The effect of video information on anxiety levels in women attending colposcopy: A randomized controlled trial.

No registrations found.

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

Summary

ID

NL-OMON24406

Source
NTR

Brief title
Colposcopy-fear study

Health condition

Anxiety, Stress, Abnormal cervical smear, Colposcopy, Video information.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. The scores on the Spielberger STATE and TRAIT Anxiety Iventory (STAI); the Hospital Anxiety and Depression scale (HADS); Visual Analog Score (VAS) and the SF12;

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, pain and quality of life questionnaires in and between group A and B;

2. Relations between demographic characteristics and questionnaire scores;

3. Cross relations between knowledge, satisfaction with information, anxiety, depression, perceiving pain, 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 fear of cancer and worries about fertility. Further, women have uncertainty about what is going to happen and what the colposcopic procedure entails. 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. These anxiety levels before primary colposcopy are not reduced by individually targeted information. There is little information that video information will reduce anxiety levels before colposcopy.

Objective:

This study will be conducted to evaluate whether providing video information before colposcopy reduces fear 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 will consist of patients who receive the standard information leaflet and additional video information. The control group will consist of patients who will only receive the standard information leaflet.

Main study parameters:

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

Study objective

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

Study design

T0: After informed consent, alle participating patients are requested to fill out all questionnaires;

T1: Before colposcopy all patients are requested to fill out all questionnaires;

T2: After colposcopy all patients are requested to fill out all questionnaires.

Intervention

Group A will consist of patients who receive the standard information leaflet and additional video information before colposcopy. Meaning that the Pap smear result, the colposcopy, the possible treatment, and some of the matters that surround will be explained by a gynecologist. Also, the hospital, the department, reception desk, room and examination will be showed in this video.

Group B will consist of patients who receive only the standard information leaflet on the Pap smear result, the colposcopy and the possible treatment. The means of the study will be explained by phone. No verbal information will be given during this phone call on medical issues.

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 video, and to answer the questionnaires.

Exclusion criteria

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

2. Pregnant women;

3. Women with mental impairment;

4. No signed informed consent;

5. Age below 18 years;

6. Insufficient knowledge of the Dutch language to understand the video, and to answer the questionnaires.

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):	01-07-2012
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-06-2012

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	NL3325
NTR-old	NTR3472
Other	METC / CCMO : 2007/072 / NL17056.091.07;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
"The role of individually targeted information to reduce anxiety before colposcopy: a randomised controlled trial"
RP de Bie, LFAG Massuger, CH Lenselink et al.