

Plain English Summary

The COVID-19 pandemic has had a catastrophic effect in care homes. COVID-19 causes illness and death in care home residents and staff. Policies to reduce viral spread into care homes, e.g. by limiting family visits, impact on health and wellbeing of residents. Beyond public health measures to prevent infection (hygiene, masks, personal protective equipment, maintaining distance), we urgently need treatments to minimise these impacts on residents. Only one treatment, dexamethasone, has been shown so far to reduce death due to COVID-19 but this only works in people with severe disease and who need oxygen therapy.

We will set up a large “platform” trial that will test several treatments intended to reduce the spread of COVID-19 within care homes, and reduce the risks of hospitalisation and death. A trial platform allows multiple treatments to be tested in parallel with results analysed regularly. As soon as a treatment is shown to be effective or ineffective, it is removed from the trial. This makes space for new treatments to be added to the trial. This process of testing treatments and then replacing them with new treatments can go on for many months or years. The exact treatments to be tested will be chosen by Government advisors. We will recruit more than 400 care homes for older people from across the UK (some of whom we have worked with before). We will recruit approximately 12,000 residents in these care homes. Care homes will be randomised (like a toss of a coin) to active treatment or control. We expect most of the interventions to be given for two months before we can see whether they have worked. We will also study whether the treatments are cost effective.

We will develop training materials including videos and audio descriptions for care home staff and information sheets for residents to allow them to make an informed decision on whether to join the trial; these materials will be adapted for use by family members and independent physicians (for use if no relative is available) who will make decisions on behalf of residents when they do not have capacity.

Patient Public and Carer involvement will be embedded in the study, including with Black and Minority Ethnic representation. The lead member, who led PPI in a large care home trial (FinCH), is a named co-applicant. A PPI team have already contributed to the development of the grant application and design of the trial. Going forward they will: advise and support involvement with the care homes including training, and advise on interpretation of results. The membership of the PPI team, through a hub (based with trial team) and spoke (regional centres) model, will seek to be representative of the communities the care homes serve.

The trial will be run from the University of Nottingham with involvement by the Universities of Cambridge, Edinburgh, Surrey and Warwick, and University College London. Our team of doctors, statisticians, trial methodologists, health economists and public partners has considerable experience in care home research, including a recently completed large trial of a different kind of intervention in care homes. The research team has assisted with the running of the RECOVERY, AGILE and PRINCIPLE platform trials and AVID-CC trial, and are running a small demonstrator care home infection prevention trial.

We will make the results of the trial rapidly available to ensure that COVID-19 guidelines are quickly updated and to prevent impact delay. This will include creating summaries for the general public, care home residents and their loved ones.