

PRINCIPLE TRIAL aims to find treatments that improve symptoms and reduce hospital admission for older people with COVID-19. **Any healthcare professional can facilitate recruitment of care home residents**, by guiding patients/their legal representative through consent and registration.

Who are we recruiting?

*Those aged 65 and over *Or aged 18-64 with shortness of breath due to COVID-19 *Or aged 18-64 with any known comorbidities including:

- Weakened immune system due to serious illness or medication (e.g. chemotherapy)
- Asthma or lung disease
- Heart disease and/or high blood pressure
- Known diabetes
- Stroke or neurological problems
- Liver disease

Presenting any of the symptoms below (within 14 days of onset):

New continuous cough

High temperature

Change/loss of smell/taste

Or confirmed COVID-19 with any symptoms

IMPORTANT – those who have had a COVID-19 vaccine or a flu vaccine are still eligible to take part in the study

Recruiting into the study and obtaining informed consent

Residents **with capacity** have three options:

- Recruit patient yourself.** Go to www.principletrial.org and click 'Enrol a patient button' Patient Information Sheet provided to go through with patient before completing consent form. *Nb. You are verbally supporting someone to self-consent to the study and transcribing this information into the online system – Good Clinical Practice (GCP) therefore not required.*
- Refer patient to study team:** **0800 138 0880**, to help guide patient through enrolment process
- Self-enrolling patient** go to: <https://www.principletrial.org/participants/how-to-join-the-trial>

Residents **without capacity**:

- Contact patient's legal representative (ideally family member or next of kin) to confirm if they are willing for the patient to take part in the study. Can email/telephone to discuss the study and role of the legal representative (approved legal representative letter available)
- Complete the screening, consent and baseline information online with the legal representative to register patient for the study: Go to www.principletrial.org and click 'Enrol a patient button'

What happens next?

Patients will be automatically randomised to receive usual care or a treatment arm, and a study pack with the relevant information is couriered directly to the care home.

For further information or support: Email: principle@phc.ox.ac.uk Tel: 0800 138 0880

GPs providing information to confirm a patient's eligibility will be reimbursed £50 per patient