

# THE CLINICAL EFFECTIVENESS OF DIGITAL THERAPEUTICS FOR BEHAVIORAL HEALTH

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# Disclosure Information

Affiliations with Square2 Systems Inc.,  
HealthSim, LLC,  
Pear Therapeutics, Inc.



Center for **Technology**  
and **Behavioral Health**  
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**Center for Technology and Behavioral Health**  
[www.c4tbh.org](http://www.c4tbh.org)

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# Digital Health Technology

## Can Provide Anytime/Anywhere Science-Based Care

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



# Ubiquity of Technology

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

# Digital Therapeutics for Addiction Treatment

Research has demonstrated that digital therapeutics, if developed well and in collaboration with the target audience:

**1** Highly useful and acceptable to diverse audiences

**2** Have a large impact on health behavior and health outcomes

**3** Can produce outcomes comparable to, or better than, clinicians

**4** Increase quality, reach, and personalization of care

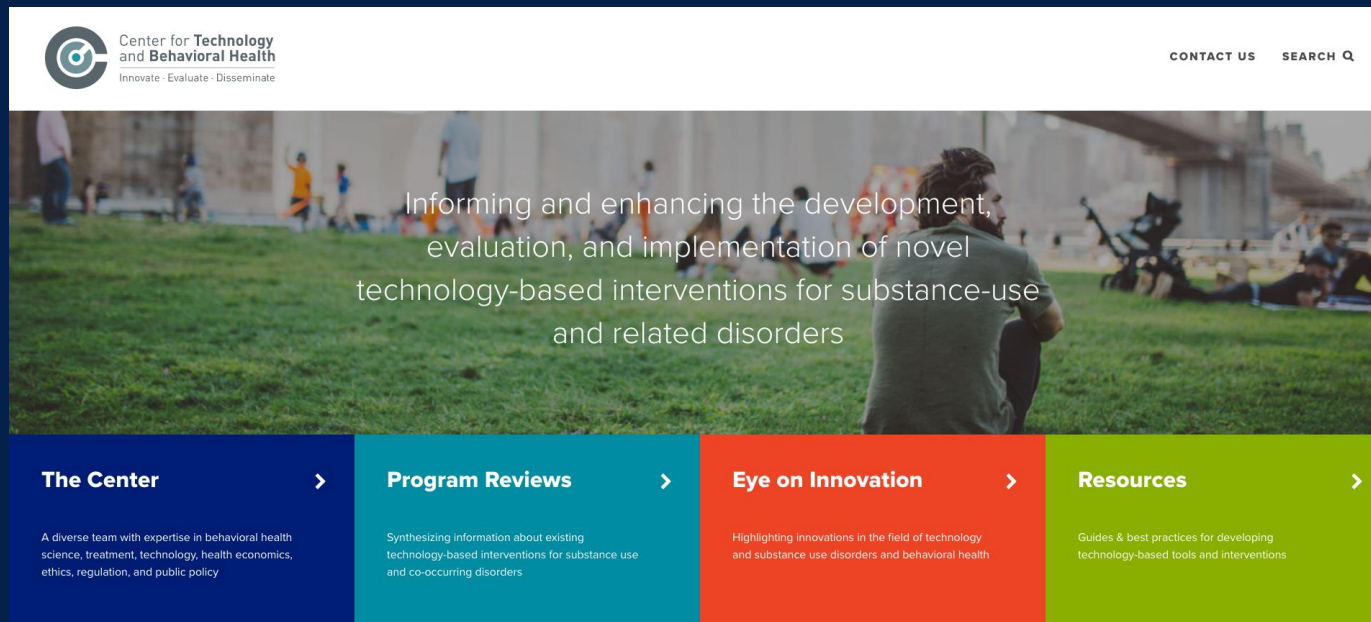
**5** Can be cost-effective

**6** Can be responsive to individuals' health behavior trajectory over time



# Center for Technology and Behavioral Health

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



The screenshot shows the homepage of the Center for Technology and Behavioral Health. At the top left is the logo with the text "Center for Technology and Behavioral Health" and the tagline "Innovate · Evaluate · Disseminate". To the right are links for "CONTACT US" and "SEARCH Q". The main content area features a background image of a person sitting on a grassy field with other people in the distance. Overlaid on this image is the text: "Informing and enhancing the development, evaluation, and implementation of novel technology-based interventions for substance-use and related disorders". Below this is a navigation bar with four colored buttons: "The Center" (dark blue), "Program Reviews" (teal), "Eye on Innovation" (orange), and "Resources" (light green). Each button has a right-pointing chevron and a brief description of its content.

**Center for Technology and Behavioral Health**  
Innovate · Evaluate · Disseminate

CONTACT US SEARCH Q

Informing and enhancing the development, evaluation, and implementation of novel technology-based interventions for substance-use and related disorders

**The Center** > A diverse team with expertise in behavioral health science, treatment, technology, health economics, ethics, regulation, and public policy

**Program Reviews** > Synthesizing information about existing technology-based interventions for substance use and co-occurring disorders

**Eye on Innovation** > Highlighting innovations in the field of technology and substance use disorders and behavioral health

**Resources** > Guides & best practices for developing technology-based tools and interventions

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

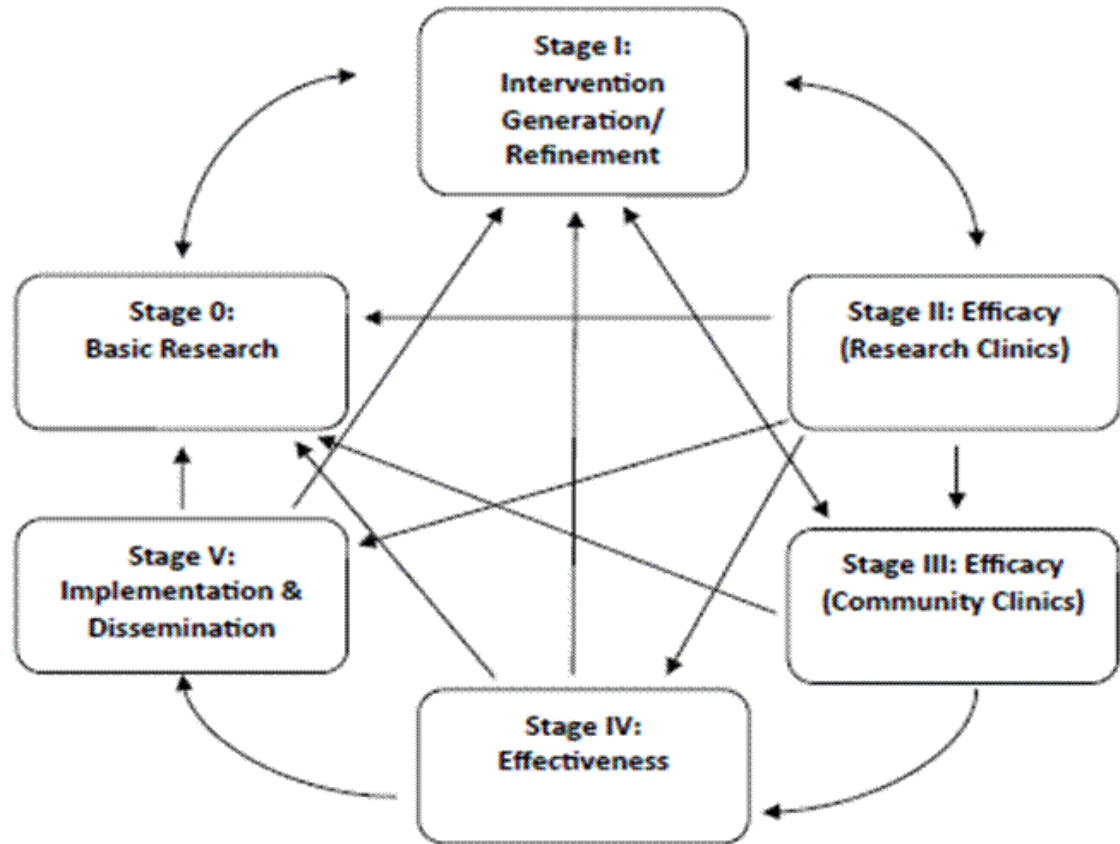
[www.c4tbh.org](http://www.c4tbh.org)



Feasibility, Acceptability, Comprehensibility



### Stage Model of Treatment Development



Formative Development  
User Interface/Experience  
Initial Feasibility



Implementation,  
Sustainability

← Focus on internal validity

← Focus on external validity

↑  
Real World Research

# 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

# An Exemplar: The Therapeutic Education System: Digital Therapeutic for Substance Use Disorders

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

# TES Digital Therapeutic for Substance Use Disorders

**TES**  
TES menu

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

**Social and Recreational Activities**

**Seemingly Irrelevant Decisions (SIDs)**

**Behavior Chains**

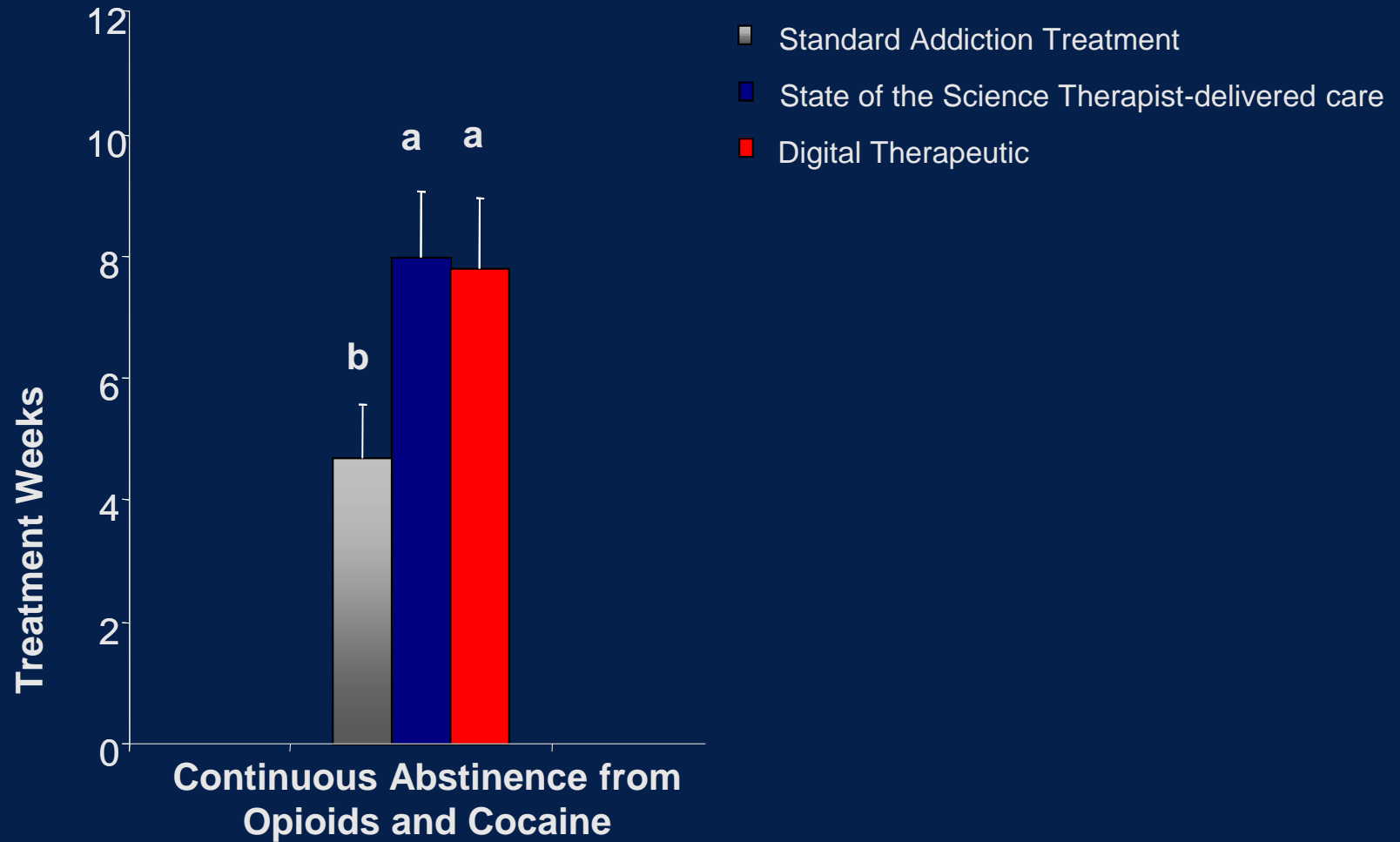
Triggers — Behavior — Consequences

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?

# Digital Therapeutic

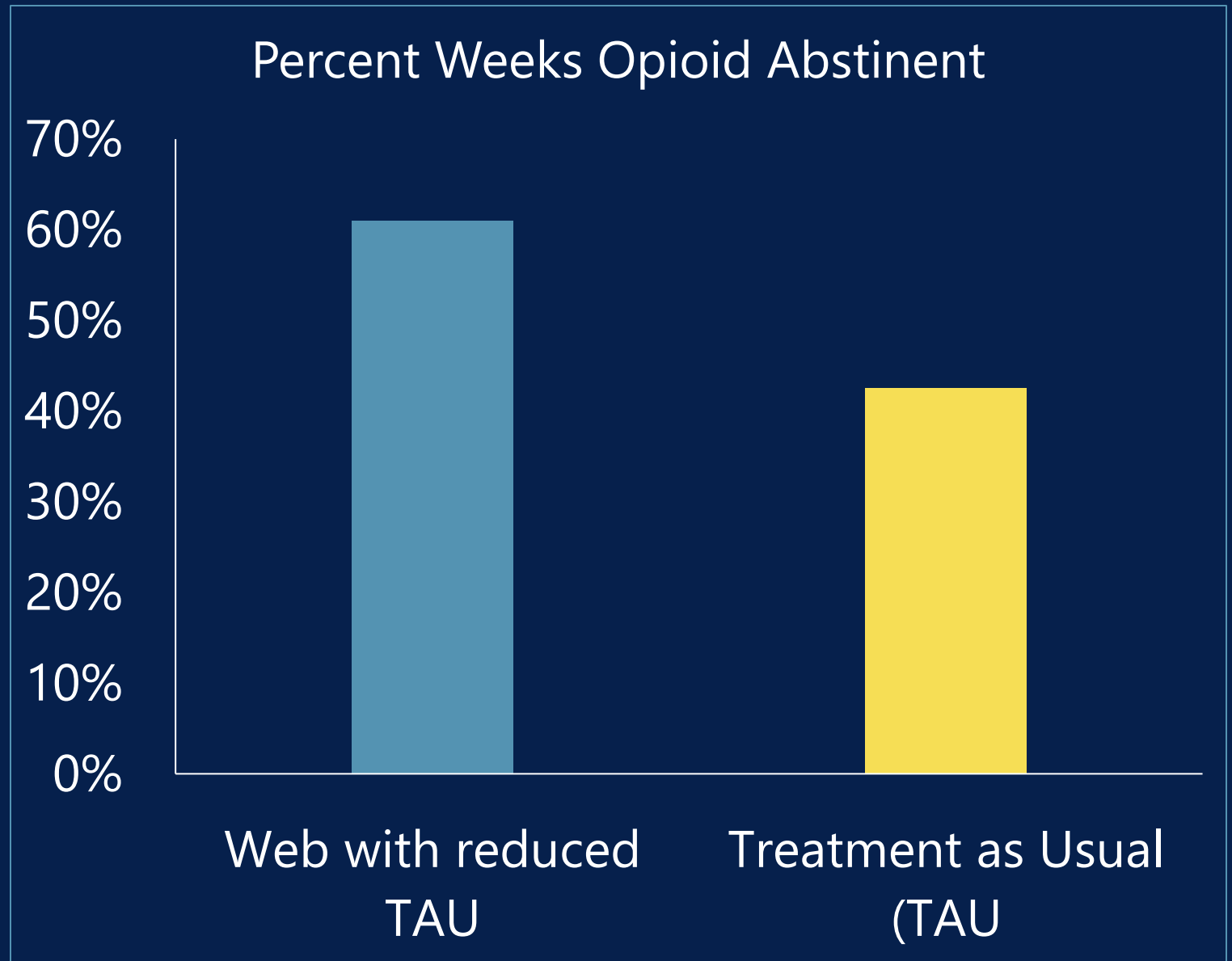
is as Effective as  
"Gold Standard"  
Clinician-Delivered  
Treatment in  
Medication-Assisted  
Treatment for OUD  
(n=135)



*(Bickel, Marsch et al., 2008)*

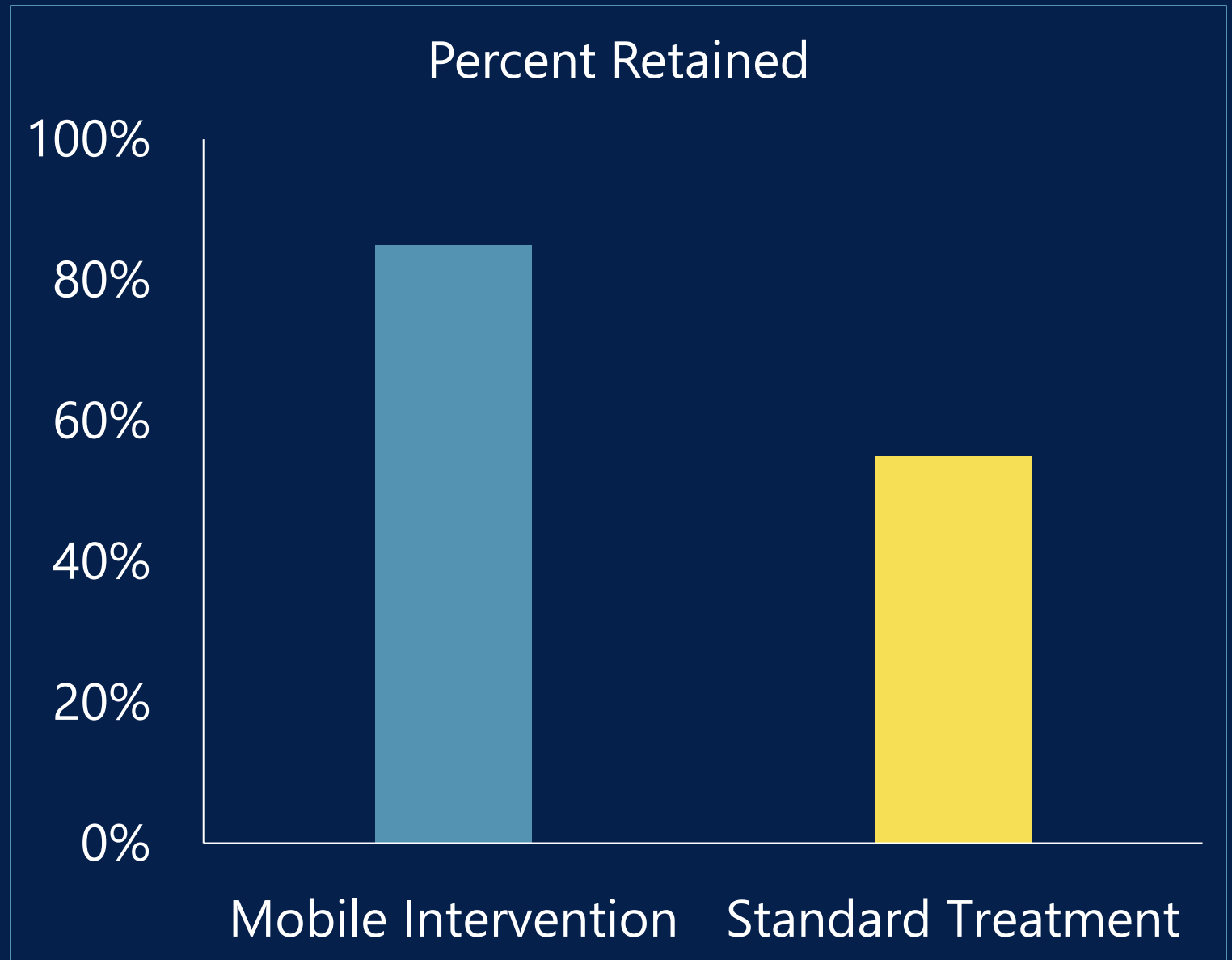
**Replacing Half of  
Clinician-  
Delivered OUD  
Treatment with  
Digital  
Therapeutic  
Produces Better  
Outcomes  
than Standard  
Medication-Assisted  
Treatment**

Marsch et al., 2014 (n=160)



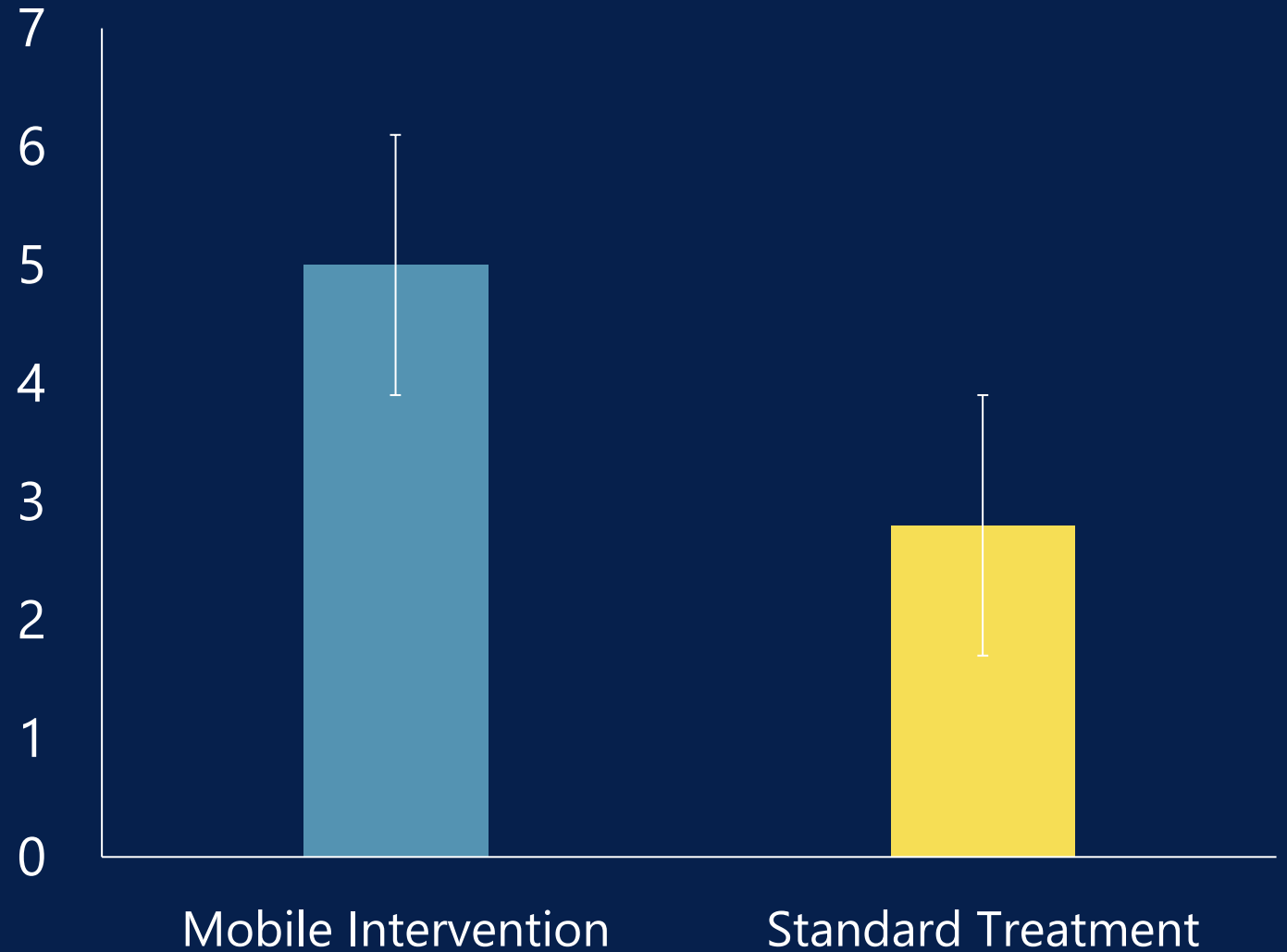


**Adding Mobile Behavioral Treatment as an Adjunct to Medication-Assisted Treatment for OUD Greatly Increases Treatment Retention**

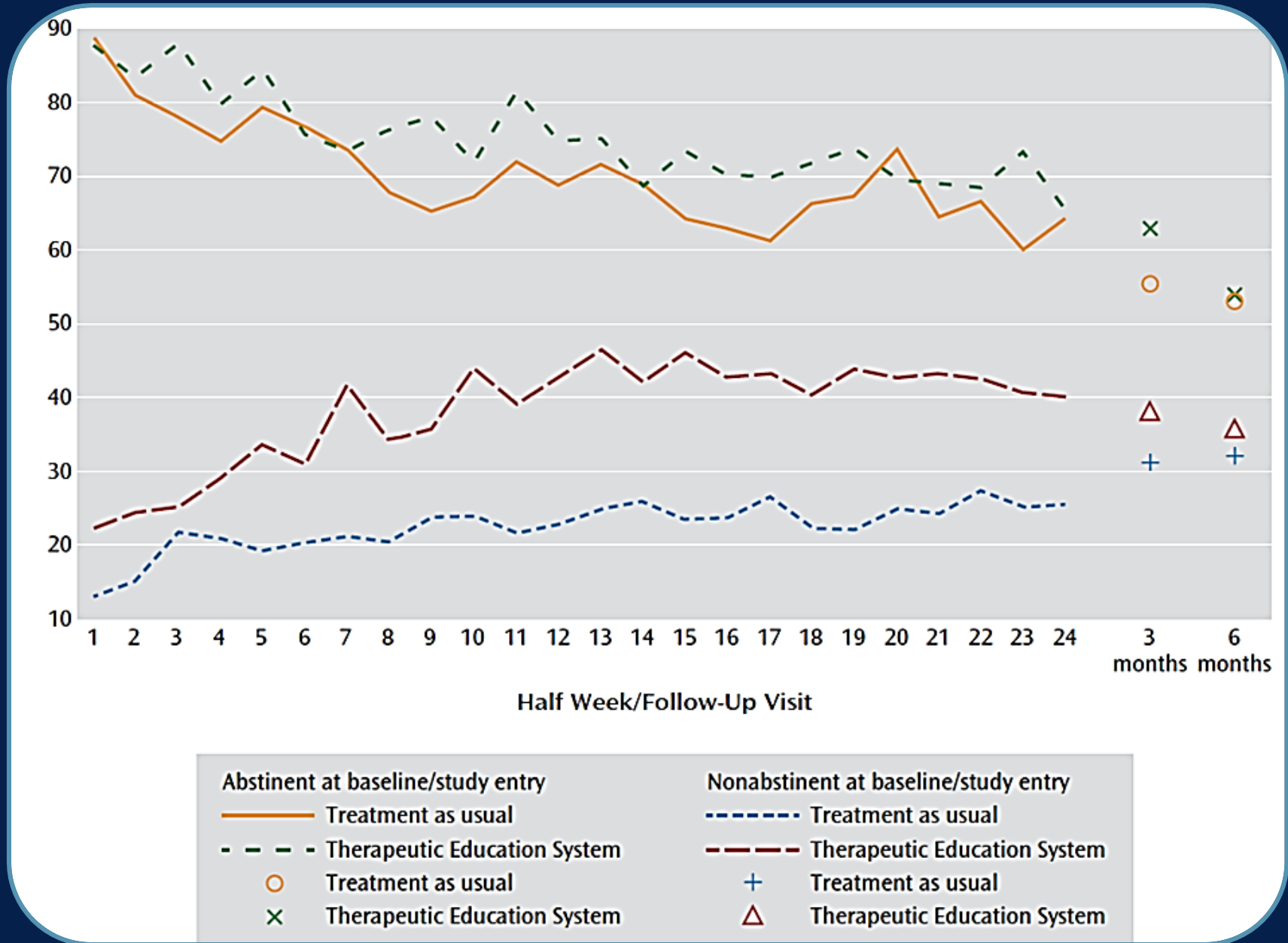


**Adding Mobile Behavioral Treatment as an Adjunct to Medication-Assisted Treatment for OUD Greatly Increases Opioid Abstinence**

Weeks of Opioid Abstinence

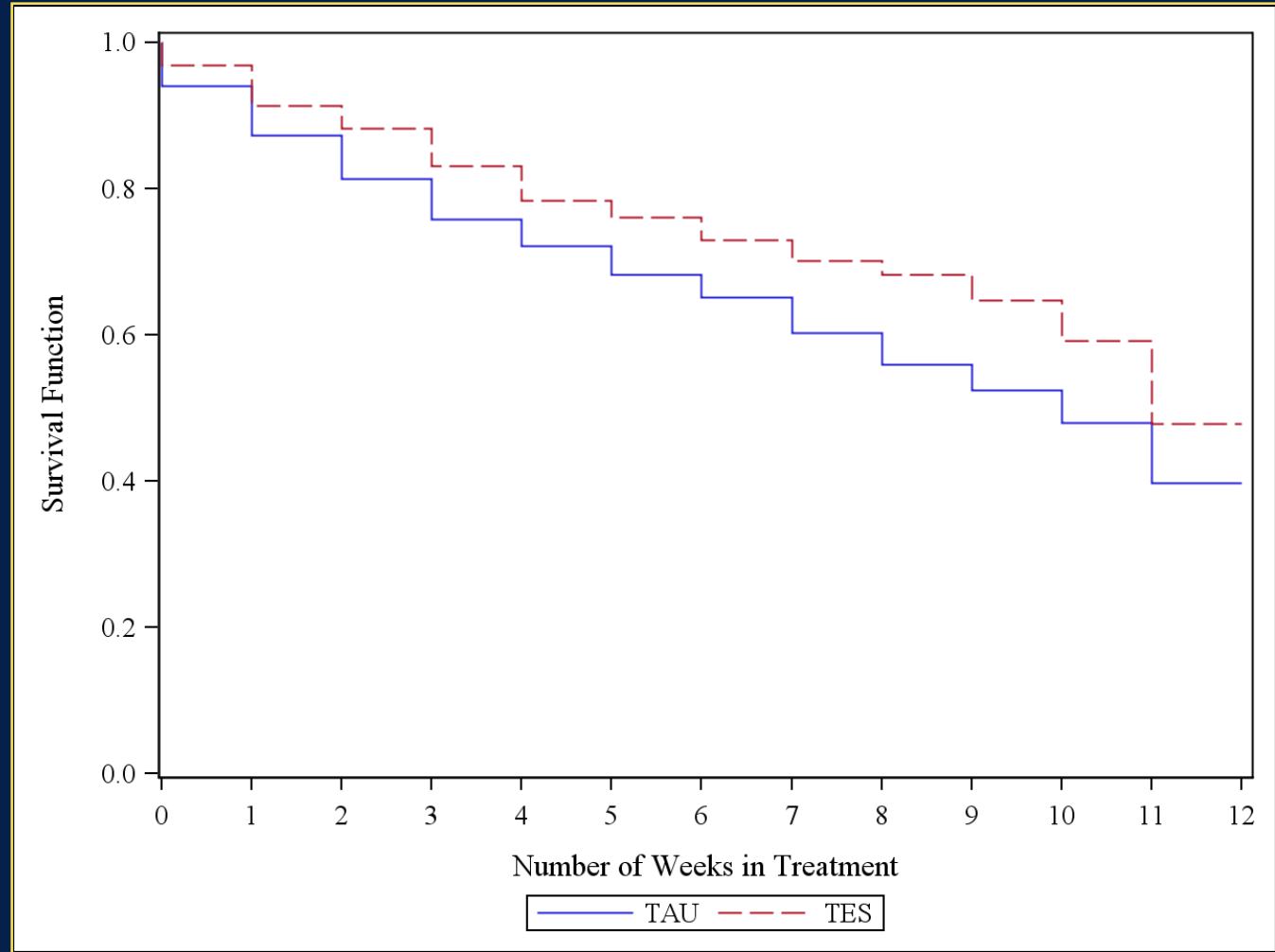


# Digital Therapeutic Improves Abstinence, Particularly Among Those Who are Non-Abstinent at Treatment Entry (n=507)



# Digital Therapeutic Improves Treatment Retention

(n=507)



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

September 2017

**U.S. FDA authorized “Prescription Digital  
Therapeutic” (reSET-O)<sup>™</sup> 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.

# 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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