Title: Implementation of a Fully Virtual Trial in an Interventional Study of the effects of caffeine on cognition and mood

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Abstract:
Introduction/: Interest in fully remote clinical studies continues to expand given the evolving capacity of such programs to increase patient reach, to improve patient environmental data, and shift operational burden away from sites. The relentless expansion of technologies for patient engagement, real time data collection, and trial management creates novel opportunities for patient outcome research. In this study, we integrated remote engagement and mobile device platforms to conduct a drug intervention virtual trial.
Methods: Over 2000 patients were self-identified via social media advertising, 759 were screened for participation via online portal yielding 414 patients for this IRB approved, twelve cohort trial examining the effects of variable caffeine dosages on cognitive function, physiological parameters, and mood. Outreach advertising employed social media filters to achieve a balanced distribution across gender and age groups. Patients were qualified and electronically consented via online questionnaire for registration into the trial. Patients were randomized into twelve cohorts and contacted by the study team to walk through the activation process of the patient engagement mobile application (Trial Guide) on patient's own mobile phone (BYOD). Trial Guide served as the hub for all patient specific protocol requirements including the study schedule, activity and engagement reminders, patient dosing, survey data collection, and cognitive assessment games. Trial Guide also hosted information including helpdesk phone number and email. We coordinated the shipping of the caffeine dosages and the electronic patch that tracked activity, galvanic skin response, skin temperature, and heat flux for direct delivery to the patient's home along with printed study and device application materials.
Results: Following the reminders and instructions in Trial Guide, patients initiated their individual study start by selecting their desired "Day 1" in the app triggering the sequence of study obligations including: application of the patch, taking the first of multiple surveys, and playing the first of four in-app cognitive games following first caffeine dose. The surveys measured several elements including lifestyle, personality traits, emotions & moods, and post-caffeine consumption characteristics while the in-app games measured attention span, reaction time, and memory. The cycle of variable caffeine dosing, time dependent survey completion, and cognitive games was repeated for the six day treatment period across the cohorts. Following the treatment period, patients removed the electronic patch and returned it for data extraction. Protocol deviations, such as missed survey time window or cognitive game, occurred at a rate of <11% over 9900 protocol directed patient activities and comparable to non-virtual trials.
Conclusions: Methods employed here for identifying, screening, and consenting patients proved to be effective and reflect the growing success of online outreach in recruiting and enrolment for both conventional and remote studies. Engagement via Trial Guide enabled patient retention and directed protocol activities including dosing, surveys, and games to be completed on time, in sequence, and remotely without site visits or other intervention. The execution of this virtual study leveraging BYOD and a wearable data collection device demonstrates the capacity of this approach for expanding patient populations and capturing unique and contextual patient information.