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Can a urine test improve uptake in cervical screening?

Submission date 22/05/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/05/2024	**Overall study status** Ongoing	
Last Edited 17/06/2025	**Condition category** Cancer	

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 1:1:1:1:1.

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)

*Does not apply for data extraction for all invited participants

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

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
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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
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 0LY

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
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M24 4DZ

Sponsor information

Organisation
University of Manchester

Sponsor details
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fbmhethics@manchester.ac.uk

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