

Video-assisted vs conventional surgical informed consent in visceral surgery, a cluster-randomized clinical trial

Submission date 28/10/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/10/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/10/2025	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study looks at two different ways of giving patients information before surgery: the traditional face-to-face talk with a doctor, and a video explanation. The goal is to see if using a video can save doctors time while still helping patients understand their surgery and feel satisfied with the information they receive.

Who can participate?

Patients who are having either their gallbladder removed or part of their colon removed at the University Hospital of Würzburg can take part in the study.

What does the study involve?

Participants are randomly placed into one of two groups. One group watches a video that explains the surgery, while the other group receives the usual in-person explanation from a doctor. Afterward, both patients and doctors fill out short questionnaires about how well the information was understood and how satisfied they were. The time spent on each method is also recorded.

What are the possible benefits and risks of participating?

The study may help improve how patients are informed before surgery in the future. There are no known risks from taking part, and all participants still receive the necessary information about their surgery, either by video or in person.

Where is the study run from?

University Hospital of Würzburg in Germany

When is the study starting and how long is it expected to run for?

The study began in September 2023 and is expected to finish in March 2025.

Who is funding the study?
University Hospital of Würzburg in Germany
The educational video used in the study was developed by medudoc education GmbH.

Who is the main contact?
Dr Svenja Leicht, svenja.leicht@web.de

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Video-assisted surgical informed consent, compared to conventional informed consent, reduces physicians' time expenditure while maintaining patient satisfaction and understanding. A cluster-randomized clinical trial

Study objectives

The objective of this study was to compare video-assisted with conventional surgical informed consent in terms of duration, patient understanding, as well as patient and physician satisfaction.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 20/01/2023, Ethics Committee of the Julius-Maximilians-University of Würzburg (Petrinstraße 33a, Würzburg, 97080, Germany; +49 931 31 48315; ethikkommission@uni-wuerzburg.de), ref: 112/22

Study design

Single center interventional cluster-randomised controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Video-assisted versus conventional surgical informed consent before elective surgery

Interventions

Patients in the intervention group receive a video developed by medudoc education GmbH, while the control group receives physician-led informed consent according to the hospital's standard. The duration of both methods is measured using a stopwatch. Patients in both groups complete questionnaires on satisfaction and understanding after the surgical informed consent and postoperatively. Upon study completion, participating physicians also complete a questionnaire to assess their satisfaction.

Randomisation was conducted manually by the study management team to achieve approximately equal numbers in the intervention and control groups.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Physician consultation time measured using a stopwatch at the consultation

Key secondary outcome(s)

Measured at the consultation:

1. Depressivity: PHQ-2
2. General anxiety: GAD-2
3. Surgery-related anxiety: APAIS
4. Illness and treatment beliefs: IPQ-R
5. Patient satisfaction: ZUF-8
6. Patient understanding: self-developed questionnaire
7. Physician satisfaction: self-developed questionnaire
8. Additionally, data on diagnosis, type of surgery, and postoperative pain (assessed via the Numeric Rating Scale, NRS) were extracted from patient records

Completion date

30/03/2025

Eligibility

Key inclusion criteria

1. Age \geq 18 years
2. Sufficient proficiency in the German language
3. Elective indication for surgery

Participant type(s)

Health professional, Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

153

Key exclusion criteria

1. Occurrence of postoperative complications classified as grade IV or V according to the Clavien-Dindo classification

Date of first enrolment

01/09/2023

Date of final enrolment

30/03/2025

Locations

Countries of recruitment

Germany

Study participating centre

Uniklinikum Würzburg

Oberdürrbacherstraße 6

Würzburg

Germany

97080

Sponsor information

Organisation

medudoc education GmbH

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Universitätsklinikum Würzburg

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in German		30/10/2025	No	Yes