Digital Therapeutics for Symptoms of Concussive Traumatic Brain Injury in United States Military Service Members and Veterans: Developments at the Center for Neuroscience and Regenerative Medicine

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BACKGROUND

- Since 2000, nearly 414,000 service members (SMs) in the United States military have been diagnosed with TBI. Approx. 83% of these injuries are classified as concussive (cTBI), or mild TBI[1].
- Disabling and common post-concussive symptoms (PCS) include insomnia, mood disturbances, and post-traumatic headache (PTH). SMs report them at higher rates than civilians and experience high rates of comorbidity[2].
- Cognitive-behavioral therapy (CBT), one of the best known forms of psychotherapy, is effective in treating a myriad of mental disorders.
- Modern technology has made it possible to deliver CBT without the guidance of a medical provider.
- Approx. 77% of US adults own a smartphone, and one in five are smartphone only internet users, meaning they no longer use traditional home broadband internet services[3].
- As technology advances, mobile mental health treatment can benefit from larger screen size, easier data input, mobility, lighter weight, and user friendliness.

DIGITAL THERAPEUTICS

- The Digital Therapeutic Alliance defines digital therapeutics (DTx) as treatments that “deliver evidence-based therapeutic interventions to patients that are driven by high quality software programs to prevent, manage, or treat a broad spectrum of physical, mental, and behavioral conditions.”
- A self-guided DTx could reach patients outside of the DoD health systems, or who do not have access to in-person therapy. To our knowledge there are no comprehensive, standalone DTx for symptoms associated with cTBI.

NOVEL DTx DEVELOPMENT

Depression

- This intervention is based on evidence-based CBT manuals: (1) the Department of Veterans Affairs’ (VA) *Cognitive-Behavioral Therapy – Depression* (CBT-D), and (2) *Cognitive-Behavioral Therapy – TBI* (CBT-TBI) manuals, developed by the research team at the Life Improvement Following TBI (LIFT) Research Group.

Post-Traumatic Headache

- The PTH intervention will take its structure from the VA’s *Cognitive-Behavioral Therapy – Chronic Pain* (CBT-CP) manual(Figure 1). Development of this DTx will be heavily integrated with first-hand experience from subject matter experts who use CBT to treat primary and PTH.

Both programs will incorporate:

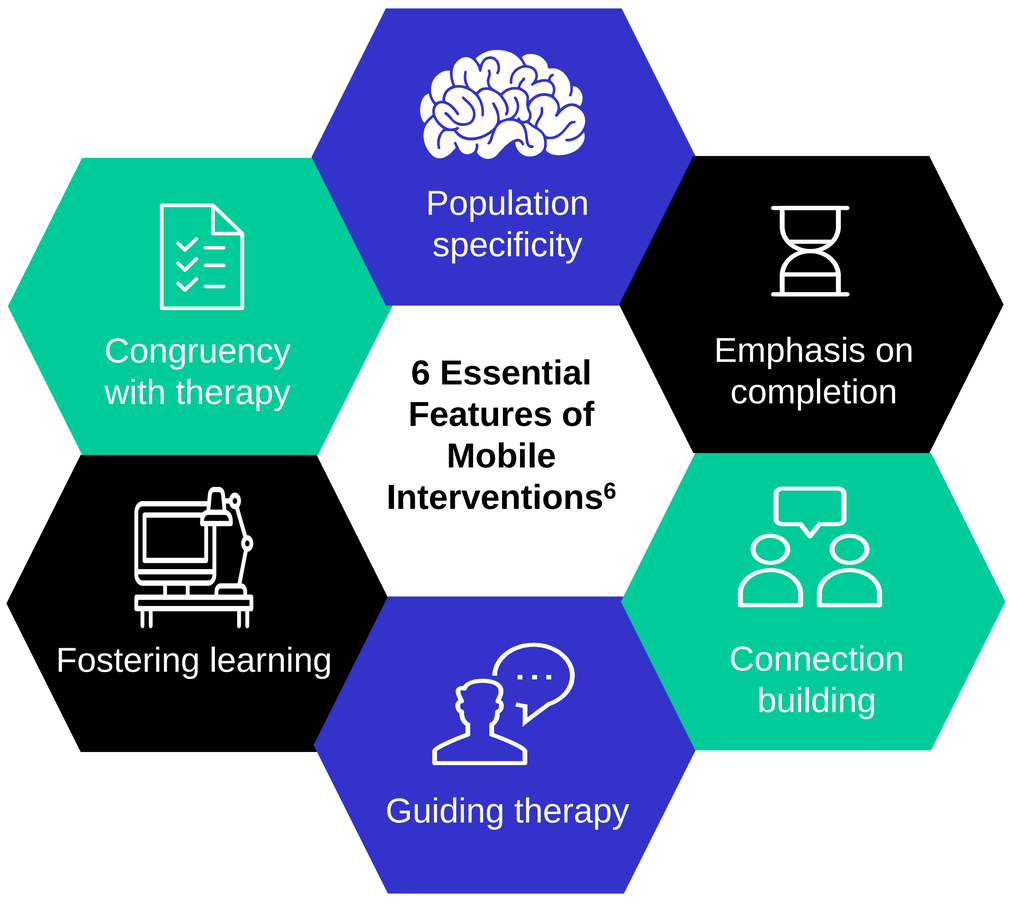
- Scientific framework to modify maladaptive behavior and reduce symptoms[5]. This model was originally used in the development of the SHUTi program (see section titled “Collaborations”).
- The six essential features of mobile application interventions to maximize compliance and minimize attrition[6].
- A focus on developing therapeutic alliance between the user and the DTx using military specific vignettes and motivational interviewing techniques.

Upon completion, each DTx will be tested in randomized controlled trials against psychoeducational comparison applications.

COLLABORATIONS

Insomnia

- CNRM has collaborated with the University of Virginia to test their internet-based CBT for insomnia program, *Sleep Healthy Using the Internet* (SHUTi)[7], in a military population. SHUTi has yielded promising results in other populations and has demonstrated similar efficacy and tolerability to conventional CBT-I.
- **Study design:** Internet-based, blinded, controlled, randomized trial with an optional, post-treatment open-label period. Up to 200 participants will be randomized to either active treatment or education comparison groups in a 3:1 ratio, respectively.



CONCLUSION

CNRM plans to use DTx to reduce PCS in a manner that is not dependent on a provider. These programs will fill the gaps where in-person therapy is not possible, rather than reduce person-to-person interaction for those able to receive it. Ideally, every SM who needs CBT would be able to engage in person-to-person therapy; realistically this is not always feasible, especially in the US military population. The Department of Defense estimates they would need 20 times the number of current therapists to address their needs. Therefore, many individuals who would potentially benefit are left without treatment. This represents a major unmet medical need.

The opinions and assertions expressed herein are those of the author(s) and do not necessarily reflect the official policy or position of USU or DOD.

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