ISRCTN71913555 https://doi.org/10.1186/ISRCTN71913555

3D-printed cardiac models for patient evaluation for congenital heart disease

Submission date	Recruitment status	[ ] Prospectively registered
31/10/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/12/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/12/2024	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Congenital heart defects that require surgical or interventional therapy are usually due to complex and individual anatomical conditions. In pediatric heart surgery or pediatric cardiology, information is typically provided in a physician-parent conversation using printed paper forms and handwritten additions, such as sketches. With the increasing availability of 3D printing, patient-specific 3D models have already been used for visualization in clinical practice. As an additional digital alternative, virtual reality technology offers the possibility of viewing a virtual three-dimensional model together with the physician and discussing interventions step by step. The aim of this study is to evaluate and establish alternative information methods for congenital heart defects. A comparison is made between paper-based information using information sheets, information with the aid of a 3D-printed model, and information using virtual reality, which displays a three-dimensional model in virtual space. The focus here is particularly on the increase in understanding as well as the impact of medical information on anxiety, restlessness, or nervousness.

Who can participate?
Parents of children with Congenital Heart Disease (atrial and ventricular septal defect, Tetralogy of Fallot, Coarctation of the aorta)

What does the study involve?
Randomization in the training group (paper-based information, 3D-printed models, or virtual reality). It begins with paper-based information, i.e., the first 35 patients receive this type of training, the next 35 patients will be trained with 3D-printed models, and then the following 35 patients will receive information through virtual reality.

Before the training, information is provided about the procedure and the purpose of the study, along with patient information and consent clarification. Consent is obtained after completing the first questionnaire. Data collection takes place immediately after the training using a second questionnaire. In the same session, patients receive an envelope with the third questionnaire, which should be filled out on the day of discharge and returned to the nursing station in a designated compartment. Instructions for this procedure are written on the envelope.

Since the training in this study does not constitute legally binding medical information, it is conducted separately from the attending physician at a time close to the discharge. The training in this study is conducted by the study leader or study assistant, who is obligated to confidentiality.

What are the possible benefits and risks of participating?
Risk: Since this is an observational study, there is no additional risk. Data are recorded in a pseudonymized manner, and anonymization occurs before data analysis. Thus, there are no data protection disadvantages for the patients.
Benefit: Participation in the study does not provide a direct benefit to the patients.

Where is the study run from?
LMU University Hospital in Munich, Germany and German Heart Center in Munich, Germany.

When is the study starting and how long is it expected to run for?
July 2021 to May 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Linda Grefen, MD (Linda.Grefen@med.uni-muenchen.de)

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
3D-VR-2022

Study information

Scientific Title
Digitalization in patient education: 3D printing for congenital heart disease

Study objectives
3D-printed models help to relieve parental anxiety in children with congenital heart disease and improve procedural understanding.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/11/2022, LMU Ethics committee and ethical vote - Faculty of Medicine (LMU Munich Geschwister-Scholl-Platz 1, Munich, 80539, Germany; +49 89-4400 55191; ethikkommission@med.uni-muenchen.de), ref: 22-0281

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Parents anxiety and procedural understanding with children suffering from CHD

Interventions
This study focused on the use of 3D-printed cardiac models for the optimization of patient education for congenital heart disease. Parents of pediatric patients were included and either educated using the standardized paper-based method (control group) or the patient education was performed with the additional use of 3D-printed cardiac models for better visualization (3D model group). Participants were randomized using an online tool. Briefly, parents took questionnaires prior to the patient education for baseline testing regarding patient characteristics, anxiety and procedural understanding. Custom-developed questionnaires were used for the evaluation of procedural understanding and satisfaction with the education. The mean duration of patient education for both groups was 25 minutes. The study concluded with the last questionnaire for the evaluation of the Trait-Anxiety Inventory (TAI) which was filled out upon discharge so there was no further follow-up after discharge of the patient.

Intervention Type
Other

Primary outcome(s)

Parental preprocedural anxiety evaluated using the Visual Analog Scale (VAS, 1-10) and the State-Trait Anxiety Inventory, made up of the State-Anxiety Inventory (STAI) and the Trait-Anxiety Inventory (TAI). The German short version of the STAI was used with 10 statements regarding the state anxiety and trait anxiety for the patient, respectively. Scores for each short inventory ranged from 10 to 40, while higher scores were associated with higher anxiety levels. Collected before discharge and after the patient education.

Key secondary outcome(s))
Parental procedural understanding and satisfaction with the patient education method measured using a
questionnaire immediately after the patient education

Completion date
15/05/2024

Eligibility

Key inclusion criteria
Parents of patients with congenital heart disease

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
57

Key exclusion criteria
1. Language barrier
2. Previously educated by physician
3. Emergency intervention or surgery

Date of first enrolment
15/11/2022

Date of final enrolment
15/05/2024

Locations

Countries of recruitment
Germany

Study participating centre
LMU University Hospital
Marchioninistrasse 15
Munich
Germany
81377

Study participating centre
German Heart Center Munich
Lazarettstrasse 36
Munich
Germany
80636

Sponsor information

Organisation
LMU Klinikum

ROR
https://ror.org/02jet3w32

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Linda Grefen, MD (Linda.Grefen@med.uni-muenchen.de)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			05/11/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes