Research Square

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VESSEL — Virtual reality education to reduce sedentary behaviour after acute stroke: protocol for a mixed-methods feasibility trial

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Study protocol

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Abstract

Background: Although physical activity is an important modifiable factor for secondary stroke prevention, many stroke patients stay inactive for many hours daily. Because movement behaviours tend to stabilise shortly after discharge, addressing this early may increase physical activity levels. Education is an established behaviour change technique, for which virtual reality offers an enhanced way to communicate complex health information, potentially filling gaps left by traditional education and promoting movement behaviour change after stroke.

Objectives: This planned randomised-controlled mixed-method feasibility trial aims to examine whether using a virtual reality education intervention, in addition to standard care during acute inpatient hospitalisation, is feasible. Secondary objectives will assess preliminary effects on movement behaviour and usability.

Methods: Adult stroke patients with minor stroke (NIHSS 1-5) are recruited within the first 48 hours after admission to the stroke unit. The intervention group will receive a one-time virtual reality-based education intervention. This includes an explanation of stroke pathophysiology, lifestyle risk factors, and motivational components. Feasibility will be evaluated by eligibility, recruitment and retention rates and safety. The analysis of movement behaviour, conducted with the Actigraph accelerometer and supplemented by interviews with participants, aims to offer initial insights into the intervention's effectiveness and usability.

Perspective: If virtual reality-based education proves feasible, it could provide valuable insights into how education is designed and in acute stroke care to support secondary prevention. This could be a first step toward a randomised-controlled trial evaluating virtual reality-based education as a behaviour change technique.

German clinical trials registration number: DRKS00041468

Protocol Version: 1

Introduction

Although they are in specialised medical care, patients with acute stroke rarely receive structured education on how their behaviour influences the risk of a recurrence, which points out a paradox. It is widely recognised that behavioural changes, especially increasing physical activity, are among the most effective strategies for secondary prevention. Virtual reality (VR) offers a promising new method: its immersive quality can make abstract health concepts more tangible, potentially addressing gaps left by traditional education formats. However, whether and how this approach can be applied in the acute inpatient stroke setting and its potential impact on physical activity behaviours remain unexplored.

Epidemiological data highlight the significant clinical importance of stroke, as it remains one of the most burdensome non-communicable diseases globally. The 2024 Global Burden of Disease Study ranked it

as the third leading cause of death, responsible for 7.3 million deaths, and the fourth leading cause of DALYs, accounting for 160.5 million years of life lost [1]. Ischaemic stroke constitutes the majority of cases at 65.3% [1]. In Germany, 2022 data show that 1.4% of the population are living with stroke-associated long-term consequences from the past ten years, with prevalence increasing steadily with age [2].

Beyond the initial event, recurrence risk remains a key clinical concern. In a 5-year follow-up study (n = 3,847), initiators of TIAregistry.org found that 12.9% of stroke patients experienced a second stroke event, a subsequent coronary syndrome, or cardiovascular death, with approximately half of these events occurring between the second and fifth post-stroke year [3]. Approximately 30% of ischemic strokes happen following a previous stroke or TIA. Arterial hypertension is a well-established risk factor for both initial and recurrent strokes [4]. Five primary risk factors—high blood pressure, smoking, abdominal obesity, diet, and physical inactivity—contribute to over 80% of the global stroke risk [5].

In this context, physical activity is especially crucial. In hospitals, patients are often inactive for most parts of the day, which increases the risk of secondary complications, functional decline, and extended hospital stays [6, 7]. This inactivity cannot be explained solely by stroke-related mobility limitations: many patients who were inactive for nine hours a day showed only mild to moderate impairments [8]. Leaving acute hospital care, some patients move on to rehabilitation centres, while others return home. This potentially creates a gap in care, during which new habits can form quickly and may significantly influence long-term functional outcomes. Wondergem et al. observed that among 140 stroke patients, 78.6% with an NIHSS score of 0–5 were highly sedentary and inactive [9]. Analysing their movement data over the first five weeks post-discharge shows that movement patterns stay relatively consistent during this period, indicating the importance of encouraging movement behaviour change immediately at time of discharge [9].

Addressing modifiable risk factors during hospitalisation may prevent patients from being discharged without starting secondary prevention, as suggested e.g. by earlier PROTECT studies [10, 11]. Behaviour change techniques (BCTs), recognised as observable and reproducible elements of behaviour modification, are an effective approach to influencing physical activity patterns [12]. While previous research has explored various BCTs and their combinations to lower stroke risk factors, risk communication through education has scarcely been evaluated, particularly not with physical activity or sedentary behaviour as the main outcome [13].

VR presents a promising method for applying education-based BCTs, as it provides an immersive environment where health information can be experienced directly rather than just presented. Moro et al. showed that augmented reality, compared to written leaflets, resulted in higher satisfaction and a more enriching learning experience in patients after stroke, although they did not examine behavioural change [14].

Objectives

The planned feasibility trial aims to examine whether the use of a virtual reality education intervention in addition to standard care during acute inpatient hospitalisation is feasible. Preliminary effectiveness and usability will be determined as secondary objectives.

Methods

Design

This study is planned as a non-blinded, two-arm, randomised controlled feasibility trial, which is to be conducted on the stroke unit of Münster University Hospital in Germany. The ethics committee of Ärztekammer Westfalen Lippe, Münster, Germany, granted ethical approval on June 4th, 2025 (ID 2025-277-f-S). This trial was registered in the German register for clinical studies (DRKS) with ID „DRKS00041468“ on 25th of September 2026. To fulfil standards of complete reporting, the SPIRIT 2025 Checklist [15] and the CONSORT extension for randomised pilot and feasibility trials [16] were applied. The GRAMMS checklist for reporting of mixed-methods studies was considered when applicable [17]. Any protocol amendments will be updated in the registry and reported in the publication of results.

Recruitment

The screening of eligibility criteria, as well as patient information and written consent, will be conducted by a medical doctor. The schedule for enrolment, intervention, and data collection is shown in Table 1.

Table 1
diagram of schedule of enrolment, interventions and assessments; adapted from SPIRIT 2025 [15]

	Trial period				
	Enrolment		**Intervention**	**Post-intervention**	**Discharge**
Timepoint	-t – t0	t0		t1	t2
Enrolment					
Eligibility screening	x				
Informed consent	x				
Randomisation		x			
Intervention/Comparator					
VR-Intervention			x		
Usual care			x		
Assessments					
Feasibility criteria		x	x		
Physical activity/ sedentary behaviour				x	
Qualitative data					x

Eligibility criteria

Patients who are admitted to the stroke unit after September 15th 2026, who are above 18 years of age, diagnosed by a doctor with a stroke expressed by an NIHSS score between 1 and 5 upon admission to the hospital and who receive neurologic stroke complex treatment (OPS-8-981) and are able to ambulate independently. All exclusion criteria are displayed in Table 2. Based on the minimum target number of participants of two per week, the recruitment period amounts to 18 weeks. Screening for eligibility is conducted within the first 48 h after admission to the stroke unit. Potential participants will be excluded when presenting with serious cognitive impairments or insufficient language comprehension according to the study doctors' assessment, as well as cardiovascular, orthopaedic or surgical indications and other health reasons that preclude independent walking. Patients, for whom bed rest is medically indicated, are excluded, unless the bed rest is temporary and ended by a doctor. All participants must give consent to participate.

Table 2
Exclusion criteria

Exclusion criteria
< 18 years of age
NIHSS < 1, > 5
Walking with supervision/support of another person
> 48h after admission to stroke unit
Cognitive impairments (according to doctors' assessment)
Insufficient language comprehension
Medical indications/ other reasons requiring bedrest (except temporary)

Sample size

Because no pilot data are available, no sample size calculation based on available data was conducted. Following the recommendations of Eldridge et al. and Whitehead et al,. a sample size was estimated based on expected effects of a subsequent main trial [18, 19]. Assuming a main trial with 90% power, a two-sided significance level of 5% and expecting a medium effect size ($\delta = 0.3–0.7$), a pilot sample size of 15 is recommended [19]. To account for a maximum attrition rate of max.15%, and rounding up to the nearest whole number, a total of 36 participants will be recruited (18 per group).

Randomisation/Allocation

Eligible participants who provide written informed consent will be randomly allocated to the intervention or control group. A computer-generated block randomisation sequence will be generated by RandIMI, which is an integrated tool in the data management tool. Block randomisation was chosen to ensure approximately balanced group sizes throughout the recruitment period. An independent person with no role in recruitment or data analysis will generate the randomisation sequence. Due to the nature of the intervention, blinding of participants and study personnel will not be feasible. However, given the nature of the intervention, it is not expected that this will have any effect on the outcome of the intervention.

Study interventions

Control group

Participants receive standard acute stroke care, which includes verbal explanations from medical doctors during routine conversations. These consultations cover possible causes, risk factors, further treatments, therapy options, and lifestyle advice. To ensure consistency, two ward doctors conduct these

explanations during the study within the control group, as well as in the intervention group. For this, a guide will be developed to summarize the content, accompanied by a checklist to record the provided information.

VR-based education (Intervention group)

In addition to the information provided by their doctor, as described for the control group, participants in the intervention group will also get an educational session that includes additional support via VR. The Meta Quest 3 VR headset, manufactured by Meta, is used for this purpose [20]. This VR session is based on the components of the behaviour change wheel[21] and has been developed by the study team. Participants are placed in a simulated environment where they receive auditory and visual cues and engage with simple selection options. Example pictures with screenshots of the intervention are shown in Figs. 1 and 2. The intervention is conducted in German; a fully translated script is available in the supplements. After familiarisation with the system, participants learn about stroke pathophysiology. In a simple game, participants must match terms and risk factors to whether they are ‘beneficial’ or ‘not beneficial’ to their risk profile. Subsequently, they receive information on hospital movement procedures, illustrated through a calming, natural simulation of a forest and lake. In the final phase, questions about motivation are posed, prompting participants to draw their preferred activity and consider social participation with friends or family. This phase encourages reflection on personal preferences, though no individualised approach is applied in earlier phases. The session lasts approximately 30 minutes and takes place in a separate hospital room. It is conducted seated and can incorporate hand tracking or game controllers. To ensure comparability, the intervention is only personalised regarding the motivational part of the intervention, but not showing or explaining individual health information.

Side effects

Evidence on VR safety during the acute stroke rehabilitation phase is scarce. In later rehabilitation stages, participants reported nausea, visual disturbances, headaches, or dizziness [22]. To ensure safety, a trained member of the project team will always be present with participants and can intervene immediately if any discomfort occurs.

Outcomes

Primary outcome

The primary focus of this trial will be feasibility, as demonstrated by eligibility and recruitment rates, which will be monitored to determine how many patients per group per week meet the inclusion criteria and can be enrolled in the study. To assess retention and the dropout rate, the percentage of participants completing both the initial assessment (t0) and assessment before discharge will be compared. Safety is evaluated by the number of adverse events, defined as falls and other unexpected events that are potentially harmful to the patient. Adverse events will be documented in accordance with hospital

regulations. The project team will document any discomfort reported by patients during the VR intervention.

Table 3
Feasibility and progression criteria

Feasibility criterion	Mode of measurement	Target
Eligibility	No. of potential participants meeting inclusion criteria per week	Mean of 5 potential participants per recruitment week
Recruitment rate	Participants enrolled per week	Mean of 2 included participants per week
Retention	% of participants not completing the study	< 15% of participants not completing the study
Safety	No. of adverse events per group	< 10% between group difference

Secondary outcomes

An initial assessment of the intervention's effectiveness on movement behaviour will be conducted. PA and SB will be measured by the Actigraph LEAP sensor, which all participants will wear on the nondominant wrist during the hospital stay. Data will be analysed using the associated ActiLife software. Physical activity will be categorised as light, moderate, and vigorous, with a separate analysis of MVPA. Sedentary behaviour will be examined separately. Both measures will undergo validation through Actigraph's wear-time validation to account for measurement errors caused by non-adherence to sensor use. ActiLife software uses Freedson's (1998) algorithm to set the cut point and follows the cut points for physical activity as internationally recognised: light PA (< 3.00 METs), moderate PA (3.0 -5.9 METs), vigorous PA (> 6.0 METs), sedentary (< 1.4 METs) [23–25].

For the qualitative analysis, interviews with participants of the intervention group will be conducted. Based on their physical activity data, interviews will be conducted with some participants who have demonstrated outstanding movement behaviour to explore it in greater depth. This is expected to be either very active, characterized by short sedentary periods and increased PA, or mainly sedentary with long bouts and minimal PA. Interviews will be conducted until theoretical saturation is reached, which is expected to happen after 6 interviews

Data collection

After the screening for eligibility, recruitment and randomisation, all participants receive a pseudonymized code. The identification list is only available to a third person who is not involved with the conduct of the study. All sociodemographic data is collected and maintained by the project lead and stored in REDCap software. Data from the Actigraph are analysed in the ActiLife software. A member of the project team will conduct interviews. No data monitoring committee will be formed; monitoring will be supported by the Medical Data Integration Centre of the University Münster.

Data analysis

Quantitative Data

Data analysis will be conducted using IBM SPSS Statistics. Participant sociodemographic characteristics will be summarised descriptively. Only complete cases will be reported, any incomplete cases will be reported with reasons given. Variables will be reported as either mean ± SD or median with IQR. The primary outcome, related to feasibility criteria, will be described narratively. For secondary continuous outcomes, an independent samples t-test will compare means between groups for normally distributed variables, with results expressed as mean differences and Cohen's d effect sizes along with 95% confidence intervals; the Mann-Whitney U test will be used for non-normally distributed variables.

Qualitative data

Post-interventional audio-recorded data will be transcribed verbatim and pseudonymized prior analysis. Data management and coding will be supported by MAXQDA software. Following approach of qualitative content analysis, the analysis will begin with an initial work-through of the material, during which memos and initial impressions will be noted [26]. Afterwards, main categories will be developed both deductively, derived from the interview guide and the behaviour change wheel and inductively, directly based on the interview material. The main categories will be applied to the entire dataset in a first coding pass. Subsequently, all text passages assigned to each main category will be compiled and further differentiated into subcategories through an inductive process, resulting in a comprehensive coding frame. The final coding frame will then be applied to the entire dataset [26].

Mixed-methods analysis

A convergent parallel mixed-methods approach will be used. After analysing the quantitative and qualitative data separately, the results will be compared to identify areas of agreement or disagreement and then interpreted. Data integration will be performed in MAXQDA. A narrative and joint display approach will be used to integrate data.

Progression criteria

Progression criteria (Table 4) were defined following the recommendations of Mellor et al. [27]. They are based on feasibility criteria (Table 3) and clinical context, and were discussed in the interprofessional project team. Recruitment rates were estimated based on the team’s clinical expertise. Team stakeholders are involved in planning and conducting the trial, as well as in implementation and clinical patient care in the specific setting.

Table 4
Progression criteria for potential definitive trial

Progression criteria	Go – proceed with RCT	Amend – proceed with changes	Stop – do not proceed unless changes are possible
Eligibility	≥ 5 potential participants per week	mean of 4 potential participants per week	≤ 2 potential participants per week
Recruitment rate	≥ 2 participants per week	≤ 1 participants per week and takes longer than expected	Unable to recruit any participants on weekly basis
Retention	< 10% of participants not completing the intervention	11–14% of participants not completing intervention	> 15% of participants not completing intervention
Safety	< 5% between group difference in no. of falls	6–9% between group difference in no. of falls	> 10% between group difference in no. of falls
Qualitative data	Delivery of intervention judged strongly feasible by qual. data	Delivery of intervention judged feasible by qual. data	Delivery of intervention judged possibly feasible by qual. data

Discussion

Assessing feasibility and potential progression before developing a definitive randomised trial is crucial for adequately evaluating an intervention. A mixed-method approach to evaluate preliminary effectiveness helps deepen understanding of results and allows for targeted refinement of the intervention for future randomised controlled trials. VR provides an immersive environment for interacting with healthcare information, moving beyond passive reading or listening, and shows promise for implementing education-based BCTs. Since current research is limited in assessing VR's use in this patient group, initial feasibility must be established to identify any safety risks, especially in acute care settings. Acceptance of VR among participants, to be explored through qualitative analysis, could pose a challenge. If VR-based education proves feasible and potentially effective in acute stroke patients, it could revolutionise how education is designed and personalised in acute care, with a focus on secondary prevention.

Abbreviations

BCT
behaviour change technique
METs
metabolic equivalent of task
PA
physical activity
SB

sedentary behaviour
VR
virtual reality

Declarations

Acknowledgement

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Ethical standards

This study was approved by the Ethics Committee of Ärztekammer Westfalen Lippe in Münster, Germany, on June 4th, 2025 (ID 2025-277-f-S) and will follow the principles of the Declaration of Helsinki. All participants will provide written informed consent before participating.

Data availability

The data which will be generated during this study will be available from the corresponding author on request.

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The authors did not receive support from any organisation for the submitted work. No funding was received for conducting this study.

Conflict of interest

All authors declare that they have no conflicts of interest to disclose.

Author contributions

All authors contributed to the study conception and design. The first draft of the manuscript was written by Annalena Paus. The virtual reality application was designed by Grégoire Delwaulle. Stephan Hause, Markus Holling, Lukas Kühn, Markus Ramm, Frederike Riethues and Antje Schmidt-Pogoda commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Figures

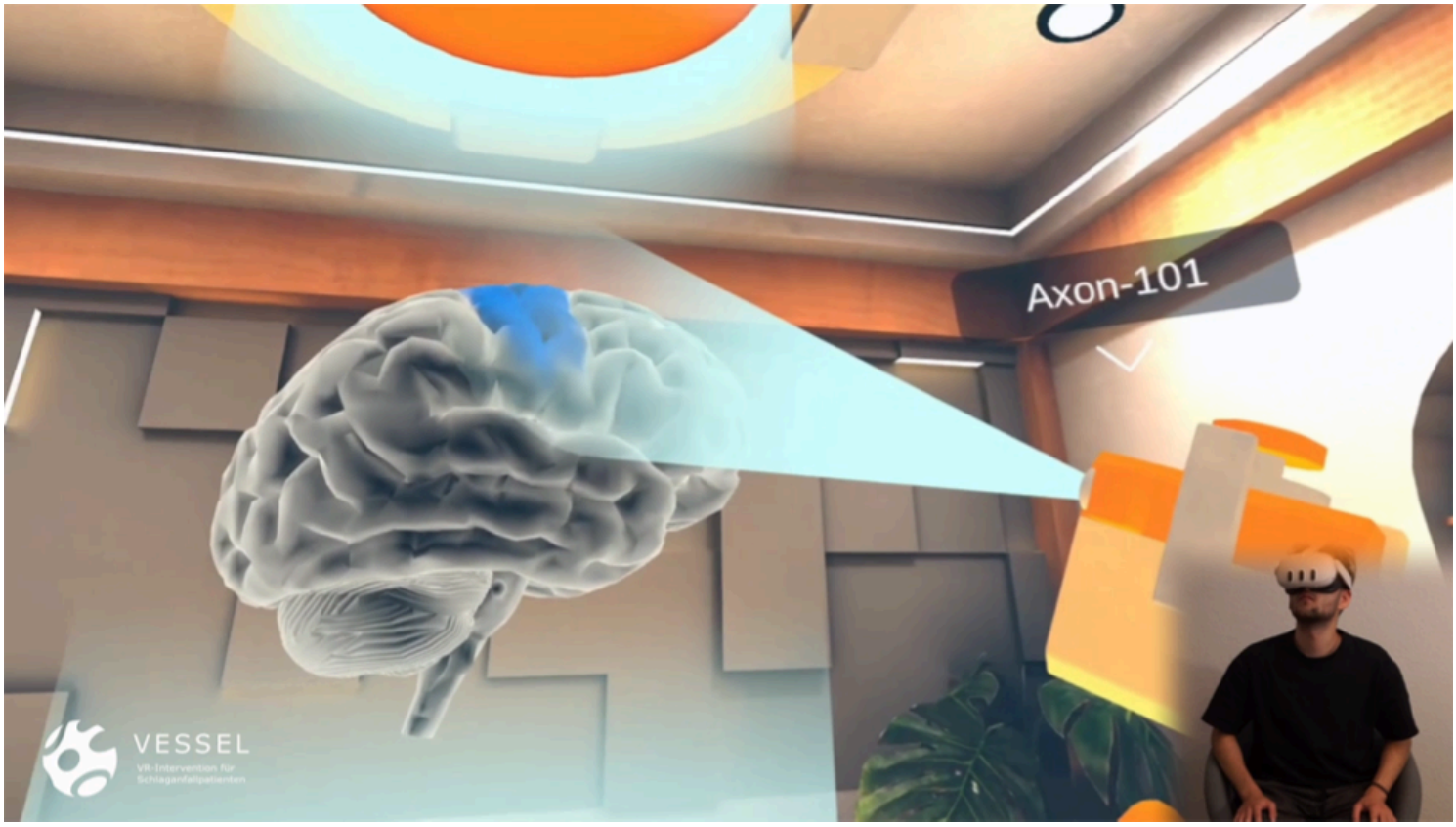

Figure 1

Screenshot from the VR Intervention showing an infarction area of the brain. Picture by Grégoire Delwaulle.

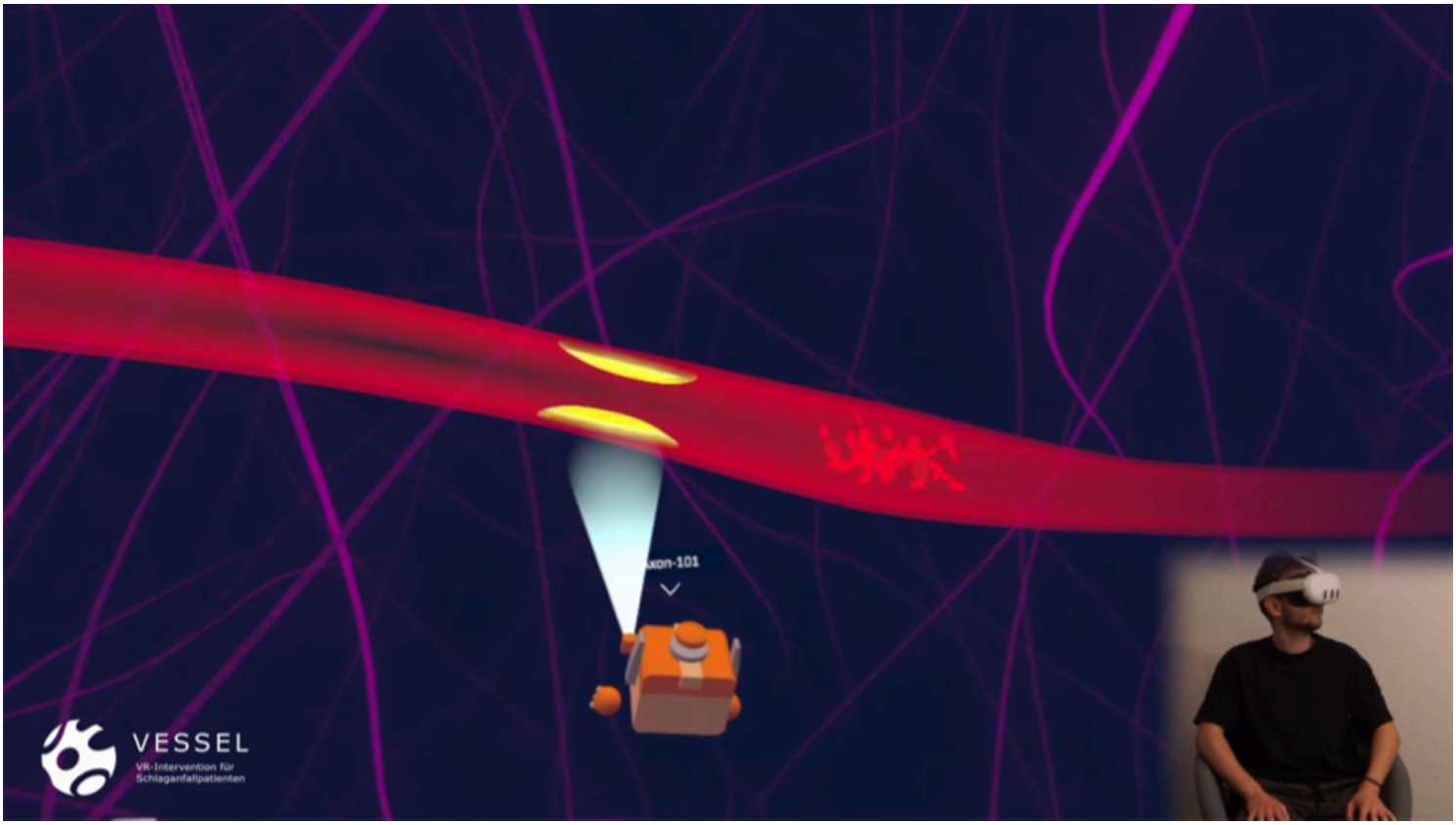

Figure 2

Screenshot from the VR Intervention showing a stenotic artery. Picture by Grégoire Delwaulle.

Supplementary Files

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- SkriptVRen.pdf
- GRAMMSchecklist.pdf
- SPIRIT2025checklist.pdf
- TIDieRchecklist.pdf