

# Digital Mental Health's Unstable Dichotomy: Wellness and Health

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For at least the last decade, digital mental health technologies like smartphone apps, virtual reality, and wearables have been expanding in scope and potential. Today generative AI has joined the list of guided (coached) and unguided (self-help) digital tools that aim to deliver mental health interventions. A groundswell of interest and investment in these technologies underscores their potential to increase access to care and deliver scalable interventions. And yet the clinical benefits of these digital mental health technologies remain largely unrealized. How can research, investment, and innovation better align to improve mental health outcomes for patients? The first step is to move past the appealing narrative of a dichotomy between wellness and health devices. Today, wellness digital mental health technologies like mindfulness apps are often viewed as having no risks and exempt from requiring substantial data to prove efficacy given they are based on wellness principles. Medical digital mental health technologies like prescription therapeutics present the opposite scenario, often claiming substantial potential risk and presenting, often weak, efficacy data. As the field faces the next challenge of engagement, transparency in safety and efficacy rather than categorial wellness or medical labels will be critical to ensure future innovations are better able to engender trust, deliver benefits, and catalyze engagement.

In the wellness space, digital mental health technologies carry no risk as they are akin to wellness products. But nearly a decade in, evidence for harm from even these wellness-focused treatment tools is mounting. While few studies thoroughly report on harm today, as large-scale digital health studies become available they are revealing surprising results. In a 2022 study of nearly 19,000 people with frequent suicidal ideation, those randomized to an online low-intensity format of DBT had higher rates of non-fatal or fatal self-harm over the 18-month trial compared to control groups<sup>1</sup>. A lack of full awareness of potential harm may have led to the 2023 rollout of the Tessa chatbot for eating disorders by the National Eating Disorders Association without a clear safety plan – resulting in users taking to social media to beg that the chatbot be turned off before the association realized the full extent of harm. Privacy concerns have also become rampant, with the FCC commissioner calling for a probe into how the Crisis Text Line service shared users’ text messages with a sister for-profit AI company in 2022. Less visible harms such as inequities in digital access and digital literacy exclude vulnerable populations from receiving any potential benefits of digital mental health technologies. While the benefits of a wellness approach can ensure products reach users faster and are not slowed by regulation, the rate of dangerous products and concerning privacy practices also appears to be accelerating. Instead of assuming no risk, we need to discuss safety plans offered by digital mental health technologies that go beyond asking users to call helplines. We need to start reporting on harm so that we can create plans to minimize harm. Labeling a digital health treatment as wellness does not abnegate the need to ensure products are safe, private, and accessible to all.

For those digital mental health interventions that have taken a more medical approach, the focus is often on proving their product is evidence-based. However, the current quality of that evidence is often limited even for those digital mental health technologies that have attempted to seek formal FDA clearance as medical devices. An analysis of clinical studies conducted on digital health products authorized by the FDA as of November 2022 found the majority lacked rigor with most conducted on a post-market bias, without blinding or digital control group, and self-funded by manufacturers<sup>3</sup>. In 2022, CMS noted they would not provide automatic Medicare coverage, noting even FDA-cleared devices often lacked sufficient patient protection and

evidence of clinical benefit<sup>4</sup>. Concerns about research quality apply broadly, with text messaging interventions also criticized for having lower quality research and inconclusive results regarding benefits in depression or anxiety<sup>5</sup>. Nonetheless in November 2023, New York City signed a \$26 million contract with a text messaging-based company to increase access to mental health services for youth, highlighting that clinical efficacy is likely not yet the prime driver in business or use decisions. Without stronger clinical evidence, the current digital mental health technology ecosystem appears to compete today based more on marketing than scientific evidence. The dangers of relying on this approach are highlighted in a 2022 review of digital health startups which found no correlation between their clinical robustness and either the number of clinical claims or total funding raised<sup>2</sup>. Now is the time to demand the evidence and look beyond marketing to ensure the quality of research matches the highest scientific standards. Systematic scientific work will likely yield more rapid progress than the current fragmented product-focused ecosystem that competes more like wellness than the healthcare industry.

While wellness products are not inherently safe and medical ones not inherently efficacious, a common challenge unites them and also underscores the need to remove the false dichotomy between wellness and medical digital mental health technologies: engagement. During the height of COVID-19, the city of Reno Nevada spent \$1.3 million for a text-messaging-based offering for its residents but opted not to renew the contract, with reports that only 0.5% of residents engaged with the service. This engagement challenge is ubiquitous in digital mental health technologies and has been well-known for at least the last 20 years. With the lack of success of any digital means, even gamification, to transform engagement there has been a recent turn to coaches, often called digital navigators<sup>6</sup>, to support technology use. The effects can be striking. In one study with this human support included, an app was reported to be effective for both depression and anxiety<sup>7</sup> but when offered during the height of COVID-19 to ~50,000 college students without human support and study incentives, only 117 downloaded that same app<sup>8</sup>. These engagement challenges are still poorly understood with a 2022 systematic review and meta-analysis of non-clinician guidance on the effectiveness of digital mental health interventions suggesting the potential of human support<sup>9</sup> and formalized digital mental health intervention coaches in the role of digital navigators gaining traction<sup>10</sup>.

The current dichotomy between wellness and medical digital mental health technologies for treatment has likely resulted in harm to patients, uncertainty about impact, and a lack of scientific progress. Focusing less on this dichotomy and instead on safety, evidence, and engagement will set the stage for the next phase of digital mental health technologies. Not all digital mental health technologies need to move away from wellness or involve formal FDA oversight (tools could still argue for ‘enforcement discretion’ based on evidence of low risk). Towards the goal, we provide the following suggestions:

Patients and clinicians should not assume wellness digital health technologies are always dangerous nor should they assume health ones are always safe. Instead, they should demand rigorous clinical study data (with digital control conditions) in addition to real-world use data.

Payers should compensate digital health technologies with risk-based contracts, based on engagement and clinical outcomes instead of fixed-price contracts based on access to the technology.

Regulators should better enforce the delineation of health and wellness products and discourage the current trend of products skating the line between both.

Researchers should focus on replicable and mechanistic outcomes for digital health technologies instead of focusing on individual products.

All parties should support and encourage digital equity through concomitant efforts to support digital access, digital literacy, and digital navigators so that everyone has the chance to benefit.

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