A tailored psychological intervention for anxiety and depression management in people with chronic obstructive pulmonary disease: TANDEM RCT and process evaluation

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Scientific summary

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Scientific summary

Background

Chronic obstructive pulmonary disease (COPD) is a major public health problem globally, and is associated with socioeconomic deprivation and with high morbidity and mortality. In the UK, about 1.2 million people have diagnosed COPD, incurring more than 140,000 hospital admissions, over a million bed-days and about 30,000 deaths each year. The condition costs the NHS around £1.9B annually.

Symptoms of anxiety and depression are common comorbidities in people with COPD, with a prevalence of 30–40% or higher. These mood disorders may reduce people's ability to manage their COPD effectively, reduce physical activity capacity and make patients susceptible to exacerbations (i.e. acute worsening of the condition), hospital admissions and re-admissions.

There is robust evidence that pulmonary rehabilitation (PR), which is a multidisciplinary exercise and education intervention, improves health-related outcomes, including functional exercise capacity, quality of life and emotional well-being, and reduces breathlessness in COPD. National and international COPD guidelines recommend offering PR to patients. Unfortunately, more than one-third of people referred to PR do not attend and only two-thirds of attendees complete the course. A recent Cochrane review concluded that psychological interventions, including cognitive–behavioural therapy (CBT), may improve depression in people with COPD, but the reviewers called for larger, more methodologically robust studies.

The current study was proposed in response to a National Institute for Health and Care Research (NIHR) Health Technology Assessment brief based on a systematic review that concluded that psychological interventions combined with exercise training resulted in clinically significant improvements in symptoms of anxiety and depression in COPD, compared with CBT alone. A more recent Cochrane review has concluded that a psychological therapy combined with a PR programme reduced depressive symptoms more than a PR programme alone.

Aims and objectives

The primary aim of the study was to evaluate a tailored psychological cognitive–behavioural approach (CBA) intervention [i.e. the TANDEM (Tailored intervention for Anxiety and Depression Management in COPD) intervention], which precedes, links into and optimises the benefits of attending an existing PR course, with the aim of reducing mild/moderate anxiety and/or depression symptoms in people with COPD and moderate to very severe airflow limitation.

Specific objectives

- To develop and refine the TANDEM intervention to develop a training programme for healthcare professionals who will deliver the programme, and to document the training programme in a manual.
- To undertake a randomised controlled trial of the TANDEM intervention to examine the effectiveness of the TANDEM intervention on clinical outcomes compared with usual care (i.e. guideline-defined care, including the offer of PR).
- To examine the affect of the TANDEM intervention (which is directed at patients) on carers (where appropriate).
- To determine the cost effectiveness of the TANDEM intervention from an NHS and Personal Social Services perspective.
- To conduct a process evaluation to assist interpretation of findings and inform the implementation of the TANDEM intervention if the trial results are positive.

Methods

Design

We carried out a pragmatic multicentre parallel-arm individual patient randomised controlled trial with an internal pilot, evaluating clinical effectiveness and health economics. A parallel process evaluation included assessing fidelity of intervention delivery. Co-primary outcomes were symptoms of anxiety and depression determined by the Hospital Anxiety and Depression Scale – anxiety (HADS-A) and Hospital Anxiety and Depression Scale – depression (HADS-D) at 6 months post randomisation. Participants were followed up for 12 months. There was full allocation concealment and baseline measures were collected before randomisation. Participants were inevitably aware of their allocation status, but all healthcare professionals were blind to allocation, as were the researchers who collected or analysed outcome measures.

Study participants were recruited from primary and secondary care and from referral to PR in 12 geographic areas in England.

Participants with chronic obstructive pulmonary disease

Inclusion criteria

- Patients who were willing to provide informed consent.
- Patients with a confirmed diagnosis of COPD and spirometry with moderate to severe airflow limitation (note that, following the internal pilot, this was extended to include very severe airflow limitation).
- Patients who were eligible for referral to PR.
- Patients with a Hospital Anxiety and Depression Scale (HADS) score at the baseline screening suggestive of mild to moderate anxiety or depression, or both (i.e. a subscale score from 8 to 15).

Exclusion criteria

- HADS scores suggestive of severe anxiety or depression.
- Patients who had received a psychological intervention in the last 6 months (note that patients on antidepressants/anxiolytics were not excluded).
- Patients who were to commence PR within 4 weeks.
- Patients with a comorbidity so severe that it would prevent engagement with the intervention/trial.
- Patients with insufficient fluency in English to complete the intervention or questionnaires (note that patients with literacy difficulties were not excluded).

Recruitment of carers

Participants were requested to identify a 'particular family caregiver or friend who helps them' for invitation to join a substudy examining the effect of the patient-directed TANDEM intervention on carers.

Randomisation

Computerised randomisation was conducted remotely by an independent statistician using a 1.25 : 1 ratio of intervention: control to account for clustering by facilitator.

The TANDEM intervention

The intervention was developed following the Medical Research Council's framework for developing complex interventions and Yardley's 'person-based approach'. The intervention consisted of a tailored, manualised intervention based on CBAs and self-management support. Therapy consisted of six to eight sessions that were delivered weekly, face-to-face, in participants' homes or in primary or secondary care

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settings, by experienced respiratory healthcare professionals (i.e. 'facilitators'). Between completing the face-to-face intervention and up to 2 weeks after completing PR, facilitators offered brief telephone support.

Facilitators were trained over 3 days (across 6 weeks) and were assessed on completion of training. Throughout intervention delivery, facilitators received regular supervision from an experienced CBT therapist.

Control arm participants

Control arm participants received usual care following local arrangements, including PR.

All participants also received informational resources from the British Lung Foundation (London, UK).

Outcome measures

In addition to our co-primary outcomes, we collected patient-reported outcomes at baseline and at 6 and 12 months using the following supervised self-complete questionnaires: Beck Depression Inventory II, Beck Anxiety Inventory, the St George's Respiratory Questionnaire, social integration and support, an adapted UK Time Use Survey, the Brief Illness Perception Questionnaire, smoking status and EuroQoL-5 Dimensions, five-level version (EQ-5D-5L). We collected information on medications and health and social care resource use via a modified Client Services Receipt Inventory. In addition, we collected information on medications and healthcare resource use from participants' general practitioners. PR attendance data were collected from local services at 12 months.

Data from carers

At baseline and at 6 and 12 months, we collected carer-reported outcomes using the Warwick–Edinburgh Mental WellBeing Scale and the Zarit Burden Interview (22 items).

Statistical analysis

Statistical analysis followed our published analysis plan. The primary analysis was by intention to treat, assuming that outcomes were missing at random. In sensitivity analyses, we tested this assumption by modelling the affect of differences between missing and non-missing outcomes on the estimated treatment effect for both co-primary outcomes. All outcomes other than smoking were analysed using a mixed linear regression model, with adjustment for baseline HADS-A and HADS-D scores, breathlessness, smoking status, NHS trust and (except for HADS scores) the measurement of that outcome at baseline. Analyses allowed for clustering by facilitator in the intervention arm by adjusting for a random effect of facilitator.

Economic evaluation

Intervention costs were calculated using a combination of data from patients' general practice records and a Client Service Receipt Inventory. General practice data acted as the primary source of information on health service contacts, and self-reported data were used as supplementary data. Health and social care utilisation were costed using NHS reference costs and unit costs of health and social care. We adopted a 'cost–utility' framework, with the incremental resource impact of TANDEM over usual care quantified from an NHS/Personal Social Services (PSS) perspective, and patient outcomes quantified as incremental quality-adjusted life-years (QALYs) gained. The QALYs gained over the 12-month follow-up were estimated, based on self-report, at baseline and at 6- and 12-month follow-up using the EQ-5D-5L. Health state utility scores applicable to the EQ-5D-5L were 'cross-walked' back to their equivalent three-level version values using a recommended algorithm. QALYs for each participant were quantified with respect to the entire 12 months' follow-up using the area under the curve method. Intervention cost effectiveness was evaluated with reference to the incremental net health benefit of TANDEM combined with usual care compared with usual care alone (expressed in QALY units) and estimated assuming a cost-effectiveness threshold of £20,000 per QALY gained. Uncertainty was addressed using cost-effectiveness planes and acceptability curves.

Adverse events

Adverse events (AEs) and serious adverse events were recorded and reported in accordance with the Data Monitoring Ethics Committee's and sponsors' requirements, and following the standard operating procedures of the Joint Research Management Office for Barts Health NHS Trust (London, UK) and Queen Mary University of London (London, UK).

Process evaluation

The process evaluation adopted a mixed-methods design, incorporating qualitative and quantitative methods. We conducted 49 one-to-one qualitative interviews with the following four groups: (1) participants and carers, (2) TANDEM facilitators, (3) TANDEM facilitators' clinical supervisors and (4) stakeholders. Data were analysed thematically using an inductive approach and constant comparison. Analysis was a reflexive, iterative process involving review and multidisciplinary discussion. NVivo 12 software (QSR International, Warrington, UK) was used to assist the organisation and analysis of the data. A thematic narrative was constructed for each group.

Fidelity

With participant permission, all TANDEM intervention sessions were recorded digitally. A bespoke fidelity treatment delivery framework, which included the Cognitive First Aid Rating Scale, and an intervention-specific adherence measure, which included assessment of whether or not core components and topic-specific sessions were delivered, were used to assess therapeutic competency. One or two entire TANDEM intervention courses were assessed per facilitator. Coding was conducted by a psychologist, and seven cases (19.4%) were duplicate coded by our co-applicant health psychologist for quality assurance.

Results

Forty-nine per cent (2191/4491) of potentially eligible participants approached agreed to be contacted by the research team, with 48% (*n* = 1062) of participants formally assessed for eligibility. Of these participants, 441 (41.5%) were eligible, 426 were recruited to the study and 423 were randomised and analysed (intervention, *n* = 242; control, *n* = 181). HADS-A and HADS-D primary outcome data were available for 205 (85%) and 204 (84%) of participants randomised to the intervention, respectively, and for 164 (90%) of control participants. At 12 months. HADS-A and HADS-D secondary outcome data were available for 191 (79%) and 190 (79%) of participants randomised to the intervention and for 150 (83%) and 152 (84%) control participants. More participants withdrew from the intervention arm (*n* = 16, 6.6%) than from the control arm (*n* = 5, 2.8%) and there were more deaths in the intervention arm than in the control arm [13 (5.4%) vs. 3 (1.7%), respectively]. No deaths or other AEs were associated with the study.

Of the participants recruited, the median age was 69 (interquartile range 62–75) years, 50% (*n* = 213) were male and 42% (*n* = 176) lived alone. Only 40 (9.5%) participants were working and most (329/416, 79%) had completed full-time education by age 16 years. Overall, participants' COPD was disabling. Participants has significant breathlessness and low health-related quality-of-life scores, and 78 (18%) participants were too breathless to leave the house. Comorbidities were common and 30% (*n* = 128) of participants were still smoking.

Forty-three carers were recruited to the substudy. Twenty-four carers cared for intervention participants and 19 carers cared for control participants.

A total of 196 (81%) intervention participants received at least two sessions of the TANDEM intervention (i.e. the predefined minimum dose) and 136 (56%) intervention participants received six or more sessions.

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Clinical effectiveness results

At 6 months, the mean difference between the two study arms for anxiety [HADS-A −0.60, 95% confidence interval (CI) −1.40 to 0.21] and depression (HADS-D −0.66, 95% CI −1.39 to 0.07) was less than the minimal clinically important differences for these scales, and the 95% CIs ruled out clinically important effects on these outcomes. As in the primary outcome analysis, CIs for HADS-A and HADS-D at 12 months, and for all other questionnaire scores at 6 and 12 months, ruled out clinically important effects of the intervention.

Overall, smoking prevalence fell across the 12 months of the study, but there was no discernible difference between participants in the two study arms (odds ratio at 12 months for intervention vs. control 0.90, 95% CI 0.54 to 1.50) and around one-quarter of participants were still smoking at 12 months.

In the intervention arm, 122 (50%) participants were referred to PR, 121 participants attended at least one PR session and 73 (30%) participants completed the course. In the control arm, 88 (49%) participants were referred, 77 (43%) participants attended at least one PR session and 54 (30%) participants completed the course.

No differences were seen in outcome measures at 6 or 12 months for carers of participants in the study arms.

Health economics results

The economic evaluation of the TANDEM intervention suggested that the intervention is highly unlikely to be a cost-effective means of improving mental health outcomes in patients with COPD. After jointly considering incremental effects on costs and QALYs, and allowing for sampling uncertainty in the trial data, there was a high degree of certainty that the TANDEM intervention would not offer sufficient value for money based on cost-effectiveness criteria routinely applied to assess whether or not new healthcare technologies should be funded by the NHS.

Process evaluation results

Respiratory health professionals recruited to train as TANDEM facilitators recognised the need for holistic care for patients with COPD and were keen to develop knowledge and skills in addressing psychological health needs. The health professionals valued developing skills in providing psychological care for patients using a collaborative decision-making approach, but the health professionals did not feel able to do this without training and found it challenging initially.

The TANDEM intervention was generally well received by patients. Developing a therapeutic alliance was considered necessary by all interviewees; however, it took time to build rapport and the complexity of the therapeutic task was highlighted in patient, carer and facilitator interviews. The fidelity study found that the TANDEM intervention was delivered with therapeutic competency and that key tasks were delivered with fidelity.

Most interviewees felt that it would not be possible to deliver the TANDEM intervention as part of usual care because of staff and financial resource constraints.

Conclusions

The study demonstrated that it is possible to train healthcare professionals to deliver a CBA competently and with fidelity, and that, overall, the TANDEM CBA intervention appeared to be popular with both those receiving it and those delivering it. However, the intervention did not improve mood or health status, nor did it improve any of our important secondary outcomes, such as uptake and completion of PR, healthcare resource use and smoking cessation.

Recommendations for further research

- Given the considerable unmet need, alternative interventions to support people with advanced COPD and symptoms of anxiety and depression are required.
- It is worth exploring whether or not an intervention like the TANDEM intervention might be effective for people with COPD much earlier in their disease trajectories.
- We suggest evaluating the incorporation of development of cognitive–behavioural skills as part of undergraduate and postgraduate training for a variety of different healthcare professionals, with the aim of integrating this approach into routine healthcare delivery for long-term conditions.

Trial registration

This trial is registered as ISRCTN59537391.

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This report

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