TANDEM Study Summary

TANDEM (Tailored intervention for ANxiety and DEpression Management in COPD): A tailored, psychological intervention for mild to moderate anxiety or depression in people with chronic obstructive pulmonary disease (COPD) HTA 13/146/02

Introduction:
Many people with COPD are affected by anxiety and/or depression. Anxiety is associated with lower levels of self-efficacy, persistent smoking, impaired health status and worse physical functioning and both anxiety and depression are associated with an increased likelihood of exacerbations, more frequent and longer hospital readmissions, and a reduced survival. Although depression is common in COPD it is widely reported as being under recognised and undertreated.

Guidelines for the management of anxiety and depression in those with physical health conditions recommend psychological treatment, pharmacological treatment or a combination. Cognitive behavioural therapy (CBT) is an evidence-based treatment, which improves anxiety and depression in a number of physical conditions including COPD. Pulmonary rehabilitation (PR) is an evidence based, guideline recommended intervention for people with COPD, which is also associated with a reduction in depression and anxiety. However referral to, uptake and completion of PR remains low.

We have developed a new intervention called TANDEM which is based on cognitive behavioural principles and is delivered by a specially trained respiratory health care professional (HCP) who is already very familiar with COPD. TANDEM optimises the potential synergy between a psychological intervention and pulmonary rehabilitation and is designed to precede routine pulmonary rehabilitation in people with mild to moderate anxiety and/or depression and moderate to severe COPD who are eligible to be offered a referral to PR.

Aims of the study:
To pilot and then fully evaluate the clinical and cost-effectiveness of the TANDEM intervention.

Phases:

Phase I: a pre-pilot study to inform intervention development. Phase I results showed that patients found the intervention beneficial.

Quote from patient: ‘I then realized I felt within so much better, which made my breathing better, which made me feel better. Whereas it became an upward spiral slightly rather than downward spiral. And it’s all because of people like you

Phase II: a pilot/ feasibility study to inform feasibility of patient recruitment, delivery of intervention and progression to a full randomised controlled trial (RCT) (recruitment target, n=45).

Phase III: Main RCT (recruitment target, n=430).

Methods:
Multicentre (London and the Midlands) pilot, pragmatic, randomised controlled trial (RCT) and parallel process evaluation of 45 participants (recruitment: June to November 2017), followed by a full scale RCT. The main RCT (commencing Spring 2018) will recruit between 385 and 430 participants - dependent on whether or not the pilot study remains an internal pilot. All participants will be randomised to routine referral to PR proceeded by TANDEM or routine referral to PR alone (1.25:1 intervention: control).

Inclusion criteria: adults with a confirmed diagnosis of COPD, post bronchodilator FEV1:FVC ratio <70%, moderate or severe COPD on spirometry, FEV1 30-80% predicted, probable mild or moderate anxiety (Hospital Anxiety and Depression Scale Anxiety Subscale (HADS-A) scores ≥8 to ≤15) and/or probable mild or moderate depression (HADS-D scores ≥8 to ≤15), and eligible for referral to their local PR service.

Intervention: TANDEM a tailored, manualised, one to one intervention delivered in participants’ own homes, doctors surgery or community clinic (at their preference) for 30-40 minutes per week over 6-8 weeks by trained respiratory HCPs.

Co-primary outcome (specified by funder): HADS-A and HADS-D at 6 months follow up (also collected as a secondary outcome at 12 months). Other outcomes collected at six and 12 months: Beck Depression Inventory (BDI-II), Beck Anxiety Inventory (BAI), Illness Perception Questionnaire (B-IPQ), health related quality of life (SGRQ), smoking status, social engagement (HEQI social engagement subscale), health-related quality of life measured with the EQ-5D-5L, and information on the use of health and social care services from the Client Service Receipt Inventory and primary and care administrative data. We will also measure uptake and completion of routine PR.

The study sponsor is Queen Mary University of London and has received all UK research governance approvals.

This project is funded by the National Institute for Health Research Health Technology Assessment programme (project number 13/146/02) The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Health Technology Assessment programme, NIHR, NHS or the Department of Health.

To get involved please see overleaf
ERS Special NEWSLETTER

TANDEM pilot study open to recruitment!

2017 has been a big year for the TANDEM study. We have seen the success of the pre-pilot study and more recently the start of the pilot study.

Current Pilot Study Centres (GP practices & hospitals) in:
- Leicester
- Loughborough
- East London
- West London

Potential New Centres for Main trial:
- South London
- Coventry
- South Warwickshire
- Ipswich and East Suffolk
- Birmingham and Sandwell

Pilot Recruitment Update

TANDEM Pilot Recruitment (target n = 45)

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<tr>
<th>Month</th>
<th>Total recruited</th>
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We are recruiting TANDEM facilitators now

- Are you a respiratory healthcare professional?
- Would you like to learn a new psychological approach to COPD?
- Can you appreciate the psychological impact of living with a chronic illness such as COPD and do you want to help?

If yes, come and join an exciting team of researchers helping to improve the lives of people living with COPD.

To find out more please contact: TANDEM Project Manager Dr Ratna Sohanpal on 02078822492 or email r.sohanpal@qmul.ac.uk

Patient and Public Involvement (PPI)

Some of our Patient & Carer Advisors

Our patient and care advisors are helping the study with advice on:
- Trial Protocol
- Intervention Design
- Patient Approach and Recruitment
- Data Collection
- Dissemination of Study Results

Meet the TANDEM Team

Professor Stephanie Taylor
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