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The effect of virtual reality information videos on anxiety in patients visiting the outpatient clinic of women with abnormal uterine bleeding

Submission date
02/04/2021

Recruitment status
No longer recruiting

Registration date
09/04/2021

Overall study status
Completed

Last Edited
04/05/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Abnormal uterine bleeding (AUB) is bleeding from the uterus that is longer than usual or that occurs at an irregular time. Bleeding may be heavier or lighter than usual and occur often or randomly.
The aim of this study is to investigate whether adding a virtual reality video to the standard information leaflet about the one-stop clinic 'Abnormal uterine bleeding' reduces anxiety.

Who can participate?
Women older than 18 and suffering from abnormal uterine bleeding, referred for a first consultation at the one-stop clinic 'Abnormal Uterine Bleeding' in Máxima MC.

What does the study involve?
Participants are randomly allocated to either the virtual reality group or the control group. The latter only receives the standard information leaflet about the clinic. Women in the VR group receive the standard information leaflet and a virtual reality video about the one-stop clinic.

What are the possible benefits and risks of participating?
Women in the virtual reality group receive additional information about the clinic, which possibly reduces anxiety. There is a small risk of motion sickness during or after watching the VR video.

Where is the study run from?
Máxima Medical Centre Veldhoven (the Netherlands)

When is the study starting and how long is it expected to run for?
November 2016 to September 2017

Who is funding the study?
Máxima Medical Centre Veldhoven (the Netherlands)

Who is the main contact?
Imke Reinders, imke.reinders@maastrichtuniversity.nl

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
N17.053

Study information

Scientific Title
The effect of VIrtual Reality information videos on anxiety in patients viSIting the ONe-stop-clinic for women with abnormal uterine bleeding

Acronym
VISION

Study objectives
Anxiety or distress will be reduced in patients visiting our outpatient clinic for abnormal uterine bleeding by providing patient information through 360˚ virtual reality videos.

Ethics approval required
Old ethics approval format

Ethics approval(s)
On 03/04/2017 the researchers received a statement from their local institutional review board that no ethics approval was required (METC Máxima MC, PO Box 7777, 5500 MB Veldhoven, De Run 4600, 5504 DB Veldhoven, The Netherlands; +31 (0)40 888 95 28; metc@mmc.nl)

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Anxiety prior to visiting a one-stop clinic for women with abnormal uterine bleeding

Interventions
Prior to their first visit at the one-stop-clinic for Abnormal Uterine Bleeding, women were informed about this study by telephone. They were not explicitly informed about the role of virtual reality, but that the effect of a new method of patient education was investigated. The women were randomized by computer-generated block randomization. Women in the control group received standard care, which consisted of an information leaflet about the one-stop clinic with a reference to online information on the hospital website. Women in the intervention group received the standard information and were given access to a virtual reality information video about the clinic.

Intervention Type
Other

Primary outcome(s)
Anxiety measured using the visual analogue scale (VAS-anxiety) at baseline (measured before randomization) and in the waiting room before visiting the one-stop clinic

Key secondary outcome(s))
1. Anxiety measured using the visual analoge scale (VAS-anxiety) during the visit (measured directly after the visit)
2. Anxiety measured using the State-Trait Anxiety Inventory (STAI-a) at baseline and in the watiting room
3. Feelings before the visit (feeling prepared, feeling worried, the feeling that better counseling would be helpful) measured on a questionnaire using a 5-point Likert scale in the waiting room.
4. Opinion about the received information about the clinic (completeness, quality, comprehensibility, remembering the information, satisfaction about the information, usefulness of the virtual reality video) measured on a 5-point Likert scale directly after the visit
5. Impression about counselling and anxiety of the women reported by the gynecologist on a 5-point Likert scale, reported at the end of the visit

Completion date
21/09/2017

Eligibility

Key inclusion criteria

1. Every woman suffering from abnormal uterine bleeding, referred for a first consultation at the one-stop clinic 'Abnormal Uterine Bleeding'
2. Women over the age of 18

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
88

Key exclusion criteria
1. Poor understanding of the Dutch language
2. Referral to the clinic because of postmenopausal bleeding
3. Referral to the clinic with another reason than abnormal uterine bleeding

Date of first enrolment
10/04/2017

Date of final enrolment
11/09/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
Máxima Medical Centre
PO box 7777
De Run 4600
Veldhoven
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5500 MB

Sponsor information

Organisation
Máxima Medisch Centrum

ROR
https://ror.org/02x6rcb77

Funder(s)

Funder type
Other

Funder Name
Investigor initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. The data will be available until 10 years after completion of this trial. All data are anonymized. The reason for viewing data must be mentioned and the researchers will judge if they give insight in (a part of) the dataset

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/05/2021	No	Yes
Protocol file			04/05/2021	No	No