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.

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Special NEWSLETTER: CRN North Thames Primare Care Research Conference 29 Nov’17

November 2017

Twitter: @tandemcopd
Website:
ISRCTN registration: 59537391

TANDEM pilot recruitment target achieved!

2017 has been a big year for the TANDEM study. We have seen the success of the pre-pilot study, pilot study is progressing well and we are getting ready for the main trial starting May 2018.

   - The Lower Clapton Group Practice
   - The Sorsby Medical Practice
   - The Masharani Practice
   - The Surgery @ Aylestone

2. Potential New sites for Main trial: (GP Practices & Hospitals)
   - East, West & South London
   - Coventry
   - South Warwickshire
   - Birmingham and Sandwell
   - Leicester
   - Loughborough
   - Reading

Pilot Recruitment Achieved
Recruited (n = 45); Screened (n=89)

Inviting primary care practices to collaborate with us in the main trial

- Reimbursement provided by NHS Service Support costs
- Opportunity for your patients to participate in a clinical trial to help improve their care
- Primary care staff will be supported fully by the TANDEM research team
- Certificate to support recruitment will be provided by the research team

If your GP practice would like to collaborate, please contact:
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TANDEM Project Manager
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We are recruiting TANDEM facilitators now in London

- Are you a healthcare professional familiar with managing patients with COPD?
- 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. Reimbursements provided for attendance in training and being facilitator in study.

To find out more please contact:
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Meet the TANDEM Project Leads

Professor Stephanie Taylor
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Collaboration for Leadership in Applied Health Research and Care
North Thames