

Trial aim:

The Platform Randomised trial of Interventions against COVID-19 in older peoPLE (PRINCIPLE) trial will involve hundreds of GP practices across the UK. It will enable researchers to rapidly evaluate different treatments that could stem the progression of COVID-19 symptoms in older people and help ease the burden on hospitals.

What we are looking for:

Patients aged ≥ 50 -64 years with any of the following known comorbidities or aged ≥ 65 even without comorbidities:

-  Heart disease and/or hypertension
-  Asthma or lung disease
-  Weakened immune system due to a serious illness or medication (e.g. chemotherapy)
-  Diabetes *not* treated with insulin
-  Stroke or neurological problems
-  Mild hepatic impairment

With these symptoms:

-  New or worsening cough
-  High temperature

Within 14 days since onset of symptoms

When you've found the right person, here's what to do next:

- 1  Ask patient to sign up on the trial website: You will have been given a practice specific URL/weblink
- 2  The Clinical Trials Unit will assess patient eligibility and contact you if the patient is eligible

Study medication plus usual care arm

GP/medically qualified practitioner/pharmacist should then:

-  Provide PHE COVID-19 self-swab pack: either post, request collection by participant's companion or courier.
-  Enter script into patient medical record (printed scripts can then be shredded).
-  Take one envelope with pre-printed trial drug label attached and add participant's details to the label.
-  Ensure participant trial drug instructions are inside the envelope. Remind participant that the swab should be taken *before* starting medication.
-  Add one blister pack (15 tablets) to the envelope, then seal.
-  Record participant ID and serial number of blister pack (from trial drug box) on trial drug accountability log.
-  Provide envelope and swab kit to participant (collection by participant's companion, post or courier).
-  Complete drug accountability log with date of collection/date sent.

Usual care arm

-  Provide PHE COVID-19 self-swab pack: request collection by participant's partner or send via courier.

Please notify all participants of their swab results.

What happens next?



Participants will start filling their online diaries from the day they start taking medication.



Participants will receive reminder phone calls over the next 28 days if they're not completing their diaries.



Please remember to report all Serious Adverse Events (SAE)s within 24 hours using the SAE form.

Deaths and/or hospitalisation *due to COVID-19* are trial outcomes. This information will be collected but not reported as SAEs.

SAEs OTHER THAN hospitalisation or death due to COVID-19 infection must be reported by the person who has discovered the SAE or nominated delegate within 24 hours of becoming aware of the event.

Please contact the team if you have any problems:

email:
principle@phc.ox.ac.uk

Phone:
0800 138 0 880

In brief, remember to:

- Provide the PHE swab pack for ALL participants
- For participants randomised to the trial treatment arm provide trial drug pack (including envelope, participant instructions, trial contact card etc)
 - Envelope
 - Participant instructions
 - One blister pack (15 tablets) of the trial drug
- Inform participants of their swab result

Trial drug supplies

Please use ImmForm to contact PHE to order more supplies.

Expected delivery times:



Trial drug:
Next day if ordered before 11am

Note: CTU will also track use and call GP to ensure reorder.