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The impact of support visits on self-isolation compliance of COVID-19 positive cases: the Havering autumn/winter isolation support trial

Submission date
09/12/2021

Recruitment status
No longer recruiting

Registration date
10/12/2021

Overall study status
Completed

Last Edited
18/12/2023

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
Practical and financial barriers prevent individuals testing positive for COVID-19 from successfully complying with self-isolation requirements, though self-isolation is an important mechanism for reducing virus transmission. There is no existing evidence on the effectiveness of home visits as an intervention to increase levels of compliance with self-isolation. This study aims to deliver an intervention to measure the impact of home visits on participants' compliance with self-isolation requirements. Secondary aims of this study include measuring whether the intervention had an impact on take-up of financial support, and on vaccination take-up among those participants who were not fully vaccinated against COVID-19 when they received the home visit.

Who can participate?
Residents of the London borough of Havering who have tested positive for COVID-19 and are between the ages of 18 and 64, who are not in receipt of social care, homeless, returnees from countries on the UK government's red list for international travel, in hospital or who have died since their positive COVID-19 test result.

What does the study involve?
Residents of the London borough of Havering who test positive for COVID-19, who are eligible for inclusion in the study, are identified as potential participants in the study when they enter their details upon initial contact tracing at the national level. Sixty percent of participants are randomly allocated to receive a visit and forty percent of participants will not receive a visit. Havering local authority staff will visit the participants who have been allocated to receive a home visit during their 10-day isolation period. During the visit, staff will inform residents of the purpose of the visit, will provide information on self-isolation and support available, as well as information on vaccinations. They will ask if additional support is needed and will leave an isolation support leaflet or post it through the door if they did not manage to make contact with the resident. In addition, those residents who are not fully vaccinated against COVID-19 will be telephoned 28 days later to provide assistance to book a vaccination.

What are the possible benefits and risks of participating?
Participants are not expected to experience any direct benefits or harm from participating in the study. Information from this study will contribute to research evidence about the effectiveness of measures to improve self-isolation compliance and may be beneficial in contributing to future policy decision-making.

Where is the study run from?
London Borough of Havering (UK)

When is the study starting and how long is it expected to run for?
November 2021 to March 2022

Who is funding the study?
London borough of Havering (UK)
UK Health Security Agency

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Assessing the impact of support visits on self-isolation compliance of COVID-19 positive cases: evidence from the Havering autumn/winter isolation support randomised controlled trial

Study objectives
Compliance with self-isolation for individuals who test positive for COVID-19 is an important way of preventing further virus transmission. However, research shows that people are prevented from complying with self-isolation due to practical and financial barriers associated with self-isolation requirements. There is limited evidence on the effectiveness of measures to increase levels of compliance with self-isolation requirements.
This study primarily aims to test whether in-person support visits during the ten days that positive cases are required to self-isolate affect their compliance with self-isolation requirements.
Secondary research aims of the study relate to whether the support visits affected other outcomes of interest, namely:
1. The likelihood of applying for financial support, through the Test and Trace Support Payment scheme
2. Vaccination uptake among those not fully vaccinated

Hypotheses underlying the research aims:
1. Individuals who receive the support visit will be provided with new or newly germane information about financial and practical support and are therefore better able to comply with self-isolation requirements. The support visits may engender norms about reciprocity and also generate an audience effect, therefore encouraging greater compliance with self-isolation requirements among those who receive the visits.
2. Individuals who receive the in-person support visits receive information on financial support that enables (or reminds) them to make greater use of this support to comply with self-isolation requirements, compared to individuals who do not receive the support visits.
3. The support visits provide information on vaccination and individuals who are not fully vaccinated are followed up with calls providing assistance with booking vaccinations, which may encourage higher vaccination uptake among those who receive the visits.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/12/2021, UKHSA Research Ethics and Governance Group (REGG) (UKHSA Research Support and Governance Office, Wellington House, 133-155 Waterloo Road, London, SE1 8UG, UK; +44 (0)1980 612922; elizabeth.coates@phe.gov.uk), ref: NR0297

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

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
Increasing compliance with self-isolation among positive COVID-19 cases

Interventions
This study will test the effectiveness of home visits to individuals in Havering Local Authority who are self-isolating as the result of testing positive for COVID-19. It is planned as a two-arm randomised control trial. Individuals in the treatment condition will be visited during their self-isolation period by outreach staff who will provide information on support available during self-isolation, as well as information on vaccination. Individuals in the control condition will not receive these visits. Havering local authority staff will visit the participants who have been allocated to receive a home visit during their 10-day isolation period. During the visit, staff will inform residents of the purpose of the visit, will provide information on self-isolation and support available, as well as information on vaccinations. They will ask if additional support is needed and will leave an isolation support leaflet or post it through the door if they did not manage to make contact with the resident. In addition, those residents who are not fully vaccinated against COVID-19 will be telephoned 28 days later to provide assistance to book a vaccination.

The visits are expected to last approximately 10 minutes, with data entry and PPE preparation and sanitising taking an additional 15 minutes (5 minutes before the visit and 10 minutes after). The intervention is planned to run for four weeks.

Sixty percent of participants are randomly allocated to receive a visit while the other forty percent of participants will not receive a visit. Randomisation will be done through a pipeline,

with positive cases being randomised at an individual level into treatment and control groups as they enter the trial. The randomisation will be blocked to ensure a balance between treatment and control in terms of two variables, age and gender. Randomisation will be conducted with an unequal treatment allocation ratio – that is, around 60% of eligible individuals will be allocated to treatment with 40% allocated to control. This is based on the teams' capacity for visiting cases so that resources are fully utilised and may change in response to changing case numbers or other operational issues.
Participants will not be blinded to their allocation group. However, clinical contact tracers from the national Test and Trace team making the check in calls (used as the outcome measure for isolation compliance) will not know whether individuals are in the treatment or control groups and therefore outcome data collection will be blind to the allocation group.
Participants will be allocated to treatment and control using random number lists generated from random.org in an excel spreadsheet, based on the chosen treatment allocation ratio. Separate random number lists will be used for each blocking group so as to achieve balance in the key variables across treatment and control groups. Balance checks will be conducted on these specific key variables at the end of the pilot by comparing means across treatment and control groups.

Intervention Type
Behavioural

Primary outcome measure
Successful compliance with self-isolation requirements is measured using indicator from the Contact Tracing Advice Service (CTAS) data that classes individuals as fully complying with self-isolation if they have successful check-in calls with contact tracers on days 4, 7, and 10 of their self-isolation period; success is defined as answering the call and confirming that they are self-isolating. This data was collected as part of the Test and Trace user journey and was available for all positive cases in England. The calls have recently ceased to all users apart from those with landlines. However, the research team is in discussion with the Trace operations team for the calls to continue for all confirmed positive cases in Havering for the period of the trial.

Secondary outcome measures
1. Take up of TTSP application measured as proportion of self-isolating individuals who make a TTSP application, linked with CTAS data on participants at the end of the intervention.
2. Take up of COVID-19 vaccination measured as proportion of non-fully vaccinated individuals who have an additional dose of vaccination within two months of the end of isolation, linked to the vaccination database two months after the visits have ended using NHS numbers of participants.

Overall study start date
01/11/2021

Completion date
18/03/2022

Eligibility

Key inclusion criteria
1. Residents of the London borough of Havering who have tested positive for COVID-19
2. Between the ages of 18 and 64 years (inclusive)

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
1250

Total final enrolment
3878

Key exclusion criteria
1. Adults and children outside of the 18 - 64 years age range
2. Adults in social care provision
3. Cases who have moved out of the borough
4. Cases who have false positive COVID-19 test results, as indicated by the contact tracing database
5. Homeless individuals
6. Travellers returned from countries on the the UK government's red list for international travel
7. Cases in hospital
8. Cases who have died since their positive COVID-19 test result

Date of first enrolment
17/01/2022

Date of final enrolment
18/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
London Borough of Havering
Adult Social Care and Health
Town Hall

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Sponsor information

Organisation
Department of Health and Social Care

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Sponsor type
Government

Website
https://www.gov.uk/government/organisations/department-of-health

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
London borough of Havering

Results and Publications

Publication and dissemination plan

Research findings will be disseminated in an internal report submitted to the research organisation (UK Health Security Agency) and the local authority conducting the trial (London borough of Havering). The researchers will apply to publish findings from this research in a peer-reviewed journal and will disseminate findings at internal workshops and conferences. No additional documents are publicly available.

Intention to publish date
01/07/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because participant data was collected under the agreement that only UKHSA and its research partners would have access to this data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		02/12/2021	10/12/2021	No	No
Results article		17/12/2023	18/12/2023	Yes	No