THE UNREALISED POTENTIAL OF DIGITAL THERAPEUTICS IN THE UK



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What is a Digital Therapeutic, or DTx?

"Digital therapeutics are evidence-based therapeutic interventions driven by high quality software programmes to prevent, manage, or treat a medical disorder or disease."

Digital Therapeutics Alliance

The current usage of health technologies across all age groups is higher now than in the past.

Current UK Usage – Patient / Consumer Perspective

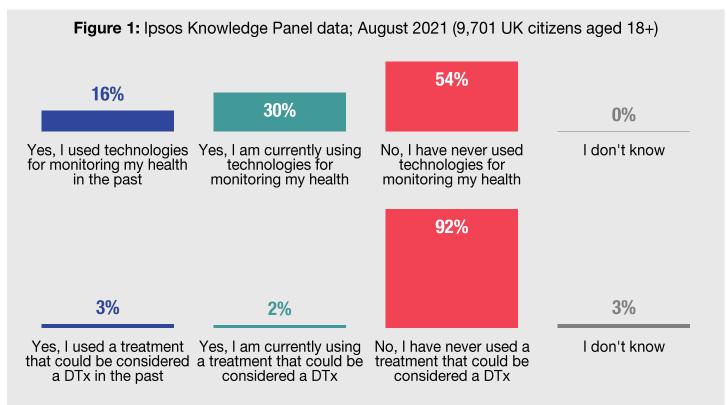
In a recent UK-wide Ipsos survey among adults aged 18+1, 1 in 2 (50%) stated that they have used some form of health technology either now or in the past. However, only 7% said that they are currently or have previously used a tool that can be considered a digital therapeutic (DTx). Even for those who have been diagnosed with a long-term condition such as diabetes, asthma or obesity (for which tools like these could arguably provide significant value due to the long-term care needed), the figure stands at just 5%.

In spite of this, a positive trend is apparent: according to our research, the current usage of health technologies across all age groups is higher now than in the past. The 2018 Connected Health Trends report from Ipsos²

² Ipsos Connected Health Trends Report, October 2018 (23,249 adults in 28 countries providing perceptual information online from May-June 2018): <u>Connected</u> <u>Health Trends 2018 | Ipsos</u>



¹ Ipsos Knowledge Panel; August 2021 (9701 UK citizens aged 18+ provided perceptual information online in August 2021)



Q202. Have you ever used any technologies for monitoring your health, such as wearables (e.g. Fitbits, smartwatches) or health apps (e.g. HealthyWage, MyFitnessPal)? Q203. Have you ever used a treatment that could be considered a digital therapeutic? Base: n=3,643

found that the use of connected health devices or tools amongst the consumer population was only 11% in Great Britain during both 2016 and 2018 – a vast difference from the 50% figure for use of health technologies in 2021. However, it is very clear that older generations with chronic health conditions use significantly fewer digital healthcare technologies (DHTs) than their younger counterparts. Our data shows that 61% of patients with a long-term disease, aged 55+ years, have never used digital technologies to monitor their health (compared to only 36% of those aged 18-34 years and 42% of those aged 35-54 years).

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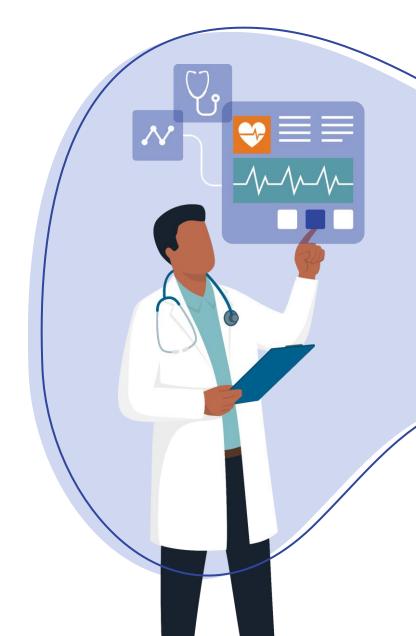
In Ipsos' Digital Doctor survey³, which explores healthcare professional (HCP) perceptions and adoption of health technology, 20% of sampled UK HCPs stated they had prescribed / recommended a DTx in 2021 versus 18% in 2020. Interestingly, the proportion of doctors in 2021 claiming not to know if they had prescribed or recommended a DTx had *increased* since the previous year. This suggests that doctors may still be unaware or unsure of what constitutes a DTx as the concept is relatively new and the definition is complex. New Ipsos data tracking this trend is due to release in March 2023.

In fact, there is not one international definition of digital therapeutics – although we like the one provided by the Digital Therapeutics Alliance, given on Page 2. Countries may have different definitions or categories of DTx, which may add to the confusion.

Megan Coder, Head of the Digital Therapeutics Alliance (DTA), told Ipsos that there is little surprise at the limited rise in adoption of DTx given what is needed to get to market. "Until there is more certainty in payer valuation frameworks and how patients will access the products via HCPs," Megan says, "then widespread adoption will take some time."

³ The Digital Doctor 2021 survey included a sample of 1,454 primary care physicians (PCPs) across 14 countries (UK, France, Germany, Italy, Spain, Brazil, USA, China, Russia, Turkey, India, Japan, Australia, South Korea). The survey was conducted online between 20 November 2020 to 22 February 2021. An extensive report covering a broad range of topics including digital therapeutics and artificial intelligence, among others, has been developed highlighting important trends to guide industry understanding of how best to support doctors in their digital health journey.

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Despite no real increase in adoption shown in the Digital Doctor results, there are other strong indicators that DTx is on a growth path, looking at the development in different countries. In the US, a national regulatory framework for digital health has been established and is being utilised. In Germany, a process was created in October 2020 for a framework to bring digital products to market. Here, HCPs have a full year to use the technology and evaluate data, with the final determination as to implementation and cost coming later. In the UK, an updated version of the evidence standards framework was published in August 2022 which provides evidence requirements for AI and data-driven technologies and aligns digital health technology classifications with regulatory requirements (see full details here: www.nice.org.uk/corporate/ecd7).

According to Reuters Pharma 2022, the situation is not dissimilar in Germany. Up to May 2022, of 130 applications made, only 31 were added to DiGA (Digital Health Applications) and prescription numbers were low - estimated to be around 50,000 last year, with only a 4% physician uptake⁴.

Availability of DTx in the UK

These advances in standards frameworks will provide important guidance to developers of DHTs, however there is a level of opacity when searching for the DTx's available and recommended for use by the NHS. The NHS

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app library, which was supported by Digital Assessment Questionnaires (DAQs), NICE endorsements, and the GP Systems of Choice (SoC) framework, was decommissioned in December 2021, leading to the catalogue of recommended apps and websites being spread through the NHS website. Whilst this has made identifying recommended apps comprehensively a challenge, our secondary research has identified a list of most DTx's approved by the NHS, as well as the DTx's which have received a CE marking, a key step in commercialising these therapeutics (please see Appendix).

It is unclear how or whether the NHS will sustain its previously structured approach to the evaluation of DTx in the UK after the decommissioning of the app library, but it is apparent that NICE is starting to bring a greater focus to emerging technologies, such as those found in the field of digital health.

⁴ www.reutersevents.com. (n.d.). Paving the payment path for DTx | Reuters Events | Pharma. Available online at: https://www.reutersevents.com/pharma/commercial/paving-payment-path-dtx [Accessed 27 Oct 2022]

Perhaps the most prominent and recognisable DTx in the UK is Sleepio, a digital sleepimprovement programme which uses cognitive behavioural therapy (CBT) approaches to drive health outcomes. Sleepio is one of the few DTx's in the UK to receive NICE recommendation after it was recommended for treatment of insomnia instead of prescription sleeping pills. The assessment of evidence of the digital health therapy Sleepio has recently (December 2021) been published in the British Journal of General Practice⁵: it was determined that over a 65- week follow up period, Sleepio users had a total cost saving of £70.44 each, on average, which was primarily driven by reductions in prescribing. It was also concluded that national rollout of this DTx could reduce primary care costs by £20 million, but this impact naturally correlates to uptake in different settings.

This is a good example of the evaluation of

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Digital Health Technology (DHT) Tier C interventions, clearly showing evidence of effectiveness relevant to the intended use(s) of the technology linked with evidence of economic impact relative to the financial risk and will certainly act as an example to DTx developers in bringing their products to the UK market under regulatory backing.

⁵ Sampson, C. et al (2021). Digital cognitive behavioural therapy for insomnia and primary care costs in England: an interrupted time series analysis. BJGP Open, Available online at: https://bjgpopen.org/content/early/2021/12/03/ BJGPO.2021.0146 [Accessed 27 Oct 22]

What do we need to do to unlock the potential of DTx?

The Ipsos Market Access Team has identified 5 top tips for achieving patient access to, and successful commercialisation of, DTx's:

1. Articulate the 'unmet human and system need':

- Consider the scale of status quo and perception of the change in need over time: need will trigger usage.
- b. Identify if it involves single or multi-point impact on the payer-to-patient pathway.
- c. Prioritise the health context most familiar and relevant to payers.

2. Know your 'customer':

- Understand how policy, level and source of funding, and requirements for assessment vary by countries/regions and level of sophistication (digital payer archetypes).
- Know their collective position on evidence requirements, benefits/risk, over-arching criteria for recommendation, willingness to pay (payer value drivers).
- c. Prioritise relevant payers aiming to make them 'champions' and 'influencers'.

3. Create a digital value story:

- a. Does the product address an unmet need and reduce uncertainties? i.e.
 Evidence (ECHO – Economic Clinical and Humanistic Outcomes) at hand.
- b. How is the DTx differentiated in terms of changing the status quo vs established competitors/comparators? (Price, Access).
- c. How relevant will it be in the current and future real world and marketplace? (Positioning, Uptake).
- d. Prioritise the key value messages matched with the payer value drivers.

4. Engage payers early in the process:

- a. Target payers early in the product life cycle with co-creation in mind, i.e., identify 'Digital Health Advocates'.
- Make it a credible, open and easy dialogue focusing on payers' objectives and concerns.
- c. It is not just about the product; the developer/manufacturer must be seen as a trusted advisor on a new/transformative service or within the appraisal process.
- d. Recognise that the payer could be government, patient, insurer or even pharma or patient.

5. Co-create solutions with customer feedback:

- Patient-centric design is as dear to payers as to the DTx developer. Patient Willingness to Use is a critical success factor.
- b. The process should be iterative so that payers feel a sense of ownership.
- c. Consider innovation test-beds for local pilots (e.g. Integrated Care Boards (ICBs) and AHSNs in the UK) are best launchpads for Proof of Concept (PoC).
 - England's 15 Academic Health Science Networks (AHSNs) were created by NHS England and operate as the NHS's key innovation arm. They work with patients, industry and the healthcare sector to facilitate patient access to the most effective digital solutions.
- d. Metrics/solutions should be scalable and sustainable, and may involve innovative contracting/tactical/strategic business models.

In conclusion, whilst current adoption (and understanding) of digital therapeutics is low among consumers, patients, and healthcare professionals, the regulatory efforts (in countries such as the UK and Germany), and the focus on evidence generation, hold great promise for the future of DTx as a category.

Fundamentally, the realisation of the potential of digital therapeutics in the UK requires some key aspects: awareness, availability and access; evidence of value, patient willingness to use, physician willingness to prescribe and payer willingness to pay. It will be important to keep a pulse on this evolving market and for companies to work collaboratively to raise awareness of DTx and communicate the benefits of these solutions.



Appendix: Digital Therapeutics Recommended by the NHS

(Note: This is based on Ipsos Secondary research and may not be a comprehensive list. Correct at time of publishing).

NHS Approved		
Deprexis	Online therapeutic support programme for depression. Available for reimbursement in some areas of the UK. https://deprexis.com/	
Oviva	Nutritional and lifestyle coaching programme for diabetes and obesity management. Offered as part of the NHS. https://oviva.com/uk/en/	
Togetherall	Online community for people who are stressed, anxious or feeling low. Provides an anonymous active forum with round-the-clock support from professionals and therapy sessions. NHS approved and partnered with a number of employers to provide free access to members.	
	https://togetherall.com/en-gb/	
MeeTwo	Online forum for teenagers to discuss any issues affecting their lives. Option to anonymously receive advice from experts or other teenagers going through similar experiences.	
	https://www.meetoo.help/	
Feeling Good	Mobile app which offers positive mental training audio programmes to lift mood or recover from stress, anxiety, and depression. Recommended for use by the NHS and free-of-charge.	
	https://www.feelinggood.app/	
Be Mindful	Online course guiding users through elements of mindfulness-based cognitive therapy to reduce stress, depression, and anxiety. NHS approved with out-of-pocket licensing fees. https://www.bemindfulonline.com/	
Cove	Mobile app wherein users create music to capture their mood and express how they feel before storing in a journal or sharing with others. http://www.cove-app.com/	

NHS Approved		
τιτο Αρβιονοά		
leso	Confidential online service which puts users in touch with mental health therapists trained in cognitive behavioural therapy. Free-of-charge in some areas of the UK.	
	https://www.iesohealth.com/how-it-works	
MyCognition Home	Brain training app to increase mental capacity, better focus and improve decision-making.	
	https://www.mycognition.com/	
Calm Harm	Mobile app designed to help manage the urge to self-harm. NHS approved and free of charge.	
	https://calmharm.co.uk/#about	
Bluelce	Mobile app to help people reduce urges to self-harm. This app is NHS approved is a prescribed intervention.	
	https://www.oxfordhealth.nhs.uk/blueice/overview/	
distract	Mobile app providing information and advice about self-harm and suicidal thoughts.	
	https://www.expertselfcare.com/health-apps/distract/	
Thrive: Feel Stress Free	Game-based mobile app to help prevent and manage stress and anxiety and educate users on methods to take control of these feelings.	
	https://thrive.uk.com/	
SilverCloud	Online course to help with managing stress, anxiety and depression. Topics are chosen by a user's therapist.	
	https://www.silvercloudhealth.com/uk	
FearFighter	Online course for people with phobias, panic or anxiety. Uses CBT and gradual exposure to drive outcomes.	
	https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-advice/IAPT/iab-fearfighter-adults-with-panic-agoraphobia-specific-phobia.pdf	
Chill Panda	Mobile app to reduce anxiety and improve wellbeing by suggesting tasks to suit users' state of mind.	
	http://chillpanda.co.uk/	

NHS Approved		
Sleep.io	Digital sleep-improvement programme using cognitive behavioural therapy (CBT) techniques. One of the few DTx's in the UK to receive NICE recommendation, as of writing.	
My Possible Self	Mobile app designed to educate users on managing fear, anxiety, stress and tackling negative thoughts. Offers symptom recording and tracking. https://www.mypossibleself.com/	
CE Marked		
Parallel	Prescription only CBT therapy for treatment of irritable bowel syndrome symptoms in adult patients. Recommended for evaluation in practice by NICE. https://www.mahanatx.com/press/mahana-therapeutics-obtains-ce-mark-for-parallel-tm-in-the-uk	
Oleena	Prescription mobile app for cancer patients to help them in symptom management and enable remote monitoring by care teams. https://oleena.com/	
EndeavorRX	Mobile-based video game treatment for children with ADHD. Currently being trialled in the US as the first and only FDA-authorised video game treatment for ADHD.	
	https://www.hcpendeavorrx.com/	
Daylight	Mobile app which uses CBT techniques to improve worry and anxiety problems in users. https://www.trydaylight.com/	
Lumi Nova	Video game-based digital therapeutic for childhood anxiety. Schools, GP or CAMHS service providers can purchase the game and provide access to affected children. https://luminova.app/	
Champions of the Shengha	Video game-based digital therapeutic for stress, anxiety and frustration which uses diaphragmatic breathing techniques to calm the user. https://www.bfb-labs.com/cots	

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You act better when you are sure.

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