Clinical and cost-effectiveness of cognitive behaviour therapy for health anxiety in medical patients: a multicentre randomised controlled trial

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Summary

Background Health anxiety has been treated by therapists expert in cognitive behaviour therapy with some specific benefit in some patients referred to psychological services. Those in hospital care have been less often investigated. Following a pilot trial suggesting efficacy we carried out a randomised study in hospital medical clinics.

Methods We undertook a multicentre, randomised trial on health anxious patients attending cardiac, endocrine, gastroenterological, neurological, and respiratory medicine clinics in secondary care. We included those aged 16–75 years, who satisfied the criteria for excessive health anxiety, and were resident in the area covered by the hospital, were not under investigation for new pathology or too medically unwell to take part. We used a computer-generated random scheme to allocate eligible medical patients to an active treatment group of five-to-ten sessions of adapted cognitive behaviour therapy (CBT-HA group) delivered by hospital-based therapists or to standard care in the clinics. The primary outcome was change in health anxiety symptoms measured by the Health Anxiety Inventory at 1 year and the main secondary hypothesis was equivalence of total health and social care costs over 2 years, with an equivalence margin of £150. Analysis was by intention to treat. The study is registered with controlled-trials.com, ISRCTN14565822.

Findings Of 28 991 patients screened, 444 were randomly assigned to receive either adapted cognitive behaviour therapy (CBT-HA group, 219 participants) or standard care (standard care group, 225), with 205 participants in the CBT-HA group and 212 in the standard care group included in the analyses of the primary endpoints. At 1 year, improvement in health anxiety in the patients in the CBT-HA group was 2·98 points greater than in those in the standard care group (95% CI 1·64–4·33, p<0·0001), and twice as many patients receiving cognitive behaviour therapy achieved normal levels of health anxiety compared with those in the control group (13·9% *vs* 7·3%; odds ratio 2·15, 95% CI 1·09–4·23, p=0·0273). Similar differences were observed at 6 months and 2 years, and there were concomitant reductions in generalised anxiety and, to a lesser extent, depression. Of nine deaths, six were in the control group; all were due to pre-existing illness. Social functioning or health-related quality of life did not differ significantly between groups. Equivalence in total 2-year costs was not achieved, but the difference was not significant (adjusted mean difference £156, 95% CI –1446 to 1758, p=0·848).

Interpretation This form of adapted cognitive behaviour therapy for health anxiety led to sustained symptomatic benefit over 2 years, with no significant effect on total costs. It deserves wider application in medical care.

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Introduction

Health anxiety, together with its approximate synonym, hypochondriasis, is a common issue in the community (lifetime prevalence 5%),[1] and in both primary and secondary care.[2–4] It places a substantial burden on health services[5] since the fear of having a serious disease leads to medical consultation, commonly followed by further investigations. Pathological health anxiety provokes substantial suffering but often goes unrecognised, or appreciated only at a superficial level. Even when recognised, expensive investigations might be carried out unnecessarily because of fear of litigation. In general hospitals, between 10% and 20% of all attenders have abnormal health anxiety, which is often undetected since many patients have a history of previous medical illnesses and

their anxiety is seen as reasonable and proportionate. Patients often rotate between different clinics depending on the focus of their symptoms. Often symptoms last for years and show little tendency to spontaneous resolution. Psychological treatment in the form of cognitive behaviour therapy delivered by expert therapists is of proven effectiveness for anxiety disorders;[6] its application to health anxiety has been shown to be more effective than waiting list controls and at least as effective as other psychological treatments.[7] These studies were done mainly in primary and psychiatric care[8–11] with specialist therapists. In a pilot study carried out by our group,[12] these results generalised to secondary medical care settings (in which costs of care are high) using less expert therapists trained for the purpose.[12] We subsequently set

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up the cognitive behaviour therapy for health anxiety in medical patients (CHAMP) trial to examine both effectiveness and cost-effectiveness of a modified cognitive behavioural treatment for health anxiety (CBT-HA) with assessment of outcomes over a 2 year period.

Methods

Study design and participants

CHAMP was a pragmatic randomised controlled trial with two parallel arms and equal randomisation of patients with health anxiety initially to receive CBT-HA or standard care in the clinics provided they satisfied the inclusion criteria listed below.

We recruited patients attending cardiology, endocrine, gastroenterology, and respiratory medicine clinics, in which health anxiety prevalence was known to be high,[4] in six general hospitals in the UK covering urban, suburban, and rural areas. Neurology clinics were not originally included, but we decided to include these clinics later in the recruitment programme because we also suspected high health anxiety levels in this setting. Because of this delay, fewer patients from neurology clinics were recruited. We approached all patients attending clinics of the relevant consultants, apart from the specific exclusions below, while they were waiting for their outpatient appointments. After patients gave written and signed consent, they completed the short form of the Health Anxiety Inventory anxiety index (HAI),[13] a self-rating scale of 14 questions that takes 5–10 min to complete. We gave a brief summary of the trial and offered the opportunity of further assessment to those who scored 20 or more on the scale, a point that has previously been shown[13,14] to discriminate between persistent worry over health and normal variation. If they were interested, we then gave participants an information sheet about the study. The last part of the initial assessment was the administration of key questions from the Structured Clinical Interview for DSM-IV[15] covering the diagnosis of hypochondriaisis. Those who satisfied the hypochondriasis diagnosis were then offered randomisation to the trial, and, if they agreed, full baseline assessments were completed and written informed consent obtained. In the course of the assessments most patients learnt new information about health anxiety that they might not have known before, so all patients in the study had this minor therapeutic intervention.

Those who satisfied the criteria for excessive health anxiety above were included if they were aged between 16 years and 75 years and had a stable residence in the area covered by the hospital, had sufficient understanding of English to read and complete study questionnaires, and gave written consent for the interviews, audio-taping of 50% of treatment sessions, and for access to their medical records. The presence of existing medical pathology, provided it was not a new diagnosis requiring further investigation, was not a study exclusion criterion. We excluded those who were felt by their consultants to

have a level of continuing major disorder that was too severe for them to take part in the study, including progressive cognitive impairment, terminal disorders, and any major comorbid disorder that would interfere with psychological treatment, those who were currently being actively investigated for significant pathology suspected by the clinician and for whom cognitive behaviour therapy might confuse or cause distress, and those currently under psychiatric care.

The study was approved by the North Nottingham Ethics Committee (08/H0403/56) before the start of data collection.

Randomisation and masking

After baseline assessment, eligible patients were allocated (in a 1:1 ratio) to receive either modified cognitive behavioural treatment for health anxiety with standard care (CBT-HA group) or standard care alone (standard care group). Randomisation was carried out by an independently operated computerised system, and according to a computer-generated random sequence using block randomisation with varying blocksize of four and six. The allocation sequence was not available to any member of the research team until databases had been completed and locked. All research assistants were unaware of trial allocation and patients were asked not to discuss their treatment at subsequent assessments. If treatment allocation was inadvertently disclosed at subsequent assessments, the researcher terminated the interview and it was completed by another colleague.

Procedures

We offered every patient in the CBT-HA group between five and ten sessions of treatment initially, but additional booster sessions were also allowed. Every therapist was supervised at 2–4 week intervals at least (by HT, GS, EM, and SF) during treatment to ensure consistency in treatment. Bias in follow-up assessments was reduced by replacing the research assessor with another research assistant if at any time they were unwittingly informed about the patient's allocation status.

Four collaborators (PS, GS, EM, and HT) trained the therapists at two workshops and also assessed treatment fidelity, together with HW. Half of all (610 of 1374) treatment sessions were audio recorded. We tested fidelity using the health anxiety modification of the Cognitive Therapy Rating Scale (CTRS-HAV).[16] A local supervisor assessed the recordings and a random sample was sent to a supervisor at a different site to assess the level of agreement, with further training ending only when an agreement level of 0·80 κ was reached.

We made assessments of health anxiety, generalised anxiety, depression, social function, quality of life, and costs over 2 years after randomisation.

The primary outcome was symptoms of health anxiety after 1 year. Those allocated to the CBT-HA group were treated by graduate research workers, nurses, or other

health professionals trained for this intervention. Our two main hypotheses, based on the results of our pilot study,[12] were that patients offered between five and ten sessions of cognitive behaviour therapy focused on health anxiety,[17,18] in addition to standard care, would have lower levels of health anxiety measured by the HAI[13] 1 year after randomisation to the trial than those treated with standard care alone, and that from a health and social care perspective, the costs of the CBT-HA and standard groups would be equivalent at 2 years (ie, costs of CBT-HA would be offset by savings in other areas).

Secondary hypotheses were that health anxiety at other timepoints, generalised anxiety and depression, social functioning, and quality of life measured by standard measures[19–21] would differ between CBT-HA and standard care, and that CBT-HA would be a cost-effective use of resources.

We made assessments of health anxiety,[13] anxiety and depression (HADS),[19] health-related quality of life (EQ-5D),[20] and social function (SFQ)[21] at baseline, and these were assessed independently by research assistants at 6 months, 12 months, and 2 years. HAI scores were additionally recorded at 3 months. We obtained service use data for the economic evaluation at baseline, 6 months, 12 months, and 2 year follow-ups using the Adult Service Use Schedule (AD-SUS), a self-report instrument assessed in interview and designed on the basis of previous economic evaluations in adult mental health populations,[22] and also by examination of computerised hospital records. Where AD-SUS data conflicted with the data obtained from records, the computerised records took precedence.

Statistical analysis

Following our pilot study[12] a sample size of 122 patients per group was needed to detect a CBT-HA/standard care score difference of 5·00 points with 95% power at a two-sided 5% significance level assuming that the standard deviation for the change of HAI at 1 year is 7·58 points. Taking into account a possible rate of dropout of 20% at 12 months, the estimated sample size was 152 patients per group. We also calculated the sample size necessary to demonstrate equivalence between CBT-HA and control in the main secondary outcome (total costs over 24 months) using data from the pilot study and with the hypothesis that evidence of lower total costs in the CBT-HA group seen in the pilot study would, over a longer follow-up, offset the cost of the therapy.[12] Assuming that the expected difference in mean cost is nil and the common standard deviation is £580, a sample size of 186 per group would have 80% power to declare that the cost of the CBT-HA and control groups were equivalent with a prespecified equivalence margin of £150.[12] Equivalence would be declared if the 95% CI fell within −£150 and £150. Assuming a 20% dropout by 24 months, 466 patients needed to be recruited. The main analysis was based on the intention-to-treat principle.

We analysed the primary endpoint using a mixed model with time, treatment, and interaction between time and treatment as fixed effects, baseline measurement as co-variate, and patient as random effect. The treatment differences at every timepoint including 12 months, together with its 95% CI, were derived from the mixed model.

We treated missing data as missing at random in the mixed model analysis. To assess the sensitivity of the result to missing values, the last observation carried forward (LOCF) strategy was used to compute the missing HAI scores at the follow-up visits. We analysed other assessments in a similar way. Additionally, we did a covariate-adjusted analysis of the primary outcome by mixed model controlling for three prespecified potential predictors for primary endpoint (clinic type, site, and age). Also, we compared the percentage of patients achieving
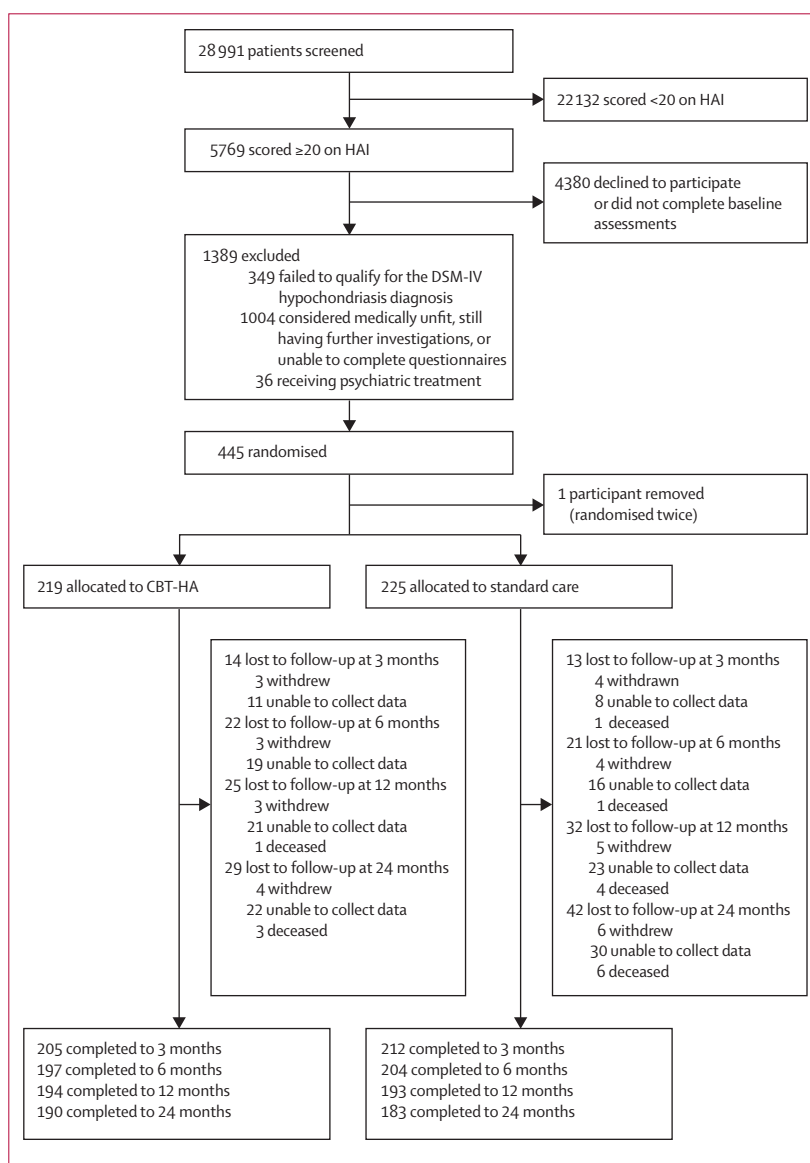

Figure 1: Trial profile
HAI=health anxiety inventory. DSM-IV=Diagnostic and Statistical Manual of Mental Disorders, 4th edition.

normal levels of health anxiety (HAI ≤10) using a general-ised estimating equation model with visit, treatment, interaction between visits and treatment as fixed effect, baseline measurement of HAI as covariate, and patient as random effect (an exchangeable covariance structure).

We applied nationally applicable unit costs to all elements of service use collected in the AD-SUS and from computerised hospital records,[23–25] including the cost of

	CBT-HA (n=219)	Standard care (n=225)
Age (year)	50·3 (13·6)	47·0 (13·4)
Sex		
Female	113 (52%)	123 (55%)
Male	106 (48 %)	102 (45%)
Ethnic origin		
White British	145 (68%)	151 (68%)
White other	26 (12%)	18 (8%)
Black/black British: African origin	6 (3%)	9 (4%)
Black/black British: Caribbean origin	5 (2%)	7 (3%)
Asian/Asian British born in Asia or UK	15 (7%)	23 (10%)
Asian/Asian British: other origin	8 (4%)	8 (4%)
Arab/Middle East	7 (3%)	4 (2%)
Chinese/Far East	2 (1%)	2 (1%)
Hospital		
Chelsea and Westminster Hospital, London	26 (12%)	23 (10%)
Charing Cross Hospital, London	31 (14%)	26 (12%)
Hillingdon Hospital, Middlesex	56 (26%)	63 (28%)
Kings Mill Hospital, Nottinghamshire	70 (32%)	74 (33%)
St Marys Hospital, London	36 (16%)	39 (17%)
Clinic type		
Cardiology	53 (24%)	57 (25%)
Endocrinology	41 (19%)	43 (19%)
Gastroenterology	77 (35%)	72 (32%)
Neurology	20 (9%)	22 (10%)
Respiratory medicine	28 (13%)	31 (14%)
HAI Score	24·9 (4·2)	25·1 (4·5)

Data are number (%) or mean (SD). CBT-HA=cognitive behaviour therapy-health anxiety. HAI=health anxiety inventory.

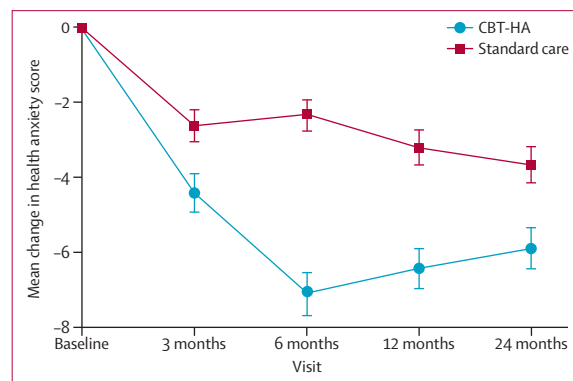***Table 1:* Baseline characteristics of patients**

***Figure 2:* Mean change in health anxiety score (±SE) by treatment**

cognitive behaviour therapy. However, we adjusted the cost of cognitive behaviour therapy to reflect the salaries of the CBT-HA therapists employed in the study, including trainee psychologists, nurses, and a dietitian. We calculated and analysed all unit costs in UK Pound Sterling for the financial year 2008–09. We discounted costs in the second year at a rate of 3·5%, as recommended by the National Institute for Health and Clinical Excellence.[26]

The economic evaluation included those patients for whom complete data at baseline, 12 and 24 months follow-up were available, with multiple imputation for missing data tested in sensitivity analysis.[27] We used standard parametric tests as recommended for the analysis of cost data[28] with the robustness of the tests confirmed using bias-corrected, non-parametric boot-strapping.[29] Details of the cost-effectiveness analysis are in the appendix.

Role of the funding source
The funding source had no role in study design, data collection, data analysis, interpretation of data, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results
During the 21 months of recruitment, between Oct 1, 2008, and July 19, 2010, we screened 28 991 patients. Of these, 5769 (20%) patients scored 20 or over on the HAI, but many of these refused to take part or were not interviewed further for several reasons (figure 1; table 1). 445 patients were randomly assigned to treatment, but since one patient was mistakenly randomised twice (both times to standard care) the later set of data was discarded and only 444 patients were included in the trial (figure 1). Five patients disclosed their treatment allocation to the research assistants, who were replaced by others. There were nine deaths (six in the standard care group and three in the CBT-HA group); all deaths were due to natural causes in patients with pre-existing medical pathology. The mean number of CBT-HA treatment sessions was 6 (range 0–22), with 15 patients receiving no treatment. We noted no important differences in outcome in those who had more rather than fewer sessions, but these data will be subject to further secondary analyses. Patients allocated to CBT-HA improved rapidly after treatment and showed significantly greater reduction in health anxiety (figure 2). These differences were highly significant at all assessment points, including 12 months, the primary outcome point (difference 2·98, 95% CI 1·64–4·33, p<0·0001). These differences were maintained in further analyses with site and baseline scores as covariates. At 1 year, 27 (14%) of the 194 patients assessed who had received CBT-HA had levels of health anxiety in the normal range (HAI score of 10 or less) compared with 14 (7%) in the 193 patients in the control group, with the odds ratio of achieving a normal level of health anxiety between CBT-HA and the control

group being 2·15 (95% CI 1·09–4·23, p=0·0273), with significant differences also being shown at 3 months and 6 months (appendix). The results of health anxiety scores remained similar when we used the LOCF strategy to impute missing HAI scores at follow-up visits (appendix). We also did a covariate adjusted analysis, and the adjusted treatment effect on the primary endpoint was similar to the unadjusted effect.

Patients in the CBT-HA group showed significantly greater improvement in self-rated anxiety and depression symptoms at 6 months and 12 months, compared with standard care (table 2). Social functioning and health-related quality of life showed no important change, apart from the EQ-5D visual analogue rating of quality of life, which approached significance in favour of CBT-HA at 6 months.

Complete data for the economic evaluation were available for 343 (77%) patients. We excluded one patient from the CBT-HA group who was classified as an outlier as a result of substantial hospital contacts due to a number of confirmed physical conditions (total 24–month cost £97 987 compared with an average per participant of £8009 (SD 10 418) for the total sample of 343), so the analysis is based on a sample of 342. We present here the results for our main economic hypothesis relating to equivalence of costs; full cost-effectiveness results are contained in the appendix.

Table 3 shows total costs per patient over 24-months follow-up. The mean cost of the CBT-HA intervention was £421·51 per patient (range 0–2383) for a mean of 6 sessions. All other categories of cost, including general practitioner contacts and hospital costs, were lower for the CBT-HA group than the control group. Total health and social care costs including the cost of the intervention were lower in the CBT-HA group (mean £7314) than the control group (£7727). In analyses adjusted for baseline cost, however, the adjusted mean difference between the two groups was £156 (95% CI –1446 to 1758, p=0·848). Although equivalence was not achieved, there was no evidence of a significant difference in cost between the CBT-HA and standard care groups. Imputation of missing data did not alter this finding.

Assessments of the fidelity of therapists' treatment showed that all except one scored at an adequate competence level or higher, and this was confirmed by the independent assessor (HW). The therapist who failed to achieve this level saw five patients. We identified no serious adverse events attributable in any way to the trial intervention in the study, but one participant in the standard care group made a serious suicide attempt.

Discussion

The results indicate that the previously noted effectiveness of CBT-HA[9,10,30] generalises to patients with substantial health anxiety in a range of general medical clinics when delivered by therapists with little previous experience in cognitive behaviour therapy but specifically trained to

	CBT-HA		Standard care		Mixed model analysis	
	N	Mean improvement from baseline (SD)	N	Mean improvement from baseline (SD)	Difference (95% CI)	p value
Health anxiety (HAI)*						
3 months	205	4·41 (7·63)	212	2·62 (6·17)	1·79 (0·48 to 3·10)	0·0076
6 months	197	7·11 (7·83)	204	2·33 (5·76)	4·86 (3·53 to 6·18)	<0·0001
12 months	194	6·44 (7·47)	193	3·20 (6·54)	2·98 (1·64 to 4·33)	<0·0001
24 months	190	5·90 (7·54)	183	3·66 (6·57)	2·05 (0·70 to 3·41)	0·0030
Generalised anxiety (HADS-A)†						
6 months	197	2·74 (4·41)	204	1·46 (3·89)	1·29 (0·52 to 2·06)	0·0011
12 months	194	2·80 (4·40)	192	1·67 (4·04)	1·04 (0·25 to 1·82)	0·0095
24 months	189	3·33 (4·57)	181	2·07 (4·35)	1·00 (0·21 to 1·79)	0·0137
Depression‡						
6 months	197	1·38 (4·32)	204	0·51 (4·14)	0·78 (–0·01 to 1·57)	0·0529
12 months	194	1·43 (4·44)	192	0·43 (3·69)	0·79 (–0·01 to 1·59)	0·0527
24 months	189	1·37 (4·95)	181	0·51 (4·38)	0·63 (–0·18 to 1·44)	0·1263
Social function§						
6 months	197	0·42 (4·46)	204	0·39 (3·68)	0·14 (–0·63 to 0·92)	0·7210
12 months	194	0·57 (4·46)	192	0·39 (3·65)	0·19 (–0·60 to 0·98)	0·6364
24 months	190	1·06 (4·76)	182	0·83 (3·81)	0·21 (–0·58 to 1·01)	0·6002
Health-related quality of life (EQ-5D scores)						
6 months	196	0·04 (0·33)	203	0·04 (0·35)	–0·00 (–0·06 to 0·06)	0·9921
12 months	194	0·08 (0·34)	191	0·08 (0·35)	–0·00 (–0·06 to 0·06)	0·9736
24 months	189	0·08 (0·32)	181	0·07 (0·34)	0·02 (–0·04 to 0·08)	0·5075
Health-related quality of life (EQ-5D visual analogue scale)						
6 months	189	6·04 (29·94)	194	2·33 (23·65)	4·32 (–0·27 to 8·90)	0·0649
12 months	185	7·06 (29·12)	184	5·72 (25·20)	1·56 (–3·10 to 6·21)	0·5121
24 months	183	9·29 (30·43)	172	5·81 (23·42)	4·06 (–0·67 to 8·79)	0·0923

CBT-HA=cognitive behaviour therapy-health anxiety. HAI=health anxiety inventory. HADS-A=hospital anxiety and depression scale. *Baseline scores: 24·91 for CBT-HA and 25·25 for standard care. †Baseline scores: 12·46 for CBT-HA and 12·36 for standard care. ‡Baseline scores: 8·79 for CBT-HA and 8·69 for standard care. §Baseline scores: 9·39 for CBT-HA and 9·40 for standard care.

Table 2: Summary statistics and results from mixed model analysis of change in outcomes from baseline, by visit

deliver treatment in these settings. The benefits of CBT-HA in terms of anxiety, noted both in the short and longer term, were achieved with no significant difference in costs to standard care and with evidence of cost-effectiveness—which is similar to a recent study demonstrating the cost-effectiveness of internet-based cognitive therapy for health anxiety.[31] Although equivalence in costs was not demonstrated, full economic data were only available for 73% of the required sample, so the study might have been underpowered for our cost hypothesis. The possibility that CBT-HA might prevent the detection of life-threatening serious illness did not receive support since deaths were twice as high in the standard care group.

No evidence of the effectiveness of CBT-HA in terms of the secondary outcomes of social functioning or quality of life was evident, with a corresponding lack of evidence of cost-effectiveness in terms of quality-adjusted life-years (QALYs; appendix). This might suggest a longer timeframe might be necessary to demonstrate the full

	CBT-HA (mean [SD], n=172)	Standard care (mean [SD], n=170)	Mean difference	Adjusted mean difference (95% CI)*	p value*
CBT-HA	421·51 (308·25)	0·00 (0·00)	421·51	..	..
General practitioner contacts	381·34 (428·83)	417·64 (586·74)	−36·30	..	..
Other community health and social care contacts	392·68 (976·43)	473·89 (392·68)	−81·21	..	..
Medication	2037·33 (2760·75)	2376·74 (4487·03)	−339·41	..	..
Hospital services	3946·81 (5583·89)	4223·31 (6353·28)	−276·50	..	..
Service provided accommodation	134·52 (1025·45)	235·83 (1640·25)	−101·31	..	..
Total	7314·20 (7429·58)	7727·40 (8324·58)	−413·20	155·86 (−1446·20 to 1757·93)	0·848

CBT-HA=cognitive behaviour therapy-health anxiety. *Applying bootstrapped costs and adjusted for baseline costs.

Table 3: Mean total cost (£) per patient over 24 months follow-up

Panel: **Research in context**

Systematic review

A systematic review[7] of psychotherapies for hypochondriasis, including health anxiety, in 2007 identified cognitive behaviour therapy as one of five psychotherapies that was effective in reducing hypochondriasis but all trials were small and there were no controlled studies of long-term outcome and no studies in hospital settings. Since this review there have been four further trials[10,11, 12, 30] of cognitive behaviour therapy, including one that included cost-effectiveness[31] in patients with health anxiety and hypochondriasis, and all of these demonstrated benefit, but none of these involved hospital patients, even though there are high levels of health anxiety in these settings.[4] The CHAMP trial was the first large scale trial of an adapted form of cognitive behaviour therapy for health anxiety (CBT-HA) which can be taught easily to naive therapists such as general nurses.

Interpretation

Before this study we had no evidence that health anxiety in medical settings could be successfully treated. Our findings demonstrate that CBT-HA is relatively cheap with an average of 6 sessions of treatment, and is effective in reducing health anxiety both in the short-term and up to two years after treatment, and also reduces generalised anxiety and depression. As health professionals with no previous training in this treatment have been shown in this study to be successful practitioners, this treatment could be generalised easily to hospital settings.

effects of improvements in health anxiety, particularly as complex and expensive investigations, even if mainly activated by health anxiety, often cover a long time scale.

The findings from this pragmatic trial suggest that staff trained to deliver CBT-HA in medical clinics would help to relieve substantially troubling anxiety in a more cost-effective manner, compared with current standard approaches. The finding that benefit was maintained over 2 years also suggests that without such intervention the morbidity of health anxiety persists, possibly because it is reinforced by continued reassurance and medical investigations, and in recent years by the internet (so-called cyberchondria).

The main strength of the study was the highly robust effect of treatment despite it being given by relatively inexperienced staff who were trained only for the CBT-HA intervention. This finding suggests that this form of management could be incorporated into medical clinics and be administered by trained staff such as cardiac rehabilitation nurses and other specialist staff in medical clinics who treat repeated attenders. Many of these attenders have existing or past medical disorders but suffer unduly from persistent and unnecessary worry over their health.

However, inclusion of patients with confirmed, chronic, and recurring medical disorders might also have been a weakness in relation to our cost hypothesis, since the medical interventions received by these patients added to the variability of cost in the group and thus had a negative effect on the power available to detect equivalence of costs. Although clear savings in costs might have been expected to have accrued from a reduction in health anxiety, total costs reported include the cost of treating existing, chronic medical disorders, which might have hindered our ability to detect differences in cost that were due to health anxiety alone and which have been found in other studies in which total costs have been much lower.[12,31] As complex investigations, even if activated mainly by health anxiety, often take a long time to be completed, a longer period of follow-up might have been necessary to show clear cost improvements.

A further weakness is that most of the patients who were potentially eligible for the study declined to take part and so the population treated might not be representative, but we have no reason to believe that those who declined to take part were fundamentally different from those who agreed. As many people with hypochondriasis and health anxiety attribute their bodily symptoms unequivocally to medical pathology,[32] and therefore feel that only medical expertise can help them, attitudes, both from staff and patients, need to change before the treatment can be given more widely. But if change does not occur, and standard medical care fails to be aware of health anxiety, an important, largely hidden, but eminently treatable cause of morbidity in medical clinics is likely to persist.

Contributors

PT and HT initiated the trial and PT, HT, PS, MC, BB, SB, DM, SD, JG, and SR designed the structure of the trial. DW, BB, and SB were involved in developing the statistical analysis plan, statistical analysis, and results interpretation, and HP, BB, and SB did the economic analyses. HT, SF, EM, and GS were therapy supervisors; HT, EM, GS, SF, and HW checked fidelity of treatment; and SC was the trial coordinator and organiser of the recruitment strategy. Aaron Beck acted as trial adviser.

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