

A Randomized Controlled Trial Assessing Two Methods for Teaching Components of Brain Death Determination for Multidisciplinary Trainees

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Abstract

Trainees graduating from critical care specialties, neurology and neurosurgery are very frequently given credentialing privileges across the country to perform clinical brain death determination. However, there continues to be a significant deficiency in effective training modalities that adequately prepares these trainees for this role. We designed a randomized controlled trial assessing two methods for teaching components of brain death determination. Our target audience are neurology, neurosurgery residents, critical care fellows with base specialties in internal medicine, neurology, anesthesia, emergency medicine, general surgery and Nurse/PA advanced practice providers. The primary outcome of this study is to measure competency and recognition of key pitfalls in brain death exams and apnea tests. The secondary outcome is the assessment of confidence level in performing brain death determination.

Background & Purpose

At hospitals around the country including Emory University hospitals, critical care providers, neurologists and neurosurgeons are credentialed to perform either components of or a complete determination of brain death. Many clinicians remain uncomfortable performing components of brain death determination due to deficiency in training afforded by their base specialties. i.e. A pulmonary critical care physician may be less comfortable performing a neurological brain death exam and a neurologist or neurosurgeon may be uncomfortable performing an apnea test (a test to determine the absence of breathing drive) having limited exposure to ventilator management. Clinicians around the country are frequently given privileges to perform brain death testing without adequate training which raises the concerns of errors in determination of brain death or avoidance in performing this role despite being credentialed. Given the high stakes involved in appropriate declaration of brain death which enables the possibility of deceased donor organ donation, errors in this process should be never events. There remains a concern that existing training methods remain insufficient to prepare multidisciplinary clinicians to perform this role effectively.

Methods

We will conduct a randomized control trial to compare two teaching methods that have been adopted to teach key components of brain death determination. Participants include neurology and neurosurgery residents and critical care fellows with backgrounds in neurology, internal medicine, anesthesia, emergency medicine, general surgery and Nurse/PA advance practice providers.

i. Primary endpoints of this study include an assessment of competency and recognition of key pitfalls in brain death assessment and apnea test measured through observing and recording performance of key interventions and behaviors recorded by video.

ii. Secondary endpoint of this study measures the comfort levels in performing brain death determination using a pre and post-course survey.

Participants and evaluators are blinded to the teaching method. Participants will only be aware of teaching modalities used in the arm they are enrolled in. We intend to enroll 40 participants based on our power calculations derived from best estimates of the scores in each arm. Total duration of participation for each participant is 5 hours. This study is anticipated to run over 24 months between October 2022 and 2024. Given flow risk nature of the study, we have submitted our IRB application to allow for verbal consent which would significantly improve recruitment.

Design Challenges:

During the design of this randomized controlled trial comparing two teaching modalities, we developed solutions to a number of challenges and complexities. These include:

1) Ensuring equal time on task/teaching in each arm - Teaching modalities a frequently not homogenous in time allocation. We had to modify each teaching modality to be equal in time to avoid the contribution of time on task/teaching to confound the results.

2) Blinded reviewers. To avoid bias additional faculty and fellow reviewers blinded to the teaching modality will score each participant using video recordings of the brain death assessment

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3) Minimizing confirmation bias for preferred mode of teaching by partially blinding participants. Participants will not be aware of the teaching modality they have been enrolled in until the actual day of participation. They will not be aware of the modality used in the other arm of the study until after participation in the course.

4) Ensuring real world applicability through the allowance of cognitive aids during assessment –In practice, clinicians often will use hospital based protocols to guide them during this brain death assessment especially since there are multiple steps to the process. Mistakes happen despite the use of this criteria. We debated if using this cognitive aid would confound the results of the study and contribute to a type II error specific to one teaching modality being more effective than the other. However, real world applicability of the study outcome in critical. We anticipate finding a difference in spite of the use of a cognitive aid.

5) Determining objective outcome measures of performance. We compiled a list of critical steps, decisions and pitfalls. Observed interventions, behaviors or decisions would be reordered in 3 categories i) performed accurately ii) performed sub optimally and iii) did not perform. We expect a 20% difference in scoring. For standard deviation of 20, power of 80% and alpha of 5% we will require at least 16 per group (32 total). We plan to enroll 40 participants total to account for withdrawal or technical glitches with video recording that renders data uninterpretable

6) Developing novel teaching aids and methods of assessment specific to brain death testing – We used a combination of commercially available teaching aids as well as modifying existing ones. We had to secure a site and equipment where this study could be easily and reproducibly performed.

7) **Most important challenge:** To ensure that we respect the time and commitment of trainees in high stress and workload specialties, we prioritized a design whereby participants in both arms will receive an equally enriched learning experience. This was a critical prerequisite that shaped the design of the entire study.

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Description of 2 methods of teaching brain death determination :

To avoid confirmation bias surrounding preferred teaching methods, details of the methods will only be available to: study faculty, Emory IRB, training program directors and participants upon completing the course. Participants will be asked to avoid discussing details of the course with other participants.



References

1. Braksick, S.A., et al., *Variability in reported physician practices for brain death determination*. Neurology, 2019. **92**(9): p. e888-e894.
2. Wahlster, S., et al., *Brain death declaration: Practices and perceptions worldwide*. Neurology, 2015. **84**(18): p. 1870-9.

*Addition references specific to teaching methods have been omitted.

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