

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	<input type="checkbox"/> Prospectively registered
Registration date 02/01/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/01/2018	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
<https://orcid.org/0000-0002-1569-6675>

Contact details
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Sweden
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Additional identifiers

Protocol serial number
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

Study type(s)

Quality of life

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 recruited from a women's 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 in 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 on 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-administered questionnaire, which the women filled out a week after they had been notified their abnormal Pap smear result.

Intervention Type

Behavioural

Primary outcome(s)

1. Satisfaction with the notification manner regarding their test result is measured using the self-administered 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

Key secondary outcome(s)

There are no secondary outcome measures.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

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

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