FluCare: results from a randomised feasibility study of a complex intervention to increase care home staff influenza vaccination rates

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Research Article

Keywords: Residential homes, nursing homes, long-term care facilities, staff, employees, influenza vaccination

Posted Date: November 29th, 2023

DOI: https://doi.org/10.21203/rs.3.rs-3273397/v1

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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.

Trial registration ISRCTN 14727552 Registered on 27/08/2021. Secondary identifiers: IRAS 305371

Key messages regarding feasibility

- Main uncertainties regarding feasibility: Effectiveness of recruitment methods; intervention implementation; most appropriate control arm to maximise data quality while minimising reactivity bias; how reliable data collection methods are; and whether there is an early indication that intervention may be effective.
- Key findings: Recruiting via sector organisations only delivers a small number of homes; only 2 clinics were run in each home due to starting at end of flu season; a monthly monitoring only control arm performs better than other possibilities; data collection via logs is effective and more reliable than relying on national health system tracker data; an acceptable signal of efficacy was observed.
- Implications for study design: More direct and personalised recruitment over a larger geographic area; trial must start early in flu season; use a control arm with monthly monitoring; collect vaccination update data directly from homes rather than healthcare system tracker.

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 (Fig. 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.

**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

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:
  - No. of times videos played (embedded in videos)
  - No. of posters displayed and locations (ethnographic visits)
  - No. of flu vaccination clinics delivered to homes (Flu clinic data collection logs)
  - Length and time vaccination provider visited care home (Flu clinic data collection logs)
  - 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.

**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.

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.

**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.

**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.

**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
- 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 \(\approx\) 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.

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

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

Competing interests

No competing interests to report

Funding

This study was funded by the National Institute of Health Research (NIHR) under its Public Health Grant Number: NIHR133455. APW also receives support from the NIHR Applied Research Collaboration (ARC) East of England (EoE). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care. The contract for this project is held by NHS Norfolk and Waveney Integrated Care Board (NWICB). The views expressed are those of the authors and not necessarily those of NWICB.

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.

Acknowledgements
The research team would like to thank the support provided by all external bodies with respect to identifying homes to participate in the study and all care homes, managers, staff and vaccination providers for participating in the trial. Special thanks go the FluCare Lay Advisory Group who have been an integral part of the team throughout the study. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

References

Tables


Figures

Barriers
- Staff lack time
- Some staff have to pay
- Perceived lack of need
- Others do not vaccinate
- Believe vaccine ineffective or causes disease

Theoretical domains

Behavior change techniques
- Restructure the physical environment
  - Community pharmacy or GP surgery-run, NHS funded flu vaccination clinics for all staff in care homes
- Information about health consequences/salience of consequences/information about others’ approval
  - Videos and information materials featuring staff/residents on the health risks of staff non-vaccination
- Information about health consequences/credible source
  - Videos and information materials challenging myths about vaccines with a trustworthy source

Figure 1

Individual level Intervention
Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CONSORTchecklist.docx
- Supplementarymaterials.pdf