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The VIVALDI Social Care Database: piloting a database to collect information on infections, vaccinations, hospitalisation, and deaths in care-home residents in England

Submission date 11/12/2023	**Recruitment status** Recruiting	☐ Prospectively registered ☒ Protocol
Registration date 28/05/2024	**Overall study status** Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 17/02/2025	**Condition category** Infections and Infestations	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Every year care home residents experience infections and outbreaks, which reduce their physical and mental health and well-being and cause avoidable hospital admissions and deaths. Many of these infections could be avoided with better evidence on ‘what works in care homes’ and systems to keep track of and therefore stop infection. Before COVID-19 there was no national system to monitor infections in care homes. We set up the first large-scale study of infection in care homes during the pandemic (VIVALDI), which helped to protect residents and reduce the spread of infection. We want to build on learning from the pandemic to reduce other, major causes of infections in care homes, like flu. We aim to establish a network of ‘research active’ care homes and to create a Research Database by collecting and linking data on residents in these homes.

Who can participate?

Care-home residents over the age of 65 years in participating homes

What does the study involve?

The VIVALDI Social Care Database will store data on infections, hospital attendances, vaccinations, antibiotic prescriptions, and deaths in older adults who live in care homes. This information will be anonymized (names and dates of birth removed) so it will not be possible to link data back to individuals. There is no national database of people who live in care homes, so the first step is to create one. We will extract NHS numbers for residents from the companies that provide electronic records to care homes and transfer these lists to NHS England. NHS England will use the NHS number to create a new, unique number for each record, and will then delete the NHS number. Next, they will transfer the dataset to a secure environment called NHS Foundry, which has been designed to store national health and social care datasets. The VIVALDI Research Database will be created by linking the list of care home residents to other NHS records that are held in Foundry using each record's unique number. The dataset will be updated regularly, and an anonymized copy of it will be transferred to the UCL Data Safe Haven, a secure datastore, for analysis by researchers.

What are the benefits and risks of participating?
The information collected will help prevent and reduce infections, hospital admissions, and deaths in care homes. It will also help to reduce the frequency and severity of outbreaks, reducing how often homes are closed to visitors or admissions.
The only risk is that someone who does not have permission accesses data. This risk is very low because we are only collecting one piece of identifiable information for residents (NHS numbers), all the data processing will take place within the NHS, and identifiable information will be removed before it is shared with the project team.

When is the study starting and how long will it run for?
August 2023 to February 2026

Who is funding the study?
1. The UK Health Security Agency
2. National Institute for Health and Care Research (NIHR) (UK)

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

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
330194

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 330194

Study information

Scientific Title
VIVALDI Social Care Database

Study objectives
Every year care home residents experience infections and outbreaks, which reduce their well-being and cause avoidable hospital admissions and mortality. Yet many of these infections could be avoided with better evidence on ‘what works in care homes’ and systems to monitor and therefore control infection. Efforts to reduce the impact of infection are hampered by multiple, complex barriers including an inadequate research and data infrastructure, the fragmentation of social care, multiplicity of providers, poor integration of health and social care and other services that impact on health and wellbeing e.g. housing, and under-developed engagement by researchers with the care sector. The sector has also failed to benefit from advances in care driven by NIHR research which is primarily focused on hospitals and primary care. To our knowledge, there are no individual-level research databases that collect information on care home residents. In the UK, the absence of a care home resident registry undermines the delivery of large-scale observational studies in care homes.

The pilot study described here aims to establish a research database that can be used for research on infectious diseases, outbreaks and Antimicrobial Resistance (AMR) in c. 15,000-30,000 care home residents in England to inform policy and practice. If this pilot study is successful, we anticipate that the scope of the research database could be extended to support research on infectious and non-infectious diseases.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/12/2023, South West - Frenchay Research Ethics Committee (Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8184; frenchay.rec@hra.nhs.uk), ref: 23/SW/0105

Study design
Multi-centre observational pilot study

Primary study design
Observational

Study type(s)
Prevention, Safety

Health condition(s) or problem(s) studied
Infections in care home residents

Interventions

The VIVALDI Social Care Database will store data on infections, hospital attendances, vaccinations, antibiotic prescriptions, and deaths in older adults who live in care homes. This information will be anonymized (names and dates of birth removed) so it will not be possible to link data back to individuals. There is no national database of people who live in care homes, so the first step is to create one. We will extract NHS numbers for residents from the companies that provide electronic records to care homes and transfer these lists to NHS England. NHS England will use the NHS number to create a new, unique number for each record, and will then delete the NHS number. Next, they will transfer the dataset to a secure environment called NHS Foundry, which has been designed to store national health and social care datasets. The VIVALDI Research Database will be created by linking the list of care home residents to other NHS records that are held in Foundry using each records unique number. The dataset will be updated regularly, and an anonymized copy of it will be transferred to the UCL Data Safe Haven, a secure datastore, for analysis by researchers.

Intervention Type

Other

Primary outcome(s)

Data on the number and type of infections, hospital attendances, vaccinations, antibiotic prescriptions, and deaths via linkage of routinely collected electronic care-home records and NHS data, between 01/02/2024 and 01/02/2025

Key secondary outcome(s))

There are no secondary outcome measures

Completion date

01/02/2026

Eligibility

Key inclusion criteria

Care home residents over the age of 65 years in England

Participant type(s)

Resident

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

65 years

Sex

All

Key exclusion criteria

1. Care home residents under the age of 65 years
2. Care-home residents at participating homes who opt out from data collection

Date of first enrolment
01/02/2024

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London
Institute of Health Informatics
222 Euston Rd
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
UCL/UCLH Joint Research Office

Funder(s)

Funder type
Government

Funder Name
UK Health Security Agency

Funder Name
National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the study will be stored in a non-publicly available repository. We will establish a Data Access Committee specifically to oversee the use of the de-personalised, pseudonymised research database. This group will include representation from residents and relatives from Care Rights UK, staff, academics, UKHSA, and providers and will be responsible for reviewing and approving proposals from researchers who wish to use the linked dataset. Scientific critique of proposals will be carried out by senior and experienced academics within this committee with experience of research in care homes. The relevance and impact of these proposals will also be reviewed by all committee members including representatives from the care sector of senior leaders, staff, residents, and their relatives. Meetings will be organised depending on frequency of applications. Decisions on whether to disclose the identity of care homes for specific projects (such as care home identifiers and address) will be made on a case-by-case basis by this committee and will only be permitted if there is a strong rationale for this. Researchers accessing the dataset will be required to sign a data access agreement and must comply with specific conditions including: all outputs must not identify specific care homes, a copy of all outputs must be submitted to the DAC before publication, use of the database must be acknowledged.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/02/2024	28/08/2024	Yes	No
Participant information sheet	Relatives version 2	22/09/2023	18/12/2023	No	Yes
Participant information sheet	Residents version 2	22/09/2023	18/12/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1	16/08/2023	18/12/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes