THE CLINICAL EFFECTIVENESS OF DIGITAL THERAPEUTICS FOR BEHAVIORAL HEALTH

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Digital technologies (web, mobile, cloud, analytics) have transformed our society (e.g., in finance, retail, travel, education, and social relations).

Digital technologies enable new models of care within and outside of formal systems of care, while increasing the quality and reach of care.

Advances in digital technologies have created unprecedented opportunities to assess and modify health behavior and health outcomes at a population level ("digital therapeutics").
Promise of Digital Therapeutics

Extends the reach and impact of clinicians

Functions as a virtual therapist in one’s pocket that markedly improves patient outcomes

Offers scalable, science-based behavioral healthcare anytime / anywhere

More timely and significant than ever during global pandemic crisis
Access to the Internet and mobile devices has been growing at extraordinary rates. The majority of the world has access to mobile devices, totaling about 8 billion mobile phone subscriptions worldwide (projected to reach 8.9 billion by 2025). There are over 5.5 billion smartphone subscriptions in the world, and smartphone access is expected to increase globally to 7.4 billion by 2025. Internet and mobile access is also high and growing among even the most traditionally underserved and vulnerable populations.
Research has demonstrated that digital therapeutics, if developed well and in collaboration with the target audience:

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<td><strong>1</strong></td>
<td>Highly useful and acceptable to diverse audiences</td>
<td><strong>2</strong></td>
<td>Have a large impact on health behavior and health outcomes</td>
<td><strong>3</strong></td>
<td>Can produce outcomes comparable to, or better than, clinicians</td>
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<td>Increase quality, reach, and personalization of care</td>
<td><strong>5</strong></td>
<td>Can be cost-effective</td>
<td><strong>6</strong></td>
<td>Can be responsive to individuals’ health behavior trajectory over time</td>
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Digital Therapeutics for Addiction Treatment
Center for Technology and Behavioral Health

P30 "Center of Excellence"
fundied by the U.S. National Institute on Drug Abuse

The Center for Technology and Behavioral Health (CTBH) is a national research center designed to use science to inform the development, evaluation, and sustainable implementation of a wide array of digital technology-based tools for substance use disorders and mental health as well as health behavior broadly.

www.c4tbh.org
Maximizes potency and implementability of intervention

Onken et al., 2013

Stage Model of Treatment Development

Stage I: Intervention Generation/Refinement

Stage II: Efficacy (Research Clinics)

Stage III: Efficacy (Community Clinics)

Stage IV: Effectiveness

Stage V: Implementation & Dissemination

Stage O: Basic Research

Formative Development
User Interface/Experience
Initial Feasibility

Implementation, Sustainability

Feasibility, Acceptability, Comprehensibility

Real World Research

Focus on internal validity

Focus on external validity

Onken et al., 2013

Maximizes potency and implementability of intervention
Privacy and Security Considerations are Paramount

Privacy considerations in digital health are among the most important key considerations across the U.S Health care system.

This may be particularly true for sensitive topics in behavioral health.

A privacy and security framework for development and regulation includes:

- Fully Informed Consent
- Written Privacy Policy
- Access Control and Authentication
- Data Protection/Data Flow Aligned with Patient Preference
Interactive, self-directed, web-based behavior therapy for substance use disorders (SUDs) based on the science-based, community reinforcement approach to SUD treatment

Interactive modules designed to help people:

- Understand and disrupt harmful behaviors and cognitions leading to self-defeating patterns of drug use
- Leverage personal, social, and vocational resources to help individuals change substance-use
- Sometimes employs motivational incentives
Press the module name below to launch that module.

- Module 1: Alcohol, Drug Use and Communication Skills
- Module 2: Analyze Your Own Behavior Chain
- Module 3: Attentive Listening
- Module 4: Challenging Automatic Thoughts
- Module 5: Giving and Receiving Compliments
- Module 6: HIV and AIDS
- Module 7: How to Express Oneself Assertively

Seemingly Irrelevant Decisions (SIDs)

Social and Recreational Activities

Behavior Chains

Triggers

Behavior

Consequences

In addition, looking at what happens as a result of a specific behavior can help you identify consequences of the behavior, both positive and negative. This may serve to increase or decrease the behavior in the future.

What Have You Decided to Do or Not Do This Weekend?

TO-DOLIST
Digital Therapeutic is as Effective as “Gold Standard” Clinician-Delivered Treatment in Medication-Assisted Treatment for OUD (n=135)

(Bickel, Marsch et al., 2008)
Replacing Half of Clinician-Delivered OUD Treatment with Digital Therapeutic Produces Better Outcomes than Standard Medication-Assisted Treatment (n=160)

Marsch et al., 2014
Adding Mobile Behavioral Treatment as an Adjunct to Medication-Assisted Treatment for OUD Greatly Increases Treatment Retention

Guarino, Acosta, Marsch 2016
Adding Mobile Behavioral Treatment as an Adjunct to Medication-Assisted Treatment for OUD Greatly Increases Opioid Abstinence

Guarino, Acosta, Marsch 2016
Particularly Among Those Who are Non-Abstinent at Treatment Entry (n=507)

Digital Therapeutic Improves Treatment Retention (n=507)

U.S. Food and Drug Administration (FDA) authorized first “Prescription Digital Therapeutic” (reSET)™ for treatment of substance use disorders (Pear Therapeutics)

September 2017
U.S. FDA authorized “Prescription Digital Therapeutic” (reSET-O)™ for opioid use disorder treatment (Pear Therapeutics)

December 2018
U.S. FDA Authorization of Rx Digital Therapeutics

- Considered as a type of medical device
- Need to be:
  - Software Driven
  - Evidence-based
  - Make a claim to prevent, manage or treat a medical disease or disorder
- Apps that promote general wellness excluded from regulatory oversight
- Can extend reach of healthcare workforce by overcoming time, place and personnel constraints that limit healthcare delivery
- This process helps clinicians know which apps are safe and effective in the treatment of behavioral health conditions.
Prescription digital therapeutics will continue to be a key piece of the emerging global digital market, which some estimate to be worth more than half a trillion dollars by 2025.

Global Market Insights, 2019
The Opportunity

• Digital therapeutics enable widespread reach and scalability of effective interventions (with goal of being maximally effective and implementable).

• The behavioral health community has the opportunity to supercharge the behavioral health workforce with digital health in their toolbox – particularly during the global pandemic.

• This line of research may allow us to make great strides in crafting “precision medicine” approaches for a wide array of populations.
Thank you!

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