

Evaluating Risk and Benefit for Electronic Psychotherapies/Cognitive Remediation

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HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

Outline

1. New Apps and Care Models

2. Regulatory Considerations around These Apps

3. Picking an App



Self Help or Hybrid Use?



A New Connection

The **mindLAMP** is one of the digital mental health aids designed to enhance interaction between therapists and patients. Here are the basics of how it works:



Traditional face-to-face therapy sessions are held either in person or over a videoconferencing platform.



A "Syka navigator" handles the technical aspects of the digital interaction between therapist and patient, from app setup and customization to data presentation and troubleshooting.

The **mindLAMP** app allows patients to access suggested mental health resources and track completion of self-care surveys about their symptoms, moods and activities, complete activities or learn skills to manage symptoms, track their own treatment progress, and communicate with their therapist. It also tracks physical activity—like the patient's daily number of steps, screen time and how well they sleep—that can be analyzed to see if it is affecting the patient's mental health.



Source: *White et al.* Digital Psychiatry, Behavioral Research, Clinical Center, Cambridge/THOMSON'S "BEST JOURNAL"



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What is Safe and Useful

Contains Nonbinding Recommendations

Enforcement Policy for Devices For Treating Disorders During the Disease 2019 (COVID-19) Health Emergency

Guidance for Industry Food and Drug Administration

April 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Engineering
Office of Product Evaluation and Quality

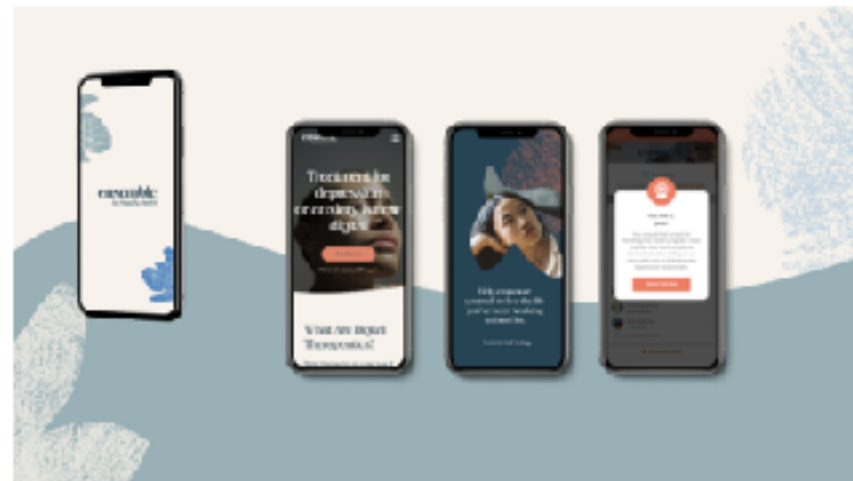
HEALTH TECH STARTUPS, SYN

Happify rolls out digital therapeutic for anxiety, depression under temporary FDA guidance

Happify is making its app-based treatment available to patients thanks to a loosened FDA guidance last year that lets digital health companies targeting some behavioral health conditions release their product without clearance. The company is launching an investigational study to get data for a [future FDA submission](#).

By ELISE REUTER

Post a comment / Jun 23, 2021 at 2:03 PM



Happify is rolling out a digital therapeutic designed to treat anxiety and depression. It's not yet FDA-cleared, but the company is making it available through a regulatory change implemented by the Food and Drug Administration during the pandemic. Photo credit: Happify Health

Billing Code: 4150-26

It has been submitted to the Office of the Federal Register [OFR] for posting on public display or published in the Federal Register. The published document if minor editorial changes are made during the review process. The document published in the Federal Register is the official HHS-approved version.

AND HUMAN SERVICES

Flexibilities Provided During the COVID-19 Public Health Emergency for Certain Medical Devices from Premarket Notification

Information, Research, Analysis, and Public Comment on

Implementation and Evidence-Based Reform of Section 510(k) Program

Food and Human Services (HHS).

Information.

FTC Weighs In



Office of the Chair

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

STATEMENT OF THE COMMISSION *On Breaches by Health Apps and Other Connected Devices*

September 15, 2021

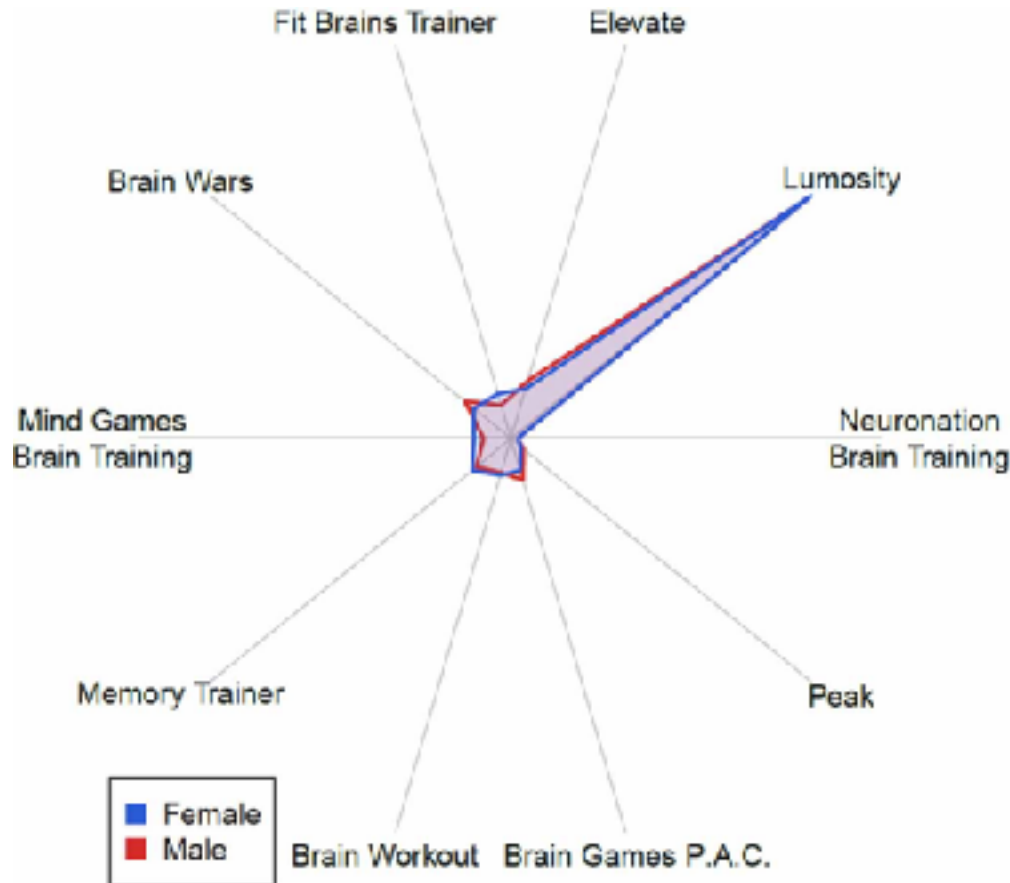
In recognition of the proliferation of apps and connected devices that capture sensitive health data, the Federal Trade Commission is providing this Policy Statement to offer guidance on the scope of the FTC's Health Breach Notification Rule, 16 C.F.R. Part 318 ("the Rule").¹

The FTC's Health Breach Notification Rule helps to ensure that entities who are not covered by the Health Insurance Portability and Accountability Act ("HIPAA") nevertheless face accountability when consumers' sensitive health information is compromised. Under the Rule's requirements, vendors of personal health records ("PHR") and PHR-related entities must notify U.S. consumers and the FTC, and, in some cases, the media, if there has been a breach of unsecured identifiable health information, or face civil penalties for violations. The Rule also covers service providers to these entities. In practical terms, this means that entities covered by the Rule who have experienced breaches cannot conceal this fact from those who have entrusted them with sensitive health information.

The Rule was issued more than a decade ago, but the explosion in health apps and connected devices makes its requirements with respect to them more important than ever. The FTC has advised mobile health apps to examine their obligations under the Rule,² including through the use of an interactive tool.³ Yet the FTC has never enforced the Rule, and many



Not the First Time the FTC Has Acted Here



FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

ABOUT THE FTC NEWS & EVENTS ENFORCEMENT POLICY TIPS & ADVICE

Home » News & Events » Press Releases » Lumosity to Pay \$2 Million to Settle FTC Deceptive Advertising Charges

Lumosity to Pay \$2 Million to Settle FTC Deceptive Advertising Charges for Its "Brain Training" Program

January 9, 2015

Company Claimed Program Would Sharpen Performance in Everyday Life and Protect Against Cognitive Decline

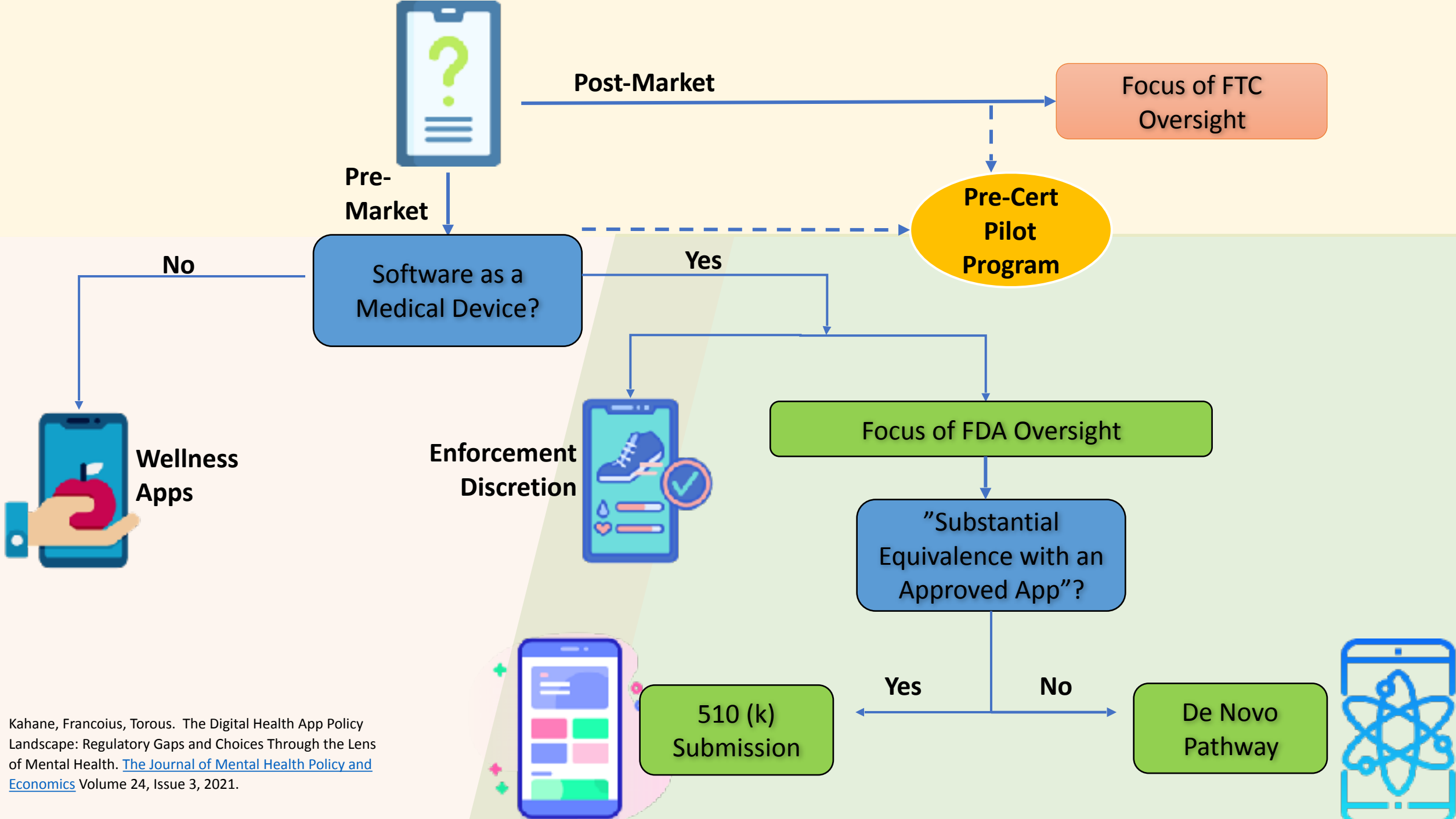
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FOR RELEASE

TAGS: Bureau of Consumer Protection | Consumer Protection | Advertising and Marketing | Health Claims | Online Advertising and Marketing

The operators and marketers of the Lumosity "brain training" program have agreed to settle Federal Trade Commission charges alleging that they deceived consumers with unfounded claims that Lumosity games can help users perform better at work and in school, and reduce or delay cognitive impairment associated with age and other serious health conditions.

No part of the settlement, Lumos Labs, the company behind Lumosity, will be required to pay any amount to the FTC.

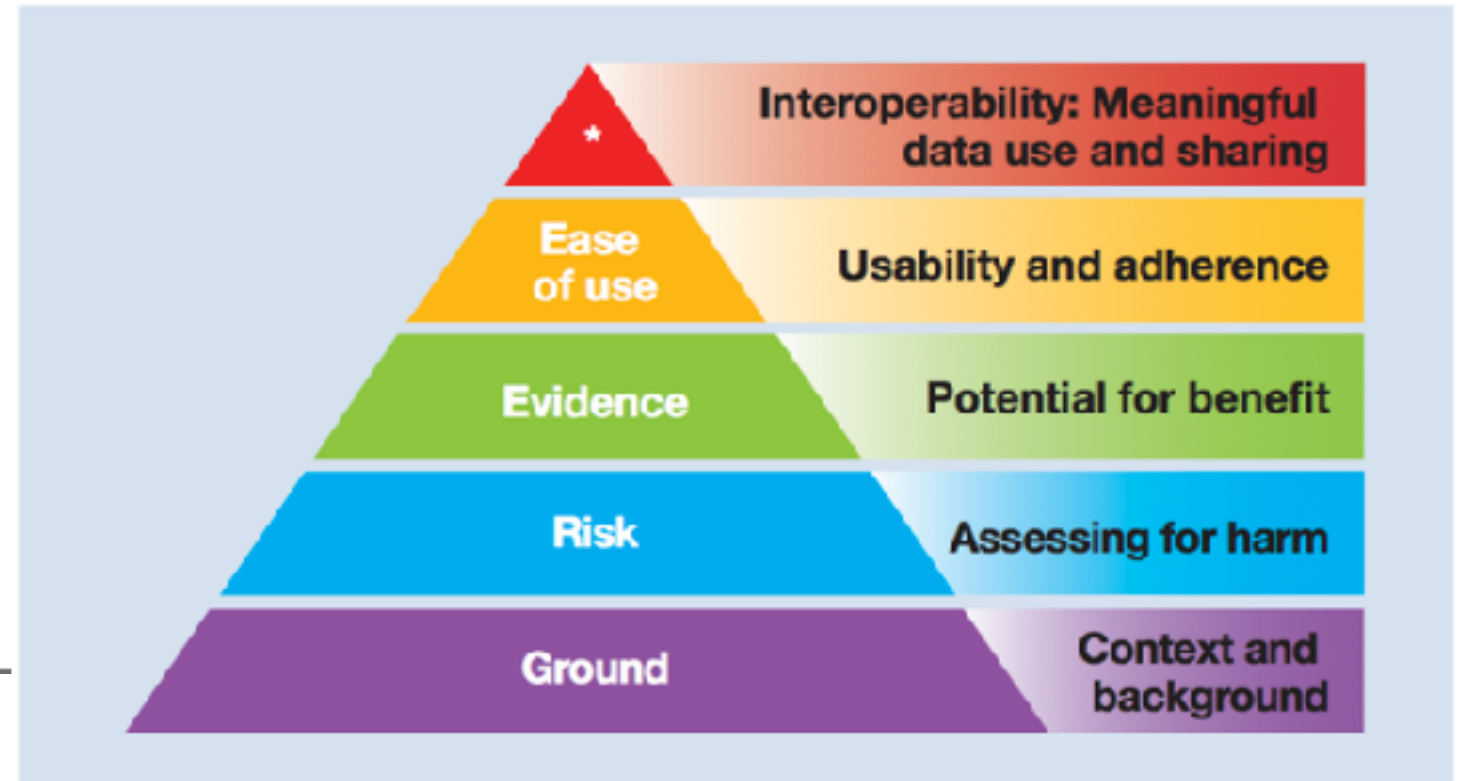


Kahane, Francois, Torous. The Digital Health App Policy Landscape: Regulatory Gaps and Choices Through the Lens of Mental Health. [The Journal of Mental Health Policy and Economics](#) Volume 24, Issue 3, 2021.

Harder to Know What is Safe and Useful








*“Consensus among relevant forum participants that FDA clearance, which focuses on safety and minimal effectiveness thresholds, **does not** provide adequate information for decision makers.”*

APA App Evaluation



Informed Decision Making Around Apps: Level 1

Mental Health Apps: Evaluation of Privacy Practices

	 7 Cups	 Betterhelp	 MindDoc	 Sanity & Self	 Talkspace	 Wysa	 Youper
Is it clear who your data is shared with in the privacy policy?	✗	✗	●	●	✗	●	✗
Does the app share data ONLY with companies named in the privacy policy?	●	✗	●	✗	✗	●	✗
Does the policy define a right to delete your data?	✗	✗	●	✗	✗	●	●
Can you easily delete your data through the app?	✗	●	●	●	✗	✗	●
Does the app ask permission before using your data for research?	✗	?	✗	✗	✗	✗	●
Can you opt out of research?	✗	?	✗	?	✗	?	●

● yes
 ✗ no
 ? unclear

Informed Decision Making Around Apps: Level 1

20,991 mHealth apps

(8074 medical and 12,917 health and fitness in the Google Play store)

88.0% included code that could potentially collect user data.

3.9% transmitted user information in their traffic.

28.1% provided no privacy policies

47.0% of user data transmissions complied with the privacy policy

Informed Decision Making Around Apps: Level 1

- Potential iatrogenic effects of apps.
 - “Unguided exposure without a treatment plan might increase symptom severity”

- Alternative therapies

- Crisis Management



Parrish EM, Filip TF, Torous J, Nebeker C, Moore RC, Depp CA. Are mental health apps adequately equipped to handle users in crisis?. *Crisis: The Journal of Crisis Intervention and Suicide Prevention*. 2021 May 27.

Informed Decision Making Around Apps: Level 2

- Although 59 apps claimed to be effective at diagnosing a mental health condition or improving symptoms, only **one app included a citation to published literature.**

Coding element	n (%) of apps
3. Positive claims	59 (81)
3.a. Claims of effectiveness	47 (64)
3.a.i. Detection or diagnosis	7 (10)
3.a.ii. Improvement in symptoms or mood	22 (30)
3.a.iii. Improvement in self-management	26 (36)
3.b. Claims of acceptability	33 (45)
4. Supporting statements	47 (64)
4.a. Scientific language	32 (44)
4.a.i. Specific technique described	24 (33)
4.a.ii. Evidence from study using app	2 (2.7)
4.a.iii. Citation to scientific literature	1 (1.4)
4.b. Technical expertise	23 (32)
4.b.i. Certification or accreditation	0
4.b.ii. Prizes or awards	2 (2.7)
4.b.iii. Credible developers	18 (25)
4.b.iv. Credible endorsements	3 (4.1)
4.c. Lived experience design	10 (14)
4.c.i. Lived experience involvement	6 (8.2)
4.c.ii. Lived experience developer	5 (6.8)
4.d. "Wisdom of the crowd"	14 (19)
4.d.i. Download, unsafe, or popularity statistics	11 (15)

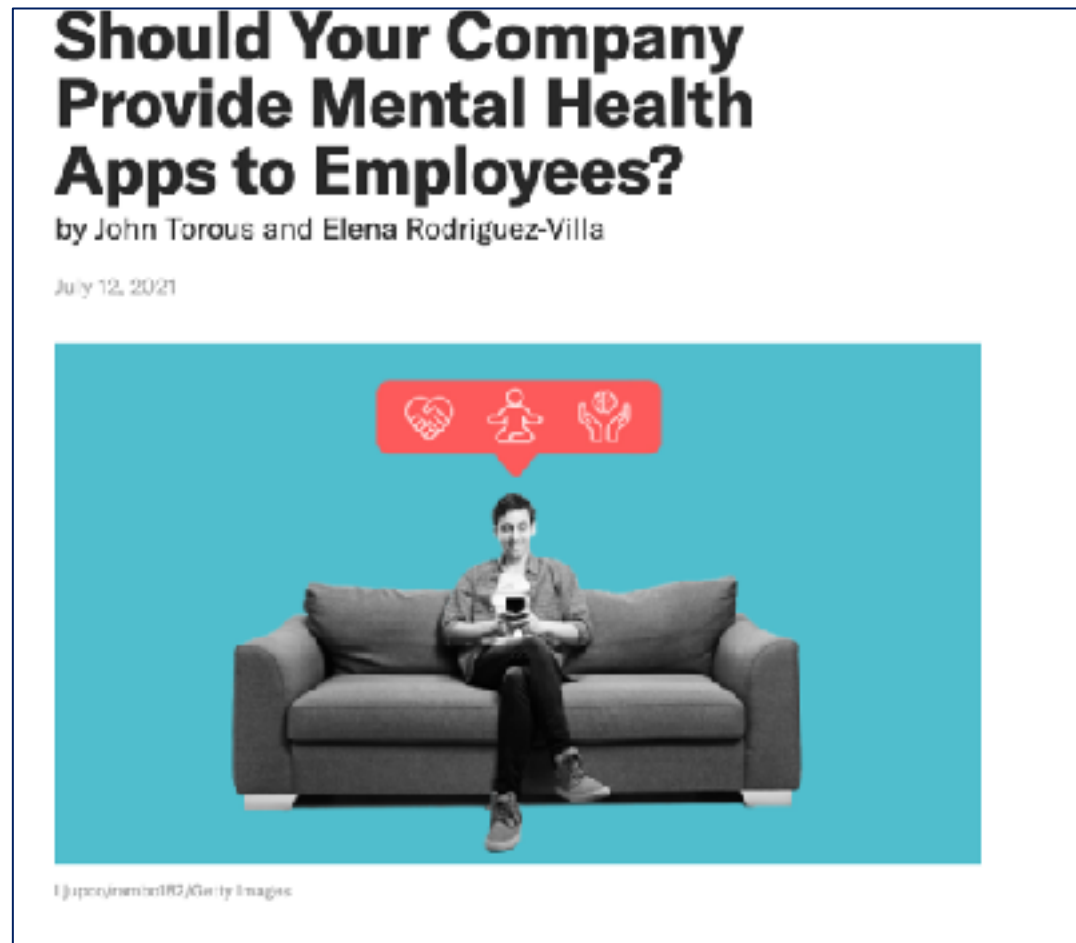
Informed Decision Making Around Apps: Level 2

- CBT apps in 2021

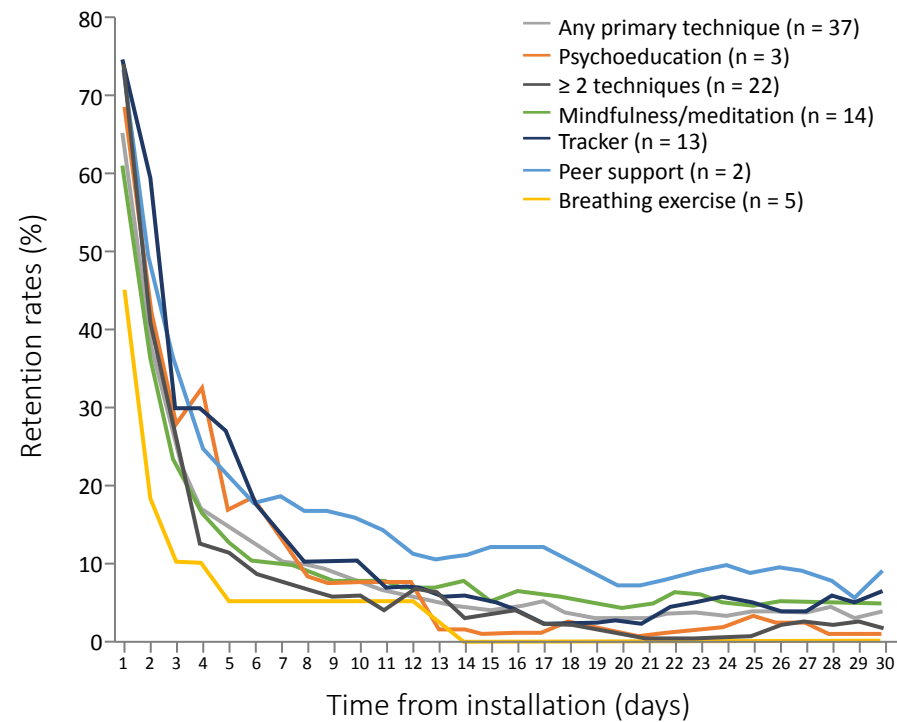
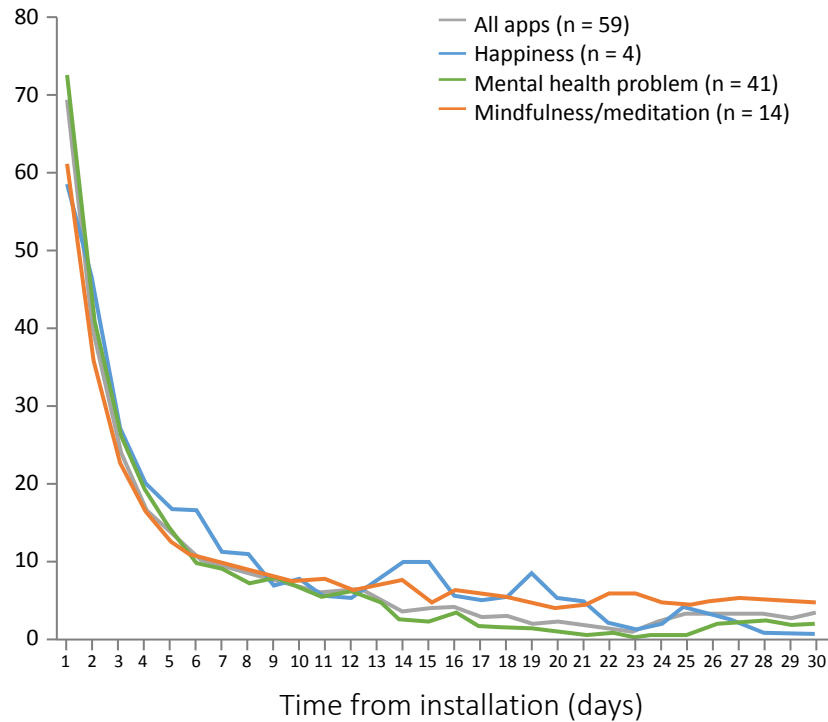
- 6% offered an RCT
- 35% explained risk of suicide with depression
- 78% offered cognitive restructuring
- 65% offered meditation or mindfulness

“heterogeneous group offering a range of evidence-based and non-evidence-based CBT techniques.”

Informed Decision Making Around Apps: Level 2



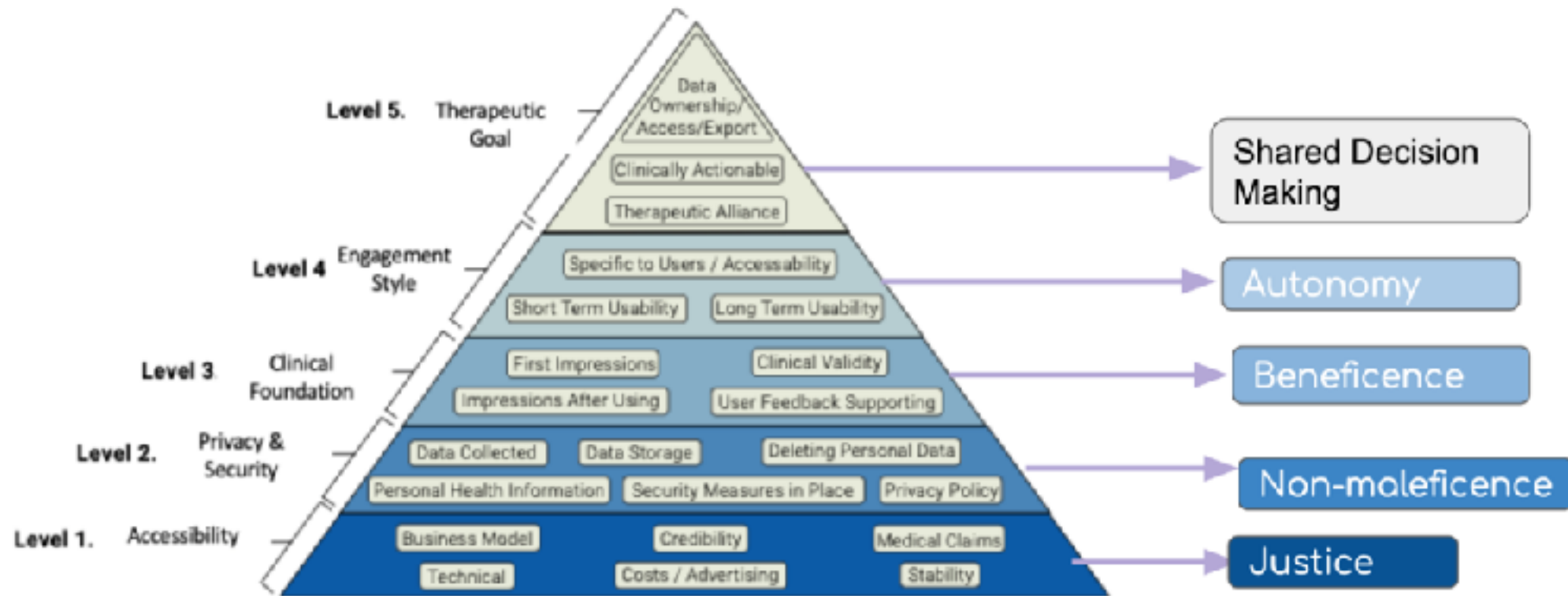
Informed Decision Making Around Apps: Level 3



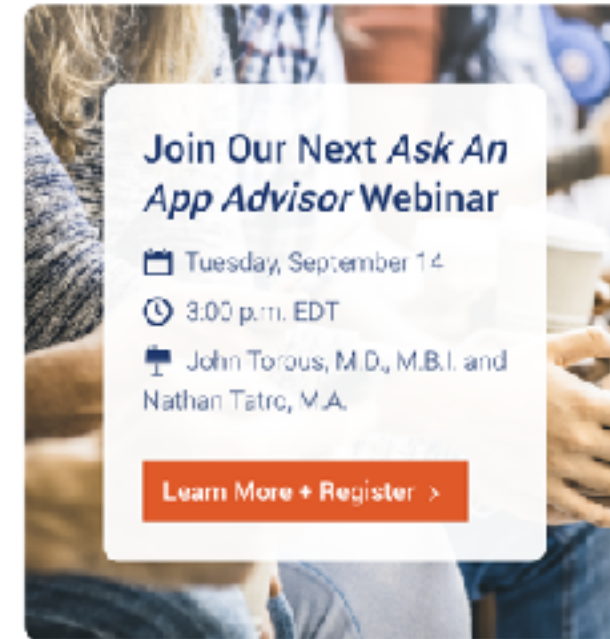
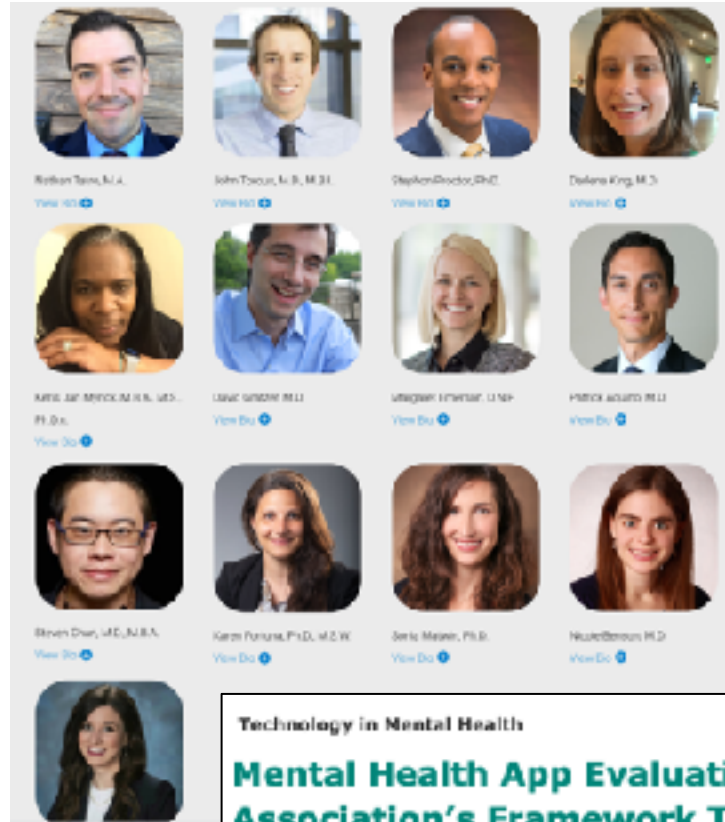
Informed Decision Making Around Apps: Level 4



A Review of all Levels



American Psychiatric Association: App Evaluation



Technology in Mental Health 🔒 No Access

Mental Health App Evaluation: Updating the American Psychiatric Association's Framework Through a Stakeholder-Engaged Workshop

Sarah Lagan, B.S., Margaret R. Emerson, D.N.P., A.P.R.N., Darlene King, M.D., Sonia Malwin, Ph.D., Steven R. Chan, M.D., M.B.A., Stephen Procter, Ph.D., Julia Tartaglia, M.D., Karen L. Fortuna, Ph.D., L.C.S.W., Patrick Aquino, M.D., Robert Welker, M.S., C.O.A.P.S., Michelle Dist, ... [See all authors](#)

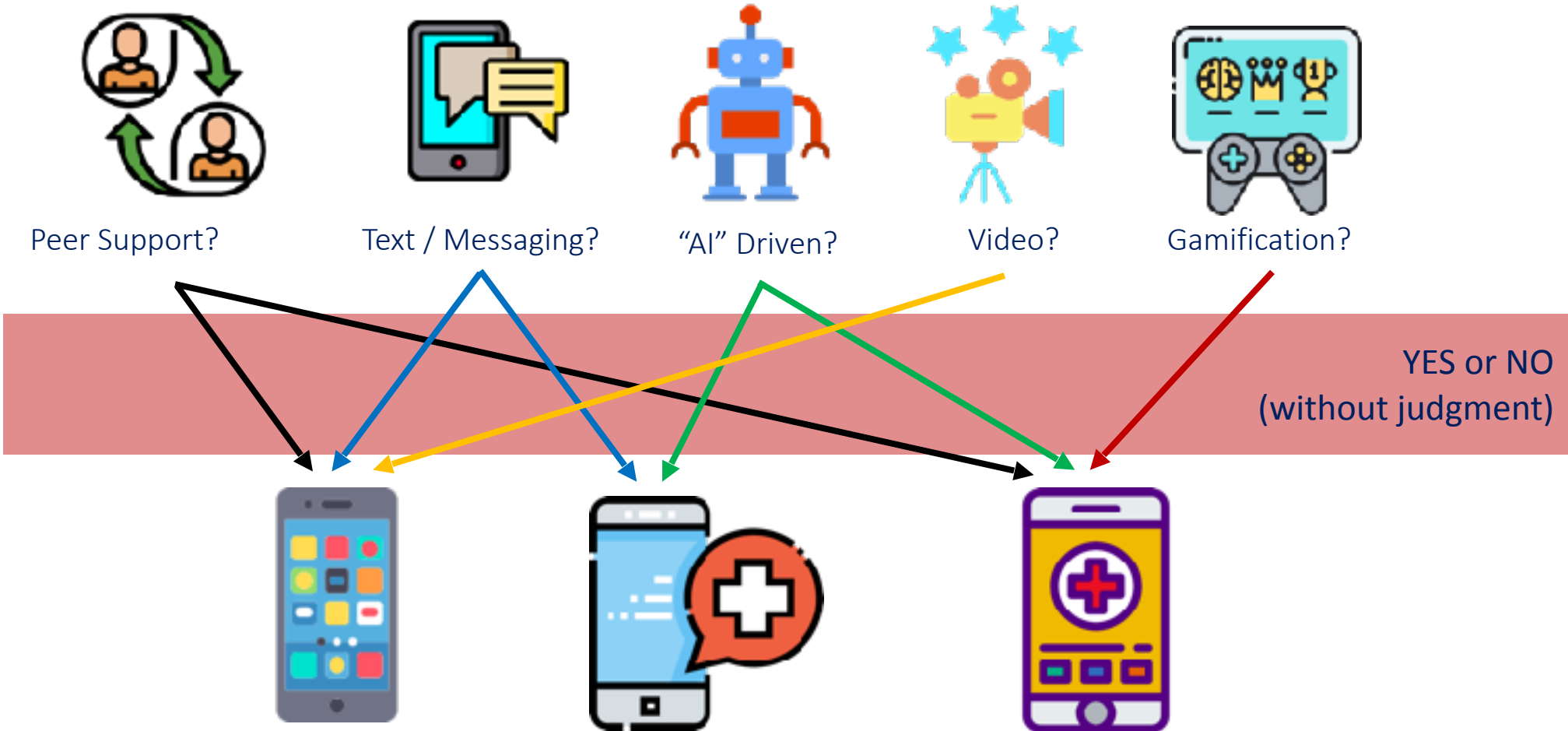
Published Online: 22 Apr 2021 | <https://doi.org/10.1176/appi.ps.20200663>

From Framework to Actionable Database

- Clinicians and patients may not have time to consider all facets of an app
- Need to review apps outside of field of expertise or comfort.
- What is a set of objective and replicable questions about an app?



From “Easy to Use” → Engagement Style

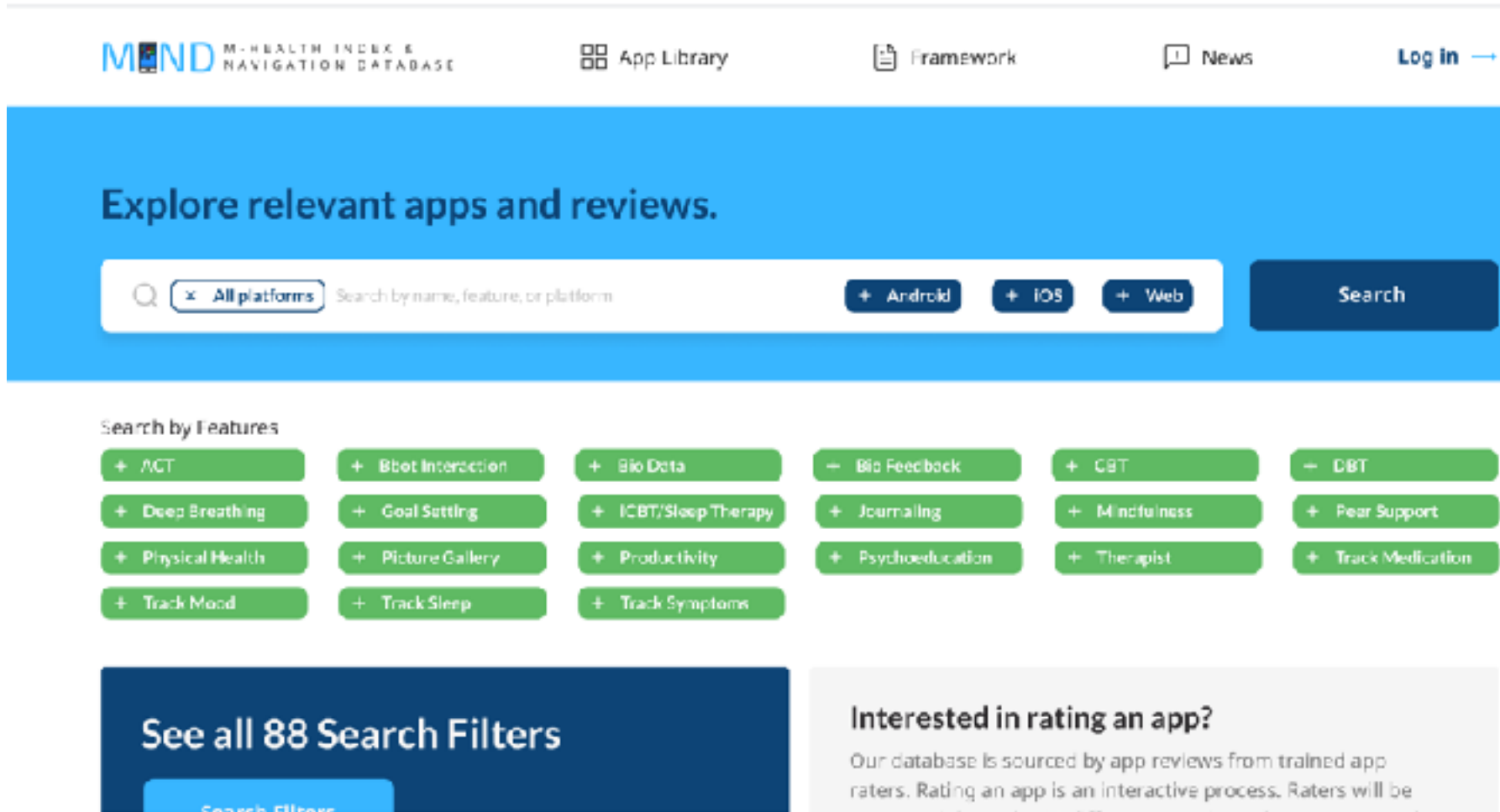


Translating Concepts into Yes/No Questions

Framework level	Average Kappa inter-rater reliability score
Background and access	0.876
Privacy and security	0.856
Clinical foundation and app evidence	0.755
User experience: inputs and outputs	0.909
User experience: features and engagement	0.928
Data integration	0.915



MindApps.org: 600+ Apps to Explore

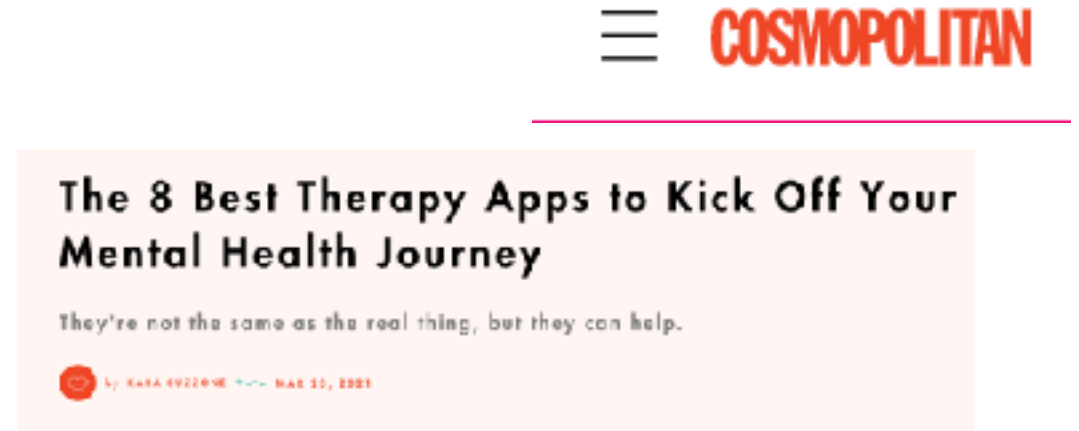


The screenshot shows the MindApps.org website. At the top, there is a navigation bar with the MIND logo (M-HEALTH INDEX & NAVIGATION DATABASE), App Library, Framework, News, and Log in links. Below the navigation bar is a large blue banner with the text "Explore relevant apps and reviews." and a search bar. The search bar contains the text "All platforms" and "Search by name, feature, or platform". To the right of the search bar are buttons for "Android", "iOS", and "Web", and a "Search" button. Below the search bar is a section titled "Search by Features" with a grid of green buttons for various features: ACT, Biot Interaction, Bio Data, Bio Feedback, CBT, DBT, Deep Breathing, Goal Setting, ICBT/Sleep Therapy, Journaling, Mindfulness, Peer Support, Physical Health, Picture Gallery, Productivity, Psychoeducation, Therapist, Track Medication, Track Mood, Track Sleep, and Track Symptoms. At the bottom of the screenshot, there is a dark blue button that says "See all 88 Search Filters" and a light gray box with the text "Interested in rating an app?" and "Our database is sourced by app reviews from trained app raters. Rating an app is an interactive process. Raters will be..."

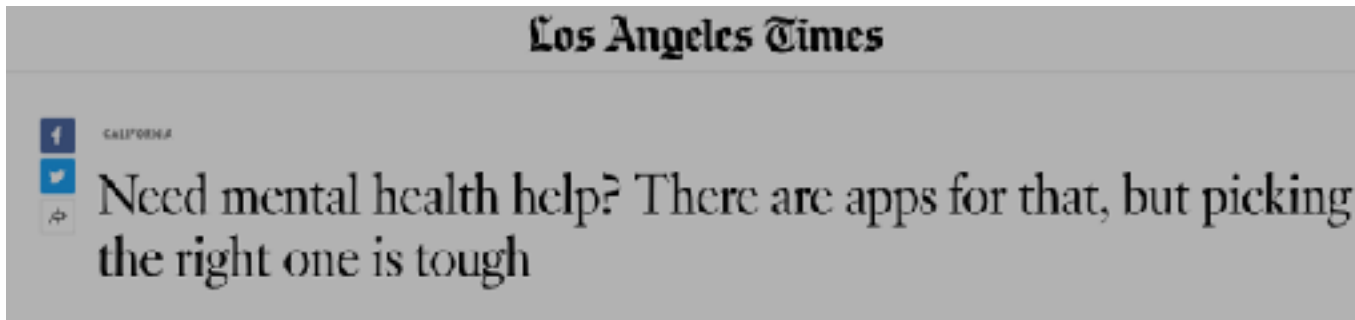
Popular Press Reception



“Websites like Mindapps.org offer information on hundreds of apps, including data privacy.”



To make it slightly easier to compare the options, he and his colleagues created [MIND](#), a database that allows you to sort through mental health apps by filtering for features that matter to you



Mindapps.org

The screenshot shows the Mindapps.org website interface. At the top, the logo 'MIND M-HEALTH INDEX & NAVIGATION DATABASE' is visible. Below it, there are navigation tabs for 'Application Library', 'Framework', and 'Community'. A search bar on the left is titled 'Search Filters' and contains a list of filters: 'Cost' (Free to Download, Totally Free, Payment, In-App Purchase, Subscription) and 'Supported Conditions' (Mood Disorders, Stress & Anxiety, Sleep, Phobias, OCD, Schizophrenia, Eating Disorders, Personality Disorders). The main content area is titled 'App Library' and shows search results for 'ptsd'. The search bar contains 'ptsd' and a dropdown menu is set to 'All Platforms'. Below the search bar, there are filters for 'PTSD' and 'Totally Free'. The first app listed is 'PE Coach 2' by the US Department of Veterans Affairs (VA). It is available on Android and iOS, is 'Totally Free | Free to Download', and has a 'Last Rating' of 'Tue Jun 22nd 2021 11:50 PM'. A 'View' button is present for this app. The second app listed is 'DoD Safe Helpline' by RAINN. It is available on Android and iOS, is 'Free to Download | Totally Free', and has a 'Last Rating' of 'Tue Aug 31st 2021 2:52 PM'. A 'View' button is present for this app. At the bottom right of the app list, it says 'Viewing 15 Applications'.

Thank You

Argosy Foundation for Supporting This Work

MindApps.org