

## 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  $\geq 65$**

**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
- Obesity

### 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>

### What to do next:

1. Send the patients the invitation test containing the trial website ([www.principletrial.org](http://www.principletrial.org)) and freephone number 0800 8138 0880
2. Confirm Eligibility (following an email request) either online using your unique login, over the phone or by providing medical summary to a member of the CTU trial team
3. Patients will be automatically randomised to usual care or a treatment arm
4. All IMP will be sent from the CTU

### 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 and 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](mailto:principle@phc.ox.ac.uk)

### What happens next?

- Participants will start completing their online diaries for 28 days, from the day they receive the diary link.
- If online access is not possible, the trial team will call participants on days 7, 14 and 28 to collect follow-up information.
- 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 text ( a letter is also available)
- ❖ Confirm patient eligibility
- ❖ Inform patients of their SWAB RESULT
- ❖ If you do prescribe 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](mailto:principle@phc.ox.ac.uk)

**Tel: 0800 138 0880**