Can a urine test improve uptake in cervical screening?

Submission date	Recruitment status	[X] Prospectively registered
22/05/2024	Recruiting	□ Protocol
Registration date	Overall study status	Statistical analysis plan
22/05/2024	Ongoing	Results
Last Edited	Condition category	Individual participant data
17/06/2025	Cancer	[X] 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 Crosbie

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Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

321531

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 62478, IRAS 321531

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

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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.

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

Phase

Not Specified

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

01/09/2020

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)

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

25 Years

Upper age limit

65 Years

Sex

Female

Target number of participants

Planned Sample Size: 10000; UK Sample Size: 10000; ACEs Choice substudy <500

Key exclusion criteria

- 1. Pregnant
- 2. Person without a uterus

^{*}Does not apply for data extraction for all invited participants

- 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

01/12/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Bowland Medical Centre

52 Bowland Road

Manchester United Kingdom M23 1JX

Study participating centre Pds Medical - Hawthorn Medical Centre

Fallowfield Retail Park Birchfields Road Manchester United Kingdom M14 6FS

Study participating centre Ancoats Urban Village Medical Practice

Old Mill Street Manchester United Kingdom M4 6EE

Study participating centre Heald Green Health Centre 2

Heald Green Health Centre Finney Lane Heald Green Cheadle United Kingdom SK8 3JD

Study participating centre West Gorton Medical Centre

2 - 6 Clowes Street Manchester United Kingdom M12 5JE

Study participating centre Washway Road Medical Centre

67 Washway Road Sale United Kingdom M33 7SS

Study participating centre John Street Medical Practice

1 John Street Oldham United Kingdom OL8 1DF

Study participating centre Didsbury Medical Centre

645 Wilmslow Road Didsbury Manchester United Kingdom M20 6BA

Study participating centre Tower Family Healthcare - Minden 22 Derby Way Bury United Kingdom BL9 0NJ

Study participating centre
St Johns Medical Centre
Altrincham Health & Wellbeing Ctr
31-33 Market Street
Altrincham
United Kingdom
WA14 1PF

Study participating centre Glodwick Primary Care Centre 137 Glodwick Road

Glodwick Roa Glodwick Oldham United Kingdom OL4 1YN

Study participating centre Ashton Medical Group

Chapel Street Ashton-under-lyne United Kingdom OL6 6EW

Study participating centre Knutsford Medical Partnership

Manchester Road Med/ctr 27-29 Manchester Road Knutsford United Kingdom WA16 OLY

Study participating centre Hollinwood Medical Practice

1 Clive Street Oldham United Kingdom OL8 3TR

Study participating centre Hill Top Surgery

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

Study participating centre Village Medical Practice

Shaw Crompton Medical Centre Westway Shaw Oldham United Kingdom OL2 8BF

Study participating centre Birtle View Medical Practice

George Street Heywood United Kingdom OL10 4PW

Study participating centre Middleton Health Centre

The Health Centre Unit F1 Middleton Shopping Centre Middleton Manchester United Kingdom M24 4EL

Study participating centre The Maples Medical Centre

2 Scout Drive Newall Green Manchester United Kingdom M23 2SY

Study participating centre Bodey Medical Centre

28 Ladybarn Lane Fallowfield Manchester United Kingdom M14 6WP

Study participating centre Brinnington Health Centre

Brinnington Road Brinnington Stockport United Kingdom SK5 8BS

Study participating centre Park View Group Practice

2 Longford Road West Reddish Stockport United Kingdom SK5 6ET

Study participating centre The Robert Darbishire Practice

Rusholme Health Centre Walmer Street Rusholme Manchester United Kingdom M14 5NP

Study participating centre Springfield Medical Centre

384 Liverpool Road Eccles

Manchester United Kingdom M30 8QD

Study participating centre Langworthy Medical Practice

250 Langworthy Road Salford United Kingdom M6 5WW

Study participating centre Surrey Lodge Group Practice

11 Anson Road Manchester United Kingdom M14 5BY

Study participating centre Withington Medical Practice

4-6 Copson Street Withington Manchester United Kingdom M20 3HE

Study participating centre Northern Moor Medical Practice

216 Wythenshawe Road Northern Moor Manchester United Kingdom M23 0PH

Study participating centre The Mosslands Medical Practice

Macdonald Road Irlam Manchester United Kingdom M44 5LH

Study participating centre Dickenson Road Medical Centre

357-359 Dickenson Road Longsight Manchester United Kingdom M13 0WQ

Study participating centre Peterloo Medical Centre

133 Manchester Old Road Middleton Manchester United Kingdom M24 4DZ

Sponsor information

Organisation

University of Manchester

Sponsor details

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Sponsor type

University/education

Website

http://www.manchester.ac.uk/

ROR

https://ror.org/027m9bs27

Funder(s)

Funder type

Government

Funder Name

NIHR Academy; Grant Codes: NIHR300650

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2027

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.crosbie@manchester.ac.uk). The consent form includes permission to share anonymised data with other researchers.

IPD sharing plan summary

Available on request