ISRCTN15082468 https://doi.org/10.1186/ISRCTN15082468

Increasing cervical cancer screening uptake in Yorkshire

Submission date
29/11/2021

Recruitment status
No longer recruiting

Registration date
01/12/2021

Overall study status
Completed

Last Edited
02/07/2024

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Cervical cancer screening aims to detect abnormal changes in the cervix. If left untreated, these changes can lead to cancer. There are a lot of things that can get in the way of going for cervical cancer screening. Research shows that if people can spot situations that might stop them from getting screened and then link them with solutions to overcome these, they are more likely to go for screening. Research also suggests that people tend to underestimate how many people like them go for screening, and this can put them off attending. The public health service would like to improve screening rates. The aim of this study is to test new materials to see if they increase the number of women going for cervical cancer screening.

Who can participate?
A randomly selected group of patients aged 24.5-65 years invited to take part in cervical cancer screening will also be asked to take part in this study on the specific day the study is taking place.

What does the study involve?
Some participants will receive some extra information through the post which will explain the numbers of people currently attending cervical cancer screening. Other participants may also have been sent a plan to go for screening which they will be asked to fill in. The researchers will then compare screening levels in all the people sent extra materials, 4 months later as well as a group of women sent an information sheet, but no additional materials.

What are the benefits and risks of taking part?
There are no disadvantages except the time that it takes to read the information provided. The benefit is that participants may be helping to improve cervical cancer screening services for their own and others' future health needs.

Where is the study run from?
University of Leeds and the NHS cervical cancer screening programme (UK)

When is the study starting and how long is it expected to run for?
January 2019 to April 2022

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Prof. Daryl O'Connor, d.b.oconnor@leeds.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Prof Daryl O'Connor

Contact details
University of Leeds
Woodhouse Lane
Leeds
United Kingdom
LS2 9JT
via MS Teams
D.B.OConnor@leeds.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
268639

Protocol serial number
IRAS 268639

Study information

Scientific Title
Increasing cervical cancer screening uptake in Yorkshire: testing the effectiveness of a behaviour change intervention in deprived and non-deprived populations

Study objectives
The aim of this research is to test a low-cost behaviour change intervention in the North of England. A randomised controlled trial will test two interventions individually and combined: (a) Implementation intention based intervention, (b) a motivational based intervention, (c) both these interventions combined, (d) usual care control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 12/10/2020, The Cervical Screening Research Advisory Committee (PHE Screening, Wellington House, 133-155 Waterloo Road, London, SE1 8UG, UK; +44 (0)20 3682 0890;

screening.research@phe.gov.uk) ref: CSPRAC_0050
2. Approved 25/03/2021, North East -Newcastle & North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8139, +44 (0)207 104 8285, +44 (0)203 443 6294; newcastlenorthtyneside1.rec@hra.nhs.uk), REC ref: 21/NE/0033
3. Approved 30/03/2021, NHS Confidentiality Advisory Group (CAG) (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8100; cag@hra.nhs.uk), ref: 21/CAG/0021
4. Approved 19/05/2021, Public Health England Office of Data Release Office for Data Release (Public Health England, Wellington House, 133 – 155 Waterloo Road, London, SE1 8UG, UK; +44 (0) 20 7654 8030; odr@phe.gov.uk) ref: CSPRAC_050 (ODR1920_239)
5. Approved 20/07/2021, NHS England DRAB Corporate Information Governance (NHS England and Improvement, Quarry House, Quarry Hill, Leeds, LS2 7UE, UK; Tel: not available; England.pdrm@nhs.net) ref: CSPRAC_050 (ODR1920_239)

Study design
Randomized controlled trial using a factorial design with four arms

Primary study design
Interventional

Study type(s)
Screening

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

Interventions
Randomisation will be at the individual level in blocks of four:
1. Implementation intention only
2. Motivational intervention only
3. Combined implementation intention and motivational intervention
4. Usual care control group

Participants will receive the intervention according to the arm that they are allocated to.

The implementation intervention will use a Volitional Help Sheet (VHS) which enables participants to form ‘if-then’ plans by connecting barriers associated with screening with potential solutions that could be applied if the barriers are encountered. The content of these barriers and solutions have been identified from previous research and through free text responses on an online survey and qualitative interviews which have identified a wide range of barriers and facilitators. To ensure the intervention is tailored to each participant given they will choose the situation and solutions that match their own needs, thereby, accounting for differences in terms of age and deprivation.

The basis of the motivational intervention is a Social Norm Approach (SNA) based on social norms theory. Social norms theory suggests that people falsely perceive the attitudes and/or behaviours of important others to be different from their own there is a tendency for individuals to underestimate the extent to which their peers engage in health behaviours which may discourage performance of the behaviour. The motivational intervention will provide accurate information about the percentage of women currently engaging in cervical cancer screening.

The combined intervention includes both the motivational and volitional interventions being sent to participants.

Intervention Type
Behavioural

Primary outcome(s)
Cervical cancer screening uptake as indicated by participant screening records at 16-week follow-up

Key secondary outcome(s))
1. Age of participants on the date of the intervention mailing
2. Socioeconomic status as indicated by the index of multiple deprivation quintile derived from the participant's postcode on the date of the intervention mailing

Completion date
06/04/2022

Eligibility

Key inclusion criteria
1. Participants eligible for cervical cancer screening
2. Aged 24.5 - 65 years
3. From Clinical Commissioning Groups (CCGs) based in Yorkshire, Humber and North East regions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Individuals not eligible for cervical cancer screening
2. Individuals outside of the 24.5 - 65 year age limits
3. Located outside of the eligible CCGs
4. Those opting out of their data being used for research (national data opt-out)

Date of first enrolment
09/12/2021

Date of final enrolment
09/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Leeds
Woodhouse Lane
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research

Alternative Name(s)
YCR

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to study ethics and data protection, raw data is not able to be shared by the study authors.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes