Participant Information Sheet

Self-applied use of the OneDraw device for COVID-19 sampling

Summary

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this research. If you choose not to take part, this will not affect the care you will get or receive.
- Please do ask us if there is anything that is not clear or if you would like more information.
- We would like you to provide two blood samples using a home collection kit (OneDraw) that is easy to administer. If you agree to also visit the MRC-Epidemiology Unit to see a field team member we will ask you for a venous blood sample, finger prick blood test and OneDraw device sample administered by the staff member in addition to completing a short questionnaire regarding the methods.
- We would also like you to provide us with feedback on the documents we provide to you to administer the blood test.
- The information and results collected will be used for research purposes only, and will not be used for clinical purposes or shared with you.
- Thank you for considering to support our research.

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If you have any questions about this study please talk to:
The OneDraw Feasibility Study Team
Email: feasibilitystudy@mrc-epid.cam.ac.uk

1 Why we are doing this study

What are we studying?

The spread of coronavirus (COVID-19) has created an unprecedented global public health emergency. We are looking to conduct a COVID-19 related study using our existing cohorts and an aspect of this would be a self-applied blood collection using a device called OneDraw. This device is currently licensed to be used by Health Care Practitioners (HCP`s) on the upper arm for diabetes testing. We would like to know the following:

a) If the OneDraw device can be used by people at home to obtain a standardised and adequate sample from the upper arm with assistance from another adult in your household or from the thigh if the device is self-administered.
b) If the supporting document(s) provided to guide you on using the device correctly is suitable for use.
c) If the samples obtained stay stable and adequate for analysis when being sent in the post.
d) Whether the samples obtained at home from this device provide the same antibody test result when compared to a venous blood sample, a finger prick dried blood spot sample and a sample collected using the OneDraw device by a HCP.

2 Why am I being asked to take part?

We would like to recruit a minimum of 40 participants, up to a maximum of 50 participants who are over the age of 18 who live or work within close proximity to our testing site (CB2 post code area). The close proximity is required for ease of dispensing and collecting the devices.

3 What will happen to me if I take part?

If you agree to help us with this research, we will ask you to fill in a short questionnaire to begin with. Please note one of the questions asks you to confirm that you are not currently experiencing COVID-19 symptoms; if you are you will be unable to take part. Please see Appendix 1 for current list of symptoms. From the rest of your answers in the questionnaire we will then split all participants into two groups:

Group 1 will be asked to provide two blood samples taken on separate occasions either on the same day or two consecutive days. One sample will be from the upper arm and you will need an adult household member to assist you with this. The second sample will be self-administered on the thigh. If you reside alone or do not have a household member who can help with the upper arm sample we will ask you to take the two samples from your thigh. Full instructions on how to take these samples will be provided. At your preference the two home collection kits will either be delivered to your home by a study team member, sent by fast-track postal service to your home address or can be collected from the MRC-Epidemiology Unit. We ask that you post the two samples back separately to our testing lab in free post envelopes that we will provide. Alongside these blood collection devices you will receive nitrile gloves, a sharps bin to dispose of the devices after use, four barcodes to be put on the cartridges, two plastic bags, two desiccant packets and two pre-paid addressed envelopes for returning the samples separately to our lab for processing. The OneDraw kit includes the device itself, alcohol wipe, gauze and plaster. We ask that you provide us with some written feedback on pain scale, how long the blood draws took and the clarity and effectiveness of the instructions for

use no later than a day after your second blood test. We request that this feedback is sent to the following email address: feasibilitystudy@mrc-epid.cam.ac.uk.

Group 2 will be invited by email to come into a secure area in the MRC-Epidemiolgy Unit to meet a field team member and have a venous sample, finger prick sample and OneDraw sample from the upper arm taken by the staff member. After this you will be asked to fill in a short questionnaire on blood draw method and pain scale. You will then be sent home with the home pack containing the two OneDraw devices, sharps bin, and other necessary supplies for home use and asked to carry out the same tasks as group 1.

4 Possible benefits and disadvantages of taking

What are the possible benefits of taking part?

You will be helping and contributing to vital research in establishing whether this medical device can be used for COVID-19 testing.

What are the possible disadvantages and risks of taking part?

As with other UK studies, **we will not be providing results to individuals on their COVID-19 antibody status**. This study is simply testing to see if the OneDraw device can be used by non-HCP's to collect sufficient blood to run and gain results of the COVID-19 test, that multiple tests on different body areas yields repeatable results and that the results from the device are comparable to other blood collection methods.

5 More information about taking part

Do I have to take part?

No, it is up to you to decide whether or not to take part in this study. You are free to withdraw at any time, without giving a reason. This would not affect the standard or type of care you receive.

Will I receive any payment for taking part?

Unfortunately it will not be possible to provide payment for taking part.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the research team who will do their best to answer your questions at: feasibilitystudy@mrc-epid.cam.ac.uk.

If you remain unhappy and wish to complain formally, the normal University of Cambridge complaints process is available to you through the University of Cambridge Clinical School Secretary: telephone: 01223 333543 or email: SchoolSec@medschl.cam.ac.uk.

What will happen to information about me collected during the study?

Information we collect during the course of the research will be kept strictly confidential. Any information about you will have your name and address removed so that you cannot be recognised from it and it will not be used or made available for any purpose other than for research. Your samples may be used for future use by ourselves or collaborators and this might include industrial or overseas collaborators.

The codes used for your blood samples will not be connected to your individual identity in any way and therefore your blood samples are anonymous from point of collection. The feedback you provide to us will also be anonymised prior to use by others within the Unit. With your permission, your information will be stored at the MRC Epidemiology Unit.

Cambridge University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this. Cambridge University will keep identifiable information about you for 20 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
You can find out more about how we use your information at https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/

What will happen to the results of the study?

If you provide us with an email address, at the end of the study we will let you know how many people in total we tested and how many people in this study tested positive. The results of this study will help us to make adjustments and changes to how we will conduct a study of a much larger cohort of participants. With your help we will better word our instructions for using the device, and better understand from you posting your blood samples if and how we would be able to use these to remotely monitor participants.

Who is organising and funding the study?

This study is organised by the MRC Epidemiology Unit, part of the University of Cambridge. The funder is the Medical Research Council.

Who has reviewed the study?

This study has been reviewed by an independent group of people, the Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. The study has been given a favourable opinion by Human Biology Research Ethics Committee.

6 Contact for further information

If you have any questions regarding the study or how you might be involved further contact information can be found below:

The Feasibility Study Team
Email: feasibilitystudy@mrc-epid.cam.ac.uk

Principal Investigator

Prof Nicholas Wareham
Unit Director
MRC Epidemiology Unit, University of Cambridge

Thank you for taking the time to consider taking part in this study.

7 Appendix 1

List of current COVID-19 symptoms:

- Persistent cough
- Fever
- Hoarseness (changes to the sound of your voice, particularly becoming strained)
- Non-persistent cough (not coughing continuously)
- Discharge or congestion in the nose
- Sneezing
- Sore throat
- Feeling breathless
- Wheeze (a whistling sound when breathing)
- Headache
- Muscle aches
- Unexplained tiredness
- Being sick or feeling sick and/or diarrhoea
- Loss of taste or smell