

# General

## Why are we doing the PROTECT-CH trial?

### General Residents and Legal Representatives

Since the start of the pandemic, the lives of care home residents and their relatives have been greatly affected by COVID-19. Efforts to reduce spread of the coronavirus into care homes, such as limiting family visits, have had a significant impact on the health and wellbeing of residents. Therefore, we need to find medications to minimise this impact. Government health ministers have asked us to set up this trial to find out how we can protect care home residents from COVID-19. We will try out different medications to see which ones may help, so that residents can stay well and resume a more normal life.

## What is the purpose of the trial?

### General Residents and Legal Representatives

The aim of the trial is to see if we can find medications to prevent or reduce the spread and impact of COVID-19 in care homes.

## Why do we need the PROTECT-CH trial when we have COVID-19 vaccines?

### General

Care homes have made major changes and advances in reducing the risk of COVID-19 through introducing personal hygiene measures (“hands, face, space”) and personal protective equipment (PPE; masks, visors, gloves, aprons/gowns). The success in vaccinating residents will further reduce the risk of COVID-19 in care homes. However, the COVID-19 vaccine may not completely stop infection for several reasons:

1. No vaccine is 100% effective, so some vaccinated people will still get infected and will go on to develop severe disease. The clinical trials of COVID-19 vaccines have shown that between 60% and 95% of participants were protected. It is important to note that none of the vaccine trials tested people in their 80s/90s/100s. The average age of care home residents is around 85 years, so it is possible the vaccines may be less effective in this group, especially since immune function declines with advanced age.
2. Although vaccines are likely to reduce transmission, some virus can still be passed on between staff/residents/family to other residents.
3. If the virus mutates, these changes may further reduce the benefit of existing vaccines. Already, some new variants of the virus appear to be partially resistant to existing vaccines and it is likely that future variants could make this problem worse. Vaccine manufacturers are already preparing to modify their vaccines to make them effective in the future although the next generation of vaccines may be many months away. This is similar to seasonal ‘flu, where a new version of the vaccine is developed each year to deal with recent changes to the ‘flu virus.
4. Initially we will look at different ways of using existing medications to prevent and treat COVID-19 when present measures (such as hygiene, PPE and vaccines) aren’t enough. The main purpose of the PROTECT-CH trial is to find additional ways to reduce COVID-19 infection and its devastating impact on care home residents.
5. If the PROTECT-CH trial finds that medications can prevent or reduce COVID-19 infection in care homes, then they may also work to protect the wider community.

## Who can take part?

### General

Residents in UK residential or nursing care homes may join the trial, but first, their care home must sign up to be part of the trial.

## What are the trial medications?

### General Residents and Legal Representatives

More information about the trial medications is available in the Participant Information Sheet or Legal Representative Information Sheet.

## How will the trial medications be allocated?

### General

Care homes will be allocated to either usual care alone (no additional trial medication) or to usual care plus a trial medication. Allocation to usual care or usual care plus a trial medication will be decided at random, i.e. like a toss of a coin. This is to ensure a fair comparison of the trial medications. Residents from the same care home who enrol in the trial will all receive the same trial medication.

## Where is the trial taking place?

### General

Care homes across all the four nations within the United Kingdom will be involved (England, Northern Ireland, Scotland and Wales).

## When will the trial start?

### General

The trial is currently being set up and we welcome expression of interests from care homes. We do not know yet when residents will begin receiving the first trial medications.

## How long will the trial last?

### General

There is no end date at present, but we will make the results of the trial rapidly available to ensure that medications can be introduced without delay and COVID-19 clinical guidelines are quickly updated.

## Who is organising and funding this trial? How has it been approved?

### General Residents and Legal Representatives

The trial is being organised by the University of Nottingham (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit (NCTU). It is being led by Professor Phillip Bath. The trial is funded through the National Institute for Health Research (NIHR) Health Technology Programme (NIHR 133443).

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion by South Central – Oxford A Research Ethics Committee.

Lay members of the public are involved in the teams that oversee the running of the trial and have helped develop the materials for residents and legal representatives.

## What role have patients and the public had in designing and running the trial?

### General

Patients' representatives were involved in designing the trial and in applying for the funding to carry out the trial. Lay members of the public are involved in the teams that oversee the running of the trial and they have helped develop the materials for residents and legal representatives.

# For Care Homes

## Our care home is interested in taking part, what do we need to do next?

### For care homes

If you are a care home manager, please tell us more information about your care home by completing our online [survey](#). A member of the research team will then contact you.

## Most/all of our residents have received their COVID-19 vaccine. Can we still take part?

### For care homes

Yes. We expect most residents to have been vaccinated before the trial starts, but residents can still take part whether or not they have been vaccinated.

## Will all care homes be included in the trial?

### For care homes

All UK residential and nursing care homes registered for old age and/or dementia with 20 or more beds can take part. To be included, care homes first need to register their interest in taking part in the trial by completing our online [survey](#). A member of the research team will then contact you.

## Can care homes stop taking part at any point?

### For care homes

If you have a serious issue at your care home and you are unable to carry on, you can contact the research team to discuss the issue. Depending on the issue, it may be possible for the research team to offer support, or pause the trial and re-start at a later date, or your care home may have to stop taking part.

## Can care homes take part in more than one COVID-19 study/trial?

### For care homes

If you are interested in taking part in PROTECT-CH, please complete our online [survey](#) and tell us about other studies/trials your care home is involved in. Your care home may still be able to take part in PROTECT-CH.

## How can I contact the PROTECT-CH research team?

### For care homes

The PROTECT-CH trial email address is [protect-trial@nottingham.ac.uk](mailto:protect-trial@nottingham.ac.uk)

# Residents and Legal Representatives

## Why are we doing the PROTECT-CH trial?

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Lay members of the public are involved in the teams that oversee the running of the trial and have helped develop the materials for residents and legal representatives.

## Why should residents take part in this trial if they have had a COVID-19 vaccine?

### Residents and Legal Representatives

As no vaccine is completely effective, some people may still get COVID-19. We still don't know whether being vaccinated will stop residents from catching and passing on the coronavirus. So, it's important we continue to look for more preventative medications.

## Why have residents been invited to take part?

### Residents and Legal Representatives

Residents have been invited to take part because they live in a UK care home which is taking part in this trial.

## Do residents have to take part?

### Residents and Legal Representatives

It is entirely up to each resident (or, if they lack capacity their legal representative) whether they take part in the trial. A member of the research team will be able to answer any questions you may have.

If residents (or, if they lack capacity their legal representative) decide they should not take part, their care will continue in the normal way. If residents (or, if they lack capacity their legal representative) decide they should take part, but then change their mind at any time, they are free to withdraw without giving a reason.

## What are the possible benefits of taking part?

### Residents and Legal Representatives

We do not know which medications could prevent or reduce the spread of COVID-19. Taking part in the trial may or may not directly benefit residents but the information we collect could help future residents and older people in general.

## What are the possible disadvantages and risks of taking part?

### Residents and Legal Representatives

As with all medications, there is a small risk of side effects which will be discussed with residents (or, if they lack capacity, with their legal representative). We will also use the information we collect from resident's GPs and talking with care home staff to decide whether a particular trial medication would be suitable for each resident to have.

## What would taking part involve?

### Residents and Legal Representatives

To understand which medications might work we need to compare these to usual care. Government health advisors will tell us which medications they want us to test.

Each care home will be allocated a particular trial medication. If residents (or, if they lack capacity their legal representative) agree to take part, they will either have their usual care plus a trial medication for 6 weeks, or carry on with their usual care alone. We won't know the allocation until all the residents in the care home have been asked if they would like to take part. Neither residents (or, if they lack capacity their legal representative), nor the care home, can choose what residents will receive. This will be decided by a computer.

If residents (or, if they lack capacity, their legal representative) agree to take part:

1. Residents (or, if they lack capacity, their legal representatives) will be asked to sign a Consent Form to be part of the trial.
2. With residents' (or, if they lack capacity their legal representative's) permission, we will inform their GP about their participation in this trial. We would also like to access each resident's medical records, including those held by their GP. We would like information about each resident's medical history and the medications they are taking. This will help us understand which of the trial medications they can have.
3. Care home staff will complete two questionnaires with details about residents' health. Residents with capacity will also be asked to complete these questionnaires. Care home staff can help with this.
4. Residents will be allocated to receive either:
  1. usual care plus a trial medication OR
  2. usual care alone
5. The researchers will collect some information from each care home about the residents' use of the trial medication and whether this has made a difference to their health. We will also collect some information from national databases and trusted third parties about each resident's general health.

## If residents get usual care what does this mean?

### Residents and Legal Representatives

If a resident's care home is allocated to deliver usual care alone this means that they will get the care which they would normally be given for any conditions or symptoms they may have. Their usual care will be decided by their care home and/or doctor as normal.

## **If residents get a trial medication what does that mean?**

### **Residents and Legal Representatives**

As well as their usual care, residents will also be asked to take one of the trial medications. This can be taken at the care home. It will be prescribed and delivered to their care home free of charge. We will train and support care home staff to give the trial medications as part of day-to-day care.

## **If residents are allocated a medication can they stop taking it?**

### **Residents and Legal Representatives**

Residents are free to stop taking the trial medication at any time, without giving any reason, and without their legal rights being affected.

If residents stop taking the trial medication, the information collected will not be erased and may still be used in the trial.

## **What if residents want to take part in the trial but cannot take the trial medication?**

### **Residents and Legal Representatives**

Residents can still take part in the trial. Their care will continue as normal and we would like to continue to collect information about their health.

## **Could there be other trial medications to test?**

### **Residents and Legal Representatives**

Yes, we could be asked to test other medications in the PROTECT-CH trial in the future. Only one trial medication will be given at a time in each care home. Residents (or, if they lack capacity their legal representatives) will be given information on any new trial medications and we will ask each resident (of, if they lack capacity their legal representative) if they are happy to remain involved. There will be a period of time in between taking any trial medications.

## **Can residents carry on in the trial if they become unable to make decisions for themselves?**

### **Residents and Legal Representatives**

Being able to make an informed decision is often referred to as having 'capacity' to make decisions for oneself. Sometimes people who live in care homes lose the ability to make decisions for themselves through illness.

If residents decide to take part in the trial, they will be asked to consent to their care home appointing a legal representative who can make decisions for them should they lose the capacity to do so.

## **What will happen if residents don't want to carry on with the trial?**

### **Residents and Legal Representatives**

Residents (or, if they lack capacity their legal representative) are free to withdraw at any time, without giving any reason, and without their legal rights being affected. If they withdraw, the information collected will not be erased and may still be used in the trial.

## **Where can residents find more about how their information is used?**

### **Residents and Legal Representatives**

Residents (or, if they lack capacity their legal representative) can find out more about how we use their information:

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/) and [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- at <https://www.nottingham.ac.uk/utilities/privacy.aspx>
- by sending an email to [protect-trial@nottingham.ac.uk](mailto:protect-trial@nottingham.ac.uk)
- by calling the PROTECT-CH team at the Nottingham Clinical Trials Unit on 0115 748 7710

## **What if relevant new information becomes available?**

### **Residents and Legal Representatives**

During the trial we may get new information about medications for COVID-19. If this happens, the care home will tell residents (or, if they lack capacity their legal representative) about this new information and discuss whether they should continue in the trial. If residents (or, if they lack capacity their legal representative) decide not to carry on, the care home will make arrangements for their care to continue as usual. If residents (or, if they lack capacity their legal representative) decide to continue in the trial, they (or, if they lack capacity, their legal representative) may be asked to sign a new Consent Form.

## **What happens at the end of the trial?**

### **Residents and Legal Representatives**

We will inform each care home of the trial findings which can then be shared with residents and legal representatives. The results of the trial will be presented at conferences and published as reports in scientific journals. Residents will not be identified in any publication.

## **What are the trial medications?**

### **Residents and Legal Representatives**

More information about the trial medications is available in the Participant Information Sheet or Legal Representative Information Sheet.