# **Guidance for Care Homes**



## 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 ≥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

### 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**

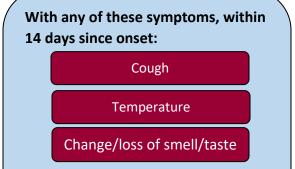
Participant pack sent to the participant:

- 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



OR a positive test for COVID-19 with any symptoms

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#### 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

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



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