Overview of the State of the Science of Applying Digital Therapeutics to Substance Use Disorder (SUD) Care

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Acknowledgements

Research funded by National Institute on Drug Abuse,
National Institutes of Health

Disclosure

- Affiliation with Square2 Systems, Inc. and Pear Therapeutics, small businesses that develop/deploy technology-based health behavior change tools

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Promise of Applying Digital Technologies to Health

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

- Digital technologies can also enable new models of health care both 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 via **web/mobile technologies ("digital therapeutics").**

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Telemedicine (distance Communication) for Substance Use Disorders (SUDs)

- About 26% of substance use treatment facilities nationwide use telemedicine (for assessment, intervention, treatment or continuing care)
- Telemedicine offers promise to reduce travel time, increase convenience, and save cost in SUD care.
- Psychiatry/behavioral health is the fastest growing specialty group to utilize telemedicine.
- Telemedicine for SUDs has shown promise in improving treatment retention and improving clinical outcomes, but experimental research in this area has been limited.

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Promise of Digital Therapeutics for Substance Use Disorders (SUDs)

- **Extends the reach and impact** of SUD clinicians

- Functions as a **virtual therapist** in one's pocket that markedly **improves patient outcomes**

- Offers **scalable, science-based** substance use and behavioral healthcare anytime/anywhere (on-demand support as patients move through their daily lives)

Ubiquity of Technology

- Access to the Internet and mobile devices has been growing at extraordinary rates.

- Approximately 90% of individuals worldwide have access to mobile phone services, totaling about **7.5 billion mobile phone subscriptions worldwide (projected at 8.9 billion by 2020)**

- There are over 3.9 billion **smartphone subscriptions** in the world, and smartphone access is expected to triple globally to **6.8 billion by 2020**.

- Internet and mobile access is also high and growing among **even the most traditionally underserved and vulnerable populations**

Digital Therapeutics for SUDs

- Digital Therapeutics have targeted nicotine/tobacco, alcohol, cocaine, cannabis and opioids.

- These tools may offer brief interventions (e.g., motivational enhancement therapy) or more intensive behavior therapy (e.g., CBT, Community Reinforcement Approach)

- Most have been computer- or web-based, but mobile interventions for SUDs are increasingly being developed/evaluated.

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Digital Therapeutics for SUDs

Research has demonstrated that digital technology behavior change tools (if developed well and in collaboration with the target audience):

- Can be highly useful and acceptable to diverse populations
- Have a large impact on health behavior and health outcomes
- Can produce outcomes comparable to, or better than, clinicians
- Increase quality, reach, and personalization of care
- Can be cost-effective
- Can be responsive to individuals' health behavior trajectory over time

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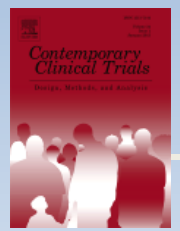
National CTN Trial

- 2-arm randomized, controlled, multi-site trial (N=507)
  - (1) Treatment as Usual (TAU)
  - (2) Modified TAU + web-based behavior therapy (TES)
- Approximately 2 hours/week of TES *substituted* for a comparable amount of face-to-face counseling
- 12 week treatment phase; 3- and 6-month post tx follow up
- Included a brief clinician check in with TES participants to coincide with standard individual sessions



- Low threshold eligibility to maximize “all comers” trial

Campbell ANC, Nunes EV, et al. (2012). *Contemporary Clinical Trials*.

Examples of Core TES Intervention Modules

- Conducting a Functional Analysis
- Effective Problem Solving
- Drug Refusal Skills Training
- Managing Negative Thinking
- Steps for Giving Constructive Criticism
- Giving and Receiving Compliments
- Communication Skills
- Sharing Feelings
- Increasing Self-Confidence in Decision-Making
- How to Express Oneself in an Assertive Manner
- HIV and AIDS
- Drug Use, HIV and Hepatitis

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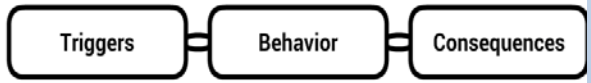
Sample Screens from TES Digital Therapeutic

Seemingly Irrelevant Decisions (SIDs)

Behavior Chains

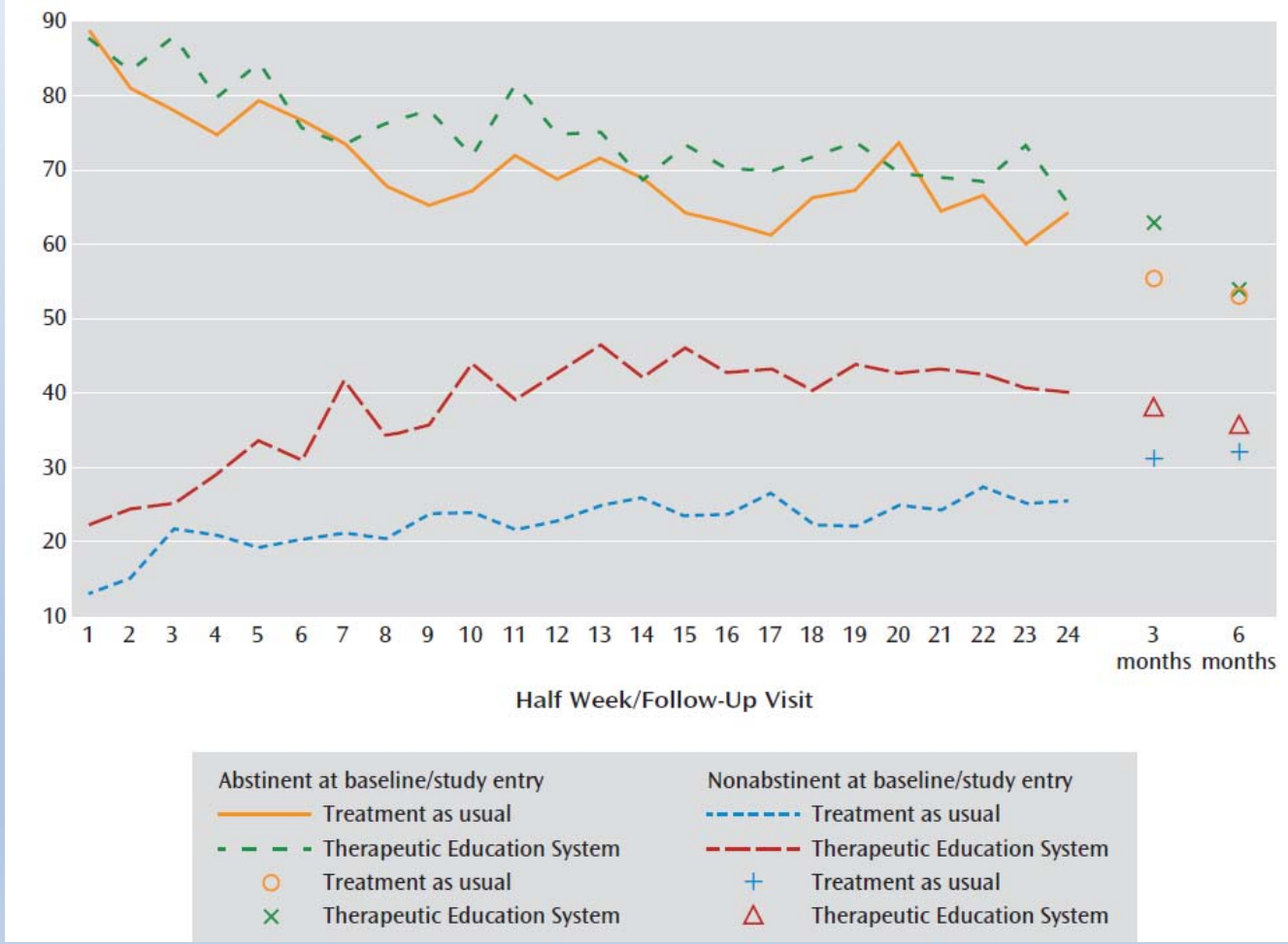


In addition, looking at what happens as a result of a specific behavior can help you identify Consequences of the behavior, both positive and negative. This may serve to increase or decrease the behavior in the future.

Social and Recreational Activities

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

Digital Therapeutic improves abstinence, particularly among those who are non-abstinent at treatment entry



Campbell ANC, Nunes EV, et al. (2014). *American Journal of Psychiatry*.

FDA just approved first “digital therapeutic” based on data from CTN Trial with TES

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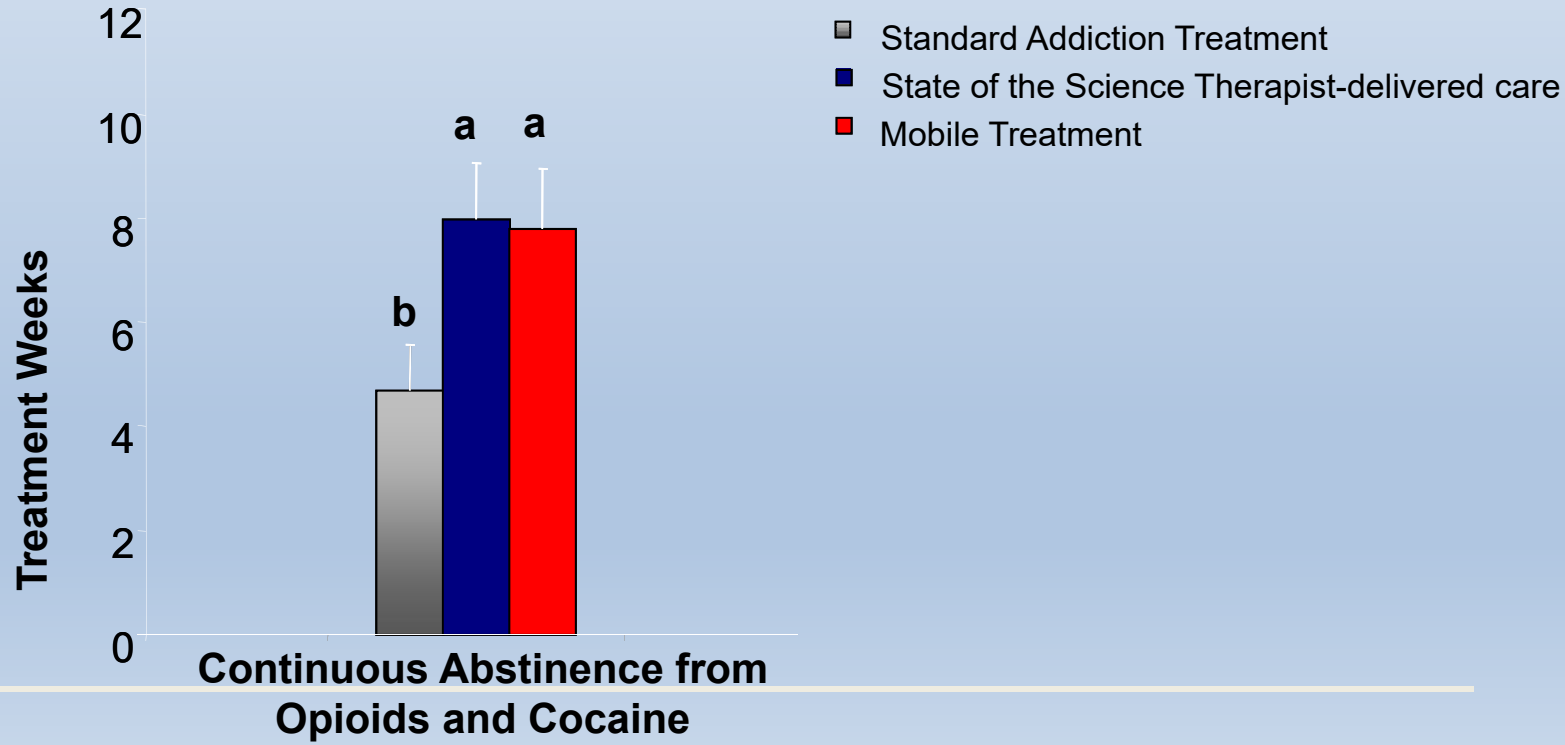
Replacing 80% of opioid addiction treatment with digital intervention is as effective as "gold standard" clinician-delivered treatment

- NIDA-funded randomized, controlled efficacy trial (n=135 opioid-addicted adults entering outpatient buprenorphine treatment)

(Bickel, Marsch et al., 2008, *Exp Clin Psychopharmacol)*



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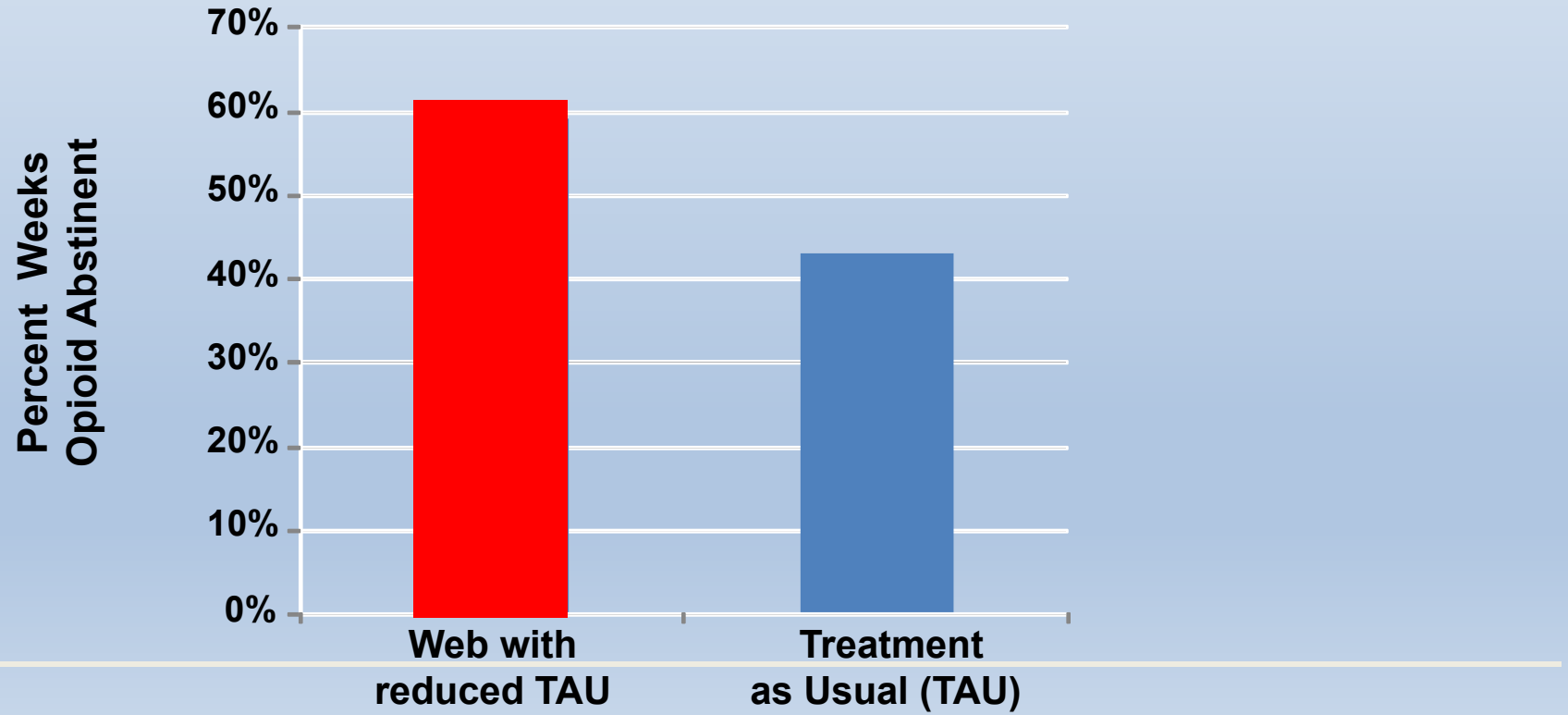
Replacing half of clinician-delivered opioid addiction treatment with digital intervention produces better outcomes than standard care

NIDA-funded randomized, controlled effectiveness trial with opioid-addicted adults (n=160; 12 month evaluation; (Marsch et al., 2014, *Journal of Substance Abuse Treatment)*



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Digital Therapeutic also produced best outcomes among high risk sub-populations of opioid-addicted adults

Participants with the following baseline risk factors had better outcomes when receiving digital therapeutic as part of treatment vs. standard treatment:

- low cognitive functioning
- high anxiety
- high ambivalence about treatment
- heavy alcohol use
- a greater number of prior treatment episodes at treatment entry

- Technology-based interventions may be useful **in minimizing the impact of specific risk factors on treatment outcome.**

(Acosta, Marsch et al., 2012; Kim, Marsch et al., 2015; 2016)

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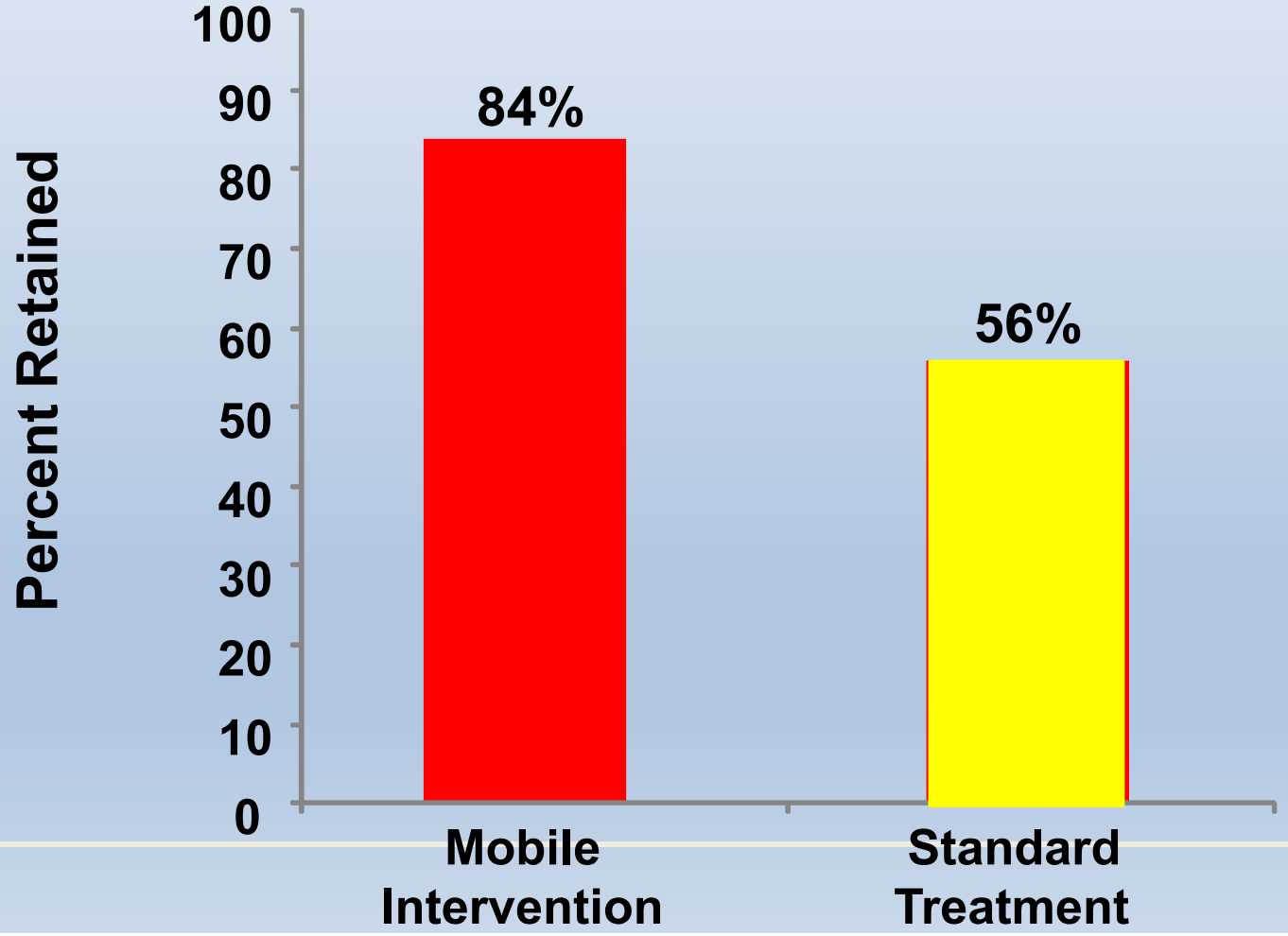
Adding mobile intervention as an adjunct to standard addiction treatment greatly increases treatment retention

(Guarino, Acosta, Marsch et al., 2016)



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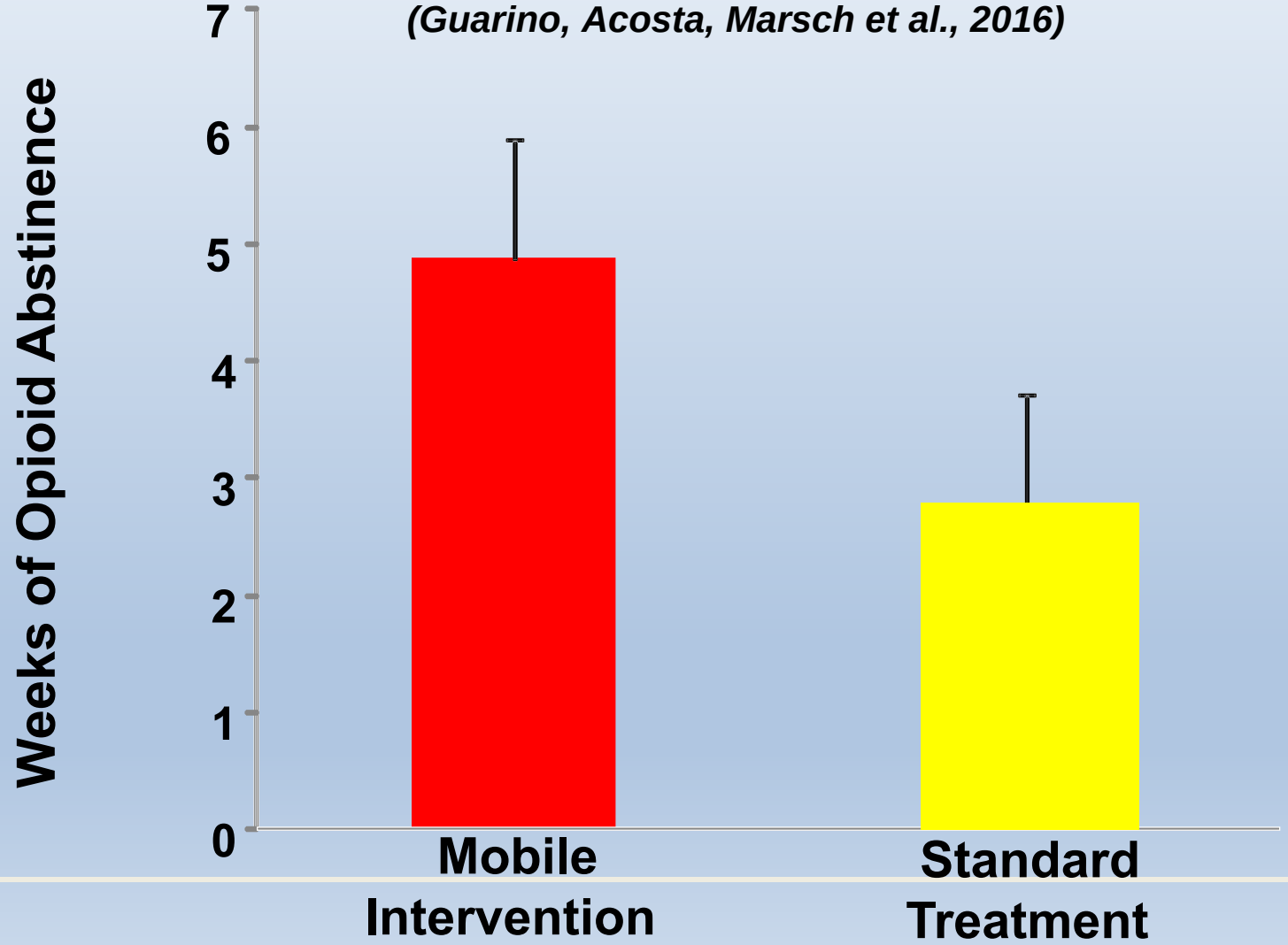
Adding mobile intervention as an adjunct to standard addiction treatment greatly increases drug abstinence

(Guarino, Acosta, Marsch et al., 2016)



Examples of related Research

- RCT, CJ-DATS network, N=494 (10 prisons) (Chaple, Marsch et al., 2013; 2016)
  - TES web-based behavior therapy comparable to clinician-delivered TAU (attendance, skills, abstinence post release; TES higher acceptability)
  - RCT, N=77 (Carroll, Ball et al., 2008)
  - Computer-based CBT increased abstinence in outpatient substance use disorder treatment compared to standard treatment alone
  - RCT, N=75 (Budney, Stanger et al., 2015)
  - Computer-based MET/CBT comparable to therapist-delivered MET/CBT for cannabis use disorders but at lower cost.

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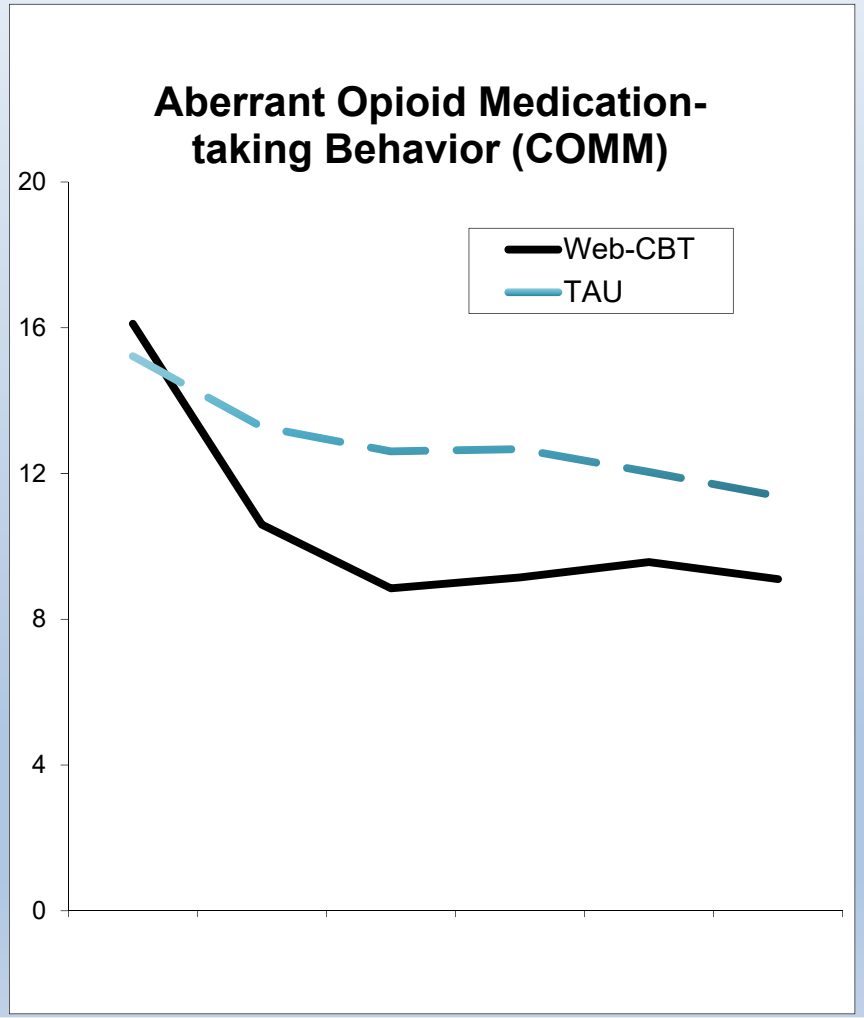
Adding digital therapeutic for chronic pain among patients with aberrant opioid taking behavior is more effective than traditional models of care



NIDA-funded; Pain Medicine, 2013

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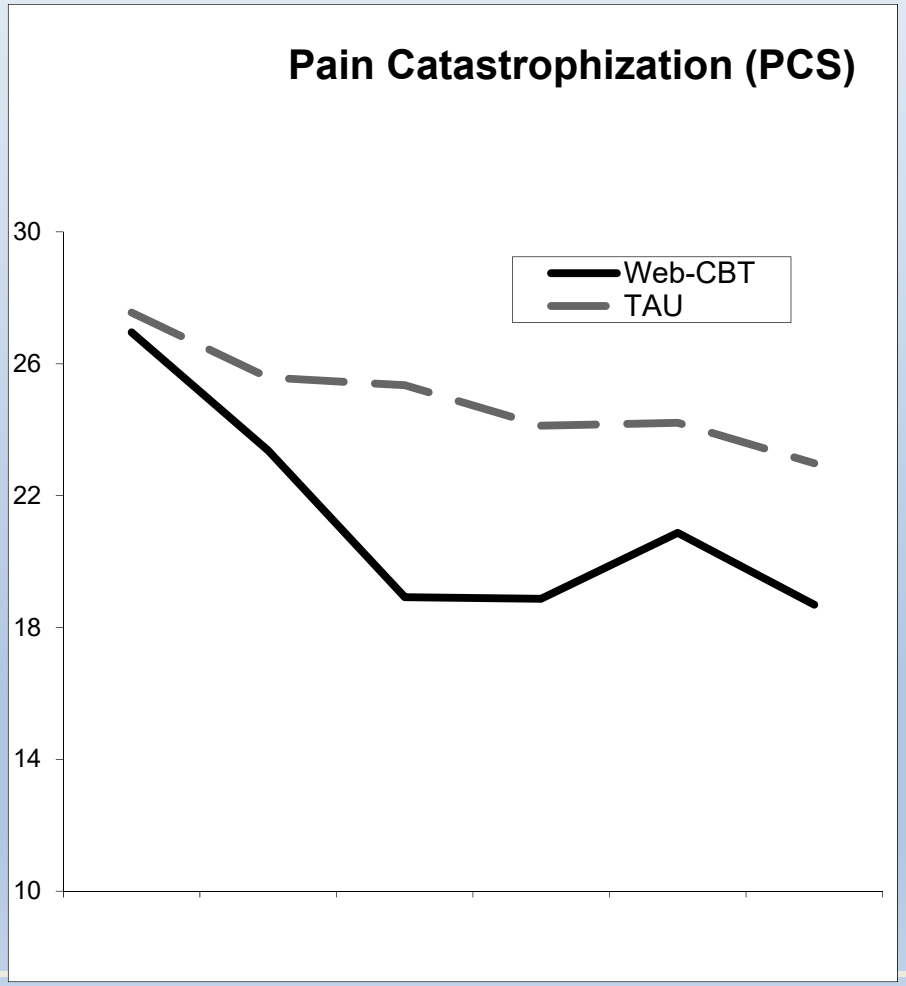

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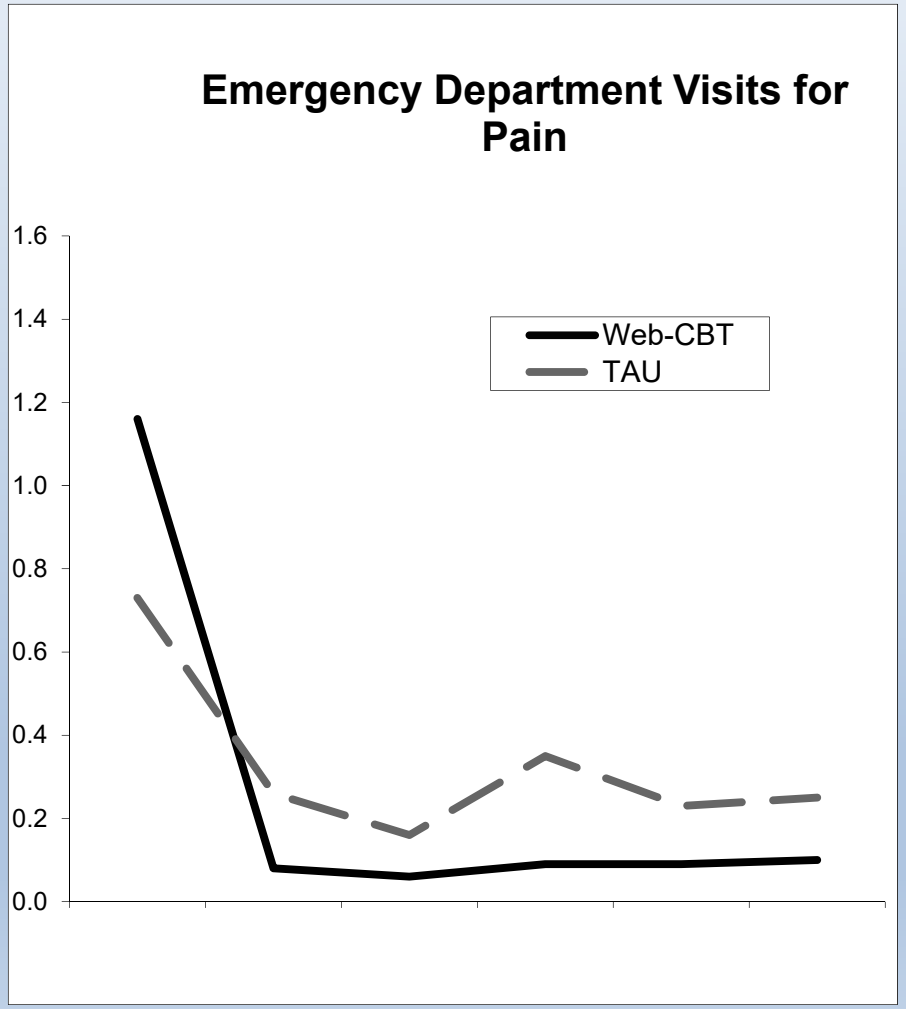

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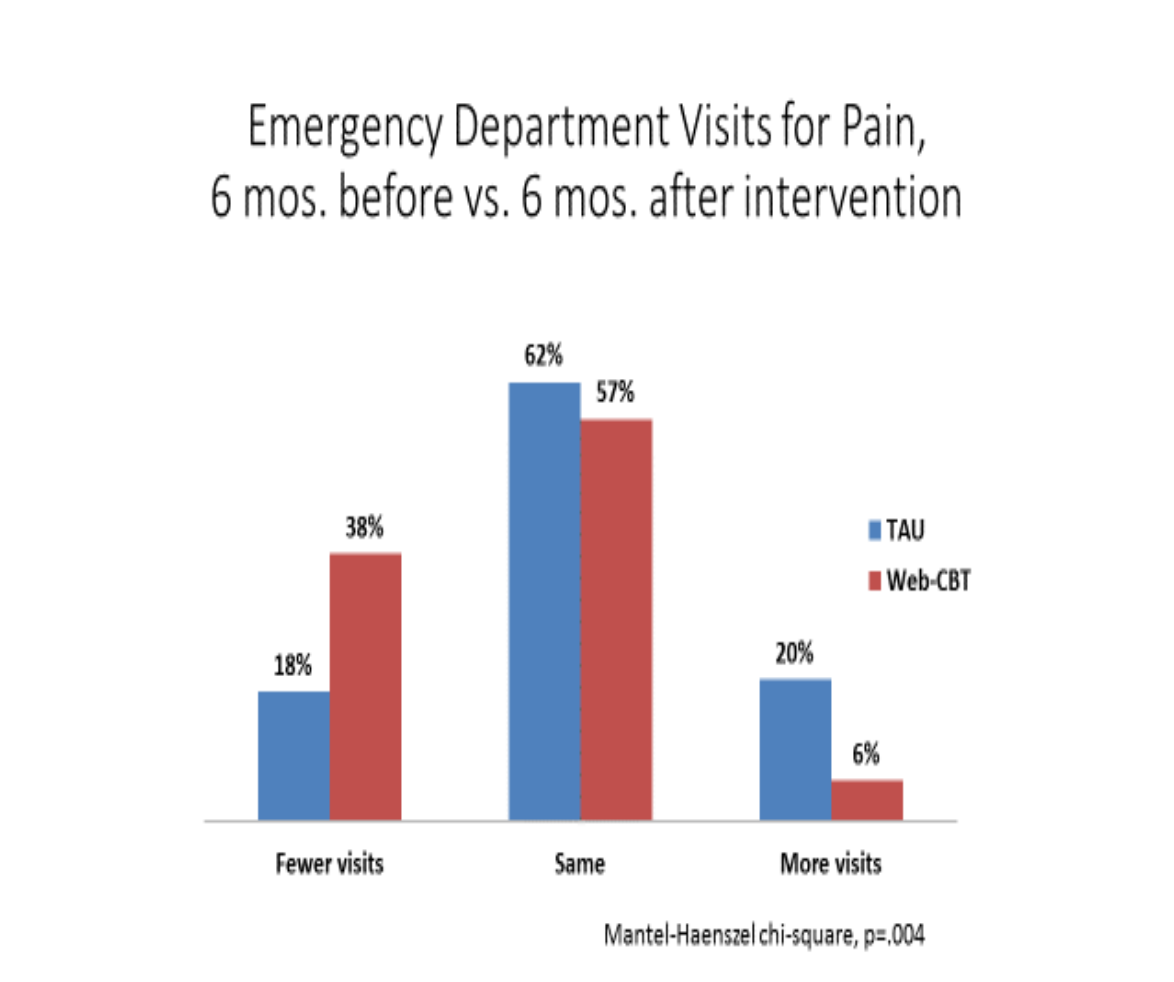

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Future Research and Clinical Opportunities

- Scale-up access to science-based therapeutic tools for SUD at a population level
- Expand understanding of mechanisms of action of digital therapeutics
- Expand responsive interventions that adapt to changing clinical trajectories over time
- Expand understanding of role of passive sensing in digital interventions to infer information about an individual's behavior, health and environment (to inform "just-in-time adaptive interventions").
- Examine role of social media for health monitoring and intervention delivery

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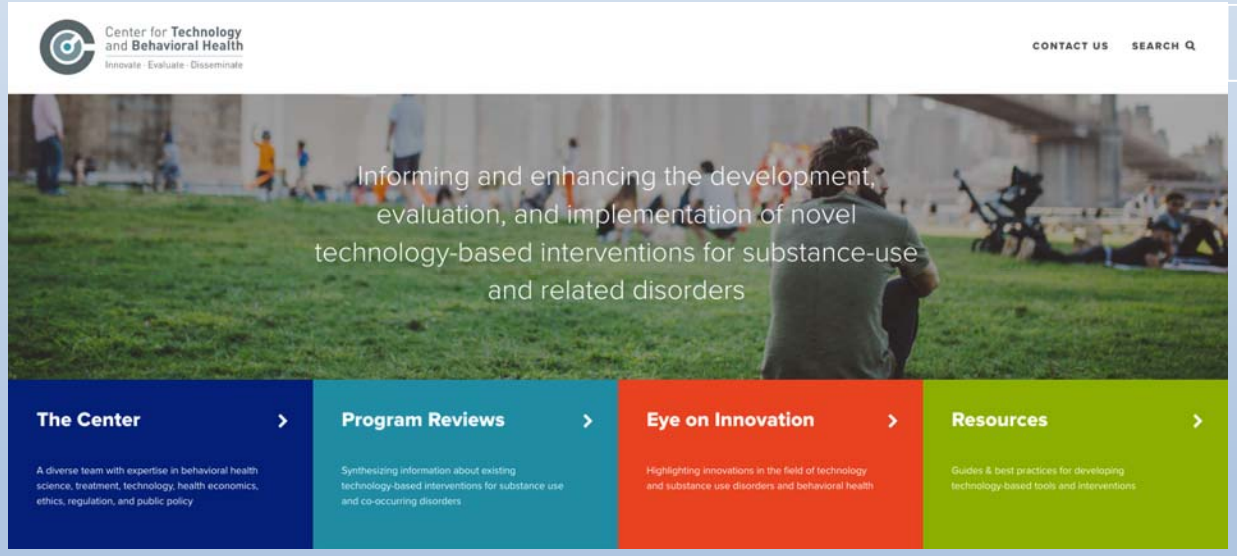

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The **Center for Technology and Behavioral Health** (CTBH) is a national research center designed to use science to inform the development, evaluation, and sustainable implementation of a wide array of digital technology-based tools for **substance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

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