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A London HPV self-sampling pilot

Submission date
19/06/2018

Recruitment status
No longer recruiting

Registration date
25/07/2018

Overall study status
Completed

Last Edited
04/12/2024

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English Summary

Background and study aims
Underscreened women are at the highest risk of developing cervical cancer, yet the number of women attending cervical screening continues to fall. A potential solution is to offer self-sampling for human papillomavirus (HPV) testing. Self-sampling addresses many of the barriers to conventional screening (cervical cytology): women can take their own sample, in private and at a time and place of their choosing. Self-sampling is slightly less accurate than HPV testing on clinician-taken samples, so would not be suitable as a primary screening test. UK studies have already shown that HPV self-sampling can increase screening uptake in non-attenders but the best approach for offering self-sampling kits (SSK) is unclear. London has consistently has the lowest cervical screening uptake nationally, making it an ideal population to assess the potential for self-sampling and provide evidence for its use in England. The aim of this study is to establish the best design for a large study of self-sampling.

Who can participate?
Women aged 25-64 who are eligible for cervical screening and are at least 6 months overdue (i.e. no cervical screening recorded in the GP records in the past 3.5 years if aged 25-49 or 5.5 years if aged 50-64)

What does the study involve?
Participating GP practices are randomly allocated to either offer self-sampling opportunistically when eligible women consult for any reason, or to provide usual care. In both groups women who have never been screened or are overdue are randomly allocated either to usual care, to receive a letter inviting them to order a self-sampling kit, or to receive a self-sampling kit in the post. Uptake of self-sampling is assessed for each approach. Cervical screening data for all eligible women is collected from GP records for 12 months after recruitment ends to assess changes in screening coverage.

What are the possible benefits and risks of participating?
Some women find it difficult to make an appointment for cervical screening because they are busy or because their GP practice is busy. Some women may find it uncomfortable or embarrassing to have a test taken by a doctor or nurse. Participants will be able to take a test for cervical screening themselves without having to be examined or to make an appointment. In other studies, some women who had not been for routine cervical screening and took a self-test were found to have abnormal cervical cells and were successfully treated. Women who have

taken self-tests in previous studies have not reported any particular problems. Feedback from women is that they found the test easy and convenient to do.

Where is the study run from?
1. Thornbury Road Centre for Health (UK)
2. Albany Practice (UK)
3. Argyle Health - Isleworth Practice (UK)
4. The Practice Heart Of Hounslow (UK)
5. Chiswick Health Centre (UK)
6. Grove Park Surgery (UK)
7. Grove Park Terrace Surgery (UK)
8. Wellesley Road Practice (UK)
9. The Medical Centre - Twickenham Park Medical Surgery (UK)
10. Gill Medical Practice (UK)
11. Crosslands Surgery (UK)
12. Firstcare Practice (UK)
13. Hounslow Family Practice (UK)

When is the study starting and how long is it expected to run for?
November 2017 to November 2021

Who is funding the study?
Cancer Research UK

Who is the main contact?
Dr Anita Lim
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
205691

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 36156

Study information

Scientific Title
Self-sampling for HPV testing in cervical screening nonattenders in London

Acronym
ALOHA

Study hypothesis
Underscreened women are at the highest risk of developing cervical cancer, yet the number of women attending cervical screening continues to fall. A potential solution is to offer self-sampling for HPV (human papillomavirus) testing. Self-sampling addresses many of the barriers to conventional screening (cervical cytology): women can take their own sample, in private and at a time and place of their choosing. Self-sampling is slightly less accurate than HPV testing on clinician-taken samples, so would not be suitable as a primary screening test. UK studies have already shown that HPV self-sampling can increase screening uptake in non-attenders but the optimal approach for offering self-sampling kits (SSK) is unclear. London has consistently has the lowest cervical screening uptake nationally making it an ideal population to assess the potential for self-sampling and provide the evidence-base for its implementation in England. This will be a randomised-controlled pilot to establish the optimal study design for a large implementation trial of self-sampling.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Brighton & Sussex Research Ethics Committee, 27/11/2017, ref: 17/LO/1655

Study design
Randomised; Both; Design type: Screening, Other, Cohort study

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

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

Condition
Cervical cancer

Interventions
This will be a randomised controlled pilot study at ~12 GP practices in London within the Hounslow Clinical Commissioning Group (CCG). Each GP practice will recruit over a period of 12 months and will be randomised 1:1 to:
1. An intervention arm - offering self-sampling kits (SSK) opportunistically to women who are overdue cervical screening by at least 6 months, when they consult for any reason, or
2. A control arm – usual care

Within both arms, women will also be individually randomised. Women who have not been screened (by cytology or self-sampling) ever or by the 15 month or 27 month anniversary of the date their last test was due will be randomised 2:1:1 to:
Group A – usual care (control)
Group B – Receiving a letter inviting them to order a SSK
Group C – Receiving a SSK in the post

STUDY PROCEDURES
1. Opportunistic offering of self-sampling
Eligible women will be automatically flagged during consultation using the electronic patient record software. GPs, nurses and healthcare practitioners will:
-confirm eligibility
-briefly explain the study
-provide a SSK to those willing to take part
-document which women are offered, accept and decline SSK in the electronic patient records

Women will collect their self-sample in the GP surgery bathroom or at home. Samples will be sent to a commercial laboratory (The Doctor's Laboratory (TDL)) for analysis. Women who take their sample at the GP practice will hand it to a member of staff who will send it to the lab via the post (daily) using postage paid envelopes. Samples taken by women at home will be posted to the lab (postage paid envelope).

2. Women who have never been screened or reach the 15 or 27 month anniversary of their last test due date
Women will be identified using the GP electronic patient records and randomised by the GP practice. Women randomised to Group B or C will receive and return SSKs in the post.
Women randomised to receive a letter inviting them to order a SSK will have several options for ordering kits: online, via post and possibly text message.

HPV TEST RESULTS REPORTING
HPV test results from kits sent to or ordered by women will be sent by the lab to the women and copied to their GP.

CLINICAL MANAGEMENT
Women who test HPV negative will not be required to do anything further for the study. Women who test HPV positive will be advised to have a routine clinician-taken cervical screening test at their GP practice. They will be managed according to their cytology results under the NHS cervical screening programme.

DATA COLLECTION
We will collect details of the participant's cervical screening results from their GP medical records. We will also collect anonymous aggregate data on cervical screening for all eligible women (including those who do not return a self-sample) from the national screening database in order to calculate coverage.

RESIDUAL SAMPLES
Residual samples will be anonymised by the laboratory and sent to researchers at Queen Mary University for possible future analysis.

Intervention Type
Other

Primary outcome measure
This is a pilot study therefore there is no formal primary outcome measure. The study will calculate measures of feasibility and acceptability such as the proportion of eligible women who are offered kits, accept and return a self-sample following each intervention (i.e. (i) opportunistic offer of self-sampling kits, (ii) women invited to order a self-sampling kit, and (iii) women sent self sampling kit) at 6 months and 12 months after the invitation/offer of self sampling

Secondary outcome measures
1. The proportion of eligible women who test HPV positive and a) attend for follow up (cytology or colposcopy) within 6 months of testing HPV positive on a SS and b) who are treated for CIN2+
2. "Coverage" of cervical screening following different interventions – when additionally counting an HPV negative test on self-sample as "screened"
3. Use of website in the intervention arm (women invited to order a kit)

Overall study start date
27/11/2017

Overall study end date
24/11/2021

Eligibility

Participant inclusion criteria

1. Women aged 25-64 years
2. Eligible for cervical screening
3. At least 6 months overdue (i.e. no cervical screening recorded in the GP records in the past 3.5 years if aged 25-49 or 5.5 years if aged 50-64)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
8420

Total final enrolment
12657

Participant exclusion criteria
Women unable to provide informed consent

Recruitment start date
09/04/2019

Recruitment end date
31/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Thornbury Road Centre for Health
Thornbury Road
Isleworth
United Kingdom
TW7 4HQ

Study participating centre
Albany Practice
Boston Manor Road

Brentford Health Centre
Brentford
United Kingdom
TW8 8DS

Study participating centre
Argyle Health - Isleworth Practice
146 Twickenham Road
Isleworth
United Kingdom
TW7 7DJ

Study participating centre
The Practice Heart Of Hounslow
92 Bath Road
Hounslow
United Kingdom
TW3 3LN

Study participating centre
Chiswick Health Centre
Fisher's Lane
London
United Kingdom
W4 1RX

Study participating centre
Grove Park Surgery
95 Burlington Lane
Chiswick
London
United Kingdom
W4 3ET

Study participating centre
Grove Park Terrace Surgery
25 Grove Park Terrace
Chiswick
United Kingdom
W4 3JL

Study participating centre
Wellesley Road Practice
7 Wellesley Road
Chiswick
London
United Kingdom
W4 4BJ

Study participating centre
The Medical Centre - Twickenham Park Medical Surgery
192 Twickenham Road
Twickenham
Feltham
United Kingdom
TW13 6HD

Study participating centre
Gill Medical Practice
32 Harlington Road East
Feltham
United Kingdom
TW14 0AB

Study participating centre
Crosslands Surgery
1 Crosslands Avenue
Southall
United Kingdom
UB2 5QY

Study participating centre
Firstcare Practice
Blenheim Centre
Prince Regent Road
Hounslow
United Kingdom
TW3 1NL

Study participating centre

Hounslow Family Practice
77 Lampton Road
Hounslow
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK; Grant Codes: C8162/A16892

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/03/2024

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 9.0	12/10/2021	15/08/2022	No	No
HRA research summary			28/06/2023	No	No