PRINCIPLE
Platform Randomised Trial of Treatments in the
Community for Epidemic and Pandemic Illnesses

Positive Results Script for NHS Digital Calls

No Reply but facility to leave message:

Hello, I am calling from Oxford University about a study looking for effective treatments for COVID-19 to help people feel better more quickly. We are contacting people who have recently tested positive for COVID-19 and your information has been provided to us by NHS Digital. If you would be interested in receiving more information about our study please call us on 0800 138 0880 or you can learn more at www.principletrial.org, thanks, good bye.

Phone Answered

Intro

- Hello, may I speak to (Patient's First name and Surname)? My name is (XXX) and I'm calling from Oxford University following your positive COVID-19 test result. We run a study looking for COVID-19 treatments to help people feel better more quickly.
- Are you interested in hearing more details about how you could help us to develop new treatments and take part? [If yes continue, if no end call politely.]
- We are contacting people like you who have tested positive for COVID-19 and your information has been provided to us by NHS Digital.
- If you chose to take part you would be randomly assigned to receive either one of the treatments we are looking at or usual care [briefly explain the current possible arms]. We would send a participant pack to your home and all follow-up contact would be online or over the phone.
- Does that sound like something you would be interested in? [if yes continue if no ask if they can tell you why to help design future studies and end call politely]
- Are you currently feeling unwell and if so, may I ask what symptoms you have?
  [If yes and have any likely related symptoms, move to next question]

  [If no] I'm glad you're feeling well, this study is only for people who feel unwell so would not suitable for you, thank you so much for your time today.

- Can I ask how long you have been feeling unwell for?

  [If over 14 days] – As we are aiming to treat the illness early on, we are looking for people who have been unwell for less than 14 days, so this study is not suitable for you. Thank you so much for your time though and I hope you feel better soon.

  [If less than 14 days] – Could I please check your age?

  [If 18 or over] It looks like you may be eligible for the study, would you like to go through the forms over the phone now – which will take around 25-30 minutes?
     If they say yes, please click on the screening link https://secure.phc.ox.ac.uk/nhsd
     and go through the forms with them

  [If under 18] Unfortunately you are not eligible to take part in the trial, thank you for your time and we hope you feel better soon

- If they are potentially eligible but do not have time to go through the forms:

  ==Do you have an email address?==

[If Yes] - ==Great, I can send you a copy of our information leaflet and link to register directly on our website?==

[if yes, see below instructions for Sending Link via Email]

Thank them for their time and end the call.

If appropriate:

You have the right to opt out of any future communications from PRINCIPLE should you wish to do so. PRINCIPLE will not retain your data should you choose not to take part.

Sending Link via email

Specific Sentry Link to email: https://secure.phc.ox.ac.uk/nhsd

Template email to send:

Dear ***,

Thank you very much for your time today and interest in the PRINCIPLE trial.

To take part, you need to be experiencing symptoms* that are likely to be caused by a COVID-19 infection and have had a **positive test for Covid-19 in the past 14 days**. The symptoms must have started within the last 14 days.

* These symptoms may include, but are not limited to: a high temperature; a new, continuous cough; loss or change to your sense of smell or taste; sore throat; shortness of breath; general feeling of being unwell; muscle pain; diarrhoea and vomiting.

If you would like to take part please follow this link https://secure.phc.ox.ac.uk/nhsd and you will be asked to answer a few questions and a clinically qualified person will review these and confirm whether or not you are eligible to take part.

Kind regards,
***
[Insert Principle signature]

Please add your initials to any calls you are planning to make, in order to prevent other people from attempting to call at the same time. Please update the tracker with the date the call was made and the following categorisation for any responses:

Call Outcomes
Not interested or does not wish to take part
No answer, left message
No answer, unable to leave message
Not eligible
Hung up, did not wish to be contacted
No - Other reasons
In hospital/too poorly
Already enrolled
Care home - please don't call
Interested, information sent
Enrolled over the phone
Incorrect number
Deceased
Requested Call Back (time specified in additional comments)
Interested - please can trial team member send email
Not eligible - false positive/misentered

There may be the odd occasion where a response does not fit into any of these categories, in which case it is ok to put additional detail.

In cases where the participant is not eligible, please complete Column J '**Not Eligible reason (if applicable)**' with the following additional information:

Not Eligible further options
Pt feeling better, nearly recovered, much improved
Does not have shortness of breath and/or listed underlying health conditions
pregnant or planning to conceive
not willing to take tablets
Other - please list in additional comments
Only has very mild symptoms

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Hello, may I speak to (Patient's Title and Surname)? My name is (XXX) and I'm calling from Oxford University following your positive COVID-19 test result. We run a study looking for COVID-19 treatments to help people feel better more quickly.

Are you interested in hearing more details about how you could help us to develop new treatments and take part?

NO → End call politely

YES ↓

We are contacting people like you who have tested positive for COVID-19 and your information has been provided to us by NHS Digital.

If you chose to take part you would be randomly assigned to receive either one of the treatments we are looking at or usual care [briefly explain the current possible arms]. We would send a participant pack to your home and all follow-up contact would be online or over the phone.

Does that sound like something you would be interested in?

NO → Ask if they can tell you why to help design future studies and end call politely

YES ↓

Are you currently feeling unwell?

NO → I'm glad you are feeling well, this study is looking to treat people who feel unwell so not suitable for you, thank you so much for your time today.

YES ↓

Can I ask how long you have been feeling unwell for?

LESS THAN 14 DAYS ↓

MORE THAN 14 DAYS → As we are aiming to treat the illness early on we are looking for people who have been unwell for less than 14 days, so this study is not suitable for you. Thank you so much for your time though and I hope you feel better soon.

Could I please check your age?

AGED 18 OR OVER ↓

AGED UNDER 18 → Unfortunately this would mean you are not eligible to take part in this study. Thank you for your interest and we hope you feel better soon.

It looks like you may be eligible for the study, would you like to go through the forms over the phone now – which will take around 25-30 minutes?
If they say yes, please click on the screening link https://secure.phc.ox.ac.uk/nhsd and go through the forms with them

If they are potentially eligible but do not have time to go through the forms, if they have an email address offer to send them the link to register directly on the PRINCIPLE Trial Website.