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

Gepubliceerd: 11-06-2012 Laatst bijgewerkt: 18-08-2022

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.

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

Samenvatting

ID

NL-OMON24406

Bron
NTR

Verkorte titel
Colposcopy-fear study

Aandoening

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

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre
Overige ondersteuning: Radboud University Nijmegen Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

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 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Dept of obstetrics/gynecology 791
Radboud University Nijmegen Medical Centre
P.O. Box 9101
P.J.W. Ketelaars
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3613198

Wetenschappelijk

Dept of obstetrics/gynecology 791
Radboud University Nijmegen Medical Centre
P.O. Box 9101
P.J.W. Ketelaars
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3613198

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 video, and to answer the questionnaires.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2012
Aantal proefpersonen:	128
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-06-2012

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

Resultaten

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