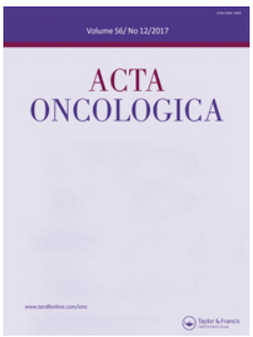

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ORIGINAL ARTICLE

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

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ABSTRACT

Objective: The aim was to investigate whether additional information, in video form, reduces anxiety, depression and pain levels in women referred for colposcopy.

Material and methods: Between September 2012 and March 2015, 136 patients referred for colposcopy were randomized into two study arms. Group A received video information in addition to the regular information leaflet, and group B (control group) received only the regular information leaflet. The patients were requested to complete standardized online questionnaires. The first online questionnaire (T1) was pre-randomization, and was completed at home, 5 days prior to the appointment. The second online questionnaire (T2) was completed directly before the colposcopy appointment, and the last online questionnaire (T3) was completed directly following colposcopy at the out-patient clinic. The questionnaires included the Spielberger State-Trait Anxiety Inventory (STAI), the Hospital Anxiety and Depression Scale (HADS), and the Numeric Rating Scale (NRS) to assess pain.

Results: The STAI state anxiety score was high (44.6), but there was no significant difference in STAI, HADS and NRS between the two groups at the three measuring points. A *post hoc* analysis showed that women with a generally higher baseline anxiety trait had significantly lower HADS anxiety levels following video information.

Conclusions: Additional information (video) before colposcopy did not significantly reduce anxiety, depression, and expected or experienced pain, as measured by the STAI, HADS and NRS in patients attending their first colposcopy appointment. However, most patients positively appreciated the video information, which may reduce the anxiety of extremely anxious patients.

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Introduction

Every 5 years, women aged 30–60 years in the Netherlands are invited for a cervical smear taken by their general practitioners (GPs) or practice assistants (nursing assistants, specifically trained to take cervical smears). About 77% of the invited women participate in the national program for cervical screening every year [1]. At present, 1–2% of the cervical smears require referral for colposcopy at the gynecologist's [2]. However, with the introduction of detection of primary high-risk human papillomavirus (hrHPV) on the cervical smear in 2017, this referral rate is expected to double [3].

Women may experience high levels of anxiety and negative emotional responses at all stages of screening for cervical cancer [4–7]. Colposcopy has been shown to be associated with high levels of anxiety, higher than before surgery. These levels are similar to women's anxiety levels following a screening test that indicates fetal abnormalities [8]. Apart from the fear of having cancer, their concerns consist of fear of pain, uncertainty about the colposcopic procedure, disappointment in their own body, sexual anxiety, and worries about reproduction [6,8].

It has been proven that women who consider the information provided by the gynecologist is inadequate have significantly higher anxiety levels. Women who have to wait a long time or who do not have a partner also have significantly higher anxiety levels. These high levels of anxiety before and during colposcopy may have several consequences including pain, discomfort and failure to return for follow-up [8]. A recent study shows even long-term (12-month) effects of emotional and physical distress after colposcopy [9]. Decreasing the levels of fear and anxiety is important to improve screening efficacy.

Qualitative research indicates that practical and detailed information provided to women may reduce stress and anxiety. Especially preparatory sensory and procedural information is needed [7,10]. However, some studies show that providing written information about abnormal cervical smears and colposcopy or offering extra information at the individual level by mail and by phone do not reduce anxiety [4,6].

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It is important to reduce the anxiety of women referred for colposcopy because of the expected higher referral rates in the new screening program. Several studies have tried to reduce anxiety, but most have achieved no positive results [8]. However, a pilot study has shown that video information on a videotape reduces anxiety significantly [11]. Since that study (1999), new, more accessible media have become available to patients for information gathering. This may lead to a better understanding of abnormal cervical smears. Therefore, the primary aim of this study was to evaluate whether digital video information compared to no additional information is effective in reducing anxiety, pain and depression in women who are referred for colposcopy.

Material and methods

Inclusion and randomization

General practitioners refer all women with an abnormal cervical smear for colposcopy. Women who were referred to the colposcopy clinic of the Radboud University Medical Center Nijmegen (Radboudumc, The Netherlands) between September 2012 and March 2015 were invited to participate in this study. Direct referral indications for colposcopy in the Netherlands are moderate dyskaryosis or worse (equaling high-grade squamous intraepithelial lesion). Furthermore, women with two consecutive smears with [1] abnormal squamous cells of undetermined significance or with low-grade squamous intraepithelial lesion and [2] a positive hrHPV test were referred for colposcopy.

All newly referred women older than 18 years who had adequate knowledge of the Dutch language were eligible for inclusion. All women referred for colposcopy received the standard information brochure about the colposcopy procedure with their appointment data by post. A study information letter and an informed consent form were also sent.

Subsequently, we called all the eligible women by phone to evaluate their willingness to participate in the study. The participants received a unique identification number and an internet link by e-mail, and we asked them to complete an online questionnaire before their colposcopy appointment. After the first online questionnaire (T1), the participants were computer-randomized into one of the two groups; blinding was not possible in this study. Group A received an internet link and a password for additional online video information. They were given access to the video on a secured website for a maximum of four times from a home computer, tablet or phone. The control group (group B) received no additional information. The investigators were notified when the women started the video information online. Informed consent was obtained from all participants. The local ethics Committee for Human Research approved the study (NTR3472).

Questionnaires

The participants were asked to complete three different online questionnaires at three measuring points: (1) at baseline before randomization to compare groups, (2) before colposcopy to measure any effect of the video intervention, and (3) after colposcopy to measure any long-term effect of the intervention. The investigators were notified automatically after completion of every online questionnaire. The first online questionnaire (T1) was completed at home before colposcopy and contained the Hospital Anxiety and Depression Scale (HADS), the State and Trait Anxiety Inventory (STAI), the RAND-12 Health Status Inventory (RAND-12 HSI), and the expected pain with the Numeric Rating Scale (NRS).

All participants were asked to arrive at the clinic at least 15 min before the scheduled colposcopy appointment to complete the second online questionnaire (T2). The second online questionnaire again contained the HADS, a short version of the STAI, the expected pain (NRS) and some additional sociodemographic questions. The third online questionnaire (T3) contained a short version of the STAI and the experienced pain (NRS), and it was completed directly following the colposcopy.

To measure depression before colposcopy, we used the HADS created by Zigmond and Snaith [12], a 14-item self-report screening scale. It contains two 7-item scales: one for anxiety and one for depression. All items are scored on a 4-point scale from 0 to 3.

We used the short version of the STAI to assess the state and trait anxieties [13]. The state anxiety represents feelings 'at the present moment', while the trait anxiety stands for anxiety 'in general'. Therefore, differences in state anxiety may reflect any anxiety differences caused by the video information. The state and trait measures each consist of 10 items measured on a 4-point scale, ranging from 'not at all' to 'very much'. The total scores range between 20 and 80, with higher scores indicating a greater anxiety level.

The RAND-12 HSI is a short 12-item version of the RAND-36 HSI. The purpose of the RAND-12 HSI is to provide estimated scores for the physical health, mental health and global health composites of the 36-item instrument [14]. We used the NRS to measure pain during colposcopy. The scale ranges from 0 (no pain) to 10 (worst imaginable pain).

Video information

The information video was specifically designed and tested by women to reduce anxiety before colposcopy. We determined the content of the video on the basis of an earlier focus group study [7]. This video included images of the hospital, the outpatient clinic with reception, the waiting and examination rooms, and the medical staff. A gynecologist explained abnormal smears, the course of the consultation, and possible treatment. The aim of this video was to provide information that might reduce anxiety and stress for women referred for colposcopy. The duration of the video was 11 min.

Sample size and statistical analysis

Sixty-four participants were needed for each group in order to find a decrease of 6 points on the STAI scores with 80% power, a 5% difference between both groups, and a standard

deviation of 12, based on the previous research [4]. Therefore, we needed a total of 128 participants. Analyses were done by intention to treat. We used Student's *t*-test for scale variables with a normal distribution and the Mann–Whitney U-test for ordinal or continuous variables without normal distribution. We used SPSS version 20 (IBM, Armonk, New York) for all statistical analyses. Additional information on videotape might give more benefit to women who are more anxious. Therefore, we analyzed the data for women with high trait anxiety at the measurement moment T1 separately in a *post-hoc* analysis. We also did a per-protocol analysis.

Results

A total of 151 women were included in the study between September 2012 and March 2015. Fifteen (9.9%) women were excluded because they did not complete the first questionnaire before their appointments ($n = 5$) or for logistic reasons ($n = 10$: illness, holiday and computer/internet connection failure). We randomly assigned 136 women to group A ($n = 66$) and group B ($n = 70$). Three women in group A and five in group B were not included in the analysis because they did not complete the second questionnaire. There were then 63 women in group A and 65 women in group B for analysis (Figure 1). Nine (14.3%) women in group A did not watch the information video prior to colposcopy.

Baseline and clinical characteristics

The first questionnaire was completed within 5 days (range 1–48) before the colposcopy appointment. No statistical differences in baseline characteristics were found between group A and group B (Table 1). The anxiety and depression levels, as well as physical, mental and overall health were comparable for the two groups. The mean STAI state anxiety levels were 39.3 in group A and 39.2 in group B ($p = .938$). The mean STAI trait anxiety levels were 37.4 in group A and 35.0 in group B ($p = .168$). The expected pain measured with the NRS was 4.5 in both groups ($p = .936$).

Outcome measures

Table 2 presents the outcome measures according to intention to treat. Neither the state anxiety levels measured by the STAI nor the anxiety or depression levels measured by the HADS were significantly different between the two groups after the video information. The mean STAI state anxiety levels were 44.3 in group A and 44.9 in group B ($p = .752$). The mean HADS anxiety levels were 6.2 for group A and 6.7 for group B ($p = .491$). The mean HADS depression levels were 2.8 in group A and 3.4 in group B ($p = .406$). Expected pain measured with the NRS showed no significant difference between the groups ($p = .342$).

The NRS was measured after colposcopic examination in the last questionnaire. Group A had a mean NRS score of 3.9 and group B, 4.1 ($p = .602$). Several participants remarked in the last questionnaire that they really appreciated the video information. Some quotes from the last questionnaire: 'It was very pleasant to see the video in advance. It really gave me an impression what to expect'. 'The information video was very clear and, as a result, I was well prepared'. 'After reading the information leaflet I became more anxious. After watching the video I was less anxious'. (The quotes have been translated from Dutch to English.) Only one participant said that neither the information leaflet nor the information video reassured her.

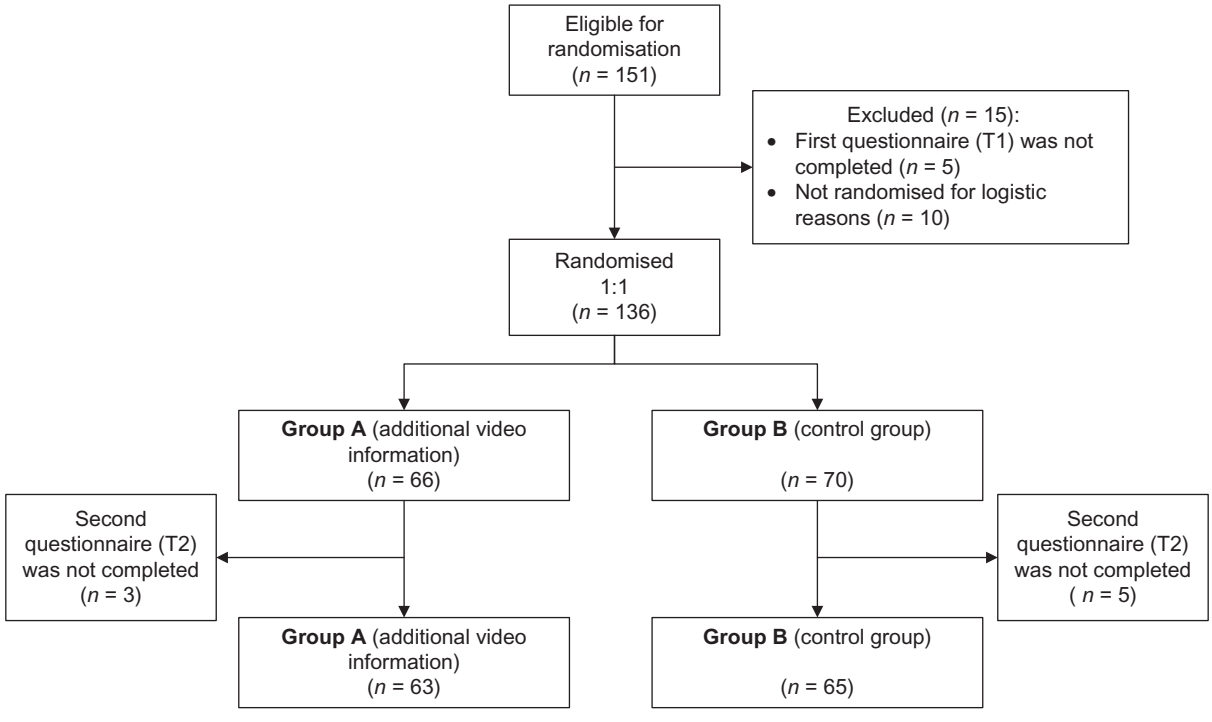

Figure 1. Flowchart.

Table 1. Baseline and clinical characteristics.

	Group A (additional video information) $n = 63$	Group B (control) $n = 65$	p Value
Age			
Mean (range in years)	35 (22–60)	37 (21–61)	.359*
Highest level of education			
Primary education	0 (0.0%)	0 (0.0%)	.279**
Preparatory secondary vocational education	12 (19.0%)	6 (9.2%)	
Senior general, secondary vocational or pre-university education	17 (27.0%)	21 (32.3%)	
Higher professional education or university	34 (54.0%)	38 (58.5%)	
Marital state			
Single, divorced, or widowed	21 (33.3%)	26 (40.0%)	.467**
Steady relationship, married, and/or cohabiting	42 (66.7%)	39 (60.0%)	
Parity			
No	28 (44.4%)	33 (50.8%)	.485**
Yes	35 (55.6%)	32 (49.2%)	
Reason for referral			
National screening	21 (33.3%)	19 (29.2%)	.291**
Repeated national screening	15 (23.8%)	27 (41.5%)	
Complaints	20 (31.7%)	14 (21.5%)	
Fertility treatment pathway	4 (6.3%)	4 (6.2%)	
Control	2 (3.2%)	1 (1.5%)	
Social support to clinic			
No	23 (36.5%)	17 (26.2%)	.254**
Yes	40 (63.5%)	48 (73.8%)	
Had read leaflet at T1			
No	3 (4.8%)	8 (12.3%)	.206**
Yes	60 (95.2%)	57 (87.7%)	
Had read leaflet at T2			
No	0 (0.0%)	1 (1.5%)	1.000**
Yes	63 (100.0%)	64 (98.5%)	
Treatment during colposcopy			
No	25 (39.7%)	23 (35.4%)	.581**
Yes	35 (55.6%)	41 (63.0%)	
Missing data	3 (4.6%)	1 (1.5%)	
Completed the first questionnaire before colposcopy			
Mean (range in days)	5 (1–48)	5 (1–29)	.776*
HADS anxiety before intervention			
Mean (SD)	6.1 (3.6)	6.6 (4.3)	.503*
HADS depression before intervention			
Mean (SD)	3.0 (3.5)	3.1 (3.6)	.882*
STAI state anxiety before intervention			
Mean (SD)	39.3 (11.9)	39.2 (12.1)	.938*
Median	36.5	38.5	
STAI trait anxiety			
Mean (SD)	37.4 (10.9)	35.0 (8.5)	.168*
Median	35.0	34.0	
NRS expected pain before intervention			
Mean (SD)	4.5 (2.4)	4.5 (2.2)	.936*
RAND-12 physical health			
Mean (SD)	47.7 (10.7)	50.6 (7.7)	.080*
RAND-12 mental health			
Mean (SD)	47.2 (10.0)	48.9 (8.6)	.303*
RAND-12 global health			
Mean (SD)	46.8 (10.7)	49.4 (8.1)	.121*

*Student's *t*-test.
**Mann–Whitney *U*-test.
HADS, Hospital and Anxiety Depression Scale; NRS, Numeric Rating Scale; RAND-12, RAND-12 Health Status Inventory; STAI, State-Trait Anxiety Inventory.

Post-hoc *analysis*

In the *post-hoc* analysis, we explored whether women with a generally higher anxiety level benefit more from video information. Twenty-four women in group A and 16 women in group B with a trait anxiety level higher than 38 at T1 were identified. The HADS anxiety level of the 24 women in group A was significantly lower after watching the video at measurement moment T2: 7.2 in group A and 9.0 in group B ($p = .018$). However, the STAI showed no significant difference (49.8 in group A versus 53.7 in group B; $p = .132$). Furthermore, in the per-protocol analyses, there were 54 women in group A and 74 women in group B. There were no significant differences between the two groups in STAI or HADS.

Discussion

In this randomized-controlled study, we studied anxiety, depression, and expected pain between two groups of women referred for colposcopy. One group did receive additional information (video) before colposcopy and the other did not. This additional information before colposcopy did not significantly reduce anxiety, depression or expected pain,

Table 2. Outcome measures.

	Group A (additional video information) $n = 63$	Group B (control) $n = 65$	Total $n = 128$	p Value
HADS anxiety after intervention				
Mean (SD)	6.2 (4.4)	6.7 (4.6)	6.4 (4.5)	.491*
HADS depression after intervention				
Mean (SD)	2.8 (3.6)	3.4 (3.9)	3.1 (3.8)	.406*
STAI state anxiety after intervention				
Mean (SD)	44.3 (10.7)	44.9 (11.0)	44.6 (10.8)	.752*
Median	44.0	44.0	44.0	.706**
NRS expected pain after intervention				
Mean (SD)	4.2 (2.5)	4.6 (2.2)	4.4 (2.3)	.342*
STAI state anxiety after colposcopy				
Mean (SD)	37.5 (10.5)	40.4 (11.7)	39.0 (11.2)	.144*
Median	35.5	39.0	37.0	.185**
NRS experienced pain during colposcopy				
Mean (SD)	3.9 (2.6)	4.1 (2.8)	4.0 (2.7)	.602*

*Student's *t*-test.
**Mann–Whitney *U*-test.
HADS, Hospital and Anxiety Depression Scale; NRS, Numeric Rating Scale; STAI, State-Trait Anxiety Inventory.

as measured by the STAI, HADS and NRS for women attending their first colposcopy appointment.

This result contrasts with the result of Freeman–Wang and colleagues' pilot study [11]. Their study reports a statistical difference on the STAI state anxiety scale between the intervention group and the control group. The video that Freeman–Wang used was comparable to the video information used in this study in that it contains images of the clinic as well as the nursing and medical staff, outlines the nature of abnormal smears, and explains the consultation and/or treatment that may follow [11]. A possible explanation for the lack of effect of video information in our study may be the easy access to a variety of information sources via internet nowadays, which was lacking at the time of the Freeman–Wang study in the late 1990s. An indication supporting this theory is the difference in mean state anxiety levels between the studies. The mean state anxiety score of the 128 women visiting our clinic was 44.6 (SD 10.8), which is lower than the average of 51.1 (SD 13.3) found in the Freeman–Wang study. The anxiety scores in the English study may have been higher because the participants had fewer opportunities to get information themselves. Additionally, our *post-hoc* analysis shows that women with higher anxiety levels do benefit from video information, and this may explain the discrepancy between our study and Freeman–Wang's study.

In the Dutch population, the mean state anxiety score of adult women is 38.8, with an SD of 13.2 [13]. Before colposcopy, women experience high levels of distress and an elevated state anxiety level [6,15]. The mean observed state anxiety score in our study was 44.6, which is concordant with other studies [4,6,16,17]. Interventions consisting of individually targeted information did not reduce anxiety. However, high levels of stress and anxiety may also be associated with better adherence to treatment and follow-up after colposcopy, as fear of cancer may be motivating [4]. Nevertheless, evidence regarding this potential correlation remains inconclusive [18].

Pain expectations are also associated with pre-colposcopy distress [16]. Kola et al.'s [16] earlier study shows that expected pain evokes a natural, negative response. Our study shows a slightly lower expected pain score in the video information group, but this was not significant when compared to the control group score.

In Bosgraaf and colleagues' [7] focus group study, psychological stress before colposcopy was caused by unsatisfactory explanations of abnormal smears and the colposcopy procedure itself. We note that GPs often do not inform patients beforehand about the possible abnormal results of cervical smear tests and how such results should be interpreted [19]. It is difficult for GPs to reassure women that most of the positive smear results do not necessarily mean cancer [19]. To improve the cervical screening program, it is important that women receive standardized information. Video information is a simple intervention, and it could reduce consultation time. It has the additional advantage that every woman receives the same information.

One of the limitations of this study is the lack of any predefined clinically important differences in STAI score in the literature. We have used a 6-point decrease as a clinically relevant difference because this has been used in other studies. However, it remains uncertain whether a 6-point decrease in anxiety is clinically relevant.

In conclusion, video information did not significantly reduce the anxiety levels of women referred for their first colposcopy. Nevertheless, there was a high patient satisfaction rate, and a small trend in anxiety reduction in the video information group, especially among the more anxious women. Because video information provides all the women with the same type of correct information and because women responded positively to the video, clinics should consider offering video information to women referred for colposcopy.

Disclosure statement

The authors declare that they have no conflict of interest with regard to any of the material presented in this paper.

Contribution to authorship

We confirm that each author has contributed materially to the paper and that no individuals qualified for authorship have been omitted. The order of authorship is related to the relative individual contributions.

Details of ethics approval

The institutional review boards approved the study protocol (2007/072 and NL17056.091.07), and the study is registered in the Dutch Trial Register (NTR- 3472).

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