Research Article

FluCare: Results from a Randomised Feasibility Study of a Complex Intervention to Increase Care Home Staff Influenza Vaccination Rates

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Abstract

Background: To protect care home residents, annual staff influenza vaccination uptake is recommended to be greater than 75%. In the UK it is under 40%. With barriers and enablers to care home staff flu vaccine uptake identified, the purpose of this study was to feasibility test a theory informed intervention to improve vaccination rates.

Methods: This was a five-arm (one intervention, four different control) study designed to inform the development of a definitive trial protocol. The intervention comprised of videos/posters to change vaccination attitudes, on-site clinics to increase access, a financial incentive for homes to reach target, and monthly monitoring of vaccination uptake. Control arms consisted of a mix of monthly or end of the study monitoring and provision of informational materials to identify the most suitable control arm for a definitive trial.

Care homes were recruited via sector associations and purposively allocated. The feasibility outcomes were: ability to recruit enough homes; data quality (variables reported, variable completeness and consistency with a national reporting system); intervention implementation; control arm reactivity bias and signal of efficacy. Staff vaccination data was collated from homes and via a national healthcare tracking system. Process evaluation and economic data collation were undertaken to optimise intervention and research design.

Results: Ten homes were recruited as per target within 11 weeks. Recruitment delays meant intervention delivery began towards end of flu season. Only 2 clinics took place in each home. All homes in intervention and chosen control arm (monthly monitoring only) reported all variables with over 90% completeness. There was a 15% difference between control homes' reported vaccination rates and that in the national healthcare tracker, home reported data was more reliable. Signal of efficacy: intervention arm had a vaccination rate 13.6% higher than control arm. Bias: control arm did not have a higher vaccination rate than usual care control.

Conclusions: Better recruitment processes, earlier start in flu season, and data collection direct from care homes are required for a definitive trial. A control arm of monthly monitoring only was identified as optimal for data collection purposes and minimising reactivity bias. The signal of efficacy was acceptable.

Keywords: Residential homes; Nursing homes; Long-term care facilities; Staff; Employees; Influenza vaccination

List of Abbreviations

CTU	Clinical Trials Unit
ENRICH	ENabling Research In Care Homes organisation
EOI	Expression Of Interest
MAQ	Mechanism of Action Questionnaire
NHS	National Health Service
NIHR	National Institute for Health and Care Research
WHO	World Health Organisation

Background

Each year seasonal influenza (flu) causes 17,000 deaths in the UK[1]. With mortality highest in older people and those with co-morbidities, flu poses a major risk for care home residents [2, 3]. Whilst vaccination of residents provides the main form of protection, vaccinating care home staff also mitigates against it by offering protection from cross infection to residents for whom vaccination is contraindicated or less effective[2, 4-7]. Evidence suggests a linear relationship between staff flu vaccine uptake and resident health outcomes [8, 9] with resultant reductions in resident flu-like illness, hospitalisation, and mortality [2, 4-7]. Additionally, staff health improves [10], implying fewer staff absences [11], improved care continuity and quality [12], and lower staff cover costs (e.g. less use of agency staff) [13].

The World Health Organization (WHO) recommends that at least 75% of health and social care staff are vaccinated against the flu [14]. Whilst the target has been consistently met for healthcare staff in England [15], the care home staff flu vaccination rate was reported to be only 34% in 2020-21 (NHS Capacity Tracker [16]). Several policy initiatives have attempted to increase flu vaccine uptake among care home staff with limited effect [17-19]. These initiatives have been dominated by provision of information to encourage vaccination and are usually designed to address one barrier to vaccination at a time, and thus do not approach the problem in a holistic manner.

Whilst providing influenza vaccination within the care home is believed to be one of the most effective methods for enhancing uptake in care home staff [20], it is unlikely to be sufficient in isolation. A large proportion of non-vaccinated staff cite access as the reason for non-vaccination [20-22].

In line with Medical Research Council (MRC) guidance for the development and evaluation of complex interventions [23] we used behavioural science [24], evidence from a systematic review and narrative synthesis (PROSPERO: CRD42021248384) and extensive stakeholder engagement

to co-design an intervention to address the key barriers to care home staff vaccine uptake (Figure 1). The intervention comprised on-site vaccination clinics delivered by a community pharmacist or a clinician from a GP Practice, and persuasive messaging designed to address motivational barriers delivered via videos and information materials (posters and leaflets). Additionally, organisational-level incentivisation and performance monitoring were incorporated to encourage care home manager support.

In line with MRC guidance, our aim was to test feasibility of both the proposed intervention and research design to inform a future definitive trial to estimate intervention effectiveness and cost-effectiveness. Study objectives were to inform definitive trial design, including: identification of the most effective approach(s) for recruiting care homes; to describe the most appropriate design for the future control arm, with respect to optimising study engagement and minimisation of reactivity bias; to assess the effectiveness of data collection methods; identify how well the intervention is implemented and to obtain a signal of efficacy for the intervention. Underpinned by behavioural science theory, approaches to optimising intervention acceptability, reach and dose, were explored including a description of the extent to which the intervention addressed key barriers to vaccination.

Methods

Study design

This was a five-arm feasibility study, one intervention arm and four different control arms, designed to identify the control arm configuration, including different elements of the intervention, which appeared most likely to provide complete data whilst not demonstrating any discernible reactivity bias.

Management

The study was managed overall by a Programme Management Group (PMG) consisting of all co-applicants and two patient and public involvement (PPI) members from the study Lay Advisory Group, who contributed to enhancing the cultural competence of the research [25]. An Expert Advisory Group (EAG) was also convened to support the PMG. A Programme Steering Committee (PSC), including two PPI members, and Data Management Committee (DMC) were convened to independently monitor study progress.

Setting

The feasibility study took place in: Norfolk, a rural county with the second largest care home population in England; Leicester/Leicestershire/Rutland (LLR), an urban and culturally diverse area; and London, a metropolis with significant variation in organisational structures for homes and pharmacies. Care homes with a focus on caring for older adults (i.e. aged 65 or older) were recruited, constituting 71% of UK care homes [26, 27].

Recruitment and sample size

Ten care homes and their supplying pharmacies and/or general practices (GP) were recruited from the Expressions Of Interest (EOI) received.

Three pathways to recruitment were identified and implemented. These included: direct contact with eligible care homes, engagement of health and social care organisations to circulate material and information about the study, and presenting the study at relevant forums and conferences.

The following organisations were used for study promotion and identification of candidate care homes (CHs):

- NHS England;
- Care and Quality Commission;
- National care home representative bodies (Care England, National Care Forum);
- Regional care home forums;
- Clinical research networks;
- ENRICH (Enabling Research in Care Homes) network;
- Care home groups.

Publicity text – detailing the FluCare study, participation, eligibility, payment and timeframe – was circulated to contacts with a link to complete an EOI form. The template text was edited throughout the publicity period according to feedback from various stakeholders. Shorter versions and variations were produced to make it suitable for different formats (for example, news bulletins).

For care home recruitment purposes, the following inclusion and exclusion criteria were used.

Expressions of Interest and consent forms received from care homes recruited via each route was recorded, as was the time taken for the recruitment process overall.

Inclusion criteria

- Long stay for older (over 65 years) residents or dementia registration;
- Self-reported staff vaccination rate <40% (triangulated with government tracking system);
- Located in London, Norfolk or LLR (Leicester/Leicestershire/Rutland);
- Signed up (or willing to sign up) to a national flu vaccination rate tracker (DHSC Capacity Tracker).

Exclusion criteria

- Fewer than 10 staff members (insufficient qualitative and quantitative data).

Homes were purposively selected to maximise variation [28] to ensure diversity in the following characteristics: type (with/without nursing care); owner (private/charity/local authority); size (beds); servicing community pharmacy type (private/corporate ownership; small/large group); and from all three locations.

For eligible care homes that returned a consent form, their GP practice and/or supplying pharmacy was contacted to ascertain whether they would be able to provide staff flu vaccination clinics to the care home. The care homes were then allocated to one of the study arms based on location, size of care home, and agreed participation of either GP practice or pharmacy. Randomisation by numerically coded homes was executed by AC, JB and AP.

Intervention

The intervention consisted of the elements outlined in Figure 1, plus a care home incentive of £850 (approx. 1,040 USD) if more than 70% of care home staff received a flu vaccination and end of study monitoring of performance. Clinics were delivered on different days, including weekends, and at different times to ensure maximum accessibility to staff with different working patterns.

Intervention and control arms

The study had four control arm versions to determine the optimal comparator for the main trial i.e., which intervention component(s) would increase study engagement (addressing, among other aspects, data quality and minimise reactivity bias).

A. Usual care with end of study monitoring i.e. collection of performance data

B. Usual care with monthly monitoring (to check for reactivity bias against Arm A)

C. Information materials (to incentivise trial engagement) with end of study monitoring

D. Information materials (to incentivise trial engagement) with monthly monitoring (check for reactivity bias against Arm C)

Arm E was the intervention arm (see above previous section for Intervention details).

Arms were delivered for 3 months: Jan – April 2022.

Data capture

The following data were collected from each home:

- Anonymised individual level data for all staff who work at any point during the flu season (e.g. vaccinated for flu or not; if vaccinated, location of vaccination; role (and FTE); age; ethnicity; gender; first language; sick days; leave days; permanent or agency staff)

- Home level data on resident morbidity and mortality (rates of resident: GP or nurse visits; hospitalisation; resident all-cause mortality)

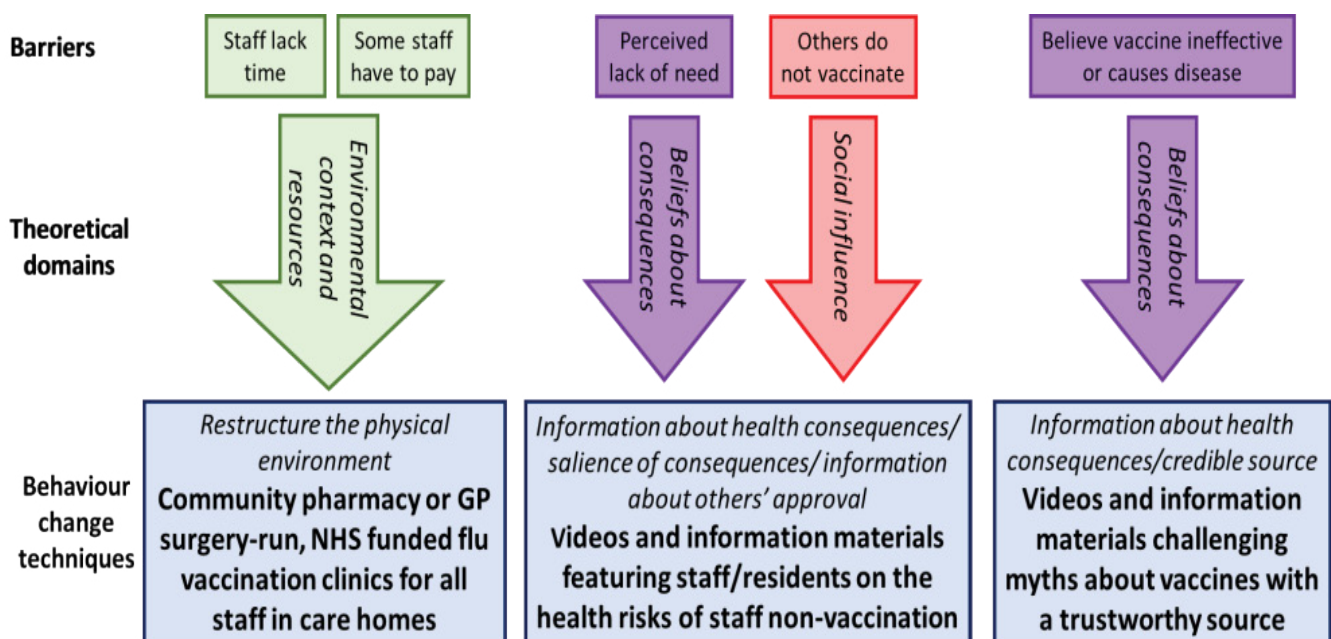- Resources (e.g., staff time) required to deliver the intervention

Figure 1: Individual-level Intervention

Staff flu vaccination rate would be the primary outcome measure of a future definitive trial and calculated as:

Total number of staff vaccinated in the flu season irrespective of time employed in the care home over total number of staff employed for any length of time throughout the flu season (all directly contracted staff e.g., direct care staff, cleaners, cooks, administrative staff and all agency staff).

In addition to vaccinations reported by the home in staff logs, vaccination providers also provided a log. Where vaccination logs indicated that a vaccination(s) had been given but not recorded on the staff log, vaccinations recorded on the vaccination log only were added to the total vaccinations recorded on the staff log.

Data for vaccination rate was also obtained from the NHS Capacity Tracker dataset where managers report home-level staff flu vaccination rates. The staff-level flu vaccination status reports were compared with the home's vaccination rate in the Capacity Tracker dataset to check for consistency.

To recompense for involvement in the study, care homes were paid £500 on provision of all requested data at the end of the study period.

Data analysis

Analysis for the statistical and health economic components was outlined in the Statistical and Health Economic Analysis Plan (SHEAP).

Analysis was descriptive, tabulating and summarising the feasibility measures with no formal statistical inference.

Primary feasibility outcomes and measures

Ability to recruit was assessed by whether we recruited the target 10 homes in time for flu season.

Data quality for a particular arm was assessed through: the number of missing variables in home reported data; the number of missing data values in the vaccination status variable; and consistency between staff vaccination reported by home and that on the National Capacity Tracker (as measured by the difference in vaccination rates).

Intervention implementation was assessed via the number of intervention homes that delivered intervention clinics and the number that displayed information materials.

Reactivity bias (from adding information materials or monitoring to homes) for a particular non-usual care control arm (Arms B-D) was assessed by comparing the average staff vaccination rate in that arm to Arm A (usual care). No formal hypothesis testing was undertaken.

The intervention's signal of efficacy was assessed by comparing the staff vaccination rate in the intervention arm (E) to that in control arms (Arms A-D). No formal hypothesis testing was undertaken.

The following comparisons in vaccination rates over the trial period were also made:

- Control homes with monthly and end of study data collection, to investigate the impact of different monitoring approaches (A versus B and C versus D);
- Control homes with and without vaccination materials provided (A versus C and B versus D).

Where vaccination status for a staff member was either recorded as "Don't know" or blank, they were treated as not having been vaccinated. Visual comparisons were also made in terms of annual change in vaccination rate.

Health economics

To inform exploring the wider impact of vaccine delivery in the definitive trial (eg use of hospitals by residents), here we explored the ability to obtain data on;

- Individual level staff data (e.g. grade, sick days, vaccinated or not and care home/agency staff);
- Care home level data (e.g. counts of: all-cause mortality; hospital attendances and admissions; GP and nurse consultations).

Rates and patterns of missingness were explored to inform refinement of the data collection tools to improve delivery of the health economic component in the main trial.

Indicative resources for, and costs of, intervention delivery are reported to help inform and refine the intervention. These primarily draw on the non-research study costs of delivering the intervention components (in particular, as vaccine providers were paid a fee delivering vaccine clinics at the care homes). Where needed, unit cost information is sourced from Jones and Burns [29]. Costs are reported in GB Sterling (£) at 2021/2022 figures. Costs are reported from the perspective of the intervention funder (at time of writing, it is not clear who would fund this intervention if implemented).

Process evaluation

A mixed-methods, parallel process evaluation in all ten homes investigated how to refine and optimise main trial delivery, including intervention delivery. The process evaluation used a previously developed fidelity framework to investigate the implementation of each intervention component in the two intervention homes (Arm E) and explore whether contextual differences affected implementation.

Data collection consisted of:

- Site Profile Questionnaire to describe and contextualise each care home at the start and end of the trial. Data

collected included: care home registration status, ownership (private/charity/local authority), no. of registered beds, no. current permanent residents; no. and type of staff; staff working arrangements; relevant vaccination/infection control policies; and previously used interventions to raise vaccine uptake.

- Mechanisms of Action Questionnaire designed to measure the extent to which the intervention addresses the intended barriers to vaccination through four statements with response options on a 5-point Likert scale (strongly disagree – strongly agree): 1) My organisation has made it possible for me to get my flu vaccine within my regular work load; 2) Getting my flu vaccination has advantages to the people I care for and/or my colleagues; 3) Getting my flu vaccination is consistent with what is expected of my profession; 4) Getting my flu vaccination has more advantages than disadvantages for me

- Mixed process measures within the intervention arm to capture and assess the feasibility measuring implementation dose:

  o No. of times videos played (embedded in videos)

  o No. of posters displayed and locations (ethnographic visits)

  o No. of flu vaccination clinics delivered to homes (Flu clinic data collection logs)

  o Length and time vaccination provider visited care home (Flu clinic data collection logs)

  o No. of incentive payments made to homes (from study records)

Interviews with staff managers and clinic providers within the intervention arm (n=20) to explore intervention acceptability, fidelity and mechanisms of action. Within the control arm (n=10) interviews explored potential for reactivity bias from intervention elements. Interviews were audio-recorded and transcribed verbatim.

A review meeting was conducted with managers at the end of the intervention period to understand how best to align data collection with their usual reporting; evaluate what further resources are needed to enable care home staff to accurately record data; and to consider what forms of information the study team might provide to encourage engagement and adherence with study data collection.

Qualitative data synthesis

A framework analysis was adopted to analyse interview data. This analysis allowed for addressing specific a priori questions and enabled visual mapping and interpretation across different arms of the feasibility study [31]. A mixed-method approach drawing on Moore's guidelines for evaluating complex interventions guided data analysis [32]. Interview transcripts were thematically analysed. For intervention arm participants, we evaluated how the process and content of the intervention functioned from the participants' perspective; identifying barriers and enablers to flu vaccination uptake that were and were not addressed by the intervention.

Progression criteria

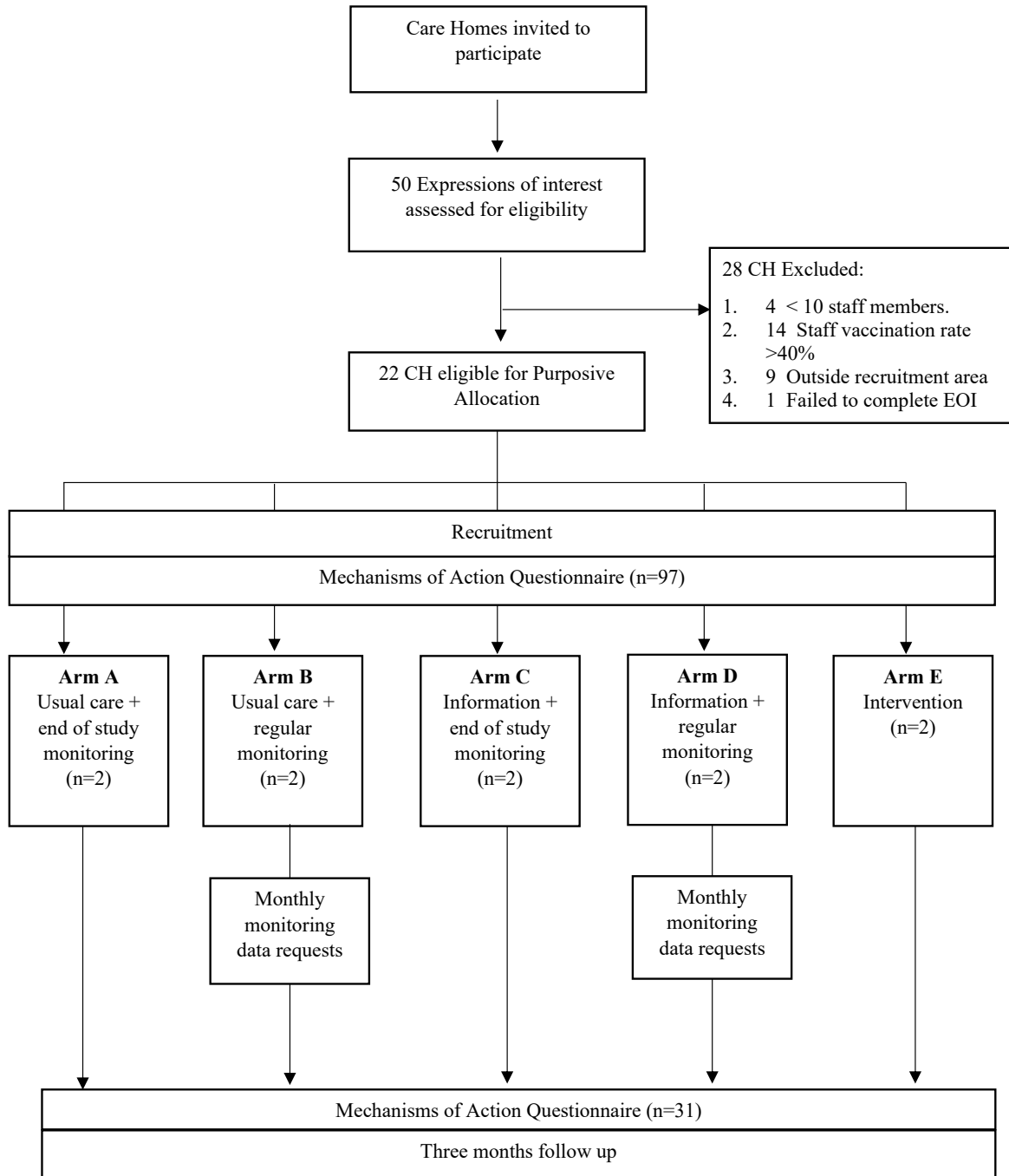Decisions to move to full trial were guided by the predetermined progression criteria outlined in Table 1.

Table 1: Definitive trial progression criteria

		Green	*Amber*	*Red*
Data quality	No. of homes in intervention arm and chosen control arms reporting on all variables requested	4	3 with at least 1 in each arm	0 homes in either arm
	Average completeness of primary outcome variable reported by homes in the intervention and chosen c ontrol arms	>90%	70-90%	<70%
	Difference between reported staff vaccination status and NHS Capacity Tracker dataset	<10% points	10-20% points	>20% points
Implementation	No. of intervention homes implementing/actioning processes for giving staff videos and information	2	1	0
	Average no. of vaccination clinics held in each intervention home	>3	3	<3
Control arm bias (arm B, C or D)	Difference in vaccination rate in chosen control arm relative to rate in usual care control arm (arm A)	<10% points	10-20% points	>20% points
Signal of efficacy	Difference in vaccination rate in intervention arm to rate in chosen control arm	>20% points	10-20% points	<10% points
Recruitment	Share of eligible homes expressing interest which consent who are invited to participate which consent	>75%	50-75%	<50%

Citation: David Wright, Amrish Patel, Jeanette Blacklock, Veronica Bion, Linda Birt, Terry Bryant, Allan Clark, Luke Cook, Alys Griffiths, Cecile Guillard, Amber Hammond, Richard Holland, Andy Jones, Liz Jones, Thando Katangwe-Chigamba, Jennifer Pitcher, Po Ruby, Sion Scott, Erika Sims, Susan Stirling, Adam P Wagner. FluCare: Results from a Randomised Feasibility Study of a Complex Intervention to Increase Care Home Staff Influenza Vaccination Rates. Archives of Clinical and Biomedical Research. 8 (2024): 273-290.

Results

Recruitment started early September 2021. A total of 50 EOIs were received by the middle of November: i.e. five EOIs per week from care homes. Eight care homes were identified through one national care home company, six via NHS England, three care homes through national representative bodies, three through ENRICH, and the remainder through local care home sector meetings and clinical commissioning groups.

A summary of the recruitment process is provided in Figure 2. Within the 22 eligible care homes, ten provided care with nursing, ten care without nursing and two provided mixed care. Three homes had less than 30 beds, 12 homes had between 31 to 120 beds and seven homes more than 120 beds. The 22 care homes who met the first four eligibility criteria were subsequently approached for consent and 14 responded. Ten were purposively selected to participate.

Figure 2: Consort Diagram

Citation: David Wright, Amrish Patel, Jeanette Blacklock, Veronica Bion, Linda Birt, Terry Bryant, Allan Clark, Luke Cook, Alys Griffiths, Cecile Guillard, Amber Hammond, Richard Holland, Andy Jones, Liz Jones, Thando Katangwe-Chigamba, Jennifer Pitcher, Po Ruby, Sion Scott, Erika Sims, Susan Stirling, Adam P Wagner. FluCare: Results from a Randomised Feasibility Study of a Complex Intervention to Increase Care Home Staff Influenza Vaccination Rates. Archives of Clinical and Biomedical Research. 8 (2024): 273-290.

The GP and pharmacy providers for the care homes initially allocated to the intervention arm were then contacted about the study. Due to issues with COVID-19 and capacity, those intervention arm care homes with a paired vaccination provider were prioritised for recruitment. All ten of the allocated care homes provided consent and none subsequently withdrew from the study.

With the emergence of the Omicron variant of COVID-19 in late November 21 and a UK Government policy to focus care home COVID-19 vaccinations, the consenting processes did not commence until January 2022.

A summary of participating care home characteristics is presented in Table 2. Five care homes were in Norfolk, three in London and two in Leicester. Most of the care homes were privately owned and registered as residential. Mean (standard deviation [sd] number of beds and residents in the care homes was 47(13) and 37(12) respectively.

Mean (sd) number of staff in the care homes at the beginning of the trial was 60 (14). Demographics of care home staff are summarised in Table 3. The majority of staff were white, female, in direct care roles and working full time.

Table 2: Care Home Characteristics

Characteristic		% (n)
Location	Leicester	20 (2)
	London	30 (3)
	Norfolk	50 (5)
Ownership	Private	70 (7)
	Charity	10 (1)
	Local Authority	20 (2)
Registration	Residential	60 (6)
	Nursing	10 (1)
	Both residential and nursing	30 (3)

Table 3: Demographics of staff in included care homes

Characteristics		Start of trial period (n=597-603)*	End of trial period (n=545)
		% (n)	
Gender			
	Female	87.8 (524)	88.1 (480)
Ethnicity			
	White	64.8 (387)	64.2 (350)
	Black	7.9 (47)	13.8 (75)
	Asian	21.9 (131)	17.6 (96)
	Mixed	2.0 (12)	1.1 (6)
	Other	1.8 (11)	3.1 (17)
Type of staff			
	Management	5.5 (33)	5.5 (30)
	Admin	2.5 (15)	2.9 (16)
	Direct Care	65.3 (392)	65.9 (359)
	Cleaning	9.7 (58)	10.1 (55)
	Kitchen	7.3 (44)	8.3 (45)
	Activities	2.8 (17)	3.7 (20)
	Maintenance	1.7 (10)	2.0 (11)
	Mixed roles	1.0 (6)	1.3 (7)
	Other	4.2 (25)	0.4 (2)
Type of contract			
	Full time	60.5 (365)	64.2 (350)
	Part time	32.3 (195)	30.1 (164)
	Bank staff	2.7 (16)	4.2 (23)
	Agency staff	3.8 (23)	1.1 (6)
	Voluntary	0.7 (4)	0.4 (2)

*Care home managers were required to provide a rough estimate of staff demographics, which they obtain from various data sources. As such, there were minor variations in the numbers provided for some of the demographic characteristics.

Table 4: Feasibility results compared to progression criteria

Domain	#	Criteria	Outcome	Mitigation	Green	Amber	Red
Data quality	1	No. of homes in intervention arm and chosen control arm reporting on all variables requested	4/4		4	At least 1 in each arm	0 homes in either arm
	2	Average completeness of primary outcome (PO) variable reported by homes in the intervention and chosen control arms	Arms B & E: Yes/No/Don't know PO categorisation: 24.7%, red; 'Confirmed' PO categorisation[1]: 100%, green	Utilise 'confirmed' PO categorisation[1];Training*; (CT same issue)	>90%	70-90%	<70%
	3	Difference between reported staff vaccination status and NHS Capacity Tracker (CT) dataset	Arm B amber (10.9% v 24.0%); Arm E green (15.7% v 18.7%)		<10% points	10-20% points	>20% points
Implementation	4	No. of intervention homes implementing/ actioning processes for giving staff videos and information	Information: 2; Videos: 0		2	1	0
	5	Average no. of vaccination clinics held in each intervention home	2 clinics held in each intervention home	Late start in flu season	>3	3	<3
Control arm bias (arm B, C or D)	6	Difference in vaccination rate in chosen control arm relative to rate in usual care control arm (arm A)	Difference at season end[2]: B=9%,A=37%, dif=-27%, green Difference from study start[3]: B=0%,A=0%, dif=0%, green	Late start in flu season; high baseline in Arm A.	<10% points	10-20% points	>20% points
Signal of efficacy	7	Difference in vaccination rate in intervention arm to rate in chosen control arm	B: 9% v E: 15.7% (red) B: 9% v 'E projected'[4]: 22.6% (amber)	Late start in flu season; flu clinic data not included	>20% points	10-20% points	<10% points
Recruitment	8	Share of eligible homes who are invited to participate which consent	10 homes invited, 10 consented		>75%	50-75%	<50%

Citation: David Wright, Amrish Patel, Jeanette Blacklock, Veronica Bion, Linda Birt, Terry Bryant, Allan Clark, Luke Cook, Alys Griffiths, Cecile Guillard, Amber Hammond, Richard Holland, Andy Jones, Liz Jones, Thando Katangwe-Chigamba, Jennifer Pitcher, Po Ruby, Sion Scott, Erika Sims, Susan Stirling, Adam P Wagner. FluCare: Results from a Randomised Feasibility Study of a Complex Intervention to Increase Care Home Staff Influenza Vaccination Rates. Archives of Clinical and Biomedical Research. 8 (2024): 273-290.

Primary Feasibility Outcomes

Table 4 provides a comparison of the primary feasibility outcome results with the progression criteria.

The progression criterion for recruitment was green as all 10 homes invited to join the study consented. The criteria for intervention implementation were green for information materials as both intervention homes (Arm E) disseminated the materials, but red for the number of clinics, with only 2 clinics taking place in each home due to the study starting late in flu season.

Remaining progression criteria concern only intervention homes (Arm E) and the chosen control arm for a future definitive trial. Arm B (monthly monitoring only) was selected as the preferred control arm. This arm showed no change in vaccination due to monthly monitoring (Arm A vs Arm B), i.e. no reactivity bias, and provided data of an acceptable quality without including any intervention elements (see Table 5 – summary of data completion and vaccination rates).

Data collection was feasible and its quality acceptable in Arms A and E. All four homes reported all variables requested. The completeness of the staff vaccination status variable was 100% (when homes are asked to confirm vaccination, rather than report yes/no/don't know). The difference between the vaccination rate reported by homes and the NHS capacity tracker was 10-20%, rated amber.

The difference in vaccination rates was less than 10% between intervention and control when using the national capacity tracker. However once care home self-report was corrected for what was known to be delivered in the study provided clinics this difference was between 10 and 20% resulting in an amber rating. For the main trial care home reported data is preferable to the national capacity tracker. The relatively small signal of efficacy is due to the study starting late in flu season.

[1]Confirmed primary outcome categorisation: 'Yes' categorised as 'confirmed' vaccination versus all other options. [2]Since the focus is to determine if the study has impacted on the control arm rate, we focus on a difference above arm A. [3]Derived from when staff were reported as being vaccinated: among all staff confirmed as vaccinated, all vaccinated before trial started. [4]The staff log (primary data collection tool) recorded fewer vaccinations occurring post trial start than those recorded in the vaccination clinic logs – we have inflated the rate for arm E to take account of these 'omitted' vaccinations (recommendations include integrating these logs more closely).

Table 5: Data quality

	Arm A (n=2)	Arm B (n=2)	Arm C (n=2)	Arm D (n=2)	Arm E (n=2)
Intervention or Control	Control				Intervention
Additional intervention elements	End of study monitoring	Monthly monitoring	Information + End of study monitoring	Information + Monthly monitoring	
Homes reporting on all outcomes (n)	1	2	2	2	2
Completeness of primary outcome variable (%)	41.1	11.1	89.2	61.9	41.7
Reported staff vaccination status % (number of staff)	37 (73)	9 (144)	21.6 (74)	16.2 (105)	15.7 (115)
Reported staff vaccination status % (number of non-agency staff)	37 (73)	10.9 (119)	22.2 (72)	16.5 (103)	15.7 (115)
NHS Capacity Tracker status % (n) (excludes agency staff)	46.7 (28/60)	24 (31/129)	54.8 (63/115)	23.6 (26/110)	18.7 (17/91)
Difference between reported and NHS Capacity Tracker (%)	-9.7	-13.1	-32.6	-7.1	-3

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Mechanism of Action Questionnaire

Tables 6a and 6b summarise MAQ completion rates and scores before and after intervention delivery. The number of responses to the MAQ were much smaller on completion of the study. No large changes in the extent to which respondents felt that the barriers to vaccination were relevant to them were identified between the different arms on completion or within arms when comparing baseline scores with scores on completion.

Table 6a: Mechanism of action questionnaire summary responses - baseline

Condition	Arm A (n=18)	Arm B (n=21)	Arm C (n=20)	Arm D (n=8)	Arm E (n=29)
	Control				Intervention
	End of study monitoring	Monthly monitoring	Information + End of study monitoring	Information + Monthly monitoring	
	Median (interquartile range) response				
My organisation has made it possible for me to get my flu vaccine within my regular work load.	4 (3 – 5)	4 (4 – 5)	4 (3 – 4.5)	4 (4 – 4.5)	4 (3 – 4)
Getting my flu vaccination has advantages to the people I care for and/or my colleagues.	4.5 (4 – 5)	4 (4 –5)*	4 (3 – 5)	4 (4 – 4.5)	4 (3 – 4)
Getting my flu vaccination is consistent with what is expected of my profession.	4 (3 – 5)	4 (4 –5)	4 (2.5 - 5)	4 (4 – 4)	4 (3 – 4)
Getting my flu vaccination has more advantages than disadvantages for me.	4 (4 – 5)	4 (4 –5)	4 (3 – 5)	4 (4 – 4)**	4 (3 –4)

*Based on 20 responses
** Based on 7 responses

Table 6b: Mechanism of action questionnaire summary responses – follow-up

Condition	Arm A (n=7)	Arm B (n=8)	Arm C (n=8)	Arm D (n=5)	Arm E (n=4)
	Control				Intervention
	End of study monitoring	Monthly monitoring	Information + End of study monitoring	Information + Monthly monitoring	
	Median (interquartile range) response				
My organisation has made it possible for me to get my flu vaccine within my regular work load.	4 (1 – 5)	4.5 (3.5 – 5)	4.5 (3.5 – 5)	4 (4 – 4)	4.5 (4 – 5)
Getting my flu vaccination has advantages to the people I care for and/or my colleagues.	5 (4 – 5)	4.5 (4 – 5)	4 (3 – 4.5)	4 (4 – 4)	3.5 (3 – 4.5)
Getting my flu vaccination is consistent with what is expected of my profession.	4 (2 – 5)	4.5 (4 – 5)	3 (2.5 – 4)	4 (4 – 4)	3.5 (2.5 – 4.5)
Getting my flu vaccination has more advantages than disadvantages for me.	5 (4 – 5)	4.5 (4 – 5)	3 (2.5 – 4.5)	4 (4 – 4)	4 (3.5 – 4)

1=strongly disagree 2=disagree 3=neither agree nor disagree 4=agree 5=strongly agree

Implementation and Theoretical Fidelity

Theoretical Fidelity

The intervention was developed using the Behaviour Change Technique Taxonomy which ensures that there is a direct link to underlying theory, ensuring theoretical fidelity.

Flu vaccination clinics

Four clinics (2 in each intervention care home) were delivered during February 2022, vaccinating a total of ten staff, seven of whom were involved in the direct care of residents. Clinic providers consisted of a community pharmacist and a nurse practitioner. Clinic duration was between 1-2 hours including time for setting up and closing down.

Intervention materials

Intervention and control arms C & D homes displayed the posters and distributed leaflets. The most reported location being the staff room. Video analytics showed that between the two intervention care homes, there was only one view

(< 1 minute) during the intervention period. Interviews with care home managers confirmed non implementation of videos and identified barriers including time and a perceived lack of means to distribute the videos. Despite poor implementation, feedback highlighted visual communication as potentially the most effective communication tool and recommended tailoring video implementation according to care home's preferred communication methods e.g. sharing links via email, text and training platforms.

Acceptability

The intervention was deemed to be acceptable to care home staff, who highlighted the importance of addressing accessibility barriers. Vaccine providers, particularly the community pharmacist, also felt the intervention was acceptable and that the provision of on-site clinics for staff should be covered as part of the enhanced service contractual agreement.

Barriers and facilitators to engagement

Although posters and leaflets were generally well received, and on-site clinics successfully addressed accessibility barriers, only a few staff reported that the intervention had influenced their decision to access the vaccines. Barriers and facilitators to vaccination are presented in Table 7. Timing

of the intervention was a key barrier to staff who wished to be vaccinated but felt it was too late in the flu vaccination season. Other barriers that were not fully addressed by the intervention included perception of lack of need for the vaccination (especially among staff that regarded themselves as being healthy and young), lack of belief in effectiveness and safety of the vaccine and negative influences of colleagues. In addition, the COVID-19 pandemic presented further barriers including safety concerns of having both the flu and COVID vaccines. The UK Government's mandatory COVID-19 vaccination policy for social care staff also presented a barrier to staff getting the flu vaccination, as some staff viewed flu vaccination as opportunity to exercise free choice.

Process evaluation interviews identified key recommendations for improving information materials to address these barriers:

- Ensure coverage and clarity of information on severity and impact of flu, the contents of the vaccine, its effectiveness and eligibility for flu vaccination in FluCare materials

- Adding benefits of vaccination for young and healthy staff, who may perceive that they do not require the vaccine

- Directly address concerns about vaccination by explaining possible side effects and vaccination manufacturing processes/ingredients

Table 7: Barriers and enablers to care home staff receiving flu vaccination based on interviews with care home staff and managers

Barrier	Enabler
Timing of clinics – end of flu season	
· *"I think it had a little bit to do with the timing of the year for flu vaccinations, it was the later part of the flu vaccination season so there was a bit of reluctance …obviously, holding the clinic at the end part of it when most people have already had it or those who have not had it don't want to have it".(*VP-LN03-E)	
· *"I had two or three people, yes three people, one didn't want it because he was undergoing other treatment so he didn't want it, but he said that if it was earlier in the season, he would have had it. And then I had another lady who I asked her and she said she had already had it as well but she would have quite happily have come to us".* (VP-NK 02-E).	
Accessibility	
· **Difficulties proving eligibility:** *because we don't work in the NHS and you don't have that documentation as such, you've just got a letter and they've got to believe it, is the way isn't it? It's harder.* (S05-NK05-C)	· **Vaccination on site in work hours:** (*) *I wasn't going to have it done it was purely because they said that they were coming to the home, I thought I'll have it because it's convenient, it's here, I haven't got to book anything.* (S11-NK02;E)
· **Issues obtaining vaccine**: *a couple of people say I've booked it and they haven't got it in, waiting for stock to come into the pharmacy* (M01-NK01-A)	· **Flexibility of employers:** *the most important thing that the home can do is just make it clear to staff that we will accommodate them having to go get the vaccine, even if it is whilst it's during their shift.* (S06-NK04-D)
COVID-19 Vaccine	

Citation: David Wright, Amrish Patel, Jeanette Blacklock, Veronica Bion, Linda Birt, Terry Bryant, Allan Clark, Luke Cook, Alys Griffiths, Cecile Guillard, Amber Hammond, Richard Holland, Andy Jones, Liz Jones, Thando Katangwe-Chigamba, Jennifer Pitcher, Po Ruby, Sion Scott, Erika Sims, Susan Stirling, Adam P Wagner. FluCare: Results from a Randomised Feasibility Study of a Complex Intervention to Increase Care Home Staff Influenza Vaccination Rates. Archives of Clinical and Biomedical Research. 8 (2024): 273-290.

· **Frustration from mandatory vaccination:** *COVID at that time was compulsory, also some of [the reason staff didn't get vaccinated for flu] was an element of, "I've got a choice in this, so I'm exercising the choice not to."* (M10-NK02-E(2))	· **Comparison of flu and COVID:** *I've had it the last two years, but maybe that is because you see what COVID can do. And flu's much the same, isn't it? Not everybody recovers from the flu* (S06-NK04-D)
· **Vaccination fatigue:** *we already have one [covid vaccine] now so why are we taking three, four or five. For our body it's too much.* (S07-LN01-D)	· **Vaccination discussions normalized**: *it comes up in conversation more than it ever used to pre-COVID… people are thinking oh I might now…. They're more likely to think about vaccine now than they used to before.* (S02-LN02-A)
· **Believing COVID vaccine covers flu:** *they think it's the same thing as COVID so they think that the vaccination they have for COVID is the same thing...that's how they think.* (M02-LN02-A)	
· **Priority given to COVID-19:** *Flu kind of disappeared for us if that makes sense. Our emphasis has been all on COVID and how we protect people from that.* (M06-NK05-C)	
· **Concerns over having both vaccines:** *it hasn't really been tested has it? I know they say it has but until you have a long-term thing then they're worried about two different vaccinations at the same time, what are they going to do? Are they going to react?* (S05-NK05-C)	
· **Unclear when you can have both vaccines:** *it's the first year probably for about five years that I haven't been vaccinated because like I said that's because of the clash between the two vaccines.* (S03-NK03-B)	
· **nfluence of COVID conspiracy theories:** *You get all the social media don't you where they say that they're going to add stuff into the flu vaccine to cover COVID and all that. Because obviously some of our staff didn't want the COVID [vaccine]* (S05-NK05-C)	
Information and awareness	
· **Lack of awareness and information on:**	· **Knowledge of severity:** *the flu mutates every year, and it can be quite nasty.* (S10-NK02-E)
o **Eligibility:** *The flu jab isn't for everybody in the public isn't it, it's just for people over 65 is it? I know in care homes they try and push it a bit more don't they.* (S08-LN03-E)	· **Being aware of how the vaccine is made and what it is for:** *I think if there is more information on it and how it works and what they do, I think that would encourage staff to have it more… Because they know what they're getting* (S05-NK05-C)
o **Severity:** *I know people get ill from flu, but it's a normal illness, not anything that's going to make me think oh I need to protect myself. It's just a normal illness.* (S08-LN03-E)	· **Access to approachable healthcare professional**: *If I had any queries, I'd ask the bloke in the chemist because he's quite friendly and he's quite approachable, as well.* (S01-NK01-A)
o **Effectiveness:** *they make it on what they think is going to happen. Whereas all the other ones, it's like a bog standard thing, there's one strain and once you've had that vaccine you pretty much are immune to it.* (S05-NK05-C)	· **Increased discussion of vaccination** (*) *We actually had more of a positive – I don't know whether it was just the mention of the project itself or not but obviously there was myself and quite a few of the care staff that actually went to go and get the flu vaccination, and I haven't had a flu vaccination since I was 16 …the flu vaccination wasn't mentioned until you mentioned the project to be honest.* (M03-LE01-**B**)

Citation: David Wright, Amrish Patel, Jeanette Blacklock, Veronica Bion, Linda Birt, Terry Bryant, Allan Clark, Luke Cook, Alys Griffiths, Cecile Guillard, Amber Hammond, Richard Holland, Andy Jones, Liz Jones, Thando Katangwe-Chigamba, Jennifer Pitcher, Po Ruby, Sion Scott, Erika Sims, Susan Stirling, Adam P Wagner. FluCare: Results from a Randomised Feasibility Study of a Complex Intervention to Increase Care Home Staff Influenza Vaccination Rates. Archives of Clinical and Biomedical Research. 8 (2024): 273-290.

· **Misinformation on vaccination ingredients:** *you've got the age-old problem with "oh I'm allergic to eggs." … I think that people don't understand all of that business about allergy to eggs.* (S02-LN02-A)	· **Effective visual information** (*): *I certain saw the fliers, the nice one with the GP on and one with the lady who was working in a care home, and I thought that's a good – they're a good motivating factor. I really should now I've seen that .. I should go for it, definitely. .. It was the visual for me … I think that's what did it.* (S10-NK02-E)
Risk perception	
· **Low risk because healthy/young:** *for other people who've got say asthma or some sort of underlying health issues, then I think maybe it's a good idea because, I think more in old people as well, because when the flu hits them it's more dangerous… maybe if I was a bit older or whatever, maybe I would have it…I don't really get sick so.* (S09-LN03-E)	· **Higher risk because older/more vulnerable**: *as you get older you get more defensive around these things, and it just takes longer to recover. So, if I can have something that will lessen the impact on me in a purely selfish way it eases me, then I'm happy to have a go at it.* (S03-NK03-B)
· **Experiencing/hearing of negative side effects:** *about the side effects, like I said my sister was so ill with it and I think that put me off a lot.* (S09-LN03-E)	· **Not experiencing side effects**: *I've always had a flu vaccine, I've never had any side effects I've sometimes not even felt it the next day in my arm* (S02-LN02-A)
	· **Risk for others:** *And the argument about protecting the residents, or members of the public, or patients, is always a good one I think* (S02-LN02-A)
Care home environment	
· **Negative or ambivalent attitudes among staff:** *I think it has a lot to do with the culture that I have in this particular home possibly as well…the vaccination rates for flu in particular are relatively low… it was just like I can't be bothered kind of attitude.* (M05-LE04-C)	· **Confident and proactive manager**: *[CH manager] tells us everything and she explains everything to us." "[having the flu jab] is becoming natural ... It's just a majority [sic] of the people what don't have it done…if any, because [Name] was not pushy but she was asking people "make sure you have it done because it's for your own sake as well as other people.""* (S01-NK01-A)
· **Not discussing impact of flu outbreaks:** *I know of my sister homes that have had a flu outbreak and that is the thing, we're not good at sharing the realities of it… And we are pressured, we are busy, there's no getting away from that but we just don't share, we don't have the tools* (M06-NK05-C)	· **Seeing the effects of sickness on residents**: *people in care homes … have the day to day reality of what I do could actually harm somebody that I know [compared with the general public]* (S03-NK03-B)
· **Lack of clear guidelines/policy for managers:** *we can't really do much … we can suggest but we can't insist and it's a very fine line, at least HR wise … just pulling someone in and having an in-depth conversation about them, about their thoughts of the flu vaccine could lead to a claim of constructive dismissal. So, we've had to kind of teeter the edge* (M05-LE04-C)	
Social care duties	
· **Not being paid enough to be expected to get vaccine:** *You get this "I had a Flu vaccine, I felt rough for the next week or so," "I had a Flu vaccine, I got Flu." I think that potentially puts people off and a lot of people in the care industry… it's not one of the best paid jobs, is it? So they're working because they need to work.* (M06-NK05-C)	· **Considering vaccine to be part of job:** *it's a career that I think you've got to be passionate about, and that comes into the vaccine side of it as well, in that if you are passionate about it and protecting your residents, you would go ahead and have the flu vaccine* (S06-NK04-D)
· **Not having time to get the vaccine:** *by the time they've done three or four shifts in a row they're exhausted so the last thing they think about is I'll go and get my flu vaccination.* (M03-LE01-B)	· **Staffing issues:** *at certain times of the year you get staffing issues when staff are poorly. I think we've had one just be off recently with 'flu, so unless you've got some sort of health reason not to have it…* (S06-NK04-D)
	· **Maintaining individual performance**: *and (b) safeguard ourselves, to ensure we're fit and healthy to actually care for them.* (S10-NK02-E)

Citation: David Wright, Amrish Patel, Jeanette Blacklock, Veronica Bion, Linda Birt, Terry Bryant, Allan Clark, Luke Cook, Alys Griffiths, Cecile Guillard, Amber Hammond, Richard Holland, Andy Jones, Liz Jones, Thando Katangwe-Chigamba, Jennifer Pitcher, Po Ruby, Sion Scott, Erika Sims, Susan Stirling, Adam P Wagner. FluCare: Results from a Randomised Feasibility Study of a Complex Intervention to Increase Care Home Staff Influenza Vaccination Rates. Archives of Clinical and Biomedical Research. 8 (2024): 273-290.

- Include COVID-specific considerations:
  - Importance of having both vaccines (i.e., COVID does not cover flu and vice versa)
  - Safety of having both vaccines
  - When you can have both vaccines (e.g., whether you can have them at the same time)
- Make paper materials bright and eye-catching to stand out among other leaflets/posters displayed around care homes
- Identify a suitable method, with care home managers, to distribute video to staff, tailored to the care home

Across four clinics, vaccination providers reported it taking a mean time of ≈2.2 hours to deliver a clinic session (including: organising session; session delivery; other time at CH; excluding travel time).

No incentive payments were made to homes at the end of the flu season.

Quality and outcome of health economics data

Data completeness for the staff logs are more generally addressed above. Focusing on the more health economic (HE) specific outcomes: detail on staff type was well reported (only missing/inappropriate in 6.7% (34) of the 511 staff reported about); numbers of sick days was well completed among directly employed staff (only 13.7% (65/473) missing). Very few (15) people took unpaid leave. Qualitative feedback from the process evaluation about using the staff log on these components was broadly positive, but advised not collecting unpaid leave as it is very uncommon.

Data collected on the care home resident health logs are summarised in Table S1 (hyphens indicate missing data). Broadly, where homes completed the logs, they completed them well (one home in Arm A did not return a log; one home in B only returned information for approximately a third of the data collection period). Where returned, no missing data on use of hospitals was apparent. Qualitative feedback from the process evaluation was broadly positive, with some suggested changes to wording, and suggestion to additionally record paramedic attendances in the care home, which did not result in hospitalisation. These results suggested the proposed data collection for the Health economic analysis of main trial is feasible.

Resources and costs of intervention delivery per care home are given in Table S2. Printing and delivery of education materials (posters and leaflets) cost £148 (printing and delivery). Vaccination clinic providers were paid £556 to accommodate delivering up to 4 clinics, on the basis of funding 4.25 hours of their time (incorporating clinic delivery, admin and travel) and other resources (mileage and PPE). Total clinic costs varied depending on the total staff vaccinated: vaccination providers received additional funding for each person vaccinated (this is part of standard practice/reimbursement, and not just part of FluCare – e.g. see NHS Electronic Tariff) (33). In Arm E (intervention arm) a mean of five people were vaccinated in clinics, giving an estimated clinic cost of £671. However, as noted above, only two clinics were delivered at each home in the intervention arm, and this was late in the flu season. If we assume four clinic sessions, vaccinating eight staff per session, total clinic costs would be £1,293. We have estimated that monitoring care homes consists of a monthly phone call of ten minutes for six months (duration of the flu season). Assuming this work could be delivered by an NHS band 3 staff, we estimate this to cost £31.

Delivering all components of the intervention would cost an estimated £850 based on study figures (five staff vaccinated at clinics), or £1,471 based on projected figures (32 staff vaccinated at flu care clinics). These figures would increase by £850 (rising to £1,700 and £2,321 respectively), where homes achieve a vaccination rate of 70% or greater, through payment of the care home incentive. No unintended consequences were reported by staff/managers/clinic providers during interviews, and therefore no additional costs were considered.

For care homes allocated to provide a single staff log at the end of the study, there vaccinations appearing on the vaccination provider log, but not on the care home reported staff log. This indicates a need for 1) more frequent data collection, and 2) and a mechanism for facilitating communication between care homes and vaccination providers to reconcile differences.

Discussion

This feasibility study has shown that we can progress to a full trial, but there are several challenges that we need to address highlighted through this study. Most importantly, despite using all identified pathways to recruitment care homes into the study, only a relatively small number of eligible homes expressed an interest over an almost three-month recruitment period. Reallocation of care homes with vaccination providers to the intervention arm will not be possible within the main trial, where homes and providers will be randomised and therefore more effective recruitment strategies are required.

The feasibility study started later in the flu season than originally anticipated and recruitment took longer, limiting time and opportunity for improving vaccination status in the care homes. To prevent this in the main trial we will need to start recruitment much earlier in the year. Given that the flu season usually ends in March then, ideally, we will seek expressions of interest as soon as the vaccination status for staff within care homes from the previous year is known.

With an inclusion criterion of <40% vaccination status in recruited homes, the number of staff within homes on average being 60, and a target of 70% vaccinated; then 18 additional staff will require vaccination against influenza in each home. With an average of two or three staff vaccinated in each clinic during the feasibility study then we will be looking for at least six clinics to be provided in each home within the main trial to achieve the 70% target. Whilst motivating the care home managers to encourage vaccination within their staff through performance monitoring and financial incentivisation, and persuading staff to access the vaccine through videos and posters should imply some off-site self-seeking vaccination behaviour, we recognise that access is the main barrier [20-22]. Provision of a number of on-site clinics will be vital for eventual trial success. The alternative to delivering large numbers of clinics for small numbers of staff each time will be to encourage provision when most staff requiring vaccination will be available.

No discernible changes in the Mechanism of Action questionnaire results were identifiable as a result of the different feasibility elements being tested. This, however, may be due to the very poor response rate post-intervention period. Strategies to enhance response to a very brief questionnaire from staff within the home will be required if we want to better understand how the intervention worked.

The videos were accessed only once during the feasibility study, thereby limiting their opportunity for effect. The recommendations to tailor distribution to the home will require implementation. As will be the need to emphasise benefits and address concerns within all information we provide. Interestingly, the emergence of a COVID vaccine seems to have created more barriers to influenza vaccination rather than less, largely due to a belief that one vaccine would protect them against both COVID and flu, and, a belief that it was unsafe to receive more than one vaccine. Consequently, this will also require consideration when the posters and videos are revised.

Collation of data required for economic analysis was found to be feasible with some costs estimated at this stage of the process. Consequently, we are confident that we will be able to estimate cost-effectiveness within the main trial. The progression criteria suggest that if we start the study earlier on within the flu season and collect data regularly from the care home then it will be appropriate to progress.

Interestingly, offering components of the intervention (i.e. information materials) to encourage care home engagement with the study provided no greater outcomes with respect to data collection than providing none at all. Furthermore, monthly monitoring alone did not appear to influence vaccination rates.

Strengths and limitations

The qualitative and quantitative approaches taken within the process evaluation enabled triangulation between data and individual described behaviours. We therefore have good insight into how to optimise different elements of the intervention and research design.

The late start of the feasibility study limited the opportunity to observe longer term effects of our multi-faceted intervention. Similarly, the small number of self-identified homes in each arm limits our confidence in inferences regarding reactivity bias or engagement.

Indicative costing does not take account of material production (e.g. design and producing the posters, videos and leaflets) as these were considered research costs within the feasibility trial. While generally not recurring, on the assumption study materials can be reused, there may be future costs for i) hosting the video and ii) "refreshing" these materials to keep them current/relevant/impactful, in line with any policy changes.

Conclusion

To secure the 78 homes needed for a main trial, recruitment must start earlier and take a more targeted/personalised approach rather than rely on representative bodies. Evidence suggests that the posters could be improved and that video dissemination should be tailored to each home. A control arm of monthly monitoring of vaccination uptake is recommended from a research and reactivity bias perspective. Cross-validating vaccination provider records with care home self-reports would provide an accurate vaccination status for each home, to be used as a primary outcome. We believe the feasibility study progression criteria will be met if the changes identified are implemented.

Declarations

Ethics approval and consent to participate

Before initiation of the trial at each care home site, care home managers provided informed written consent. All participants who completed the MAQ and attended online interviews provided informed written consent prior to participation. The University of East Anglia, Faculty of Medicine and Health Sciences Research Ethics Subcommittee and the HRA approved the study protocol in December 2021 (Ref no. ETH2122-1471; IRAS ID 305371).

Consent for publication

All authors have given consent for publication.

Availability of data and materials

Data is available from Norwich Clinical Trials Unit via e.sims@uea.ac.uk

Authors' contributions

DW, AP, LB, AC, AG, RH, AJ, LJ, SS, ES and AP were co-applicants on the original grant application. All authors contributed to at least one of trial design, delivery, data collection, data analysis and project management.

DW prepared the first draft of the paper for AC, TK, SS and APW to review and contribute their elements. AP assumed responsibility for finalising the paper, responding to the review of the paper by all authors.

References

1. Public Health England. Surveillance of influenza and other respiratory viruses in the UK (2019).

2. Lansbury LE, Brown CS, Nguyen-Van-Tam JS. Influenza in long-term care facilities. Influenza Other Respira Viruses 11 (2017): 356-366.

3. Matias G, Taylor RJ, Haguinet F, Schuck-Paim C, Lustig RL, et al. Modelling estimates of age-specific influenza-related hospitalisation and mortality in the United Kingdom. BMC Public Health16 (2016).

4. Hayward AC, Harling R, Wetten S, Johnson AM, Munro S, et al. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. BMJ 333 (2006):1241.

5. Hayward AC. Influenza Vaccination of Healthcare Workers Is an Important Approach for Reducing Transmission of Influenza from Staff to Vulnerable Patients. PloS one 12 (2017): e0169023.

6. Thomas RE, Jefferson T, Lasserson TJ. Influenza vaccination for healthcare workers who care for people aged 60 or older living in long-term care institutions. Cochrane Database of Systematic Rev 6 (2016).

7. Lemaitre M, Meret T, Rothan-Tondeur M, Belmin J, Lejonc J-L, et al. Effect of Influenza Vaccination of Nursing Home Staff on Mortality of Residents: A Cluster-Randomized Trial. J Am Geriatri Soci 57 (2009): 1580-1586.

8. Wendelboe AM, Grafe C, McCumber M, Anderson MP. Inducing Herd Immunity against Seasonal Influenza in Long-Term Care Facilities through Employee Vaccination Coverage: A Transmission Dynamics Model. Comput Math Methods Med 2015 (2015): 1-6.

9. Van Den Dool C, Bonten MJM, Hak E, Heijne JCM, Wallinga J. The Effects of Influenza Vaccination of Health Care Workers in Nursing Homes: Insights from a Mathematical Model. PLoS Med 5 (2008): e200.

10. Ng ANM, Lai CKY. Effectiveness of seasonal influenza vaccination in healthcare workers: a systematic review. J Hospital Infect 79 (2011): 279-286.

11. Pereira M, Williams S, Restrick L, Cullinan P, Hopkinson NS. Healthcare worker influenza vaccination and sickness absence – an ecological study. Clin Med 17 (2017): 484-489.

12. World Health Organization. Continuity and coordination of Care (2018).

13. Franklin B, Hochlaf D. An Economic Analysis of Flu Vaccination. The International Longevity Centre (2018).

14. World Health Assembly. Prevention and control of influenza pandemics and annual epidemics. Geneva (2003).

15. Public Health England. Seasonal influenza vaccine uptake amongst frontline healthcare workers (HCWs) in England (2020).

16. NHS Capacity Tracker dataset. In: NHS England and NHS Improvement (2021).

17. NICE. Flu vaccination: Increasing uptake. In: National Institute for Clinical Excellence (2018).

18. Public Health England. Flu and flu vaccination 2019/20: A toolkit for care homes (2019).

19. NHS England and NHS Improvement. Social care:

guidance for workforce flu vaccination. In: NHS England and NHS Improvement (2019).

20. Patel A, Peryer G, Copping D, Purser C. Survey of frontline workers in social care settings (2020).

21. Kenny E, McNamara Á, Noone C, Byrne M. Barriers to seasonal influenza vaccine uptake among health care workers in long-term care facilities: A cross-sectional analysis. British J Health Psychol 25 (2020): 519-539.

22. Halpin C, Reid B. Attitudes and beliefs of healthcare workers about influenza vaccination. Nursing Older People 31 (2019): 32-39.

23. Council. MR. Developing and evaluating complex interventions (2006).

24. Atkins L, Francis J, Islam R, O'Connor D, Patey A, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implement Sci 12 (2017).

25. Razai MS, Osama T, McKechnie DGJ, Majeed A. COVID-19 vaccine hesitancy among ethnic minority groups. BMJ (2021): n513.

26. MHA. Facts & Stats (2018).

27. Statista. Annual number of adult social care homes in England (2021).

28. Suri H. Purposeful Sampling in Qualitative Research Synthesis. Qualitative Res J 11 (2011): 63-75.

29. Jones KB A. Unit Costs of Health and Social Care 2021, Personal Social Services Research Unit, University of Kent, Canterbury (2021): 77 .

30. Atkins L, Francis J, Islam R, O'Connor D, Patey A, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implement Sci 12 (2017): 77.

31. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol 13 (2013): 117.

32. Moore GF, Audrey S, Barker M, Bond L, Bonell C, et al. Process evaluation of complex interventions: Medical Research Council guidance. Bmj 350 (2015): h1258.

33. NHS Electronic Tariff. Part VIE - Enhanced Services (Pharmacy Contractors) (England) and Additional Clinical Services (Pharmacy Contractors) (Wales) (2023).