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Estimating the effectiveness and cost-effectiveness of a complex intervention to increase care home staff influenza vaccination rates

Submission date
09/08/2022

Recruitment status
No longer recruiting

Registration date
24/08/2022

Overall study status
Completed

Last Edited
21/08/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

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 the 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, the researchers 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.
This study 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
The aim is 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?
This study will take place over 3 years. It has been designed assuming that COVID-19 is still with us. The researchers will spend two months developing each of the above approaches with care home staff and pharmacies. During the 2021-2022 flu season, they will test the approaches in 10 care homes. This will show 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, the researchers will refine the service and decide which mixture of approaches to study on a larger scale. They will do this by carefully listening to those involved and by looking at the quality of information they collect. During the 2022-2023 flu season, using the information from the first two stages, the main study will recruit care homes in England 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”. Care homes in the 'new service' group will be allocated to implement the FluCare intervention and pharmacy and/or GP practices will provide vaccination services. At the end of the flu season, the researchers will compare how many staff are vaccinated in the 'new service' and 'service as usual' groups. They will collect measures of resident health and costs related to the new service. This will show if the service improves resident health and saves money for the NHS. At the same time, the researchers will find out whether people used the new service as intended. They will also listen to people involved to find out what did and did not work to learn how to improve the service. Finally, they will use their findings to develop a toolkit. This will tell people about the new service and encourage them to use it. The researchers will work closely with PPI groups (residents and relatives) who will help 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. making 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 Clinical Trials Unit 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?
September 2021 to August 2025

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
1. Dr Amrish Patel, Amrish.Patel@uea.ac.uk
2. Prof David Wright, d.j.wright@leicester.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
316820

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
R209939, CPMS 53812

Study information

Scientific Title
FluCare Phase 3: Estimating the effectiveness and cost-effectiveness of a complex intervention to increase care home staff influenza vaccination rates – a definitive study

Acronym
FluCare

Study objectives
By providing short videos, posters, leaflets, together with onsite within hours and out of hours vaccination service provided by GP practice and/or pharmacies, it is possible to change the behaviour of care home staff in England to increase uptake of the influenza vaccination compared to usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/08/2022, The University of East Anglia Faculty of Health and Medical Sciences Ethics Board (Faculty of Medicine and Health Sciences Research Ethics Subcommittee, The School of Medicine, University of East Anglia, Norwich Research Par,k Norwich, NR4 7TJ, UK; Tel: not available; fmh.ethics@uea.ac.uk), ref: ETH 2122-2419

Study design
Two-arm open-label randomized controlled 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
In this study the researchers will recruit 78 care homes in England.

Stratified randomisation will be used. The sequence will be generated using REDCAP based on stratified randomisation with a binary variable of the percentage of staff identifying as non-white. Blocked randomisation will be undertaken, however, given the small number of homes randomised in order to ensure that the risk of imbalance is small a small block size will be used and specified in the allocation system specification. The classification of the percentage of staff identifying as non-white into two groups will be decided on the basis of the collection of the site profile questionnaires which are expected to be collected for a number of care homes prior to the start of any care home being randomised.

39 care homes will be allocated to implement the FluCare intervention and pharmacy and/or GP practices will provide vaccination services. 39 care homes will be allocated to the control arm.

Usual Care
Arm A (39 care homes): Usual care with regular monitoring

Intervention:
Arm B (39 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 October 2022 to March 2023, and follow-up data collection (for both arms) will last 1 month after the intervention ends.

Added 09/07/2024:
The study duration has been extended by the NIHR. Steps were needed to further reduce recruitment challenges and data collection burden. For the former, the researchers will use community pharmacists as the primary mechanism for recruiting CHs, utilising their existing local relationships. For the latter, they will utilise routinely collected data as our outcome data. These steps will reduce administrative burden during the trial, as contracting with CHs will no longer be required. Additional refinements have been made to the FluCare intervention to reflect its new focus as a community pharmacy-led intervention. Due to the shift to a community pharmacy led intervention, additional materials guiding engagement with care homes using findings from the earlier trials will be implemented in addition to the original flu care intervention materials and incentives.

The embedded process evaluation will identify and explore initiatives within Integrated Care Systems for increasing care home staff flu vaccination initiatives, characteristics of community pharmacies (and their staff) delivering the intervention and their relationships with care homes to which the intervention is being delivered, and barriers and enablers to delivery of the intervention. As the intervention will be delivered as a service to care homes and all data used in this study will be from routine data collection sources, care homes will not be aware that the opportunity to receive the intervention (or not) is part of a research study. Care homes will not therefore be consented. However, after the end of the flu season, community pharmacy staff involved with delivering the vaccination clinics, care home managers and staff in care homes who received the intervention will be invited to participate in a focus group or semi-structured interview.

Intervention Type
Behavioural

Primary outcome(s)

Staff flu vaccination rate: the total number of staff vaccinated in a flu season over the total number of staff employed at any point throughout that flu season (all directly contracted staff (care staff, cleaners, cooks, administrative staff) + agency staff), measured using anonymised staff data logs on a monthly basis, starting at baseline for 6 months or until the end of March 2023, whichever is the earliest

Key secondary outcome(s))

Measured using anonymised staff data logs and aggregated resident data logs on a monthly basis, for 6 months or until the end of March 2023, whichever is the earliest:
1. Staff flu vaccination rate disaggregated by caregiving and non-caregiving roles at the end of November
2. Number of staff sick days
3. GP and nurse visits to care home
4. Care home resident hospitalisations
5. Care home resident mortality

Health economic outcomes:
1. Intervention delivery costs
We will conduct a within-trial (i.e., up to the 6 months of the trial) cost-consequences analysis (CCA) comparing costs and outcomes between trial arms across different perspectives /stakeholders (e.g., care homes, NHS and staff). CCA is a standard evaluation approach recognized as being particularly useful for evaluating interventions that have impacts on multiple domains of outcome and perspectives.

We will determine the resources involved in, and associated costs of, delivering the FluCare intervention. Resources required for intervention delivery are expected to consist primarily of clinician time to deliver the FluCare clinics and the vaccinations. Information on these and other resources will be collected from clinic logs, process evaluation and augmented with expert opinion as needed. Resources will be costed in the most recent cost year for which published NHS and PSS unit costs are available.

Process evaluation outcomes:
1. The amount (or dose) of the intervention delivered to each home
In Intervention care homes the dose of intervention material will be described -
1.1. No. of times videos played (embedded in videos)
1.2. Where posters displayed and engagement with them (interviews at the end of study)
1.3. No. of pharmacy visits to homes (pharmacist logs completed and returned after each clinic)
1.4. Length and time of pharmacist/healthcare practitioner visits to home (Vaccination log completed and returned after each clinic)
1.5. No. of incentive payments made to homes (study records at the end of study)
2. The mechanisms of action, adaptions and variations across care homes
The MAQ will be distributed to a purposively selected number of intervention and control care homes at the beginning of the study, inviting the care home staff to take part in the survey. Care Home staff who complete the first survey will be invited to take part in the second survey approximately 4 months later. Care Home staff who complete the survey may be invited to take part in process evaluation interviews to further understand their views and thoughts about the study.

Added 09/07/2024:
Aggregate, care home level resident hospitalisations and mortality as reported to the CQC over that flu season counted as 01/09/2024 to 31/03/2025

Health Economic Outcomes:
1. Resource use and costs of delivering staff vaccination and the FluCare intervention, measured using vaccination logs, CQC data, the DHSC capacity tracker, and earlier study components (e.g. previous trial) collected throughout the trial period and analysed using a within-trial approach.
2. The wider impact on the NHS in terms of resident hospitalisations, measured using aggregated CQC data collected over the trial period.

Process Evaluation Outcomes:
The amount (or dose) of the intervention delivered, measured using:
1. Clinics: clinic logs for numbers of clinics delivered and staff vaccinated per care home
2. FluCare video: video analytics (number of clicks and duration of video viewed per care home)
This is collected for each care home at the end of the intervention period.

Completion date
31/08/2025

Eligibility

Key inclusion criteria
Care homes (CHs):
1. Registered to provide care for older residents, which may include people with dementia
2. Self-reported staff vaccination rate <40%
3. Must be signed up or willing to sign up to the DHSC Capacity Tracker and willing to submit weekly updates on flu vaccine status of staff and residents

Added 09/07/2024:
Community pharmacies:
1. Has an ongoing relationship with a care home that meets the CH inclusion/exclusion criteria
2. Willing to provide flu vaccinations within the care home to all directly employed care home staff
3. Have adequate staff available to deliver a flu vaccination clinic within the care home

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Fewer than 10 staff members (as insufficient qualitative and quantitative data likely to be produced)
2. Participated in the FluCare feasibility trial

Added 09/07/2024:
3. Planning a flu vaccination initiative similar to the FluCare intervention
4. Participated in FluCare feasibility or randomised controlled study

Date of first enrolment
10/10/2022

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norwich Clinical Trials Unit
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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 and Care 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 datasets generated by the FluCare Programme of research, including this current study, will be available upon request from Dr Amrish Patel, (amrish.patel@uea.ac.uk). Consent has been sought for data sharing for secondary analysis. The requested data will be provided anonymously. During the trial and up to the publication of results, Dr Patel and the Programme Management Group will consider and approve requests, where appropriate. Following the publication of the results, Dr Amrish Patel should be contacted in the first instance. Dr Patel, representatives from the FluCare collaboration as well as Sponsor, will be responsible for reviewing and approving requests.

Data, including pseudonymised care home staff and resident data logs, vaccination logs, site profile data and anonymised interview transcripts will be retained for 10 years. All data will be anonymised prior to sharing for secondary analysis, as requested by HRA.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/12/2022	12/12/2022	Yes	No
Protocol article	Protocol of the process evaluation	15/09/2023	18/09/2023	Yes	No
Other publications	Process evaluation	21/08/2025	21/08/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.1	05/08/2022	28/10/2022	No	No
	version 1.2		10/01		

Protocol file		15/11/2022	/2023	No	No
Protocol file	version 1.3	10/01/2023	10/02 /2023	No	No
Study website	Study website	11/11/2025	11/11 /2025	No	Yes