

Participant Pictorial Information Sheet

Platform Randomised Trial of Treatments in the Community for Epidemic and Pandemic Illnesses

PRINCIPLE Trial

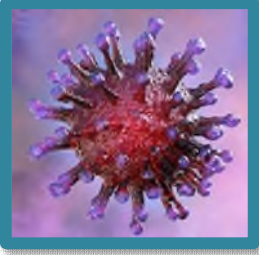

Platform Randomised Trial of Treatments in the Community for Epidemic and
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Pictorial Participant Information Booklet v2.5, 13 March 2021,

EudraCT number:2020-001209-22

Professor Christopher Butler IRAS Project no. 281958 REC Reference no.:20/SC/058

What is the trial about?



	1.	COVID-19 is caused by a new virus that is spreading quickly in many countries.
	2.	Being infected with the virus is more likely to cause more serious problems if you are older, or you have medical problems such as a diagnosis of high blood pressure or heart disease.

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	<p>3.</p>	<p>At the moment, we do not have treatments for COVID-19 that we know definitely work to help recovery and prevent hospitalisation.</p>
	<p>4.</p>	<p>The aim of this trial is to test possible treatments for COVID-19. We hope to find treatments that help people recover quicker.</p> <p>We are testing treatments that have been used for many years. We will also assess less familiar treatments which might have beneficial effects for the treatment of COVID-</p>

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		<p>19, but which do not yet have a license for use in the UK. There are no reasons to believe the medicines are unsafe. A trial nurse/doctor and/or your GP will review your medical notes and confirm that the medication you may have been given, is safe for you to take.</p>
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Who can take part?

	<p>Anybody aged 65 years or over.</p> <p>AND</p> <p>Anybody aged 18-64 and experiencing shortness of breath as part of COVID-19 illness.</p> <p>5. AND</p> <ul style="list-style-type: none">• Anybody aged 18-64 with certain underlying health conditions: weakened immune system (e.g. taking chemotherapy)• Known heart disease• Known asthma or lung disease
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- Known diabetes
- Known Liver disease
- Known stroke or neurological problem
- Obesity

WITH

A new continuous cough or fever or a change in taste/smell

OR

You have had a **positive test** for SARS-Co-V2 infection which was taken fewer than 15 days ago, AND are unwell with symptoms of COVID-19.

These symptoms may include, but are not limited to, shortness of breath, general feeling of

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	<p><i>being unwell, muscle pain, diarrhoea, vomiting, fever and cough, and you must have had them for fewer than 15 days.</i> If you are starting to feel better, this study isn't for you.</p>
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What will happen if I take part?



	<p>6. If you develop a fever or a new continuous cough or change in taste/smell, OR if you have a positive test for SARS-Co-V2 infection with symptoms in the past 14 days, please visit our trial</p>
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		<p>website (see end of this leaflet).</p>
	<p>7.</p>	<p>We will ask you to fill in a short form online, to check that you can take part</p>
	<p>8.</p>	<p>Your care will not be affected, whether or not you do take part in the trial.</p>

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9. If you are suitable to take part in the trial, you will be asked to fill in a consent form online, and to answer a few questions about yourself and your symptoms.





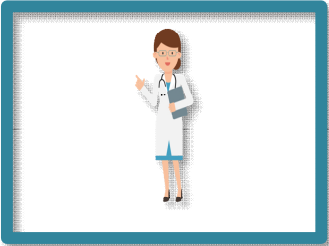
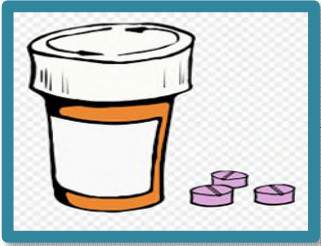
10. We will ask you to add details of a 'trial partner'. This is somebody that might be able help you with the study, and who we can also contact for information about how you are getting on.

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	<p>11.</p>	<p>The information that you give us will be shared with your GP and the study team, so that we can double check that everything is in order for you to take part.</p>
	<p>12.</p>	<p>If you can take part, you will be randomly (like tossing a coin) entered into a group:-</p>
 <p>a) Usual care for your symptoms</p>	<p>Or</p>	 <p>b) You will receive one of the treatments that we are testing, in addition to usual</p>

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		<p>care for your symptoms.</p> <p>We will provide you with the trial medication and instructions on how to take it.</p>
	<p>13.</p>	<p>Whichever group you are in, we will ask you to answer a few questions each daily in an online diary for up to 28 days, so that we know how you are feeling.</p> <p>If you have been given a less well known treatment, we will contact you within one day of joining the trial to explain what medication you have been given.</p>

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	<p>14.</p>	<p>If you are unable to answer questions online, or forget to complete the questions, we might give you a phone call or send you a text message reminder.</p>
	<p>15.</p>	<p>If you are admitted to hospital, we would ask you, or someone close to you, to let us know.</p>
	<p>16.</p>	<p>If you agree to join the study, we will contact you at 28 days to see whether you are happy for us to arrange to speak with you in more detail about your</p>

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	<p>experience of taking part in the trial. Samples you have given or go on to give for COVID-19 in your standard care may also be used for national surveillance, if this is the case we would like to access the results from any samples (including testing swabs and convalescent blood samples) held in your GP record or by PHE.</p>
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What will happen to my information?

	<p>17. We will use the information you give us to find out which treatments work. We may also look at your general practice and hospital medical records for further information about you and your illness.</p>
	<p>18. Any information that we collect about you will be kept safe. Your name will not go on any reports, presentations or publications.</p>

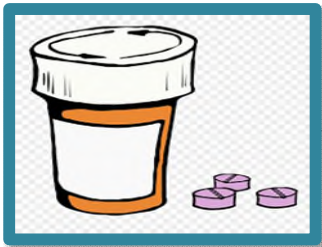
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What are the disadvantages of taking part?



19.

There is a risk of side effects when taking any medicine. If you are taking a trial medication and have any symptoms, you can record them in the daily online diary.

A trial doctor will monitor any side-effects you may experience and contact you or your GP if needed. You will also be able to call the trial nurse/doctor if you experience any side-effects.


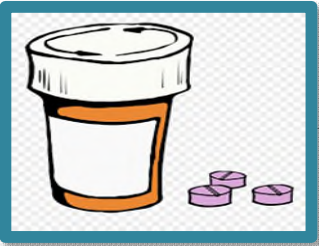
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What are the benefits of taking part?

	20.	You will be contributing to important research to find effective treatments for COVID-19.
	21.	We have designed the trial so that whilst the trial is ongoing, if we find that one treatment is more effective, more people might receive this treatment. This means that more people in the trial have

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		<p>a chance of receiving the most effective trial treatment.</p>
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Will I be reimbursed for taking part?

	<p>22.</p>	<p>You will receive a gift voucher for £20 once we receive your completed online symptom diary, as a thank you for taking part.</p>
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What if I do not want to carry on being part of the trial?

	23.	You can decide to stop taking part at any time without needing to give a reason. This will not affect the care you receive now or in the future.
	24.	If you decide to withdraw from the trial, we will use the information collected up to that point.


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What if there is a problem?

	<p>25. If you have a concern about any aspect of this trial at any time, you can contact the trial team or the University of Oxford Clinical Trials and Research Governance (CTRG) office (Contact details below).</p>
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Trial contact details

	26. Trial team: principle@phc.ox.ac.uk 0800 138 0880 Trial Website: www.principletrial.org CTRG: ctrig@admin.ox.ac.uk 01865 616480
	27. Thank you for taking the time to think about taking part in this trial.

Thank you!

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