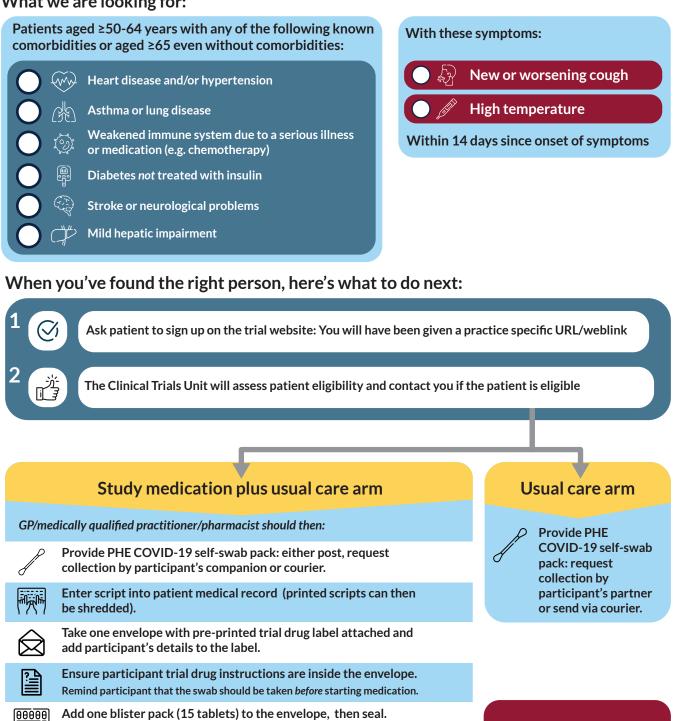


Trial aim:

00000 00000

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:



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.

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 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)



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.



 NUFFIELD DEPARTMENT OF

 PRIMARY CARE

 HEALTH SCIENCES

 Clinical Trials Unit



