Cognitive–behaviour therapy for health anxiety in medical patients (CHAMP): a randomised controlled trial with outcomes to 5 years

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Scientific summary

The CHAMP RCT

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Scientific summary

Background

Health anxiety is a special form of anxiety-related worry over illness. It has only recently been recognised as a separate condition that is closely linked, but not identical, to the former diagnosis of hypochondriasis. Most people with significant health anxiety have hypochondriasis but a proportion of those with hypochondriasis are not significantly anxious. One of the reasons for separating health anxiety from other forms of hypochondriasis is that it may be amenable to psychological interventions for anxiety, particularly cognitive–behaviour therapy (CBT).

People with health anxiety constantly fear that they have an undiagnosed medical illness and monitor and check their bodies frequently in response to this. They respond to their fears by consulting doctors, other health professionals and even relatives frequently, both for reassurance and for tests to exclude the feared disease. This group of patients attends primary care and secondary care clinics frequently. Previous trials have demonstrated the benefits of cognitive–behaviour therapy in patients in primary care and the pilot trial in secondary care also showed similar benefits, together with cost savings.

A large trial was therefore planned to see patients with excessive health anxiety attending secondary care clinics in general hospitals and to randomise them to a modified form of CBT specially adapted for health anxiety (CBT-HA) or standard care in the clinic. This was a pragmatic trial designed to replicate conditions in ordinary practice and so the therapists chosen to administer the treatment were not particularly skilled, but we hoped to train them to a sufficient standard to give the therapy effectively. We also wanted to examine the influence of personality status and obsessional symptomatology on outcomes.

As evidence of cost-effectiveness in the initial pilot trial was delayed, we planned to look at cost-effectiveness after 2 years but clinical effectiveness after 1 year. Follow-up was planned over a 5-year period.

Objectives

To determine the clinical effectiveness and cost-effectiveness of CBT-HA compared with standard care in the treatment of pathological health anxiety.

To examine the influence of concurrent personality pathology and obsessional symptoms on outcome in both treatment groups.

Design

The design was a single-blind randomised controlled trial with assessments by research assistants masked to allocation of treatment.

Setting

The trial took place in five types of medical clinic in five general hospitals in England.

Participants

A total of 444 patients aged 16–75 years who had a score of ≥ 20 on the Health Anxiety Inventory (HAI) and satisfied the diagnostic criteria for *Diagnostic and Statistical Manual of Mental Disorders*-Fourth Edition (DSM-IV) hypochondriasis, and who were regarded as suitable for treatment by their consultants, took part in the trial. We identified potentially eligible participants by screening with the HAI.

Randomisation

Each patient was randomised to CBT-HA or standard care by a computerised system (Open Clinical Data Management System, Centre for Health Informatics, University of Manchester, Manchester, UK) using block randomisation with no stratification in randomised blocks of four and six.

Masking of assessments

A total of 17 research assistants were involved in recruiting and assessing patients over the 5-year period of the study. Patients were asked not to disclose the nature of their treatment to the research assistants and, if this was accidentally disclosed, a different research assistant was chosen to be involved in further assessments.

Interventions

Cognitive–behaviour therapy for health anxiety

Trainee psychologists, other interested health professionals in the clinics and nurses were chosen to administer CBT-HA. They were trained initially at two all-day workshops, and subsequently supervised by a practitioner trained in CBT-HA in administering between 4 and 10 sessions of treatment over a 2- to 4-month period. Each practitioner also received a written handout giving the essentials of the treatment. Recording 50% of interviews and assessing these independently at different centres allowed us to subsequently check the fidelity of treatment. As far as possible, treatment was given in or close to the clinic concerned. The possibility of a booster session after completing treatment was also allowed.

Standard care

Patients allocated to standard care continued to receive care in both primary and secondary care services as normal. The general practitioners and consultants were informed that they had qualified for excessive health anxiety at baseline.

Measures

Baseline information

The following assessments were carried out at baseline:

- HAI (initial screen)
- DSM-IV hypochondriasis diagnosis (initial assessment before randomisation)
- Hospital Anxiety and Depression Scale [(HADS) including generalised anxiety and depression components]
- Social Functioning Questionnaire (SFQ) – an eight-item self-rating scale
- personality assessment using the Quick Personality Assessment Schedule in an interview of 30 minutes, followed by conversion to the new *International Statistical Classification of Diseases*, Eleventh Edition personality severity levels in 2011

- the Short Obsessive–Compulsive disorder Screener (SOCS) (a set of seven questions that identify the likely presence of obsessive–compulsive disorder)
- the Dependent Personality Questionnaire (DPQ), an assessment of dependent personality traits (this was included as both dependent personality and obsessional symptoms associated with another condition may handicap response or complicate treatment)
- the EuroQol-5 Dimensions (EQ-5D) scale to measure quality of life
- the Adult Service Use Schedule (ADSUS) to record interventions and service usage at interview
- hospital data recording inpatient, outpatient and accident and emergency attendances, and investigations over the 5-year period.

Primary clinical outcome

The primary clinical outcome was set originally as the difference between baseline score and 1-year score on the HAI in the two treatment groups. After 5 years this was no longer relevant, so the primary outcome at this point was the difference between baseline score and 5-year score in the HAI.

Secondary clinical outcomes

The secondary clinical outcomes were changes between scores in the two groups in (1) the HAI at 3, 6, 24 and 60 months and overall; (2) the HADS at 6, 12, 24 and 60 months and overall; (3) the EQ-5D at 6, 12, 24 and 60 months and overall; and (4) the SFQ at 6, 12, 24 and 60 months and overall.

Economic outcomes

The economic evaluation took a health and social care perspective. The impact of the addition of productivity losses was examined in a sensitivity analysis.

Sample size

We calculated sample sizes for both the primary outcome measure (change in HAI score at 1 year) and the first secondary outcome measure, cost, choosing the larger of the two for the study.

Based on the pilot study in a genitourinary medicine clinic we assumed that the true difference in the change of HAI score between CBT and control at 2 years was 5.00 points (higher than a meaningful clinical difference) and that the standard deviation (SD) for the change of HAI score at 2 years was 7.58 points. Taking into account a 20% dropout by 24 months, the sample size was therefore estimated to be 152 patients.

There remains no agreed approach to calculate the sample size required for an economic evaluation, particularly in areas such as health anxiety, in which the willingness to pay for improvements in outcomes is unknown. Based on the pilot study, we considered that the CBT intervention would be cost-effective if it improved HAI score and was no more costly than the control treatment. The sample size calculation for the economic evaluation was therefore based on the total costs over 24 months being equivalent.

With a sample size of 186 per group, the study had 80% power to reject the null hypothesis that the costs of the CBT and control are not equivalent (when the difference in mean costs is ≈£150) in favour of the alternative hypothesis that the means of the two groups are equivalent, assuming that the expected difference in means is 0 and the common SD is 580 (from pilot study data). With 466 patients, or fewer if the dropout rate is less, the study was therefore adequately powered to both detect the assumed difference in the primary outcome and assess the equivalence in the secondary economic outcome between CBT-HA and standard care groups.

Statistical measures and outcomes

The primary end point was analysed using a mixed model with time, treatment and time × treatment interaction as fixed effects, baseline measurement as covariate and patient as random effect. The treatment differences at each time point together with the 95% confidence interval were derived from the

mixed model. Missing data were treated as missing at random in the mixed-model analysis. To assess the sensitivity of the result to missing values, the last observation carried forward strategy was used to compute the missing HAI at the follow-up visits. Other assessments were analysed in a similar way. In addition, covariate-adjusted analysis was performed on the primary outcome analysis by a mixed model, controlling for three pre-specified potential predictors for the primary end point (clinic type, site and age).

All statistical analyses used the intention-to-treat principle using the statistical package SAS, version 9.3 (SAS Institute Inc., Cary, NC, USA). Deaths were reported separately for each group. The Consolidated Standards of Reporting Trials (CONSORT) procedure was used for reporting flow through the trial.

The primary economic evaluation included only those for whom complete data at baseline and at the 12-, 24- and 60-month follow-ups were available.

For each piece of service use information collected with the ADSUS, a unit cost was applied and the total costs calculated. The total cost per participant was calculated by summing all costs. All unit costs were for the financial year 2008–9. Costs beyond the first year were discounted at a rate of 3.5%.

Results

A total of 28,991 patients were screened during the 21 months of recruitment, and 20% of these ($n = 5769$) had HAI scores of ≥ 20 points. Many of the positive scorers for health anxiety declined to take part or were excluded for others reasons. A total of 445 patients were randomised, but one had been randomised twice, on both occasions to standard care, and only the first of these randomisations was included. A mean of six sessions of treatment was given to patients allocated to CBT-HA.

The primary outcome (HAI-score difference between groups at 1 year) was 2.97 points fewer in the CBT-HA group than in standard care ($p < 0.0001$). Significant differences in HAI score in favour of CBT-HA over standard care began at 3 months and were maintained on all occasions over the 5-year period (overall $p < 0.0001$), with no loss of efficacy between 2 and 5 years. Generalised anxiety ($p = 0.0018$) and depression scores ($p = 0.0065$) on the HADS also showed significantly greater improvement over the 5-year period. Differences between groups were maximal after 6 months. Patients treated in gastroenterology and cardiology clinics showed the greatest gains for CBT, with those for cardiology being maximal after 5 years ($p = 0.0012$). Secondary analyses showed therapist differences in outcome, with treatment given by nurses being superior to standard care, with an overall change of 5.5 points in HAI score ($p < 0.0001$). Deaths were similar in both groups, but those allocated to standard care died earlier than those allocated to CBT-HA, suggesting that CBT-HA did not lead to diagnostic overshadowing and failure to identify serious life-threatening disease.

Patients with mild personality disorder and personality difficulty had a markedly better outcome with CBT-HA than those with no personality dysfunction or moderate personality disorder. Similar findings were found with dependent personality measured by the DPQ. Those with high scores on the SOCS scale (≥ 6 points) at 5 years showed non-significant improvement with CBT-HA (score difference of 1.31 points) compared with those with low SOCS scores (score difference of 2.73 points; $p = 0.004$), suggesting that those with concurrent obsessional symptoms do not retain gains with treatment.

Total costs were similar in both groups over the 5-year period, but there was no evidence that CBT-HA is cost-effective in terms of quality-adjusted life-years (QALYs) as measured using the EQ-5D. There is some evidence that CBT-HA is cost-effective in terms of HAI outcomes and in those without serious personality disturbance. The large number of patients who had concurrent medical illnesses that had a disproportionate effect on costs complicated the economic evaluation.

Conclusions

Cognitive–behaviour therapy for health anxiety is a highly effective treatment for pathological health anxiety in patients attending medical clinics and its benefits are maintained over 5 years without reinforcement. Symptoms of anxiety and depression also improved with CBT-HA to a significantly greater extent than with standard care, and were also maintained over 5 years. There was no evidence that the treatment led to 'diagnostic overshadowing' of medical illness, and, among those who died, those who were allocated to standard care died earlier than those in the CBT-HA group. This supports recent evidence that untreated health anxiety is associated with premature mortality. The presence of personality abnormality is not a bar to a successful outcome. There was no evidence that CBT-HA was cost-effective in terms of QALYs, but concurrent medical illnesses obscure potential savings in costs and have a negative impact on quality of life. In terms of the HAI, CBT-HA has a > 50% probability of being cost-effective for almost all willingness-to-pay values, but the EQ-5D figures do not show the same advantages, probably because of considerable concurrent medical pathology that obscures gains made by psychological improvement. CBT-HA allows therapists with no previous experience to be trained relatively easily. It therefore has the potential to be used widely in general hospital settings under appropriate supervision, and so further joint mental and physical health care.

Trial registration

This trial is registered as ISRCTN14565822.

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