

# COVID-19 home antibody testing study

<b>Submission date</b> 26/07/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 08/08/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/09/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The COVID-19 home antibody testing study will invite Avon Longitudinal Study of Parents and Children (ALSPAC) participants who previously completed the COVID-19 questionnaire to complete a home antibody test. This is part of a collaborative effort across UK cohorts to collect serological data on past infection status. In particular, cohorts have been selected to provide information on prevalence across important areas of variation – ethnicity, age, socioeconomic status and geography.

### Who can participate?

Volunteers aged 28 to 50 years old of the ALSPAC longitudinal study

### What does the study involve?

This is an antibody research study. In this study, the results of antibody tests that participants have taken at home are used to help understand how many people in Children of the 90s may have been infected with the virus which causes COVID-19.

### What are the possible benefits and risks of participating?

The aim of the study was to have results that inform public policy/public health in the time of a pandemic. Risks include potential bruising associated with the test kit.

Note, this was an antibody research study rather than a medical device study. Covid19 test kits had not been licensed when this study ran. Because of this, the study was run as a device study.

### Where is the study run from?

ALSPAC (Children of the 90s), University of Bristol (UK)

### When is the study starting and how long is it expected to run for?

April 2020 to January 2021

### Who is funding the study?

1. Medical Research Council (UK)
2. Wellcome Trust (UK)
3. University of Bristol (UK)

Who is the main contact?  
Nicolas Timpson, N.J.Timpson@bristol.ac.uk (UK)

## Contact information

### Type(s)

Principal investigator

### Contact name

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## Additional identifiers

### Central Portfolio Management System (CPMS)

46980

### Protocol serial number

B3566

# Study information

## Scientific Title

Serological testing for COVID-19 in ALSPAC (G0/G1)

## Study objectives

Serological testing for COVID-19 in ALSPAC (G0/G1) (Lay title: COVID-19 home antibody testing study) will invite ALSPAC participants who have previously completed a COVID-19 questionnaire to complete a home antibody test.

This is part of a collaborative effort across UK cohorts to collect serological data on past infection status. In particular, a set of cohorts have been selected to provide information on prevalence across 4 important areas of variation – ethnicity, age, socio-economic status and geography. (Please note each cohort is running its studies separately and are have its own protocol and route to ethics approval).

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 21/07/2020, ALEC - ALSPAC ethics and Law committee (ALSPAC (Children of the 90s), Bristol, BS8 2BN, United Kingdom; +44 (0)117 455 3687; lynn.molloy@bristol.ac.uk), ref: 110264

## Study design

Case-control across within a longitudinal study

## Primary study design

Observational

## Study type(s)

Screening

## Health condition(s) or problem(s) studied

COVID-19 home antibody testing study

## Interventions

Our outcome measure is lateral flow test derived evidence of positive antibody response to COVID-19 given knowledge of the sensitivity and specificity of the Fortress Home Test kit. This is relevant given our objectives in this work.

The broad objective of this work (and contribution to the work already underway by REACT and UKBiobank) is the collection of epidemiological-grade biological test data for COVID-19 infection across a series of select studies across the UK which provide information on prevalence across 4 main axes of variation important for developing mitigation strategy relevant evidence (age, geography, socio-economic position, ethnicity/ancestry) and with the ability to assess this against information on existing comorbidities. The study's aim is to have results that are policy useful in a short period reflecting the burden of COVID-19 retrospectively across these important gradients but also to allow for the effective planning of research into the nature of the events before, during and after infection. This can only be done in longitudinal studies with retrospective data that are continuing (and part of funded examinations into COVID-19 studies)

in the future. The Avon Longitudinal Study of Parents and Children (ALSPAC) is the first of 5 studies to have DHSC procured Fortress lateral flow tests available to do this.

This approach will use the same testing approach as the existing REACT-2 study (<https://www.reactstudy.org>) and consequently, methods are based directly on this successful investigation which has recruited and tested over 100,000 participants. Participants are invited to read the instructions of the antibody kit and do the test themselves at home. The test uses a drop of blood taken from your finger. An instruction booklet is provided with the test for detailed guidance on taking the test.

Participants are also asked to go online to complete a short questionnaire that will ask them to:

1. Record any COVID-19 symptoms you may have had in recent months
2. Record your test result
3. Upload a photograph of your test result (this step is optional)

In total, this should all take around 45 minutes.

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

COVID-19 home antibody test

### **Primary outcome(s)**

Covid 19 infection status measured using a COVID-19 home antibody test at one timepoint

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **Completion date**

20/01/2021

## **Eligibility**

### **Key inclusion criteria**

Eligible participants in ALSPAC, a longitudinal study

### **Participant type(s)**

Population

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

28 years

**Upper age limit**

50 years

**Sex**

All

**Key exclusion criteria**

1. Any participant who responded 'No' to the question that asked if they would be happy for the study team to send information about research involving testing for COVID-19 in the 'Learning more about COVID-19' questionnaire
2. Increased risk of bleeding (participants will be asked at the consenting stage to self-declare any issues related to bleeding disorders)
3. Participants outside the UK. Costs and timescales for postage outside the UK make this impractical.
4. Participants who are flagged as deceased, withdrawn, no to questionnaires and no to contact.

**Date of first enrolment**

16/09/2020

**Date of final enrolment**

14/10/2020

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****At participants homes**

ALSPAC (Children of the 90s)

Population Health Sciences

Oakfield House

Bristol

United Kingdom

BS8 2BN

**Sponsor information****Organisation**

University of Bristol

**ROR**

<https://ror.org/0524sp257>

# Funder(s)

## Funder type

Research council

## Funder Name

Medical Research Council

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

## Funder Name

University of Bristol

## Alternative Name(s)

Universitas Bristolliensis, bristoluniversity, bristoluni

## Funding Body Type

Government organisation

## Funding Body Subtype

Universities (academic only)

## Location

United Kingdom

## Funder Name

Wellcome Trust

## Alternative Name(s)

Wellcome, WT

## Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

Through numerous media types, the ALSPAC communications team continue to summarise and describe the footprint of ALSPAC research (<http://www.bristol.ac.uk/alspac/covid-19/>). This includes usual social media routes and looks to acknowledge the diversity of the study. This is an essential addition for a volunteer participant group like ALSPAC as it provides an important route to disseminate results aimed specifically at population-based or epidemiological findings. Please find a link to ALSPAC's Access Policy - [ALSPAC\\_Access\\_Policy.pdf](#) ([bristol.ac.uk](http://bristol.ac.uk)).

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	24/01/2023	07/08/2023	Yes	No
<a href="#">Funder report results</a>		24/01/2022	07/08/2023	No	No
<a href="#">Participant information sheet</a>	version 0.1		07/08/2023	No	Yes
<a href="#">Preprint results</a>		22/05/2022	07/08/2023	No	No
<a href="#">Protocol file</a>	version 2.1	01/08/2020	07/08/2023	No	No