



Defining, Clarifying, and Implementing Digital Health Tools

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Objectives

Define digital health tools



Clarify the application of digital tools in mental health treatment



Outline the implementation of digital tools in clinical practice



Define Digital Health Tools

Prevalence of Mental Illness in the US



52.9 million US adults (**21.0%**) had a mental illness in 2020¹



Only **46.2%** of those with a mental illness received mental health services in 2020¹



In 2020, **~21.0 million** adults (**8.4%**) had ≥ 1 major depressive episode²

US, United States.

1. National Institute of Mental Health. Mental Illness. Jan 2022. <https://www.nimh.nih.gov/health/statistics/mental-illness>. Accessed May 27, 2022.

2. National Institute of Mental Health. Major Depression. Jan 2022. <https://www.nimh.nih.gov/health/statistics/major-depression>. Accessed May 27, 2022.

Access to Adequate Mental Health Treatment Is Insufficient; Digital Tools Can Help

Patients experience many barriers to accessing mental health care¹⁻⁸



Digital tools can improve access to mental health care^{2,6,9,10-15}









1. Ofonedu ME et al. *J Child Fam Stud*. 2017;26(3):863-876.
2. Mongelli F et al. *Focus (Am Psychiatr Publ)*. 2020;18(1):16-24.
3. Andrilla CHA et al. *Am J Prev Med*. 2018;54(6 Suppl 3):S199-S207.
4. Khalifeh AH et al. *J Psychosoc Nurs Ment Health Serv*. 2021;59(1):39-51.
5. Arnaez JM et al. *J Ment Health*. 2020;29(2):182-190.

6. Stubbe DE. *Focus (Am Psychiatr Publ)*. 2020;18(4):424-427.
7. Saxon V et al. *J Ment Health Clin Psychol*. 2018;2(3):23-26.
8. Wakida EK et al. *Syst Rev*. 2018;28;7(1):211.
9. Toll ET et al. *JAMIA Open*. 2019;2(3):282-290.
10. Larrison CR et al. *J Behav Health Serv Res*. 2018;45(1):133-142.

11. Torous J et al. *J Technol Behav Sci*. 2019;4:73-85.
12. Patel NA and Butte AJ. *NPJ Digit Med*. 2020;3:159.
13. Dang A et al. *J Fam Med Prim Care*. 2020;9:2207-2213.
14. Friis-Healy et al. *JMIR Ment Health*. 2021;8(1):e25456.
15. Powell AC et al. *BJPsych Open*. 2020;6(2):e16.

Digital Solutions in the US

	Digital Health	Digital Medicine	DTx	
			Nonprescription DTx  	Prescription DTx (PDT)  
Definition	All technologies that engage patients in their health and well-being (eg, smart devices, telehealth, wearables, apps) ¹	Evidence-based technologies to measure and intervene in the service of human health (eg, remote patient monitoring devices, digital diagnostics, digital biomarkers) ^{1,2}	Evidence-based therapeutic interventions (driven by software) to manage a medical condition (eg, apps, digital sensors, games to improve behavioral functioning) ¹⁻⁴	Evidence-based therapeutic interventions (driven by software) to manage or treat a medical condition (eg, apps, digital sensors, games to improve behavioral functioning) ¹⁻⁴
Regulatory Oversight	Not subject to FDA review ⁴	FDA review/approval depends on product ^{4,5}	Subject to regulation by the FDA ^{1,5}	Regulated and cleared by the FDA ^{1,5}
Clinical Evidence	Not required ⁴	Required ⁴	Required ^{1,4,5}	Required ^{1,4,5}

DTx, digital therapeutics; FDA, Food and Drug Administration, PDT, prescription digital therapeutic; US, United States.

1. Dang A, et al. *J Family Med Prim Care*. 2020;9(5):2207–2213.
2. Coravos A, et al. *Digit Biomark*. 2019;3:31–71.
3. Chung JY. *Transl Clin Pharmacol*. 2019;27(1):6–11.

4. Digital Therapeutics Alliance. Digital Health Industry Categorization. Nov 2019. https://dtxalliance.org/wp-content/uploads/2019/11/DTA_Digital-Industry-Categorization_Nov19.pdf. Accessed May 26, 2022.
5. Hong JS, et al. *Comput Methods Programs Biomed*. 2021; 209:106319.

Clarify the Application of Digital Tools in Mental Health Treatment

Digital Health Tools From the HCP's Perspective

Digital tools can factor into a patient's mental health care plan in several ways¹⁻¹¹

Diagnostics

Examples include:

- Computer tablet at a clinic visit to screen patients for suicidal thoughts¹
- Wearables-derived data associated with cardiovascular risk markers²

Therapeutics

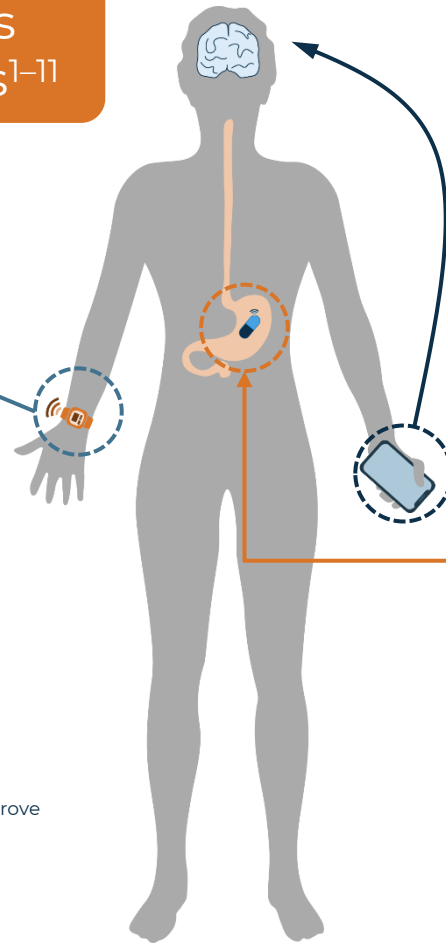
Examples include:

- CBT for patients with chronic insomnia³
- Video game-based treatment for children with ADHD⁴

Monitoring

Examples include:

- Electronic health records to coordinate care¹
- Pills with embedded electronic sensors that detect when a pill was ingested⁵
- Smartphone apps for patients to self-record mood and energy levels⁶



ADHD, attention-deficit/hyperactivity disorder; CBT, cognitive behavioral therapy; FDA, Food and Drug Administration; GPS, global positioning system; HCP, health care provider.

1. Falconer E et al. *Neuropsychiatr Dis Treat.* 2018;14:2337-2349.
2. Zhou W et al. *J Med Internet Res.* 2022;24(7):e34669.
3. Morin CM. *Expert Rev Med Devices.* 2020;17(12):1239-1248.
4. FDA News Release. FDA Permits Marketing of First Game-Based Digital Therapeutic to Improve Attention Function in Children with ADHD. June 15, 2020.
5. Aldeer A et al. *Applied System Innovation.* 2018;1:14.
6. Rajagopalan A et al. *Brain Sci.* 2017;7:150.
7. Dang A, et al. *J Family Med Prim Care.* 2020;9(5):2207-2213.
8. Hilty DM et al. *J Technol Behav Sci.* 2021;1:26.
9. Umbricht D et al. *Front Psychiatry.* 2020; 11:574375.
10. Corden ME et al. *Digit Health.* 2016; 2:2055207616663069.
11. Waltz E. *Nat Biotechnol.* 2018 Jun 6;36(6):481-482.

Evaluating Digital Tools From the HCP's Perspective

Digital tools should be able to integrate into existing clinical care workflows¹

What might HCPs consider for digital tools?

- Coverage by standard malpractice insurance²
- Data privacy / security assured by EHR vendor and by HCP's own practice or hospital²
- Reimbursement for time spent using digital tools²

What do HCPs want from digital tools?

- Improved work efficiency²
- Increased patient safety²
- Enhanced or more accurate diagnostic abilities²
- Reduced stress and burnout²
- Better quality of patient-HCP relationships²

How will the digital tool be used?

- Interactions outside of clinic visits³
- Synchronously or asynchronously used³
- Integration with clinic workflows and health care systems¹
- Established plan for patient emergencies³

EHR, electronic health record; HCP, health care provider.

1. Mathews SC et al. *npj Digit Med*. 2019 May 13;2:38.

2. American Medical Association. Digital Health Study. Physicians' motivations and requirements for adopting digital clinical tools. 2020. <https://www.ama-assn.org/system/files/2020-02/ama-digital-health-study.pdf>. Accessed August 22, 2022.

3. Stubbe DE. *Focus (Am Psychiatr Publ)*. 2020;18(4):424-427.

Evaluating Digital Tools From the Patient's Perspective

Digital health tools should demonstrate real-world applicability and usability¹

What might patients consider for digital tools?

- Products that are **safe** and **effective**²
- To be given appropriate **informed consent**^{2,3}
- Ongoing **optimization** and analysis of tool performance²
- Product and provider compliance with **privacy** and **security** standards^{2,3}

What do patients **want** from digital tools?

- To understand the tool's intended **purpose**, main **features**, potential **benefits**, and possible **risks**³⁻⁵
- **Interactive elements**⁴
- Ease of navigation⁴
- Readability⁴
- **Easier access** to their data⁶

How will the digital tool be used?

- Accessible on a **range of platforms**⁴
- Option to **communicate with providers** to share questions and concerns⁷
- Data can be collected **passively or actively**^{8,9}

1. Mathews SC et al. *npj Digit Med*. 2019 May 13;2:38.

2. Digital Therapeutics Alliance and Health Advances, LLC. Guidance to Industry: Classification of Digital Health Technologies. June 2023. <https://dtxalliance.org/wp-content/uploads/2023/06/Guidance-to-Industry-Classification-of-Digital-Health-Technologies-2023Jun05.pdf>. Accessed August 18, 2023.

3. Stubbe DE. *Focus (Am Psychiatr Publ)*. 2020;18(4):424-427.

4. Patel S et al. *J Med Internet Res*. 2020;22:e16228.

5. Mordecai D et al. *NEJM Catalyst Innov Care Deliv*. 2021;1:2(1).

6. Pew Trusts. Most Americans Want to Share and Access More Digital Health Data. <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/07/most-americans-want-to-share-and-access-more-digital-health-data>. Accessed August 22, 2022.

7. Rajagopalan A et al. *Brain Sci*. 2017;7:150.

8. Hategan A et al. *J Technol Behav Sci*. 2019;4:171-177.

9. Ben-Zeev D. *Psychiatr Serv*. 2017;68:107-108.

How Can Digital Tools Enhance Mental Health Care?

Patient Perspective

Provide education/information on condition and care plans^{1,2}

Reinforce behavioral changes^{1,3}

Aid in self-monitoring¹

Increase access to care (24/7 access)^{1,3,4}

CARE MENU

Health & Wellness Apps

Suggested Apps

Monitoring & Self-Assessment Apps

Telehealth/DTx

In-person Visit

HCP Perspective

Increase clinical efficiency⁵

Strengthen HCP-patient relationship⁴

Improve clinical outcomes such as^{5,6}:

- Symptomology and functioning^{5,6}
- Patient hospitalizations⁶

Provide remote care^{5,6}

- Send and receive health care data, monitor patient status, provide evidence-based care

DTx, digital therapeutics; HCP, health care provider.

1. Birnbaum F, et al. Acad Emerg Med. 2025;22(6):754-756.
2. Polillo A, et al. JMIR Ment Health. 2021;8(5):e24567 doi: 10.2196/24567.
3. Torous J, et al. JAMA Network Open. 2020;3(7):e2010918 doi:10.1001/jamanetworkopen.2020.10918.
4. Presti LL, et al. Sustainability. 2019;11,220 doi:10.3390/su11010220.

5. Henry TA. AMA. 5 insights into how physicians view, use digital health tools. October 2022. <https://www.ama-assn.org/practice-management/digital/5-insights-how-physicians-view-use-digital-health-tools>. Accessed May 26, 2023.
6. Hatch A, et al. JMIR Ment Health. 2018;5(2):e46 doi: 10.2196/mental.9777.

Considerations for Implementing Digital Tools

- HCPs should consider **patient disposition** and **ability to interact** with the given tools
 - Ideal candidates are patients who are:
 - Highly motivated^{1,2}
 - Functioning well in their occupations¹
 - Able to access required resources^{1,2}
 - Interested in utilization of new technology^{1,2}
 - Digital tools may not work as well for patients who:
 - Have limited digital literacy or access to devices or charging³
 - Need the tool in a different language than is offered⁴
 - Do not have insurance coverage¹
 - Have more severe symptoms or substance use struggles¹
- Patients should have a thorough understanding of the potential risks, including privacy breaches, issues with trust or misunderstandings, and technical problems⁵



HCP, health care provider.

1. Hatch A, et al. *JMIR Ment Health*. 2018;5(2):e46 doi: 10.2196/mental.9777.

2. Birnbaum F, et al. *Acad Emerg Med*. 2025;22(6):754–756.

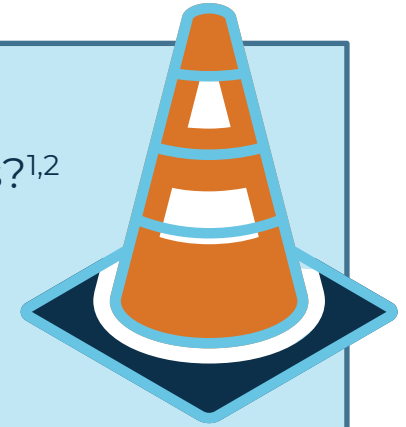
3. Torous J et al. *JMIR Ment Health*. 2020;7(3): e18848.

4. Hoffman L et al. *Front. Psychiatry*. 2019;10:94.

5. Stubbe DE. *Focus (Am Psychiatr Publ)*. 2020;18(4):424–427.

Outline the Implementation of Digital Tools in Clinical Practice

Factors That Can Challenge Integration of Digital Tools



Feasibility considerations

- How will the digital tool fit in with daily clinical care?¹
- Will it increase administrative time?¹

Ethical implications

- Have informed consent documents been implemented consistently?^{2,3}
- How can HCP-patient boundaries be maintained?²

Cultural considerations

- What ethnic, racial, and socioeconomic factors may impact how care is offered and received?²

Legal requirements

- What are the practice guidelines?^{1,2}
- What are the local or regional practice guidelines?²
- What issues of privacy, security, and HIPAA / HITECH laws need to be considered?^{1,2}

Potential risks of digital tool usage

- What are the limits of the tool's technology?^{2,4}
- How can you ensure patient adherence?³
- How will you be reimbursed?⁵
- Will the tool adversely affect patient lifestyle?⁶

HCP, health care provider; HIPAA, Health Insurance Portability and Accountability Act; HITECH, Health Information Technology for Economic and Clinical Health.

1. Stubbe DE. *Focus (Am Psychiatr Publ)*. 2020;18(4):424–427.

2. Mishkind M. Apps & eHealth Programs for Mood Disorders. National Network of Depression Centers 12th Annual Conference. *Advances In Psychiatry: COVID-19 And Beyond*. Virtual Meeting. October 2, 2020. <https://nndc.org/wp-content/uploads/2020/10/Matt-Mishkind-2020-NNDC-Conference.pdf>. Accessed August 22, 2022.

3. Coravos A et al. *Digit Biomark*. 2019;3:31–71.

4. Gordon WJ et al. *npj Digital Medicine*. 2020;3:14.

5. IQVIA. *Digital Health Trends 2021: Innovation, Evidence, Regulation, and Adoption*. July 2021. <https://www.iqvia.com/insights/the-iqvia-institute/reports/digital-health-trends-2021>. Accessed January 31, 2022.

6. Patel S et al. *J Med Internet Res*. 2020;22:e16228.

Implementing Digital Health Tools: A Role for Digital Navigators?

- Human support for technology is an unmet need that **can help bridge the gap** between individuals and HCPs, support technology users, and improve clinical outcomes^{1,2}

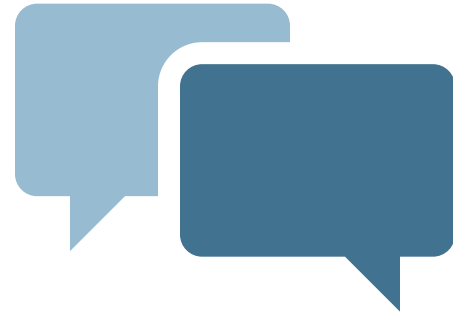


- A **digital navigator** is a newly proposed role within the care team, who aims to³:
 - Help select evidence-based apps
 - Create clinically meaningful summaries of patient app data
 - Troubleshoot technology issues for patients

HCP, health care provider.

1. Ben-Zeev D. *Psychiatr Serv.* 2017;68:107–108.
2. Dopke CA et al. *JMIR Form Res.* 2021;5:e25810.
3. Connolly SL et al. *Curr Psychiatry Rep.* 2021;7:23(7):38.

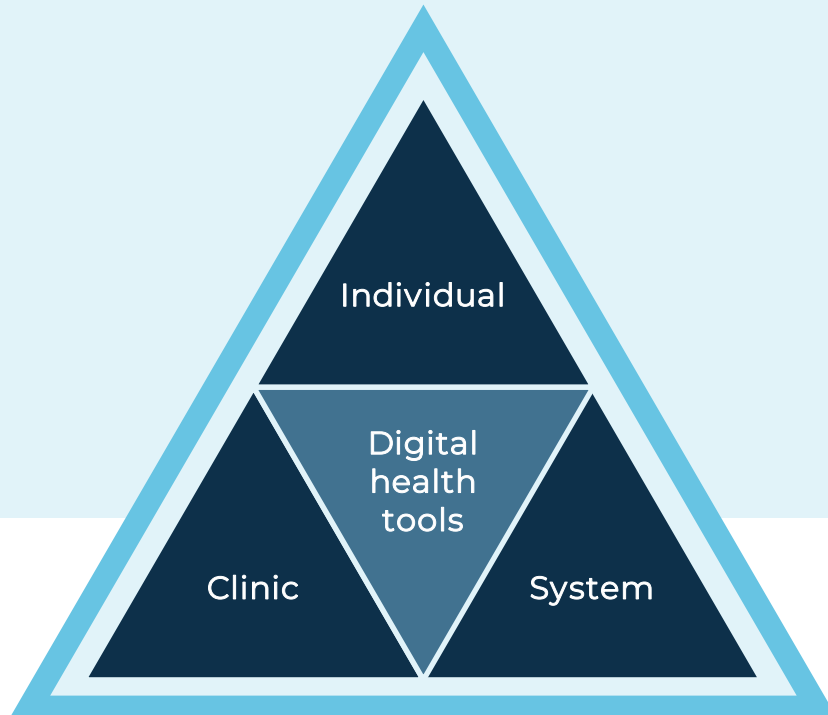
How are digital tools currently used in practice?



What hurdles or strategies have you considered for implementation?

HCP Setup and Utilization of Digital Tools

Integrated care: Always evolving^{1,2}



EHR, electronic health record; HCP, health care provider.

1. Torous J, et al. *World Psychiatry*. 2021 Oct;20(3):318–335.

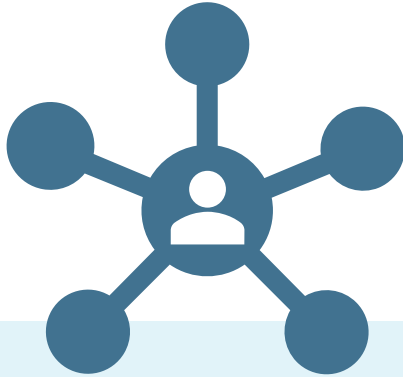
2. Emerson MR, et al. *Transl Behav Med*. 2023 Aug 11;13(8):612–623..



Technical tips: Split-screen setup

- EHR and workflow tabs **side-by-side**
- Ready access to information **during the visit**
- Central floating camera appears patient-side as if you are **face-to-face**

Flowchart of Workflow Integration

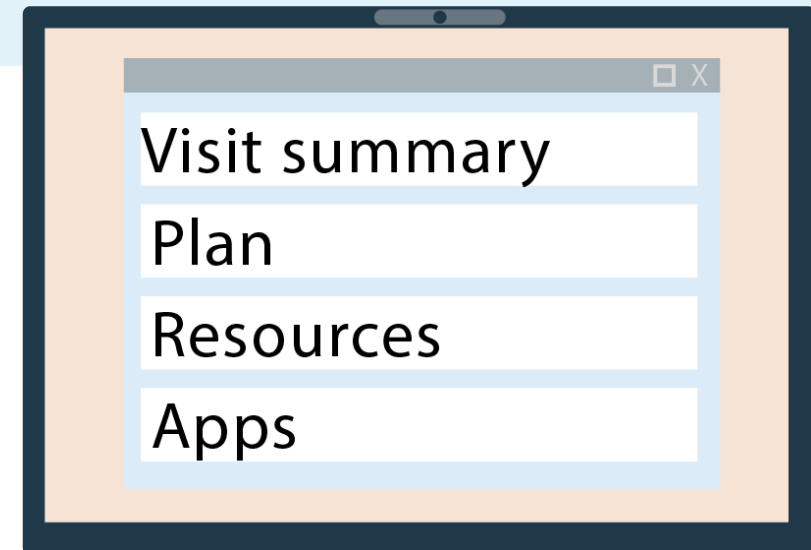


Example of how Dr Emerson builds a digital tool care team

- Overcome technical and time constraints to maximize utilization of care team
- Trained nurses may fill the role of digital navigators
- Social workers can further guide patients on app options and answer queries

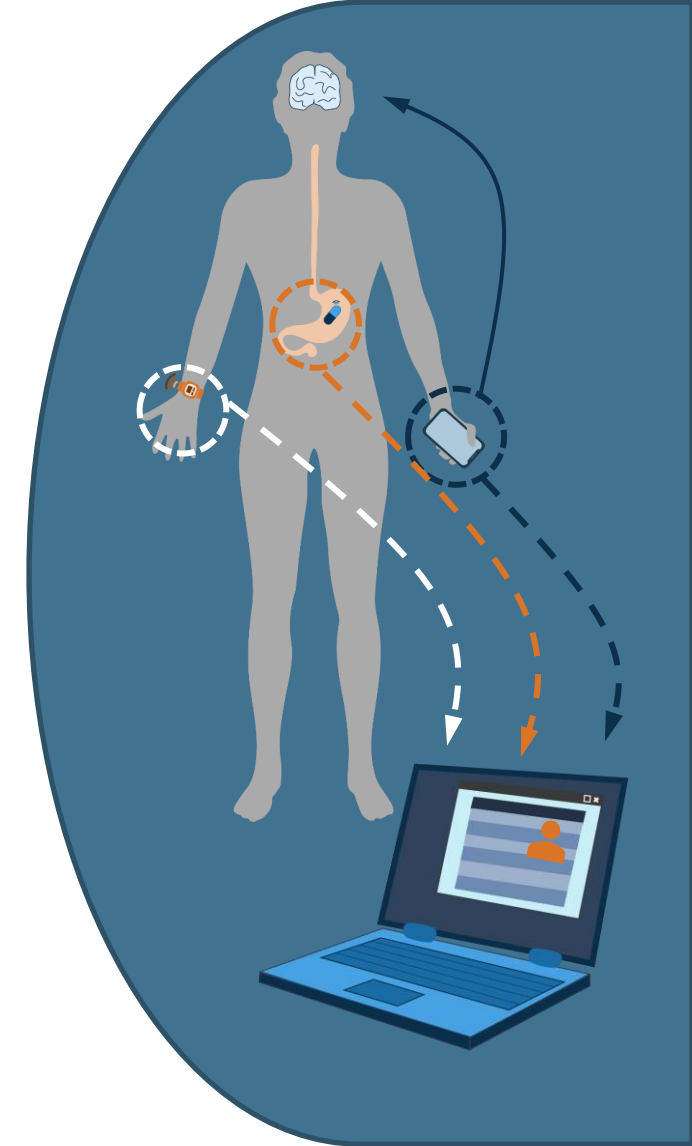
Example of how Dr Behrens integrates digital support

- Include rich text within the “Visit Summary”
- Hyperlinks within for patients to access additional information



Summary

- Digital tools can help **address unmet needs** in accessing mental health treatment¹
- **A wide variety** of digital health tools exist^{2,3}:
 - Health and wellness apps
 - Patient monitoring and assessment tools
 - Digital therapeutics
- To guide successful implementation⁴⁻⁶:
 - Determine patients who **want** digital tools as part of their care
 - Confirm **necessary staff/IT support** to integrate digital tools into clinical workflow
 - Develop agreed upon **goals and communication frequencies**



IT, information technology.

1. Dang A et al. *J Fam Med Prim Care*. 2020;9:2207–2213.

2. Digital Therapeutics Alliance and Health Advances, LLC. Guidance to Industry: Classification of Digital Health Technologies. June 2023. <https://dtxalliance.org/wp-content/uploads/2023/06/Guidance-to-Industry-Classification-of-Digital-Health-Technologies-2023Jun05.pdf>. Accessed August 18, 2023.

3. Digital Therapeutic Alliance. Digital Health Industry Categorization. https://dtxalliance.org/wp-content/uploads/2019/11/DTA_Digital-Industry-Categorization_Nov19.pdf. Accessed August 22, 2022.

4. Hatch A, et al. *JMIR Ment Health*. 2018;5(2):e46 doi: 10.2196/mental.9777.

5. Connolly SL et al. *Curr Psychiatry Rep*. 2021;7:23(7):38.

6. Stubbe DE. *Focus (Am Psychiatr Publ)*. 2020;18(4):424–427.

Closing

Digital Role-play Coming Soon!

Welcome to a virtual role-play created for you to practice your communication skills

This interactive experience is your opportunity to interact with fictional representations of the people you speak with. You'll choose your scenario and have a discussion with a patient, a parent or a multi-disciplinary team member. The goal of the conversation will be to accomplish the specific aim of the role-play you select.

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