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Strategies to increase cervical screening uptake at first invitation

Submission date	Recruitment status	[X] Prospectively registered
04/08/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/08/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/10/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-ways-increasing-number-of-young-women-who-take-up-offer-of-cervical-screening-strategic

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 09/164/01

Study information

Scientific Title
STRATEGIes to increase Cervical screening uptake at first invitation: a cluster randomised trial

Acronym
STRATEGIC

Study objectives
How effective, and cost effective, are complex interventions designed to increase receptivity to, and uptake of, cervical screening in women aged 25 who are receiving their first invitation to the NHS Cervical Screening Programme?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0916401
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0005/55193/PRO-09-164-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
REC within Greater Manchester via IRAS - approval pending as of 05/08/2011

Study design
Cluster randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised 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

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

Interventions
1. Pre-leaflet arm (Phase 1) - Surgeries will be cluster randomised with women either receiving the pre-leaflet in combination with a standard invitation letter or the standard invitation letter alone.
2. Internet booking arm (Phase 1, Manchester only) - Surgeries will be cluster randomised to

women either receiving a standard invitation and reminder letter which gives them the opportunity to book online or the standard invitation and reminder letter alone.
3. Self-sampling arm (Phase 2) - Surgeries will be cluster randomised to women receiving the offer of a self-sampling test compared with standard practice of a reminder letter.
4. Nurse navigator arm (Phase 2) - Surgeries will be cluster randomised to women receiving the offer of speaking to a specialist nurse compared with standard practice of a reminder letter.
5. Timed appointment arm (Phase 2) - Surgeries will be cluster randomised to women receiving a timed appointment from their general practitioner (GP) compared with standard practice of a reminder letter.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The uptake of cervical screening:
1.1. In response to the pre-leaflet (phase 1)
1.2. In response to the offer of each of the interventions (nurse navigator, self-sampling, timed appointments) (phase 2)
2. The uptake of internet booking (phase 1)

Measured at 3, 12 and 30 months after the date the woman become eligible for cervical screening (i.e. her 25th or 20th birthday).

Secondary outcome measures
1. The differences between outcomes in Aberdeen between vaccinated and unvaccinated women
2. The differences between Aberdeen and Manchester
3. Cost-effectiveness of the interventions, individually and as packages of interventions

Overall study start date
01/11/2011

Completion date
31/10/2015

Eligibility

Key inclusion criteria
Women aged 25 in Manchester and 20 in Aberdeen who are due to receive their first invitation for cervical screening

Participant type(s)
Patient

Age group
Adult

Sex

Female

Target number of participants
9,600

Total final enrolment
10126

Key exclusion criteria
1. Women who are not aged 25 (20 in Aberdeen) and receiving their first invitation for screening will not be eligible to participate
2. Women who are pregnant
3. Women who do not have a cervix
4. Women who have made an informed decision not to participate in the cervical screening programme

Date of first enrolment
01/11/2011

Date of final enrolment
31/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
c/o Professor Nalin Thakker
Oxford Road
Manchester
England

United Kingdom
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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
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/09/2016		Yes	No
Results article	results	01/06/2018	27/08/2019	Yes	No
Plain English results			25/10/2022	No	Yes