

## 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

### 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 residents with suspected or confirmed COVID-19 and ask them if they're interested in taking part in PRINCIPLE. Provide the pictorial Patient Information Sheet if possible.
- **Participants must have capacity to consent**

### What to do next:

1. Identify a **Study Partner** to support the resident with registering for the trial and completing follow-up information. This can be a family member, carer or friend.
2. Ask resident to register on the trial website (you will have been provided with a specific weblink). If online access is not available arrange a call with the trial team.
3. The resident will provide screening information and informed consent

A **clinically qualified member** of the trial team will then confirm the participant's eligibility through access to their medical notes or by contacting their GP.

The participant is then randomised to either:

### 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

## 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.

## 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**

## In brief remember to:

- ❖ Identify potential participants with suspected/confirmed COVID-19
- ❖ Identify a Study Partner (if possible)
- ❖ Help the resident register for the trial:
  - Notify the trial team, who will call the resident/study partner
  - OR
  - Provide the study link to the resident/Study Partner to register online
- ❖ Support the resident with taking their self-swab and medication (instructions will be provided)
- ❖ Support the resident with trial follow-up: online diary for 28 days OR phone calls from the study team at day 7, 14 and 28.

*The Study Partner can provide information online or over the phone, particularly if the resident is unwell*