PROTECT-CH

Prophylactic Therapy in Care Homes Trial

Trial assessments & Follow-up Training Module

Final version 1.0 01-Sep-2021

Purpose of training

This training module is aimed at **Care Home Managers, Research Champions** within the care home, and **Care Home Staff** who are involved in data collection.

It will help familiarise you with the information, (also referred to as 'data'), that will be collected before and after randomisation and throughout the follow-up period of the trial.

What type of data will be collected as part of the trial and when?

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Resident Self-reports:

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Care Home Data Collection:

Includes collection of participant clinical information from **pre-randomisation** to the **end of follow-up** (Day 60) (which is the end of the care home's involvement in data collection).

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Routinely-Collected Health Data:

Includes number of COVID-19 infections at care home, admissions to hospital and deaths experienced from the **day after randomisation** (Day 1) to **Day 120**.

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Routinely-Collected Health Data:

Includes number of COVID-19 infections at care home, admissions to hospital and deaths experienced from the **day after randomisation** (Day 1) to **Day 120**.

Randomisation takes place after a COVID-19 outbreak at care home.

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Trial Database

Resident self-reported information and care-home collected information will be recorded on the trial database (REDCap).

The database can be accessed via this link:

https://redcap01.nottingham.ac.uk/

or

by scanning this QR code from a mobile device:

Please refer to the 'Data Entry' video for further information on the trial database.

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Trial Database

You will need login details to access the database.

To receive your login details, you will need to complete a database access form (provided by the trial team) and email the completed form back to the team.

Once the trial team receives the completed form, they will email you your login details and any further instructions.

Please refer to the 'Data Entry' video for further information on the trial database.

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Data collection throughout the trial

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)

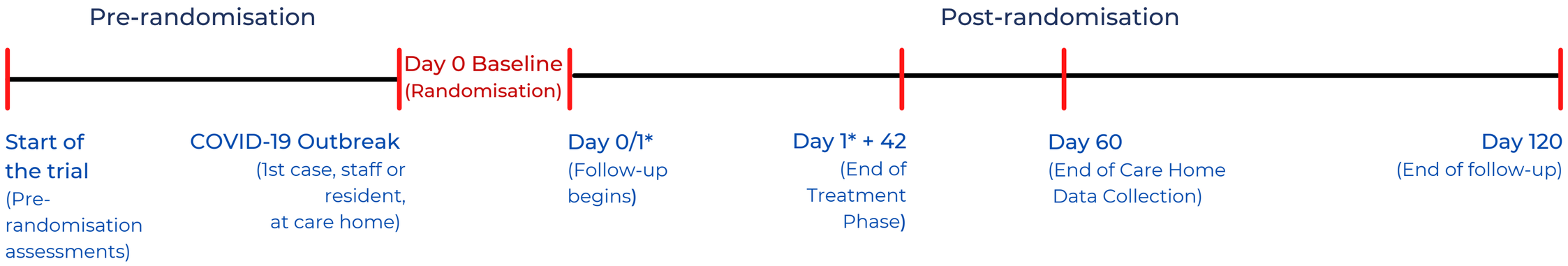
- Safety Reporting

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



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Data collection throughout the trial

*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 starts taking 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.

Pre-randomisation
(Pre-randomisation)

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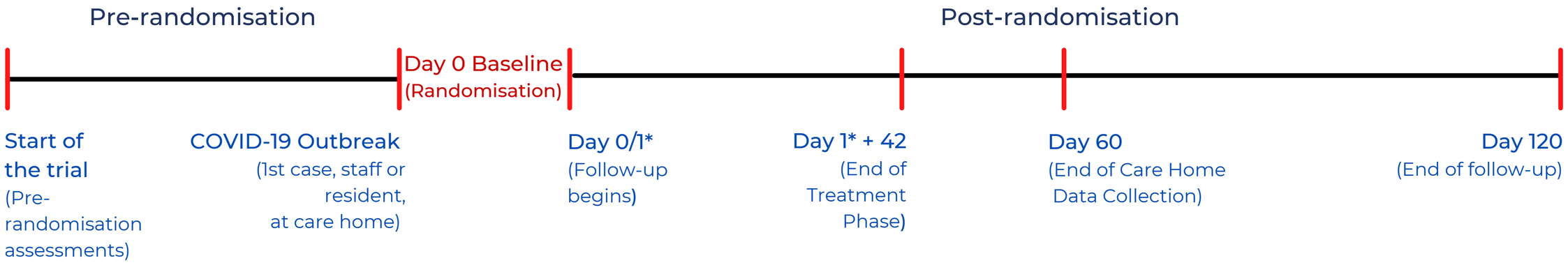

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Data collection throughout the trial

Important: This is critical information needed to answer the research question (if the trial medications make a difference).

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(Pre-randomisation)

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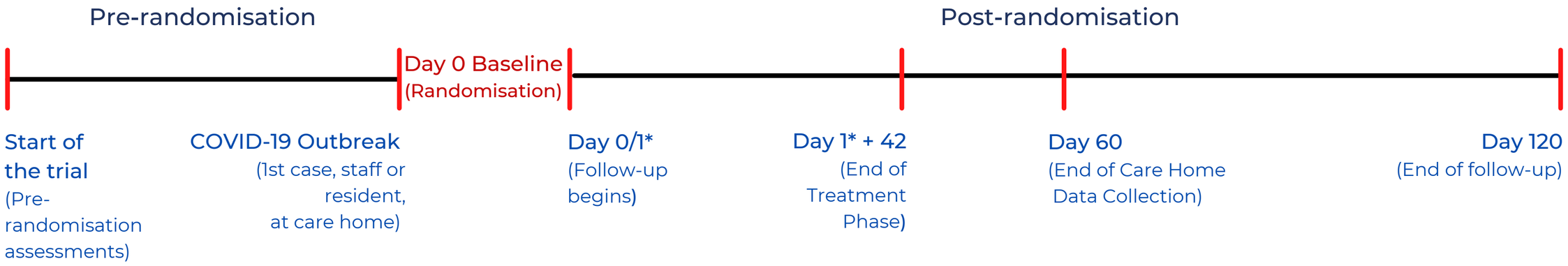

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Data collection throughout the trial

No care home staff involvement needed in the collection of this data

Pre-randomisation
(Pre-randomisation)

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

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Follow-up: Primary Outcome Data
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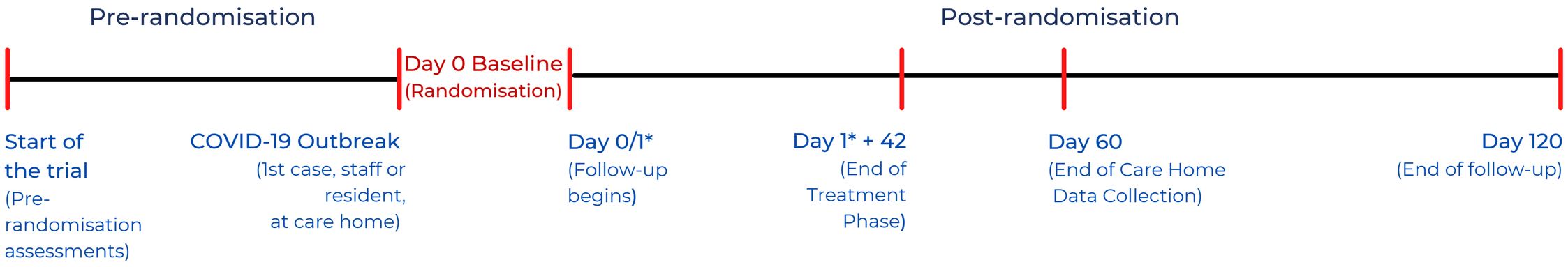

Pre-Randomisation Data Collection

Pre-randomisation Data Collection: Eligibility Screen

When care homes start the trial they will be asked to collect the following information:

1. **Eligibility screen:** Is each resident eligible to take part in the trial?

Care home staff should answer this question for each resident prior to approaching them with information on the trial and assisting with the consent appointment.

Pre-randomisation Data Collection: Eligibility Screen

Resident eligibility should be assessed against a list of inclusion and exclusion criteria (see next slide). Residents are eligible and can be enrolled in the trial if they meet ALL the inclusion criteria and do not meet ANY of the exclusion criteria.

Once consent has been taken, eligibility information should be logged on the trial database.

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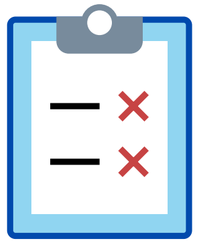
Resident Inclusion & Exclusion Criteria



Inclusion Criteria:

- Resident in a Care Home.
- Age ≥ 65 years
- Informed consent from resident or Personal Legal Representative (PLR).

Please refer to the 'Data Entry' training module for detailed instructions on how to complete the Eligibility assessment.

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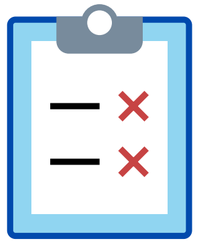
Resident Inclusion & Exclusion Criteria



Inclusion Criteria:

- Resident in a Care Home.
- Age ≥ 65 years
- Informed consent from resident or Personal Legal Representative (PLR).

Exclusion Criteria:

- 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.

Please refer to the 'Data Entry' training module for detailed instructions on how to complete the Eligibility assessment.

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Pre-randomisation Data Collection: Informed Consent

2. **Informed consent**: Has either the resident or their Personal Legal Representative (a close friend or family member) given consent for the resident to take part in the trial?

Informed Consent is taken by the Research Nurse (RN)
(in PROTECT-CH, the term RN is also used to refer to other Allied Health Professionals).

Care home staff will be helping, for example, by arranging for the resident to be in a quiet space in the care home with a tablet or laptop at the time of the consent appointment.

Please refer to the 'Data Entry' and 'Consent and Enrolment' training modules for further information on Consent.

Pre-randomisation Data Collection: Demographics and medical history

3. **Demographics and medical history** (including **vaccination status**): What is the resident's demographic information and medical history?

Care home staff should record resident information, such as, height, weight and smoking status, on the Demographics and medical history form in the trial database.

Please refer to the 'Data Entry' training module for further information on completion of these forms.

Pre-randomisation Data Collection: Demographics and medical history

After consent, **care home staff** should also record:

1) all the **COVID-19 vaccinations** a resident has **ever** received and,
2) all the **non-COVID-19 vaccinations** the resident has received **in the 14 days prior to consent**.

You should continue to record any new non-COVID-19 vaccinations until the day of randomisation and only any new COVID-19 vaccinations until day 60.

Please refer to the 'Data Entry' training module for further information on completion of these forms.

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Pre-randomisation Data Collection: Quality of Life Questionnaires

4. **Quality of Life Questionnaires**: What is the resident's general quality of life **on the day of the assessment**?

Care home staff will be required to complete a quality of life questionnaire called EQ-5D-5L Proxy for **all** residents.

The member of staff completing the EQ-5D-5L Proxy should be involved directly in the care of that resident.

Please refer to the 'Data Entry' training module for further information on completion of this form.

Pre-randomisation Data Collection: Quality of Life Questionnaires

For residents with capacity to consent for themselves: The consented resident should complete a quality of life questionnaire called **EQ-5D-5L** with their own assessment of their general quality of life, following the completion of the EQ-5D-5L Proxy by the care home staff .

For residents lacking capacity, the EQ-5D-5L will not be completed by the resident. Only the EQ-5D-5L Proxy by the **care home staff**.

Please refer to the 'Data Entry' training module for further information on completion of these forms.

Quality of Life Questionnaires: EQ-5D-5L Important Note

Care home staff can assist the resident with capacity in completing their (EQ-5D-5L) questionnaire if necessary.

However, **the responses given should be those of the resident**.

Quality of Life Questionnaires: EQ-5D-5L and EQ-5D-5L Proxy

Both Quality of Life questionnaires consist of two parts:

1. The first part describes someone's health using five questions with five possible answers:

Questions on:
mobility
self-care
usual activities
pain/discomfort
anxiety/depression

Answer level:
no problems
slight problems
moderate problems
severe problems
extreme problems

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Quality of Life Questionnaires: EQ-5D-5L and EQ-5D-5L Proxy

When completing the first part of the questionnaire, the residents with capacity (EQ-5D-5L) and **care home staff** (EQ-5D-5L Proxy) will need to **select ONE answer** that they feel best describes the resident's state, for example:

MOBILITY

- ○ No problems in walking about
- ○ Slight problems in walking about
- ◉ Moderate problems in walking about
- ○ Severe problems in walking about
- ○ Unable to walk about

PAIN / DISCOMFORT

- ○ No pain or discomfort
- ○ Slight pain or discomfort
- ○ Moderate pain or discomfort
- ◉ Severe pain or discomfort
- ○ Extreme pain or discomfort

ANXIETY / DEPRESSION

- ○ Not anxious or depressed
- ◉ Slightly anxious or depressed
- ○ Moderately anxious or depressed
- ○ Severely anxious or depressed
- ○ Extremely anxious or depressed

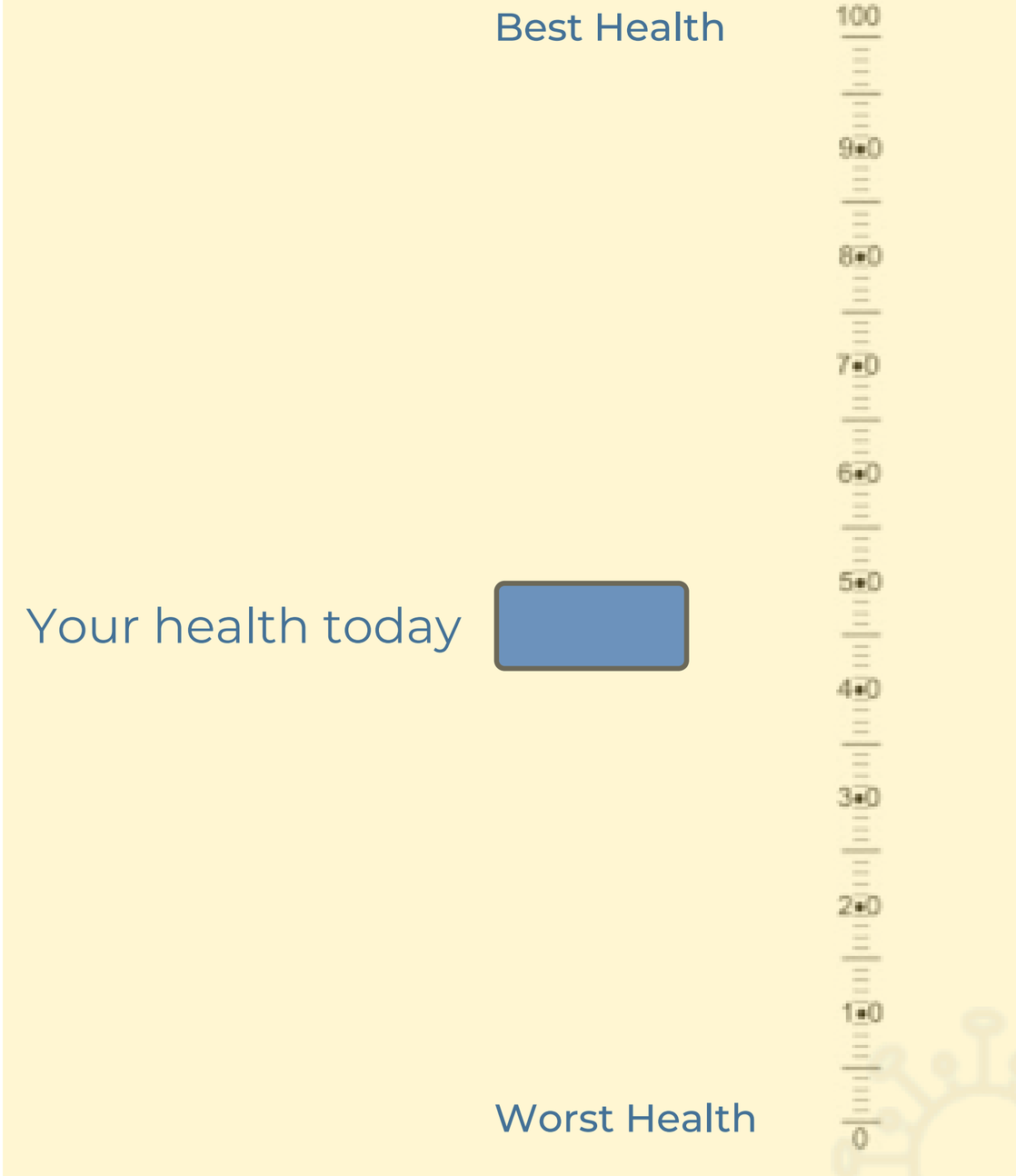
USUAL ACTIVITIES

- ◉ No problems doing my usual activities
- ○ Slight problems doing my usual activities
- ○ Moderate problems doing my usual activities
- ○ Severe problems doing my usual activities
- ○ Unable to do my usual activities

Quality of Life Questionnaires: EQ-VAS

2. The second part (called EQ-VAS) records the resident's health on a scale from zero to 100, where the top and bottom of the scale are:

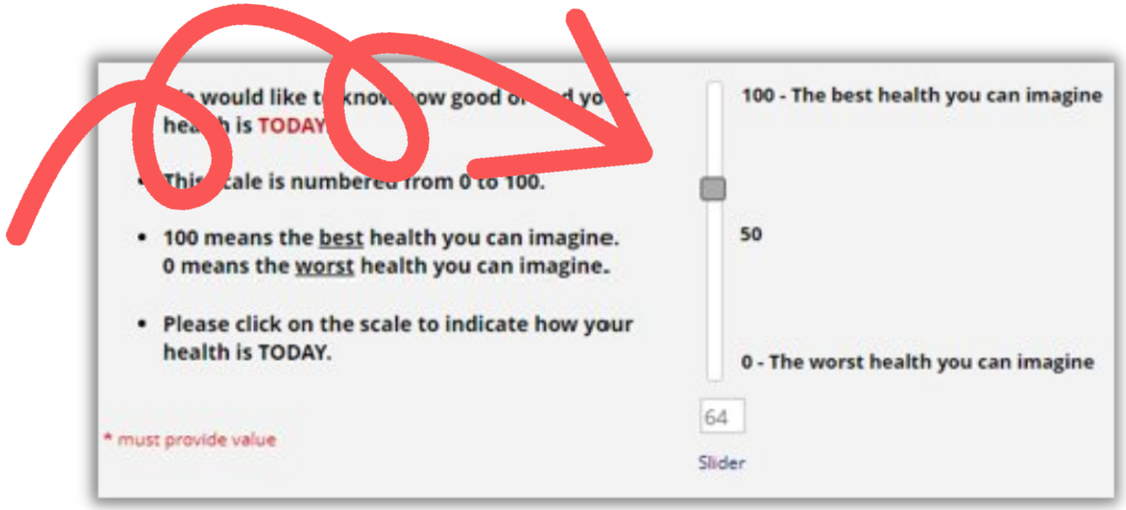
- 'The best health you can imagine' (100)
- 'The worst health you can imagine' (0)



Quality of Life Questionnaires: EQ-VAS

The EQ-VAS will be completed by care home staff (for all residents) and by the resident (if they have capacity).

At times the scale in the database can stick a little, **please ensure that the scale moves** to the appropriate place before saving the form.



GP Eligibility Assessment

GP Eligibility Assessment

It is important all the questionnaires and forms following consent are completed promptly as this will allow the resident to progress to the GP eligibility assessment.

Outcome of GP Eligibility Assessment

Following consent and the completion of the relevant questionnaires and forms on the trial database, the resident's GP will be carrying out the eligibility assessment.

- The outcome of this assessment will be communicated to Personal Legal Representatives (PLRs) of residents lacking capacity (to consent for themselves) by the trial team.
- For residents with capacity, care home staff will need to inform the residents of the GP eligibility check outcome.

Please refer to the 'Data Entry' training module for further information on the actions you need to take following the GP eligibility check.

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COVID-19 Outbreak Data Collection

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Outbreak Data collection

If there is a positive COVID-19 case (staff or resident) in the care home,
care home staff will need to record this in the Outbreak form on the trial database.

It is important to complete this form
as soon as you become aware of the positive result.

Please refer to the 'COVID-19 Outbreak Guidance' and 'Data Entry' training modules for further information.

COVID-19 Outbreak Data collection

After the Outbreak form submission, **care home staff** should check that the resident's vaccination record is up to date and
upload 7 days of Medication Administration Record (MAR) charts for each resident in the trial on the PROTECT-CH Documents' vault.

The information described above is collected at the point of Outbreak for Post-Exposure Prophylaxis (PEP) treatments only.
Please see 'Site Initiation Visit' and 'Background to trial' training modules for further information on PEP.

Please refer to the 'COVID-19 Outbreak Guidance' and 'Data Entry' training modules for further information.

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Follow-up: Day 0-60 Data Collection Overview

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Follow-up: Day 0-60 Data Collection

During this period the following information should be recorded for each resident in the trial:

1.Number of COVID-19 infections in residents in the care home (total number including residents not participating in PROTECT-CH)

2. Numbers of residents with and without COVID-19 infection in care home.

3. Admission to hospital, all cause.

4. Death, all cause.

5. Targeted adverse events, Serious Adverse Events (within 24h of becoming aware) and serious adverse reactions.

6. EQ-5D-5L (and proxy) and EQ-VAS at 60+/-2 days

7. Healthcare resource use and costs

8. Total number of residents in care home on day 60; including number of confirmed COVID-19 infections (whether the resident is enrolled or not).

Please refer to the 'Data Entry' and 'Safety' training modules for further information.

Baseline (Day 0)
Data Collection

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Randomisation (Day 0): Baseline data collection

Care homes who have a COVID-19 outbreak, will be assigned to a group to take either:

the **trial medication + standard care**

OR

standard care alone (no trial medication)

This choice is made at random by computer software and the process is called randomisation.

At randomisation, the number of residents in care home should be recorded on the trial database. This is the number of all residents regardless of whether they are enrolled in the trial or not.

Please refer to the 'Data Entry' training module for further information.

Follow-up: Treatment Phase

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Follow-up: Treatment Phase

- For care homes allocated to **standard care** (alone), the treatment phase covers the period from the day of randomisation **(Day 0) to Day 42**.
- For care homes allocated to trial medication + standard care, this phase covers the period from the date the care home records the resident as having started treatment to 42 days later.

During this phase, care home staff should report on the trial database any adverse events weekly and serious adverse events within 24 hours of becoming aware.

Please refer to the 'Safety' training module for further information on adverse event and serious adverse event reporting.

Follow-up:
Day 60 Data Collection

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Day 60: Quality of Life Questionnaire Completion

End of follow-up data collection for care home

On Day 60 (+/-2 days):

- Residents with capacity should complete an **EQ-5D-5L** Quality-of-life questionnaire themselves.

We recommend an iPad or tablet is used and that **care home staff** assist the resident in completing this.

*A **care home staff member** may complete the **EQ-5D-5L** questionnaire if the resident (with capacity) is unable to enter the data themselves.*
Please note, however, that the responses recorded should be those of the resident not the staff member's.

Please refer to the 'Data Entry' training module for further information on completion of these forms.

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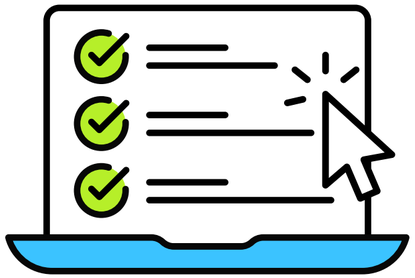
Day 60: Quality of Life Questionnaire Completion

End of follow-up data collection for care home

For both **residents with capacity** and residents lacking capacity, **care home staff** should complete the **EQ-5D-5L proxy** at the same time point.

Important Note: For **residents with capacity**, the care home staff should complete the **EQ-5D-5L proxy** first and following that, the resident should complete their EQ-5D-5L.



Please refer to the 'Data Entry' training module for further information on completion of these forms.

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Day 60: Quality of Life Questionnaire Completion

End of follow-up data collection for care home

Day 60 data collection can be completed in a window of +/-2 days:

You should always try to complete the data collection on day 60 but if there are any issues e.g. the trial database is down, the window allows for an earlier or later collection by two days.

Please refer to the 'Data Entry' training module for further information on completion of these forms.

Day 60: Healthcare Resource Use

At the end of the follow-up period (Day 60 +/-2 days), **care home staff** will record information on health care resource (you may also see this referred to as 'support') use on the trial database.

Healthcare resource use refers to the use of healthcare services, including healthcare professional time, facilities etc.

Please refer to the 'Data Entry' training module for further information on Healthcare Resource Use form completion.

Day 60: Healthcare Resource Use

Non-routine healthcare support visits: These should only be contact with NHS healthcare professionals and services external to the care home.

Please do not report any internal healthcare support (e.g. nursing contact with a nurse based in care-home).

The total number of non-routine healthcare support visits should be reported for each participant for the period up to and including 60 days post-randomisation.

Please refer to the 'Data Entry' training module for further information on Healthcare Resource Use form completion.

Day 60: Healthcare Resource Use

The information recorded should include:

1. Whether the visits were face-to-face or remote,
2. Which healthcare professionals and services were used,
3. The number of times contact (i.e. phone calls, visits etc.) was made.

Please refer to the 'Data Entry' training module for further information on Healthcare Resource Use form completion.

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Day 60: The '60-day check'

On Day 60 (+/-2 days):

Care home staff should check that the following information has been recorded on the relevant forms ('event logs') for each of the participants:

- Resident health events (e.g. hospital admissions, death)
- Resident vaccination status
- Trial treatment doses and adverse event

Please refer to the 'Data Entry' training module for further information on the 60-day check.

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Day 60: Reminders

On Day 58:

You will receive an email from the trial team
as a reminder to complete the Day 60 EQ-5D-5L proxy, EQ-5D-5L (self-completed by residents with capacity), Healthcare Support and 60 Day Check forms.

Routinely Collected Health Data: Day 1-120

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Day 1-120: Routinely collected health data

We will be using routinely collected NHS data to gather information on how study treatments modify longer-term adverse outcomes as a consequence of COVID-19, e.g. long-COVID.

Care home staff will **not** need to do anything to facilitate this type of data collection.

Day 1-120: Routinely collected health data

The following information will be collected from routine sources from Day 1 to Day 120 post randomisation:

- Number of residents with COVID-19
- Number of residents with COVID-19 infection who stayed in care home
- Number of admissions to hospital (COVID-19 related and total)
- Number of deaths (COVID-19 related and total)
- Most serious medical event experienced during the 120 days post-randomisation

Participant Withdrawal

Adjusting participant involvement

Participants or their personal legal representatives (PLRs) may wish to change which parts of the trial the residents are involved in.

For example, they may choose one of the following options:

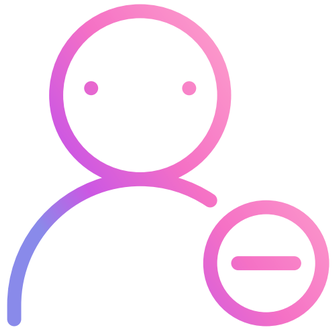
- Stop receiving trial medication but allow the care home team to continue collecting trial data and allow routinely-collected health data to be obtained for analysis,
- Stop receiving trial medication and trial data provision but allow routinely-collected health data,
- Stop trial medication and any data collection from that point onwards.

The participant's choice should be recorded by care home staff on the 'Trial status' form in the trial database.

Please refer to the 'Data Entry' training module for information on completing the 'Trial status' form.

Clinician-led Withdrawal

Participants' General Practitioners (GPs), one of the trial doctors (known as Principal Investigators (PIs)) or the Chief Investigator, may decide that it is against the participant's best interest to stay in the trial.



Clinician-led Withdrawal

The participant will be taken off the trial medication if:

- **They are hospitalised.**

Trial medication should be restarted if the participant returns to the care home within the 42-day treatment period. Medication administration should continue up to the original planned stop date.

- Treatment may also be stopped **if a participant experiences unacceptable side effects** (specified in the IMP protocol appendices) and their assessing clinician considers it inappropriate for them to continue taking the trial medication.

Clinician-led Withdrawal

Participants who have been withdrawn from taking trial medication and who are experiencing ongoing side effects will be followed up until the side effect stops.

These participants will continue to receive the most appropriate standard of care treatment available under the guidance of their GP or other treating clinician.

Withdrawal: Important note

Information collected before the resident stops participating in the trial will not be deleted and will be included in analyses.

Routinely collected health data will still be obtained for use in the analysis unless the participant or their Personal Legal Representative (PLR) explicitly states otherwise.

Please refer to the 'Data Entry' training module for information on completing the 'Trial Status' form.

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Module Overview & Self-certification Link

In this module we have covered the following:

- Purpose of training
- What type of data will be collected as part of the trial and when
- Pre-randomisation data collection
- GP eligibility assessment
- COVID-19 outbreak data collection
- Follow-up: Day 0-60 data collection overview
- Baseline (Day 0) data collection
- Follow-up: Treatment phase
- Follow-up: Day 60 data collection
- Routinely collected health data: Day 61-120
- Participant withdrawal

Thank you for watching!

You have now completed the

Trial Assessments and Follow-up

Training Module.

Please remember to complete your self-certification form to confirm you have undertaken this training

This can be found at:

https://w3.abdn.ac.uk/hsru/NCTU-Protect/Public/Public/SelfCertification.cshtml?TrainingModule=91&ModuleVersion=1

Or you can access it via mobile here:

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

protect-trial@nottingham.ac.uk

0115 74 87710