PROTECT-CH

Prophylactic Therapy in Care Homes Trial

COVID-19 Outbreak Guidance Booklet

Final Version 1.0 20-JUL-2021

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Purpose of training

This booklet will give you information on what to do for the trial when there is a COVID-19 outbreak in your care home. It comprises an Outbreak Process flowchart followed by detailed explanations of all the steps.

An outbreak for PROTECT-CH is defined as the first COVID-19 case (resident or staff member) at a care home after Green Light has been issued and consent has been taken from ALL the residents who have agreed to take part.

The PROTECT-CH trial team are available to assist with the outbreak process and any other questions you may have:

Email: protect-trial@nottingham.ac.uk

Phone: 0115 74 87710

Outbreak flowchart: First COVID-19 case

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Positive COVID-19 test at Care Home (staff or resident)

1. Complete the **Outbreak form** on the trial database: https://redcap01.nottingham.ac.uk/
2. Ensure your **residents' vaccination records** are up-to-date on the trial database: https://redcap01.nottingham.ac.uk/
3. Upload **7 days of residents' MAR* charts** to the PROTECT-CH Documents Vault: https://protect-vault.nottingham.ac.uk/

These three steps need to be completed as soon as you become aware of a positive COVID-19 test result (rapid or lab test).

You will be informed of your group (trial medication + standard care or standard care alone) via an email from: protect-trial@nottingham.ac.uk

Please check your spam/junk folder for this email.

**Medication Administration Records*

Outbreak flowchart: Next Steps

Trial Medication + Standard Care

OR

Standard Care alone

You will receive an email telling you the trial medication's estimated date and time of arrival

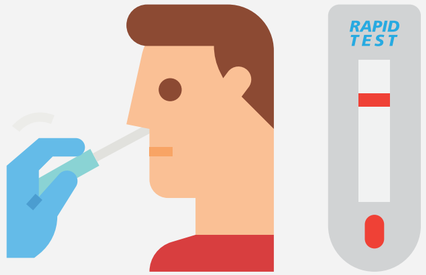
Trial medication arrives at care home

1) Trained staff member to sign upon receipt
2) Check all the medication and any additional equipment (e.g. spacers) expected have arrived and are not damaged
3) Inform the trial team of receipt
4) Store according to instructions
5) Administer to consented residents and record on trial MAR chart

Please upload trial data on the trial database weekly,
any COVID-19 events as they happen and
serious adverse events on the trial database within 24 hours of becoming aware

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 usually within minutes.



A **Polymerase Chain Reaction (PCR)** test is analysed at a **lab** and it usually takes 24-48 hours for its results to become available.

First positive COVID-19 test result at care home (staff member or resident)

- As soon as you become aware of a staff member's or resident's **positive** test (LFT or PCR; whichever test result comes first), please log into the trial database and let us know by completing the Outbreak form.
- After completing and submitting your Outbreak form, you will also need to check that your residents' vaccination records are up-to-date on the trial database and upload your residents' Medication Administration Records (MAR)s on the PROTECT-CH Documents vault.

It is important that you complete the Outbreak form as soon as you become aware of a positive COVID-19 result!

Outbreak form

In order to complete the outbreak from, you will need to access the trial database (REDCap), which you can do via the following link:

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

or

by scanning this QR code from a mobile device:

PROTECT-CH REDCap Database

Please refer to the 'Data entry' training module for specific instructions on how to complete the outbreak form on the trial database.

Residents' vaccination records

During the trial, you are asked to inform us about all the vaccinations (not just the COVID-19 ones) that residents within the trial receive by completing the relevant form on the trial database.

The residents' vaccination records should be updated in real time and product names should be included.

At the point of the outbreak, you will need to check that the consented residents' vaccination records are up-to-date. This is critical for the team of trial doctors (known as Principal Investigators or PIs) to assess the residents' eligibility to receive the trial medication.

Please refer to the 'Data entry' training module for specific instructions on how to record vaccination record data on the database.

Medication Administration Record (MAR)

Following the report of the outbreak on the trial database and the update (if needed) of the residents' vaccination records, you will be required to upload a copy of the MAR chart for each resident who has provided consent to take part in the trial.

7 days of MARs must be uploaded for each resident to a secure vault (PROTECT-CH Documents Vault).

PROTECT-CH Documents Vault

In order to upload your residents' MAR charts, you need to log into the PROTECT-CH vault. To access the vault, please follow this link:

https://protect-vault.nottingham.ac.uk/

or

scan this QR code from a mobile device:

PROTECT-CH Documents Vault

You will need to upload the MAR charts of all the residents who have provided consent.

Please refer to the 'Data entry' training module for specific instructions on how to upload the MAR document(s) to the vault.

Notifications

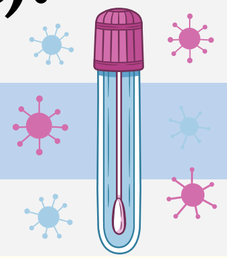
When you submit an outbreak form, this will trigger automatic email notifications from the PROTECT-CH trial mailbox to:

1) the PROTECT-CH trial team based at the University of Nottingham Clinical Trials Unit (NCTU),
2) Principal Investigators (PIs),
3) the trial research nurses (RNs),

and once eligibility has been confirmed by the PIs:

4) the Personal Legal Representatives (residents' close friends or family); for those residents who lack capacity to consent for themselves.

What to do if you receive a positive LFT (rapid test) result followed by a negative PCR (lab test) (and no one else at care home has a positive test).



Negative PCR result follows a positive LFT:

1. **Please inform the PROTECT-CH trial team immediately via email to protect-trial@nottingham.ac.uk**

2. **If you have already received the trial medication, please quarantine it immediately (see page 14 for further information). The trial team will arrange collection from your care home.**

3. **If medication has already been administered to residents, please do not give any further doses.**

You should continue recording the participants' data on the trial database weekly, any COVID-19 events as they happen and any serious adverse events within 24 hours of you becoming aware.

Quarantine of trial medication

If you receive a positive LFT (rapid test) result followed by a negative PCR (lab test),
no one else at the care home, staff or resident, has had a positive test and you have already received the trial medication, you will need to quarantine it immediately and inform the trial team.

To quarantine the trial medication you need to store all the medication so that it cannot be administered to any participants. If possible a locked cabinet should be used. It may also be useful to label the medication so that people know not to use it.

Principal Investigator (PI) eligibility check

After you have reported a COVID-19 outbreak, the PIs will carry out a final check of your residents
based on the information provided by the GPs and
the MAR charts you have uploaded.

Randomisation

The PIs will then randomise* your care home to one of two groups:

1) **a trial treatment (and standard care)** or

2) **standard care alone**.

*The group your care home is given will be decided by computer software based on chance, a process called 'randomisation'.

You will be notified of which group your care home is in via email.

It may take <u>several hours</u> from the Outbreak Form submission to the receipt of the email informing you of your group allocation. Please check your email, including your Junk/Spam folder.

Care home allocated to Standard Care

If your care home is randomised to standard care:

1. You will need to be uploading data to the trial database **weekly** and COVID-19 events **as they happen**.

Please refer to the 'Trial Assessments & Follow-up' and 'Data Entry' training modules for specific instructions on the weekly data collection and how to record data on the trial database.

2. You need to report any adverse events on the trial database in a **timely fashion** (**within 24 hours** if Serious Adverse Event).

Please refer to the 'Safety' training module for specific instructions on safety events, the different types of safety events, the reporting process and timelines.

Care home allocated to Trial Medication

You will receive an email from the trial team informing you of the trial medication's estimated date and time of arrival.

When the trial medication arrives:

1. **Sign upon receipt.**
2. **Check all the medication and spacers expected have arrived and are not damaged.**
3. **Store at room temperature according to instructions.**
4. **Email the PROTECT-CH trial team (protect-trial@nottingham.ac.uk) to inform them that you have received the trial medication.**
5. **Administer to consented residents at the care home and record in the trial MAR chart.**

Please refer to the 'Therapy' training module for specific instructions on storage, handling and administration of the trial medication.

Care Home allocated to Trial Medication

1. You will need to be uploading data to the trial database **weekly** and COVID-19 events **as they happen.**

Please refer to the 'Trial Assessments & Follow-up' and 'Data Entry' training modules for specific instructions on the weekly data collection and how to record data on the trial database.

2. You need to report any adverse events on the trial database in a **timely fashion** (**within 24 hours** if Serious Adverse Event).

Please refer to the 'Safety' training module for specific instructions on adverse events, the different types of safety events, the reporting process and timelines. and the reporting process.

Thank you for reading!

You have now completed the

COVID-19 Outbreak Guidance

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=5&ModuleVersion=1

Or you can access it via mobile here:

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

protect-trial@nottingham.ac.uk

0115 74 87710

Thank you