FluCare

FluCare Phase 3: Estimating the effectiveness and cost-effectiveness of a complex intervention to increase care home staff influenza vaccination rates.

Version	Version 2.2
Date	29th January 2025
Sponsor	University of East Anglia
Trial registration	ISRCTN 22729870
IRAS #	316820

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1 Administrative information

This document was constructed using the Norwich Clinical Trials Unit (NCTU) Protocol template Version 4.1. It describes the FluCare trial, sponsored by University of East Anglia and co-ordinated by NCTU.

It provides information about procedures for entering participants into the trial, and provides sufficient detail to enable: an understanding of the background, rationale, objectives, trial population, intervention, methods, statistical analyses, ethical considerations, dissemination plans and administration of the trial; replication of key aspects of trial methods and conduct; and appraisal of the trial's scientific and ethical rigour from the time of ethics approval through to dissemination of the results. The protocol should not be used as an aide-memoire or guide for the treatment of other patients. Every care has been taken in drafting this protocol, but corrections or amendments may be necessary. These will be circulated to registered investigators in the trial. Sites entering participants for the first time should confirm they have the correct version through a member of the trial team at NCTU.

NCTU supports the commitment that its trials adhere to the SPIRIT guidelines. As such, the protocol template is based on the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2012 Statement for protocols of clinical trials [1]. The SPIRIT Statement Explanation and Elaboration document [2] can be referred to, or a member of NCTU Protocol Review Committee can be contacted for further detail about specific items.

1.1 Compliance

The trial will be conducted in compliance with the approved protocol, the Declaration of Helsinki (2008), the principles of Good Clinical Practice (GCP) as laid down by the Commission Directive 2005/28/EC with implementation in national legislation in the UK by Statutory Instrument 2004/1031 and subsequent amendments, the UK Data Protection Act, and the UK Policy Framework for Health and Social Care Research, and other national and local applicable regulations. Agreements that include detailed roles and responsibilities will be in place between participating sites and NCTU.

Participating sites will inform NCTU as soon as they are aware of a possible serious breach of compliance, so that NCTU can fulfil its requirement to report the breach, if necessary, within the timelines specified in the UK Clinical Trials Regulations (currently 7 days). For the purposes of this regulation a 'serious breach' is one that is likely to affect to a significant degree:

- The safety or physical or mental integrity of the subjects in the trial, or
- The scientific value of the trial.

1.2 Sponsor

University of East Anglia is the trial sponsor and has delegated responsibility for the overall management of the FluCare trial to the Co-Chief Investigators and NCTU. Queries relating to sponsorship of this trial should be addressed to Dr Amrish Patel or via the trial team. University of East Anglia is data controller.

1.3 Structured trial summary

Primary Registry and Trial Identifying Number	ISRCTN **22729870**
Date of Registration in Primary Registry	to be confirmed
Secondary Identifying Numbers	RIN R209939 IRAS number: 316820
Source of Monetary or Material Support	National Institute of Health Research Public Health Research Funding Stream
Sponsor	University of East Anglia
Contact for Public Queries	Flu.care@uea.ac.uk
Contact for Scientific Queries	Dr Amrish Patel Associate Professor in Economics (School of Economics) University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ Email: Amrish.Patel@uea.ac.uk Telephone: 01603 597644
Short Title or Acronym	FluCare Study
Scientific Title	FluCare Study: Estimating the effectiveness and cost-effectiveness of a complex intervention to increase care home staff influenza vaccination rates.
Countries of Recruitment	England
Health Condition(s) or Problem(s) Studied	The World Health Organization (WHO) recommends that at least 75% of health and social care staff are vaccinated for flu. Whilst the target has been met for healthcare staff in England, the figure was last reported at only 25% for social care staff.

Intervention(s)	**Usual Care** Arm A: Usual care **Intervention:** Arm B: A multi-component intervention, addressing the barriers to care home staff flu vaccine uptake, comprising online videos, and supporting information materials (including posters and leaflets) and incentives.
Key Inclusion and Exclusion Criteria	**Community pharmacies** Inclusion criteria: • Willing to provide staff with flu vaccinations in the care home within the same ICS meeting the inclusion criteria. • Have appropriate and sufficient staff available to deliver a flu vaccination clinic within the care home. Exclusion criteria: None
Study Type	A two arm, pragmatic trial of Pharmacist led FluCare intervention to increase flu vaccination rates in care home staff, compared to usual care. Four Community Pharmacy [Local] Committees (CP [local]C) aligned with Integrated Care Boards (ICSs) will act as gatekeepers to support recruitment of community pharmacies. Two CP [local]C/ICSs will be purposively allocated to receive the FluCare intervention, and two to Usual Care. CP[LOCAL]COMMITTEEs will be allocated aiming to balance geographical and ethnic diversity of staff within Care Homes between arms. Pharmacies within the CP[LOCAL]COMMITTEEs allocated to intervention will be invited to participate in the trial.
Date of First Enrolment	July 2024
Target Sample Size	4 Integrated Care Systems
Outcome(s)	Primary Outcome: Total number of staff vaccinated in a flu season over total number of staff employed at any point throughout that flu season as submitted to the DHSC Capacity Tracker for all directly employed staff (care staff, cleaners, cooks, administrative staff)

	Secondary Outcomes: Aggregate, care home level resident hospitalisations and mortality as reported to the CQC over that flu season counted as 1st September 2024-31st March 2025 Health Economic Outcomes: Cost per additional percentage point of staff vaccinated from the perspectives of the: i) vaccination programme funder and ii) NHS (incorporating programme funder costs and resident use of the NHS – such as hospitalisation). Process Evaluation Outcomes: Report the dose, reach, fidelity, adaptions and contextual variations across care homes and vaccine providers.

1.4 Roles and responsibilities

These membership lists are correct at the time of writing; please see terms of reference documentation in the TMF for current lists.

1.4.1 Protocol contributors

Name	Affiliation	Role [individuals who contribute substantively to protocol development and drafting should have their contributions reported]
Dr Amrish Patel	UEA	Co-Chief Investigator
Professor David Wright	University of Leicester	Co-Chief Investigator
Dr Erika Sims	UEA	Clinical Trial Operations
Dr Alys Griffiths	University of Sheffield	PPI academic lead
Professor Richard Holland	University of Exeter	Professor of Public Health Medicine and hon. Consultant in public health
Dr Linda Birt	University of Leicester	Process Evaluation and qualitative analysis lead
Dr Sion Scott	University of Leicester	Behavioural science and qualitative analysis
Dr Adam P Wagner	UEA	Trial Health Economist
Professor Andy Jones	C3 Health	Design and implementation of intervention evaluation
Dr Allan Clark	UEA	Trial Statistician

Mr Tony Dean	Norfolk Local Pharmaceutical Committee	Advise on configuring and commissioning pharmacy services and implementation
Dr Liz Jones (LJ-PPI)	PPI	PPI representative (relative of care home resident); Expert Panel Lead
Susan Stirling	UEA	Senior Research Associate (Statistics)
Dr Thando Katangwe-Chigamba	UEA	Process Evaluation
Mrs Veronica Bion	UEA	NCTU Trial Manager
Mrs Jennifer Pitcher	UEA	NCTU Clinical Trial Manager

1.4.2 Role of trial sponsor and funders

Name	Affiliation	Role
Julie Frith	UEA	Sponsor Representative
Clare Symms	Norfolk and Waveney ICS	Host Representative

1.4.3 Programme Management Group

Name	Affiliation	Role and responsibilities
Dr Amrish Patel	UEA	Co-Chief Investigator
Professor David Wright	University of Leicester	Co-Chief Investigator
Mr Matthew Hammond	UEA	Deputy Director of the Norwich Clinical Trials Unit
Dr Erika Sims	UEA	Clinical Trial Operations
Dr Alys Griffiths	University of Sheffield	PPI academic lead
Professor Richard Holland	University of Exeter	Consultant in public health
Dr Linda Birt	University of Leicester	Process Evaluation and qualitative analysis lead
Dr Sion Scott	University of Leicester	Behavioural science and qualitative analysis
Dr Adam P Wagner	UEA	Health economics lead

Dr Allan Clark	UEA	Statistician
Mr Tony Dean	Norfolk Local Pharmaceutical Committee	Advice on configuring and commissioning pharmacy services and implementation
Dr Liz Jones (LJ-PPI)	PPI	PPI representative (relative of care home resident) and PPI Lead
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Helen Risebro	UEA	Senior Research Associate (Health economics)
Jennifer Pitcher	UEA	CTU Clinical Trial Manager
Adaku Anyiam-Osigwe	UEA	CTU Research Associate
Mr Faisal Alsaif	UEA	Post-graduate PhD Student
Ms Cecile Guillard	UEA	NCTU Data Programmer
Mr Martin Pond	UEA	NCTU Data Manager
Li Ting Ooi	UEA	CTU Clinical Trial Assistant
Gosia Majsak-Newman	Norfolk & Waveney ICB	R & D Officer

1.4.5 Programme Steering Committee

Name	Affiliation	Role and responsibilities
Professor Michael Dewey	Kings College London	Independent Chair and Independent Statistician
Professor Stephen Byrne	University College Cork, Ireland	Independent Trialist
Dr Amrish Patel	UEA	Co-Chief Investigator
Professor David Wright	Leicester	Co-Chief Investigator
Professor Martin Green	Care England	Independent Stakeholder Representative; Chief Executive Officer;
Clare Symms	Norfolk and Waveney ICB	Head of Research Management, Finance and PPI, Observer
Dr Allan Clark	UEA	Statistician
Dr Adam Wagner	UEA	Trial Health Economist, Observer
Dr Erika Sims	UEA	NCTU Research Lead – Complex Interventions, Observer
Dr Krystal Warmoth	University of Hertfordshire	Independent; Behavioural Scientist
Ms Helen Jackson	PPI	Independent PPI member
Ms June Sanson	PPI	Independent PPI member

1.4.6 Data Management Committee

Name	Affiliation	Role and responsibilities
Professor Julius Sim	University of Keele	Independent Statistician
Ms Tara Marshall	RGN, DipHE, MA Patient Safety CIEHF and Q Member	Independent Member

1.4.7 Expert Advisory Panel

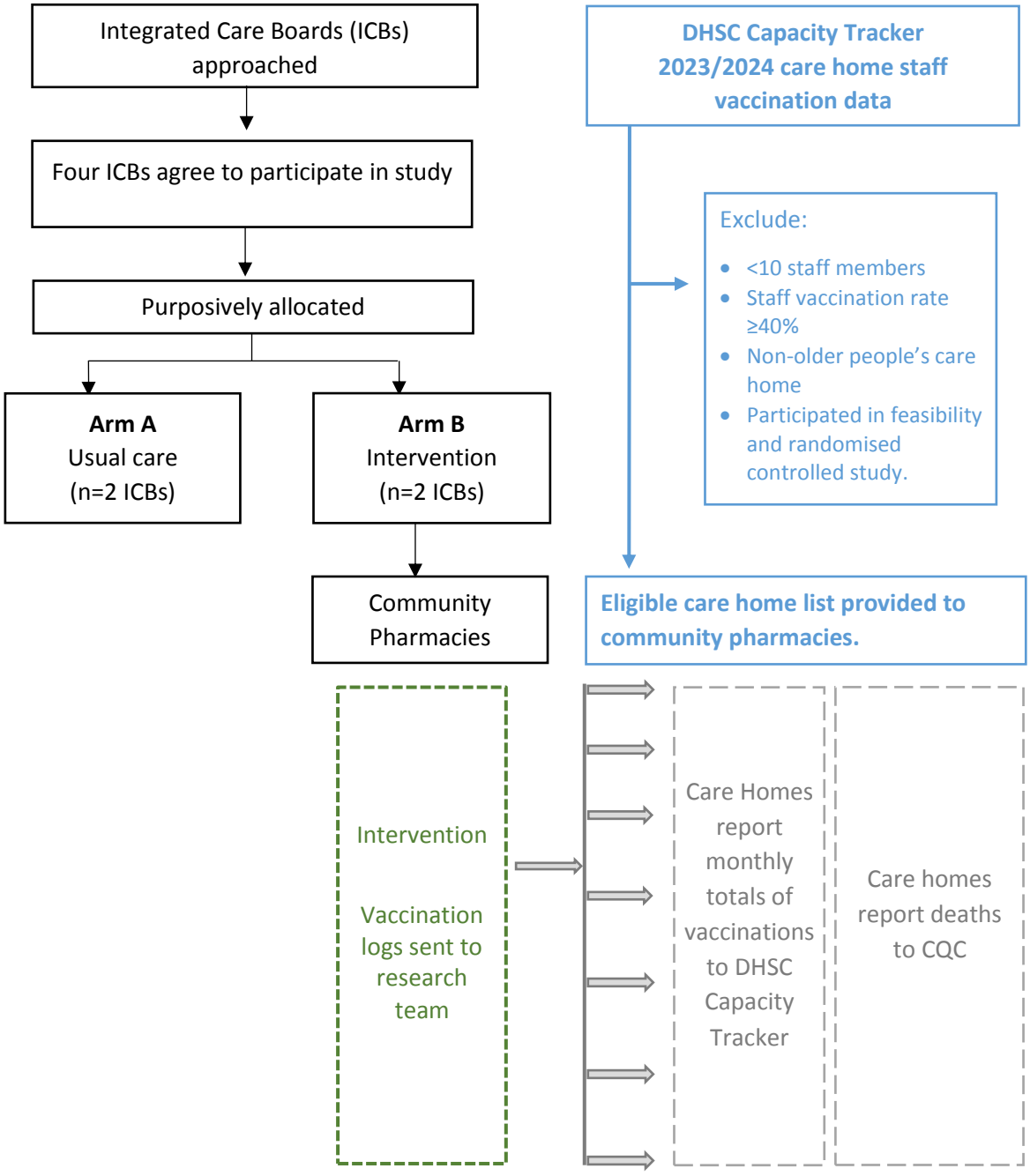
Name	Affiliation	Role and responsibilities
Liz Jones (LJ-EAP)	National Care Forum (NCF)	Policy Director at NCF
David James	CQC	Head of Adult Social Care Policy
Emma Smith	Wakefield Council	Health Protection Manager
Chris Pearson	HC-One	Flu Campaign Manager
Catherine Heffernan	NHS England and NHS Improvement	Public Health Advisor

1.4.8 PPI Advisory Group

Name	Affiliation	Role and responsibilities
Dr Liz Jones (LJ-PPI)	PPI Lead	PPI representative (relative of care home resident); PPI co-Lead
Dr Alys Griffiths	University of Sheffield	PPI academic lead
Alison Bryant	PPI member	PPI representative
Robert T Bryant	PPI member	PPI representative
Hilary Garrett	PPI member	PPI representative
Keith Holt	PPI member	PPI representative
Saima Gul	PPI member	PPI representative
Saiqa Ahmed	PPI member	PPI representative

2 Trial diagram

*Two hundred and eighty care homes, 140 intervention and 140 usual care.



Primary Outcome: care home staff vaccinated in a flu season over total number of staff employed throughout that flu season as submitted to the DHSC Capacity Tracker [all directly employed staff (care staff, cleaners, cooks, administrative staff)

Secondary Outcomes: Aggregate, care home level resident mortality as reported to the CQC and aggregate care home level resident hospitalisations as recorded by NHS England in Secondary Uses Service dataset over the flu season counted as 1st September 2024-31stMarch 2025.

3 Abbreviations

AE	Adverse Event
BCT	Behaviour Change Techniques
CH	Care Home
CEA	Cost-Effectiveness Analysis (CEA)
CI	Chief Investigator
CRF	Case Report Form
DMC	Data Management Committee
GCP	Good Clinical Practice
HEAP	Health Economics Analysis Plan
HRA	Health Research Authority
ICS	Integrated Care System
ITT	Intention to Treat
CP [LOCAL]C	Local Pharmaceutical Committee
NCTU	Norwich Clinical Trials Unit
PI	Principal Investigator
PID	Participant Identification Number
PIS	Participant Information Sheet
PMG	Programme Management Group
PSC	Programme Steering Committee
QA	Quality Assurance
QC	Quality Control
QMMP	Quality Management and Monitoring Plan
R&D	Research and Development
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SSA	Site Specific Approval
SWAT	Study within a Trial
TDF	Theoretical Domains Framework
TMF	Trial Master File
TMT	Trial Management Team
ToR	Terms of Reference
UEA	University of East Anglia

4 Glossary

Social Care Workers – for the purpose of this project, social care workers are care home staff.

5 Introduction

5.1 Background and rationale

Each year seasonal influenza (flu) causes 17,000 UK deaths [3]. This creates a major risk for older residents of care and nursing homes [4], [5]. Vaccinating care staff is known to mitigate against this [4], [6], [7], [8], [9].

Evidence suggests a linear relationship between staff flu vaccine uptake and resident health outcomes [10], [11]. Higher staff flu vaccination rates reduce residents' flu-like-illness, hospitalisation and mortality [4], [6], [7], [8], [9]. Staff health improves [12], implying fewer sick days [13], improved care continuity and quality [14], lower staff cover costs [15], and more financially viable homes. The World Health Organization (WHO) recommends that at least 75% of health and social care staff are vaccinated for flu [16]. Whilst the target has been met for healthcare staff in England [17], the figure was last reported at only 25% for social care staff [18]. Our survey (415 care home staff respondents) found a 38% vaccination rate for the 2019-20 flu season [19]. For 2020-21, a 34% flu vaccination rate was reported for care home staff (NHS Capacity Tracker [20]), despite the COVID pandemic.

Policy initiatives based on the existing (mostly healthcare sector) evidence have been enacted (e.g. NHS funded vaccines; pharmacist-led vaccinations; evidence-based flu campaign guidelines [21], [22], [23]) with little effect on care home staff uptake. Despite a 2020 policy change allowing pharmacists to administer NHS flu vaccine to staff in care homes, few do so due to the costs involved. Several policy initiatives have attempted to increase flu vaccine uptake in care home staff with limited effect (e.g. NHS funded vaccines; pharmacy vaccinations; flu campaign guidelines [21], [22], [23]). These initiatives usually address one barrier to vaccination at a time and do not approach the problem in a holistic manner. An intervention designed to overcome all barriers and use all enablers simultaneously to maximise effectiveness is required.

The UK's COVID vaccination programme has been very successful, in part due to the high perceived need for vaccination. Over time COVID risks will likely become normalised and the perceived urgency of booster vaccinations is likely to be significantly lower. Furthermore, COVID lockdowns and social distancing mean that a severe resurgence of flu is likely as immunity is lower than usual, and selective pressures on the virus mean a more transmissible strain emerging is more probable [24]. Outcomes of this research project will be used to inform the design and delivery of future COVID booster vaccination programmes, especially if the flu and COVID vaccinations are combined [25].

We have developed an intervention to support flu vaccination uptake for care home staff, in line with MRC guidance [26], and underpinned by behavioural science using the Theoretical Domains Framework (TDF)[27], a systematic review and narrative synthesis of the literature (Prospero: CRD42021248384) plus extensive stakeholder engagement. We propose to evaluate this intervention against usual care.

5.1.1 Explanation for choice of comparators

The 2018 NICE evidence review on increasing flu vaccination uptake [21] identified a number of areas lacking evidence: (i) The effectiveness and cost-effectiveness of interventions to increase uptake for carers (including care home staff); (ii) The effectiveness and cost-effectiveness of community-based

flu vaccination provision models (e.g. pharmacy) and (iii) How information should be tailored/delivered to increase vaccine uptake.

Systematic reviews and meta-analyses on the effectiveness of interventions aiming to increase health/social care worker flu vaccine uptake [21], [28], [29], [30] suggest that most existing studies examine healthcare workers (e.g. NICE review, only 5 of 31 studies were on care homes and none were UK-based [21]).

In 2017-18, Wakefield Council commissioned two pharmacies to proactively contact 27 homes and offer in-home staff vaccination clinics [31]; vaccination rates rose from 10% to 40%. Our research will: determine whether a more optimised intervention (e.g., regular clinics accounting for shift-work and financial incentives for care homes) can achieve the WHO's 75% target; provide evidence that is more detailed (by including a process evaluation), and robust determine how delivery costs, and whether improvements in resident health lead to reductions in NHS costs that offset vaccination costs. NICE evidence review found no cost- effectiveness studies on interventions that increase staff access to flu vaccination [21].

While there is limited evidence whether financial incentives for staff increase vaccine uptake [32], we have not identified any studies estimating the effectiveness of an intervention containing financial incentives for homes to encourage vaccination.

By combining a range of interventions into our multi-component intervention we provide evidence for a new more holistic intervention specifically designed for UK care home staff. There are no trials registered on the WHO International Clinical Trials Registry Platform [33] exhibiting significant overlap with our proposed research.

From collation of the evidence obtained from our narrative synthesis, survey, and qualitative work, we identified five main individual-level barriers to flu vaccination (two non-cognitive and three cognitive):

1. Access (non-cognitive): Staff lack time to access vaccine through traditional routes. Although GPs and pharmacists are permitted to vaccinate staff in care homes, most do not do so (e.g., Boots UK, >50% care home market) as it is not financially attractive given the current commissioning model. Care home staff working shifts and nights are thus expected to make their own way to GP practices and pharmacies for vaccination. This is a major barrier. Care home staff often cite this barrier and suggest the natural solution: "The single most helpful action would be to offer flu vaccination in-house" [19]. "Convenience" is one of the three categories of barrier that comprise the WHO's 3Cs model of vaccine hesitancy [34].

2. Cost (non-cognitive): Some care home staff (e.g. agency) are required to pay for vaccine. Staff directly employed by a home and closely involved in resident care are entitled to an NHS flu vaccination [23]. Other staff (e.g. agency/temp staff, 10% of the workforce [35]) are not entitled to a free NHS vaccination. Cost is a well-known vaccine uptake barrier [34], [36].

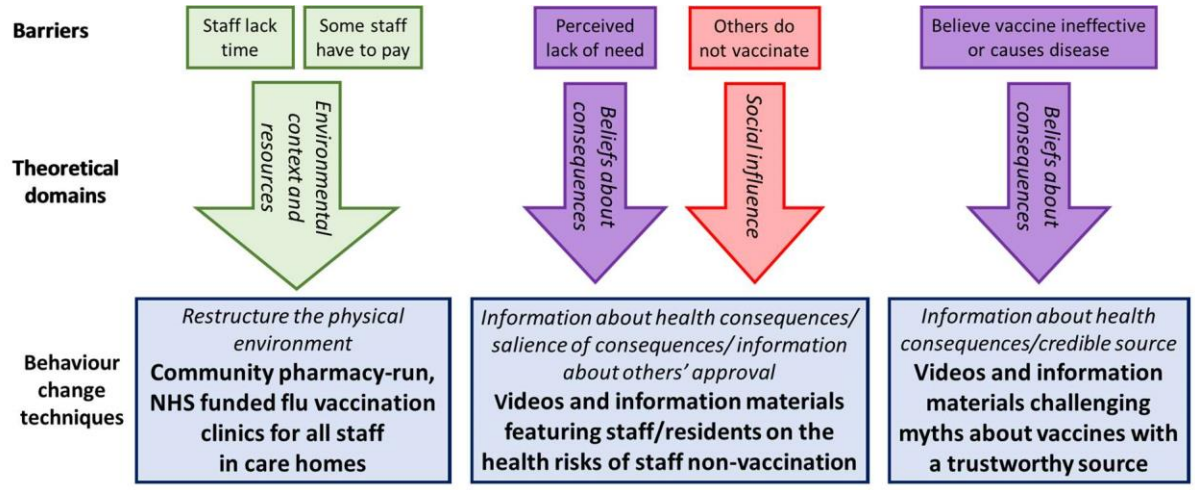
3. Perceived lack of need (cognitive): Staff perceive no need for the vaccine as they are healthy. A large share of non-vaccinating staff cite this as the reason for non-vaccination (e.g. 23%- 67% [19] [37] [38]). "Complacency" is another barrier category in the WHO's 3Cs model[34].

4. Vaccine beliefs (cognitive): Beliefs that vaccine is either ineffective or causes disease. A large proportion of non-vaccinating staff cite these reasons for non-vaccination (e.g. 34-60%[19] [39] [38] [40]). "Confidence" (e.g. in vaccine effectiveness) is again another barrier category of WHO's 3Cs model of vaccine hesitancy [34].

5. Peer influence (cognitive): Negative influence of non- or anti-vaccination movement. Non-vaccinated staff often remark how very few other staff get vaccinated in their workplace [19]. Peer effects and norms are important determinants of vaccine uptake [37].

Figure 1 provides our mapping of the five barriers to care home staff vaccination to the TDF domains which require addressing. Using the mapping table by Cane et al. [41], we identified 31 potentially appropriate Behaviour Change Techniques (BCTs), the active ingredients of behaviour change interventions, with evidence for addressing the TDF domains in Figure 1. We subsequently convened a Nominal Group Technique stakeholder consensus study [42] with 13 care home staff and managers to develop an intervention. Stakeholders selected from the list of BCTs, those which met the APEASE criteria (affordable, practicality, effectiveness, acceptability, side-effects, equity) for addressing the barriers [43].

Figure 1 Relationship between behaviour change techniques, barriers and theory



After selecting BCTs to include in the intervention, Nominal Group Technique stakeholders proceeded to characterise how each BCT may be operationalised in practice. This characterisation was refined by public and patient involvement (care home residents and relatives) and stakeholder input to arrive at the following:

Restructure the physical environment: A pharmacy will offer NHS funded flu vaccination clinics to all staff (inc. agency) in homes. Stakeholders identified that clinics should be run by the pharmacy currently supplying the home's resident medication to leverage the existing trusted relationship. PPI

input suggested that several clinics would have to be run at convenient times to account for shift-/night-work and maximise access.

Information about health consequences, salience of consequences and information about others' approval (operationalised together): Information on the health risks of low staff vaccine uptake featuring staff and residents. Stakeholders believed that an engaging 5–10-minute video would work best, with residents and vulnerable staff (older and younger) discussing serious health risks to them arising from poor staff vaccine uptake and how vaccination protects everyone. They also believed the videos should be integrated into existing staff processes (e.g., handovers, inductions, or staff apps) to ensure engagement and that posters or other information materials could reinforce the main images/messages. PPI highlighted that materials should reflect staff cultural diversity (i.e. multi-lingual with a range of socio-demographics), particularly given low vaccine uptake in BAME communities [44].

Information about health consequences and credible source (operationalised together): Information from a trustworthy source e.g., General Practitioner, challenging the myths about vaccines. Stakeholders identified a similar format (i.e., short video supported by information materials) and developed some of the myths to be challenged. These included: that the vaccine is dangerous to pregnant women and that it causes flu.

While our intervention targets staff level behaviour change, it is widely recognised that for staff to undertake a behaviour, they must feel it aligns with the priorities of their organisation [45]. Employer encouragement is a known enabler for staff vaccination [21], [46], [47]. Care homes receive staff flu campaign guidance (NHS [23]; PHE [22]) based on a NICE evidence review [21] and are required to facilitate staff vaccination. Implementation is variable: 16% of our care home staff survey respondents said their employer did not promote vaccination; a further 10% made statements like: "I noticed a poster but there's no encouragement" [19].

Our intervention (Figure 1) is thus complemented by financial incentives for care homes with staff vaccination rate ≥70%.

Evidence suggests that incentivisation, monitoring and feedback facilitate organisational-level support for behaviour change (e.g. CQUIN financial incentives in the NHS increasing healthcare staff flu vaccine uptake [48]). The use of incentive payments was viewed as particularly powerful by sector leaders as it signalled equity between health (NHS) and social care. Many local authorities pay premia to homes to incentivise care quality in general [49].

Finally, several care home managers reported shortages of vaccine supplies [50]. In-home clinics should mean staff get vaccinated earlier (i.e., before shortages occur) and our intervention pharmacies will be required to withhold sufficient vaccines to support vaccination of any new members of care home staff starting during the intervention period.

The FluCare feasibility trial undertaken during the 2021/2022 flu season, confirmed that care homes and vaccination providers (GPs and Pharmacists) could be successfully recruited and were willing to participate. The feasibility study informed the frequency of data collection and design of the control arm. While the frequency of data collection (monthly versus end of study), did not influence the uptake of flu vaccination in the control arm, monthly data collection was preferred by sites. Although the provision of posters and leaflets appeared to have a small but limited effect, stakeholder input suggested that these were still important for staff engagement. Strategies to improve data collection

and data were also identified and used to inform the design of the randomised controlled trial (phase 3 extension) of the FluCare intervention versus usual care in care homes in England.

This RCT was initially undertaken during the 2022/2023 flu season (September/October 2022). Due to successive delays, the trial missed the September start of the flu season and did not start fully until late November, with the majority of clinics delivered between January and February 2023. Delays were due primarily to care homes requiring permission from their owners to participate in the trial, which had a subsequent impact on recruitment of vaccination providers. In turn, this resulted in the intervention being delivered in the latter stages of the flu vaccination season when vaccine supplies were reduced and interest in flu vaccination had waned. Process evaluation results indicated that the uptake of the flu vaccine would have been greater had the intervention been implemented at the beginning of the flu season. As a result, we have not been able to demonstrate conclusively that the intervention will work if rolled out or provide a meaningful increase in vaccination rate. To address this, the requirement for care homes to undertake research activities (contracting, consent and collecting data) has been removed with primary outcome data now coming the Department of Health and Social Care Capacity Tracker and secondary outcomes from Care Quality Commission Care Home Dataset. Allocation to intervention arm has been revised to the level of the Integrated Care System (ICS), with 2 ICSs allocated to control and 2 to intervention. Community Pharmacies in the ICSs allocated to intervention will be invited to participate in the research and offer the intervention to eligible care homes in their ICS.

5.2 Objectives

The overall objectives of this study are to:

1. Estimate the effect of the intervention on staff vaccination rates (primary outcome) and secondary outcomes identified in the logic model (e.g., resident mortality Appendix 1)
2. Explore the economic impact of the intervention (e.g., cost per vaccination percentage point increase)
3. Examine variations in intervention implementation and outcomes (in an embedded process evaluation)

Specific process evaluation objectives are to:

1. Describe implementation of the intervention
2. Investigate the mechanisms of impact
3. Describe the perceived effectiveness of relevant intervention components (including videos, leaflets, posters, flu clinics and care home incentive payments) from participant (care home manager, care home staff and flu clinic providers) perspectives
4. Generate suggestions to support wider implementation of the intervention to other care homes

5.3 Trial Design

This is a low risk two arm, open label, non-randomised controlled effectiveness, and cost-effectiveness trial of pharmacy led FluCare, a behaviour change intervention designed to improve uptake of influenza vaccination by staff in care homes in England, compared to usual care, with an embedded process evaluation.

The design of the trial was informed by a 2-arm randomised controlled randomised controlled trial in 78 care homes. The trial confirmed steps were needed to further reduce recruitment challenges and data collection burden. For the former, we will use community pharmacists as the primary mechanism for recruiting CHs, utilising their existing local relationships. For the latter, we 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 CHs using findings from the earlier trials will be implemented in addition to the original flu care intervention materials and incentives.

To highlight the opportunity of in care home flu vaccination clinics for staff, a message will be pushed to the CHs via the DHSC Capacity Tracker advising the CH of the opportunity to receive in-care home flu vaccination clinics for staff as part of a pilot delivered by the ICB for 24/25 flu season. The message will appear as a pop-up when the CH representative logs in to the capacity tracker. Similar messaging will also be sent out to CH managers and owners/executives of CH groups via the Care Provider Alliance, which brings together the ten main national associations which represent independent and voluntary adult social care providers in England. Care home group owners and executives are responsible for directing CH manager engagement with external opportunities such in care home flu vaccination clinics. Engaging the owners and executives will increase the likelihood that CH managers will take up the offer of the clinics.

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, some Community pharmacy staff involved with delivering the vaccination clinics, some care home managers and some staff in care homes that received the intervention will be invited to participate in a focus group or semi structured interview.

6 Methods

6.1 Recruiting Site Selection

The trial sponsor has overall responsibility for site and investigator selection and has delegated this role to the CI and NCTU.

6.1.1 Study Setting

Sites

Community pharmacies in high streets, neighbourhood centres or community locations providing in person clinical services, including vaccinations.

Care Homes are service recipients of the community pharmacies.

Community based private, charity, corporate or local authority care homes in England that are registered to provide residential, nursing or dementia care for older age residents and are registered with the DHSC capacity tracker.

6.1.2 Recruiting Site/Investigator Eligibility Criteria

Four Community Pharmacy [Local] Committees (CP [local]C) aligned with Integrated Care Boards (ICSs) will act as gatekeepers to support recruitment of community pharmacies. The Site Investigator for UEA is Dr Amrish Patel, Professor David Wright from University of Leicester is Co CL for the FluCare project and grant holder.

6.2 Participating Site approval and activation

Participating sites are Community Pharmacies, which will hereafter be referred to as sites.

Sites will be required to complete and sign a site agreement prior to providing consent to participate. Following confirmation of Sponsor approval, the site will be able to provide consent to participate. For the community pharmacies, completion of the Site agreement constitutes site activation.

As care homes are the recipient of the community pharmacy delivered service provided as part of the intervention, and are not providing data for the trial, care homes are not considered sites for the purpose of site approval and activation. Care home data will be obtained from DHSC Capacity Tracker, CQC and NHS England for which DHSC, CQC and NHS England DARS approvals will be sought along with any other data sources used.

6.3 Participants

6.3.1 Community Pharmacists

6.3.1.1 CP [local]Committee and ICS selection

There will be NO EXCEPTIONS (waivers) to eligibility requirements at the time of allocation. Questions about eligibility criteria should be addressed PRIOR to attempting to allocate the participant.

Chief Officers for CP [local]Committee and Public Health Directors for ICSs in England will be invited to express an interest for their area to participate by completing a short questionnaire about flu vaccination initiatives for care home staff planned for the 2024/2025 flu season. Those CP [local]Committee/ICSs that are planning initiatives similar to the FluCare intervention will be excluded.

Of the eligible ICSs, four will be purposively allocated to receive the FluCare intervention or Usual Care (two ICSs to each arm). ICSs will be allocated, if possible, to ensure a balance of urban/rural, socioeconomics and ethnic diversity of population. Chief Officers at CP [local]Committees for ICSs allocated to intervention or control will be requested to approve the project being undertaken within their area.

6.3.2 Community Pharmacy Eligibility Criteria

- Willing to provide staff with flu vaccinations in the care home within the same ICS meeting the inclusion criteria.
- Have appropriate and sufficient staff available to deliver a flu vaccination clinic within the care home.

6.3.2.1 Care Home selection

Community pharmacists will be offered a list of care homes within their ICS identified as having less than 40% vaccination rate 2023/24 flu season using the DHSC tracker data [21], [34][51], [52][9], [53][6][54][55].

6.3.2.2 Care Home Inclusion Criteria

- Within the geographical area of the participating ICSs.
- Registered to provide care for older residents, which may include people with dementia.
- Staff vaccination rate below 40% as reported to the DHSC Capacity tracker for 2023/2024 flu season.

6.3.2.3 Care Home Exclusion Criteria

- Located outside the geographical area of the participating ICSs.
- Registered to provide care for residents under 65
- Staff vaccination rate above 40% as reported to the DHSC Capacity tracker for 2023/2024 flu season.

6.3.3 Community pharmacy eligibility criteria (Intervention ICSs only)

- Willing to provide staff with flu vaccinations in the care home within the same ICS meeting the inclusion criteria.
- Have appropriate and sufficient staff available to deliver a flu vaccination clinic within the care home.

6.3.3.1 Community pharmacy selection criteria

All Community pharmacies within the CP[LOCAL]Committee associated with an ICS that is allocated to receive the intervention will be invited to participate.

6.3.3.2 Community pharmacy Inclusion Criteria

- Willing to provide flu vaccinations within the care home to care home staff (permanent, agency, voluntary)
- Have appropriate and sufficient staff available to provide a flu vaccination service within the care home, including early mornings, evenings-and/or weekends.

6.3.3.3 Pharmacy vaccination provider(s) Exclusion Criteria

- Unable to provide offsite, in care home, flu vaccination clinics.

Community pharmacies declaring an established relationship on the site profile questionnaire with one or more care homes will be requested to offer the intervention to those care homes first. After 4 weeks of recruitment, community pharmacies will be requested to approach any remaining eligible care homes.

6.3.4 Care Home Managers and Care Home Staff (Focus Groups/Semi-Structured Interviews only)

6.3.4.1 Care Home Managers and Staff Selection Criteria

Care home managers and directly employed staff working in care homes within the two ICSs allocated to receive the intervention will be invited to participate in one hour focus groups. Ideally, in total 15 care home managers and 15 members of staff will participate in the focus groups, although if more interest than additional focus groups may be undertaken subject to funding.

6.3.3.2 Care Home Managers and Care Home Staff Inclusion Criteria

- Employed to work in the care home.

6.3.3.3 Care Home Managers and Care Home Staff Exclusion Criteria

- Agency staff
- Volunteers working within the care home.

6.3.5 Director of Public Health and Community Pharmacy [Local] Chief Officers (Semi-Structured Interviews only)

6.3.5.1 Director of Public Health and Community Pharmacy [Local] Chief Officers Selection Criteria

Directors of Public Health at ICSs participating in the trial (intervention and control) and Community Pharmacy [Local] Chief Officers at ICSs participating in the intervention arm only, will be invited to participate in a one-hour interview.

6.4 Interventions

6.4.1 Arm A Usual Care

Usual care, which is defined as whatever the CP[LOCAL]Committee/ICS does usually for promotion of flu vaccination within care homes.

6.4.2 Arm B – Flu Vaccination Behaviour Change Intervention

The multi-component intervention will comprise of:

- Guide for community pharmacies on engaging and delivering flu vaccination clinics for staff within care homes. This will be supported by:
    - Online video of stakeholders endorsing flu vaccination (GP, Residents, and care home staff) and associated materials (including posters and leaflets) to raise awareness of, address misconceptions and advertise opportunity for staff to receive flu vaccinations.
    - Care home incentive scheme comprising of £850 incentive if more than 70% of care home staff receive a flu vaccination as reported on the Department of Health and Social Care Capacity Tracker.
- Community pharmacy vaccination provision comprising of up to five vaccination clinics organised around care home shifts, the maximum number of FluCare clinics that the Community Pharmacy will be able to claim for will be dependent upon the number of staff employed in the care home as shown below:
    - 2 clinics for each ‘small care home’ of 1-20 staff
    - 3 clinics for each ‘medium care home’ of 21-50 staff
    - 4 clinics for each ‘large care home’ of 51-80 staff
    - 5 clinics for each ‘very large care home’ of more than 81 staff.
- Care Provider Alliance will send out emails targeted to care home providers with care homes in the intervention ICBs to highlight to owners and executives the in-care home staff flu vaccination being offered by the ICB, and to check clinics.
- Pop-up message on DHSC Capacity Tracker will appear when care home staff log into the capacity tracker, highlighting that the ICB is offering in-care home flu vaccination clinics as part of a pilot for the 24/25 flu season and if interested, to contact either their community pharmacy or a community pharmacist that is offering the service within their ICS (accessed via an online link or a list).

6.4.3 Concomitant Care

Care Home staff will be able to access NHS care via their usual GP and/or pharmacy provider. Should a member of staff in the intervention home prefer to receive their flu vaccination via their own GP or local pharmacy provider, this is permitted.

6.4.4 Protocol Treatment Discontinuation

Local Pharmaceutical Committee

Permission is being sought from the CP[LOCAL]Committees to conduct the trial within the geographical footprint of the ICS. Once the trial intervention has started, as Community Pharmacies in the intervention arm are providing their own consent to participate and site agreements, it will not be possible for the CP[LOCAL]Committee or ICS to discontinue the trial. However, reasons for requesting discontinuation of the trial will be recorded. CP[LOCAL]Committee will be involved to request circulation of materials to Community Pharmacies in the intervention arm.

Flu vaccination providers (intervention only)

Community Pharmacy participation as flu clinic providers in the trial will be voluntary, although they will be contracted and remunerated for services provided. Should a provider withdraw consent, this will be recorded by the research team.

6.5 Outcomes

6.5.1 Primary Outcomes

Staff flu vaccination rate is the primary outcome measure and will be calculated as:

As reported at the end of the flu season (end of March 2025), the highest number of staff vaccinated in the care home over highest number of staff employed in the care home).

6.5.2 Secondary Outcomes

Resident hospital admissions (including elective, emergency) as recorded in NHS England Secondary Uses Service dataset.

We will be requesting for the 24/25 influenza season (1st September 2024 to 31st March 2025):

- CH level for qualifying CHs (with the CHs needing to be identified)
- aggregate ICB level of qualifying CH
- aggregate ICB level for all CHs

We would like for each of all admissions; elective admissions; emergency admissions: emergency admissions relating to influenza (using ICD-10 codes identified in UKHSA document)

- Numbers of admissions
- Total days in hospitals across relevant admissions
- Number of residents involved

Resident mortality (total) as reported to CQC.

Care home staff illness data as submitted to DHSC Capacity Tracker. Care home staff ethnicity data as submitted to DHSC Capacity Tracker.

6.5.3 Health economic outcomes

We will estimate costs of vaccine delivery between arms, including the additional FluCare Intervention components. Where one arm does not dominate (have both lower costs and higher rates of vaccination), we will calculate the incremental cost-effectiveness ratio for cost per additional vaccination percentage point.

6.5.4 Process Evaluation

The previous feasibility study and main trial process evaluations have provided substantial understanding on barriers and enablers to implementation and mechanisms of outcomes, including exploration of the underpinning behavioural change theory. Therefore, this process evaluation will adopt a pragmatic stance to examine and define how the FluCare intervention does or does not work in a real-life delivery context. The process evaluation methods and objectives align with Medical Research Council guidance on evaluating complex interventions[56][57].

6.5.4.1 Process evaluation objectives:

1. To describe the intervention as delivered in terms of dose.
2. To further investigate the mechanisms of impact.

3. To describe the perceived awareness of and effectiveness of relevant intervention components (including videos, leaflets, posters, flu clinics and incentive payments) from participant (care home manager, care home staff, community pharmacy, Director of Public Health and CP[LOCAL]COMMITTEE Chief Officer) perspectives.
   Generate suggestions to support wider implementation of the intervention to other homes.

6.6 Participant Timeline

	Expression of Interest	Allocation	Enrolment	Intervention Delivery	Post trial activities
TIMEPOINT*	June2024	July 2024	August 2024	June 2024 to March 2025	*April 2025 onwards*
CP[LOCAL]COMMITTEE/ICS Expressions of Interest	X				
CP[LOCAL]COMMITTEE/ICS selection and allocation		X			
Identification of eligible care homes from Capacity Tracker		X			
Usual Care (Arm A)					
FluCare Intervention (Arm B)			X	X	X
Invitations sent to CP via CP [local]Committee			X		
CP contracting and Informed consent			X		
CP advise research team of CH(s) agreeing to receive intervention				X	
Intervention materials sent to care homes by research team				X	
CP conducts FluCare clinics**				X	
ASSESSMENTS:					
Vaccination log completion during FluCare Clinics and send to NCTU (intervention only)				X	
DHSC Capacity Tracker Data					X
CQC Aggregate Resident Data					X
PROCESS EVALUATION					
Focus Groups or Semi-structured Interviews with:					
Community Pharmacists					X
Care Home Managers*					X
Care Home Staff*					X
Interviews					
Chief Officers (CP[LOCAL]COMMITTEE) and Director of Public Health					X

CP [LOCAL]C: Local Pharmaceutical Committee; CP: Community Pharmacies; CHs Care Homes; *Invited from care homes that had receive the intervention only. **maximum number of funded clinics dependent upon size of the care home.

6.6.1 Integrated Care System Assessments

Director of Public Health at ICS and Chief Officer for Community Pharmacy [locals] will be requested to complete an expression of interest which will include information on current and planned initiatives for flu vaccination for the ICS as a whole as well as for the care home sector specifically.

6.6.2 Care Home Assessments

Care Home flu vaccination rates as submitted to the Department of Health and Social Care (DHSC) Capacity Tracker. Data will include the total number of employed staff within the care home and number of staff reported vaccinated. .

Resident hospital admissions (and admissions for respiratory conditions if available) and deaths as submitted to the Care Quality Commission.

6.6.3 Community Pharmacy Assessments

Community Pharmacy completed - Site Profile Questionnaire (SPQ)

Community pharmacists will be requested to complete a short survey at the start and again at the end of the trial period to capture the demographics of the pharmacy including:

- Confirmation of eligibility criteria
- Type of ownership (chain, private)
- Number of Staff in pharmacy and job titles
- Number of care homes they support.

Vaccination Logs

Vaccination logs will capture:
who delivered the clinic, their role (e.g. community pharmacist, nurse or paramedic etc) start and end time of the clinic, number of vaccination discussions and outcome of the discussion (vaccine given or not given).

6.6.4 Early Stopping of Follow-up

If a community pharmacist chooses to stop participation, NCTU should be informed of the withdrawal in writing and will record this on the FluCare database. Data already collected will be kept and included in analyses according to the intention-to-treat principle for all participants who stop follow up early.

6.6.5 Loss to Follow-up

Community Pharmacy loss to follow-up:

As community pharmacies are being recruited, loss to follow-up is unlikely as remuneration for the onsite clinics, tested during WP3 was considered adequate and not a dis-incentive. However, the study has been powered to accept loss of community pharmacies (20% attrition has been included in the sample size). In the event that a community pharmacy has changed management/ownership, attempts will be sought to obtain informed consent from the new owner/manager.

6.6.6 Trial Closure

The end of the trial is defined as 1 month following the last focus group and return of last data collection form, whichever is the latter, to allow for data entry and data cleaning activities to be completed.

6.7 Sample Size

A total of 14,535 care homes are in England, across 42 ICSs this gives approximately 346 *per ICS.* Approximately 65% of care homes have a vaccination rate of 40% or less, so approximately 225 eligible care homes per ICS. Taking the worst case-scenario we expect a vaccination rate of 40% in the control sites. For the intervention sites we will assume that 40% of the eligible homes receive the intervention (and hence 60% of care homes will have a rate of 40%), of those who get the intervention we expect 70% of them will improve a little (by 15%) and 30% will increase by a lot (30%). This gives a rate in the intervention group of 47.8%.

Based on data reported in the FluCare Randomised controlled trial (WP3), the mean and standard deviation (SD) of care home vaccination rates were:

	Intervention	Control
Vaccination rate	28.25 (21.50)	25.49 (19.04)

Using the SD of 20, then in order to detect the mean change of 7.8% would require 140 care homes in each arm using a two-sample t-test at 90% power and the 5% level of significance. Although this may seem small it is an increase of at least 15%-30% (mean 19.5% increase) in the care-homes that will actually receive the intervention.

6.8 Recruitment, Retention and Data Completeness

6.8.1 Recruitment

All Community Pharmacy Clinical Leads for ICBs (n=42) and Chief Officers of Local Pharmaceutical Committees (CP [LOCAL]Cs) in England (which align with the ICBs) will be invited to express an interest for the trial to be undertaken in their area. From those that express an interest, four ICBs/CP[LOCAL]COMMITTEEs will be selected and allocated to intervention or control.

Chief Officers for CP[LOCAL]COMMITTEEs allocated to intervention will be requested to distribute trial information to community pharmacies within their area.

Clinical research networks (CRN) associated with the ICSs allocated to intervention will also be requested to flag the trial to community pharmacists within their area.

6.8.2 Retention

As community pharmacies will only be participating in the trial over one winter flu season, we do not anticipate that retention will be an issue.

6.8.3 Data Completeness

Wherever possible mandatory fields will be used increase data completeness. Community Pharmacists will be guided in completing the site profile questionnaire and flu clinic logs, respectively. In the feasibility study and randomised controlled trial, the use of mandatory fields gave rise to more accurate data recorded. Community Pharmacists will be reminded to send in data logs in a timely manner.

6.9 Assignment of Intervention

6.9.1 Allocation

Once the four ICSs are identified, they will be divided into two groups based on the best possible split to balance the following characteristics: number of pharmacies, and vaccination rate for the previous year.

6.9.1.1 Allocation Concealment

Concealment is ensured as all ICSs will be recruited prior to the allocation taking place.

6.9.1.2 Allocation Implementation

ICSs will be purposively allocated to intervention or control arms. Where possible the ICSs will be allocated to the arms to ensure approximately equal representation of rural/urban, ethnicity population demographics between the arms. This will be a manual process.

6.9.2 Blinding

Director of Public Health and Chief Officer for Community Pharmacy [local] will be advised to which arm their ICS/CP [local]Committee[local]Committee has been allocated (both intervention and control). There will be no engagement with care homes by the research team in this trial. Care home outcome data will be received directly from DHSC and CQC.

Statistics and Health Economics will not be blinded to the allocation for the purpose of analysis. (Health economics will require details of clinics held by homes to calculate corresponding fees, which will identify trial arms).

Payments to care homes in the intervention arm achieving ≥70% vaccination rate will receive £850 payment via the Clinical Research Network.

6.10 Data Collection, Management and Analysis

6.10.1 Data Collection Methods

6.10.1.1 Department of Health and Social Care Capacity Tracker data

A data sharing agreement will be in place between the DHSC and Sponsor. Data will be requested at the end of the 2023/2024 and 2024/2025 flu seasons. The 2023/2024 data will be used to identify care homes reporting a flu vaccination rate of less than 40%. The 2024/2025 data will be used to provide primary outcome data.

Aggregate flu vaccination data on employed staff and residents as a .csv file will be sent securely to Data Management in NCTU. As the Capacity Tracker only holds aggregate data, there is no risk of sharing of personal identifiable information.

6.10.1.2 Care Quality Commission (CQC) data

A data sharing agreement will be in place between the CQC and Sponsor. Data will be requested at the end of the 2024/2025 flu season. A list of identifiers for care homes located within the participating ICSs that had a vaccination rate of <40% will be submitted to CQC.

Aggregate resident death data will be requested to be sent as a .csv file to Data Management in NCTU. As the request is only for aggregate data, there is no risk of sharing of personal identifiable information.

6.10.1.3 NHS England Secondary Uses Service data (aggregate resident hospitalisations)

A data sharing agreement will be in place between the NHS England and Sponsor. Data will be requested at the end of the 2024/2025 flu seasons. A list of identifiers for eligible care homes located within the participating ICSs will be submitted to NHS England.

Aggregate resident hospitalisation data will be requested to be sent as a .csv file to Data Management in NCTU. As the request is only for aggregate data, there is no risk of sharing of personal identifiable information.

6.10.1.4 Community Pharmacists in Intervention Arm

Each community pharmacy that participates will be given a unique trial Participant Identification Number (PID). Data will be collected at the time-points indicated in the Trial Schedule.

Community pharmacists wishing to participate will be requested to complete an enrolment form (to confirm eligibility) and site profile questionnaire. To register a care home to receive the FluCare intervention, community pharmacists will be required to email the name and contact details of the care home to the Research Team. Upon receipt of acknowledgement of the email by the research team, the community pharmacist will be able to deliver the onsite clinics.

Vaccination logs will be provided in a simple to use format either in paper or Excel spreadsheet. Vaccination logs will not contain names of care home staff but will capture simple demographics about the staff who engaged with the pharmacist, including staff group (e.g., care giver, non-care giver) . Vaccination logs submitted to NCTU will be entered into the NCTU database. Community pharmacist, or delegate, name, role, and grade will also be requested on the log.

for the purpose of inviting staff who delivered clinics to interview/focus group. Data collection, data entry and queries raised by a member of the FluCare trial team will be conducted in line with the NCTU and trial specific Data Management Standard Operating Procedures.

Community pharmacists, or their approved delegate, will be requested to complete a log of care home staff attending the clinic and leave this with the care home manager for their records to inform the upload to the capacity tracker.

Logs containing community pharmacist contact information will be stored on a REDCap on UEA's secure server to enable community pharmacists to be contacted by the central trial team for the purpose of sending reminders to register care homes and newsletters during the trial. There will be a clear logical separation of identifiable data from the trial data.

Clinical trial team members will receive trial protocol training. All data will be handled in accordance with the Data Protection Act 2018.

6.10.1.5 Process evaluation data collection methods

Process evaluation activities will be divided into three elements:

Chief Officer, Local Pharmaceutical Committee and Director of Public Health

- Expression of Interest questionnaire will capture flu vaccination initiatives planned for the 2024/2025 flu season for the ICS as a whole, and for care home staff. This information will be used to identify potential ICS/CP [LOCAL]Committee that may be running initiatives which would substantially overlap with the intervention.
- Interviews to be conducted online or face to face at the end of the follow-up period with Director of Public Health Chief Officers for the ICS/LA selected to participate in the trial and Chief Officers for the 2 CP [LOCAL]Committees corresponding to the ICSs receiving the intervention to understand other vaccination initiatives in place in their ICS/LA/CP [LOCAL]Committee/ICS during the trial and their thoughts on wider implementation.

Community Pharmacy

All community pharmacies will be characterised at the start to identify characteristics (i.e., type (independent/chain); previous experience delivering vaccinations in care homes including initiatives; no. and type of staff trained in delivering vaccination. For each care home identified by the community pharmacist, the CP will be requested to detail relationship with care home including services provided (i.e., prescription medicines, delivery to care home, onsite working in the care home)

Focus groups or semi-structured interviews will be undertaken at the end of the intervention with community pharmacists in those ICSs allocated to receive the intervention:

- Community pharmacists delivering the intervention: aim to understand barriers and enablers to implementation and considerations of opportunities for wider roll-out of the intervention. Purposive sample across the two ICB in intervention arm of community pharmacists (n=15) to take part in one of two online focus groups.

Care Home Manager and Care Home Staff

Focus groups or semi-structured interviews will be undertaken at the end of the intervention with care home managers and separately with care home staff in those ICSs allocated to receive the intervention. Care homes that received the intervention will be identified to the research team by the community pharmacist.

- Care home managers in intervention arm: aim to understand barriers and enablers to intervention and mechanisms of outcomes including contextual variation. Purposive sample of up to 15 Care home managers invited to one of two focus groups.

- Care home staff in intervention arm: aim to examine engagement with intervention and mechanism of impact Purposive sample of care home staff (n=15) invited to one of two focus group interviews.

  All interviews/focus groups

For care home managers and staff, demographic information will be collected to include role in the care home, working hours (part or full-time), age group (under 20, 20-29, 30-39, 40-49, 50-59, 60-69 over 70 years) and ethnicity. A pseudonymised identifier will be used to link demographic data to de-identified transcriptions.

Pharmacist/healthcare practitioner completed vaccination logs will be used to collect data clinic frequency, duration and vaccination uptake during clinics.

6.10.2 Data Management

Data will be entered under the community pharmacy and participant PID number onto the central database stored on the servers based at NCTU. Access to the database will be via unique, individually assigned (i.e., not generic) usernames and passwords, and only accessible to members of the FluCare trial team, and external regulators if requested. The servers are protected by firewalls and are patched and maintained according to best practice. The physical location of the servers is protected physically and environmentally in accordance with University of East Anglia's General Information Security Policy 3 (GISP3: Physical and environmental security).

The database and associated code have been developed by NCTU Data Management, in conjunction with the FluCare trial team. The database software provides a number of features to help maintain data quality, including maintaining an audit trail, allowing custom validations on all data, allowing users to raise data query requests, and search facilities to identify validation failure/ missing data.

After completion of the trial, the database will be retained on the servers of NCTU for on-going analysis.

Participant identifiable data will be held within the REDCap database separated from the research data by logical separation. Identifiable data will be deleted at the end of the study, with the exception of information required for financial regulators (for payment of vouchers).

6.10.3 Non-Adherence and Non-Retention

Non-adherence to the allocated trial arm and withdrawal of consent will be captured in trial logs and reviewed by the Programme Management Group. These data will be reviewed as part of the progression criteria to the randomised controlled trial.

6.10.4 Statistical Methods

Analysis based on the intention-to-treat principle, using all available data regardless of whether the care home received a vaccination clinic or not. The vaccination rate will be measured at the level of the care-home. Vaccination rates will be presented for each group separately and compared using a linear regression model. Although there is clustering by ICS, due to the small numbers this will be ignored in the analysis. Additionally, there will potentially be clustering due to pharmacies running vaccination clinics in multiple homes, this will also be ignored as we feel that this is likely to introduce only little correlation of results between care-homes.

The number of hospitalisations, the number of respiratory related hospitalisations and the number of deaths will be measured at the level of the care-home and compared between arms using either a Poisson regression or a Negative binomial regression with an offset, or a fixed effect, for the size of the care-home.

Assumptions will be checked and if violated then either a nonparametric bootstrap or non-parametric test approach will be used.

The following exploratory analysis will be undertaken:

A) A comparison of the eligible care homes in the ICSs allocated to the control arm with the care homes in the ICSs allocated to the intervention arm which received a clinic
B) In the ICSs allocated to the intervention, outcomes compared between eligible care homes that did not receive a clinic to those who did receive a clinic using the same modelling techniques as the main analysis;
C) Characteristics of the care-homes in the ICSs in the study will be compared to the characteristics of the care-homes in the ICSs not included in the study to help judge the generalisability of study results. This will be a descriptive analysis only;
D) Intervention group ICSs outcomes will be compared to the outcomes of all other ICS in the country (with available data) using the same modelling techniques as the main analysis;
E) The ICS in the control group the outcomes will be compared to the outcomes of all other ICS in the country with available data using the same modelling techniques as the in the main analysis to assess potential control-group bias.

Full details will be agreed and documented in the Statistical Analysis Plan (SAP) before final analysis. Where there is a discrepancy between the SAP and protocol, the SAP will have priority.

6.10.5 Health Economic Methods

We will conduct a within trial cost-effectiveness analysis (CEA) comparing costs and vaccination rate between trial arms. The primary costing perspective will be that of costs to the NHS of funding the flu vaccination programme among CH staff.

We will determine the resources involved in, and associated costs of/fees paid for, delivering the FluCare intervention. Resources required for intervention delivery are expected to consist primarily of clinician time to deliver the FluCare clinics and vaccination materials. Information on these and other resources will be collected from vaccination logs, CQC data, the DHSC capacity tracker, NHS England Secondary Uses Service data, earlier study components (e.g., the 2022/23 RCT), and augmented with expert opinion as need. We will use the most recent cost year for which published NHS and PSS unit costs (e.g. [58]) are available.

If the intervention is effective, we will determine the cost per increased percentage point of vaccination rate. Sensitivity analysis will explore the impact of expanding the costing perspective to additionally include costs of resident hospitalisations (allowing exploration of whether potentially increased vaccination costs may be offset by improved resident health, as measured by reduced resident hospitalisation). Exploratory analysis will draw on data from the 2022/23 RCT to assess impacts on wider resource use by residents (building on a relationship estimated between vaccination rate and resident health resource use). Other sensitivity analyses will repeat the health economic analysis, extending the comparator arm to include all non-intervention ICSs.

The analysis will adopt a 'within trial' approach, i.e., up to the six months of the trial. Given the duration of less than a year, discounting will not be required. Missing data is expected to be low and will be in line with the statistical analysis; decisions relating to the treatment of missing data will be made in consultation with the study CIs and statistician.
Data will be analysed on an intention-to-treat basis. If adjustment for other factors is needed (e.g., care home size), costs and effects will be analysed using appropriate regression-based methods

(ignoring clustering among CHs within the same ICS, in line with the statistical methods). Analyses will be performed in a variety of packages, likely to include MS Excel; R; and STATA.

In accordance with NCTU practice we will draft a health economic analysis plan (HEAP) prior to conducting the economic analysis. This will be shared and discussed with members of the TMG and other key personnel before analysis is undertaken.

6.10.6 Process Evaluation Methods

6.10.6.1 Analysis of interviews

Interview data will be subject to thematic analysis [59]. Data will be interrogated for barriers and enablers to implementation, how engagement with elements of the intervention impacted on mechanisms of outcome and actively examined for contextual differences across ICB, home and stakeholder groups [27]. Analysis will begin with researchers familiarising themselves by reading and re-reading transcripts to immerse themselves in the data. Following this, researchers will generate codes, noting similarities and patterns across transcripts. Once all transcripts are coded, themes will be constructed and reviewed, clustering or combining codes into bigger and more meaningful patterns. The final themes will be defined and named.

The analysis will be conducted in NVivo to allow collaborative analysis from all researchers on the project. Throughout the analysis, discussions regarding generated codes and constructed themes will take place between the research team including the PPI Advisory Group.

6.11 Data Monitoring

6.11.1 Data Monitoring Committee (DMC)

The intervention being evaluated is to encourage and support individuals to access flu vaccination. This trial is not designed to evaluate the safety of the flu vaccine. As such, the DMC and PSC have agreed that there are no safety issues. The primary risk to the project is trial failure (for example failure to recruit and poor data collection). Further details of the roles and responsibilities of the DMC, including membership, relationships with other committees, decision making processes, and the timing and frequency of interim analyses (and description of stopping rules and/or guidelines where applicable) are described in detail in the FluCare DMC Terms of Reference (ToR).

6.11.2 Interim Analyses

No interim analyses are planned.

6.11.3 Quality Assurance and Control

6.11.3.1 Risk Assessment

The Quality Assurance (QA) and Quality Control (QC) considerations for the FluCare trial are based on the standard NCTU Quality Management Policy that includes a formal Risk Assessment, and that acknowledges the risks associated with the conduct of the trial and proposals of how to mitigate them through appropriate QA and QC processes. Key risks identified in this project include recruitment (care homes and vaccination providers), intervention production and delivery, funding (specifically excess treatment costs) and data collection (staff, resident, and vaccination logs). The risks will be detailed in a risk assessment approved by the PMG prior to the start of the project.

QA is defined as all the planned and systematic actions established to ensure the trial is performed and data generated, documented and/or recorded and reported in compliance with the principles of

GCP and applicable regulatory requirements. QC is defined as the operational techniques and activities performed within the QA system to verify that the requirements for quality of the trial related activities are fulfilled. The trial is embedded within the NCTU Quality Management System, and NCTU working practices and working instructions will be followed throughout trial set-up, delivery, and analysis. QC checks will be performed on consent, data collection and Quality Management and Monitoring Plan will be produced for this trial. This will include QC checks on consent, intervention initiation (receipt of intervention materials by sites) and data collection (frequency and quality).

6.11.3.2 Central Monitoring at NCTU

Delegated FluCare trial team members will review data for errors and missing key data points. The trial database will also be programmed to generate reports on errors and error rates. Essential trial issues, events, and outputs, including defined key data points, will be detailed in the FluCare trial Data Management Plan.

6.11.3.3 On-site Monitoring

Due to the single centre recruiting design and the low-risk nature of the trial, onsite monitoring will not be undertaken. As NCTU are involved in all elements of the project at the single centre (UEA) any issues that arise will be escalated accordingly.

6.11.3.4 Trial Oversight

Trial oversight is intended to preserve the integrity of the trial by independently verifying a variety of processes and prompting corrective action where necessary. The processes reviewed relate to participant enrolment, consent, eligibility, and allocation to trial groups; adherence to trial interventions and policies to protect participants, including reporting of harms; completeness, accuracy, and timeliness of data collection; and will verify adherence to applicable policies detailed in the Compliance section of the protocol. Independent trial oversight complies with the NCTU trial oversight policy.

6.11.3.4.1 Programme Management Group

A Programme Management Group (PMG) will be set up to assist with developing the design, co-ordination, and day to day operational issues in the management of the trial, including budget management, and strategic management of the trial. The membership includes the co-Chief Investigators (Behavioural Economist and Pharmacist/Clinical Trialist); co-investigators with expertise in trial operations, PPI engagement, public health, process evaluation, qualitative research and behavioural science, health economics, statistics and intervention evaluation, advisors on configuring and commissioning pharmacy services and implementation, PPI including care home management and relatives of care home resident), and research and NCTU staff supporting care home research delivery, process evaluation, and trial set-up and delivery. A sub-group of the PMG meet weekly to review, agree and implement deliverables, and full meetings held approximately quarterly to review progress oversee trial conduct. The authority will be covered in the PMG terms of reference.

6.11.3.4.2 Independent Programme Steering Committee

The Independent Programme Steering Committee (PSC) is the independent group responsible for oversight of the trial in order to safeguard the interests of trial participants. The PSC provides advice to the CI, NCTU, the funder and sponsor on all aspects of the trial through its independent Chair. The independent membership includes Statistician, Public Health Specialist, Trialist, Behavioural Scientist, three stakeholder representatives (Care England; National Care Forum and Pharmacy Chain) and two

PPI members. The PSC meets approximately 6 monthly to review progress, including mitigations as necessary. Authority of the PSC is covered in the PSC terms of reference.

In this project, the Data Management Committee (DMC) will meet jointly with the PSC.

6.11.3.4.3 Data Monitoring Committee

The Data Monitoring Committee (DMC) has been appointed to ensure additional rigour of the FluCare research programme. As the intervention is to improve care home staff access to flu vaccination, and not the safety of the flu vaccination, there are no participant safeguarding issues. As the CQC and DHSC Capacity Tracker data won't be available until the end of the follow-up period (March 2025), the DMC will not have access to unblinded accumulating comparative data. Numbers of clinics delivered, and staff vaccinated (as reported on vaccination logs) will be available for reporting. The DMC will meet jointly with the Programme Steering Committee during the trial to review trial progress including recruitment and data log return. The DMC will also consider data in accordance with the statistical analysis plan and will advise the TSC through its Chair.

6.11.4.4.4 Trial Sponsor

The University of East Anglia is the trial sponsor. The role of the sponsor is to take on responsibility for securing the arrangements to initiate, manage and finance the trial. The Sponsor is responsible for ensuring that the study meets the relevant standards and makes sure that arrangements are put and kept in place for management, monitoring, and reporting. The University of East Anglia has delegated some Sponsor's activities to the CI and NCTU, these are documented in the Collaboration Agreement.

7 Ethics and Dissemination

7.1 Research Ethics and Health Research Authority Approval

Before initiation of the trial at any clinical site, the protocol, all informed consent forms, and any material to be given to the prospective participant will be submitted to University of East Anglia Faculty of Medicine and Health Sciences Ethics Committee and to the HRA for approval. Any subsequent amendments to these documents will be submitted for further approval.

The rights of the participant to refuse to participate in the trial without giving a reason must be respected.

7.2 Competent Authority Approvals

This is not a Clinical Trial of an Investigational Medicinal Product (IMP) as defined by the EU Directive 2001/20/EC. Therefore, a CTA is not required in the UK.

7.3 Other Approvals

Confirmation from the community pharmacy will take the form of a site agreement signed by the Sponsor and the relevant care home.

The protocol has received formal approval and methodological, statistical, clinical, and operational input from the NCTU Protocol Review Committee.

7.4 Amendments

Amendments to the Protocol and other documents (e.g., changes to eligibility criteria, outcomes, sample size calculations, analyses) will be agreed by the PMG and NIHR (as funder). Such amendments

will be forwarded to the Sponsor for confirmation as to whether it is either substantial or non-substantial and will then be submitted to the Health Research Authority or Ethics Committee for categorisation and approval. Once the amendment has been categorised it will be sent to the recruiting site for implementation in accordance with standard HRA processes and timescales. Amendments must not be implemented until HRA approval is received and recruiting site has confirmed acceptance. Notification will be sent by NCTU to trial personnel to confirm when an amendment can be implemented.

7.5 Consent

Care Homes

As routine data submitted to DHSC capacity tracker and CQC is being used to evaluate the impact of the intervention versus control on care home staff vaccination rates and resident mortality and hospitalisations, care home manager consent for use of the aggregate data will not be taken. Furthermore, as the community pharmacies in the intervention arm will be offering the FluCare intervention clinics and materials as part of a service, as recipients of the service the care homes will not be asked to give research consent to receive the clinics and associated materials.

Community Pharmacist

The research team will advise NHS England/Community Pharmacy England which ICSs are allocated to intervention. NHS England will distribute invitation letters and trial information via email, to community pharmacists within the selected ICSs. Community Pharmacists interested in participating will be asked to complete a short Redcap registration form to view a list of eligible care homes. Once interest in the study has been established, e-consent will be sought following the same procedure outlined above.

Consent to participate in focus groups.

Community pharmacists will be asked to give consent to be contacted about participating in a focus group about their experience of delivering the intervention. As multiple pharmacists/healthcare professionals may be involved in delivery of the flu clinics, the lead pharmacist will be requested to distribute PIS and consent forms to colleagues who have delivered flu clinics for the colleagues to confirm they are willing to participate in the interview.

Care home managers of care homes that have received the intervention will be invited to participate in an online focus group about their experience of receiving the intervention. Focus groups will be organised out of normal working hours and managers will receive a £50 voucher for participation. E-consent will be obtained prior to participation in the focus group.

Care home managers of care homes that have received the intervention will distribute recruitment information to their staff. Staff can then express an interest to take part in an online focus group about their experience of receiving the intervention. Focus groups will be organised out of normal working hours and managers will receive a £50 voucher for participation. E-consent will be obtained prior to participation in the focus group.

Commissioning professionals from the Integrated Care System and national bodies will be invited to participate in an online focus group about how the intervention could be implemented into routine care. E-consent will be obtained prior to participation in the focus group.

Consent to participate in interviews.

Directors of Public Health for ICS/LA and Chief Officer, Community Pharmacy Local Committee will be invited to participate in an online semi structured interview to understand levers and barriers to delivery of the intervention and other vaccination initiatives in place in their ICS/LA/CP [LOCAL]Committee/ICS during the trial and their thoughts on wider implementation of the intervention into routine care.

Copies of the approved consent forms are available from the NCTU trial team.

7.6 Confidentiality

Any paper copies of personal trial data will be kept at the participating site in a secure location with restricted access. Following consent, identifiable data will be kept on the trial database to allow authorised members of the trial team to contact care home staff for follow-up assessments. Only authorised trial team members will have password access to this part of the database. This information will be securely destroyed within 6 months of the end of the trial, expect for where required to be retained to meet financial regulations.

Confidentiality of care home staff personal data is ensured by not collecting names on CRFs and limiting access to personal information held on the database at NCTU. At trial enrolment the member of staff will be issued a participant identification number, and this will be the primary identifier for the participant. Care Home Manager and Pharmacy Consent will be collected electronically following discussion with the research team. Identifiable data will be held securely with logical separation from outcome data. Identifiable data will be deleted within 6 months of study completion.

7.7 Declaration of Interests

The investigators named on the protocol have no financial or other competing interests that impact on their responsibilities towards the scientific value or potential publishing activities associated with the trial.

7.8 Indemnity

As sponsor, UEA has appropriate indemnity to cover their responsibilities as Sponsor and any liability in respect of this. UEA holds insurance to cover participants for injury caused by their participation in the study. Participants may be able to claim compensation if they can prove that UEA has been negligent. However, as the intervention is being undertaken by community pharmacists as a service to care home staff, the community pharmacy and care home continues to have a duty of care to the participant in the study; UEA does not accept liability for any breach in the community pharmacy or care home's duty of care (to staff or resident), or any negligence on the part of community pharmacy or care home employees. This does not affect the participant's right to seek compensation via the non-negligence route.

7.9 Finance

FluCare is fully funded by an NIHR PHR grant number NIHR133455. It is not expected that any further external funding will be sought.

7.10 Archiving

The investigators agree to archive and/or arrange for secure storage of FluCare trial materials and records, including consent forms for 10 years after the close of the trial unless otherwise advised by the NCTU.

7.11 Access to Data

Requests for access to trial data will be considered, and approved in writing where appropriate, after formal application to the Programme Management Group and Programme Steering Committee. Considerations for approving access are documented in the PMG/PSC Terms of Reference. In line with NIHR desire for data to be shared wherever possible, we will endeavour to facilitate the request following appropriate review by sponsor and research team.

7.12 Ancillary and Post-trial Care

The Sponsor is not responsible for providing ancillary or post-trial care following influenza vaccination advocated by this trial. Should care home staff decide to receive the influenza vaccination, any issues arising from that vaccination should be reported to MHRA using the standard yellow card reporting process.

7.13 Publication Policy

7.13.1 Trial Results

The results of the trial will be disseminated regardless of the direction of effect. Authorship guidelines have been agreed as part of the overarching research programme (see document FluCare Publication Policy). Following publication of the trial results, data will be made available for secondary research purposes.

A protocol paper will be published for FluCare Work Package 4.

8 Protocol Amendments

Protocol Version	Date	Summary of Changes
V1.0		Pre-Ethical/HRA approval
V1.1	05/08/22	Original
V1.2	15/11/22	Minor text clarifications and edits Clarification that data logs will be collected prior to randomisation or as near to randomisation date as possible.
V1.3	10/01/23	Minor text clarification and edits Clarification of the demographics of care home staff interview participants.
V1.4	27/02/23	Edits and additions to sections 6.5.5.2 & 7.5 to allow the Process Evaluation team to invite all Pharmacists/Healthcare Professionals in the intervention arm to be interviewed. To include those who were unable to deliver on-site flu staff clinics to explore the barriers and challenges that prevented them from providing the service. Minor typographical errors
V2.0	04/06/24	Extension of trial duration to 31 Aug 2025 and for trial to be repeated during 2024/2025 Flu season. Removal of care home consent and contracting for data collecting Change of source of primary and secondary (resident data) outcomes. Removal of staff sick days and Staff flu vaccination rate disaggregated by care-giving and non-care giving roles from secondary outcomes. Addition of community pharmacists introducing intervention to care homes in intervention arm Change of randomisation from care home level to Integrated Care System level Change of sample size due to inclusion of all eligible care homes irrespective of whether they received the intervention or not in the analysis

		Minor typographical errors
V2.1	21/08/24	Removal of exclusion criteria Added information around dissemination of intervention communications to care home executives along with added information of Capacity Tracker pop up emails to eligible care homes informing of the pilot.

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10 Appendix 1 – Logic model

<table>
<tr><th>Context</th><th>Individual staff barriers [TDF domain]</th><th>Intervention components [Behaviour change technique]: Individual staff-focused</th><th>Inputs</th><th>Outputs</th><th>Short-term Outcomes</th><th>Medium-/Long-term outcomes</th></tr>
<tr>
<td rowspan="3">Evidence suggests that care home staff vaccination reduces resident morbidity and mortality

The WHO recommends that at least 75% of staff should get vaccinated

Homes have a trusted relationship with the community pharmacy providing their residents' medication

Pharmacists are permitted to vaccinate staff in homes, but few do so due to the costs involved and demand uncertainty

Care staff employers have a responsibility to facilitate vaccination, but this</td>
<td>Environment; Behavioural Regulation
Lack time to go to GP or pharmacy to get vaccinated

Environmental context and resources
Some staff (e.g. agency) are ineligible for free vaccination.

Beliefs about consequences
Believe they are fit and healthy so do not need vaccination

Believe the vaccine is ineffective or causes flu

Social influences
Staff question why they should get vaccinated when others do not.</td>
<td>Restructuring the physical environment; Review goal.
Community pharmacies commissioned to proactively offer regular staff vaccination clinics in homes at convenient times. If uptake is low, line managers talk to staff to understand why

Restructuring the physical environment
NHS funded vaccination available for all directly employed staff.

Information about health consequences and others' approval; Salience of consequences; Framing/re-framing
Two short videos featuring: (1) Residents and vulnerable (older and younger) staff explaining that others' non-vaccination causes their flu and describing their experience of it. (2) Explanation of why vaccines cannot be 100% effective but still work and why it cannot cause flu.

Emphasising a message of protecting yourself and your own family. Integrated into existing staff processes and reinforced via posters.</td>
<td rowspan="3">Integrated Care System resources to commission pharmacies; provide incentives and monitoring services

Vaccine cost for staff not eligible for NHS vaccination

Pharmacist and dispenser time, PPE and other service delivery costs

Care home manager and staff time

Videos and information campaign resources</td>
<td rowspan="3">No. of pharmacy visits to homes

Length of pharmacy visit to home

No. of times videos played.

No. of posters displayed

No. of incentive payments made to homes</td>
<td rowspan="3">Increase in staff flu vaccination rates

Residents have fewer episodes of flu-like illness, GP visits and hospitalisations

Reduced resident mortality

Fewer staff sick days

Reduced staff costs and NHS costs

Fewer staff misconceptions around vaccination

Residents have the same carer more often

Staff better appreciate how their behaviour affects residents</td>
<td rowspan="3">Managers develop their own flu campaign

Better infection control and occupational health culture

Reduced health inequities

Higher quality old age care

Higher life expectancy

Improved mental and physical health

More financially sustainable homes

Staff more willing to take vaccines in general

Vaccination model adapted and used in</td>
</tr>
<tr><td colspan="2">Organisation-level strategies</td></tr>
<tr><td colspan="2">Incentives
Care homes receive (CQUIN-like) incentive payment and certificates for achieving >70% of staff vaccinated.

Monitoring and feedback</td></tr>
</table>

is only one of their many responsibilities	Regular monitoring of and feedback on vaccination uptake and efforts to promote				other social care settings