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Regular asymptomatic COVID-19 testing in care home staff

Submission date
24/11/2022

Recruitment status
No longer recruiting

Registration date
05/12/2022

Overall study status
Completed

Last Edited
16/07/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
This study will investigate whether the continued use of regular asymptomatic COVID-19 testing in care home staff is a feasible, effective and cost-effective strategy to reduce the impact of COVID-19 in care homes. The findings will shape policy across the UK for COVID-19 and inform wider strategies to prevent other respiratory viruses in care homes, such as influenza. This study aims to measure the benefits and harms of regular asymptomatic testing in care home staff to inform policy. Regular asymptomatic testing may reduce the risk of severe disease in residents and the frequency and severity of outbreaks.

Who can participate?
Participants for the testing intervention will be care home staff from a target of 280 care homes. This will also include temporary (agency) staff with no restrictions (i.e. catering staff, administrative staff, and maintenance staff), in addition to those in a resident-facing role. These care home staff as well as residents, visitors and relatives are all eligible to participate in interviews undertaken as part of the process evaluation.
Participants for the data collection and analysis of the outcomes specified will be care home residents.

What does the study involve?
To finalise the intervention, a series of workshops will be held with care home stakeholders (e.g. home managers, staff, providers) and policymakers (including those with knowledge of testing logistics) to explore the intervention components. These workshops will: 1) consolidate existing insights into routine testing gleaned through past experiences with the COVID-19 pandemic; 2) discuss the intervention prototype; and, 3) operationalise it in ways which are likely to be acceptable and appropriate within the sector.
Any care home staff Interested in participating can either liaise with the care home manager or respond directly to the research team. Upon receipt of staff contact details, interested staff will then be sent participant information sheets about the study, given the option to ask questions about the study, complete online consent forms and provide brief sociodemographic details. The study team will then arrange a time for data collection to take place. Within data collection (focus groups or one-to-one interviews), having checked online consent has already been given and after exploring any remaining unanswered questions raised by the PIS, the participants will

be asked to also give recorded oral consent to participate. This consent will be recorded on the audio/video file. Interviewees will be reimbursed for their time (vouchers).
The researchers will also recruit a single workshop with around eight residents (with the capacity to consent), relatives, or visitors to assist with intervention development. Interested parties will then either liaise with the care home manager about their participation or respond directly to the research team. Upon receipt of resident, relative or visitor contact details, interested parties will then be sent participant information sheets about the study, given the option to ask questions about the study, complete online consent forms and provide brief sociodemographic details. The study team will then arrange a time for data collection to take place. Within data collection (focus groups or one-to-one interviews), having checked online consent has already been given, and after exploring any remaining unanswered questions raised by the Participant Information Sheet, the participants will be asked to also give recorded oral consent to participate. This consent will be recorded on the audio/video file. Interviewees will be reimbursed for their time (vouchers).
The testing intervention will be comprised of four modules that will be delivered in combination. Module 1: Support payments for staff to enable them to self-isolate when unwell. Module 2: Branding and messaging around testing to promote engagement with testing. Module 3: Accessible training, protocols and planning. Module 4: Regular asymptomatic staff testing for COVID-19.
In module 4 care homes participating in the intervention arm of the trial will be provided with lateral flow tests. Asymptomatic testing will be in addition to symptomatic testing for staff and residents and testing as part of the outbreak response.
Non-intervention care home residents and staff will be subject to the testing policy that is in place nationally at the time of the trial. Care home staff in control homes will not receive support payments (Module 1) and testing in control homes will not be supported by branding or messaging (Module 2). The degree to which training and testing protocols are already in place in control homes (Module 3) will be investigated in the stakeholder workshops.

What are the possible benefits and risks of participating?
Regular asymptomatic testing may reduce the risk of severe disease in residents and the frequency/severity of COVID-19 outbreaks. The trial may identify policies and approaches to testing in care homes which could reduce the risk of reducing residents' risk of severe outcomes following infection in these settings. Participants will indirectly benefit from this research through its influence on the COVID-19 policy on testing in care homes.
The trial could lead to loss of income for providers if asymptomatic testing results in increased detection of low-risk cases leading to potentially unnecessary care home closures. This is mitigated by the trial team who will risk-assess asymptomatic cases that have been detected in staff in the intervention arm to avoid unnecessary escalation of low-risk cases to local public health teams. The trial team includes a number of individuals who have trained in health protection and are thus qualified to undertake this role.
Increased staff sickness absence may reduce staffing ratios and the quality of care that is delivered to residents. There is a risk of introducing infection into the care home when the study team conduct personal data collection (although most data collection is virtual). This risk will be mitigated by complying with infection control protocols in place at the time of the study (including asymptomatic testing where appropriate), not attending if unwell and using virtual meetings where possible.

Where is the study run from?
University College London (UK)

When is the study starting and long is it expected to run for?
November 2022 to April 2024

Who is funding the study?
1. Health and Social Care Delivery Research (HSDR) Programme (UK)
2. UK Health Security Agency (UK)

Who is the main contact?
Prof. Laura Shallcross, l.shallcross@ucl.ac.uk

Study website
https://www.ucl.ac.uk/health-informatics/research/vivaldi/vivaldi-clinical-trial

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
320847

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
V1.0, IRAS 320847

Study information

Scientific Title
Shaping care home COVID- testing policy: a pragmatic cluster randomised controlled trial of asymptomatic testing compared to standard care in care home staff

Acronym
VIVALDI-CT

Study objectives
Continued use of regular asymptomatic testing in care home staff is a feasible, effective and cost-effective strategy to reduce the impact of COVID-19 in care homes. Findings will shape policy across the UK for COVID-19 and inform wider strategies to prevent other respiratory viruses in care homes, such as influenza.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/12/2022, London - Bromley Research Ethics Committee (Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, UK;
+44 (0)207 104 8118; bromley.rec@hra.nhs.uk), ref: 22/LO/0846

Study design

Multi-centre open-label interventional cluster randomized controlled Phase III/IV superiority trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Care home, Workplace

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Prevention of severe COVID-19 (SARS-CoV-2 infection) related outcomes in care home residents

Interventions
Intervention: Regular asymptomatic testing of care home staff for COVID-19 using lateral flow devices (LFDs) combined with support payments for sickness absence in those who test positive.
Control: COVID-19 testing policy for care home staff that is in place nationally at the time of trial operation.

There will be two arms: Arm A and Arm B.
Arm A will be comprised of the intervention. This intervention will be delivered via four modules:
Module 1: Support payments for staff to enable them to self-isolate when unwell and reimbursement for providers for costs associated with backfill to cover staff absence
Module 2: Branding and messaging around testing
Module 3: Accessible training, protocols and planning
Module 4: Regular asymptomatic staff testing for COVID-19 – twice weekly
The intervention will take approximately 3 months.

Arm B - Residents and staff in non-intervention care homes will be subject to the testing policy that is in place nationally at the time of the trial. Care home staff in control homes will not receive support payments and providers in control homes will not receive funding to reimburse the costs of employing agency staff since there is no asymptomatic testing. The degree to which training and testing protocols are already in place in control homes (Module 3) will be investigated in the stakeholder workshops.

There is no standard follow-up period.

Care homes will be randomised to standard care (the testing policy that is in place at the time of trial) versus intervention (multi-component testing intervention) in a 1:1 ratio. If all providers are ready for trial participation at the same time then all participating homes will be randomised at the same time. Otherwise, the homes from different providers will be randomised in a phased approach, as they become ready.

The results of the randomisation process will be communicated to each provider's project manager. They will be responsible for informing care home managers whether they have been randomised to the control or intervention group. The trial team will draft an email/text that can be used to explain the process of randomisation to care home managers.

Randomisation will be performed by the trial statistician after enrolment of care homes and prior to implementation of the intervention, based on pseudo-random number generation. Restricted randomisation (specifically covariate-constrained randomisation) will be used to ensure balance on care home provider, size and region.

Intervention Type
Other

Primary outcome measure
The incidence of COVID-19-related hospital admissions in residents, defined as admissions with relevant ICD-10 codes (COVID hospitalisations to be defined as any hospital admission record with a primary or secondary ICD10 code of 'U071') and/or admissions in residents who test positive for COVID-19 within 24 h following admission or in the 7 days before hospital admission. This has been selected because it is the most important outcome for policymakers.

Secondary outcome measures
1. Incidence rate of hospital admissions (all-cause) in residents for non-elective care, measured as events per 100,000 person-days of follow-up over the duration of the trial
2. Incidence rate of COVID-associated mortality in residents, measured as events per 100,000 person-days of follow-up over the duration of the trial*
3. Incidence of all-cause mortality in residents, measured as events per 100,000 person-days of follow-up over the duration of the trial
4. Testing uptake in staff, measured as the proportion of staff at each home participating in testing during each week of the trial
5. Prevalence of SARS-CoV-2 among staff who test, measured as the proportion of staff with positive test results among those with at least one test recorded during each week of the trial
6. Incidence rate of SARS-CoV-2 infections detected in residents, measured as events per 100,000 person-days of follow-up over the duration of the trial
7. Incidence rate of home-level outbreaks, measured as events per 1000 days of follow-up over the duration of the trial
8. Duration of outbreaks, measured as days from first to last case within outbreaks occurring within the trial period
9. Incidence rate of care home closures due to outbreaks, measured as events per 1000 days of follow-up over the duration of the trial
10. Proportion of staff per home who are off sick at each home during each week of the trial
11. Proportion of all shifts filled by agency staff at each home during each week of the trial

*COVID-associated mortality will be defined as death within 28 days of a positive SARS-CoV-2 test and/or COVID-19 recorded as the primary or secondary cause of death on the death certificate (using ICD-10 coding)

Overall study start date
01/11/2022

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Only care home staff are eligible to participate in the testing intervention. This includes temporary (agency) staff with no restrictions i.e. catering staff, administrative staff, maintenance staff, in addition to those in a resident-facing role.
2. All care home staff, residents, visitors and relatives are eligible to participate in interviews undertaken as part of the process evaluation.
3. All care home residents at participating homes are eligible for data collection and analysis of the outcomes specified.

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
280 care homes (the subjects of the trial are the care homes)

Total final enrolment
81

Key exclusion criteria
1. Visitors, residents and relatives are not eligible to take part in the testing intervention.
2. Staff who visit the care home to provide care but are not employed by the care home (e.g. GPs, health visitors) are not eligible to take part in either the interviews or the testing intervention

Date of first enrolment
05/12/2022

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Not currently confirmed
-

-
United Kingdom
-

Sponsor information

Organisation
University College London

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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Health and Social Care Delivery Research

Alternative Name(s)
Health and Social Care Delivery Research Programme, HSDR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
UK Health Security Agency

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/04/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Laura Shallcross (cctu.vivaldi@ucl.ac.uk).
The type of data that will be shared: Fully anonymised data collected from care home records.
Dates of availability: From 1st May 2024
Whether consent from participants was required and obtained: Consent was not required under an S251 exemption from CAG
Comments on data anonymization: Fully

Added 27/04/2023:
The datasets generated for analysis of primary and secondary outcomes for this study will be available for research purposes upon request from the Comprehensive Clinical Trials Unit (CCTU) at UCL (cctu.vivaldi@ucl.ac.uk), subject to the provision of a feasible analysis plan and ethical approval. Individual-level consent has not been obtained from participants in this study, and so any data shared would be fully anonymized with minimal individual-level information. Fully anonymised data from the study will be stored by CCTU without a defined time limit.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Protocol article		14/11/2023	16/11/2023	Yes	No
Protocol article	VIVALDI ASCOT and Ethnography Study	07/08/2024	09/08/2024	Yes	No
Results article		02/07/2025	16/07/2025	Yes	No