Digital Mental Sundhed

Netværksmøde, 20. marts 2024

TEKNOLOGISK INSTITUT

Dagens program

København

Velkommen

V. Co-founder & CEO Simon Lajboschitz fra Khora & Forretningsleder Martin Grønbæk Jensen fra Teknologisk Institut

Digital mental sundhed: Et nyt økosystem på vej

Oplæg v. Martin Grønbæk Jensen fra Teknologisk Institut

Oplægsholdere

- *Brøndby Kommune*: Velfærdsteknologikonsulent Mira Valentina Krogstrup: Det gode samarbejde og udfordringer med monitorering

- *HEKA VR*: Project Manager, Katalin Vikuk: VR som værktøj til opsporing og behandling af skizofreni, herunder The Challenge Project og samarbejdet med Region Hovedstaden Psykiatri

- *Howdy*, partner Gunnar Brabrand : En platform til forebyggelse af stress og udbrændthed

- *TETATET AI*, Co-founder Paula Petcu: AI coaching, terapi og selvudvikling

Uformel networking og mulighed for at se og prøve Khoras VR-løsninger og de helt nye Apple Vision Pro.

Khora

Simon Lajboschitzl, CEO

Digital mental sundhed: Et nyt økosystem på vej

Martin Grønbæk Jensen, forretningsleder
Teknologisk Institut

DAGSORDEN

1. Baggrund og formål

2. Mental sundhed og digitale løsninger

3. Økosystemer

4. Udfordringer

BAGGRUND OG FORMÅL

at understøtte opbygningen af det danske økosystem i forhold til digital mental sundhed og udbrede viden om eksisterende aktører, løsninger og forretningsmodeller med henblik på at styrke udviklingen og skaleringen af digitale løsninger, som kan mindske den mentale mistrivsel i Danmark

Workshop og to netværksmøder
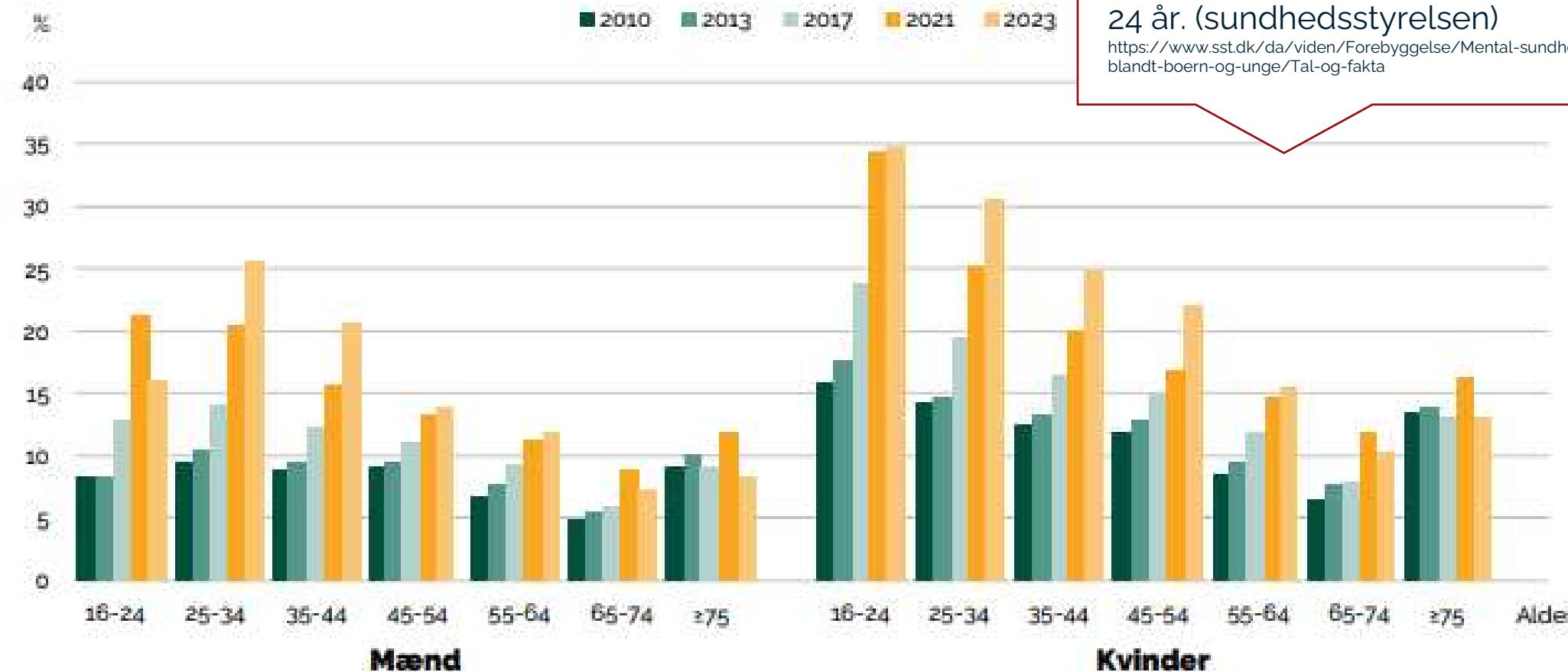
Danish **Life Science** Cluster

HEALTH TECH HUB COPENHAGEN

Nordic Health Lab ⊕

Danskernes mentale sundhed

Cirka 15 pct. af alle børn har været i behandling for en psykisk sygdom, som fx ADHD, angst eller depression, inden de fylder 18 år. Samlet set udgør denne type psykiske sygdomme den største sygdomsbyrde blandt børn og unge fra 1 til 24 år. (sundhedsstyrelsen)

https://www.sst.dk/da/viden/Forebyggelse/Mental-sundhed/Mental-sundhed-blandt-boern-og-unge/Tal-og-fakta

Kilde: Sundhedsstyrelsen (2024): Danskernes sundhed, Den Nationale Sundhedsprofil, Midtvejsundersøgelsen 2023

Teknologisk Institut

Stort økonomisk marked internationalt

Growth in searches for apps across various conditions

Use/Condition	Relative increase in searches during UK lockdowns
Mindfulness	2483%
Relaxation	437%
OCD	422%
Anxiety	328%
Anger	324%
Fear	221%
Mood	202%
Depression	156%
Stress	113%

Source: ORCHA Health

Ashall-Payne states that the organisation observed a 25% increase in downloads of health apps from pre-pandemic to now. "Every day 5 million people will download a health app and that's increasing all the time."

\sifted/ News Insights Newsletters Events Podcasts Access

Analysis March 4, 2024

16 mental health startups to watch, according to VCs

Sifted spoke to VCs from Boost Capital, Molten Ventures, UNIQA Ventures, InHealth Ventures, Calm/Storm and NLC Health Ventures
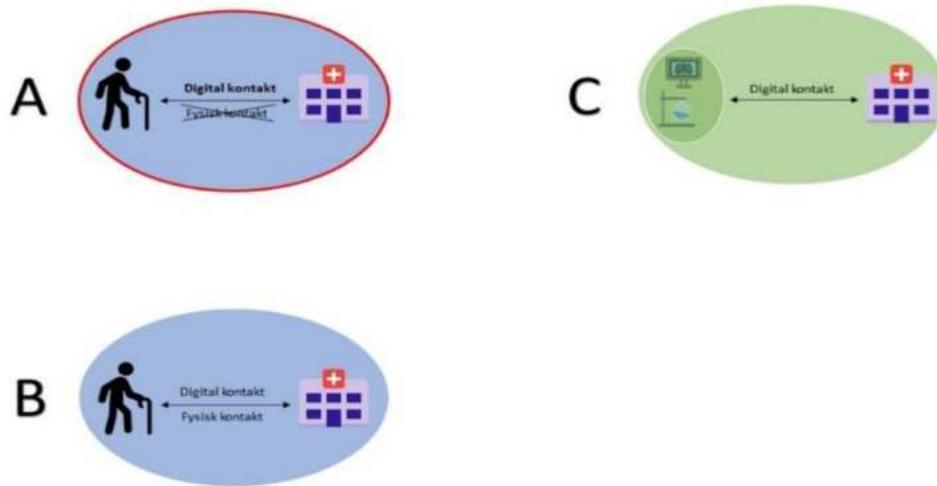
Kai Nicol-Schwarz 7 min read

Mental health startups in Europe raised $1.2bn during the boom of 2021. It's fair to say that funding has fallen a long way since then.

Startups in the sector picked up just $343m in 2022, falling to just $80m in 2023, amid a wider pullback from digital health funding.

But despite VC confidence in the sector waning, the global mental health market is estimated to be worth $38bn this year (20% of the entire digital health market). That presents a huge opportunity for mental health startups that can convince investors to part with their cash.

Teknologisk Institut

Digital forebyggelse og behandling

"Digital sundhedsfaglig behandling er, når sundhedspersoner udfører behandling rettet mod den enkelte patient ved hjælp af digital teknologi fx apps eller internetsider. Der gælder som udgangspunkt de samme regler for digital sundhedsfaglig behandling, som for anden sundhedsfaglig behandling."

Digital sundheds- faglig behandling – pligter og ansvar
En guide til sundheds- faglige behandlingssteder

Aktører og løsninger globalt

Center for Digital Psykiatri estimerer, at der pt. findes cirka 260.000 digitale løsninger globalt, inkl. wellness apps i den ene ende til CE-mærket medicinsk udstyr i den anden ende.

Growth of mental health apps on iOS & Android stores

Cumulative volume of apps, 2009–2022

Source: ORCHA Health

EUDAMED - European Database on Medical Devices

Home   Actors ⌄   Devices/SPPs ⌄   Certificates ⌄   News
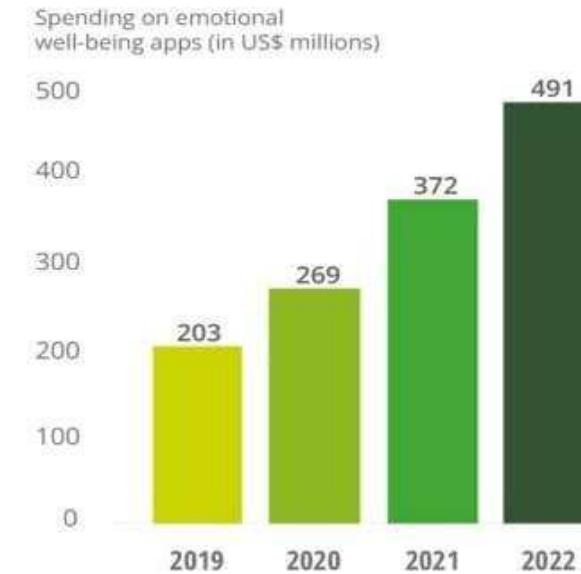
Home ›

EUDAMED database

The creation of a European database on medical devices (EUDAMED) is one of the key aspects of the new rules on medical devices (Regulation (EU) 2017/745) and in vitro diagnostic medical devices (Regulation (EU) 2017/746).

Mental health and well-being apps will see strong growth through 2022

Global spending on mental health and well-being mobile apps, 2019–2022, US$ millions

Spending on emotional well-being apps (in US$ millions)

Note: Spend estimates for 2021 and 2022 are predictions.
Source: SensorTower, Mobile Wellness Market Trends 2021.

Deloitte Insights | deloitte.com/insights

Teknologisk Institut

Aktører og løsninger i Danmark

Svært at anslå konkret antal

Mange wellness apps
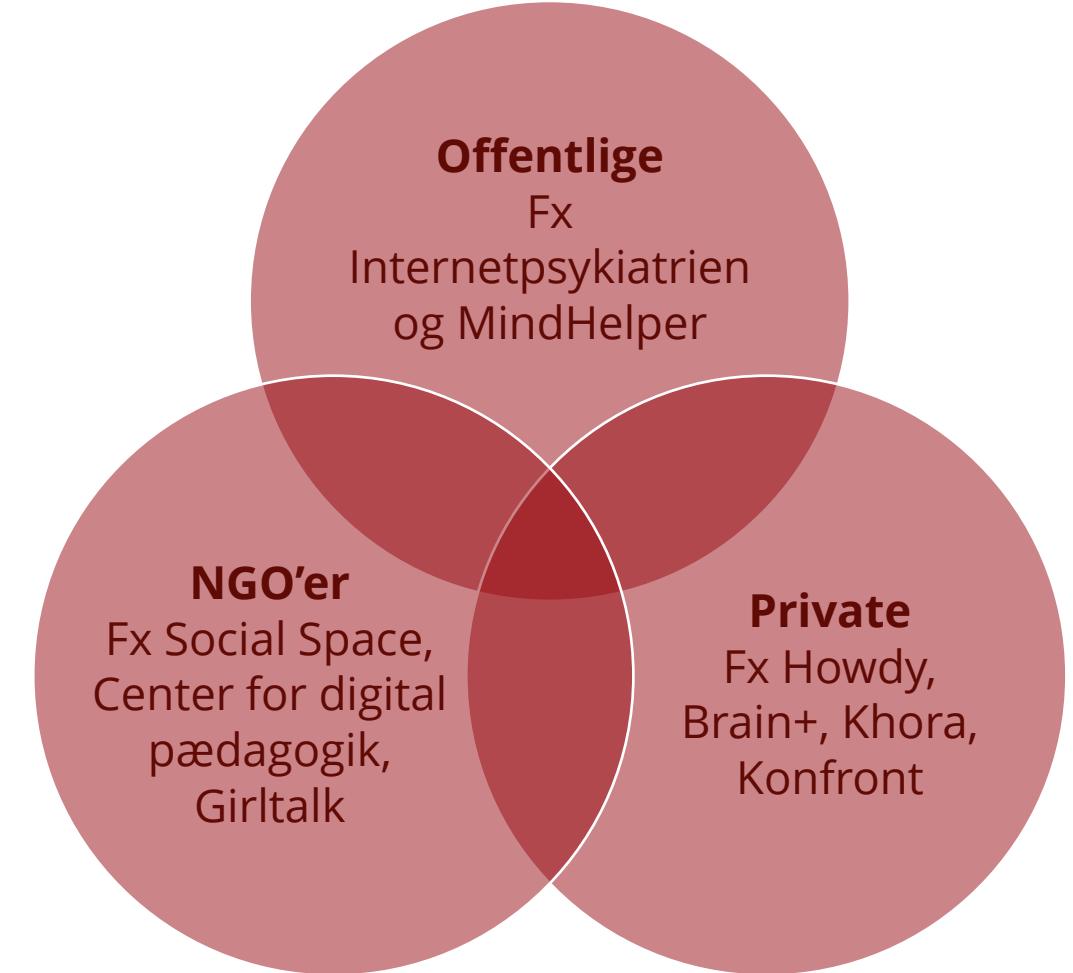
Få har opnået (international) skalering

Få DtX (Digital therapeutics) med klinisk dokumenterede effekter
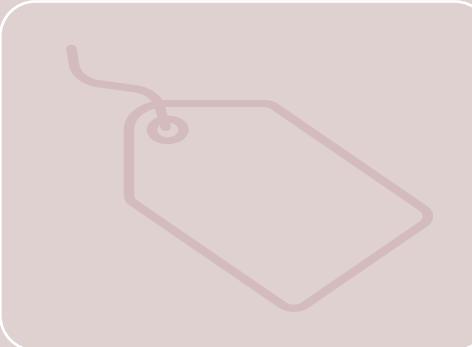
Ingen DMD (digitalt medical device) med MDR-godkendelse / CE-mærkning

Vækst i platforme og AI-drevne løsninger

Vækst i offentlige og private funding til mental sundhed

Offentlige
Fx Internetpsykiatrien og MindHelper

NGO'er
Fx Social Space, Center for digital pædagogik, Girltalk

Private
Fx Howdy, Brain+, Khora, Konfront

Teknologisk Institut

Udfordringer

REGULERING

Servicelov

Sundhedslov

MDR

AI

mv.

VALIDERING

HTA

Metoder til vurdering af kliniske og ikke-kliniske effekter

SKALERING

Test

Markeds-validering

Business cases

Vækst

Regulering

Medicinsk udstyr

Klasse III
Klasse IIB
Klasse IIA
Klasse I

Høj risiko
Lav risiko
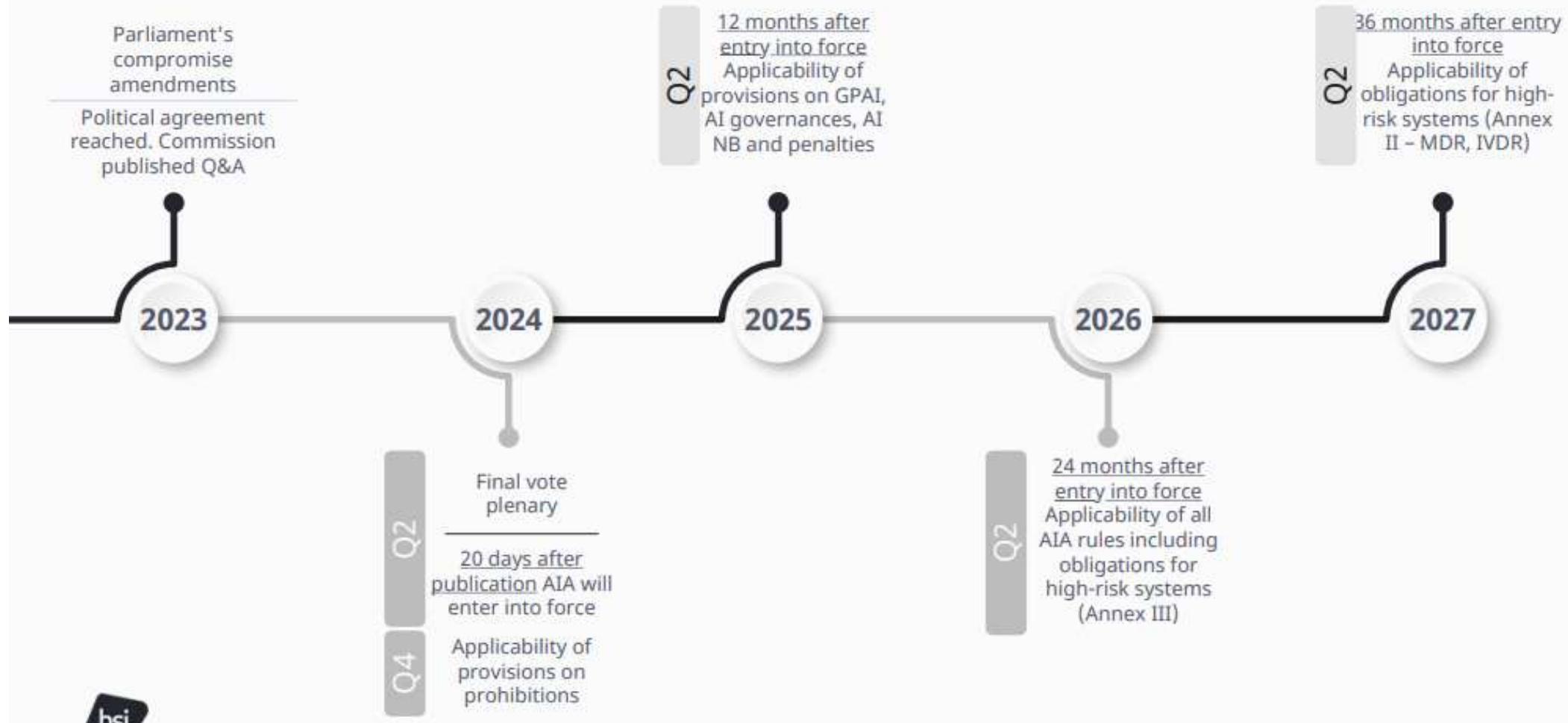
Medicinsk udstyr er produkter, der bruges til at diagnosticere, forebygge, lindre eller behandle sygdomme, handicap eller skader. Der findes mere end 500.000 forskellige typer medicinsk udstyr, som kan være alt fra kørestole og briller til diagnostiske analyser, pacemakere, apps på mobiltelefoner og avanceret operationsudstyr.

(Kilde: Lægemiddelstyrelsen)

AI-regulering på vej

The AI Act Journey - Route to applicability

2023 — Parliament's compromise amendments | Political agreement reached. Commission published Q&A

2024
- Q2: Final vote plenary | 20 days after publication AIA will enter into force
- Q4: Applicability of provisions on prohibitions

2025 — Q2: 12 months after entry into force — Applicability of provisions on GPAI, AI governances, AI NB and penalties

2026 — Q2: 24 months after entry into force — Applicability of all AIA rules including obligations for high-risk systems (Annex III)

2027 — Q2: 36 months after entry into force — Applicability of obligations for high-risk systems (Annex II – MDR, IVDR)

titut

Validering i Danmark

Behandlingsrådet arbejder ud fra fire principper:

1) Mere sundhed for pengene

2) Faglighed og armslængde til det politiske system

3) Åbenhed

4) Lighed

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Teknologisk Instituts vurderingsparadigme for velfærdsteknologi

medcom

Forside › Nyheder og aktiviteter › Apps i almen praksis: En stor milepæl er nået

Nyhed

Apps i almen praksis: En stor milepæl er nået

19. januar 2024 · Læsetid: 2 minutter

Den tekniske løsning er udviklet og vi har nu sparket pilotafprøvningen i gang, hvor 5 alment praktiserende læger deltager. Det betyder, at de nu kan anbefale sundhedsapps til udvalgte patienter.

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Nyheder / 2024 / Nyt nævn skal vurdere sundhedsapps

Nyheder

Nyt nævn skal vurdere sundhedsapps

8. februar 2024

Ny politisk aftale baner vej for etableringen af et Nævn for Sundhedsapps, der får til opgave at vurdere, om sundhedsapps kan anbefales og vises på sundhed.dk.

Validering i EU

Towards a European evaluation framework for digital medical devices (DMDs) in the European Union – Launch of a European taskforce

PRESS RELEASE - Posted on Oct 26 2022

October 26, 2022

MINISTÈRE DE LA SANTÉ ET DE LA PRÉVENTION | Délégations ministérielle au numérique en santé | HAS HAUTE AUTORITÉ DE SANTÉ | eunethta

Inria | Inserm | uni.lu | Université Paris Cité

eit Health | Co-funded by the European Union | Federal Institute for Drugs and Medical Devices

The objective of the European taskforce is to reach a mutual understanding between competent agencies with competences in health technology assessment for digital medical devices (DMDs) at national level, in order to harmonise the assessment criteria in the European Union. The first results of the three work packages were presented at the Digital Medicine Conference in Luxembourg on October 26-27.

Final version Definition / Scope

Digital Medical Devices are health technologies falling into the definition of Medical devices as outlined in the Regulation (EU) 2017/745 and which main function is based on digital technologies intended to support one or more of the following medical purposes:
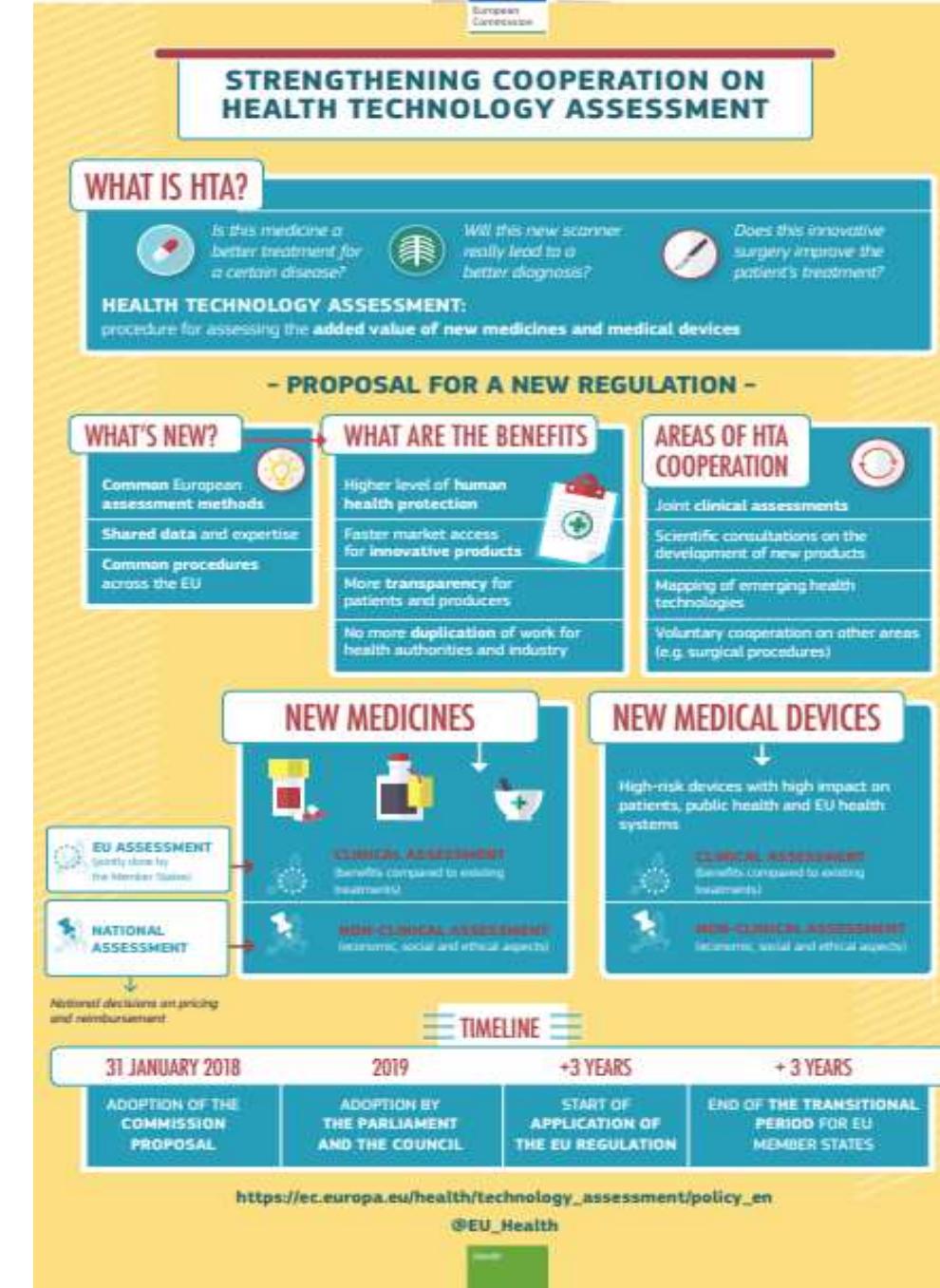
- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

These devices could include software intended to be used alone or in combination with hardware (e.g. scanners, sensors, monitors...), and include static and self-learning algorithms (e.g. artificial intelligence, machine learning).

DMD can be used by patients, caregivers, healthcare professionals and health system users in the broadest sense.

They do not include:

- Devices that are not intended to support medical purposes (e.g. wellness apps) ;
- Software qualified as an accessory for a hardware (intended to drive or influence the use of a hardware without having or performing a medical purpose on its own, or creating information on its own for one or more of the medical purposes described in the definition of a medical device regulation) ;
- Administrative softwares.

DMD-struktur: Digitale løsninger på recept

DIGITALE GESUNDHEITSANWENDUNGEN

DIGA

DIGA'er er produkter, som hjælper med at identificere og lindre sygdomme ved brug af digitale platforme som apps. For at en digital løsning kan blive godkendt som en DIGA, skal en række krav fremsat af det føderale institut BfArM opfyldes, heriblandt:

- CE-certificering, klasse I eller II
- Videnskabelige forstudier
- GDPR-databeskyttelse

Der findes i øjeblikket 35 DIGA'er i registreret, hvoraf en nogle af dem stadigvæk er under godkendelse. De er rettet mod behandling af forskellige sygdomme, bl.a. diabetes, depression, stress, tinnitus m.m.

TYSKLAND

DIGITAL SUNDHEDSBØLGE I TYSKLAND

Den tyske regering investerer frem mod 2024 årligt 200 mio. EUR i digitalisering af den tyske sundhedssektor. Vores danske repræsentationer i Tyskland kan hjælpe dig ind på markedet!

I Frankrig er man også begyndt at gøre noget lignede kaldet PECAN, hvor man også giver digitale løsninger på recept, som kan dækkes af forsikringen.

Teknologisk Institut

Reform af sundhedsvæsenet på vej...

Sundhedsvæsenet

Kronik: Vi skal ruste sundhedsvæsenet til fremtiden med et nationalt center for sundhedsinnovation

20.02.2024

I fremtiden vil færre medarbejdere skulle behandle flere patienter med stigende behov. Derfor har vi brug for flere løsninger, der frigør arbejdskraft til at løse sundsvæsenets kerneopgaver. Og vi har brug for en effektiv skalering af de løsninger, der virker.

Af Anders Kühnau, formand for Danske Regioner, Lars Sandahl Sørensen, administrerende direktør i Dansk Industri, Camilla Rathcke, formand for Lægeforeningen og Klaus Lunding, formand for Danske Patienter. Kronik bragt i Avisen Danmark d. 20. februar 2024.
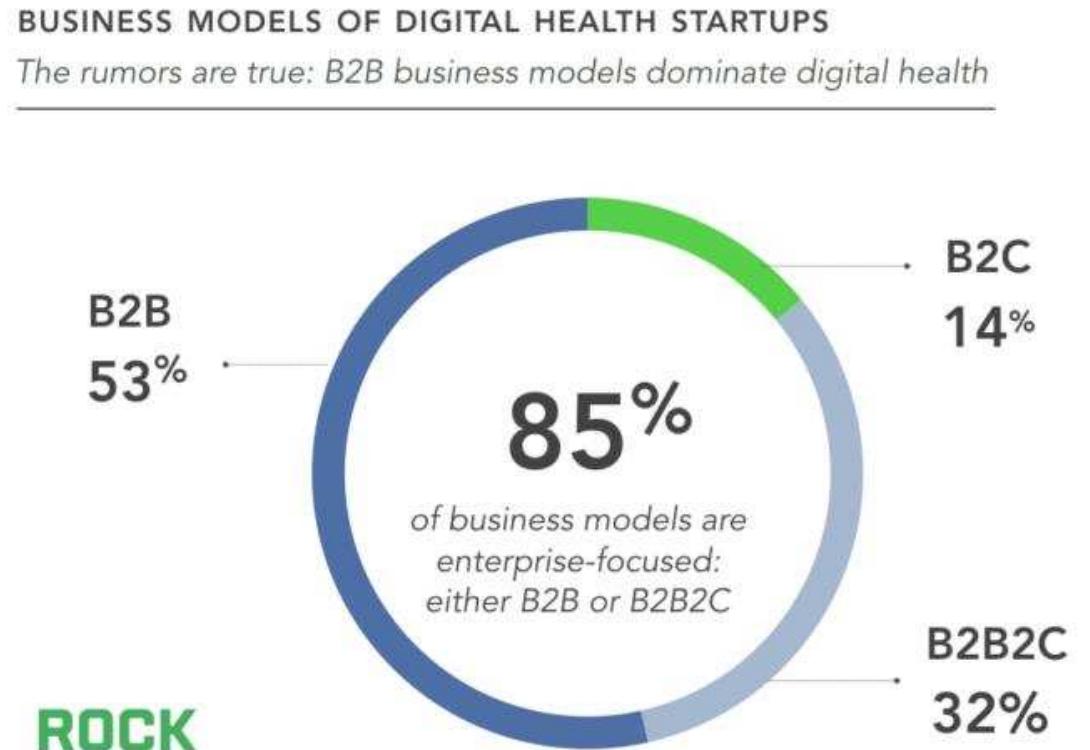
DANMARK HAR IKKE EN FREMTIDSSIKRET DMD-STRUKTUR ...

Apps i Almen Praksis og National App Guide er hver især gode initiativer, og bemandet med dygtige folk, som arbejder hårdt for at indfri succeskrierier i de pågældende projekter.

De er dog givet nogle begrænsede rammer, vilkår og ressourcer, som er markant under ambitionsniveauet og potentialet fra andre europæiske lande.

Skalering

- Få digitale sundhedsløsninger skaleres

- Mange løsninger forbliver prototyper eller lokale løsninger

- Mangel på nationalt overblik

- Mangel på investeringsvilje og finansiering

- Mangel på fælles standarder for kliniske og ikke kliniske valideringsstandarder

- Mangel på offentlig "infrastruktur" og klare nationale rammer for godkendelse og afregning (DMD struktur)

BUSINESS MODELS OF DIGITAL HEALTH STARTUPS

The rumors are true: B2B business models dominate digital health

B2C
14%

B2B
53%

85%
of business models are
enterprise-focused:
either B2B or B2B2C

B2B2C
32%

ROCK
HEAL+H

Erhvervsfyrtårn life science

Åben national pulje: 32 mio. kr. rettet mod løsninger inden for mental sundhed og lighed i sundhed

ERHVERVSFYRTÅRN
LIFE SCIENCE

LIGHED I SUNDHED

Hvem kan være med til at skabe nye, kommercielle løsninger og ny viden inden for lighed i sundhed og mental sundhed? Ny pulje i Erhvervsfyrtårn Life Science kan nu søges af partnere, som for eksempel kan være med til at opbygge lettilgængelige tilbud til børn og unge med psykisk mistrivsel eller bidrage til indsatser inden for oplysning og afstigmatisering

Mental sundhed – udfordringerne kan kun løses via innovative partnerskaber

Medfinansieret af
Den Europæiske Union

Angst, depression, stress og dårlig trivsel. Mental mistrivsel er blevet én af Danmarks dyreste og mest bekymrende sundhedsudfordringer. Udfordringerne er synlige i skolerne, blandt de unge, på arbejdspladserne og blandt de ældre.

28. februar 2024 | Caroline Neubert, csn@danishlifesciencecluster.dk

Det gode samarbejde, og monitoreringens udfordringer

Erfaringer fra Brøndby Kommune

Mira Valentina Krogstrup,
Cand.It. i Digital design og Interaktive teknologier
Konsulent i velfærdsteknologi

Teknologisk Instituts Netværksmøde for Digital Mental Sundhed, 20. marts 2024

Kommunens ansvar for demensramte

Daglig behandling, pleje og omsorg

Forankret i Serviceloven - ikke samme lovbestemmelser som i Sundhedsloven (regionerne)

Selvbestemmelse og retssikkerheden for psykisk og mentalt udsatte borgere, står centralt i serviceloven.

Vi er i borgerens eget hjem.

Borgeren har ikke mulighed for at give et habilt samtykke, og der kan ikke indhentes stedfortrædersamtykke.

Borger og medarbejder i Brøndby Kommune

Demensramtes mentale sundhed
Beboere på ældrecentre

80 % af beboere på ældrecentre er påvirket af demens eller anden mental svækkelse, og oplever i særlig grad symptomer som:

- Depression, angst og panik
- Forstyrret søvn
- Forvirring, samt mangel på tidsperspektiv
- Agitation og agression
- Øgede Infektioner i kroppen, der kan udløse delir/forvirring
- Gangbesvær og faldtendens
- Sprogforstyrrelser og talebesvær

Nationalt Videnscenter for Demens, 2022

Borger i Brøndby Kommune

Teknologisk perspektiv:

Tryghedsskabende Velfærdsteknologi

§

Ind- og udgangssignalgivere, fald- og anfaldsalarmer, og lokaliserings- og sporingssystemer
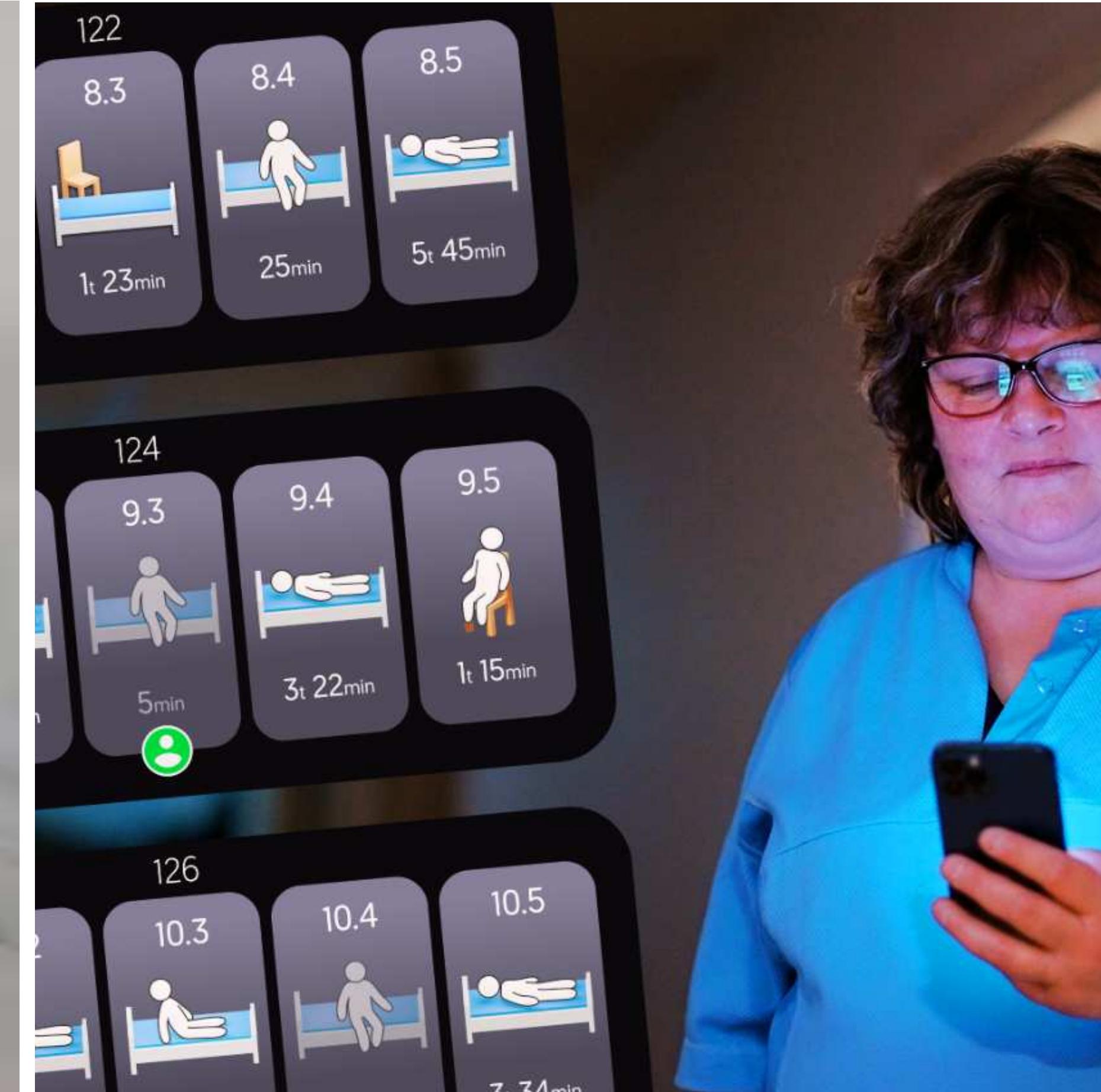
- Ofte sensorer - *Dog aldrig video-kig ind*.
- Skal sikre personens tryghed, værdighed og omsorg, og forebygge fare

§ Hjemmel i servicelovens kapitel 24 om magtanvendelse

§ 136 e Personalet kan som led i omsorgen anvende tryghedsskabende velfærdsteknologi for at sikre personens tryghed, værdighed og omsorg, medmindre den pågældende *modsætter sig anvendelsen.*

Hvad er digitalt tilsyn?

Sensormonitorering med Teton A.I.

Teton A.I.

Sensor-monitorering i ældreplejen

Digitalt Tilsyn som koncept

Teknologi

Automatiseret sensordetektion via computervision og AI, til specifikke hændelser såsom fald, søvn, og toiletbesøg.

➡️ **Understøtter borgerens talebesvær**

Funktioner

- Faldalarmer

  ➡️ Hurtig hjælp og minimering af tid på gulvet

- Generering af databaserede døgnrytmeanalyser

  ➡️ Arbejde med søvnforbedring
  Tidlig opsporing af infektioner (ex. urinveje)

- (Faldvideoer / video-kig ind)

  ➡️ Forebygge fald, træning og miljø
  Give rette behandling (ex. hjernescanning)

Det gode samarbejde

om digitale og teknologiske løsninger i kommunerne

Open source vidensdeling

Leverandøren sidder med mange kommunale samarbejdspartnere, og er ofte "eksperten" i implementeringsprocessen.

Den kommunale faglighed

Forstå hvilke fagligheder der skal anvende teknologien, og hvordan deres omsorgspraksisser udfoldes i det daglige arbejde. Justér herefter.

Forskning

Uvildig forskning i nye eller uafprøvede teknologier.

Etik

Brug tid på at overveje etiske dilemmaer. Se det Digitale Etikkompas for inspiration.

Økonomi

Kommunerne har en økonomisk virkelighed. Udvikl en realistisk business case, hvis teknologien er tids- eller arbejdskraftbesparende

Lovgivning

At teknologiens design og anvendelse, indtænkes inden for de lovmæssige rammer, øger tilliden i samarbejdet, og sparer kommunerne for mange ressourcer.

Udfordring
Compliance på tværs af økosystemet

?

Juridisk compliance og etiske overvejelser understøtter tilliden mellem private og offentlige aktører — så hvordan sikrer vi lovmæssigt forankrede teknologier, på tværs af økosystemet?

Mira Valentina Krogstrup,

Cand.It. i Digital design og Interaktive teknologier

Konsulent i velfærdsteknologi, Brøndby Kommune

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linkedin.com/in/miravalentinakrogstrup/

UNMET NEED

Amadeus is telling me that I should cut off your arm and fry it.

30% of patients with schizophrenia are treatment-resistant

Meltzer HY. (1997)

those whose symptoms get better from medication experience significant side-effects and often discontinue taking their meds

Lieberman, J. A., et al. (2005)

This is the most expensive disease to treat in psychiatry and has enormous societal costs

Kadakia A. et al, 2022, Christensen, M.K. et al, 2022, Fasseeh,A. et al., 2018,

Avatar therapy

Invented in 2008 by Julian Leff to treat voice hearing (Leff et al., 2014)
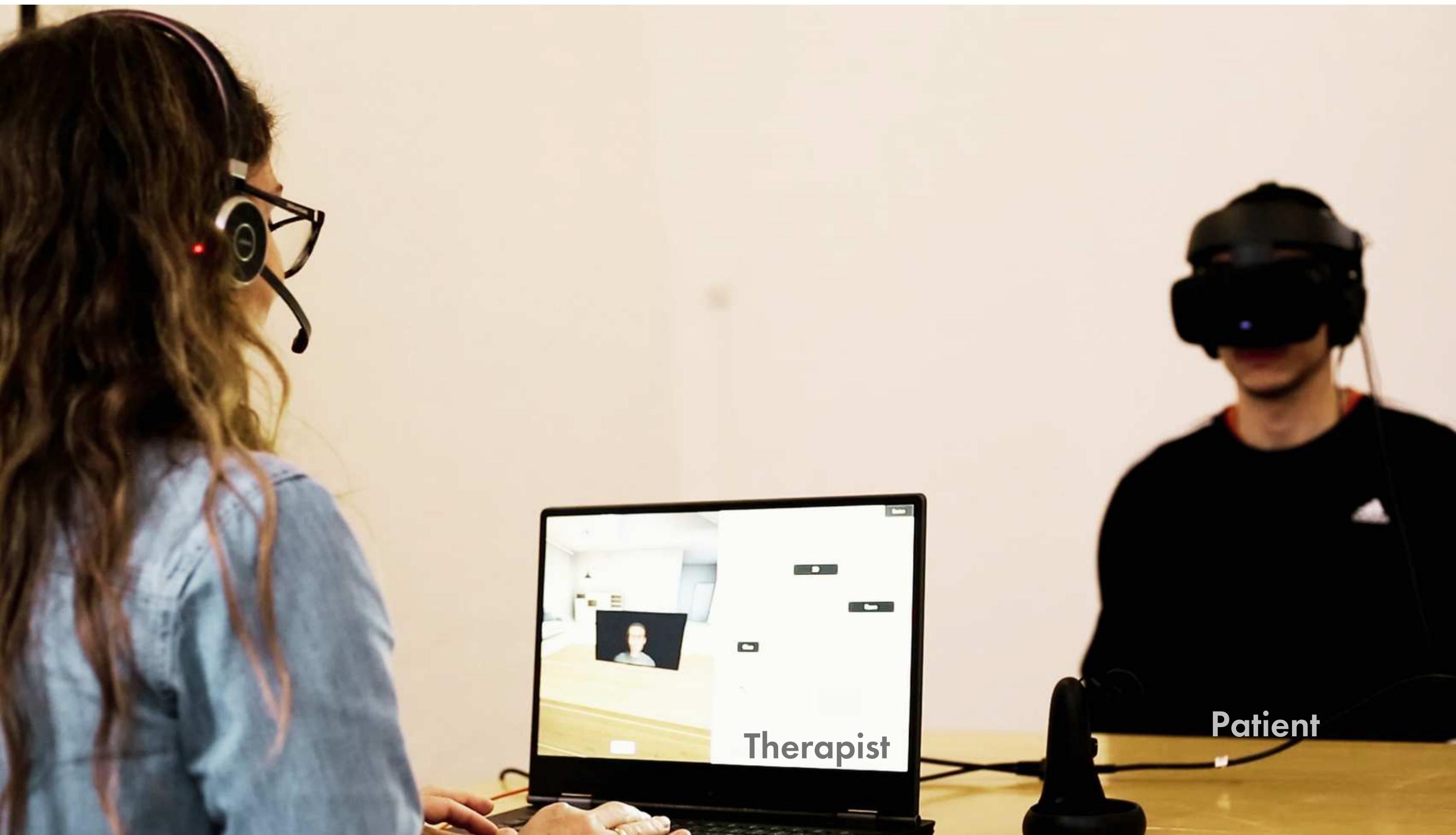
HEKA VR

Virtual Reality

Immersive experience could enhance the effects of therapy. (Freeman et al., 2017)

Heka VR is the first VR simulation to support the treatment of auditory hallucinations

IN THERAPY

Therapist

Patient

certified under the EU MDR

Basic characteristics

Gender

Female   Male

Age

Young   Old

Body Gender

Female   Male

Show key

A face creation module

The therapist and the patient together can create a visual representation of the patient's voice.

A face creation module

Gender, age, and facial characteristics are all customisable.

Face

Eye color >
Skin color >
Hair style >
Hair color >
Beard style >
Facial hair color >
Glasses >
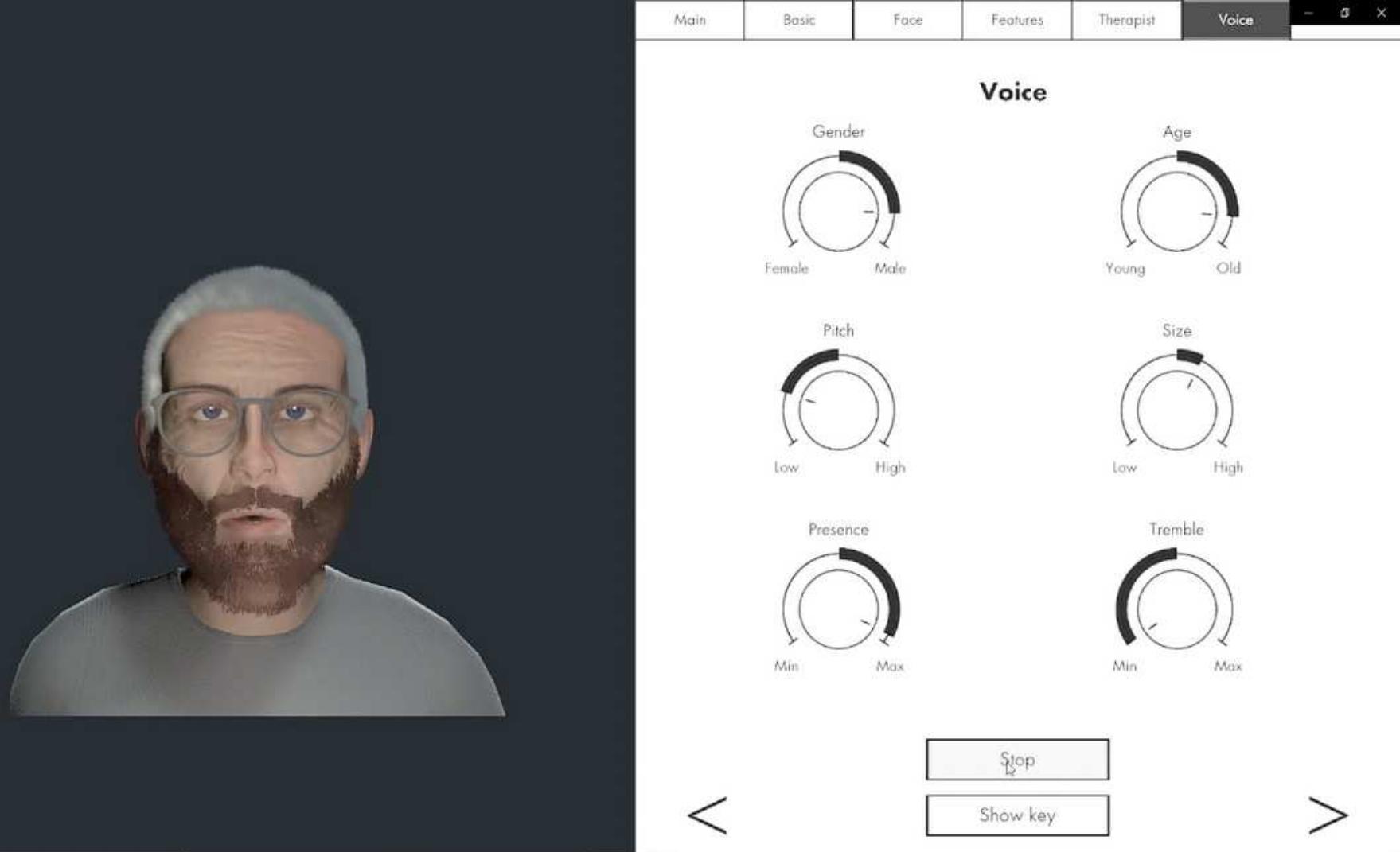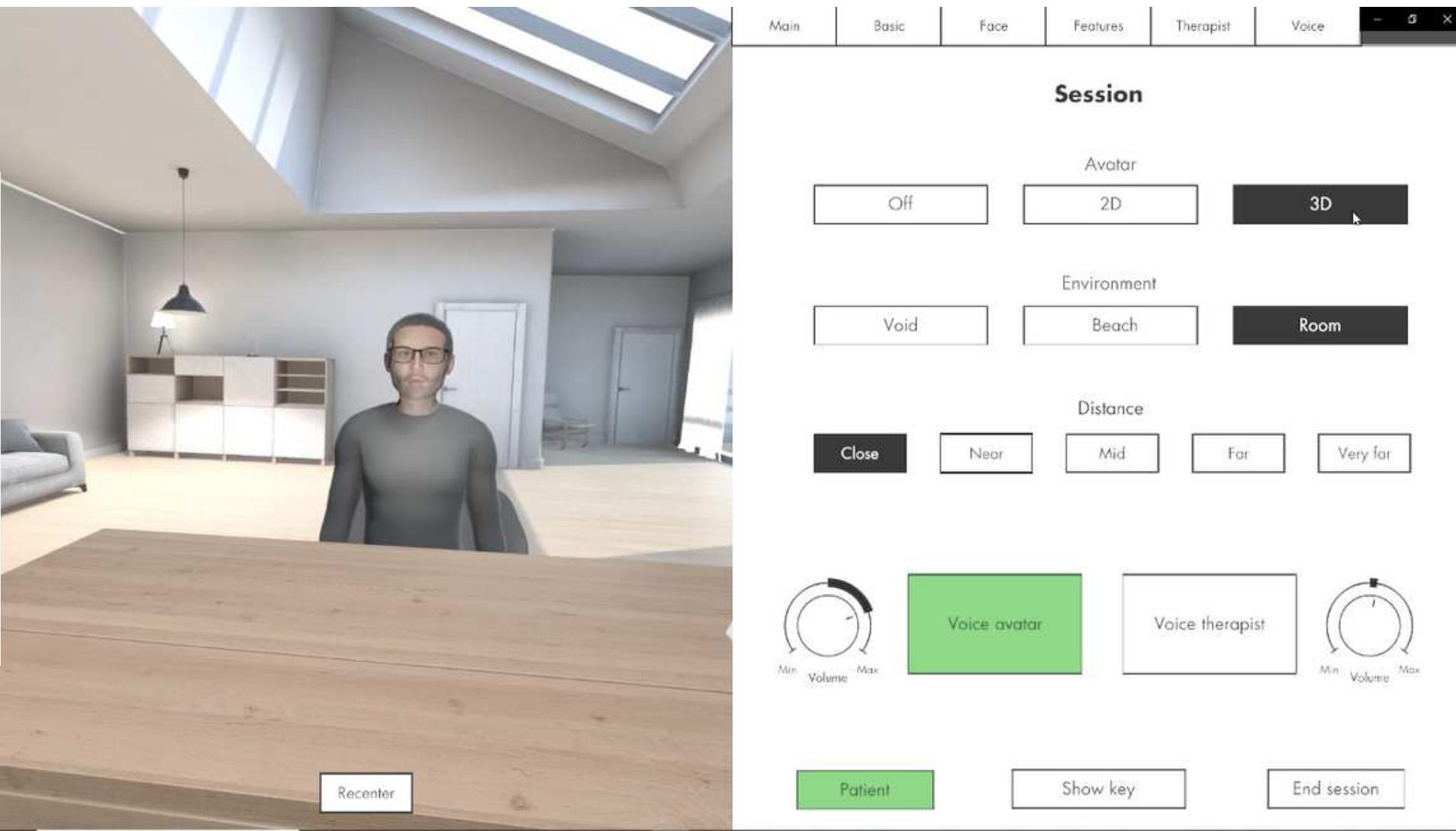
Show key

Real-time voice modulation

The therapist's voice can be modulated – by changing age, gender, pitch, and other traits – to resemble the voice in the patient's head.

The real-time VR simulation
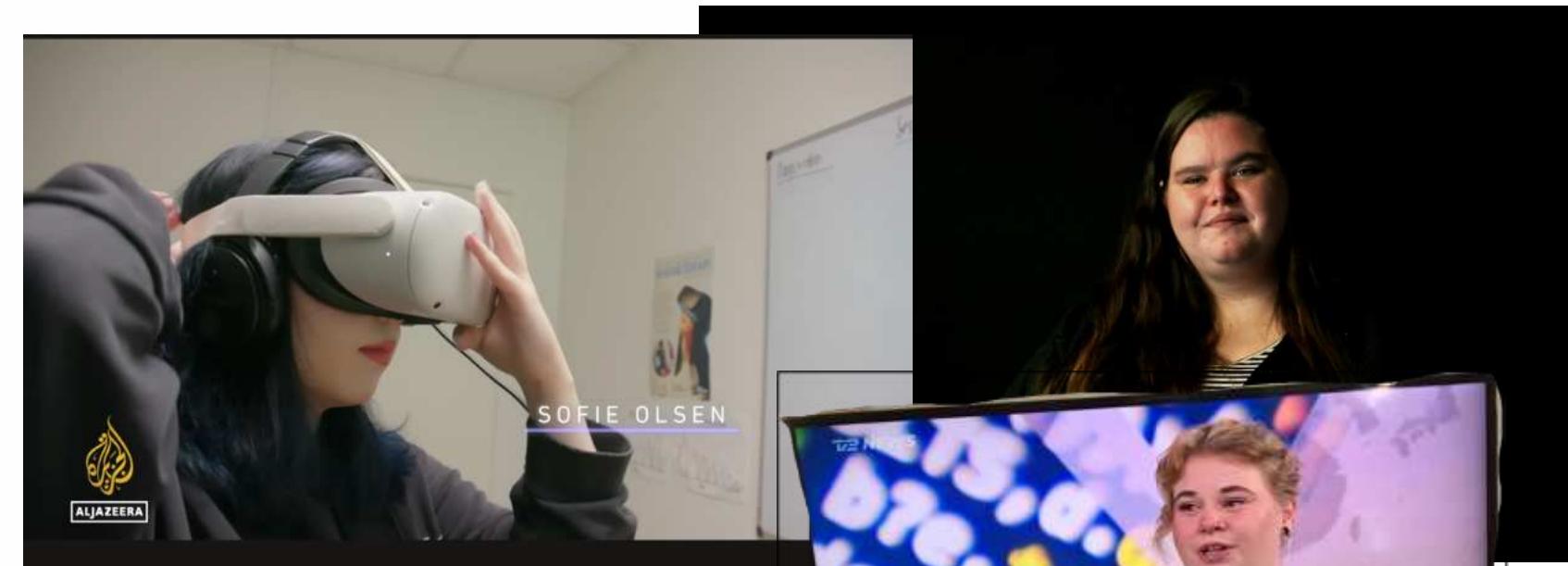
The patient can engage in a dialogue with the visual representation of the voice in VR and practice confronting it whilst the therapist is acting as the voice via the real-time voice modulation feature.

OUR PATIENTS

> "It's crazy. Already it has helped much more than I could have hoped for. It's absolutely insane"

Cille after therapy

> "My reality has become a shared reality"

Patient at 3. session

> "After 27 years of hearing voices, I have now been voices-free for 2 years"

Vibeke after therapy

> "It has given me an extreme amount of freedom inside my head"

Denis after therapy
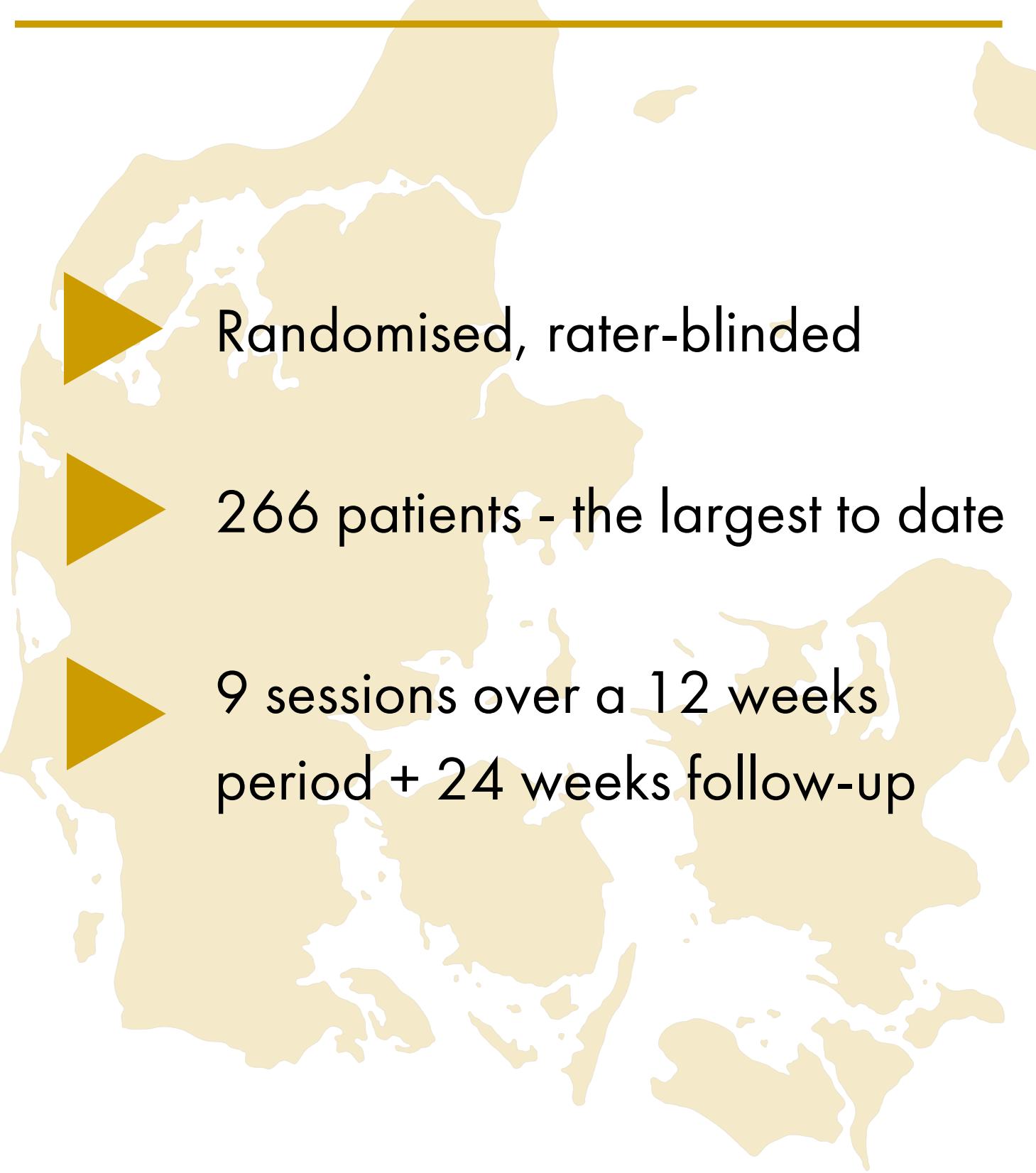
> "...mosquitoes buzzing around my head which I am able to fan away"

Mark after therapy

SOFIE OLSEN

PSYKISK SYGDOM
Ny terapi med VR-brille mod skizofreni
10:46 SENESTE estriktioner mod Rusland har påført cubanske biejere en stor udfordring

VR-BRILLER MOD SKIZOFRENI
33 Avatar-terapi Succes
NYHEDERNE

Dennis har hørt stemmer, siden han var seks år - nu får han endelig en pause

CHALLENGE TRIAL

RESULTS Q1 2024

▶ Randomised, rater-blinded

▶ 266 patients - the largest to date

▶ 9 sessions over a 12 weeks period + 24 weeks follow-up

▶ Reduction in frequency and distress of auditory hallucinations
  - At least 3.8 point reduction on PSYRATS-AH
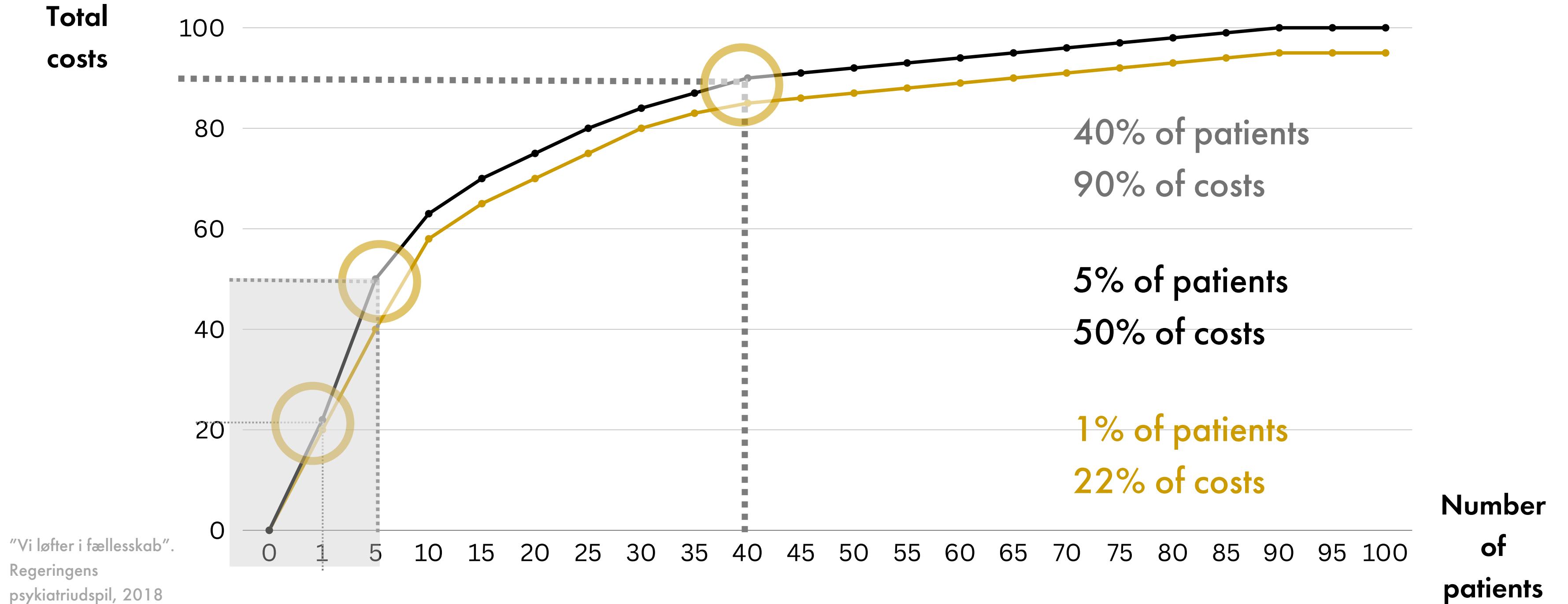
▶ Reduction in Depressive symptoms
  - Calgary Depression Scale (CDS)

▶ Improved social functioning and QoL
  - Social Functioning Scale (SFS)
  - Personal and Social Performance Scale (PSP)
  - Suicidal Ideation Attributes Scale (SIDAS)
  - Pittsburg Sleep Quality Index (PSQI)

Helping the most severe, 5% of patients can significantly reduce costs of psychiatry

GLOBAL PRESENCE

N of patients in VR Avatart
Therapy Clinical Trials:

Heka VR **74%**

Canada **15%**

Switzerland **11%**

Established relationship

Negotiations/ Plans

HEKA VR IS THE MOST USED SOLUTION FOR VR-AT GLOBALLY!

SCHIZOPHRENIA SINCE 2019

Country	Trial description	Target group	Project duration
Denmark	RCT n=266	VR-AT-SCH Adults	2020-2023
NY, USA	RCT n=40	VR-AT-SCH Adults	2023-2025
Australia	RCT n= 212	AT-SCH Adults	2023-2025
Denmark	Pilot N=12	VR-AT-SCH Children and Youth	2023-2023
Spain	Pilot n=30	VR-AT-SCH Adults	2024-2025
Poland	Pilot n=30	VR-AT-SCH Adults	2024-2025
Hungary	Pilot n=60	VR-AT-SCH Adults	2023-2025
Denmark	Feasibility n=10	VR-AT-SCH-EEG Adults	2024-2025
South Africa	Feasibility n=15	VR-AT-SCH Adults	2024-2024
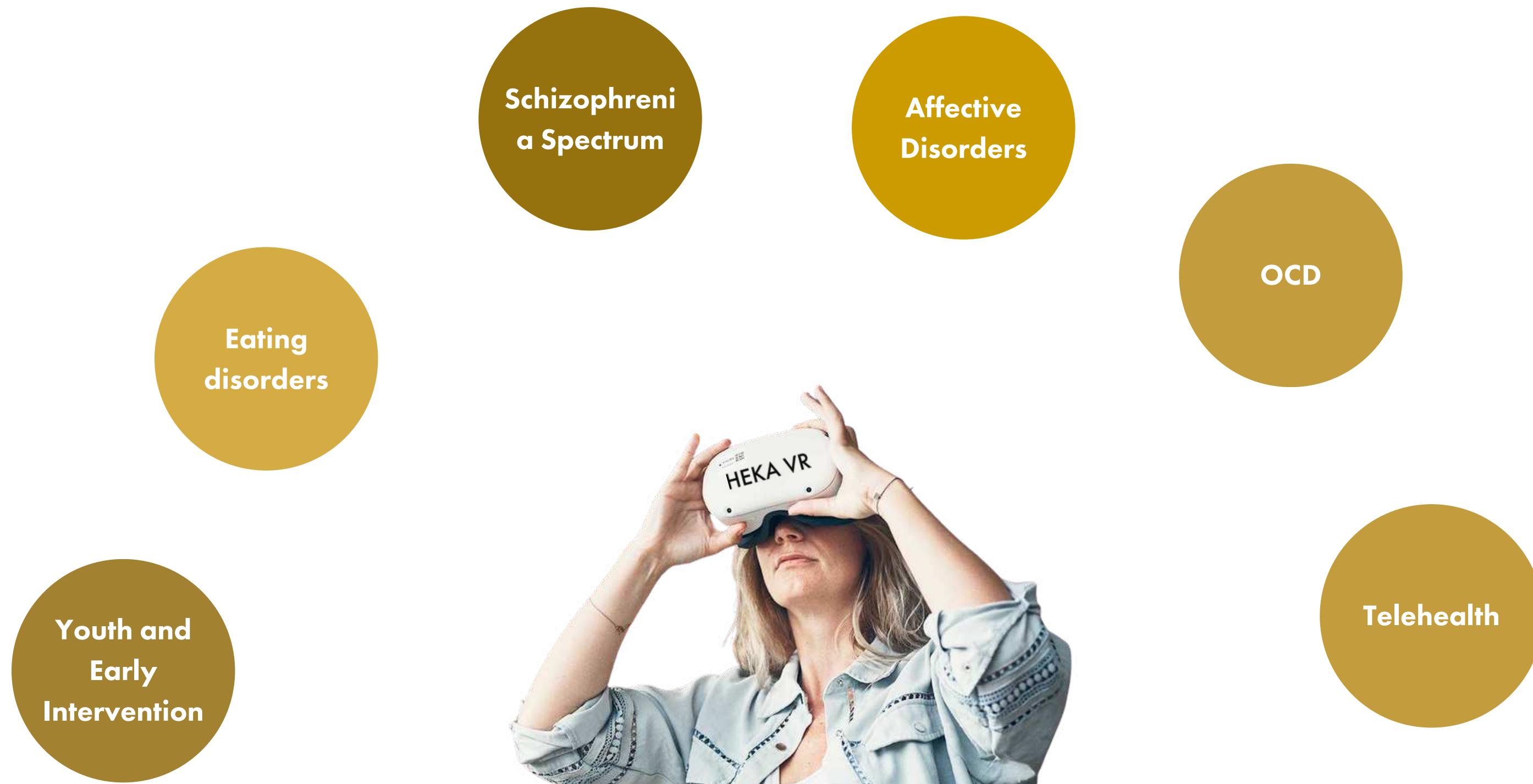
NEW DISEASE AREAS AS OF 2023

Country	Trial description	Target group	Project duration
Denmark	RCT n=62	Eating Disorders Adults	2023-2025
Germany	Pilot n=8	OCD Adults	2023-2024
Czech Republic	Pilot n= 30	Depression Adults	2024-2027

PENDING

Country	Trial description	Target group	Project duration
France	RCT	SCHIZ + Bipolar Adults	2024-?
Sweden	Pilot	Bipolar Disorder Adults	2023-?
Canada	Pilot	Bipolar Disorder Adults	2024-?

USE CASES

Schizophrenia Spectrum

Affective Disorders

OCD

Eating disorders

Youth and Early Intervention

Telehealth

HEKA VR

"
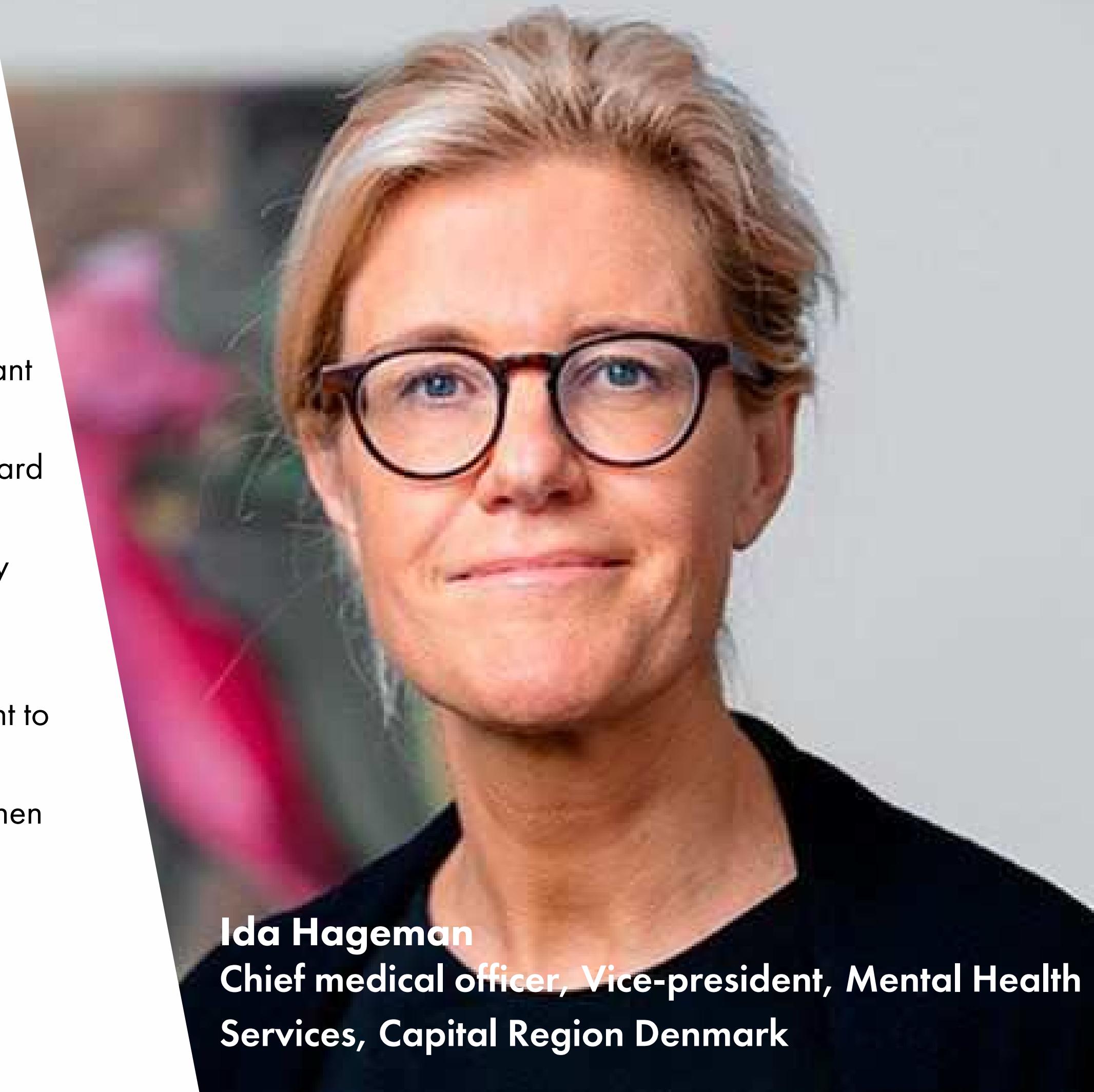
"The Heka software and the avatar therapy are very relevant and promising as it targets a big patient group who are severely ill and not always sufficiently helped by our standard treatments. Moreover, due to the insufficient treatment responses patients with severe mental illness are very costly for the regional healthcare system and society in general .

I believe that this therapy will become a regular supplement to how we treat patients with Schizophrenia in Denmark and internationally. And if the therapeutic effect is substantial, then it's definitely something we want to implement."

Ida Hageman
Chief medical officer, Vice-president, Mental Health Services, Capital Region Denmark

THE TEAM

Advisors

Farah Shiraz PhD
CSO, Psychologist
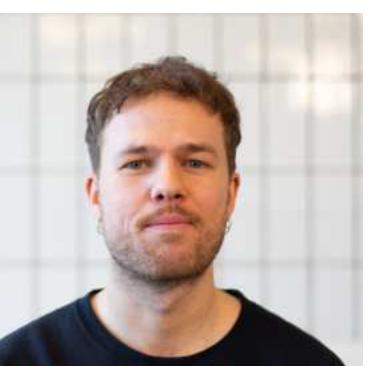
Katalin Vikuk
Psychologist, Mental
Health Tech,
Regulatory Compliance

Andras Csikos
Unity Developer

Simon Lajboschitz
CEO

Anders Bargum
Phd: Voice transformation

Katarina Michelova
Global health and
Soft Funding specialist

Helena Blazincic
Digital health expert,
clinical trial manager

Peter Fisher
CTO

Tahir Hussain
CFO

**Johan Winther
Kristensen**
Technical
implementation
specialist

Full time

Merete Nordentoft
Professor of Psychiatry

Jesper Grønbæk
Health Tech Hub CEO

Johan Källstrand
Dig. Health Expert

Stefania Serafin
Prof in Media Technology

NO ME
NORDIC MENTOR NETWORK
for ENTREPRENEURSHIP

AMBASSADORS

Don't be a stranger!
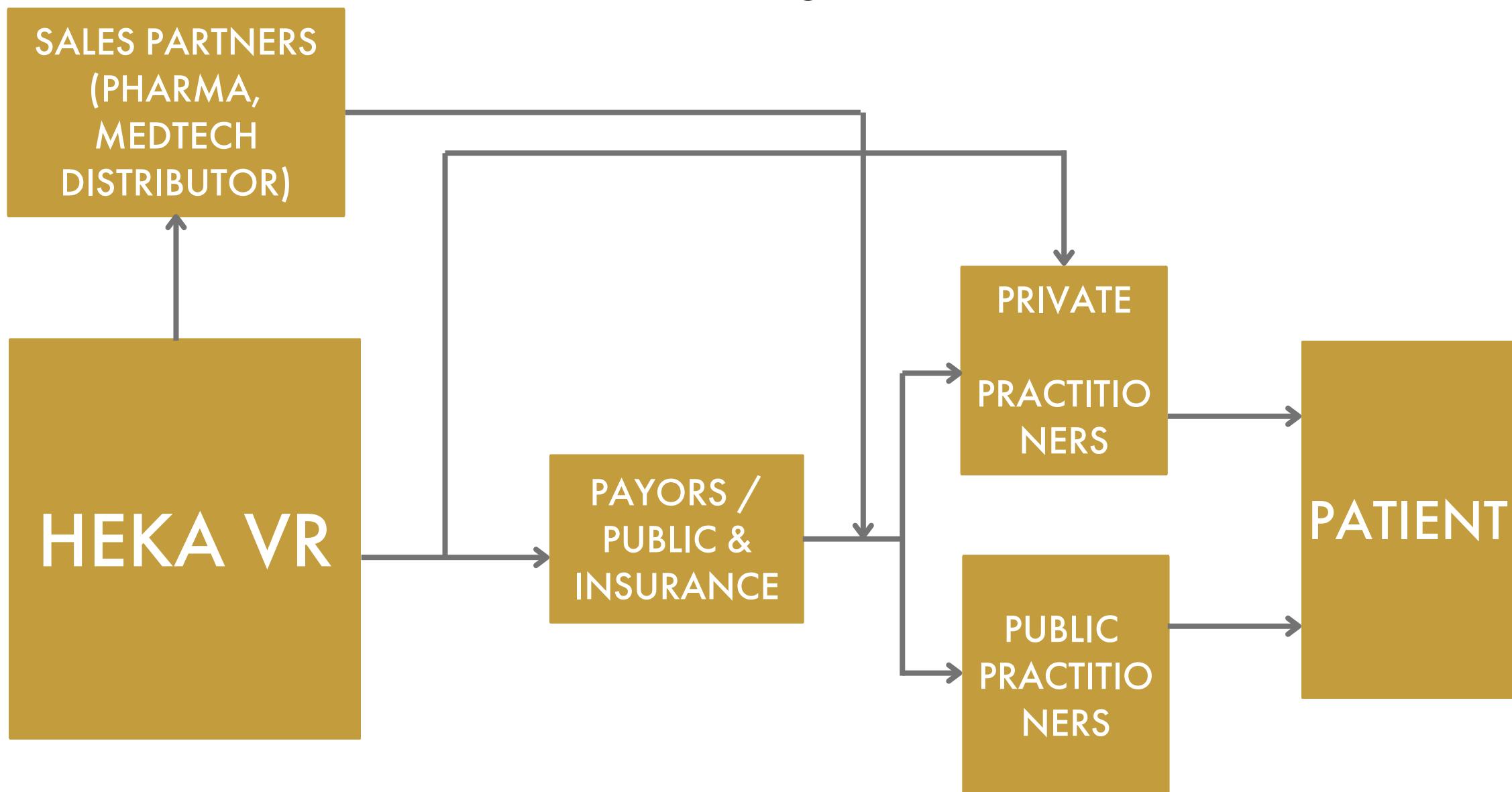
hekavr.com

Fund	Country	Type	HekaVR	To R&D
Innovationsfonden	DK	Grant	€335.287	€2.012.000
BioInnovation Institute	DK	Convertible loan	€536.458	-
Eating Disorder	DK	Grant	€26.823	€577.000
Youth Psychosis	DK	Grant	€24.141	€88.516
TeleHealth Version	Australia	Grant	€53.646	€980.000
Manhattan Trial	USA	Grant	€10.729	€536.000
Industry PhD	DK	Grant	€93.880	-
Self-investment	DK	Investment	€402.344	-
DLSC	DK	Grant	€24.141	€30.846
EIT Health & EU Comission	EU	Loan	€500.000	€1.428.000
Lundbeck Foudation	DK	Grant	€46.940	€201.000
European Comission: Desire	EU	Grant	€60.000	€30.000
European Comission: Innowwide	EU	Grant	-	€26.000
TOTAL			€2.115.000	€5.909.000

BUSINESS MODEL

We can help 24 000 000+ patients worldwide fight auditory hallucinations by using VR

- First line of treatment for 30% of patients who are medication resistant.

- Learnings from facing difficult situations in VR can be transferred to the real world.

- Shorter, more effective, personalized, 12-week therapy with fewer side effects.

- Cost-effective compared to SoC

- CE marked

- Evidence-based

- Already demonstrated efficiency in schizophrenia

PRICING

Set up cost (first time only/per setup)			
Hardware and Installation	€10.000	per computer setup	
Clinical and technical training	€1000	per therapist	
Clinical supervision	€1500	per therapist	15 sessions, 1st year only
Yearly licence fee incl ongoing support, software updates and hardware updates			
	€24.000	yearly	fixed per computer setup

Regulatory compliance & IP

Regulatory Strategy: 5 Year Plan

CE approved Class 1 Medical Device

CE

EUDAMED - SRN: DK-MF-000035625
as of April 2023

EU

BSI, TUV SYD, and i3c global

CE mark Class IIa in Q3 2024 for
schizophrenia application
depending on new clinical evidence

USA FDA
(2025)

AUSTRALIA
(2028)

Reimbursement Strategy

EU: Denmark, Poland, Spain, Hungary,
Germany, France, Italy

US FDA

National reimbursement strategy
development funded by EU grants
2024-2025

Intellectual Protection Strategy

- Full FTO and no infringement with similar solutions
- Currently treated as a trade secret
- Patenting voice modulation feature as part of PhD research will be patented when ready

TETATET.AI

Supporting Mental Wellbeing
Through Focused Exercises
With An Emotion Aware AI Coach

tetatet.ai

Paula Petcu
Co-founder of TETATET.AI | Ex CTO Brain+ | Ex Digital Health Lead Lundbeck

We are on a mission to prevent and reverse the growing mental health crisis by democratizing access to high-quality and personalized coaching.

High-achieving professionals struggle to balance high-stress careers with personal well-being, often at the cost of their mental and emotional wellbeing.

Growing mental health crisis

More people are suffering from everyday stress, anxiety or mental health disorders than ever before.

67%

people experience everyday stress

chronic and unmanaged stress

has been identified as a primary precursor to numerous mental health disorders and chronic diseases, imposing substantial costs on our society

Limited time availability & expensive

limited time for both the professional
and the mental wellbeing/ healthcare professionals

19-46%

dropout rate from psychotherapy
(i.e. don't complete the therapy)

Limited affordable options that are truly personalized to the individual

High-achieving professionals struggle to balance high-stress careers with personal well-being, often at the cost of their mental and emotional wellbeing.

BØRSEN SENESTE NYT KURSER

"Rekordstress koster arbejdspladser 16,4 mia. hvert år – nu skal der gøres noget"

Sygefravær i forbindelse med stress koster danske arbejdspladser 16,4 mia. kr. hvert år. Arkivfoto: Mads
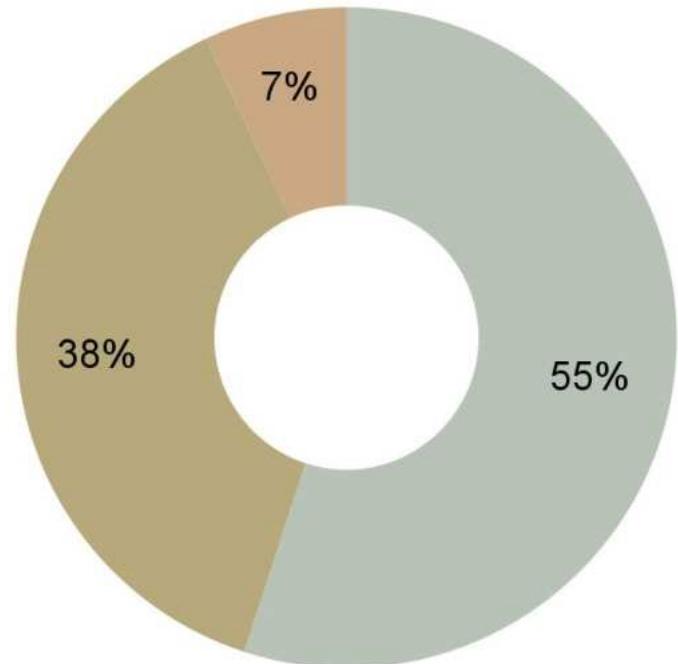
Stigende stressproblem koster "sindssygt mange penge" for pensionsbranchen

Unge mennesker, i særdeleshed kvinder, er overrepræsenteret, når det kommer til stress. Det er stort problem for pensionsselskaberne. Arkivfoto: Mads Claus Rasmussen/Ritzau Scanpix

How we communicate feelings and attitudes

research by body language researcher Albert Mehrabian

7%

38%

55%

● Body Language   ● Voice Tone   ● Words used

Current AI-based health coaches/ therapists are text based...

Emotion Aware AI Health Coach

Guided conversations

Using the device's camera and microphone, it picks up on conscious and unconscious cues from facial expressions, voice and speech, to identify opportunities for individual coaching, and empathically speaks back.

Available at any time, while keeping data safe.

Active engagement via role play

With interactive and adaptive role playing exercises, you get to practice in a safe space, simulating different scenarios, preparing you for real life difficult situations.

Personalized

Enables effortless personalized coaching. It remembers previous entries and brings them back to surface as needed.

Based on DTU Research

DTU

How it works: At home

① Find a space where you feel comfortable.

② Explore exercises (guided conversations) and courses

③ Start a guided conversation focused on the selected topic. It's like a FaceTime chat.

From the camera and microphone, the emotion AI will pick up on clues that are used to adapt the conversation.

Behavioral AI

Unlike traditional text-based solutions, the TETATET AI is learning how to read **facial micro-expressions** and **tone of voice**, and **combine different inputs** to more accurately extract meaning from what is being said. And **adapts accordingly**, without judging.

Based on DTU Research

Testimonials

Dimitri, Prev Tech Manager Corti, Early tester

"It understands questions! Very organically! Voice + face tone detection worked magically for me! […] Cool interaction between components, and it felt really deep."

Clara, Clin Psych, Early tester

"I found myself invested in the exercise and found it very relieving to engage in. It helped alleviate my anxiety/agitation"

Nehar Mortuza, Life Science Leader, Early tester

"Love TETATET.AI and what you guys are building. Had the privilege to test it and think it's quite impressive. It blew away all my assumptions of an Ai coach, both can coexist and have different functions. Look forward to seeing the final product. "

Claus, Product Owner, Coloplast, Survey respondent

"Good luck with the project - I think it's something many people would need"

Anonymous survey respondent

"[I want] an affordable (compared to my current, human coach 😂) but efficient coach whom I can bounce ideas and hardships with."

Julius, Product Manager Corti, Survey respondent

"Let me know when you need a beta tester. This sounds super exciting."

Timing

The number of people experiencing **stress and mental health issues is growing worldwide**.

Stress accounts for 37% of all work-related illness and 45% of sick days. Employees often experience excessive pressure in their job.

Stress management segment is growing at the CAGR of 8.1%.

There is an **increased awareness of the importance of mental health**, yet at the same time, there is a **shortage of mental health professionals** and it will only get worse.

Explosion in generative AI research and applications since the launch of ChatGPT (Nov 2022). The generative AI market is projected to reach 208.8 Billion by 2032, CAGR of 35.1%. (Acumen Research)

People are more inclined to use AI health products for health, with some even preferring talking to a robot rather than a person. There is a **growing market for digital solutions addressing mental health.**

Founding Team with Previous Experience within Startups, Pharma, Clinical Research, and Mental Health Tech

Extended team and advisors

Paula Petcu
Chief Executive Officer
Product, Sales, Fundraising
Prev. CTO at Brain+, Digital Health Manager Lundbeck

Troels Nielsen
Chief Technology Officer
Tech, AI
Prev. Senior Data Science Specialist at Lundbeck

Frederik Sally
Chief Marketing Officer
Marketing, Branding, Design, Sales
Prev. CMO at GoodTimes, CMO at Ackermann

Line Clemmensen
Chief Scientific Officer (DTU)
Grants, AI Research
Professor specialized in AI & Machine Learning at DTU

Michaela Raaby
Psychotherapist

Louise Bergøe
Psychologist,
Occupational Coaching

Nicolai Elmqvist
Serial entrepreneur,
Business Development

Emily Axelsson
Marketing Intern

Clara Weber
Clin Psychology Intern

Daniel López Ríos
Ari Goldhar Menachem
MSc Students
DTU Compute, Machine Learning

Interested?

Invitation to collaborate
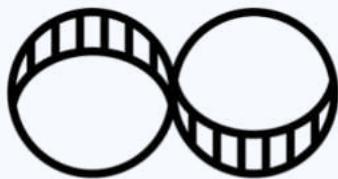
Inviting for collaboration with interested therapists, coaches, healthcare professionals, researchers, and mental health advocates to join us in this pioneering endeavour.

Pilot project in companies

For modern companies that see their employees as human beings. We provide add-on modules for HR and managers to get a pulse on their employee wellbeing.

Investor relations

Currently we are bootstrapping, but with a financial investment we would be able to speed time to market and use that for product development and sales hires. However, we want to identify the right investor match and timing, so let's just start with an intro call.

TETATET AI is a health tech startup founded by people who love the science behind health. We are on a mission to prevent and reverse the growing mental health crisis by making coaching available to everyone.

Based in Copenhagen, Denmark

Reach out at: contact@tetatet.ai
Website: tetatet.ai

Examples of patient monitoring and and self-help in mental health

March, 2024

Nanna Iversen, COO · iversen@monsenso.com · +45 27267120 · monsenso.com

Monsenso at a glance

- Validated, research-based SaaS-based digital health solution
- Customisable to support clinical pathways and research
- 9 years of international experiences from research and implementation projects
- CE marked, GDPR compliant, ISO 13485 and ISO 27001 certified
- Continuous development, innovation and research

12
languages
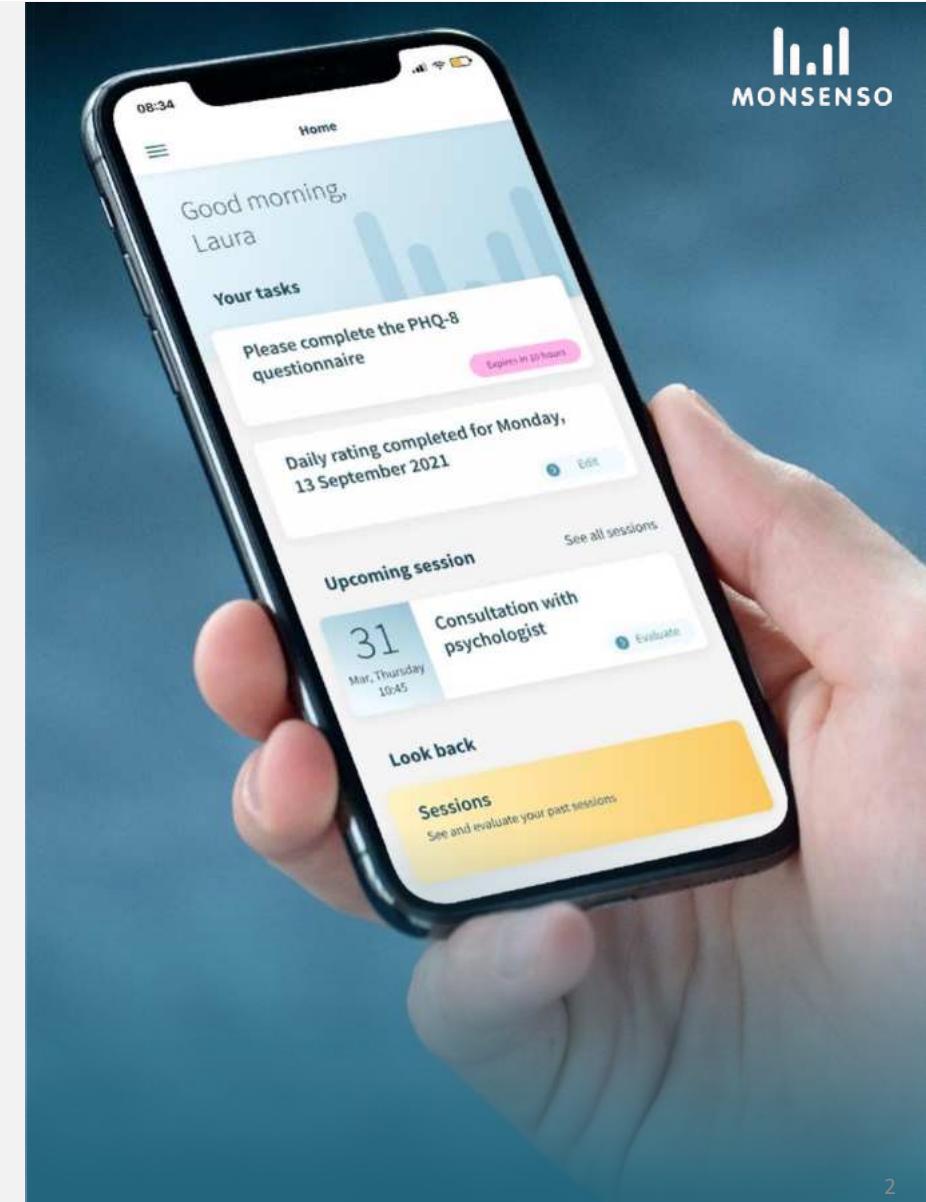
13
psychiatric, neurological, chronic disorders
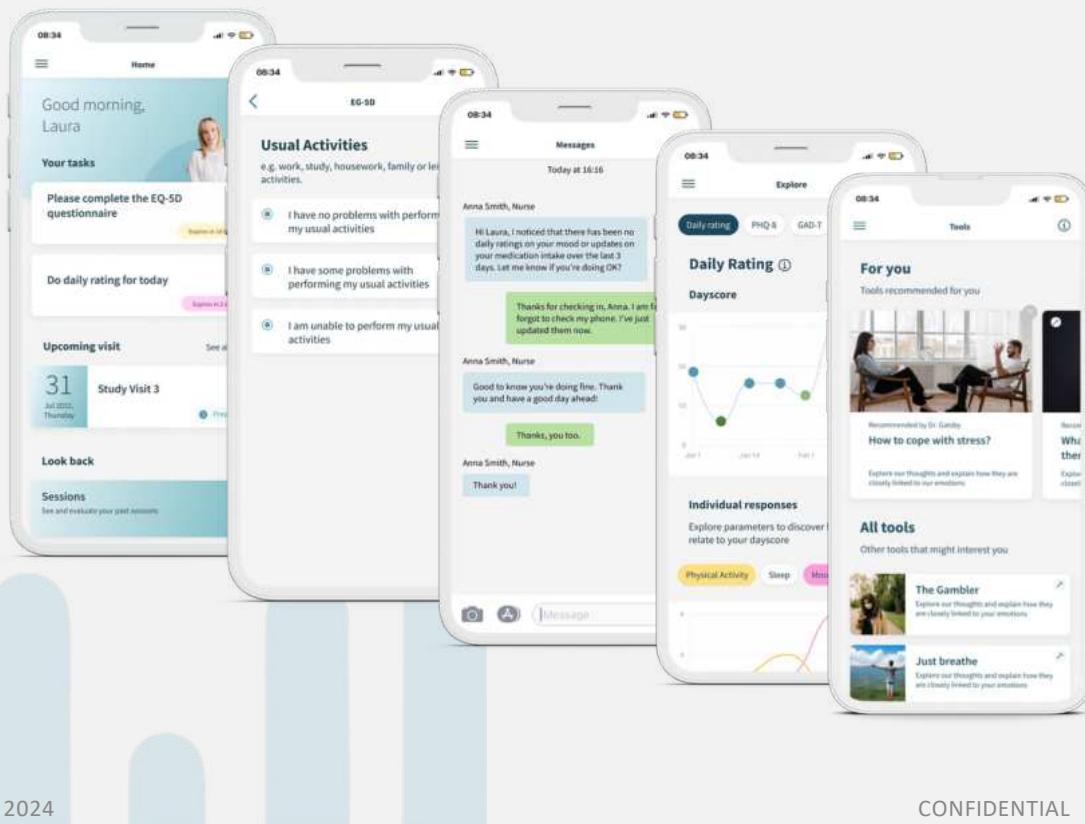
20+
research projects and engagements

70+
published peer-reviewed papers

# App for engaging and empowering users

Customisable app

- Reminders/notifications
- Patient reported outcomes & questionnaires
- Appointment planning
- Library of info, exercises and tools
- Secure communications
- Medication compliance tracking
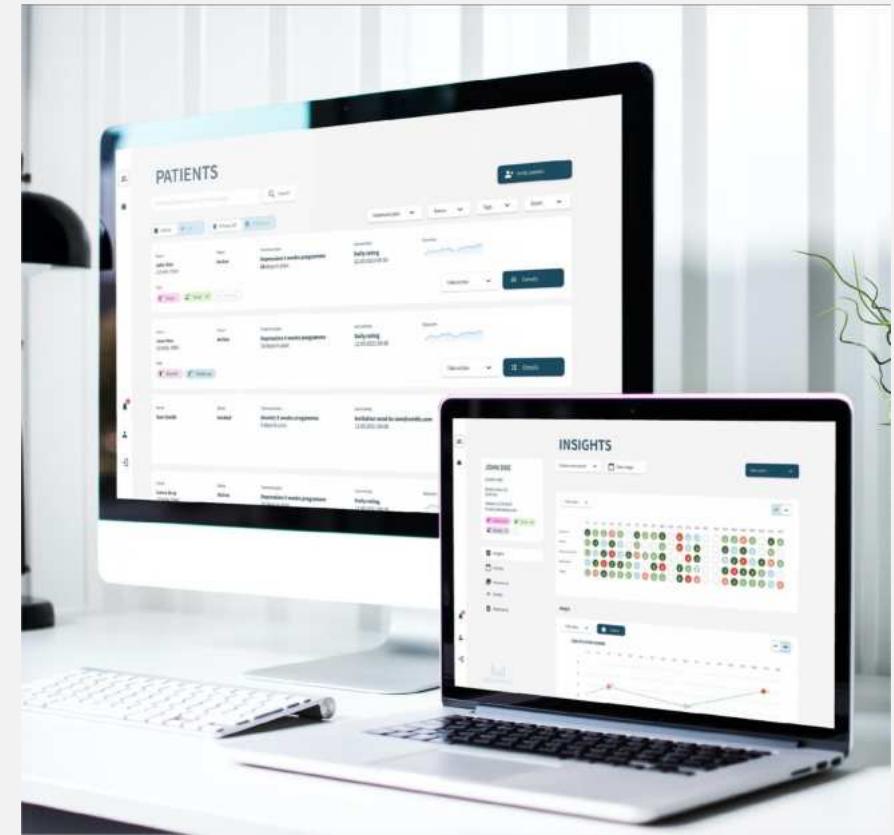
Clinical web portal for actionable insights
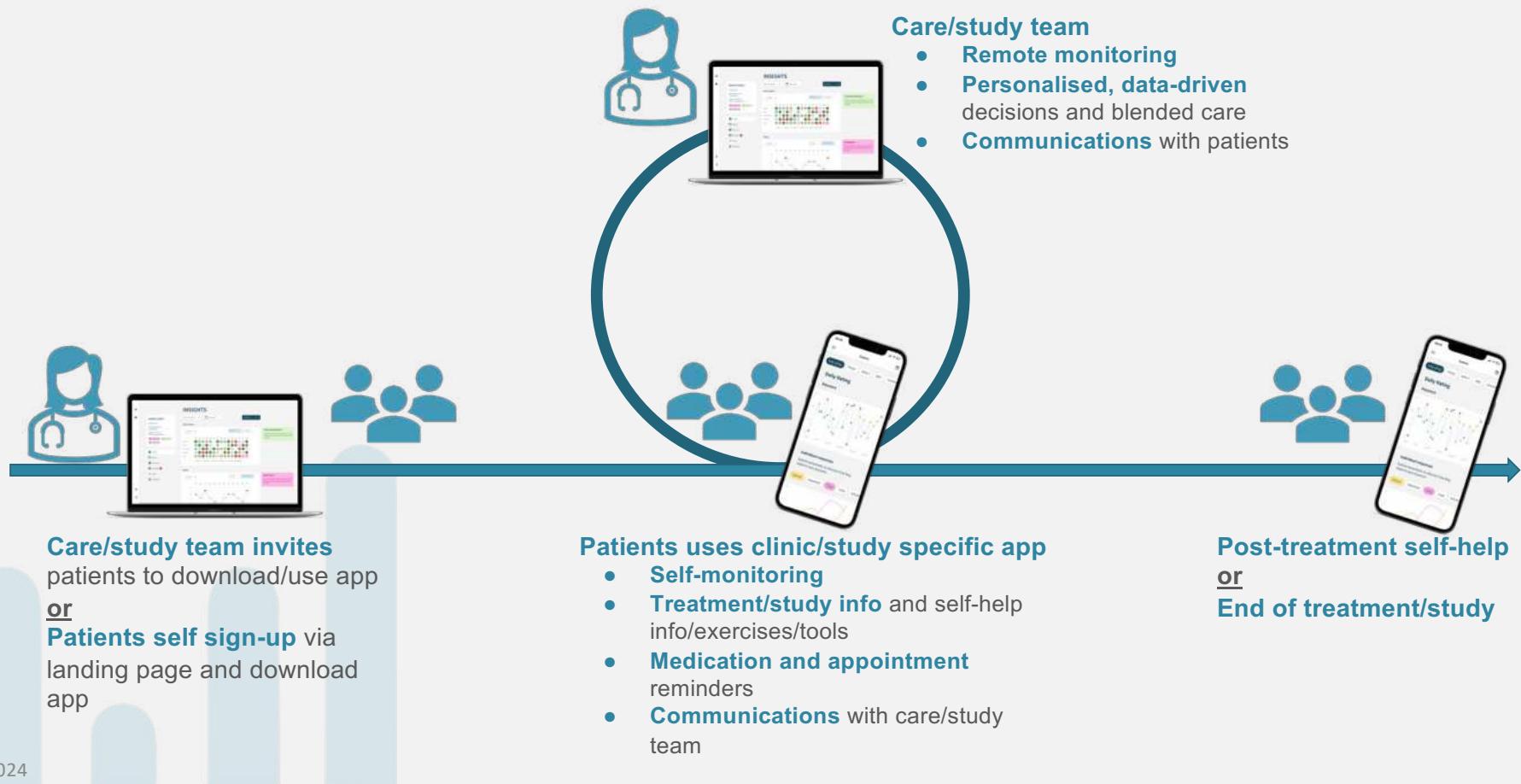
Customisable web portal
- Overview dashboard and specific patient details for clinicians (and researchers)
- Historic symptom and progress visualisation
- Secure messaging
- Content recommendation
- Medication compliance overview
- Rule-enabled tags, stratification and recommendations

Case studies

Research & Clinical implementations in mental health

- Bipolar, depression, schizophrenia, anxiety, borderline personality disorder, addiction, ADHD
- Young people and adults

RWD/Decentralised research projects

- Depression, bipolar, sclerosis, obesity, diabetic foot ulcers, chronic urticaria, migraine

Research project involvement

- 7 H2020/ EUFP7/Eurostars projects
- 6 Innovation Fund Denmark projects
- 10+ customer funded projects
- 70+ peer-reviewed articles published

Pharma 1   Pharma 2   Pharma 3

ECoWeB

Background

- Horizon 2020 call from 2018-2022

- University of Exeter, LMU, Ghent, Monsenso and other partners

Problem

- Promote wellbeing and prevent mental illness among young people by introducing an emotional competence and wellbeing app

Solution

- RCTs with 3800 users in UK, ES, DE, BE:
  a. Monsenso app-only solution configured with CBT content
  b. Monsenso app-only solution configured with personalised emotional competence content
  c. Monsenso app without content

Results

- Prevention of depression and increse of quality-of-life possible in high-risk group. Presented at EACBT in Barcelona 2022

ECo WeB
Emotional Competence ⌃ Well-Being

We developed an evidence-based app to promote emotional wellbeing and prevent mental health problems in youth

We conducted two large randomized controlled trials: PROMOTE and PREVENT

We had over 3,800 participants across the UK, Germany, Spain and Belgium

PROMOTE showed that a low intensity intervention did not reduce depression or improve wellbeing in a well-functioning group

PREVENT showed that the CBT-based app prevent the increase in depression and improve quality of life for a high-risk group

Mental health apps need to be evidence-based and tailored and targeted to higher risk groups of young people

UK Rumination Trial

Background

- 16-24 year old

Problem
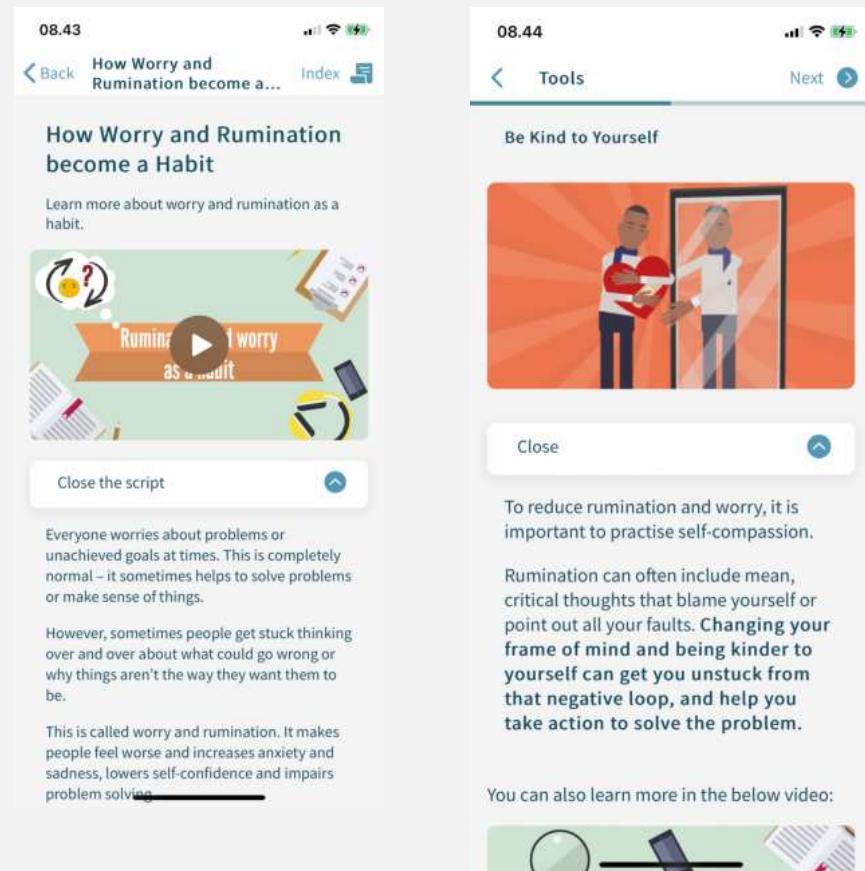
- Wanted to offer a self-help app to limit rumination and worry

Solution

- Monsenso solution configured as pure self-help app with rumnation content from ECoWeB (MyMOodCoach).
- RCT with 236 users
  a. 6 weeks of app usage
  b. Waitlist control without app until 6 weeks later

Results

- Significant positive effect on rumination and worry, well-being, anxiety and depression

> "
>
> Monsenso's platform allows the ECoWeB consortium to provide self-help information, tools, exercises and reminders customised to build emotional competence for young people while also collecting important behaviour and day-to-day data. This approach will potentially be of **great value to universities, insurers and young people themselves to promote well-being and prevent poor mental health**"

Ed Watkins

Professor of Experimental and Applied Clinical Psychology, University of Exeter

"

The aim of the PERSONAE project is to combine cutting-edge individualised mobile intervention technologies including ease of use, high-resolution data collection and adherence enhancing technologies with a matched care service design and artificial intelligence for data driven automation and decision support system. **In short: digital matched and adaptive treatment for depression.**"

Kim Mathiasen,
Associate Professor Kim Mathiasen, Ph.D.,
Centre for Digital Psychiatry, Region South Denmark

"

'We have worked with Monsenso for a number of years on research projects and the implementation of their solution for all patients with bipolar disorder in the Capital Region of Denmark. We see **great potential** in using the solution to both **support research and to optimise treatment** and proactively keep an eye on how patients are doing to **prioritise the right help to the right patients at the right time** to avoid relapse and to improve the quality of life"

Lars V. Kessing'
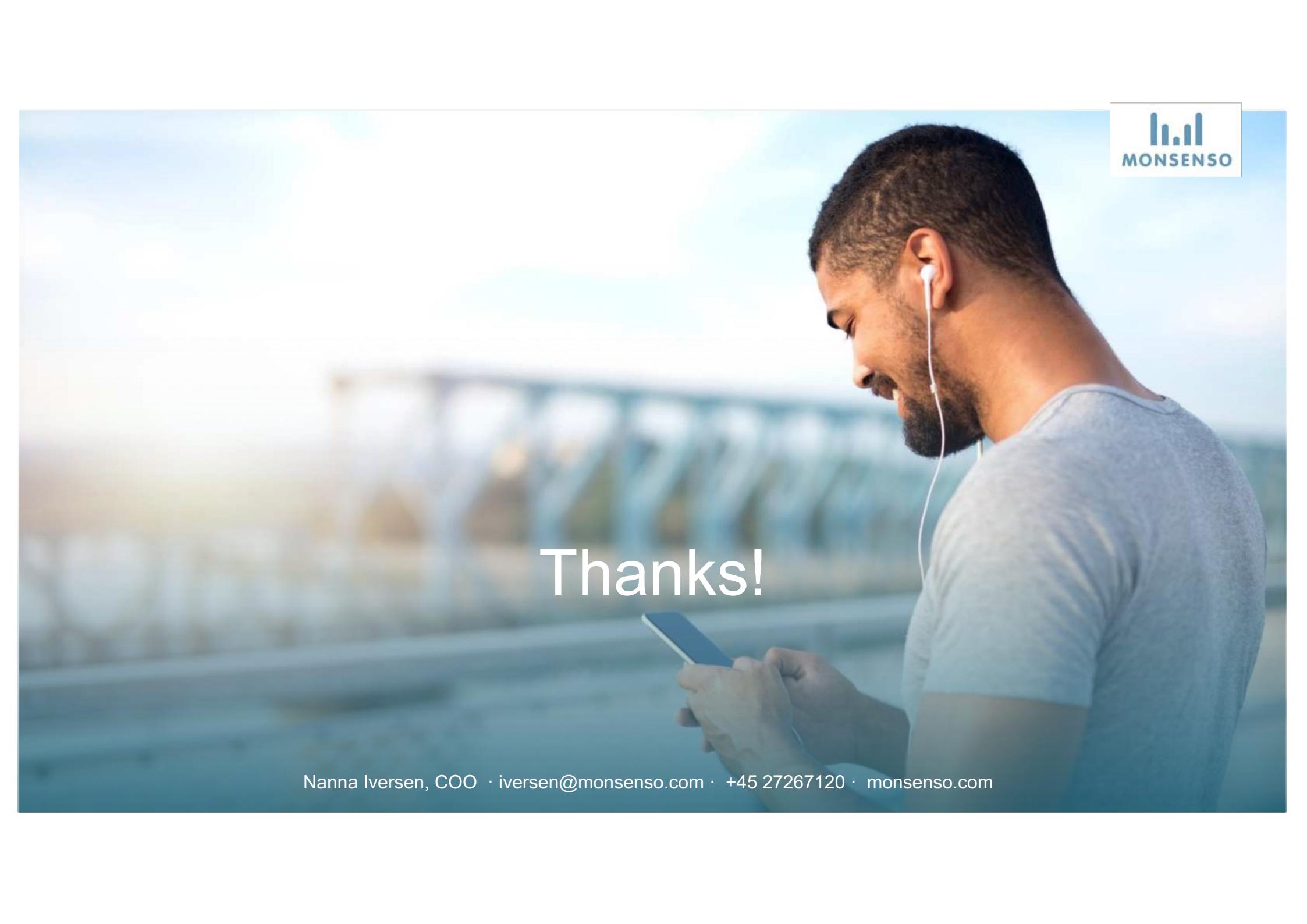
Professor of Psychiatry, Capital Region of Denmark and University of Copenhagen

"

... all project partners are impressed
with the work Monsenso does in the
project. With the people involved, the
progress and the responsibility you
take"

Frederik Mølgaard Thayssen,
Alexandra Instituttet,
Project Manager of the PhaseV project

Thanks!

Nanna Iversen, COO · iversen@monsenso.com · +45 27267120 · monsenso.com