

Executive summary

Randomised controlled trial of non-directive counselling, cognitive-behaviour therapy and usual general practitioner care in the management of depression as well as mixed anxiety and depression in primary care

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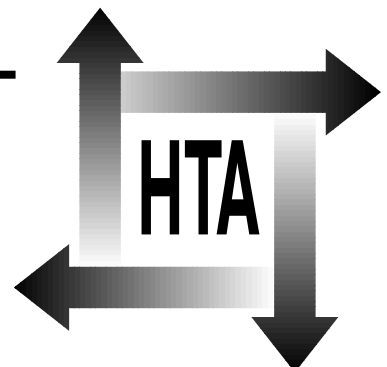
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**Health Technology Assessment
NHS R&D HTA Programme**





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Objectives

The aim of this study was to determine both the clinical and cost-effectiveness of usual general practitioner (GP) care compared with two types of brief psychological therapy (non-directive counselling and cognitive-behaviour therapy) in the management of depression as well as mixed anxiety and depression in the primary care setting.

Design

The design was principally a pragmatic randomised controlled trial, but was accompanied by two additional allocation methods allowing patient preference: the option of a specific choice of treatment (preference allocation) and the option to be randomised between the psychological therapies only. Of the 464 patients allocated to the three treatments, 197 were randomised between the three treatments, 137 chose a specific treatment, and 130 were randomised between the psychological therapies only. The patients underwent follow-up assessments at 4 and 12 months.

Setting

The study was conducted in 24 general practices in Greater Manchester and London.

Subjects

A total of 464 eligible patients, aged 18 years and over, were referred by 73 GPs and allocated to one of the psychological therapies or usual GP care for depressive symptoms.

Interventions

The interventions consisted of brief psychological therapy (12 sessions maximum) or usual GP care.

- Non-directive counselling was provided by counsellors who were qualified for accreditation by the British Association for Counselling.

- Cognitive-behaviour therapy was provided by clinical psychologists who were qualified for accreditation by the British Association for Behavioural and Cognitive Psychotherapies.
- Usual GP care included discussions with patients and the prescription of medication, but GPs were asked to refrain from referring patients for psychological intervention for at least 4 months.

Most therapy sessions took place on a weekly basis in the general practices. By the 12-month follow-up, GP care in some cases did include referral to mental healthcare specialists.

Main outcome measures

The clinical outcomes included depressive symptoms, general psychiatric symptoms, social function and patient satisfaction. The economic outcomes included direct and indirect costs and quality of life. Assessments were carried out at baseline during face-to-face interviews as well as at 4 and 12 months in person or by post.

Results

At 4 months, both psychological therapies had reduced depressive symptoms to a significantly greater extent than usual GP care. Patients in the psychological therapy groups exhibited mean scores on the Beck Depression Inventory that were 4–5 points lower than the mean score of patients in the usual GP care group, a difference that was also clinically significant. These differences did not generalise to other measures of outcome. There was no significant difference in outcome between the two psychological therapies when they were compared directly using all 260 patients randomised to a psychological therapy by either randomised allocation method.

At 12 months, the patients in all three groups had improved to the same extent. The lack of a significant difference between the treatment groups at this point resulted from greater improvement of the patients in the GP care group between the 4- and 12-month follow-ups.

At 4 months, patients in both psychological therapy groups were more satisfied with their treatment than those in the usual GP care group. However, by 12 months, patients who had received non-directive counselling were more satisfied than those in either of the other two groups.

There were few differences in the baseline characteristics of patients who were randomised or expressed a treatment preference, and no differences in outcome between these patients.

Similar outcomes were found for patients who chose either psychological therapy. Again, there were no significant differences between the two groups at 4 or 12 months. Patients who chose counselling were more satisfied with treatment than those who chose cognitive-behaviour therapy at 12 months. There were no significant differences in Beck Depression Inventory scores at either outcome point between participants who were randomised and those who chose each psychological therapy.

No differences in direct or indirect costs between the three treatments were observed at either 4 or 12 months. However, the finding of no difference in costs must be interpreted with caution. As is usual, cost data were highly variable, and the study may have been underpowered to detect differences in costs that would be considered important by decision-makers.

Conclusions

In the primary care setting, non-directive counselling and cognitive-behaviour therapy were both significantly more effective clinically than usual GP care in the short term. However, there were no differences between these three treatments in either clinical outcomes or costs at the 12-month follow-up.

Psychological therapy provided in primary care was found to be a cost-effective method of reducing depressive symptoms in the short term, but the comparative benefits were relatively circumscribed and did not endure over the long term. Compared with usual GP care, no differences in overall costs were observed. The additional costs associated with providing practice-based psychological therapy

were recouped due to savings in visits to primary care, psychotropic medication and other specialist mental health treatments.

Implications for healthcare

Based on this study's observed equivalence in the clinical and economic outcomes of usual GP care compared with on-site psychological therapies in primary care, the commissioners of psychological services would be justified in considering additional factors when determining service configuration. These factors could include patient satisfaction, the preferences of practitioners and staff availability.

Recommendations for future research

Future research is needed in the following areas:

1. the long-term outcome for patients treated with psychological therapies
2. the relationship between the quality of psychological therapies and patient outcomes
3. the effectiveness of other therapies, different modes of treatment administration and the comparative effectiveness of psychological and pharmacological treatments
4. statistical techniques and methods for dealing with issues such as missing data and clustering of patients around therapists, GPs and practices
5. the psychological and social processes involved in patient preferences and how these relate to other psychological processes of relevance to controlled trial research, such as the placebo and Hawthorne effects
6. the content and interpretation of 'usual GP care'
7. patients who refuse to consider participation in trials, even when treatment preference arms are available.

Publication

King M, Sibbald B, Ward E, Bower P, Lloyd M, Gabbay M, *et al.* Randomised controlled trial of non-directive counselling, cognitive-behaviour therapy and usual general practitioner care in the management of depression as well as mixed anxiety and depression in primary care. *Health Technol Assess* 2000;4(19).

NHS R&D HTA Programme

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The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care. It was identified as a priority by the Primary and Community Care Panel and funded as project number 93/07/66.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for the recommendations for policy contained herein. In particular, policy options in the area of screening will be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

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Series Editors: Andrew Stevens, Ken Stein and John Gabbay

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The editors and publisher have tried to ensure the accuracy of this report but do not accept liability for damages or losses arising from material published in this report. They would like to thank the referees for their constructive comments on the draft document.

Copies of this report can be obtained from:

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ISSN 1366-5278