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**PARTICIPANT INFORMATION SHEET**

**If you would like a large print version of this information sheet please contact 0207 882 2492**

You are invited to take part in a lung research study for patients with Chronic Obstructive Pulmonary Disease (COPD); also known as chronic bronchitis or emphysema.

You have been invited because your healthcare professional has referred you for a pulmonary rehabilitation programme.

Before you decide if you want to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

**1. What is the purpose of the study?**

We know that having COPD can affect many aspects of your life; breathing difficulties can limit your day-to-day activities, and can make you feel worried (anxious) or feel low (depressed).

Our study looks at whether a new TANDEM approach, which involves one-to-one sessions provided by a trained respiratory healthcare professional, before going to pulmonary rehabilitation, helps you feel better both physically and emotionally.

The sessions are based on a Cognitive Behavioural approach. This means that the professional will talk to you about your current problems, how they make you feel and together find ways to help you deal with your problems in a positive way and improve your overall health.

**2. What will happen if you decide to take part in the study?**

**Appointment 1 (& 2): To discuss study eligibility and participation with TANDEM Researcher**

If you express an interest in joining the study, you will be contacted by a TANDEM study Researcher who will arrange an appointment to meet with you.

At this appointment we will assess whether you are eligible for the study. You will answer a short questionnaire to assess your current well-being and do a simple hand-held breathing test (called spirometry) to check your lung health. The meeting may last about 30 minutes. With your permission, we will send a copy of these results to your GP.

If you meet the study’s eligibility criteria you will have the opportunity to ask any further questions about the study to the researcher before deciding whether or not you would like to take part. If you agree, we will ask you to sign a consent form to confirm your participation in the study. If you would like a little longer to consider taking part, the TANDEM Researcher will arrange a follow up appointment a few days later (Appointment 2).

After giving consent, we will ask you to complete a further questionnaire to find out more about your health and well-being.

You will not be examined, you will not be given any medicines and we will not be taking any blood samples.

**Which study group will you be assigned?**

To test the TANDEM approach, we need to compare people who receive the TANDEM sessions with similar people who receive usual treatment. To do this we will divide people into 2 groups **by chance** and the results are then compared between the two groups. The groups are uneven so you will have a slightly higher chance of being in the TANDEM group. We will inform you which group you will be in at the end of this appointment.

**Appointments 3 & 4 with TANDEM researcher**

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| --- | --- |
| You will be involved in the study for 1 year in total. The TANDEM Researcher will arrange to meet with you at 6 and 12 months. At these visits we will: * Ask you to complete a questionnaire to assess your health and well-being which will take about 30-40mins.
* Ask you about your medication use and if you have had any hospital admissions in the last 6 months and over the course of the study. If you agree we can contact your GP practice/hospital clinic to collect this information
 | http://www.independentnurse.co.uk/article-images/73632/iStock_000026655738Large_popup.jpg |

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* Ask you to complete a questionnaire to assess your health and well-being which will take about 30-40mins.
* Ask you about your medication use and if you have had any hospital admissions in the last 6 months. If you agree we can contact your GP practice/hospital clinic to collect this information.

We will be able to assist you if you need any help with completing the questionnaire.

**We may ask you for an interview (Appointment 5)**

We may invite you to take part in an interview to ask about your experience of taking part in the TANDEM study and how it might be improved. If you decide to take part, the TANDEM Researcher will arrange this with you. The interview will be audio-recorded which may last about 40 minutes but you can rest or take a break at any time if you wish.

**3. What will happen if you are in the TANDEM group?**

**Appointment with TANDEM Facilitator**

If you are in the TANDEM group a respiratory healthcare professional (TANDEM Facilitator) will arrange an appointment to meet with you. This will be the first of between 5 and 8 one-to-one sessions, depending on your individual needs. Each session will be about 30-40 minutes. It will involve talking about how you manage your COPD, how it makes you feel and if there are ways of doing things that might help you feel better both physically and emotionally. With your permission, the sessions may be audio-recorded so that we can understand whether the one-to-one sessions was delivered as planned by the respiratory health professional. This will help us to improve the course for other people with COPD.

After completing the one-to-one sessions, you may decide to attend the pulmonary rehabilitation programme. If you do the TANDEM Facilitator will follow you up with weekly telephone calls lasting about 10-15minutes to see how you are getting on. With your permission, we will also send a case summary letter of your progress to your GP and your respiratory healthcare professionals.

**4. What will happen if you are not in the TANDEM group?**

You will continue to receive your usual care from your GP practice, the hospital or your respiratory healthcare professional.

**5. What will happen to the audio-recordings?**

The audio-recordings will be typed up later in full. The recordings or the typed documents will not be seen or heard by anyone other than the study team and will be kept securely. You may read the document or listen to the recordings if you wish to do so.

**6. Invitation for a Caregiver to join the study**

If there is someone who helps and supports you at home (a family member or friend), the TANDEM Researcher will ask to approach them and invite them to take part in the study as well. We will not speak to anyone without your consent.

If they decide to take part, the TANDEM Researcher will ask them to sign a consent form. Once consent is given, we will ask them to complete a questionnaire. We will ask them to complete further questionnaires at 6 and 12 months. It is up to them if they would like to take part or not. We may also invite them to take part in an interview so we can understand their viewpoints as well.

**7. Where will the appointments with the TANDEM researcher or TANDEM facilitator take place?**

All appointments with the researcher or facilitator will be decided with you at a time and place that is convenient to you. This may be your home, GP practice or chest clinic whichever you prefer. We will pay for your travel expenses if you choose to meet at the clinic.

**8. What are the possible benefits of taking part?**

We cannot promise the study will help you, but the information we collect and the feedback you provide will help us to improve the care of other people with COPD in future.

**9. Do you have to take part?**

No, it is up to you to decide whether or not to take part. If you would like to take part you can let us know by returning the reply slip on the accompanying letter, by phoning or by emailing the TANDEM Researcher. They will be happy to provide you with any further information and answer any questions you may have.

**10. Can you change your mind about taking part?**

Yes. You are free to withdraw from the study at any time and without giving a reason. This will not affect the standard of care you receive now or in the future. If you choose to withdraw from the study, we will ask you if you would like us to destroy all the information we collected from you. All information collected will be destroyed in line with the Data Protection Act.

**11. Are there any risks of taking part?**

No. We do not foresee any risks if you decide to take part in the study, however, during the one-to-one sessions or interview if you say something that may indicate any risk to you or others, we will contact your GP or healthcare professional so appropriate arrangements can be made for your care.

**12. Will taking part in the study be kept confidential?**

Yes. Your name or personal details will not be known to anyone other than the study team and no information will be given to anyone outside of the study team. Your responses will be treated confidentially and will remain anonymous by giving a unique TANDEM study ID. You will not be personally identifiable in any way from the information you provide. The information will be treated as strictly confidential and will be securely kept at (XXX Queen Mary University of London or other site name XXX) and managed in accordance with the Data Protection Act and all necessary clinical and research governance procedures. At the end of the study all the audio-recordings will be destroyed.

We will ask for your written permission if we can share the information you provide, anonymously to other researchers, to support other research in the future.

Relevant sections of your medical notes and data collected during the study, may be looked at by individuals from Queen Mary University of London, from regulatory authorities or from the NHS Trust, where it is relevant to your taking part in this research. We will ask your permission for these individuals to have access to your records

**13. What will happen to the results of the study?**

The results of the study will be used to improve the care of people with COPD. We will write a report for the National Institute for Health Research (part of Department of Health) which is funding the study. We will also publish the results in medical journals. You will not be identified in any of the reports or publications. We will also send all participants a brief report of the findings of the study.

**14. Who has reviewed the study?**

This study has been reviewed and approved by London - Queen Square Research Ethics Committee. The reference number of the review is 17/LO/0095.

**15. Who is funding the study?**

The TANDEM study is funded by the National Institute for Health Research’s Health Technology Programme **13/146/02.**

**16. What happens if something goes wrong?**

Queen Mary University of London has insurance to protect research participants. Your wellbeing will always be our priority. We believe that this study is safe and do not expect you to suffer any harm or injury because of your participation. However, Queen Mary University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated. In such a situation, you will not have to prove that the harm or injury which affects you is anyone’s fault. These special compensation arrangements apply where harm is caused to you that would not have occurred if you had not taken part in the study. These arrangements do not affect your rights to pursue a claim through legal action.

As an independent alternative, you may contact your local Public Health department or your professional organisation for advice. However, we would aim to deal with any complaints or problems to your satisfaction.

**If you have a complaint, please contact:**

The Complaints Officer, c/o Chief Operating Officer for the Barts and The London, School of Medicine and Dentistry Wardens Office, 32 Newark Street, Whitechapel, London, E1 2AA

**17. What if you have some questions about the study?**

You can contact:

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| TANDEM Researcher as per site XXX | Site PI or CI Professor Stephanie Taylor  | Professor Hilary Pinnock |
|  | Chief Investigator | Co-Chief Investigator |
|  | 02078822495 | 0131 650 3237 |
|  | s.j.c.taylor@qmul.ac.uk | Hilary.Pinnock@ed.ac.uk |
|  | Centre for Primary Care and Public Health58 Turner StreetLondonE1 2AB | Usher Institute for Population Health Sciences and Informatics, University of Edinburgh Medical School, Teviot PlaceEdinburgh, EH8 9AG |

**Thank you for taking the time to read this information.**