



Empowering patients by professional stress avoidance and recovery services

FINAL CONFERENCE



Agenda

- 09.00 Welcome and introduction
- 09.05 Overview of STARS PCP: from unmet needs to clinical prototype testing
- 09.25 The solution developed by Adhera Health
- 09.40 The solution developed by Evidenze
- 09.55 Coffee Break
- 10.10 Field testing overview, user experience, testimonials, and buyers group insights
- 10.40 Good practices and lessons learnt from the PCP process
- 10.55 Q&A
- 11.10 Closing remarks



Overview of STARS PCP: from unmet needs to clinical prototype testing

Ine Vandewauw (Maastricht University, coordinator)

Perioperative stress

Although considered to be a normal part of the surgical experience

→ pervasive problem with far-reaching health outcomes



- <https://www.youtube.com/watch?v=BAIdt4JgaiA>

Mission statement

Five leading European hospitals challenge the European industry to design and develop a resilient support tool to be applied in the field of patients planned for surgery, with the aim of reducing stress during the entire care path.

The available budget for the development of this innovative solution is 4.7 million euro of which 3.26 million (including VAT) will flow to the industry.



Consortium

Laurea-ammattikorkeakoulu Oy

Zenit Zentrum für Innovation und Technik in NRW - GmbH

Universiteit Maastricht

Academisch Ziekenhuis Maastricht

Agència de Qualitat i Avaluació Sanitàries de Catalunya

Hospital Sant Joan De Déu

Fundació Parc Taulí

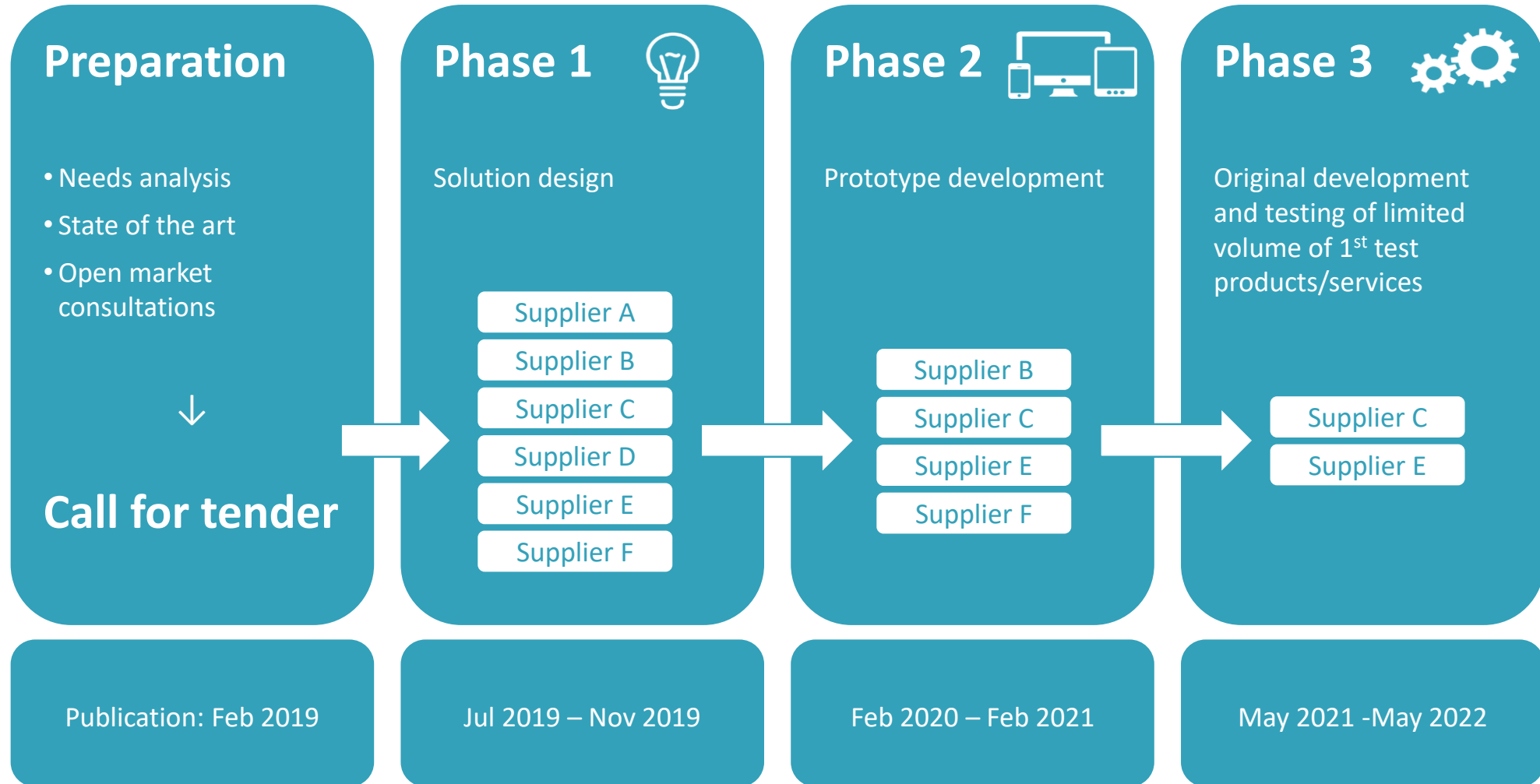
Servicio Andaluz De Salud

Bedin Sara (independent expert on innovation procurement)

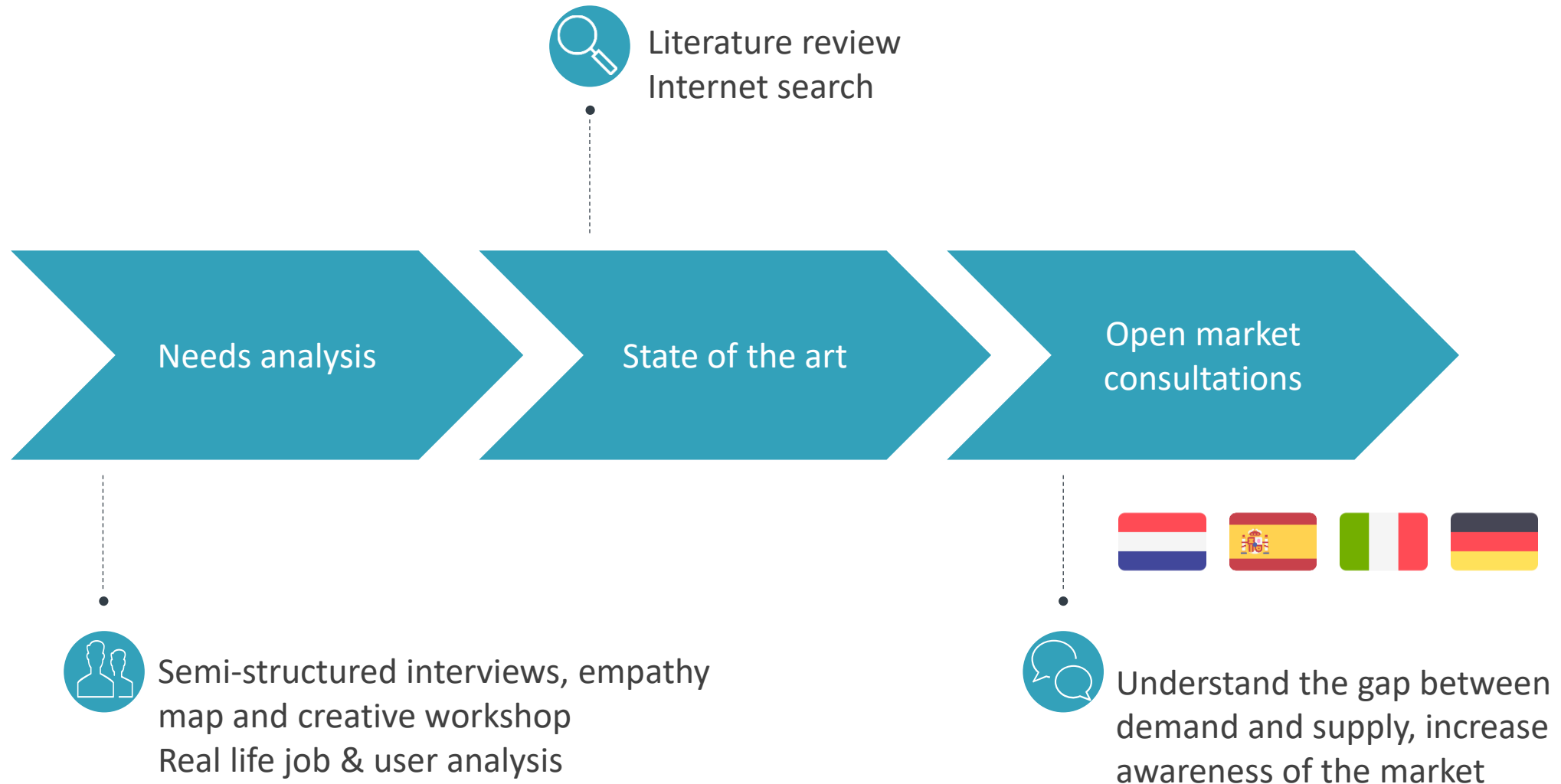
Istituto Nazionale di Riposo e Cura per Anziani INRCA

Ethniko Kai Kapodistriako Panepistimio Athinon

Pre-commercial procurement process



Preparatory phase



Requirements for the solution



Information and
education



Follow-up and
monitoring



Communication



Enabling
autonomy

Requirements for the solution



From children to elderly



Different surgeries



Different cultures

Call for tender



21 bids

- 5 joint consortia
- 33 entities
- 24 start-ups or SMEs
- 8 different countries

PCP process



Phase 1

Adhera Health



Evidenze



Mysphera



Bahia



Linkcare



Fundació Eurecat



PCP process



Phase 1



Phase 2

Adhera Health



Evidenze



Mysphera



Bahia



Linkcare



Fundació Eurecat



PCP process



Phase 1



Phase 2



Phase 3

Adhera Health



Evidenze



Mysphera



Bahia



Linkcare



Fundació Eurecat



Field testing at 5 locations



Hospital Universitario
Reina Sofía



Parc Taulí Hospital
Universitari



Hospital Sant Joan de
Déu



Maastricht UMC+



Istituto di Ricovero e
Cura e Carattere
Scientifico



The solution developed by Adhera Health

Luis Fernandez-Luque



CARINAE - Empowering patients by professional STress Avoidance and Recovery Services

Consortium:

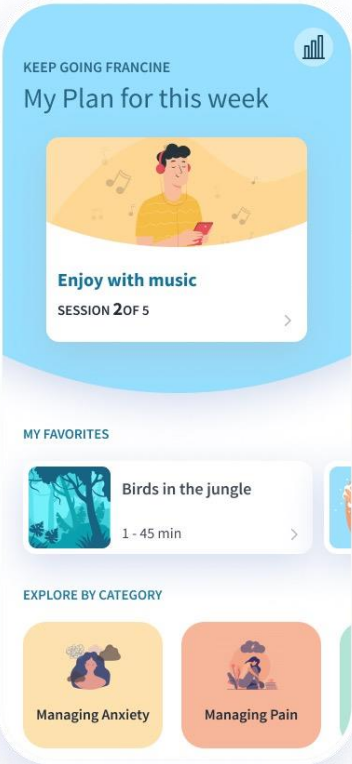


Subcontractors:

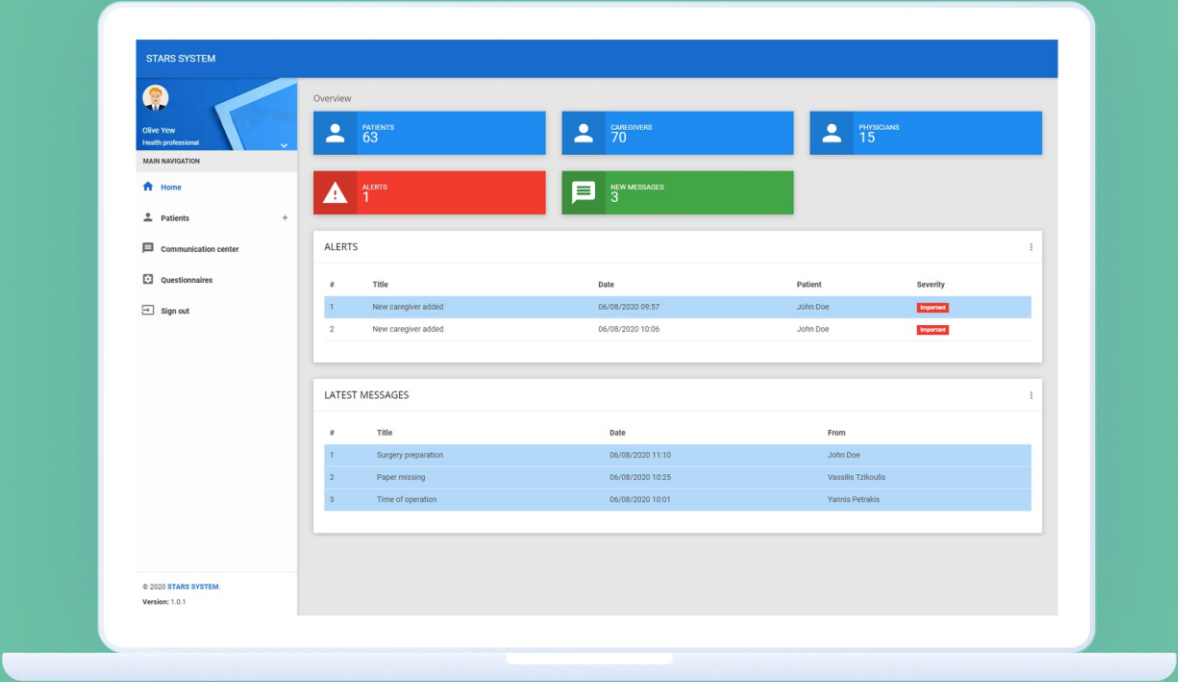


CARINAE Solution

For Patients and Caregivers



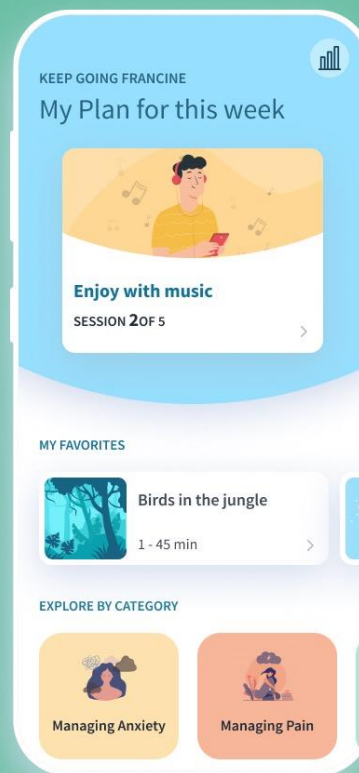
For Healthcare Professionals



- See movie on the STARS website – PCP phases – Phase 3

CARINAE Learnings

- Implementation is very complex, specially during COVID19.
- High interest on the topic of stress/mental health across therapeutic areas.
- One size does not fit all - We need to adapt services/offerings to personalized support at each implementation.



CARINAE Next Steps

- R&D to support reimbursement strategy
- Expanding evidence generation to specific therapeutic areas
 - Stronger focus on implementation research (pragmatical trials)
- New partnerships with clinical partners





Thanks!

luis@adherahealth.com

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The solution developed by Evidenze

Ana Génova & Joan Escudero



Stress Adaptive Manager (SAM)

Empowering patients by professional **ST**ress **A**voidance and
Recovery **S**ervices (STARS PCP)

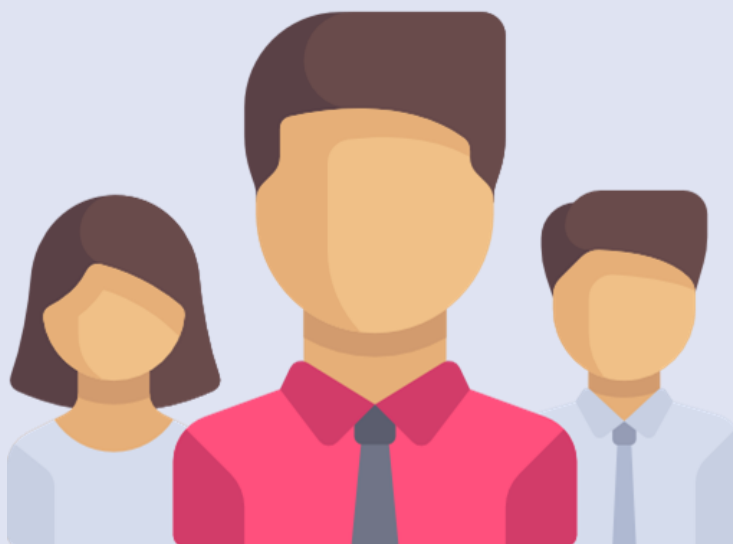
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no. 727585

Ana Génova
Joan Escudero

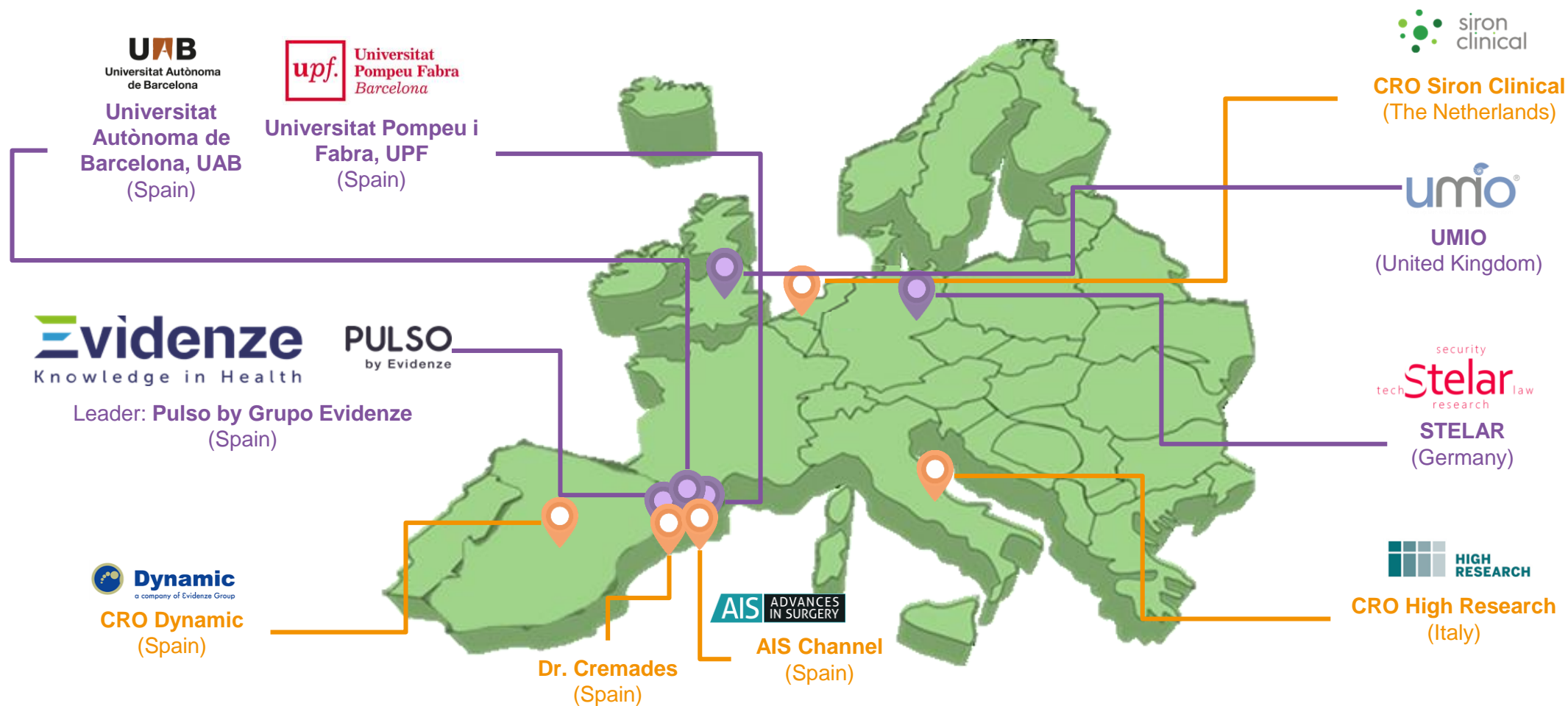
June 22nd, 2022



Entities composing the consortium



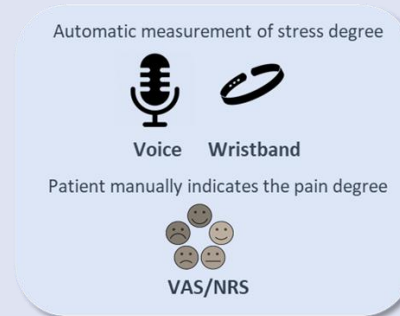
Consortium and subcontractors



Description of the SAM solution



MONITORING of patient stress and pain



Stress and pain degree



Personalized SOLUTIONS to reduce stress



Personalized solutions algorithms

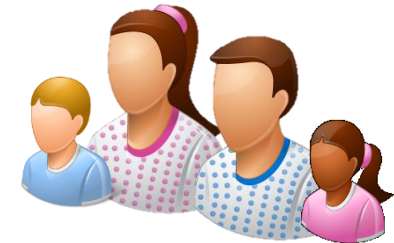
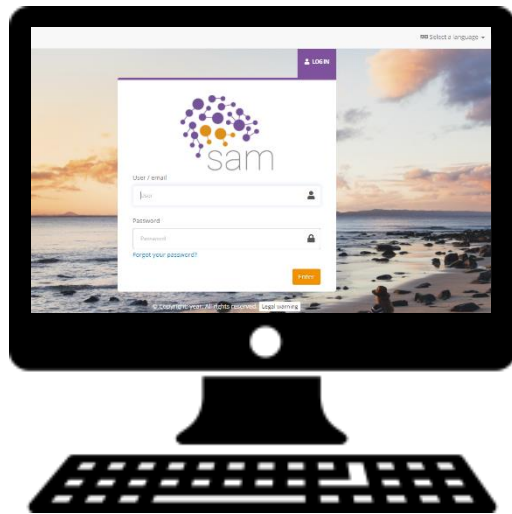


Patient and Caregiver

The solution

Scheme

HEALTHCARE PROFESSIONALS



PATIENTS/CAREGIVERS

Innovative** technological solution that **empowers** patients and allows them to **self-assess** and **self-manage** their perceived stress caused by an **upcoming surgical operation



Demo of the SAM solution - video

Video content:

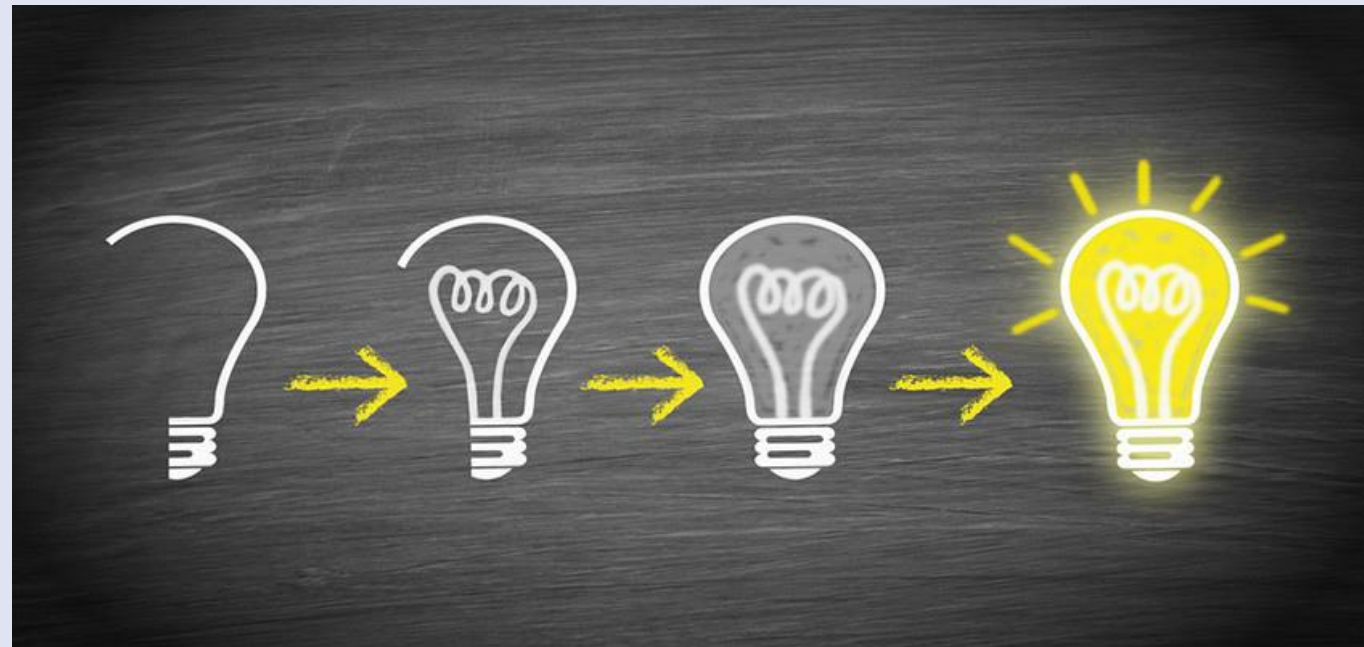
1. Short intro of the solution
2. Demonstration of the main functionalities and components with links to the PCP challenge description and functionalities
3. How it works along the path
4. Distinctive innovative aspects of the proposed solution. Why does the solution represent a breakthrough on the market?
5. Main benefits for who, attested by results/evidences.



*The video was recorded at the hospital facilities of the Procurers' hospital, **Hospital Parc Taulí** in Sabadell, Spain*

- See movie on the STARS website – PCP phases – Phase 3

Lessons learned and next steps



STARS PCP



Lessons Learned

- 1 Efficient communication between buyers (procurers) and contractors has been a key success factor, specially to overcome difficulties derived from SARS-CoV2 pandemic
- 2 Importance to work hand-in-hand with CRO for the pilot phase and to involve end-users from the beginning and make them part of the solution



Next Steps

- 1 Real unmet need, cross-europe (even worldwide) which will allow us to develop new business lines
- 2 Implement feedback from end-users of Phase 3 to improve our SAM solution
- 3 In the process of evaluating the commercialization of SAM at private (pharma) and/or Procurers' level

Future potential of SAM



Increase and intensification in the **desire for personal well-being**

Huge growth in demand for **wellness technologies and services** [1]



Considering **good usability feedback** and post-pandemic **surge of desire for wellness and wellbeing**



SAM IS IDEALLY POSITIONED TO SUCCEED IN SURGICAL STRESS MARKET AND BEYOND

[1] The Global Wellness Institute forecasts the global mental wellness market to be worth c \$200 bn and the workplace wellness market c \$50 bn



Q&A

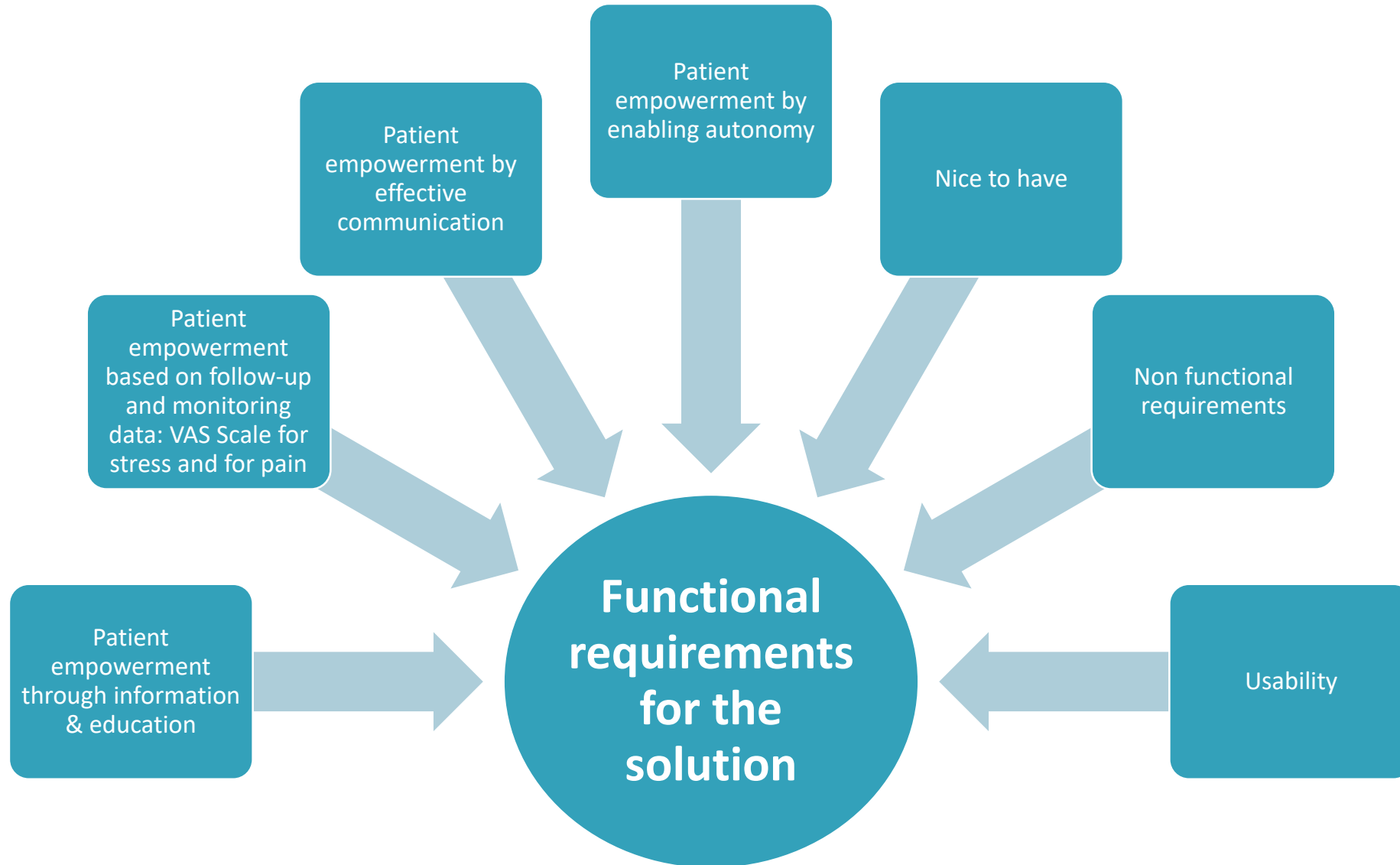
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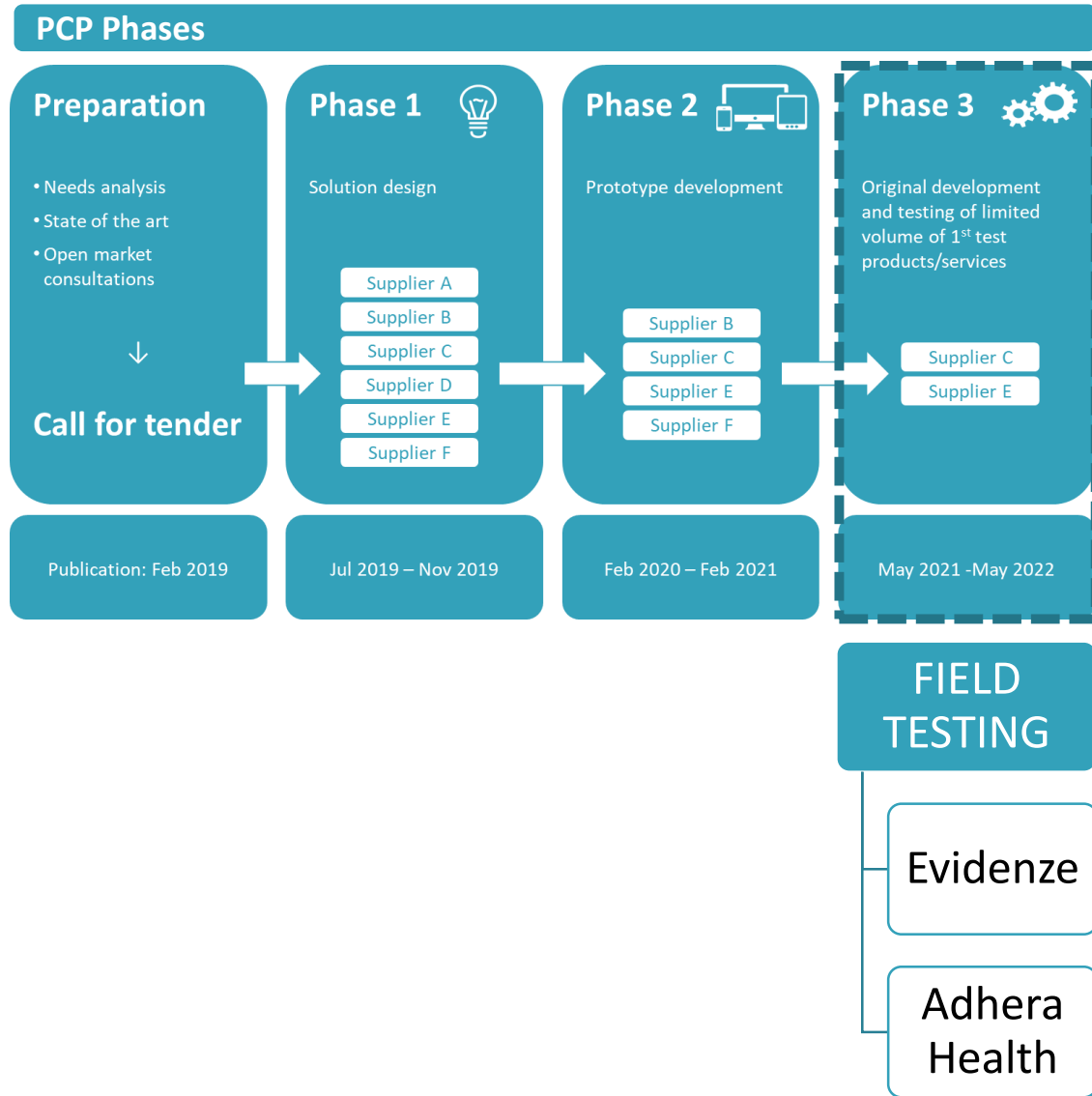
Field testing overview, user experience, testimonials and buyers group insights

Andrea Vallejo, MD (Parc Taulí, buyer)

Objectives for the solution: call for tender



Who, when, where?



5 leading European hospitals



Methods – inclusion criteria

- Adults (apart from paediatric Hospital Sant Joan de Déu: children ≥ 8 years old)
- Planned surgery of the following selected types:
 - Coronary bypass surgery: MUMC
 - Orthognathic surgery: HSJD
 - Idiopathic scoliosis without mental impairment and hip surgery: HSJD
 - Maxillofacial surgery: HSJD
 - Hip and knee replacement: Parc Taulí
 - Prostate and bladder cancer surgery: INRCA
 - Cardiac valve replacement, possibly in combination with coronary bypass surgery: Reina Sofia
- Planned surgery 2 to 4 weeks after the moment of inclusion/signing the informed consent
- Signed informed consent (by the patient or legal representative in paediatric cases)

Methods – exclusion criteria

- Dementia
- Any other psychiatric disorder
- Pregnant women
- Categorised by American Society of Anaesthesiologists (ASA) IV (for children of hospital Sant Joan de Déu \geq IV)

Methods – study design

- Multicentre
- Open-label
- Randomized 1:1 to the:
 - Intervention group
 - Control group (routine clinical follow-up)
- Study calendar: December 2021 – April 2022
- Sample number: 60 patients each contractor (24 per site)

Methods – study objectives

Primary study objective

- Assessment of changes in stress exhibited by patients using the solution versus those in the control group during the surgical procedure

Secondary study objectives

- Assessment of changes in the stress between groups in the different phases
- Assessment of changes in pain
- Assessment of changes in patient empowerment or self-assessment
- Assessment of changes in quality of life
- Assessment of differences in wound healing problems
- Usability and satisfaction with the solution according to patients and healthcare professionals' experience during the study
- Assessment of correlation of stress levels measures with VAS with levels identified by other tools

Methods – study schedule



Evidenze

- Visit 1 - baseline (2-4 weeks before surgery)
 - ICF, eligibility, randomization
- Visit 2 - hospital admission
 - stress, pain scale, usability
- **Visit 3 – surgery**
 - **stress pain scale, usability**
- Visit 4 - hospital discharge
 - stress, pain scale, usability, wound healing
- Visit 5 - 14 days post-surgery visit
 - stress, pain scale, usability, wound healing, recovery VAS



Adhera Health

- Visit 1 - baseline (2-4 weeks before surgery)
 - ICF, eligibility, VAS, questionnaires
- Visit 2 - hospital admission
 - VAS, questionnaires, usability, satisfaction
- Visit 3 - hospital discharge
 - VAS, questionnaires, usability, satisfaction
- Visit 4 - 14 days post-surgery visit
 - VAS, questionnaires, usability, satisfaction

Results



- Patients included: 42; 2 excluded to the inability to operate SAM

- Patients randomized and analysed: 40

- ✓ 12 HSJD
- ✓ 12 INRCA
- ✓ 10 Parc Taulí
- ✓ 6 Reina Sofía
- ✓ 2 MUMC

21p (52,5%) randomised to SAM group
19p (47,5%) randomised to control group



30p (81,1%)
patients finished
the study as the
protocol

- Reasons for uncompleted patients

- ✓ Lost follow up
- ✓ Informed consent withdrawal
- ✓ Covid infection
- ✓ Adverse event

Conclusions



1. Changes in stress, pain, empowerment, quality of life, and wound healing did not significantly differ between the two groups
2. Patients' use of the solution during the patient journey:
 - ✓ around 90% at least once
 - ✓ approximately 75% at least once a week
3. Positive usability and satisfaction evaluation, solution considered to be an added value, easy to use, pleasant, clear, non-intrusive nor physically demanding
4. Intuitive and clear information
5. High satisfaction scores
6. Participants would recommend SAM to a friend
7. Patients appreciated the tools to manage stress, the breathing and relaxation exercises, the feeling of being more accompanied and protected, the information about procedures, and the visual distribution of the app

Conclusions



8. Psychology section, communication with the medical team, and access to music could be improved
9. Participants expressed a desire for a more personalized solution providing individualized, adapted content, contextualized stress-experience and medical history questionnaires, and more detailed surgery-specific explanations
10. Limited knowledge on effectiveness of digital health interventions for reducing stress in patients with planned surgery, further and larger studies are needed
11. Some patients suggested a more personalized solution in term of adapted topics, questionnaires, explanations, and feedbacks
12. SAMs voice and wristband measurement technologies seemed promising, but were not fully tested making it impossible to establish if these are reliable clinical landmarks of stress
13. Home automation was only tested in 2 sites due to the short time in the clinical trial and the IT needed to support it.

Results CARINAE

- Patients included: 50

- Patients randomized and analysed: 50



23p (46%) randomised to CARINAE group
27p (54%) randomised to control group

- ✓ 13 HSJD
- ✓ 11 INRCA
- ✓ 10 Parc Taulí
- ✓ 5 Reina Sofía
- ✓ 0 MUMC

39p (78%) patients
finished the study
as the protocol

- Reasons for uncompleted patients:

- ✓ 10 patients drop off the study
- ✓ 1 died during the surgery

Conclusions

1. Changes in stress, pain, quality of life, emotional status, mental well-being, and self-efficacy did not significantly differ between the two groups
2. The control group shows greater relationships between the more negative psychological dimensions, such as anxiety, stress, negative emotions and depression, whereas the intervention group shows more positive relationships between the psychological dimensions of self-efficacy, self-management and mental well-being
3. CARINAE solution could have a positive effect and impact on the reduction of stress and negative emotions
4. The control group showed levels of stress, depression, anxiety and negative emotions that remained constant throughout the entire perioperative process
5. The intervention group shows a greater perception of mental well-being, self-efficacy and self-management during the entire perioperative process and not only at the end of the process

Conclusions

6. Patients considered CARINAE clear, helpful, and easy to use
7. Patients perceived it pleasant, clear and requiring minimal effort to use it
8. CARINAE was moderately able to help patients in increasing the feeling of control and reduce stress levels
9. Patients would recommend CARINAE to other patients, providing a high grade to the solution
10. Most patients used CARINAE once a week, while the older patients used daily
11. Patients negatively reported the communication chat with the healthcare professionals and caregivers
12. Similar opinions were expressed by the healthcare professionals
13. Patients reported engagement, appreciating the approach on psychoeducational contents on surgeries and the easiness to use of the mobile application

Highlights - strengths

- Both solutions have promising functionalities in an integrated and innovative app
- Holistic approach that combines stress assessment, educational content and stress reduction activities according to our requirements in the call for tender
- We have learnt and understood valuable information about stress during the patient journey
- Crucial role of the research assistant hired by the contractors for the recruitment
- Some patients were really interested in taking part as a treatment group (not wanted to be control)
- Surgical stress may be alleviated partly from the fact that patients involved in the field testing receive more attention from clinical researchers and even hospital staff
- As every medical device, a blind placebo is not possible and so any research intervention inevitably creates a modification in the patient's experience prior to any actual use of the device or app itself
- There were high expectations from clinical team and patients in reducing stress
- Despite the pandemic, we could see high commitment from patients and clinical staff with the clinical trial
- Flexibility in the time before surgery to include patients to increase the number of patients
- Usability aspects, evaluating the need of older people and children should be considered

Highlights - weaknesses

- Delayed start of clinical trial due to Covid and Ethical Committees/Medical Regulation Agencies (EU change regulations)
- Covid impact on clinical trial:
 - Surgery cancellations due to high occupancies rates
 - Difficult recruitment due to constant cancellation and rescheduling
 - Non presential visits
 - Lack of healthcare professionals
- A longer period for phase 3 would have been beneficial
 - Due to covid, a live demo was not possible, which made some challenges occur only in the trial phase
 - Some technical issues that delayed the start of the trial and needed to be addressed during it and some connectivity problems
- Very complex perioperative process and heterogeneous population: different types of surgeries and different countries
- Some questionnaires were very long and could be an important factor for patients withdrawal
- Patients request a more personalized solution: a better organized and AI enhanced content management is necessary, we hope this will be improved, also with the assessment made by the buyers and patients
- Challenge to obtain minimum quality solutions in Dutch: due to time-consuming content development, multiple revisions and translation issues, one contractor was able to include only 2 patients, the other contractor couldn't include patients
- Integration could not be tested (e.g. patient tracking and changing surgery date done manually): this may help and improve the solutions in the future

Where are we going?

- STARS field testing is the first stone in validating with real patients and healthcare professional integrative digital solutions about stress
- The field testing has been challenging in all senses
- Our assessment and the lessons learned from the clinical trial have been crucial to improve the solutions
- Both contractors are looking forward to test with more patients in order to find clinical signification



Good practices and lessons learnt from the PCP process

Ine Vandewauw (Maastricht University, coordinator)

Esther Lacko-van der Slikke (Academic Hospital Maastricht, lead buyer)

Collaboration within the consortium



Joint understanding of PCP process



Physical and regular meetings



Committed, skilled and experienced staff



Coordination work and budget

PCP process



Limited adaptability PCP project



Good writing no guarantee for good solution



Contact contractors – equal level playing field



Live demo's and testing necessary

Field testing



Ethical approval and MDR takes time



Technical gap between lab and field testing



Align expectations – TRL levels



Translation to the local languages

Challenge and solutions



Broad challenge: various ages, surgeries, cultures



Need for more personalisation



Stress reduction trending and relevant topic



Need increased even more due to pandemic



Q&A



Closing remarks

Ine Vandewauw

- <https://www.youtube.com/watch?v=BAIdt4JgaiA>

It was worth the **stress!**



Thank you!

www.stars-pcp.eu; info@stars-pcp.eu



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