

PRINCIPLE study

Platform Randomised trial of
Interventions against COVID-19 In older
peoPLE

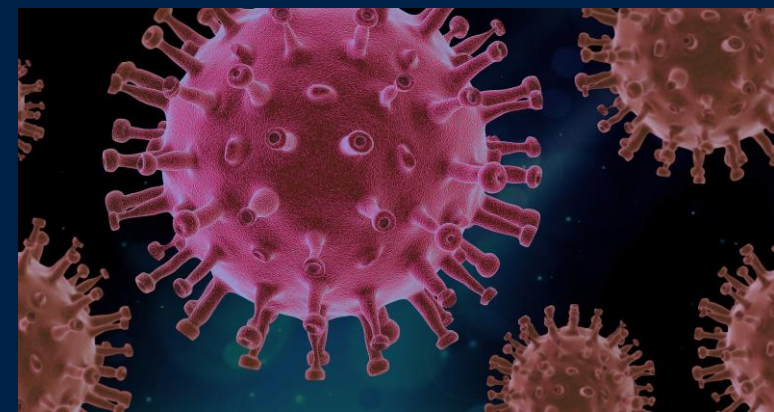
Chief Investigator: Professor Chris Butler

Sponsor: University of Oxford

Funded by UKRI/NIHR

Aim:

To find out whether potential treatments for COVID-19-like-illness that are suitable for use in the community might help affected individuals recover more quickly and reduce the risk of hospitalisation and/or death.



We are looking at...

Existing drugs
that may be
active against
COVID-19

VS

Best usual
primary care

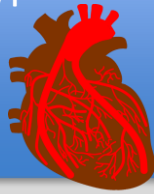


We are looking for

We are looking for: Patients aged ≥ 18 -64 years with any of the following underlying health conditions:

Known weakened immune system due to a serious illness or medication (e.g. chemotherapy);

Known heart disease and/or hypertension



Known chronic lung disease (e.g. asthma)



Self-reported obesity or BMI ≥ 35 kg/m²

Known diabetes

Known mild hepatic impairment

Known stroke or neurological problem

OR

Patients in this age group reporting Shortness of Breath as a symptom of Covid-19

OR Patients aged ≥ 65 with or without comorbidity

WITH

New Continuous
Cough

And/Or

A high
temperature
(hot to touch)

And/Or

Change/loss of
smell/taste

within 14 days of inclusion

OR

A positive COVID-19 test in the
last 14 days with any
symptoms





**When you have found the
right person**

here are the next steps...

Register your patient using site direct link or PRINCIPLE website and help them complete screening, informed consent and baseline. Alternatively provide them with direct link to complete at home on their own.

All assigned researcher's will receive an email once a patient has provided baseline

Please follow the email link and log in to **Sentry/Secure** and confirm whether the patient is eligible to take part in the study.

Sentry vs Sentry Secure Systems

Original Sentry system

(This system was originally set up for participants who enrol via a practice- specific link they've often received in a text from the practice; their participant IDs would start XXX0...). These site specific links were distributed with the Green Light and contained a 3-letter practice specific code. Most sites have now moved away from using these but some patients do still register via this pathway.

Link: <https://sentry.phc.ox.ac.uk/sentry/login>

Newer Sentry system


(Which is used when people self-refer, ie don't use a practice-specific link, and enrol via our website; their participant IDs start XXX4....)

Link: <https://secure.phc.ox.ac.uk/sentry/login>

Please note that the email to request an eligibility review will contain the link to the correct site, and if you do not have a login you will be provided with one at the same time.

Sentry/Secure


You will be taken to the ‘Participant Eligibility’ page




Hannah Swayze [Logout](#)

[Home](#) [Study](#) [Database](#) [Db Activity](#) [Site](#) [Site Activity](#) [Participant](#) [Form](#) [Eligibility](#)

PRINCIPLE >> Demo >> Site >> Site A >> Participant >> STA00003 >> Eligibility

 NUFFIELD DEPARTMENT OF
PRIMARY CARE
HEALTH SCIENCES

Primary Care |
Clinical Trials Unit

 **PRINCIPLE**
Platform Randomised trial of Interventions
against COVID-19 In older people

Participant Eligibility

Participant ID

STA00003

Participant's NHS Number

Inclusion Criteria

Participant is ≥50 years old with at least one of the comorbidities listed below, or aged ≥65.

Yes

- weakened immune system due to a serious illness or medication (e.g. chemotherapy)

You will be asked to enter the Participant’s NHS number and confirm that the Participant meets the Inclusion Criteria.

Inclusion Criteria

Participant is ≥50 years old with at least one of the comorbidities listed below, or aged ≥65.

Yes

- weakened immune system due to a serious illness or medication (e.g. chemotherapy)
- heart disease
- asthma or lung disease
- diabetes not treated with insulin
- liver disease
- stroke or neurological problem

Do you agree?

Sentry/Secure

Confirm the Participant does not meet the exclusion criteria

Exclusion Criteria

Is currently taking chloroquine?	No
Pregnant or planning on becoming pregnant within the next few weeks.	No
Do you agree?	<input type="button" value="Confirm"/> <input type="button" value="Not confirm"/>
Breastfeeding or planning on starting during the course of the trial.	No
Do you agree?	<input type="button" value="Confirm"/> <input type="button" value="Not confirm"/>
Has porphyria.	No
Do you agree?	<input type="button" value="Confirm"/> <input type="button" value="Not confirm"/>
Has type 1 diabetes or insulin dependent type 2 diabetes mellitus.	No
Do you agree?	<input type="button" value="Confirm"/> <input type="button" value="Not confirm"/>
Has a G6PD deficiency.	No
Do you agree?	<input type="button" value="Confirm"/> <input type="button" value="Not confirm"/>
Has myasthenia gravis.	No
Do you agree?	<input type="button" value="Confirm"/> <input type="button" value="Not confirm"/>
Has severe psoriasis.	No
Do you agree?	<input type="button" value="Confirm"/> <input type="button" value="Not confirm"/>
Has a severe neurological disorder (especially those with a history of epilepsy).	No
Do you agree?	<input type="button" value="Confirm"/> <input type="button" value="Not confirm"/>
Has had a previous adverse reaction to hydroxychloroquine.	No
Do you agree?	<input type="button" value="Confirm"/> <input type="button" value="Not confirm"/>
Is currently taking hydroxychloroquine.	No
Do you agree?	<input type="button" value="Confirm"/> <input type="button" value="Not confirm"/>
Has a retinal disease (e.g. macular degeneration).	No
Do you agree?	<input type="button" value="Confirm"/> <input type="button" value="Not confirm"/>
Has a severe hepatic impairment.	<input type="button" value="Yes"/> <input type="button" value="No"/>
Has a severe renal impairment.	<input type="button" value="Yes"/> <input type="button" value="No"/>
Comments	<input type="text"/>
<input type="button" value="Cancel"/>	<input type="button" value="Submit"/>

When you click CONFIRM the Participant will automatically be Randomised

Eligible

Eligible for randomisation to Budesonide	Yes
Eligible for randomisation to Colchicine	No

Randomisation

Budesonide

Randomisation

Participants will be randomised to either

Usual Care

OR

Usual Care
Plus Trial
Medication

Randomisation result instant, copy automatically sent to trial team and participant, randomisation will also provide participants trial ID

Trial Medication & Swab will be
dispatched from Oxford CTU.
If you chose to prescribe Trial
Medication CTU **MUST** be
informed without delay

USUAL CARE GROUP

- GPs to provide clinical care and advice according to current practice
- Participants will be advised to contact their GP if their condition worsens or they have concerns about their illness at any time during the trial.
- All participants will be able to take their usual prescribed medications and medicines such as paracetamol but they should agree not to take any experimental or unlicensed drugs for their illness.

* The study team will not be responsible for the usual medical care of the participants illness



Serious Adverse Event Reporting

IF YOU BECOME AWARE OF AN SAE
PLEASE REPORT WITHIN 24 HOURS
(principle@phc.ox.ac.uk or 0800 138
0880).

What SAEs should I report?

An event which:

- i) leads to **hospitalisation or death** NOT
DUE to COVID-19
 - i) is **life-threatening**
 - ii) results in persistent or significant
disability/incapacity
 - iii) consists of a **congenital anomaly or
birth defect***.

- Hospitalisation or death due to COVID-19 DO NOT need to be reported as SAEs

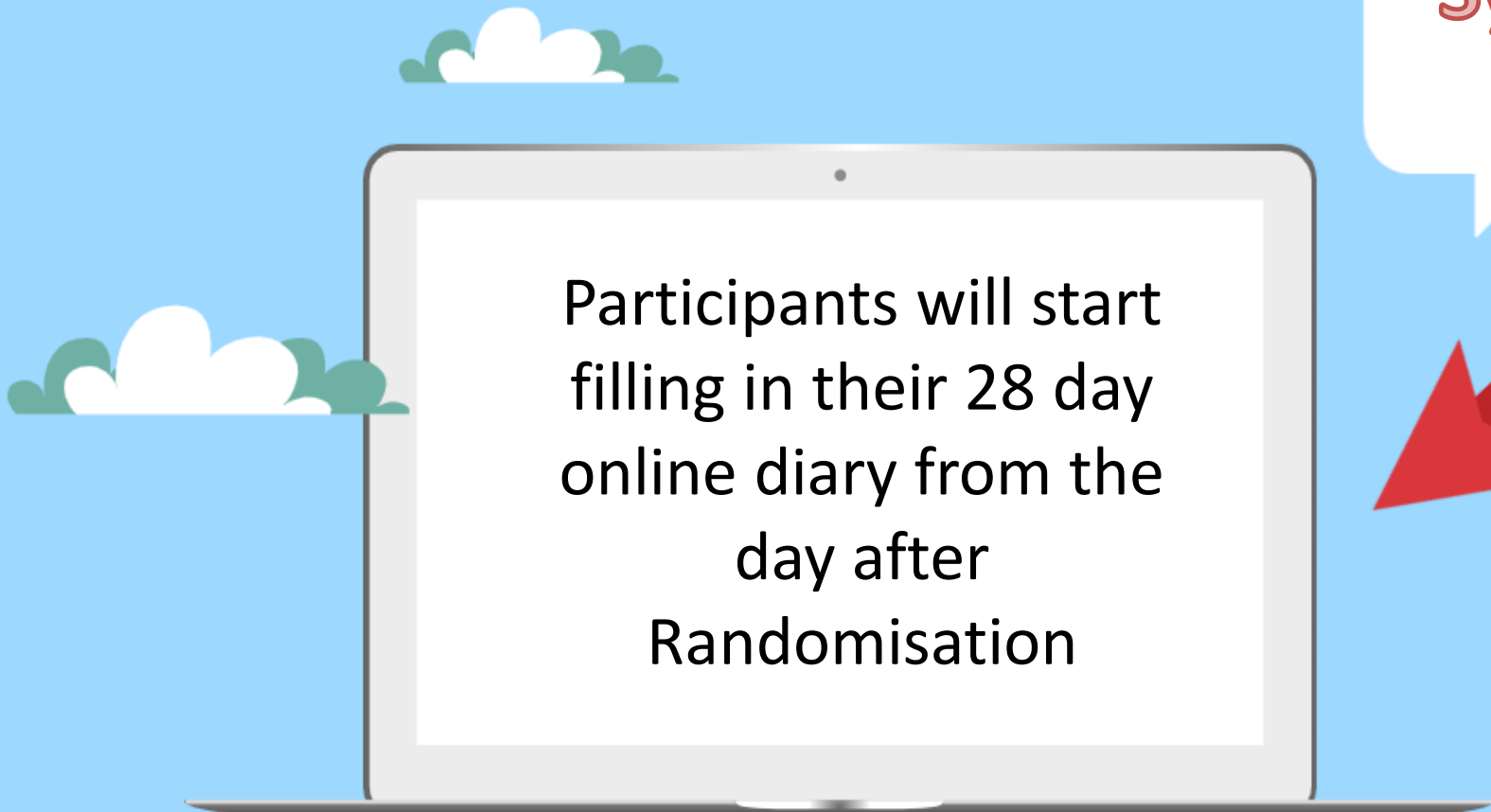
CREATED USING
POWTOON



That's it for the recruiters!



CREATED USING
POWTOON 



Participants will start
filling in their 28 day
online diary from the
day after
Randomisation

**Symptom
Diaries**



Participants will receive a
telephone call on day 7, 14
and 28 if they're not
completing their daily
diary online

In addition, all participants
are called on Day 3 to
confirm IMP receipt and
trial procedures





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Thank you

and good luck

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Please contact the team if you have any problems:

Email: principle@phc.ox.ac.uk

Phone Number: 0800 138 0880