


ARTICLE

A randomized controlled trial of the impact of support visits on self-isolation compliance: The Havering winter/spring support trial

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Abstract

Objectives: Limited evidence exists on the policies to increase self-isolation compliance, with no experimental evidence. This trial aimed to evaluate the effect of a home visiting intervention in the London Borough of Havering on compliance with self-isolation guidance, relative to positive COVID-19 cases who received no home visits.

Design: Mixed method evaluation involving a two-arm randomized controlled trial (RCT) with an implementation and process evaluation.

Methods: A total of 3878 cases who tested positive for COVID-19 were randomly allocated with equal probability to receive home visits from Havering outreach team staff ($n = 1946$) or to a control group ($n = 1932$) who did not receive home visits. Randomization was implemented through a spreadsheet consisting of random numbers generated online that was used to randomly allocate cases to treatment and control. Check-in calls were conducted by a separate blinded contact tracing team on day six of isolation to measure successful self-isolation compliance. The primary intention-to-treat (ITT) analysis was conducted on 3860 cases as 18 patients were excluded from analysis because of the missing outcome data. For the implementation and process evaluation, qualitative, semi-structured, one-to-one interviews were conducted with trial participants in the treatment arm of the RCT ($n = 15$) and stakeholders within the London

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Borough of Havering's Adult Social Care and Health Team ($n=8$). Qualitative data was analysed thematically using a framework approach.

Results: Positive cases who were allocated to receive the home visiting intervention ($n=1933$) were more likely to report successful self-isolation compared to those allocated to the control group ($n=1927$), an effect that was statistically significant (odds ratio 1.204 [95% CI: 1.052, 1.377]; absolute probability difference: 4.1 percentage points [95% CI: 1.2–6.9]). The implementation and process evaluation found that a key driver of compliance was altruistic motivation based on its perceived importance for protecting the community with some participants also reporting the potential of being caught not complying as a driving factor. Participants also reported that the intervention helped them 'feel supported', provided them with information about practical and financial support, and clarified their understanding or increased their awareness of self-isolation and COVID-19 guidance. No harms were reported from this trial. The trial was registered at the ISRCTN registry, number ISRCTN10030612.

Conclusions: A home-visiting intervention conducted between January and March 2022 increased the self-isolation compliance of positive COVID-19 cases allocated to receive home visits. The implementation and process evaluation highlighted that the intervention increased individuals' motivation to comply with guidance, and addressed some barriers associated with opportunity and capability to comply. This trial provides much-needed evidence to inform the policy and intervention design to support public health and social measures in future outbreak scenarios.

KEYWORDS

COVID-19, mixed methods, quarantine, self-isolation, support visits

INTRODUCTION

Self-isolation of individuals who have tested positive for a communicable disease is a key public health strategy in the face of epidemics and was an important policy response to the COVID-19 outbreak in the United Kingdom. On the 28 September 2020, the Government introduced a legal duty to isolate if an individual received a positive test for COVID-19 (Department of Health and Social Care, 2020), and this legal duty remained in force until 24th February 2022 (UK Health Security Agency, 2022). Self-isolation was supported by the Test and Trace Support Payment Scheme (TTSP), which was available if certain stringent work and income-related conditions were met (UK Health Security Agency, 2020). Initially, all cases were required to isolate for 10 days from when they started experiencing symptoms. However, by January 2022 cases could end their self-isolation early if two consecutive lateral flow tests (LFTs) returned negative results (with the tests having to be taken 24 h apart starting from day five of the isolation period).

Compliance with self-isolation requirements among those who had tested positive for COVID-19 was measured through a series of monthly surveys conducted by the Office for National Statistics (Office for National Statistics, 2021). The surveys began in February 2021 and ran until April 2022.

Statement of contribution

What is already known on this subject?

- Self-isolation, along with community testing and contact tracing, was a key behavioural and policy tool to reduce COVID-19 transmission in the United Kingdom.
- There was a legal requirement to self-isolate after testing positive for COVID-19 between 28 September 2020 and 24 February 2022.
- There is little evidence on measures that increase self-isolation compliance.
- Compliance with self-isolation was generally high when the legal requirement to self-isolate was in place.

What does this study add?

- Support visits during individuals' self-isolation periods are effective in improving compliance with self-isolation when there was no legal requirement to self-isolate.
- Support visits could increase compliance through increasing individuals' motivation to comply and addressing barriers associated with their opportunity and capability to do so. Support visits increased some individuals' confidence in their ability to self-isolate, and awareness of the financial and practical support options available.
- Exploratory analysis found no evidence that home visits increased uptake of the national financial support scheme (though only a small fraction of participants were eligible for the scheme) or led to additional vaccination uptake.

Between February 2021 and January 2022, the proportion of people reporting fully complying with self-isolation requirements did not fall below 75%. However, this figure fell to 64% in February 2022 and to 51% in the last survey that ran at the end of March/beginning of April 2022, after the legal requirement to isolate had lapsed.

Although compliance with self-isolation requirements was relatively high while the legal duty was in place, a substantial minority of individuals reported not fully complying. To help address this issue the Adult Social Care and Public Health Teams in the London Borough of Havering developed an intervention that involved an outreach team visiting homes of residents who were self-isolating after testing positive for COVID-19. During the visit, the outreach team offered guidance related to infection control, isolating within the home, the support available to those self-isolating (including the Test and Trace Support Scheme), and the benefits of vaccination against COVID-19. Residents who were not fully vaccinated were called 28 days after the start of their isolation period to provide further information and were supported to book vaccinations if residents responded positively. The intervention was hypothesized to increase the self-isolation compliance through the provision of information about financial and practical support and vaccination during a period that it was particularly salient and therefore attended to, engendering norms about reciprocity (Whatley et al., 1999), and through an audience effect (Cañigueral & Hamilton, 2019).

Havering local authority had run an initial intervention in summer 2021 that checked compliance to self-isolation regulations using a home visiting approach, which found that compliance was below 100%, despite existing telephone check-ins that were run by the national Test and Trace team. The local authority used Public Protection Officers to visit individuals who had not engaged with either the national or local Test and Trace teams. The Isolation Outreach team also helped individuals who had tested positive using a lateral flow device to confirm their positive result using a polymerase chain reaction (PCR) test, and provided LFTs to help test other individuals within the household and stop the spread of the virus within the household. This face-to-face approach was deemed

necessary due to the low compliance levels and lack of engagement, but also provided a holistic approach that allowed for staff to check whether individuals needed any financial and/or non-financial support during their isolation period. Aspects such as providing additional support and testing would not have been possible without a face-to-face approach. Furthermore, there is existing evidence that interventions are effective at increasing compliance with treatment recommendations, with single home visits by multidisciplinary teams having been effective in increasing asthma patients' adherence to maintaining inhaler use and reduced healthcare utilization a year after the intervention, and other studies showing multiple home visits by nurse practitioners or other trained health practitioners resulting in improved health outcomes (Ghimire et al., 2021; Lawlor et al., 2009; Shelledy et al., 2009; Trilla et al., 2018).

In the health psychology literature, the provision of information and social support have been effective at increasing the level of desired outcomes in populations of interest (Swain et al., 2023). Systematic reviews have shown that factors that incentivize compliant behaviour and remove economic barriers to compliance have been effective at increasing adherence to health treatment guidelines, especially in the short run (Arad et al., 2021; Ghimire et al., 2021; Lutge et al., 2015; McDermott et al., 2016). Telephone-based follow-ups and interventions have been useful in increasing adherence to treatment guidelines among populations at risk, where telephone follow-ups can be a source of further information. In the context of the COVID-19 pandemic, communication of shared norms around responding to risks was seen as important to influence behaviour change at the community level (Michie et al., 2021). However, there was little evidence of the effectiveness of measures to increase adherence with self-isolation, with the majority of measures addressed at increasing financial support and targeting vulnerable populations. There is no existing evidence of the effectiveness of similar interventions, whether home visits or phone based, to increase compliance with self-isolation, however, studies have shown that strategies to increase communication are likely to improve compliance, though there is little robust evidence using systematic methods (Cardwell et al., 2021). This article contributes to this gap in the evidence by providing novel systematic robust evidence using a randomized control trial (RCT) to show that home visit interventions were effective in increasing compliance with self-isolation.

Though the home visits might have been seen by recipients to have had a compliance or enforcement aspect (which were partly behind their motivation), they did also provide support to individuals who were self-isolating by providing information around financial and practical support available that was provided by the home visiting team. The staff delivering the home-visits also provided support with testing and vaccination, as well as additional information on self-isolation, if required. As such, the visits were designed overall to help support individuals who faced barriers with self-isolation, rather than to enforce compliance. The trial was designed as a two-arm RCT, but the end of the legal requirement to self-isolate partway through the intended trial period on 24 February 2022 meant that there was a quasi-experimental element that allowed for an evaluation of the effectiveness of the intervention under different legal contexts, as shown in [Figure 1](#).

As systematic reviews indicated that few interventions aimed at increasing compliance with self-isolation had been robustly evaluated, with no examples of studies that utilized quasi-experimental or experimental methods (Cardwell et al., 2021; Cheatley et al., 2020; Nussbaumer-Streit et al., 2020; Patel et al., 2021), the UK Health Security Agency agreed to collaborate with the London Borough of Havering's Adult Social Care and Public Health Teams to design and implement a RCT to evaluate the intervention. Note that the trial took place during a rapidly changing policy environment, with existing infrastructure in place to deliver the intervention – the study was not designed to assess the cost-effectiveness of implementing the intervention at scale, and therefore it is important to note the limitations to extrapolating the results from this study to a wider context.

This article conducts a mixed methods evaluation of the RCT, where the primary objective of the impact evaluation was to investigate the extent to which the home visiting intervention increased compliance with self-isolation. Secondary objectives were to assess whether the intervention resulted in higher application rates to the TTSP scheme, and the extent to which the intervention encouraged vaccination uptake among non-fully vaccinated individuals. An implementation and process evaluation was also

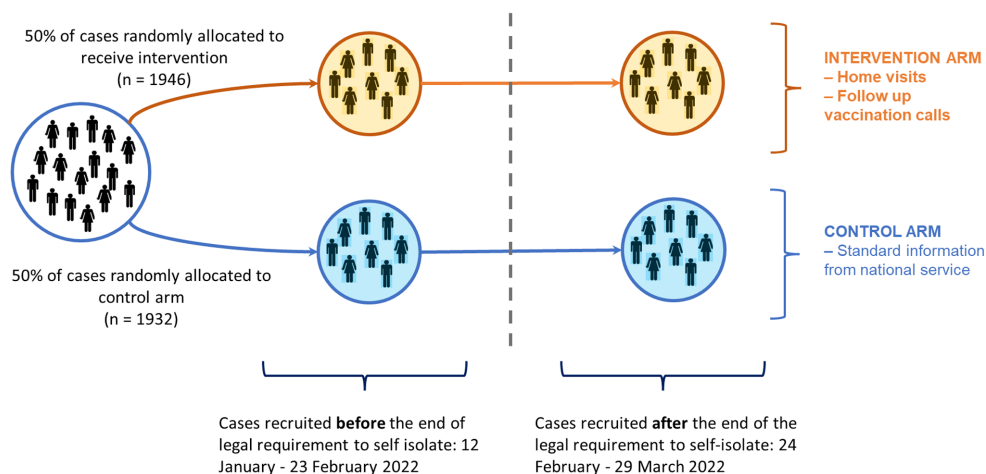


FIGURE 1 Havering RCT design.

conducted alongside, that was concerned with three main research questions: first, the range of experiences of delivering and receiving the intervention; second, the barriers and facilitators to the delivery of the intervention, and finally, the factors that influenced the perceived effectiveness of the intervention.

METHODS

Intervention design

Recruitment and participants: RCT

The RCT was designed as a two-arm parallel trial with participants allocated to treatment and control using random number lists generated from [random.org](https://www.random.org) based on the chosen treatment allocation ratio of 50:50. Separate random number lists were used for groups stratified by two blocking variables, age, and gender, to achieve balance in the key characteristics across treatment and control groups. The randomization procedure was developed by UKHSA and built into the Havering local authority's case management Microsoft Excel spreadsheet. The procedure made use of Excel formulas and a hidden worksheet consisting of the random number lists so that the generation of the random number sequence was separate from the allocation and implementation of the randomization. This meant that the team implementing the randomization was kept blind to the random number sequence used. Randomization was done through a pipeline, with positive cases randomized on a daily basis at an individual level as they entered the trial.

Inclusion and exclusion criteria: RCT

The population of interest for this study were residents of the London Borough of Havering aged between 18 and 64 who tested positive for COVID-19 between 12 January 2022 and 29 March 2022. The following categories of positive COVID-19 cases were excluded from the study: adults and children in social care provision, cases who moved out of the borough, cases with a false-positive result, homeless individuals, travellers returning from red list countries, cases in hospital or who died since their positive test result (prior to randomization), and cases who had not completed their contact tracing details by day 4 of isolation.

Participant recruitment: Implementation and process evaluation

The implementation and process evaluation (IPE) involved in-depth interviews with two key groups. The first was council stakeholders, including members of the outreach team. Council stakeholders were selected using a purposive sampling approach. This meant that the participants were selected based on key characteristics related to their involvement in the intervention that were expected to affect their views, experiences and, behaviours around the intervention. [Table 1](#) shows the achieved council stakeholder sample.

The second group were participants who were in the treatment arm of the RCT, who again were selected using a purposive sampling strategy. Participants were selected based on their age-group, vaccination and compliance status (see [Table 2](#)). Data on individual's vaccination status was taken from the national Contact Tracing and Advisory Service database.

Recruitment process

In this study, the participants were initially identified by the Havering Council. To specifically identify trial participants, the Contract Tracing and Advisory Service and internal data from the home-visiting service were utilized. The recruitment process involved senior members of the council approaching trial coordinators and inviting them to participate. Subsequently, the trial coordinators were asked to provide consent to have their email addresses shared with the research team.

The recruitment process for both involved sending potential participants an email which provided both a brief summary of the trial within the body of the email, as well as a more comprehensive participant information sheet. Participants were given the option to decline participation in the study by responding via email. In the event that no response was received, a member of the research team contacted the individual by telephone to gauge their interest in participating. During this telephone call, a verbal explanation of the study was provided, and an interview time and date were arranged if the individual expressed a willingness to participate.

Description of the intervention

[Figure 2](#) outlines the logic model underlying the RCT, including the overarching context behind the trial, as well as the intervention details and the implementation, hypothesized mechanisms of impact and the targeted outcomes (Moore et al., 2015). The intervention consisted of pairs of council outreach officers visiting trial participants on day four of their isolation period to offer in-person isolation support. These visits were made without an appointment on an ad-hoc basis. Staff wore personal protective equipment (PPE) and were briefed on the appropriate health and safety guidance to prevent transmission. The visits lasted approximately 10 min, with data entry and PPE preparation and sanitizing taking an additional 15 min.

Four teams of two people each were involved in the delivery of the intervention, with all team members being agency staff members. The Isolation Outreach team went through broad training that followed the local authority standard operating procedure, with some additional training as part of preparation for the RCT implementation. As the face-to-face intervention was already in place in

TABLE 1 Achieved sample of council stakeholder interviews.

Council stakeholders	n = 8
Senior council staff	3
Home-visiting team members	5

TABLE 2 Achieved sample of trial participant interviews.

Trial participants	n=15
Age group	
18–29	3
30–39	5
40+	7
Sex	
Female	11
Male	4
Self-isolation compliance outcome	
Complier	8
Non-complier	7
Ethnicity	
White, British	6
Undisclosed	3
White, European	2
Afghan	1
African	1
Arab	1
White, Asia-pacific	1
Benefits status	
Undisclosed	6
Not in receipt of benefits	5
Universal credit	2
Child benefit	1
Housing and disability benefit	1
Legal status of self-isolation (during self-isolation period)	
Legal requirement	13
Post legal requirement	2
COVID-19 vaccination status (at time of interview)	
Full vaccination	11
Partial vaccination (single dose)	2
Unvaccinated	2

Havering local authority for those in adult social care outside of the inclusion criteria for the RCT, further training for the RCT was more at the managerial level than at the operational level. This including making sure the staff carrying out the RCT were provided with scripts, guidance, etc. to ensure they were able to carry out the role. No new staff were recruited for the RCT.

Individuals in the treatment arm were visited during their self-isolation period by outreach staff who provided information on support available during self-isolation, as well as information on vaccination. Individuals in the control condition did not receive these visits, and instead were contacted the national NHS Test and Trace team for contact tracing purposes (as were individuals in the intervention group).

During the visits, discussion with residents was based on a 23-item checklist (see Appendix S1), relating to a range of self-isolation support options and advice. This information was also left with residents in the form of a leaflet (see Appendix S2). For those who had not been vaccinated against COVID-19 or were not fully vaccinated up until that point, advice was provided on the benefits

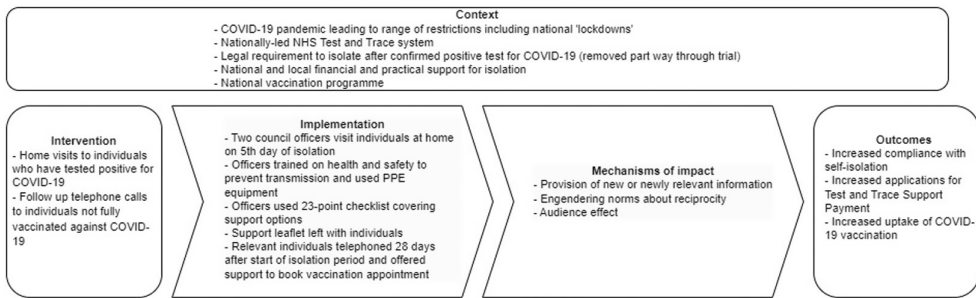


FIGURE 2 Logic model for the Havering RCT.

of vaccination. Residents who were not fully vaccinated were subsequently telephoned to provide further support around vaccination, including help with booking a vaccination appointment where relevant. Staff followed a script when conducting these calls, which can be found in Appendix S3. The telephone calls were made 28 days after the start of resident's isolation period as this reflected guidance on the minimal time between testing positive for COVID-19 and receiving a vaccine.

Adaptations to the intervention

Due to the removal of centrally funded financial and practical support measures at the same time that the legal requirement to isolate was removed, the service pivoted away from providing information on these measures and instead focused on promoting safe behaviours and the importance of voluntary adherence as a contribution to collective well-being. Home visiting staff also continued to provide emotional support and signpost residents to locally led practical and social support.

Outcomes

Outcomes: RCT

The primary outcome of interest for the evaluation of the RCT was successful compliance with self-isolation requirements. This was measured using check-in calls by a separate local contact tracing team in Havering that was blind to treatment allocation. Individuals were classed as successfully complying with self-isolation if they answered the check-in call on day five of their self-isolation period and verbally confirmed that they were self-isolating. A maximum of three attempts were made to reach individuals by phone, with these attempts approximately 2 h apart. These calls were modelled on the scripts used by national contact tracers during check-in calls on days 3, 7 and 10 of self-isolation – the national contact tracing check-in calls ended in January 2023 along with the shortening of the required isolation period from ten to a minimum of 6 days. The Havering contact tracing team that conducted the check-in calls did so without a prior appointment with self-isolating individuals.

The secondary outcome was uptake of the TTSP support. The outcome metric was the proportion of individuals in treatment and control groups that made a TTSP application within 6 weeks of the end of their isolation period. As the TTSP scheme ended on 24 February 2022 along with the legal requirement to self-isolate, this research question was only investigated for the sub-group of individuals who were recruited into the trial before 24 February 2022. The other secondary outcome was uptake on vaccination of those not fully vaccinated against COVID-19. The outcome metric was the proportion of individuals identified who were not fully vaccinated and who received an additional dose of the vaccine within 8 weeks of the end of their isolation period.

Sample size and attrition: RCT

The trial was intended to run for a period of 5 weeks. It was estimated that a participant pool of 4000 cases in Havering would be available, with 2750 eligible for randomization. The intended sample size was powered to detect an effect size of a four-percentage point increase in the primary outcome of the proportion of cases successfully self-isolating for the treatment group, with a two-sided 5% significance level, and a power of 80%. The anticipated minimum detectable effect size was calculated relative to a baseline of 81.14% (which was based on the NHS Test and trace check-in call data for Havering between 16 August and 12 October 2021).

The main reasons outcome data was not available for individuals in intervention and control groups would be hospitalization and/or death after recruitment into the trial, as well as invalid contact details to administer the check-in calls. In total, 18 individuals eligible for randomization were lost to follow-up and therefore the primary outcome analysis, with 13 of these individuals in the treatment group and 5 in the control group. This represented .5% of the sample.

Data collection challenges: Implementation and process evaluation

In the course of data collection, the research team experienced various challenges that impeded their ability to achieve the intended sample size. These challenges included a high rate of refusal among prospective participants, which complicated the recruitment process, a shortage of staff available to conduct interviews, which hindered the data collection process, and time limitations, which necessitated an earlier cessation of data collection than initially planned. As a result of these challenges, the research team opted to conclude data collection upon reaching saturation, which denotes the point at which no additional information is acquired from subsequent interviews.

Participants did not receive any incentives or compensation for their involvement in the study. While refusal rates were not formally recorded, some potential participants declined participation due to disinterest or time constraints.

Analysis

Approach to analysis: Impact evaluation of RCT

Analysis of the data did not start until the end of the trial and so investigators were kept blind to outcomes until the end of the data collection period. The main analysis conducted was the ITT analysis, where all randomized participants were analysed in the groups they were allocated to, regardless of whether they complied with their allocated status (Angrist et al., 1996; Gupta, 2011; Kendall, 2003; Lutge et al., 2015; McDermott et al., 2016; Moher et al., 2001; Swain et al., 2023), though the cases lost to follow up were excluded from the analysis. Attrition of outcome data reduces the validity of ITT estimates, though as only .5% of the total sample randomized had missing outcome data, the resulting risk of bias was judged to be minimal.

Estimation of the average effect of the intervention for those cases who received the intervention (the effect of treatment on the treated, or the local average treatment effect (LATE) (Angrist et al., 1996; Arad et al., 2021)) is presented separately. The effect of treatment on the treated is estimated by instrumenting for cases' actual treatment status with their assigned treatment status, therefore adjusting ITT estimates by the differences in compliance rates between treatment and control groups and accounting for non-random non-compliance with treatment allocation.

Full details of the main and additional analysis were pre-specified in the statistical analysis plan (included in Appendix S4), with all analysis conducted using R (version 4.1.3, 2022-03-10).

Implementation and process evaluation

Alongside the RCT, an IPE was undertaken. Process evaluations offer insight into the features of 'complex interventions' by elucidating aspects of their implementation, mechanisms of impact, the wider contexts affecting delivery as well as the reported value, barriers, and facilitators of the intervention (French et al., 2020). The IPE involved in-depth interviews with council stakeholders, including key public health officials, those who delivered the intervention and the individuals receiving it. Broadly, it was designed to answer the following research questions:

- What were the range of experiences of delivering and receiving the intervention?
- What were the barriers and facilitators to the delivery of the intervention?
- What factors influenced the effectiveness of the intervention?

Method

This study utilized a qualitative research design, employing semi-structured interviews and purposive sampling to explore the implementation and delivery of the intervention, and to investigate the mechanisms of impact associated with the quantitative outcomes. Qualitative data aims to provide a rich and detailed understanding of the meaning and interpretation of experiences, attitudes, beliefs, and behaviours of individuals or groups, which is often overlooked in quantitative research (Braun & Clarke, 2013; Creswell, 2013). Semi-structured interviews were chosen as the data collection method due to their ability to capture the nuance and complexity of health interventions (Hoddinott et al., 2016). This is particularly crucial in understanding how and why health interventions work, with multiple components and interactions occurring between different actors.

The data collected from the interviews was analysed using the Framework method, developed by the National Centre for Social Research (Cardwell et al., 2021). This involved summarizing the data into a matrix where each row represented an individual case and each column represented themes. This allowed for a systematic analysis of the data that was grounded in the participants' accounts, facilitating both within-case and between-case analyses. The framework approach is a widely used and highly regarded approach to qualitative data analysis that can help provide valuable insights into complex social phenomena (Ritchie & Spencer, 1993).

To examine the essential elements of behaviour modification that relate to the intervention and its interplay with self-isolation, we utilized a thematic analysis method guided by the COM-B framework (Michie et al., 2011) to analyse the data obtained from the trial participants. This approach enabled us to explore the various factors that impact behaviour change, including individual, social, and environmental determinants.

Reporting

The research findings were presented chronologically in adherence to the British Journal of Health Psychology guidelines and the APA Journal Article Reporting Standards, with the aim of enhancing accessibility (American Psychological Association, 2019).

Two distinct methods were utilized to structure the findings. First, the Medical Research Council (MRC) guidance on process evaluations was adopted to report on the implementation and delivery processes of the intervention. Given the complexity of the intervention, a pragmatic approach was adopted, which encompassed topics such as barriers and facilitators to the intervention's delivery, intervention fidelity, adherence, and the target population's level of engagement and response towards the intervention (Steckler & Linnan, 2002).

Secondly, the mechanisms of impact were guided naturally by the COM-B model's structure, with each section structured by its individual components (see [Figure 2](#) for the underlying logic model). By combining

the COM-B model with the framework approach, the aim was to present the results in a comprehensive and structured manner that provided insights into the behaviour change process (Steckler & Linnan, 2002).

Methodological integrity

The adequacy of the data was assessed to ensure that it captured relevant forms of diversity that were most pertinent to the research question, goals, and inquiry approach. To limit the impact of the researchers' perspectives on the data collection and analysis, steps were taken to manage these perspectives. This included training on how to manage perspectives during data collection and analysis, covering topics such as bias awareness, data interpretation, and the importance of remaining open-minded.

The findings were grounded in evidence through the use of quotes, excerpts, and descriptions of the researchers' engagement in data collection. Contradictions and disconfirming evidence in the data were addressed to present the findings coherently. Consistency was maintained throughout the analytic process by ensuring interrater reliability. Additionally, relevant contextual information was provided to contextualize the findings, such as the setting of the study, and participant information.

Researcher–participant relationship

There was no prior relationship between the researchers and trial participants as they were recruited through the council and contacted by email or telephone. However, there was a professional relationship between the service deliverers who implemented the intervention and the researchers conducting the IPE. The service deliverers were aware of the research taking place and provided consent for the researchers to conduct interviews with them. Ethical considerations were considered, and the service deliverers were assured that their participation was voluntary and would not impact their employment status. The relationship between the researchers and service deliverers did not appear to impact the research process, as the service deliverers were forthcoming in their responses and provided valuable insights into the implementation of the intervention.

FINDINGS

RCT results

Recruitment for the RCT took place between 16 January 2022 and 30 March 2022, with home visits occurring between 17 January 2022 and 31 March 2022. Check-in calls started on 17 January 2022 and continued until 3 April 2022. [Figure 1](#) shows the numbers of participants who were recruited into the trial, allocated to treatment and control arms, and included in analysis through a flow diagram. Note that the treatment and control group sizes differ from the numbers who received the treatment and control arms. In the case of the treatment arm, individuals who were allocated to receive a home visit were not necessarily present at home when they were visited, whereas individuals who were allocated to the control group shared a household with those in the treatment group (meaning that their actual treatment status would be contaminated). This can be seen in the flow diagram in [Figure 3](#), though it must be noted that it is not fully possible to identify treatment status contamination in all cases.

Randomization supports the assumption that there are no systematic differences in unobservable characteristics between treatment and control groups (Higgins et al., 2011). The achieved sample of 3860 is powered to detect an effect of a three percentage point difference in compliance with self-isolation between treatment and control groups, under the assumption that with a sample of this size, any

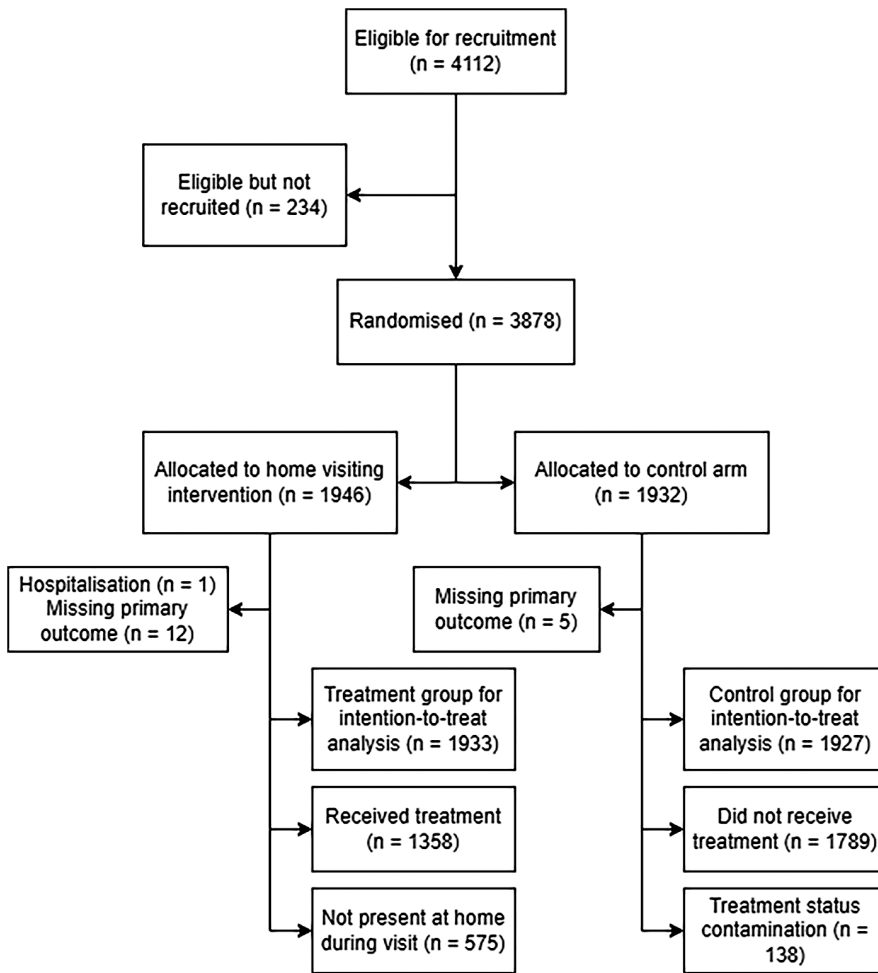


FIGURE 3 Flow diagram of Havering RCT participant recruitment and losses.

bias and noise in estimation would be sufficiently minimized to detect a meaningful estimate of the specified size as being statistically significant.

Table 3 shows that the treatment and control arms were balanced on observed characteristics. Note, however, that ethnicity data is only available for cases who could be linked back to the contact tracing data and is incomplete for 21% of cases (20% of control group and 22% of treatment group). Additional imbalance checks that showed that treatment allocation was not associated with characteristics or missing outcome data are included in Appendix S5.

Table 4 summarizes the main impact evaluation results for the primary and secondary outcomes of interest. Effects are estimated using binary logistic regression and are presented both in relative (odds ratios) and absolute terms (probability differences).

The results for the primary outcome indicate that the home visiting intervention had a positive and statistically significant impact on the likelihood of successfully complying with self-isolation requirements. The likelihood of compliance with self-isolation was increased by 20.4% (95% CI: 5.2% to 37.7%) for cases allocated to receive the home visit intervention compared to cases allocated to control. This represents an absolute increase in the probability of successfully self-isolating of 4.1 percentage points (95% CI: 1.2 to 6.9) from 65% to 69.1% for the treatment group relative to control. Compared to the baseline likelihood of self-isolation compliance for the control group, a higher proportion of 71.5%

TABLE 3 Baseline characteristics by treatment arm.

	Total	Control	Treatment	<i>p</i> value
Age group				
18–29	573 (14.8%)	292 (15.2%)	281 (14.5%)	.584 (2)
30–39	1168 (30.3%)	573 (29.7%)	595 (30.8%)	
40–49	1109 (28.7%)	569 (29.5%)	540 (27.9%)	
50–64	1010 (26.2%)	493 (25.6%)	517 (26.7%)	
Gender				
Female	2412 (62.5%)	1189 (61.7%)	1223 (63.3%)	.045 (2)
Male	1439 (37.3%)	730 (37.9%)	709 (36.7%)	
Unknown	9 (.2%)	8 (.4%)	1 (.1%)	
Ethnicity (N = 3044; C = 1535; T = 1509)				
White	1991 (65.4%)	999 (65.1%)	992 (65.7%)	.833 (2)
Asian/Asian British	265 (8.7%)	138 (9.0%)	127 (8.4%)	
Black/Black British	76 (2.5%)	34 (2.2%)	42 (2.8%)	
Mixed/Multiple Ethnic Groups	37 (1.2%)	19 (1.2%)	18 (1.2%)	
Unspecified	675 (22.2%)	345 (22.5%)	330 (21.9%)	
IMD rank of LSOA	19,067.400 (7931.499)	19,063.454 (7928.625)	19,071.334 (7936.413)	.975 (1)
England's 30% most deprived LSOAs	.167 (.373)	.169 (.375)	.165 (.371)	.730 (1)
Number of observations	3860	1927	1933	

Note: Figures are counts (%) for categorical variables or means (standard deviations) for continuous variables. *p*-values are from (1) *t*-tests of equality for continuous variables, or (2) Pearson's chi-squared tests for categorical variables.

of cases in the ONS Cases Insights Survey (Office for National Statistics, 2021) reported complying with self-isolation on average between January and March 2022.

The results in Table 4 do not suggest that the home visiting intervention had any significant impacts on either the secondary outcomes of TTSP application rates or additional vaccination uptake among cases who were not fully vaccinated when they were self-isolating. The difference in probability of applying for the TTSP scheme between the treatment and control groups is not statistically significant at .5 percentage points. Similarly, the difference in the probability of getting an additional vaccination dose between treatment and control groups is .2 percentage points and is not statistically significant. Note, however, that the sample sizes for both these outcomes are smaller than the sample size for the primary outcome, and hence these analyses may be underpowered to detect a small but significant effect. These results are not sensitive to the way in which outcomes are defined, as shown in additional analysis using different outcome definitions included in Appendix S5.

The main subgroup analysis considered whether the effect on self-isolation compliance differed between the two policy environments in place during the trial: while the legal requirement to self-isolate was in place, and after it was removed. Specification (1) in Table 5 shows that having the legal requirement to isolate made a difference to the overall likelihood of compliance with isolation guidance: cases allocated to the control group were 20 percentage points more likely to report as self-isolating when there was a legal requirement to isolate compared to after it was removed. This is consistent with findings from the ONS Cases Insights Survey which showed a 20 percentage point reduction in self-isolation compliance among cases on average between February and March 2022 (Office for National Statistics, 2021).

There was no statistically significant effect of the intervention on self-isolation compliance when the legal requirement was in place – this may be due to a ceiling effect as compliance was relatively high among the control group when the legal requirement was in place. The trial had a positive

TABLE 4 Main results for primary and secondary outcomes.

	Primary outcome: Self-isolation compliance	Secondary outcome I: TTSP application rate	Secondary outcome II: Vaccination uptake
Treatment allocation odds ratio [95% CI]	1.204** [1.052, 1.377]	.856 [.550, 1.332]	1.106 [.523, 2.340]
Intercept odds ratio [95% CI]	1.855*** [1.689, 2.037]	.040*** [.029, .053]	.024*** [.015, .039]
Probability difference [95% CI]	4.1 pp [1.2 pp, 6.9 pp]	-5 pp [-1.7 pp, 1.2 pp]	-2 pp [-1.1 pp, 3.0 pp]
Treatment group	1335 (69.1%)	38 (3.3%)	12 (2.6%)
Control group	1252 (65.0%)	44 (3.8%)	17 (2.4%)
Number of observations (treatment, control)	3860 (1933, 1927)	2316 (1160, 1156)	1174 (458, 716)

Note: $^{\dagger} p < .1$, $^* p < .05$, $^{**} p < .01$ and $^{***} p < .001$. The odds ratios for the treatment allocation indicator and intercept are estimated using binary logistic regressions, with 95% confidence intervals in parentheses. The counts and percentages of successful outcomes are reported for the treatment and control groups, as well as the absolute differences in probability of successful outcome between these groups (reported in percentage points, along with 95% confidence intervals for these estimated probability differences in parentheses).

TABLE 5 Results from the subgroup analysis for self-isolation compliance.

	Self-isolation compliance (1)	Self-isolation compliance (2)	Self-isolation compliance (3)	Self-isolation compliance (4)
Treatment allocation	1.226* [1.003, 1.500]	1.337*** [1.129, 1.585]	1.401** [1.088, 1.804]	1.217* [1.035, 1.431]
Legal duty to isolate	2.407*** [1.986, 2.916]		2.532*** [1.987, 3.225]	
Legal duty × treatment allocation	.979 [.744, 1.290]		.917 [.648, 1.299]	
Male		1.189 ⁺ [.979, 1.444]	1.264 [.940, 1.699]	
Male × treatment allocation		.753* [.570, .995]	.694+ [.457, 1.054]	
Male × legal duty			.864 [.579, 1.287]	
Male × treatment allocation × legal duty			1.205 [.681, 2.130]	
Age 30–39 years				.924 [.753, 1.133]
Age 30–39 years × treatment allocation				.968 [.723, 1.295]
Intercept	1.124 [.976, 1.295]	1.739*** [1.546, 1.956]	1.033 [.866, 1.233]	1.899*** [1.698, 2.125]
Probability difference (T–C, subgroup = 0)	5.0pp [1 pp, 9.6 pp]	6.4pp [2.9 pp, 9.4 pp]	Women: 8.3pp [2.1 pp, 13.8 pp] Men: -.7 pp [–16.1 pp, 12.2 pp]	–1.8pp [–6.8 pp, 2.7 pp]
Probability difference (T–C, subgroup = 1)	3.5pp [–6.8 pp, 8.9 pp]	.2pp [–10.9 pp, 7.8 pp]	Women: 4.7 pp [–8.4 pp, 10.4 pp] Men: 1.4 pp [–31.3 pp, 8.2 pp]	–2.4 pp [–14.8 pp, 6.4 pp]
Control group, subgroup = 0	52.9%	63.5%	Women: 50.8% Men: 56.6%	65.5%

(Continues)

TABLE 5 (Continued)

	Self-isolation compliance (1)	Self-isolation compliance (2)	Self-isolation compliance (3)	Self-isolation compliance (4)
Control group, subgroup = 1	73.09%	67.4%	Women: 72.3% Men: 74.1%	69.8%
F-statistics	13.459***	7.032**	.212	.277
Number of observations	3860	3860	3860	3860

Note: $\dagger p < .1$, $*p < .05$, $**p < .01$, $***p < .001$. Odds ratios from binary logistic regressions are reported with 95% confidence intervals in parentheses. Proportion of successful outcomes are reported for the control groups in each subgroup, where the subgroups are defined by the interaction variables of interest in each specification – in specifications (1) and (3), subgroup = 0 indicates the legal duty was not in place, and subgroup = 1 indicating the period of the legal duty; in specification (2), subgroup = 0 indicates female and other unspecified genders, subgroup = 1 indicates the male gender. The table also reports absolute differences in the probability of successful outcomes between these groups (reported in percentage points, along with 95% confidence intervals for these estimated probability differences in parentheses). Reported F -statistics are from the tests of linear hypotheses that the effects of treatment for each subgroup were statistically significantly different.

significant effect on isolation compliance after the legal requirement to isolate was removed, with cases allocated to receive home visits in this period being five percentage points more likely to report that they were isolating compared to control cases. An F -test of the equality of coefficients confirms that the effect of the intervention was significantly different after the legal requirement to isolate was removed.

An additional exploratory analysis (not pre-specified) was conducted to consider the drivers of this result: specification (2) in [Table 5](#) presents results from interacting the treatment allocation indicator with gender, and specification (3) summarizes results including a three-way interaction between treatment allocation, the legal requirement, and gender. These results indicate that men were more likely to comply with self-isolation guidance when in the control group (67% compliance compared to 63% for women); these patterns differ from the ONS Cases Insights Survey where men were less likely to report complying with self-isolation on average than women (69.3% for men compared to 73.2% for women, on average between January and March 2022; Office for National Statistics, 2021). The interaction between the male indicator and the treatment allocation variable showed that men were less likely to successfully self-isolate because of the intervention. The positive treatment effect seen overall in [Table 4](#) was driven by the treatment effect on women, who were 6.4 percentage points more likely to comply with self-isolation guidance when allocated to treatment. In particular, the effect was stronger after the legal requirement to isolate was ended; treated women in this period were 8.3 percentage points more likely to successfully self-isolate than women in the control group, an effect that is statistically significant at the 5% level.

Self-isolation compliance levels were low among those in age-group 30–39 in preliminary trials of the home visiting intervention in Havering over summer 2021, so additional pre-specified subgroup analysis considered whether the intervention had a positive effect on self-isolation compliance for individuals in this age group. Specification (4) in [Table 5](#) shows that there was no differential impact of the intervention on this age group.

The hypothesis underlying the primary research question for the trial states that individuals are financially and practically constrained from successfully complying with self-isolation requirements. The home visits are expected to increase knowledge about financial and practical support available during self-isolation and are particularly expected to benefit more deprived individuals. The pre-specified subgroup analysis of individuals resident in Havering LSOAs with Index of Multiple Deprivation scores within the top three deciles investigated whether the effects of the intervention on both self-isolation compliance and TTSP applications were different for individuals in more deprived areas. Specifications (1), (2), and (3) in [Table 6](#) show that there were no differential impacts of treatment allocation on self-isolation compliance or TTSP applications in the most deprived Havering LSOAs.

The final prespecified subgroup analysis considered whether there were differences in impact on vaccination uptake for ethnic minority groups compared to the ethnic majority (White) group, as vaccination uptake was lower in ethnic minority groups. The F -test of equality of coefficients does not show evidence that the impact on vaccination uptake in ethnic minority groups were (jointly) different from that in the white population.

Additional robustness checks were pre-specified to account for any characteristics that remained imbalanced after randomization, however, these results (included in [Appendix S1](#)) show that the baseline results in [Table 4](#) are robust to changes in specifications including additional variables.

Local average treatment effect analysis

Data on the actual treatment status of individuals allowed for the estimation of the average effect of the intervention for those cases who received the intervention – the LATE (Patel et al., 2021). Results in [Table 7](#) show that the average effect of the intervention for those who received the home visit was larger than the ITT estimates: the proportion of these cases who successfully complied with self-isolation

TABLE 6 Results from the subgroup analysis for self-isolation compliance and secondary outcomes.

	Self-isolation compliance (1)	Self-isolation compliance (2)	TTP application (3)	Vaccination uptake (4)
Treatment allocation	1.192* [1.029, 1.381]	1.195 ⁺ [.970, 1.473]	.688 [.401, 1.181]	1.688 [.673, 4.231]
IMD deciles 1–3	.935 [.729, 1.199]	.795 [.570, 1.109]	1.618 [.803, 3.259]	
IMD deciles 1–3 × treatment allocation	1.058 [.738, 1.516]	1.030 [.637, 1.665]	2.003 [.760, 5.280]	
Asian/Asian British ethnicity (ref. White)				2.146 [.571, 8.067]
Black/Black British ethnicity (ref. White)				4.220 ⁺ [.861, 20.690]
Mixed/multiple ethnicity (ref. White)				.000*** [.000, .000]
Other/unspecified ethnicity (ref. White))				.454 [.098, 2.105]
Asian/Asian British ethnicity × treatment allocation				.324 [.027, 3.891]
Black/Black British ethnicity × treatment allocation				.000*** [.000, .000]
Mixed/multiple ethnicity × treatment allocation				.592 [.164, 2.142]
Other/unspecified ethnicity (× treatment allocation				.716 [.081, 6.348]
Intercept	1.876*** [1.693, 2.079]	2.820*** [2.441, 3.258]	.036*** [.025, .051]	.024*** [.013, .044]
Probability difference (T–C, subgroup = 0)	–1.5pp [–7.5pp, 3.9pp]	–4.7pp [–12.6pp, 1.9pp]	2.0pp [–.5pp, 8.8pp]	
Probability difference (T–C, subgroup = 1)	–.2pp [–15.1pp, 9.8pp]	–3.7pp [–23.9pp, 7.1pp]	5.0pp [–.3pp, 44.3pp]	
Control group, subgroup = 0	65.2%	73.8%	3.5%	

TABLE 6 (Continued)

	Self-isolation compliance (1)	Self-isolation compliance (2)	TTS application (3)	Vaccination uptake (4)
Control group, subgroup = 1	63.7%	77.1%	2.4%	
F-statistics	.026	.024	.377	.510
Number of observations	3860	2316	2316	1174

Notes: d^+ , d^* , d^{**} , d^{***} $p < .01$, $p < .05$, $p < .01$, $p < .001$. The odds ratios from binary logistic regressions are reported with 95% confidence intervals in parentheses. The proportion of successful outcomes are reported for the control groups in each subgroup, where the subgroups are defined by the interaction variables of interest in specifications (1), (2), and (3), where subgroup = 0 indicates IMD deciles higher than three, and subgroup = 1 indicates IMD deciles 1 to 3. The table also reports absolute differences in the probability of successful outcomes between these groups (reported in percentage points, along with 95% confidence intervals for these estimated probability differences in parentheses). These proportions and differences in probability are not reported for the last specification due to the number of subgroups. Reported F-statistics are from the tests of linear hypotheses that the effects of treatment for each subgroup were statistically significantly different.

TABLE 7 LATE estimates of marginal effects on the outcomes of interest.

	Primary outcome: Self-isolation compliance	Secondary outcome I: TTSP application rate	Secondary outcome II: Vaccination uptake	First stage: Actual treatment
Treatment status [95% CI]	.065** [.018, .112]	-.008 [-.031, .015]	.005 [-.034, .045]	
Treatment allocation [95% CI]				.631*** [.608, .654]
Intercept [95% CI]	.645*** [.621, .669]	.039*** [.026, .051]	.023*** [.010, .037]	.072*** [.060, .083]
Weak instruments F-statistics	2785.26***	1883.724***	432.495***	
Wu-Hausman test statistic	2.811 [†]	.328	.049	
F-statistics				2785***
Number of observations	3860	2316	1174	3860

Note: $^{\dagger}p < .1$, $^*p < .05$, $^{**}p < .01$, $^{***}p < .001$. Coefficients are the marginal effects estimated using instrumental variables analysis with the first-stage regression presented in the final column, with 95% confidence intervals in brackets.

requirements was higher by 6.5 percentage points compared to those who did not receive a home visit. The LATE estimates are similar in nature to the ITT estimates for the secondary outcomes; though larger in magnitude they do not show any statistically significant effect of the intervention (on those who were treated) for TTSP application and vaccination uptake.

The first stage regression presented in the final specification shows that treatment allocation is a valid instrument for treatment status, as being allocated to the treatment group is a strong and statistically significant predictor of receiving the home visits, with the *F*-test on this regression also suggesting that the instrument is sufficiently strong to explain the variation in actual receipt of treatment. The weak instruments *F*-statistics also confirm that treatment allocation is strongly correlated with the receipt of treatment. The Wu–Hausman test statistic is only weakly statistically significant for the primary outcome of self-isolation compliance. This suggests that treatment status is weakly endogenous in this regression and therefore it is beneficial to instrument using treatment allocation to account for the resulting bias.

Differences between ITT and LATE estimates are likely to be driven by non-compliance with treatment allocation – where individuals who were allocated to receive a visit from Havering were not actually present at home when they were visited. Other sources of non-compliance may arise through intra-household effects when individuals who were allocated to the control group shared a household with those in the treatment group (meaning that their actual treatment status would be contaminated).

No adverse events were reported as occurring due to the trial.

Implementation and process evaluation results

The IPE results are presented in four sections. The first focusses on the barriers and facilitators for setting set-up from the perspective of the council stakeholders and the second describes the delivery of the intervention. The third section describes the experiences of the intervention from the perspective of those both delivering and those receiving it. Finally, the last section identifies factors influencing the effectiveness of the home visiting programme.

Barriers and facilitators for setting-up and delivering the intervention

This section outlines the barriers and facilitators of the interventions set-up from the perspective of the council stakeholders, as well as giving an overview of the processes involved in moving from set-up to delivery.

Three main barriers were identified from the data: the nuance of the service; employee recruitment and retention; and the council's IT systems.

Despite the council's previous experience of delivering a home-visiting service, a key barrier to delivery was a lack of comparable interventions to draw experience. The process of developing the service required considerable time and resource, as operational systems and structures needed to be mapped and built, and a standard operating model developed.

The challenge we faced was that this was a completely new service, it wasn't like a council or government service that had been running for years and years... we had to work off of our own manual and specification.

– Senior Council Stakeholder

A further concern identified during the development phase was the councils existing IT software. Broadly, these concerns related to the robustness of the council's case management software and its ability to administer additional processes required for the delivery of the intervention. These concerns were realized, to some degree, with staff describing the system as 'clunky' and prone to error. Ultimately,

this made data input and processing a more onerous task which had implications for time and resource delegation.

Stakeholders also anticipated challenges with both recruiting and maintaining its roster of home visiting employees. A two-pronged approach was adopted, both redirecting staff from existing asymptomatic testing initiatives and using external recruitment campaigns. Due to the temporary nature of the intervention, the council was unable to offer long-term job security, opting for the creation of short fixed-term positions. This resulted in the programme experiencing issues with staff retention and recruitment which ultimately caused issues for the council's ability to delegate adequate resource to the core elements of the home-visiting function.

On the positive side, one of the key facilitators highlighted by senior stakeholders was the ability to redirect staff at both a middle-management and junior level, giving the intervention a core set of experienced and dedicated personnel to build from. The advantage was that employees were familiar with the councils existing systems and structures and had experience of working in 'high-risk' COVID-19 settings. However, regardless of their experience, all staff received a six-part training programme (see Appendix S6) both to reiterate safety precautions and prepare them for the home-visiting process.

Senior stakeholders cited the significance of having the ability to test and quality assure service delivery processes during training, while the service deliverers largely welcomed the practical experience gained from the sessions. Furthermore, service deliverers were particularly complementary of the scenario-based training, which went some-way in preparing them for the variety of situations they would encounter during the home-visits. Senior staff also credited this process with ensuring service continuity across a variety of contexts.

Delivery in practice

This section explores the delivery of the intervention and uses data from trial participants and council stakeholders. It focusses on *fidelity/adherence*: the extent to which implementers adhered to the intended treatment model; and *dose received*: the extent to which the target population responded and engaged with the intervention.

Intervention fidelity/adherence

The programme was delivered within a continuously changing context which had positive and negative implications for both the programme as it was implemented. The introduction of Government test-to-release regulations meant that information provided to trial participants had to be updated, the day on which the home visiting team conducted their visit changed and additional training and guidance for staff was needed. Data from the home visiting staff indicated that they adhered to the interventions intended delivery model, that is: working in pairs when conducting the home visits; wearing the adequate PPE and identification; following the doorstep checklist; and referring or signposting isolation support services where applicable. This was largely corroborated by trial participants. However, some deviation from the standard operating procedure was identified. Some trial participants reported that their interaction with the home visiting staff lasted 2–3 min, rather than the 10 min envisaged in the service specification. The short length of the visits was mainly attributed to a lack of need for support services from trial participants. Home visiting staff also noted the difficulty in adhering to the visiting checklist when engagement from trial participants was limited. This process relied heavily on the individual's willingness and acceptability to participate with the intervention, with evidence suggesting this was not always achieved. This will be covered in more detail within the dose section below.

Dose received

The dose of the intervention appeared to be variable based on several factors highlighted by both trial participants and the home visiting team. As reported earlier, the ability to deliver the whole intervention, that is: asking all 23 questions in the visit checklist; supplying isolation support materials; and providing additional guidance where necessary, relied on the willingness and acceptability of trial participants to engage. Evidence suggested that typically, there was a broad willingness to engage with the service, although this was not always the case. Factors such as prior awareness of the intervention; personal safety concerns; preconceptions about the interventions intended aims; and the perceived usefulness of the service, had an influence on trial participants acceptability of the intervention.

Interview data with trial participants also showed that intended recipients were not always present for the intervention. On two occasions, cohabitators engaged with home visiting staff on behalf of a trial participant. This had consequence for the referral of isolation-support services. For example, one individual whose parent engaged with staff was reluctant to interact with the service and as a result, the home visiting team was unable to effectively signpost self-isolation support options. This trial participant was later made aware of the TTSP scheme after the end of their isolation period by a friend, leading them to question why this service was not highlighted during the visit.

Another challenge noted by staff was that male participants tended to be more hesitant and less willing to engage when compared to female participants. Staff also described some difficulty in engaging with trial participants in their twenties and thirties, finding that those in their forties and above tended to be more open and responsive.

Intervention experiences

This section explores the experiences of the home visits from the perspectives of both intervention recipients and providers. Through separating intervention experiences from mechanisms of impact, the results hope to provide a more comprehensive understanding of the intervention's efficacy. This approach offers a nuanced examination of the functioning of the intervention and facilitates the identification of specific areas that may require improvement in intervention delivery and implementation.

Experiences of delivering the intervention

Staff described their roles as rewarding but also identified several delivery challenges. Among the more gratifying aspects of providing the service, staff reported being able to provide tangible support to individuals who were experiencing challenging periods of self-isolation. This included, providing emotional support; supplying individuals with LFTs; helping to clarify COVID-19 rules and regulations; and providing non-clinical medical assistance.

Despite this, the reception outreach staff received was not always positive, with some experiencing verbal and physical abuse. For example, one staff member recalled visiting a COVID positive individual who was both physically and verbally abusive.

They started being totally abusive... the man came out of the house, who was COVID positive, blew his nose in a tissue and threw it in the car [we were sitting in].

– Home-Visiting Staff Member

However, successful deescalating situations was felt to be particularly rewarding.

Sometimes people are a bit aggressive when they open the door, and sometimes you sort of talk them round, calm them down... I've had it on a number of occasions where I've [said] okay that's fine, listened to their side of things, you know, given them a chance.

– Outreach staff member

Overall, staff were keen to highlight the positives of their roles, such as the support received from colleagues and line management. These aspects were praised by the outreach team for ensuring their well-being and safety.

Experiences of receiving the intervention

Among some residents, prior knowledge of the intervention was mixed. Some reported being aware before the visit, while others were unaware when outreach staff visited them. Those who had prior awareness of the intervention had either seen the visits being delivered in the community or had been notified by someone in their social network.

Irrespective of prior awareness and before engaging with the intervention, participants had varying views of the aims of the intervention. Before the legal end of self-isolation, one perception was that it was a mechanism to monitor and enforce self-isolation compliance. Within this view, there was scepticism about the assertion that the intervention was a 'well-being' or 'support service'.

I'm cynical about that, it comes across to me that it's not something the council are remotely interested in... it feels very much that the council deal with...money and amenities rather than...health and wellbeing.

– Outreach Staff Member

However, the belief that the intervention was aimed at reinforcing compliance was not always viewed negatively. There was a strong sense among some participants that non-compliance was an substantial issue, something expressed even by people who were themselves non-compliant (though they might not be aware of the fact).

The data speaks for itself, the spreading rate implies that people don't follow the rules, so you know, they have to have ways of cracking down on that. So, if the council have to go door to door to check on that, then so be it.

– Trial Participant

In contrast, all those interviewed who were visited after the end of isolation as a legal requirement, viewed the intervention as focused on support and/or well-being.

Some participants said that initially they were hesitant about engaging with the outreach team, especially those who had no prior awareness of the intervention. One reason for this was feeling uncomfortable answering the door to an unknown individual, and this was particularly a concern among those participants with vulnerable characteristics. Within this context, interviewees noted the importance of visible staff uniforms and badges, which helped to legitimize the service.

Home visiting staff were commonly described as professional, kind, and caring and that the outreach team took a genuine interest in their personal circumstances and their concerns about self-isolation.

Those people are really lovely; they were really concerned about me personally... they make sure they ask you so many questions and make sure that you really feel okay.

– Trial Participant

However, despite the positive view of outreach staff, the perception of the usefulness of the intervention was mixed, especially among those who felt it had limited personal applicability. Despite this, others appreciated the importance of providing support during self-isolation for individuals with disabilities, single parent families, the elderly, and those experiencing possible cases of domestic violence.

Mechanisms of impact

This section presents an in-depth analysis of the processes that underpin the intervention's outcomes, based on data collected from both trial participants and council stakeholders. Drawing upon the COM-B model, we have organized the factors that influenced the intervention's efficacy into three broad categories: capability (ability to perform the necessary actions for behavioural change); opportunity (external factors that may affect an individual's capacity to engage in a particular behaviour); and motivation (the value that individuals place on self-isolation for themselves and others).

Table 8 presents an overview of the key themes and sub-themes related to self-isolation behaviours and the intervention's interaction with these factors. However, it should be noted that the key themes are explored in greater detail in the text that follows the table.

Capability

Participants' ability to engage in self-isolation and protective measures, considering their psychological and physical capacities and knowledge of the behaviour and its outcomes, varied. Findings indicate that at times, participants displayed inconsistent and sometimes incorrect understanding of the rules and regulations related to COVID-19. Comprehension around the 'correct' period of self-isolation, test-to-release measures, and the potential health implications of receiving a COVID-19 vaccine were evident.

In certain cases, misinterpreting the rules contributed to non-compliance. Despite receiving the intervention with some participants continuing to misinterpret the rules. For example, one non-compliant and unvaccinated individual reported feeling 'lost' in the volume and contradictory information they had received and was sceptical about the interventions ability to change this.

It was just like information everywhere; it was on the news it was on the internet it was like when you're walking down the street. I was talking to people, everyone's been informed of different things... I just didn't know.

– Trial Participant

Other people felt their comprehension of COVID-19 rules and regulations was already high before the home visit, with many attributing their knowledge to the longevity of the pandemic and their frequent exposure to COVID-19 messaging across various mediums. It was reported by some of these individuals that the intervention had limited bearing on improving their knowledge and understanding of the processes related to self-isolation.

You'd have to be under a rock if you didn't know what to do... I already knew how long the self-isolation period was and when I should be testing.

– Trial Participant

However, there were participants for whom the intervention appeared to have a positive effect on their knowledge and awareness of COVID-19 rules and regulations. For example, one stated that the home visiting team successfully supplied the correct test-to-release information, alleviating their financial and practical concerns.

TABLE 8 Key themes related to the intervention's effect on self-isolation behaviours.

Theme	Sub-theme	Description
Capability	Knowledge and skills	Ability to cope with self-isolation and follow guidelines
Financial resources	Ability to meet financial needs during self-isolation	Ability to afford expenses during self-isolation
Social support	Ability to access social support networks	Availability of emotional and practical support from family and friends
Access to healthcare	Ability to access healthcare resources if needed	Availability of medical resources and access to medical services if needed
Opportunity	Support during self-isolation	Availability of emotional, social and practical support during self-isolation
Perceptions of support visits	Perception of whether support visits are for monitoring compliance or for providing support	Perception of the purpose of support visits
Access to information	Availability of information on self-isolation guidelines and resources	Access to accurate information on self-isolation guidelines and resources
Access to technology	Ability to access technology to stay connected with others	Availability of technological resources to stay connected with others
Motivation	Risk perception	Perception of personal risk and the severity of the situation
Perceived susceptibility to infection	Perception of vulnerability to contracting the virus	Perception of personal susceptibility to COVID-19
Attitude towards self-isolation	Attitude towards the need for self-isolation and willingness to comply	Perception of the importance of self-isolation and willingness to follow guidelines
Perceived social norms	Perception of social norms surrounding self-isolation	Perception of societal expectations surrounding self-isolation
Legal duty and post-legal duty	Perception of legal requirements and potential consequences of non-compliance	Perception of the legal and social consequences of non-compliance
Pandemic fatigue	Feeling of desensitization to COVID-19	Feeling of exhaustion or indifference towards COVID-19
Vaccine safety perceptions	Perception of vaccine safety and efficacy	Perception of the safety and effectiveness of COVID-19 vaccines
Perceived effectiveness of the intervention	Perception of the effectiveness of support visits	Perception of the effectiveness of support visits in addressing personal and community needs

I was feeling upset and depressed, because I felt lonely, I have no family, no one...after [the visit] I did not feel like that anymore... [I felt] positive, that Havering Council [came to] help me...they said after 5 days you can get a test and if you get a negative test in a row, you will be free, we can go out so that was really helpful.

– Trial Participant

Opportunity

The provision of social support from family members, friends, and healthcare professionals played a crucial role for some in enabling successful adherence to self-isolation protocols. Individuals with existing social support networks sometimes viewed the intervention as unnecessary as a practical

and/or welfare support instrument. These participants prioritized their primary support networks over formal support structures, such as the intervention. However, for others, despite their existing support networks, the intervention provided a further level of assurance in their ability to self-isolate. In these cases, participants said that the visits reassured them and increased their feelings of safety and support.

I suppose because of our circumstances, we didn't need financial help and we were alright for shopping, and we had family and friends that could [have] done a drop off...but it gave us as a family the reassurance that we could...ask for help if it was needed.

– Trial Participant.

The intervention appeared especially advantageous for individuals who were without or had inadequate access to personal support networks. One participant who faced multiple practical, financial, and emotional challenges due to the absence of an accessible social support network, said that the visits made a substantive difference to feeling supported, adding that this had improved their ability to self-isolate.

At the beginning... on the first and second day [of self-isolation] I didn't know how to get support, I was confused, I was worried...but [when] I received the visit...my thoughts and my feelings completely changed...they [provided] me a life light...it changed my mind.

– Trial Participant

Another aspect of the visits was the provision of LFTs. It was reported that this was important for reducing the amount of time spent in isolation and for providing evidence of negative results to employers.

Though some participants reported that the visits improved their understanding of what support options were available, evidence suggested that there were practical limitations on the intervention's ability to improve uptake of the TTSP scheme. For many individuals, the TTSP scheme was simply unsuitable, either because they were able to work from home, earned above the income threshold, did not lose income because of self-isolation, or were unemployed, which are key facets of the scheme's exclusion criteria.

Motivation

The level of motivation demonstrated by participants appeared to be influenced by a range of factors, including access to accurate information about the risks and benefits of self-isolation, previous experiences with COVID-19 or similar illnesses, and the perceived severity of the pandemic. A crucial factor that underpinned the motivation of the participants was the belief that self-isolation was an essential tool to promote public health, leading them to express their commitment to self-isolation even beyond the legal requirements and sometimes at the cost of their own mental and financial well-being. However, some participants reported that the possibility of being visited by the outreach team did affect their attitude towards complying with self-isolation. For example, one individual explained that following the visit, they were 'scared to go out' because they were afraid of receiving a fine and thought that this might similarly motivate others to stay indoors. Nevertheless, this individual stated that they would still prioritize their mental well-being in future periods of self-isolation, noting that they would leave their home regardless of the consequences.

Someone told me it could have been a check-in, then I was frightened to go out... [but] I would put my well-being first...I was struggling anyway and if I hadn't of done that it could have been a lot more difficult for me.

– Trial Participant

Challenges with mental well-being also featured in other participants' accounts, with these individuals reporting 'feeling trapped' and 'needing to go outside'. In these instances, the intervention appeared unable to provide the type of support needed to improve compliance. In some cases, the difference between complying and not complying appeared to be the degree to which individuals were able to tolerate these negative consequences.

Individuals with negative views about the Government's response to the pandemic and the lack of trust this fostered appeared harder to motivate, and senior council stakeholders and home visiting staff highlighted the communities' negative perceptions of NHS Test and Trace as a barrier to persuading people to fully self-isolate. They felt that trial participants assumed the intervention was part of the NHS Test and Trace programme, which they said was viewed unfavourably by a large proportion of residents.

Some of the barriers we've faced haven't been about our service, it's been about the whole test and trace programme...they talk to us and they kind of see us as an extension of that.
– Senior Council Stakeholder

Among some council stakeholders and trial participants it was felt that the intervention would have had a greater impact during the earlier stages of the COVID-19 pandemic when understanding of the virus was low and uncertainty about its trajectory was high.

In the first wave, because that was when everybody was so frightened, obviously nobody knew how long it was going to go on for...it would have been more helpful then, than maybe now.
– Trial Participant

Chiming with this was the view was that the intervention would have been more impactful when non-compliance with self-isolation had a greater effect on public health in the absence of the vaccine.

I was kind of thinking, why didn't they come a year ago?... I just find it all a bit odd they weren't coming around [when]...people hadn't been vaccinated... it seems a bit weird.
– Trial Participant

In contrast, it was felt that at the time the service was delivered, individuals had a more relaxed attitude towards the virus due to mass vaccination, particularly after the removal of the legal requirement to self-isolate.

I think the fear factor with COVID is no longer there... [people] have mentally moved on from it... if you read the news we are moving in a direction of less and less restrictions.
– Senior Council Stakeholder

There was mixed evidence regarding the potential for the intervention to positively influence vaccination uptake. Within the sample there were individuals who held both 'vaccine hesitant' and actively 'anti-vaxxer' views. Participants' motivations for incomplete or partial vaccination included having a negative reaction to their first vaccine dose or feeling 'too busy to book an appointment'. For these individuals there was a more favourable view of the intervention, with evidence to suggest that it might have influenced them to take an additional dose by improving its accessibility.

Yeah, you know I'm about to get another appointment...it hasn't been arranged yet...I had a call and I felt it was really, really helpful, because people are calling you and asking you, [do you] want a second jab.
– Trial Participant.

However, there were also examples of individuals who said that the visit was unlikely to influence them to be inoculated against COVID-19 because of a lack of trust in the government.

Everything that was going on in Parliament and I thought, how come everyone else is taking this so seriously and you guys aren't? ...I think everything else is handled [too] poorly for me to trust to get a vaccine.

– Trial Participant

DISCUSSION

There is limited existing evidence relating to interventions aimed increasing compliance with self-isolation requirements, particularly evidence based on experimental designs. This study aimed to fill that gap by providing robust evidence on the effectiveness of a home visiting programme on increasing compliance with self-isolation, along with its effect on the take up of support and take up of vaccination, through a RCT. Overall, the trial indicated that the intervention was effective in increasing self-isolation compliance, though it did not find evidence that the home visits increased take-up of financial support or additional doses of COVID-19 vaccine.

There is little experimental evidence in the existing literature that considers factors associated with compliance with self-isolation guidelines, and this study provides a novel contribution towards fill this evidence gap. It finds evidence that a community-based intervention successfully increased self-isolation compliance through the implementation of a home visiting programme. It also provides evidence about the key facilitators and barriers to compliance within the context of the intervention from the perspectives of stakeholders, recipients, and facilitators, and as such can inform future research into this area and the development of effective health interventions.

The implementation and process evaluation provided some insight into why the intervention was successful, including evidence supporting the service's hypothesized mechanisms as detailed in the logic model in [Figure 2](#). In terms of capability, there was evidence that some participants did not fully understand or appreciate the requirements around self-isolation and that the home visits clarified their understanding. This is in line with one of the theoretical underpinnings of the intervention, that new or newly salient information provided through the home visits could support compliance with self-isolation. This finding is in line with existing research that suggests that knowledge of self-isolation guidance and their importance is a key predictor of reported adherence with self-isolation (Smith et al., 2020, 2021, 2022; Webster et al., 2020). These findings suggest that communicating the importance of self-isolation even after the legal requirement was removed, contributed towards encouraging adherent behaviour. This is particularly the case as the RCT findings illustrated that the home visiting programme were driven by stronger effects after the legal requirement to self-isolate had ended, suggesting that the intervention would be of most use in contexts when self-isolation is required outside of a national 'crisis' and so is not supported by wider communications and established social norms.

In terms of people's opportunity to self-isolate, several participants said that the home visits made them 'feel supported' as well as having provided them with information about practical and financial support that they were not previously aware of. This effect may link with the potential reciprocation effect, in that feeling more supported may have encouraged reciprocation in the form of greater adherence to the rules and guidelines regarding self-isolation.

In terms of motivation, some participants reported being more likely to comply after the visit because of wanting to avoid financial or other consequences of non-compliance. This was in line with another theoretical assumption underlying the intervention - the 'audience effect', which posits that people are more likely to follow rules if they believe that their behaviour will be observed. However, the relevance of the 'audience effect' is undermined by the fact that the intervention seemed to only have an impact

on compliance after the end of the legal requirement and the removal of the potential consequences of being observed to not comply.

In terms of implications for future policy, the evidence from this study is that a home visiting programme is a potentially effective way of increasing compliance with self-isolation requirements though it does not provide evidence that such an intervention will increase take up of support services or increased vaccination rates. As the intervention seemed to be effective primarily after the end of the legal requirement, it may be that it is a more useful approach when isolation is not supported by a wider system that is reinforcing the importance of compliance.

The trial was registered at the ISRCTN registry and full details of the trial protocol can be accessed at the trial registry website. The trial protocol and statistical analysis plan are included with the full text of this article in Appendices S4 and S7. No adverse events were reported as occurring due to the trial.

Limitations

The trial was conducted in the London Borough of Havering, where the council had undertaken home visits to vulnerable adult populations, so there may have been a degree of local awareness about the programme, limiting external validity of the findings to other settings, especially as only one local authority was involved in this trial. It is also important to note that the trial was undertaken at a point in the pandemic when the UK policy response to it was undergoing rapid change – particularly after the end of the legal requirement there may have been uncertainty about the importance of complete self-isolation, given the change in public policy and communications. The end of the legal requirement to isolate was part of a wider ramping down of policy measures around COVID-19 and therefore the findings on the legal duty analysis need to be interpreted with caution, with the additional caveat that the overall findings may not necessarily be replicated under different policy contexts.

The intervention was carried out in a fast-changing policy environment, under a specific set of contextual factors, and as such the outcomes that resulted from the trial may not necessarily be replicable in other contexts. The trial also benefited from there already being existing protocols in place at the local authority to deliver home visits, without adding much additional cost in terms of staffing and resources – this may not be easily replicated at the population level and so there may be limited external validity to these findings outside of the specific context delivered in this setting. The trial showed an increase in self-isolation compliance as a result of the home visiting intervention and discusses key facilitators and barriers for stakeholders and recipients of the intervention, which would help inform future research in this area. Additional research considering the cost and resource implications would inform health policy practitioners interested in this area as to the feasibility of implementing similar approaches for disease control.

The cost-effectiveness of this approach was not considered within the scope of the evaluation questions, partly due to time and other resource constraints, but such an assessment would be recommended for follow-up research, due to the importance of assessing the feasibility of a home-visiting trial for wider implementation. This would be particularly important as there are few studies conducted using robust experimental methods to consider the effectiveness of interventions addressing compliance with self-isolation. While it may not be feasible to implement home visits to increase self-isolation compliance at population level for a disease that affects a broad range of the population, this approach may be more applicable for diseases such as mpox that affect only a subset of the population, so that the intervention can be targeted to the specific affected populations that are most at risk of the disease. While this trial was geared towards assessing whether home visits increased self-isolation compliance, such visits may also be targeted towards compliance with other aspects of health policy such as health check-ups, vaccination uptake, etc. particularly among high-risk populations with low mobility and/or facing high levels of financial and other constraints.

The outcome measure of self-isolation compliance used in the trial is limited in terms of both its validity and the information available as it is a behavioural measure that partly relies on cases self-reporting that they are complying with regulations. This measure uses the self-reporting of compliance status

during check-in calls as a proxy measure for actual compliance. This measure therefore does not contain full information about actual compliance status and is instead expected to capture a signal of the true compliance status. This measure is likely to be biased if individuals who were allocated to receive home visits were more likely to inaccurately report that they were compliant with regulations (when actually non-compliant), compared to individuals who were allocated to the control condition of not receiving home visits. It does not have more detailed information such as whether they have continued to follow the regulations for the period of their isolation nor information about the extent of non-compliance, such as the number of times individuals left the home, which could have provided a more nuanced understanding of the impact of the intervention. A further limitation with this analysis is that it does not include value-for-money considerations as to whether the intervention provided sufficient impact for the cost incurred in implementing it.

In terms of the implementation and process evaluation, the sample used in the participant interviews were identified with the support of Havering Council, who gained consent for their contact details to be shared with the evaluation team. Therefore, it is possible that those who declined permission to share their contact details may differ systematically from those who did, which would undermine the range and diversity achieved through the purposive sampling.

AUTHOR CONTRIBUTIONS

Liza Benny: Conceptualization; data curation; formal analysis; investigation; methodology; project administration; software; validation; visualization; writing – original draft; writing – review and editing. **Cameron Smith:** Conceptualization; formal analysis; investigation; methodology; visualization; writing – original draft; writing – review and editing. **Matthew Barnard:** Conceptualization; formal analysis; funding acquisition; investigation; methodology; project administration; resources; supervision; validation; visualization; writing – original draft; writing – review and editing. **Emily Wolstenholme:** Conceptualization; investigation; methodology; project administration; resources. **Mehr Panjwani:** Conceptualization; data curation; investigation. **Maria Ionescu:** Data curation; resources; software; validation. **Troy Aitken:** Conceptualization; data curation; funding acquisition; methodology; project administration; resources; supervision. **Jack Davies:** Conceptualization; funding acquisition; methodology; project administration; resources; supervision; validation. **Pete Austin:** Conceptualization; data curation; funding acquisition; methodology; project administration; resources; supervision. **Lee Watson:** Conceptualization; funding acquisition; project administration; resources; supervision. **Richard Amlôt:** Conceptualization; funding acquisition; methodology; project administration; writing – review and editing.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Research data not shared by the authors.

ETHICS STATEMENT

UK Health Security Agency Research Ethics and Governance Group (REGG Approval Reference NR0297).

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SUPPORTING INFORMATION

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