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The Westminster self-sampling study for women who do not attend for cervical screening

Submission date	Recruitment status	[_] Prospectively registered
15/04/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/05/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2020	Cancer	

Plain English summary of protocol

Background and study aims:
The NHS Cervical Screening Programme has a target is to ensure that 4 out of 5 women are screened. However, it has been seen that this is not consistent throughout the population. In recent years, young women (under 30 years) have been showing a greater reluctance to attend for smears, due to fear of the examination.
A screening programme can only be successful if it covers a large proportion of the population coverage. It has been proven that those who do not attend are at higher risk of developing cervical cancer. As a result, any measure which would encourage women to take part would save lives and also would save the National Health Service (NHS) money, due to reduced costs of cancer treatment.

Who can participate?
3000 women, aged 25 64 years living in the Westminster Primary Care Trust (PCT) area, who have not responded to two cervical screening invitations.

What does the study involve?
Self–sampling means the woman can perform a test (using a swab, a bit like a long cotton bud) in the comfort
and privacy of her own home. We have already carried out studies which have shown that women of quite different educational levels find this easy to do without supervision, using a leaflet which we developed with the help of psychologists. There are around 16,000 women within Westminster PCT who have not responded to two invitations to come for a smear test. We propose to randomly select 3000 of them: half will just be sent a further invitation for a smear and the other half will be sent a self–sampling kit, together with information. We will compare the response rates, both to the initial screening test, and to follow up investigations, for those who have a positive test. A control group (will not receive a self–sampling kit) will simply be sent a third invitation to attend for a smear.

What are the possible benefits and risks of participating?
As these women have not previously attended for their cervical smears, they may benefit by

having an
abnormality discovered before it becomes serious. They may also be reassured by having a normal result.

Where is the study run from?
Centre for Cancer Prevention, Wolfson Institute, Queen Mary University of London

When is study starting and how long is it expected to run for?
The study started in May 2009, and ended in May 2011.

Who is funding the study?
NIHR - Research for Patient Benefit Programme ref: PB-PG-0407-13358

Who is the main contact?
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Study website
http://www.screening-study.org.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00977392

Secondary identifying numbers
1

Study information

Scientific Title
The potential role of self-sampling in women who do not attend for cervical screening: a randomised controlled trial

Study objectives
The NHS Cervical Screening Programme has stated that its target is to ensure that 80% of eligible women are screened. Although overall this target is being reached, it is recognised that uptake is not consistent throughout the population. In recent years, young women (aged under 30 years) have been showing a greater reluctance to attend for smears, with fear of the examination being cited as a factor.

A screening programme can only be successful if it achieves high population coverage, and it is well documented that those who do not attend are at higher risk of developing cervical cancer. Therefore any measure which would encourage such women to take part would save lives and also would save the NHS money, in terms of reducing costs of invasive cancer treatment.

Many women find having a cervical smear embarrassing and unpleasant, even among those who are willing to have them done. We know that around a quarter of the women who are invited to have a smear do not go for the test at all. There are various reasons for this, but important ones are the anticipation that the test will be embarrassing, may be performed by a man (they are not aware they can insist on a woman) and may be painful. Far from improving, in recent years attendance for screening appears to be falling, especially among women under 30 years.

Self-sampling means the woman can perform a test (using a swab, a bit like a long cotton bud) in the comfort and privacy of her own home, without the need for a speculum (which is the instrument used to open the vagina and which is responsible for the discomfort which may be felt). We have already carried out studies which have shown that women of quite different educational levels find this easy to do without supervision, using a leaflet which we developed with the help of psychologists. A study in the Netherlands has recently shown that a third of women who had not gone for a smear, did send back a self-sample. If we even got a fifth of women in the UK, who have not gone for their smear, to send in a self-sample, it would save lives and it would save the NHS money (because it costs much more to treat a cancer than to do smears and investigate abnormalities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Mary's Research Ethics Committee (REC) approved on the 1st October 2008 (ref: 08/H0712 /88)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Can be found at http://www.screening-study.org.uk/

Health condition(s) or problem(s) studied
Cervical cancer

Interventions
A randomised screening study with two groups allocated either to receive an invitation for a routine cervical smear or human papillomavirus (HPV) self-sampling test.
Control group: sent a further invitation letter for cervical screening and cervical screening survey
Study group: sent a self-sampling test kit and an invitation to take their own HPV sample and return it to the research group for processing. They will also be sent the cervical screening survey.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Comparison of the percentages of women responding to the invitation to return a self-sampling kit versus responding to an invitation for a cervical smear, measured 5 months from the beginning of recruitment.

Secondary outcome measures
1. Response to the invitation for further investigation following a positive test result (colposcopy for women with a smear showing mild dyskaryosis or above, smear +/- colposcopy for those with a positive HPV test), measured 14 months from the beginning of recruitment
2. Response to the request to return a survey regarding demographic information and reasons for previous non-attendance for screening, measured 12 months from the beginning of recruitment

Overall study start date
15/05/2009

Completion date
01/05/2011

Eligibility

Key inclusion criteria

1. Women aged between 25 - 64 years
2. Eligible for routine cervical screening
3. Have not responded to two invitations to attend for smears

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
3000

Key exclusion criteria
1. Women who have written to the primary care trust (PCT) to document their refusal to take part in the NHSCSP
2. Women who are not due routine screening as part of the NHSCSP
3. Pregnancy
4. Total abdominal hysterectomy
5. Never been sexually active

Date of first enrolment
15/05/2009

Date of final enrolment
01/05/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cancer Research UK
London
United Kingdom
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Sponsor information

Organisation
Queen Mary University of London (UK)

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ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) (ref: PB-PG-0407-13358)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/03/2011		Yes	No