

Trial Aim

The PRINCIPLE trial 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 ≥ 65

OR aged $\geq 50-64$ with any of the following known comorbidities:

- Weakened immune system due to a serious illness or medication (e.g. chemotherapy)
- Asthma or lung disease
- Heart disease and/or hypertension
- Diabetes
- Stroke or neurological problems
- Mild hepatic impairment

With any of these symptoms, within 14 days since onset:

Cough

Temperature

Change/loss of smell/taste

OR a positive test for COVID-19 with any symptoms

Finding the right participant:

- Identify patients with suspected or confirmed COVID-19 through running a search: <https://sites.google.com/nih.ac.uk/it-solutions-tv-sm/study-resources/principle>
- Opportunistic recruitment – those who present with COVID-19 symptoms

What to do next:

1. Send patients the invitation text containing the practice specific enrolment link (if you are unsure what your link is please check with the trial team)
2. Confirm eligibility (following an email request) either online using your unique login or over the phone with a member of the CTU clinical team
3. Patients will be automatically randomised to usual care or a treatment arm
4. Patients will be sent a participant pack

Treatment Arm

Participant pack sent to the participant:

- ❖ Participant ID card
- ❖ Self-swab and instructions and return envelope
- ❖ Booklet
- ❖ Medication
- ❖ Letter for care home

Usual Care Arm

Participant pack sent to the participant:

- ❖ Participant ID card
- ❖ Self-swab and instructions and return envelope
- ❖ Booklet
- ❖ Letter for care home

For USUAL care participant packs

GPs confirming eligibility online with swabs and materials: send the usual care pack to the patient. Notify the team if you don't have swabs

GPs confirming eligibility over the phone with the CTU – arrangements for sending the pack will be made during this call

For MEDICATION participant packs

The CTU will send the pack directly to the participant for next day delivery. If clinicians wish to prescribe the medication, they **MUST** let the CTU know by emailing principle@phc.ox.ac.uk

What happens next?

- Participants will start completing their online diary for 28 days
- If online access is not possible, the trial team will call participants on days 7, 14 and 28
- All participants will be called on day 3 to check that they have received their participant pack

Please notify the trial team of any Serious Adverse Events:

- Hospitalisation or death **NOT due to COVID-19** infection **MUST** be reported by the person who has discovered the SAE within 24 hours of becoming aware.
- We will collect deaths and/or hospitalisation *due to COVID-19* as trial outcomes and so these don't need to be reported.

In brief remember to:

- ❖ Identify potential participants with suspected/confirmed COVID-19
- ❖ Invite patients to take part with your practice specific link via text (a letter is also available)
- ❖ Confirm patient eligibility
- ❖ Inform patients of their SWAB RESULT
- ❖ If you do prescribe the medication to a participant (e.g. following a consultation for immediate treatment), **please let the CTU know**

Please contact the team if you have any problems:

Email:

principle@phc.ox.ac.uk

Tel: 0800 138 0880