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Understanding anxiety and attendance in cervical screening

Submission date
07/05/2019

Recruitment status
No longer recruiting

Registration date
03/06/2019

Overall study status
Completed

Last Edited
19/07/2023

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Human papillomavirus (HPV) is a common sexually transmitted infection which causes nearly all cervical cancers. There are around 3,000 new cases of cervical cancer every year in the UK. The NHS Cervical Screening Programme (NHSCSP) aims to prevent cervical cancer by looking for abnormal cells in the cervix and removing them before they turn into cancer. The NHSCSP will soon test all cervical screening samples for HPV before deciding whether to look for abnormal cell changes. This is called HPV primary testing and it will be rolled out across England from 2019. This means that all women attending cervical screening will learn their HPV test results through letters delivered to their home. The results letters will tell women whether they are HPV positive or HPV negative, as well as whether they have any abnormal cell changes. It is very important that psychological research helps decide what NHSCSP results letters and information leaflets say. It is known that knowledge about HPV and its connection to cervical cancer is poor among women in the UK, and that some women can get upset, confused and/or experience stigma after testing positive for HPV, partly because of it being sexually transmitted. Therefore, the wording and information in NHSCSP letters needs to make sense and be clear so that women correctly understand their risk of getting cervical cancer. It is also very important that women are not worried about their results if they do not need to be. In HPV primary testing, one group of women who might especially struggle to understand their screening results is those who test positive for HPV but have no abnormal cell changes. This is because they will find out they have HPV, but they will not get invited to screening again for another 12 months and will not get any treatment. This is because although HPV puts them at higher risk of getting cervical cancer, without any abnormal cell changes it is very unlikely that they will get cervical cancer within 12 months. It is likely that their immune system will get rid of HPV in this time. However, this can be complicated for women to understand and difficult for the NHSCSP to know how to communicate in letters. The researchers think that some women in this group may not understand these test results. It is important that these women are not too worried or upset about their test results, and they come back to cervical screening again in 12 months. The aim of this study is to identify psychological predictors of anxiety and attendance in women testing HPV positive with no abnormal cell changes, with a sub-study built in to test whether the application of behavioural science in cover letters influences response rate. An interview study also assesses anxiety and beliefs in women testing HPV positive with normal cytology.

Who can participate?
Women aged 24-65 who have tested positive for HPV with normal cytology within the last 2 weeks at NHSCSP HPV primary screening

What does the study involve?
Anxiety and beliefs about HPV are assessed in women testing positive for HPV with normal cytology within 2 weeks of receiving their test result.
Participants are randomly allocated to receive either a standard invite to participation cover letter or a cover letter that uses behavioural science techniques (wording, format, layout etc), to see whether this influences the response rate.
Participants fill in a questionnaire and send it back to UCL using a pre-paid envelope provided. They can also indicate whether they would like to be considered for a confidential 1:1 interview 2-8 weeks later. If they select “yes, I would like to be considered” in their questionnaire, and they are chosen to take part, the interview lasts for around 1-1.5 hours and is audio-recorded. Participants are asked about their views on their test result and cervical screening, and their opinion on information to include in NHS test results letters.

What are the possible benefits and risks of participating?
There are no guaranteed benefits from taking part in this study. However, participation will contribute to important research and may help to improve the quality of NHS services for other women in the future. Participants may also find taking part in this research enjoyable and interesting.

Where is the study run from?
1. NHS London North West Trust (UK)
2. NHS Manchester University Trust (UK)

When is the study starting and how long is it expected to run for?
October 2017 to December 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Emily McBride
e.mcbride@ucl.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Emily McBride

Contact details
1-19 Torrington Place
Department of Behavioural Science and Health
University College London (UCL)
London
United Kingdom

N7 9FU
+44 (0)207 679 1940
e.mcbride@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DRF-2017-10-105; 39303

Study information

Scientific Title
HPV primary testing in cervical cancer screening: using behavioural science to understand anxiety and attendance

Study objectives
What are the strongest predictors of anxiety in women testing positive for HPV with normal cytology?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/08/2018, East Midlands - Leicester South Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, Tel: +44 (0)207 104 8107; Email: nrescommittee.eastmidlands-leicestersouth@nhs.net), Research Ethics Committee ref: 18/EM/0227, Confidentiality Advisory Group ref: 18/CAG/0118

Study design
Observational cross-sectional, with embedded RCT (study within a trial; SWAT) and a separate qualitative study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)

Screening

Participant information sheet

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

Interventions
The primary observational component is assessing anxiety and beliefs about HPV in women testing positive for HPV with normal cytology within 2 weeks of receiving their test result. It is a cross-sectional study (one timepoint).

The interventional component is testing whether the use of behavioural science techniques (wording, format, layout etc) within invite to participation cover letters vs standard invite to participation cover letters influences recruitment response rate. Approached patients are randomised to receive the control or intervention invite letter to take part in the study. This is also cross-sectional (one timepoint).

Participants fill in a questionnaire and send it back to UCL using a pre-paid envelope provided. They can also indicate whether they would like to be considered for a confidential 1:1 interview 2-8 weeks later. If they select “yes, I would like to be considered” in their questionnaire, and they are chosen to take part, the interview will last for around 1-1.5 hours and will be audio-recorded. Participants will be asked about their views on their test result and cervical screening, and their opinion on information to include in NHS test results letters.

Intervention Type
Behavioural

Primary outcome measure
For the observational component:
State anxiety and anxiety specific to cervical screening, measured using the State Trait Anxiety Inventory (S-STAI-6) and Cervical Screening Questionnaire (CSQ), respectively

For the interventional component:
Participation response rate

All outcomes measured at one timepoint only

Secondary outcome measures
1. Illness beliefs measured using B-IPQ
2. Symptom perception measured using adapted IPQ-R
3. Coping style measured using adapted Brief COPE
4. Concerns about HPV, disclosure of results, intention to re-attend screening, barriers to screening re-attendance, all measured using questions developed for the study
5. Prospective 12-month screening attendance, measured using clinical records
6. Demographics including: ethnicity, marital status, and highest level of education (all self-report)
7. Age, index of multiple deprivation score, number of previous cervical screens, and NHS site, collected via clinical records
8. Self-reported history of anxiety or depression

All outcomes with the exception of prospective 12-month cervical screening attendance measured at one timepoint only

Overall study start date
01/10/2017

Completion date
31/12/2020

Eligibility

Key inclusion criteria
Women aged 24-65 who have tested positive for HPV with normal cytology within the last 2 weeks at NHSCSP HPV primary screening

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
300

Total final enrolment
646

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
07/05/2019

Date of final enrolment
01/05/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

NHS London North West Trust
Pathology Department
London
United Kingdom
HA1 3UJ

Study participating centre
NHS Manchester University Trust
Cytology Centre
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
University College London (UCL)

Sponsor details
Joint Research Office
Gower Street
London
England
United Kingdom
WC1E 6BT
+44 (0)203 447 2198
uclh.randd@nhs.net

Sponsor type
University/education

Website
www.ucl.ac.uk/jro

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Research findings will be disseminated via internal report, presented at scientific conferences and published in peer-reviewed journals.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Emily McBride (e.mcbride@ucl.ac.uk). Only quantitative data will become available and will be anonymised, it will become available after the work has been published.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/12/2021	20/12/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative study	09/09/2020	19/07/2023	Yes	No
Results article		21/04/2021	19/07/2023	Yes	No