

# Can a urine test improve uptake in cervical screening?

<b>Submission date</b> 22/05/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/05/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/03/2026	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cervical screening can save lives, yet only 7 in 10 in the UK attend, the lowest rate in 20 years. Reasons include embarrassment, fear of examination and inconvenience. The aim of this study is to find out if self-collected urine and vaginal tests could increase uptake in cervical screening. The tests have the potential to remove many of the current barriers to screening. They can be taken at home at a time most convenient for the patient.

### Who can participate?

To be eligible to take part in this study participants must be aged 25-65 years and overdue cervical screening by 6 months or more

### What does the study involve?

The researchers will work with GP practices across Greater Manchester to identify potential participants through overdue cervical screening lists. Participants will be randomly allocated into one of five groups.

1. Group 1 will be posted a urine sample collection pack.
2. Group 2 will be posted a vaginal sample collection pack.
3. Group 3 will receive a letter offering the choice of a urine or vaginal sample collection pack.
4. Group 4 will receive a letter offering a urine sample collection pack.
5. Group 5 will receive a letter offering a vaginal sample collection pack.

The researchers will also advertise through social media, at face-to-face community events, and using posters and leaflets in community settings. Participants recruited through this method will not be randomly allocated and will instead be offered the choice of a urine or vaginal self-sample kit.

Participants will self-collect a sample at home and complete a questionnaire. samples will be returned via Royal Mail. Samples will be tested for high-risk human papillomavirus – the virus known to cause cervical cancer. The researchers will look at how many samples are returned and whether there is a preference for urine or vaginal sample collection.

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

There are no expected risks or direct benefits expected for participants, however, a positive urine sample may prompt a non-attender to book routine cervical screening which in turn could

prevent cervical cancer. Self-sampling may encourage more people to attend cervical screening in future.

Where is the study run from?  
University of Manchester (UK)

When is the study starting and how long is it expected to run for?  
September 2020 to December 2026

Who is funding the study?  
National Institute for Health Research (NIHR) (UK)

Who is the main contact?  
ACES@manchester.ac.uk

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Emma Davidson

### ORCID ID

<https://orcid.org/0000-0003-0284-8630>

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### Type(s)

Public

### Contact name

Miss Suzanne Carter

### Contact details

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## Additional identifiers

**Integrated Research Application System (IRAS)**  
321531

**Central Portfolio Management System (CPMS)**  
62478

## Study information

### Scientific Title

Alternative CErvical Screening study - ACES At Home: can a urine test improve uptake in cervical screening?

### Acronym

ACES At Home

### Study objectives

Self sampling for HPV testing as an alternative to routine cervical screening, will improve cervical screening attendance in people overdue screening by 6 months or more.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 23/05/2024, London - Camberwell St Giles Research Ethics Committee (postal address not available; +44 (0)20 7104 8222; camberwellstgiles.rec@hra.nhs.uk), ref: 24/LO/0385

### Study design

Randomized; Interventional; Design type: Screening, Prevention, Active Monitoring

### Primary study design

Interventional

### Study type(s)

Screening

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

Cervical screening

### Interventions

This study will see if a urine or vaginal at-home self-sample test can improve cervical screening uptake in non-attenders.

Women, and people with a cervix, who are registered at GP Practices, who meet the eligibility criteria will be randomised into five groups in the ratio 1:1:1:1:1.

Group one will receive a text message/letter to advise them that they will receive a urine self-sampling pack by post to their registered home address. Urine collection packs will then be sent to their home address 2 weeks later.

Group two will receive a text message/letter to advise them that they will receive a vaginal self-sampling pack by post to their registered home address. Vaginal sample collection packs will then be sent to their home address 2 weeks later.

Group three will receive an invitation letter and participant information sheet offering them the opportunity to request a urine or vaginal self-sampling pack.

Group four will receive an invitation letter and participant information sheet offering them the opportunity to request a urine self-sampling pack.

Group five will receive an invitation letter and participant information sheet offering them the opportunity to request a vaginal self-sampling pack

Samples will be tested for high-risk HPV. The participant and GP will receive a copy of the results. The study sample will not replace or update the NHS cervical screening record.

In each intervention group the researchers will record and compare the number and type of requested packs (where applicable), the number of returned samples and the number of participants who attend routine cervical screening if they test HPV positive.

If an inadequate sample result is returned, the participant will be asked to collect a second sample using the same method.

Participants will answer a short acceptability questionnaire to gauge their views on self-sample testing for cervical screening.

The researchers will collect cervical screening data on all participants invited to ACES At Home. This will be extracted from the GP practice records at the time of identifying and inviting eligible participants approximately 6 months later.

Added 28/01/2025: The researchers will estimate spontaneous attendance for routine cervical screening within the 3 months prior to the study invitation for each GP practice. This will be compared to the proportion in each randomisation arm who do not respond to self-sampling but instead are prompted to attend cervical screening at their GP practice.

A sub-study (ACES Choice) will invite individuals who self-identify as non-attenders to routine cervical screening to take part: in person, at community events and gatherings; social media/web adverts; posters/leaflets at GP practices, clinics, pharmacies and community settings.

Participants will be given a choice between a urine or vaginal at-home self-sampling pack. People will also have the option to contact the research team via email.

The researchers will assess community choice for urine or vaginal self-sampling according to demographics to ascertain if certain communities are likely to prefer one method of self-sampling over another.

## Intervention Type

Other

### Primary outcome(s)

ACES AT Home:

Improvement in uptake is measured by the number of individuals returning an adequate self-sample within the study period. The preference for urine testing will be measured by the proportion of individuals opting for urine self-sampling in the choice arm during the study period.

ACES Choice sub-study:

Preference for type of self-sampling is measured by the proportion of individuals requesting a urine or vaginal self-sampling pack during the study period

### Key secondary outcome(s)

ACES At Home:

1. The proportion of individuals who test HPV+; who attend follow-up procedures; referred for colposcopy; CIN2+ on histology measured by medical record follow-up
2. The proportion of individuals with inadequate samples providing repeat samples during the study period
3. The acceptability of urine and vaginal self-sampling to individuals who are overdue cervical screening and previous barriers to screening measured using study questionnaire at the point of sample collection
4. The impact of age, gender, sexual identity, disability status, time since last cervical screen, ethnicity, religion, education/ employment status and postcode (as a measure of socioeconomic deprivation) on uptake of urine and vaginal self-sampling measured using study questionnaire at the point of sample collection
5. The proportion of invited individuals who attend cervical screening during the study period measured by medical record data extraction at baseline and end of study
6. The proportion of non-responders from ACES at Home who respond to ACES Choice measured 6 months and onwards following ACES At Home invitation

ACES Choice:

1. The proportion of individuals who return a self-sampling kit within the study period
2. The proportion of individuals who return a self-sampling kit within the study period based on method of approach (in the community, via social media, at GP practice or clinic)
3. The acceptability of urine and vaginal self-sampling to women who are overdue cervical screening and previous barriers to screening measured using study questionnaire at the point of sample collection (baseline)
4. The impact of age, ethnicity, religion, disability status, gender, sexual orientation, education/ employment status, socioeconomic status and time since last screen on uptake of urine or vaginal self-sampling measured using study questionnaire at the point of sample collection

### Completion date

01/12/2026

## Eligibility

### Key inclusion criteria

1. Aged 25-65 years
2. Person with a cervix

3. Written, informed consent to participate\*
4. Overdue routine cervical screening by 6 months or more
5. Reside in the catchment for laboratory (Aces Choice only)

\*Does not apply for data extraction for all invited participants

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

Yes

**Age group**

Mixed

**Lower age limit**

25 years

**Upper age limit**

65 years

**Sex**

Female

**Total final enrolment**

2012

**Key exclusion criteria**

1. Pregnant
2. Person without a uterus
3. Unable to provide vaginal or a urine sample, including indwelling urinary catheter (for offering urine HPV testing only)
4. Unable to understand the Participant Information Sheet and consent form
5. Any condition that would compromise participant safety or data integrity
6. Due screening in the next 3 months
7. Type 1 objectors (i.e. those who dissent from their medical data being shared)

**Date of first enrolment**

01/08/2024

**Date of final enrolment**

31/12/2025

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

United Kingdom

England

**Study participating centre**

**Bowland Medical Centre**

52 Bowland Road

Manchester

England

M23 1JX

**Study participating centre**

**Pds Medical - Hawthorn Medical Centre**

Fallowfield Retail Park

Birchfields Road

Manchester

England

M14 6FS

**Study participating centre**

**Ancoats Urban Village Medical Practice**

Old Mill Street

Manchester

England

M4 6EE

**Study participating centre**

**Heald Green Health Centre 2**

Heald Green Health Centre

Finney Lane

Heald Green

Cheadle

England

SK8 3JD

**Study participating centre**

**West Gorton Medical Centre**

2 - 6 Clowes Street

Manchester

England

M12 5JE

**Study participating centre**

**Washway Road Medical Centre**

67 Washway Road

Sale

England

M33 7SS

**Study participating centre**

**John Street Medical Practice**

1 John Street

Oldham

England

OL8 1DF

**Study participating centre**

**Didsbury Medical Centre**

645 Wilmslow Road

Didsbury

Manchester

England

M20 6BA

**Study participating centre**

**Tower Family Healthcare - Minden**

22 Derby Way

Bury

England

BL9 0NJ

**Study participating centre**

**St Johns Medical Centre**

Altrincham Health & Wellbeing Ctr

31-33 Market Street

Altrincham

England

WA14 1PF

**Study participating centre**

**Glodwick Primary Care Centre**

137 Glodwick Road

Glodwick

Oldham

England  
OL4 1YN

**Study participating centre**

**Ashton Medical Group**

Chapel Street  
Ashton-under-lyne  
England  
OL6 6EW

**Study participating centre**

**Knutsford Medical Partnership**

Manchester Road Med/ctr  
27-29 Manchester Road  
Knutsford  
England  
WA16 0LY

**Study participating centre**

**Hollinwood Medical Practice**

1 Clive Street  
Oldham  
England  
OL8 3TR

**Study participating centre**

**Hill Top Surgery**

Hilltop Surgery  
Fitton Hill Neighbourhood Centre  
Fircroft Road  
Oldham  
England  
OL8 2QD

**Study participating centre**

**Village Medical Practice**

Shaw Crompton Medical Centre  
Westway  
Shaw

Oldham  
England  
OL2 8BF

**Study participating centre**  
**Birtle View Medical Practice**  
George Street  
Heywood  
England  
OL10 4PW

**Study participating centre**  
**Middleton Health Centre**  
The Health Centre Unit F1  
Middleton Shopping Centre  
Middleton  
Manchester  
England  
M24 4EL

**Study participating centre**  
**The Maples Medical Centre**  
2 Scout Drive  
Newall Green  
Manchester  
England  
M23 2SY

**Study participating centre**  
**Bodey Medical Centre**  
28 Ladybarn Lane  
Fallowfield  
Manchester  
England  
M14 6WP

**Study participating centre**  
**Brinnington Health Centre**  
Brinnington Road  
Brinnington  
Stockport

England  
SK5 8BS

**Study participating centre**

**Park View Group Practice**

2 Longford Road West

Reddish

Stockport

England

SK5 6ET

**Study participating centre**

**The Robert Darbishire Practice**

Rusholme Health Centre

Walmer Street

Rusholme

Manchester

England

M14 5NP

**Study participating centre**

**Springfield Medical Centre**

384 Liverpool Road

Eccles

Manchester

England

M30 8QD

**Study participating centre**

**Langworthy Medical Practice**

250 Langworthy Road

Salford

England

M6 5WW

**Study participating centre**

**Surrey Lodge Group Practice**

11 Anson Road

Manchester

England

M14 5BY

**Study participating centre**  
**Withington Medical Practice**  
4-6 Copson Street  
Withington  
Manchester  
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M20 3HE

**Study participating centre**  
**Northern Moor Medical Practice**  
216 Wythenshawe Road  
Northern Moor  
Manchester  
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M23 0PH

**Study participating centre**  
**The Mosslands Medical Practice**  
Macdonald Road  
Irlam  
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M44 5LH

**Study participating centre**  
**Dickenson Road Medical Centre**  
357-359 Dickenson Road  
Longsight  
Manchester  
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M13 0WQ

**Study participating centre**  
**Peterloo Medical Centre**  
133 Manchester Old Road  
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M24 4DZ

# Sponsor information

## Organisation

University of Manchester

## ROR

<https://ror.org/027m9bs27>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Academy; Grant Codes: NIHR300650

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Emma Crosbie ([emma.davidson@manchester.ac.uk](mailto:emma.davidson@manchester.ac.uk)). The consent form includes permission to share anonymised data with other researchers.

## IPD sharing plan summary

Available on request