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Virtual reality used to reduce anxiety before a gynaecologic surgery or during chemotherapy - is it working?

Submission date
23/10/2025

Recruitment status
Recruiting

Registration date
28/10/2025

Overall study status
Ongoing

Last Edited
28/10/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Preoperative anxiety poses a significant challenge in gynaecologic surgery, affecting patient outcomes and healthcare costs. Virtual reality (VR) relaxation therapy show s promise as an alternative intervention, supported by literature findings and a survey revealing high patient interest. This study aims to investigate the effectiveness of VR relaxation therapy in reducing preoperative anxiety levels, potentially informing innovative approaches to anxiety management in surgical settings. In the second part, the effect of VR relaxation on patient wellbeing during application of chemotherapy or Immunotherapy for a gynaecological malignancy will be analysed. Previous studies found a reduction of side effects from chemotherapy in patients with lower levels of stress and anxiety.

Who can participate?
Female patients above the age of 18 years scheduled for elective gynaecological surgery (part I) or IV cancer treatment (arm II)

What does the study involve?
The study involves a VR therapy of 15 minutes with relaxing film and music as well as the filling out questionnaires.

What are the possible benefits and risks of participating?
Benefits:
1. Reduction in anxiety and stress
2. Enhanced patient comfort and satisfaction
3. Non-invasive intervention with a minimal risk of adverse effects
Risks:
1. Potential discomfort during VR sessions
2. Limited generalizability of study findings
3. Time and resource constraints for implementation of VR therapy sessions

Where is the study run from?
Inselspital Bern, Frauenklinik (Switzerland)

When is the study starting and how long is it expected to run for?
August 2025 to September 2026

Who is funding the study?
1. Angela Reiffer Stiftung (Switzerland)
2. Johanna-Dürmüller-Bol Stiftung (Switzerland)
3. Parrotia Stiftung (Switzerland)

Who is the main contact?
Dr Flurina Saner, flurina.saner@insel.ch

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
01

Study information

Scientific Title
Virtual reality – an emerging source for relief of anxiety in patients undergoing gynaecologic surgery or during chemotherapy? A randomised controlled clinical trial

Acronym
VRelax

Study objectives
Aim 1: The primary objective of the study is to evaluate the efficacy of Virtual Reality Relaxation Therapy in reducing preoperative anxiety levels among adult female patients undergoing elective gynaecological surgery.
Aim 2: In women requiring chemotherapy for a gynaecological cancer, we aim to analyse if the use of Virtual Reality Relaxation Therapy during application of intravenous chemotherapy improves patient wellbeing.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/08/2025, Kantonale Ethikkommission (KEK) (Murtenstrasse 31, Bern, 3010, Switzerland; +41 (0)31 633 70 70; katharina.kunzelmann@be.ch), ref: 2025-00877

Study design
Single-center non-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Anxiety before surgery and during chemotherapy

Interventions
Method of Randomization: via REDcap

Part I:
1. Ambulatory vs stationary (x2)
2. Suspected or diagnosed cancer vs benign (x2)
3. Aged 18-59 years vs 60+ years (x2)

Part II:
1. Chemo (single agent and combined treatment) vs immuno-/targeted-/antibody therapy (x2)
2. Breast vs gynaecological cancer (x2)
3. Aged 18-59 years vs 60+ years (x2)

There are two arms with the same layout, but in ‘different’ situations:
1: VR Therapy prior to gynaecological operation
2: VR Therapy during application of chemotherapy/immunotherapy

During the study intervention, participants will be equipped with VR goggles to provide a relaxing VR session. The investigator will adjust the goggles while the patient lies in bed or sits on a chair and will play a 15-minute video featuring nature scenes and relaxing music.

The VRelax videos have been produced for this study specifically; all participants can choose one out of three 4K high-resolution videos available based on their interest. The three videos available contain relaxing nature scenes (landscapes and animals) on either snow/winter,

underwater scenes or savannah. Patients can remove the goggles and stop the intervention at any time, and the investigator will demonstrate how to do so. The investigator will monitor the patient for any signs of distress during the session and assist in removing the goggles afterward. In case of early termination of the VR procedure, the timepoint will be recorded. This approach ensures a controlled, supportive environment to maximize the effectiveness of VR relaxation therapy in reducing anxiety and stress.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
VR goggles (MetaQuest 3)

Primary outcome(s)
Anxiety measured by the Hamilton Anxiety Score Hospital Anxiety and Depression Scale (HADS) before and after the VR intervention

Key secondary outcome(s))
1.Anxiety measured by the Amsterdam Preoperative Anxiety and Information Scale (APAIS) before and after the VR intervention
2. Anxiety measured by Visual Analogue Scales for Anxiety (VAS-A) before and after the VR intervention
3. Stress in arm I measured by cortisol sputum levels before and after the VR intervention
4. Side effects of chemotherapy measured by anamnesis 3 days after the VR intervention

Completion date
01/09/2026

Eligibility

Key inclusion criteria
1. Female gender
2. Aged 18 years or older
3. Scheduled for elective gynaecological surgery (arm I) or IV cancer treatment (arm II)
4. Absence of severe visual or mental impairments
5. Willing and able to consent
6. No epilepsy or depression or anxiety disorder

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Aged below 18 years
2. Severe motion sickness
3. Pre-existing epilepsy, depression or anxiety disorder
4. Significant respiratory disease requiring continuous oxygen administration
5. Medical conditions requiring intensive medical care
6. Inability to wear the VR device
7. Pregnancy

Date of first enrolment
11/11/2025

Date of final enrolment
01/09/2026

Locations

Countries of recruitment
Switzerland

Study participating centre
Inselspital Bern, Frauenklinik
Friedbühlstrasse 12
Bern
Switzerland
3010

Sponsor information

Organisation
Frauenklinik Inselspital Bern

Funder(s)

Funder type
Charity

Funder Name
Angela Reiffer Stiftung

Funder Name
Dürmüller-Bol Stiftung

Funder Name
Parrotia-Stiftung

Alternative Name(s)
Parrotia Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date (01/01/2027)

IPD sharing plan summary
Data sharing statement to be made available at a later date