Collaborative care for depression and anxiety problems in primary care (Protocol)

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TABLE OF CONTENTS

[Intervention Protocol]

Collaborative care for depression and anxiety problems in primary care

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

This review aims to evaluate the clinical effectiveness of collaborative care for depression and anxiety in primary care settings.

BACKGROUND

Common mental health problems

Common mental health problems, such as depression and anxiety, are highly prevalent. Depression affects about 121 million people worldwide, and an estimated 5.8% of men and 9.5% of women will experience a depressive episode in any given year (WHO 2001a).

Depression and anxiety are a major cause of disease burden and disability (Ustun 2004) with depression projected to become the second most common cause of loss of disability-adjusted life years in the world by 2020 (World Bank 1993). The impact on social and occupational functioning, physical health and mortality is also substantial (Ormel 1999), and often anxiety and depression present together, disabling the person further (APA 1994). Depression also accounts for two-thirds of all suicides (Sartorius 2001).

Depression and anxiety are often chronic in nature, characterised by high instances of relapse and reoccurrence. Following their first episode of depression, at least 50% of people will go on to have one or more further episodes, with the risk of relapse increasing to 70% after the second episode, and as high as 90% after a third episode (Kupfer 1991). Therefore, common mental health problems have recently been likened to other chronic illnesses such as asthma and diabetes.

Current management in primary care

It is estimated that 90-95% of patients with depression and anxiety are treated solely in primary care (NICE 2004). However, the management of these disorders is often suboptimal (NHS 2002). Medication for depression and anxiety is often prescribed by primary care practitioners in non-therapeutic doses and patients do not take the medication for a variety of reasons including fears of addiction and dependency and side-effects. Care for patients with chronic problems is often not proactive, and patients do not receive ongoing monitoring and care designed to reduce the burden of disorder and the likelihood of recurrence and relapse.

It has been recognized that improving the care of common mental health problems is a very complex task, which requires changes to the way care is provided, together with additional resources to develop the appropriate systems to enable primary care professionals to deliver high quality care (Katon 2001,Katon 1997, Gilbody 2003a). Bower and Gilbody (Bower 2005) have identified four distinct models of quality improvement in common mental health problems: training primary care staff, consultation-liaison, replacement/referral and collaborative care.

Collaborative care

Collaborative care models are exemplars of 'complex interventions', which 'comprise a number of separate elements which seem essential to the proper functioning of the intervention, although the active ingredient of the intervention that is effective is difficult to specify' (Medical 2000). The collaborative care model is based on the principles of chronic disease management and can involve a large number of different interventions including: screening, education of patients, changes in practice routines, and developments in information technology (Wagner 1996).

Research has suggested that a key ingredient of effective collaborative care is 'case management' (Gilbody 2003a). Case management has been described as a health worker in primary care taking responsibility for proactively following up patients, assessing patient adherence to psychological and pharmacological treatments, monitoring patient progress, taking action when treatment is unsuccessful and delivering psychological support (Von Korff 2001). Case managers work closely with the primary care practitioner (who retain overall clinical responsibility) and receive regular supervision from a mental health specialist (Katon 2001, Gilbody 2003a).

The collaborative care model is of increasing interest in the development of primary care mental services, and a significant number of studies have been published recently. Therefore, a high quality, up to date review is indicated.

OBJECTIVES

This review aims to evaluate the clinical effectiveness of collaborative care for depression and anxiety in primary care settings.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials involving patients with common mental health problems

It is envisaged that in some studies the intervention will be compared to usual care (i.e. patients already recognised and treated in primary care), and in other studies patients will be identified by screening (and the comparison group will be largely untreated). This important distinction will be examined in the analyses.

The review will be restricted to studies conducted in primary care. Although the definition of primary care is complex, for the purposes of the current review it is characterised as medical care involving first contact and on-going care to patients, regardless of the patient's age, gender or presenting problem (Boerma 1999, WHO 2001b).

Types of participants

Trial participants will be either male or female patients of all ages. The participants will have a primary diagnosis of anxiety and/or

depression according to Research Diagnostic Criteria (RDC), Diagnostic and Statistical Manual (DSM) (APA 1994) or International Classification Disorder (ICD) (WHO 1992) criteria, or will have been assessed for significant symptoms through self-rated or clinician-rated validated instruments e.g. Beck Depression Inventory (BDI) (Beck 1987) or Beck Anxiety Inventory (BAI) (Beck 1988).

Types of interventions

The term 'collaborative care' captures a range of interventions of varying intensity, ranging from simple telephone interventions to encourage compliance with medication, through to more complex interventions that involve intensive follow up, and which incorporate a form of structured psychosocial intervention.

The term collaborative care was first used by Katon (Katon 1995) to describe an intervention which was delivered by the patient's GP and a psychiatrist. However, there have been significant developments in the model since that time, and thus clear specification of the meaning of the term in line with current thinking is important.

For the purposes of this review, collaborative care is defined as a multifaceted intervention which involves 3 distinct professionals working collaboratively within the primary care setting. One professional works as a case manager, one as a primary care practitioner and the other as the mental health specialist (Katon 2001). The specific roles each of these professionals are detailed below:

- Primary care practitioner: will provide the initial recognition, diagnosis and treatment.
- Case manager: will provide medication management and psychological intervention, proactively follow-up patients, assess adherence to treatment and monitor progress and feedback to the primary care physician.
- Mental health specialist: will provide support/consultation to either the case manager or the primary care physician. This role maybe played by others other than a medically qualified professional i.e. nurse specialists (Gask 2005).

Collaborative care will be compared against 'usual care', a control group or alternative intervention (i.e. psychological therapy, consultation-liaison).

Types of outcome measures

Primary outcome

The primary outcomes of interest will be level of depression and/or anxiety, as measured by a validated interview-based or self-report outcome measure.

Secondary outcomes

Secondary outcomes of interest will be:

1. Medication use and adherence, including guideline adherence

The following outcomes will be included only when a validated tool has been used:

2. Social functioning e.g. Social Adaptation Self-evaluation Scale (SASS)(Bosc 1997)
3. Quality of life e.g. Short Form Health Survey (SF-36,SF-12) (Ware 1993)
4. Patient satisfaction e.g. Client Satisfaction Questionnaire (CSQ)(Attkinson 2003).

Outcomes will be categorised as short term (0-6 months), medium term (7-12 months) long term (13-24 months) and very long term (25 months or more).

Search methods for identification of studies

1. Electronic searches

Electronic searches will be conducted using the Cochrane Collaboration Depression Anxiety and Neurosis group trials and reference databases (CCDANCTR-Studies and CCDANCTR-References). These registers are updated regularly adding the results on searches of The Cochrane Library, CINAHL, EMBASE, LILACS, MEDLINE, National Research Register, PSYCLIT, PSYCINFO, PSYNDEX and SIGLE. Also, quarterly systematic screening of relevant journals and conference proceedings takes place (for information on the full search strategies, visit http://web1.iop.kcl.ac.uk/IoP/ccdan/index.htm.)

i) CCDANCTR-Studies

Diagnosis = Depress* or Dysthymi* or "Adjustment Disorder*" or "Mood Disorder*" or "Affective Disorder" or "Affective Symptoms" or Anxiety or Anxious or Panic or Phobi* or Obsess* or Post-traumatic*

and

Setting "General Practice" or "Primary Care" or "Community Mental Health" or "Family Practice" or "Health Maintenance Organization" or HMO or Home or "University Clinic" or Private or Ambulatory

and

Intervention = Enhanced or "Stepped Care" or Collaborat* or Education or Manage* or Multicomponent or Prevent* or "Quality Improvement" or Physician or Nurs* or pharmaci* or Pharmacy or Algorithm or Guideline* or PsychoEducation or Informat* or "Disease Manage*" or reminder or feedback or Consult* or adheren*

ii) CCDANCTR-References

Keyword = Depress* or Dysthymi* or "Adjustment Disorder*" or "Mood Disorder*" or #45= "Affective Disorder" or "Affective Symptoms" or Anxiety or Anxious or Panic or Phobi* or Obsess* or Post-traumatc*

AND

Free-Text = "General Pract*" or "Primary Care" or "Primary Health Care" or "Community Mental Health" or "Family Practice" or "Health Maintenance Organization" or HMO or Home or "University Clinic" or Private

and

Free-Text = Enhanced or "Stepped Care" or Collaborat* or Education or Manage* or Multicomponent or Prevent* or "Quality Improvement" or Physician or Nurse or Algorithm or Guideline*

2. Reference lists

Reference lists will be searched and citation searches conducted on all identified studies.

3. Personal communication

We will contact first authors of all identified studies and other experts in this area to find information about unpublished or ongoing studies.

Data collection and analysis

Selection of studies

Studies identified will be scanned independently by two review authors (JF and one other review author from the team) who will exclude the studies according to the criteria above, on the basis of titles and abstracts. Full copies of the studies deemed eligible by one of the review authors will be retrieved for closer examination. If there is uncertainty or disagreement, consensus will be reached by discussion and consultation with a third review author. A log of all studies which initially appear to meet the inclusion criteria but are excluded on retrieval of the full text will be detailed in a table of excluded studies. A record will be kept of the reasons for exclusion.

Data extraction

Data will be extracted using standardised proforma relating to the following issues:

i) The nature of the intervention (e.g. types of interventions used, amount of contact between patient and professional, and amount of collaboration between professionals)

ii) The patient population (demographic and clinical characteristics)

iii) Internal validity (concealment of allocation, blinding, sample size and power calculations, attrition, statistical analyses)

iv) External validity (context of recruitment, methods of recruitment, proportion of eligible patients included in the trial).

Where crucial information is ambiguous or missing, attempts will be made to contact the author(s) of the study. If outcome data are missing, attempts will be made to contact authors. If no contact is possible and the required data are unavailable, we will exclude the study from the main review although the results will be described qualitatively.

Quality assessment

The quality of included studies will be assessed using the Quality Rating Scale (QRS) (Moncrieff 2001) (available at: http://web1.iop.kcl.ac.uk). Using the QRS, data on a number of quality criteria will be extracted, including:

- Objectives and specification main outcomes a priori
- Sample size
- Planned duration of trial including follow up
- Power calculation
- Method of allocation
- Concealment of allocation
- Clear description of treatment
- Blinding of subjects
- Sample recruitment
- Use of diagnostic criteria
- Record of exclusion criteria and number of exclusions and refusals reported
- Description of sample demographics
- Blinding of assessor
- Record of number and reasons for withdrawal by group
- Outcome measures described clearly or use of validated instruments
- Information on comparability and adjustment for differences in analysis
- Inclusion of withdrawals in analysis
- Presentation of results with inclusion of data for re-analysis of main outcomes
- Appropriate statistical analysis
- Conclusions justified
- Declaration of interests

Each study will then be awarded a score ranging from 0 to 2 for each of the criteria measured (the higher the score the better the quality of data), depending on the quality of the data provided. Data will be extracted by one review author (JF) and independently checked by a second review author. Uncertainty or disagreement will be solved by discussion with PB or SG.

Choice of methods for pooling data

Meta analysis will be conducted if the studies included in the review are of relatively high quality, contain sufficient information on the key issues and the studies report similar outcomes such as improvement in anxiety/depression symptomology. Separate meta-analysis will be conducted for studies interested in improving anxiety and studies improving depression symptom levels.

This review will report both discrete (e.g. recovered/not recovered) and continuous outcomes. For categorical outcomes, such as recovered/not recovered, we will calculate risk ratios (Relative Risk - RR). For continuous outcomes, such as patient scores on self-report outcome measures, we will calculate weighted mean differences (WMD) where there is a common metric between studies, and standardised mean differences (SMD) if different scales are used to measure the same underlying construct. Initially a fixed effects model will be used, assuming that the underlying true treatment effect in each trial is the same and that the observed differences are due to chance.

Assessment of heterogeneity

We will formally test for heterogeneity using the I^2 statistic, which estimates the percentage of total variation across studies that can be attributed to heterogeneity rather than chance. If a moderate

to high (50% or more) level of heterogeneity is found (Higgins 2003), the random effects model will be applied (Sutton 1998). The random effects model assumes the true treatment effect in different trials is randomly placed around some central value (Thompson 1991) and incorporates the within and between-study variation into the calculation (DerSimonian 1986) generating a wider confidence interval and allowing for an appropriate degree of statistical caution.

Unit of analysis issues

It has been identified that 'unit of analysis' errors are common in the evaluation of collaborative care (Gilbody 2003a), which may make studies more susceptible to Type I errors. Studies using cluster randomisation will be identified and where necessary the precision of these studies will be adjusted in the meta-analysis using a sample size/variation inflation method recommended by the EPOC group of the Cochrane Collaboration (Anderson 2005) and assuming an intra-class correlation of 0.02 in line with published estimates (Adams 2004). The effects of adjustment for clustering will be examined in a sensitivity analysis using intra-class correlations of 0.00 and 0.05 (Donner 2002). It has been identified that 'unit of analysis' errors are common in the evaluation of collaborative care (Gilbody 2003a), which may make studies more susceptible to Type I errors. Studies using cluster randomisation will be identified and where necessary the precision of these studies will be adjusted in the meta-analysis using a sample size/variation inflation method recommended by the EPOC group of the Cochrane Collaboration (Higgins 2006) and assuming an intra-class correlation of 0.02 in line with published estimates (Adams 2004). The effects of adjustment for clustering will be examined in a sensitivity analysis using intra-class correlations of 0.00 and 0.05 (Donner 2002).

Subgroup analyses and investigation of heterogeneity

If significant heterogeneity exists, the effects of trial characteristics which could have influenced heterogeneity will be examined. This may include the complexity of the intervention (such as the number of sessions planned duration of sessions, content of intervention, case manager liaison with primary care physician, case manager liaison with mental health specialist. background of case manager, training and education of case manager), the age of the trial participants (adolescents, adults and older patients), baseline severity and method of patient recruitment (screening or identified by GP).

We will undertake a series of exploratory analyses using meta-regression, to examine the influence of these and other individual study-level factors in predicting the magnitude and direction of outcomes (Thompson 2002). We will assess the significance of predictive factors (selected a priori and outlined above) in explaining between study heterogeneity, as measured by the I^2 statistic, according to a method proposed by Higgins 2004.

Sensitivity analysis

Sensitivity analyses provide an approach for testing how robust the results of a review are relative to key decisions and assumptions that have been made in the process of conducting the review. Sensitivity analyses will be carried out to measure the impact of including and excluding lower quality studies (as measured by allocation concealment and the QRS).

Assessment of reporting biases

Psychiatric research is especially prone to publication bias (Gilbody 2003b), and we will investigate publication bias through the use of 'funnel plots' where feasible (Egger 1997).

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* *Indicates the major publication for the study*

WHAT'S NEW

Last assessed as up-to-date: 18 January 2007.

29 October 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 2, 2007

19 January 2007	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

JF led the writing of the protocol

PB supervised and commented on each draft of the protocol

SG supervised and commented on each draft of the protocol

DR signed up to final protocol and assistance with the review

LG signed up to final protocol and assistance with the review

KL supervised and commented on each draft of the protocol

DECLARATIONS OF INTEREST

The authors have been involved in the conduct of a trial of collaborative care in the UK funded by the UK Medical Research Council, but have no financial or other conflicts of interest in the results of the present review or the outcomes of this trial.

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