



How you can support someone to take part in a study to find treatments for coronavirus/COVID-19

Date:

Hello,

I'm writing to let you know how you can support someone taking part in a research study to help find treatments for coronavirus / COVID-19.

The study is called PRINCIPLE and it is run by the University of Oxford. It aims to find treatments for people with symptoms of COVID-19, and who are aged 65 years and over, or aged 50-64 with underlying health conditions. PRINCIPLE is supported by the UK government's Chief Medical Officer as a national priority study to find possible treatments for COVID-19.

People can get more information and sign up by telephoning 0800 138 0880 or at www.principletrial.org. There, they can also download a detailed patient information leaflet and a shorter summary that explains the study. All participants should understand the study before agreeing to take part. They will be able to nominate a 'Study Partner' (family, friend or carer e.g. care home staff) to help them with some of the things that will happen in the study. If you have any questions, please call/email the trial team, 0800 138 0880/principle@phc.ox.ac.uk.

Someone you know, who has already joined the PRINCIPLE study, may have asked you to be their Study Partner. Or you may know someone who is interested in joining and is thinking about asking you to be their Study Partner. The person joining the study has provided your contact details. Please see the Patient Information Sheet (<https://www.phctrials.ox.ac.uk/principle-trial/how-to-join>) for details about what will happen to personal data collected in the trial. The things that you could help with by being a Study Partner are described below:

What will happen in the study	How the Study Partner can help
People interested in joining the study will need to answer some questions on the telephone or online to check whether they are suitable, and provide consent.	<p>Help with accessing information about the study and calling the study team on 0800 138 0880, or completing the online form at www.principletrial.org.</p> <p>Provide your email and/or telephone number for the</p>

Platform Randomised trial of Interventions against COVID-19 in older peoPLE

Study Partner Letter Version/Date: v1.2 7th January 2021, EudraCT number:2020-001209-22

Professor Christopher Butler IRAS Project number: 281958 REC Reference number: 20/SC/058



	PRINCIPLE team to contact you as the Study Partner
Their GP, or a study nurse or doctor, will also check their medical notes to make sure it is safe for them to be in the study.	
Once signed up, the participant will either receive usual care, or usual care and a study medication which will be delivered from their GP, or directly from the study team. Some study medications are already widely used in the NHS and have been approved as safe for use in this study. We will test treatments that are well known and have been used for many years around the world, and already have a license for use in the UK. We will also assess less familiar treatments which might have beneficial effects for the treatment of COVID-19, but which do not yet have a license for use in the UK.	Help the participant to take the medication according to instructions in the medication pack.
If they can access the internet, for the next 28 days we would like them to complete an online diary of their symptoms and medical care they have received. The trial team may also phone them or their study partner after 2, 7, 14 and 28 days to get this information, especially if accessing the internet is difficult.	Help the participant with completing the online diary and/or by receiving telephone calls after 2, 7, 14 and 28 days (these can be timetabled with the study team). The Study Partner can also complete the diary or take the telephone calls themselves if the participant is unable to do this (for example if they feel too unwell).



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Clinical Trials Unit



Many thanks for thinking about supporting this study to find treatments for COVID-19, your help is much appreciated.

Yours Sincerely,

The PRINCIPLE Trial Team

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