

## 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 evaluate the clinical and cost-effectiveness of the TANDEM intervention.

### Study design:

Randomised Controlled Trial. Recruitment target, n=430.

**Quote from study participant in pilot study:** *'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'*

### Methods:

Multicentre (London, outer London and the Midlands) pragmatic, randomised controlled trial (RCT) and parallel process evaluation. All participants will be randomised to routine referral to PR preceded by TANDEM intervention 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 to very severe COPD on spirometry, FEV1<80% predicted, probable mild or moderate anxiety (Hospital Anxiety and Depression Scale Anxiety Subscale (HADS-A) scores  $\geq 8$  to  $\leq 15$ ) and/or probable mild or moderate depression (HADS-D scores  $\geq 8$  to  $\leq 15$ ), and eligible for referral to PR at their local PR service. **Participating practices only help identify potential participants - the TANDEM Team does everything else.**

Intervention: TANDEM a tailored, manualised, one to one intervention delivered in participants' own homes, primary care or community clinic (at their preference) for approx. 40 minutes per week over 6-8 weeks by trained respiratory HCPs (called 'Facilitators').

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. **Participating practices only help identify potential participants - the TANDEM Team does everything else.**

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 (NIHR) Health Technology Assessment programme (project number 13/146/02) The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

**To get involved please see overleaf or complete the contact sheet**

# tandem



working together against COPD

## Special NEWSLETTER: BJGP Conference 29 March 2019

### TANDEM main trial ongoing

Twitter: @tandemcopd  
 Website: <http://www.tandemcopd.co.uk>  
 ISRCTN registration: 59537391

The TANDEM main trial started in July 2018 and is progressing well.

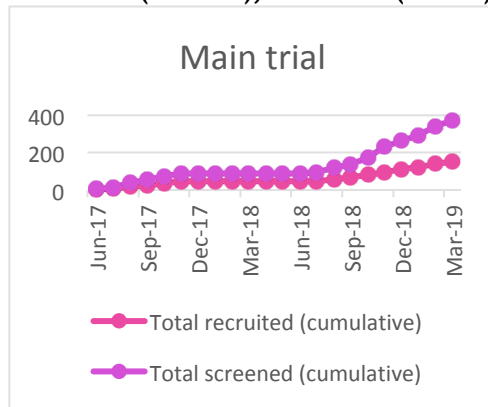
The current recruitment period is to July 2019 with likely extension until Jan 2020. PLEASE GET INVOLVED!

#### Study sites in Main trial: (GP Practices & Hospitals)

- ◆ Homerton University Hospital NHS Foundation Trust
- ◆ NHS City and Hackney CCG
- ◆ Imperial College Healthcare NHS Trust
- ◆ NHS North West London CCG
- ◆ Guy's and St Thomas' NHS Foundation Trust
- ◆ King's College Hospital NHS Foundation Trust
- ◆ NHS South London CCGs
- ◆ University Hospitals of Leicester NHS Trust
- ◆ Leicestershire Partnership NHS Trust
- ◆ Leicestershire CCGs
- ◆ Sandwell and West Birmingham Hospitals NHS Trust
- ◆ South Warwickshire NHS Foundation Trust
- ◆ University Hospitals Coventry and Warwickshire NHS Trust
- ◆ NHS Coventry and Rugby CCG
- ◆ Berkshire Healthcare NHS Foundation Trust
- ◆ Southern Health NHS Foundation Trust
- ◆ North Bristol NHS Trust

#### Main trial recruitment

Recruited (n = 153); Screened (n=372)



Inviting primary care practices (within NHS City and Hackney CCG, North West London CCG or South London CCG) to collaborate with us in the main trial:

- Full reimbursement for involvement provided
- 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:

Dr Ratna Sohanpal  
 TANDEM Project Manager  
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#### We are recruiting TANDEM facilitators 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.

New TANDEM training dates are 7, 8 May 2019 and 14 June 2019

Reimbursements provided for attendance in training and being facilitator in study.

To find out more please contact:

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#### Meet the Project Leads



Professor Stephanie Taylor  
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