

Counselling in primary care:  
a systematic review of the evidence

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British Association for  
Counselling & Psychotherapy

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## Executive summary

### Objective

At a time when the use of psychological therapies is expanding, this study aims to locate, appraise and synthesise diverse research evidence, including the findings of:

- randomised controlled trials (RCTs)
- practice-based evidence
- cost-effectiveness studies
- studies of patient satisfaction and treatment preferences,

in order to obtain a reliable overview of the effectiveness, cost-effectiveness and acceptability of counselling in primary care.

### Scope of the review

#### Counselling

Counselling is defined as a type of psychological therapy which:

- is flexible and centred on the patient's needs
- involves what can be referred to as 'core' activities such as sensitive and empathic listening on the part of the therapist
- involves a high level of mutuality between therapist and client
- involves a focus on specific areas of difficulty
- promotes the facilitation of emotional, cognitive and behavioural changes which are acceptable to the client
- is generally offered on the basis of a 'therapeutic hour', which normally refers to a face-to-face session of 50–60 minutes.

This differentiates counselling sessions from the plethora of often quite brief interventions used by many health professionals involving the use of listening skills, advice-giving, emotional support and guidance. Generally, studies have been included that use the term 'counselling' to describe at least one of the interventions that form the focus of the study. Cognitive-behavioural therapy (CBT) has only been included where the two interventions (counselling and CBT) have been compared in the same study. Even when described as 'counselling', psychosocial interventions that are primarily educative, advisory or directed at treatment adherence (eg interventions directed at smoking-cessation, exercise or weight loss) have been excluded, as has work with couples, which is viewed as a specialist area in its own right.

#### Primary care

The review includes both UK and international studies written in the English language located in the primary care setting. Primary care is the first point of access for medical advice and treatments, and the General Practitioner (GP) is at the centre of this level of healthcare service.

#### Types of participants

Both males and females of all ages who accessed counselling in primary care via a consultation with their GP were eligible for inclusion in the review and there was no restriction on the type of psychological problem presented for treatment.

### Types of research evidence

Studies that fell into any of the following domains of research evidence were included in the review:

- *Efficacy research* Well-conducted RCTs and systematic reviews of RCTs.
- *Practice-based evidence* Evaluations of routine practice using pre and post outcome measures – such as Clinical Outcomes in Routine Evaluation (CORE) – which don't use randomisation or control conditions.
- *Economic issues* Cost-effectiveness studies. Studies of health service utilisation.
- *User perspectives* Patient preference surveys. Patient satisfaction surveys. Qualitative research investigating patients' experiences of counselling.

To be included, studies required a clearly described and rigorous research design.

### Review methods

- 7 electronic databases were searched from 1996 onwards
- 6 journals were hand-searched
- A call for grey literature and a search for research in progress was undertaken
- 3,193 citations were located and screened for relevance
- 338 full papers were obtained and screened for relevance
- 29 unique studies were included and critically appraised in the final review
- EPPI Reviewer Software (EPPI Reviewer 3.0, EPPI-Centre, Social Science Research Unit, Institute of Education, University of London, 2006) was used to track and maintain an audit trail of all studies as they passed through the review process, and to produce data for this final report
- Studies included in the review were graded high (++), good (+) or poor (–), and the findings drawn from 26 studies that were graded good or high quality are presented in a thematic narrative review of the evidence
- Conclusions were drawn by weighing the number of studies which supported a particular finding and the quality rating of those studies.

### Conclusions

- In terms of mental health outcomes, brief counselling is more effective than routine primary care in the short term.
- Evidence relating to counselling's long-term effects is equivocal and further research is needed.
- Counselling is as effective as CBT with typical heterogeneous primary care populations.
- Counselling may be as effective as medication.
- Counselling and medication in combination may be more effective than either intervention offered as a single treatment.
- Individual counselling may be more effective than counselling delivered in groups in this setting.
- Counselling is more effective than routine primary care in the treatment of non-specific, generic psychological problems. As a flexible intervention, it is effective in the

treatment of those heterogeneous psychological problems typically presented in primary care populations.

- In the treatment of anxiety and depression (including postnatal depression), counselling is more effective than routine primary care.
- No evidence was found that counselling is superior to routine primary care in the treatment of psychosomatic disorders, and further research is needed in this area.
- There is some evidence that counselling is as effective as CBT in the treatment of chronic fatigue, but further research is needed in this area.
- There is mixed evidence regarding the cost-effectiveness of counselling and the cost-impact on other areas of health service utilisation, and further research is needed.
- Primary care patients prefer counselling to medication.
- The preference for counselling is unaffected by factors such as age, the presence of mental health problems, or problem severity.
- Receiving a preferred intervention improves treatment take-up and compliance but there is no clear evidence that the receipt of a preferred treatment improves clinical outcomes.
- Evidence indicates that patients prefer individual rather than group counselling.
- Patients are highly satisfied with the counselling they have received in primary care.

### ***Implications for future research***

- Future systematic reviews in this field should combine methodological rigour with the inclusion of efficacy and effectiveness research in order to produce evidence with high levels of both internal and external validity.
- Longitudinal pragmatic trials should be undertaken to produce more reliable evidence of counselling's long-term effects.
- Triallists should produce clearer descriptions of routine primary care control conditions to enable a better understanding of exactly what counselling is being tested against in clinical trials.

- The more widespread use of CORE in service evaluations may help to standardise data collection and strengthen practice-based evidence by increasing the scale of national datasets.
- There is an urgent need for rigorous cost-effectiveness studies in this field using analyses of wider societal costs such as lost productivity due to sickness absence, informal care provided by family and friends and formal social care to provide a more comprehensive picture of counselling's economic impact.
- Studies of treatment preferences among UK ethnic minority users of primary care services are necessary, as relatively little is known in this area.
- As treatment preferences data has been mostly gathered from recruits to clinical trials there is a need to survey the preferences of more typical users of primary care services outside of the trial setting.
- Further research is needed into the preferences and perceptions of patients who have been referred for counselling but do not present for treatment, as little is known in this area.

### **Acknowledgements**

This report was produced as a result of collaboration between two research centres at the University of Salford, Institute of Health and Social Care Research: Salford Centre for Social Work Research and Salford Centre for Nursing, Midwifery and Collaborative Research. The authors would like to thank colleagues in these research centres for their assistance with this study. We would especially like to thank Paula Ormandy and Janelle Yorke who reviewed articles for inclusion in the review, and Matthew Newton who provided clerical support.

Many thanks, too, to Peter Bower of the University of Manchester for acting as consultant to the project and to the research team at BACP: Nancy Rowland for clarity and guidance, Sukhdeep Khele for keeping the report on track and Kaye Richards for advice and guidance using EPPI software, the peer reviewers for helpful comments, and finally to BACP for funding the project.

## Section 1: Introduction

### The development of counselling in primary care

The first reports of counselling services in UK primary care date back to the early 1970s (Harray, 1975; Anderson and Hasler, 1979). Around this time, significant variations in the nature and provision of counselling services between different European countries were reported (Cohen, 1979). From these early developments, primary care counselling expanded on an ad hoc basis contributing to an uneven distribution of services (Kendrick et al, 1993). The popularity of counselling services among GPs was reported by Sibbald et al (1993) who found that, of those practices without a counselling service, 80 per cent of doctors stated that they would like to provide such a service. In more recent years, the provision of counselling and psychological therapies in primary care has been promoted by the Department of Health (DH, 2004). Providers have responded, to the point where approximately 80 per cent of English GP practices are reported to have on-site counselling services (Mellor-Clark, 2000).

### The problem

The prevalence of psychological problems in primary care has been highlighted by researchers over many years. Goldberg (1991) reported that in the UK at any given time 13 per cent of the population suffers from psychological disorders, 90 per cent of whom are cared for in primary care: an estimated 6.4 million patients per year. Other researchers report up to a third of patients presenting in primary care with primarily psychological problems (Pringle and Laverty, 1993). Hemmings (2000) reported that one quarter of GP consultations were for people with mental health problems, the vast majority being treated solely by primary care. In addition to those patients presenting with a diagnosable psychological disorder, many routine GP consultations have a psychosocial component, estimates ranging from 33 per cent (Goldberg, 1995) to 60 per cent (Newman and Rosensky, 1995).

More recently, the UK government, in its National Service Framework for Mental Health, has prioritised mental health, stating that, along with coronary heart disease, it is the most significant cause of ill health facing the UK (DH, 1999). The framework proposes that the extent of the problem has been under-recognised, that psychological problems have often been left undiagnosed and that the psychosocial problems often faced by those with an organic disease have been underestimated. It is reportedly estimated that only about 30–50 per cent of depression in primary care is recognised by GPs (DH, 1999). However, the complexity of problem presentation is recognised. Mental health problems may be masked by physical health problems; problems such as depression may contribute to physical health problems, and co-morbidity and dual diagnosis are common, particularly where substance misuse and personality disorder are present.

At any one time, one in six people in the UK will suffer from a mental health problem (DH, 1999). The most common problems are depression (including postnatal depression), eating disorders and anxiety disorders. In the case of postnatal depression, between 10 and 15 per cent of women suffer, increasing the risk of suicide – which is the second most common form of maternal death in the year after birth (DH, 1999). Depression, generally, is the single most common cause of disability in the UK with a prevalence of 17 per cent of those with a physical or mental health disability

(The Centre for Economic Performance Mental Health Policy Group (CEPMHPG), 2006). Annually, one woman in 15 and one man in 30 will be affected by depression, and every GP will see between 60 and 100 people with depression. It is estimated that most of the 4,000 suicides committed each year in England can be attributed to depression (DH, 1999). Depression in people from the Afro-Caribbean and Asian communities, and among refugees and asylum seekers, is under-recognised, despite the fact that the prevalence rate has been found to be 60 per cent higher than in the white population. It is also the case that those from black and minority ethnic communities are much less likely than white people to be referred to psychological therapies (DH, 1999).

Even for those people whose mental health problem has been diagnosed, problems may be left untreated; only one in four of those who suffer from depression or chronic anxiety receives treatment of any kind (CEPMHPG, 2006). The consequent costs in terms of human suffering, poor social functioning and loss to the economy are significant. With regard to the latter, in 2004, of those receiving incapacity benefit for disabilities of any kind, 38 per cent were for mental health problems. The fact that there are now more people in the UK receiving incapacity benefits than unemployment benefits highlights the scope of the problem. The total loss of output due to depression and chronic anxiety is estimated to be £12 billion per year which is one per cent of the UK national income. Calculated in terms of incapacity benefits and lost tax receipts, the cost to the tax payer is an estimated £7 billion (CEPMHPG, 2006). The moral, social and economic arguments for improving the treatment of mental health problems are compelling.

### The response

It has been recognised that most people with mental health problems are cared for by their GP and primary care team, and this is what they prefer. For every 100 patients who consult their GP with a mental health problem, only nine will be referred to specialist services for assessment, advice or treatment (DH, 1999). The UK government has identified primary care as a key point of treatment for those with psychological problems. Standards 2 and 3 of the National Service Framework for Mental Health highlight this: 'To deliver better primary mental health care, and to ensure consistent advice and help for people with mental health needs, including primary care services for individuals with severe mental illness' (DH, 1999, p28). The emphasis is upon easily accessed services that are responsive and sensitive to cultural needs, particularly those of people from black and minority ethnic communities. Reference to 'severe mental illness' also recognises that primary care teams will be working with a wider range of patients than simply the 'worried well'.

Charged with the task of producing the clinical guidelines necessary to support the clinically and cost-effective implementation of the National Service Frameworks, the National Institute for Health and Clinical Excellence (NICE) supports the use of psychological therapies as an adjunct or alternative to medication in the treatment of anxiety and depression. In the case of mild to moderate depression, psychological treatments such as problem-solving therapy, CBT and counselling are recommended in courses of six to eight sessions delivered over 10–12 weeks. The guideline also recommends, especially for those with mild to moderate depression, that patient preference should be considered when deciding on treatment. The importance of the therapeutic alliance and its association with positive outcomes regardless of the type of therapy provided is likewise highlighted (NICE, 2007a).

The NICE guidelines are explicit about the need for stepped care. In the case of the depression guideline (NICE, 2007a), the fact that depression is a spectrum disorder with varying levels of severity is clearly recognised. Five levels of severity are specified and different types of treatment recommended at each level. So, for example, guided self-help, computerised CBT and counselling are recommended for mild depression, contrasting with inpatient care, medication and electroconvulsive therapy for the most severe forms of the disorder. The model also acknowledges that if patients do not respond to lower-level treatments, their care may be 'stepped up' to the more intensive treatments recommended for a higher level of depression (NICE, 2007a).

The development of clear policy and clinical guidelines over recent years has not necessarily been matched by improved services for primary care patients with mental health problems. Long waiting lists have persisted, with the associated prolonged human suffering, economic and social costs. *The Depression Report* (CEPMHPG, 2006, p8) noted: 'No NICE guidelines are so far from being implemented as those for depression and anxiety...' and by way of comparison: 'If the NICE guidelines for breast cancer were not implemented, there would be uproar.' To address the gap between policy and practice, a new model of service provision has been proposed, involving multidisciplinary teams of psychological therapists, employment advisors, housing and benefits advisors, each working with a population of approximately 200,000. This would suggest that 250 teams would be needed nationally. Patients will either refer themselves or be referred through GPs, occupational health services or job centres. The intention is to give quick access for large numbers of people to high-quality psychological therapy delivered locally in GP surgeries, job centres, workplaces and voluntary/community premises. Within each team, these 'spokes' would be monitored and supervised from a central 'hub'. It is estimated that an extra 10,000 therapists are needed to deliver services on such a scale (CEPMHPG, 2006). In response to these proposals, the Improving Access to Psychological Therapies (IAPT) programme was launched in May 2006 with the opening of two demonstration sites, one in Doncaster and the other in Newham, East London. These centres assess patients within 48 hours of referral and offer psychological treatment based on NICE guidelines within seven days. If the data from these two pilot sites is positive, the plan is to roll out the service model on a national basis over a five to 10 year period (Gray, 2007).

## Which therapy?

The utility and effectiveness of psychological therapy in the treatment of common mental health problems has now been clearly recognised. Indeed, for the treatment of mild to moderate disorders, psychological therapy is recommended above medication (NICE, 2007). Unlike analogous areas of medicine, where medications are specific and homogenous compounds delivered in regulated dosages, psychological therapy is an umbrella term comprising hundreds of different approaches to treatment. This raises the question: if psychological treatment is recommended, what form should it take? There are strong arguments on both sides as to whether the definition of psychological therapy should be narrowed or whether diversity of treatment should

be preserved. Certainly, patients need clarity in order to understand exactly what the treatment is to which they are consenting, and service providers need to know exactly what treatment to provide and to whom. On the other hand, mental health diagnostic categories are notoriously imprecise. This is clearly recognised in the NICE guideline for depression, where authors state: 'The most significant limitation is with the conception of depression itself. The view of the Guideline Development Group is that it is too broad and heterogeneous a category, and has limited validity as a basis for effective treatment plans' (NICE, 2007a, p10). Mental health problems such as depression are not unitary phenomena and so it is arguable that flexible and diverse treatments are necessary to respond to the diverse presentations of the disorder. Likewise, to offer a range of effective treatments supports the principle of patient choice, which is fundamental to NICE clinical guidelines: 'Patient preference... should be considered when deciding on treatment' (NICE, 2007b, p12).

As already stated, the NICE depression guideline recommends several psychological treatments (problem-solving therapy, CBT, counselling) for mild to moderate depression, and CBT specifically for more severe forms (NICE, 2007a). Couple-focused therapy is recommended for patients who have a regular partner and have not benefited from a brief individual intervention. Psychodynamic psychotherapy is recommended for the complex comorbidities that may accompany depression, and interpersonal therapy is recognised as an effective treatment for moderate to severe depression. In a relatively narrow interpretation of the guidelines, Layard (2006) has noted: 'While further research will probably show the wider value of other types of treatment, it seems sensible to base any proposed expansion at this stage predominantly on CBT.' Based on the fact that there is a greater amount of evidence from randomised controlled trials (RCTs) supporting the effectiveness of CBT as compared with other therapies, this can be seen as a pragmatic decision aimed at getting good-quality treatment to those who need it as quickly as possible. It does not, however, obviate the need for continuing investigation into the relative effectiveness of different forms of psychological therapy in the primary care setting.

## This study

The aim of this study is to investigate the evidence base relating to the use of counselling in primary care. The approach involves the location, appraisal and synthesis of diverse forms of research evidence, including the findings of RCTs, practice-based evidence, cost-effectiveness studies and studies of patient satisfaction and treatment preferences. The intention is to provide evidence to support practice and policy-making and to contribute to the debate as to which types of psychological therapy should be made available to patients in primary care. Hence the review may be of interest to policy makers, service users, commissioners, researchers, GPs, primary care counselling managers and counselling practitioners. Counselling in primary care has a long history, and early studies have reported positive outcomes and high levels of satisfaction (Waydenfield, 1980; Coe, 1996; Booth, 1997; Keithley, 1995). With the expansion of psychological therapies in primary care, an update of the evidence base is timely.



## Section 2: Methodology

### Aim of the study

This review aims systematically to locate, appraise and synthesise evidence from scientific studies in order to obtain a reliable overview of the clinical- and cost-effectiveness of counselling in primary care and to summarise user perspectives. In order to carry out the study, clarity is needed with regard to definition of terms.

### Counselling

Counselling is a broad and generic term which has been used over many years to describe a psychological therapy that is flexible and centred on the patient's needs. As it encompasses many different approaches and techniques, arrival at a precise definition is no easy matter. McLeod (2001) emphasises the importance of motivation and agency on the part of the patient. It is not simply a matter of giving consent and thereafter being a passive recipient of treatment, as counselling demands a high degree of active participation from the patient in order to be effective. Counselling is also distinctive in its responsiveness to individual needs, requiring both an empathic understanding of the patient on the part of the counsellor and a flexibility of response. The aim of the intervention is to bring about change in the psychological domain, ie cognitive, affective and behavioural functioning. In its *Ethical Framework for Good Practice in Counselling and Psychotherapy* (2002), the British Association for Counselling and Psychotherapy (BACP) offers further clarification, defining outcomes in terms of the alleviation of personal distress and suffering, the fostering of a meaningful sense of self and the increase in personal effectiveness. While not attempting to resolve the debate as to whether counselling differs from psychotherapy, this review recognises that both terms are prevalent in the literature. Although there are differences in the training of counsellors and psychotherapists and the professional organisations which represent them, the interventions offered by both these professionals are indistinguishable in terms of how they are delivered and experienced by patients. From a service user's point of view, these interventions would tend to be seen as 'talking therapy' as distinct from medication.

While perhaps of limited interest to service users, from a service provider's point of view it is important to acknowledge the complexity of techniques and approaches encompassed by the term counselling. It is beyond the scope of this review to offer a comprehensive overview. However, a brief (and simplistic) summary will assist in the definition of terms. Counselling approaches broadly fit within four main traditions, with an additional fifth that seeks to integrate aspects of these four other traditions:

- *Humanistic/experiential* approaches tend to emphasise emotional expression and the development of a greater understanding and acceptance of affective, sensory and visceral experience.
- *Psychodynamic* approaches tend to focus on unconscious experience and areas of relational and developmental difficulty.
- *Cognitive-behavioural* approaches seek to identify and change patterns of thinking that lead to emotional and behavioural difficulties, while at the same time reinforcing positive behavioural change.
- *Post-modern/post-structural* approaches tend to focus on the role of language in shaping people's personality and

worldview. The therapeutic dialogue is seen as a potent way for people to change their sense of self and how they see the world.

- *Integrative* approaches seek to draw concepts and techniques from the above traditions in a coherent manner in order to tailor the therapy to the individual patient.

All approaches require what can be referred to as 'core' activities, such as sensitive and empathic listening on the part of the therapist, a high level of mutuality between therapist and client, a focus on specific areas of difficulty and the facilitation of emotional, cognitive and behavioural changes that are acceptable to the client.

Counselling is generally offered on the basis of a 'therapeutic hour', which normally refers to a face-to-face session of 50–60 minutes. This differentiates counselling sessions from the plethora of often quite brief interventions used by many health professionals involving the use of listening skills, advice-giving, emotional support and guidance. Although such interventions are often described as 'counselling' in the literature, it is important to make a distinction between this type of work and sessions of therapy that are contracted for and clearly delineated as a discrete treatment. Even if described as 'counselling', psychosocial interventions that are primarily educative, advisory or directed at treatment adherence (eg interventions directed at smoking-cessation, exercise or weight loss) have been excluded from the review, as has work with couples, as this is viewed as a specialist field in its own right. It is also recognised that although the most common mode of service delivery in primary care is individual therapy, counselling can be also offered in groups, and so it is reasonable for both modalities to be included in the review.

Initially, the decision was taken to view counselling as an overarching term comprising many different theoretical approaches, including CBT, problem-solving therapy and interpersonal therapy. As this decision led to an unfeasibly large yield of studies, the definition of counselling was narrowed at a later stage in the review process (see below).

### Primary care

The review has included both UK and international studies written in the English language, in order to capture as wide a range of relevant research as possible. Although this facilitates the location of the latest research in the English-speaking world, it must be acknowledged that variations in the systems of healthcare delivery across national boundaries make problematical a unitary definition of primary care. Primary care is the first point of access for medical advice and treatments, and the general practitioner is at the centre of this level of health care service. Treatment is delivered in medical centres/GP surgeries as opposed to hospital settings, and consequently there is an emphasis on outpatient care within the community as opposed to inpatient treatment. An earlier review (Bower and Rowland, 2006) found that primary care and domiciliary care were closely linked and so psychological treatments delivered in the client's own home were incorporated into our definition of primary care. The location of treatment delivery is seen as a central feature as regards inclusion in the review. It is recognised that in a number of cases psychology departments (sometimes defined as secondary care services) provide counselling services in GP surgeries. For the purpose of this review, despite the fact that such services are delivered by what could be viewed as a secondary care service, they are defined as primary care counselling so long as the counselling is delivered in GP surgeries.

## Types of participants

Both males and females of all ages who access counselling in primary care via a consultation with their general practitioner were eligible for inclusion in the review. There was no restriction on the type of psychological problem presented for treatment.

## Types of research evidence

The review seeks to address a number of key questions relevant to the delivery of counselling in primary care. The questions are interrelated and are based on the rationale that for a treatment to be funded and supported it must be of proven efficacy in scientific trials. It must also be proven to be effective in the complex and unpredictable world of routine clinical practice. Additionally, the cost of service delivery should be economical when balanced against clinical benefits, and the service should be consistent with, and not detract from, the delivery of other health treatments. The impact of offering this treatment on other areas of health service delivery (eg waiting lists for psychological treatments in secondary care, general practitioner consultation time) also needs to be considered. Patient perspectives are likewise of importance, in that they indicate whether and how far a treatment is acceptable to those receiving it. An understanding of patient preferences is important when planning services, particularly when a choice of equally effective treatments is available.

In order to address these questions, studies that fall into any of the following domains of research evidence were included in the review:

*Efficacy research* Well-conducted RCTs and systematic reviews of RCTs.

*Practice-based evidence* Evaluations of routine practice using pre and post outcome measures but which do not use randomisation or control conditions.

*Economic issues* Cost-effectiveness studies. Studies of health service utilisation.

*User perspectives* Patient preference surveys. Patient satisfaction surveys. Qualitative research investigating patients' experiences of counselling.

The above domains are viewed as interrelated in a non-hierarchical manner, providing a comprehensive overview of the research evidence for counselling in primary care. As each domain seeks to address a different question, the optimal research design for answering each question will differ between domains. For example, the best method of gathering patient preference data is by a survey. Testing whether CBT is more effective than counselling in the treatment of chronic fatigue is best undertaken by an RCT. Only those studies with an appropriate, rigorous and clearly described study design were included in the review. Unsystematic literature reviews and papers based on author opinion were excluded.

## Methods

### Locating the evidence

A number of methods were used to ensure that a comprehensive set of studies was located for potential inclusion in the review. Initially, scoping searches were carried out on the PsycINFO database to identify relevant search terms and key words in relation to counselling and primary care. This included a variety of search terms to ensure that international studies originating from countries with different terminology to describe primary care were located.

This process also helped establish an initial set of inclusion/exclusion criteria. Comprehensive searches were undertaken on the following seven databases:

- MEDLINE (biomedical information)
- CINAHL (nursing and allied health)
- Cochrane Library (systematic reviews of interventions and randomised controlled trials)
- EMBASE (biomedical information)
- HMIC (Health Management Information)
- PsycINFO (psychological literature)
- Social Policy and Practice (social policy and practice information).

The search strategies used can be found in Appendix A. These databases were selected because they cover a range of perspectives and so were likely to produce a comprehensive set of studies on the topic area. Due to resource limitations, included papers were restricted to those written in the English language and published after 1996 (although systematic reviews include earlier published studies). Electronic database searching was supplemented by the hand-searching of six journals (listed in Appendix B), and a call for grey literature and research in progress (details in Appendix B).

This process located a potential 3,193 unique papers for inclusion in the study. All references identified were loaded onto EPPI Reviewer Software (EPPI Reviewer 3.0, EPPI-Centre, Social Science Research Unit, Institute of Education, University of London, 2006). This database software was used to track and maintain an audit trail of all studies as they passed through the review process and to produce data for this final report. The titles and abstracts of all references were scanned by one of two reviewers (AB or AH) to determine their relevance to the review. Full papers were obtained for those that appeared to be relevant (n=338). These papers were checked against the inclusion criteria (see below). This process is illustrated in Figure 1.

### Inclusion and exclusion criteria

A set of inclusion/exclusion criteria was identified from the aims of the study and the initial scoping of the literature. These were discussed, refined and agreed by members of the project team and BACP.

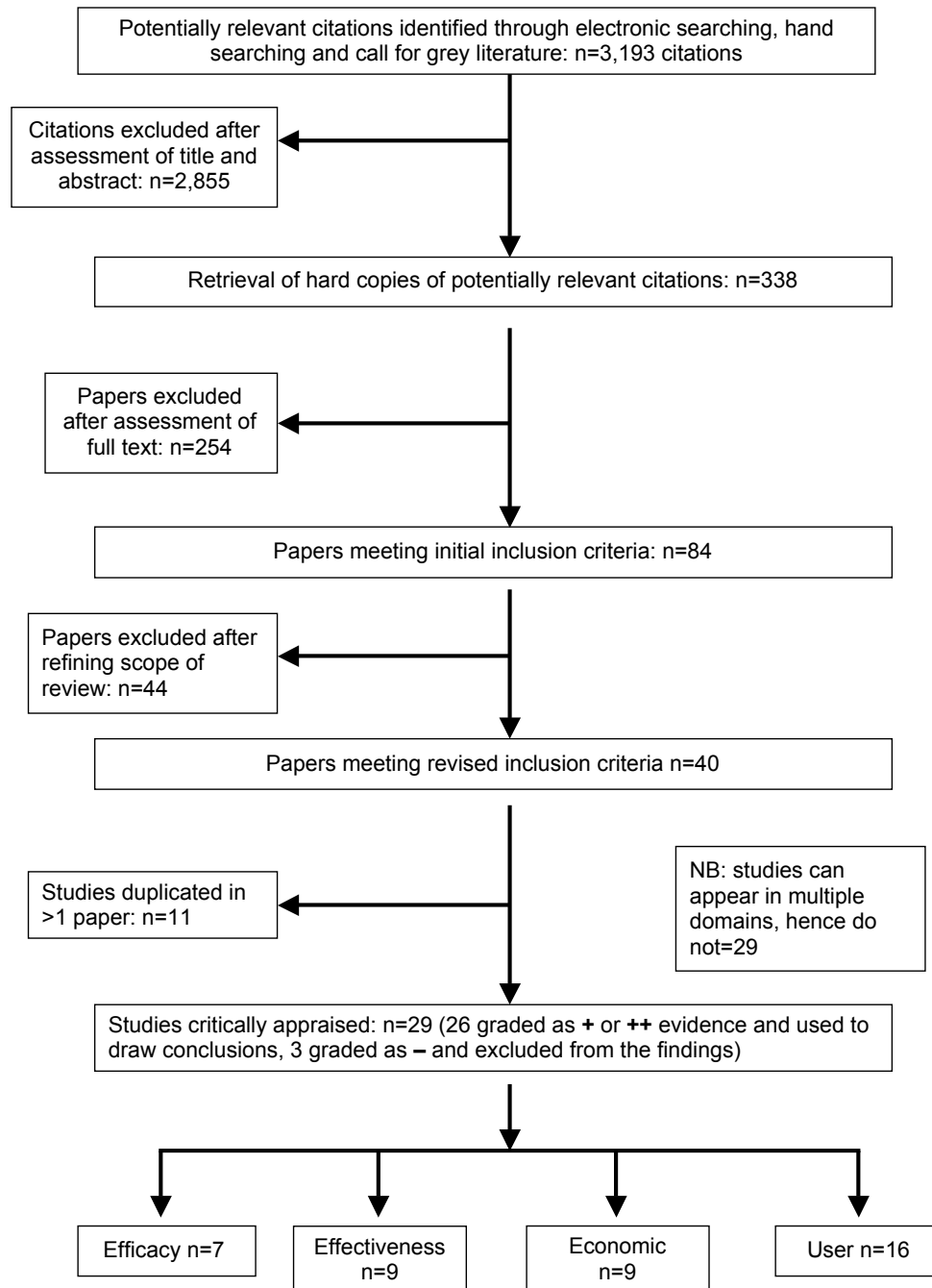
To be included in the review, studies had to:

- test interventions which fall within the BACP definition of counselling; are delivered within specific therapeutic sessions as opposed to brief listening and advice-giving interventions; are provided by trained counsellors as opposed to other professionals who may use counselling skills as part of their role; are with individuals or groups on a face-to-face basis
- test interventions which take place within a primary care setting (GP surgery, medical centre, individual's home)
- be written in English
- be published post 1996 (unless included in a systematic review published post 1996)

Furthermore, each included paper had to address *at least one* of the following four domains of research evidence relating to the delivery of counselling in primary care:

- *Efficacy*
  - RCTs
  - Systematic reviews of RCTs

Figure 1. Overview of literature search and retrieval



■ *Effectiveness (practice-based evidence)*

- Systematic reviews of practice-based evidence
- Studies of routine practice using pre and post outcome measures

■ *Economic issues*

- Cost-effectiveness of counselling
- The impact of counselling services on other areas of health service utilisation (eg impact on GP consultations, referral to waiting lists for other mental health services, prescription of medication)

■ *User perspectives*

- Studies investigating patients' perceptions of counselling
- Studies of patient satisfaction with counselling
- Studies of patients' treatment preferences.

Studies were excluded if they investigated:

- bibliotherapy
- self-help computer packages
- telephone counselling
- online counselling
- directive counselling interventions eg for weight loss, smoking cessation, alcohol intake reduction

- specialist services such as genetic counselling, couple counselling, family therapy
- hypnosis
- interventions provided by non-counsellors (eg nurses and general practitioners who have not trained in counselling/psychotherapy)
- evaluations of treatment packages comprising multiple interventions including counselling but where the effects of counselling cannot be separated from the other interventions in the package
- interventions in hospital settings
- interventions provided by secondary or tertiary services such as clinical psychology or psychiatry departments where the therapy takes place outside of primary care
- the diagnostic/referral behaviour of GPs
- training programmes for primary care counsellors
- the prevalence of psychological disorders.

Likewise studies were excluded if they lacked a rigorous method of data collection and analysis, for example:

- subjective discussions of case material
- discussions of how to treat certain conditions
- unsystematic literature reviews
- expert opinion
- book reviews, books and chapters of books, unless clearly reporting research findings.

This yielded 84 studies, which was deemed unmanageable to appraise within the resources and time frame of the project. An overview of these studies is provided in Appendix C. Following discussion with the project funders (BACP), it was decided to refine the scope of the review and exclude:

- studies if they had already been appraised within a relevant systematic review (Bowers and Rowland, 2006; Hemmings, 1999; Van Schaik, 2004)
- structured psychological interventions such as cognitive-behavioural therapy (CBT), interpersonal therapy (IPT) and problem-solving therapy (PST).

As a general rule, studies were included that use the term 'counselling' to describe at least one of the interventions which form the focus of the investigation. Studies of CBT were only included where counselling was used as a comparison condition. It is acknowledged that reducing the scope of the review in this way limits the review's ability to weigh the evidence relating to a wider range of interventions.

## Evaluating and synthesising the evidence

This re-scoping exercise resulted in 40 relevant papers. However, closer scrutiny revealed that in some cases a single study would be reported in several papers. This led to the identification of 29 unique studies. Each study was independently critically appraised by one reviewer from a team of five, using a data extraction template developed by two members of the review team (AH and AB; see Appendix D). To monitor the consistency of this process, a 15 per cent sample of the studies was appraised by a second reviewer and any discrepancies resolved by discussion. All data extraction was conducted directly using EPPI reviewer software.

## Quality of studies

The data extraction sheet (Appendix D) was designed to cope with diverse study designs, allow the reviewer to summarise the main elements of the study and make a judgement on the study quality (for example, by asking questions about sample selection, sample size, whether steps had been taken to minimise bias). Depending on the design of the study, the reviewer completed different sections on the data extraction sheet eg qualitative studies included details on the rigour of data analysis, whereas trials included details on allocation to groups and blinding. As part of the data extraction and critical appraisal process, each study was given a quality score, using a system adopted by the National Institute of Health and Clinical Excellence (NICE, 2006). Studies were graded according to the following criteria:

- ++ High quality. All or most of the criteria have been fulfilled. Conclusions very reliable. Had unfulfilled criteria been fulfilled, the conclusions of the study are thought very unlikely to alter. These studies were used to compile 'best evidence' within this review.
- + Good quality. Some of the criteria have been fulfilled. Conclusions quite reliable. Had unfulfilled criteria been fulfilled, the conclusions of the study are thought very unlikely to alter. These studies were used to compile 'supporting evidence' within this review.
- – Poor quality. Few of criteria fulfilled. Conclusions not reliable. Had unfulfilled criteria been fulfilled, the conclusions of the study would most likely have changed. These studies were appraised but their findings were not used as evidence within the review.

Although both 'high' and 'good quality' evidence were classed as reliable, a distinction between the two gradings was made on the basis of methodological rigour. This facilitated a more subtle weighing of the evidence. A study was not viewed as high quality simply by virtue of its design. For example, the study conducted by Hemmings (1999) would traditionally be placed at the top of the evidence hierarchy because it is a systematic review (Guyatt et al, 1995) and could potentially be viewed as high-quality evidence. However, the review methods were not clearly reported, making it difficult to determine whether the review was comprehensive and well conducted. This study was therefore rated as good (+) quality or supporting evidence. Equally, a well-conducted patient preference survey with a large sample size would be viewed as high quality evidence, even though this study design would traditionally be placed lower down a hierarchy of evidence.

Twenty-six studies were classified as reliable evidence. The quality of these studies was graded as ++ (high) or + (good). The conclusions reported in the following sections are drawn from these studies and are presented with their gradings to allow the reader to judge the weight of the evidence given to the findings. Summary tables of the evidence from all the studies are presented in Section 8, and a full list of studies included in the review can be found in the references section.

The evidence from the studies is presented as a narrative synthesis covering four domains: efficacy, effectiveness, economic issues and user perspectives. Each section comprises an overview, a summary table of the studies included in this domain, the findings relevant to each domain, together with a discussion of the methodological issues relevant to the studies within the domain. It is noteworthy that several studies, particularly systematic reviews, appear in more than one domain.

## Section 3: Efficacy

A glossary of abbreviations is provided in Appendix E, which may assist in interpreting the findings discussed in this and the following sections.

### Rationale

'Efficacy may be defined as the potency of an intervention when assessed under highly controlled conditions which serve to ensure that other factors cannot account for that potency.' (Bower, 2003, p334) It is only under highly controlled conditions that it can confidently be asserted that a particular intervention causes a reduction in certain symptoms; put simply, that a particular treatment ameliorates a particular disorder. Psychological symptoms are affected by a whole range of complex variables including the severity and chronicity of the problem, the patient's personality, the patient's environment and the simple passage of time, as most problems spontaneously remit in a percentage of patients. It is only by controlling for such variables that the effects of specific treatments on specific disorders can be revealed.

Efficacy has a central position in the evidence-based practice paradigm, which proposes that, with regard to healthcare, practice should be based upon those interventions that have strong evidence of efficacy. Evidence-based medicine is described by Sackett et al (1996, pp71–72) as 'the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients'. The aim is to integrate clinical judgement with high-quality research findings so that practice is both flexible and guided by the best contemporary knowledge, in order to maximise health outcomes for patients.

In order to provide reliable evidence of efficacy to guide clinical practice, the randomised controlled trial (RCT) has long been viewed as the research design of choice (Cochrane, 1972). The main characteristics of this study design are specificity of intervention and target problem, randomisation of participants to either an active treatment or a control group, the blinding of participants and researchers to the treatment conditions received, and the use of well-validated outcome measures pre and post intervention.

The implications of this for counselling research are that the therapeutic intervention should be standardised and delivered according to a protocol, to ensure that all participants receive the same treatment, and that the intervention can be replicated in other clinical and research settings. Participants should be carefully recruited on the basis of having a specific disorder and at a specific level of severity. Randomisation procedures are necessary to ensure that both intervention and control groups are equal in terms of all measured and unmeasured variables. Participants need to be allocated to a no-treatment group in order to control for spontaneous remission over time. The blinding of participants to treatment received is designed to control for the placebo effect (patients start to feel better if they think they are being treated) and the blinding of researchers is to avoid possible bias (researchers may treat those who are receiving the intervention differently from those who are not). If this level of experimental control is achieved then the study has a high level of internal validity. It can establish whether or not the intervention has caused the observed changes (Bower, 2003). Studies with this level of experimental control are often termed explanatory trials.

One of the main problems with efficacy research lies in the fact that the controls necessary to maintain high levels of internal validity inevitably reduce the external validity

of the study (Hemmings, 1999). External validity refers to the confidence with which the findings of a study can be generalised to other contexts (Bower, 2003). The external validity of a study is increased when the intervention is delivered as it would be in routine practice and the sample approximates a representative cross-section of those who use interventions in naturalistic healthcare settings.

Clinical trials in counselling tend to be pragmatic rather than explanatory in the way they attempt to strike a balance between internal and external validity in order to produce findings that are both reliable and applicable to real-world settings. This is achieved by locating the trial in the context of naturalistic practice, testing interventions as delivered by therapists as part of their routine work, rather than according to a specific therapeutic protocol. Study participants are typical service users, rather than those selected according to specific diagnostic criteria. Whereas it is unfeasible to blind both patients and therapists to the interventions delivered, it is possible for the researcher undertaking the analysis to be blind to the treatment received. The ethical dilemma of allocating people in distress to a no-treatment control condition is overcome with the use of a comparison group receiving an active treatment such as medication or usual GP care. Such trials seek to address the issues both of causality and generalisability. Studies in this domain of the review are either pragmatic clinical trials or systematic reviews, which generally summarise the findings of pragmatic clinical trials. One of the reviews (Hemmings, 1999) includes both clinical trials and small-scale naturalistic evaluations of counselling services which use pre and post measures but lack the usual controls associated with RCTs.

### Overview of studies

Searches in this domain located a total of seven studies, including two systematic reviews (Hemmings, 1999; Bower and Rowland, 2006) and five clinical trials (Bellamy and Adams, 2000; Kolk et al, 2004; Milgrom et al, 2005; Murray et al, 2003; Ridsdale et al, 2001). All were UK studies apart from Kolk et al (2004) which was carried out in Holland, and Milgrom et al (2005) which was an Australian study. It is also noteworthy that Hemmings' systematic review (1999) includes international studies. The studies investigate a range of interventions including generic counselling, person-centred therapy, psychodynamic counselling, CBT and integrative approaches. These are most frequently tested against routine primary care. In Bower and Rowland (2006), CBT is included as one of the comparison conditions, and in Ridsdale et al (2001), CBT is tested against generic counselling. The target problems identified in the systematic reviews (Bower and Rowland, 2006; Hemmings, 1999) tended to be wide-ranging. These included anxiety and depression along with generic psychological problems defined as all those clients referred to counselling with some kind of psychological distress. More specific target problems were present in some of the studies, particularly postnatal depression (Hemmings, 1999; Milgrom et al, 2005; Murray et al, 2003), psychosomatic disorders (Hemmings, 1999; Kolk et al, 2004), and chronic fatigue (Ridsdale et al, 2001). Two of the studies were rated as best evidence (Bower and Rowland, 2006; Ridsdale et al, 2001) and five studies as supporting evidence (Bellamy and Adams, 2000; Hemmings, 1999; Kolk et al, 2004; Milgrom et al, 2005; Murray et al, 2003) indicating that, on the whole, this set of studies represents good quality evidence with reliable findings.

### Findings

All studies in this domain use routine primary care (usual GP care) as a control condition, apart from one (Ridsdale et al,

**Table 1: Overview of studies addressing the efficacy of counselling in primary care**

Study	Study type	Country of origin	Main intervention(s)	Comparison/control conditions	Target problem	Quality rating
Bellamy and Adams (2000)	Clinical trial	UK	Non-specific generic counselling	Usual GP care	Depression Anxiety	+
Bower P, Rowland N (2006)	Systematic review	UK	Non-specific generic counselling Non-directive/supportive/person-centred counselling Psychodynamic counselling Integrative/eclectic/mixed-approach counselling CBT	Usual GP care/routine primary care Usual GP care plus medication CBT	Non-specific, generic psychological problems Depression Anxiety	++
Hemmings A (1999)	Systematic review	UK  International studies included	Non-specific generic counselling Non-directive/supportive/person-centred counselling Integrative/eclectic/mixed-approach counselling CBT Problem-solving therapy Interpersonal therapy	Usual GP care/routine primary care Medication Usual GP care plus medication	Non-specific, generic psychological problems Depression Anxiety Postnatal depression Psychosomatic/medically unexplained symptoms	+
Kolk AM, Schagen S, Hanewald GJ (2004)	Clinical trial	Holland	Non-directive/supportive/person-centred counselling Integrative/eclectic/mixed-approach counselling CBT	Usual GP care/routine primary care	Psychosomatic/medically unexplained symptoms	+
Milgrom J, Negri LM, Gemmill AW, McNeil M, Martin PR (2005)	Clinical trial	Australia	Non-specific generic counselling CBT	Usual GP care/routine primary care	Postnatal depression	+
Murray L, Cooper PJ, Wilson A, Romaniuk H (2003)  Also reported in: Cooper PJ, Murray L, Wilson A, Romaniuk H (2003)	Clinical trial	UK	Non-directive/supportive/person-centred counselling Psychodynamic counselling CBT	Usual GP care/routine primary care	Postnatal depression	+
Ridsdale L, Godfrey E, Chalder T, Seed P, King M, Wallace P, Wessely S, Fatigue Trialists' Group (2001)  Also reported in Chisholm et al (2001)	Clinical trial	UK	CBT	Non-specific generic counselling	Chronic fatigue	++

2001) which compares CBT with counselling. Routine primary care consists of regular consultations with a GP or health professional and in some cases medication as an additional intervention.

### Systematic reviews

Two systematic reviews (Bower and Rowland, 2006; Hemmings, 1999) provide a wealth of evidence relating to the

efficacy of counselling in primary care. Bower and Rowland (2006) undertook a review for the Cochrane Collaboration that aimed to assess the efficacy and cost-effectiveness of counselling in primary care by reviewing outcome data in randomised controlled trials for patients with psychological and psychosocial problems considered suitable for counselling. Eight trials published before June 2005 were included in their review and, as noted earlier, these trials (Boot, 1994; Harvey, 1998; Hemmings, 1997; Friedli, 1997;

King, 2000; Simpson, 2000; Chilvers, 2001; Barrowclough, 2001) have not been re-analysed for the purposes of this review. Bower and Rowland (2006) included trials if they were explanatory or pragmatic, and covered males and females of all ages consulting with a GP for psychological or psychosocial problems. Specialist areas of counselling (drug and alcohol, debt, genetic and abortion counselling) were excluded, as were trials covering somatic or psychosomatic problems such as pain and fatigue. Each trial was assessed for quality using a standardised procedure, and overall treatment effects were calculated by the review team using 95 per cent confidence intervals (CIs). Authors found counselling to be more effective than usual GP care in the short term. The results and findings of the review are reported in more detail in the relevant sections below.

In another systematic review, Hemmings (1999) sought to evaluate the effects of counselling in primary care, taking on board evidence from both RCTs and more naturalistic counselling service evaluations. His conclusions were based on literature searches undertaken between 1975 and 1998. He found counselling to be more effective than usual GP care. He concluded that evidence from RCTs should be supplemented by findings from more naturalistic practice-based evidence. The inclusion criteria for the review are not clear. However, it appears that a much broader definition of counselling and primary care has been used than the one adopted for the purposes of this review and the one by Bower and Rowland (2006), making comparisons of the findings difficult. The overall aim of the review meets the inclusion criteria for this review, but it is likely that some of the individual studies would not meet our inclusion criteria. Although a wide range of studies is included and described in the review, their quality is not assessed individually and nor are the results drawn together in a way that allows the studies to be compared. Hemmings lists and briefly describes eight RCTs which used criterion-based diagnostic assessments – a different set of studies than those assessed by Bower and Rowland (2006) – and 11 controlled studies that he suggests produced positive results for counselling practice: apart from one, none of these are included in the Bower and Rowland (2006) review. He also provides a table of 20 RCTs which he classifies as providing evidence of effectiveness rather than efficacy as they are undertaken in clinical settings. Where relevant, Hemmings' (1999) efficacy-specific and overall findings have been reported below.

### ***Efficacy of counselling in the short term (up to eight months)***

Bower and Rowland (2006) found that counselling is more effective than usual care in terms of mental health outcomes in the short term. However these advantages did not endure in the longer term. This finding was based on six trials reporting short-term outcomes and utilising 'usual care' as a comparison. Patients receiving counselling had significantly lower psychological symptom scores than patients receiving 'usual care' (overall standardised mean difference -0.28, 95% CI -0.43 to -0.13, n=772). As a short-term, time-limited therapy, it has a short-term impact. This finding is supported by Murray et al (2003) who found that counselling for postnatal depression was beneficial only in the short term. This is based on 193 women who were randomly assigned to one of three interventions or a control. The benefits of treatment were apparent immediately post treatment at 4.5 months postpartum but not at nine months postpartum). Ridsdale et al (2001) used 129 patients to compare CBT and counselling for fatigue, assessing outcomes at six weeks (post treatment) and six months, and found that both treatments reduced fatigue at six months with a non-significant trend in favour of counselling. Kolk et al (2004) examined unexplained physical and psychological

symptoms and found that self-reported, unexplained physical symptoms decreased in the short term (six months) and the longer term (12 months) for both the counselling and control groups. When comparing an intervention group (n=54) with a no-treatment waiting list group (n=16), moderate but not statistically significant mean effect sizes were found by Bellamy and Adams: 0.27 at eight-week follow-up and 0.32 at 16-week follow-up.

### ***Efficacy of counselling in the longer term (nine to 18 months)***

Bower and Rowland (2006) found that the advantages of counselling in the short term were not sustained over a longer time period. This was based on four trials reporting long-term outcomes and utilising usual GP care as a comparison. Patients receiving counselling did not differ in psychological symptom scores compared to patients receiving usual care (overall standardised mean difference -0.09, 95% CI -0.27 to 0.10, n=475). There were similar findings for counselling in terms of very long-term outcomes (two years post treatment). However, this finding was based on one that included chronic patients only. This was again supported by Murray et al (2003) who measured outcomes at 4.5, nine, 18 and 60 months and found that the advantages of counselling were only sustained at 4.5 months.

### ***Number of counselling sessions offered***

Studies varied in the number of counselling sessions that were offered as part of the intervention. Ridsdale et al (2001) offered six sessions, Milgrom et al (2005) offered nine, Murray (2003) offered 10 and Kolk et al (2004) offered a maximum of 12. In the Bower and Rowland (2006) review, there was greater homogeneity between studies, with the majority offering six sessions.

### ***Counselling versus routine primary care***

Milgrom et al (2005) investigated the efficacy of counselling versus routine primary care in a study targeting postnatal depression. The study compared the effects of CBT and counselling with routine primary care and assessed the relative value of group and individual forms of therapy. Both forms of therapy were found to be superior to routine care in terms of reductions in both depression and anxiety (by around seven points on the Beck Depression Inventory (BDI) and eight points on the Beck Anxiety Inventory (BAI)). Studies in this domain of the review provide relatively few data as to the effectiveness of counselling compared with medication. However, on the basis of one small study comparing counselling with GP antidepressant treatment, Bower and Rowland (2006) found that counselling did not differ in effectiveness from medication. There were no significant differences in outcome in either the short (standardised mean difference 0.04, 95% CI -0.39 to 0.47, n=83) or long term (standardised mean difference 0.17, 95% CI -0.32 to 0.66, n=65).

### ***Efficacy of different types of counselling***

Several studies compare the effects of different types of counselling in the primary care setting (Bower and Rowland, 2006; Milgrom et al, 2005; Murray et al, 2003; Ridsdale et al, 2001). Based on the results of two trials (King, 2000; Barrowclough, 2001), Bower and Rowland (2006) found that counselling did not generally differ in effectiveness from CBT. One trial comparing counselling with CBT in depressed patients found no significant differences in outcome either in the short (standardised mean difference 0.02, 95% CI

-0.28 to 0.24, n=229) or long term (standardised mean difference 0.13, 95% CI -0.14 to 0.41, n=209). Another study comparing counselling with CBT in anxious older patients found no significant differences in outcome in the short term (standardised mean difference 0.53, 95% CI -0.09 to 1.14, n=43), long term (standardised mean difference 0.47, 95% CI -0.18 to 1.12, n=39) or very long term (standardised mean difference 0.49, 95% CI -0.16 to 1.14, n=39). In the treatment of postnatal depression, Milgrom et al (2005) tested both group and individual interventions against routine care. Post treatment, the percentages of women whose BDI scores fell below the threshold for clinical depression were: group CBT 55 per cent, group counselling 64 per cent, individual counselling 59 per cent. This compares with 29 per cent in the routine primary care group. No significant differences in outcomes were discerned between CBT and counselling, but individual counselling yielded the best outcome in terms of depression (by three to five points on the BDI).

Murray et al (2003) undertook a longitudinal study of the effects of non-directive counselling, CBT and psychodynamic therapy with postnatal depression, measuring outcomes at 4.5, 9, 18 months and 5 years postpartum. The authors found that at 4.5 months, psychodynamic therapy produced a rate of reduction in depression significantly superior to that of the other groups. They also found that non-directive counselling produced better infant emotional and behaviour ratings at 18 months and more sensitive early mother-infant interactions.

A trial by Ridsdale et al (2001) set out to discern whether counselling is as effective as CBT in the treatment of chronic fatigue. This study also included an economic element described by Chisholm et al (2001), which is covered in Section 5 of this review. No significant difference in effect was found between CBT and counselling, although a non-significant trend in favour of counselling was discerned. Mean fatigue score at baseline using the Fatigue Questionnaire was 27.5. At six-month follow-up, this was 18.6 (SD=8.4) in the counselling group and 20.8 (SD=9.7) in the CBT group. No significant differences were discerned between the two therapies in measures of anxiety, depression or social adjustment outcomes.

### **Target problems**

Two studies (Bower and Rowland, 2006; Hemmings, 1999) have non-specific psychological problems as the focus of investigation, whereas a further five studies address more specific psychological disorders (Milgrom et al, 2005; Murray et al, 2003; Kolk et al, 2004; Ridsdale et al, 2001).

#### **Non-specific psychological problems**

Two systematic reviews (Bower and Rowland, 2006; Hemmings, 1999) address the effects of counselling with non-specific psychological problems. By definition, primary care is normally the first point of contact for patients who are distressed. GPs tend not to undertake detailed psychological assessments of patients in order to diagnose a mental health disorder. Hence patients are normally referred to primary care counselling services without diagnosis of a specific disorder but with an identified problem that is viewed as primarily emotional or psychological. The fact that users of primary care counselling services are clinically heterogeneous is recognised by Bower and Rowland (2006) and therefore the types of measures used to evaluate outcomes in this population will be varied. Therefore, studies using measures of mental health symptoms such as anxiety and depression as well as social and occupational functioning are included in their review. With regard to the non-specific psychological problems experienced by this heterogeneous population,

their review found that counselling is more effective than usual care in the short term. These findings are supported by Hemmings (1999) whose systematic review similarly includes clinically heterogeneous samples of patients with non-specific psychological problems and concludes that counselling is more effective than usual GP care.

#### **Anxiety and depression**

Studies of anxiety and depression are included in the two systematic reviews (Bower and Rowland, 2006; Hemmings, 1999). Of the eight studies included in Bower and Rowland (2006), six include participants with either depression or anxiety, or a mixture of both disorders. Of the eight trials included in Hemmings (1999), seven target depression and one anxiety. Hence the overall findings of these reviews are relevant to depressed and anxious primary care populations. Bellamy and Adams (2000) found that on depression scores, 11 per cent of the control group achieved clinically significant change as compared with 61 per cent in the intervention group. They also found clinically but not statistically significant outcomes in terms of anxiety scores. Post intervention, 13 per cent of the control group as opposed to 48 per cent of the treatment group achieved clinically significant change. However, the sample size was too small to draw definitive conclusions.

#### **Postnatal depression**

Two studies test the effects of counselling with samples of postnatally depressed patients (Milgrom et al, 2005; Murray et al, 2003). Milgrom et al (2005) found both CBT and counselling superior to routine care in terms of reductions in both depression and anxiety. The study concluded that both counselling and CBT for women with postnatal depression leads to clinically significant reduction in symptoms and that the benefits of these therapies may be maximised by offering them on a one-to-one basis.

Murray et al (2003) evaluate the long-term effects of counselling for postnatal depression. Non-directive counselling, CBT and psychodynamic therapy are assessed in relation to three variables: the mother-child relationship, child development and maternal mood. In the case of maternal mood, the study found that at 4.5 months postpartum, immediately following treatment, 40 per cent of the control group had remitted from depression. This compares with 61 per cent of the treatment groups, a difference of 21 per cent favouring treatment. However, the benefits of the interventions disappeared at longer-term follow-up. At nine months, there is a difference between treatment and controls of only four per cent in favour of treatment. At 18 months, 11 per cent fewer in treatment groups remitted as compared with controls. At five years, just four per cent more in treatment groups remitted compared with controls. Hence, after 4.5 months postpartum, treatments were not significantly different from the control condition in reducing symptoms of postnatal depression.

With regard to other variables immediately post treatment, all three conditions had a significant benefit on maternal reports of early difficulties in relationships with the infants. The interventions had no significant impact on maternal management of early infant behaviour problems, security of infant-mother attachment, infant cognitive development or any child outcome at five years. The study concludes that counselling was beneficial in the short term, immediately following treatment, there being no superiority over routine primary care in the long term.

#### **Psychosomatic symptoms**

In an investigation of the effects of counselling on psychosomatic symptoms, Kolk et al (2004) randomised



participants to one of two conditions, counselling plus usual GP care and usual GP care only. Authors found that the intervention and control groups did not differ in symptom reduction post treatment, and so counselling produced no advantage over usual GP care. A possible interpretation of this finding is that psychosomatic symptoms may be less amenable to psychological treatment than disorders such as depression and anxiety.

### **Chronic fatigue**

Among a population with chronic fatigue, a trial by Ridsdale et al (2001) set out to discern whether counselling is as effective as CBT. No significant difference in effect was found between CBT and counselling. Mean fatigue score at baseline using the Fatigue Questionnaire was 27.5. At six-month follow-up, this was 18.6 (SD=8.4) in the counselling group and 20.8 (SD=9.7) in the CBT group. Although a non-significant trend in favour of counselling was discerned, there were no significant differences in effect between the two therapies in terms of anxiety and depression or social adjustment outcomes. The use of antidepressants and GP consultations decreased after therapy but there were no differences between groups. The study concluded that CBT and counselling were both beneficial and equivalent in effect for patients with chronic fatigue in primary care.

## **Methodological issues**

### **Systematic reviews**

The two systematic reviews included in this domain of evidence (Hemmings, 1999; Bower and Rowland, 2006) have distinct differences in methodology. Bower and Rowland's (2006) review has strict inclusion criteria restricting the analysis to well-conducted clinical trials of counselling delivered by therapists trained to BACP standards. The review process involved a detailed quality assessment of relevant studies to determine whether the findings were reliable enough for inclusion. Just eight studies were then subjected to a meta-analysis, producing pooled effect-sizes. The findings produced by such a rigorous review method can be regarded as the highest level of evidence with regard to efficacy. The strict inclusion criteria also render the findings relevant to counsellors and counselling services as defined by BACP rather than to the plethora of other psychological therapies.

In contrast, Hemmings (1999) argues that the utility of clinical trials in evaluating the effectiveness of clinically representative service delivery is severely limited. As a result, his review is much more wide-ranging and includes more diverse study types, particularly small-scale evaluations of counselling services. It was conducted seven years prior to the Bower and Rowland (2006) review and so provides evidence which is less contemporary. A greater number of studies using a wide-ranging definition of counselling and incorporating different types of therapies has been included (>50), resulting in a very comprehensive review. A narrative rather than a meta-analytical approach has been taken to the presentation of results. The studies were not subjected to a quality assessment or analysed in a systematic way, making problematical comparisons between the studies in the review itself, and comparisons between this and other systematic reviews. The included interventions are delivered by a wide range of professionals: GPs, nurses, social workers, clinical psychologists. Hence the interventions are much more heterogeneous than in the Bower and Rowland (2006) review. Only a limited number (n=3) of electronic databases were searched between 1975 and 1998. As the review has been conducted by an individual researcher, there is no evidence of studies being double-reviewed and so the review process

is more susceptible to bias. So in summary, the Hemmings (1999) review is more comprehensive and wide-ranging in its scope but its findings should be regarded as less reliable than Bower and Rowland (2006).

### **Clinical trials**

Bower and Rowland (2006) make the distinction between pragmatic and explanatory trials. While the latter attempt to discern causal relationships between interventions and outcomes in highly controlled environments, the former attempt to test routine interventions in naturalistic settings with typical patients. While the findings of pragmatic trials are obviously more generalisable to routine practice than those of explanatory trials, they are less able confidently to establish that a particular intervention produces a particular effect. If trials are to be conducted in naturalistic settings, compromises have to be made to study design. Randomisation is often unacceptable to patients in primary care who may have a strong preference for a particular treatment. The blinding of participants to the type of intervention received is likewise unfeasible with a treatment such as counselling. It is the norm for patients in primary care to be referred for counselling without a specific mental health diagnosis. Hence samples will be more heterogeneous than those recruited in well-controlled RCTs. It follows that in treating heterogeneous populations, counsellors need to be flexible in their approach to meet a variety of individual needs, as opposed to adhering to manualised therapeutic protocols, which is often a demand of the RCT study design.

For ethical reasons, the use of no-treatment control groups in order accurately to measure the effects of an intervention is also unfeasible in naturalistic settings, as patients with genuine problems cannot be left untreated. Hence pragmatic trials tend to compare two or more active interventions (such as counselling versus usual care) rather than treatment versus no treatment. A problem with this type of trial lies with the widespread use of usual GP care as a comparison condition. This active intervention is rarely described in detail and as different GPs make use of varying levels of attention, listening skills and empathy, such variations will impact on the resulting calculation of the counselling intervention's effect. It could be argued that such trials test one counselling intervention delivered by a professional counsellor with another less intense counselling intervention delivered by GPs.

Similarly in a study of postnatal depression by Murray et al (2003), health visitors formed part of the counselling intervention group having been trained to deliver psychological interventions in patients' homes, and the 'usual care' group also involved health visitors carrying out regular home visits. Delivery of two treatments by similar professionals is likely to lead to a lack of differentiation between the two interventions. The selection of an appropriate comparison condition is also discussed by Ridsdale et al (2001) who, in a well-conducted study, tested CBT with counselling. Authors found a lack of differential effects between the two therapies and concluded that usual GP care would have been a more appropriate control condition against which to test the CBT intervention.

Regardless of the demands of naturalistic settings, some trialists manage to maintain high levels of experimental control. For example, Kolk et al (2004) made use of randomisation and concealment along with a wide range of well-validated outcome measures. A level of concealment was achieved, as, in order to reduce bias, steps were taken to ensure researchers were unaware who had been allocated to which treatment group. However, difficulty in recruiting participants to the trial led to a relatively small control group, thus reducing the power of the study. This problem may

result from patients being reluctant to accept randomisation. Similar problems are reported by Milgrom et al (2005) in a well-controlled study using randomisation, concealment and measures of treatment adherence. The attrition rate in the study was high, as only 57 cases were available at 12-month follow-up, compared with the 192 participants who entered the trial. As a result, the intended 12-month follow-up was abandoned, and the study reports on short-term effects only. The fact that patients were allocated to treatment rather than exercising a choice may have contributed to the high attrition rate. Bellamy and Adams (2000) found that GPs were reluctant to randomise distressed patients to a 'usual care' control group, thus compromising the internal validity of their trial.

On the other hand, a study by Murray et al (2003) uses randomisation and concealment and manages to retain a low attrition rate even at five-year follow-up: 193 participants were randomised to groups pre treatment and a total of 138 completed measures at five years. This is a complex study using different outcome measures at different points of follow-up. For example, mother-child relationship was measured

by means of video tapes plus a researcher-completed scale; infant attachment was measured using the Ainsworth Strange Situation Procedure; and children's behavioural problems were measured by teachers completing a behaviour checklist when the children reached the age of five. The investigation of such a wide range of variables on developing children over a long time period inevitably necessitates the use of such a wide variety of measures. However, it is difficult to determine whether changes have occurred in the variables over time, except in the case of maternal mood where one scale is used consistently.

Clinical trials generally tend to measure 'cure' rather than 'care' (Bower and Rowland, 2006). The effects of interventions are often measured in terms of mental health disorder symptom reduction in order to establish whether a particular treatment ameliorates a particular problem. While this is an important question, as with many health interventions, counselling can also be seen as a form of care for those with psychological problems. This dimension may be captured more successfully where trials use measures of satisfaction and subjective well being.

## Section 4: Effectiveness

### Rationale

As discussed in the last section, the difficulties inherent in conducting RCTs of counselling in naturalistic settings means that this type of study in its purest form cannot easily be replicated in the primary care context. It is also the case that the findings of RCTs which have been conducted under highly-controlled experimental conditions cannot readily be generalised to primary care populations and settings. This has fuelled calls for a new research paradigm that focuses on the effectiveness of counselling in routine settings with typical populations. The term practice-based evidence (in contrast with evidence-based practice) has been coined to describe this type of research (Barkham and Mellor-Clark, 2000). The characteristics of efficacy and effectiveness research are contrasted in Table 2.

As discussed earlier, pragmatic trials tend to bridge the gap between efficacy and effectiveness research, addressing the need for both internal and external validity. Although, like efficacy studies, effectiveness studies measure outcomes pre and post intervention, for the purposes of this review they differ from efficacy research by their lack of a control or comparison group. Hence the main difference is that trials are concerned with statistical differences between groups. Effectiveness studies do not have a comparator and can only report on change within the treatment group or with regard to an external criterion, such as whether post-treatment participants achieved a level of problem severity typical of a non-clinical population. The emphasis on both statistical and clinical significance in effectiveness research has given rise to the concept of reliable and clinically significant change (Evans et al, 1998).

Efficacy studies tend to rely on the rigorous application of inclusion/exclusion criteria to create samples which are representative of particular populations. Effectiveness research relies on the collection of large multi-centre data sets, which by their very size and geographical distribution may make them representative of service users generally. However, it must be recognised that, regardless of these features, low response rates within studies have the effect of reducing external validity. For example, if only 10 per cent of those entering an effectiveness study complete the end-of-therapy measures, the sample cannot be claimed to be representative. In order to collect meaningful data on a large scale, standardised methods are necessary, involving,

preferably, a single, widely used, well-validated outcome measure. CORE is an example of this kind of measure. It is client-completed and contains 34 items in the domains of subjective wellbeing, symptoms, functioning and also risk and harm to self or others. Collection of data on a large scale assists the establishment of national benchmarks against which individual services can be evaluated. From a national data set, parameters can be established relating to clinical outcomes, the demographic profile of service users, the types of problem presented, the severity of problems at intake, levels of risk and waiting times (Evans et al, 2003). In this way, effectiveness research can have the dual function of generating practice-based evidence and providing a platform for the quality assurance of individual services.

The complementary and interrelated nature of efficacy and effectiveness research has been modelled by some researchers in terms of a continuum, with the two research paradigms occupying different positions. For example, Salkovskis (1995) describes how a clinical problem may be identified by practitioners and explored on a small scale. This may then lead to more strictly controlled experimental research (efficacy) and finally to the broadening out of the research findings into practice settings with typical service users (effectiveness). The sequencing of the efficacy and effectiveness research in this way is based on the principle that internal validity must be established before external validity (Hoagwood et al, 1995). It is only when both of these criteria have been met that research findings constitute evidence which is both rigorous and relevant to practice.

### Overview of studies

Searches in this domain located a total of 10 studies, including one systematic review comprising efficacy and effectiveness research (Hemmings, 1999) and nine pre and post studies (Baker et al, 2002; Booth et al, 1997; Evans et al, 2003; Gordon and Graham, 1996; Kates et al, 2002; Mellor-Clark et al, 2001; Murray et al, 2000; Nettleton et al, 2000; Newton, 2002). Hemmings' (1999) systematic review summarises evidence from both clinical trials and small-scale pre and post studies. A wide variety of well-validated outcome measures is used in the studies (see Table 3). Just one study (Murray et al, 2000) uses only measures specifically designed for the study, although others supplement well-validated measures with specifically designed ones (Gordon and Graham, 1996). Two studies (Booth et al, 1997; Newton, 2002) use goal attainment scales (GAS) where participants specify their therapeutic goals pre counselling and rate their

**Table 2: Characteristics of efficacy and effectiveness research**

	Efficacy	Effectiveness
Research setting	Controlled conditions	Real-world conditions
Therapist variables	Manualised therapy	Degree of practitioner autonomy
Patient variables	Single diagnosis	Frequent co-morbid diagnosis
Model of research	Randomised controlled trials	Naturalistic service evaluation
Level of internal validity	High	Low
Degree of generalisability	Low	High
Primary reference group	Research community	Service providers, managers, practitioners

**Table 3: Overview of effectiveness studies**

Study	Study type	Country of origin	Outcome measure(s) (see Appendix D for full description)	Intervention	Target problem	Quality rating
Baker et al (2002)	Pre and post study	UK	DSSI Rosenberg self-esteem scale QOL	Non-specific generic counselling	Non-specific, generic psychological problems Depression Anxiety	++
Booth et al (1997)	Pre and post study	UK	HAT QOL GAS	Humanistic/eclectic Psychodynamic	Non-specific, generic psychological problems	+
Evans et al (2003)	Pre and post study	UK	CORE	Non-specific generic counselling	Non-specific, generic psychological problems	++
Gordon and Graham (1996) Also reported in Gordon and Wedge (1998)	Pre and post study	UK	SCL-90R HADS EOL Satisfaction questionnaire and problem rating scale specifically designed for the study	Person-centred counselling	Non-specific, generic psychological problems Depression Anxiety	+
Hemmings A (1999)	Systematic review	UK International studies were included	Measures used in included studies not listed	Non-specific generic counselling Non-directive/supportive/person-centred counselling Integrative/eclectic/mixed-approach counselling CBT Problem-solving therapy Interpersonal therapy	Non-specific, generic psychological problems Depression Anxiety Postnatal depression Psychosomatic/medically unexplained symptoms	+
Kates et al (2002)	Pre and post study	Canada	GHQ CESD SF-36 CSQ VSQ	Non-specific generic counselling	Non-specific, generic psychological problems	+
Mellor-Clark et al (2001)	Pre and post study	UK	CORE	Non-specific generic counselling	Non-specific, generic psychological problems	++
Murray et al (2000)	Pre and post study	UK	Specifically designed measures of GP satisfaction with service, and therapist and GP perceptions of outcome	Non-specific generic counselling	Non-specific, generic psychological problems	+
Nettleton et al (2000)	Pre and post study	UK	Adapted General Wellbeing Index	Non-specific generic counselling	Non-specific, generic psychological problems	+
Newton (2002)	Pre and post study	UK	GAS	Non-specific generic counselling	Non-specific, generic psychological problems	+

attainment of these goals at the end of therapy. All studies were conducted in the UK, apart from Kates et al (2002) which is Canadian and Hemmings' (1999) systematic review, which includes international studies. The majority of studies investigate the effects of non-specific, generic counselling (n=9), although Hemmings (1999) also includes a range of other psychological therapies (see Table 3). In one study (Gordon and Graham, 1996), the intervention is person-centred counselling, and in another (Booth et al, 1997), it is described as humanistic, eclectic and psychodynamic. All studies have non-specific, generic psychological problems as the target of the intervention, although depression and anxiety are also specified in three studies (Baker et al, 2002; Gordon and Graham, 1996; Hemmings, 1999). Hemmings' (1999) wide-ranging review also includes postnatal depression and psychosomatic disorders. In terms of quality, 30 per cent (n=3) of this group of studies were rated as the highest level of evidence and 70 per cent (n=7) were rated as good-quality supporting evidence. Hence evidence in this domain can be regarded as generally reliable.

## Findings

### Systematic reviews

One systematic review provided evidence that can be used in this section. Hemmings (1999) conducted a systematic review that included evidence from randomised controlled trials (discussed in previous section) and studies using non-RCT methods, both located in the published and grey literature. Fourteen studies using a range of methods (survey, descriptive studies, cross-sectional studies for example) are briefly described, together with 26 reports of grey literature. As noted in the efficacy section, this review is presented in the form of tables and a narrative, making it difficult to compare evidence between studies.

### The clinical effectiveness of primary care counselling

#### Short term (up to eight months post treatment)

Several studies focus on the short-term effects of brief counselling interventions (Evans et al, 2003; Gordon and Graham, 1996; Hemmings, 1999; Kates et al, 2002; Mellor-Clarke et al, 2001). In a high-quality study by Mellor-Clarke et al (2001), patients were offered six sessions of counselling, the average number attended being 4.3. With a response rate of 95 per cent, a large sample of 1,087 clients completed pre and post counselling measures, with 76 per cent of the sample making a statistically reliable positive change. A large pre-post effect size of 1.52 was found. Three out of four clients reported reliable improvement and of these, three out of every five reported clinically meaningful improvements, suggesting that the intervention was effective. Similar findings are reported by Evans et al (2003) who, in a very large multi-centre sample (n=6610), found that four out of five patients achieved reliable and clinically significant improvement post treatment. These findings are supported by Hemmings (1999) whose systematic review summarised the findings of 14 published and 26 unpublished counselling service evaluations, concluding that studies of effectiveness support the use of counselling in primary care.

Using the Hospital and Depression Anxiety Scale (HADS) and Symptom Checklist (SCL-90R), Gordon and Graham (1996) evaluated outcomes pre, post, and at three-month follow-up for 95 patients who had received a six-session counselling intervention. Immediately following the intervention, 37 out of

64 patients with anxiety experienced reductions in symptoms, 27 remaining in a clinical range. Also, at this point, 16 out of 28 patients with depression experienced symptom reduction, with 12 remaining in a clinical range. Hence over half of patients referred with mood disorders were recovered post intervention. This improvement was maintained at four-month follow-up. Similarly, Kates et al (2002) evaluated outcomes for 900 patients from 36 medical practices in Southern Ontario. The authors report that 82 per cent of the sample moved from a clinical to a non-clinical score on the General Health Questionnaire (GHQ) measure and 73 per cent on the Center for Epidemiological Studies Depression Scale (CESD) measure following the intervention.

#### Long term (nine months to two years post treatment)

The long-term effects of counselling are evaluated by Baker et al (2002). This paper reports on a long-term follow-up of an earlier study (Baker et al, 1998) which was reviewed by Hemmings (1999). The original study made use of a waiting list control group at baseline and post therapy (three months from baseline). As participants in the control group commenced counselling after an average of 10 weeks on the waiting list, this group was not available for comparison at longer-term follow-up and so data was analysed for the treatment group only. A sample of 796 patients completed measures following a brief (eight-session) counselling intervention and long-term follow-up was carried out at one year and two years post treatment. At two-year follow-up, 265 (33 per cent) of the original participants completed measures. Improvements found at three months with regard to anxiety, depression, adjustment disorder, self-esteem and quality of life were maintained at two-year follow-up, but data attrition would tend to undermine the robustness of these findings.

A long-term follow-up of Gordon and Graham's original (1996) study was conducted two years post intervention using both HADS and a scale specifically designed for the project (Gordon and Wedge, 1998). The follow-up sample consisted of 41 of the original 95 participants. Results using HADS indicated that the reduced levels of anxiety and depression, recorded post counselling were maintained at follow-up. Of the follow-up sample, 30 per cent reached 'caseness' for anxiety and 10 per cent for depression. This compares with 67.4 per cent and 29.5 per cent respectively for the pre-therapy group. Using the bespoke measure, 87.8 per cent felt that counselling had helped their original problems either moderately or greatly. Some recurrence of their original difficulties over the two-year period was reported by 63.4 per cent, but, of these, 73.5 per cent felt the original intervention helped them at least moderately in dealing with relapse. Authors conclude that the benefits of the original brief intervention were maintained at two-year follow-up.

#### Concurrent medication

Just one study (Baker et al, 2002) reports the effects of counselling in combination with antidepressant medication. Authors found that, in terms of depression scores, counselling plus medication was superior to counselling alone or medication alone.

#### Number of counselling sessions offered

The interventions evaluated in this domain of evidence tended to be brief, mostly between six and 10 sessions. In Baker et al (2002), an eight-session counselling model is used. In Mellor-Clarke et al (2001), six sessions are offered to patients with an average of 4.3 attended. In Kates et al (2002), 50 per cent of patients were seen for just one session, the average number of sessions per referral being 5.7. In this study, the average duration of session was 48 minutes. The study by

Gordon and Graham (1996) used a six-session counselling intervention. Authors found that 20 per cent of patients felt that counselling had ended too soon and concluded that for a minority of patients, particularly those with episodic or chronic mental health issues, longer-term counselling may be preferred. In some studies (Booth et al, 1997; Murray et al, 2000; Nettleton et al, 2000; Newton, 2002), there is a wider variation in the number of sessions offered. In Booth et al (1997), the number of sessions varies between two and 18, the mean being seven. In Murray et al (2000), the range is one to 25 with a mean of seven. In Nettleton et al (2000), the number of counselling sessions had a mean of 5.4, with a range of one to 26. In this study, authors found the number of counselling sessions was not associated with outcome.

### **Target problems**

The majority of studies report the effects of counselling on non-specific generic psychological problems. However, several studies report counselling's effect on depression (Baker et al, 2002; Gordon and Graham, 1996) and on anxiety (Gordon and Graham, 1996).

#### **Non-specific generic psychological problems**

As all the studies in this domain have non-specific generic psychological problems as at least one of their target problems, the short- and long-term effects reported above relate to the treatment of this type of psychological problem.

#### **Depression**

Baker et al (2002) found a significant reduction in the severity of depression both in the short and long term. The combination of medication and counselling was associated with the most significant positive outcomes for patients with depression. Gordon and Graham (1996) found that, immediately following the intervention, 16 out of 28 patients with depression experienced symptom reduction, 12 remaining in a clinical range.

#### **Anxiety**

As with depression, Baker et al (2002) found a significant reduction in anxiety scores both in the short and long term. Gordon and Graham (1996) found that, immediately following the intervention, 37 out of 64 patients with anxiety experienced reductions in symptoms, 27 remaining in a clinical range.

#### **Wellbeing and goal attainment**

A number of studies (Baker et al, 2002; Booth et al, 1997; Nettleton et al, 2000; Newton, 2002) measure non-clinical outcomes such as subjective wellbeing and the attainment of personal therapeutic goals. The assessment of such variables aims to evaluate whether counselling can support and enhance wellbeing in patients. Baker et al (2002) found that at three months, self-esteem scores significantly increased for the intervention group and that this improvement was maintained over the two-year follow-up period. In a sample of 51 participants, Booth et al (1997) found significant improvement in quality of life, goal attainment and problem resolution. Nettleton et al (2000) found statistically significant improvements in patient wellbeing in a sample of 58 patients. Similarly, a sample of 100 patients (Newton, 2002) were asked to set three goals each prior to a counselling intervention and rate progress towards achieving these goals post counselling using a standard scale. Results indicated that 43 per cent of goals were rated as fulfilled, 30 per cent as nearly fulfilled, 22 per cent as part fulfilled and five per cent as not fulfilled at the end of counselling. The author concluded that high levels of progress towards personally significant goals were achieved following counselling.

### **Demographic profile of service users**

Just one study in this domain (Evans et al, 2003) undertakes a detailed analysis of patient demographics and their impact on service usage. The demographic profile of those using the service is an important factor when evaluating whether a service is meeting the needs of its patients, especially as services may not always serve populations that are typical. Evans et al (2003) used the CORE outcome measure to evaluate a counselling service in the south of England serving a population with a high proportion of ethnic minority clients (n=661). This population was compared with a large national dataset (n=5097) in order to assess whether or not it was typical in terms of demographic profile. Disproportionately high numbers of Pakistani, Bangladeshi, Black African and Afro-Caribbean patients prompted an analysis of service usage by these groups. Before counselling, across all users of the service (White/European and ethnic minority), patients on average scored higher than the national dataset on initial problem severity. Ethnic minority (EM) patients tended to be referred for counselling at a slightly younger age than White/European (WE) patients, although it was unclear if this was related to the characteristics of that population, or to GP referral/patient help-seeking patterns. EM clients in the service were more likely to be employed, and living alone than WE clients, and to score more highly on all scores except wellbeing. EM clients were also more likely to have an unplanned ending, particularly in the case of Pakistani/Bangladeshi and Black African/Caribbean clients. No significant differences in clinical outcomes were found between EM and WE patients.

### **Methodological issues**

#### **External validity**

The fact that the interventions tested in these studies are flexible, non-manualised and delivered in the process of routine practice and that the samples studied may be fairly typical service users (although data on sample representativeness is often absent) suggests these studies may have high external validity. As is typical in primary care, patients generally present for treatment with non-specific, generic psychological problems rather than with specific diagnoses. The nine pre and post studies within this domain of evidence have a pooled sample of 4,933, ranging from 56 (Murray et al, 2000) to 1,724 (Baker et al, 2002). Additionally, the service evaluations that form a part of Hemmings' (1999) systematic review have a pooled sample of >8,500. Hence the findings in this domain are based on a large sample of > 13,458 primary care patients from a variety of geographical locations. However, despite the size and diversity of this sample, it must be borne in mind that the generalisability of findings can be reduced by low response rates within the studies.

#### **Internal validity**

The limitations of this type of research relate to the difficulty in controlling the many variables that may affect counselling in routine practice. Patients may be in receipt of other interventions such as usual GP care and medication during the course of counselling. The majority of studies fail to take account of this when assessing outcomes. This problem is exemplified in Gordon and Graham (1996), where during the two-year period following the original intervention some patients received medication and some additional sessions of counselling. The addition of these interventions undermines the study's ability to evaluate the long-term effects of the original intervention.

The ethical and practical difficulties in using no-treatment control groups in routine practice means that studies cannot control for the passage of time. Since a percentage of all psychological problems remit over time, unless a study accounts for this the benefits of counselling may be exaggerated.

Attrition rates in this type of research are a particular problem where many services may experience a high percentage of unplanned endings among their patients. Where those recruited for a clinical trial may commit to completing the treatment and the relevant outcome measures, patients accessing routine counselling may not share such a commitment and the studies often lack the resources to ensure that follow-up remains high even in those who drop out of treatment. Unplanned endings tend to mean that post-therapy measures are not completed, reducing the reliability of the data collected. If unplanned endings are associated with poor therapeutic outcomes and planned endings with the converse, then this will obviously skew the results of pre and

post studies in a positive direction. Data attrition varies among the studies, some (Booth et al, 1997) experiencing high rates (53 per cent). Other studies manage to achieve very low rates. For example, in Mellor-Clarke et al (2001) only five per cent of patients failed to complete end of therapy forms.

#### **Outcome measures**

Studies tend to use a wide variety of well-validated outcome measures, the most frequently used being SCL-90R, Quality of Life (QOL), HADS and CORE. The number of measures used in a single study varies from one (Evans et al, 2003; Mellor-Clarke et al, 2001; Nettleton et al, 2000; Newton, 2002) to five (Kates et al, 2002). One study (Murray et al, 2000) uses a specifically-devised, non-validated measure, reducing the reliability of their findings. Two studies (Booth et al, 1997; Newton, 2002) use a goal attainment scale (GAS) to measure therapeutic outcomes. The value of this measure lies in its ability to measure the effects of counselling in terms of subjective, patient-specified, non-clinical variables.

## Section 5: Economic issues

### Rationale

Macro-level economic assessments relating to psychological therapy and mental health problems have estimated that, currently in the UK, the total loss of output due to depression and chronic anxiety is approximately £12 billion per year. This compares with an estimated cost of £0.6 billion per year to provide appropriate therapy for this population (CEPMHPG, 2006). Such analyses are conducted to inform national policy. Economic analyses are also necessary at a micro level to help shape local service provision. The increasing demand for counselling services needs to be set in the context of limited funds and resources (Simpson et al, 2003). Given limited resources, it is vital that they are deployed in a cost-effective manner.

Cost-effectiveness analysis (CEA) provides one such tool in the decision-making process. CEA facilitates comparison of different interventions based on the relative costs and consequences (typically the effectiveness) of treatment. In order to calculate the costs of providing an intervention, resource use is identified, quantified and valued. Resources may include medication prescribed, referrals to other healthcare services or GP consultations. Measures of the benefit a programme provides typically mirror those used in studies of effectiveness. The costs and outcomes included in any such analysis will be primarily determined by the perspective of the study. CEAs are often carried out from the viewpoint of the service provider and as such include only those costs accruing to the health service. There are, as indicated above, likely to be wider societal costs including, for example, lost productivity due to sickness absence from employment.

CEA is typically presented in the form of Incremental Cost-Effectiveness Ratios (ICERs). ICERs calculate the additional costs one service or programme imposes over another, compared to the additional benefits or effects it delivers (Drummond et al, 1999). When there are multiple outcomes and absence of a principal effect that can be expressed in a single dimension, the costs and outcomes of the programmes being compared may be presented in a disaggregated form, leaving the reader to decide which of the outcomes, if any, they consider to be the most important. This is known as cost-consequence analysis.

Cost-utility analysis is a special case of cost-effectiveness analysis whereby the effectiveness of an intervention is measured in changes to the quality of life. The analysis allows comparison of the quantity of life gained after an intervention and the quality. The analyses are usually expressed in cost per Quality Adjusted Life Year (QALY).

### Overview of studies

Nine studies covered economic issues relating to counselling in primary care. Two systematic reviews (Bower and Rowland, 2006; Hemmings 1999) investigate both the clinical effectiveness and costs of counselling in primary care. Bower and Rowland (2006) undertook an economic analysis on six of the eight studies included in their review, describing them according to a range of criteria: analysis type (eg 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). The studies in the Bower and Rowland (2006) review (including one meta-analysis) examined a range of economic and cost issues in relation to the provision of counselling in primary care

(Boot, 1994; Hemmings, 1997; Harvey, 1998; Friedli, 1997; King, 2000; Simpson, 2000; Chilvers, 2001; Bower, 2003). This included a comparison of the cost of counselling with usual care, psychotropic drug prescription rates, consultation and drug-use data, analysis of direct and indirect costs such as primary care and counsellor staff time, medication rates and referral to other agencies.

Hemmings (1999) provides a table of 16 studies that examine costs or cost-effectiveness, together with descriptions of studies in the grey literature that examine effects on referral rates, but presents no detailed analysis of the studies. In addition to these two systematic reviews, three clinical trials evaluate both clinical- and cost-effectiveness (Bellamy and Adams, 2000; Kolk et al, 2004; Chisholm et al, 2001). All three combine a randomised controlled trial with a cost-consequence analysis. Three studies (Gordon and Graham, 1996; Kates et al, 2002; Nettleton et al, 2000) investigate the effectiveness of counselling using pre and post measures but no control or comparison group, together with cost-consequence analyses. Just one study (Simpson et al, 2003) evaluates the economic impact of counselling on health service (resource) utilisation without attempting to measure clinical effectiveness, and as such is simply a cost analysis as opposed to a CEA. Seven of the nine studies were conducted in the UK, although one of these (Hemmings, 1999) is a systematic review including both UK and international studies. One study (Kolk et al, 2004) was carried out in Holland and another (Kates et al, 2002) was a Canadian study.

The interventions investigated in the studies constitute a broad range of therapeutic approaches widely used in routine practice: generic counselling, person-centred, psychodynamic, integrative and CBT. Similarly, interventions target a wide range of problems: generic psychological problems, depression (including postnatal depression), anxiety, psychosomatic symptoms and chronic fatigue. Of the nine studies, two (Bower and Rowland, 2006; Chisholm et al, 2001) were rated by reviewers as the highest level of evidence (++), whereas the other seven studies (Bellamy and Adams, 2000; Gordon and Graham, 1996; Hemmings, 1999; Kates et al, 2002; Kolk et al, 2004; Nettleton et al, 2000; Simpson et al, 2003) were rated as good quality (+). Hence this body of research can largely be viewed as *supporting* as opposed to *best evidence*.

A summary overview of the papers can be found in Table 4.

### Findings

The evidence with regard to the economic implications of the provision of counselling is mixed.

### Cost implications

Six trials included in Bower and Rowland (2006) examined costs associated with providing counselling services, or compared the costs of providing counselling with CBT or usual care. Based on the analysis of these studies, it was concluded that counselling does not reduce overall costs. However, one of the studies included was a meta-analysis (Bower et al, 2003) that suggested that counselling may be more cost-effective than usual care over the longer term. Chisholm et al (2001) compared the costs and outcomes of counselling against those of CBT in a primary care setting for the treatment of fatigue. Both counselling and CBT led to improvements in fatigue and slightly reduced informal care and lost productivity costs. Although rates of GP contact fell, this did not compensate for the increased costs of the counselling or CBT intervention. Overall, no cost-effectiveness



Table 4: Overview of studies covering economic issues

Item	Which domain(s) do/ does the paper fit into?	What type of study is this?	In which country did the study take place?	What type of intervention(s) is/are the main focus of the study?	What is the target problem?	Quality rating
Bellamy and Adams (2000)	Efficacy Economics	Clinical trial	UK	Non-specific generic counselling	Depression Anxiety	+
Bower and Rowland (2006)	Efficacy Economics	Systematic review includes cost-effectiveness	UK	Non-specific generic counselling Non-directive/supportive/person-centred counselling Psychodynamic counselling Integrative/eclectic/mixed-approach counselling CBT	Non-specific, generic psychological problems Depression Anxiety	++
Chisholm et al (2001) Also reported in Ridsdale et al (2001)	Economics	Clinical trial, a randomised controlled trial incorporating a cost-consequence analysis	UK London and South Thames region	Non-specific generic counselling	Chronic fatigue	++
Gordon and Graham (1996) Also reported in Gordon and Wedge (1998)	Effectiveness Economics	Pre and post study	UK	Person-centred counselling	Non-specific, generic psychological problems Depression Anxiety	+
Hemmings A (1999)	Efficacy Effectiveness Economics User perspectives	Systematic review includes cost-effectiveness	UK Although the review was carried out in the UK, international studies have been included	Non-specific generic counselling Non-directive/supportive/person-centred counselling Integrative/eclectic/mixed-approach counselling CBT Problem-solving therapy Interpersonal therapy	Non-specific, generic psychological problems Depression Anxiety Postnatal depression Psychosomatic/medically unexplained symptoms	+
Kates et al (2002)	Effectiveness Economics	Pre and post study	Canada	Non-specific generic counselling	Non-specific, generic psychological problems	+
Kolk et al (2004)	Efficacy Economics	Clinical trial, includes cost-consequence analysis	Holland	Non-directive/supportive/person-centred counselling Integrative/eclectic/mixed-approach counselling CBT	Psychosomatic/medically unexplained symptoms	+
Nettleton et al (2000)	Effectiveness Economics	Pre and post study	UK	Non-specific generic counselling	Non-specific, generic psychological problems	+
Simpson et al (2003)	Economics	Cost analysis comparing the cost of prescribing and referrals to mental health services between GP surgeries with and without counselling provision	UK Derbyshire, England	Psychodynamic counselling Integrative/eclectic Cognitive-behavioural approach	No details are given of the target population or of the target problem. The only details are of the drugs of interest: antidepressants, hypnotics, CNS drugs	+

advantage was found for either form of therapy. As there were more counsellors available than CBT therapists, the authors concluded that it may be more feasible to offer counselling than CBT.

### **Health service utilisation**

Several studies assess the impact of counselling on other areas of health service utilisation, particularly use of medication, the number of GP consultations and referral to other mental health services (Bellamy and Adams, 2000; Bower and Rowland, 2006; Gordon and Graham, 1996; Hemmings, 1999; Kates et al, 2002; Kolk, 2004; Nettleton et al, 2000). Such data provides evidence as to whether, in addition to the clinical benefits, counselling produces economic benefits in terms of reduced demand for other healthcare services. Hemmings (1999) noted that 11 studies reported a reduction in GP visits or the use of psychotropic medication and that almost half the grey literature studies he examined attempted to measure the economic impact of counselling, including the impact on referrals.

### **Use of medication**

Three studies provide mixed evidence about the impact of counselling on the use of medication (Bower and Rowland, 2006; Nettleton et al, 2000; Simpson et al, 2003). Bower and Rowland (2006) found that counselling may be associated with some reduction in medication. This was based on three studies that demonstrated that counselling was associated with lower usage of medication (including psychotropic drugs and antidepressants). In contrast, Nettleton et al (2000), having evaluated a counselling service in three GP practices over a period of one year, found that there was actually no decrease in drug use by those patients receiving counselling. Simpson et al (2003) compared the cost of prescribing and referrals to mental health services between GP surgeries with and without counselling provision. The findings revealed a statistically significant difference (for some years) in prescribing data between GPs who had had counsellors for more than four years (prescribing was lower) compared with those surgeries with counsellors for less than four years. The prescribing of medications increased over an eight-year period for both GPs with and without counselling services. The findings show little evidence to support differences in prescribing rates between GPs with/without counsellors.

### **GP consultations**

Evidence relating to the impact of counselling on GP consultations was also mixed. Bower and Rowland (2006) found one study suggesting a reduction in the short term and one study finding no difference. Bellamy and Adams (2000) compared the number of GP consultations in a control and treatment group pre and post intervention. A modest decrease in GP consultations in the treatment group was found in the six-month period following treatment compared with the six months before the start of counselling. The mean number of consultations per patient in the six months prior to treatment was 4.66 for the treatment group and 4.1 for the control. In the six months following counselling, the treatment group had reduced to 3.25 whereas the control group remained relatively unchanged at 4.0. Kolk et al (2004) tested the effect of psychological intervention on multiple medically unexplained physical symptoms, psychological symptoms, and health care utilisation in addition to usual care. The number of GP consultations decreased in both groups but the statistical significance is not reported.

### **Psychiatric referral**

The impact of counselling on psychiatric referrals was positive in the majority of studies that examined this issue. Bower

and Rowland (2006) found that one study demonstrated a reduction in referrals to outside agencies. Nettleton et al (2000) found that counselling was provided for a substantial minority of referred patients (22 per cent; n=28) who would otherwise have been referred for psychiatric care, thus suggesting the counselling service may reduce the demand for other mental health services. In a large sample (n=900) Kates et al (2002) found a 65 per cent reduction in referrals to psychiatry outpatient services following the introduction of a counselling service. Psychiatric inpatient admissions also reduced by 10 per cent and for those admitted the hospital stay was eight per cent shorter than for patients from practices without a counselling service.

However, Gordon and Graham (1996) found that, while for the majority of patients (n=76) short-term counselling was sufficient, a significant subgroup (n=19) with higher initial levels of symptomatology still required referral to other mental health services. This suggests a continuing demand for other services despite the establishment of counselling provision. Simpson et al (2003) found only one statistically significant difference in referral data, and only in one year: GPs with counsellors referred more to the community mental health team (no figures given) than those without, providing little evidence to support differences in referral rates between GPs with/without counsellors.

### **Societal costs**

In addition to the health service costs, Chisholm et al (2001) investigated the cost of lost employment and informal care. The study showed large standard deviations, owing to a small number of participants with a prolonged period of work disability. Cost of lost working days and informal care over the six-month period however, did not show a statistically significant difference. Incremental cost-effectiveness ratios for healthcare and treatment, patient and family burden, and the combination of the two revealed no statistically significant differences between the two groups. A comparison of change scores between baseline and six-month follow-up revealed no statistically significant differences between the two groups in terms of aggregate healthcare costs, patient and family costs or incremental cost-effectiveness (cost per unit of improvement on the fatigue score).

## **Methodological issues**

### **General overview**

Two systematic reviews were included in this section. Bower and Rowland (2006) is a very well-conducted study constituting the highest level of evidence, examining a range of trials and a meta-analysis for economic outcome data. Each trial is individually analysed and subjected to a stringent analysis. The findings of Hemmings' (1999) systematic review of the practice evidence are less reliable, as the studies containing economic elements are listed with a selected number of studies highlighted. It is unclear on which studies or criteria the conclusions are drawn.

Three clinical trials were included (Bellamy and Adams, 2000; Kolk et al, 2004; Chisholm et al, 2001). Bellamy and Adams (2000) scrutinised counselling service surgery records to monitor the number of visits made to GPs in the six months before and the six months after treatment. Difficulties in recruiting a control group weakened the study's rigour, with just 16 participants in the usual care group and 54 in the treatment group. The study by Kolk et al (2004) is a well-conducted study and uses a wide range of well-validated measures along with randomisation and

concealment. However, difficulty in recruiting participants led to a relatively small control group, thus reducing the power of the study. Chisholm et al (2001) was a well-designed study. Whilst the authors note that the study is underpowered to detect differences in costs, this is not uncommon in this type of analysis where power calculations usually relate to effectiveness rather than cost data. The heterogeneity of cost data can lead to a larger sample size being needed than for the clinical outcomes (Drummond et al, 1999). Its main failing is, as the authors note, the omission of a usual care control group (the study compares counselling and CBT). Hence the authors conclude that while no cost advantage was found between the therapies they are unable to determine how each would compare to usual care.

The study by Simpson et al (2003) compared practices with and without counsellors. However, as these were not matched, patient mix and other baseline data could have affected the findings. There is no measure of clinical effectiveness against which to balance the costs.

### **Costs and cost-effectiveness**

Chisholm et al (2001) undertake a cost-consequence analysis that adopts a wide, societal perspective in which the costs to both the service provider and to patient and family are included. Cost and effectiveness data are taken from the same group of patients over a six-month period. The year of price valuation is not explicit but 1998 may be assumed from references given. Cost data were collected at the level of the individual and no discounting was necessary given that the data relate to a period of less than one year. Valuation (which takes account of any uncertainty arising from the use of estimates) was made using estimates from recognised sources, and statistical analysis was complete and well documented together with a one-way sensitivity analysis. This suggests that the study was reliable.

The Simpson et al (2003) study is a cost analysis. There is no measure of effectiveness, although the authors cite mixed evidence referring to the effectiveness of counselling in GP surgeries. Within the analysis, resource use is identified from a number of different sources and valued (where clear) using standard unit costs. Only costs to the health service are included (as opposed to wider societal costs) and only the amount and costs of prescribing, time and cost of the counsellor (including overheads) and cost of referrals are reported. For the latter, it is not clear how these have been valued and if overheads were included. Of those costs for

which valuation is clear, they are valued using 1998 prices. No sensitivity analysis is used to take account of uncertainty resulting from the use of estimates. Total costs are not reported but the mean costs per 1,000 patients receiving counselling plus the mean cost per 1,000 patients receiving central nervous system (CNS) drugs is given. The basis for the calculation of costs is very narrow, as there are likely to be other costs accruing to the health authority in both the primary and acute sectors. The lack of cost detail limits the generalisability of the study.

Similarly, the Kolk et al (2004) study – a cost-consequence analysis that presents GP consultations and outcomes in a disaggregated form – only considers the number of consultations with the GP (at the practice, at home or by telephone). The paper gives only frequency (mean number) of consultations. No monetary value is placed on the consultations nor is there a breakdown of the numbers of these consultations in each category (practice/home/telephone), which are likely to attract very different costs. Much of the study reports on a model to identify patient-related predictors of change in symptoms and care utilisation, and the analysis is focused on this area. The paper does not report any differences between the control and intervention groups in number of consultations or the effectiveness outcomes and thus it is not possible to draw any clear conclusions.

Three studies use pre and post measures (without control groups) to evaluate the effectiveness of counselling, along with aspects of health service utilisation (Gordon and Graham, 1996; Kates et al, 2002; Nettleton et al, 2000). Gordon and Graham's (1996) study is weakened by missing data. A sample of 95 participants visited their GP on average five times in the six months before treatment. However, the rate of GP consultation post treatment is not reported. With regard to medication, data was only available for 88 out of 95 participants. The study by Kates et al (2002) was well conducted and recruited a large sample (n=900). Hence the 65 per cent reduction of referrals to psychiatry following the introduction of a counselling service can be viewed as a robust finding. Nettleton et al (2000) attempted to assess the effect of a counselling service on utilisation of other mental health services by asking GPs what type and quantity of referrals they would make in the absence of a counselling service. The effect of the counselling service on mental health service utilisation was then inferred from this data. Findings based on this type of data collection should be treated with caution.

## Section 6: User perspectives

### Rationale

There are many reasons why user perspectives should be considered when evaluating a healthcare intervention.

- In addition to an intervention's clinical effectiveness, it is important to evaluate how acceptable the treatment will be to potential users (Hill and Brett, 2004). Such information will help services support patient choice and respond to individual needs, an approach promoted by NICE (2007), seeking to produce patient-centred clinical guidance.
- When interventions are of equal clinical effectiveness, it is logical for the choice of treatment to be decided either by patient preference, economics, or a mixture of the two.
- It is important for service providers to know which treatments are going to be most popular and therefore in greatest demand in order to make adequate provision and to avoid unnecessary waiting lists.
- The relationship between patient preferences and demographic or clinical factors may likewise assist in the organisation of service provision, allowing services to be matched to particular populations.
- Improving treatment take-up is also a priority for many services, and so to understand whether receipt of preferred intervention increases the number of patients entering treatment is likewise of great importance.
- Also of crucial importance is whether matching treatment to patients' preferences has an effect on clinical outcomes; whether patients recover more rapidly when they get the treatment they prefer.

### Overview

Sixteen studies address user perspectives. Three of these (Arean et al, 2002; Cooper et al, 2003; Wetherell et al, 2004) are surveys of patient treatment preferences. There are four clinical trials where data on patient treatment preferences have been gathered as part of baseline data collection (Lin et al, 2005; Ridsdale et al, 2001; Unutzer et al, 2003; Wagner et al, 2005). There are three systematic reviews (Bower and Rowland, 2006; Hemmings, 1999; Van Schaik et al, 2004), one of which is a review of patient preferences research only (Van Schaik et al, 2004) and the others wide-ranging studies that evaluate clinical effectiveness and cost-effectiveness, along with levels of patient satisfaction (Bower and Rowland, 2006; Hemmings, 1999). Five pre and post studies assess levels of patient satisfaction with counselling along with the effectiveness of the intervention (Booth et al, 1997; Gordon and Graham, 1996; Kates et al, 2002; Nettleton et al, 2000; Newton, 2002). A further study uses a qualitative design to explore patients' experience of being offered counselling (Snape et al, 2003).

Half of the studies in this domain have been carried out in the UK and the other half are international studies. One systematic review was conducted in Holland (Van Schaik et al, 2004) and it is noteworthy that two systematic reviews (Van Schaik et al, 2004; Hemmings, 1999) include international studies. Table 5 provides a summary overview. The majority of studies explore patients' attitudes to non-specific, generic counselling (n=12), although attitudes to psychodynamic, integrative/eclectic, person-centred and CBT, while less prevalent, are also explored. The majority of studies explore attitudes to counselling for the treatment of non-specific generic psychological problems (n=11) followed by depression (n=6). Attitudes to counselling for the treatment of anxiety (n=4), chronic fatigue (n=1), postnatal

depression (n=1) and psychosomatic symptoms (n=1) are less prevalent among the studies. As regards the overall quality of the studies in this domain, 31 per cent of the studies (n=5) were rated ++, and a further 69 per cent (n=11) rated as good quality (+). Hence the findings can be regarded as generally reliable.

### Findings

#### *Satisfaction with counselling*

Two systematic reviews found that patients were highly satisfied with the counselling intervention they had received (Bower and Rowland, 2006; Hemmings, 1999). Bower and Rowland's (2006) systematic review included five trials that measured levels of patient satisfaction with counselling (Boot, 1994; Chilvers, 2001; Hemmings, 1997; Friedli, 1997; King, 2000). Just one of these compared satisfaction between the randomised and the preference groups of patients (Chilvers, 2001). Two trials reported generally high levels of satisfaction with counselling but did not make a direct comparison with satisfaction with usual GP care (Hemmings, 1997; Boot, 1994). In the study by Hemmings (1997), 132 patients received counselling and 96 of these completed questionnaires assessing levels of satisfaction. The majority of patients (82 per cent) felt that counselling had been helpful and that they had been understood (80 per cent).

In the study by Boot (1994), 54 per cent of patients in the counselling group and 47 per cent of patients in the usual GP care group completed satisfaction questionnaires six weeks post intervention. Significantly more patients in the counselled group reported that they were satisfied with their treatment. Two trials (Friedli, 1997; King, 2000) directly compared patient satisfaction with counselling and satisfaction with usual GP care, both finding higher levels of satisfaction in the counselling group at short- and long-term follow-up. Hemmings' (1999) review assessed levels of patient satisfaction, along with clinical and cost-effectiveness. Among those patients who had received counselling, he found the results of naturalistic, practice-based research to be almost entirely supportive of the acceptability to patients of counselling interventions in primary care.

Several pre and post studies view levels of satisfaction with treatment as a useful indicator of its utility (Booth et al, 1997; Gordon and Graham, 1996; Kates et al, 2002; Nettleton et al, 2000; Newton, 2002). Using both a Consumer Satisfaction Questionnaire and a Visit Satisfaction Questionnaire in a large-scale study by Kates et al (2002), 92 per cent of patients were found to be satisfied with the counselling they had received. These findings are supported by smaller-scale studies (Booth et al, 1997; Gordon and Graham, 1996; Nettleton et al, 2000; Newton, 2002). Gordon and Graham (1996) found that, of the total sample (n=41), 34 per cent felt counselling had actually caused them some distress. Similarly, Booth et al (1997) found that patients reported unhelpful events during the course of counselling. However, such negative experiences did not reduce overall levels of satisfaction with the treatment. Newton (2002) utilised a Goal Attainment Scale, where participants specified personal goals pre counselling and rated achievement of these post counselling. In a sample of 100 participants, the study sought to discover client's goals in therapy and to elicit their evaluations of therapeutic outcome. The study found that high levels of progress towards achieving personally significant goals occurred following the counselling intervention and results indicated that participants were highly satisfied with the treatment.

#### *Preference for counselling*

A number of studies have found that a broad cross-section of users of primary care services prefer counselling to other forms

**Table 5: Summary overview of the evidence relating to user perspectives**

Study	Study types	Country of origin	Type of intervention(s)	Target problem	Quality rating
Arean et al (2002)	Survey	USA	Non-specific generic counselling	Non-specific, generic psychological problems	++
Booth et al (1997)	Pre and post study	UK	Humanistic/eclectic Psychodynamic	Non-specific, generic psychological problems	+
Bower and Rowland (2006)	Systematic review	UK	Non-specific generic counselling Non-directive/supportive/ person-centred counselling Psychodynamic counselling Integrative/eclectic/mixed- approach counselling CBT	Non-specific, generic psychological problems Depression Anxiety	++
Cooper et al (2003)	Survey conducted by telephone	USA	Non-specific generic counselling	Depression	+
Gordon and Graham (1996) Also reported in Gordon and Wedge (1998)	Pre and post study	UK	Person-centred counselling	Non-specific, generic psychological problems Depression Anxiety	+
Hemmings (1999)	Systematic review	Review was carried out in UK International studies included	Non-specific generic counselling Non-directive/supportive/ person-centred counselling Integrative/eclectic/mixed- approach counselling CBT Problem-solving therapy Interpersonal therapy	Non-specific, generic psychological problems Depression Anxiety Postnatal depression Psychosomatic symptoms	+
Kates et al (2002)	Pre and post study	Canada	Non-specific generic counselling	Non-specific, generic psychological problems	+
Lin et al (2005)	Clinical trial including patient preferences survey	USA	Non-specific generic counselling CBT	Depression	++
Nettleton et al (2000)	Pre and post study	UK	Non-specific generic counselling	Non-specific, generic psychological problems	+
Newton (2002)	Pre and post study	UK	Non-specific generic counselling	Non-specific, generic psychological problems	+
Ridsdale et al (2001)	Clinical trial including patient preferences survey	UK	CBT and non-directive counselling	Chronic fatigue	++
Snape et al (2003)	Qualitative	UK	Non-specific generic counselling	Non-specific, generic psychological problems	+
Unutzer et al (2003) Also reported in Gum et al (2006)	Clinical trial including patient preferences survey	USA	Non-specific generic counselling	Depression	++
Van Schaik et al (2004)	Systematic review	Review was carried out in Holland International studies included	Non-specific generic counselling	Non-specific, generic psychological problems	+
Wagner et al (2005)	Clinical trial including patient preferences survey	USA	Psychodynamic counselling	Anxiety	+
Wetherell et al (2004)	Survey	USA	Non-specific generic counselling	Non-specific, generic psychological problems	+

of treatment for depression (Arean et al, 2002; Cooper et al, 2003; Unutzer et al, 2003; Lin et al, 2005; Van Schaik et al, 2004).

### **Adult primary care patients**

In a systematic review of patients' treatment preferences, with regard to psychotherapy and antidepressant medication, Van Schaik et al (2004) located eight relevant papers relating to treatment preferences of depressed primary care patients, along with 10 papers relating to preferences in non-depressed populations. The pooled sample size of depressed participants was 3,861 and non-depressed participants 8,794. Studies were conducted between 1993 and 2002. In all studies, counselling was preferred to antidepressants. Counselling was preferred because it was assumed to provide an opportunity for personal exchange and to solve the problem underlying the depression. Antidepressants were often seen as addictive and their use associated with a fear of losing control. Authors concluded that the majority of patients prefer counselling but also that the underlying reasons for treatment preferences may not necessarily be very well informed, in that participants expressed misconceptions about the effects of medication.

In a telephone survey of 829 adult primary care patients with depression, Cooper et al (2003) found 70 per cent of patients view antidepressant medication to be an acceptable treatment for depression, whereas 86 per cent of patients view individual counselling to be an acceptable treatment for depression. In a sample of 335 participants with an age range of 24-84, average age 57, Lin et al (2005) examined patients' preferences for antidepressant medication alone, counselling alone, or both in combination. The study found that 15 per cent of participants preferred medication, 24 per cent counselling and 61 per cent found both acceptable.

### **Older primary care patients**

A high-quality study by Arean et al (2002) examined the preferences of older patients (55 years and older) for psychological services, including the types of services they would be interested in and who should provide them. The study found that individual counselling was the most popular treatment option, with 71 per cent of the whole sample indicating a preference for this. The sample included both depressed and non-depressed participants. In a large-scale survey of 1,801 depressed, older primary care patients, Unutzer et al (2003) found that most participants indicated a preference for counselling as opposed to antidepressant medications. However, just eight per cent had received such treatment in the past three months, and only one per cent reported four or more sessions of counselling in the prior three months. Of the sample, 51 per cent said they would prefer counselling, 38 per cent expressed a preference for antidepressant medication and four per cent preferred no treatment at all. This survey of patient preferences formed part of a large-scale, multi-site randomised controlled trial into improving depression treatment.

## **Relationship between preferences and patient characteristics**

### **Clinical characteristics**

In their survey, Arean et al (2002) used well-validated measures of mental health problems (GDS, BAI, SMAST) to create two subgroups, one clinical and the other non-clinical, in order to discern whether the presence of mental health disorders affected treatment preferences. The study found no significant differences between the groups, 70 per cent (n=83) of the non-clinical group and 73 per cent (n=63) of the clinical group preferring individual counselling. This finding is supported by Van Schaik et al (2004) who likewise found no difference in treatment

preference between those with and those without a depressive disorder.

In a sample of primary care patients (n=801) with anxiety disorders, Wagner et al (2005) used telephone interviews to examine beliefs about psychotropic medications and counselling. They found the presence of specific anxiety disorders did not impact on strength of beliefs about either medications or counselling. They did, however, find a trend for the presence of depression co-morbid with anxiety to relate to more favourable attitudes toward psychotropic medications.

### **Demographic characteristics**

Several North American studies investigate whether there are links between ethnicity and treatment preferences for depression (Lin et al, 2005; Cooper et al, 2003) and for anxiety disorders (Wagner et al, 2005). From a sample of 659 White, 97 African American and 73 Hispanic patients, Cooper et al (2003) found 79 per cent of African Americans, 86 per cent of White persons and 95 per cent of Hispanics preferred individual counselling for depression. However, despite these differences, the authors concluded that ethnic and racial differences did not generally explain differences between the acceptability of antidepressant medication and individual counselling for depression. From a sample of 335 participants, Lin et al (2005) found that those who preferred medication were more likely to be Caucasian than members of ethnic minorities. Among a sample of primary care patients with anxiety disorders, Wagner et al (2005) found that ethnic minority patients reported less favourable attitudes toward both medications and counselling as compared with Caucasian patients.

A survey by Wetherell et al (2004) compared mental health treatment preferences in both older (n=77) and younger (n=312) primary care patients. The study found that both older (>60 years) and younger adults (<60 years) reported a stronger preference for counselling than for medication. Older adults' preference for medications was just 11 per cent and younger adults 10 per cent. However, studies by Lin et al (2005) and Van Schaik et al (2004) found a higher preference for medication among older as opposed to younger primary care patients.

Studies have also found that previous experience with a treatment type is a strong predictor of preference (Van Schaik et al, 2004; Unutzer et al, 2003). Hence the treatment patients have received in the past (either counselling or medication) tends to determine their preference for future treatment. Both of these studies also found that a preference for medication is associated with male and preference for counselling with female gender.

## **The relationship between treatment preference matching and treatment take-up**

Based on the findings of one study (Dwight-Johnson et al, 2001), in their systematic review Van Schaik et al (2004) concluded that to receive a preferred intervention improves treatment compliance, as where patients preferred counselling but did not receive it they were likely to go without treatment altogether. In a qualitative study, Snape et al (2003) investigated ways of increasing the number of patients taking up counselling among those referred for this treatment. Authors concluded that to provide better information about counselling services and what to expect from the treatment would be an important way to address this issue.

## **The relationship between treatment preference matching and clinical outcome**

Van Schaik et al (2004) concluded that there is no evidence that allocating patients to their preferred treatment improves

outcomes. Authors noted that in two partially randomised patient preference trials, preference did not predict outcome (Bedi et al, 2000; King et al, 2000). This is supported by Unutzer et al (2003) who, in another clinical trial, found that the receipt of preferred treatment did not predict depression outcomes. On the other hand, a trial by Lin et al (2005) found that depressed patients matched to their treatment preference (either counselling or antidepressant medication) had a greater reduction in SCL score from baseline to three months (0.29 versus 0.11,  $p < .05$ ) than did unmatched patients, and a non-significant reduction at nine months (0.37 versus 0.21,  $p = 0.64$ ). Both matched and unmatched groups of patients evidenced improvement over time, but those who received treatment of preference enjoyed more rapid response. Hence authors conclude that matching patients with their preferred treatment does improve outcomes in the short term.

### **Preference for modality and type of counselling**

Only a small number of studies ( $n=3$ ) explored patients' preferences for modality and type of counselling. With regard to modality, in a sample of older adults, Arean et al (2002) found that just 34 per cent said they would take part in group therapy as compared with 71 per cent indicating a preference for individual counselling. In a study comparing the preferences of older and younger primary care patients, Wetherell et al (2004) likewise found that both age groups preferred individual counselling to group treatment (older adults preferring individual therapy: 64 per cent; younger adults: 72 per cent). Additionally, older adults seemed to hold a preference for psychodynamic or supportive types of therapies, whereas younger participants preferred more skills-based therapies such as CBT. In a clinical trial, Ridsdale et al (2001) compared the effectiveness of CBT with counselling for patients with chronic fatigue ( $n=160$ ) and assessed their satisfaction with care. Authors found higher levels of satisfaction with therapy in the CBT intervention group than in the counselling group, even though there were no differences in outcome.

## **Methodological issues**

### **Surveys**

Sample size and response rate are key features of treatment preference surveys; the smaller the sample and the lower the response rate, the less reliable the findings of the study. Also, if the sample has been recruited from several primary care settings, findings are likely to be more generalisable. The sample sizes in the included studies ranged from 183 (Arean et al, 2002) to 829 (Cooper et al, 2003). Likewise, in those studies which attempt to compare preferences between subgroups within the overall sample, the size of the subgroups is important. For example, Cooper et al (2003) compared the treatment preferences of 659 White, 97 African-American and 73 Hispanic patients, with an overall enrolment response rate of 83 per cent. Wetherell et al (2005) compared the preferences of 312 younger patients with those of 77 older participants, with an estimated overall response rate of 60 per cent. If the subgroup size is relatively small, it will lack the statistical power to demonstrate any significant differences between groups with regard to patient preferences.

Sample composition is also an important consideration. This is a particularly salient issue with international studies, where population demographics and methods of health care delivery may differ from the UK. For example, Arean et al (2002) drew a sample from a North American urban setting with participants on low incomes. Wagner et al (2005) recruited a sample from clinics in the West Coast of the USA with a relatively high

proportion of African-American and Hispanic ethnic minority participants. Wetherell et al (2004) recruited older patients from a North American Veteran Affairs clinic resulting in a predominantly male, Caucasian and low-income sample. Caution needs to be exercised when generalising the findings of such studies to UK primary care populations. Whether a study uses a clinical or non-clinical population is also a relevant factor. Clinical samples who may be at the point of trying to access treatment are more likely to yield accurate and realistic preference data compared with non-clinical populations who may not have given as much thought to treatment options and are not experiencing the same sense of urgency.

The number and type of treatment options made available in the survey questionnaire will inevitably affect results. For example, Arean et al (2002) focused purely on psychological treatments and so medication was not included in the survey as a treatment option. It is probable that if medication had been included, results would have been different. Another example of a questionnaire design issue is the use of a 'both medication and psychotherapy' category (Lin et al, 2005), which tended to pool participants who wanted to receive both treatments and those who would be happy to receive either (ie those with a lack of a strong preference). Giving those without a strong preference a combined treatment does not necessarily match preference with treatment and hence is a weakness in the study.

### **Clinical trials**

The recruitment of samples to clinical trials presents a number of issues. Where a survey of patient preferences forms part of a randomised control trial, a key consideration is that participants recruited to the trial understand and accept they will be randomised to treatment. Patients willing to accept randomisation are likely to have weaker treatment preferences than those who would not accept randomisation. Hence such samples may not be typical of primary care patients, where preferences may be more strongly held. Those entering clinical trials are also likely to be better motivated and more willing to accept treatment than typical primary care patients. Several patient preference trials have considered these issues (Lin et al, 2005; Ridsdale et al, 2001; Unutzer et al, 2003; Wagner et al, 2005).

### **Systematic reviews**

Key issues in this type of study relate to whether a comprehensive body of relevant evidence has been located, whether attempts have been made to avoid bias and whether the quality of the included studies has been rigorously appraised. Hemmings (1999) searched just three electronic databases between 1975 and 1998. Similarly, Van Schaik et al (2004) searched three databases between 1990 and 2003. The range of these searches could be viewed as quite limited. In neither of these two studies is there evidence that papers were reviewed by two reviewers to reduce bias and no method of quality assessment is reported. However, both reviews are international in their scope and summarise large bodies of evidence clearly and thoughtfully. Methodological weaknesses should be considered when interpreting the results of these studies.

### **Pre and post studies**

As with surveys, the amount of missing data or attrition rates weakens the findings of pre and post studies. In the Booth et al (1997) study, over half of the participants ( $n=58$ ) dropped out of the study, leaving a sample size of just 51. Gordon and Graham (1996) achieved a higher response rate, with 75 per cent of the original sample completing measures at three-month follow-up.

Kates et al (2002) collected satisfaction data from a sample of 900 patients drawn from 3,550 users of a primary care counselling service. In a much smaller-scale study, Nettleton et al (2000) had a response rate of 63 per cent from a sample of 110 patients. Newton (2002) analyses data pertaining to 100 patients of a counselling service but does not report the size of the overall pool of service users from which this sample is drawn.

### **Qualitative research**

Searches located just one relevant qualitative study (Snape et al, 2003). This study explores the perceptions of those patients who, having been referred for counselling, fail to

enter treatment. The analysis was based on semi-structured interviews with 22 participants and written comments from a further 24 participants. Interviews were transcribed, combined with the written comments and broken down into themes. One of the key themes to emerge was that long waiting times following referral had a significant effect on treatment take-up. Patients either became de-motivated or the passage of time led to changes which rendered the referral no longer necessary. For a qualitative study, the sample size is quite large (n=46). More demographic and clinical data would have produced a richer description of the sample. The study is well conducted and provides useful suggestions for improving the uptake of counselling services following GP referral.



## Section 7: Conclusions and implications for research and practice

The conclusions were drawn by weighing the number of studies that supported a particular finding and the quality rating of those studies. Below are the conclusions, along with, in italics, the evidence on which each is based. The quality rating of each study is noted in brackets after each citation; and, in the case of systematic reviews, where it has been possible, the number of RCTs within the review, on which a particular finding is based, has been indicated. Efficacy (a) and effectiveness studies (b) have been differentiated where conclusions are drawn about the effectiveness and cost-effectiveness of counselling. This differentiation was not deemed relevant for conclusions relating to treatment preferences. Hence the robustness of the conclusions can be judged in terms of the weight of evidence which supports them.

### The effects of counselling

- Efficacy research indicates that in terms of mental health outcomes counselling is more effective than routine primary care in the short term.

a *Bower and Rowland, 2006(++); Hemmings, 1999(+); Murray, 2003(+); Ridsdale et al, 2001(++); Bellamy and Adams, 2000(+)*

- This is supported by the effectiveness research which demonstrates that as a brief, six- to 10-session intervention, in the short term, between 60 per cent and 80 per cent of patients achieve reliable and clinically significant improvements.

b *Evans et al, 2003(++); Gordon and Graham, 1996(+); Hemmings, 1999(+); Kates et al, 2002(+); Mellor-Clarke et al, 2001(++)*

- Counselling's long-term effects are more equivocal, with effectiveness studies supporting the long-term (up to two years) effectiveness of counselling, and efficacy research finding a lack of effects. Such contradictory evidence points to the need for further research before firm conclusions can be drawn about counselling's long-term effects.

*Lack of long-term effects:*

a *Bower and Rowland, 2006[four RCTs](++); Murray et al, 2003(+)*

*Presence of long-term effects:*

b *Baker et al, 2002(++); Gordon and Graham, 1996(+)*

- Efficacy studies testing the two treatments together have established that counselling is as effective as CBT with typical heterogeneous primary care populations.

a *Bower and Rowland, 2006[two RCTs](++); Milgrom et al, 2005(+); Ridsdale et al, 2001(++)*

- There is some evidence from the efficacy research that counselling may be as effective as medication.

a *Bower and Rowland, 2006[one RCT](++)*

- Counselling and medication in combination is more effective than either intervention offered as a single treatment.

b *Baker et al, 2002(++)*

- There is some evidence from efficacy research that individual counselling may be more effective than counselling delivered in groups in the treatment of postnatal depression.

a *Milgrom et al, 2005(+)*

### Target problems

- Both efficacy and effectiveness research confirms that counselling is more effective than routine primary care in the treatment of non-specific, generic psychological problems. As a flexible intervention, it is effective in the treatment of the heterogeneous psychological problems typically presented by primary care populations.

a *Bower and Rowland, 2006(++); Hemmings, 1999(+)*

b *Baker et al, 2002(++); Booth et al, 1997(+); Evans et al, 2003(++); Gordon and Graham, 1996(+); Hemmings, 1999(+); Kates et al, 2002(+); Mellor-Clarke et al, 2001(++); Murray et al, 2000(+); Nettleton et al, 2000(+); Newton, 2002(+)*

- Both efficacy and effectiveness studies also indicate that in the treatment of anxiety and depression (including postnatal depression) counselling is more effective than routine primary care.

a *Bower and Rowland, 2006(++); Hemmings, 1999(+); Bellamy and Adams, 2000(+); Milgrom et al, 2005(+); Murray et al, 2003(+)*

b *Baker et al, 2002(++); Gordon and Graham, 1996(+); Hemmings, 1999(+)*

- No evidence was found that counselling is superior to routine primary care in the treatment of psychosomatic disorders, but further research is needed in this area.

a *Kolk et al, 2004(+)*

- There is some evidence from efficacy research that counselling may be effective in the treatment of chronic fatigue, but further research is needed particularly with the use of routine primary care as a control condition.

a *Ridsdale et al, 2001(++)*

### Costs

- Efficacy and effectiveness research suggests that counselling may reduce levels of referral to psychiatric services.

a *Bower and Rowland, 2006[one RCT](++)*

b *Nettleton et al, 2000(+); Kates et al, 2002(+)*

- There is little evidence that counselling produces reductions in the use of medication or the number of GP consultations.

a *Bower and Rowland, 2006[two RCTs](++); Bellamy and Adams, 2000(+); Kolk et al, 2004(+)*

b *Simpson et al, 2003(+); Nettleton et al, 2000(+)*

- There appears to be no evidence that counselling reduces overall costs.

a *Bower and Rowland, 2006[six RCTs](++); Chisholm et al, 2001(++)*

- When counselling was compared with CBT there was no cost-effectiveness advantage for either form of therapy compared with usual GP care; however, counselling is typically cheaper to provide than CBT.

a *Chisholm et al, 2001(++)*

- The paucity of well-designed and comprehensively powered cost-effectiveness studies, together with the mixed findings on health service utilisation, points to a need for further research regarding economic issues.

- a *Bower and Rowland, 2006(++); Chisholm et al, 2001(++); Bellamy and Adams, 2000(+); Kolk et al, 2004(+)*
- b *Nettleton et al, 2000(+); Kates et al, 2002(+); Gordon and Graham, 1996(+); Hemmings, 1999(+); Simpson et al, 2003(+)*

## Treatment preferences

- Studies in the users' perspectives domain provide clear evidence that among primary care patients, for the treatment of depression, there is a strong preference for counselling as opposed to other treatments, particularly medication.

*Arean et al, 2002(++); Cooper et al, 2003(+); Unutzer et al, 2003(++); Lin et al, 2005(++); Van Schaik et al, 2004(+)*

- The preference for counselling is unaffected by factors such as age, ethnicity, the presence of mental health problems, or problem severity.

*Lin et al, 2005(++); Cooper et al, 2003(+); Wagner et al, 2005(+); Wetherell et al, 2004(+)*

- The receipt of a preferred intervention improves treatment take-up and compliance but there is no clear evidence that the receipt of a preferred treatment improves clinical outcomes.

*Van Schaik et al, 2004[three RCTs](+); Unutzer et al, 2003(++)*

- There is evidence which indicates that patients prefer individual rather than group counselling.

*Arean et al, 2002(++); Wetherell et al, 2004(+)*

- Patients are highly satisfied with counselling they have received in primary care.

*Bower and Rowland, 2006(++); Hemmings, 1999(+); Booth et al, 1997(+); Gordon and Graham, 1996(+); Kates et al, 2002(+); Nettleton et al, 2000(+); Newton, 2002(+)*

## Implications for future research

There is a need for systematic reviews in this field to combine methodological rigour with the inclusion of more diverse types of evidence. This would allow reviews to synthesise both efficacy and effectiveness research in order to produce evidence with high levels of both internal and external validity. Longitudinal

pragmatic trials should be undertaken to produce more reliable evidence of counselling's long-term effects. The matching of treatments with patients' preferences in pragmatic trials may improve recruitment and reduce drop-out. Trialists should produce clearer descriptions of routine primary care control conditions; how much GP time is involved; whether the GP uses brief psychological interventions; whether medication has been prescribed. This will enable a better understanding of exactly what counselling is being tested against in clinical trials.

With regard to effectiveness research, it would be useful to reduce the range of outcome measures used in pre and post studies. Within the 10 studies in the effectiveness domain, at least 17 different measures were used and only two studies used CORE. The implication here is that either CORE is not yet used on a very wide scale or that those services using the outcome measure are not publishing their results in academic journals. Bearing in mind the high cost of conducting RCTs and the relative lack of funding for counselling research, it may be more feasible to prioritise the more widespread use of CORE and a higher level of publication of research findings based on its use. This would have the effect of standardising service evaluation and strengthening practice-based evidence.

In view of the lack of rigorous cost-effectiveness studies, further research should be undertaken, taking into account the myriad costs and potential cost savings likely to accrue to not only the service provider but also to the wider health sector. An analysis of wider societal costs – such as lost productivity due to sickness absence, informal care provided by family and friends and formal social care – would provide a more comprehensive picture.

An understanding of user perspectives is key to the delivery of patient-centred care. It ensures that services are sensitive to the needs of particular communities. As relatively little is known about the treatment preferences of UK ethnic minority users of primary care services, this would be a key priority for future research. Similarly, as treatment preferences data has been mostly gathered from recruits to clinical trials, there is a need to survey the preferences of more typical users of primary care services outside of the trial setting. Patients who have been referred for counselling who then do not attend appointments waste valuable health resources. Further research is needed into the preferences and perceptions of such patients in order to maximise attendance and ensure resources are used efficiently. In the domain of user perspectives, there are good opportunities for small-scale qualitative research as well as larger-scale surveys.

## Section 8: Evidence tables

Best evidence (++)		Summary evaluative comments	
Study details	What are the aims of the study?	Findings and conclusions	Summary evaluative comments
<p>Araon et al (2002)</p> <p>Study type: Survey</p> <p>Country of origin: USA</p> <p>Review domain: User perspectives</p>	<p>To examine the preferences of older patients (55 years and older) for psychological services, including the types of services they would be interested in and who should provide them.</p>	<p>A sample of n=183 was surveyed and analysed in two subgroups clinical (as measured by 15 or above on GDS, or 18 or above on BAI or four or more on SMAST) or non-clinical. 79% of the whole sample indicated they would use a psychological service of some kind. Just 34% said they would take part in group therapy. Individual counselling was the most popular preference at 71% (n=146) of the whole sample. Treatment preferences did not vary significantly between clinical and non-clinical groups: 70% (n=83) of the non-clinical group preferred individual counselling as compared with 73% (n=63) of the clinical group. Therefore psychological services, particularly individual counselling, are acceptable to older primary care patients regardless of levels of psychological distress. Individual counselling is preferred to group therapy.</p>	<p>The study measured levels of psychological distress among participants to discern whether the existence of mental health problems affects preferences. Asking patients their preferences at the point where they are in need of services may provide more accurate data than surveys of purely non-clinical populations. Well-validated and reliable measures were used to screen participants for mental health problems at entry to the study. The sample was drawn from a USA urban setting with many participants on low incomes. Hence generalisability may be limited. Medication was not included in the survey as a treatment option, as the focus was psychological treatments. However the inclusion of this optional treatment may have affected the results. This is a well-conducted study with a good sample size and justifiable conclusions.</p>
<p>Baker et al (2002)</p> <p>Study type: Pre post study</p> <p>Country of origin: UK</p> <p>Review domain: Effectiveness</p>	<p>To evaluate outcomes of all clients referred to a primary care counselling service at set intervals (pre counselling, three months, six months, one year and two years post counselling). Outcomes are compared with a naturally occurring waiting list group from the same service.</p>	<p>The study found highly significant reductions in the severity of symptoms for anxiety, depression and adjustment disorder at three months, gains which were subsequently maintained from six months to two years following a short-term (eight-session) counselling intervention. The reduction in severity of anxiety and depression over time was significantly less for the waiting list group. Self-esteem scores also significantly increased for the counselled group at three months and were maintained over the two-year period. Some clients in both waiting list and counselled groups received medication, but only those who received medication and counselling showed significant improvement. The combination of these two treatments, particularly for those with depression, was associated with the most significant positive outcomes for clients.</p>	<p>The study has a large sample (n=1724) taken from one particular geographical location (Dorset Primary Care) drawn from 45 different GP practices. Standardised questionnaires were used at each point of follow-up. The relative lack of controls within the study renders external validity quite high. Data attrition was high: of the 1,724 entering the study only 265 (15%) completed measures at two years. The waiting list control group was much smaller and also experienced high attrition (n=367 at baseline, n=81 (22%) at follow up). Differences between the counselling and waiting list groups at baseline may have influenced outcomes. This is a well-conducted service evaluation with findings generalisable to UK primary care populations. The lack of controls typical of this type of study should prompt some caution in interpreting the results.</p>
<p>Bower and Rowland (2006)</p> <p>Study type: Systematic review</p> <p>Country of origin: UK</p> <p>Review domain: Efficacy, Economic issues, User perspectives</p> <p>Also reported in: Bower et al (2002) Bower, Byford et al (2003) Bower, Rowland et al (2003) Rowland et al (2001) Rowland et al (2000)</p>	<p>To assess the effectiveness and cost-effectiveness of counselling in primary care by reviewing cost and outcome data in randomised controlled trials for patients with psychological and psychosocial problems considered suitable for counselling.</p>	<p>Counselling is more effective than usual care in terms of mental health outcomes in the short term. However, these advantages do not endure in the longer term. Counselling may not differ in effectiveness from medication and CBT, although the standardised mean difference in outcomes between CBT and counselling in older patients with anxiety was relatively large. Counselling may be associated with some reduction in health service utilisation, but overall costs did not seem to be reduced, and may be increased. Patients are generally satisfied with counselling in primary care. Counselling may make a useful addition to primary care services alongside other mental health treatments. As a time-limited therapy, it has a short-term impact. Longer treatment or maintenance treatment with booster sessions may be helpful to improve longer-term outcomes. The notion of 'care' as well as 'cure' is important. Trials tend to measure the latter. More investigation of counselling as a form of patient care is needed.</p>	<p>This is a very well-conducted review constituting the highest level of evidence. Studies included in the review were pragmatic rather than explanatory trials. Such studies attempt to test routine interventions in naturalistic settings with typical patients. Hence external validity is high. On the other hand, compromises have to be made with regard to internal validity, making interpretation of results difficult. Counsellors in the studies offered a range of interventions: person-centred, psychodynamic, eclectic, CBT. Treatments were also offered over varying periods of time, making it difficult to draw conclusions about the effects of different amounts of therapy. Often, the control condition (usual GP care) is not described in detail. In some cases, this may include medication and/or the use of counselling skills by GPs. Despite these methodological issues, the review methods were rigorous, resulting in the location and critical appraisal of eight good-quality trials.</p>

Best evidence (++)			
Findings and conclusions		Summary evaluative comments	
Study details	What are the aims of the study?	Findings and conclusions	Summary evaluative comments
<p>Chisholm et al (2001)</p> <p>Study type: Clinical trial – reported in Ridsdale et al (2001) incorporating a cost-consequence analysis</p> <p>Country of origin: UK</p> <p>Review domain: Efficacy, Economic issues, User perspectives</p>	<p>To compare the relative costs of cognitive-behaviour therapy as compared with counselling for patients with chronic fatigue.</p>	<p>A comparison of change scores between baseline and six-month follow-up revealed no statistically significant differences between the two groups in terms of aggregate healthcare costs, patient and family costs or incremental cost-effectiveness (cost per unit of improvement on the fatigue score). While rates of GP contact fell, this did not compensate for the increased costs of the counselling or CBT intervention.</p> <p>Both counselling and CBT led to improvements in fatigue, while slightly reducing informal care and lost productivity costs. Counselling is less costly than CBT (mean cost of counselling = £109, SD=49; mean cost of CBT = £164, SD=67) but no overall cost-effectiveness advantage was found for either form of therapy.</p> <p>It may be economically preferable to offer counselling rather than CBT because of its greater availability and cheaper cost, even though it produces no marked superiority in cost-effectiveness terms.</p>	<p>This study is a cost-consequence analysis carried out as part of an RCT. It takes a societal perspective in which the costs to both the service provider and to patient and family are included. Cost and effectiveness data are taken from the same group of patients over a six-month period. Valuation was made using estimates from recognised sources. The statistical analysis was complete and well documented together with one-way sensitivity analysis. This is a well-designed cost-consequence analysis on 129 patients from GP practices in London, and whilst the authors note that the study is underpowered to detect differences in costs, this is a common deficiency in this type of analysis (where power calculations usually relate to effectiveness rather than cost data). The main weakness of the study, as the authors note, is the omission of a usual care control group. Whilst the paper concludes from the data that no cost advantage was found from either form of therapy, it is unable to determine how each would compare with usual care.</p>
<p>Evans et al (2003)</p> <p>Study type: Pre post study</p> <p>Country of origin: UK</p> <p>Review domain: Effectiveness</p>	<p>To describe how national referential ('benchmark') data on primary care counselling can be established using the CORE database. To compare CORE data for a particular service with this referential data, in order to evaluate the service with particular reference to the ethnicity of service users.</p>	<p>The study found that when compared with national referential data, a particular counselling service in the south of England saw a higher proportion of clients from ethnic minority (EM) backgrounds. EM clients tended to be referred for counselling at a slightly younger age than White/European (WE) clients, though it was unclear if this was related to characteristics of that population, or GP referral/client help-seeking patterns. EM clients in the service were more likely to be employed and living alone than WE clients, and to score more highly on all scores except wellbeing. EM clients were also more likely to have an unplanned ending, particularly in the case of Pakistani/Bangladeshi and Black African/Caribbean clients. There were no significant differences in clinical outcomes between EM and WE patients.</p>	<p>The study sample size is quite large (n=661). The national referential dataset is based on a pooled multisite sample of 5,097. A well-validated outcome measure is used (CORE).</p> <p>Because the national dataset has been gathered from routine practice, generalisability is high. However, authors recognise that the profile of this data will be influenced by those services nationwide who have submitted data, and therefore may not be typical. The findings that EM clients were more likely to have unplanned endings than WE clients but that overall therapeutic outcomes between the two groups were not significantly different can be seen as robust findings for this particular service. It is unlikely that findings are generalisable beyond the locality of the service.</p>

Study details	What are the aims of the study?	Best evidence (++) Findings and conclusions	Summary evaluative comments
<p>Lin P et al (2005)</p> <p>Study type: Clinical trial</p> <p>Country of origin: USA</p> <p>Review domain: Efficacy, User perspectives</p>	<p>To examine the relationships amongst patient preferences for treatment modality, receipt of treatment and improvement in depressive symptomatology. To explore whether preference matching was related to patient outcomes.</p> <p>It was hypothesised that demographic and clinical factors would demonstrate relationships with treatment preferences and preference matching. It was expected that 'treatment preference matched' participants would evince more improvement in depression relative to unmatched patients.</p>	<p>Patients were originally recruited via a parent randomised controlled trial. Participants' preferences for treatment modality (ie antidepressant medication alone, psychotherapy alone, or both) were elicited, and then an initial treatment assignment was made according to preference where appropriate. The sample (n=335) had an age range of 24-84 with an average age of 57. 95% of the sample was male and 78.8 Caucasian. The study found that 15% preferred medication, 24% psychotherapy and 61% both. Those who preferred medication only were older and more likely to be married, Caucasian and to have completed high school. Receipt of a particular treatment in the past predicted current treatment preferences. Patients matched to their treatment preference had a greater reduction in SCL score from baseline to three months (0.29 vs 0.11 p&lt;.05) than unmatched patients, and a reduction (but less significant) at nine months (0.37 vs 0.21, p=0.64). Both matched and unmatched evidenced improvement over time; but those who received treatment of preference enjoyed more rapid response.</p> <p>Matching patients with their preferred treatment improves outcomes in the short term. Treatment preferences are associated with ethnicity, age, illness severity.</p>	<p>The study is well conducted. Researchers are blind to the treatment conditions received by participants. There is a reasonable sample size. Participants were veterans of the US armed forces, hence predominantly male. Their health status was worse than the average primary care patient, hence generalisability is limited. In the devising of the questionnaire about preferences, the 'both medication and psychotherapy' category tended to pool participants who wanted to receive both treatments and those who would be happy to receive either (ie lack of a strong preference). Giving those with lack of a strong preference a combined treatment does not closely match preference with treatment and hence is a weakness in the study. Likewise, there was a lack of specificity with regard to treatment. The type of counselling received was not clearly described and the quality of such interventions not monitored. Hence participants may be matched to their treatment of choice, but this does not necessarily mean that the treatment was adequate. A wide range of well-validated outcome measures was used, ensuring the collection of relevant and reliable data.</p>
<p>Mellor-Clark et al (2001)</p> <p>Study type: Pre post study</p> <p>Country of origin: UK</p> <p>Review domain: Effectiveness</p>	<p>To provide an initial profile of an ongoing, large-scale naturalistic study of counselling in primary care settings. To explore the feasibility of collecting high quality data from routine counselling practice.</p> <p>To explore the extent to which CORE systems data have the potential to inform NHS clinical governance requirements for monitoring National Service Frameworks (NSFs).</p>	<p>A sample of 1,087 clients completed pre and post counselling scores; 76% of this sample made a statistically reliable positive change.</p> <p>Potentially high-quality data was obtained at intake on 96% clients. End-of-therapy forms were completed for 95% of all clients accepted for counselling. 88% of clients having a planned ending completed CORE-OM at final session. The within-study pre-post effect size was 1.52. Three out of four clients reported reliable improvement. Of these, three out of every five reported clinically meaningful improvements, suggesting that primary care counselling can be effective. CORE system has considerable strengths for profiling how counselling can be an effective intervention to assist primary care practice to meet NSFs.</p>	<p>This is a large-scale study of the effectiveness of counselling in primary care, drawing data from nine UK counselling services.</p> <p>A well-validated measure is used and data attrition is generally low. The within-study effect size is comparable with the findings of clinical trials in primary care eg Bedi et al, 2000.</p>
<p>Ridsdale et al (2001)</p> <p>Study type: Clinical trial incorporating a cost-consequence analysis (reported in Chisholm et al (2001))</p> <p>Country of origin: UK</p> <p>Review domain: Efficacy, Economic issues, User perspectives</p>	<p>To compare the clinical effectiveness of cognitive-behaviour therapy as compared with counselling for patients with chronic fatigue and to describe satisfaction with care.</p>	<p>Patients were randomised to six one-hour sessions of counselling or CBT. 160 entered the trial and 129 completed the follow-up. No significant difference in effect was found between the CBT (n=64) and counselling (n=65) groups. The mean fatigue score at baseline using the Fatigue Questionnaire was 27.5. At six-month follow-up, this was 18.6 (SD=8.4) in the counselling group and 20.8 (SD=9.7) in the CBT group. A non-significant trend in favour of counselling was discerned, although there were higher levels of satisfaction with therapy in the CBT group than in the counselling group.</p>	<p>One of the limitations of the study, reported by the authors, is the lack of data as to how CBT and counselling compare with usual GP care in the treatment of chronic fatigue. The original hypothesis was that CBT would prove to be superior to counselling and that the latter would act as a control condition. Lack of differential effects led authors to conclude that usual GP care would have been a more appropriate control condition. This is a well-conducted study with reliable findings and justified conclusions. Both treatments followed manualised protocols and treatment adherence was monitored. However, there is lack of clarity in describing the counselling intervention, which is, on the one hand, described as 'a psychodynamic approach' and on the other, 'non-directive and client-centred'.</p>

Best evidence (++)			
Study details	What are the aims of the study?	Findings and conclusions	Summary evaluative comments
<p>Unutzer et al (2003)</p> <p>Study type: Survey of treatment preferences conducted as part of a clinical trial</p> <p>Country of origin: USA</p> <p>Review domain: User perspectives</p> <p>Also reported in Gum et al (2006)</p>	<p>To examine rates and predictors of lifetime and recent depression treatment in a sample of 1,801 depressed older primary care patients participating in an RCT.</p> <p>To investigate factors which predict depression in this population, to evaluate whether patients receive adequate treatment and to identify patient treatment preferences.</p>	<p>This large survey of patient preferences (n=1801) formed a relatively small part of a large-scale, multi-site randomised controlled trial into improving depression treatment. Most participants indicated a preference for counselling (51%) as opposed to antidepressant medications (38%). 8% had received such treatment in the past three months, and only 1% reported four or more sessions of counselling in the prior three months.</p> <p>A small percentage (4%) preferred no treatment at all. Participants who preferred psychotherapy had significantly lower rates of lifetime or recent depression treatment than those who preferred antidepressants.</p> <p>The second paper (Gum et al, 2006) reports treatment preferences in a subgroup (n=1602) of the original sample (n=1801) of those participating in the depression treatment RCT. Findings indicated that more patients preferred counselling (57%) than medication (43%). Previous experience with a treatment type was the strongest predictor of preference. Men and those with a diagnosis of major depression were more likely to prefer medication. The receipt of preferred treatment did not predict satisfaction or depression outcomes. Authors conclude that as many depressed older primary care patients prefer counselling as a treatment for depression, this should be made more widely available in primary care.</p>	<p>The large sample makes this a powerful study. All participants met criteria for the presence of depression, making assessment of treatment preferences relevant to a clinical population. A possible confound is that patients who express a preference for counselling may change their mind when faced with more information about what is involved in terms of time commitment, travelling etc. Furthermore, participants were recruited to the RCT on the understanding that randomisation would be part of the procedure. Patients willing to accept randomisation are likely to have weaker treatment preferences than those who would not accept randomisation. Hence this sample may not be typical of primary care patients. Although much of this study addresses more general issues concerning depression treatment, the preference data is reliable and clearly reported.</p>

Supporting evidence (+) Findings and conclusions		Summary evaluative comments
<p><b>Study details</b></p> <p>Bellamy and Adams (2000)</p> <p>Study type: Clinical trial using waiting list control group</p> <p>Country of origin: UK</p> <p>Review domain: Efficacy</p>	<p><b>What are the aims of the study?</b></p> <p>To investigate the effectiveness of a counselling psychology service by comparing the outcomes of a treatment group with those of a waiting list control group receiving usual GP care. To explore the impact of the service on patient improvement and wellbeing using SCL-90R, HADS, and to evaluate the effects on rates of GP consultations.</p>	<p>Although designed as a trial, there are a number of weaknesses in the design that limit the conclusions of the study. Participants are those routinely referred by GPs for counselling rather than those with a specific diagnosis. There is no description of the intervention other than 'counselling psychology service'. The number of sessions or the period of time over which the treatment is delivered is not specified. The paper hints that the intervention is delivered by the researcher, without collaboration with other therapists or researchers. This introduces a major bias. The randomisation protocol breaks down, as, for ethical reasons, GPs find it difficult to accept the randomisation of distressed patients to a no-treatment condition. Hence the control condition is mostly composed of those who have refused to have counselling. Group size is relatively small (54 in the treatment group; 16 in the control condition) and so it is likely that the study is underpowered. No account is taken of loss to follow-up (11 were lost from the treatment group and none from the control group). The study can be seen as a useful small-scale evaluation of a particular service which has demonstrated clinically – rather than statistically – significant effects.</p>
<p><b>Study details</b></p> <p>Booth et al (1997)</p> <p>Study type: Pre post study</p> <p>Country of origin: UK</p> <p>Review domain: Effectiveness</p>	<p><b>What are the aims of the study?</b></p> <p>To discover the most frequent helpful and unhelpful impacts reported by patients after counselling sessions and to assess the intensity of these types of events.</p> <p>To explore how clients' reports of the frequency and intensity of impacts relate to their overall assessment of outcome.</p> <p>To discover if there is a relationship between the frequency and intensity of impacts and clients' ratings of the attainment of different types of goal.</p>	<p>The methodological limitations of this study include the use of non-standardised outcome measures of which reliability and validity were not known. The sample description is limited. Gender and the number of sessions received are noted but not other sample characteristics. There is a high proportion of missing data for clients who completed outcome measures. Fifty-eight participants dropped out of the study leaving a sample size of just 51. This leaves open the possibility that those completing the study were better motivated than the average primary care user of counselling services. Similarly, more information on the therapists and the types of intervention delivered would have allowed more precise conclusions to be drawn. In assessing the study's limitations, authors acknowledge that more qualitative measures could have been used to capture deeper information regarding the clients' perceived needs and goals and the counsellors' responses to those needs. This would provide more detailed information about the nature of different change processes and the impact of significant events over time. Generalisability of the findings to wider populations is questionable.</p>
	<p><b>Supporting evidence (+) Findings and conclusions</b></p> <p>Counselling psychology service was clinically effective. On all measures, clients improved over the period of treatment and did so to a greater extent than patients in the control condition. However, benefits were not sufficient to achieve statistical significance.</p> <p>Moderate but not statistically significant mean effect sizes were discerned:</p> <ul style="list-style-type: none"> <li>– at eight-week follow-up = 0.27</li> <li>– at 16-week follow-up = 0.32</li> </ul> <p>In terms of GP consultations, the mean number of visits six months prior to treatment were:</p> <p>Treatment = 4.6666</p> <p>Control = 4.1</p> <p>Six months following treatment:</p> <p>Treatment = 3.25</p> <p>Control = 4</p> <p>Results indicated the counselling service was effective in reducing patient distress.</p>	

Supporting evidence (+) Findings and conclusions		Summary evaluative comments
<p><b>Study details</b></p> <p>Cooper et al (2003) Study type: Survey Country of origin: USA Review domain: User perspectives</p>	<p><b>What are the aims of the study?</b></p> <p>To examine whether racial and ethnic differences exist in patients' attitudes towards depression care.</p>	<p>The study is generally well conducted. However, the sample size of the Hispanic and African American groups was relatively small compared with the White group and so possibly lacked the statistical power to demonstrate any significant differences between groups with regard to patient preferences. Authors acknowledge that attitudes, beliefs and social norms are complex and may not be adequately captured using a structured questionnaire administered by telephone. In-depth qualitative approaches may be more useful. As the study was conducted in the USA, generalisability to UK primary care populations, where the ethnic mix is different, is questionable. The findings offer some insight into differences that exist between ethnic groups, and highlight the need for further research in this important area.</p>
<p>Gordon and Graham (1996) Study type: Pre post study Country of origin: UK Review domain: Effectiveness Also reported in Gordon and Wedge (1998)</p>	<p>To evaluate outcomes of short-term and long-term effects of a brief counselling intervention in primary care.</p>	<p>The intervention was delivered by three counsellors attached to three GP practices in one. The sample size was reasonable (n=95) and sample characteristics were described in detail. Two well-validated outcome measures were used in the original study. Data were available for 75% of the original sample at three-month follow up.</p> <p>At two-year follow-up, 55 of the original sample (n=95) did not complete measures, raising the issue as to whether the follow-up sample was representative of the original one. Analysis of the follow-up group indicated that it was almost five years older than the 55 non-responders, and had poorer outcomes on immediate post-counselling HADS scores. This could suggest that the results actually present a somewhat conservative estimate of the long-term maintained benefits of counselling. A bespoke measure was devised and used solely at two-year follow-up, reducing the study's ability accurately to compare data at different points. As is often the case with long-term follow-up data, attrition is high and so the results should be interpreted with caution. Participants received other interventions during the follow-up period, particularly medication and further sessions of counselling, rendering it difficult to attribute the long-term effects to the original intervention. The fact that 63.4% of the sample reported some recurrence of their problems during the follow-up period could suggest the original intervention may have only weak longer-term benefits. However, it is clear that clients perceived the original intervention as helpful and effective, indicating high levels of satisfaction with this form of treatment.</p>
	<p>A telephone survey was conducted of 829 adult primary care patients who were experiencing depression. Of the total sample, 659 were White, 97 African American and 73 Hispanic. 70% of the whole sample viewed antidepressant medication to be an acceptable treatment for depression and 86% found individual counselling to be an acceptable treatment. In terms of ethnicity, 79% of African Americans, 86% of White persons and 95% of Hispanics found individual counselling acceptable for depression. Authors concluded that African Americans and Hispanics are less likely than White persons to find antidepressant medication acceptable. Hispanics are more likely to find counselling acceptable than White persons.</p> <p>Authors suggest that clinicians managing ethnic minority patients with depression should elicit patients' explanatory models for depression and address social and cultural perspectives and commonly held negative beliefs towards treatment which may serve as a barrier to care.</p> <p>Outcomes relating to 95 patients who had received a six-session counselling intervention were evaluated pre, post, and at follow-up (variously reported in the papers as at three months and at four months) using HADS and SCL-90R scales. Immediately following the intervention, 37 out of 64 patients with anxiety experienced reductions in symptoms, 27 remaining in a clinical range. Also at this point, 16 out of 28 patients with depression experienced symptom reduction, 12 remaining in a clinical range. Hence over half of patients referred with mood disorders were recovered post intervention. This improvement was maintained at four-month follow-up.</p> <p>For the majority of patients (n=76) short-term counselling was sufficient. A subgroup (n= 19) with higher initial levels of symptomatology required referral to other services, suggesting that the benefits of counselling are more evident in the treatment of anxiety and depression than other psychiatric disorders.</p> <p>A long-term follow-up of the study was conducted two years after the intervention, using HADS and a scale specifically designed for the project, on 41 of the original 95 (also reported as 96) participants. HADS results indicated that the reduced levels of anxiety and depression, recorded post counselling, were maintained at follow-up. Of the follow-up sample, 30% reached 'caseness' for anxiety and 10% for depression. This compares with 67.4% and 29.5% respectively for the pre-therapy group. Using the bespoke measure, 87.8% felt that counselling had helped their original problems either moderately or greatly. 63.4% reported some recurrence of their original difficulties over the two-year period, but of these, 73.5% felt the original intervention helped them at least moderately in dealing with relapse.</p> <p>Authors conclude that the benefits of the original brief intervention were maintained at two-year follow-up and that patients were highly satisfied with the counselling received.</p>	



Supporting evidence (+)			Summary evaluative comments
Findings and conclusions			
Study details	What are the aims of the study?		
<p>Hemmings A (1999)</p> <p>Study type: Systematic review</p> <p>Country of origin: UK</p> <p>– international studies included</p> <p>Review domains: Efficacy, Effectiveness, Cost-effectiveness, User perspectives</p>	<p>The review aims to assess the effectiveness of counselling in primary care, taking on board evidence from both RCTs and other types of research and evaluation. Cost-effectiveness and levels of patient satisfaction are also summarised.</p>	<p>The author asserts that the utility of RCTs in evaluating the effectiveness of clinically representative service delivery is limited and that naturalistic practice-based evidence should supplement evidence from RCTs. The review found that there is support for the hypothesis that psychological interventions are more effective than usual GP care. Naturalistic studies support the use of psychological interventions in primary care and the theme of the grey literature was almost entirely positive from the point of view of patients and GPs alike. Several studies show evidence of the cost-effectiveness of counselling in primary care. The author concludes that psychological interventions are both effective in primary care and acceptable to patients and GPs.</p>	<p>This is a wide-ranging and comprehensive review. The number of included studies is not clearly stated but is upward of 65. Weaknesses in the types of research included in the review are discussed but the limitations of the review itself are not stated. Review methods are not clearly reported, making problematic judgements about the rigour of the review. The interventions included are quite heterogeneous. Interpersonal therapy, cognitive-behavioural therapy are included along with non-directive counselling and problem-solving therapy (and thus a significant amount of the evidence is not relevant for this review). Interventions are delivered by a wide range of health professionals: GPs, nurses, social workers, clinical psychologists. Only three electronic databases were searched between 1975 and 1998. Criteria for the inclusion/exclusion of studies are not specified. There is no description of data extraction methods and no evidence of the double reviewing of studies. Methods of quality assessment are not clear and details of the grey search not apparent. The grey search yielded 26 reports but most of these came from a single source (Counselling in Primary Care Trust). The review appears to have been conducted by just one person and so a level of bias cannot be ruled out. A large amount of evidence has been usefully summarised but findings should be interpreted with a degree of caution.</p>
<p>Kates et al (2002)</p> <p>Study type: Pre post study</p> <p>Country of origin: Canada</p> <p>Review domain: Effectiveness</p>	<p>To evaluate a programme that integrates counsellors into primary care settings.</p> <p>To present data on patient outcomes and levels of satisfaction with the service.</p>	<p>The counselling service involves 36 medical practices in Southern Ontario. Outcomes for the first 900 patients who had completed the service since its introduction were analysed. Significant reductions in mental health problems were discerned; 82% of the sample moved from a clinical to a non-clinical score on the GHQ measure and 73% on the CESD following the intervention. The study found a 65% reduction in referrals to psychiatry outpatient services among participating family physicians since the establishment of the counselling service.</p> <p>Using the Consumer Satisfaction Questionnaire (CSQ), 92% of patients indicated they were satisfied with the treatment. Among GPs there were high levels of satisfaction with the service. Authors concluded that counselling in primary care complements traditional mental health outpatient services by extending the continuum of care services available to patients. The service also offers opportunities for the early detection of mental health problems and early initiation of treatment.</p>	<p>This is a well-conducted service evaluation using routinely collected outcome data. The sample size is quite large and clinical and demographic characteristics are described. The intervention is quite heterogeneous and is delivered by qualified therapists from a range of professional backgrounds (nursing, social work, psychology). Similarly, patient problems are quite varied, the most prevalent being depression. Several well-validated measures are used to assess outcomes, yielding good-quality data. There is no analysis of the sample to indicate whether participants are typical primary care patients and, as a Canadian study, there may be issues concerning generalisation to UK populations. It is not clear whether participants received any other treatments such as medication or usual GP care during the period of the intervention.</p>

Supporting evidence (+)		Summary evaluative comments	
Findings and conclusions		What are the aims of the study?	
Study details	Findings and conclusions	What are the aims of the study?	Summary evaluative comments
<p>Kolk et al (2004) Study type: Clinical trial Country of origin: Holland Review domain: Efficacy, Cost-effectiveness</p>	<p>A sample of 98 patients was recruited to the trial and randomised to either a counselling intervention group or a usual GP care group. Measures were taken at baseline, after six months and 12 months. GP consultations were monitored over a period of 1.5 years. The study found that self-reported and GP-rated unexplained physical symptoms decreased from pre test to post test to follow-up. Psychological symptoms and consultations decreased from pre test to post test. However, no differences were discerned between the intervention and control groups in terms of symptom reduction. Pre test to post test, the mean scores of both groups in terms of unexplained symptoms, depression and anxiety decreased from a clinical to non-clinical population. The number of GP consultations decreased only in the six months prior to therapy and the six months during therapy. Authors concluded that psychological treatment was not superior to routine primary care in the treatment of medically unexplained physical symptoms.</p>	<p>To test the effects of a counselling intervention on multiple medically unexplained physical symptoms, psychological symptoms, and health care utilisation using usual GP care as a control condition.  To identify patient-related predictors of change in symptoms and care utilisation.</p>	<p>In many respects, this is a well-conducted study. A wide range of well-validated measures are used along with randomisation and concealment. However, difficulty in recruiting participants led to a relatively small control group (n=18), thus reducing the power of the study. There was less symptomology in the control group than in the intervention group pre test, which may have influenced outcomes. The intervention is described as a mixture of CBT, client-centred and eclectic counselling and, whereas this may approximate the reality of routine practice, the lack of treatment specificity limits what conclusions can be drawn about the effects of particular therapies.</p>
<p>Milgrom et al (2005) Study type: Clinical trial Country of origin: Australia Review domain: Efficacy</p>	<p>192 women recruited via a community screening programme were randomly allocated to one of four treatment groups. 121 of these completed post-intervention measures. Psychological interventions were superior to routine care in terms of reductions in both depression and anxiety (by around seven points on the BDI and eight points on the BA). Post treatment, the percentages of women whose BDI scores fell below the threshold for clinical depression were as follows:  Group CBT – 55%, group counselling – 64%, individual counselling – 59%, routine primary care – 29%  No significant differences in outcomes were discerned between CBT and counselling. Individual counselling yielded the best outcome in terms of depression (by three to five points on the BDI). Authors concluded that psychological interventions for women with PND can lead to clinically significant reduction in symptoms. Counselling was as effective as CBT. The benefits may be maximised by offering psychological interventions on a one-to-one basis.</p>	<p>To establish the efficacy of psychological interventions versus routine primary care for the management of postnatal depression (PND). To provide a direct comparison of CBT versus counselling and to compare the relative value of group and individual formats.</p>	<p>Generally this is a well-conducted study using randomisation and a level of concealment, although the number of patients in each group was quite small and not evenly distributed. Treatment adherence is measured, and well-validated outcome measures are used. Data attrition was quite high, perhaps resulting from the fact that patients were not allowed to choose their treatment. Hence obtaining sufficient follow-up data at 12 months was unfeasible and so no formal analysis was possible at this point of follow-up. Only 57 cases were available at 12 months (192 had entered the trial). The study therefore measures only short-term effects. Generalisability needs careful consideration, as routine primary care for mothers in Australia may differ from that experienced in the UK. Participants were offered consultations with a specialist nurse, which may not necessarily be the norm in the UK. Drug-free treatments for this kind of problem are particularly important where mothers may be breast-feeding.</p>
<p>Murray et al (2000) Study type: Pre post study Country of origin: UK Review domain: Effectiveness</p>	<p>Few differences were found between the way in which the counsellor and the clinical psychologist delivered the service, although the latter dealt with more complex problems and saw more male patients. Therapist and GP ratings showed high levels of positive outcome/satisfaction with the service and there was significant agreement between therapists and GP regarding outcomes/satisfaction. On a scale of 1-10, the mean rating by therapists and GP was 7.  Patients who received more sessions and who completed treatment were more likely to receive a higher outcome score by both therapist and GP than those who did not. Authors concluded that differential referral to a clinical psychology service and to a counsellor, in terms of the perceived severity of patient problems, can produce high levels of perceived patient positive outcome, agreement in positive ratings by therapist and GP, and GP satisfaction with the psychological services being offered.</p>	<p>To evaluate a counselling service provided by a counsellor, clinical psychologist and assistant psychologist to a primary care clinic in terms of GP and therapist evaluation of patient outcome and GP satisfaction with the service.</p>	<p>This is a small-scale evaluation of a counselling service in a single GP practice and thus may not be generalisable. The sample is quite small (n=56) and the service evaluation data is based on patient demographic data and GP and therapist ratings of satisfaction with the service. Satisfaction is measured using a Likert-type scale specifically devised for the evaluation. The study provides useful data about the differential work of counsellors and clinical psychologists in terms of client profile. Little can be concluded about the effects of counselling, as patients' perceptions of their own outcomes are not measured. That GPs are satisfied with this service and view the outcomes as positive for their patients is a robust finding.</p>

Supporting evidence (+)		Summary evaluative comments
Study details	What are the aims of the study?	Findings and conclusions
<p>Murray et al (2003) Also reported in Cooper et al (2003) Study type: Clinical trial Country of origin: UK Review domain: Efficacy</p>	<p>To evaluate the effects of non-directive counselling, CBT and psychodynamic therapy for postnatal depression.</p>	<p>The study uses randomisation and the blinding of researchers to reduce bias. The sample size is reasonable and data attrition is modest: 193 randomised to groups, 138 completed measures at five years. The study has two unusual findings: that only psychodynamic therapy was superior to the control condition in targeting depression, and that non-specialist therapists were more effective than specialist therapists. Confounds in the delivery of interventions may have produced these. Authors suggest that non-specialist therapists (health visitors) trained for the purposes of the study were experienced in making home visits, which may have produced these superior effects. Health visitors were also responsible for the delivery of the usual care control condition. Despite the fact that supervision sessions were held to ensure treatment fidelity, it may well be the case that therapist variables rather than the treatment techniques per se may have produced differential effects. The rate of remission in the control condition was higher than normal rates of spontaneous remission, thus reducing the differential outcomes between intervention and control groups.</p> <p>The study used a variety of different measures at different points of follow up: patient-completed reports, observational measures completed by researchers and other professionals. Some measures were devised for the purpose of the study. Some measures may have lacked validity, and even though able to discern differences between groups, may have been unreliable measures of treatment effects. Because the study was assessing child development and behaviour over a long period of time, different measures were needed at different points eg behaviour measurement in a toddler is different to that in a five-year-old. However, it was not possible to tell if the variables had actually changed or the instruments were measuring different things. This is a complex longitudinal study where the findings relating to maternal mood are likely to be more reliable than those pertaining to mother-child relationship and child development, as this was measured using the same instrument throughout the study.</p>
<p>Nettleton et al (2000) Study type: Pre post study Country of origin: UK Review domain: Effectiveness</p>	<p>To evaluate a counselling service provided over a period of one year by one counsellor to three rural GP practices using patient demographic data and reports from patients, GPs and the counsellor.</p>	<p>Patient outcomes were measured by a combination of a questionnaire devised for the study and a standard, well-validated tool (the Adapted General Wellbeing Index). Counsellor and GP perceptions of the service were measured using both questionnaires and qualitative interviews. GPs monitored any changes in the use of medications following the intervention. The number of counselling sessions delivered to patients varied between one and 26 (mean=5.4). The total sample size is not clearly reported. 131 patients were referred to the service but different sub-samples completed different measures. For example, just 53% (n=58) completed the post-counselling wellbeing scale. Although a large amount of data was collected to evaluate the service, an unsystematic approach to data collection and widespread data attrition indicates a need for caution in interpreting the results.</p>
	<p>The study measures both short- and long-term effects of different psychological therapies using the following variables: – maternal mood, mother-child relationship, child development.</p> <p>In terms of maternal mood, at 4.5 months postpartum (immediately following the intervention) 40% of the control group had remitted from depression. This compares with 61% of the treatment groups, a difference of 21% favouring treatment. This benefit disappeared after the 4.5-month assessment. At nine months there was a difference between treatment and controls of only 4% in favour of treatment. At 18 months, 11% fewer in treatment groups had remitted as compared with controls. At five years, just 4% more in treatment group had remitted compared with controls. Hence after 4.5 months postpartum, treatments were not significantly different from control condition in reducing postnatal depression. Only psychodynamic therapy produced a rate of reduction in depression significantly superior to that of the control. Greater reduction in EPDS scores were found for those treated by non-specialist therapists (those trained purely for the purposes of the study) as opposed to specialists. Authors suggest that the fact that non-specialists were experienced home visitors may have produced this effect.</p> <p>In terms of mother-child relationship and child development immediately post intervention, all three treatments had a significant benefit on maternal reports of early difficulties in relationships with the infants. Counselling produced better infant emotional and behaviour ratings at 18 months and more sensitive early mother-infant interactions. Interventions had no significant impact on maternal management of early infant behaviour problems, security of infant-mother attachment, infant cognitive development or any child outcome at five years.</p> <p>Authors concluded that psychological therapies were beneficial in the short term, immediately following treatment. But there was no superiority over routine primary care in the long term. Non-specialists may be the best personnel to deliver interventions</p>	<p>The study is a small-scale evaluation of a counselling service which was piloted in three GP practices. The total sample size is not clearly reported. The study found no decrease in drug use by patients who had received counselling. Statistically significant improvements in patient wellbeing were found in patients who completed the measures (n=58) (P&lt;0.001). The perceptions of 11 nurses and one practice manager obtained by group discussions (moderated by independent researcher) were very positive. High levels of patient satisfaction were found and the views of GPs were also positive.</p>

Supporting evidence (+)		Summary evaluative comments
Study details	What are the aims of the study?	Findings and conclusions
<p>Newton (2002)</p> <p>Study type: Pre post study</p> <p>Country of origin: UK</p> <p>Review domains: Effectiveness, User perspectives</p>	<p>To evaluate the effects of a counselling service in terms of patients' attainment of their goals.</p> <p>To categorise clients' goals using a content analysis system.</p>	<p>This is a small-scale study involving 100 patients counselled by seven therapists in a particular UK NHS trust. The study is reported quite briefly, making it difficult to draw out the implications for counselling in primary care generally. The sample is not described in any detail and so it is not possible to discern how typical participants were of primary care populations. Data attrition is not reported and the intervention is not clearly described. However, the measuring of outcomes uses an innovative and interesting method where therapeutic effects are evaluated according to criteria set by patients themselves. A problem with this method is that 20% of patients changed their criteria during the course of the intervention. While this is perfectly understandable in terms of therapeutic practice, in research terms it undermines the study's ability to measure change pre and post intervention.</p>
<p>Simpson et al (2003)</p> <p>Study type: Economic evaluation of a service</p> <p>Country of origin: UK</p> <p>Review domain: Economic issues</p>	<p>To investigate the effect of employing counsellors in general practice on rates of psychotic drug prescription and referral rates to mental health services.</p>	<p>The study was conducted in one geographical region, comparing non-matched practices: patient mix or other baseline data could therefore have affected the findings. Differential patterns of patient referral and drug prescription may have existed among GPs regardless of whether or not they had counselling services. The cost analysis is undertaken from the perspective of the service provider looking to make comparisons between: general practices with and without counsellors; general practices with counsellors in place less than four years and more than four years. The study does not attempt to measure clinical effectiveness and so a cost-effectiveness analysis was not possible.</p> <p>Resource use is identified from a number of different sources and valued using standard unit costs. The cost boundary is the service provider and only the amount and costs of prescribing, the time and cost of counselling (including overheads), and cost of referrals are reported. For the latter, it is not clear how these have been valued and whether overheads were included. Costs are valued using 1998 prices and no sensitivity analysis was used to take account of estimates. Total costs are not reported but the mean costs per 1,000 patients of counselling plus prescribing cost of CNS drugs is given, together with mean cost per 1,000 patients of CNS drugs for general practices with counsellors. The cost of each, including referral, is also presented. The overall cost boundary is very narrow. There are likely to be other costs accruing to the health authority in both the primary and secondary sectors. This is a useful study but lack of controls and cost detail limits the generalisability of study.</p>

Supporting evidence (+) Findings and conclusions			
Study details	What are the aims of the study?	Summary evaluative comments	
<p>Shape et al (2003) Study type: Qualitative Country of origin: UK Review domain: User perspectives</p>	<p>To explore the meanings people attribute to their decisions not to take up a counselling referral.</p>	<p>This is an interesting study as it produces data relating to the attitudes of those potential patients who have decided against having the intervention. There is a paucity of such data in the research literature, as most studies sample participants who have either received counselling or would be happy to do so. This study is based on a small sample; only 20% of those contacted responded and 10% of these were interviewed. However, the study provides some useful suggestions for improving the uptake of counselling services following GP referral.</p>	
<p>Van Schaik et al (2004) Study type: Systematic review Country of origin: Holland – international studies included Review domain: User perspectives</p>	<p>To discern which treatments people with and without depression prefer for depressive disorder in primary care. To investigate the underlying assumptions and factors associated with patients' preferences and whether patients' preferences affect treatment compliance and outcome in clinical trials.</p>	<p>A limited range of electronic sources was searched (Medline, Psycinfo and the Cochrane library) between 1990 and January 2003, together with citation tracking of relevant studies. Data was extracted from studies in a standardised format but there was no assessment of study quality. There is no evidence of the double-reviewing of papers to reduce bias or the use of a data extraction template. Because of the variety of studies included, a narrative approach was taken to analysing the data. A fairly comprehensive yield of papers was achieved, which was summarised clearly and thoughtfully. As an international study, the findings are quite far-reaching and generalisable. The study discusses the possibility that the underlying reasons for treatment preferences are not necessarily very well informed.</p>	
<p>Wagner et al (2005) Study type: Survey Country of origin: USA Review domain: User perspectives</p>	<p>To examine beliefs about psychotropic medications and psychotherapy among a sample of primary care patients with panic disorders.</p>	<p>Patients (n=22) who had been referred for counselling in a UK GP practice were interviewed or invited to submit comments relating to why they did not take up the referral. A qualitative study design with semi-structured interviews was used. Authors found that the referral itself was sometimes experienced as therapeutic, in the way that it legitimised clients' distress. GPs' responses affected participants' decision whether to take up counselling or not. Lack of knowledge about counselling and concern about the stigma attached to seeing a counsellor likewise affected people's decisions. Authors conclude that providing information about counselling services and what to expect from counselling seems to be important for many people.</p> <p>Patients' preferences with regard to psychotherapy and antidepressant medication were investigated. The systematic review located eight relevant papers relating to treatment preferences of depressed primary care patients, along with 10 papers relating to preferences in non-depressed populations. In all studies, psychotherapy was preferred to antidepressants. Psychotherapy was preferred because it was assumed to provide an opportunity for personal exchange and to solve the problem underlying the depression.</p> <p>Antidepressants were often seen as addictive. Using psychotropic drugs was accompanied by more fear of losing control than using drugs for physical diseases. Being female, former experience with psychotherapy and being middle-class were associated with a preference for psychotherapy. Previous treatment with psychotropic drugs and old age were predictors of a preference for antidepressants. It was not clear whether giving patients their preferred treatment enhances compliance and improves outcome. However, it was found that where patients preferred counselling but did not receive it they were likely to go without treatment altogether. Patients with strong preferences were not likely to accept randomised as part of clinical trials. Authors noted that in two partially randomised patient preference trials, preference did not predict outcome. They concluded that as the majority of patients prefer counselling/psychotherapy, this should be a regular treatment option in primary care and that if patients are not offered their treatment of choice, they may go without treatment.</p> <p>The study used telephone interviews to examine beliefs about psychotropic medications and counselling/psychotherapy among a sample of primary care patients (n=801) with anxiety disorders. The presence of specific anxiety disorders was not found to impact on strength of beliefs about either medications or psychotherapy. There was a trend for the presence of comorbid depression to relate to more favourable attitudes toward psychotropic medications, and ethnic minority patients reported less favourable attitudes toward both medications and psychotherapy. Authors highlight the importance of assessing patients' beliefs prior to the initiation of either psychotropic medications or psychotherapy.</p>	<p>The sample in this study, although of a reasonable size, was recruited from clinics in the West Coast of the USA, which may limit generalisability to UK primary care populations. The results reported were derived from baseline measures collected in an RCT with a sample prepared to accept randomisation to either counselling or medication treatments. Such participants may have weaker treatment preferences than typical primary care populations. However, despite these limitations, the study is generally well conducted and the findings reliable.</p>

Supporting evidence (+)			Summary evaluative comments
Study details	What are the aims of the study?	Findings and conclusions	
<p>Wetherell et al (2004)</p> <p>Study type: Survey</p> <p>Country of origin: USA</p> <p>Review domain: User perspectives</p>	<p>To compare mental health treatment history and preferences in older and younger primary care patients.</p>	<p>This survey compared mental health treatment preferences in both older (n=77) and younger (n=312) primary care patients. The study found that older adults (&gt;60 years) were less likely than younger (&lt;60 years) to report a history of, or current participation in, mental health treatment. Older adults were less likely than younger adults to indicate that they currently desire help with emotional problems. However, participants of all ages reported a stronger preference for counselling than for medication. Older adults' preference for medications was just 11% and younger adults 10%. Older adults seemed to hold a preference for psychodynamic or supportive therapies whereas younger participants preferred more skills-based therapies such as CBT. Participants preferred individual therapy to group treatment (older adults preferring individual therapy = 64%, younger adults = 72%). Authors conclude that there is a need for services to target older people and that an understanding of age-differential treatment preferences is important in order to design interventions that optimise utilisation among both younger and older adults.</p>	<p>Although conducted with a reasonable degree of rigour, the study has certain limitations. The older patients were recruited from a veteran affairs clinic and were predominantly male, Caucasian and on low incomes. As such, it is unlikely that they were typical of wider primary care populations. The older participants were also a much smaller group than the sample of younger participants, raising the question as to whether the group was large enough for statistically significant comparisons to be made. There are also relatively high rates of missing data, which weakens the study's findings.</p>

<b>Poor-quality evidence (-)</b> <b>(Not used in compiling the findings of this review)</b>				
<b>Study details</b>		<b>What are the aims of the study?</b>	<b>Findings and conclusions</b>	<b>Summary evaluative comments</b>
Cape and Parham A (1998) Study type: Pre post study Country of origin: UK Review domain: Cost-effectiveness	To investigate the relationship between the provision of counselling in general practice and the use of outpatient psychiatry and clinical psychology services across a geographical area.	The authors found that there was a higher median referral rate to clinical psychology from practices with counsellors ( $p < 0.001$ ). No relationship between median referral rate to outpatient psychiatry and provision of counsellors in practices. Concludes that provision of practice counselling was associated with higher referral rates to clinical psychology.	This is not strictly a cost study as it merely looks at the number of referrals. The study is severely limited, as the overall study design has a control group and an intervention group that has no measure of baseline demographics; thus any difference is not attributable to the intervention ie differences may have existed prior to inception of counselling service. In addition, the authors note that the majority of practices with a counsellor had only recently initiated the counselling process, which suggests the referral pattern may still have been in transition. This further undermines their conclusion that the provision of counselling is associated with higher referral rates.	
Greasley and Small (2005) Study type: Pre post study Country of origin: UK Review domain: Effectiveness	To evaluate the effectiveness of a primary care counselling service via longitudinal research, with measures at beginning of counselling, at six-month and 12-month follow-up.	No data obtained on ethnicity because referral form did not obtain this information. Small sample, due to attrition, limited value of findings. Some useful qualitative data on service provision from two focus groups, one of counsellors, and a second group of GPs, practice managers, nursing staff and office staff. These related to issues of confidentiality; obtaining suitable rooms; and relationship between counselling and practice staff.	This is a small scale, longitudinal survey of primary care counselling in a single Primary Care Trust. The initial sample of 188 clients referred for counselling is affected by a high rate of DNA (30%), and of attrition in terms of return of follow-up measures at six-month ( $n=16$ ) and 12-month follow-up ( $n=11$ ), which limits the value of the findings in terms of effectiveness. There is some useful qualitative data obtained via focus groups, but this is not described in detail, and is presented as largely additional to the main statistical survey findings.	
Howey and Ormrod (2002) Study type: Pre post study Country of origin: UK Review domain: Effectiveness	<ol style="list-style-type: none"> <li>To evaluate the effectiveness of short-term primary care counselling for clients with specific psychological problems (including personality disorder) in the context of good overall functioning.</li> <li>To evaluate the prevalence of personality disorder amongst clients referred for counselling, and the impact of this on outcome.</li> </ol>	Two client groups completed pre and post scores on CORE and DIS(B). One group fulfilled criteria for personality disorder. No differences emerged between the groups in terms of the number of sessions of counselling received, nor in the amount of change made by the two groups. The two groups showed reduction on CORE scores below clinical cut-off levels. However, while nine of the personality disorder group showed reductions below the cut-off, five in this category continued to score above this cut-off. Conclusions: Clients likely to be referred for counselling will contain substantial numbers meeting criteria for Cluster B personality disorder (50% in this sample: 38/76). Short-term primary care counselling can provide limited, if measurable, benefits to some clients with personality disorder, a group not thought suitable in NHS guidelines (DH, 2001) for counselling as such. Person-centred counselling can be effective for clients meeting Cluster B personality disorder criteria in reducing scores below clinical cut-off for a proportion, and producing levels of client satisfaction with the counselling service provided.	The authors are making a case for person-centred counselling as being effective with a specialist group of clients, ie those with personality disorder. While these clients showed reduction in CORE scores, 5/14 clients with personality disorder remained above clinical cut-off. Also, while the counsellors were trained in person-centred counselling, there was no independent confirmation that they actually conformed to person-centred practice for the purposes of this study.	

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- \* Bower, P., Rowland, N. (2006) Effectiveness and cost effectiveness of counselling in primary care. N. Rowland, *Cochrane Database of Systematic Reviews*.
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Note:

Chisholm, D., Godfrey, E. et al. (2001) Chronic fatigue in general practice: economic evaluation of counselling versus cognitive-behaviour therapy. *British Journal of General Practice*. 51(462):15–18.

and

Ridsdale, L., Godfrey, E. et al. (2001) Chronic fatigue in general practice: is counselling as good as cognitive-behaviour therapy? A UK randomised trial. *British Journal of General Practice*. 51(462):19–24.

Originated from the same RCT, but as the aspects of the papers were very distinct – Ridsdale et al covered clinical effectiveness and Chisholm et al covered economic effectiveness – the two papers have been treated separately.

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## Appendices

### Appendix A: Databases and search strategies

#### *CINAHL (Ovid interface)*

1. counselling.sh.
2. psychotherapy.sh.
3. behaviour therapy.sh.
4. cognitive therapy.sh.
5. transactional analysis.sh.
6. validation therapy.sh.
7. psychotherapeutic processes.sh.
8. ("transference (psychology)" or "countertransference (Psychology)").sh.
9. psychotherapy\$.mp.
10. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
11. primary health care/
12. (clinical adj psycholog\$.mp.
13. primary care.mp.
14. Family Practice/
15. general practi\$.mp.
16. Physicians, Family/
17. family physician\$.mp.
18. 11 or 12 or 13 or 14 or 15 or 16 or 17
19. health behaviour/
20. nutrition education/
21. health education/
22. nicotine replacement therapy/
23. smoking cessation/
24. diet records/
25. blood glucose\$.sh.
26. glycemic control\$.sh.
27. mammography/
28. exp health promotion/
29. alcohol abuse/
30. incontinence\$.sh.
31. hiv infection\$.sh.
32. 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31
33. counsel\$.mp.
34. 32 and 33
35. 10 and 18
36. 35 not 34
37. limit 36 to (research and English and y=1996-2007 and (clinical trial or questionnaire/scale or research or research instrument or systematic review))

#### *Cochrane Library (all parts)*

1. exp counselling all trees
2. exp psychotherapy all trees
3. 1 or 2
4. exp primary health care all trees
5. exp Family Practice all trees
6. exp Physicians, Family all trees
7. 4 or 5 or 6
8. 3 and 7

#### *EMBASE (DataStar interface)*

1. psychotherap\$.ti
2. psychotherapy#.w.mj.
3. counsel\$.ti.
4. 1 or 2 or 3
5. primary adj care
6. primary-health-care#.de. or primary-medical-care.de.
7. (primary adj care).ti,ab
8. family adj practice
9. general-practice.de.
10. (family adj practi\$.ti,ab.
11. (general adj practi\$.ti,ab.
12. 5 or 6 or 7 or 8 or 9 or 10 or 11
13. 4 and 12
14. lg=en
15. 13 and 14
16. types-of-study#.de.
17. 15 and 16

#### *HMIC (Ovid interface)*

1. Counsellors/or general practice counsellors/
2. counselling services/ or counselling methods/ or bereavement counselling/ or systematic counselling/ or counselling/ or rational emotive counselling/
3. exp psychotherapy/
4. psychotherapy\$.mp.
5. counsel\$.mp.
6. exp primary care/
7. exp primary care groups/ or primary care trusts/
8. 7 or 8
9. 6 and 9
10. limit 9 to 1996–2007

### **MEDLINE (Ovid interface) (Search 1)**

1. Family Practice/
2. general practi\$.mp.
3. Physicians, Family/
4. Primary Health Care/
5. primary health care.mp.
6. (primary adj1 care).mp.
7. 1 or 2 or 3 or 4 or 5 or 6
8. counsel\$.mp.
9. psychotherapy\$.mp.
10. Counseling/
11. psychotherapy/ or behaviour therapy/ or biofeedback (psychology)/ or cognitive therapy/ or gestalt therapy/ or imagery (psychotherapy)/ or nondirective therapy/ or exp psychoanalytic therapy/ or psychotherapeutic processes/ or psychotherapy, brief/ or psychotherapy multiple/ or psychotherapy, rational-emotive/ or reality therapy/ or socioenvironmental therapy/
12. 8 or 9 or 10 or 11
13. 7 and 12
14. exp Research/
15. 13 and 14
16. limit 15 to English lang and yr=1996–2007

### **MEDLINE (Ovid interface) (Search 2)**

1. Family Practice/
2. general practi\$.mp.
3. Physicians, Family/
4. Primary Health Care/
5. primary health care.mp.
6. (primary adj1 care).mp.
7. 1 or 2 or 3 or 4 or 5 or 6
8. counsel\$.mp.
9. psychotherapy\$.mp.
10. Counseling/
11. psychotherapy/ or behaviour therapy/ or biofeedback (psychology)/ or cognitive therapy/ or gestalt therapy/ or imagery (psychotherapy)/ or nondirective therapy/ or exp psychoanalytic therapy/ or psychotherapeutic processes/ or psychotherapy, brief/ or psychotherapy multiple/ or psychotherapy, rational-emotive/ or reality therapy/ or socioenvironmental therapy/
12. 8 or 9 or 10 or 11
13. 7 and 12
14. limit 13 to (clinical trial or clinical trial, phase I or clinical trial, phase II or clinical trial, phase III or clinical trial, phase IV or controlled clinical trial or evaluation studies or meta analysis or randomized controlled trial or review or scientific integrity review or validation studies)
15. limit 14 to English lang and yr=1996–2007

### **PsycINFO (Ovid interface)**

1. exp psychotherapy/
2. psychotherapy\$.mp.
3. counselling.mp.
4. exp counselling/
5. exp Primary Health Care
6. primary health care.mp.
7. primary care.mp.
8. general practiti\$.mp.
9. general practi\$.mp
10. family medicine/
11. family practice.mp.
12. family physician\$.mp.
13. 1 or 2 or 3 or 4
14. 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
15. 13 and 14
16. smoking cessation/
17. tobacco smoking/
18. exercise/
19. health behaviour/
20. 16 or 17 or 18 or 19
21. counsel\$.mp.
22. psychotherapy\$.mp.
23. 21 or 22
24. 20 and 23
25. 15 not 24
26. limit 25 to English language and yr=1996–2007

### **Social Policy and Practice (Silverplatter interface)**

1. (psychotherap\*)
2. counsel\*
3. COUNSELLING in DE
4. 1 or 2 or 3
5. GP
6. general practice
7. primary health care
8. 5 or 6 or 7
9. 4 and 9

## Appendix B: Additional sources of evidence including grey literature

### Internet search

#### Google

“Counselling primary care”

“Counselling primary care evaluation”

#### National Research Register – ReFeR

“(counselling or psychother\*) and primary care”

#### Personal contact with experts in field

John Mellor-Clark  
Melanie Shepherd

#### Hand-search of journals (restricted to resources available at University of Salford)

Counselling and Psychotherapy Research: 2001–2007

Counselling Psychology Quarterly: 1999–2005

British Journal of Guidance and Counselling: 1996–2007

Journal of Counseling Psychology: 1999–2007

Psychotherapy Research: 1999–2007

Counseling Psychologist: 1996–2007

## Appendix C: Overview of studies meeting initial inclusion criteria

### Using the original definition of counselling, searches yielded:

Total papers 84

### The papers contained the following characteristics:

<i>Characteristic</i>	<i>Number of papers with the relevant characteristic</i>
UK studies	53
International	33
Generic therapy	11
Counselling	44
CBT	26
Psychodynamic	3
Problem solving therapy	3
IPT	6
Generic problems	32
Depression	34
Anxiety	13
Hypochondria	4
Chronic fatigue	3
RCT	42
Pre-post evaluation	14
Systematic reviews	10
Survey	13
Analyses of medical data	6

## Appendix D: Data extraction template

### Section A: Review details

- A.1 Name of reviewer
- A.2 Date review took place
  - A.2.1 Date

### Section B: Study details

*Note: to provide additional information click on answer to open text box*

#### B.1 Which domain(s) does the paper fit into?

*Select one or more categories*

- B.1.1 Efficacy
- B.1.2 Effectiveness
- B.1.3 Cost-effectiveness
- B.1.4 User perspectives

#### B.2 What type of study is this?

- B.2.1 Clinical trial

*Study which has a control/comparison group, along with an intervention group, and uses pre and post measures*

- B.2.2 Systematic review
- B.2.3 Service evaluation

*Clinical or cost-effectiveness of counselling measured using a variety of methods. Control/comparison group not used*

- B.2.4 Survey

*Preferences of patients gathered by questionnaire methods*

- B.2.5 Qualitative

#### B.3 What are the aims of the study?

- B.3.1 Specify the aims

#### B.4 In which country did the study take place?

- B.4.1 USA
- B.4.2 Canada
- B.4.3 UK
- B.4.4 Europe (non-UK)
- B.4.5 Australia
- B.4.6 Other (specify)

#### B.5 What type of intervention(s) is/are the main focus of the study?

*Select as many as applicable*

- B.5.1 Non-specific generic counselling
- B.5.2 Non-directive/supportive/person-centred counselling
- B.5.3 Psychodynamic counselling
- B.5.4 Integrative/eclectic/mixed-approach counselling
- B.5.5 CBT
- B.5.6 Other (specify)

#### B.6 How is the counselling delivered?

- B.6.1 Group
- B.6.2 Individual
- B.6.3 Not stated

#### B.7 How many sessions does the intervention consist of?

- B.7.1 1–5
- B.7.2 6–10
- B.7.3 11–15
- B.7.4 16–20
- B.7.5 > 20
- B.7.6 Other (specify)
- B.7.7 Not stated/not applicable

#### B.8 Over what period of time did the intervention take place?

- B.8.1 1–5 weeks
- B.8.2 6–10 weeks
- B.8.3 11–15 weeks
- B.8.4 16–20 weeks
- B.8.5 >20 weeks
- B.8.6 Other (specify)

#### B.9 What are the comparison/control conditions?

*Select one or more*

- B.9.1 Usual GP care/routine primary care
- B.9.2 Medication
- B.9.3 Usual GP care plus medication
- B.9.4 Waiting list
- B.9.5 Non-specific generic counselling
- B.9.6 Non-directive/supportive/person-centred counselling
- B.9.7 Psychodynamic counselling
- B.9.8 Integrative/eclectic/mixed-approach counselling
- B.9.9 CBT
- B.9.10 Other (specify)
- B.9.11 Not applicable

#### B.10 What is the target population?

- B.10.1 Adults
- B.10.2 Older people over 55 years
- B.10.3 Other (specify)

#### B.11 What is the target problem?

- B.11.1 Non-specific, generic psychological problems
- B.11.2 Depression
- B.11.3 Anxiety
- B.11.4 Personality disorder
- B.11.5 Postnatal depression
- B.11.6 Chronic fatigue
- B.11.7 Psychosomatic/medically unexplained symptoms
- B.11.8 Other (specify)
- B.11.9 Not applicable

#### B.12 What data collection methods were used?

*Select one or more*

- B.12.1 Therapist completed scale/test/questionnaire
- B.12.2 Client completed scale/test/questionnaire
- B.12.3 Researcher completed scale/test/questionnaire
- B.12.4 Survey questionnaire
- B.12.5 Interview
- B.12.6 Observational methods

- B.12.7 Case notes/service data/health records/referral letters
- B.12.8 Other (specify)

**B.13 What are the study's key findings?**

*Author(s) key findings plus reviewer's interpretations. Report any effect sizes*

- B.13.1 Key findings (specify)

**B.14 What are the implications of the findings for policy and practice?**

- B.14.1 Implications for policy and practice (specify)

**Section C: Quality assessment (all studies)**

*Note: to provide additional information click on answer to open text box*

**C.1 How was the sample selected?**

- C.1.1 Convenience
- C.1.2 Purposive
- C.1.3 Random
- C.1.4 Other (specify)
- C.1.5 Can't tell

**C.2 Was the method of sample selection appropriate?**

- C.2.1 Yes
- C.2.2 Partially
- C.2.3 No
- C.2.4 Can't tell

**C.3 Were all participants entering the study accounted for at its conclusion?**

- C.3.1 Yes
- C.3.2 Partially
- C.3.3 No
- C.3.4 Can't tell

**C.4 Was the sample size adequate to minimise the play of chance?**

*Consider – was there a power calculation?*

- C.4.1 Yes
- C.4.2 Partially
- C.4.3 No
- C.4.4 Can't tell

**C.5 Have researchers taken steps to minimise/account for bias?**

*Consider possibilities of observer bias, uncontrolled confounders*

- C.5.1 Yes
- C.5.2 Partially
- C.5.3 No
- C.5.4 Can't tell

**C.6 Are the findings reliable?**

*eg Is a confidence interval or p-value reported?*

- C.6.1 Yes
- C.6.2 Partially
- C.6.3 No
- C.6.4 Can't tell

**C.7 Are the conclusions justified?**

*Do findings support conclusions? Have assumptions been made in the drawing of conclusions?*

- C.7.1 Yes
- C.7.2 Partially
- C.7.3 No
- C.7.4 Can't tell

**C.8 Are the findings generalisable?**

*Consider sample selection. Does the intervention approximate routine practice? Is the setting naturalistic? Generalisable to which population/service setting?*

- C.8.1 Yes
- C.8.2 Partially
- C.8.3 No
- C.8.4 Can't tell

**C.9 Were ethical issues addressed appropriately?**

*Was ethics committee approval granted? Did participants give informed consent?*

- C.9.1 Yes
- C.9.2 Partially
- C.9.3 No
- C.9.4 Can't tell

**Section D: Quality assessment (trials only)**

*Only answer this section if the study is a clinical trial using comparison/control groups and measures are applied pre and post intervention*  
*Note: to provide additional information click on answer to open text box*

**D.1 Were participants appropriately allocated to intervention and control/comparison groups?**

*Consider whether a method of randomisation was used. Were the groups well balanced? Could differences between the groups at entry to the trial account for any outcomes?*

- D.1.1 Yes
- D.1.2 Partially
- D.1.3 No
- D.1.4 Can't tell

**D.2 Were reasonable attempts made to use 'blinding'?**

*Ideally participants, therapists and researchers should be blind to the condition received by participants. This is to avoid 'observer bias'. However, blinding is not always possible*

- D.2.1 Yes
- D.2.2 Partially
- D.2.3 No
- D.2.4 Can't tell

**D.3 Was the intervention delivered in a consistent and appropriate way?**

*For example, are there controls to ensure the intervention consistently follows a particular model of counselling? If more than one therapist delivers the intervention, are there controls to ensure consistency between therapists in how they deliver the therapy?*

- D.3.1 Yes
- D.3.2 Partially
- D.3.3 No
- D.3.4 Can't tell

#### D.4 What outcome measures were used?

Select as many as appropriate

- D.4.1 SCL-90
- D.4.2 HADS
- D.4.3 Beck (BAI)
- D.4.4 Beck (BDI)
- D.4.5 General Health Questionnaire
- D.4.6 SF-36
- D.4.7 Edinburgh PND
- D.4.8 Structured clinical interview (SCI)
- D.4.9 Other

Please specify

#### D.5 Were outcome measures appropriate and correctly administered?

Consider whether measures are widely used and well validated. Are they of sufficient breadth? Was there sufficient length of follow-up? Was there consistency in the collection of data from all groups in the study?

- D.5.1 Yes
- D.5.2 Partially
- D.5.3 No
- D.5.4 Can't tell

#### D.6 What is the length of follow-up?

How long after completion of the intervention were the measures applied?

- D.6.1 Immediately on completion of the intervention
- D.6.2 1–6 weeks after completing the intervention
- D.6.3 7–12 weeks after completion of the intervention
- D.6.4 3–6 months after completing the intervention
- D.6.5 7–12 months after completing the intervention
- D.6.6 13–18 months following completion of the intervention
- D.6.7 More than 18 months following intervention (specify)
- D.6.8 Other (specify)

### Section E: Quality assessment (systematic reviews only)

Only answer this section if the study is a systematic review.

Note: to provide additional information click on answer to open text box

#### E.1 Did reviewers try to identify all relevant studies?

Consider the range of bibliographic databases used; whether there was follow-up from reference lists; whether a 'grey' search was undertaken

- E.1.1 Yes
- E.1.2 Partially
- E.1.3 No
- E.1.4 Can't tell

#### E.2 Did reviewers assess the quality of the included studies?

Consider whether clear inclusion/exclusion criteria were applied; a data extraction template was used employing a scoring system; whether papers were assessed by more than one reviewer

- E.2.1 Yes
- E.2.2 Partially
- E.2.3 No
- E.2.4 Can't tell

#### E.3 If the results of the study have been combined, was it reasonable to do so?

Consider whether the results of each study are clearly displayed. Were the results similar from study to study (look for tests of heterogeneity)? Were reasons for any variations in results discussed?

- E.3.1 Yes
- E.3.2 Partially
- E.3.3 No
- E.3.4 Can't tell

### Section F: Quality assessment (service evaluations only)

Only answer this section if the study evaluates a counselling service using a specific outcome measure or measures

Note: to provide additional information click on answer to open text box

#### F.1 What outcome measures were used?

Select as many as appropriate

- F.1.1 CORE
- F.1.2 GHQ
- F.1.3 CESD
- F.1.4 SF-36
- F.1.5 CSQ
- F.1.6 VSQ
- F.1.7 General Wellbeing Index
- F.1.8 SCL-90R
- F.1.9 HADS
- F.1.10 EOL
- F.1.11 Problem-rating/goal-attainment scale
- F.1.12 DSSI
- F.1.13 Rosenberg self-esteem scale
- F.1.14 QOL
- F.1.15 DIS(BI)
- F.1.16 Other outcome measure [specify]

#### F.2 Were the measures used appropriate and correctly administered?

Consider whether measures were taken both pre and post intervention or post only. Are measures widely used and well validated? Are they of sufficient breadth? Was there sufficient length of follow-up?

- F.2.1 Yes
- F.2.2 Partially
- F.2.3 No
- F.2.4 Can't tell
- F.2.5 Not applicable

#### F.3 Are outcomes considered with reference to reliable benchmarks?

Consider whether national benchmarks for service usage/clinical effectiveness are used. Are benchmarks of clinical cut-off referred to?

- F.3.1 Yes
- F.3.2 Partially
- F.3.3 No
- F.3.4 Can't tell

### Section G: Qualitative studies (only)

Only answer this section if the study has a qualitative design.

Note: to provide additional information click on answer to open text box



**G.1 Were data collected in a way that addressed the research issue?**

*Consider whether the setting for data collection was justified. Was there a clear method of data collection?*

- G.1.1 Yes
- G.1.2 Partially
- G.1.3 No
- G.1.4 Can't tell

**G.2 Has the relationship between researcher and participants been adequately considered?**

*Consider whether researchers have critically examined their own role and the potential for bias. How did researchers respond to events? Were there changes made to the research design during the course of the study?*

- G.2.1 Yes
- G.2.2 Partially
- G.2.3 No
- G.2.4 Can't tell

**G.3 Was the data analysis sufficiently rigorous?**

*Consider whether the process of analysis is described in depth; if there are sufficient data to support the findings; whether contradictory data are taken into account; whether triangulation, respondent validation, more than one analyst have been employed; whether saturation of data is discussed*

- G.3.1 Yes
- G.3.2 Partially
- G.3.3 No
- G.3.4 Can't tell

**Section H: Quality rating (all studies)**

**H.1 Does the author discuss the limitations of the study?**

- H.1.1 Yes
- H.1.2 No
- H.1.3 Partially

**H.2 Summary evaluative comments**

*Include authors' and reviewers' evaluation of study limitations*

- H.2.1 Specify

**H.3 How would you rate the quality of this study?**

- H.3.1 ++

*All or most of the criteria have been fulfilled. Conclusions very reliable. Had unfulfilled criteria been fulfilled the conclusions of the study are thought very unlikely to alter*

- H.3.2 +

*Some of the criteria have been fulfilled. Conclusions quite reliable. Had unfulfilled criteria been fulfilled the conclusions of the study are thought very unlikely to alter*

- H.3.3 -

*Few of the criteria fulfilled. Conclusions not reliable. Had unfulfilled criteria been fulfilled the conclusions of the study would most likely have changed.*

**Appendix E: Glossary of abbreviations**

- BAI – Beck Anxiety Inventory
- BDI – Beck Depression Inventory
- CBT – Cognitive Behavioural Therapy
- CEA – Cost Effectiveness Analysis
- CEPMHPG – Centre for Economic Performance Mental Health Policy Group
- CESD – Center for Epidemiological Studies Depression Scale
- CI – Confidence Interval
- CNS – Central Nervous System
- CORE – Clinical Outcomes for Routine Evaluation
- CSQ – Customer Satisfaction Questionnaire
- DSSI – Delusions Symptoms State Inventory
- EM – Ethnic Minority
- EOL – End of Life
- GAS – Goal Attainment Scale
- GDS – Geriatric Depression Scale
- GHQ – General Health Questionnaire
- GP – General Practitioner
- HADS – Hospital Anxiety and Depression Scale
- ICER – Incremental Cost Effectiveness Ratios
- IPT – Interpersonal Therapy
- QALY – Quality Adjusted Life Year
- QOL – Quality of Life
- RCT – Randomised Controlled Trial
- SCL-90R – Symptom Checklist
- SD – Standard Deviation
- SF-36 – Short Form-36
- SMAST – Short Michigan Alcohol Screening Test
- VSQ – Visit Satisfaction Questionnaire
- WE – White European

*Counselling in primary care: a systematic review of the evidence* is published by the British Association for Counselling & Psychotherapy, BACP House, 15 St John's Business Park, Lutterworth, Leicestershire, LE17 4HB.

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BACP is the largest professional organisation for counselling and psychotherapy in the UK, is a company limited by guarantee 2175320 in England and Wales, and a registered charity, 298361.

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First published September 2008

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ISBN: 978-1-905114-28-3

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