ACQUIREICD

Region Syddanmark
OUH
Odense Universitetshospital
Svendborg Sygehus

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A personalized and interactive web-based innovation to AdvanCe the QUalIty of life and caRE in patients with an Implantable Cardioverter Defibrillator

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Acknowledgements

Innovation Fund Denmark

The Southern Denmark Growth Forum

patient@home

Seeding grant DKK 244,500

Med støtte fra TrygFonden

DKK 7 mill

LUNDBECKFONDEN

DKK 4.3 mill

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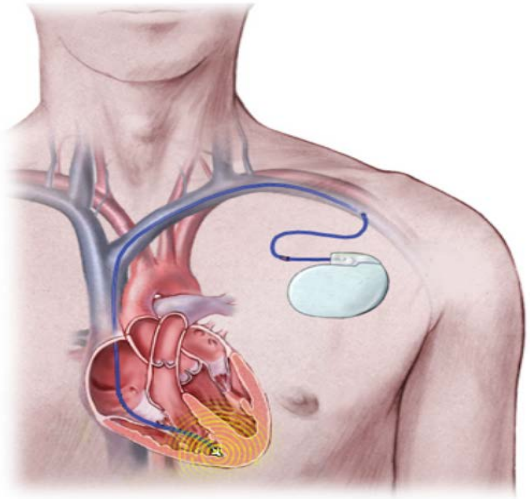
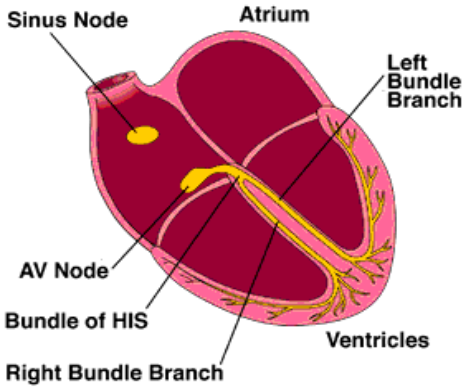
Implantable cardioverter defibrillator





- ICD is used as **primary** and **secondary prevention** of **sudden cardiac death**
- **Superior** to **anti-arrhythmic drugs** in saving lives

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ICD shock – from the patient perspective

- **It is physically painful (6 on a 0-10 point pain scale)**
- ***"It's like getting kicked in the chest by a big horse!"***

Up to 840 volts – compare that to 220 volts….

Ahmad et al. Pacing Clin Electrophysiol 2000;23:931-3

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Shift in the care and management

- **Majority** of patients being on **home monitoring** as a **replacement** for **face-to-face in-clinic visits**
- **Advantages:**
  - Efficient and **cost saving**
  - **Early detection** of **clinical** or **technical problems**
  - **Reduce medicalization** of patients

- **Disadvantages:**
  - **Missed opportunities** for ICD patients / relatives to **ask questions** and **voice concerns** about their device and treatment
  - **Limited opportunities** to **spot vulnerable patients** and to provide information, care, and support that patients' need for **successful adaptation**

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ACQUIRE-ICD: A paradigm shift

- Relies on **patient-centered** and **personalized tools**
- Involves **patients** as more **active co-managers** of their own **disease**
- Emphasis on **patient empowerment**
- Use of **IT** and **eHealth tools** in an **integrated system**
- **Sustainable approach**

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Objectives

To evaluate the clinical efficacy and cost-effectiveness of the ACQUIRE-ICD care innovation as add-on to usual care as compared to usual care alone

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Hypotheses

That the ACQUIRE-ICD care innovation will:

- ***Enable patients to live a better life with their device and their disease***
  - *Better health status*
  - *Greater empowerment*
  - *More knowledge about their treatment / device*
  - *Reduced distress*
  - *Greater likelihood of returning to work.*
- ***Be cost-effective*** *(reduction in hospital visits etc.)*

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Design and Participants

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Study design

Mixed-methods study

- **Qualitative: Patient focus groups and expert panels to develop the care innovation**
- **Multi-center randomized controlled trial**
  - Patients are randomized to the care innovation versus usual care (1:1), stratifying by center and NYHA class I-II versus III-IV
  - A random allocation sequence will be generated for each center by an independent statistician using Stata 12 statistical software
  - Not possible to blind patients with respect to study condition

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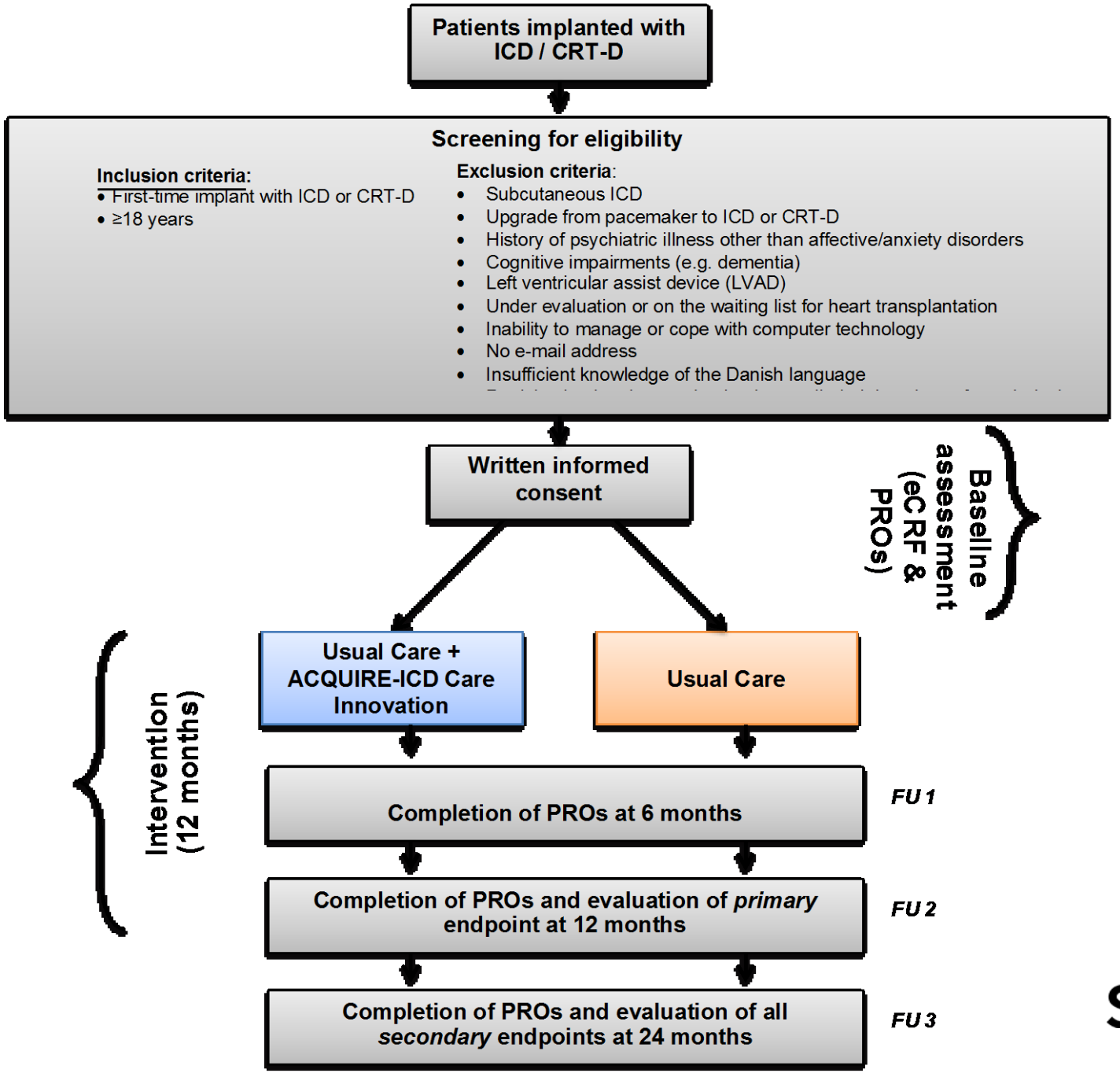
Patients implanted with ICD / CRT-D
Screening for eligibility
Inclusion criteria:
• First-time implant with ICD or CRT-D
• ≥18 years
Exclusion criteria:
• Subcutaneous ICD
• Upgrade from pacemaker to ICD or CRT-D
• History of psychiatric illness other than affective/anxiety disorders
• Cognitive impairments (e.g. dementia)
• Left ventricular assist device (LVAD)
• Under evaluation or on the waiting list for heart transplantation
• Inability to manage or cope with computer technology
• No e-mail address
• Insufficient knowledge of the Danish language
Written informed consent
Baseline assessment (eCRF & PROs)
Usual Care + ACQUIRE-ICD Care Innovation
Usual Care
Intervention (12 months)
Completion of PROs at 6 months
FU 1
Completion of PROs and evaluation of primary endpoint at 12 months
FU 2
Completion of PROs and evaluation of all secondary endpoints at 24 months
FU 3

Study endpoints

Evaluated at:

Primary: Device acceptance (FPAS)

12 months

Secondary:

- Health status (SF-12)
- Patient empowerment (ICD-EMPOWER)
- ICD concerns (ICDC)
- ICD knowledge (ICD-KNOW)
- Anxiety (GAD-7)
- Depression (PHQ-9)
- Health status (KCCQ-12; heart failure specific)
- Return to work
- Time to first ICD therapy defined as ATP, cardioversion or shock
- Time to first hospitalization due to a cardiac cause
- Mortality
- Cost-effectiveness

12 and 24 months

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Assessments

Table 1. Patient-reported outcomes, cost-effectiveness and their assessment

Construct	*Scale acronym*	*Items*	T_0	T_6	T_{12}	T_{24}
Health status (generic)	SF-12	12	■	■	■	■
Health status (HF specific)	KCCQ	12	■	■	■	■
Depression	PHQ-9	9	■	■	■	■
Anxiety	GAD-7	7	■	■	■	■
Expectations to ICD treatment	EXPECT-ICD	10	■			
Expectations to use of platform/app	EXPECT-APP	6	■			
Experience with use of platform/app	EXPERIENCE-APP	9		■	■	
ICD patient concerns	ICDC	8	■	■	■	■
ICD empowerment	ICD-EMPOWER	14	■	■	■	■
Illness perceptions	B-IPQ	9 + 1	■			
Adherence	MMAS-8	8	■	■	■	■
Type D personality	DS14	14	■			
Device acceptance	FPAS	18	■	■	■	■
Loneliness	UCLA	3	■	■	■	■
Cost-effectiveness Health utilities / QALY	EQ-5D-5L + VAS	6	■	■	■	■
Cost-effectiveness including resource use	Purpose-designed / registry	-	■	■	■	■

T_0 = Baseline; T_6 = 6 months; T_{12} = 12 months; T_{24} = 24 months
** Both patients in the treatment group and usual care group will complete all measures at T_0, T_6, T_{12}, and T_{24}*

***B-IPQ** = Brief Illness Perceptions Questionnaire; **DS14** = Type D Scale; **EQ-5D-5L** = EuroQoL; **EXPECT-ICD** = Expectations to ICD treatment questionnaire; **EXPECT-APP** = Expectations towards use of app; **EXPERIENCE-APP** = Experience with use of app; **FPAS**= Florida Patient Acceptance Survey; **GAD** = Generalized Anxiety Disorder scale; **ICD-EMPOWER** = ICD Empowerment Scale; **ICDC** = ICD Patients' Concerns Questionnaire; **ICD-KNOW** = ICD Knowledge Scale; **KCCQ** = Kansas City Cardiomyopathy Questionnaire; **MMAS-8** = Morisky Medication Adherence Scale; **PHQ-9** = Patient Health Questionnaire; **QALY** = quality adjusted life year; **SF-12** = Short Form Health Survey; **UCLA** = UCLA Loneliness Scale; **VAS** = visual analogue scale*

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Ethics

- **Regional Committees on Health Research Ethics for Southern Denmark** [S-20160063]
- Permission from the **Danish Data Protection Agency** [16/16935]
  - Data storage: **REDCap** (Research Electronic Data Capture)
  - Analyses: STATA and SPSS via **OPEN Analyse** - an analysis environment (platform), where data are stored and processed securely on a server at the Regional IT.
- Registered on www.clinicaltrials.gov [NCT02976961]

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Participating centers

- Odense University Hospital
- Aarhus University Hospital
- Aalborg University Hospital
- Copenhagen University Hospital
- Zealand University Hospital - Roskilde
- Gentofte Hospital

NATIONAL STUDY!!

Sample size calculation

- Based on historical data from the **WEBCARE** study
- Expecting a 3-point (SD: 9 points) increase in the Florida Patient Acceptance Survey over 12 months
- Targeting power analysis to show a difference of 3 points between the two groups in the change from baseline to 12 months, a **Type I** error of **0.05 (two-sided), power of 90%, assuming** an **SD=9 in both groups** - we need **382 patients**
- To compensate for loss to follow-up (estimated at 20%), we will include a total of **478 patients (239 in each arm)**

Pedersen, Spek, Theuns et al (2009). Trials, 10:120
Habibovic, Denollet, Cuijpers , Pedersen et al (2014). Psychosomatic Medicine, 76:593-602

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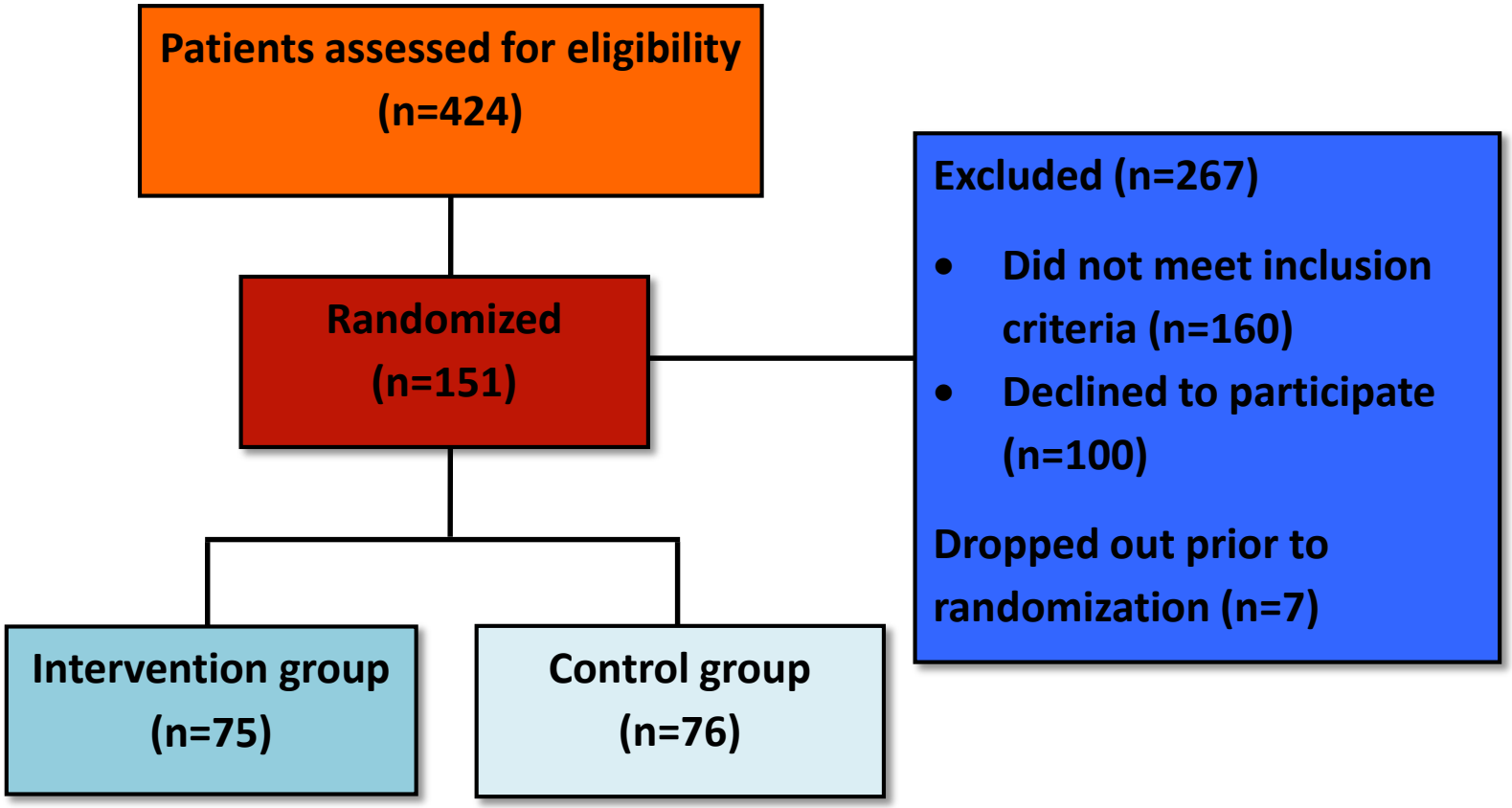
Status: Patient recruitment



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Features of the 12 Months' Intervention

Using the Liva Healthcare Platform / App

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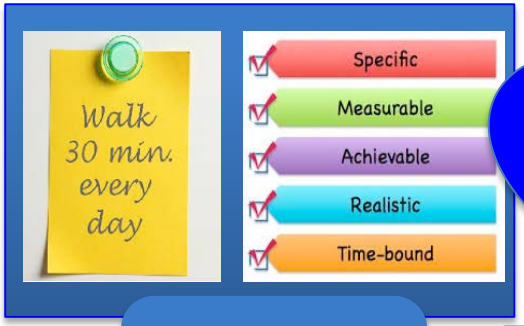
Healthy Heart Empowerment Tool and Care Plan

ICD treatment according to current guidelines



Shared decision making

Multidisciplinary ICD Team

Personal Care Plan

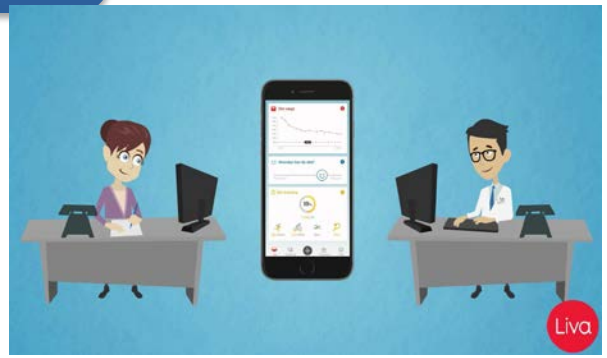
Patient contacted

Data received and processed for trends and alerts

Barriers and Facilitators of Change

Informed, Empowered Patient

Information to and from the Liva Platform



Patient's Physiological Indicators

Monitoring of Health Status, Anxiety and Depression

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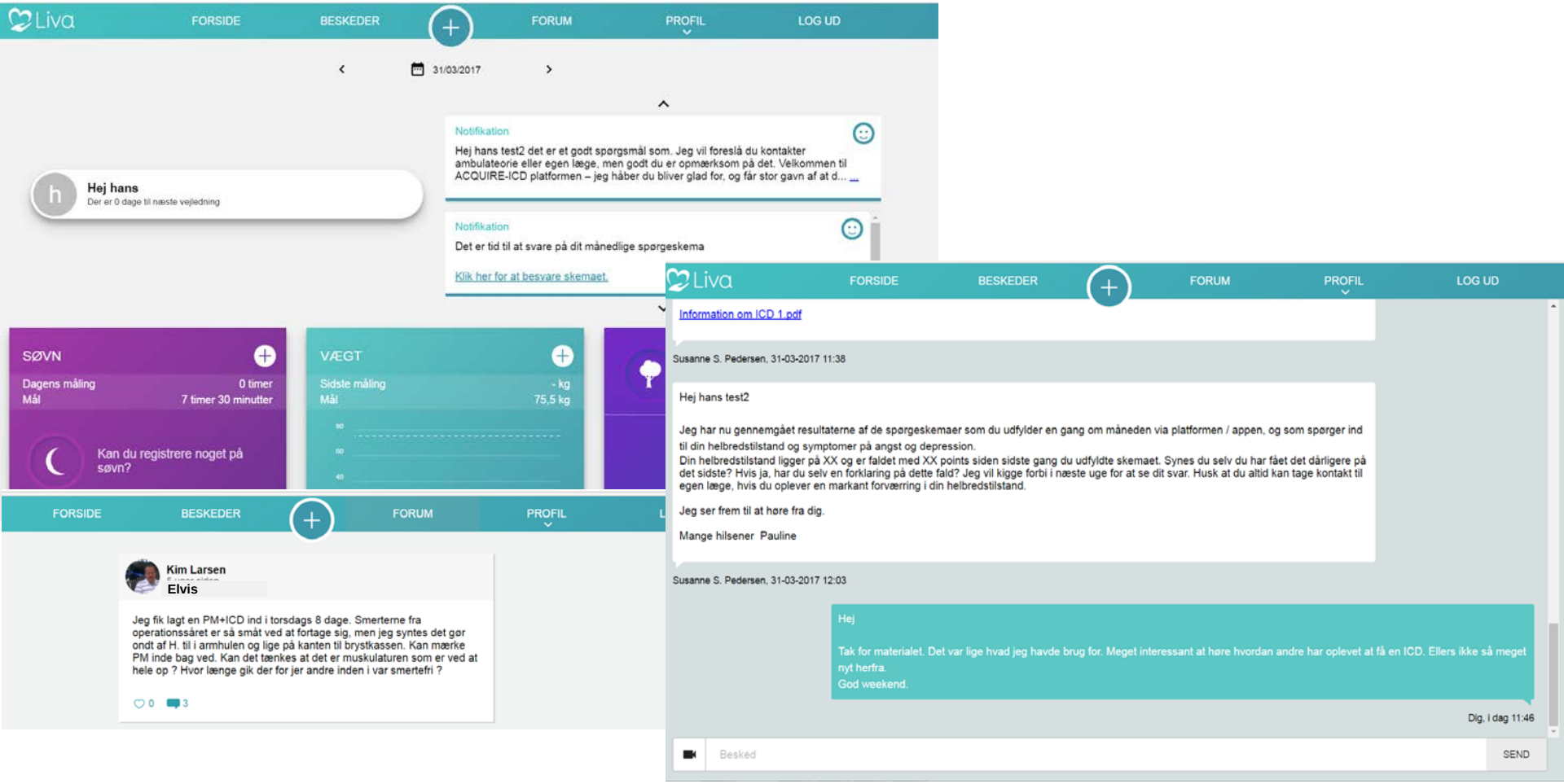
The Liva healthcare platform/app

- An existing platform (almost) matching our needs



Guidance and feedback

- **Months 1-3: Once a week**
- **Months 4-12: Once a month**

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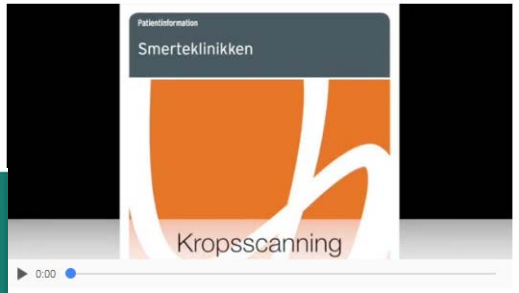
12 months intervention

- Overview of material sent to patients
- Intensive in the first 3 months
- Then once a month in the last 9 months
- Outline of the role of nursing staff – feedback on goals, sending out materiale, dialogue with patients (answer questions), feedback on monthly questionnaires
- Role of psychologists
- Challenges in the project so far – status on recruitment

Topics sent to patients

- Project information
- Why monitoring symptoms through questionnaires?
- Knowledge of ICD and treatment
- ICD shocks
- Travelling with ICD
- Home monitoring
- Psychological reactions – anxiety, stress, depression
- Transition to a new life
- Relationships, new roles, intimacy and sex
- Stress management tools
- Relaxation and mindfulness exercises
- Changing lifestyle/habits and motivation
- Sleep, tiredness and fatigue
- Physical activity

Information om ICD 1.pdf



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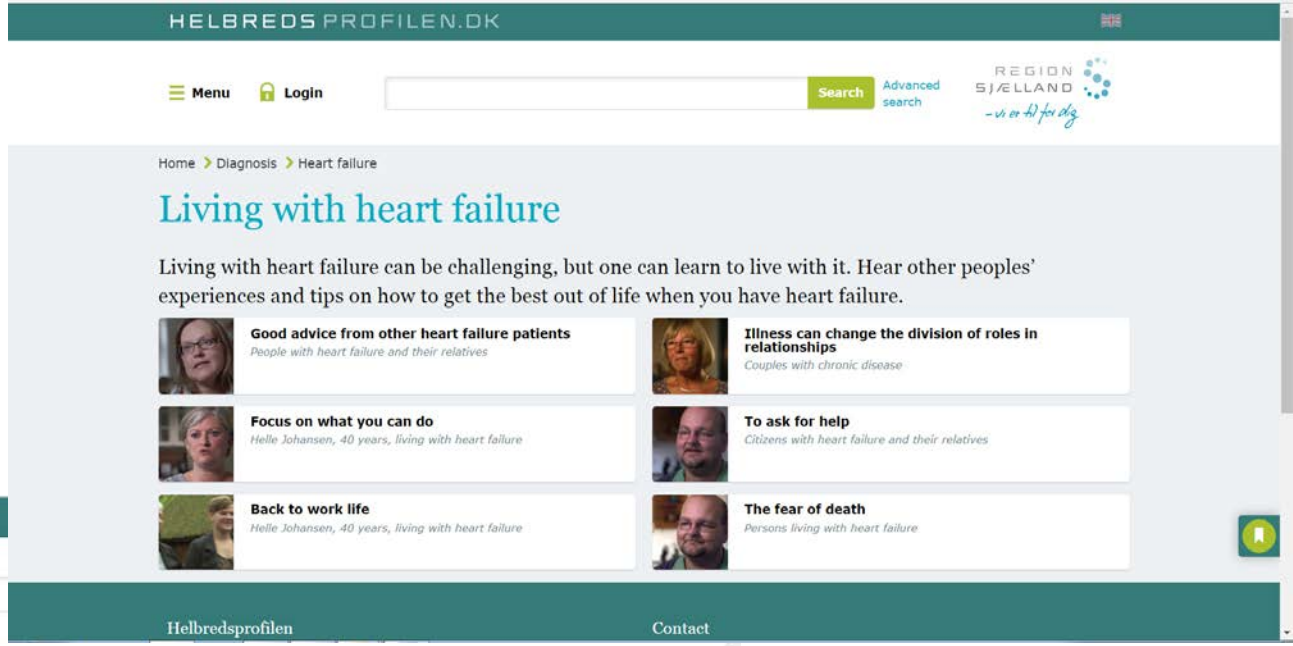
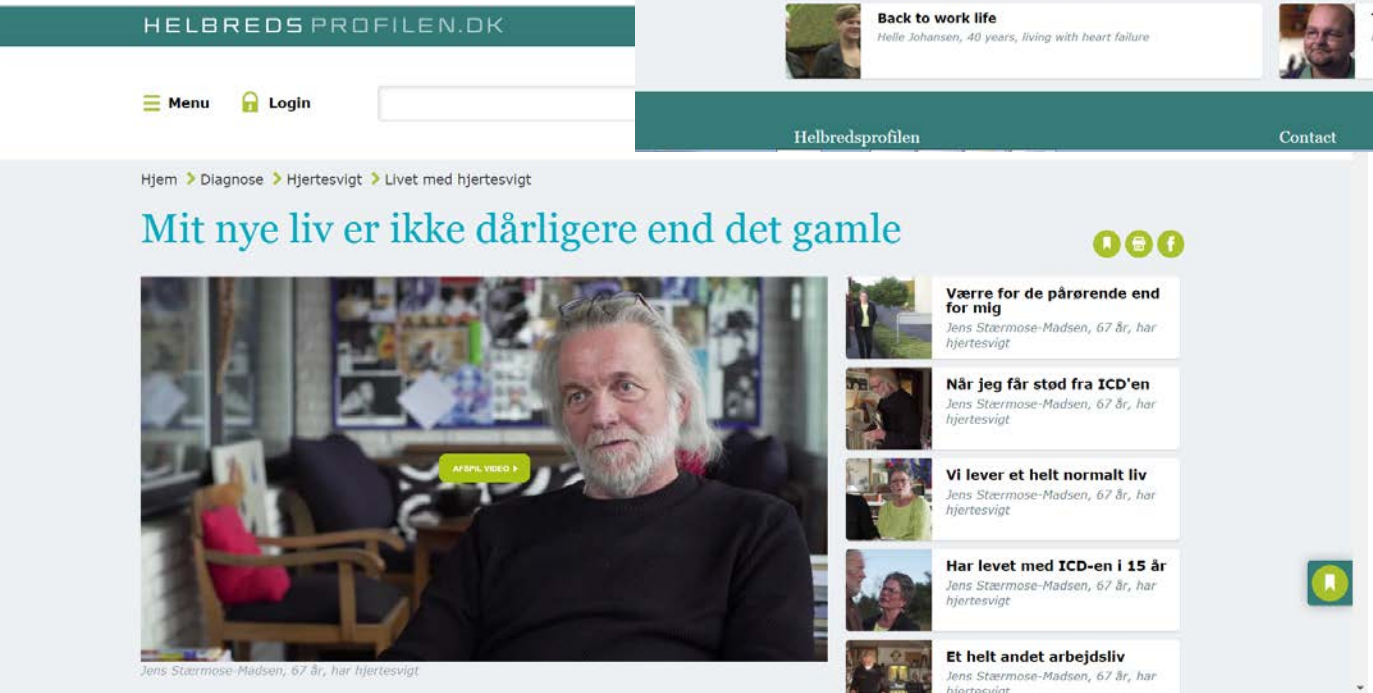
Educational vodcasts
Helbredsprofilen, Region Zealand





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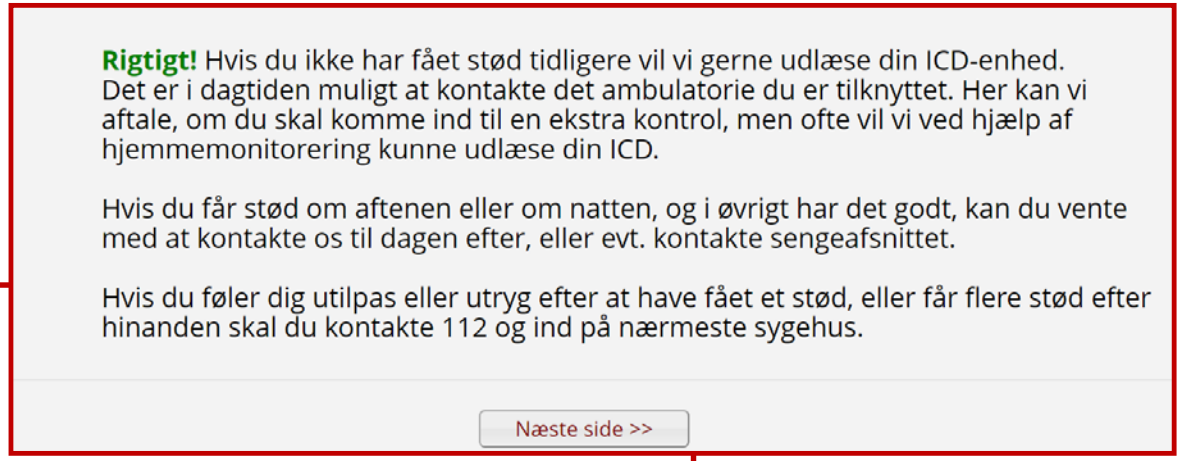
ICD QUIZ – to increase knowledge

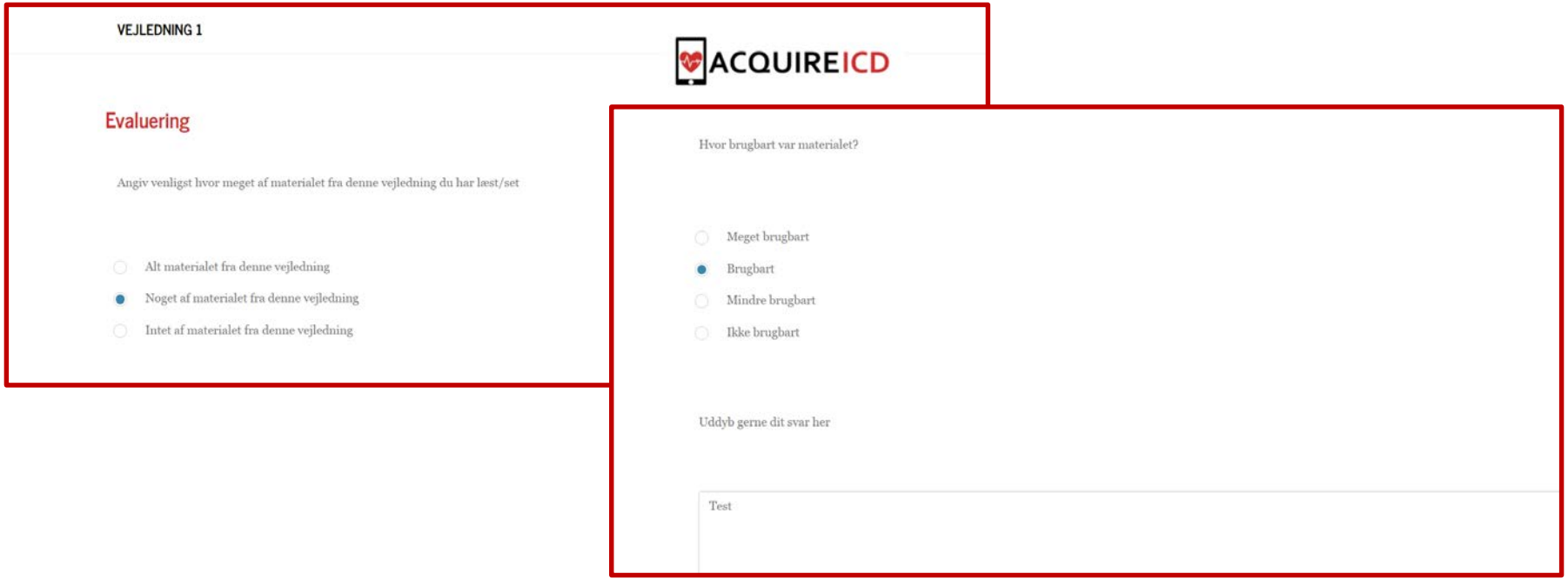
- **Quiz 1:** 13 questions (distributed after 9 weeks and 8 months)
- **Quiz 2:** 13 questions (distributed after 4 and 10 months



Instant evaluation of content

Feedback link is attached to each message (OBS: anonymous)

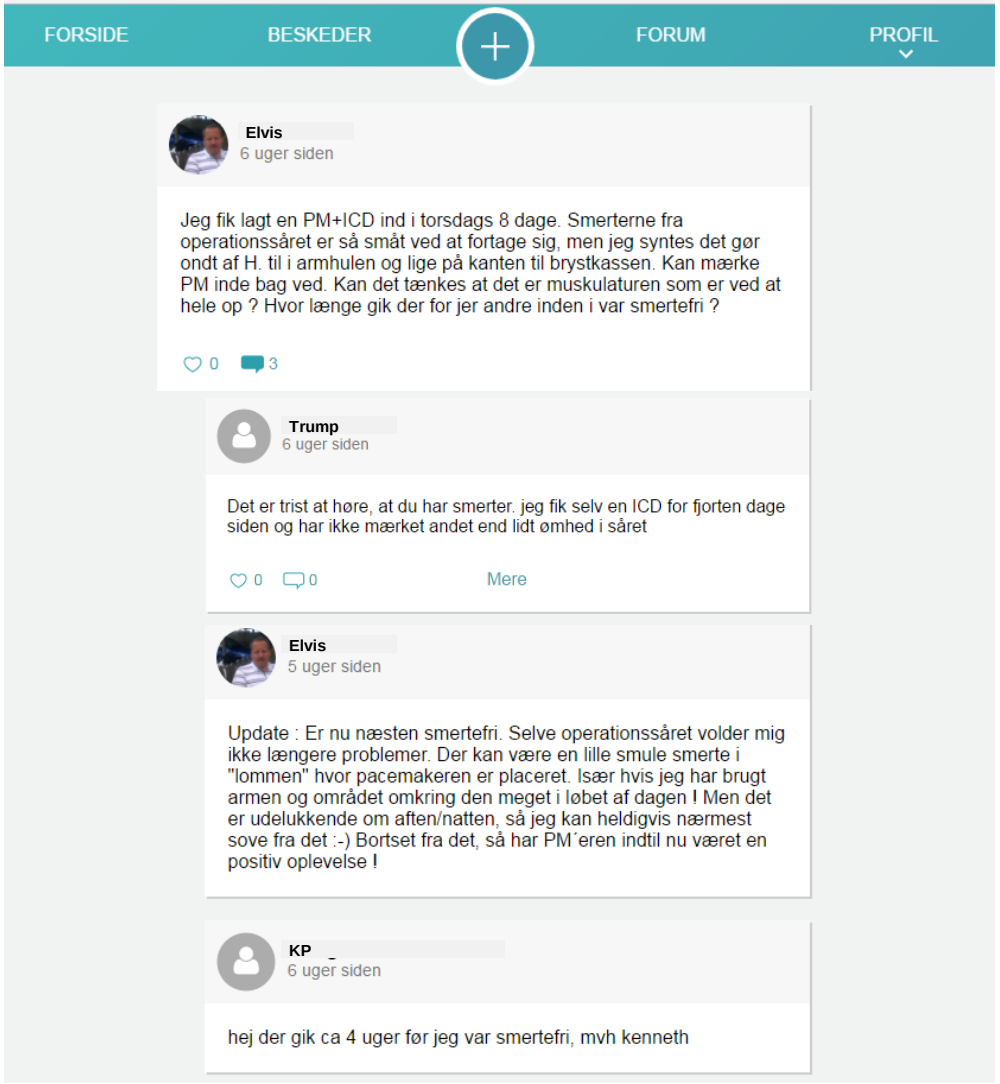
- ***How much of this week's content did you read/watch?*** *(All, Some, Nothing)*
- ***How useful did you find it?*** *(Not useful, Less useful, Useful, Very useful)*



Goal setting

Forum

- Share
- Comment
- Like



Screening and monitoring

Once a month, patients complete and monitor:

- **Health status** (EQ-VAS)
- **Depressive symptoms** (PHQ-8)
- **Anxiety** (GAD-7)

Mastenbroek, Spertus, Pedersen et al. (2014). European Journal of Heart Failure, 16:384-93
Pedersen et al. (2012). Expert Reviews of Medical Devices, 9:377-88

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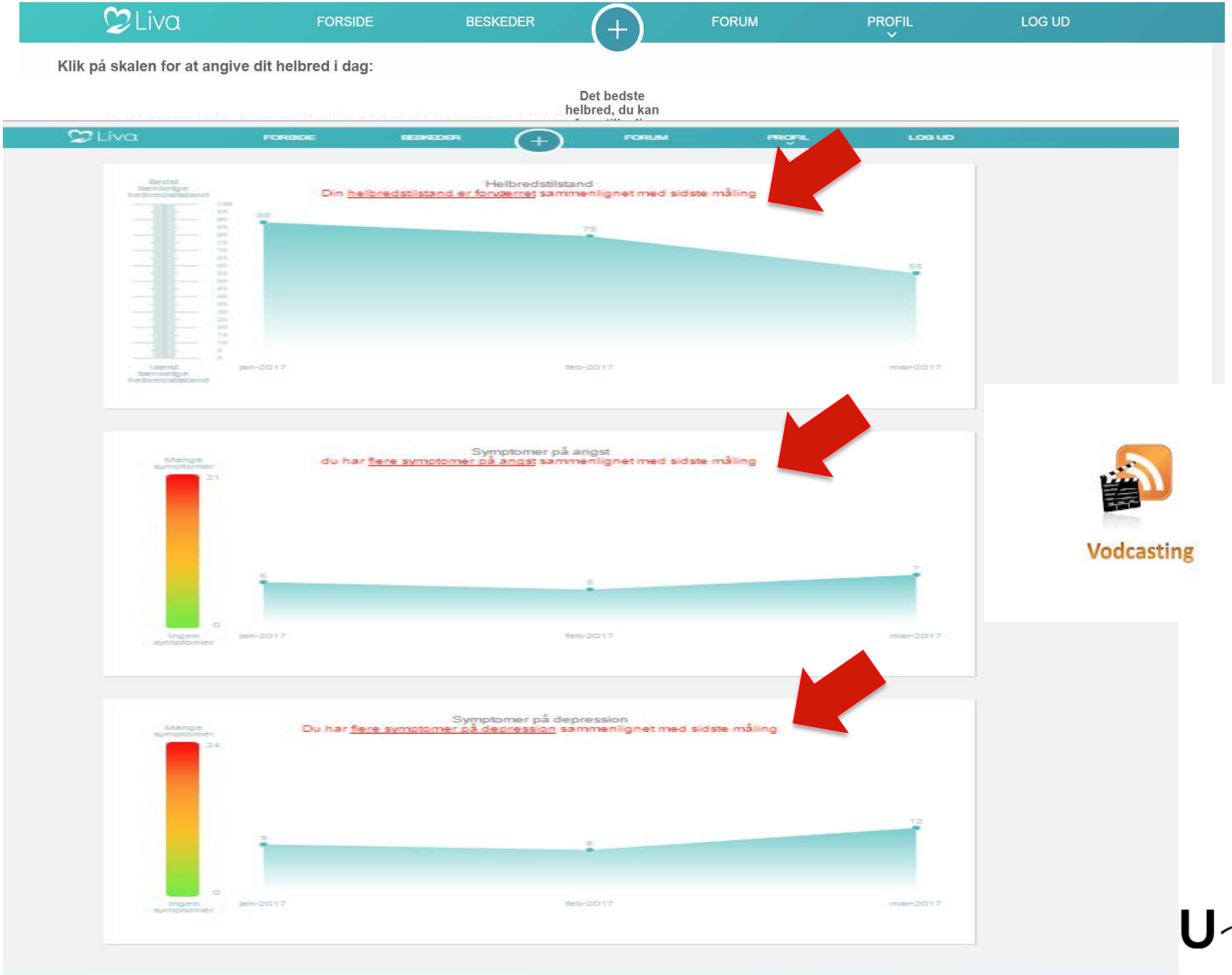
Liva
FORSIDE
BESKEDER
FORUM
PROFIL
LOG UD
Klik på skalen for at angive dit helbred i dag:
Det bedste helbred, du kan
Helbredstilstand
Din helbredstilstand er forværret sammenlignet med sidste måling
Symptomer på angst
du har flere symptomer på angst sammenlignet med sidste måling
Symptomer på depression
Du har flere symptomer på depression sammenlignet med sidste måling
Vodcasting

Psychological intervention (1)

- Patient scores ≥10 on PHQ-8 (depressive symptoms) *or* GAD-7 (anxiety) – nurse contacts psychologist
- Psychologist contacts patient for intake to determine if patient should be offered intervention
- Intake is done by phone going through:
  - Responses to items on PHQ-9 / GAD-7
  - Life with a chronic disease / device
  - Cognitive difficulties
  - Social network and hobbies
  - Marital status
  - Prior contact with psychologist / psychiatry

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Psychological intervention (2)

7-week intervention based on value-based cognitive behavioral therapy:

- **Step 1: ICD and its impact**
- **Step 2: When one's life changes**
- **Step 3: The impact of thoughts on mood and actions**
- **Step 4: Acceptance and values – living a purposeful life**
- **Step 5: How does my daily life look like?**
- **Step 6: Find a good routine**
- **Step 7: To continue to develop and accept stagnation or relapse**

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Data Management

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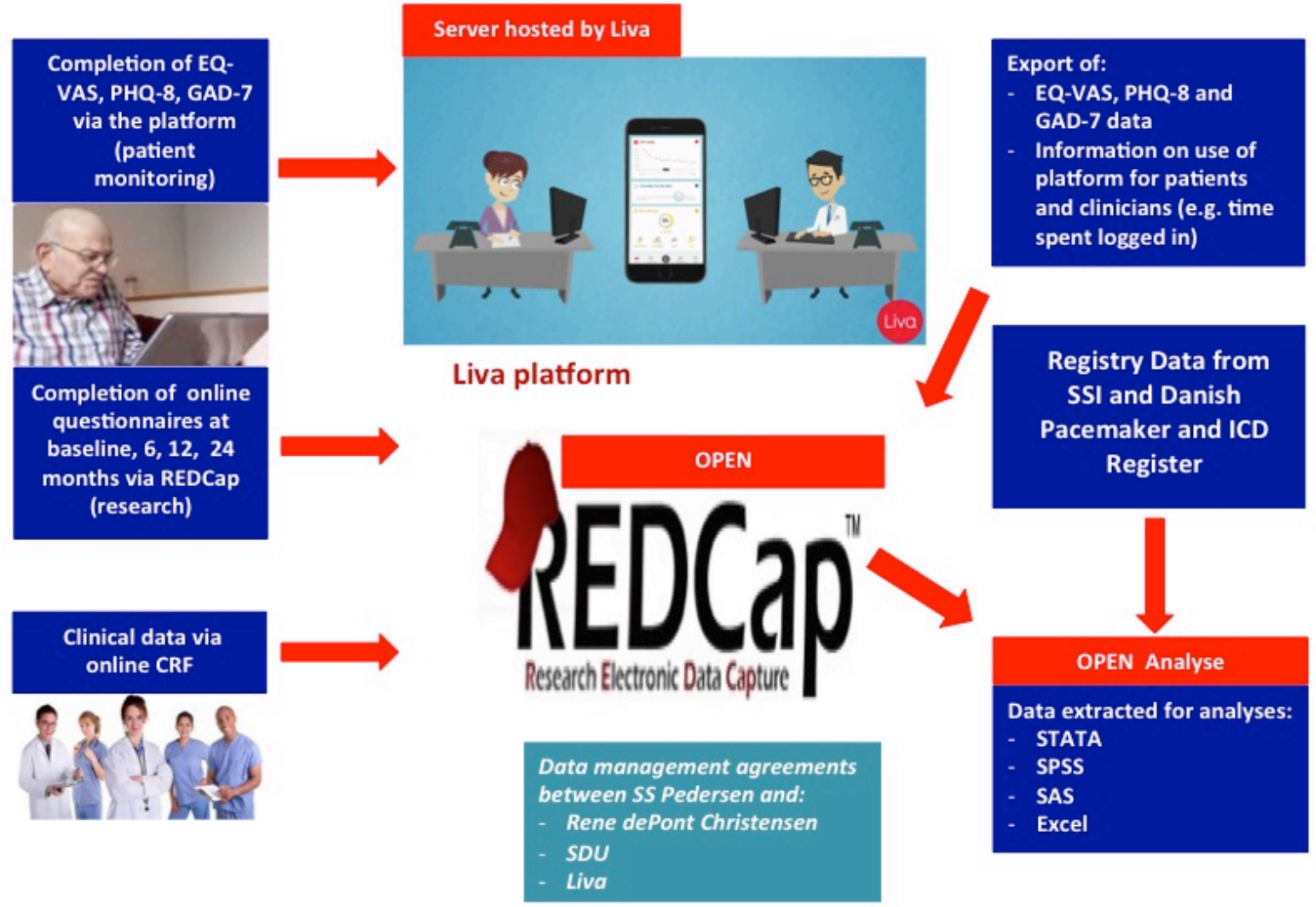
ACQUIRE-ICD data flow and responsible partners



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Project Management Structure

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TRIAL STEERING COMMITTEE

Chair: Prof. Susanne S Pedersen (SDU-DP, OUH)

Members:
- Prof. Jens Cosedis Nielsen (Aarhus University Hospital)
- Dr. Jens Brock Johansen (Odense University Hospital)
- Dr. Sam Riahi (Aalborg University Hospital)
- Dr. Charlotte Ellen Larroudé (Gentofte Hospital)
- Dr. Carl Brandt (SDU-GP)

ADVISORY BOARD

- Dr. John Spertus (MAHI, USA)
- Dr. John Cleland (ICL, UK)
- Dr. Sissel Vorstrup (Lundbeck Foundation)

Project Manager Søren Jensen Skovbakke

INTERNATIONAL COLLABORATORS

- Dr. John Spertus (MAHI, USA)
- Dr. Kim Smolderen (MAHI, USA)

PROJECT MANAGEMENT TEAM

- Prof. Susanne S Pedersen – PI (SDU-DP, OUH)
- Søren Jensen Skovbakke – Project manager (SDU-DP)
- Lars Søgaard – Data Manager (SDU-OPEN)
- Rene DePont Christensen – Statistician (RD Statistics)
- Camilla Sødequist – Research Assistant (SDU-DP)

RESEARCH TEAM

- Prof Susanne S. Pedersen (SDU-DP, OUH)
- Prof. Uffe K Wiil (SDU-MMMI)
- Prof. Jan Sørensen (SDU-COHERE)
- Thomas Schmidt - Post-doc IT (SDU-MMMI)
- NN - Post-doc cost-effectiveness (SDU-CAST)
- NN - PhD psychology (SDU-DP, OUH)

DEVELOPMENT AND SUPPORT TEAM

- IT experts (Liva Healthcare ApS)
- Psychologists (SDU-DP)
- Helbredsprofilen
- Consultant Telemedicine (CIMT)
- Nurses (participating hospitals)

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Output and Dissemination

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Publications

- **Pedersen SS**, Schmidt T, Skovbakke SJ, Wiil UK, Egstrup K, Smolderen KGE, Spertus J (2017). *A personalized and interactive web-based health care innovation to AdvanCe the QualIty of life and caRE of patients with heart failure (ACQUIRE-HF): A mixed-methods feasibility study.* Journal of Medical Internet Research – Research Protocols, In Press.
- Nørgaard B, Sandvei M, Rottmann N, Johannessen H, Wiil UK, Schmidt T, **Pedersen SS** (2017). *Development of (a Danish) web-based care innovation for patients with heart disease. Lessons learnt from a participatory design study.* Journal of Medical Internet Research – Research Protocols, 2017;6(5):e75).

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Presentations

Poster presentation

- Pedersen SS, Schmidt T, Skovbakke SJ, Wiil UK, Egstrup K, Smolderen KGE, Spertus J. *A personalized and interactive web-based health care innovation to AdvanCe the QualIty of life and caRE of patients with heart failure (ACQUIRE-HF): A feasibility study*. American Psychosomatic Society's annual meeting, Sevilla 15-18 March 2017.

Invited keynote

- *2017 Annual Scientific Meeting (ASM) of the Cardiac Society of Australia and New Zealand in Perth on August 12.*

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