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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

Submission date
17/02/2022

Recruitment status
No longer recruiting

Registration date
28/02/2022

Overall study status
Completed

Last Edited
15/07/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Protocol serial number
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; +386 2 321 2489), ref: UKC-MB-KME-77/21

Primary study design
Interventional

Study design
Experimental prospective randomized clinical trial

Study type(s)
Quality of life

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 (availabile 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 questionaries.

Intervention Type
Other

Primary outcome(s)
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)

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
Ljubljanska ulica 5
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Sponsor information

Organisation
University Clinical Centre Maribor

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, Horizon 2020 Framework Programme (H2020), Rahmenprogramm Horizont 2020, Horizont 2020, Programa Marco Horizonte 2020, Horizonte 2020, Programme-cadre Horizon 2020, Orizzonte 2020, Programma quadro Orizzonte 2020, H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

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?
Results article		30/04/2025	15/07/2025	Yes	No
Protocol article		25/09/2022	15/11/2022	Yes	No