

Challenges in Utilizing App Based Data for Assessing Effectiveness

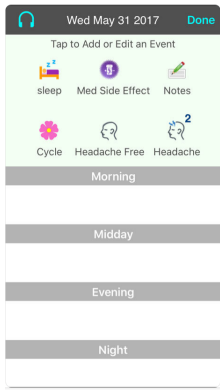
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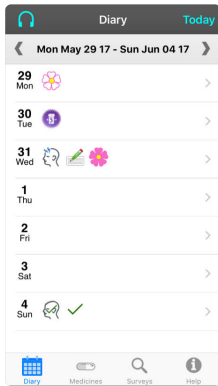
Context

- ▶ Mobile application developed to provide relaxation therapy for patients with certain neurologic disorder
- ▶ Participants are expected to play the relaxation therapy for upto 22 minutes every day
- ▶ Therapy is expected to improve patient outcomes:
 - ▶ pain intensity
 - ▶ frequency
 - ▶ overall well being

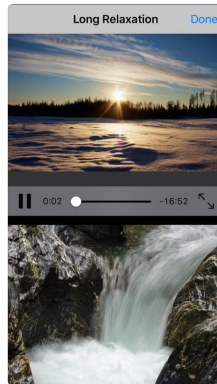
Snapshot of the App



Diary



Diary



Treatment

Randomization to Evaluate Effectiveness

- ▶ Participants were randomly assigned to control or treatment arm
 - ▶ Control arm receives standard care and diary feature in the mobile app
 - ▶ Treatment arm will have access to special therapy feature in the mobile app
- ▶ Participants in treatment arm are expected to use the therapy for up to 22 minutes every day
- ▶ Both groups have access to diary in mobile app to record their daily progress

Data

- ▶ Baseline characteristics were measured during enrollment and entered in a registry
 - ▶ Demographics
 - ▶ Certain comorbidities
 - ▶ Past medical history and medication use
- ▶ Diary data as updated by the participants in the app
- ▶ Usage data: how often and for how long the therapy was used
- ▶ Follow-up based survey data
 - ▶ from the app
 - ▶ from follow-up calls
- ▶ Linking or integration from various data sources is needed!

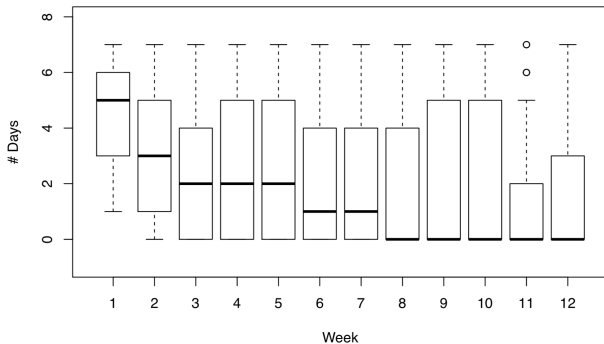
Outcomes

- ▶ Daily diary entries
- ▶ Follow-up call every month
- ▶ Survey using the mobile application
- ▶ Include measures of frequency, intensity, other severity scores

Goal

Assess if the app based therapy is helping participants improve neurologic disability related outcomes

Per Week Frequency of Use of the App in Treatment Arm



Per Week Frequency of Use of Diary

Figure: Treatment Arm

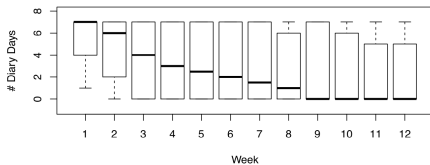
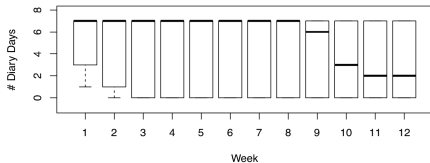


Figure: Control Arm



Related questions

- ▶ How do we frame the question around whether the app is effective in alleviating the disability?
 - 1 Are the participants who are assigned to treatment arm more likely to have better outcomes compared to standard of care?
 - 2 Those who use the app more often have better health outcomes compared to those who are not using it often?

- ▶ What is the role of randomization?

Thinking Out Loud

- ▶ Are we in the IV regime now?
- ▶ Are those who are not using the app frequently non compliant?
- ▶ Can we think of the treatment as continuous exposure?
- ▶ Role of randomization
 - ▶ Participants were randomized to have a balance between control and treatment arm
 - ▶ Balance between different level of treatment is not assured
- ▶ Is micro randomized trial design the only alternative?

Thank You!

- ▶ Clinical collaborator: Dr. Mia Minen, MD, MPH
- ▶ Research scientist: Liz Piragella, MS
- ▶ Collaborators at NYU Langone Hospitals and NYU School of Medicine