Testing the Effectiveness of Night Shift, a Theory-based Customized Video Game
NCT06063434
9-19-2023

Night Shift Trial – Intervention and Control Groups
Consent via Qualtrics

Thank you for your interest in this NIH-funded research study. My name is Deepika Mohan and I am a researcher at the University of Pittsburgh – School of Medicine. The purpose of this study is to test the effect of a video game on the implementation of clinical practice guidelines in trauma triage. Specifically, we are interested in whether video games have a greater effect on physician behavior than more conventional continuing medical education, like reading journal articles.

As part of this study, we will be randomizing 800 physicians to one of two arms: the intervention or usual care (control). Physicians in the intervention group will be asked to play a video game (*Night Shift*) for two hours within two weeks of enrollment, and then return to the game for three twenty-minute booster sessions at 3-month intervals. They will be asked to report on their experience with the game after the initial two-hour session, and again after the third booster session. They will also be asked to complete a web-based tool that assesses decision making, after playing the game for the first time. Participants in the control group will be asked to complete the web-based tool that assesses decision making and a questionnaire. Completing study tasks will depend on the group you are randomized to and may take 1-4 hours over nine months. Tasks can be completed at the convenience of the participant within some general time spans as noted above between January – September 2024.

We will provide trial participants in the intervention group with an Apple iPad on which to play the video game and complete study tasks. Participants keep the iPad as part of their honorarium at the end of the study. In addition, the intervention group will receive $25 in gift card format per twenty-minute video game booster session completed. Participants in the control group will receive an honorarium of $100/hour in gift card format spent on study tasks. As per IRS guidelines, all compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099-Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

There will be no direct benefit of participation to you. We will be linking your responses to claims data to identify how you make decisions for patients in the Emergency Department, and the effect of the intervention on those decisions. The primary risk would be a breach of confidentiality, which might damage your reputation if your description of how you manage patients is judged in a negative fashion. To prevent this from happening, the identifiers will be stored separately, and your responses will be coded and stored on a secure server maintained by the Data Center in the Department of Critical Care Medicine.
Your email address will be stored alongside the responses you provide and any game usage data that we collect. We will subsequently de-identify the data prior to analysis. The linkage file that ties your name to the identifier will be kept on a secure server behind the University of Pittsburgh firewall. The research team, the University of Pittsburgh Office of Research Protections, and personnel from the NIH, will have access to the research records. Also, your University of Pittsburgh STUDY23070156 Effective: 9/19/2023 Expires:
research data may be shared with investigators conducting other research; however, this information will be shared in a de-identified manner (without identifiers).

Obviously, your participation in this study is completely voluntary (and much appreciated). You may withdraw at any time. Should you choose to withdraw, all data will continue to be used up to the point of withdrawal unless you request that we destroy it. There is no penalty for refusing to participate or withdrawing. A description of the clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most the website will include a summary of the results. You can search this website at any time. Any questions or concerns should be directed to me as the principal investigator in this study: Deepika Mohan. The phone number where I can be reached is412-647-0860. If you have any concerns about the study or your rights as a participant, you can contact the University of Pittsburgh human subject protection advocate phone line (1-866-212-2668).

If you are willing to participate, please fill out the following items below which will be used as an electronic signature:

1. Full name
2. Birthdate
3. Name of your high school
4. Are you willing to participate in this study (yes/no)
5. Do you provide your permission to be audio/video recorded for the purposes of this study (yes/no).

If yes to #4 and 5, participant will proceed with demographic questions.