



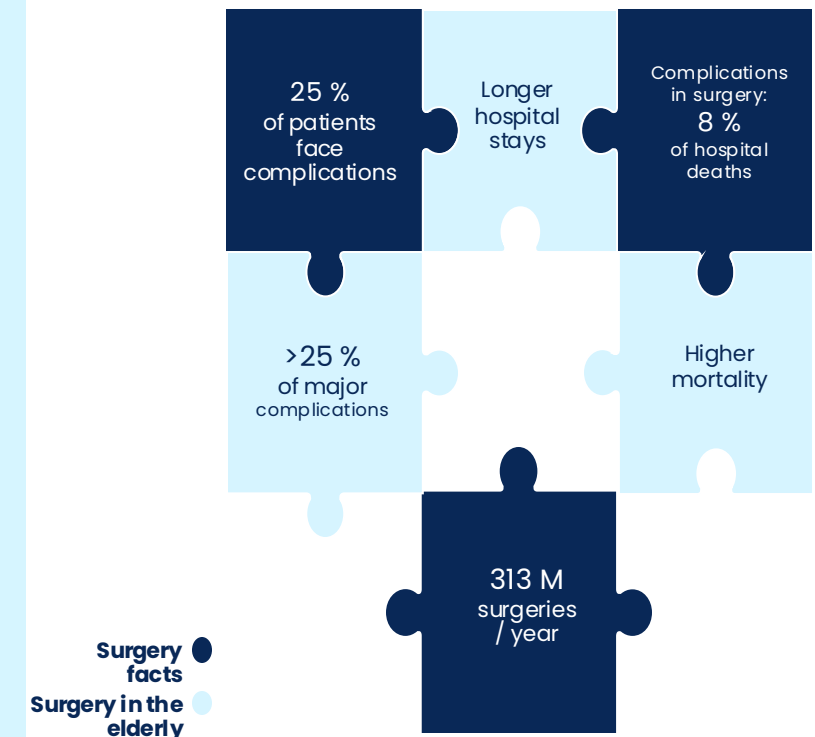
**Prehab – how a simple idea has become one of the hot digital topics in the daily care of our patients**



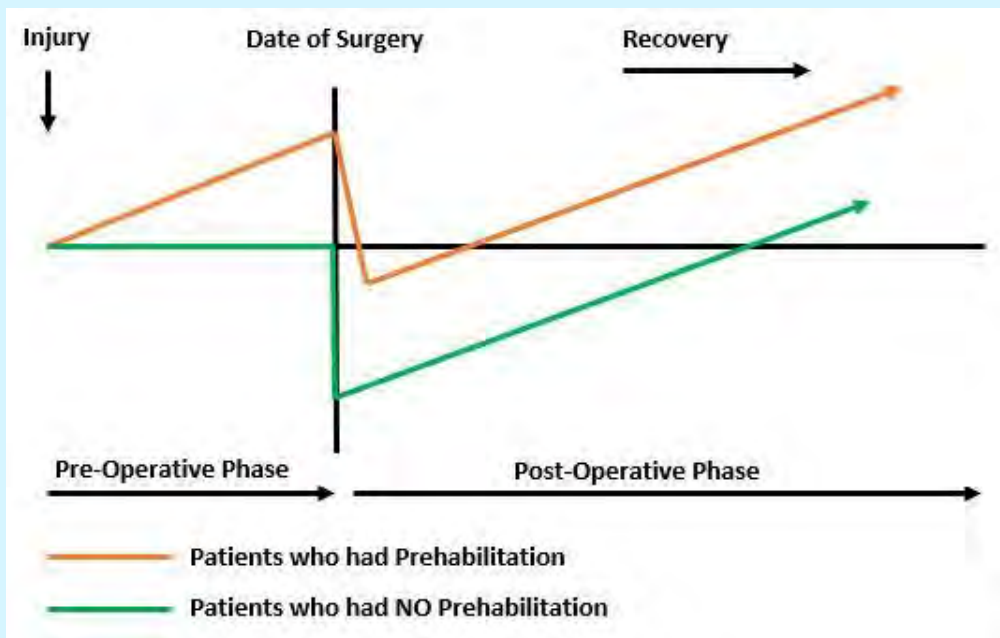
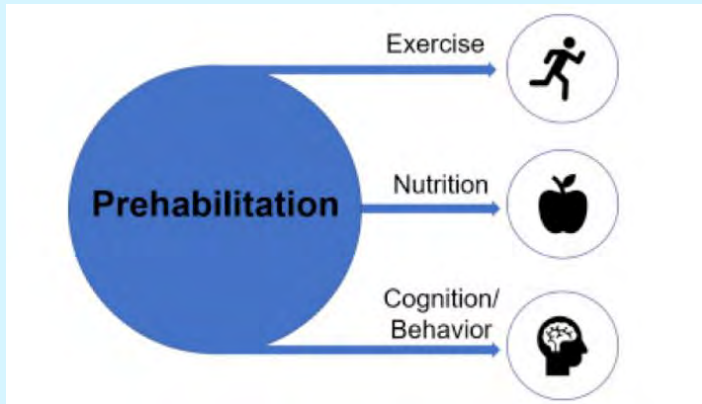
# Problem

## Improvable Surgical Preparation

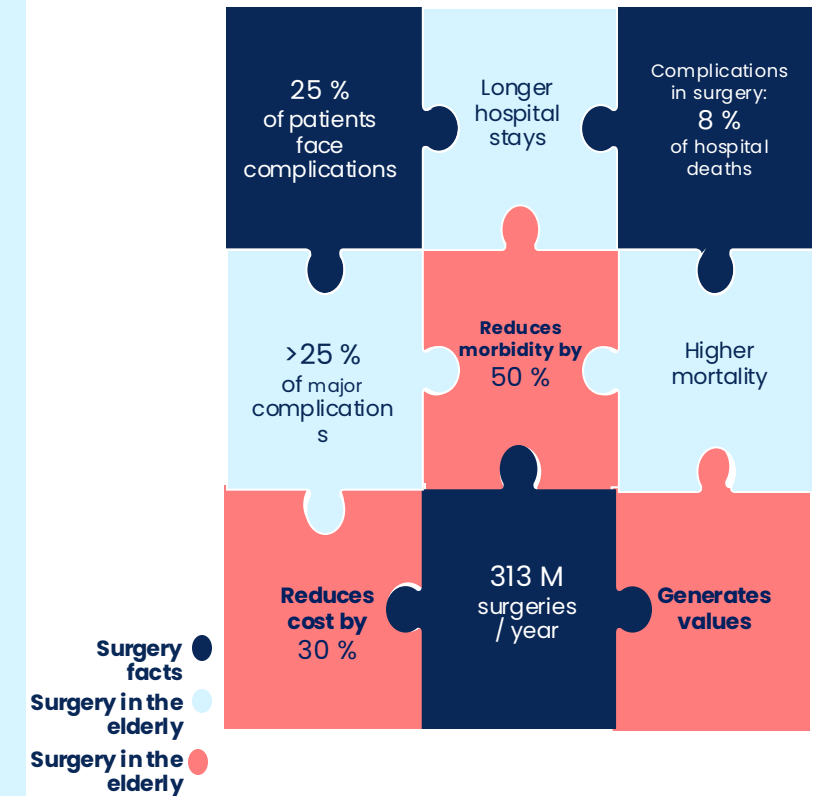
- Surgery has a high risk of harming the patient.
- This leads to exploding costs in healthcare systems.
- Many patients feel uncertain and unprepared before surgery.
- Ineffective communication between doctors and patients aggravates the issue.
- Global healthcare crises strain hospital capacities, highlighting the need for more efficient patient management (brain drain).



# Solution



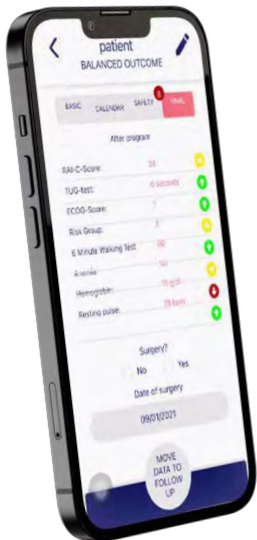
CAPREOLOS Pioneering in digital prehabilitation



Sliwinski, Frontiers of Surgery 2023  
 Barberan Garcia, Ann Surg 2019  
 Molenaar, Jama, 2023

# The Prep4Surg App

## Doctor view



## Intuitive usability

- Doctors enter patient data
- Automated individual calculation for every patient
- Patients get access to individualized nutrition and exercise based on their medical condition

## Benefits

- Individualized prehabilitation program
- Makes the patient fit before surgery
- Home-based aerobic tracked exercising program in combination with a smart watch

## Patient view



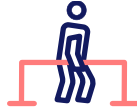
**But: highly regulated field**  
(MDR, Cybersecurity & Data protection)

# Clinical Application



First pre-operative visit

3-6 weeks  
before surgery



Training period

Out-patient training  
up to six weeks



Reassessment & Surgery

In-patient  
treatment period



Post-operative care

Period up to 90 days  
after surgery

## Rudolph. K.

- 64 y/o male, married, two kids, early retirement
- Newly diagnosed with colon cancer
- Indicated procedure: Colon resection
- Secondary diagnoses: hypertonus, diabetes, hypercholesterinemia
- Medication list: Amlodipine, Atorvastatin, Ramipril
- 20 packyears (1 pack of cigarettes for 20 years)
- Average mobility: cycling, regular walks

# Clinical & Economic Evaluation

	Surgery	Prehab	Digital Therapies
Medical facts	<ul style="list-style-type: none"> <li>70% of early-stage tumors undergo surgery</li> <li>Up to 25% of complications are severe</li> <li>1 out of 7€ is spent to treat complications</li> </ul>	<ul style="list-style-type: none"> <li>Lacks adequate infrastructure</li> <li>Healthcare workforce crisis</li> <li>Low penetration in hospitals</li> <li>Economic pressure</li> </ul>	<ul style="list-style-type: none"> <li>The next generation of patients is digitized (45 to 75 years old)</li> <li>High impact within a short time</li> <li>Empowers patients</li> <li>Are a clear WHO will</li> </ul>
With the Prep4Surg App	<ul style="list-style-type: none"> <li>3 to 6-week exercise program adapted to individual needs</li> <li>Best possible state prior to surgery under doctor's remote control</li> <li>Interactive risk-based communication</li> <li>Reduced complication risk up to 50%</li> <li>Better quality of life before &amp; after surgery</li> </ul>	<ul style="list-style-type: none"> <li>Improved surgery results</li> <li>Reduced patient mortality</li> <li>Reduced complication rates</li> <li>Shorter hospitals stays</li> </ul>	<ul style="list-style-type: none"> <li>Increased standards of patient care</li> <li>Cost reduction by up to 30 % due to fewer complications and shorter hospital stays</li> <li>Increased safety and quality of care</li> </ul>



- Stepwise increase of patients to 50% on prep4surg
- Max. investment of 300K €/y for hospitals per 1.000 treated patients worldwide


**Cost reduction due to less complications and increase in total hospital revenue (=1.3M €/J) PLUS**



**Shorter hospital stays**  
1 to 1.5 d



**Up to 150 pats/y**  
more per 1.000 treated



**Reduced cost for M&M**  
by up to 5.8B €/y worldwide



**Increased revenue stream**  
by up to 17B €/y worldwide

# Creating the Evidence

## Protego Maxima

Completed in 2023

Usability Trial (summative evaluation)

- Structured evaluation
- Use Scenarios
- Heuristic Evaluation



- Great usability and design
- safety and high-risk scenarios performed effortlessly.

- 300 Patients (Risk assessment)
- 75 Users/Pats (Safety assessment)

- Outcome Screening
- Use Scenarios
- Validity and Safety compared to certified ECG



- Valid risk assessment tool
- Good prediction of 90-day outcomes after major surgeries.

## LUMOS

July 2024–February 2025 (Ethics approval in June 2024, Start of Recruiting in August/September)

- Multicentric Randomized-controlled trial
- Two arms:  
interventional prehab vs. information only



Primary endpoint

- Reduction of 90 day morbidity

Secondary endpoints

- Vigilance, costs, compliance etc.



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Hessische Ministerin für  
Digitale Strategie und Entwicklung



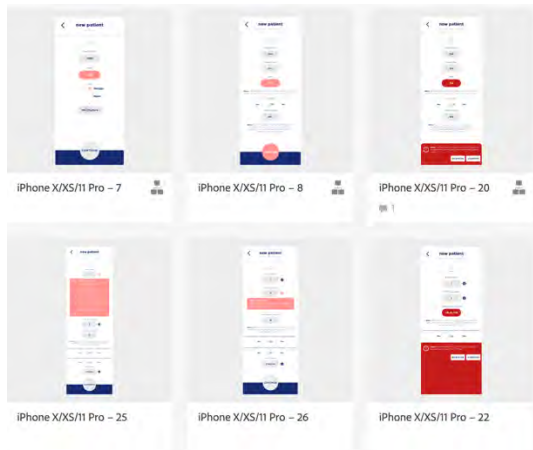
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Kröner  
Fresenius  
Stiftung

2021\_EKTP10

# Step I: Usability



8 Experts  
8 Patients

Structured evaluation

uMARS, ABACUS,  
Trustworthiness Checklist,  
APS App Checklist

Use Scenarios

Heuristic Evaluation, Risk Evaluation

Faqar, BMJ open, 2023



# Step I: Usability

Demographics and Summary Scores	Task I				Task II			
	Total n=16	Expert n=8	Lay n=8	p-value	Total n=16	Expert n=8	Lay n=8	p-value
Age Mean ± SD	51,6 ± 13,1	43,6 ± 5,7	59,5 ± 13,8	0,009	51,6 ± 13,1	43,6 ± 5,7	59,5 ± 13,8	0,009
Sex (f/m)	7/9	4/4	3/5	0,61	7/9	4/4	3/5	0,61
Trustworthiness/APS Score (Sum ± SD)	51,0 ± 2,3	51,3 ± 2,7	50,8 ± 2,1	0,60	53,1 ± 0,7	52,9 ± 0,8	53,3 ± 0,7	0,66
MARS Engagement Summary (Mean ± SD)	4,3 ± 0,4	4,5 ± 0,2	4,2 ± 0,4	0,34	4,3 ± 0,2	4,3 ± 0,2	4,3 ± 0,2	0,27
MARS Functionality Summary (Mean ± SD)	4,7 ± 0,5	4,8 ± 0,5	4,6 ± 0,5	0,33	4,5 ± 0,5	4,6 ± 0,5	4,3 ± 0,5	1,00
MARS Aesthetic Summary (Mean ± SD)	4,8 ± 0,4	4,8 ± 0,4	4,7 ± 0,5	0,69	4,5 ± 0,2	4,5 ± 0,3	4,5 ± 0,3	1,00
MARS Information Summary (Mean ± SD)	4,6 ± 0,3	4,5 ± 0,3	4,6 ± 0,2	0,48	4,4 ± 0,2	4,4 ± 0,2	4,5 ± 0,1	0,06
MARS Subjective Quality (Mean ± SD)	4,3 ± 0,4	4,5 ± 0,3	4,2 ± 0,5	0,54	4,6 ± 0,4	4,6 ± 0,4	4,6 ± 0,4	0,72
MARS Perceived Impact (Mean ± SD)	4,6 ± 0,4	4,9 ± 0,2	4,4 ± 0,3	0,04	4,9 ± 0,3	4,9 ± 0,2	4,8 ± 0,3	0,35
MARS App Quality Score (Mean ± SD)	4,6 ± 0,3	4,6 ± 0,2	4,5 ± 0,3	0,67	4,4 ± 0,2	4,5 ± 0,2	4,4 ± 0,2	0,35

# Summative Evaluation

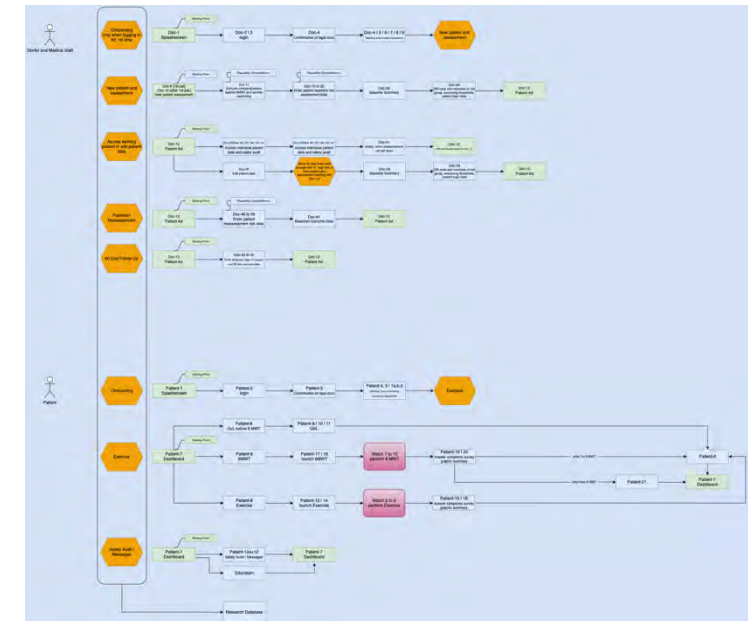
## Doc-Scenarios

- onboard and enter a first patient (Scenario D1)
- correct a wrong data entry (Scenario D2)
- onboard the patient and explain the app workflow (Scenario D3)
- read and click the safety audit (Scenario D4)
- perform a 90 day follow up assessment (Scenario D5).

## Patient scenarios

- perform an onboarding (Scenario P1)
- explore the app by navigating through the tabs (Scenario P2)
- start a 6MWT and an exercise (Scenario P3)
- fill out the symptom checker after an exercise (Scenario P4)
- react to the notifications in the safety audit generated by the software (Scenario P5).

## Usability Workflow of Prep4Surg



Schnitzbauer, JMIR 2024 under review

# Summative Evaluation

	Usability Scenario	Duration (Seconds ± SD)	Satisfaction with ease of compl. (mean ± SD)	Timely satisfaction (mean ± SD)	Support satisfaction (mean ± SD)	Evaluator (mean ± SD)
<b>D1</b>	Create a new patient and enter the risk assessment data	211 ± 13	1,50 ± 0,53	1,50 ± 0,53	1,38 ± 0,52	1,0 ± 0
<b>D2</b>	Correct patient data if an error has occurred	103 ± 38	1,25 ± 0,46	1,63 ± 0,52	1,0 ± 0	1,0 ± 0
<b>D3</b>	<b>Launch system on patient smartphone, onboarding, workflow presentation</b>	<b>1213 ± 191</b>	<b>2,75 ± 0,46</b>	<b>3,38 ± 0,52</b>	<b>3,5 ± 0,53</b>	<b>2,0 ± 0</b>
<b>D4</b>	Notification and reaction to safety audit	77 ± 6	1,25 ± 0,46	1,25 ± 0,46	1,25 ± 0,46	1,0 ± 0
<b>D5</b>	Detect patient in follow up list and perform 90 day follow up	147 ± 11	1,50 ± 0,53	1,38 ± 0,52	1,38 ± 0,52	1,0 ± 0
<b>P1</b>	<b>Safe onboarding and smartwatch connection</b>	<b>1266 ± 136</b>	<b>3,13 ± 0,35</b>	<b>3,38 ± 0,52</b>	<b>3,38 ± 0,74</b>	<b>2,0 ± 0</b>
<b>P2</b>	Dashboard and content exploration	220 ± 26	1,88 ± 0,35	1,63 ± 0,52	1,63 ± 0,52	1,0 ± 0
<b>P3</b>	Launch 6MWT or exercise	78 ± 16	1,50 ± 0,53	1,63 ± 0,52	1,63 ± 0,52	1,0 ± 0
<b>P4</b>	Fill out post exercise PROM	47 ± 15	1,38 ± 0,52	1,38 ± 0,52	1,13 ± 0,35	1,0 ± 0
<b>P5</b>	Notification and reaction to safety audit	116 ± 20	1,88 ± 0,35	1,75 ± 0,46	1,25 ± 0,46	1,0 ± 0
<b>P6*</b>	Reaction to haptic and optical alarm on smartwatch	10 ± 8	2,03 ± 1,32	1,97 ± 1,31	1,99 ± 1,31	1,41 ± 0,57

## Usability Summary

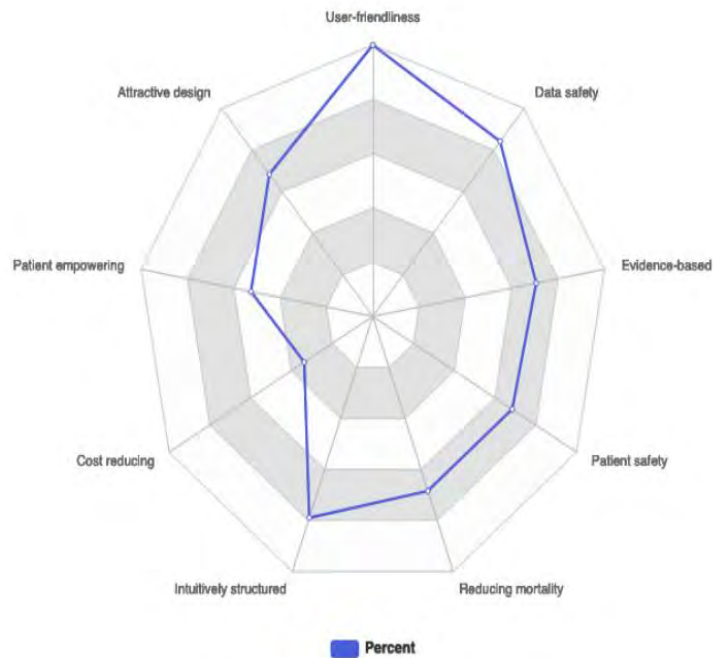
1. Usability and design rated high.
2. Patients, doctors and experts were able to perform the safety and high-risk scenarios effortlessly.

### Top 3 best features:

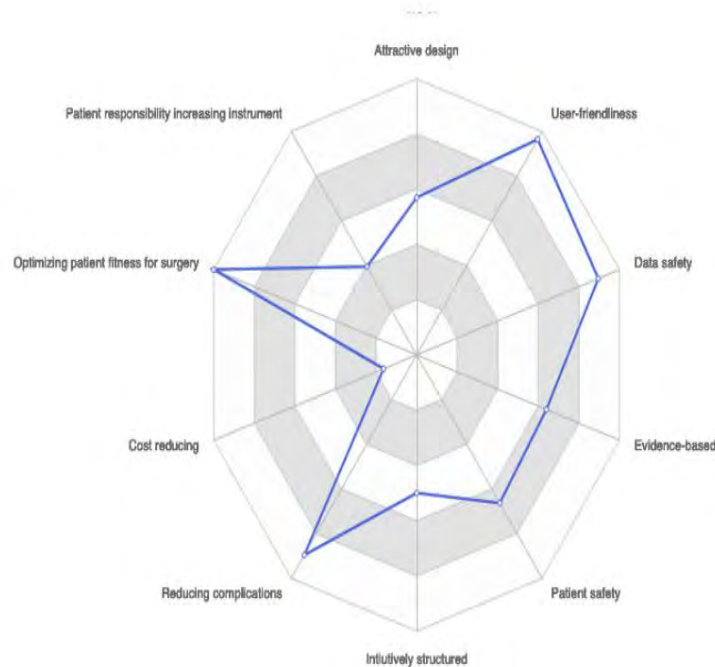
- 'good instructions'
- 'intuitive'
- 'dashboard' and 'dashboard functions'
- 'simple'
- 'clear'
- 'design and layout'
- 'structured risk assessment', 'outcome data', 'benchmarking'
- 'thresholds'

Schnitzbauer, JMIR 2024 under review

# Evidence for digital willingness



115 Ärzte



37 Patienten

Harvard Business Review

TECHNOLOGY

## Don't Put a Digital Expert in Charge of Your Digital Transformation

by Nathan Furr, Jur Gaarlandt and Andrew Shipilov  
AUGUST 05, 2019



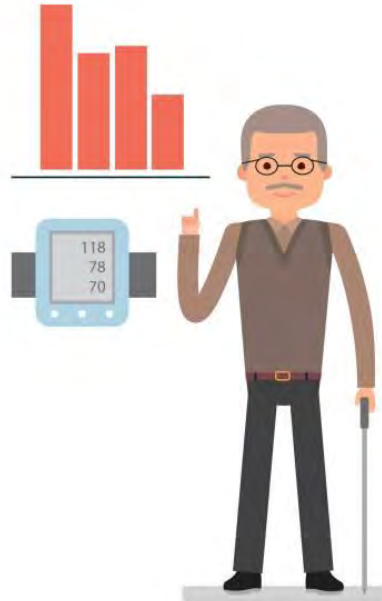
SHANA NOVAK/GETTY IMAGES

- Age is not a digital show stopper
- Interest is present in admin, docs and patient

Just do it!

Schnitzbauer, Lancet Dig Health 2024

# Step II: Validity & Safety



300 Patients (Task IIIa: Risk assessment)

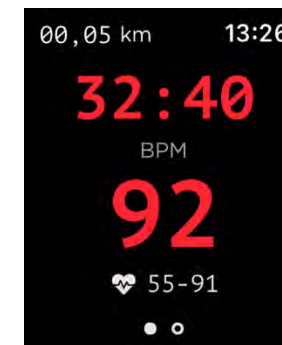
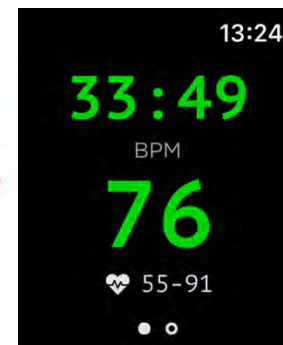
75 Proband/Patienten (Task IIIb: Use scenarios)

Screening -Outcome

Validity of Software/Smartwatches

Use Scenarios

Validity and Safety correlations



Faqar, BMJ open, 2023

# Validity of the Risk Calculator

- 300 Patienten in App Risk Assessment
- ECOG, TUG, RAI (12 Item Risk score!)
- Age, HR at rest, HR-changing drugs
- Karvonenmethod -> Exercise Program
- Correlation of risk scores with postoperative 90d-OS

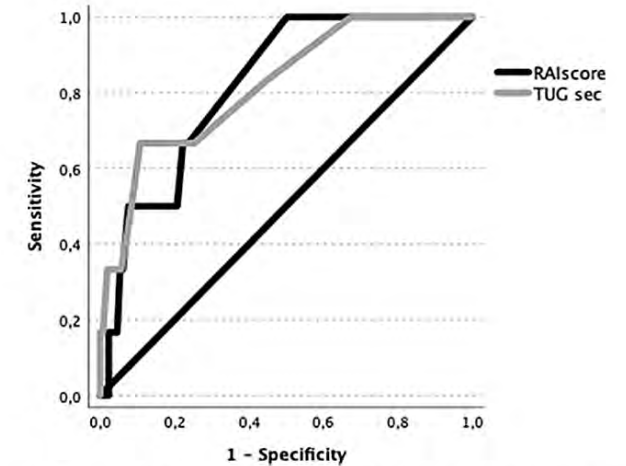
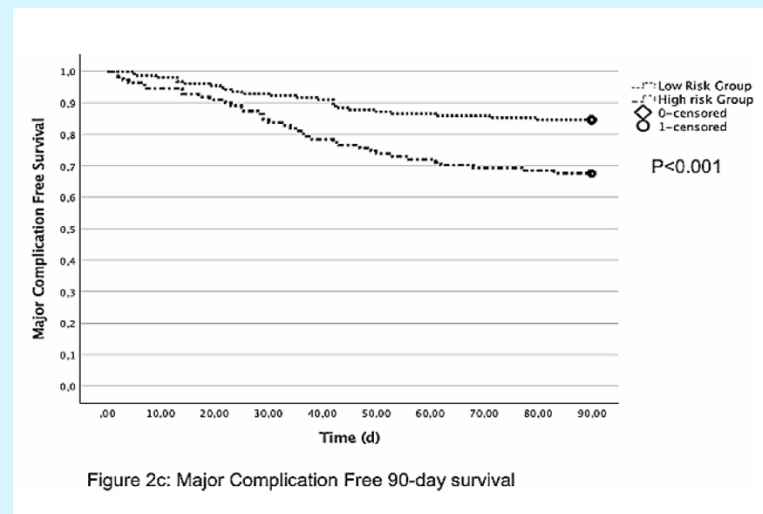


Fig. 1 Receiver Operator Curves (ROC) for the Timed Up and Go Test (TUG) and the Risk Analysis Index (RAI score). The area under the curve (AU)-ROC for the TUG was 0.818, with a predictive cut-off of 8 s (Sensitivity 75%, specificity: 65%,  $p < 0.001$ ). The AU-ROC for the RAI scoring was 0.804, with a predictive cut-off of 25 (Sensitivity 83%, specificity 62%,  $p < 0.001$ )

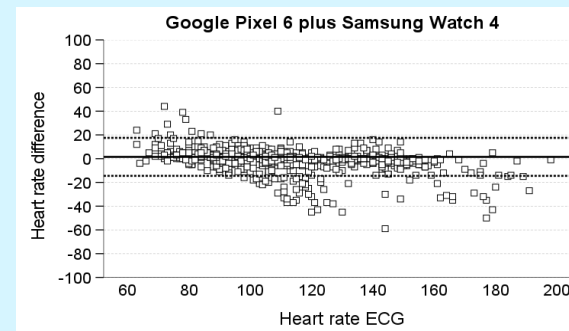
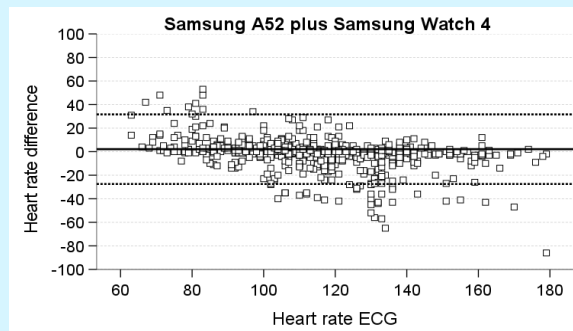
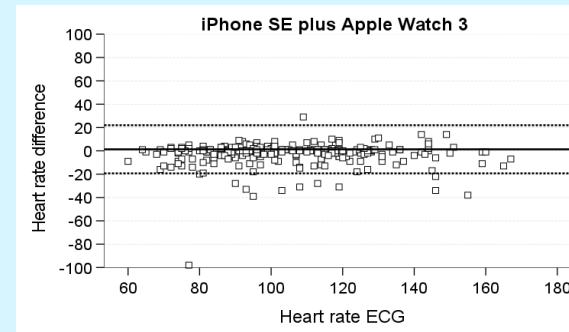
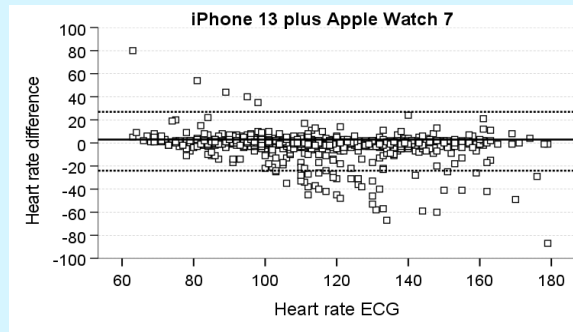


High risk group and outcome AUROC = 0.842  
 Low-risk group and outcome AUROC = 0.990  
 $p = 0.01$

TUG 8s AUROC 0.818 (Sens: 75%, Spec 65%;  $p > 0.001$ )  
 RAI 25 AUROC 0.804 (Sens 83%, Spec 62%;  $p < 0.001$ )

# Validity of Smart Watches (iOS/google wear OS)

- Test Smartwatch plus Software against certified ECG (300 datasets)
- 10 healthy students, 65 patients with/without risk factors
- Supervised exercising and 6MWT on treadmill
- Bland Altman Plotting
- Labcontrol



- Extremely low <5% deviation in HR
- Acceptable deviation in distance measurement
- Low AE rates
- No signs of too strenuous exercising in cfDNA signatures & standard lab controls

# Conclusions after PM

1. Usability and design were rated very high by patients, doctors and experts.
2. Patients, doctors and experts were able to perform the safety and high-risk scenarios effortlessly.
3. The risk assessment tools used are reliable
4. The preoperative risk calculator can predict 90-day outcomes after major surgeries
5. The Prehab App can be safely applied in patients before major surgeries under supervision and should be tested in a remote setting.
6. The Prehab App software in combination with iOS and Google wear OS wearables delivered accurate pulse measurements when compared to a certified ECG with a deviation of less than 5bpM.





# Next Step LUMOS

**A multicenter prospective randomized controlled trial to test the safety and efficacy of a systematic app-based remote and home-based prehabilitation program in comparison to education only before major surgeries:**

## The LUMOS Study



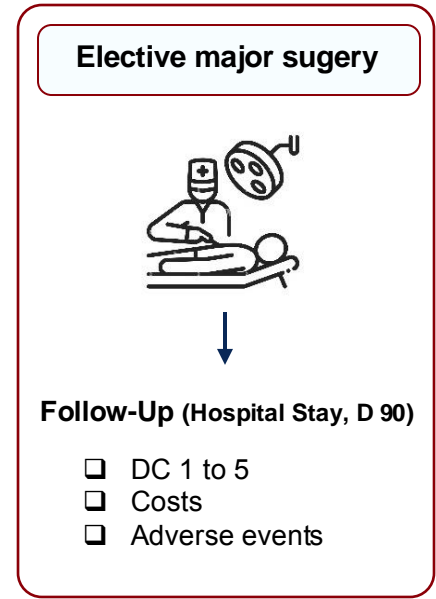
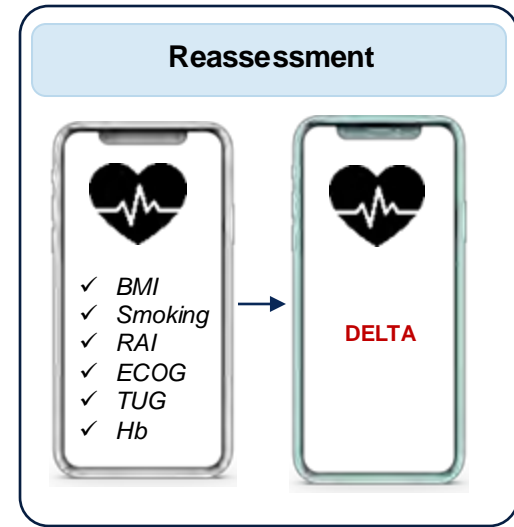
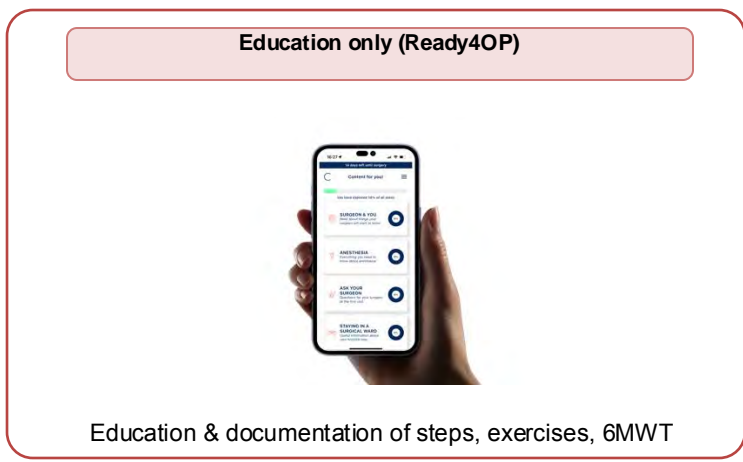
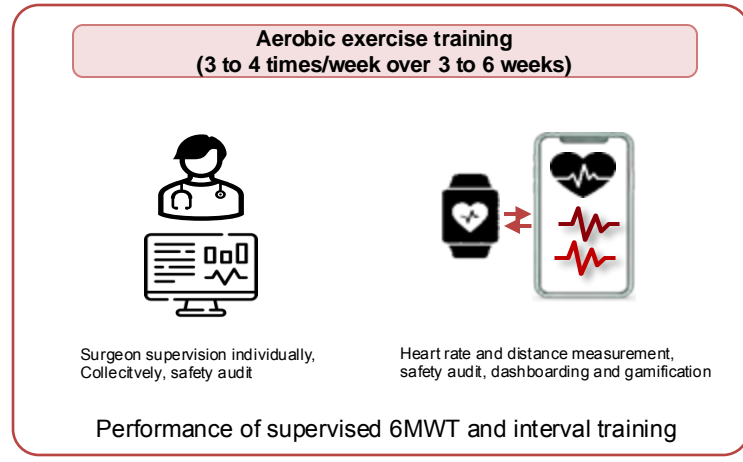
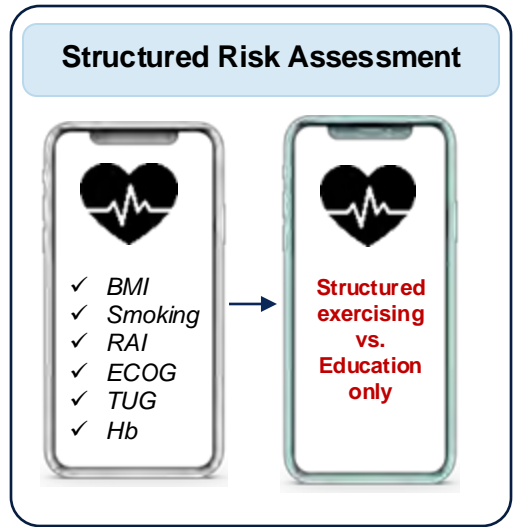
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Digitale Strategie und Entwicklung



**digitales.hessen**  
**DISTR@L**



# Next Step LUMOS



Screening & Assessment

Randomization & Intervention

Reassessment

Surgery & FU



# Next Step LUMOS

## Interoperability & Integration

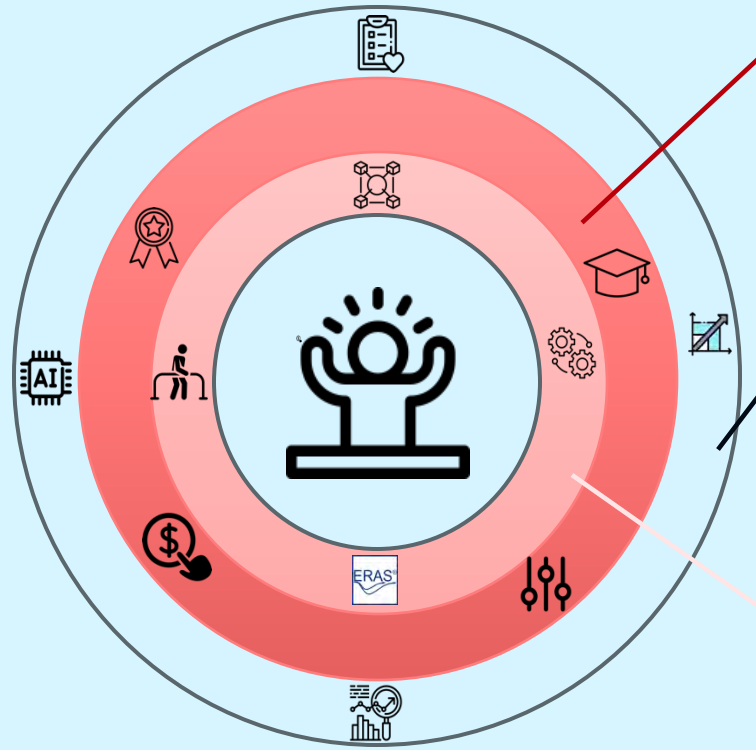
- FHIR/HL7 standard
- HIPPA compliant
- DIN ISO 27001 compliant/C5 certificate
- ERAS & rehabilitation

## Quality & Education

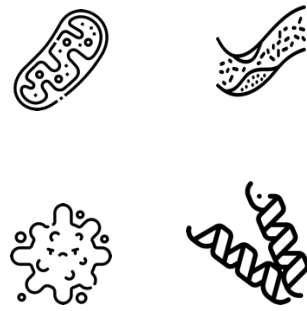
- Training & CME for docs and pats
- Steering tool for payment & patient streams
- Quality measurement instrument

## Support & Analytics

- Benchmarking & dashboarding
- AI steering of exercises
- Integrated careplans
- Maintenance & support team



High potential to clarify the mechanisms of prehabilitation



# A big hoooooray to...



Dr. med. Svenja Sliwinski  
Dr. med. Fatima Faqar Uz Zaman  
Charlotte Detemble  
PD Dr. Johannes Fleckenstein  
Lisa Mohr

