



Tecnologie digitali: traiettorie future per la pratica medica

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FBK

Centro dHWB & TS4.0

Centro Digital Health&WellBeing – Fondazione Bruno Kessler



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DIGITAL HEALTH AND WELLBEING

Le attività del Centro Digital Health&Wellbeing riguardano principalmente la ricerca scientifica di eccellenza nell'ambito delle tecniche e metodologie della Computer Science e della AI per la salute e la sanità, nonché l'innovazione sociale e tecnologica per un impatto importante sia sulla comunità locale, sia a livello nazionale e internazionale.

[DIGITALHEALTHCENTER.FBK.EU/HOME](https://digitalhealthcenter.fbk.eu/home)

VISION

Nell'ambito della missione FBK, che mira a raggiungere risultati di eccellenza scientifica e produrre un impatto sulla società, il focus del Centro è su una sanità del futuro basata sul paradigma della 4P medicine (Predittiva, Preventiva, Personalizzata, Partecipativa) e sui principi di equità e citizens empowerment.

MISSION

Promuovere e supportare la catena di valore che combina ricerca scientifica di alta qualità (sia di base che applicata) e innovazione (tecnologica e di processo) per produrre un impatto significativo sul sistema sanitario e sul mercato. Alcune delle linee di ricerca sono dedicate alle attività del centro di competenza per lo sviluppo della sanità digitale TrentinoSalute4.0, nato dalla collaborazione tra l'Azienda provinciale per i servizi sanitari, la Provincia autonoma di Trento e la FBK.

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<https://www.fbk.eu/it/digital-healthwellbeing/>

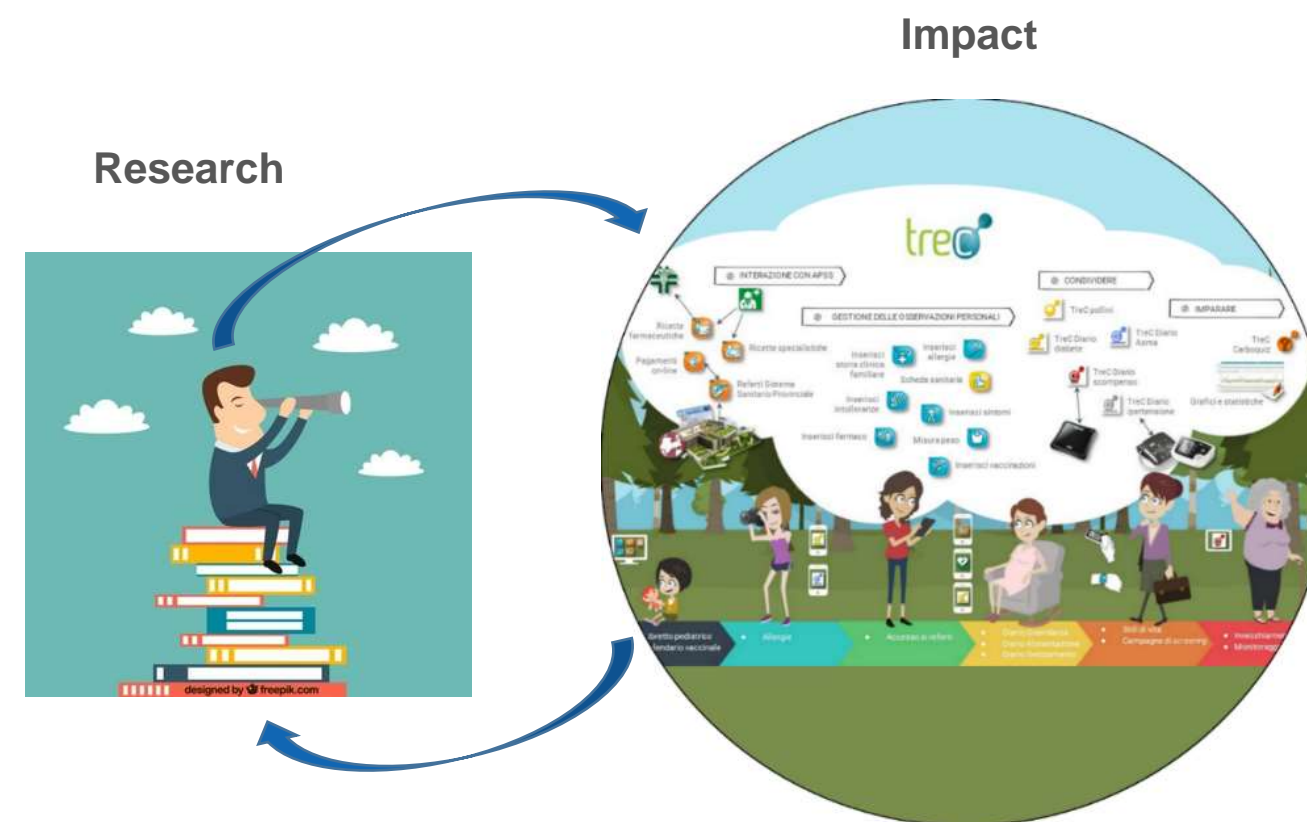
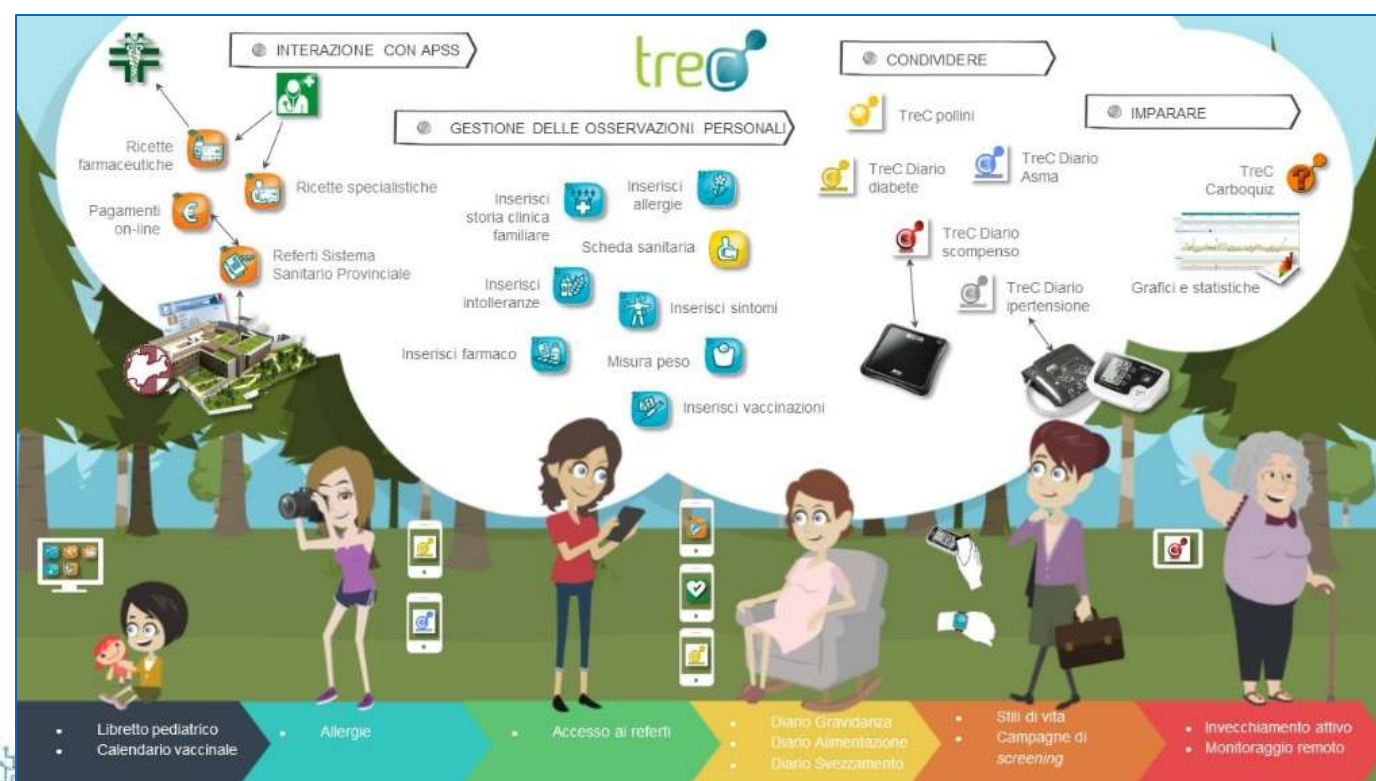
VISION - MISSION

Vision

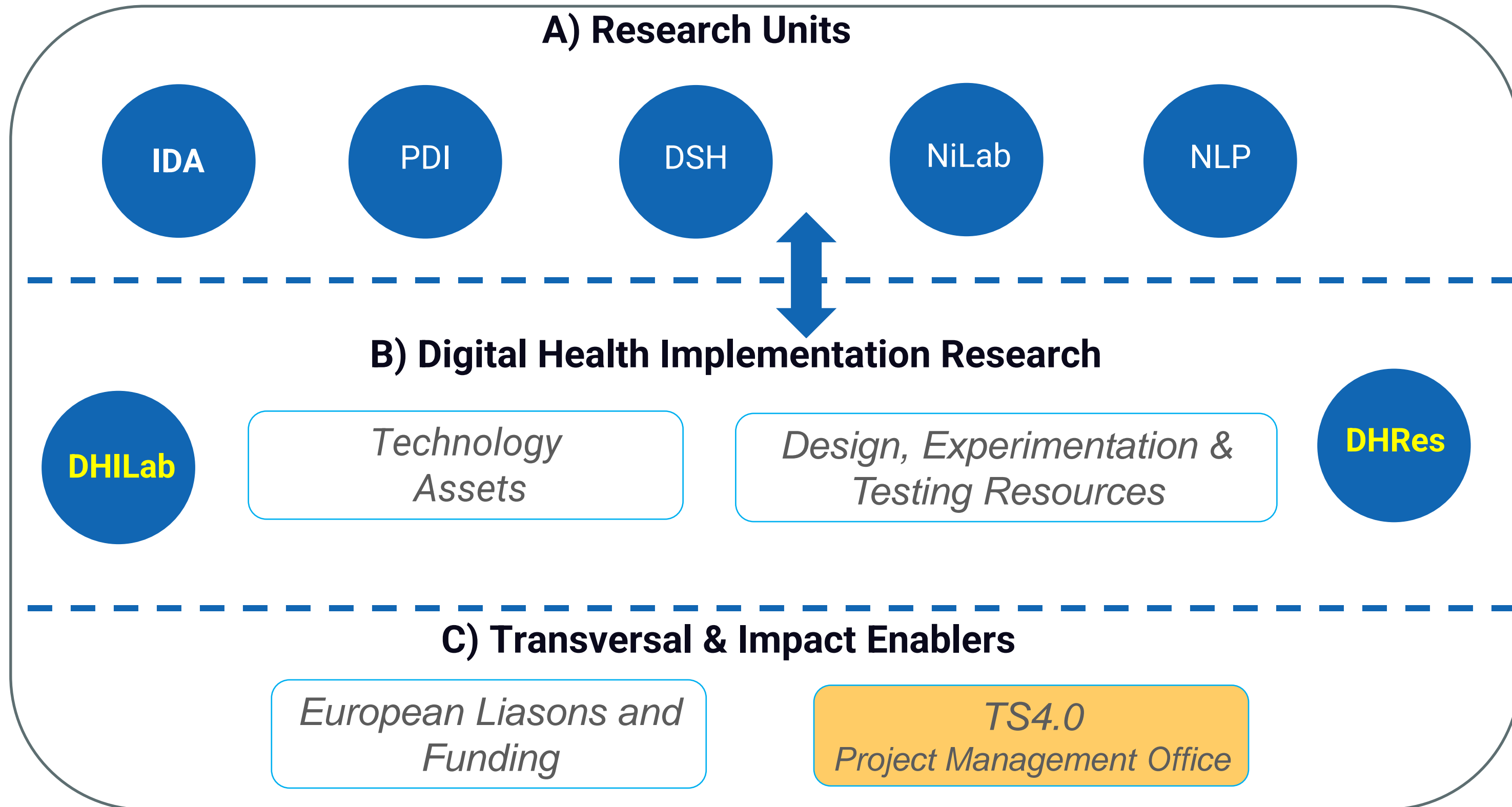
Supportare un **Sistema Sanitario Pubblico “equo e sostenibile”** basato sull’utilizzo pervasivo delle tecnologie sanitarie e della IA da parte sia dei cittadini che degli operatori sanitari.

Mission

Promuovere e supportare la **catena di valore** che combina **ricerca scientifica** di alta qualità (sia di base che applicata) e **innovazione** (tecnologica e di processo) per produrre un impatto significativo sul sistema sanitario e sul mercato.

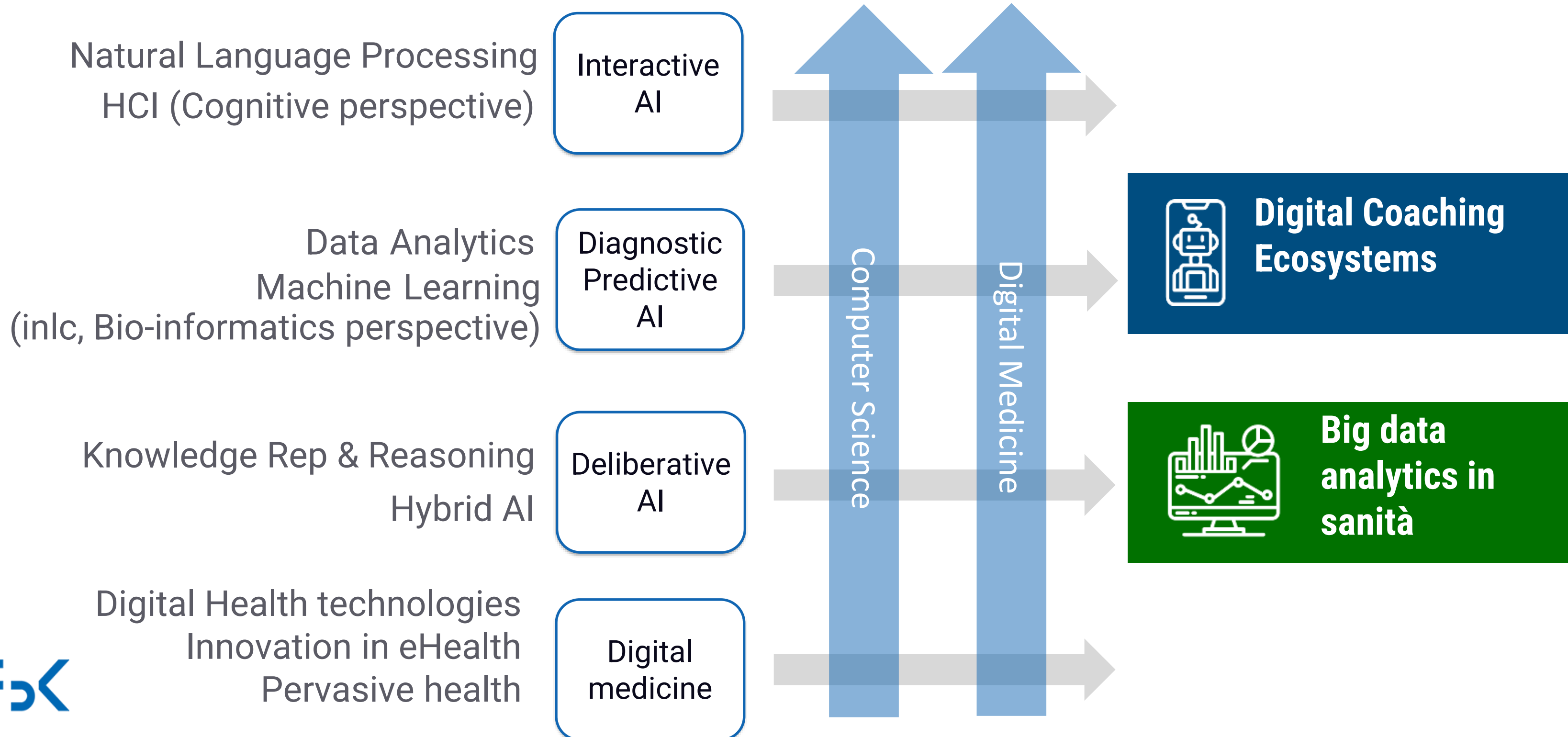


(RI)ORGANIZZAZIONE



COMPETENZE SCIENTIFICHE IA & DATA SCIENCE & DIGITAL MEDICINE

Strategia di Ricerca





Digital Coaching Ecosystems

Terapie Digitali
Prevenzione e gestione dei pazienti cronici
Strategie di intervento persuasive e motivazionali

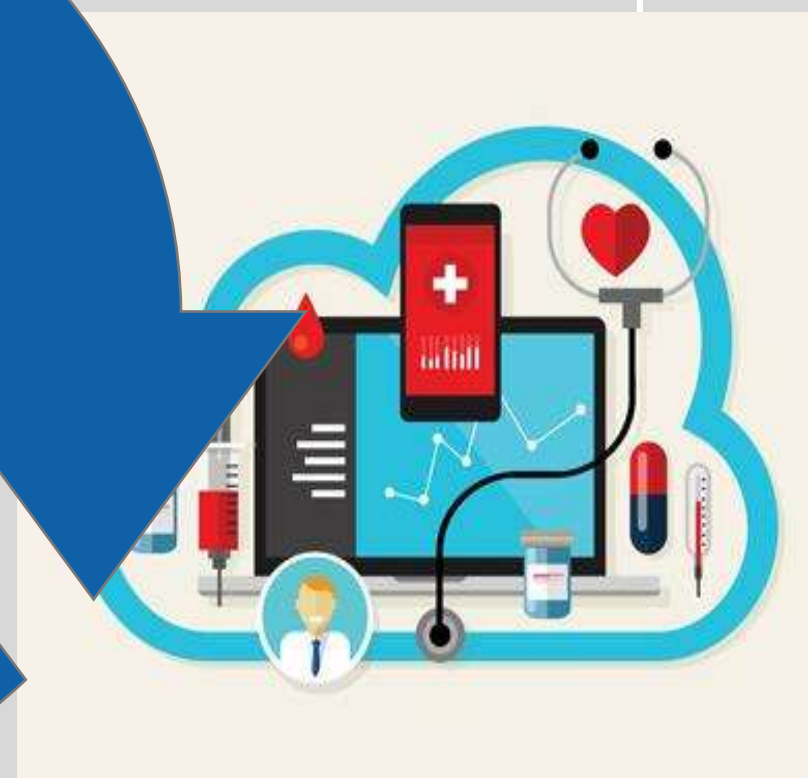
DUE SCENARI SFIDANTI

Impatto

Ricerca



Modelli computazionali del linguaggio per il dominio medico



Supporto alla diagnosi/prognosi clinica



Supporto all'organizzazione



Big data analytics in sanità

Modelli predittivi per classificazione e Prevenzione del rischio
Supporto al clinici e all'organizzazione

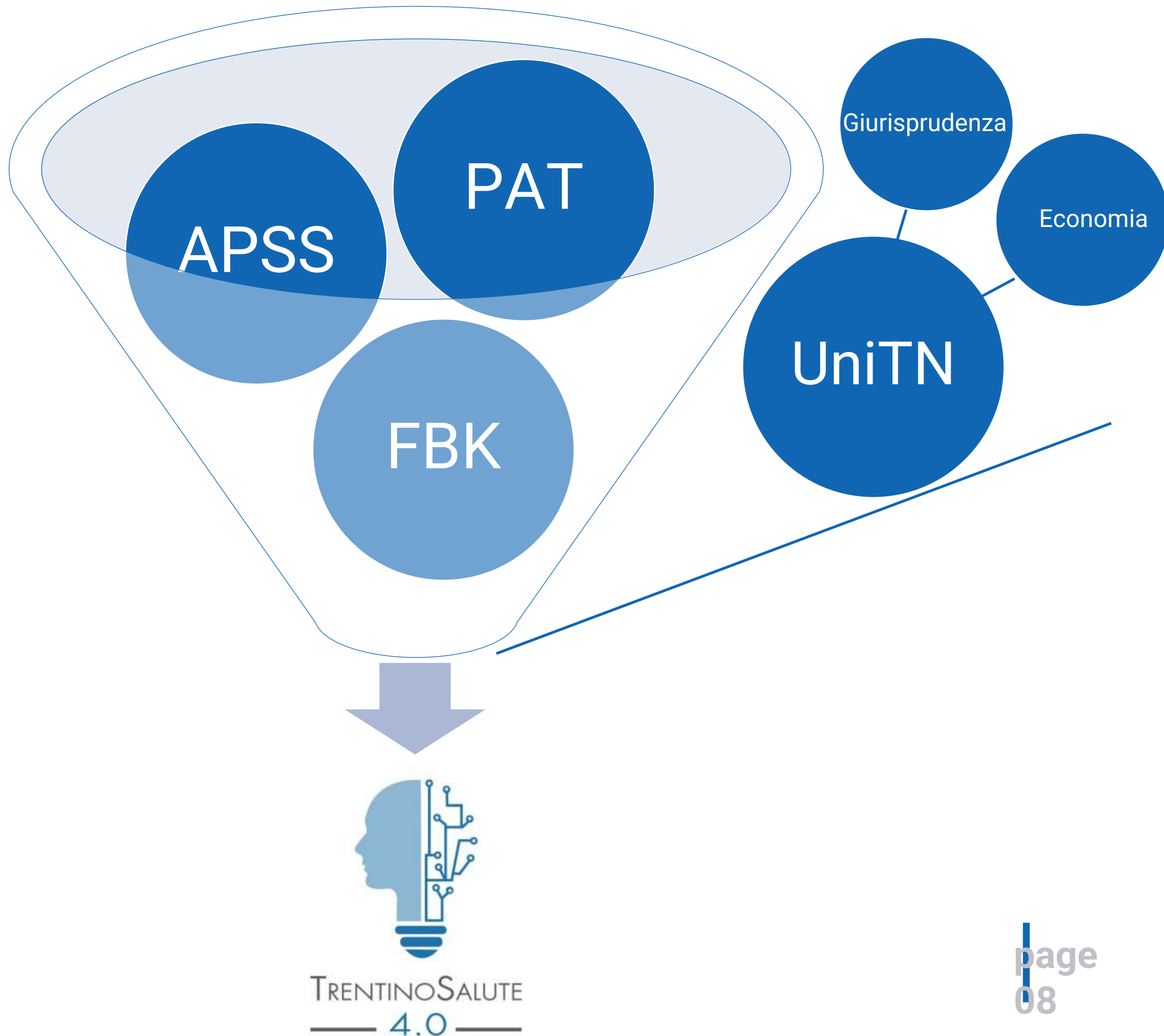
TRENTINOSALUTE4.0

2017

PAT, FBK and APSS hanno lanciato il **Centro di Competenza sulla Sanità Digitale**, "TrentinoSalute4.0» (TS4.0), con l'obiettivo di rafforzare e accelerare il processo di adozione delle tecnologie digitali all'interno del Servizio Sanitario attraverso un **approccio collaborativo di sistema**.

2023-2025

La Giunta provinciale ha rinnovato il finanziamento per TS4.0 per il triennio (2023-2025)



Contenuti

- Introduzione
- Parte I: AI & Data Science for Health
- Parte II: Digital Therapeutics (DTx)
- Parte III: Un progetto di TS4.0
- Parte IV: Piattaforma TreC_Ricerca
- Parte V: Conclusioni & Discussione

Introduzione

Tecnologie Digitali

Tecnologie sanitarie digitali



Technological advances impacting healthcare and the magnitude of disruption.

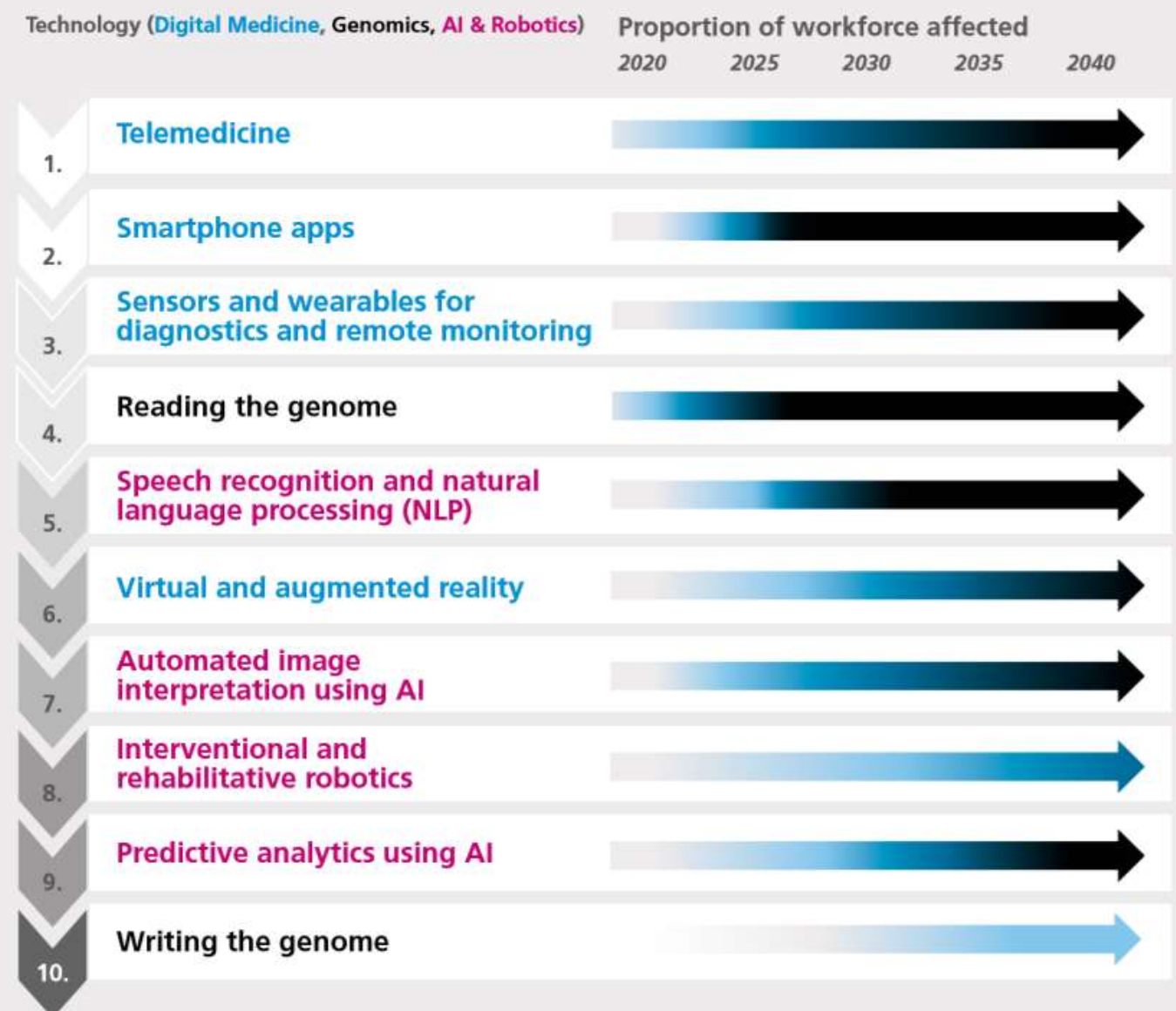
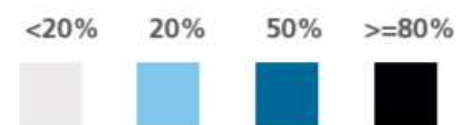
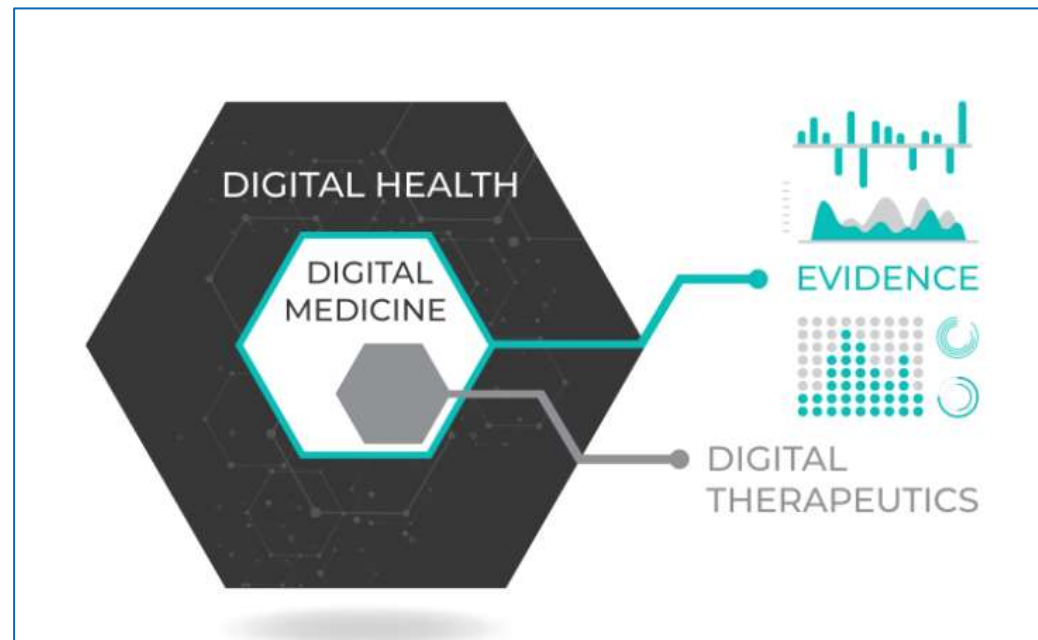


Figure 1: Top 10 digital healthcare technologies and their projected impact on the NHS workforce from 2020 to 2040

Arrow heat map represents the perceived magnitude of impact on current models of care and, by inference, on the proportion of workforce affected



Digital Medicine



REVIEW ARTICLE

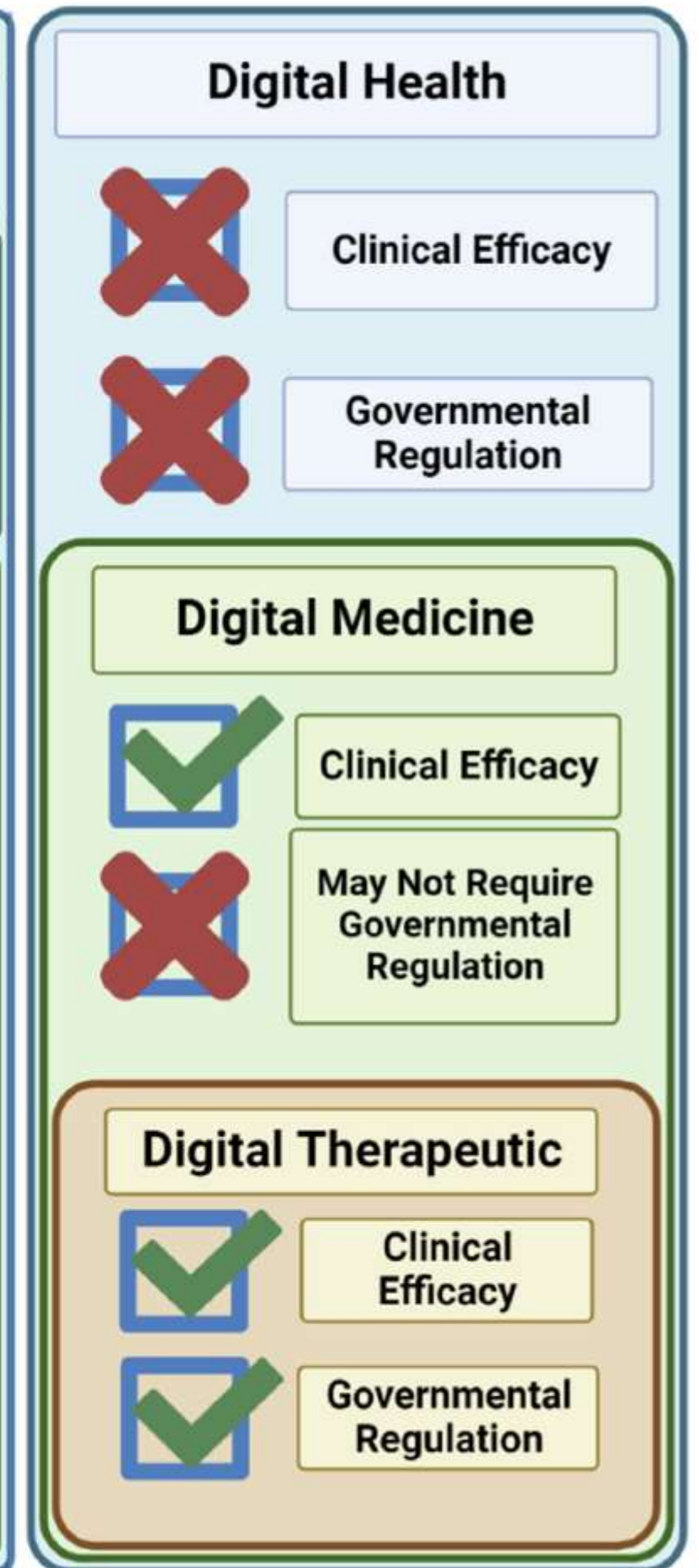
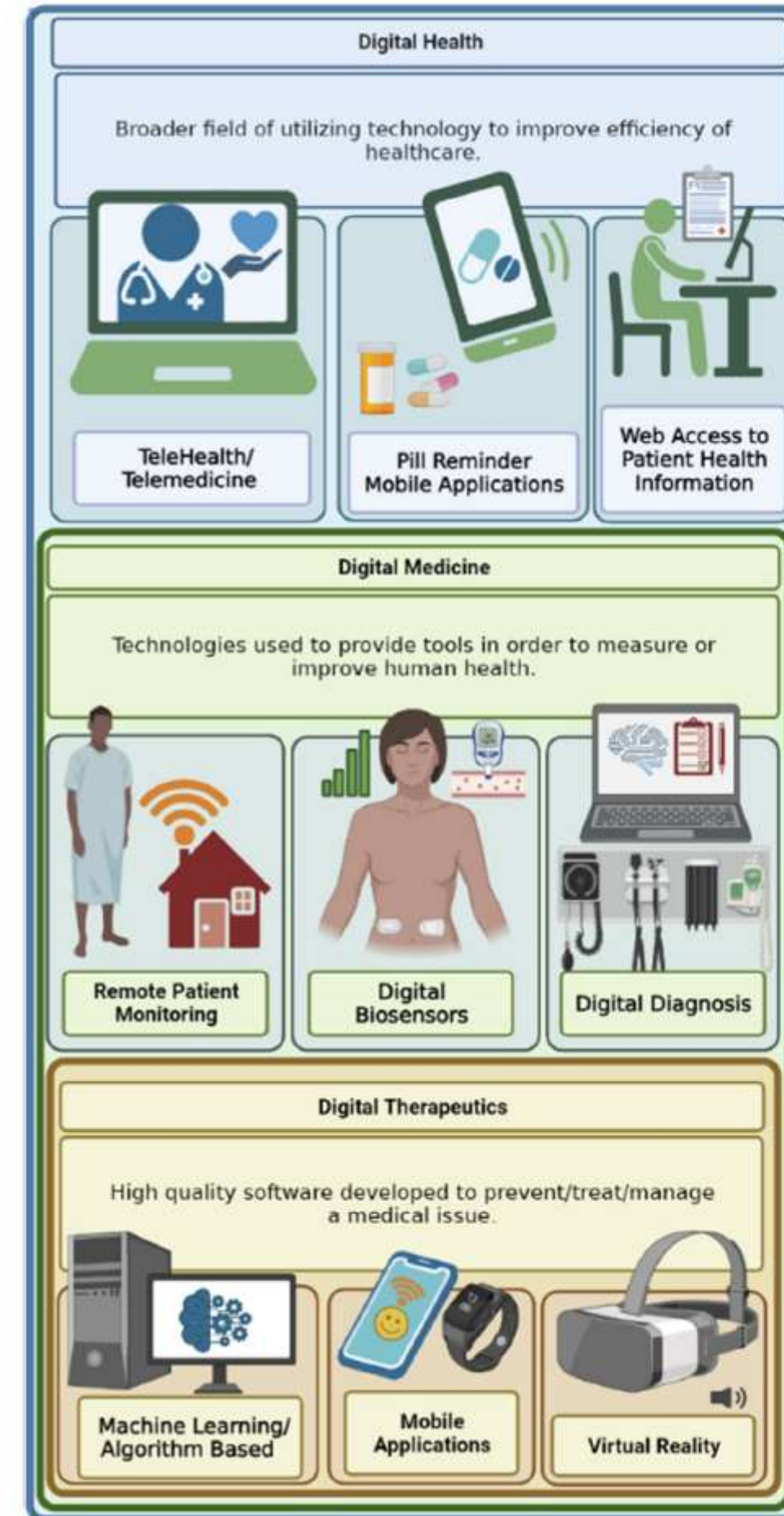
Digital therapeutics in the clinic

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²John A. Paulson School of Engineering and Applied Sciences, Harvard University, Cambridge, Massachusetts, USA
³Wyss Institute for Biologically Inspired Engineering at Harvard University, Boston, Massachusetts, USA

Abstract
 Digital therapeutics are emerging as a new form of therapeutics, digital therapeutics deliver patients using an evidence-based, clinically evaluated software to prevent diseases. Digital therapeutics manifest in diverse applications, mobile applications on smart devices, virtual stand-alone treatments or in combination with conventional adherence and/or efficacy. Here, we review the clinical trials. We summarize FDA-approved products and their ongoing clinical trials, and discuss challenges for their development to overcome the same.

KEYWORDS
 digital therapeutics, digital therapeutics, digital health, digital medicine, digital therapeutics, prescription digital therapeutics

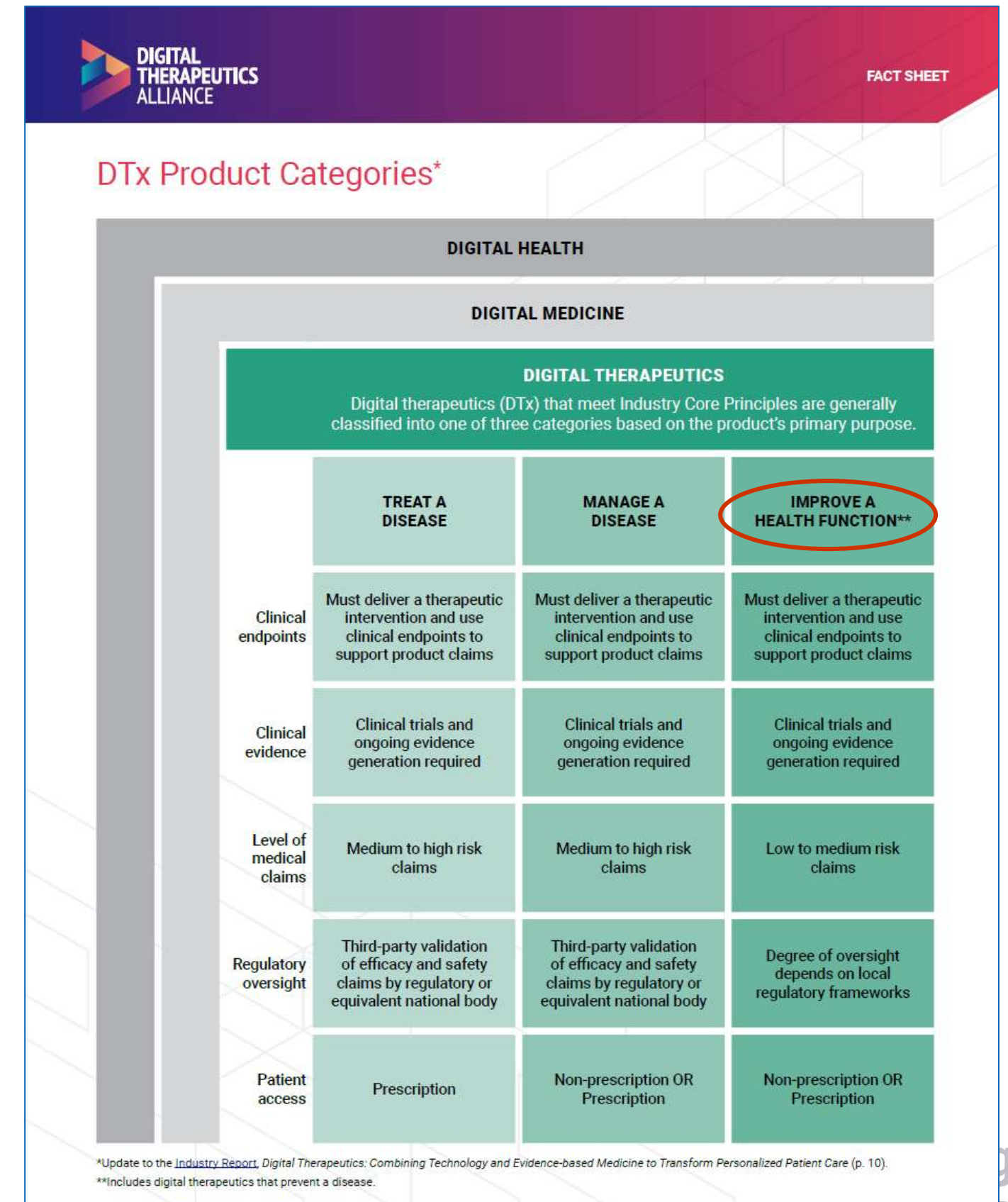


Digital Health - Digital Medicine - DTx

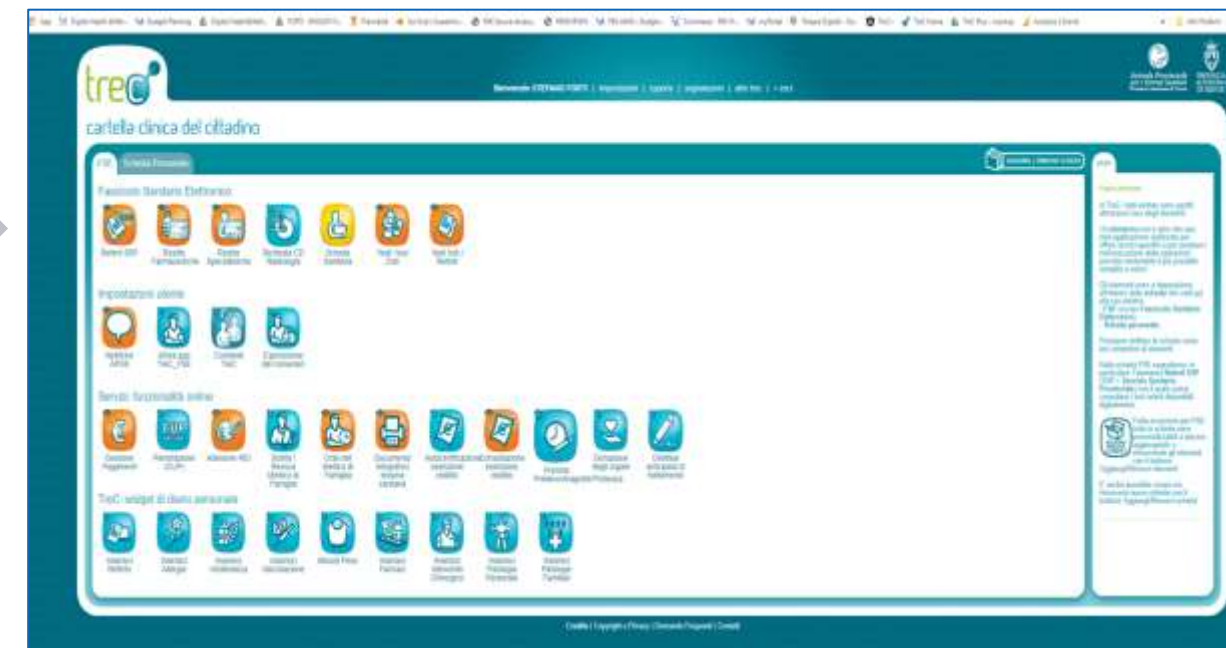
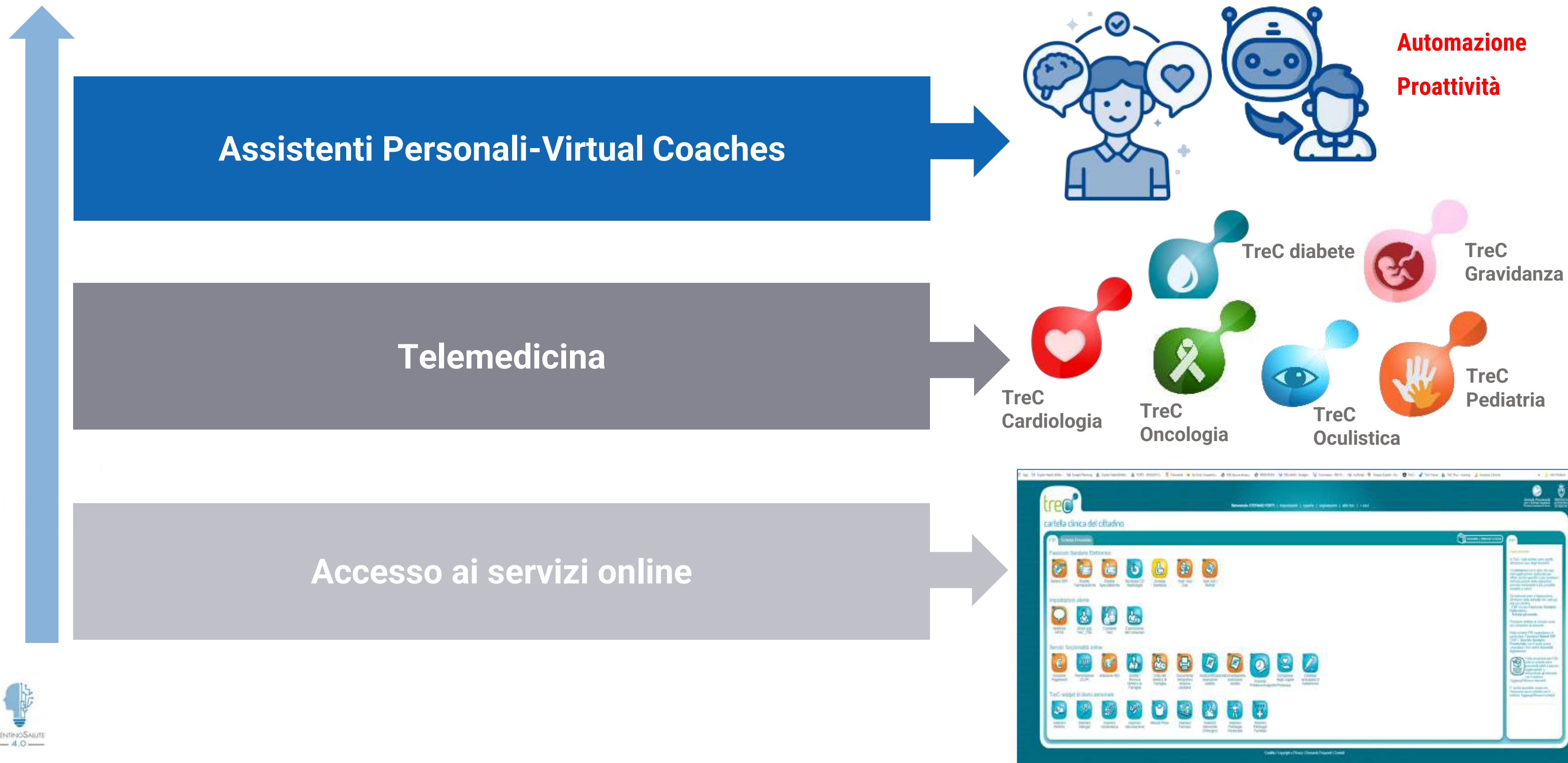


	Digital Health	Digital Medicine	Digital Therapeutics
Product Examples	<p>Data and information capture, storage, and display</p> <ul style="list-style-type: none"> • User-facing technologies <ul style="list-style-type: none"> - Lifestyle apps - Fitness trackers - Nutrition apps - Medication reminder apps - Scheduling apps <p>• Health Information Technology (HIT)⁴</p> <ul style="list-style-type: none"> - Electronic medical record systems - Electronic prescribing⁵ and order entry systems <p>• Consumer health information</p> <ul style="list-style-type: none"> - Online repositories - Personal health records - Patient portals <p>Data and information transmission</p> <ul style="list-style-type: none"> • Telehealth - Telemedicine virtual visits - Remote care programs that do not include remote monitoring <p>• Decision support software that:⁶</p> <ul style="list-style-type: none"> - Presents information for independent clinician review - Does not make recommendations that the user could not find through channels other than the software • Enterprise support - Clinical trial operations and management tools - Trial management software - Trial recruitment platforms <p>• Clinical care administration and management tools</p> <ul style="list-style-type: none"> - Revenue cycle management tools - Clinical staffing management tools - Length of stay monitoring and management tools 	<p>Measurement products</p> <ul style="list-style-type: none"> • Digital diagnostics - Software-driven connected technologies that detect or confirm the presence of a disease or condition of interest or to identify individuals with a subtype of the disease • Digital biomarkers - Digital tools that measure patient characteristics that are objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention - Includes all BEST biomarkers <p>• Electronic clinical outcome assessments</p> <ul style="list-style-type: none"> - Digital measures of how patients feel, function, or survive • Remote patient monitoring - Remote monitoring tools - Medication adherence tools - Sensor technologies that measure vitals and physiologic data <p>• Decision support software that:⁷</p> <ul style="list-style-type: none"> - Relies on data inputs from medical imaging or in vitro diagnostic devices - Process or analyze this information without clinician input <p>Measurement and intervention products</p> <ul style="list-style-type: none"> • Digital companion⁸ - Digital component integrated with either a drug or biologic - Ingestible sensors - Connected drug delivery device - Insulin pump <p>• Digital products that both 1) measure and intervene, and 2) do not require human intervention to serve primary purpose</p> <ul style="list-style-type: none"> - Artificial pancreas - Pacemaker - Cochlear implant - CPAP 	<p>Software that delivers a therapeutic intervention</p> <p>Medical claims include:</p> <ul style="list-style-type: none"> • Treat a disease <p>Digital therapeutics that deliver a medical intervention to treat a disease.</p> <ul style="list-style-type: none"> • Manage a disease <p>Digital therapeutics that deliver a medical intervention to manage a disease.</p> <ul style="list-style-type: none"> • Improve a health function <p>Digital therapeutics that deliver a medical intervention to improve a health function and/or prevent a disease.</p> <p>Core principles all digital therapeutics must adhere to:⁹</p> <ul style="list-style-type: none"> • Prevent, manage, or treat a disease • Deliver a software-driven medical intervention • Employ design, manufacture, and quality best practices • Ensure end user engagement • Implement privacy and security protections • Apply product deployment and maintenance best practices • Conduct clinical trials and publish results • Undergo applicable regulatory reviews • Make appropriate claims • Utilize real world outcomes

Table 2: Examples of products of Digital Health, Medicine and Therapeutics [3].



Un ecosistema di assistenti personali/virtual coaches



Strumenti di Telemedicina

FAMIGLIA



App diario

Cruscotto

Lista appuntamenti

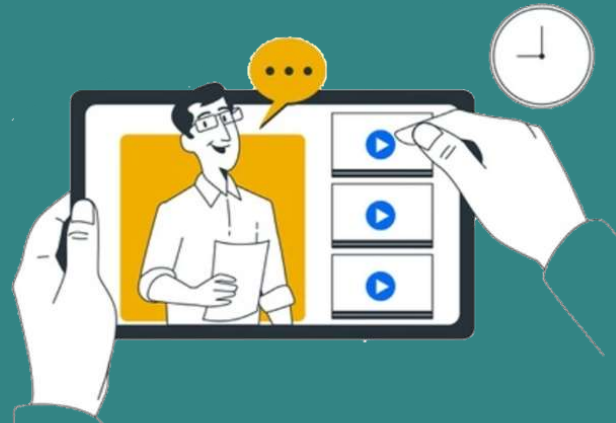


Integrazione con i servizi sanitari

**OPERATORI
SANITARI**



Materiale informativo/educativo multimediale



Videocall



Chat



INTERVENTI STRUTTURATI di un ASSISTENTE VIRTUALE

FAMIGLIA



Q
CHIEDE



Personalizzazione e adattività degli interventi

A
RISPONDE



Raccoglie informazioni

Dati (es. peso)

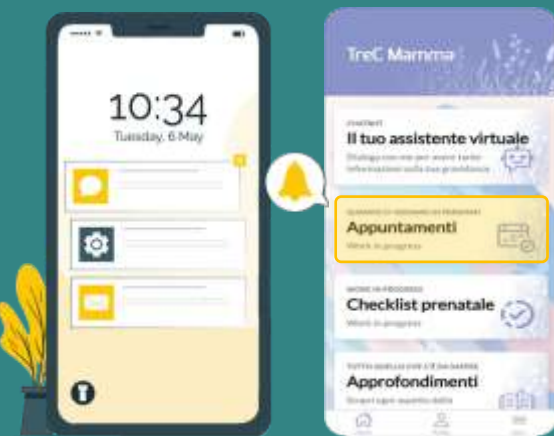
Questionari

Ricorda

Incoraggia

Segnala agli op. san.

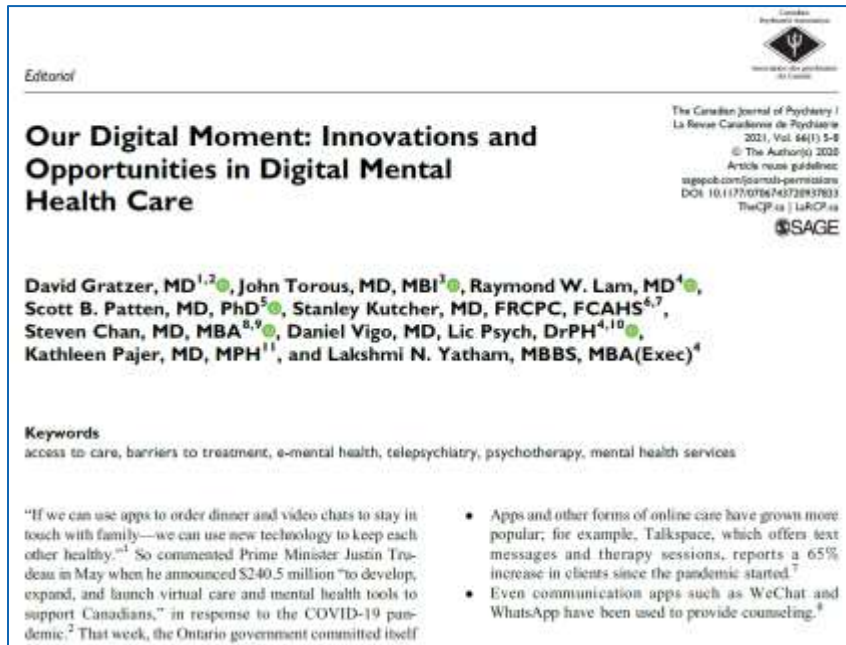
Motiva



Lista appuntamenti



DTx a supporto di un modello *Stepped Care*

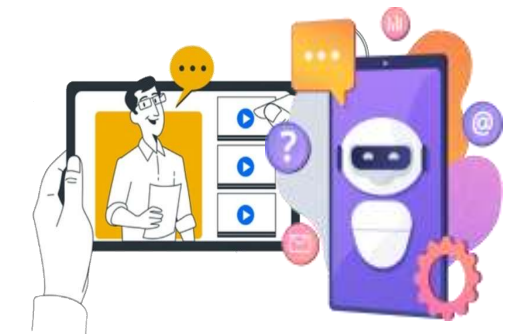
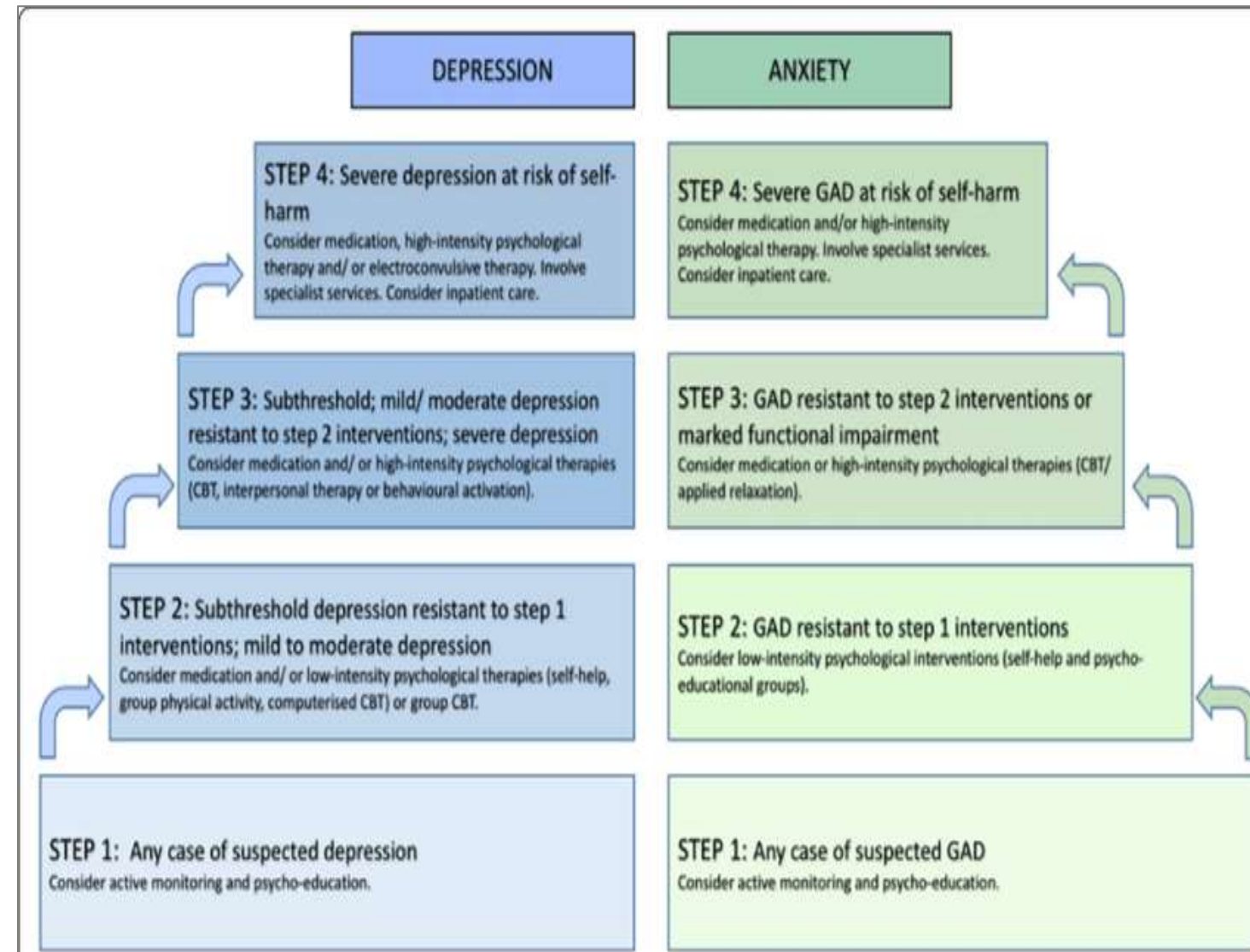


Digital options can be easily incorporated into a **stepped model of care**, particularly for those **with mild to moderate depression or anxiety disorders...**

... who may start with **self-help modules or chatbots**;

... those who do not improve may move to the **next "step" to seek therapist guided digital therapy**;

... Non-responders would receive **face-to-face therapy**.

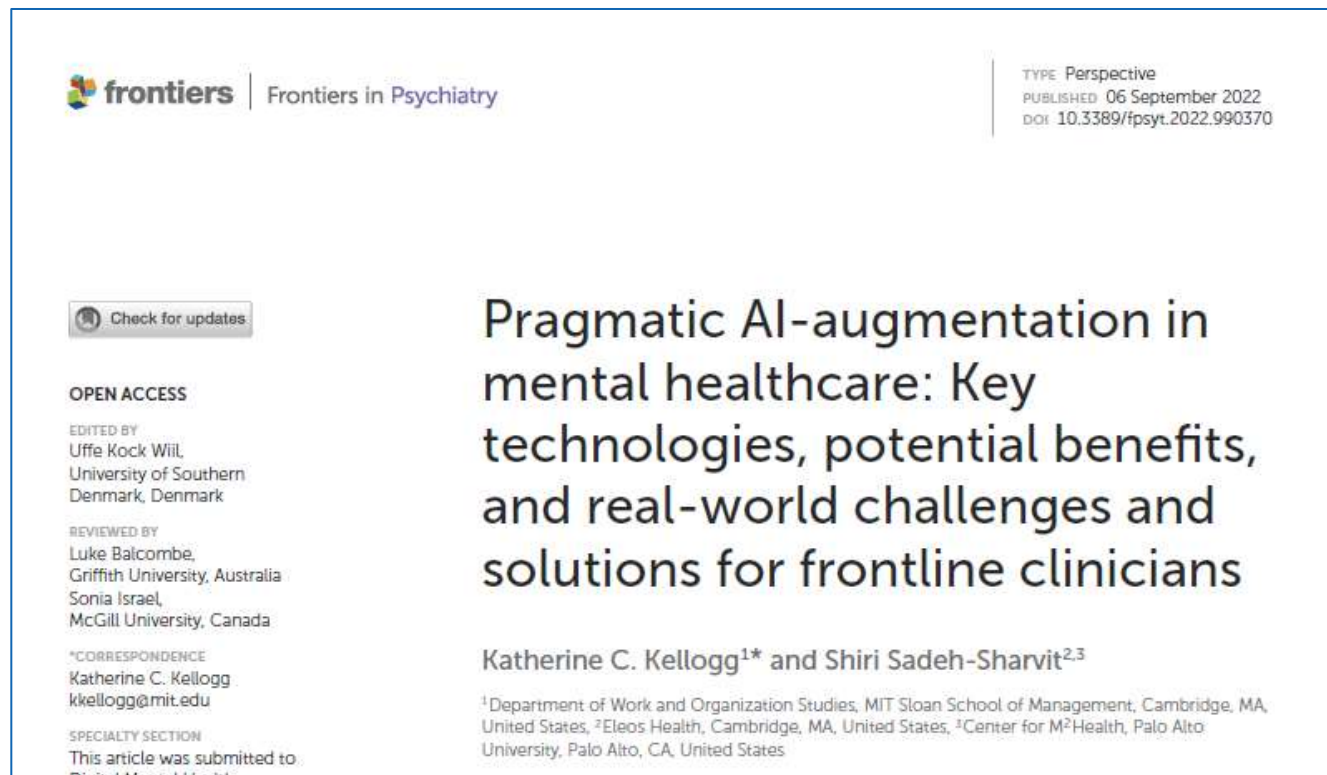


Tecnologie digitali e Sostenibilità del SSN

- **La Telemedicina** è molto utile ed efficace per casi specifici di cura e assistenza ma prevede un impegno importante di risorse umane e cambiamenti organizzativi e **non è scalabile** per attività di promozione della salute e prevenzione.
- **le Terapie digitali** possono essere utili come **complemento alla telemedicina**, erogando interventi che possono **supportare/replicare** alcune attività umane **soprattutto nell'ambito della promozione della salute e della prevenzione** (es. monitoraggio, educazione, interventi comportamentali e cognitivo-comportamentali, ecc), avendo i seguenti vantaggi:
 - ✓ Scalabilità
 - ✓ Sostenibilità
 - ✓ Omogeneità della qualità degli interventi (evidence-based)
 - ✓ Equità (Disponibilità, Accessibilità, Fruibilità, Gratuità, ecc)
 - ✓ Altro (es, stigma, ecc)
 - ✓

Un modello di riferimento

Pragmatic AI augmentation



AI-Augmentation incorporates a pragmatic approach, led by the frontline clinician, wherein AI technology **informs and augments, rather than replaces**, clinician experience and cognition.

We argue that, in order to realize the promise of AI technologies in MHC, it is necessary to answer **three questions**:

- (1) What are some **specific AI technologies** that frontline MH clinicians can leverage to inform and augment their human intelligence in clinical practice?
- (2) What **challenges** are likely to arise for MH clinicians as they attempt to use these AI technologies in their daily work?
- (3) What **solutions** can clinical leaders and technology developers use to help address MH clinicians' AI implementation challenges?

Pragmatic AI augmentation

frontiers | Frontiers in Psychiatry

TYPE Perspective
PUBLISHED 06 September 2022
DOI 10.3389/fpsy.2022.990370

Check for updates

Pragmatic AI-augmentation in mental healthcare: Key technologies, potential benefits, and real-world challenges and solutions for frontline clinicians

OPEN ACCESS
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Digital Mental Health

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TABLE 1 Key AI technologies, example applications in mental healthcare, and potential benefits.

	Automation technologies DTx	Patient engagement technologies	Clinical decision support technologies DataScience
Key AI technologies	<ul style="list-style-type: none"> • Computer vision • Machine learning • Natural language processing 	<ul style="list-style-type: none"> • Conversational Agents • Chatbots 	<ul style="list-style-type: none"> • Machine learning • Neural networks • Deep learning
Example applications in MH	<ul style="list-style-type: none"> • Screening for autism, eating disorders • Administering digital surveys • Generating insights from a patient's talking patterns, tone, word choice 	<ul style="list-style-type: none"> • Coaching for smoking cessation, exercise, nutrition • Scripted CBT, MI, dialectical behavioral therapy 	<ul style="list-style-type: none"> • Depression and anxiety prediction • Stroke prediction • Suicide ideation prediction
Potential benefits	<ul style="list-style-type: none"> • Increase early screening • Increase patient access • Improve clinician quality of work life 	<ul style="list-style-type: none"> • Increase patient access • Increase patient engagement • Extend services provided by organizations adopting a hybrid therapy model 	<ul style="list-style-type: none"> • Help clinicians identify mental illnesses at an earlier stage when interventions may be more effective • Help clinicians customize treatments based on a patient's characteristics
AI-augmentation in MH practice	<ul style="list-style-type: none"> • Automation technologies could assist alleviate some of the severe staffing shortages in mental healthcare by extending rather than replacing the knowledge and expertise of human clinicians 	<ul style="list-style-type: none"> • AI engagement tools could complement the therapist's interventions in a blended therapy model. To support skill practice between sessions, for example, the therapist could assign a specific GSH component, extending therapy beyond the meeting 	<ul style="list-style-type: none"> • To increase clinicians' readiness to consider using AI tools to help decision-making, there has to be more openness about how algorithms are developed, the data utilized for their creation, and the engagement of mental health practitioners and service users in their evaluation and improvement



Parte I

Ai & Data Science

(Giuseppe Jurman)



Parte II

Digital Therapeutics-DTx

TERAPIE DIGITALI (DTx)



DIGITAL THERAPEUTICS ALLIANCE FACT SHEET

Digital Therapeutics Definition and Core Principles

Digital therapeutics definition:

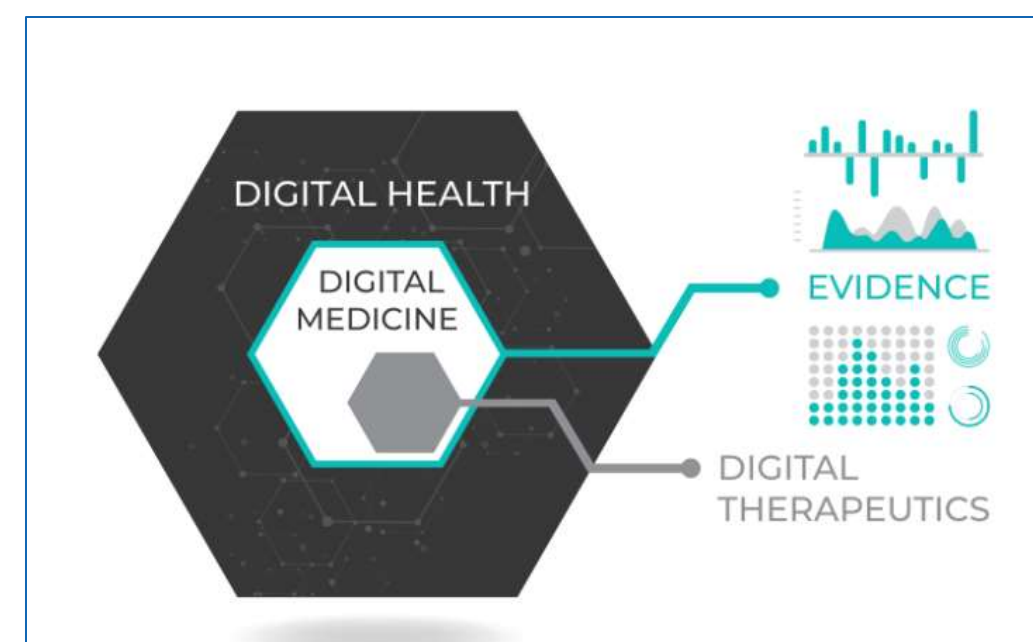
Digital therapeutics (DTx) deliver evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.

DTx products incorporate advanced technology best practices relating to design, clinical evaluation, usability, and data security. They are reviewed and cleared or certified by regulatory bodies as required to support product claims regarding risk, efficacy, and intended use.

Digital therapeutics empower patients, clinicians, and payers with intelligent and accessible tools for addressing a wide range of conditions through high quality, safe, and effective data-driven interventions.

https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf

Le Terapie Digitali (DTx) *“offrono interventi terapeutici che sono guidati da **programmi software di alta qualità**, basati su evidenza scientifica ottenuta attraverso sperimentazione clinica metodologicamente rigorosa e confermatrice, per prevenire, gestire o trattare un ampio spettro di condizioni fisiche, mentali e comportamentali”*.



CARATTERISTICHE DELLE DTx

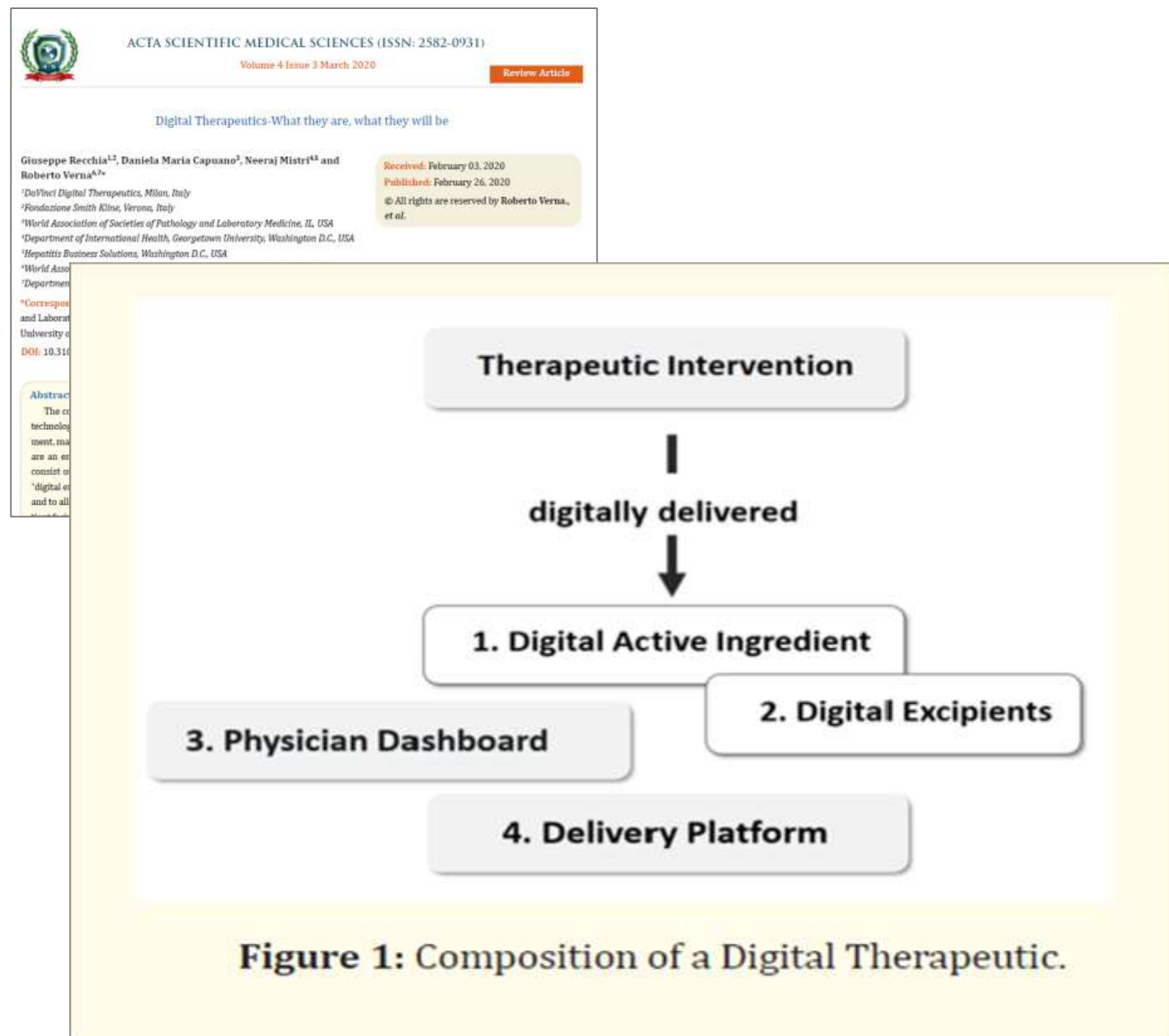
Le terapie digitali sono **interventi terapeutici non-farmacologici** somministrati per **modificare il comportamento dei pazienti** e quindi migliorare il loro stato di salute

Caratteristiche essenziali:

- Sono sviluppate e validate attraverso **studi clinici controllati**,
- Per poter essere utilizzate nella pratica clinica devono essere **certificate** e autorizzate da enti regolatori
- Possono essere **rimborsate** dal Sistema sanitario pubblico e/o private (es England and Germany)
- Possono essere **prescritte** dal dottore



DTx: Il paradigma della terapia farmacologica



Active ingredients

Il principio attivo digitale è l'elemento della terapia responsabile dell'effetto clinico (sia favorevole che indesiderato, come nel caso delle reazioni avverse). Le terapie digitali possono utilizzare, come principio attivo, un intervento terapeutico già disponibile nella letteratura scientifica (nel quale caso rappresentano una modalità alternativa di erogazione di un trattamento noto, come ad esempio la **Terapia Cognitiva Comportamentale – CBT**) oppure creato ex novo, utilizzando elementi di diverse opzioni terapeutiche o impiegando tecnologie o bio-tecnologie.

Digital Excipients

Gli eccipienti digitali svolgono la stessa funzione di quelli chimici che servono a dare forma al principio attivo e favorirne la assunzione, rendendolo il più biodisponibile possibile. Nelle DTx l'eccipiente digitale può comprendere **l'assistente virtuale in grado di interagire pro-attivamente con il paziente**, moduli per il rewarding del paziente, reminders per l'assunzione della terapia digitale e delle terapie complementari, moduli per collegare il paziente con il proprio medico.

Terapia Cognitivo Comportamentale



Che cos'è la TCC?

Le Cognizioni si riferiscono ai nostri pensieri e i Comportamenti alle nostre azioni.

La Terapia Cognitivo-Comportamentale (TCC) è una forma di psicoterapia evidence-based (è derivata dalla ricerca scientifica) e strutturata ("passo dopo passo") che si propone di modificare il ciclo di pensieri (cognizioni) negativi, che producono emozioni disfunzionali e conseguenti azioni inadeguate.

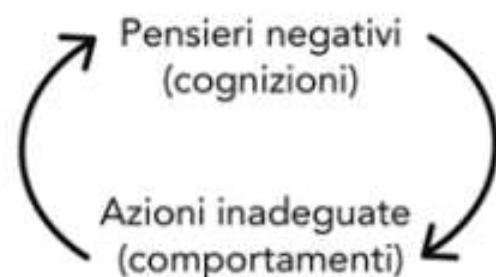


Figura 1: Il ciclo di cognizioni (pensieri) negative che hanno come risultato azioni inadeguate.

La ricerca ha mostrato che la TCC è molto efficace nell'interrompere questo circolo in persone che hanno problemi come depressione, scarsa fiducia, mancanza di assertività, difficoltà nel risolvere i problemi quotidiani e mancanza di sostegno da parte degli altri.

Questo ciclo viene interrotto in tre modi:

- Cambiando il modo di pensare – i pensieri, le convinzioni, le idee, gli atteggiamenti, le credenze, le rappresentazioni mentali e i modi di orientare l'attenzione – in meglio. Questo è l'**aspetto cognitivo** della TCC.
- Aiutando la madre a fare un collegamento fra i pensieri e le emozioni negative che - quando sono così intense - possono portare a comportamenti disfunzionali.
- Per riuscirci, si aiuta la madre ad affrontare le sfide e le opportunità di crescere il proprio bambino con mente consapevole e con serenità e- quindi- intraprendere azioni che probabilmente saranno efficaci. Questo è l'**aspetto comportamentale** della TCC

Telemedicina

CASA DEL PAZIENTE

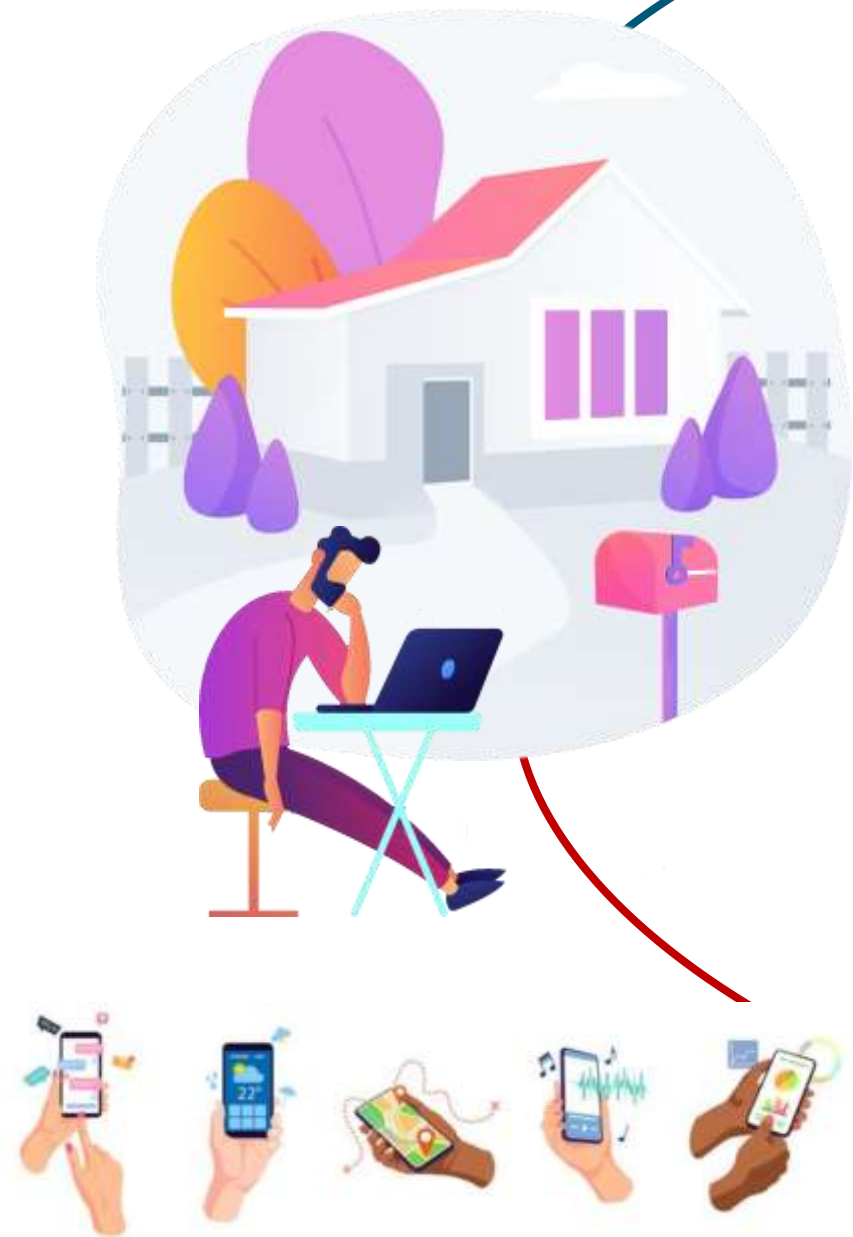
PSICOTERAPEUTA



Materiale informativo/educativo multimediale

Videocall

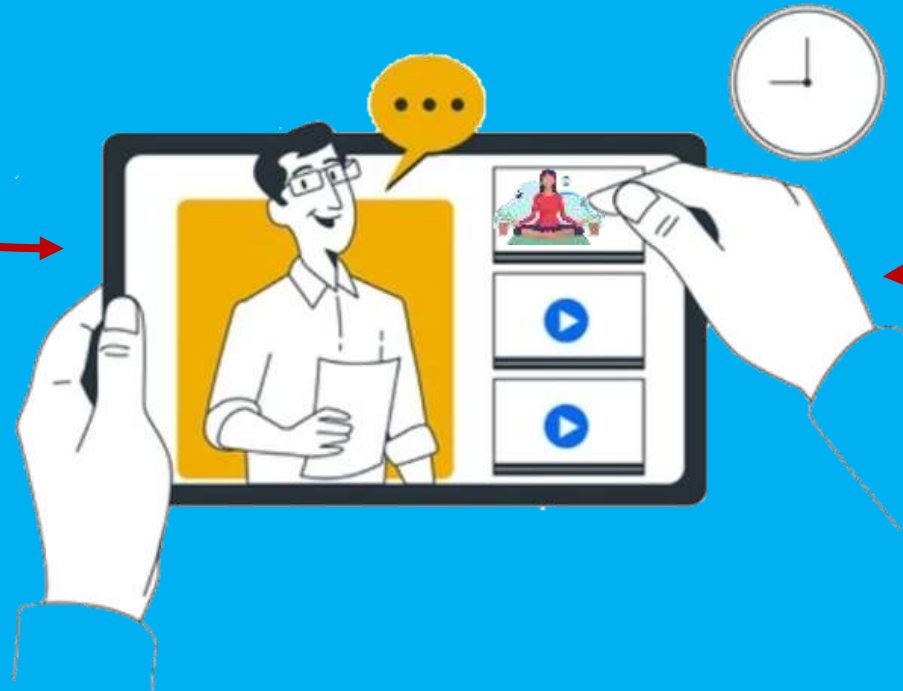
Chat



Human Guided self-help

Intervento di
Terapia Cognitivo Comportamentale
attraverso materiale online
con il support di un assistente umano

CASA DEL PAZIENTE



PERSONALE FORMATO/ ADDESTRATO,
NON SPECIALISTICO



*Incoraggia
Suggerisce
Ricorda
Motiva
Raccoglie informazioni*

UNguided self-help

*Intervento di
Terapia Cognitivo Comportamentale attraverso
materiale online
senza il supporto umano*

CASA DEL PAZIENTE



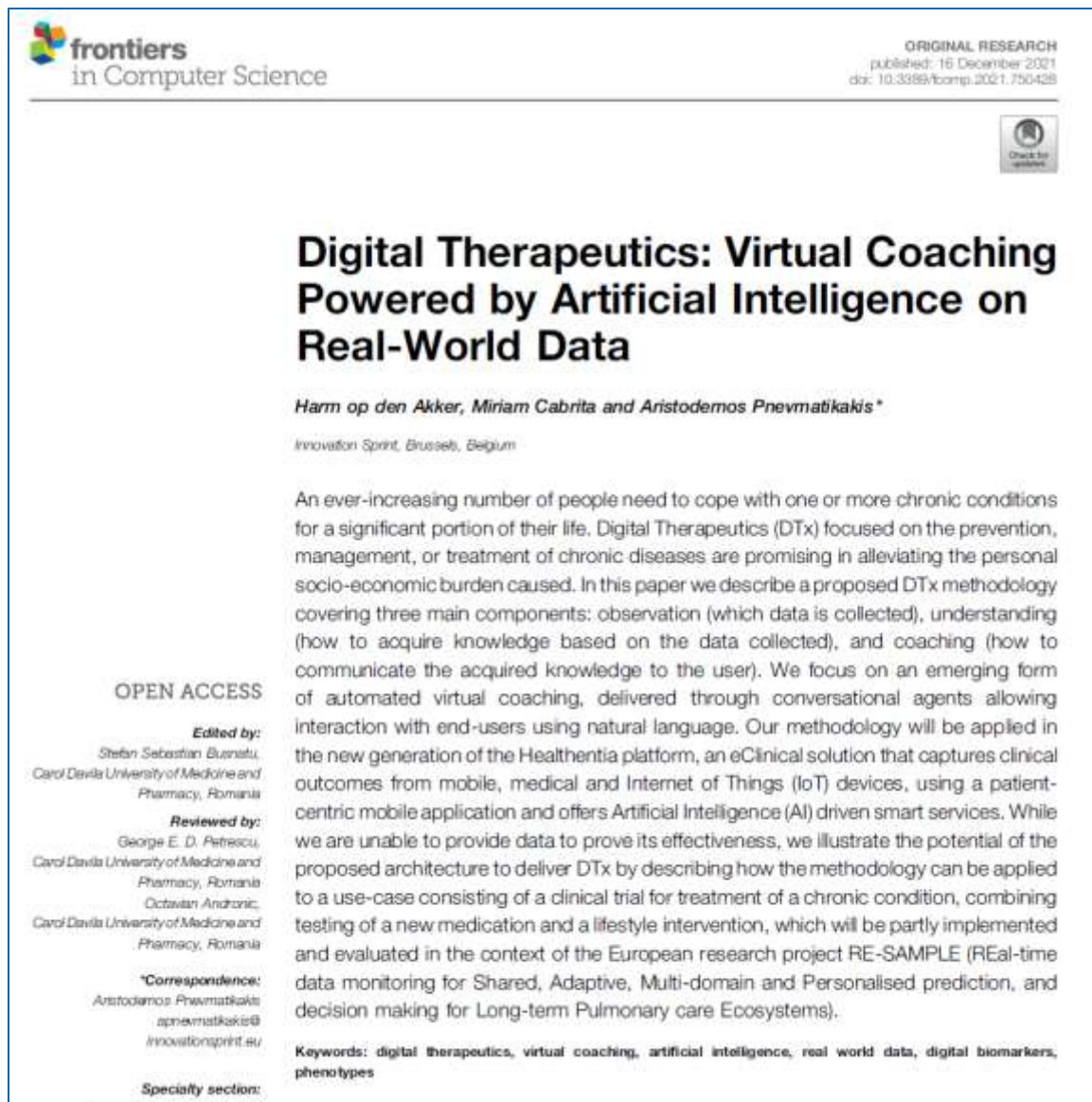
*Lezione di
rilassamento*



**PERSONALE FORMATO/ ADDESTRATO,
NON SPECIALISTICO**



DTx EROGATE DA VIRTUAL COACHES



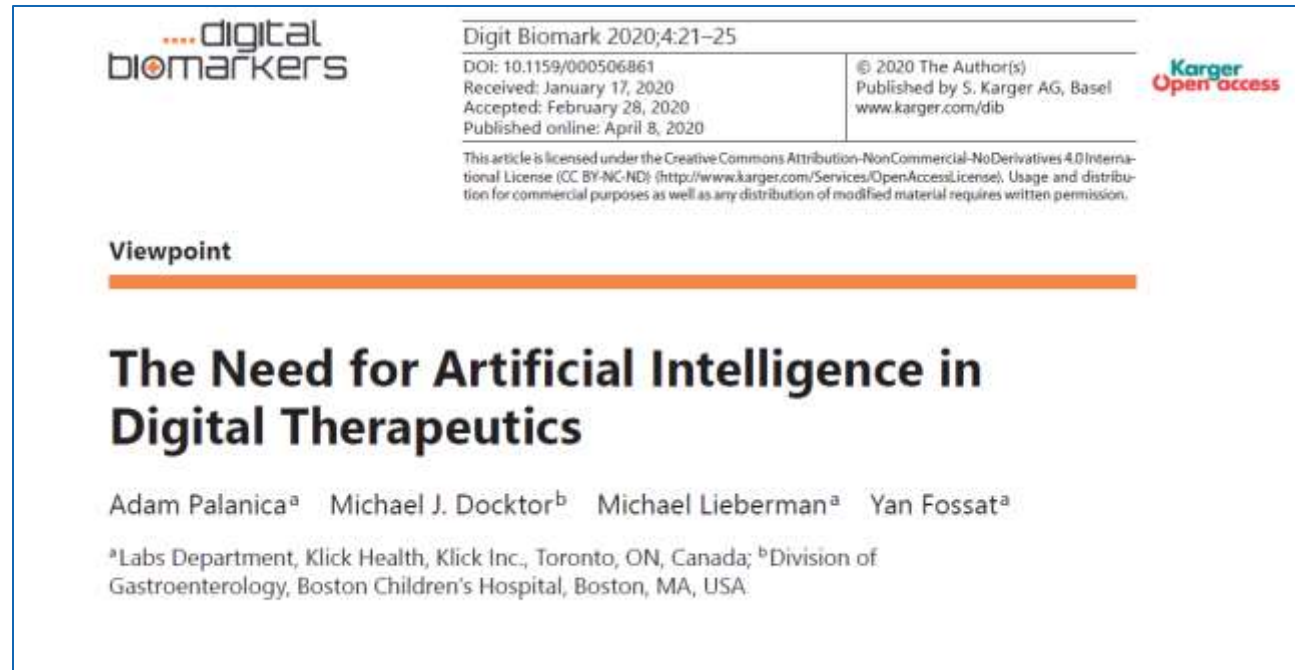
Ubiquitous technology such as smartphones and wearables design facilitate personalized DTx interventions that **observe, understand, and coach** the individual in their daily life.

The first step—**observing**—consists of collection of data that is, meaningful for the management or treatment of the disease.

By applying artificial intelligence techniques to the data collected, we reach the second step—**understanding** what is going on—for example, by finding interactions between clinical outcomes.

The third and last step—**coaching**—concerns providing information to the user that is, understandable and actionable in a way that **supports individuals with chronic conditions in reaching the desired behaviours.**

SFIDE DI AI PER LO SVILUPPO DI DTx PERSONALIZZATE



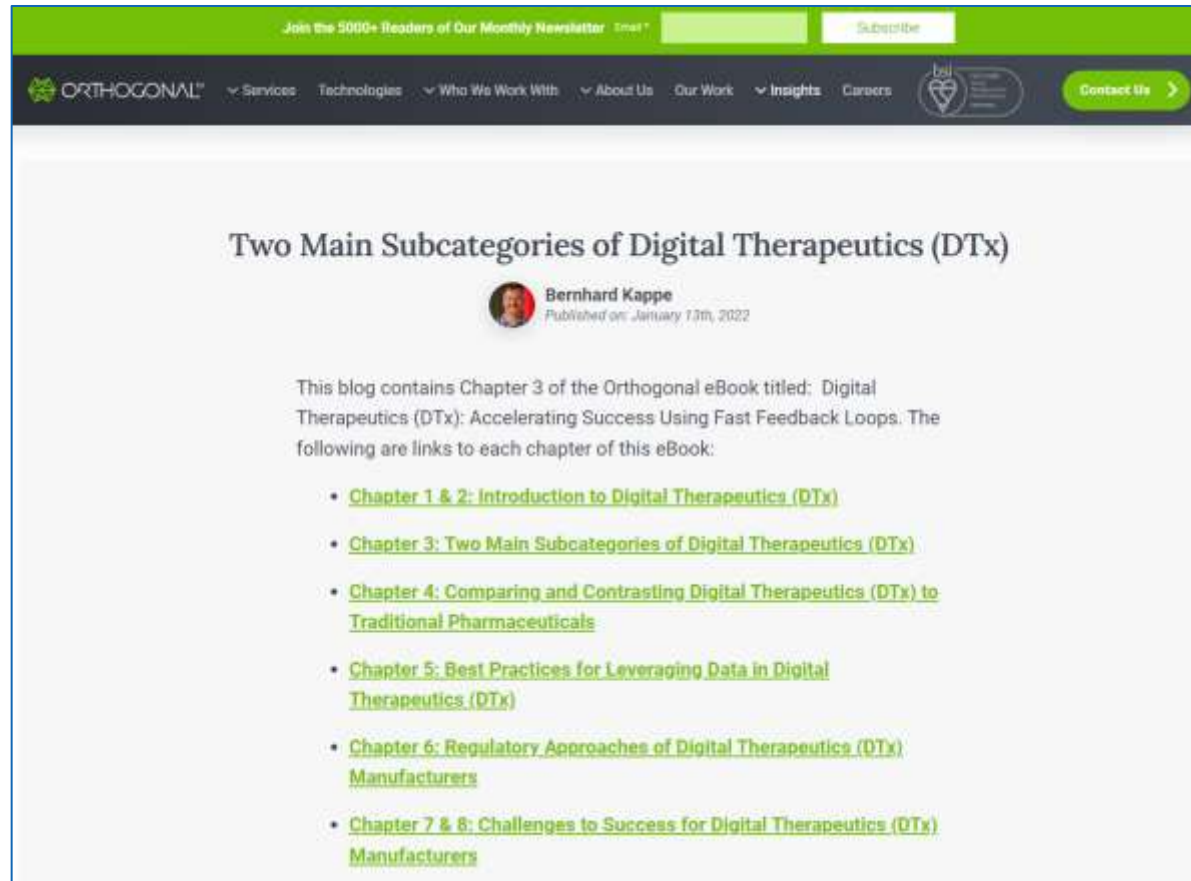
- Engagement
- Trust
- Personalization

We argue that the field of digital therapeutics **should not only involve fixed or generic software**, but rather focus on implementing more **adaptive algorithms** and flexible interventions via artificial intelligence and machine learning.

Artificial intelligence and machine learning make it possible for systems **to automatically learn from new experiences**, adjust outputs, and **perform human-like tasks without being explicitly programmed**.

This vital differentiation of digital therapeutics compared to other forms of therapeutics enables a **more personalized form of healthcare** that actively adapts to patients' individual clinical needs, goals, and lifestyles.

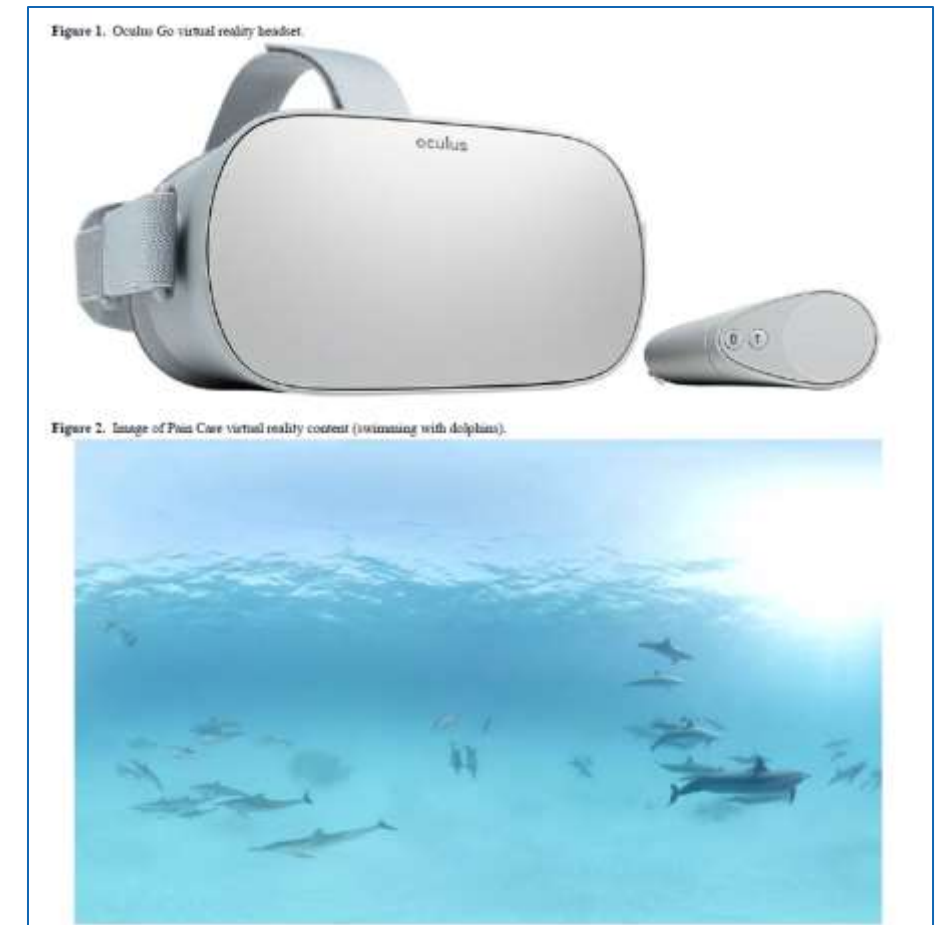
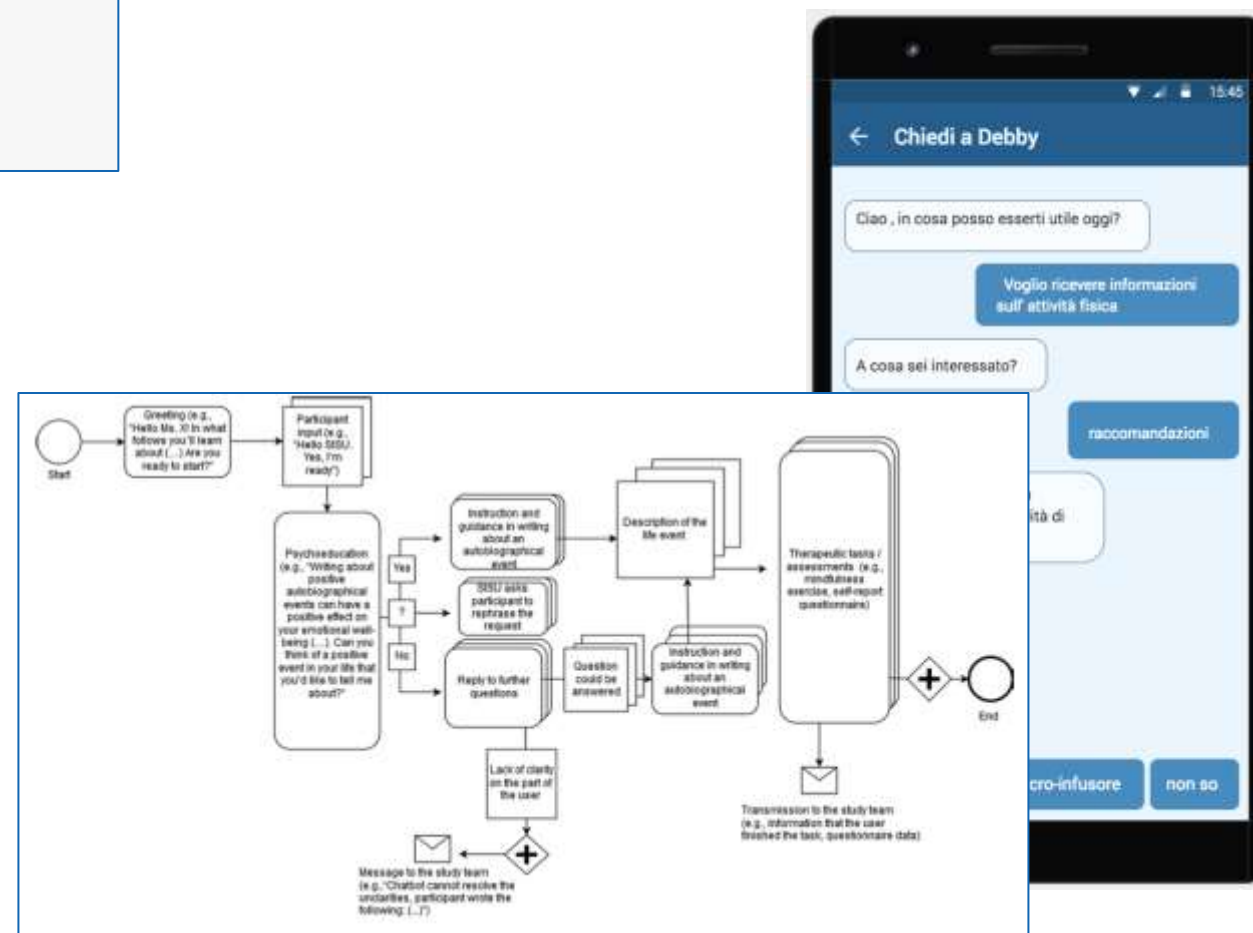
2 tipologie di DTX



La prima sottocategoria comprende **la digitalizzazione e l'automazione** di terapie collaudate, offline, non digitali.

La seconda sottocategoria comprende terapie digitali che creano e forniscono interventi innovativi **non possibili nella tradizionale assistenza da uomo a uomo**.

<https://orthogonal.io/insights/digital-therapeutics/dtx-2-two-main-subcategories-of-digital-therapeutics-dtx/>



Modello di sviluppo di una DTx

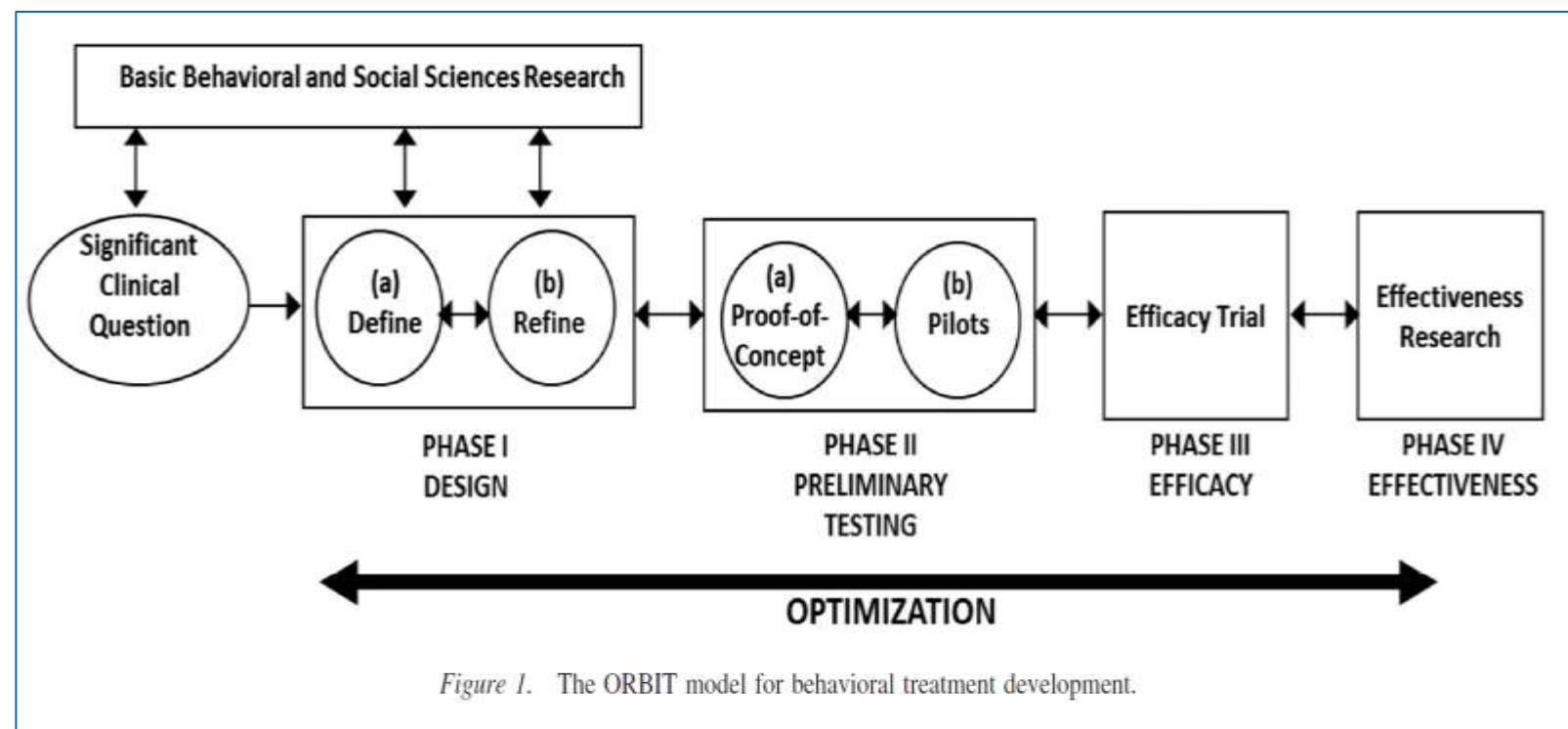
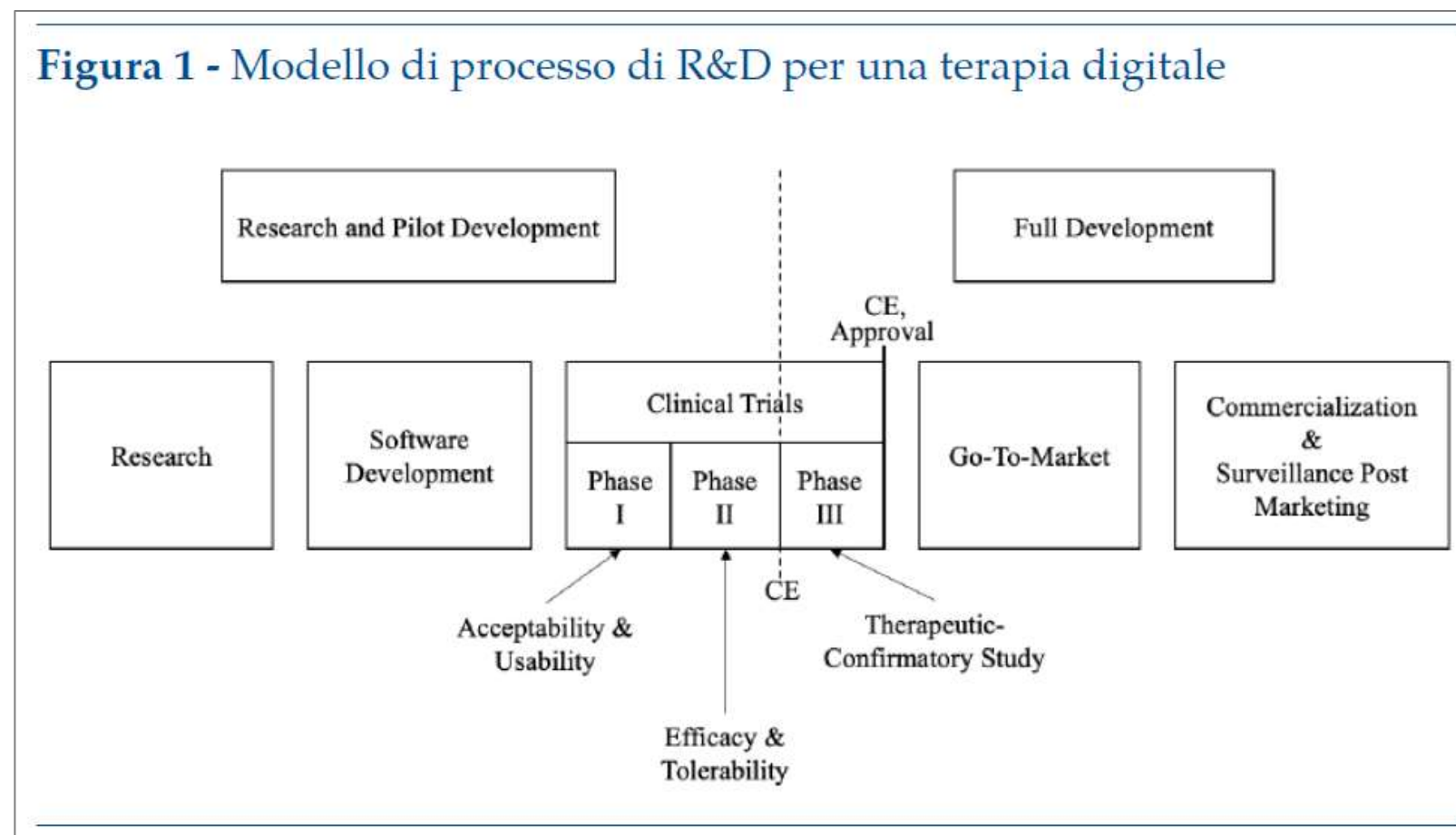


Figura 1 - Modello di processo di R&D per una terapia digitale



DTx: in Germania

20 ottobre 2020

Sono adesso prescrivibili in Germania le prime due terapie digitali

20 Ottobre 2020 • Massimo Mangia • Leave a comment



Dopo undici mesi dall'approvazione della Digitale Versorgung Gesetz (DVG), la legge sulla sanità digitale (DVG), sono ora prescrivibili dai medici tedeschi due app.

Continue reading →

Digital Therapies, Mobile Health
acufene, ansia, App, digital therapeutics, DVG, Germania, Kalmeda, Velibra

<https://salutedigitale.blog/2020/10/20/sono-adesso-prescrivibili-in-germania-le-prime-due-terapie-digitali/#more-3139>

9 marzo 2021

DIGITAL THERAPIES

Germania: boom delle terapie digitali

9 Marzo 2021 • Massimo Mangia • Leave a comment



Sono 11 le terapie digitali già approvate mentre altre 21 sono in corso di approvazione. Ecco quali sono.

Continue reading →

Digital Therapies, Mobile Health, Normative
App, BfArM, digital therapeutics, Mobile, regolamentazione, terapia

Terapie digitali: cosa sono, a cosa servono, come operano

<https://salutedigitale.blog/category/digital-therapies/>

Le 11 applicazioni di salute digitale approvate sono:

- deprexis e Selfapy che trattano la **depressione**;
- elevida che si rivolge ai pazienti con sclerosi multipla che soffrono di **stanchezza cronica**;
- Invirto e velibra per i pazienti con disturbi di **panico, fobie sociali e disturbi d'ansia**;
- Kalmeda per la terapia comportamentale per gli **acufeni**;
- M-Sense per il **mal di testa e l'emicrania**;
- Rehapp per la cura dei pazienti colpiti da **ictus**;
- Somnio per i **disturbi del sonno** non provocati da cause organiche;
- Vivira tratta i **dolori** alla schiena, al ginocchio e all'anca causati, per esempio, dall'artrosi, ma anche i dolori non specifici intorno alla colonna vertebrale, alle anche, alle ginocchia e alla schiena;
- Zanadio per i problemi associati al **sovrappeso**.

DTx

npj | digital medicine www.nature.com/npjdigitalmed

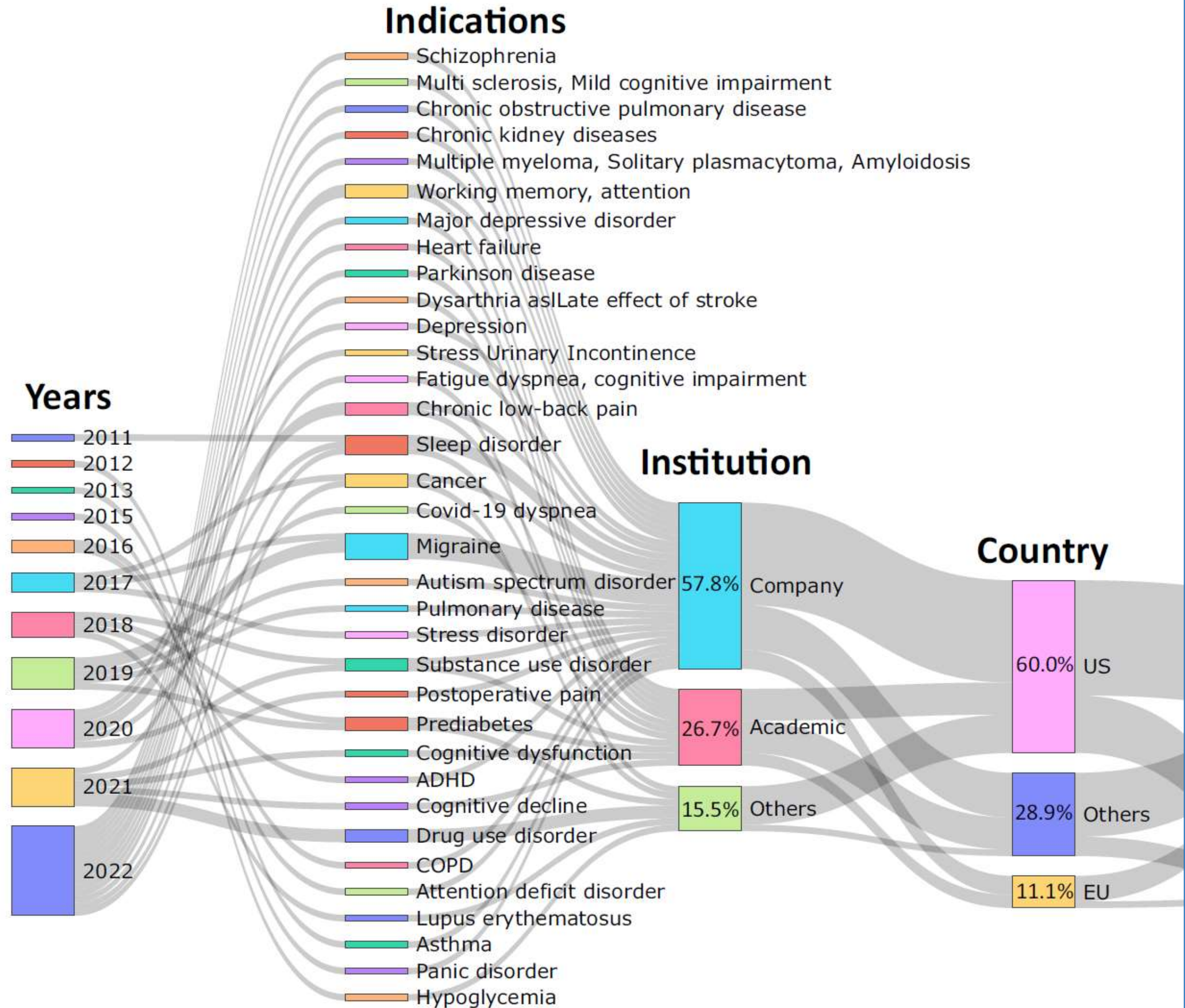
ARTICLE OPEN Check for updates

Digital therapeutics from bench to bedside

Changwon Wang^{1,2}, Chungkeun Lee^{1,2} and Hangsik Shin^{1,2*}

As a new therapeutic technique based on digital technology, the commercialization and clinical application of digital therapeutics (DTx) are increasing, and the demand for expansion to new clinical fields is remarkably high. However, the use of DTx as a general medical component is still ambiguous, and this ambiguity may be owing to a lack of consensus on a definition, in addition to insufficiencies in research and development, clinical trials, standardization of regulatory frameworks, and technological maturity. In this study, we conduct an in-depth investigation and analysis of definitions, clinical trials, commercial products, and the regulatory status related to DTx using published literature, ClinicalTrials.gov, and web pages of regulatory and private organizations in several countries. Subsequently, we suggest the necessity and considerations for international agreements on the definition and characteristics of DTx, focusing on the commercialization characteristics. In addition, we discuss the status and considerations of clinical research, key technology factors, and the direction of regulatory developments. In conclusion, for the successful settlement of DTx, real-world evidence-based validation should be strengthened by establishing a cooperative system between researchers, manufacturers, and governments, and there should be effective technologies and regulatory systems for overcoming engagement barriers of DTx.

npj Digital Medicine (2023)6:38; <https://doi.org/10.1038/s41746-023-00777-z>



Review DTx/iCBT in Oncology

The Emerging Role of Digital Therapeutics in Medical, Surgical and Radiation Oncology

Will Jin, MD;^{1*} Santosh Mohan, MMCI, COPHIMS;² Matt Adams, BS;³ Sarah Hoffe, MD;⁴ Edmondo Robinson, MD, MBA²

Annals of Research in Oncology
Vol. 2(1), 55-69, 2022

NARRATIVE REVIEW

DIGITAL THERAPEUTICS IN ONCOLOGY: FINDINGS, BARRIERS AND PROSPECTS. A NARRATIVE REVIEW

G. Gussoni
F. Perrone



Journal of Artificial Intelligence and Big Data, 2022, 2, 1-8
www.scipublications.org/journal/index.php/jaibd
DOI: 10.31586/jaibd.2022.347

Review Article

Digital Therapeutics in Oncology: A Better Outlook for Cancer Patients in the Future

Gunjan Lath ^{1,*}, Raju Rhee ², Kaveri Nikam ²

¹ Rajiv Gandhi University of Health Sciences, India

² Tata Institute of Social Sciences, India

*Correspondence: Gunjan Lath (gunjan.kreativo@gmail.com)

Journal Pre-proof

Effects of internet-based cognitive behavioral therapy on anxiety and depression symptoms in cancer patients: A meta-analysis

Tingting Liu, Juan Xu, Hui Cheng, Yueyue Zhang, Shaotong Wang, Lu Lin, Li Tian



PII: S0163-8343(22)00111-6

DOI: <https://doi.org/10.1016/j.genhosppsy.2022.09.003>

Reference: GHP 7831

To appear in: *General Hospital Psychiatry*

Received date: 1 August 2022

Revised date: 17 September 2022

Accepted date: 19 September 2022

Products

The Emerging Role of Digital Therapeutics in Medical, Surgical and Radiation Oncology

Will Jin, MD;^{1*} Santosh Mohan, MMCI, COPHIMS;² Matt Adams, BS;³ Sarah Hoffe, MD;⁴ Edmondo Robinson, MD, MBA⁵

PRODUCT	COMPANY	THERAPEUTIC AREA	MECHANISM	STUDY POPULATION	TRIAL DESIGN	OUTCOMES
Oleena, Moovcare, Kaiku Health ^{16,17}	Voluntis, Sivan Innovation, Elekta	Remote care monitoring	Patient reports symptom, DTx evaluates symptom severity, DTx provides a personalized recommendation to manage the symptom	Advanced solid cancer patients, n = 766	RCT of DTx vs conventional symptom monitoring; survival endpoint	Median OS improved 31.2 mos vs 26 mos, P = 0.03. Significantly better HRQL and lower ER admission. Oleena patients remained on CTx longer.
Oleena, Moovcare, Kaiku Health ¹⁸	Voluntis, Sivan Innovation, Elekta	Remote care monitoring	Patient reports symptom, DTx evaluates symptom severity, DTx provides a personalized recommendation to manage the symptom	Lung cancer patients, n = 98	Prospective f/u with DTx vs retrospective conventional	Median OS improved, 22.4 mos vs 16.7 mos, P = 0.0014
Oleena, Moovcare, Kaiku Health ¹⁹	Voluntis, Sivan Innovation, Elekta	Remote care monitoring	Patient reports symptom, DTx evaluates symptom severity, DTx provides a personalized recommendation to manage the symptom	Lung cancer patients, n = 121	RCT of DTx vs routine f/u	Median OS improved 22.4 mos vs 16.7 mos, P = 0.0014
Oleena ²⁷	Voluntis	Remote care monitoring	Patient reports symptom, DTx evaluates symptom severity, DTx provides a personalized recommendation to manage the symptom	Ovarian cancer patients, n = 16	Pilot study to assist managing hypertension and diarrhea	87% of diarrhea events limited to grade 1
Attune ²⁸	Blue Note	Symptoms of anxiety and depression related to cancer	DTx that incorporates principles of CBSM and CBT	Breast cancer patients, n = 123	RCT evaluating DTx CBT vs relaxation training vs control	Greater increases in stress management skills in CBT/relaxation groups, P < 0.001
Attune ⁷⁴	Blue Note	Symptoms of anxiety and depression related to cancer	DTx that incorporates principles of CBSM and CBT	Advanced prostate cancer patients, n = 192	RCT of 10 weeks Attune CBSM vs health promotion	Men in DTx CBSM group reported greater improvement in ability to relax
Untire ²⁹	Tired of Cancer	Cancer-related fatigue	Step-by-step program incorporating stress reduction exercises, physical activity, educational topics and daily tips	Patients with cancer-related fatigue, n = 799	RCT evaluating DTx vs control	DTx group showed greater improvements in fatigue severity, interference and QOL, P < 0.01

PRODUCT	COMPANY	THERAPEUTIC AREA	MECHANISM	STUDY POPULATION	TRIAL DESIGN	OUTCOMES
Kaiku Health ⁴⁰	Elekta	Remote care monitoring	Tool to report symptoms	Patients with advanced cancer treated with anti PD-L1, n = 37	Prospective single-arm study	Study showed feasibility
Kaiku Health ⁷⁵	Elekta	Remote care monitoring	Tool to report symptoms and educational material on management	Advanced lung cancer patients, n = 21 and providers n = 48	Single-arm study with DTx	Tool improved communication with provider, saved time by decreasing phone consultations
Optimune ⁷⁶	Gaia	Remote care monitoring	Internet-based intervention based on CBT techniques to treat depression, anxiety and fatigue	Breast cancer patients, n = 363	RCT of standard care + DTx vs standard care	DTx group showed greater improvements in QOL and dietary habits
Bliss ⁹⁰	N/A	Symptoms of care-induced pain	Immersive intervention based around pictures and videos in VR	Bone Marrow Biopsy patients, n = 126	Randomized phase III study	Showed feasibility in use of DTx to aid pain and anxiety caused by procedures
Sidekick Health ¹⁵	Sidekick Health	Remote care monitoring	Tools to log food, track activity, report symptoms and receive educational material	Breast Cancer patients, n = 18	4-week, single-arm study	High level of retention and engagement showed feasibility of wide-scale use in treatment of breast cancer
Zemedy ⁹³	Bold Health	GI symptoms of abdominal pain, altered bowel habits and defecation-related anxiety	DTx offering GI and IBS-specific CBT	Patients with IBS, n = 121	Crossover RCT	Showed benefit and reduction of symptoms for patients suffering from IBS and similar symptoms
SHUTI ²³	N/A	General insomnia/cancer-related insomnia	DTx using CBT for insomnia	Patients who downloaded the app, n = 7216	Real-world data	Showed high levels of engagement and clinically meaningful improvements in sleep
University of Pennsylvania ²³	N/A	Symptoms of anxiety experienced in the waiting room before oncology appointments	VR-guided meditation using pictures and videos, followed by surveys	Patients, family and staff in a radiation oncology setting, n = 119	Random population study	Showed positive responses and reported decreases in pre-appointment anxiety
Ileva Pelvic Digital Health System ⁶¹	Renovia, Inc.	Symptoms of fecal incontinence	Use of a motion-based VBF device and adjacent app	Women with fecal incontinence, n = 27	Single-arm study	Showed a significant improvement in symptom severity and showed an improvement in QOL

Abbreviations: CBT, cognitive behavioral therapy; CBSM, cognitive behavioral stress management; CTx, chemotherapy; DTx, digital therapeutics; ER, emergency room; f/u, followup; GI, Gastrointestinal; HRQL, health-related quality of life; IBS, irritable bowel syndrome; mos, months; OS, overall survival; PD-L1, programmed death ligand 1; QOL, quality of life; RCT, randomized controlled trial; VBF, vaginal biofeedback; VR, virtual reality.

PRODUCT	COMPANY	THERAPEUTIC AREA	MECHANISM	IMPACT	REVENUE MODEL	FDA APPROVAL TYPE
BlueStar RX ⁴²	WellDoc	T1DM, T2DM	Mobile app providing personalized digital coaching	1.7-2.0 average decrease in HbA1c in first 3-6 months of use	Employers or health plans	510(k)
Insulia ⁴³	Voluntis	T2DM	Mobile app to assist with insulin titration	Higher rates of HgA1c < 7% at 4 months	Commercial insurance	510(k)
dNav ⁴⁴	Hygieia	T2DM	Mobile app leverages AI to make insulin dosing adjustments	Lower HgA1c within 3 months	Medicare and commercial insurance	510(k)
reSET ⁴⁵	Pear Therapeutics	Substance use disorder	Mobile app that delivers therapy based on community reinforcement approach	Doubled abstinence rates (40% vs 18%) and retention rate (76% vs 63%)	Commercial insurance	de novo
reSET-O ⁴⁶	Pear Therapeutics	Opioid use disorder	Mobile app to assist transmucosal buprenorphine therapy	Increased retention by almost 15%	Commercial insurance	510(k)
Somyst ⁴⁷	Pear therapeutics	Chronic insomnia	Mobile app delivers 9 weeks of CBT	45% quicker time to fall asleep, 52% reduction in time spent awake at night, 45% reduction in severity of insomnia	Employers	510(k)

Abbreviations: AI, artificial intelligence; CBT, cognitive behavioral therapy; FDA, Food and Drug Administration; HgA1c, hemoglobin A1C; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.



Osservatorio Terapie Digitali

The screenshot shows the website's header with navigation links: CHI SIAMO, COMITATO SCIENTIFICO, REDAZIONE, DOCUMENTI, CONTATTI. The main logo features a stylized 'O' with a DNA helix and the text 'OSSERVATORIO TERAPIE AVANZATE'. Below the logo is the tagline: 'IL PORTALE ITALIANO DEDICATO ALL'INFORMAZIONE E ALLA DIVULGAZIONE SULLE TERAPIE AVANZATE TERAPIA GENICA, TERAPIA CELLULARE, EDITING GENOMICO, CAR-T E ALTRE TERAPIE DI PRECISIONE'. A secondary navigation bar includes: HOME, TERAPIE AVANZATE, TERAPIE APPROVATE, INNOVAZIONI TECH, REGOLATORIO E ACCESSO, BIOETICA, FOCUS, PROGETTI, EVENTI OTA. The breadcrumb trail reads: Sei in: Home | Innovazioni Tech | Terapie Digitali. The main heading is 'Terapie Digitali' with a search bar and a 'VAI' button. The introductory text states: 'Le terapie digitali, regolamentate come i farmaci, integrano tecnologia e terapie tradizionali, aumentando gli strumenti per la gestione di alcune malattie'. A 'Newsletter' sign-up box is visible on the right with the text 'Iscriviti alla nostra Newsletter' and a 'Seguici su' button.

<https://www.osservatorioterapieavanzate.it/innovazioni-tecnologiche/terapie-digitali>

Trattare l'insonnia con una app: in UK è realtà



Il NICE ha raccomandato una app per il trattamento del disturbo del sonno come valida alternativa ai farmaci, con una diminuzione dell'utilizzo di sonniferi e un risparmio del denaro pubblico

Consigli sulla cosiddetta "igiene del sonno", cioè una serie di comportamenti che favoriscono un riposo di migliore qualità e che possono contrastare l'insonnia, e sonniferi: questi sono stati fino ad ora i trattamenti proposti a chi soffre di un disturbo del sonno. Ora, **in base alle nuove linee guida del National Institute for Health and Care Excellence (NICE)** – l'ente pubblico deputato alla salute nel Regno Unito – **potrebbe essere offerta una app al posto delle pillole**. Infatti, il NICE **raccomanda Sleepio** come alternativa efficace ai farmaci – tra cui lo zolpidem e lo zopiclone, che possono anche causare dipendenza – sottolineando che l'analisi economica effettuata su un anno di trattamento ha rilevato **costi sanitari inferiori con l'uso della app, soprattutto per un minor numero di visite e di prescrizioni di sonniferi**.

Di: Rachele Mazaracca , 22 Giugno 2022

[LEGGI TUTTO...](#)

Terapie digitali: la realtà virtuale per il dolore cronico



Autorizzato da poco negli USA, un sistema di realtà virtuale utilizza la terapia cognitivo-comportamentale per ridurre il dolore lombare cronico che colpisce le persone adulte

La tecnologia applicata alla medicina si sta ritagliando una fetta sempre più grande nel mondo della ricerca – e del mercato – per rispondere ai bisogni ancora insoddisfatti di pazienti affetti da diverse patologie. A novembre la Food and Drug Administration (FDA) statunitense **ha autorizzato** la commercializzazione di **EaseVRx**, un sistema di realtà virtuale (VR) immersiva – fruibile con prescrizione medica – che utilizza la **terapia cognitivo-comportamentale per ridurre il dolore lombare cronico** in pazienti adulti (con età superiore ai 18 anni). La riduzione del dolore è fondamentale nel caso di mal di schiena cronico: un aspetto che, se migliorato grazie alla **terapia digitale**, può influenzare in positivo la qualità della vita delle persone.

Di: Rachele Mazaracca , 31 Gennaio 2022

[LEGGI TUTTO...](#)

Terapie digitali: una app per l'ipertensione



Si tratta di una delle prime dimostrazioni di efficacia per una terapia digitale in ambito cardiovascolare. Lo studio è stato pubblicato su un'importante rivista scientifica del settore

Una **terapia digitale (DTx) per l'ipertensione primaria** (o essenziale) è stata studiata tramite un trial clinico condotto l'anno scorso in Giappone. I risultati sono stati annunciati a fine agosto al Congresso ESC 2021 e pubblicati sull'*European Heart Journal*, una delle principali riviste che si occupano di malattie cardiovascolari. La app terapeutica **HERB Mobile** - sviluppata da CureApp e dalla Jichi Medical University, sotto la guida del professor Kazuomi Kario – **permette di gestire i miglioramenti nello stile di vita**, fondamentali nel caso di questa patologia cronica, **e di monitorare parametri come la pressione sanguigna, le ore di esercizio fisico e di sonno**. Come per altre terapie digitali, agire sulla consapevolezza e il mantenimento delle buone abitudini si è rivelato vincente.

Di: Rachele Mazaracca, Eugenio Santoro (Istituto di Ricerche Farmacologiche Mario Negri IRCCS) , 17 Gennaio 2022

[LEGGI TUTTO...](#)

Ipertensione

ESC European Society of Cardiology European Heart Journal (2021) 42, 4111–4122 **FASTTRACK CLINICAL RESEARCH** Epidemiology and prevention

Efficacy of a digital therapeutics system in the management of essential hypertension: the HERB-DH1 pivotal trial

Kazuomi Kario¹, Akihiro Nomura^{2,3,4}, Noriko Harada¹, Ayako Okura¹, Kiyose Nakagawa⁵, Tomoyuki Tanigawa⁵, and Eisuke Hida⁶

¹Division of Cardiovascular Medicine, Department of Medicine, Jikei Medical University School of Medicine, 3311-1, Yakushiji, Shinjuku-ku, Tokyo 162-8601, Japan; ²Innovative Clinical Research Center, Kanazawa University, 13-1 Takaramachi, Kanazawa, Ishikawa 920-8641, Japan; ³Department of Cardiovascular Medicine, Kanazawa University Graduate School of Medical Sciences, 13-1 Takaramachi, Kanazawa, Ishikawa, 920-8641, Japan; ⁴Department of Biomedical Informatics, CareApp Institute, 4136-1 Asayokozawa, Higashi-Ku, Kanagawa, Nagano 389-0111, Japan; ⁵CareApp, Inc., 1 Kodenma-Cho 15 building 4th floor, 113-3 Mikoyogata, Minami-Ku, Chiba-ku, Tokyo 103-0001, Japan; and ⁶Department of Biostatistics and Data Science, Osaka University Graduate School of Medicine, Yamato-koji 2-2, Suita-Shi, Osaka 565-0871, Japan

Received 25 June 2021; revised 7 July 2021; editorial decision 2 August 2021; accepted 4 August 2021; online publication of article 29 August 2021

See page 4123 for the editorial comment for this article "Digital therapeutics and lifestyle: the start of a new era in the management of arterial hypertension", by L.M. Rutledge, P.L. Valenzuela, and A. Lucia, <https://doi.org/10.1093/eurheartj/ehab694>.

Aims Digital therapeutics is a new approach to facilitate the non-pharmacological treatment of hypertension using software programmes such as smartphone applications and/or device algorithms. Based on promising findings from a small pilot trial, the HERB Digital Hypertension 1 (HERB-DH1) pivotal trial investigated the efficacy of digital therapeutics in patients with hypertension not receiving antihypertensive medication.

Methods and results This prospective, open-label, randomized controlled study was performed at 12 sites in Japan. Patients with hypertension [office systolic blood pressure (SBP) 140 to <180 mmHg and 24h SBP ≥130 mmHg] were randomly assigned 1:1 to the digital therapeutics group (HERB system + standard lifestyle modification) or control group (standard lifestyle modification alone). The primary efficacy endpoint was the mean change in 24h ambulatory SBP from baseline to 12 weeks; key secondary efficacy endpoints were mean changes in office and home blood pressure (BP) from baseline to 12 weeks. All analyses were conducted in the full analysis set population. Between December 2019 and June 2020, 390 patients were randomly assigned to the digital therapeutics group (n = 199) or control (n = 191) group. Between-group differences in 24-h ambulatory, home, and office SBPs at 12 weeks were -2.4 (95% confidence interval -4.5 to -0.3), -4.3 (-6.7 to -1.9), and -3.6 (-6.2 to -1.0) mmHg, respectively. No major programme-related safety events occurred up to 24 weeks.

Hypertension Research (2022) 45:1899–1905
<https://doi.org/10.1038/s41440-022-01016-w>

MINI REVIEW

The first software as medical device of evidence-based hypertension digital therapeutics for clinical practice

Kazuomi Kario¹ · Noriko Harada¹ · Ayako Okura¹

Received: 15 August 2022 / Accepted: 27 August 2022 / Published online: 7 October 2022
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Abstract

In 2021, the open-label randomized HERB-Digital Hypertension 1 (HERB-DH1) trial showed for the first time that hypertension digital therapeutics (a hypertension treatment app) successfully reduced blood pressure (BP) in patients with hypertension. Patients in the digital therapeutics group who used the app and home BP monitoring (HBPM) showed significant and persistent decreases in office, home and ambulatory BP values compared with the control group (who were under physician management using HBPM and lifestyle modifications). The results of the pivotal study led to the first global approval of this app for the treatment of hypertension in Japan in 2022, including medical insurance reimbursement. As a result, this hypertension app is expected to become widely used in the clinical management of all stages of hypertension. The most important remaining research issues include the identification of patients likely to respond to this therapeutic approach and the development of clinical efficacy indices. In addition, guidelines for the appropriate use of hypertension apps in the treatment of hypertension are needed. Next steps include the development and research of digital tools to facilitate the behavioral modifications required to prevent hypertension.

Keywords Digital therapeutics · Hypertension · Software as medical device · Digital hypertension · Digital behavior modification · Lifestyle modifications

HERB Mobile permette di gestire i **miglioramenti nello stile di vita**, fondamentali nel caso di questa patologia cronica, e di monitorare parametri come la pressione sanguigna, le ore di esercizio fisico e di sonno...

Lo studio clinico multicentrico, randomizzato e controllato di Fase III per valutare sicurezza ed efficacia di HERB si è svolto tra gennaio e dicembre 2020 e ha coinvolto **390 pazienti**...la differenza nella pressione sanguigna sistolica (SBP) in 24 ore tra i due gruppi (valore medio) ha indicato un effetto ipotensivo significativo nel gruppo di intervento che utilizzava l'app terapeutica rispetto al gruppo di controllo

Ipertensione

Hypertension

REVIEW

Digital Therapeutics in Hypertension: Evidence and Perspectives

Kazuomi Kario, Noriko Harada, Ayako Okura

ABSTRACT: Digital therapeutics refers to the programs to treat, manage, or prevent a met of hypertension, a common condition that interventions can help facilitate uptake of pressure monitoring, decrease therapeut of moderate quality, and are highly heter Therefore, additional studies are needed therapeutic strategies designed with heal trials with objective end points. Hopefully, pandemic can be utilized to maximize adva

Key Words: blood pressure, can

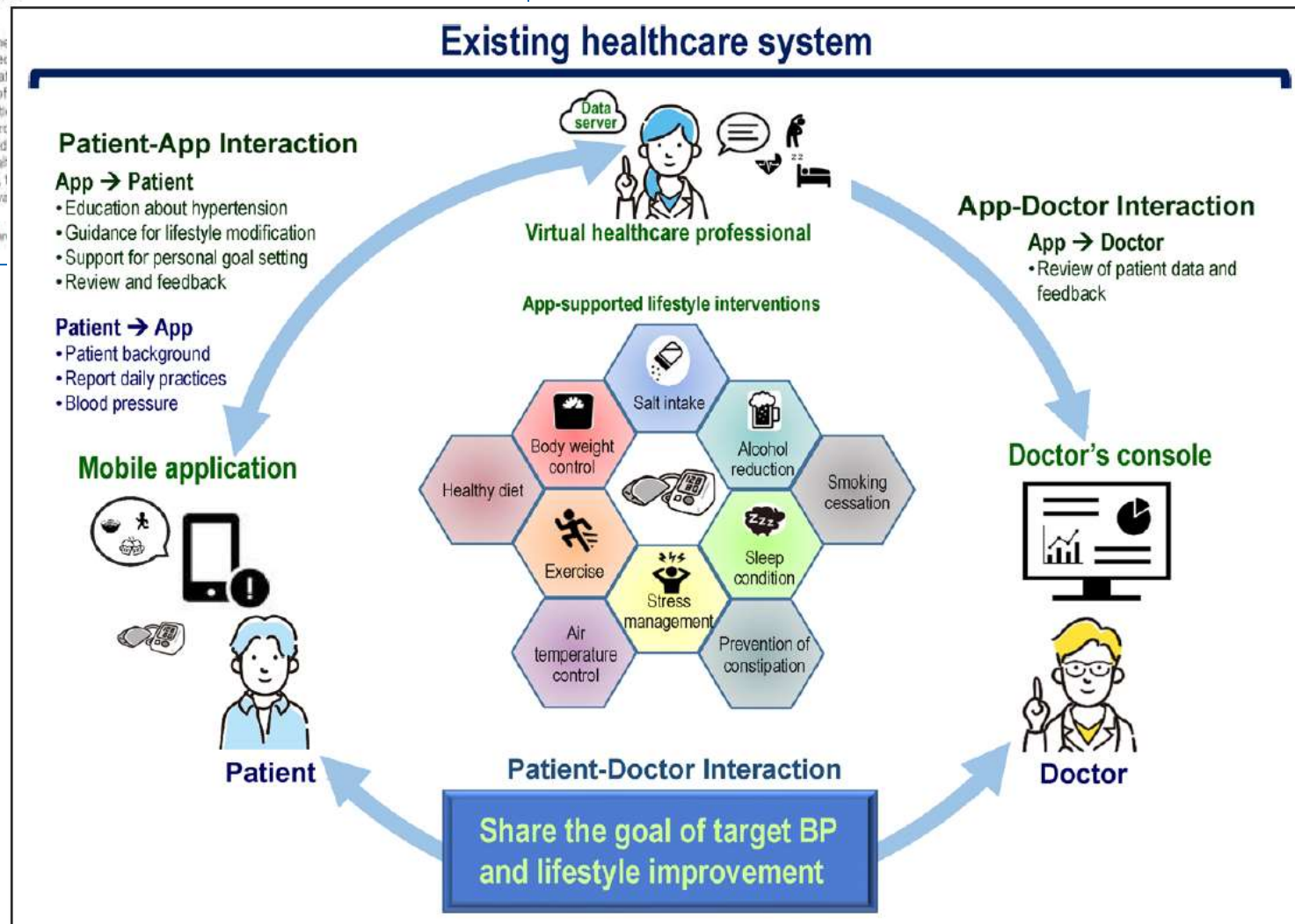


Figure 2. Components of a theoretical digital therapeutics platform for hypertension: interactive approach for optimized personalized intervention. BP, blood pressure.

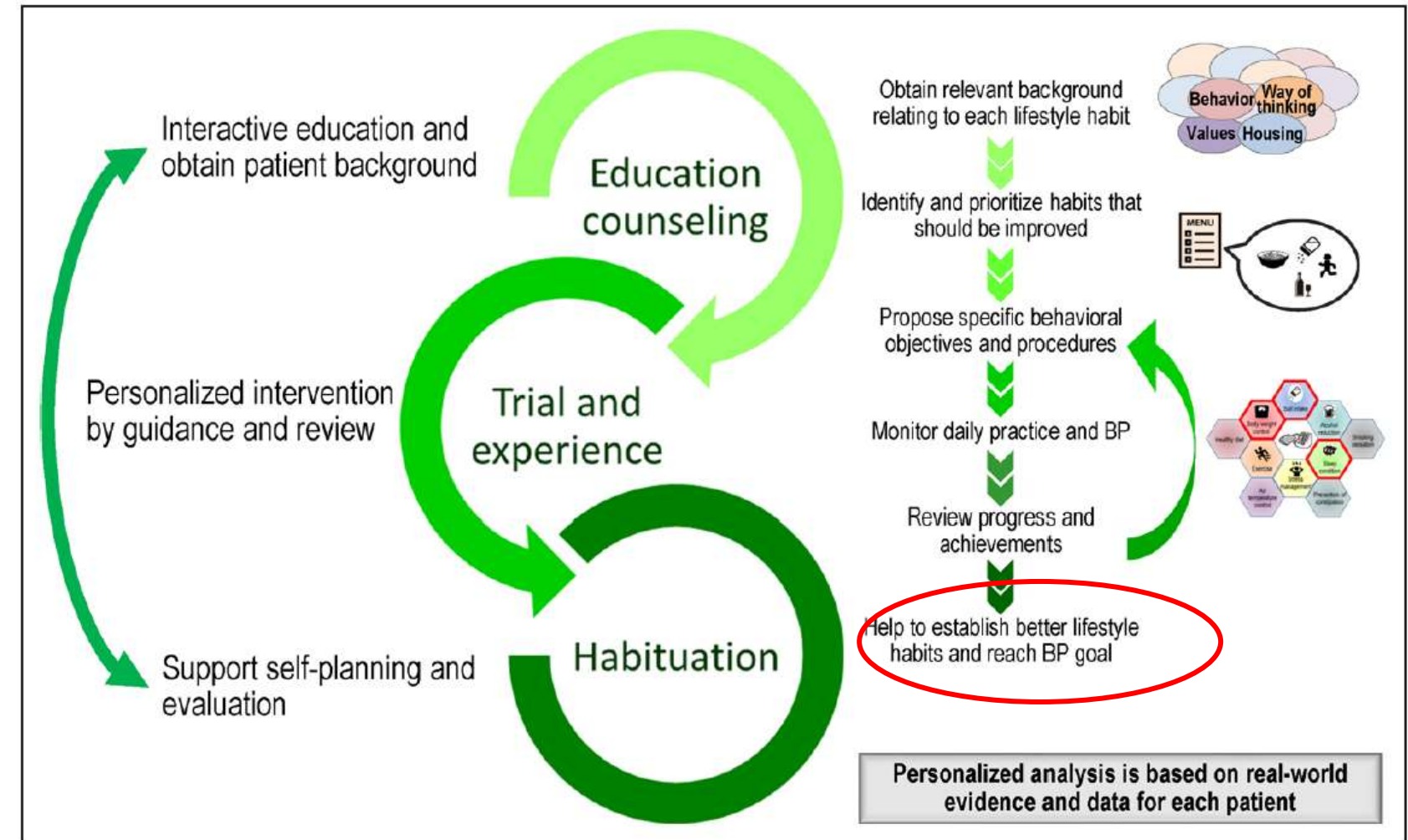


Figure 3. Digital therapeutics process for hypertension (lifestyle modifications based on personalized analysis). BP indicates blood pressure.

...the patient will be able to select from the behavior modification options presented by the application and experience success in their daily management, thereby **fostering self-efficacy** (i.e., the confidence that a certain behavior can be successfully performed, and the ability to trust oneself and take effective action).

Self-efficacy is an important determinant of health behavior, and a recent meta-analysis showed that digital interventions can have a positive effect on selfefficacy.

Insonnia

NICE National Institute for Health and Care Excellence

Guidance ▾ Standards and Indicators ▾ Life sciences ▾ British National Formulary (BNF) ▾ British National Formulary for Children (BNFC) ▾ Clinical Knowledge Summaries (CKS) ▾ About ▾

Home > News

NICE recommends offering app-based treatment for people with insomnia instead of sleeping pills

Hundreds of thousands of people suffering from insomnia who would usually be prescribed sleeping pills could be offered an app-based treatment programme instead, NICE has said.

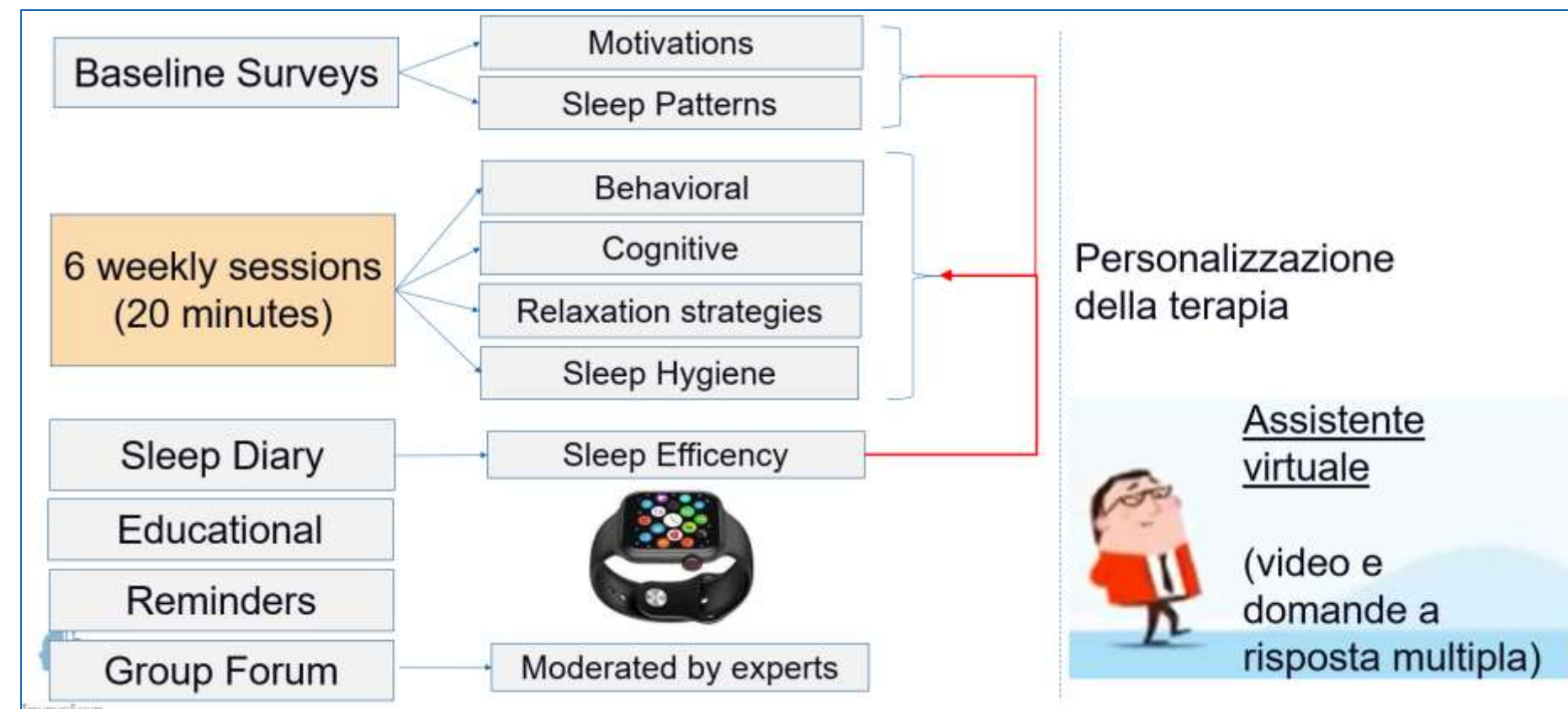
20 May 2022

NICE has recommended Sleepio as an effective alternative to sleeping pills, which would save the NHS money as well as reducing prescriptions of medicines such as zolpidem and zopiclone that can be dependency forming. Economic analysis found that healthcare costs were lower at one year when using Sleepio, mostly because of fewer GP appointments and sleeping pills prescribed.

“ Our guidance on Sleepio provides GPs and their patients with evidence-based recommendations on a digital treatment option for insomnia.

Jeanette Kusel, acting director for MedTech and digital

La questione dei costi diretti e indiretti dell'insonnia – anche questi parametri riportati nelle linee guida – è stata affrontata in diversi studi ben strutturati, tra cui uno del 2010 che confrontava i costi in Europa relativi a diversi disturbi del sonno. Questo studio li ha classificati al nono posto tra tutti i disturbi neuropsichiatrici per quanto riguarda i costi diretti, ad esempio farmaci e visite, e indiretti, ad esempio le assenze lavorative. **È stata calcolata una somma totale media dei costi di 790 euro all'anno, per paziente.**



La app ha un costo molto ridotto rispetto ai costi calcolati per i trattamenti standard: **45 sterline (circa 50 euro)** per persona che inizia la prima sessione. Anche se il programma è concepito per essere completato in sei settimane, l'accesso resta attivo per 12 mesi dalla registrazione, permettendo alle persone di completare le sessioni con i propri tempi e di rivederle se necessario.

Per quanto riguarda la raccomandazione del NICE, le prove cliniche presentate sono state sostenute da 12 studi clinici randomizzati e controllati, che hanno dimostrato che la app è più efficace nel ridurre l'insonnia rispetto all'igiene del sonno e ai sonniferi.

Depressione

JOURNAL OF MEDICAL INTERNET RESEARCH

Meyer et al

Original Paper

Effectiveness of a Novel Integrative Online Treatment for Depression (Deprexis): Randomized Controlled Trial

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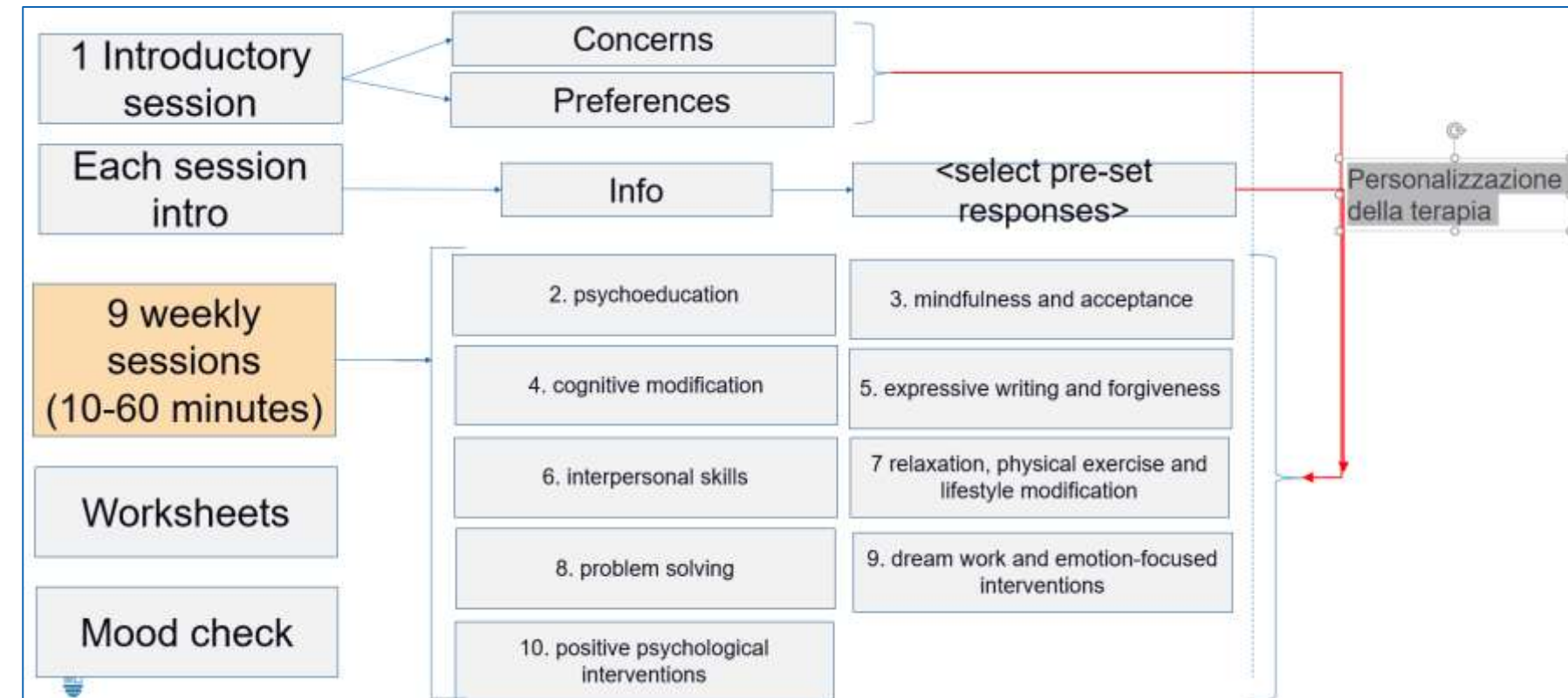
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Abstract

Background: Depression is associated with immense suffering and costs, and many patients receive inadequate care, often because of the limited availability of treatment. Web-based treatments may play an increasingly important role in closing this gap between demand and supply. We developed the integrative, Web-based program *Deprexis*, which covers therapeutic approaches such as behavioral activation, cognitive restructuring, mindfulness/acceptance exercises, and social skills training.



Obesità

Digital Therapeutics for Obesity and Eating-Related Problems

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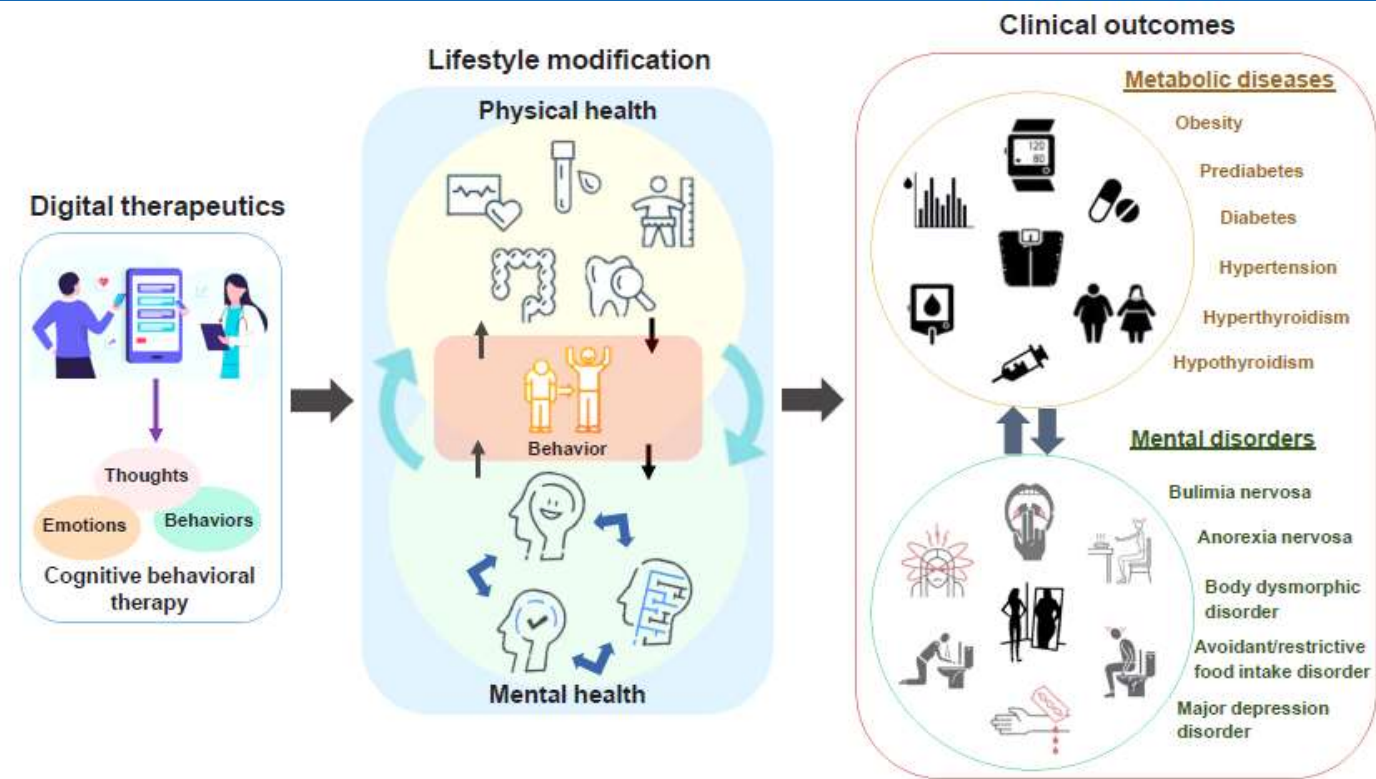


Fig. 1. Interaction between mental and physical health for lifestyle modification via digital therapeutics.

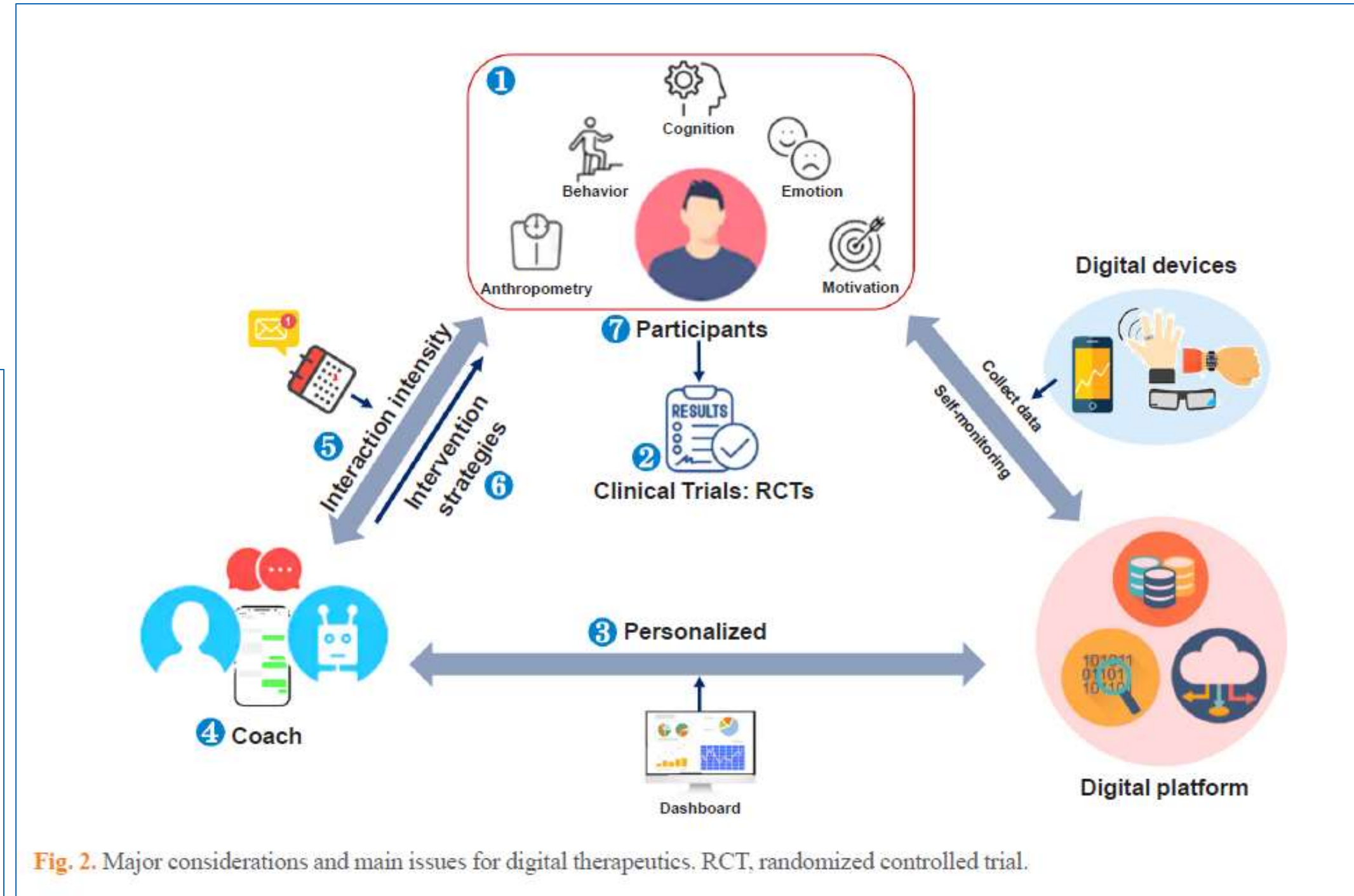


Fig. 2. Major considerations and main issues for digital therapeutics. RCT, randomized controlled trial.

Malattia renale cronica



OSSERVATORIO TERAPIE AVANZATE

IL PORTALE ITALIANO DEDICATO ALL'INFORMAZIONE E ALLA DIVULGAZIONE SULLE TERAPIE AVANZATE: TERAPIA GENICA, TERAPIA CELLULARE, EDITING GENOMICO, CAR-T E ALTRE TERAPIE DIGITALI

HOME TERAPIE AVANZATE TERAPIE APPROVATE INNOVAZIONI TECH REGOLATORIO E ACCESSO BIOETICA

Sei in: Home | Innovazioni Tech | Terapie Digitali |

Terapie Digitali

Terapia digitale per insufficienza renale: ok alla sperimentazione in Italia



Il Ministero della Salute ha dato il via libera allo studio clinico della prima DTx per il trattamento della malattia renale cronica: l'obiettivo è l'ottenimento della marcatura CE

È recente la notizia dell'autorizzazione del Ministero della Salute alla sperimentazione di KidneYou, prima terapia digitale (DTx) per il trattamento della malattia renale cronica (MRC). Lo studio clinico, che aveva già ricevuto il via libera da parte dei Comitati Etici dei centri clinici coinvolti, servirà per validare la DTx come trattamento per la patologia e ottenere la marcatura CE per la commercializzazione.

Pur essendoci un grande interesse da parte dei diversi stakeholder, in Italia non ci sono ancora state approvazioni nell'ambito delle terapie digitali: il quadro normativo è molto complesso, e servono sperimentazioni cliniche solide e rigorose prima di poter somministrare queste terapie ai pazienti. Si tratta quindi di un'ottima notizia che permette di procedere lungo il percorso delle DTx anche nel nostro Paese.

<https://www.osservatorioterapieavanzate.it/innovazioni-tecnologiche/terapie-digitali/terapia-digitale-per-insufficienza-renale-ok-alla-sperimentazione-in-italia>

KidneYou è una applicazione che eroga un intervento terapeutico per la gestione delle abitudini alimentari e di esercizio fisico e permette il monitoraggio delle condizioni di salute dei pazienti.

La DTx, infatti, prevede un **programma nutrizionale**, un programma di **attività fisica** e un programma di meditazione volto ad alleviare lo **stress associato alla patologia**.

La piattaforma, dal lato visibile al personale sanitario, agevola la **raccolta, la conservazione e la visualizzazione dei dati clinici per gestire al meglio il percorso clinico**.

La sperimentazione clinica - in aperto, randomizzata e a doppio braccio - ha l'obiettivo di valutare il miglioramento delle condizioni cliniche nei pazienti in trattamento non-farmacologico. I primi pazienti sono già stati arruolati, ma è previsto il coinvolgimento di un totale di 210 persone (maggioresi e di entrambi i sessi) entro un anno.

Realtà virtuale e dolore cronico

FDA NEWS RELEASE

FDA Authorizes Marketing of Virtual Reality System for Chronic Pain Reduction

For Immediate Release: November 16, 2021

Español

The U.S. Food and Drug Administration today authorized marketing of EaseVRx, a prescription-use immersive virtual reality (VR) system that uses cognitive behavioral therapy and other behavioral methods to help with pain reduction in patients 18 years of age and older with diagnosed chronic lower back pain.

“Millions of adults in the United States are living with chronic lower back pain that can affect multiple aspects of their daily life,” said Christopher M. Loftus, M.D., acting director of the Office of Neurological and Physical Medicine Devices in the FDA’s Center for Devices and Radiological Health. “Pain reduction is a crucial component of living with chronic lower back pain. Today’s authorization offers a treatment option for pain reduction that does not include opioid pain medications when used alongside other treatment methods for chronic lower back pain.”

Chronic lower back pain, which is defined as moderate to severe pain in the lower back lasting longer than three months, is one of the most common chronic pain conditions in the U.S. Chronic pain may inhibit mobility or daily activities and has been linked to anxiety and depression, poor perceived health or reduced quality of life and dependence on opioids. Current treatment plans for chronic lower back pain often include, among other options, prescription and over-the-counter pain medications, exercise, steroid injections, surgery and transcutaneous electrical nerve stimulation. Cognitive behavioral therapy (CBT) may be used to reduce the burden of chronic pain and increase function through an emotional, cognitive and behavioral approach to shift negative beliefs held by

JMIR FORMATIVE RESEARCH Darnall et al

Original Paper

Self-Administered Skills-Based Virtual Reality Intervention for Chronic Pain: Randomized Controlled Pilot Study

Beth D Darnall¹, PhD; Parthasarathy Krishnamurthy², MBA, PhD; Jeannette Tsuei³, MA; Jorge D Minor⁴, MD

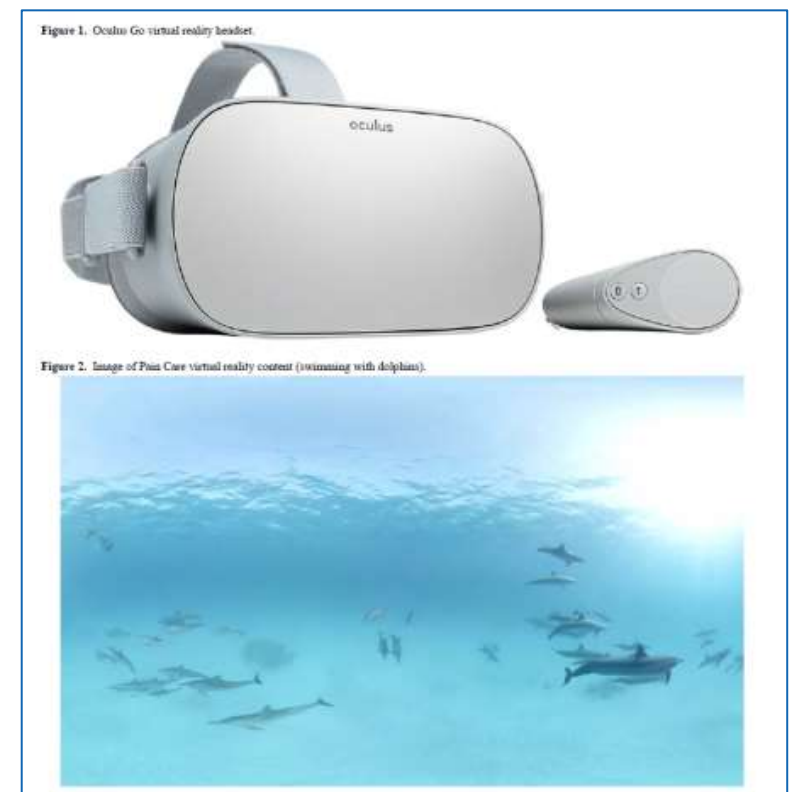
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³AppliedVR, Inc, Los Angeles, CA, United States
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Abstract

Background: Patients with chronic pain often have limited access to comprehensive care that includes behavioral pain management strategies. Virtual reality (VR) is an immersive technology and emerging digital behavioral pain therapy with analgesic efficacy for acute pain. We found no scientific literature on skills-based VR behavioral programs for chronic pain populations.

Objective: The primary aim of this study is to evaluate the feasibility of a self-administered VR program that included content and skills informed by evidence-based behavioral treatment for chronic pain. The secondary aim is to determine the preliminary efficacy of the VR program in terms of average pain intensity and pain-related interference with activity, stress, mood, and sleep, and its impact on pain-related cognition and self-efficacy. The tertiary aim was to conduct a randomized controlled trial (RCT) and compare the VR treatment with an audio-only treatment. This comparison isolated the immersive effects of the VR program.



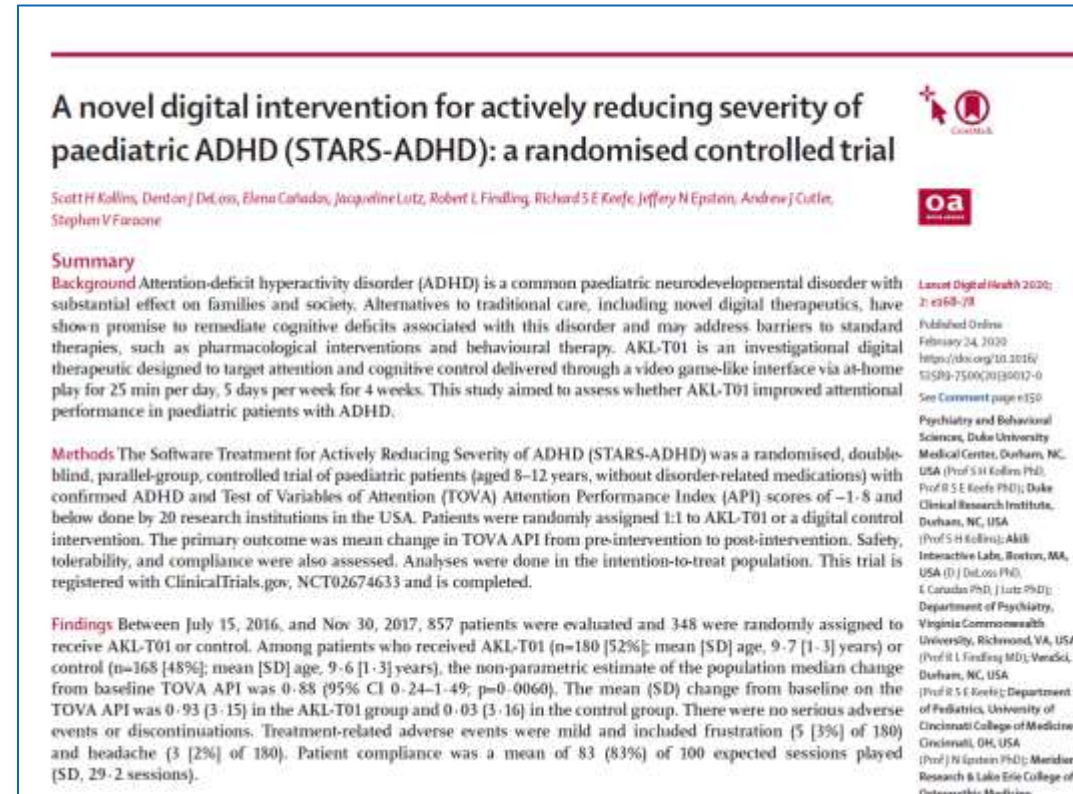
EaseVRx, un sistema di realtà virtuale (VR) immersiva – fruibile con prescrizione medica - che utilizza la **terapia cognitivo-comportamentale** per ridurre il dolore lombare cronico in pazienti adulti (con età superiore ai 18 anni)...realtà virtuale immersiva, **utilizzabile da casa**, che consiste in un programma quotidiano di **8 settimane con 56 sessioni di VR di 2-16 minuti di lunghezza**

Uno studio di otto settimane su 179 persone con dolore lombare che durava da sei mesi o più. Metà dei partecipanti ha usato il programma EaseVRx, mentre l'altra metà ha utilizzato un altro programma di realtà virtuale bidimensionale che però non prevedeva la terapia cognitivo-comportamentale. Circa **due terzi delle persone che hanno usato EaseVRx hanno detto di aver avuto più del 30% di riduzione del dolore e il 46% ha riportato una riduzione del dolore superiore al 50%.**

Sindrome da deficit di attenzione e iperattività



<https://www.osservatorioterapieavanzate.it/innovazioni-tecnologiche/terapie-digitali/terapie-digitali-fda-approva-un-videogioco-per-l-adhd>



A novel digital intervention for actively reducing severity of paediatric ADHD (STARS-ADHD): a randomised controlled trial

Scott H Collins, Denton J DeLoos, Elena Cabada, Jacqueline Lutz, Robert L Findling, Richard S E Koefie, Jeffrey N Epstein, Andrew J Cutler, Stephen V Faraone

Summary

Background Attention-deficit hyperactivity disorder (ADHD) is a common paediatric neurodevelopmental disorder with substantial effect on families and society. Alternatives to traditional care, including novel digital therapeutics, have shown promise to remediate cognitive deficits associated with this disorder and may address barriers to standard therapies, such as pharmacological interventions and behavioural therapy. AKL-T01 is an investigational digital therapeutic designed to target attention and cognitive control delivered through a video game-like interface via at-home play for 25 min per day, 5 days per week for 4 weeks. This study aimed to assess whether AKL-T01 improved attentional performance in paediatric patients with ADHD.

Methods The Software Treatment for Actively Reducing Severity of ADHD (STARS-ADHD) was a randomised, double-blind, parallel-group, controlled trial of paediatric patients (aged 8–12 years, without disorder-related medications) with confirmed ADHD and Test of Variables of Attention (TOVA) Attention Performance Index (API) scores of -1.8 and below done by 20 research institutions in the USA. Patients were randomly assigned 1:1 to AKL-T01 or a digital control intervention. The primary outcome was mean change in TOVA API from pre-intervention to post-intervention. Safety, tolerability, and compliance were also assessed. Analyses were done in the intention-to-treat population. This trial is registered with ClinicalTrials.gov, NCT02674633 and is completed.

Findings Between July 15, 2016, and Nov 30, 2017, 857 patients were evaluated and 348 were randomly assigned to receive AKL-T01 or control. Among patients who received AKL-T01 ($n=180$ [52%]; mean [SD] age, 9.7 [1.3] years) or control ($n=168$ [48%]; mean [SD] age, 9.6 [1.3] years), the non-parametric estimate of the population median change from baseline TOVA API was 0.88 (95% CI 0.24–1.49; $p=0.0060$). The mean (SD) change from baseline on the TOVA API was 0.93 (3.15) in the AKL-T01 group and 0.03 (3.16) in the control group. There were no serious adverse events or discontinuations. Treatment-related adverse events were mild and included frustration (5 [3%] of 180) and headache (3 [2%] of 180). Patient compliance was a mean of 83 (83%) of 100 expected sessions played (SD, 29.2 sessions).

Lancet Digital Health 2020; 2: e168–78

Published Online February 24, 2020

[https://doi.org/10.1016/S2530-7502\(20\)30010-0](https://doi.org/10.1016/S2530-7502(20)30010-0)

See Comment page e150

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(Prof R L Findling MD); Wake Forest School of Medicine, Winston-Salem, NC, USA

(Prof R S E Koefie); Department of Pediatrics, University of Cincinnati College of Medicine, Cincinnati, OH, USA

(Prof J N Epstein PhD); Meridian Research & Lake Erie College of Osteopathic Medicine

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<https://www.youtube.com/watch?v=z75jhsQknjE>

EndeavorRx™ è il primo **videogioco-terapia** approvato nel mondo e la prima terapia digitale per la **sindrome da deficit di attenzione e iperattività (ADHD)**. Indicata per i bambini dagli **8 ai 12 anni**, negli Stati Uniti potrà essere prescritta dai medici come terapia di supporto affiancata da farmaci e/o programmi educazionali e da un percorso clinico.

...348 pazienti, in quasi il 50% dei casi i genitori hanno rilevato un miglioramento dopo 4 settimane e, a distanza di un altro mese, la percentuale superava il 65%. La somministrazione del gioco (o del "placebo") prevedeva **25 minuti al giorno di attività per 5 giorni a settimana**.

JMIR MHEALTH AND UHEALTH Hunt et al

Original Paper

Efficacy of Zemedy, a Mobile Digital Therapeutic for the Self-management of Irritable Bowel Syndrome: Crossover Randomized Controlled Trial

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Abstract

Background: Patients with irritable bowel syndrome (IBS) experience abdominal pain, altered bowel habits, and defecation-related anxiety, which can result in reduced productivity and impaired health-related quality of life (HRQL). Cognitive behavioral therapy (CBT) has been shown to reduce symptoms of IBS and to improve HRQL, but access to qualified therapists is limited. Smartphone-based digital therapeutic interventions have potential to increase access to guided CBT at scale, but require careful study to assess their benefits and risks.

Objective: The aim of this study was to test the efficacy of a novel app, Zemedy, as a mobile digital therapeutic that delivers a comprehensive CBT program to individuals with IBS.

JMIR MHEALTH AND UHEALTH Hanser-Ulrich et al

Original Paper

A Smartphone-Based Health Care Chatbot to Promote Self-Management of Chronic Pain (SELMA): Pilot Randomized Controlled Trial

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Abstract

Background: Ongoing pain is one of the most common diseases and has major physical, psychological, social, and economic impacts. A mobile health intervention utilizing a fully automated text-based health care chatbot (TBHC) may offer an innovative way not only to deliver coping strategies and psychoeducation for pain management but also to build a working alliance between a participant and the TBHC.

Objective: The objectives of this study are twofold: (1) to describe the design and implementation to promote the chatbot painSELMA (SELMA), a 2-month smartphone-based cognitive behavior therapy (CBT) TBHC intervention for pain self-management in patients with ongoing or cyclic pain, and (2) to present findings from a pilot randomized controlled trial, in which effectiveness, influence of attention to change behavior, pain duration, working alliance, acceptance, and adherence were evaluated.

JMIR FORMATIVE RESEARCH Gudmundsson et al

Original Paper

Evaluating the Feasibility of a Digital Therapeutic Program for Patients With Cancer During Active Treatment: Pre-Post Interventional Study

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Abstract

Background: Increasing evidence shows that lifestyle interventions can improve the symptoms, quality of life (QoL), and even overall survival of patients with cancer. Digital therapeutics (DTx) can help implement behavioral modifications and empower patients through education, lifestyle support, and remote symptom monitoring.

Original Article

Randomized Trial for Weight Loss Using a Digital Therapeutic Application

Journal of Diabetes Science and Technology
 2022, Vol. 16(5) 1150-1158
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 DOI: 10.1177/19322968211000815
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Tryggvi Thorgeirsson, MD^{1,2}, **Johanna E. Torfadottir, PhD³**, **Erlendur Egilsson, MSc⁴**, **Saemundur Oddsson, MD¹**, **Thrudur Gunnarsdottir, PhD¹**, **Thor Aspelund, PhD³**, **Anna S. Olafsdottir, PhD⁵**, **Unnur A. Valdimarsdottir, PhD^{3,6,7}**, **Ichiro Kawachi, PhD⁸**, **Hans-Olov Adami, MD^{6,7,9}**, and **Ragnar G. Bjarnason, MD²**

Abstract

Background: Smartphones present a near-ubiquitous channel through which structured lifestyle change can reduce risk or progression of the most common noncommunicable diseases. We explored whether a digital structured lifestyle program enhances weight loss.

Fitterfly Diabetes CGM Digital Therapeutics Program for Glycemic Control and Weight Management in People With Type 2 Diabetes Mellitus: Real-world Effectiveness Evaluation

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Abstract

Background: Digital therapeutic platforms facilitate health care through patient-centered strategies based on multidisciplinary teams and shared decision-making. Such platforms can be used for developing a dynamic model of diabetes care delivery, which can help in improving glycemic control by promoting long-term behavior changes in people with diabetes.

JOURNAL OF MEDICAL INTERNET RESEARCH Roy et al

Original Paper

Clinical Efficacy and Psychological Mechanisms of an App-Based Digital Therapeutic for Generalized Anxiety Disorder: Randomized Controlled Trial

Alexandra Roy¹, BA; Elizabeth A Hoge², MD; Pablo Abrante¹, BSc; Susan Druker³, MA; Tao Liu⁴, PhD; Judson A Brewer¹, MD, PhD

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Abstract

Background: Current treatments for generalized anxiety disorder (GAD) often yield suboptimal outcomes, partly because of insufficient targeting of underlying psychological mechanisms (eg, avoidance reinforcement learning). Mindfulness training (MT) has shown efficacy for anxiety; yet, widespread adoption has been limited, partly because of the difficulty in scaling in-person-based delivery. Digital therapeutics are emerging as potentially viable treatments; however, very few have been empirically validated.



Parte III

Un progetto di TS4.0

(Silvia Rizzi)

Parte IV

TreC_Ricerca

Progetti strategici 2023-2025



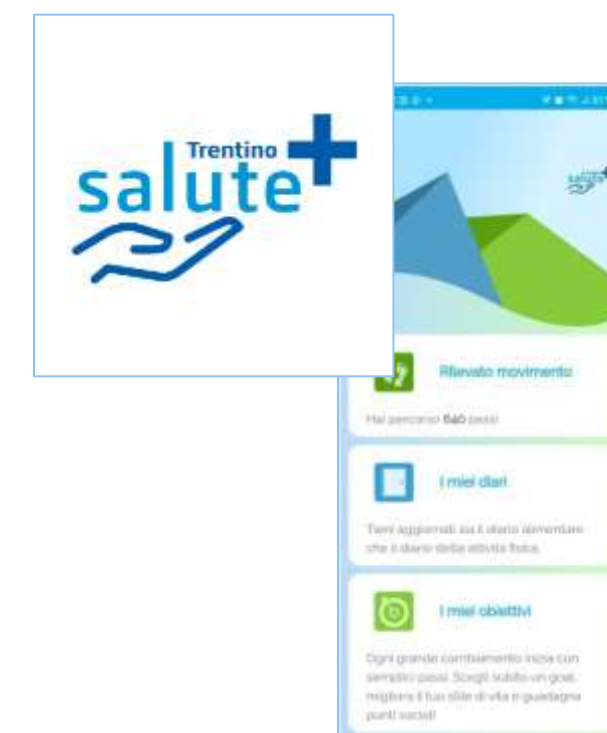
Progettare, realizzare e validare un ecosistema di **Terapie Digitali** per il **sistema sanitario pubblico** italiano per la promozione della salute e la **prevenzione secondaria e terziaria**



Primi 1000 giorni di vita



Oncologia (breast cancer)



Salute+

PRIMI 1000 GIORNI DI VITA



Tabella 1: i 7 PERIODI considerati

1PP	- Periodo preconcezionale
2PT	- Primo trimestre di gravidanza
3ST	- Secondo e terzo trimestre di gravidanza
4TP	- Travaglio-parto-nascita
5PM	- Primo mese di vita
6PA	- Primo anno di vita
7SA	- Secondo anno di vita

Ogni periodo, dopo una breve introduzione, analizza in maniera schematica i principali rischi riconducibili a undici **aree tematiche** (riportate nella Tabella 2) che, pur essendo le stesse per ogni periodo, affrontano i principali rischi specifici propri del periodo considerato, a cui sono associati i possibili esiti/effetti, e le azioni più appropriate per ridurre tale specifico rischio in quel determinato momento, per raggiungere l'obiettivo associato all'area tematica analizzata.

Tabella 2: le 11 AREE TEMATICHE analizzate

1	CONOSCENZE E COMPETENZE GENITORIALI
2	ALIMENTAZIONE E NUTRIZIONE
3	ALTRI STILI DI VITA
4	FARMACI
5	PATOLOGIE e SCREENING/ESAMI
6	MALATTIE GENETICHE
7	SALUTE MENTALE
8	INFEZIONI E VACCINAZIONI
9	RUOLO E SALUTE DEL PADRE
10	FATTORI AMBIENTALI
11	FATTORI SOCIALI E ACCESSO AI SERVIZI

Pongono domande

Rispondono alle domande

Segnalano agli operatori sanitari



Un'ecosistema di assistenti personali



Propongono materiale informativo

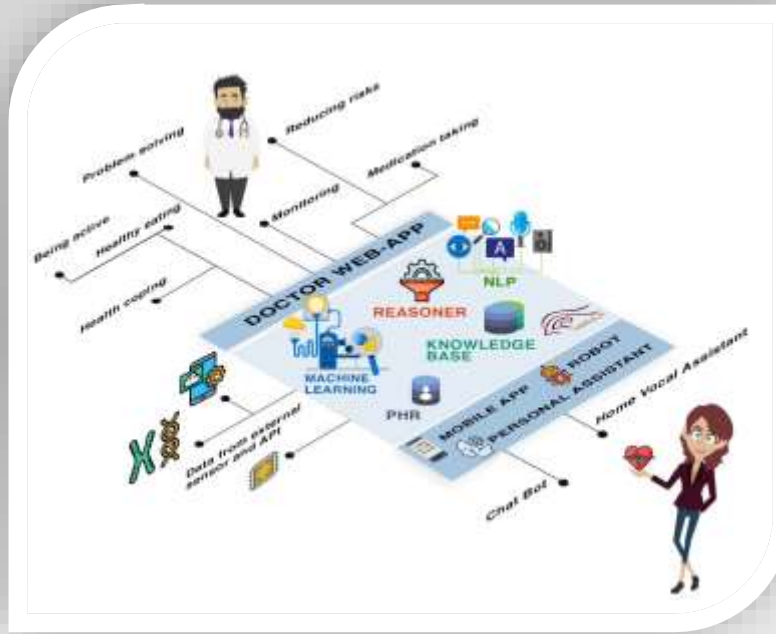
Motivano al cambiamento



CONOSCENZE & COMPETENZE GENITORIALI



Suggeriscono di contattare un operatore sanitario



ALIMENTAZIONE & NUTRIZIONE



Raccolgono dati



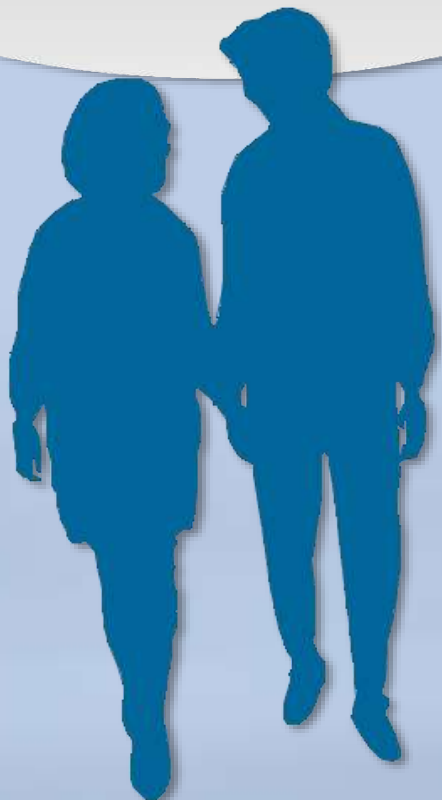
BENESSERE MENTALE



STILI di VITA

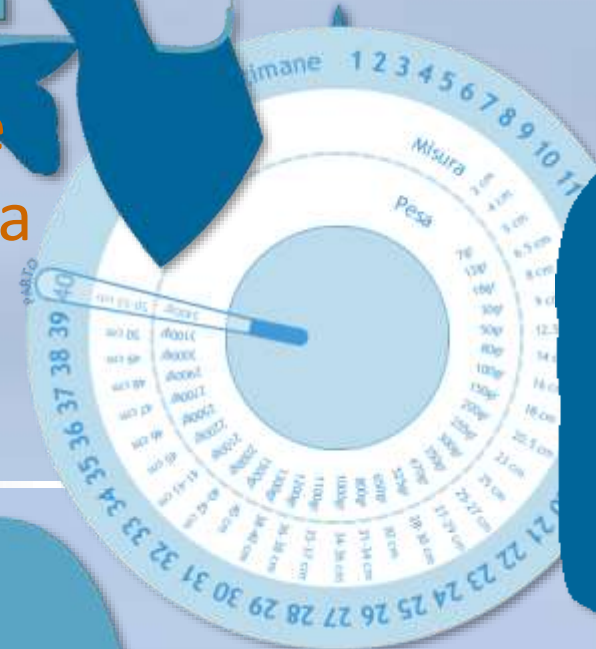


Elaborano dati



1° trimestre di gravidanza

Periodo preconcezionale



2° e 3° trimestre di gravidanza



Travaglio Parto - Nascita



1° mese di vita



1° anno di vita



2° anno di vita



Progetti flagship: cambio di paradigma

“prima Servizio, poi Laboratorio di R&I & RWE”

TreC_Ricerca è la piattaforma per:

- ✓ fornire **servizi base**
- ✓ per validare **interventi innovativi basati DTx**
- ✓ per effettuare **ricerca real-world**

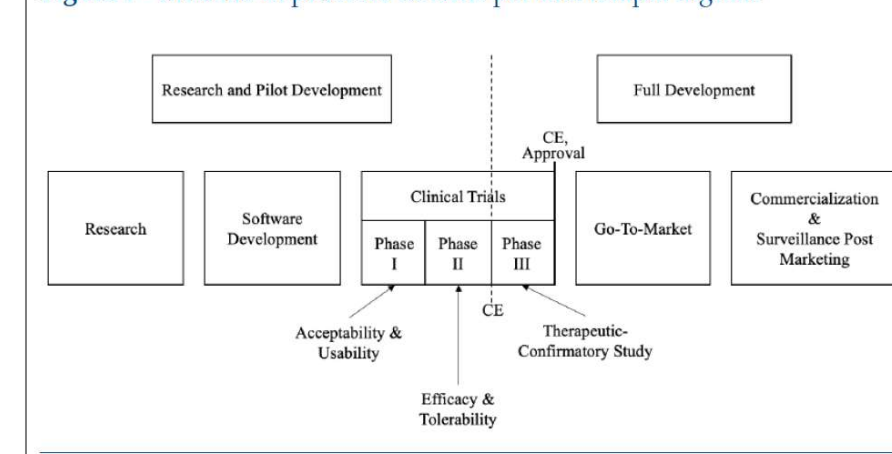


Laboratorio territoriale di ricerca e innovazione tecnologica

- Primi 1000 giorni di vita
- Breast Cancer

- ❑ **co-progettare** con operatori sanitari e realizzare interventi soluzioni digitali (es. **terapie digitali**, algoritmi predittivi)
- ❑ da **validare clinicamente con studi pilota** attraverso **DCT**
- ➔ ❑ raccogliendo dati in un contesto di ricerca **“real-world evidence”**
- ❑ coinvolgendo i cittadini (**Patto con il Cittadino**)
- ❑ collaborando con **Uni-TN** per aspetti legali-privacy e impatto socio-economico (joint lab con Giurisprudenza e DEM)
- ❑ collaborando anche con imprese IT per la certificazione, la messa in produzione di terapie digital offerte dal SSN (**software open source**)

Figura 1 - Modello di processo di R&D per una terapia digitale



Real World Evidence (RWE)

“data relating to patient health status and/or delivery of health care *routinely* collected from a variety of sources”

An important strength of real-world data is that data are **captured from patients in routine care**

Although RCTs are the gold standard for generating evidence on cancer therapies with robust internal validity, there remain evidence gaps relating to patients, clinical practice and outcomes.

Real-world data plays an important role in generating evidence that is complementary to conventional RCT evidence and improving clinical trial design.



Table 1. Strengths and limitations of clinical trials and studies leveraging real-world data.

	Strengths	Limitations
Clinical trials	<ul style="list-style-type: none"> • Gold standard for assessing efficacy • Provide precise measures of treatment efficacy and acute toxicity of new treatments under ideal conditions • Process of randomization in randomized trials promotes even distribution of confounders between treatment groups • Conducted by well-established methodological rules • High internal validity, i.e., provides robust comparison between intervention and control 	<ul style="list-style-type: none"> • Costly, cumbersome and resource-intensive • Limited number of patients • Low external validity due to: <ul style="list-style-type: none"> - Highly selected participants due to strict inclusion and exclusion criteria - Under-representation of groups such as older adults and people with comorbidities - Protocols that may not reflect typical care - Use of surrogate endpoints that may not be valid measures of patient benefit • Limited ability to detect rare and long-term side-effects
Real-world data studies	<ul style="list-style-type: none"> • High external validity due to inclusion of large numbers of patients in routine care • Provides evidence of effectiveness of new treatments in the general population, including those under-represented in clinical trials • Can be performed relatively quickly and at low cost once data infrastructure is established • Large sample sizes allow identification of rare events • Facilitates long follow-up of patients 	<ul style="list-style-type: none"> • Susceptible to confounding and selection bias as interventions are not randomised • Methodologically difficult to do well • Variable data quality <ul style="list-style-type: none"> - Data may not include key clinical details, e.g., treatment plans, comorbidities, performance status - Higher levels of missing data

Ricerca: Decentralized clinical trials

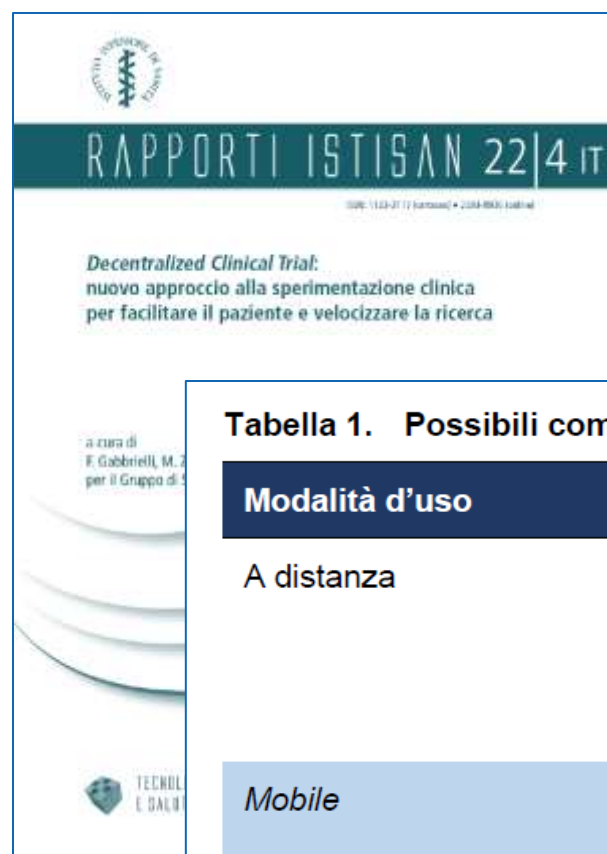


Tabella 1. Possibili componenti dei DCT, raggruppati in base alle modalità d'uso*

Modalità d'uso	Componente
A distanza	Controllo centralizzato Aderenza alla terapia Contenuti di <i>engagement</i> <i>Community Lab</i> locale Monitoraggio remoto o SDR o SDV
Mobile	Servizi <i>direct-to-patient</i> Visite mediche a domicilio Visite assistenziali a domicilio
Digitale	Firma elettronica App Piattaforme software per DCT Dispositivi o <i>wearable</i> o sensori <i>Digital biomarker</i> o <i>Endpoint</i> eCOA o ePRO eCONSENT-ICF o eSignature <i>eDiary</i> <i>eSource</i> <i>eInvestigator site file</i> <i>eMedical records</i> o <i>e-Health records</i> <i>eProtocol optimization</i> <i>eRecruitment</i> <i>eScreening</i> <i>eHealth</i>

il DCT è un **approccio dirompente** che consiste nell'organizzare lo studio clinico attorno al paziente piuttosto che centralizzarlo sul centro clinico.

i DCT hanno una buona possibilità di **migliorare l'accesso dei pazienti alle sperimentazioni**, aumentare la partecipazione di popolazioni diversificate e migliorare la raccolta dei dati.

Si sottolinea che le tecnologie digitali portano con sé un altro concetto molto importante sulla raccolta dei dati: nella sperimentazione clinica tradizionale i dati sono inseriti dal medico, che fa da intermediario tra paziente e raccolta dei dati. **Nel modello DCT ci sono alcuni dati, se non tutti, che sono direttamente inseriti dal paziente**: sia in modo passivo attraverso i sensori, che in modo attivo attraverso i questionari

Decentralized Clinical Trials (DCT)



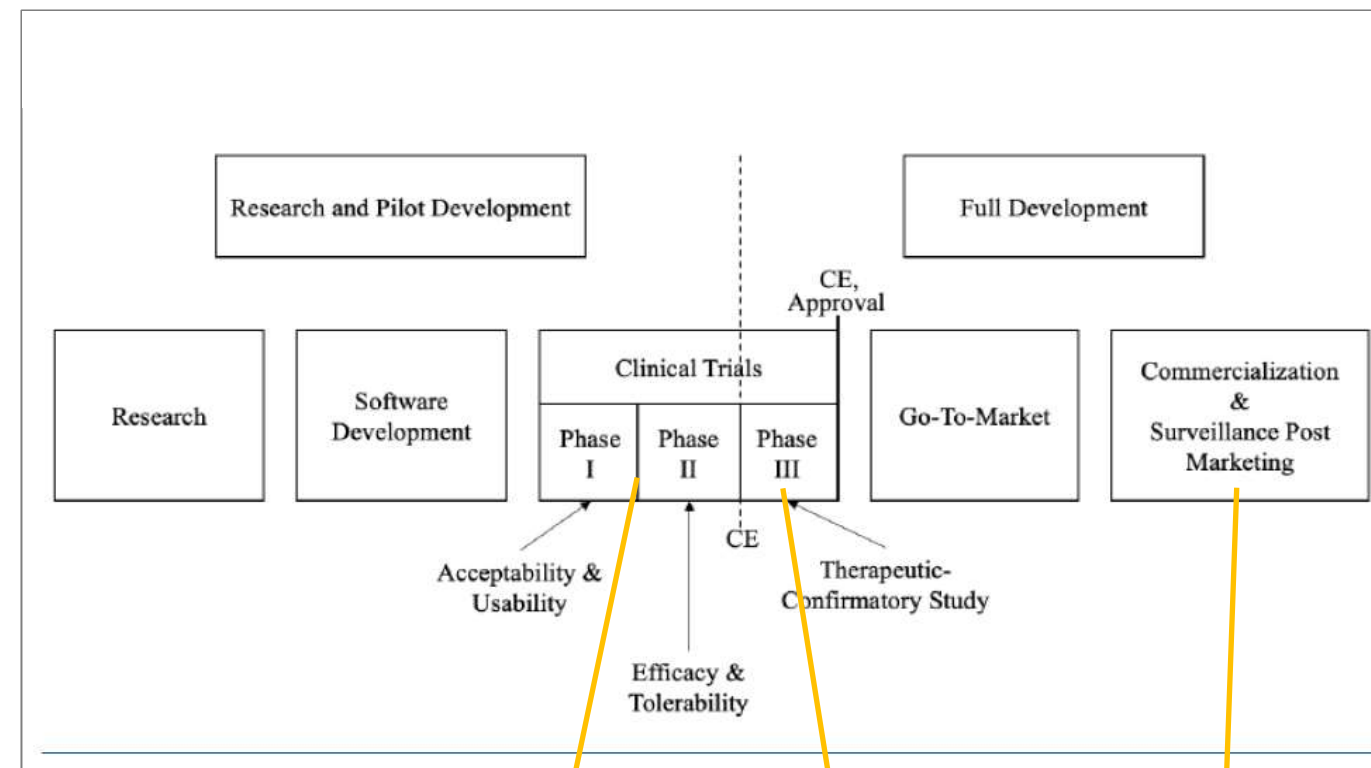
Il punto più qualificante in prospettiva consiste nell'associare tutto quanto detto sopra con la possibilità di **colmare il divario tra lo sviluppo delle sperimentazioni cliniche controllate e gli studi sui dati raccolti nel cosiddetto "mondo reale" (Real World Data), mentre il paziente è comunque adeguatamente seguito dall'assistenza domiciliare.**

La maggiore efficienza degli studi clinici può accelerare l'accesso dei pazienti alle scoperte mediche e l'impiego dei servizi territoriali pubblici apre la strada a **nuove modalità di collaborazione pubblico-privato nella sperimentazione clinica.**



Concept "TreC_Ricerca"

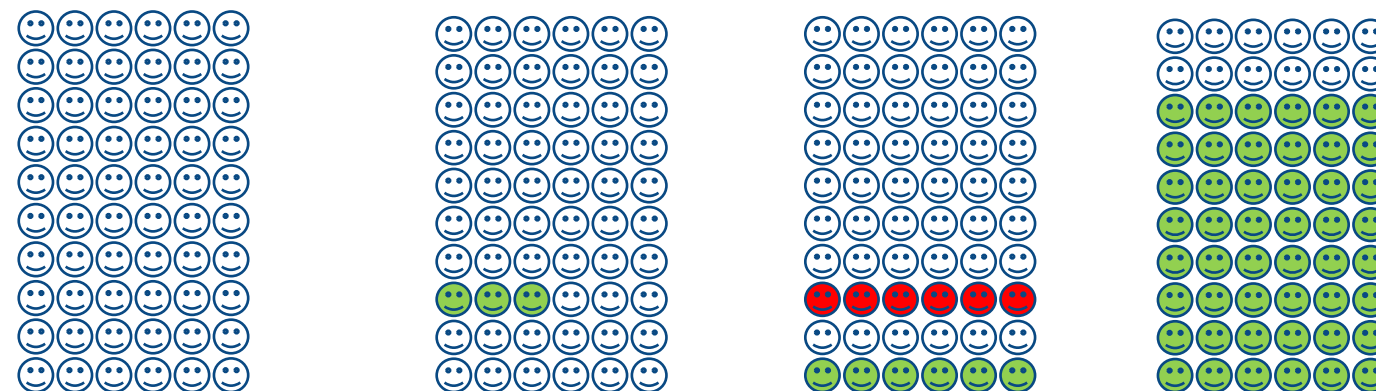
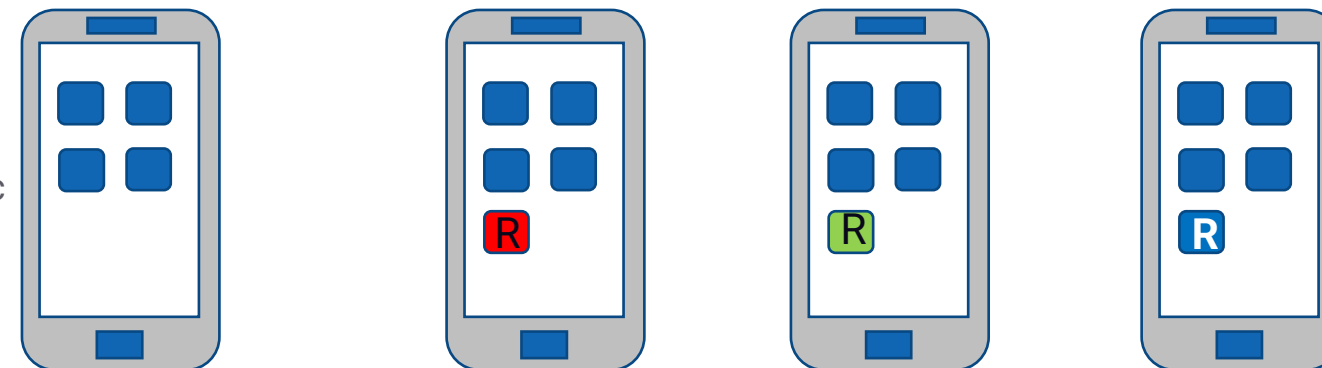
...una piattaforma a supporto della **pipeline** progettazione, sviluppo, validazione di soluzioni di sanità digitale attraverso DCT e RWE



Servizio

DCT

Pilot Pivotal Post market



- Mat educativo
- Accesso CUP, ecc
- Comunicazione
-

TreC-Primi 1000 giorni

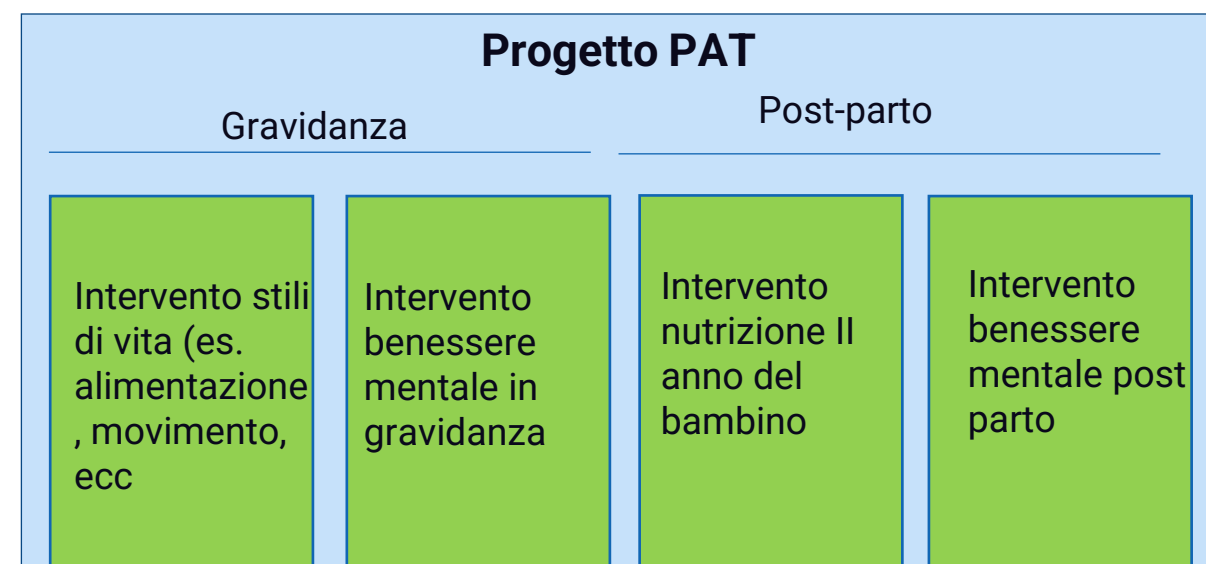
Primo rilascio

Funzionalità base:

- Materiale educativo-informativo
- CUP
-



Studi clinici



Altri studi

- Monitoraggio remoto (es. ipertese, obese)
- Intervento gestione aumento del peso
-
-

trecMamma

Studi epidemiologici

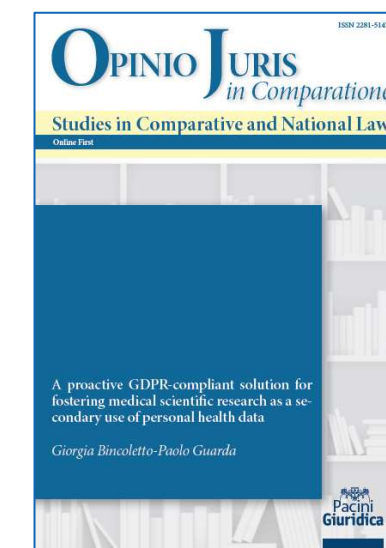
- Quante donne a rischio di depressione
- Come mangiano
- Cosa fanno delle diete mediterranee
- Come dormono
- Quanto si muovono
-

Il patto con il cittadino

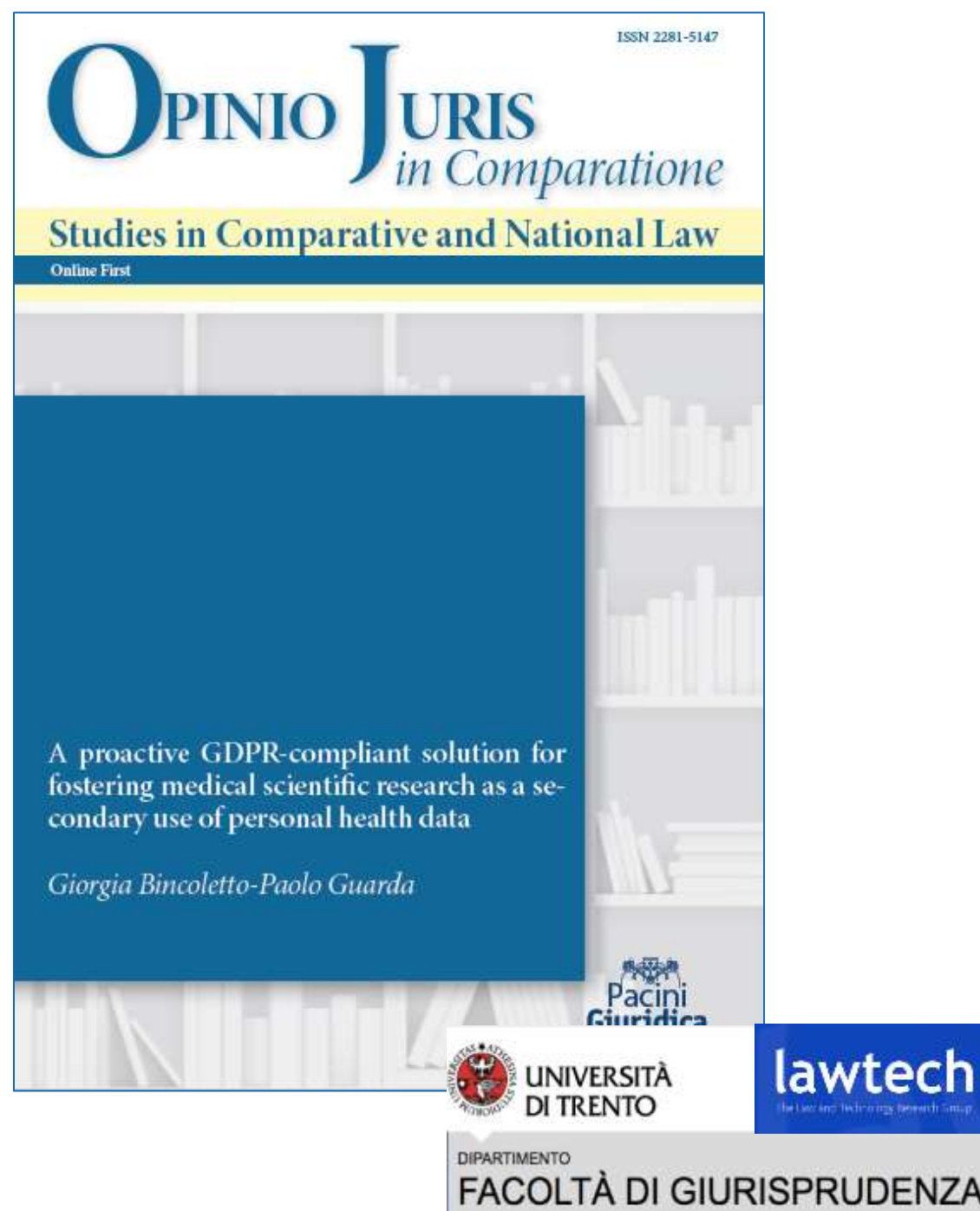
Il patto con il Cittadino

Percorso in cui un intermediario tecnologico con funzionalità di chatbot si relaziona con i cittadini / pazienti:

- ✓ **Informandoli** su iniziative di ricerca e sulle ricadute di queste iniziative
- ✓ **Raccogliendo il consenso** dei cittadini a partecipare ad iniziative di ricerca



Compliance with GDPR

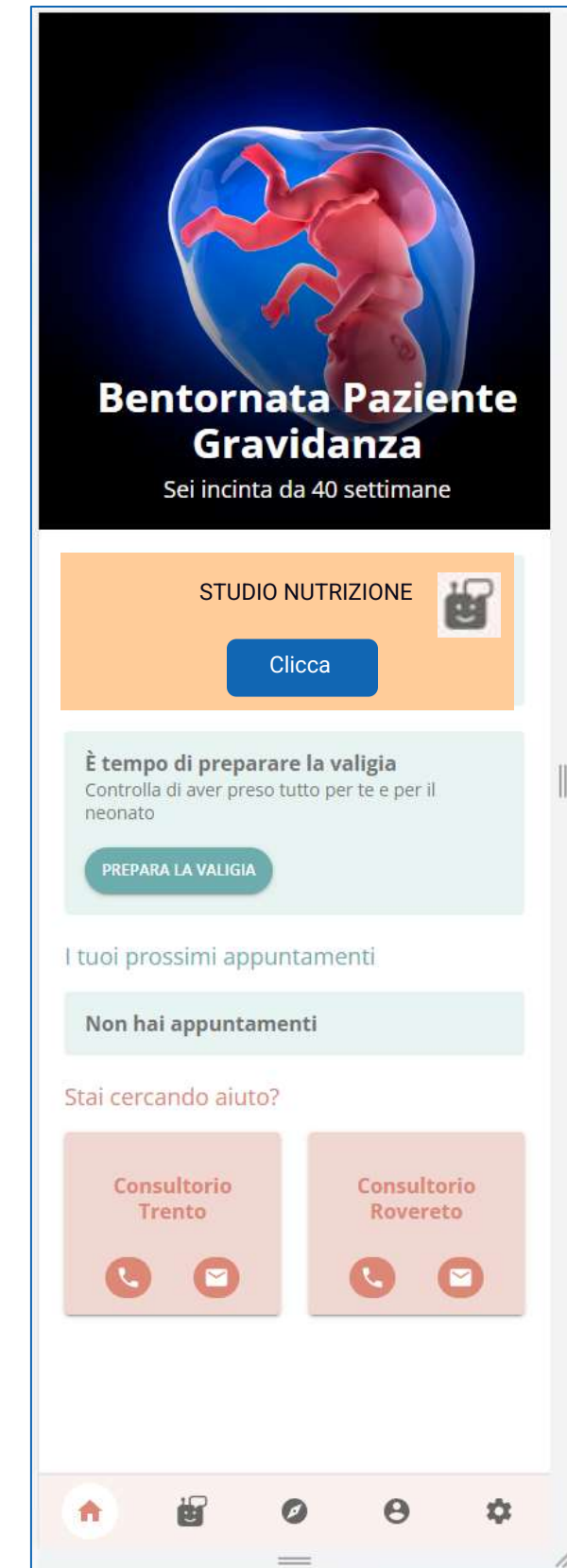
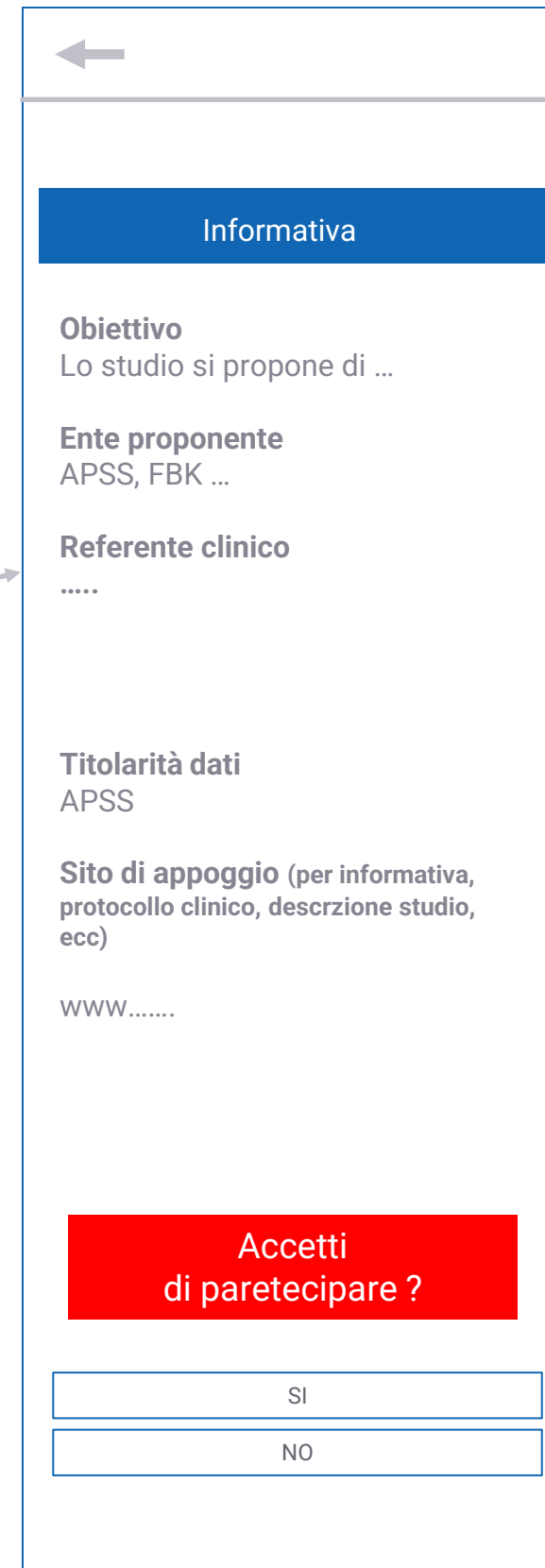


...we propose a **proactive**, legal-technical e-health solution that complies with the rules and principles of the legal frameworks and empowers the individual's control over personal health data while promoting medical research.

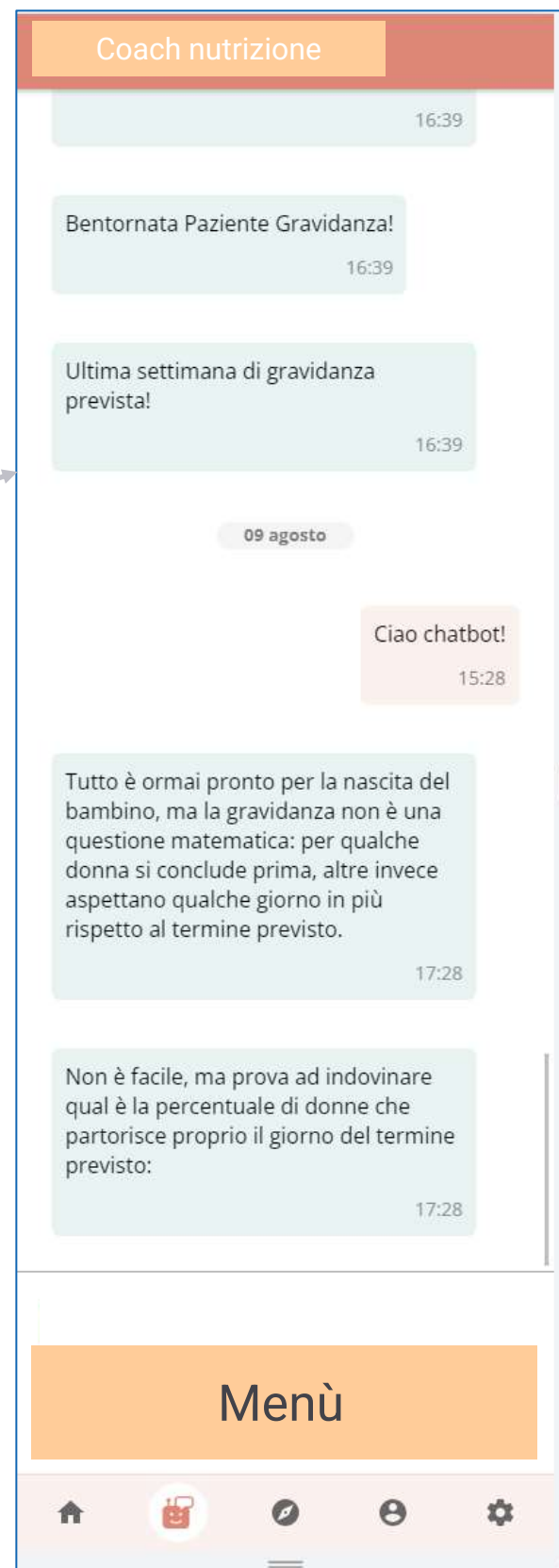
To this end, the **data protection by design concept** plays a central role, and an interdisciplinary approach is fundamental in combining legal and technical perspectives.

In this way, **public entities** lead the process and support scientific innovation.

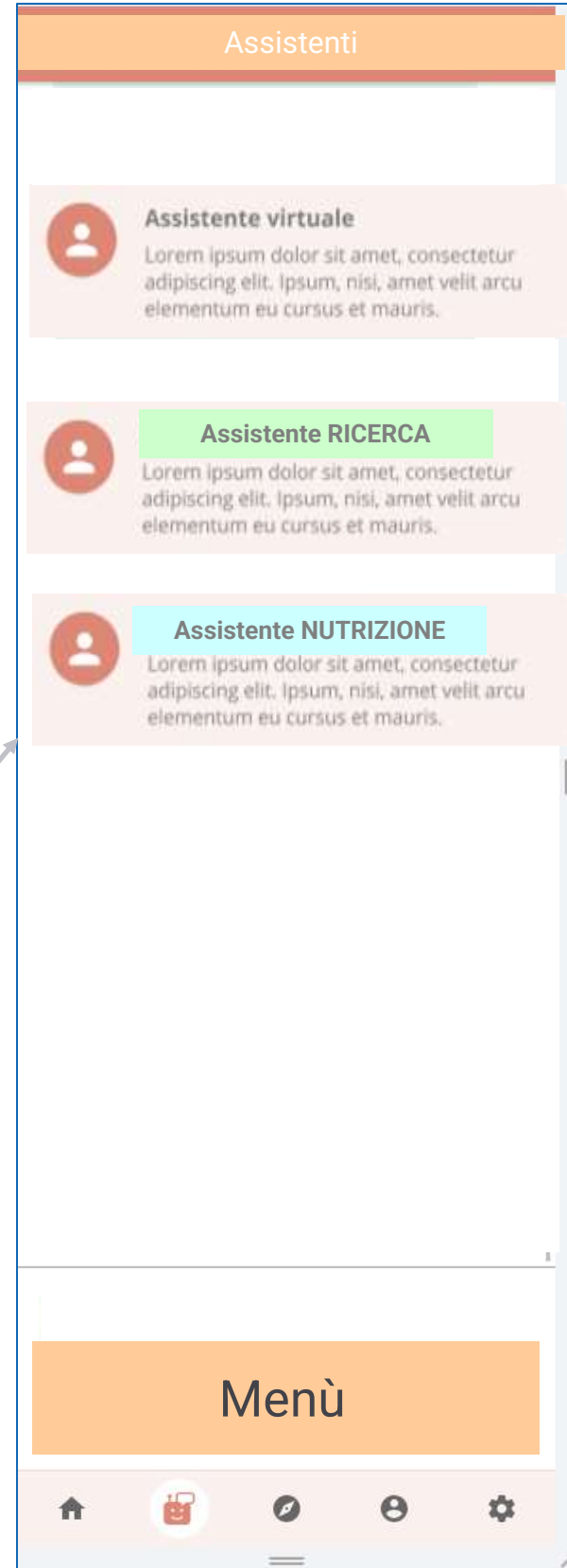
Patto con il cittadino: Proposta di partecipazione ad attività di ricerca



Partecipazione allo studio validazione clinica



Studio effectiveness (RWE)



Conclusioni/Discussione

Blocchi concettuali

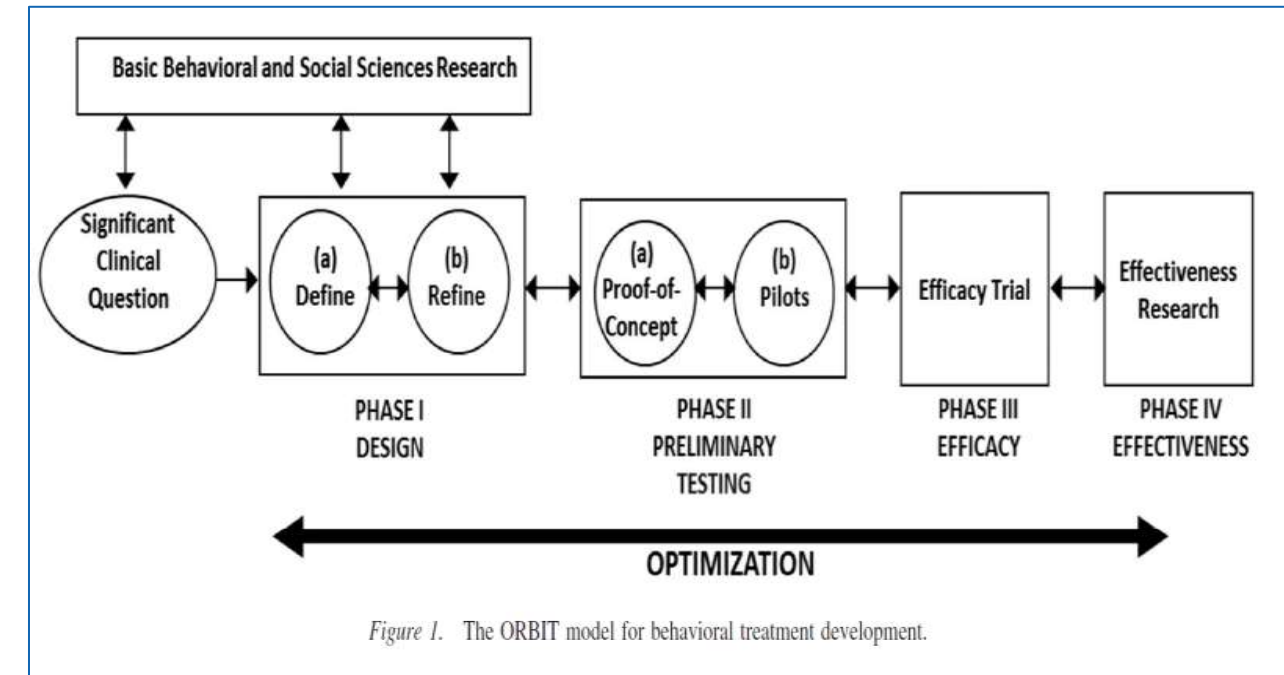
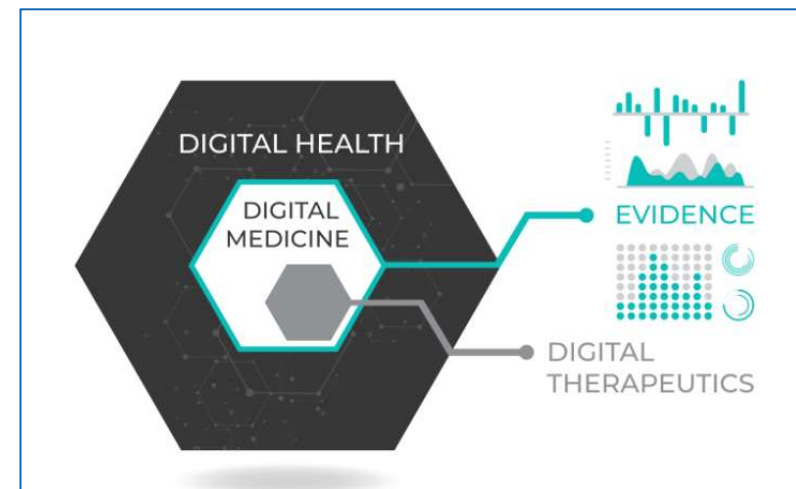
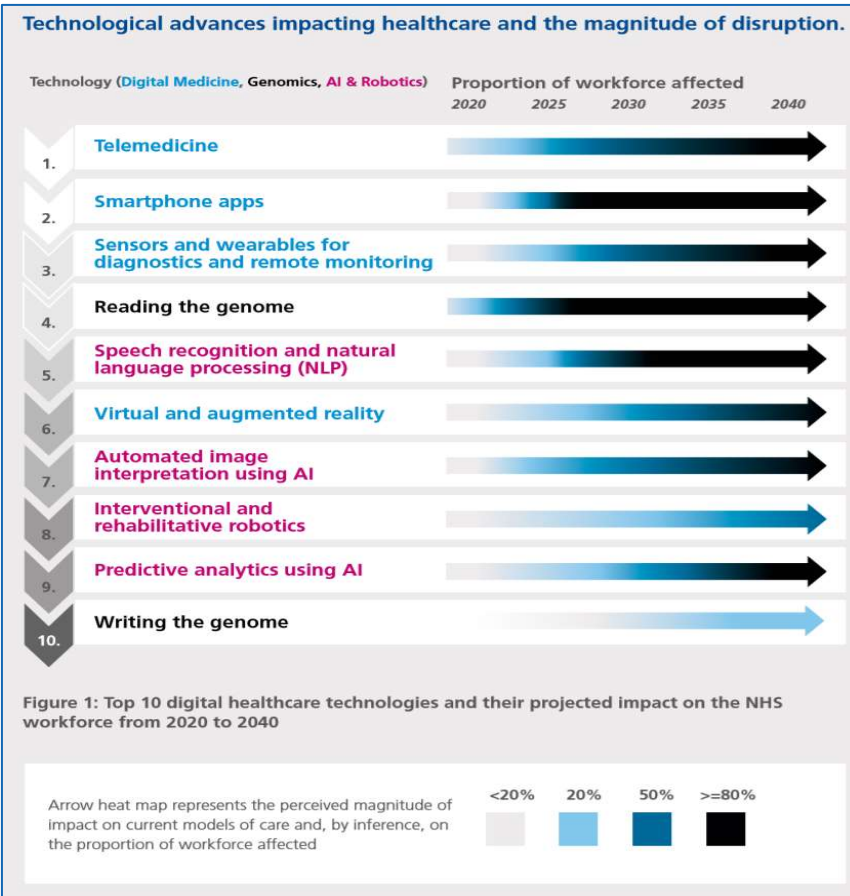
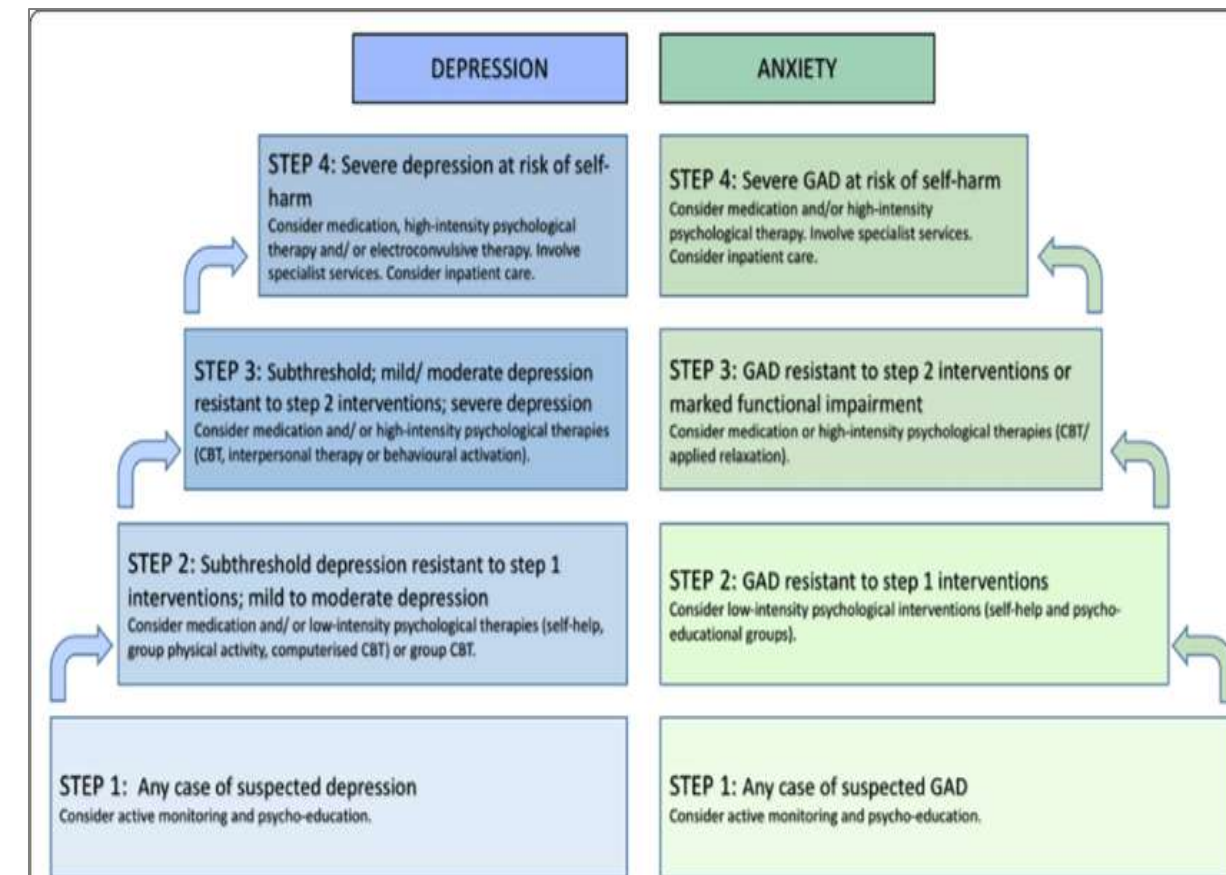
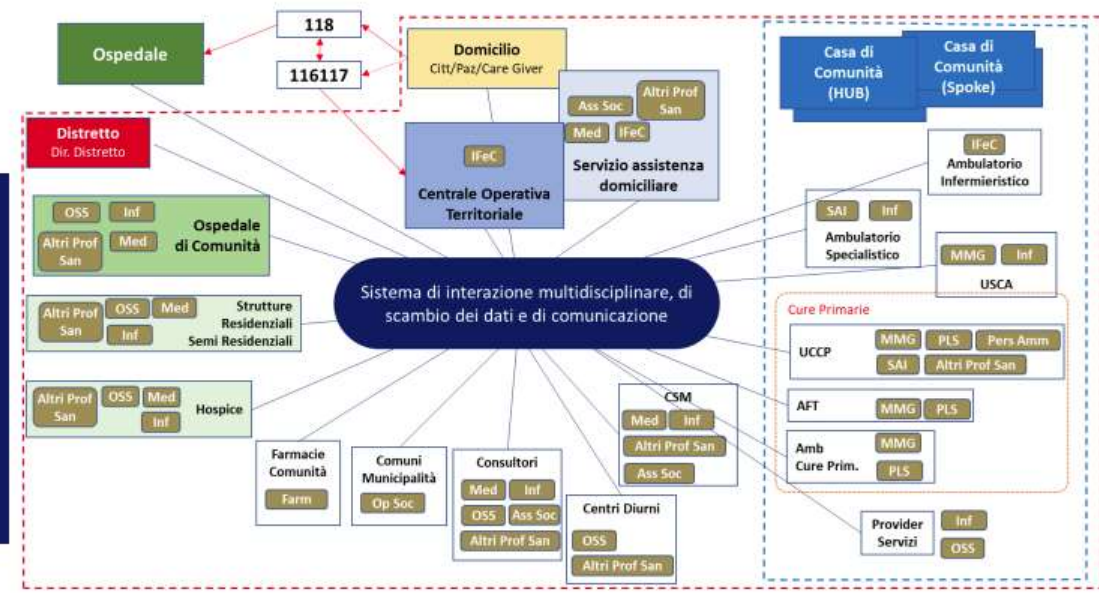


Figure 1. The ORBIT model for behavioral treatment development.

PNRR: riorganizzazione del territorio

- Infrastruttura di interoperabilità e cooperabilità fra unità funzionali e operatori
- Un sistema complesso in cui possono dialogare, in tempo reale, tutti gli attori attivi sul territorio



Una sfida a supporto del SSN

Costuire una **vision** di **AI-Augmentation** a supporto della pratica clinica nelle cure primarie



Pragmatic AI - Augmentation

	Automation technologies	Patient engagement technologies	Clinical decision support technologies
Key AI technologies	<ul style="list-style-type: none">• Computer vision• Machine learning• Natural language processing	<ul style="list-style-type: none">• Conversational Agents• Chatbots	<ul style="list-style-type: none">• Machine learning• Neural networks• Deep learning

Progettare, realizzare, validare un **ecosistema di DTx “pubbliche”** nelle cure primarie



Validazione intervento OMS sullo stress nel contesto delle cure primarie

Avviare studi di **RWE** nelle cure primarie



Screening, studi epidemiologici, PRO, PRE, ecc

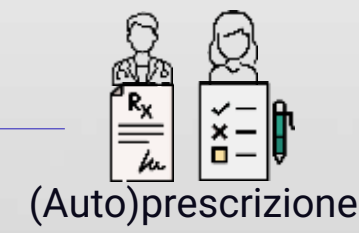
Pongono domande

Rispondono alle domande

Segnalano agli operatori sanitari



Un'ecosistema di assistenti personali



Propongono materiale informativo

Motivano al cambiamento



EMICRANIA



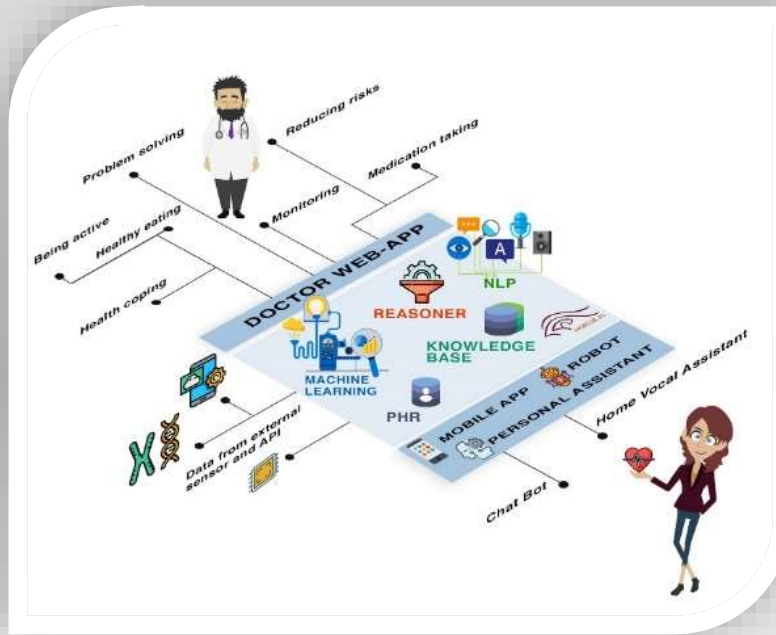
DOLORE CRONICO



Suggeriscono di contattare un operatore sanitario



BENESSERE MENTALE (ANSIA, DEPRESSIONE)



ALIMENTAZIONE & NUTRIZIONE



Raccolgono dati



STILI di VITA



Elaborano dati



Grazie dell'attenzione

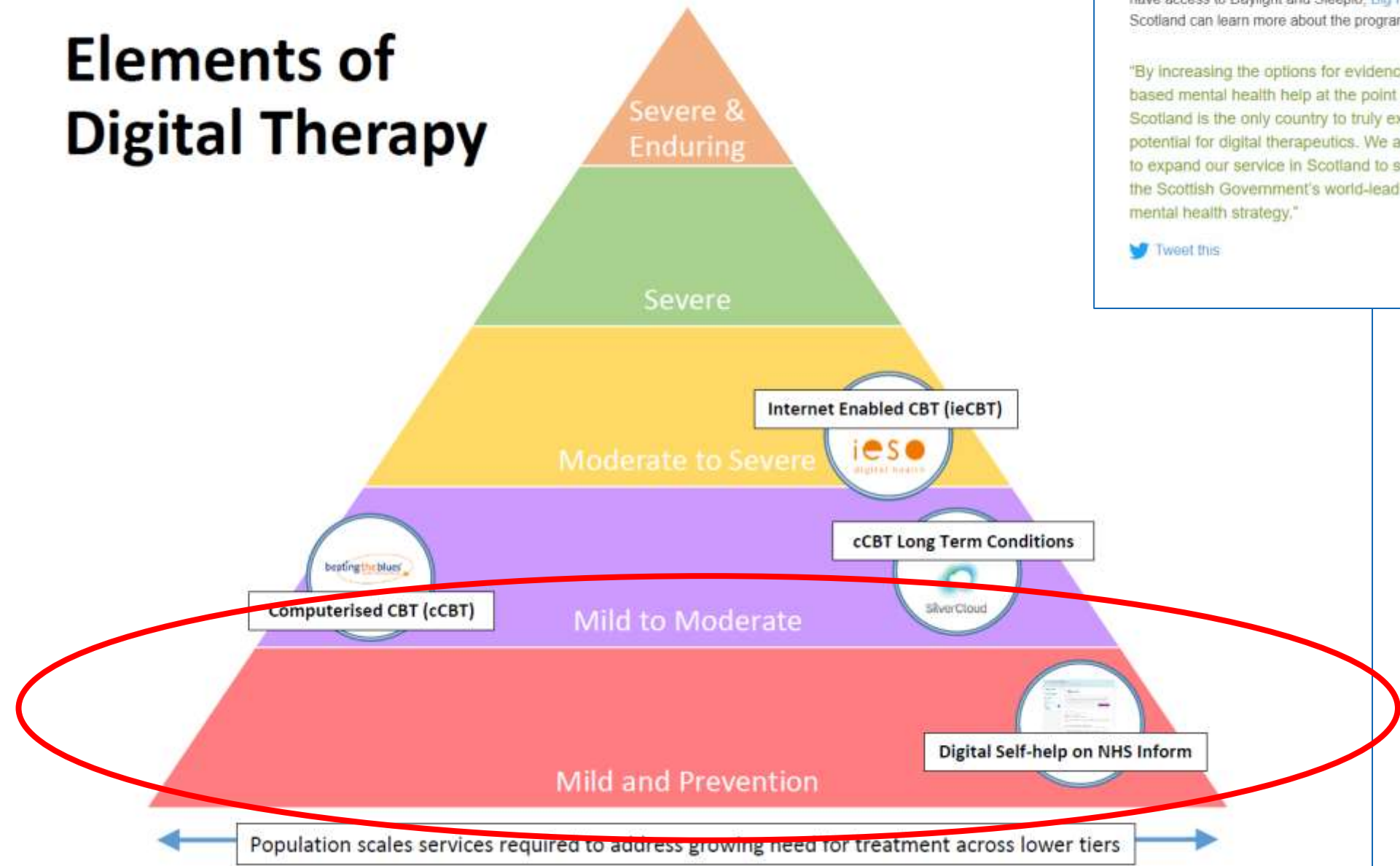
Discussione

Vision: Scottish strategy

Mental Health Strategy:
2017-2027



Elements of Digital Therapy



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Search

Scotland Becomes First Country *in the World* to make Digital Therapeutics for Anxiety and Insomnia Available Nationally

Through an expanded relationship, NHS Scotland will offer Big Health's digital therapeutics for anxiety and insomnia to all adults, providing more than five million people access to cognitive behavioural therapy

October 13, 2021 03:00 AM Eastern Daylight Time

LONDON & GLASGOW, Scotland--(BUSINESS WIRE)--The Scottish Government today announces that all adults living in Scotland have access to Daylight and Sleepio, Big Health's digital therapeutics for anxiety and insomnia, as part of their NHS services. People in Scotland can learn more about the programs and sign up for Daylight via self-referral [here](#) and Sleepio [here](#), or by visiting their GP

"By increasing the options for evidenced-based mental health help at the point of need, Scotland is the only country to truly exploit the potential for digital therapeutics. We are proud to expand our service in Scotland to support the Scottish Government's world-leading mental health strategy."

Through this new service, Scotland becomes the first country to implement fully digital solutions that provide instant help for anxiety and insomnia nationwide and at no cost to the user. People across all 14 NHS Scotland Health Board Areas will have 24/7 instant access to Big Health's digital therapeutics as the first-line treatment for anxiety and insomnia, effectively scaling access to care through the Computerised CBT (cCBT) & Digital Mental Health programme.

In October 2020, the Scottish Government made Daylight and Sleepio available across five NHS Health Boards. To date, nearly 70 percent of Big Health users in Scotland experienced an improvement in their anxiety symptoms and gained an average of seven additional hours of sleep per week.

Tweet this

DIGITAL MEDICINE & AI PER LA PREVENZIONE

Opzione o necessità per il SSN?

Il contesto

Sostenibilità del Sistema Sanitario Nazionale (SSN)
↓ Personale sanitario
↑ Domanda di servizi sanitari

Dati generati dal cittadino
Sensori + App + Cloud....

Importanti investimenti BigTech & BigPharma in Sanità
Grandi aziende tecnologiche e farmaceutiche stanno offrendo soluzioni e servizi sanitari basati su AI direttamente ai cittadini



L'uso



Applicazioni di AI

- Assistenti personali/coach virtuali
- Terapie digitali
- Modelli predittivi



Medicina «4P»

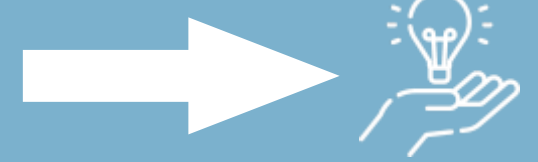
- 1) **p**redittiva
- 2) **p**reventiva
- 3) **p**ersonalizzata
- 4) **p**artecipata



Gestione cronicità

Empowerment del cittadino per la self-care

Digital Medicine-AI rappresenta una risorsa necessaria per il SSN nell'ambito della promozione della salute, del benessere mentale, della prevenzione



Automatizzazione di alcune attività attraverso un ecosistema di assistenti/coach virtuali prescrivibili dagli operatori sanitari e/o autoprescrivibili dai cittadini stessi



per stabilire l'efficacia e la sicurezza di un nuovo trattamento bisogna confrontare i dati di gruppi di pazienti quanto più uniformi possibile tra loro, che non presentino altre patologie o troppi "fattori confondenti", perché potrebbero alterare il risultato. In una parola, sono gruppi di pazienti "selezionati" e posti in situazioni "protette", ideali.

Si tratta sempre di pazienti reali, certo, ma questa selezione fa sì che le popolazioni di malati su cui viene testato un nuovo farmaco - così come un trattamento chirurgico o radioterapico - non corrispondano esattamente a quelle che si ritrovano in qualsiasi reparto di oncologia. Un esempio tra tutti: spesso vengono esclusi i pazienti anziani o fragili, che sono quelli più colpiti dalle malattie oncologiche, cancro al seno compreso.

Ecco perché i dati dei pazienti "ideali" degli studi clinici, fondamentali per arrivare all'approvazione del farmaco, hanno bisogno di essere integrati con i dati dei pazienti "reali". E proprio per questo si parla sempre più di Real World Data (RWD): ossia dati di pazienti di solito raccolti nelle cartelle cliniche elettroniche, nei database delle strutture sanitarie e nei registri di patologia. Su di questi si basano, a loro volta, i dati di Real World Evidence (RWE), e cioè le evidenze cliniche sull'uso, sui benefici e sui rischi di un determinato farmaco prescritto non più all'interno di uno studio clinico, ma nella vita di tutti i giorni.





Review

The Development and Use of Chatbots in Public Health: Scoping Review

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¹Centre for Policy Futures, University of Queensland, St Lucia, Queensland, Australia

²Department of Computer Science and Technology, University of Cambridge, Cambridge, United Kingdom

Corresponding Author:

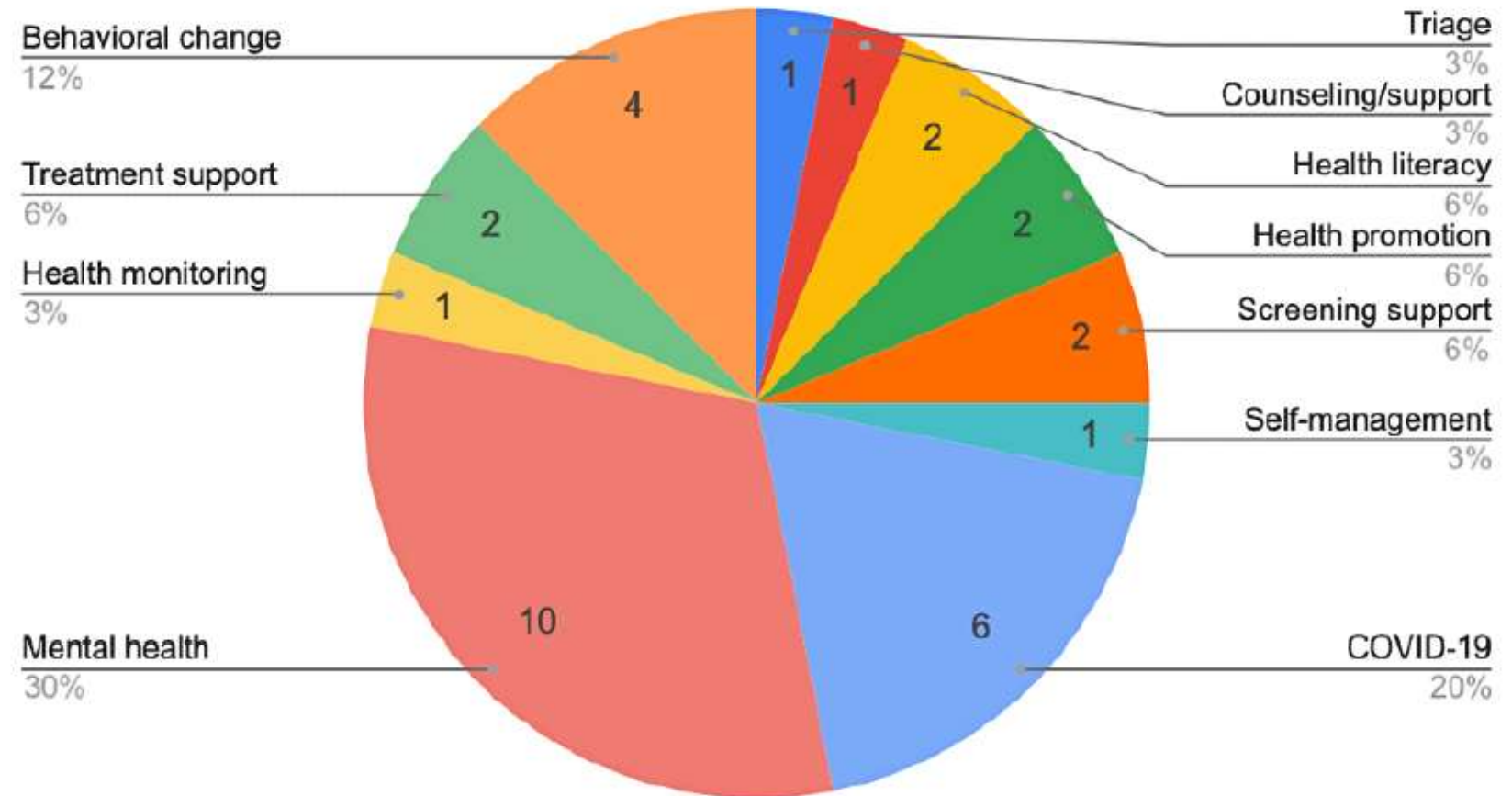
Lee Wilson, PhD
Centre for Policy Futures
University of Queensland
Level 3, Michie Building (9)
St Lucia, Queensland, 4072
Australia
Phone: 61 0795318198
Email: l.wilson7@uq.edu.au

Abstract

Background: Chatbots are computer programs that present a conversation-like interface through which people can access information and services. The COVID-19 pandemic has driven a substantial increase in the use of chatbots to support and complement traditional health care systems. However, despite the uptake in their use, evidence to support the development and deployment of chatbots in public health remains limited. Recent reviews have focused on the use of chatbots during the COVID-19 pandemic and the use of conversational agents in health care more generally. This paper complements this research and addresses a gap in the literature by assessing the breadth and scope of research evidence for the use of chatbots across the domain of public health.



Figure 2. Distribution of included publications across application domains. Mental health research and COVID-19 form the majority of the studies. Due to the small numbers of papers, percentages must be interpreted with caution and only indicate the presence of research in the area rather than an accurate distribution of research.



DTx in Primary care

JMIR FORMATIVE RESEARCH Ma et al

Original Paper

Developing Digital Therapeutics for Chronic Pain in Primary Care: A Qualitative Human-Centered Design Study of Providers' Motivations and Challenges

Kris Pui Kwan Ma¹, PhD; Kari A Stephens¹, PhD; Rachel E Geyer¹, MPH; Maria G Prado¹, MPH; Brenda L Mollis¹, MPH, MA, MPA; Susan M Zbikowski², PhD; Deanna Waters², MA, LMHC; Jo Masterson², RN, MBA; Ying Zhang¹, MPH, MD

¹Department of Family Medicine, University of Washington, Seattle, WA, United States
²Morrow Inc, Kirkland, WA, United States

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Email: krisma@uw.edu

Abstract

Background: Digital therapeutics are growing as a solution to manage pain for patients; yet, they are underused in primary care where over half of the patients with chronic pain seek care. Little is known about how to successfully engage primary care providers in recommending digital therapeutics to their patients. Exploring provider motivations in chronic pain management would potentially help to improve their engagement and inform the development of digital therapeutics.

.....

2023



Come raggiungere l'Obiettivo Strategico ?

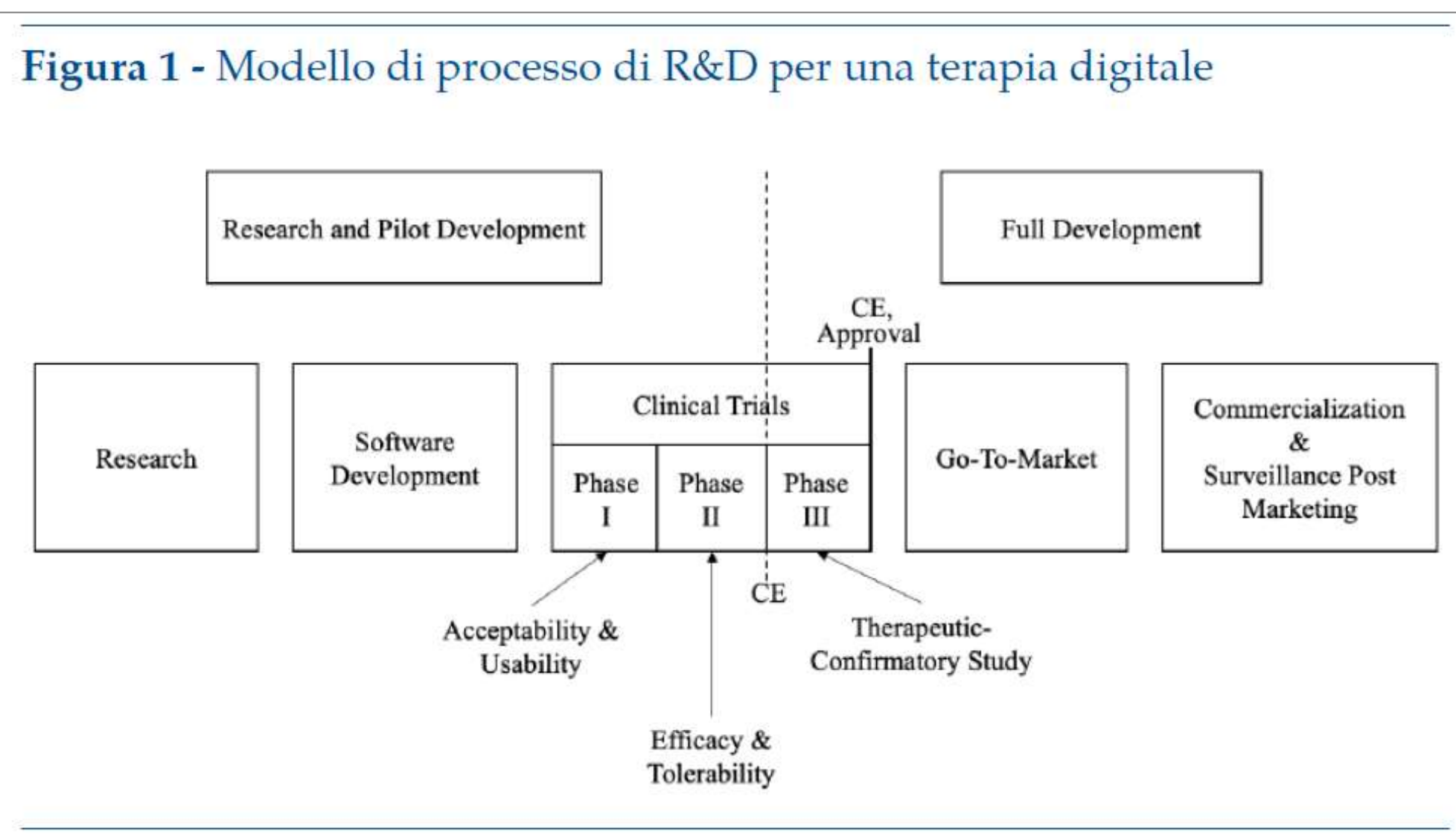
Progettazione e validazione di una DTx basata su un trattamento **OMS** di terapia cognitivo comportamentale (CBT) per la gestione dello stress



Casi di studio

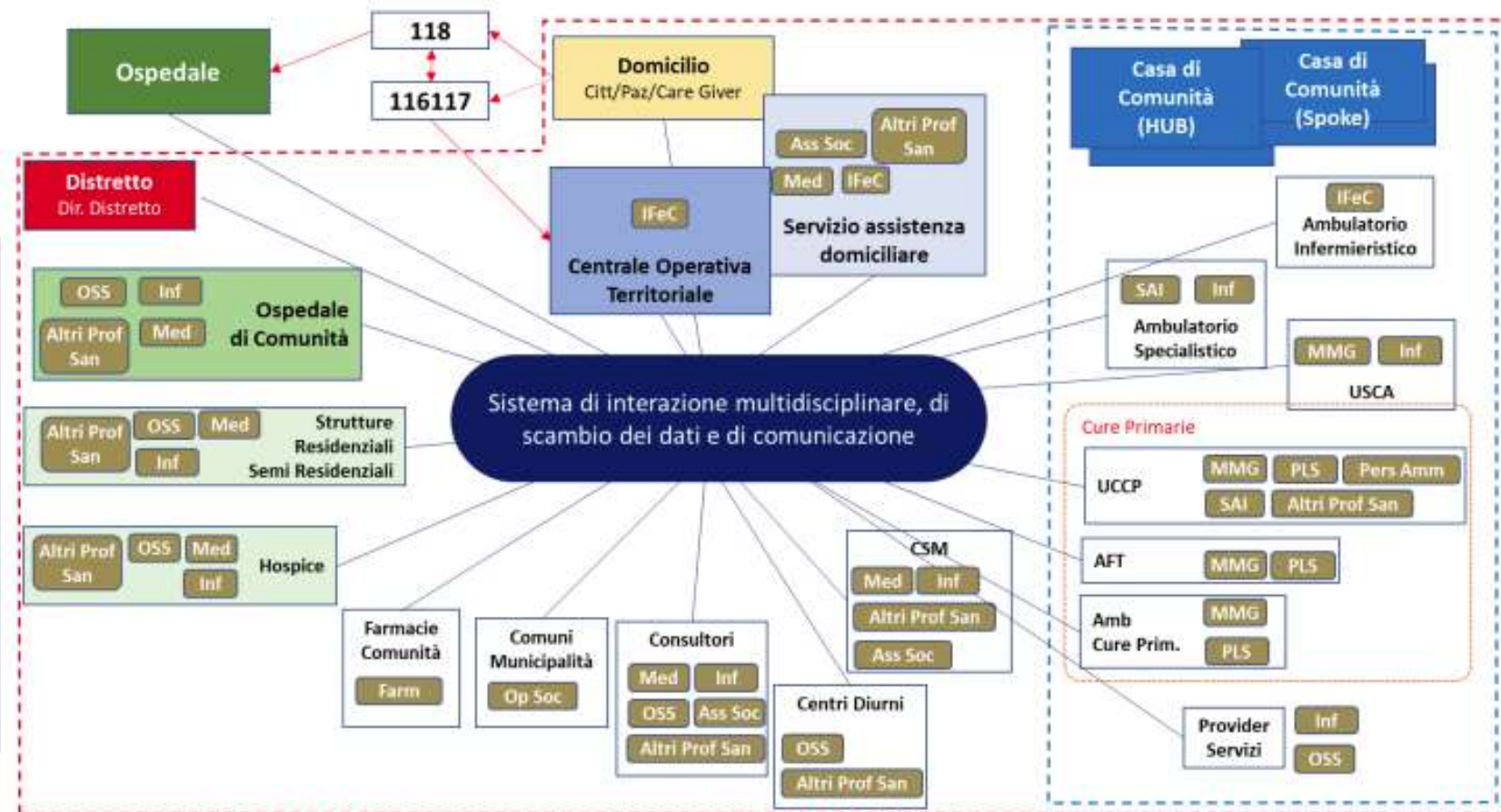
- Gestione del benessere mentale nelle donne in Gravidanza
- Gestione del benessere mentale in pazienti con Breast Cancer
- Altri setting (es. favorire benessere mentale nei luoghi di lavoro)

Figura 1 - Modello di processo di R&D per una terapia digitale



PNRR: riorganizzazione del territorio

- Infrastruttura di interoperabilità e cooperabilità fra unità funzionali e operatori
- Un sistema complesso in cui possono dialogare, in tempo reale, tutti gli attori attivi sul territorio



DM 77 – Le Case della Comunità

Standard:

1 Casa della Comunità Hub ogni 40.000 – 50.000 abitanti

- **Organizzazione capillare** su tutto il territorio
 - Struttura fisica in cui opera un **équipe multiprofessionale** di:
 - MMG e PLS
 - Medici specialisti
 - Infermieri di Famiglia e Comunità
 - Altri professionisti della salute
 - Può ospitare anche assistenti sociali
- Punto di **referimento continuativo per la popolazione** che permette di garantire la presa in carico della comunità di riferimento anche attraverso
 - Una infrastruttura informatica
 - Un punto prelievi
 - La strumentazione polispecialistica e diagnostica di base


**VERRANNO REALIZZATE 1350 CASE DELLA
COMUNITÀ HUB CON I FONDI PNRR**



DM 77 – Le Case della Comunità

Servizi	Casa della Comunità hub
Servizi di cure primarie erogati attraverso équipe multidisciplinari (MMG, PLS, SAI, IFeC, ecc.)	obbligatorio
Punto Unico di Accesso	obbligatorio
Servizio di assistenza domiciliare di livello base	obbligatorio
Servizi di specialistica ambulatoriale per le patologie ad elevata prevalenza	obbligatorio
Servizi infermieristici	obbligatorio
Sistema integrato di prenotazione collegato al CUP aziendale	obbligatorio
Integrazione con i Servizi Sociali per la cronicità	obbligatorio
Partecipazione della Comunità e valorizzazione co-produzione	obbligatorio
Presenza medica	obbligatorio h24, 7/7 gg
Presenza infermieristica	obbligatorio h12, 7/7 gg fortemente raccomandato h24, 7/7 gg
Servizi diagnostici finalizzati al monitoraggio della cronicità	obbligatorio
Continuità Assistenziale	obbligatorio
Punto prelievi	obbligatorio
Servizi Sociali alla persona e alla famiglia	fortemente raccomandato
Servizi per la salute mentale, le dipendenze patologiche e la neuropsichiatria infantile e dell'adolescenza	raccomandato
Medicina dello sport	raccomandato
Attività Consultoriali	raccomandato
Programmi di screening	facoltativo
Vaccinazioni	facoltativo

Medicina generale & Salute mentale

Un approfondimento su ...

L'integrazione tra medicina generale e servizi pubblici di salute mentale: rassegna della letteratura e dell'esperienza sul campo in tre Regioni italiane

The integration between Primary Care and Mental Health Services: review of the scientific literature and on-field experience in three Italian regions

SARA GEMIGNANI¹, VALDO RICCA^{1*}, GIUSEPPE CARDAMONE²
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¹SOD Complessa Psichiatria, AOU Careggi; Dipartimento Scienze della Salute, Università di Firenze

²Area Salute Mentale Adulti, Dipartimento Salute Mentale e Dipendenze, Azienda USL Toscana Centro, Regione Toscana

RIASSUNTO. Questo articolo vuole far luce sul problema, ancora irrisolto e tuttora molto discusso, dell'integrazione tra servizi di salute mentale e medicina generale nel nostro Paese. A questo scopo, dopo una breve rassegna della letteratura scientifica internazionale su alcuni modelli di integrazione tra questi due ambiti dei servizi sanitari, sono state prese in esame le esperienze realizzate in tre Regioni italiane (Lombardia, Emilia-Romagna e Toscana) con l'obiettivo di ottenere una migliore cooperazione in questo ambito della sanità pubblica.

PAROLE CHIAVE: medicina generale, servizi di salute mentale, modelli organizzativi, collaborative care, integrazione.

Tabella 1. Linee guida NICE (National Institute for health and Care Excellence) 2004 per la "stepped care".

Responsabile della cura	Focus	Trattamento
1. MMG e infermiere delle cure primarie	Riconoscimento di un problema mentale	Assessment
2. Gruppo delle cure primarie	Depressione lieve	Attesa vigilante, auto-aiuto guidato, esercizio fisico, brevi interventi psicologici
3. Gruppo delle cure primarie	Depressione moderata	Farmaci, interventi psicologici, supporto sociale
4. Servizi di salute mentale territoriali	Quadri resistenti, ricorrenti, depressione atipica o psicotica	Farmaci, interventi psicologici complessi, trattamenti combinati
5. Servizi di salute mentale ospedalieri	Situazioni ad alto rischio per la vita e per la cura di sé	Farmaci, trattamenti combinati