

# Evaluating the clinical impact of integrating a computerized clinical decision support system and a social robot into discussion of patient cases with the care team

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<b>Registration date</b> 28/02/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/07/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Decision-making in the clinical context is often complex and can lead to errors. Electronic systems designed to support clinical decision-making (i.e., clinical decision support systems) can reduce these errors by, for example, helping clinicians with drug-dose calculations, alerts, reminders, and so on. However, the use of such systems is so far limited due to several factors. In the present study, we will develop a valid, informative, and safe system that will be integrated into the existing protocols and implemented in an innovative manner via a tablet attached to the socially assistive robot. This could make the use of an electronic system more effortless and engaging. In the present study, we will evaluate the clinical impact of integrating such an electronic system into grand rounds and pre/post-operative care of patients.

### Who can participate?

Participants of this study have to be vascular or thoracic surgery patients being treated in the clinical center, or clinicians, nurses, and employees, working in either of these two wards.

### What does the study involve?

The participating vascular and thoracic surgery patients will be subjected either to the standard treatment or the intervention. The standard treatment will, for example, employ traditional progression charts during grand round and pre/post-operative care. On the other hand, the intervention will additionally employ the novel clinical decision support system delivered via a social robot. Participants will also be asked to fill out questionnaires (in both conditions).

### What are the possible benefits and risks of participating?

While the researchers cannot guarantee that the prepared interventions will help all participants, it is hoped that the extended patient's clinical background, available in real-time, will improve the pre- and post care routine resulting in improved health quality parameters

The researchers do not foresee any potential for significant distress or adverse events, as participants will sign the informed consent before the beginning of their participation. However, it is possible that the presence of a socially assistive robot will lead to slight discomfort, especially in earlier stages of their deployment. Participants who will feel distressed for any reason will be able to withdraw their consent or/and get individualized support.

Where is the study run from?

University Clinical Centre Maribor (Slovenia)

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

October 2021 to June 2024

Who is funding the study?

The study will be carried out within the HosmartAI project (Grant No. 101016834), funded under the Horizon 2020 call "AI for the smart hospital of the future (DT-ICT-12-2020)". Horizon Europe is the EU's key funding programme for research and innovation.

Who is the main contact?

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## Contact information

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

UKC-MB-KME-77/21

## Study information

### Scientific Title

Impact of computerized clinical decision support system and socially assistive humanoid robots in grand round routine, during pre/post-operative care of patients with vascular and thoracic diseases and conditions: a randomized clinical trial

### Acronym

HosmartAI-SRS-CDSS

### Study objectives

H1. The computerized clinical decision support system with real-time and patient-centric access to health data, supported by socially assistive humanoid robot, will be perceived as added value tool during grand round routine.

H2. The use of a computerized clinical decision support system will have a positive impact on health quality measures and the quality of life of patients with vascular and thoracic diseases and conditions compared to control.

### Primary scientific questions:

SQ1. How is the developed CDSS system perceived regarding its usability during grand rounds by clinicians?

SQ2. To what extent do clinicians accept the use of the developed CDSS system during grand rounds?

SQ3. What is the added value of having real-time access to patients' electronic health records and intuitive search options available during Grand Rounds?

### Secondary scientific questions:

SQ5. How, if at all, does the provision of an extended clinical background to clinicians impact the

diagnostic and treatment workflows?

SQ4. Does the use of CDSS have an impact on patients' health quality measures (i.e. blood pressure, heart rate, body temperature, pain, and quality of life)?

SQ5. How satisfied are the patients admitted to vascular and thoracic surgery wards exposed to clinical routine with CDSS compared to the control group?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 15/12/2021, Medical Ethics Commission (University Medical Center Maribor, Ljubljanska ulica 5, 2000 Maribor, Slovenia; [eticna.komisija@ukc-mb.si](mailto:eticna.komisija@ukc-mb.si); +386 2 321 2489), ref: UKC-MB-KME-77/21

### **Study design**

Experimental prospective randomized clinical trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Quality of life

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet.

### **Health condition(s) or problem(s) studied**

Impact of robot delivered computerized clinical decision support system on health quality measures and the quality of life of patients with vascular and thoracic diseases and conditions compared to control.

### **Interventions**

Each participant will be followed during 3-5 days' stay in the ward; during the preparation, procedure, and post-procedure care. Eligible participants will be informed of the characteristics of the study and provided with an informed consent form. To those who will consent to participate in the study, baseline questionnaires will be administered. Subjects are randomized to:

1. Intervention Group (Computerized Clinical Decision support system and Computerized physician system is actively used) and
2. Control Group (CCDS and CPS are not actively used; instead, only standard workflow and progression charts are utilized).

Blinding is achieved by handling the same tools at the grand and work rounds (Robot, Tablets). However, in the control group, the robot and tablet will not provide any information to

clinicians. Blinding is furthermore achieved by adhering to the usual workflow and paper progression charts in all patients in both groups.

During the stay, Health Care Quality Measures are collected for both groups 2 times a day:

1. Blood pressure; in all in-patients, blood pressure is recorded daily (standing order) and recorded on a progression chart. In the Intervention Group the CCDS and CPS are used to flag deviations from 150/ 90 mmHg standard and alert the treating physician. In the Control Group, the standard progression chart is used as per hospital protocol. The treating physician is autonomous to decide to step up or modify antihypertensive treatment. The difference between both groups in terms of average deviation from 150/90 mmHg is evaluated.
2. Pain; in all in-patients, VAS (10 cm) is recorded on daily basis (standard procedure) and recorded on a progression chart. In the Intervention Group the CCDS and CPS are used to flag all VAS values of 5 and above and alert the treating physician. In the Control Group, the standard progression chart is used as per hospital protocol. The treating physician is autonomous to decide to step up or modify analgetic treatment. The difference between both groups in terms of average deviation from VAS 0-4 is evaluated.
3. Patient reported outcome measure (PROM) (EQ - 5D - 3L instrument) is used in both groups. The difference in both groups in EQ-5D-3L score are evaluated and compared to the value set for Slovenia (available since 2000 VAS methodology, 2019 TTO methodology).

After each iteration, the clinicians from the both wards, will evaluate the clinical usability and the acceptance of the CDSS system by answering SUS-SI and UTAUT2 questionnaires.

## **Intervention Type**

Other

## **Primary outcome measure**

Measured at the end of the study:

1. Clinical usability of the CDSS system measured with a System Usability Scale (SUS)
2. Acceptance of the CDSS system measured with a unified theory of acceptance and use of technology and its extension (UTAUT and UTAUT2)

## **Secondary outcome measures**

Measured twice per day during hospital stay:

1. Health Quality Measures: blood pressure (sphygmomanometer) and heart-rate (clinician)
2. Pain level VAS (10 cm)
3. Patient reported outcome measure: EQ - 5D (quality of life)

## **Overall study start date**

01/10/2021

## **Completion date**

30/06/2024

# **Eligibility**

## **Key inclusion criteria**

1. In-patients in Vascular Surgery and Thoracic Surgery wards
2. Over the age of 18 years
3. Without any major psychological disorders
4. Capable of signing the letter of consent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

200 patients, 100 per ward

**Key exclusion criteria**

1. Emergency patients
2. Patients without consent
3. Patients already randomized on either vascular or thoracic surgery ward (no-double enrolment)
4. Patients with Abbreviated Mental Test score 6 or lower
5. Patients with special needs or appointed guardians
6. Patients allocated to an intensive step-down unit and/or regimen are excluded

**Date of first enrolment**

01/06/2022

**Date of final enrolment**

31/05/2024

**Locations****Countries of recruitment**

Slovenia

**Study participating centre**

University Medical Centre Maribor

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**Sponsor information**

**Organisation**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.ukc-mb.si/en/>

**ROR**

<https://ror.org/02rjj7s91>

**Funder(s)****Funder type**

Government

**Funder Name**

Horizon 2020 Framework Programme

**Alternative Name(s)**

EU Framework Programme for Research and Innovation H2020, Horizon 2020, Rahmenprogramm Horizont 2020, Programa Marco Horizonte 2020, Programme-cadre Horizon 2020, Programma quadro Orizzonte 2020, Program ramowy Horyzont 2020, Horizont 2020, Horizonte 2020, Orizzonte 2020, Horyzont 2020, Horizon 2020 Framework Programme (H2020), H2020

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location****Results and Publications**

Publication and dissemination plan

Publication and dissemination plan: The researchers plan to publish a detailed study protocol in 2022 and an empirical peer-reviewed article with completed results in 2025. These publications will be accompanied by presentations at international scientific conferences.

**Intention to publish date**

31/12/2024

**Individual participant data (IPD) sharing plan**

Anonymized participant-level data can be retrieved by contacting Dr. Izidor Mlakar (Izidor.mlakar@um.si). The researchers are willing to share anonymized raw data with researchers for use in meta-analyses or for other research-related purposes (with no time restriction). They are not willing to share data for commercial purposes under any circumstances. They would also like to note that participants will be made aware of how the data will be used, stored and shared in the informed consent form.

**IPD sharing plan summary**

Stored in non-publicly available repository, Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		25/09/2022	15/11/2022	Yes	No
<a href="#">Results article</a>		30/04/2025	15/07/2025	Yes	No