Title: The effect of Virtual Reality information videos on anxiety in patients visiting the one-stop-clinic for women with Abnormal Uterine Bleeding.

Short name: VISION-study

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Design: Prospective

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Background

Over the past years, several gynecological procedures, such as hysteroscopy and endometrial ablation have turned into common outpatient procedures. Certain 'one-stop', 'see and treat' services are used for acute gynecology conditions for patients with severe menorrhagia, irregular vaginal bleeding, pelvic pain, and postoperative complications. (1) In our clinic, Máxima Medical Center Veldhoven, we have access to such an outpatient service where diagnostic and therapy can be performed. The main reason for people to visit the outpatient clinic is because they suffer from severe menorrhagia or irregular vaginal bleeding. Diagnostic tools such as hysteroscopy and therapy like removing small myomas or polyps can be performed.

This move from inpatient to outpatient health care has been seen in all medical specialties, because the outpatient setting is convenient and cost-effective. A recent systematic review reported that women undergoing outpatient hysteroscopy suffer from significant levels of preoperative anxiety, comparable to those experienced before major surgery under general anesthesia. Besides, this preoperative anxiety was associated with increased postoperative pain, nausea and vomiting. This suggests that there is a big difference between the clinician’s view of minimally invasive procedures and the expectations of the patient about these procedures. (2)

In our clinic, we perform several ‘minimally invasive’ procedures in a one-stop-clinic with a see-and-treat approach. Gupta et al reported about patient’s experiences associated with these clinics. They concluded that outpatient hysteroscopy is associated with significant anxiety. However, dissatisfaction was not associated with the outpatient clinics (3). Anxiety is defined as an "abnormal and overwhelming sense of apprehension and fear often marked by physiological signs, doubt concerning the reality and nature of the threat, and by self-doubt about one's capacity to cope with it". (2) There are several reasons for being anxious before or during the procedure. For instance some people are anxious for visiting a hospital in general, performing the several gynecological procedures. Also the possible outcome of the examinations can cause many concerns.

These conclusions make it important that effort should be made to develop interventions that could help in preventing or reducing anxiety. Common methods are pharmacological interventions with anxiolytics, sedatives and pain medication. Patient education is perhaps even more important in anxiety reduction. Clarity is an important factor when giving patient education, for instance by visualizing information through video. Video education for surgery and medical interventions improves immediate and short-term knowledge, but to date, an effect on general anxiety (and anxiety and satisfaction with the consent process) is not uniformly shown. (4) Authors who did show a decreased level of anxiety after video educating emphasize on the good quality of the video and the use of patient input for developing it. (5) Because of sterility issues, it is impossible to have a 'life guided tour' through the operation room, but virtual reality video might be a realistic alternative, giving the perception already having experienced the medical procedure.

Currently, there is no literature on the use of *virtual reality* videos for patient education.

Virtual reality might literally add a dimension to patient education. One advantage of virtual reality compared to 'normal videos' is that the person can 'watch away' if they expect something scary or confronting might be shown. With virtual reality video, patients themselves will be in charge of what they see. This might help to make such videos more accessible.

Also, videos can be made in different languages very easily and, additionally, videos in general may be more accessible than written information for people with low literacy.

The hypothesis is that current information methods (written information and verbal information by the care provider) on a visit to our one-stop-clinic for women with Abnormal Uterine Bleeding may be further improved by using virtual reality videos to reduce anxiety and providing clarity about the procedure.

Methods

Hypothesis

- **Primary Hypothesis:**

- Anxiety or distress will be reduced in patients visiting our outpatient clinic for Abnormal Uterine Bleeding by providing patient information through 360˚VR.

· **Secondary Hypothesis:**

- Patients will be better informed about the procedure of the Abnormal Bleeding outpatient clinic through Virtual Reality compared to information given through normal care.
- The experience of the treatment will be more positive resulting in less delay when a patient again will have to undergo the same procedure in the outpatient clinic.

All women older than 18 years that are planned for a first visit to our one-stop-clinic Abnormal Uterine Bleeding will be included. Woman without knowledge of the Dutch language and women with the indication of postmenopausal bleeding will be excluded.

Approximately two weeks before their visit, woman will be asked by telephone if they want to participate in this study, after being informed about the study. During this conversation other inclusion – and exclusion criteria will be asked directly to the patient. If interested, patients will receive the information folder. Patients are not told what information tool is used and that virtual reality video is the subject of our study, so they are blinded. The researcher will ask for informed consent. The women will fill out an online questionnaire before randomization. Subsequently, the women will be randomized into 2 groups: 1 group (intervention group) who will receive normal care and additionally, get informed by virtual reality (VR) about the outpatient clinic and a second group (control group) receiving standard information (written and verbal information). To avoid cross-over, the virtual reality video is only accessible for those women who are randomized to the VR group. They will get instructions on how to download the application, and a code to see the video. The video can only be opened on one phone per code and will no longer be available after their visit to the clinic. Patients will receive a cardboard, where they can place their phone, to use the virtual reality video.

Patients of both groups will receive a questionnaire at the day of the visit in the waiting room. Directly after the investigations and/or treatment, women will receive a questionnaire about their information

requirement and experience during the visit. Also the doctor who sees the patient during the one-stop-clinic will fill out a questionnaire regarding the performed examinations and overall impression of the patient.

Normal care is defined as the written information brochures about the one-stop-clinic from our hospital.

Inclusion criteria:

- Adults (>18 years) that are planned to visit our one-stop-clinic Abnormal Uterine Bleeding for the first time

Exclusion criteria:

- Postmenopausal bleeding
- Poor understanding of the Dutch language
- Prior visit for abnormal uterine bleeding in our or other clinic
- Current psychological treatment for pain or anxiety disorders
- Severe psychosocial problems (such as anxiety disorders and depression)
- Medical history of mental disorders
- Hearing or visual impairment such as stereoscopy, blindness or nystagmus

Explanatory variables:

- Demographics: age, race, BMI
- Obstetric and gynecological history
- Medical history in general
- Visiting the clinic alone or with partner or friend
- Waiting time
- Use of premedication

- The indication for the visit
- Ways of information obtained (appointment doctor, flyer, stories friends, YouTube films, etc.)

Virtual reality

- 360 degree virtual reality videos are provided to patients in the intervention group. They will receive a unique password to install and watch (unlimited) the video on their smartphone (placed in a cardboard) and/or tablet. We will record the number of times patient watched the video.

Time schedule

Moments of measurements

1. Before randomization
2. At the day of the visit in the waiting room
3. Directly after the visit
    a. Questionnaire for patient
    b. Short questionnaire for gynecologist

Measured variables before randomization

- Visual analogue scale of Anxiety (VAS-A)
- State-Trait Anxiety Inventory (STAI-S)

Measured variables before the visit in the waiting room:

- Demographics
- Visual analogue scale of Anxiety (VAS-A)
- State-Trait Anxiety Inventory (STAI-S)
- General questions on information provision
- Premedication, medical history in general and obstetric and gynecological history

Measurements during the visit:

- Waiting time
- Impression of the anxiety assessed by the gynecologist/resident

- Impression of how well a patient is informed, assessed by the gynecologist/resident
- Impression of the progress of the procedure in relation to any anxiety
- Report of possible complications

Measured variables directly after the visit

- VAS-A
- Evaluation of information

Statistical Analysis

Descriptive statistics are used to describe the data; frequencies with percentages are used for categorical variables, mean and standard deviation are used for normally distributed continuous variables.

Power Analysis

Based on the primary outcome measurement VAS-A we will include about 40 patients in both the intervention and control group.

$Z\alpha = 1.96$ 2-tailed 0.05 hypothesis test

$Z\beta = 0.842$ power = 0.8

Effect size $(\mu 1 - \mu 2)/\sigma = 0.2$

$N = 2(Z\alpha + Z\beta)^2 / [(\mu 1 - \mu 2)/\sigma]^2 = 2(1.96 + 0.84)^2 / 0.2^2 = 39.25$

Discussion References

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