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FluCare Phase 2: Increasing care home staff influenza vaccination rates

Submission date 25/08/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 27/08/2021	**Overall study status** Completed	
Last Edited 24/01/2023	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims

Every year flu, caught from staff and visitors, causes serious illness and death in care home residents. The best defence against flu is vaccination, which prepares the body to be able to fight it. While vaccines work in most people, there are always some for whom they do not work. That means that if we give vaccines to care home residents, some will still not be protected. The best way to protect residents is, therefore, to vaccinate care home staff as well. This further reduces residents' chances of catching flu. To best protect care home residents, the World Health Organisation, therefore, recommends that over three-quarters of care home staff should be vaccinated. In the UK less than half of care home staff are vaccinated which means that residents are put at higher risk.

After reviewing the evidence and speaking to care home staff and managers, we found three main reasons for why staff do or do not get vaccinated. These are: how easily they can access vaccines; how important their manager sees staff vaccination; and attitudes and beliefs around vaccination.

Our research will test if the following approaches can increase how many staff get vaccinated:
1. Community pharmacists vaccinating staff in the care home
2. Providing free vaccinations for everyone
3. Offering incentives to managers who increase the number of vaccinated staff
4. Monitoring how many staff get vaccinated and giving feedback to the home
5. Providing vaccine information leaflets and videos for staff and managers

We want to find out which of these approaches is most likely to increase the number of staff who are vaccinated and provides the best value to the NHS.

Who can participate?

All staff employed at the long-stay care homes for older residents or dementia registration recruited to the study.

What does the study involve?
Our research has five stages that will take place over 3 years in East Anglia, London, and the East Midlands. It has been designed assuming that COVID-19 is still with us.

We will first spend two months developing each of the above approaches with care home staff and pharmacies. Then, in the middle of next flu season, we will test the approaches in 10 care homes. This will show us how the ideas work in practice, how to best collect data, and what happens in groups who carry on with “service as usual”. Learning from this, we will refine the service and decide which mixture of approaches to study on a larger scale. We will do this by carefully listening to those involved and by looking at the quality of information we received.

Using information from these first three stages, in our main study we will work with 70 homes with low vaccination levels. Homes will be allocated at random (like flipping a coin) to either get our new service or to carry on with “service as usual”. At the end of the flu season, we will compare how many staff are vaccinated in the “new service” and “service as usual” groups. We will collect measures of resident health and costs related to the new service. This will show us if the service improves resident health and saves money for the NHS. At the same time, we will find out whether people used the new service as we intended. We will also listen to people involved to find out what did and did not work to learn how to improve the service. Finally, we will use our findings to develop a toolkit. This will tell people about our new service and encourage them to use it.

While we do this research, we will work closely with residents and relatives. They will help us design and manage the studies, collect information, look at the results and present them to the outside world.

What are the possible benefits and risks of participating?
There are several direct benefits for those taking part in the study. First, helping to provide evidence to obtain more investment in the social care sector (e.g. make flu vaccination free for all staff). Second, improved resident health. Third, reduced costs on the NHS and social care sector.

There are no obvious risks for those taking part in the study. Any adverse events will be managed by the research team working closely with care homes and pharmacies affected. There will be close oversight from the Trial Steering Committee and Norwich CTU in handling any difficulties.

Where is the study run from?
University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
From August 2021 to June 2022

Who is funding the study?
The National Institute of Health Research (UK)

Who is the main contact?
1. Dr Amrish Patel, Amrish.Patel@uea.ac.uk
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
R209939

Study information

Scientific Title
FluCare Phase 2: Estimating the effectiveness and cost-effectiveness of a complex intervention to increase care home staff influenza vaccination rates – a feasibility study

Acronym
FluCare

Study objectives
It is feasible to conduct a cluster-randomised controlled trial to evaluate the effectiveness and cost-effectiveness of a multi-component care home staff focused influenza vaccination engagement intervention compared to usual care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/12/2021, The University of East Anglia Faculty of Health and Medical Sciences Ethics board, ref: ETH 2122-0456

Study design
Multicentre five-arm parallel cluster-randomized controlled feasibility trial, with an embedded process evaluation

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Influenza vaccination in care home staff

Interventions
10 homes will be selected from all eligible expressions of interest in order to maximise variation in important characteristics (e.g. care home size; type of pharmacy; with or without nursing). These homes will then be randomised equally across the 5 trial arms, 4 usual care arms, and 1 intervention arm.

Usual Care
Four variations of usual care will be undertaken to establish the optimal comparator for the

main trial (i.e. which intervention component(s) (information materials) would increase study engagement but minimise reactivity bias).

Arm A (2 care homes): Usual care with end of study monitoring
Arm B (2 care homes): Usual care with regular monitoring (to check for reactivity bias)
Arm C (2 care homes): Information materials with end of study monitoring
Arm D (2 care homes): Information materials with regular monitoring

Intervention:
Arm E (2 care homes): A multi-component intervention targeting barriers to care home staff flu vaccine uptake: free, in-care home vaccination clinics; information/videos for staff; regular monitoring and feedback; financial incentives for managers.

The intervention duration is November 2021 to February 2022, follow-up data collection (for all arms) will last 1 month after the intervention ends.

Intervention Type
Behavioural

Primary outcome(s)
Proportion of the total number of staff employed at any point throughout a flu season (of all directly contracted staff such as care staff, cleaners, cooks, administrative staff, and all agency staff) who receive a flu vaccine measured using vaccination and staffing data provided by care homes weekly between November 2021 and March 2022

Key secondary outcome(s))
Recruitment outcomes:
1. Proportion of care homes willing to participate and time taken to recruit measured using recruitment logs during the recruitment period
2. Proportion of recruited care homes completing the site profile questionnaire at the start and end of the trial measured using site profile questionnaire responses at 4 months
3. Proportion of staff in intervention homes who consented to complete Mechanisms of Action Questionnaire (MAQ) measured using recruitment logs at 4 months

Data Collection outcomes:
1. Number of missing variables in home-reported data at the individual staff level and care home level measured using home-reported data at 4 months
2. Number of missing data values for at the individual staff level and care home level data in variables reported by homes measured using home-reported data at 4 months
3. Proportion of MAQ completed (by staff in intervention homes only) measured using MAQ responses at 4 months
4. Number of missing variables and data values for intervention delivery resource use measured using intervention delivery resource use responses at 4 months
5. Staff vaccination reporting measured using Department of Health and Social Care (DHSC) reported vaccination data at 4 months

Intervention implementation outcomes:
1. Number of times videos played (embedded in videos) and duration that video played measured using website data recorded continuously between 0 and 3 months (during intervention delivery)
2. Number of posters displayed and locations measured using ethnographic between 0 and 3

months
3. Number of pharmacy visits to homes measured using a pharmacist log submitted at 4 months
4. Length and time of pharmacy visits to home measured using a pharmacist log submitted at 4 months
5. Number of incentive payments made to homes measured using payment logs at 4 months

Process evaluation outcomes:
1. Acceptability of intervention components (including video/information materials and pharmacist visits) including cultural adaptations competent measured using a mixed-methods process evaluation at 3 months
2. Identification of intervention elements likely/unlikely to increase vaccination rates measured using descriptive statistics across trial arms and the mixed-methods process evaluation at 3 months
3. Acceptability of monitoring and provision of information in control arms (to inform choice of control arm) measured using a mixed-methods process evaluation at 4 months
4. Description of intervention reach and how to enhance it measured using a mixed-methods process evaluation at 4 months

Completion date
01/06/2022

Eligibility

Key inclusion criteria
Care homes:
1. Long stay for older residents or dementia registration
2. Self-reported staff vaccination rate <40% (verified with DHSC Capacity Tracker)
3. Must be signed up to the DHSC Capacity Tracker and willing to provide weekly updates on flu vaccine status of staff and residents

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Care homes with fewer than 10 staff members

Date of first enrolment
10/12/2021

Date of final enrolment
31/01/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norwich Clinical Trials Unit
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Study participating centre
University of Leicester
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Sponsor information

Organisation
University of East Anglia

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes