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An abnormal Pap smear and the impact of notification manner on women's health-related quality of life, coping and awareness of human papillomavirus

Submission date
22/11/2017

Recruitment status
No longer recruiting

Registration date
02/01/2018

Overall study status
Completed

Last Edited
02/01/2018

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
A pap smear is a test that detects any abnormal cells on the cervix which is the entrance to the womb from the vagina. The notification of an abnormal Pap smear can create negative psychological reactions. The aim of this study is to assess if a phone call notification of an abnormal Pap smear delivered by a trained healthcare provider have an effect on women's health-related quality of life (HRQoL) and coping, as well as women's awareness of human papillomavirus (HPV).

Who can participate?
Women aged 23-65 years old who have an abnormal Pap smear.

What does the study involve?
Participants are allocated to one of two groups. Those in the first group are notified about their Pap smear via a phone call by a trained healthcare provider. Those in the second group receive their results from a standard letter. Participants are followed up using a questionnaire to assess their quality of life, awareness of HPV and their coping abilities.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their quality of life and coping abilities after hearing their have an abnormal pap smear. There are some questions in the questionnaire about the women's sex life, which could intrude on women's integrity. Getting a questionnaire could raise question by itself and create anxiety among the women. For this, a curator is contacted and has given her permission for anxious women to calling her.

Where is the study run from?
Women's Health Clinic, Kalmar län (Sweden)

When is the study starting and how long is it expected to run for?
December 2015 to May 2017

Who is funding the study?
Linnaeus University (Sweden)

Who is the main contact?
Ms Marie Rask

Contact information

Type(s)
Scientific

Contact name
Ms Marie Rask

ORCID ID
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Notification of an abnormal Pap smear: An intervention study

Study objectives
A phone call notification of an abnormal Pap smear delivered by a trained healthcare provider minimizes the negative psychological consequences of receiving the test result.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee for Human Research Faculty of Health Sciences Linköping University, 16/12/2015, ref: Dnr 2015/338-31

Study design
Interventional non randomised controlled study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
An abnormal Pap smear result. Diagnosed as ASC-US+HR-HPV, LSIL+HR-HPV or HSIL.

Interventions
Participants who have an abnormal Pap smear are consecutively recruitment from a womens health clinic. Participants are allocated to one of two groups. Those in the intervention group receive their results of their Pap smear from a phone call by a trained healthcare provider and those the control group receive a standard letter.

The intervention consists of a phone call with a trained healthcare provider notifying the abnormal Pap smear. The training includes lectures and forum play. Healthcare providers at the women's health clinic participate in two half-day lectures. The education focuses on ethics, as well as factual knowledge about the cervical cancer screening program, HPV, abnormal Pap smear result and treatment. Thereafter, led by a drama teacher, ten of the healthcare providers participate in a one day education with forum play focused empathetic communication. Furthermore, healthcare providers are designated to notify women their abnormal Pap smear orally by phone. This phone call provides an opportunity for the women to have a dialogue with the healthcare provider and express their concerns and have questions answered. Women in the comparison group are notified about their abnormal Pap smear by an ordinary standard letter according to the routine of the women's health clinic.

The outcomes are assessed using a self-administrated questionnaire, which the women filled out a week after they had been notified their abnormal Pap smear result.

Intervention Type
Behavioural

Primary outcome measure

1. Satisfaction with the notification manner regarding their test result is measured using the self-administrated questionnaire at week one
2. Health related quality of life is measured using the Functional Assessment of Chronic Illness Therapy-Cervical Dysplasia (FACIT-CD) and the Hospital Anxiety and Depression Scale (HADS) at week one

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
10/12/2015

Completion date
02/05/2017

Eligibility

Key inclusion criteria
1. Women aged 23–65-years old
2. Diagnosed with ASC-US + HR-HPV, or LSIL + HR-HPV, or HSIL

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Intervention gorup: 113 women, and the comparison group 122 women

Key exclusion criteria
Diagnosed with cervical cancer.

Date of first enrolment
01/02/2016

Date of final enrolment
28/04/2017

Locations

Countries of recruitment
Sweden

Study participating centre

Women's Health Clinic, Kalmar län
Landstinget i Kalmar län
Box 601
Kalmar
Sweden
391 26

Sponsor information

Organisation
Kamprad Family Foundation

Sponsor details
Västra Esplanaden 3
Växjö
Sweden
352 30

Sponsor type
Charity

Website
http://familjenkampradsstiftelse.se/fakta/kontakt/

ROR
https://ror.org/03qb1q739

Funder(s)

Funder type
University/education

Funder Name
Linnéuniversitetet

Alternative Name(s)
Linnaeus University

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Publication and dissemination plan
We plan to send the study to Acta Obstetricia et Gynecologica Scandinavica.

Intention to publish date
11/12/2017

Individual participant data (IPD) sharing plan
The women´s name or address is not expected to be made available, and it is looked up in a cabinet that only Marie Rask had access to. The data from the women´s answer in the questionnaire is imputed in the SPSS, and coded, and that dataset could be obtained from Marie Rask.

IPD sharing plan summary
Not expected to be made available