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**PARTICIPANT INFORMATION SHEET – PEOPLE LIVING WITH COPD**

**Study title:** Co-design of a very brief behavioural change approach to assist healthcare professionals discuss pulmonary rehabilitation with people with COPD

**Invitation Paragraph:** You are being asked to take part in a research study. Before you decide, 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. Please get in touch if there is anything that is not clear or if you would like more information email: chat\_study@brunel.ac.uk or telephone 01895 265949. Take time to decide whether or not you wish to take part. Thank you for reading this.

**What is the purpose of the study?** Pulmonary rehabilitation (called rehab for short) is an exercise and education programme for people with lung conditions. It improves breathlessness and quality of life and results in fewer and shorter hospital admissions. Despite this, only a small number of people are referred for rehab and not everyone who is referred, agrees to attend the programme.

In the past, there were similar problems with the referral of smokers to stop smoking services. However, a way of changing people’s behaviour, called Very Brief Advice, has increased the number of people referred for support and who stop smoking. Very Brief Advice, which is widely used in the NHS, involves an online training course for healthcare workers that teaches them how to discuss a referral to stop smoking services with smokers. Changing Very Brief Advice so it can be used by healthcare workers to discuss a rehab referral with people with COPD may be a way to increase the number of people who agree to be referred to rehab.

The aim of this one-year study is to work with people with COPD, their carers and family and healthcare workers to change Very Brief Advice so it can be used by healthcare workers to discuss a rehab referral with people with COPD.

**Why have I been invited to participate?** A total of 16 people with lung disease and 16 healthcare professionals will take part in the study. You are being invited to take part because you have expressed an interest in the study, are 18 years or older, live with COPD or emphysema and can provide informed consent

**Do I have to take part?** As participation is entirely voluntary, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to complete an online screening form to check whether you’re eligible to take part in the study. If you are ineligible to take part in the study, all of the information you submitted on the screening form will be deleted once we let you know that we can’t enrol you in the study. If you are eligible to take part, you will be asked to complete an online consent form to make sure you are satisfied with all aspects of the study.

If you do not use the Internet, a researcher will telephone you to complete the screening form over the phone. This will involve the researcher reading the screening questions to you and noting your response. After this, if you are eligible to take part, a researcher will send you the consent form and stamped addressed envelope. You can choose to complete the consent form by hand and return it in the stamped addressed envelope, or a researcher will telephone you and complete the consent form on your behalf. This will involve the researcher reading each point on the consent form to you. You can indicate whether or not you agree with each point, the researcher will record your response and send you a copy of the completed form. This process will be witnessed by a second researcher.

If you decide to take part you are still free to withdraw at any time without detriment or without having to give a reason. However, it will not be possible to extract your interview data if they have been anonymised (one month after your interview), nor will it be possible to extract your data from the workshop or focus groups due to their group nature.

**What will happen to me if I take part?** This study will last 18 months and participants will be involved on two to five occasions over 18 months. The study will involve the following:

* **Interview:** You will be invited to attend an online interview with a member of the research team. If you don’t use the Internet, the researcher can telephone you or visit you in your home to do the interview. You can invite your carer or family member to the interview. The purpose of the interview is to ask your opinion about using how healthcare professionals should discuss rehab with their patients. The interview will last 30-40 minutes and you will be offered a comfort break after 30 minutes. The interview will be audio-recorded. If the interview is done online, the audio-recording will be transcribed by the research team or an external company. If the interview is done by telephone, the audio-recording will be sent to an external company by email or file transfer to be transcribed. You can indicate whether or not you give permission for this by way of the consent form. Once transcribed, your name and organisation will be anonymised and the audio-recording deleted.
* **Two workshops** **(optional):** You do not have to do this part of the study, it is optional. You can indicate whether or not you want to be selected to be involved in the consent form. Two people with COPD, three healthcare professionals who took part in the interviews will be invited to take part in two online workshops. You can invite your carer or family member to the interview. During the workshop, you and the rest of the group will work with the research team to discuss the results of the anonymised interviews and design Very Brief Advice for rehab. The two online workshops will last for one to two hours and a comfort break will be offered after one hour. The workshops will be audio-recorded and transcribed by the research team or external company (the audio-recording will be sent to an external company by email or file transfer). You can indicate whether or not you give permission for an external company to transcribe your interview by way of the consent form. Once transcribed, your name and organisation will be anonymised and the audio-recording deleted.
* **Two focus groups:** You will be invited to attend an online focus group involving eight people, which will be facilitated by the research team. If you don’t use the Internet, a member of the research team will telephone you instead. You can invite your carer or family member to the focus group. The purpose of the focus group is to allow the research team to present the results of the interviews and ask for feedback. The focus group will last one hour with a comfort break after 30 minutes. The focus group will be audio-recorded. If the focus group is done online, the audio-recording will be transcribed by the research team. If done by telephone, the audio-recording will be sent to an external company by email or file transfer to be transcribed. You can indicate whether or not you give permission for this by way of the consent form. Once transcribed, your name and identifying details will be anonymised and the audio-recording deleted.

You are encouraged to be open and honest about their opinions during the study.

As a gesture of thanks, you will be given a £25 voucher for taking part in the interview and two focus groups. Participants who take part in the two co-design workshops will be given an additional £25 voucher.

**Are there any lifestyle restrictions?** There are no lifestyle restrictions.

**What are the possible disadvantages and risks of taking part?** This is a low-risk study. Care will be taken to minimise any distress during the study and the following distress protocol will be used to manage any distress that arises:

* If you become upset during any study activity e.g. consent, interview, workshop, focus group, the researcher will first offer to pause, postpone or stop the activity and advise again that your participation is voluntary. In the case of severe distress, you will be encouraged to share their feelings with a member of your healthcare team. The researcher will offer to contact your healthcare team on your behalf. We anticipate that distress caused by the research will be infrequent and is likely to reflect the presence of COPD and not the research processes.

**What are the possible benefits of taking part?** This study does not involve any treatment and people who take part are unlikely to benefit from taking part. As a gesture of thanks, you will be given a £25 voucher for taking part in the interview and two focus groups. Participants who take part in the two co-design workshops will be given an additional £25 voucher.

**What if something goes wrong?** If you wish to make a complaint about any aspect of the way you have been approached or treated during the course of the study, you can contact the research team or the research office. Details of how to do this are on page 6. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it.

**Will my taking part in this study be kept confidential?** All data will be handled in accordance with the Data Protection Act (2018), the EU General Data Protection Regulation (GDPR) and the conditions of the research ethics committee. All study information will be kept strictly confidential and saved in secure, user-restricted, password-protected files on a Brunel University London server. Data will be stored for 10 years in line with Brunel University London policy.

Interviews, focus groups and workshops will be audio-recorded and transcribed. The transcriptions will be checked for accuracy, anonymised and all reference to participant’s names and organisations will be removed. The audio-recordings will then be deleted.

With your permission, we may use anonymised quotes from the interview and focus group which will include your age and rehab experience and lung. An example of this is: *“I found pulmonary rehabilitation helpful” 75 years, completed rehab, person with COPD.* You can indicate whether or not you give permission for this by way of the consent form.

If during the course of the research evidence of harm or misconduct come to light, then it may be necessary to break confidentiality. We will tell you at the time if we think we need to do this, and let you know what will happen next.

Any information about you which leaves the University will have all your identifying information removed. With your permission, anonymised data will be stored and may be used in future research – you can indicate whether or not you give permission for this by way of the consent form.

**Will I be recorded, and how will the recording be used?** The interview, focus groups and workshop will be audio-recorded (on Microsoft Teams for online interviews/workshop or an audio-recording device if done by telephone or in your home) and transcribed. Once the transcriptions have been checked for accuracy and anonymised, the audio-recordings will be deleted. Both recordings and transcriptions will be saved in secure, user-restricted, password-protected files on a Brunel University London server.

**What will happen to the results of the research study?** The results of the study will be shared with you at the end of the study by email or letter – you can indicate your preference for hearing about the study in the consent form. The study results will be published in a research journal, presented at a research conference and shared on the study website and will lung disease charities and healthcare professional societies. The research team will then investigate the feasibility of using Very Brief Advice for rehab in the NHS, and whether people find it acceptable.

**Who is organising and funding the research?** This study is organised by Dr Claire Nolan, Brunel University London. The study sponsor is Brunel University London. The study is funded by a National Institute for Health and Care Research Advanced Fellowship.

**What are the indemnity arrangements?** Brunel University London provides appropriate insurance cover for research which has received ethical approval.

**Who has reviewed the study?** The College of Health, Medicine and Life Sciences Research Ethics Committee has reviewed this study.

**Research Integrity:** Brunel University London is committed to compliance with the Universities UK [Research Integrity Concordat](http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pdf). You are entitled to expect the highest level of integrity from the researchers during the course of this research.

**Contact for further information and complaints**

**Researcher name and details:**

Dr Claire Nolan │ claire.nolan@brunel.ac.uk │ 01895 265949

**For complaints, Chair of the Research Ethics Committee:**

Professor Louise Mansfield │Louise.Mansfield@brunel.ac.uk

If you choose to take part in the study, you will be given a copy of the information sheet and signed consent form to keep.

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