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- treatment of those heterogeneous psychological problems typically presented in primary care populations.
- Q In the treatment of anxiety and depression (including postnatal depression), counselling is more effective than routine primary care.
- Q 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.
- Q 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.
- Q 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.
- Q Primary care patients prefer counselling to medication.
- Q The preference for counselling is unaffected by factors such as age, the presence of mental health problems, or problem severity.
- Q 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.
- Q Evidence indicates that patients prefer individual rather than group counselling.
- Q Patients are highly satis ed with the counselling they have received in primary care.

Implications for future research

- Q Future systematic reviews in this eld should combine methodological rigour with the inclusion of ef cacy and effectiveness research in order to produce evidence with high levels of both internal and external validity.
- Q Longitudinal pragmatic trials should be undertaken to produce more reliable evidence of counselling's long-term effects.
- Q 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.

- Q 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.
- Q There is an urgent need for rigorous cost-effectiveness studies in this eld 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.
- Q Studies of treatment preferences among UK ethnic minority users of primary care services are necessary, as relatively little is known in this area.
- Q As treatment preferences data has been mostly gathered fpicturr 1.575 0 Td [(Studies of rnar)18(ea.)]rnal aeg 0.8 cture of



Section 2: Methodology

Aim of the study

This review aims systematically to locate, appraise and synthesise evidence from scienti c 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 de nition of terms.

Counselling

Counselling is a broad and generic term which has been used over many years to describe a psychological therapy that is exible and centred on the patient's needs. As it encompasses many different approaches and techniques, arrival at a precise de nition 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 exibility 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 clari cation, de ning 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 de nition of terms. Counselling approaches broadly t within four main traditions, with an additional fth that seeks to integrate aspects of these four other traditions:

- Q Humanistic/experiential approaches tend to emphasise emotional expression and the development of a greater understanding and acceptance of affective, sensory and visceral experience.
- Q Psychodynamic approaches tend to focus on unconscious experience and areas of relational and developmental dif culty.
- Q Cognitive-behavioural approaches seek to identify and change patterns of thinking that lead to emotional and behavioural dif culties, while at the same time reinforcing positive behavioural change.
- Q 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.
- Q 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 speci c areas of dif culty 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 eld 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 de nition 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 Englishspeaking world, it must be acknowledged that variations in the systems of healthcare delivery across national boundaries make problematical a unitary de nition of primary care. Primary care is the rst 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 de nition 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 de ned 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 de ned 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 ef cacy in scienti c 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 bene ts, 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:

Ef cacy 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:

- Q MEDLINE (biomedical information)
- Q CINAHL (nursing and allied health)
- Q Cochrane Library (systematic reviews of interventions and randomised controlled trials)
- Q EMBASE (biomedical information)
- Q HMIC (Health Management Information)
- Q PsycINFO (psychological literature)
- Q 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 identi ed 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 nal 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 identi ed from the aims of the study and the initial scoping of the literature. These were discussed, re ned and agreed by members of the project team and BACP.

To be included in the review, studies had to:

- Q test interventions which fall within the BACP de nition of counselling; are delivered within speci c 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
- Q test interventions which take place within a primary care setting (GP surgery, medical centre, individual's home)
- Q be written in English
- Q 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:

- Q Ef cacy
 - Q RCTs
 - Q Systematic reviews of RCTs

- Q Effectiveness (practice-based evidence)
 - Q Systematic reviews of practice-based evidence
 - Q Studies of routine practice using pre and post outcome measures
- Q Economic issues
 - Q Cost-effectiveness of counselling
 - Q 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)
- Q User perspectives

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

Studies were excluded if they investigated:

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

- specialist services such as genetic counselling, couple counselling, family therapy
- Q hypnosis
- Q interventions provided by non-counsellors (eg nurses and general practitioners who have not trained in counselling/ psychotherapy)
- Q 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
- Q interventions in hospital settings
- Q interventions provided by secondary or tertiary services such as clinical psychology or psychiatry departments where the therapy takes place outside of primary care
- Q the diagnostic/referral behaviour of GPs
- Q training programmes for primary care counsellors
- Q the prevalence of psychological disorders.

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

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

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 re ne the scope of the review and exclude:

- Q studies if they had already been appraised within a relevant systematic review (Bowers and Rowland, 2006; Hemmings, 1999; Van Schaik, 2004)
- Q structured psychological interventions such as cognitivebehavioural 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 identi cation of 29 unique studies. Each study was independently critically appraised by one reviewer from of a team of ve, 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:

- Q ++ High quality. All or most of the criteria have been ful lled. Conclusions very reliable. Had unful lled criteria been ful lled, the conclusions of the study are thought very unlikely to alter. These studies were used to compile 'best evidence' within this review.
- Q + Good quality. Some of the criteria have been ful lled. Conclusions quite reliable. Had unful lled criteria been ful lled, the conclusions of the study are thought very unlikely to alter. These studies were used to compile 'supporting evidence' within this review.
- Q Poor quality. Few of criteria ful lled. Conclusions not reliable. Had unful lled criteria been ful lled, the conclusions of the study would most likely have changed. These studies were appraised but their ndings 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 dif cult 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 classi ed 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 ndings. 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: ef cacy, effectiveness, economic issues and user perspectives. Each section comprises an overview, a summary table of the studies included in this domain, the ndings relevant to each domain, together with a discussion of the methodological issues relevant to the studies within the domain. It is noteworthy that

Section 3: Ef cacy

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

Rationale

'Ef cacy may be de ned 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 con dently 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 speci c treatments on speci c disorders can be revealed.

Ef cacy 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 ef cacy. 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 ndings so that practice is both exible and guided by the best contemporary knowledge, in order to maximise health outcomes for patients.

In order to provide reliable evidence of ef cacy 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 speci city 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 speci c disorder and at a speci c 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 ef cacy 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 con dence with which the ndings 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.

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Table 1: Overview of studies addressing the ef cacy 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-speci c generic counselling	Usual GP care	Depression Anxiety	+	
Bower P, Rowland N (2006)	Systematic review	UK	Non-speci c 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-speci c, generic psychological problems Depression Anxiety	++	
Hemmings A (1999)	Systematic review	UK International studies included	Non-speci c generic counselling Non-directive/supportive/person-centred counselling Integrative/eclectic/mixed-approach counselling Non-speci c, generic Usual Grandout in expectations			URidsdale L, (Godfesy]TJ
			primarily expression Mdica floories by us medication Psychodsoatic	UK (linical)Tj T -1.2∕dī⊡≰á≝ counsell	ந்நூலychodynamic ingCBT		
			20064)Tj 11.213 1.2	Td (Clinical)Tj T* (trial)Tj 6.	024 1.2 Td (UHoland T	j 6.732 0 Td (Non-dir)18(6

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 ef cacy of counselling in primary care. Bower and Rowland (2006) undertook a review for the Cochrane Collaboration that aimed to assess the ef cacy 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 con dence intervals (CIs). Authors found counselling to be more effective than usual GP care in the short term. The results and ndings 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 ndings from more naturalistic practice-based evidence. The inclusion criteria for the review are not clear. However, it appears that a much broader de nition 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

-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 signi cant 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 signi cant differences in outcomes were discerned between CBT and counselling, but individual counselling yielded the best outcome in terms of depression (by three to ve 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 signi cantly 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 signi cant difference in effect was found between CBT and counselling, although a nonsigni cant 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 signi cant 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-speci c psychological problems as the focus of investigation, whereas a further ve studies address more speci c psychological disorders (Milgrom et al, 2005; Murray et al, 2003; Kolk et al, 2004; Ridsdale et al, 2001).

Non-speci c psychological problems

Two systematic reviews (Bower and Rowland, 2006; Hemmings, 1999) address the effects of counselling with non-speci c psychological problems. By de nition, primary care is normally the rst 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 speci c disorder but with an identi ed 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-speci c psychological problems experienced by this heterogeneous population,

their review found that counselling is more effective than usual care in the short term. These ndings are supported by Hemmings (1999) whose systematic review similarly includes clinically heterogeneous samples of patients with non-speci c 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 ndings 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 signi cant change as compared with 61 per cent in the intervention group. They also found clinically but not statistically signi cant 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 signi cant change. However, the sample size was too small to draw de nitive 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 signi cant reduction in symptoms and that the bene ts 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 bene ts 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 ve years, just four per cent more in treatment groups remitted compared with controls. Hence, after 4.5 months postpartum, treatments were not signi cantly different from the control condition in reducing symptoms of postnatal

With regard to other variables immediately post treatment, all three conditions had a signi cant bene t on maternal reports of early dif culties in relationships with the infants. The interventions had no signi cant impact on maternal management of early infant behaviour problems, security of infant-mother attachment, infant cognitive development or any child outcome at ve years. The study concludes that counselling was bene cial 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 nding 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 signi cant 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-signi cant trend in favour of counselling was discerned, there were no signi cant 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 bene cial 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 ndings were reliable enough for inclusion. Just eight studies were then subjected to a meta-analysis, producing pooled effect-sizes. The ndings produced by such a rigorous review method can be regarded as the highest level of evidence with regard to ef cacy. The strict inclusion criteria also render the ndings relevant to counsellors and counselling services as de ned 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 de nition 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 indings 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 ndings of pragmatic trials are obviously more generalisable to routine practice than those of explanatory trials, they are less able con dently 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 speci c 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 exible 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 triallists 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, dif culty 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 ve-year follow-up: 193 participants were randomised to groups pre treatment and a total of 138 completed measures at ve 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 ve. 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 dif cult 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

Section 4: Effectiveness

Rationale

As discussed in the last section, the dif culties 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 ndings 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 ef cacy and effectiveness research are

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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-speci c, 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 personcentred counselling, and in another (Booth et al, 1997), it is described as humanistic, eclectic and psychodynamic. All studies have non-speci c, generic psychological problems as the target of the intervention, although depression and anxiety are also speci ed in three studies (Baker et al, 2002; Gordon and Graham, 1996; Hemmings, 1999). Hemmings' (1999) wide-ranging review also includesostnatal 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 brie y described, together with 26 reports of grey literature. As noted in the ef cacy section, this review is presented in the form of tables and a narrative, making it dif cult 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 ve reported clinically meaningful improvements, suggesting that the intervention was effective. Similar ndings are reported by Evans et al (2003) who, in a very large multicentre sample (n=6610), found that four out of ve patients achieved reliable and clinically signi cant improvement post treatment. These ndings are supported by Hemmings (1999) whose systematic review summarised the ndings 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

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

Table 4: Overview of studies covering economic issues

advantage was found for either form oftherapy. 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 bene ts, counselling produces economic bene ts 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 ndings revealed a statistically signi cant 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 ndings 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 nding 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 signi cance 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 suf cient, a signi cant 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 signi cant difference in referral data, and only in one year: GPs with counsellors referred more to the community mental health team (no gures 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 signi cant difference. Incremental cost-effectiveness ratios for healthcare and treatment, patient and family burden, and the combination of the two revealed no statistically signi cant differences between the two groups. A comparison of change scores between baseline and six-month follow-up revealed no statistically signi cant 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 ndings 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.

concealment. However, dif culty 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

Section 6: User perspectives

Rationale

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

- Q In addition to an intervention's clinical effectiveness, it is important to evaluate how acceptable the treatment will be to potential users (Hill and Brettle, 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.
- Q 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.
- Q 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.
- Q 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.
- Q 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.
- Q 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;

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

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 signi cant 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 nding is supported by Van

outcomes. Authors noted that in two partially randomised

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 signi cant 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 nding 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 nding is based, has been indicated. Ef cacy (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

- Q Ef cacy research indicates that in terms of mental health outcomes counselling is more effective than routine primary care in the short term.
 - Bower and Rowland, 2006(++); Hemmings, 1999(+); Murray, 2003(+); Ridsdale et al, 2001(++); Bellamy and Adams, 2000(+)
- Q 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 signi cant improvements.
 - b Evans et al, 2003(++); Gordon and Graham, 1996(+);

b

- 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

- Q 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(+)
- Q 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(+)
- Q 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(++)
- Q There is evidence which indicates that patients prefer individual rather than group counselling.
 - Arean et al, 2002(++); Wetherell et al, 2004(+)
- Q Patients are highly satis ed 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 eld to combine methodological rigour with the inclusion of more diverse types of evidence. This would allow reviews to synthesise both ef cacy and effectiveness research in order to produce evidence with high levels of both internal and external validity. Longditudinal

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. Triallists 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 ndings based on its use. This would have the effect of standardising service

Section 8: Evidence tables

of the state of th	C. John C. St. Co.	Best evidence (++)	
Arean et al (2002) Study type: Survey Country of origin: USA Review domain: User perspectives	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.	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 signi cantly 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.	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-walidated 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 justi able conclusions.
Baker et al (2002) Study type: Pre post study Country of origin: UK Review domain: Effectiveness	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.	The study found highly signi cant 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 signi cantly less for the waiting list group. Self-esteem scores also signi cantly 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 signi cant improvement. The combination of these two treatments, particularly for those with depression, was associated with the most signi cant positive outcomes for clients.	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 externa 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 in uenced outcomes. This is a well-conducted service evaluation with ndings generalisable to UK primary care populations. The lack of controls typical of this type of study should prompt some caution in interpreting the results.
Bower and Rowland (2006) Study type: Systematic review Country of origin: UK Review domain: Ef cacy, Economic issues, User perspectives Also reported in: Bower et al (2002) Bower, Byford et al (2003) Bower, Rowland et al (2001) Rowland et al (2001)	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.	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 satis ed 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	

	Summary evaluative comments	
		tively It three ling in nts time or ssants. ces ns4 of lifetime or
		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. A small percentage (4%) preferred no treatment at all. Participants who preferred psychotherapy had signi cantly lower rates of lifetime or recent depression treatment than those who preferred antidepressants. The second paper (Gum et al, 2006) reports treatment preferences in a subgroup (n=1602) of the original sample (n=1801) m 0 0 ms4 of lifetime or
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Best e		This large survey of patient preferences (n=1801) formed a rela 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 antidepressar medications (38%). 8% had received such treatment in the past months, and only 1% reported four or more sessions of counself the prior three months. A small percentage (4%) preferred no treatment at all. Participal who preferred psychotherapy had signi cantly lower rates of lifet recent depression treatment than those who preferred antidepre. The second paper (Gum et al, 2006) reports treatment preferen in a subgroup (n=1602) of the original sample (n=1801) m 0 0 m.
		nd predictors tt depression le of 1,801 mary care g in an RCT. s which predict opulation, to attients receive and to identify eferences.
		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. To investigate factors which predict depression in this population, to evaluate whether patients receive adequate treatment and to identify patient treatment preferences.
		Study type: Survey of treatment preferences conducted as part of a clinical trial country of origin: USA Review domain: User Also reported in Gum et al (2006) To examine rates and predictors of lifetime and recent depression treatment and to identify adequate treatment preferences.

Summary evaluative comments		
Supporting evidence (+) Findings and conclusions		
Study details What are the aims of the study?	Bellamy and Adams (2000) Study type: Clinical trial using waiting list control group	

	+	
Summary evaluative comments	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 signi cant 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 po8mrt,9 adulwas conducted in the Authors sugge(1996) Authors sugge(1996) Review domain: User	
Supporting evidence (+) Findings and conclusions	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 nd antidepressant medication acceptable. Hispanics are more likely to nd counselling acceptable than White persons. 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.	
What are the aims of the study?	To examine whether racial and ethnic differences exist in patients' attitudes towards depression care.	
Study details	Cooper et al (2003) Study type: Survey Country of origin: USA Review domain: User perspectives	

Summary evaluative comments	In many respects, this is a well-conducted study. A wide range of well-validated measures are used along with randomisation and concealment. However, dif culty 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 in uenced 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 speci city limits what conclusions can be drawn about the effects of particular therapies.	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 suf cient 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	
Supporting evidence (+) Findings and conclusions	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.	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 BAI). 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 signi cant differences in outcomes were discerned between CBT and counselling. Individual counselling yielded the best outcome in terms of depression (by three to ve points on the BDI). Authors concluded that psychological interventions for women with PND can lead to clinically signi cant reduction in symptoms. Counselling was as effective as CBT. The bene ts may be maximised by offering psychological interventions on a one-to-one basis.	
What are the aims of the study?	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.	To establish the ef cacy 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.	
Study details	Kolk et al (2004) Study type: Clinical trial Country of origin: Holland Review domain: Ef cacy, Cost- effectiveness	Milgrom et al (2005) Study type: Clinical trial Country of origin: Australia Review domain: Ef cacy	

		Supporting evidence (+)	
Study details			
Wetherell et al (2004) Study type: Survey Country of origin: USA Review domain: User perspectives	Wetherell et al (2004) Study type: Survey Country of origin: USA Review domain: User perspectives	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 (n=77) and younger (n=312) primary care patients. The study found that older adults (n=312) primary care patients. The study found that older adults (n=312) primary care patients. The study found that older adults (n=312) primary care patients. The study found that older adults (n=312) primary care patients. The study found that older adults (n=312) primary care patients. The study found that on expension and on low a history of, or current participation in, mental health treatment. Older adults were less likely than younger (<60 years) were predominantly male, Caucasian and on low 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 participants of all ages reported a stronger participants preference for medications was just 11% and younger adults of posthodynamic 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 to group treatment (older adults preferring of age-differential treatment preferences is important in order to design interventions that optimise utilisation among both younger and on low a battery of group were predominantly male, Caucasian and on low and entered for bodynamic or supportive care populations. The older patients and adults preferred individual therapy to group treatment (older adults prefe	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 signi cant comparisons to P (.Ps, ns to PnDcttions. The older patients ry t 0.1 S Q = 72%). Authors & Confidentify as to whethet 18 (omnoemtasu an un11)1 dual(h = 72%); tory a(1998s-1.(ee ful 55.36 ell etmina oniogy T* tween)]TJ T*

		Poor-quality evidence (–) (Not used in compiling the ndings of this review)	
Study details			Summary evaluative comments
Cape and Parham A (1998) Study type: Pre post study Country of origin: UK Review domain: Costeffectiveness	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 ndings. 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 of ce staff. These related to issues of con dentiality; 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 ndings 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 ndings.
Howey and Ormrod (2002) Study type: Pre post study Country of origin: UK Review domain: Effectiveness	1. To evaluate the effectiveness of shorterm primary care counselling for clients with speci c psychological problems (including personality disorder) in the context of good overall functioning. 2. To evaluate the prevalence of personality disorder amongst clients referred for counselling, and the impact of this on outcome.	Two client groups completed pre and post scores on CORE and DIS(BI). One group ful lled 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. Conclusions: Conclusions: Cients 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, bene ts 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 con rmation that they actually conformed to person-centred practice for the purposes of this study.

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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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Hoagwood, K., Hibbs, E., Brent, D., Jensen, P. (1995) Introduction to special section: ef cacy and effectiveness studies of child and adolescent psychotherapy. Journal of Consulting and Clinical Psychology. 63:683–687.

Keithley, J., Marsh, G. (1995) Counselling in primary health care. Oxford: Oxford University Press.

Kendrick, T., Sibbald, B., Addington Hall, J., Brenneman, D., Freeling, P. (1993) Distribution of mental health professionals working on site in English and Welsh general practices. British Medical Journal. 307(6903):544–6.

Keany Merihord http://www.ise.facturlia/www.landermis_edune (28)87. 2100) Counselling in th[(woplac8(e controlled trial of non-directive counselling, cognitive ournalash anusuriah general practitioner careations was eons mixeld xietash andep Preatic

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.

11 or 12 or 13 or 14 or 15 or 16 or 17

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 eld

John Mellor-Clark Melanie Shepherd

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

Counselling and Psycotherapy 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 de nition of counselling, searches yielded:

Total papers 8

The papers contained the following characteristics:

Characteristic	Number of papers with the relevant characteristic
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 t into?

Select one or more categories

B.1.1 Ef cacy

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

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

B.13 What are the study's key ndings?

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

- B.13.1 Key ndings (specify)
- B.14 What are the implications of the indings 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 ndings reliable?

eg Is a con dence 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 justi ed?

Do indings 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 ndings 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

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

Consider whether the setting for data collection was justi ed. 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 suf ciently rigorous?

Consider whether the process of analysis is described in depth; if there are suf cient data to support the ndings; 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 ful lled. Conclusions very reliable. Had unful lled criteria been ful lled the conclusions of the study are thought very unlikely to alter

H.3.2 -

Some of the criteria have been ful lled. Conclusions quite reliable. Had unful lled criteria been ful lled the conclusions of the study are thought very unlikely to alter

H.3.3

Few of the criteria ful lled. Conclusions not reliable. Had un I lled criteria been ful lled 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 - Con dence 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 Screeening Test

VSQ - Visit Satisfaction Questionnaire

WE – White European

