disorder/

7. anxiety/

8. (anxi* or depress* or melancholi* or neuros* or neurotic or psychoneuro* or stress* or distress* or emotion*).tw.

9. or/1-8

[Intervention]

10. exp counseling/

11. counsel*.tw.

12. (supportive adj2 (therap* or psychotherap*)).tw.

13. humanistic.mp.

14. (client adj (cent* or orient*)).tw.

15. (non-directive or non directive).tw.

16. experiental.tw.

17. ((insight or client) adj orient*).tw.

18. (person adj (cent* or orient*)).tw.

19. (nonprescriptive or non prescriptive).tw.

20. rogerian.tw.

21. or/10-20

[Setting]

22. exp primary health care/

23. exp professional practice/

24. physician/ or general practitioner/

25. (primary adj2 (care or health*)).tw.

26. ((general or family) adj (practice* or practitioner*)).tw.

27. (GP or GP's).tw.

28. community health nursing/ or community psychiatric nursing/

29. exp nurse practitioner/

30. ((family or community or practice*) adj (medic* or doctor* or physician* or health* or nurs*)).tw.

31 ((in or at or based or own) adj2 (home or homes)).ab.

32. private practice*.tw.

33. exp ambulatory care/

34. (ambulatory adj2 care).tw.

35. ((antenatal or ante-natal or prenatal or pre-natal) adj2 (care or clinic)).tw.

36. or/22-35

[RCT Filter]

37. randomized controlled trial.de.

38. randomization.de.

39.  placebo.de.

40. placebo$.ti,ab.

41. randomi#ed.ti,ab.

42. randomly.ab.

43. ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$ or dummy)).mp.

44. factorial$.ti,ab.

45. allocat$.ti,ab.

46. assign$.ti,ab.

47. volunteer$.ti,ab.

48. crossover procedure.de.

49.  (crossover$ or cross over$).ti,ab.

50. (quasi adj (experimental or random$)).mp.

51. (control$ adj3 (trial$ or study or studies or group$)).ti,ab.

52. ((animal or nonhuman) not (human and (animal or nonhuman))).de.

53. or/37-51

54. 53 not 52

 *[Update Search 2010 to 2011]*

55. (2005* or 2006* or 2007* or 2008* or 2009* or 2010* or 2011*).em,yr.

*[Combine Sets]*

56. (9 and 21 and 36 and 54 and 55)


**OVID PsycINFO** was searched (2005 to May 2011) using a more sensitive set of terms (the search was not restricted by condition)

*[Intervention]*

1. exp counseling/

2. exp counselors/

3. counsel*.mp.

4. supportive psychotherapy/

5. (supportive adj2 (therap* or psychotherap*)).tw.

6. humanistic psychotherapy/ or client centered therapy/ or exp humanistic psychology/

7. humanistic.tw.

8. (client adj (cent* or orient*)).tw.

9. (non-directive or non directive).tw.

10. exp experiential learning/

11. experiential psychotherapy/

12. experiental.tw.

13. insight therapy/

14. ((insight or client) adj orient*).tw.

15. (person adj (cent* or orient*)).tw.

16. (nonprescriptive or non prescriptive).tw.

17. rogerian.tw.

18. "rogers (carl)"/

19. or/1-18

[Setting]

20. family medicine/ or family physicians/ or general practitioners/

21. primary health care/

22. (primary adj2 (care or health*)).tw.

23. ((general or family) adj (practice* or practitioner*)).tw.

24. (GP or GP's).tw.

25. community mental health/ or community mental health centers/ or community mental health services/ or community psychiatry/ or community psychology/

26. home care/ or home visiting programs/ or homebound/

27. outreach programs/

28. ((family or community or practice*) adj (medic* or doctor* or physician* or health* or nurs*)).tw.

29. ((in or at or based or own) adj2 (home or homes)).ab.

30. private practice*.mp.

31. (ambulatory adj2 care).tw.

32. ((antenatal or ante-natal or prenatal or pre-natal) adj2 (care or clinic)).tw.

33. walk in clinics/ or crisis intervention services/

34. or/20-33

[RCT Filter]

35. treatment effectiveness evaluation.sh.

36. clinical trials.sh.

37. mental health program evaluation.sh.

38. placebo.sh.

39. placebo$.ti,ab.

40. randomly.ab.

41. randomi#ed.ti,ab.

42. trial.ti,ab.

43. ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$ or dummy)).mp.

44. (control$ adj3 (trial$ or study or studies or group$)).ti,ab.

45. factorial$.ti,ab.

46. allocat$.ti,ab.

47. assign$.ti,ab.

48. volunteer$.ti,ab.

49. (crossover$ or cross over$).ti,ab.

50. (quasi adj (experimental or random$)).mp.

51. "2000".md.

52. or/35-51

[Update Search 2010 to 2011]

53. (2005* or 2006* or 2007* or 2008* or 2009* or 2010* or 2011*).an,up,yr.

[Combine Sets]

54. (19 and 34 and 52 and 53)


**The Cochrane Central Register of Controlled Trials (CENTRAL), Issue 2, 2011** was searched using the following terms:

#1 MeSH descriptor Mental Disorders, this term only

#2 MeSH descriptor Adjustment Disorders explode all trees

#3 MeSH descriptor Anxiety Disorders explode all trees

#4 MeSH descriptor Mood Disorders explode all trees

#5 MeSH descriptor Neurotic Disorders, this term only

#6 MeSH descriptor Affective Symptoms, this term only

#7 (anxi* or depress* or melancholi* or neuros* or neurotic or psychoneuro* or stress* or distress* or emotion*)

#8 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7)

#9 MeSH descriptor Counseling explode all trees

#10 counsel*

#11 (supportive NEAR/3 therap*) or (supportive NEAR/3 psychotherap*)

#12 humanistic

#13 (client NEXT cent*) or (client NEXT orient*)

#14 (non-directive or (non NEXT directive))

#15 experiental

#16 (insight NEXT orient*) or (client NEXT orient*)

#17 (person NEXT cent*) or (person NEXT orient*)

#18 (nonprescriptive or (non NEXT prescriptive))

#19 rogerian 44

#20 (#9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19)

#21 MeSH descriptor Primary Health Care

#22 MeSH descriptor Primary Care Nursing, this term only *[New MeSH Term 2011]*

#23 MeSH descriptor Home Nursing, this term only

#24 MeSH descriptor Family Nursing explode all trees

#25 MeSH descriptor Physicians, Family, this term only

#26 MeSH descriptor Physicians, Primary Care, this term only

#27 MeSH descriptor General Practice explode all trees *[New MeSH Term 2011]*

#28 MeSH descriptor General Practitioners, this term only *[New MeSH Term 2011]*

#29 (primary NEAR/3 care) or (primary NEAR/3 health*)

#30 (general NEXT practi*) or (family NEXT practi*)

#31 GP or GP's

#32 MeSH descriptor Nurse Practitioners, this term only

#33 MeSH descriptor Community Mental Health Services, this term only

#34 MeSH descriptor Community Health Nursing, this term only

#35 MeSH descriptor Community Health Centers explode all trees

#36 (family or community or practice*) and (medic* or doctor* or physician* or health* or nurs*)

#37 (home or homes)

#38 MeSH descriptor Private Practice explode all trees

#39 (private NEXT practice*)

#40 MeSH descriptor Ambulatory Care, this term only

#41 (ambulatory NEAR/3 care)

#42 (antenatal NEAR/3 care) or (ante-natal NEAR/3 care) or (antenatal NEAR/3 clinic) or (ante-natal NEAR/3 clinic)

#43 (#21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42)

#44 (#8 AND #20 AND #43), from 2005 to 2011

### Appendix 2. Search strategies for earlier versions of this review

Details of the search for the first version of the review, published 2001.

1. Electronic searching of databases. A qualified librarian assisted researchers with electronic searches of several databases: MEDLINE, EMBASE, AMED, ASSIA, HLPA/HEALTHSTAR, DHSS DATA, DARE, NHSeed, HELMIS, ECONLIT and CINAHL. Searches commenced in 1996 and were updated throughout the review.
2. Specialised databases were searched including PSYCLIT and COUNSEL.LIT. Searches commenced in 1996 and were updated throughout the review period.
3. Hugh McGuire, Cochrane Collaboration Depression, Anxiety and Neurosis (CCDAN) Trials Co-ordinator, searched the Cochrane Controlled Trials Register on the Cochrane Library, 1997; Issue 2. In addition, the CCDAN Review Group trials register was searched.
3. Handsearching of a specialist counselling journal was undertaken by one of the reviewers (NR), in consultation with the Baltimore Cochrane Centre, which is co-ordinating the development of the International Register of Clinical Trials for the Collaboration, including the co-ordination of handsearching efforts.

4. Grey literature (e.g., Conference proceedings, dissertations, government documents, internal reports, agency reports) was searched. The grey literature database, SIGLE, was searched electronically, as was DISS (Dissertations Index).

5. Reference lists from books, journal publications and grey literature were scanned, and references followed up.

6. Personal communication. The researchers contacted subject experts and CCDAN members to identify further published or unpublished controlled trials.

SEARCH TERMS

The electronic search of databases was comprehensive. The breadth of the key word search (terms for counseling/psychotherapy in general practice/primary care) meant that the reviewers identified many studies that were not controlled trials. The key word search was deliberately not restricted to methodological key words, because it was anticipated that some controlled trials would be missed due to poor indexing. Moreover, given the range of patients that counsellors treat, and the range of professionals who offer counselling, a broad search strategy was considered essential in order to include all relevant trials. DARE (Database of Reviews of Effectiveness) and NHSeed (NHS Economic Evaluations database) were searched at the outset of the Review (1996) and again in 1998. Both databases are produced by the NHS Centre for Reviews and Dissemination at York, England.

Search update 2001

For the first update of the review (May 2001), searches were restricted to those databases judged to be high yield in the first version of the review: MEDLINE, EMBASE, PSYCLIT and CINAHL, the Cochrane Controlled Trials register and the CCDAN trials register. These databases were searched using the same keywords, from the date of the original searches to June 2001.

Search update 2005

For the second update of the review, searches were conducted on MEDLINE, EMBASE, PsycINFO, CINAHL, the Cochrane trials register and the CCDAN trials register (25-10-2005).

For a comprehensive list of search terms used, see previous versions of this review (available on the Cochrane Library).

## WHAT'S NEW

| Date | Event | Description |
|---|---|---|
| 14 July 2011 | New search has been performed | Review updated to include one new study. |
| 14 July 2011 | New citation required but conclusions have not changed | Review updated with new methodology, including changing the title to reflect handbook guidance. In addition two new authors were added. |

## HISTORY

Protocol first published: Issue 1, 1998
Review first published: Issue 1, 2001

| Date | Event | Description |
|---|---|---|
| 1 November 2008 | Amended | Converted to new review format. |
| 24 May 2006 | New citation required and conclusions have changed | Substantive amendment |

## CONTRIBUTIONS OF AUTHORS

For the 2011 update, PB conducted the searches (with specialist assistance from Sarah Dawson), assessed studies for inclusion, conducted risk of bias assessments, and wrote the update report. NR assessed studies for inclusion. SK and PC assessed studies for inclusion, conducted risk of bias assessments, and commented on drafts of the update report.

## DECLARATIONS OF INTEREST

NR is Director of Research, Policy and Professional Practice at the British Association of Counselling and Psychotherapy

PB is a paid scientific consultant for the British Association of Counselling and Psychotherapy

## SOURCES OF SUPPORT

### Internal sources

- National Primary Care Research and Development Centre, University of Manchester, UK.
- Health Sciences Research Group, University of Manchester, UK.

  Support for PB, SK and PC

### External sources

- NINR/Department of Health Cochrane Review Incentive Scheme, UK.

  Incentive payment for preparing updated reviews by agreed dates

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The 2011 update of the review added two new authors (SK and PC) involved in study selection, risk of bias assessment and commenting on the updated review.

The 2011 update also involved updating the methods of the review to reflect the standards set out in the latest version of the Cochrane Handbook (Higgins 2008), including most notably risk of bias assessments. Additional detail added to methods section on dealing with missing data.

## NOTES

Title changed August 2011. Previous title: Effectiveness and cost effectiveness of counselling in primary care

## INDEX TERMS

### Medical Subject Headings (MeSH)

*Primary Health Care [economics]; *Psychotherapy [economics]; Cost-Benefit Analysis; Counseling; Family Practice [economics]; Patient Satisfaction; Randomized Controlled Trials as Topic

### MeSH check words

Female; Humans; Male