Guidance for GPs, pharmacists, nurses recruiting care home residents.

PRINCIPLE
Platform Randomised trial of INterventions against COVID-19 In older peoPLE

PRINCIPLE TRIAL aims to evaluate treatments that could stem progression of COVID-19 symptoms in older people

Any healthcare professional can facilitate recruitment of care home residents to this study by guiding patients/their legal representative through consent and registration

Who are we wanting to recruit?

Patients aged ≥65

OR aged ≥50-64 with any 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
- Self-report obesity or body mass index ≥35 kg/m^2

Those with any of the symptoms below and within 14 days of onset:

- New continuous cough
- High temperature
- Change/loss of smell/taste
- OR a positive test for COVID-19 with any symptoms

Finding the right participant:

- GPs and pharmacists aware of care home with a recent positive test for SARS-Cov-2 or COVID-19 like symptoms, can help facilitate their enrolment into the study.

IMPORTANT – anyone who has already had the COVID-19 vaccine or a flu vaccine is still eligible to take part in the study

Obtaining consent

Residents **with capacity** to consent:

i) **Recruit the patient yourself**. Go to www.principletrial.org and click **'Enrol a patient button'**
Please read through the illustrated Patient Information Sheet with the patient before completing the consent form.
Nb. You are verbally supporting someone to self-consent to the study and transcribing this information into the online system. Therefore, GCP is not required.

ii) **Refer the patient to the study team**: **0800 138 0880,** who will guide the patient through enrolment

iii) **Self-enrolling patient** go to : https://www.principletrial.org/participants/how-to-join-the-trial

Residents **without capacity** to consent:

i) Identify a personal legal representative for the patient: *a person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the adult*

ii) **If a personal legal representative cannot be identified only then can a professional legal representative be sought.** A professional legal representative may be *a doctor responsible for the medical treatment of the adult if they are independent of the study, or a person nominated by the healthcare provider*

The PRINCIPLE 'Legal Representative Letter' must be completed by the legal representative, before the next step is completed

iii) Complete the screening, consent and baseline information online to register the patient for the study

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What to do next?

2. GP, pharmacist or nurse to confirm eligibility, by either i) **online** using your sentry login (Sites only) or ii) **by phone** to the study team or iii) forwarding a patient **medical summary** to the study team.
Once the patient is registered, the study team will be alerted to contact you to request the information required to confirm eligibility.

3. Patients will be automatically randomised to usual care or a treatment arm and the study team will courier a study pack directly to the care home. The study pack contains a copy of the consent form, participant ID card, self-swab, instructions and return envelope, information booklet and if applicable the medication and medication instruction card.
* If Clinicians wish to prescribe the study medication themselves only **after randomisation** to the treatment arm, please let the Study team know* *Please see the protocol for medication doses.*

A Study Partner including a family member, carer or friend, can support the resident with registering for the study and completing follow-up information.

What happens next?

- If online access is not possible, the study team will telephone participants on days 7, 14 and 28 to collect information about how the participant is feeling.
- Participants will start completing their online diary for 28 days and will receive an email with a link to the online diary system. They will be asked daily questions about their symptoms and contact with healthcare providers (approx. 10 mins/day required to complete)
- All participants will be telephoned on day 3 to check they have received their participant pack

In brief please remember to:

- Identify potential participants with suspected/confirmed COVID-19
- If possible recruit the patient directly. If the patient does not have capacity to consent, contact their next of kin.
- GP/Nurse: confirm/provide information to confirm patient eligibility
- If you prescribe the medication to a participant after randomisation (e.g. following a consultation for immediate treatment), **please let the study team know**

Please contact the team if you have any problems:

Email:

principle@phc.ox.ac.uk

Tel: 0800 138 0880

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