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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27208

Bron
Nationaal Trial Register

Verkorte titel
colposcopy-fear study

Aandoening

abnormal cervical smear
colposcopy
fear
stress

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre
Overige ondersteuning: Fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

All questionnaires will be completed just before the planned colposcopy.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-12-2007
Aantal proefpersonen:	128
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-01-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A