The effects of additional information on fear and stress in women with an abnormal cervical smear result.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27208

Source
Nationaal Trial Register

Brief title
colposcopy-fear study

Health condition

abnormal cervical smear
colposcopy
fear
stress

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre
Source(s) of monetary or material Support: Fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

1. The scores on the Spielberger STATE and TRAIT Anxiety Inventory (STAI);

2. The effect of information on the anxiety, fear and quality of life among women with an abnormal pap-smear result.

Secondary outcome

1. Differences in scores of anxiety, depression and quality of life questionaires in and between group A and B;

2. Relations between demographic characteristics and questionaire scores;

3. Knowledge level of pap-smear results, HPV, and colposcopy in each group;

4. Differences in knowledge level of pap-smear results, HPV, and colposcopy between both groups;

5. Cross relations between knowledge, satisfaction with information, anxiety, depression, and quality of life in group A and B.

Study description

Background summary

Rationale:

An abnormal Pap smear result can affect a woman’s life in a negative manner. Women do not anticipate abnormal smear results and are taken by surprise. It frequently results in fears of cancer and worries about reproduction. In order to reach the greatest benefit from the screening programme, it seems to be important to decrease the fear and anxiety, and to improve information supply.

Objective:

This study will be conducted to see whether providing information on an individual level reduces fear and stress in women with an abnormal cervical smear result referred to the colposcopy clinic.

Study design:

Randomized controlled trial.

Study population:

The study population will consist of all new patients, 18 years and older, who are referred for colposcopic evaluation due to an abnormal Pap smear result.

Intervention:

One group (A) will consist of patients who receive extra information on a personal level. The other group (B) will consist of patients who will receive no extra information on the Pap smear result, the colposcopy and the possible treatment.

Main study parameters:

The effect of information on the anxiety, fear and quality of life among women with an abnormal Pap smear result.
The differences in scores of anxiety, depression and quality of life between group A and B.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

A researcher will contact patients by phone after they have made their first appointment at the colposcopy clinic. The participants who are randomized in group A will receive additional information. On arrival, prior to their first appointment, all participating patients are requested to fill out the following validated anxiety, depression and quality of life surveys: Hospital Anxiety and Depression scale (HADS), the Spielberger State and Trait Anxiety Inventory (STAI), and the Rand 36, as well as a short self-administered questionnaire, containing questions on demographics, knowledge of cervical cancer, knowledge of Human Papillomavirus (HPV), and the provided information.

Study objective

This study will be conducted to see whether providing information on an individual level reduces fear and stress in women with an abnormal cervical smear result referred to the colposcopy clinic.

Study design

All questionnaires will be completed just before the planned colposcopy.

Intervention

Group A will consist of patients who receive extra information on a personal level. Meaning that the pap-smear result, the colposcopy, and the possible treatment will be explained by phone. Questions from the patient will be answered. After this phone call extra brochures containing information on the study, the diagnosis, the colposcopy, and the possible treatment, will be sent by mail.

Group B will consist of patients who will conceive no extra information on the pap smear results, the colposcopy and the possible treatment. The patients will receive the usual/standard information brochures on colposcopy. The means of the study will be explained by phone. Questions from the patients will be answered.

Contacts

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Eligibility criteria

Inclusion criteria

1. New patient referred for colposcopy with an abnormal pap-smear result;

2. Signed informed consent;

3. Age 18 years or above;

4. Mentally capable to understand and comprehend the study and its implications;

5. Sufficient knowledge of the Dutch language to read and understand the information brochures, and to answer the questionnaires.

Exclusion criteria

A former referral for colposcopic evaluation due to an abnormal cervical smear result.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-12-2007
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-01-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2038
NTR-old	NTR2155
Other	CMO / ABR dossiernr. : 2007/072 / NL17056.091.07
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A