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Evaluation of coronavirus self-isolation interventions

Submission date	Recruitment status	[X] Prospectively registered
04/08/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/08/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/10/2020	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.
In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.
Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.
Self-isolation is the most important way to reduce the rate of new COVID infections, yet there is some early evidence that compliance is low. The aim of this study is to test the impact of two light-touch interventions on compliance: sending supportive SMS messages and making phone calls to people self-isolating. The intervention aims to increase compliance with self-isolation, and therefore to reduce the spread of coronavirus.

Who can participate?
All contacts over 18 years old who have been notified to self-isolate and have provided a contact mobile number, or landline and email address, will be automatically recruited into the study.

What does the study involve?
Participants are randomly allocated to one of five groups to receive:
1. Business as usual (BAU): No communication between the initial call and final phone survey at the end of self-isolation period.
2. BAU+: Participants receive only the interim SMS/email survey (day 10 and 15) and the final phone survey.

3. Daily SMS/email: Participants receive daily support SMS/email self-isolation messages (day 1 to 14 inclusive) and interim SMS/email survey (day 10 and 15) and the final phone survey (SMS will be replaced by email if the participant does not have a mobile number but still has a landline number).
4. 2x calls: Participants receive two support calls from contact tracing call handlers (day 3 and 8) and an interim SMS/email survey (day 10 and 15) and final phone survey.
5. Daily SMS/email + 2x calls: Participants receive daily support SMS/email self-isolation messages (day 1 to 14 inclusive), two support calls (day 3 and 8) and an interim SMS/email survey (day 10 and 15) and final phone survey.
Participants will receive the interventions and surveys in the 15 days after they enter self-isolation.

What are the possible benefits and risks of participating?
Participants will not receive monetary incentives by participating. The researchers believe the intervention in this study is sufficiently low risk, and the need to support the national effort to combat COVID-19 to be sufficiently urgent, to warrant initial randomisation into the study without consent in this instance. Furthermore, personally identifiable or sensitive data will not be transferred to any parties, and participants will be given conspicuous opportunities to withdraw from the study at several other points.

Where is the study run from?
The Behavioural Insights Team (UK)

When is the study starting and how long is it expected to run for?
July 2020 to August 2020

Who is funding the study?
Department of Health and Social Care NHS Test and Trace Programme (UK)

Who is the main contact?
Unfortunately, this study is not recruiting public volunteers at this time. This is because the research isn't ready for volunteers yet or the researchers are directly identifying volunteers in certain areas or hospitals. Please do not contact the research team as they will not be able to respond. For more information about COVID-19 research, visit the Be Part of Research homepage.

Contact information

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Additional identifiers

Protocol serial number
TP_2020065

Study information

Scientific Title
Do SMS reminders or calls increase the public's compliance with self-isolation advice in the UK? A randomised controlled field trial

Study objectives
The proposed trial will test the impact of two light-touch interventions on compliance: sending supportive SMS messages and making phone calls to people self-isolating. It is hypothesised that SMS reminders or calls will increase the public's compliance with self-isolation requests compared to the business-as-usual control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/07/2020, Public Health England Research Ethics and Governance Group (REGG) (PHE Research Support and Governance Office, Porton Down, Salisbury, Wilts, SP4 0JG, UK; +44 (0)1980 612922; Elizabeth.Coates@phe.gov.uk), ref: R&D 403

Primary study design
Interventional

Study design
Randomised controlled field trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Randomised controlled field trial with three treatment arms (SMS only; Call only; SMS plus call) and two control arms. The first control arm will be used to assess the effectiveness of each treatment arm in the final phone survey. The second control arm will be used to assess the effectiveness of each treatment arm in the SMS/email survey.

Interventions
Support communications delivered to people who have been in contact with someone who tested positive for coronavirus and are advised to self-isolate for 14 days.

Randomisation
Participants will be randomised at the individual level to the five arms in daily batches as they enter the Contact Tracing and Advice Service (CTAS).

Arms:
1. Business as usual (BAU) (control 1): No communication between the initial call and final phone survey at the end of self-isolation period.
2. BAU+ (control 2): Participants receive only the interim SMS/email survey (day 10 and 15) + final phone survey.
3. Daily SMS/email: Participants receive daily support SMS/email self-isolation messages (day 1 to 14 inclusive) and interim SMS/email survey (day 10 and 15) + final phone survey (SMS will be replaced by email if the participant does not have a mobile number, but still has a landline number).
4. 2x calls: Participants receive 2x support call from contact tracing call handlers (day 3 and 8) and interim SMS/email survey (day 10 and 15) + final phone survey.
5. Daily SMS/email + 2x calls: Participants receive daily support SMS/email self-isolation messages (day 1 to 14 inclusive), 2x support call (day 3 and 8) and interim SMS/email survey (day 10 and 15) + final phone survey.

Duration: Participants will receive the interventions and surveys in the 15 days after they enter self-isolation according to CTAS.

(Note that the tracing system is not currently able to prevent participants from entering the trial multiple times. Conditional on data availability, participants entering multiple treatment arms will be excluded from the trial analysis.)

Intervention Type
Behavioural

Primary outcome(s)
Number of times a person reports leaving the house while self-isolating, as reported in SMS survey on day 15 of self-isolation

Key secondary outcome(s)
Number of risky contacts a person reports having while self-isolating, as reported in SMS survey on day 15 of self-isolation

Completion date
30/09/2020

Eligibility

Key inclusion criteria
The researchers aim to recruit 10,000 participants into the sample over the trial period using a pipeline method. All contacts will be eligible for the trial if:
1. They are entered into the CTAS system since trial launch and have been successfully given isolation advice (Contacts are entered into the CTAS system if they are entered into the CTAS web form either by someone who has tested positive for coronavirus, or a call handler on behalf of someone who has tested positive)
2. They are over 18
3. CTAS has either a mobile phone number, or a landline number and email address

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Minors (less than 18 years old)
2. CTAS does not have their mobile phone number, or a landline number and email address

Date of first enrolment
04/08/2020

Date of final enrolment
05/09/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Behavioural Insights Team
United Kingdom
SW1H 9NP

Sponsor information

Organisation
Department of Health and Social Care

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Department of Health and Social Care NHS Test and Trace Programme

Results and Publications

Individual participant data (IPD) sharing plan
Since the participants of the trial will be close contacts of the confirmed COVID-19 cases, they can be potentially identified if the researchers make the data publicly available. To best protect their data privacy, their data will be stored securely in the DHSC data environment and analysed using DHSC laptops.

IPD sharing plan summary
Not expected to be made available