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PROTECT-CH
Prophylactic Therapy in Care Homes Trial

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Prophylactic Therapy in Care Homes Trial

Site Initiation Visit
Training Module

Final Version 1.0 23-Aug-2021

Agenda - Overview

- Background to trial & Trial Design
- Care Home Enrolment & Green Light
- Resident Enrolment & Consent
- COVID-19 Outbreak, PI Eligibility Assessment & Randomisation
- Trial Medication
- Trial assessments
- Good Clinical Practice
- Safety
- Data Protection
- Trial Protocol, Protocol Violations & Monitoring
- Record Keeping
- Roles & Responsibilities Summary
- Next steps: Training
- Q&A
- Self-Certification & Trial Team Contact Details

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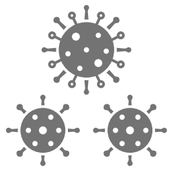
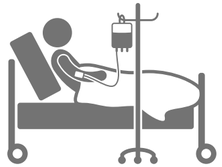
Background to trial & Trial Design

Background: Impact of COVID-19 on care homes

- Major cause of illness
- Major cause of disability, for example, long-COVID
- Major cause of death
- Major impact on normal care and life in the home (PPE, isolation),
- Limits visits from family and friends,
- Impacts on quality of life and mental health of residents and staff







Background: With vaccines, why do we still need a trial?

- Infection prevention and control measures will not completely prevent COVID-19 transmission
- Not all residents and staff are vaccinated
- Vaccines are not 100% effective, and may be less so in the elderly

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- Vaccines are not 100% effective, and may be less so in the elderly
- Visiting relatives (some unvaccinated) increases the risk
- Vaccines only partially effective at reducing transmission
- Vaccines may not be as effective against new variants
- What happens if virus is found at care homes in spite of the above?
- We need a back-up plan, i.e. to be able to prevent/treat in care homes

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PROTECT-CH: Aim and Research question

Aims

1. Reduce the incidence and severity of SARS-CoV-2 infection at care homes
2. Reduce transmission of SARS-CoV-2 at care homes

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PROTECT-CH: Aim and Research question

Aims

1. Reduce the incidence and severity of SARS-CoV-2 infection at care homes
2. Reduce transimission of SARS-CoV-2 at care homes

Research Question

To determine which drug or antibody interventions
when compared to standard care
are effective, safe and cost-effective as prophylaxis for COVID-19.

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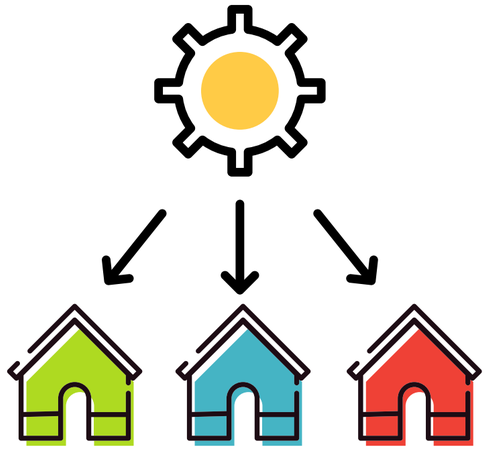
Primary Outcome

The PROTECT-CH follow-up period lasts 120 days.

Day 0 is the day your care home will be allocated to a group (trial medication+ standard care or standard care alone).



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Primary Outcome

- From Day 0 to Day 60, care home staff will be asked to share data with us that will include the following:

1. **No SARS-CoV-2 infection in care home; i.e. residents without COVID-19.**
2. **SARS-CoV-2 infection but resident remains in care home.**
3. **Hospitalisation, all cause.**
4. **Death, all-cause.**

- We will also collect data from national data registries, i.e. NHS digital(Day 61-120).

Primary Outcome Data Analysis

When we analyse the data we will take into account things such as:

- Age group
- Sex
- Size of care home
- Type of care home
- Previous COVID-19 cases in the care home
- Capacity vs no capacity
- Vaccination status

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PROTECT-CH Trial Design

Intervention:

A trial medication chosen by the Department of Health which aims to reduce transmission and seriousness of COVID-19 (plus standard care).

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PROTECT-CH Trial Design

Intervention:

A trial medication chosen by the Department of Health which aims to reduce transmission and seriousness of COVID-19 (plus standard care).

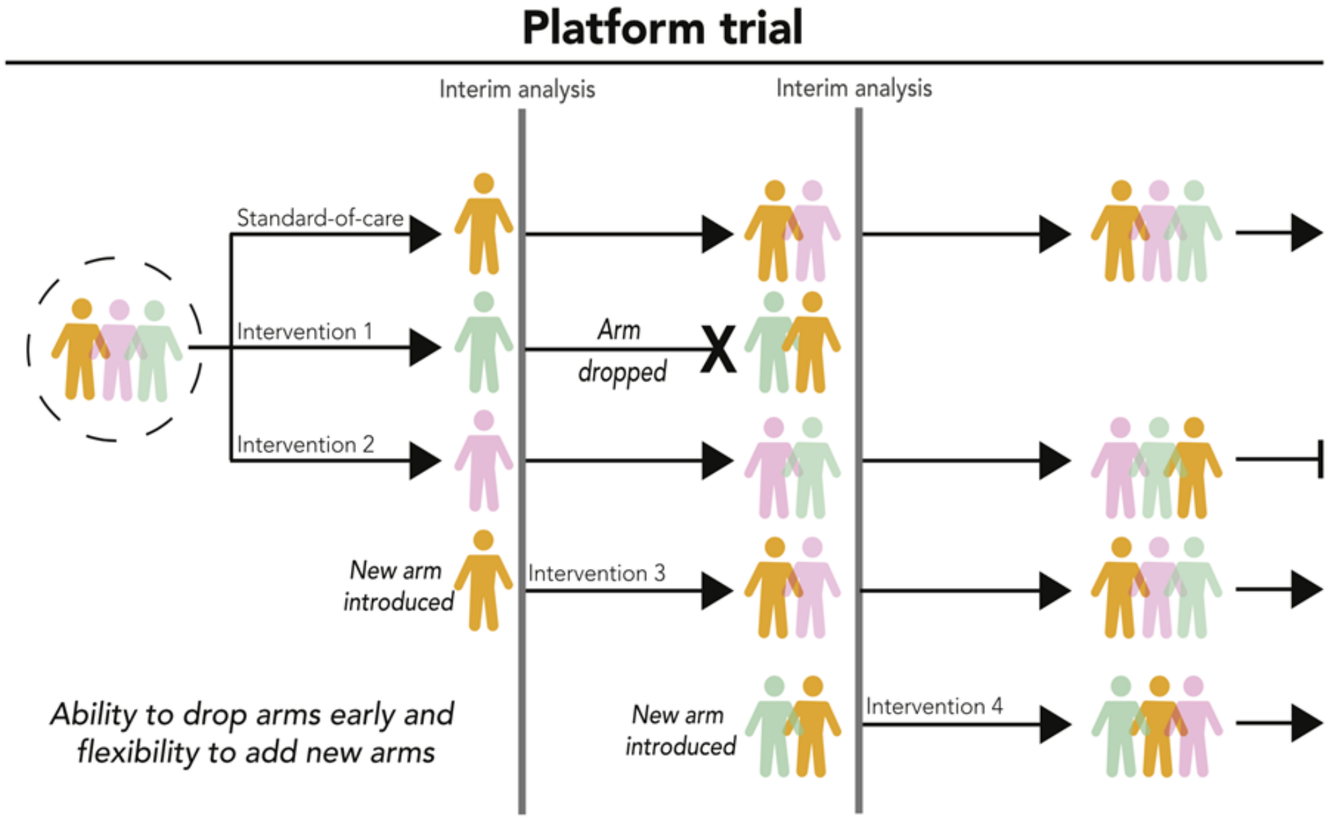
Comparator:

Standard care

PROTECT-CH: A platform trial

What is a platform trial?

- Allows multiple interventions to be tested at the same time and in sequence
- Other platform trials, e.g. RECOVERY



Park et al. *J Clin Epi* 2020; 125: 1-8

PROTECT-CH: A cluster trial

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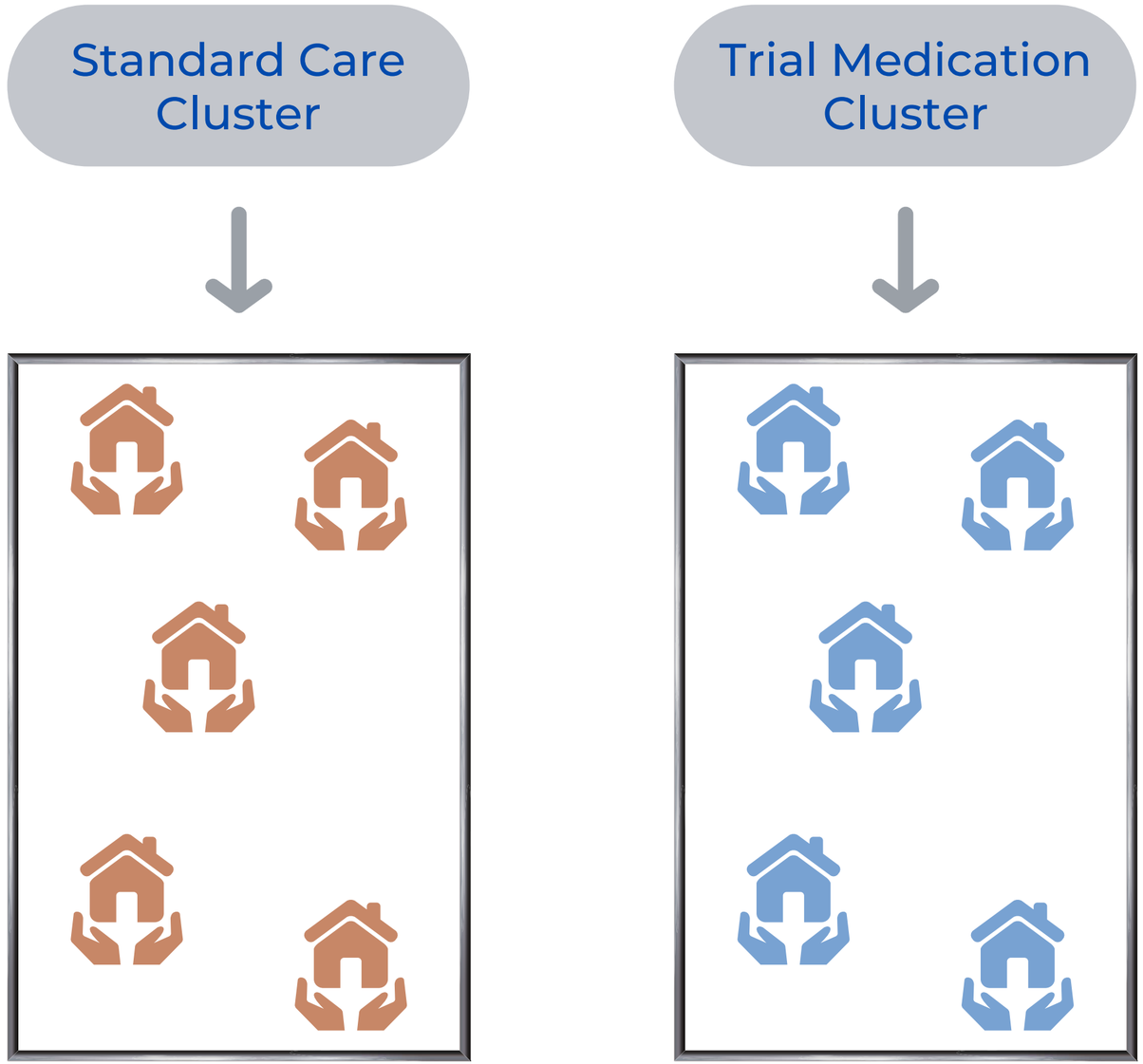
What is a cluster design?

- Care homes (not residents) randomised to a group (trial medication + standard care or standard care alone)
- Reflects way intervention will be used, i.e. across the whole care home
- Active intervention (i.e. trial medication) may protect non-participating residents because of less transmission



Clemens et al. *Lancet Infect Dis* 2011; 11: 482-87

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The medications that will be tested will either be:

PRE-EXPOSURE (PrEP):

These will be given before an outbreak of COVID-19 occurs at a care home

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OR

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The medications that will be tested will either be:

PRE-EXPOSURE (PrEP):

These will be given before an outbreak of COVID-19 occurs at a care home

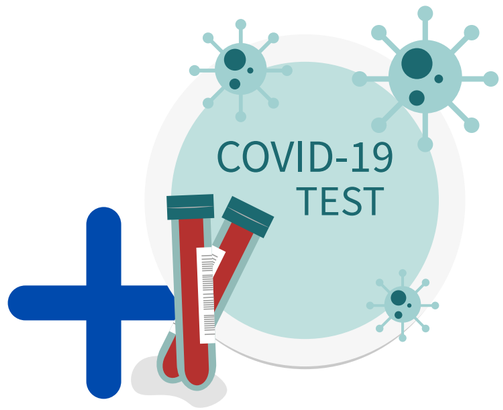
OR

POST- EXPOSURE (PEP):

These will be given after an outbreak of COVID-19 occurs at a care home

At the moment we are testing PEP treatments only:

All participants start treatment at the same time when a positive LFT/PCR test (asymptomatic or symptomatic) occurs in the care home (resident or member of staff).



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COVID-19 Tests

Lateral Flow Test (LFT) commonly known as rapid test, is a self-administered test that can be done **at the care home** and produces results within minutes.

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Polymerase Chain Reaction (PCR) test is a test the results of which are analysed **at a lab**. It usually takes 24-48 hours for the PCR results to become available.

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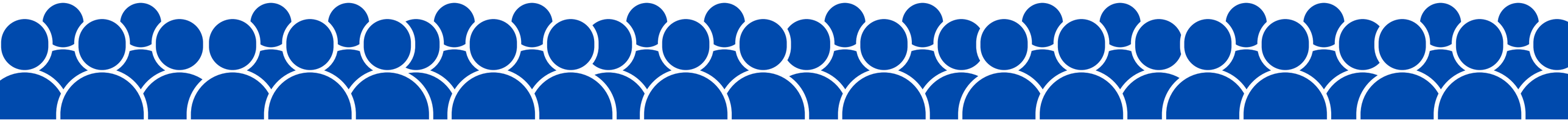
PROTECT-CH Design: Sample Size

- 100 care homes / 3,200 residents per arm
- 1 active vs 1 control = 200 CH / 6,400 residents



PROTECT-CH Design: Sample Size

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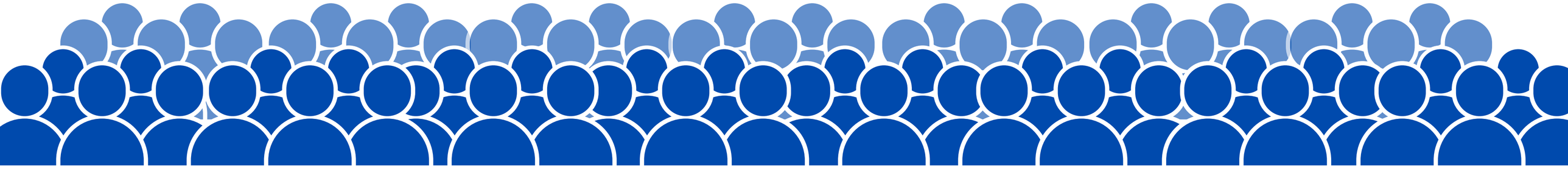
- 2 active vs 1 control = 300 CH / 6,600 residents



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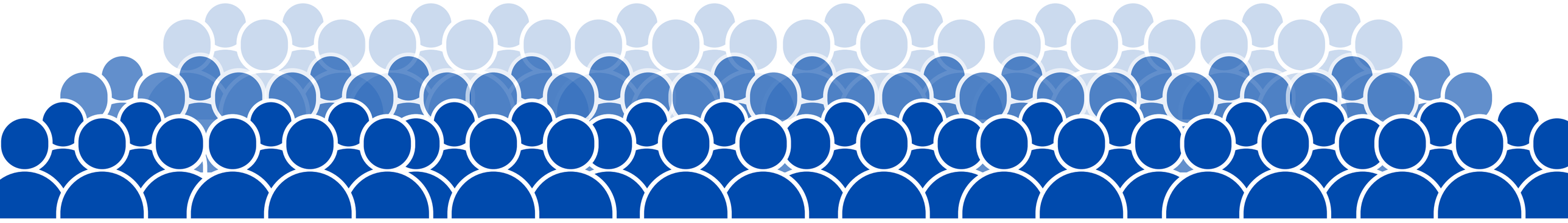
- If 40% of care homes experience a COVID-19 outbreak while in the study, then we need 750 care homes and 24,000 residents!



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Care Home Enrolment & Green Light

Recruitment Process

Trial Staff

Care Home Staff

Research Nurses

General Practitioners

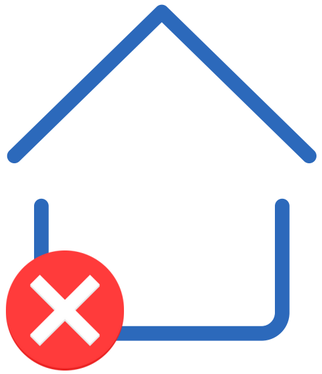
Principal Investigators

Care Home Enrolment: Inclusion & Exclusion Criteria

Inclusion Criteria:

- UK residential and nursing care homes for older people.
- Size: ≥ 20 beds in the care home.

Exclusion Criteria:



- Care Quality Commission quality: Inadequate or equivalent in devolved administrations.
- **Exclusion at treatment phase**: Current positive antigen/PCR test for SARS-CoV-2 in any resident and/or staff member within the previous 4 weeks.

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Care Home Enrolment: GPs

Once the PROTECT-CH trial team has confirmed the care home is eligible to take part, the residents' GP(s) will be approached.

Once the GP(s) have informed the trial team of their interest in taking part and have signed their contract, the care home will be notified in order to sign their contract and start their required training on the study.

GPs will also receive the necessary training to fulfil their duties on the trial.

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Care Home Enrolment: Principal Investigators, Research Nurses and GPs

Each care home will be under the care of a trial doctor, known as a Principal Investigator (PI). Care home staff can meet their PI at a Q&A session held when the care home staff have completed their training.

The trial is also supported by a number of Research Nurses (RNs) who will be mainly responsible for taking consent as well as supporting data entry.

Your PI and at least one GP will be fully trained on the trial before your care home can start approaching residents with information on the trial.

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PROTECT-CH Online Data Capturing Systems

1) Trial database (REDCap):

You can access it via the following link:
https://redcap01.nottingham.ac.uk/
or
with this QR code from a mobile device:

PROTECT-CH REDCap Database

2) PROTECT-CH documents vault:

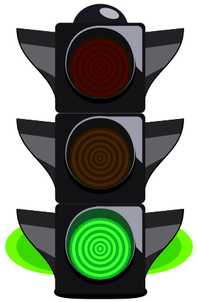
You can access it via the following link:
https://protect-vault.nottingham.ac.uk/
or
with this QR code from a mobile device:

PROTECT-CH Documents Vault

Green Light

Once all contracts have been signed and all essential team members have completed their training, the trial team will email you to confirm 'Green Light' to recruit.

Only after you have received the email informing you of Green Light status, should you start approaching residents to assess capacity and provide information about the study.



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Resident Enrolment & Consent

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Residents: Inclusion & Exclusion Criteria

Inclusion Criteria:

- Resident in a Care Home.
- Age ≥ 65 years
- Informed consent.

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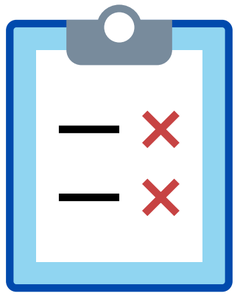

- Identified by care home staff to have entered end-stage palliative care.
- Resident in care home for short-term respite care.
- Resident's general practitioner is unable to support their involvement in the trial.

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Assessing Capacity

Explain to the resident 3 pieces of information about the trial:

1. The trial is trying to reduce COVID-19

2. with a medicine

3. that reduces the chance of infection.

A capacity assessment only needs to take place for those residents you are uncertain of whether they have the capacity to consent for themselves.

Assessing Capacity

Then ask 3 questions to check that the Resident understood:

1. What is the trial about? *Reducing COVID-19*

2. What is being tested? *A medicine*

3. What does the trial hope to do? *Reduce the chance of infection*

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PROTECT-CH: Consent

Consent is important in clinical trials. It involves giving potential participants sufficient and clear information so they can make an informed choice on whether to take part in the trial.

- Informed consent if residents have capacity.
- For those without capacity, their closest family member or friend, known as Personal Legal Representative (PLR), can act as consultee and provide consent.

It is important that the resident/PLR understands that participation is voluntary and that they have the right to withdraw from the trial at any time.

Please see 'Consent & Enrolment' training module for more information.

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PROTECT-CH: Consent

Once the resident or PLR has expressed interest in taking part in the trial, you should seek verbal permission (from the resident or their PLR) to enter their details (Date of Birth, Name and Gender) into the trial database.

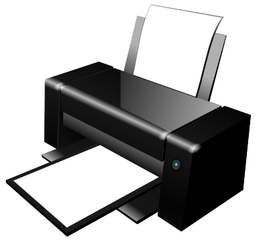
A research nurse (or allied health professional)will then be in touch with them to arrange their Consent appointment.
Care home staff will need to help arrange this appointment.

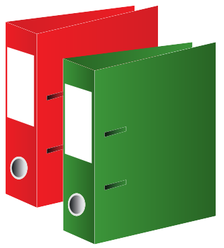
PROTECT-CH: Consent

- The research nurse will discuss the trial with the resident or their PLR, answer any questions they may have and take consent; which will be recorded on the trial database (REDCap).

- Following signatures, a copy of the fully signed consent form will be available to care home staff to view and:

1) share with the consented resident, 2) upload to their care home records.





Baseline data collection

- Following consent, the care home will need to complete the resident's baseline quality-of-life questionnaire (EQ-5D proxy) on the trial database.
  Your answers should not be shared with the resident.

- The resident (only if they have capacity) should then be asked to complete their quality of life questionnaire (EQ-5D) on the trial database.

- Finally, the care home should complete and submit the Demographics and Care Home Eligibility forms on the trial database.

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PROTECT-CH: Initial Eligibility Assessment

- Once a resident or PLR has consented to taking part and their baseline data has been collected, their GP will receive an email asking them to assess the consented resident's eligibility.

- The GP will check and confirm that the resident can take part in the trial and will provide information to the Principal Investigator (PI) about the resident's health. This will be used to confirm the resident can safely take the trial medication.

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COVID-19 Outbreak, PI Eligibility Assessment & Randomisation

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COVID-19 Outbreak

First positive COVID-19 case at care home (staff or resident)

1. Inform the trial team immediately by completing the Outbreak form on the trial database.
2. Ensure your residents' vaccination records are up-to-date on the trial database.
3. Upload 7 days of residents' Medication Administration Records (MAR) charts to the PROTECT-CH Documents Vault.

Please see 'COVID-19 Outbreak Guidance' training module for more information.

Principal Investigator (PI) Eligibility Assessment

The PIs will be assessing eligibility of consented residents using information provided by:

1. GPs

and

2. care homes (7-day MAR charts and up-to-date vaccination records) .

Randomisation

The group your care home is in, will be decided by computer software based on chance (like the toss of a coin); a process usually referred to as *randomisation*.

Following eligibility checks, the PIs will randomise your care home to one of two groups:

1) a group receiving **trial medication (and standard care)**

or

2) a group receiving **standard care (alone).**

Trial Medication

Ciclesonide

- Ciclesonide (by inhalation of aerosol) is currently licensed in the UK as a treatment to control persistent asthma in adults and adolescents (12 years and older). It is well tolerated and safe.
- Ciclesonide has been shown to reduce the ability for the coronavirus to produce new virus particles. It also reduces inflammation in the nose and lungs.
- The product being supplied for use in the trial is an unlicensed formulation identical to that of the UK licensed formulation (Alvesco).
- One puff via spacer and mask through nose (where possible) followed by two puffs via spacer and mask through mouth should be administered once daily.

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Ciclesonide

- Further information on Ciclesonide is available in Appendix A of the protocol and the Alvesco Summary of Product Characteristics (SmPC). Both documents can be found on the trial website.
- Appox 5% of patients experienced adverse reactions in clinical trials with Alvesco. In the majority of cases these were mild and did not require discontinuation of treatment (refer to section 4.8 of Alvesco SmPC for more details).
- Side effects sometimes reported with nebulization procedures include bronchospasm and coughing.

Please see 'Therapy: Ciclesonide' training module for more information.

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Niclosamide

- Recent studies have shown Niclosamide may be a potential treatment for viral infections such as SARS-CoV-2 (COVID-19).
- SARS-CoV-2 initially replicates predominantly in the nasal cavity so the administration of Niclosamide as a nasal spray may be an effective post-exposure prophylactic for early-stage infection when the viral load is the main issue. In its nasal form, it has been well-tolerated according to previous research (see Investigator's Brochure for further information).
- Niclosamide is not licensed for COVID-19 prophylaxis but is approved and safely used overseas for the oral treatment (at 500x dose of that used in PROTECT-CH) of tapeworm infections.
- In PROTECT-CH, one intranasal spray should be administered into each nostril twice daily.
- Further information on Niclosamide is available in Appendix B of the protocol and the Investigator's Brochure. Both documents can be found on the trial website.

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Niclosamide

- Niclosamide has previously been administered as oral tablets. Side effects of the nasal spray are not yet known.
- The occasional side effects reported for the oral tablet are detailed below. These are not expected when using the nasal spray.
- Allergic reaction (e.g. patches of skin redness (erythema), itching (and skin rash), nausea, gastrointestinal pain, abdominal pain, gagging, diarrhoea, dizziness, blue colour to skin or lips (cyanosis), excessive sweating (hyperhidrosis) and fatigue.

Please see 'Therapy: Niclosamide' training module for more information.

If allocated to one of the trial medication groups:

Central Pharmacy Staff	Care Home Staff	Research Nurses	Care Home Staff	Care Home Staff with help from PIs	Care Home Staff

IMP: Investigational Medicinal Product, i.e. trial medication

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Trial Assessments

Data collection throughout the trial

In trials we need to collect data about participants (residents in this case) to determine whether the trial drugs make a difference.

In PROTECT-CH, data collection at care homes will take place at various timepoints from the day of consent to day 60 post randomisation.

Please see 'Trial assessments & follow-up' training module for more information.

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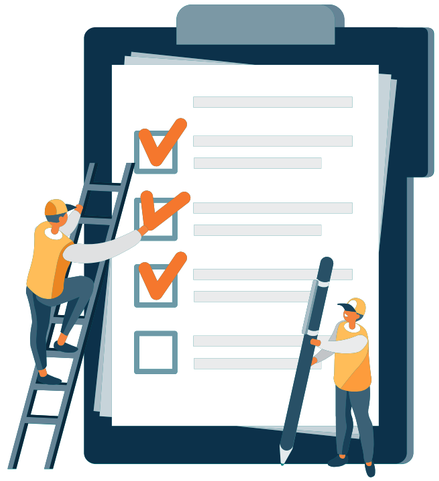
Trial assessments & Follow-up

We are asking care home staff to record important information for the trial, including the following, on the trial database:

- Baseline: demographics and medical history
- Weekly data collection
- Primary outcome data, resident:
  - COVID-19 positive
  - Hospitalised
  - Died
- Serious adverse events (SAEs)
- End of follow-up outcomes (Day 60)



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Schedule of Assessments

No care home staff involvement needed at this stage

Pre-randomisation
(Pre-randomisation)

- Eligibility screen/assessment
- Informed consent
- Demographics & medical history
- Quality of Life (QoL) Questionnaires
- Number of residents in care home

Follow-up: Treatment Phase
(Day 0/1 of Medication administration* to 42)

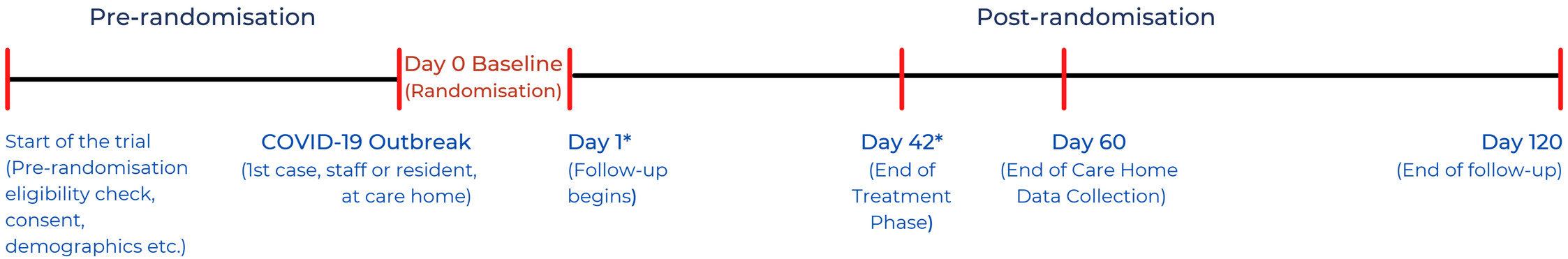
- Safety Reporting

Follow-up: Primary Outcome Data
(Day 1 to 60)

- Number of care home residents with COVID-19
- Number of hospital admissions
- Number of deaths and causes
- Day 60: - Healthcare Resource Use & Day 60 Check
  - QoL Questionnaires

Follow-up:
Routinely Collected Health Data
(Day 1 to 120)

- Routinely collected health data:
  - Number of infections
  - Number of infections who stayed at care home
  - Admissions to hospital
  - Deaths
  - Most serious medical events



Treatment phase duration

*The treatment phase will last 42 days for all residents.

For those in the control group, this will be day 0 to 42.

For those in the trial medication (treatment) group, it will be 42 days from the date the resident has started the trial medication.

For example, if the medication is administered for the first time on Day 2 (from randomisation) the end of treatment will be on Day 44.

Good Clinical Practice

Good Clinical Practice (GCP)

'A standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials that provides assurances that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected'

GCP ensures that:

- The research is safe for patients
- The results are meaningful for clinicians
- The results can change practice for the future
- Applies to all clinical trials

Care Home staff working on the trial must complete the trial-specific GCP training to understand these standards.

Please see 'Trial-specific GCP' training module for more information.

Safety

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Safety (1)

Both trial medications have been found to be well-tolerated and safe. Nevertheless, we have a duty of care towards residents (trial participants) to ensure their safety while participating in the trial. Therefore, processes have been put in place as part of PROTECT-CH **to protect the safety of residents (trial participants) who take part in the trial**.

It is important that the safety of trial participants is regularly monitored as part of the trial.

Safety monitoring requires the **reporting of any medical problems that trial participants experience during the course of a trial**.

Safety (2)

- Medical problems identified during the trial, known as 'adverse events', must be recorded and closely monitored in case they are caused by one of the trial medications.

  The terminology you may see used to refer to those medical problems includes:

- Adverse event (AE) - Any medical problem in a patient administered a treatment whether related to the product or not.

Safety (3)

- Serious Adverse Event (SAE) - Any adverse event that:
  - results in death;
  - is life-threatening;
  - requires hospitalisation or prolongation of existing hospitalisation;
  - results in persistent or significant disability or incapacity;
  - consists of a congenital or birth defect.

Please see 'Safety' training module for more information.

Data Protection

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Data Protection (1)

It is essential that to collect and use a resident's:

personal data *(name, date of birth, NHS number and address)*

AND

research data *(any data collected as part of the trial)*

the research staff must have received consent from either the resident or their PLR.

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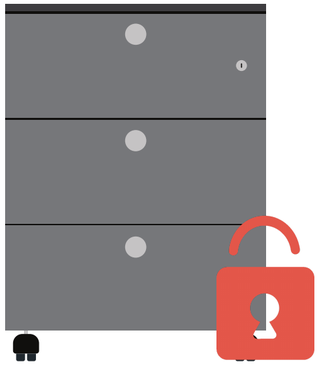
Data Protection (2)

All data collected as part of the trial must be stored securely, either on the trial password-protected database or a locked cabinet in a restricted-access office.

Please ensure that all resident personal
and
research data is stored securely.



Please see 'Data Protection' training module for more information.

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Trial Protocol, Protocol Violations & Monitoring

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Prophylactic Therapy in Care Homes Trial

Trial Protocol

The trial protocol outlines the research idea (background, aims, question) and plan for the delivery of the trial including measures to ensure the safety of trial participants and the high quality of data collected.

It has been reviewed and approved by an Ethics committee, MHRA and other regulatory bodies as appropriate.

The protocol should be used as an instruction manual and therefore, processes must be followed as outlined.

The protocol can be found on the trial website. http://

Protocol Violations

If you notice any deviations from the trial protocol,
please record them on the violation form on the trial database.

All reports on the trial database will be reviewed by the trial team and where believed to be a protocol violation or a potential serious breach will be further investigated.

Please see 'Data Entry' training module for more information.

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Protocol Violations

If the following things occur, we need to know about them.
Therefore, you will need to record them on the trial database:

- Treatment without consent
- Treatment administered to ineligible residents
- Non-reporting of primary outcome measures
- Non-reporting of serious adverse events

If you are unsure if an incident is a protocol violation, please contact us.

Monitoring

Monitoring in trials is a practice where the trial team review the local site's procedures and records to confirm the processes as outlined by the protocol have been followed and data collection at the site is reliable and accurate.

Monitoring is important in trials as it ensures participant rights and safety are protected and high quality data is collected and analysed in order to answer the research question is answered.

PROTECT-CH Monitoring

In PROTECT-CH, there will not be any routine onsite monitoring visits unless triggered by remote checks and it is feasible to conduct these.

The trial team will be monitoring trial processes are followed as per protocol centrally through the trial database. The team may be in touch with you if any further information is needed.

Record Keeping

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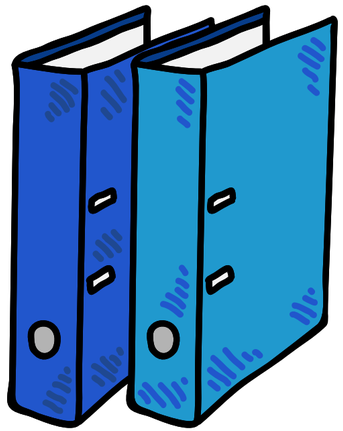
Record Keeping:
Care Home File Maintenance

The trial team will send you a PROTECT-CH 'care home trial document pack' containing all documents and materials to set up the trial in your care home. As part of your pack, you will receive a trial file, you may see this referred to as 'care home site file' or 'simply site file'.



This contains all essential documents to conduct the study (or the location where they are stored, for example, trial website).

The maintenance of the care home site file is a responsibility that can be delegated by the care home manager to other staff members as appropriate.

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Record Keeping: Correspondence

Please remember **not** to include **confidential** information in your **correspondence**.

If you need to email the trial team a query in relation to a specific participant, you may include the following identifiers:

1) their initials,
2) their trial ID number and
3) the name of their care home.

Please include all three identifiers to ensure the correct identification of the individual.

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Roles & Responsibilities Summary

Roles & Responsibilities: Care Home Staff

1. Identifying residents for participation
2. Identifying and contacting PLRs for those who lack capacity.
3. Helping with consent process.
4. Completing baseline and follow-up data, mainly focussing on:
    a. Reporting death, hospitalisation, SARS-CoV-2 diagnosis
    b. Reporting SAEs
    c. Positive COVID-19 test results
    d. Contact with the NHS (GP, 111, 999)

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Roles & Responsibilities: Care Home Research Champion

Will lead on the following:

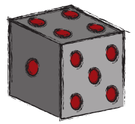
- Contacting PLRs
- Supporting resident screening
- Providing GP contacts to trial team
- Scheduling and supporting residents with their consent appointments
- Working with care home team to ensure that baseline and follow-up data will be completed
- Ensuring care home staff training remains up-to-date throughout the trial
- Regular educational support through PROTECT-CH care home meetings.

Roles & Responsibilities: Principal Investigators (PIs)

Will work on a rota on the following tasks:

- Eligibility assessment following COVID-19 outbreak
- Randomisation
- Trial Medication Prescribing*
- Serious adverse event (SAE) review
- Adjudicate SAEs from other care homes

**PIs will work regionally with their care homes but nationally for prescribing.*


Delegation of Responsibilities: PIs, Care Home Managers and Research Champions

In trials, different staff members can have different responsibilities depending on their role.

One such role is the local lead investigator at each care home, who is a trained staff member that has overall responsibility for the delivery of the trial (according to the protocol) at the site. This investigator is the care home manager in PROTECT-CH.

The Care Home Manager's overall responsibility is delegated to them by the care home's Principal Investigator (PI) who has the ultimate responsibility for trial conduct at the care home.
The care home manager in turn delegates to the Research Champion and chooses staff members who are going to help with the trial.

Roles & Responsibilities: PIs, Care Home Managers and Research Champions

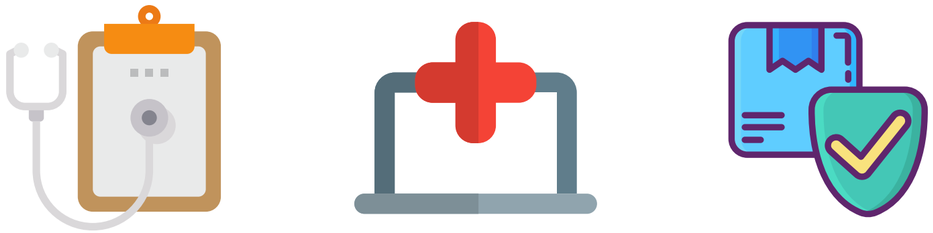
Together, they will all:

- Follow the protocol
- Make sure each resident or PLR has given consent
- Make sure care home staff are trained and know what they have to do
- Store the trial medication in a safe cool room according to instructions
- Ensure that each participating resident receives the appropriate dosage (if allocated to the trial medication group)
- Maintain good communication with the trial team, GPs, PIs and RNs, as appropriate, throughout the trial

Roles & Responsibilities: General Practitioners (GPs)

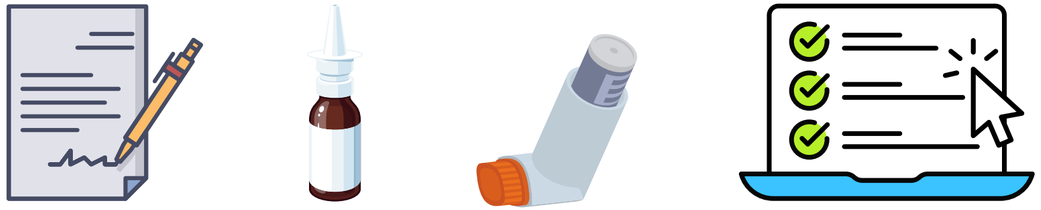
Residents' own GPs:

- Assess eligibility following consent
- Submit summary care record (SCR) or equivalent in devolved nations
- Report Serious Adverse Events (SAEs) within 24 hours of becoming aware
- Provide to the PIs information in relation to Serious Adverse Events as needed



Roles & Responsibilities: Research Nurses (RNs)

- Managing and conducting conversations with the resident or their representative to inform them of the study and seek consent.
- Assisting care homes at the point of outbreak to administer trial medication and facilitate trial processes.
- Assisting care homes with completion of data collection on day 60.



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Next Steps: Training

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PROTECT-CH Training: 3-step process

Site initiation visit

Training modules

Follow-up Q&A

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Training Overview

1

- Care home staff involved in the trial will first receive the Set-up training module.
- Once the contract has been signed, this training (Site initiation visit, (SIV)) will take place. Care home manager and research champion (or another staff member if research champion and care home manager are the same person) are required to attend the SIV meeting.
- After the SIV, care home staff can start completing their training modules.

2

All care home staff involved in the trial will be required to complete the following modules:

- Background to trial
- Safety
- Trial Specific Good Clinical Practice
- Data Protection
- COVID-19 Outbreak Guidance

3

The other training modules will be dependent on role in the trial. These are:

- Consent and Enrolment
- Data Entry
- Therapy (Information on each specific trial medication)
- Trial Assessments and Follow Up
- Close out & Archiving

Next steps: Accesing your training modules

Following this SIV, you may access your modules by following this link: https://www.protect-trial.net/

Three staff members (care home manager, second attendee of SIV and a third staff member) should complete **all** training modules before the next stage.

Please remember to refer to your **Set-up module** and **Training Information Sheet** for further information on the trial's training requirements.

Training Complete: What happens next?

After completing training you will be able to sign up for a Q&A with a PI to answer any further questions you may have.

Once all training has been completed and all the other documentation is in place we will issue GREEN LIGHT via email, which means you can start approaching residents about the trial and arranging consent conversations.

Any questions?

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Thank you for watching!

You have now completed the

Site Initiation Visit

Training Module

NEXT

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Please complete your self certification form to confirm you have attended this visit.

This can be found at:

https://w3.abdn.ac.uk/hsru/NCTU-Protect/Public/Public/SelfCertification.cshtml?TrainingModule=15&ModuleVersion=1

Or via mobile here:

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If you have any questions, please do not hesitate to contact us:

protect-trial@nottingham.ac.uk

0115 74 87710