Cognitive behavioural intervention for adults with anxiety complications of asthma: prospective randomised trial

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
The objective was to assess the impact of cognitive-behavioural therapy (CBT) to prevent or reduce fear and panic during an asthma attack, for patients with asthma, aged 18 to 65 years. The authors concluded that CBT had a modest clinical effect, but no cost advantage. There were a few limitations to the study, so the authors’ conclusions should be considered with these in mind.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The objective was to assess the effectiveness of cognitive-behavioural therapy (CBT) to prevent or reduce fear and panic during an asthma attack, for patients with asthma, aged 18 to 65 years.

Interventions
The CBT consisted of an introductory session of 1.5 hours, followed by four to six one-hour sessions, either weekly or fortnightly, with two optional follow-up one-hour sessions. On the basis of the therapist's assessment, each patient could receive a range of educational, awareness and behavioural therapy elements. The comparator was standard clinical care.

Location/setting
UK/out-patient care.

Methods
Analytical approach:
The outcome and cost data were from a prospective randomised controlled trial of 94 patients, with 50 receiving CBT and 44 receiving usual care. The main analysis was intention to treat; a supplementary analysis used complete-case data. An analysis of covariance was completed to correct for anticipated baseline imbalances between the groups. The authors did not explicitly state the perspective of the study.

Effectiveness data:
The primary clinical outcome was the reduction in asthma-specific fear, measured using the Asthma Symptom Checklist (ASC) panic-fear subscale. A clinically meaningful change was defined as 0.5 standard deviations. The patients completed questionnaires at baseline (when consenting to trial), after intervention (three months from baseline), and at follow-up (six months later). For participants who were withdrawn, on the basis of clinical assessment data, after intervention or at follow-up, no change (no benefit from CBT) was assumed. For all other missing data, imputation was the last observation carried forward.

Monetary benefit and utility valuations:
Health-related quality-of-life was measured using the Hospital Anxiety and Depression Scale (HADS), the EQ-5D questionnaire (including the visual analogue scale), the Asthma Bother Profile, and the Asthma Multidimensional Health Locus of Control (AMHLC). Health utility values, for the EQ-5D data, were derived using general population valuations of the health states. All measures were from the patient-completed questionnaires at baseline, after treatment, and at follow-up.
Measure of benefit:
The measure of benefit was improvement in the health-related quality-of-life scores (e.g. HADS reduction, or EQ-5D increase).

Cost data:
The resource use data were from general practice case notes and hospital computer records. The resource items included the number of general practice consultations, total contact with asthma nurses and out-of-hours care, the number of prescriptions, and the number of patients who were admitted to hospital. The resource use six months before entry to the trial was compared with the use from baseline to after treatment, and from after treatment to follow-up. The cost of the CBT was estimated, based on the therapists’ hourly rates. All costs were in UK £.

Analysis of uncertainty:
Sampling uncertainty was presented as standard deviations, for each of the outcomes, and 95% confidence intervals, for the mean differences.

Results
Full details of all clinical and health-related quality-of-life outcomes were presented. After treatment, data were available for 20 CBT and 29 usual care patients; and at follow-up, there were 28 CBT and 31 usual care patients.

ASC panic-fear: In the main intention-to-treat analysis, there was a reduction in ASC panic-fear scores with CBT, after treatment (-1.20, SD 3.71), and an increase with usual care (1.10, SD 3.91). This difference in the mean (-2.30, 95% CI -3.99 to -0.60) was statistically significant, but not clinically meaningful, according to the set definition. The analysis of covariance found a significant net difference reduction in score of -2.59 (95% CI -4.39 to -0.79), which was clinically significant. Comparing follow-up with end of treatment, for usual care the mean ASC score fell by -1.08 (SD 4.83), and for CBT the mean reduction was -3.34 (SD 5.39). This difference (-2.26, 95% CI -4.55 to 0.02) was statistically significant and clinically meaningful. The analysis of covariance found a significant reduction in score of -2.87 (95% CI -5.12 to -0.62).

EQ-5D: The EQ-5D scores did not differ significantly, between CBT and usual care, at the end of treatment. At six-month follow-up, there was a significant reduction in scores for the treatment group, compared with the control group (intention-to-treat ANCOVA -0.11, 95% CI -0.20 to -0.03; complete-case ANCOVA -0.12, 95% CI -0.25 to 0.02). There were no differences between groups on the EQ-5D visual analogue scale.

Costs: There were no statistical differences between groups on any of the service use indicators. The CBT cost an average of between £378 and £798 per patient, depending on the number of sessions attended.

Authors’ conclusions
The authors concluded that CBT had a modest clinical effect, but no cost advantage.

CRD commentary
Interventions:
The intervention was adequately reported and the most appropriate comparator (usual care) was used, but the content of usual care was not described. The authors discussed several alternative psychological interventions to help adults manage their asthma, including patient education, stress reduction by relaxation, hypnotherapy, biofeedback, and rational-emotive group therapy, but they stated that these did not explicitly address the needs of patients with high panic or fear.

Effectiveness/benefits:
The outcomes were directly from the randomised controlled trial, which appears to have been well conducted and designed with an integral economic analysis. The identification, selection and randomisation of participants were reported. Power calculations were conducted, but recruitment was stopped prior to attaining the desired numbers, so it is possible that the sample was insufficient to accurately detect a clinically meaningful change in outcomes. Primary and secondary outcomes were reported clearly and a range of health-related quality-of-life outcomes was presented. Three separate analyses were undertaken: intention-to-treat, complete case and analysis of covariance, which adjusts for baseline imbalances between the groups. The results of all three were presented.
Costs:
The resource use was accurately collected, alongside the clinical trial, and service use was clearly reported in a table. No perspective was reported, so it is not clear if all the relevant costs were included. Only the resources of the hospital were considered, so the analysis appears to have been undertaken from a hospital perspective. The unit costs were not reported. The time horizon was less than one year, so discounting was not conducted and not necessary. The price year was not reported, which may hinder future reflation exercises.

Analysis and results:
No summary cost-effectiveness outcome was derived. The uncertainty was not investigated, only statistics demonstrating the variability in the sampling uncertainty were presented. Multiway deterministic sensitivity analysis or probabilistic sensitivity analysis, to explore the overall parameter uncertainty, could have quantified the uncertainty around the results. The authors stated that a limitation of their study was the loss of eight patients in the CBT group and one in the usual care group, who were referred to alternative treatments after randomisation. The intention-to-treat analysis imputed zero change for these patients, but their inclusion could have altered the results unfavourably. The authors stated that future studies should have more detailed screening of the willingness of patients to undertake CBT, and assessment of the suitability of CBT for them. Given the lack of information on usual care, it is difficult to assess the generalisability of the results.

Concluding remarks:
There were a few limitations to the study, so the authors’ conclusions should be considered with these in mind.

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