

Update to Inclusion Criteria.

PRINCIPLE has Recruited

2572

Participants!



The PRINCIPLE Trial Team would like to inform all sites that those participants who are already taking antibiotics for an acute condition will no longer be excluded from the trial.

Please continue to support recruitment in any way you can!

GP Process Flowchart

Guidance for GPs

PRINCIPLE aims to rapidly evaluate different treatments that could stem the progression of COVID-19 symptoms in older people and help ease the burden on hospitals. Any healthcare professional can facilitate recruitment into the PRINCIPLE trial, by guiding patients through screening, consent and registration and performing an eligibility check or by sign-posting to the trial.

Who do we want to recruit:

Patients aged ≥65
OR aged 250-64 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
- Self-report obesity or body mass index ≥35 kg/m²

With any of these symptoms, within 14 days since 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:

- Run a daily search for patients with a recent positive test for SARS-CoV-2.
- Run a search for all people who might be eligible if they were to become ill. This can be found at <https://sites.google.com/nhrc.ac.uk/it-solutions-tv-sm/study-resources/principle>

What to do next:

1. If the patient is suitable, please complete one of the following actions:
 - i) Recruit the patient yourself! Go to www.principle.ac.uk and click 'enrol a patient better'! Please read through the illustrated Patient Information Sheet with the patient before completing the consent form.
 - ii) You are verbally supporting someone to self-consent to the trial and transcribing this information into the online system. Therefore, GCP is not required.
 - iii) Refer the patient to the study team: 0200 126 0200, who will guide the patient through enrolment
 - iv) Refer patient to self-enrolment page: <https://www.principle.ac.uk/participants/when-to-join-the-trial>
2. Confirm eligibility, by either i) online using our entry logs (sites only) or ii) over the phone with the study clinical team or iii) send a patient medical summary to the study clinical team. The study team will contact you to request the information required and to let you know how to provide it.
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 patient. The study pack contains a participant ID card, self-swabs, instructions and return envelope, information booklet and if applicable the medication and medication instruction card. * If clinicians wish to prescribe the trial medication themselves, please let the trial team know* Please see the protocol for medication doses.

A flowchart can now be found on our website on the 'For Health & Care Professionals' tab.

This provides guidance for GP's about The PRINCIPLE Trial to use at your convenience.

Thank you!



As we get closer to the Christmas period, we would like to take this opportunity to thank you for all your hard work and commitment to the trial.

Especially in the most recent weeks!

We really appreciate it!

GP locations of participants recruited in the last 10 weeks



We now have over 1000 sites working with the PRINCIPLE Trial across the nation. A small increase in recruitment and outreach at each site makes a huge impact.

TOP RECRUITING CRNs (numbers randomised)

1. North West Coast
2. North East and Cumbria
3. Yorkshire and Humber
4. Thames Valley and South Midlands
5. West of England
6. West Midlands
7. South West Peninsula
8. East Midlands
9. Eastern
10. Greater Manchester

