UK Biobank

COVID-19 Self-Test Antibody Study: Phase 1

Version 1.0

www.ukbiobank.ac.uk
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This documentation was prepared by UK Biobank's Health Data Group.

UK Biobank SARS-CoV-2 coronavirus self-test antibody study overview document
Phase 1 (Fortress Fast COVID-19 device)

Background and rationale

Large-scale research studies that measure markers of past infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (the betacoronavirus responsible for coronavirus disease-19 [COVID-19]) via serological antibody testing are crucial for extending epidemiological investigations into the effect of SARS-CoV-2 on health outcomes. This study therefore recruited UK Biobank participants to perform a SARS-CoV-2 antibody self-test using a lateral flow device at home and to report their result to UK Biobank.

Study design

Design: Cross-sectional seroprevalence study of UK Biobank participants.

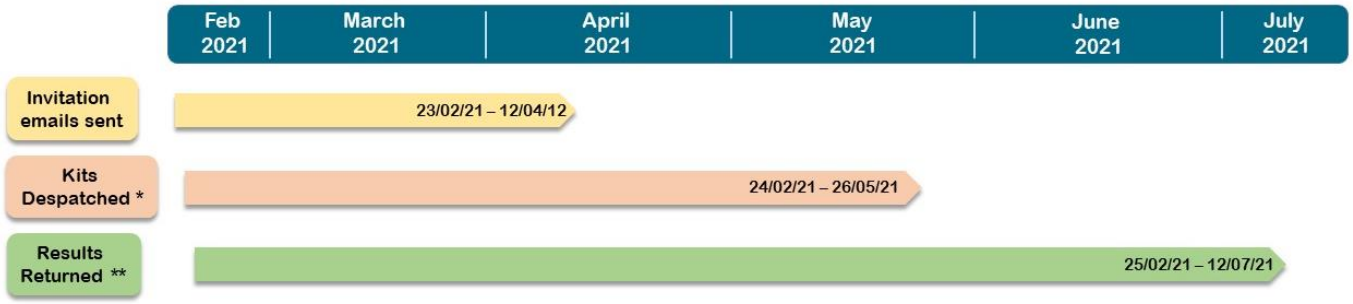
Setting: Community – UK Biobank population**.**

Data collection: Participants received a self-administered lateral flow test (LFT) - the Fortress Fast COVID-19 Device.

Participants were asked to provide UK Biobank with their antibody result via a short test result questionnaire accessed via the UK Biobank website. In order to minimise the number of false-positive results, participants who returned a result that was positive for SARS-CoV-2 antibodies and confirmed that they had not yet received a COVID-19 vaccine were sent a second kit within 14 days and asked to repeat the test.

Study duration: Recruitment and data collection took place over a period of approximately five months.

Study timeline:



* Including first, second and replacement kit despatches.
The majority of first kits were despatched over a period of approximately two months, from 24/02/21 to 19/04/21.

** Including first, second and replacement kit results.
The majority of participants returned their results from the first kit over a period of approximately 3 months, between 21/02/2021 and 08/05/2021.

Sample size: The study aimed to recruit 50,000 participants, initially inviting 34,713 participants who had previously attended a UK Biobank imaging assessment centre and who were eligible to join the study (i.e. those who were still alive and willing to be re-contacted by UK Biobank). The rationale for focusing on these 34,713 individuals was to use the antibody self-test data to identify seropositive and seronegative participants for invitation to a repeated imaging assessment (in order to assess the effect of SARS-CoV-

2 infection on changes in internal pathophysiology). A further 22,390 participants aged 79 and over were subsequently invited to participate, followed by 21,405 participants aged 77 and 78.

Participant selection: Both men and women were invited, across all ages of the UK Biobank cohort (i.e. 50 to80 years; average age of 66 years).

Inclusion criteria

- UK Biobank participant had previously attended a baseline UK Biobank imaging assessment (this criterion was removed after the first sample was identified);
- UK Biobank participant was alive (regardless of health status);
- UK Biobank participant was willing to be contacted by UK Biobank;
- UK Biobank participant had a valid email address;
- UK Biobank participant was resident in mainland UK;
- UK Biobank participant was willing and able to give informed consent for participation in the study.

Exclusion criteria

- UK Biobank participant had not previously attended a baseline UK Biobank imaging assessment (this criterion was removed after the first sample was identified);
- UK Biobank participant was dead (as identified through national death registry records or via information from a relative);
- UK Biobank participant had informed UK Biobank that they no longer wished to receive notifications;
- UK Biobank participant had an invalid email address;
- UK Biobank participant was resident in non-mainland UK or overseas (owing to the logistics of distributing kits overseas);
- UK Biobank participant was not willing to provide consent for participation in the coronavirus antibody self-test study.

Methods

Recruitment (see study flowchart below): Participants meeting the eligibility criteria described above were invited to take part via email. The email invitation provided brief information about the study, weblinks to the study information sheet, an instructional video (https://www.youtube.com/watch?v=gWX3NyZ0RbQ), a list of frequently asked questions (FAQs) and the online consent form, plus details of how to contact UK Biobank if they had further questions. Participants who were unable or unwilling to participate were encouraged to visit the UK Biobank participant website to confirm that they would not be participating. A reminder email was sent to participants who had not responded seven days after receiving the original invitation.

If interested, participants were encouraged to visit the UK Biobank participant website to confirm their contact details and consent to receive a lateral flow self-test kit at their home address and to complete a brief questionnaire about their test result and their receipt of a COVID-19 vaccine.

Consented participants received an acknowledgement email confirming their participation in the study and notifying them when they could expect to receive their antibody testing kit. One to three days prior to kit despatch, participants were sent an email to let them know that their kit was being despatched and participant addresses were securely transferred to a third party mailing house and shipping company.

A reminder email was sent to participants who had not returned a test result one week after their kit was despatched.

Data collection: Participants were mailed a SARS-CoV-2 antibody self-test kit – the Fortress Fast COVID-19 Device kit (assembled by Una Health) and accompanying instructions.

Participants used a microsampling finger-prick device to obtain a drop of blood which they then applied to the test cassette's sample port (either directly from the finger or using the supplied pipette). Participants then added buffer solution to the sample port and waited for 10-15 minutes for the result to appear.

Results were interpreted visually by the presence or absence of a narrow coloured band at the test region of the device. Interpretation of results was described in the instruction booklet.

Provision of test results: Participants were asked to complete an online UK Biobank questionnaire which requested brief details about their test result (IgM or IgG positive [presence of antibodies], negative, invalid) and test date, and their COVID-19 first and second vaccination status and dates. Participants could also provide their result via an Interactive Voice Recognition (IVR) system. The date on which participants submitted their results, either for online or IVR returns, was automatically recorded and is shared with researchers along with the self-reported date on which the test was taken.

On receipt of a completed test result questionnaire, a thank you SMS was sent to participants who had provided a mobile phone number.

Participants who provided a positive test result received an email confirming receipt of their positive test result and informing them that UK Biobank would be sending them a second antibody self-test kit (in order to double-check that they were likely to have been previously infected). The same methods described above for the first kit were then used for the second kit. Data relating to the first and second test result submissions are indicated by Instance values of 0 and 1 respectively.

Participants were free to opt out of receiving a second sampling kit and to withdraw their consent at any time.

Data cleaning: Prior to being made available, data collected from the study have undergone a small amount of cleaning. The data cleaning process involved the following steps:

- the removal of data relating to an invalid antibody test result;
- the retention of the most recently submitted test result data where results were reported twice or more for the same instance. In some cases participants provided incorrect information in their first submission that they then followed up to correct, therefore any records received prior to the latest submission have been discarded;
- the removal of invalid self-reported test dates. Test dates were defined as invalid if they fell after the date they were reported, or before the date the first test kits were sent out to participants;
- the removal of invalid self-reported vaccination dates. Vaccination dates were defined as invalid if they fell before the start of 2020 or after the date they were reported.

Occasionally participants provided different vaccination dates when submitting the results of their first and second antibody tests, and no attempt to reconcile such inconsistencies have been made. Finally, reported vaccination dates that fall during 2020 but before the beginning of the UK's COVID-19 vaccination roll-out in December 2020 may be due to either trial participation or self-report error.

Study flowchart