

PainWeek®

Digital Therapeutics: Why is it and Why Does it Matter

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Disclosure

- No conflicts to disclose

Learning Objectives

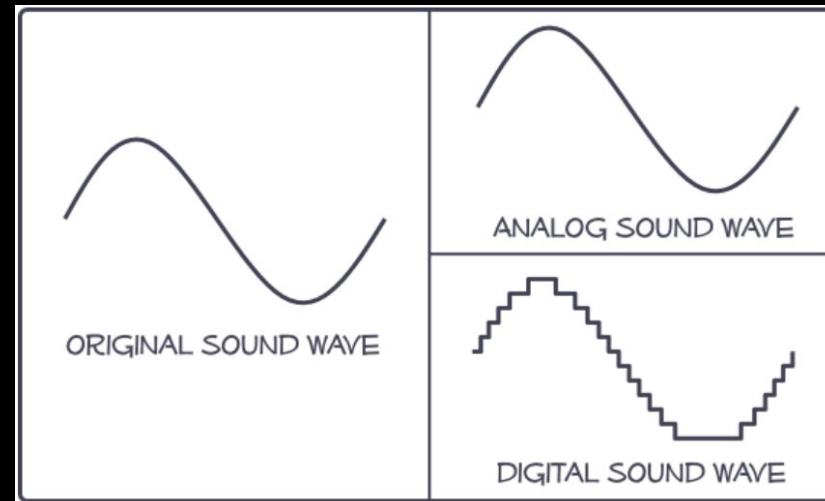
- Examine the analogue and digital worlds
- Discuss the digital arc from mainframes to wearable fitness monitors to interactive handheld devices
- Review the term digital therapeutics
- Review some of the applications of digital therapeutics in chronic pain management

Analogue Devices

- Human beings are ‘wired’ to experience the world on a continuous scale
 - Sphygmomanometer – mercury, aneroid, (eventually) digital
 - We experience and measure things on a continuous basis
 - Whether unconsciously or consciously, we experience things on a continuum
 - Music – continuous waves of sound
 - Photography – infinite palate of colors
 - Computers – the first calculators were human – Katherine Johnson, NASA “Hidden Figures” -20th Century Fox 2016
 - Mathematicians who used pencil and paper, eventually electromechanical devices to explore space

Digital Devices

- So, why “Digital”
 - Historically, most devices were analogue
 - An **analog** signal is a continuous signal that represents physical measurements
 - **Digital** signals are time separated signals. **Digital** signal uses discrete 0 and 1 to represent information



Analog vs Digital Computers

- An analog computer is a type of computer that uses the continuously variable aspects of physical phenomena such as electrical, mechanical, or hydraulic quantities to model the problem being solved.
- Digital Computers represent varying quantities symbolically and by discrete values of both time and amplitude.
 - If you use voltage to represent numbers:
 - 2 volts plus 8 volts = 10 volts
 - If we use mechanical representations – ie logarithmic measure
 - The Slide Rule Analog computer

In the beginning...

- Computers went from refrigerated rooms to desktops, handhelds and now, wearable computers
 - With decreased size came increased performance
 - Data entry progressed from punched cards, to magnetic tape and now, real time information input/output with immediate processing and data storage
- No longer just $2+1=3$ but rather $a+b=c$ where “a” and “b” can be any number and results are compared, grouped and sorted
 - The addition of logical operators and ultimately artificial intelligence has been part of the logical and ongoing progress of computer science

Wearable Digital Devices

- “FitBIT®” and similar devices are able to track, in real time personal activity; estimate distances traveled; calculate calories burned; log actual routes taken using GPS
 - Did they improve health? Maybe
 - Did they motivate activity? Perhaps
 - Are their claims studied in a controlled fashion and subject to peer review?
 - NO!** and that is where Digital Therapeutics steps in!

Digital Therapeutics (DTx)

- "Digital therapeutics are evidence-based behavioral treatments delivered online that can increase accessibility and effectiveness of health care."^{*}
- These are prescribed by physicians and meet (Health Canada) federal requirements for a Class II medical device
 - '...recognized as a pharmaceutical or supplement, intended as a diagnoses, cure, or preventive treatment of a disease, with the intention to affect the structure of a human or animal body.'^{**}

^{*}*Sepah, Cameron S.; Jiang, Luohua; Peters, Anne L. (2015). "Long-Term Outcomes of a Web-Based Diabetes Prevention Program: 2-Year Results of a Single-Arm Longitudinal Study". Journal of Medical Internet Research. **17** (4): e92.*

^{**}*Lougheed, T., How "digital therapeutics" differ from traditional health and wellness apps. CMAJ, 2019. **191**(43): p. E1200-1*

Digital Therapeutic Categories

- Generally, two general categories

- Treatment Augmentation

- Compliment and/or improve existing standards of care
 - The goal is often to replace or decrease the sustained need for pharmacotherapy
 - Fairly good clinical evidence to support this

- Treatment Replacement

- Intended to fully replace standard interventions such as face-to-face therapy; in person physical therapy or even pharmaceutical/surgical interventions
 - Requires further study and ongoing trials to establish efficacy

Digital Therapeutics

- Clearly, the current DTx applications are often based on Cognitive Behavioral Therapy
- At present, there are only 5 FDA prescription Digital Therapeutic apps

<https://kenblockconsulting.com/fda-submissions>

Company	Product Name	Therapeutic Area	FDA Status
Pear Therapeutics	reSET	Substance Use Disorder	De Novo
Pear Therapeutics	reSET-O	Opioid Use Disorder	510(k)
Pear Therapeutics	Somryst	Insomnia	510(k)
Akili Interactive	EndeavorRx	ADHD	De Novo
Amalgam	iSage Rx	Diabetes	510(k) Class II

<https://www.mobihealthnews.com/news/physicians-will-decide-fate-digital-therapeutics-industry>

Benefits of Digital Therapeutics

- Always available – anywhere; any time
 - Reduces logical friction – ie clinic space/scheduling
- Reduced stigma – as a non-compliance issue
 - Enhanced engagement
- Affordable
 - Said to be a ‘reduced cost’ means of delivering mental health interventions
- Timely positive reinforcement
 - Immediate positive feedback and reinforcement
- Self-management and engagement
 - True partnership in care healthcare delivery
- Scalability, Standardization and Personalization

Positive Reinforcement

- “immediate positive feedback and reinforcement to help a patient celebrate small milestones”*
 - ‘the frequency of success matters more than the size of the success’
- Immediate positive feedback and reinforcement helps maintain positive behavioral change**
 - Some applications offer contingency management as a means to ‘reward’ task completion i.e. vouchers at coffee shop; bookstores

*Fogg, B.J., *Persuasive technology: Using computers to change what we think and do*. Ubiquity, 2002. **2002**(December).

**Rogozinski, B., et al., *Digital Therapeutics in the Management of Chronic Pain*, in *Handbook of Pain and Palliative Care*, R.J. Moore, Editor. 2018, Springer Nature. p. 601-21.

Potential Risks

- Digital Therapeutics might not be for everyone
 - Internet addiction
 - Gamer addiction
 - Gambling addiction
- Especially with contingency management, risk of transferring one dependency for another

Digital Therapeutics – a rough start

- Digital health technologies were initially touted as a panacea for all healthcare delivery problems (Lupton 2017)
 - Many missteps, exaggerated promises and hundreds of millions of lost investment dollars
 - Initially over 260,000 “healthcare” applications and even more online websites, electronic devices....
 - But today, this is much less the case
 - The challenge will be in finding DTx ‘rightful place’ in 21st Century healthcare

What's the Hold Up?

- While the market for DTx is expected to reach \$9 billion by 2025, physicians seem to be the rate limiting step but...
 - There are difficulties in distinguishing DTx from more general health and well-being applications
 - Uneven incentives in the healthcare environment
 - Who pays?
 - Rough start to the industry – much promised – less delivered
- Adoption of DTx may take longer than desired, but DTx is here to stay

Digital Therapeutics in the Management of Chronic Pain

- Optimal care for chronic pain always includes combination therapy
 - Most pain experts agree that a focus on the “functional restoration approach” results in improved outcomes for patients – American Chronic Pain Association
 - Addressing the psychological factors such as stress, fear of reinjury, avoidance behaviors, motivation, catastrophization, sleep disturbance, poor social support, substance abuse, negativity issues
 - All issues that lend themselves to Digital Therapeutics
 - The ability to track performance while educating -> physical therapy combined with cognitive behavioral therapy can be realized 24/7 through digital access with patient supplied digital platforms i.e. iOS, Android phones/tablets or clinic supplied devices

Digital Therapeutics for Chronic Pain

■ Research and Validation for Digital Trackers

- Digital trackers and diaries are considerably easier to use than pen and paper (Vardeh et al 2013)
 - They are also used more reliably and more likely to be used regularly
 - Self-monitoring via smartphone has been shown to increase self-awareness
 - Activity tracking has been shown to improve health outcomes

■ Research and Validation for Education/Coaching Programs

- Following pain psychology learning and physical therapy – digital education and coaching can provide 24/7 ‘on demand’ access to daily treatment (Castro Sweet et al 2017)
 - Measurable compliance metrics to evaluate treatment progress and future options

Digital Therapeutics for Chronic Pain

- Cognitive Behavioral Therapy (CBT)
 - CBT has been shown to be an effective treatment chronic pain
 - For pain management, CBT is a form of education and neuroplasticity training helping patients focus on positive and controllable aspects of their life
 - Digital CBT apps provide interactive/multimedia lessons on identification of negative thoughts/behaviors that can worsen pain
- Research and Validation Digital CBT
 - Andrews et al. 2010 reviewed 22 RCTs looking at computerized CBT for major depressive disorders – shown to be equal to or better than traditional CBT

Specific DTx approaches to Chronic Pain*

- Trackers and diaries for chronic pain
- Education/coaching programs
- Cognitive behavioral therapy (CBT)
- Mindfulness-based interventions
- Acceptance and commitment therapy (ACT)
- Biofeedback
- Complimentary and alternative medicine (CAM) therapeutics
- Virtual environments and virtual reality

*Rogozinski, B., et al., *Digital Therapeutics in the Management of Chronic Pain*, in *Handbook of Pain and Palliative Care*, R.J. Moore, Editor. 2018, Springer Nature. p. 601-21.

Digital Therapeutics for Chronic Pain

- Mindfulness-Based Interventions (MBI) for chronic pain
 - Idea advanced by Jon Kabat-Zinn in 1979 (Kabat-Zinn 1982) that helps focus attention away from pain and related distress, reducing pain processing by the nervous system
- Research and Validation of Digital and online mindfulness interventions
 - Spijkerman et al 2016 reviewed RTCs for 15 digitally delivered versions of MBI showing a small but significant impact on depression, well-being and mindfulness – largest effect was on stress

What's the future hold?

- A digital software system developed by Finnish drugmaker Orion uses a VR headset to guide Chronic Pain Patients through a series of CBT exercises designed to overcome the fear of movement (Kinesiophobia)
 - Their system, using VIRPI (virtual immersive reality program interface) in collaboration with Prof Christopher Eccleston of University of Bath's Centre for Pain Research have shown that the TSK score (Tampa Scale for Kinesiophobia)
 - Developers optimistic of the utility / acceptance of this technology, especially due to COVID-19 restrictions placed on face-to-face and group therapy

VIRPI

- The principle of the technology is to create an immersive environment that is so engaging, the patients' "limbic system and prefrontal cortex are hijacked, allowing the patient to conquer their fear of movement"
 - At present, the CBT coach is presented as the "Voice of God" but they plan to move toward a culturally sensitive, virtual therapist the patient can form an emotional bond with
 - The problem of the "Uncanny Valley", which is the sense of something strange or being "not quite right" with a humanoid avatar is averted by using a non-human representation – "...a Mr. Paperclip on steroids"

Conclusions

- Digital therapeutics holds great promise for the future of cost-effective delivery of evidence-based care
 - The current COVID-19 pandemic has shown that the time is now to leverage digital technology for the safe delivery of healthcare
- Let's hope that this will be a compliment to, rather than a replacement of traditional clinical care
- Now, Dr Lantie Jorandby will now explore digital therapeutics through the eyes of a seasoned addiction psychiatrist

References/resources

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