UK Health Security Agency

A randomised controlled trial of the impact of support visits on self-isolation compliance: the Havering autumn/winter isolation support trial

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PICO Statement

Problem	Compliance with self-isolation for individuals who have tested positive for COVID-19 is an important way of preventing the transmission of the virus. A number of pilots testing different approaches to supporting isolation compliance are underway, some funded by the UKHSA and others supported by the UKHSA in other ways, such as through analytical support. None of the pilots are testing home visiting as an intervention and to the study team's knowledge, there have been no robust studies of home visiting as an approach to improving isolation compliance in England during the current pandemic. Havering Local Authority previously undertook a pilot that involved staff visiting confirmed positive cases to confirm isolation compliance, identify barriers to self-isolation and determine whether support could be offered that would increase isolation compliance. The pilot generated knowledge regarding self-isolation compliance levels for cases in the Havering borough, and post visit surveys indicated that residents felt that the visits provided welcome detail on support services and guidance, although staff felt that more was needed to promote vaccination. The current study will aim to robustly measure the impact of home visiting through undertaking a randomised control trial (RCT) of the intervention. It will focus on whether the visits increase the likelihood of isolation compliance among positive cases, the uptake of available support, and the uptake of COVID-19 vaccinations. This study will add to the evidence base about what is known in terms of supporting self-isolation compliance by robustly testing whether this intervention improves self-isolation compliance along with associated behaviours, including uptake of support and COVID-19 vaccination. The primary aim of the study is: 1. To measure the extent to which the intervention increases the compliance with requirements to self-isolate of those who test positive for COVID-19. The secondary aims of this study are:

	1. To measure the extent to which the intervention increases the uptake of available financial support through the Test and Trace Support Payment Scheme (TTSP) among those who test positive for COVID-19. 2. To measure the extent to which the intervention increases the uptake of COVID-19 vaccination among those who are not fully vaccinated and test positive for COVID-19.
Population	Residents of the London borough of Havering who have tested positive for COVID-19
Inclusion / exclusion criteria	Inclusion criteria: Positive COVID-19 cases who are between the ages of 18 and 64. Exclusion criteria: - Adults and children outside of the 18-64 age range - Adults in social care provision - Cases that have moved out of the borough - Cases with a false positive result - Homeless individuals - Travellers who have returned from red listed countries - Cases who are in hospital - Cases who have died since their positive test result.
Intervention	This study is a two-arm RCT investigating the effect of in-person isolation support visits to the homes of individuals who test positive for COVID-19. During the visits, Havering council will check if the isolating resident is home and offer information on available practical and financial support during isolation, as well as providing information on vaccination. Follow up calls will be made after 28 days to individuals who are not fully vaccinated to offer support to book a vaccination appointment.
Comparison	Individual cases will be randomly allocated to the treatment condition or the control condition. Those in the treatment condition will receive the visit from Havering council, while those in the control condition will not be visited. Individual cases will be randomised as they sequentially enter the system using random numbers generated in advance via an online random number generator (random.org). Randomisation will be done at a case level, however if there are multiple positive cases in a single

	household, they will all receive the support visit and will therefore all be assigned to the same trial arm. In this case, randomisation is done at household level. It may be necessary to either cluster analysis at the household level or to remove such individuals from analysis, depending on the magnitude of this occurring. The outcome will be compared between the treatment group and the control group.
Outcomes	Primary outcome: 1. Self-isolation compliance as measured by having 100% successful check-in calls on days 4, 7, and 10 of self-isolation. Secondary outcome: 1. Vaccination take-up as measured by cases who were not fully vaccinated having received additional doses of vaccination against COVID-19 within 2 months of being visited. 2. Take-up of financial support: TTSPS application rate among self-isolating positive cases
Setting	London borough of Havering

1. Policy area, trial rationale and challenges

Compliance with self-isolation for individuals who have tested positive for COVID-19 is an important way of preventing the transmission of the virus. However, research has identified that people experience both practical and financial barriers associated with isolation requirements[1]. A number of pilots testing different approaches to supporting isolation compliance are underway, some funded by the UKHSA and others supported by the UKHSA in other ways, such as through analytical support. However, none of the pilots are testing home visiting as an intervention and to the study team's knowledge, there have been no robust studies of home visiting as an approach to improving isolation compliance in England during the current pandemic.

The proposed study aims to generate evidence in this area by undertaking an RCT of a home visiting programme being delivered by Havering Local Authority. Havering Local Authority outreach staff will visit individuals who have tested positive for COVID-19 in the Havering community during the resident's 10-day isolation period. During the visit, Local Authority staff will check whether residents are at home and will provide information on available financial and practical support, as well as on COVID-19 vaccination. 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. This study fits within the 'What Works' programme introduced by the Department for Health and Social Care (DHSC) in March 2021, which is a central government framework focused on trialling community led interventions to improve engagement with the test, trace and isolate system. The programme supports local authorities to develop non-pharmaceutical interventions (NPIs), allowing these responses to be more attuned to varying local operational, political, and social contexts.

Havering Local Authority has previously used home visits to offer welfare support to its residents self-isolating as a result of testing positive for COVID-19. However, the council has not been able to evaluate the impact of this approach in a rigorous way. This study will enable the effect of the support visits on self-isolation compliance, Test and Trace Support Payment (TTSPS) application rate, and vaccination uptake using a robust evaluation design. The research will enable conclusions to be drawn about the impact of the intervention on compliance by making comparisons between a treatment group and a no-treatment control group that receives the standard level of support from national and local teams. In addition, qualitative interviews will supplement the quantitative analysis to provide insights into the factors that make isolation easier or more difficult, as well as providing exploring participants

experiences and views on the visits and the support they received. The use of multiple, integrated approaches is deemed particularly useful in the evaluation of the effects of complex health and social care interventions as these involve social or behavioural processes that are difficult to explore or capture using quantitative methods alone[1].

2. Plan, roles and responsibilities in this trial

Individual roles and responsibilities for the different elements of the study are outlined in the table below.

Who is responsible for...	**Organisation name**	**Person responsible**
Data sharing agreements	UKHSA	Cameron Smith
Extracting outcome data	UKHSA	Maria Ionescu
Randomisation	UKHSA	Liza Benny & Emily Wolstenholme
Delivering the intervention	Havering Local Authority	Lee Watson Pete Austin
Intervention Design	Havering Local Authority	Jack Davies Troy Aitken
Analysis	UKHSA	Liza Benny, Emily Wolstenholme, Harpreet Chawla, Cameron Smith
Trial oversight	UKHSA	Matt Barnard & Richard Amlot

A flow chart for the study can be viewed in Appendix A.

3. Research Aims, questions and hypotheses

The mechanisms through which the intervention could affect the outcomes are thought to be through the provision of new or newly germane information about financial and practical

support and vaccination, engendering norms about reciprocity[1], and through an audience effect[2]. Thus, we hypothesise that doorstop visits will increase the likelihood of self-isolation compliance (H1), increase the rate of TTSP applications (H2), increase the likelihood of individuals getting vaccinated (H3).

The primary research question this study aims to investigate is:

(1) To what extent does the intervention result in increased compliance with self-isolation compared to individuals who did not receive a home visit?

Secondary research questions relate to whether the trial had impacts on other outcomes of interest:

(1) To what extent does the intervention result in increased applications to the TTSP scheme compared to individuals who did not receive a home visit?
(2) To what extent does the intervention encourage vaccination uptake compared to individuals who did not receive a home visit and a follow up telephone call?

4. Intervention(s) being tested in this trial

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. 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.

The pilot will use existing outreach staff who will wear personal protective equipment (PPE) and will be briefed on the appropriate health and safety guidance to prevent transmission of the virus to themselves and others. During the visits, staff will inform residents of the purpose of the visit, 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. The visits are expected to last approximately 10 minutes, with data entry and PPE preparation

[1] Roser Cañigueral, Antonia F. de C. Hamilton,Being watched: Effects of an audience on eye gaze and prosocial behaviour, Acta Psychologica, Volume 195, 2019, Pages 50-63

2 Mark A. Whatley, J. Matthew Webster, Richard H. Smith & Adele Rhodes (1999) The Effect of a Favor on Public and Private Compliance: How Internalized is the Norm of Reciprocity?, Basic and Applied Social Psychology, 21:3, 251-259

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. Current case rates are around 150 per day, with about 60% of these eligible for randomisation. If case rates drop, or the distribution of cases change so that fewer are eligible for randomisation, the intervention will need to run for more weeks in order to achieve the required sample size. This will be reviewed as the trial progresses.

5. Design

This trial is planned as a two-arm RCT. Individuals who test positive for COVID-19 will be randomised into a treatment group, which will receive a support visit, or a control group, which will not receive a visit. Randomisation will be done at a case level, however if there are multiple positive cases in a single household, they will all receive the support visit and will therefore all be assigned to the same trial arm. In this case, randomisation is done at household level. It may be necessary to either cluster analysis at the household level or to remove such individuals from analysis, depending on the magnitude of this occurring.

Given this approach, there is a medium risk of contamination; it may be that individuals who tested positive share a household with other individuals who tested positive prior to the start of the RCT. As the council is planning to run the pilot without the randomisation element before the start of the RCT, this may mean that such individuals could have become aware of the isolation support available due to a prior support visit, even if they are assigned to the control arm. This is likely to downwardly bias the estimated treatment effect, causing the effect of the intervention to be underestimated.

6. Outcome measures

The primary outcome of interest is successful compliance with self-isolation requirements. This will be measured using an indicator from the Contact Tracing Advice Service (CTAS) data. Individuals are classed as fully complying with self-isolation if they have successful check-in calls 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 research questions are related to take-up of TTSP, and vaccination uptake among unvaccinated individuals. Data on TTSP applications as well as their outcomes are collected when individuals apply to the scheme, and it is possible to link this data with the CTAS data to identify positive cases in scope of the trial. The outcome metric will be the proportion of individuals in control and control groups that make a TTSP application. Data on vaccinations is collected for all individuals who are vaccinated and can be linked to case data using individuals' NHS numbers. The outcome metric will be the proportion of individuals identified who are not fully vaccinated who have an additional dose of the vaccination within two months of the end of isolation.

7. Sample selection and eligibility

If the trial runs for four weeks, the estimated size of the participant pool is about 1785. Positive cases resident in Havering are eligible for randomisation if they are between ages 18 and 64 and are not in adult social care. Cases are not eligible if they are in hospital or have died since receiving their positive test result. It is estimated that this means approximately 1250 cases will be eligible for randomisation. The cases will be identified using data from the PHE dashboard.

Attrition

Attrition is expected to be low, as the main reason outcome data will not be available on individuals in intervention and control groups would be hospitalisation and/or death. In the month leading up to 20 October, there were approximately 100 COVID-19 hospitalisations in the Barking, Havering and Redbridge University Hospitals NHS Trust. In the same month, there were 10 deaths within 28 days of a positive COVID-19 test result in Havering. While some of these would be ineligible for inclusion in the study as they will have been hospitalised or have died before the doorstep visits, others will drop out after the visits have taken place, so that there will be no follow-up information for these individuals. It is therefore expected that about 40 individuals will be lost due to hospitalisation and/or death, as well as other reasons due to which they may not be able to be followed up, representing 3% of individuals eligible for randomisation. It is not expected that this will differ systematically between treatment and control.

8. Randomisation

Randomisation will be done through a pipeline, with positive cases be randomised at an individual level into treatment and control groups as they enter the trial. The randomisation will be blocked to ensure 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.

9. Power calculations

The desired sample size was determined using a power calculation. These calculations describe the relationship between the effect size, sample size, significance level and statistical power.

Table 1. Summary of Power Calculation assumptions & inputs

Alpha (significance level)	5%
Power	80%
Total planned sample size	1250 This planned sample size refers to the total number of individuals eligible to be randomised

	having gone through the inclusion/exclusion criteria.
Clustered trial?	No
Number of trial arms	Two – one treatment and one control
Base rate or SD	Baseline rate of compliance with self-isolation as measured by 100% successful check-in calls was around 84.1% between 12 September and 12 October 2021.
What is the planned MDES for this trial?	A 7-percentage point difference between treatment and control.
Anticipated *statistical effect size* of the intervention?	Cohen's *h* of 0.20
Anticipated *substantive* effect of the intervention?	A difference in compliance of 10 percentage points between treatment and control individuals.
Is the planned MDES the same as or smaller than the anticipated effect of the intervention? i.e. E.g. MDES is 0.15 and intervention effect is 0.20	Yes
Have you corrected for multiple comparisons?	No – the power calculations have been calculated based on the single primary outcome of interest. Since the study is primarily concerned with effects on self-isolation compliance, the power calculations have been made with this in mind. Analysis will therefore have the power to detect effects of the specified size for this primary outcome (at the least). This is based on the assumption of 1-minimal power – power achieved is will be sufficient to detect statistically significant impacts on at least this key outcome.

10. Analytical Strategy

Binary logistic regression will be used to assess the intention-to-treat (ITT) effect of the treatment (doorstop visits) on the outcome measures of the interest (compliance, financial support applications, and vaccine uptake). An alpha level of 0.05 will be set, with p values of <0.05 indicating statistical significance. Heteroskedasticity robust standard errors will be used for inference.

The binary logistic regression used in analysis will be as follows:

$$P(Y) = \frac{1}{1 + e^{-(b_0 + b_1 T + \mathrm{X_i}\Gamma)}}$$

where errors are assumed to be identically and independently normally distributed with a mean of zero and variance σ_i, and where

- *P* is the probability of the primary or secondary outcome of interest (Y) occurring
- e is the natural logarithm base (= 2.7182818284…)
- b_0 is the intercept at the y-axis, representing the average log odds for the control group when all explanatory variables take on zero values.
- b_1 is the line gradient, indicating the degree to which the probability of the outcome occurring changes with belonging to the intervention group (as indicated by the variable T = 1 for treated individuals and T=0 for individuals in the control group). It is the main coefficient of interest and can be used to calculate the odds ratio of the outcome of interest associated with belonging to the treatment versus control group. X_i is a vector of covariates such as age, ethnicity, gender, and index of multiple deprivation in LSOA of residence,
- and Γ represents the vector of coefficients on these demographic covariates.

Gender and age will be included as covariates in the analysis.

Sensitivity analysis will be conducted using logistic regression to assess the extent to which results are sensitive to linearity of the regression assumptions, as well as assumptions of normality in the outcome distribution.

Balance checks will be conducted to assess the degree to which treatment and control groups are balanced in terms of key covariates on which stratification was performed. If there is significant imbalance, block-specific intercepts may be included in the analysis equation to allow for differences in outcomes across blocks.

Missing data on outcomes is likely to result from attrition arising from deaths and hospitalisations. If the numbers of cases with missing data is small, these individuals will be excluded from analysis. However, checks will also be conducted to assess the degree to which attrition is unbalanced between treatment and control – if there is significant imbalance in attrition, checks can be conducted to assess whether missingness is as if random. If not, Heckman sample selection correction can be used to correct for biased likelihood of attrition.

11. Qualitative component

In addition to establishing whether change takes place, a second aim of the study is to understand why and how change happens. The range of outcomes and the mechanisms of change will be explored using a qualitative approach. Individual service user interviews will be undertaken with residents in the treatment arm of the RCT. Individual interviews will also be undertaken with Havering Local Authority staff (or focus groups if individual interviews are difficult for logistical reasons) to provide an understanding of the implementation of the intervention. Topic guides will be used to structure the interviews in both cases.

The research questions addressed by the qualitative component of the study are:

1. What were the range of experiences of the intervention?
2. What were the range of benefits of the intervention from the perspective of those who received it?
3. What were the barriers and facilitators to the delivery of the intervention?
4. What factors influenced the effectiveness of the intervention?

Residents will be selected using a purposive sampling strategy. Unlike sampling for a quantitative survey, where the intention is to achieve a numerically representative sample, the aim of purposive sampling is to achieve range and diversity against key characteristics that are likely to affect the views and experiences being explored. Table 2 (below) outlines the proposed sampling matrix for service user interviews.

Table 2. Sampling approach for service user interviews

Received 2 welfare check-ins

Age group	*Complier*	*Non-complier (based on check-in calls)*
18-29	2	2
30-39	2	2
40+	2	2
Total	6	6

N=12

The themes covered in the service-user topic guide will include:

- experiences of engaging with welfare-check in staff (positive and negative);
    - key outcomes from the welfare checks: understanding of health promoting behaviours; including the reduction of in-house transmission;
    - understanding of self-isolation guidance and changes to the advice over time;
    - ability to access to self-isolation support (financial and practical);
    - understanding of any additional support required;
    - vaccination uptake, and why people did and did not want to receive the vaccine;
- key factors affecting ability to comply with self-isolation guidelines (exploring possible barriers) and why people did and did not comply with isolation guidelines;
- factors affecting broader engagement with NHS T&T system, including behaviours, attitudes, and personal circumstances; and what, if any, influence the welfare checks had on this.

Havering Local Authority senior leaders, local co-ordinators and frontline staff involved in the intervention will also be interviewed. This component will also explore enablers and barriers to success across the lifecycle of the programme. Key stakeholders will also be asked to share documents to give a fuller picture of the characteristics of the scheme.

The make-up of the council teams and community support organisations are diverse, so a key contact will be identified within each team to help the research team to recruit staff and volunteers for interviews, based on guidance from the research team on achieving diversity in the sample. Given the likely challenges of recruiting stakeholders to take part, it is proposed that a combination of interviews, paired interviews or small groups are used based on participant availability. Table 3 (below) outlines the proposed sampling matrix for for the interviews with stakeholders.

Table 3. Sampling approach for stakeholder interviews

	Council stakeholders
Senior council staff	*3*
Compliance check-in staff	6
Total	**9**

Themes covered in the stakeholder topic guide will include:

- understanding of the programmes key aims and objectives;
- attitudes towards the programme;
- barriers and facilitators the interventions delivery;
- views on whether the intervention reached its intended goals;
- key factors used to gauge the success and/or unsuccessful components of the programme.

Qualitative data analysis

Data will be analysed using the Framework method developed by the National Centre for Social Research (NatCen)[2]. Within this approach, the data gathered from the interviews will be summarised into a framework developed in Microsoft Excel, subdivided into main themes and sub-themes where columns represent themes and each row is an individual case. This means the data is arranged in a systematic way that is grounded in the accounts of the participants while closely tied to the research objectives and facilitates analysis to take place both between and within cases.

The final stage of analysis involves working through the framework in detail, drawing out the range of experiences and views, identifying similarities and differences, developing and testing hypotheses, and interrogating the data to seek to explain emergent patterns and findings. The aim of the analysis is to develop categories of behaviour, experiences and explanations that are comprehensive in the sense of capturing the full range of views, experiences and explanations.

12. Data Storage and Transmission

All data will be appropriately handled and securely stored in accordance with the Data Protection Act (2018) and GDPR. All data will be managed and stored securely on UKHSA systems. Only those in the research team (UKHSA and Havering council) will have access to the raw data and personal data will be handled by the study team where essential only. Only data that needs to be shared for study reasons will be used. Data will be shared from the Havering team to the research team in UKHSA securely using egress. Data will not be shared from UKHSA to any external organisation. All permissions for data use are agreed in advance. Personal Data will be handled by the research team where essential only and files will be password protected. The data will be held for a period of 8 years before being destroyed.

13. Trial Procedure

The trial will be conducted by randomising positive cases in Havering to treatment or control groups. Those in the treatment group will receive doorstep visits from Havering council while those in the control condition will not. UKHSA will conduct qualitative interviews with a sample of those in the treatment condition to investigate their experiences and views on the treatment received.

Steps for Trial Implementation:

- UKHSA will action data protection impact assessment and data sharing agreements to enable data sharing, prior to the trial beginning.
- UKHSA will send Havering a randomization tool in the form of an excel spreadsheet.
- Havering staff will identify positive covid-19 cases in Havering using the CTAS database and will input case details to the spreadsheet, which will automatically determine which cases to visit (treatment group) or not (control group).
- Havering staff will visit the addresses of those in the treatment group. During the visit, havering staff will inform residents of the purpose of the visit, will ask if additional

support is needed and will give a post an isolation support leaflet through the door afterwards.

- Havering staff will input the outcomes of the visit to the excel sheet (e.g. resident home vs. not home, further support requested vs. not requested).
- Once data collection is complete, Havering staff will send the data file to the UKHSA team securely using egress.
- The UKHSA team will analyse the results, will share the findings with Havering and will produce a written research report.
- UKHSA will contact cases in the treatment condition to take part in qualitative interviews.
- UKHSA will conduct the interviews, analyse the results, share the results with Havering, and produce a written research report of the findings.

Intervention timeline:

Timing	**Owner**	**Action**
End of October 2021	UKHSA	Prepare randomization tool
Beginning of November 2021	Havering	Pilot randomization tool
Beginning of November 2021	UKSA	Prepare necessary documentation for research to take place; data sharing agreement, data protection impact assessment, ethical review
End of November 2021	Havering	Begin data collection once above documentation approved
End of December 2022	Havering	Data collection ends. Havering sends data to UKHSA
January 2022	UKHSA	Data analysis
February 2022	UKHSA	Findings shared with Havering, report drafted
March	UKHSA	Final report shared with Havering

Qualitative interviews timeline:

Timing	**Owner**	**Action**
End of December 2022	Havering	Havering sends data file
January 2022	UKHSA	Participant recruitment and data collection

February 2022	UKHSA	Data collection complete
March 2022	UKHSA	Data analysis and draft report
April 2022	UKHSA	Final report shared with Havering

Steps for Quality Monitoring:

- The randomization tool determines which cases to visit. As visits are done in person, it will be clear whether those in the treatment group have received the treatment, i.e. the visit.
- The data will be checked afterwards to assess the balance of missing data across the conditions. If needed, analysis will be adjusted to account for any imbalances.

Stopping rules:

- No harm is expected to participants in the trial as a result of the intervention. The intervention is an addition to the existing support and guidance available to individuals, which is deemed adequate by the Department of Health and Social Care and UKHSA. On this basis, no stopping rules are proposed.

13. Ethical Issues and Review

This trial was self-assessed as being:	**Low risk**
The reason for assessment was...	Whether or not the RCT goes ahead, Havering Local Authority will be undertaking the intervention as it is part of their local strategy for maximising compliance with self-isolation and improving vaccination uptake. Havering local authority has limited resources to undertake the visits, so the RCT will not affect how many people receive visits only which individuals receive them. The outcomes data is already collected and is held centrally by the research team so no new quantitative data will be collected.

Key ethical considerations for the project:

- We considered there to be low potential risks to participants taking part in this research and there to be potential benefits (e.g. support offered to those isolating, increased knowledge on facilitators and barriers to isolation and vaccination).
- We considered there to be low possible risks/harms to researchers. Researchers at UKHSA conducting the qualitative interviews have line management support and access to a confidential employee assistance programme that provides mental health and wellbeing support if needed.
- We considered ethical considerations relating to data management and storage and have appropriate procedures in place to mitigate these (e.g. DPIA and DSA in place).

Informed consent from participants:
Whether or not the RCT goes ahead, Havering Local Authority (LA) will be undertaking the intervention as it is part of their local strategy for maximising compliance with self-isolation and improving vaccination uptake. The LA has limited resources to undertake the visits, so the RCT will not affect how many people receive visits only which individuals receive them. The outcomes data is already collected and is held centrally by the research team so no new quantitative data will be collected. The LA is concerned that if people are informed that they are involved in an RCT and that people are allocated into intervention and control groups, self-isolation compliance among those in the control group might be undermined. Therefore, for practical and public health reasons it is proposed that consent for taking part in the RCT is not obtained.

Consent to take part in the qualitative interviews will be sought at several points during recruitment process. Firstly, potential participants will be contacted by phone and asked if they are interested in taking part in an interview and at this point it will be made clear that taking part is entirely voluntary and they do not have to if they do not wish to. Verbal informed consent will then be obtained again at the start of the interviews and again it will be made clear to participants that they are not be obliged to take part. It will also be emphasized that they are not obliged to answer any questions and can withdraw from the interview at any time without giving a reason. Participants will separately be asked to give their consent for the interview to be recorded. Researchers will take written notes in cases where participants consent to take part in the interview but do not want their interview to be recorded.

Consideration of harms to participants might arise and how to deal with them:
Potential harm to participants has been considered. We do not anticipate that there will be adverse effects as a result of participating in the study. We have considered privacy and confidentiality in the procedures in place for data storage and data management, as well as the communication of results. All data will be stored and handled securely in compliance with the GDPR (2018). Raw data will be accessible only by researchers involved in the study (Havering and UKHSA). Once the data has been analysed, personal identifiers will be removed.

14. Risks

Risk	Strategy to mitigate risk	Responsibility	Timeframe (if applicable)
Intervention may backfire (based on X risk) and lead to worse outcomes	Trial will be monitored and if any evidence occurs of backfiring, the governance group will be immediately alerted.	Havering Local Authority	Monthly
Randomisation failure	Randomisation tool will be piloted by Havering Council as well as internally by UKHSA to assess effectiveness prior to trial start date.	UKHSA	Before start of pilot
Compliance with randomisation checks	There is low risk of non-compliance as the trial comprises of visits from a local team. Trial will be monitored to assess the extent of refusal to participate. If these numbers are high, procedures will be re-evaluated.	Havering Council/ UKHSA	Weekly

Fidelity to intervention plan	The detailed trial procedure will be shared with Havering team to ensure that implementation goes according to plan.	Havering Council / UKHSA	Before start of pilot
Imbalance	Blocked randomisation is used to reduce the risk of imbalance between treatment and control groups. Balance between treatment and control on these covariates will be assessed as the trial progresses so that any imbalance can be corrected for using revised procedures where necessary.	UKHSA	Weekly
How to check for harms?	This pilot has been conducted previously by Havering council. Staff are aware of potential harms and have received training on different scenarios which could occur. Havering teams are signed off after training and from then on have a monthly assessment of competency.	Havering council	Before start of the pilot, monitored during pilot
Missing data	Individuals with missing data will	UKHSA	Weekly

	not be included in analysis. The risk of attrition is low however attrition imbalance can be assessed on an ongoing basis to see if there is anything that can be changed in implementation to reduce this risk.		

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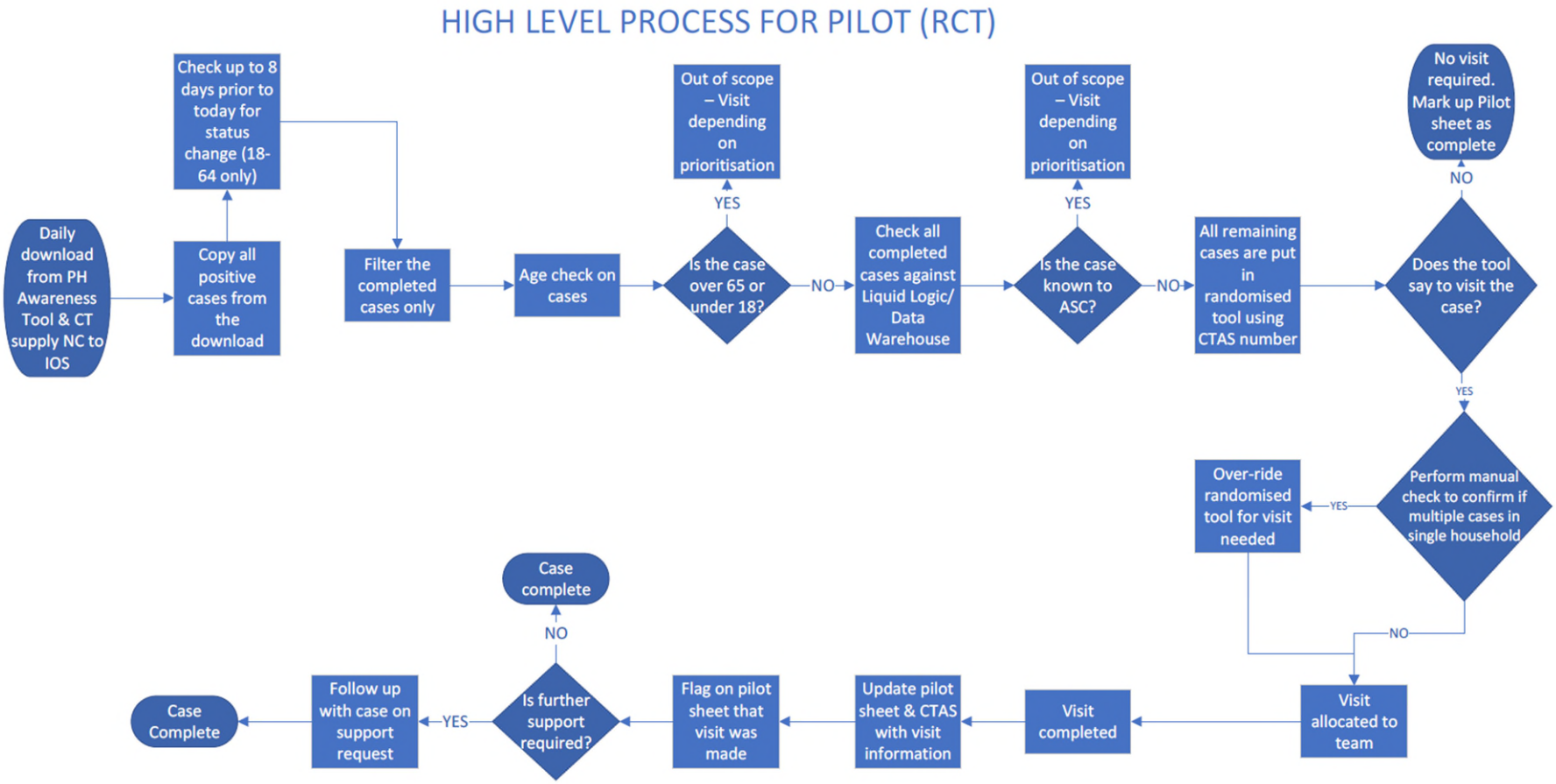
Appendix A High level process map



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[1] Campbell M, Fitzpatrick R, Haines A, Kinmonth A-L, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. BMJ2000;321:694-6.

[2] Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG, editors. Analyzing qualitative data. London, United Kingdom: Routledge; 1993. p. 173-94.