DCTclock as a Recruitment Tool for Clinical Trials

Daniel Lawler MD, Stephen Thein PhD, Jill Crusey PhD
Pacific Research Network, an ERG Portfolio Company
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Hypothesis

The Digital Cognition Technologies (DCTclock) has the potential to become an effective and efficient recruiting tool in rapidly identifying potential Alzheimer's disease clinical trial participants. It was theorized this pen-like device and scoring algorithm would:

1. Engage the subject without promoting test anxiety
2. Require a minimum of time and skill to administer vs. conventional tests
3. Earlier identification of memory impaired people

Conclusions

The DCTclock was accurate and required significantly less time to identify subjects with memory impairment. It allowed for many more screenings following memory "talks", and other outreach events where free memory screens were offered.

Background

Patient recruitment has become the largest single reason cited as a delay in on-time clinical trial completion. Lovato et al. (1997) cite profound barriers in clinical trial recruitment. Kadam et al. (2016) states, "Successful recruitment of patients is known to be one of the most challenging aspects in the conduct of randomized controlled trials." One solution identified was to "cast a wider net" in identifying memory-impaired patients through a method of rapid identification, spending valuable time only on those identified as potentially cognitively impaired. Denial of impairment adds to the problem when using conventional, labor-intensive and confrontational assessment techniques, such as the MMSE, MOCA and AVLT. These require the examiner to master special skills while also taking a longer time to administer.

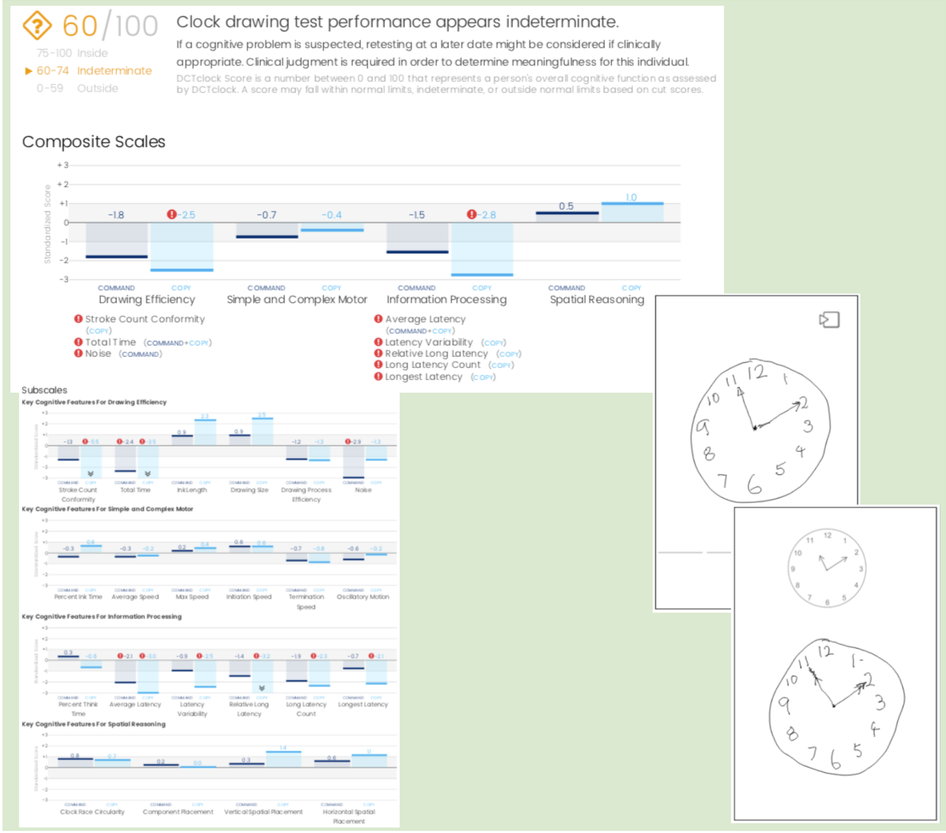
DCTclock

The DCTclock is FDA approved for the assessment of impairment in cognition via a simple clock drawing process, that is quickly administered (less than 5 minutes) and requires only simple directions for administration and scoring.

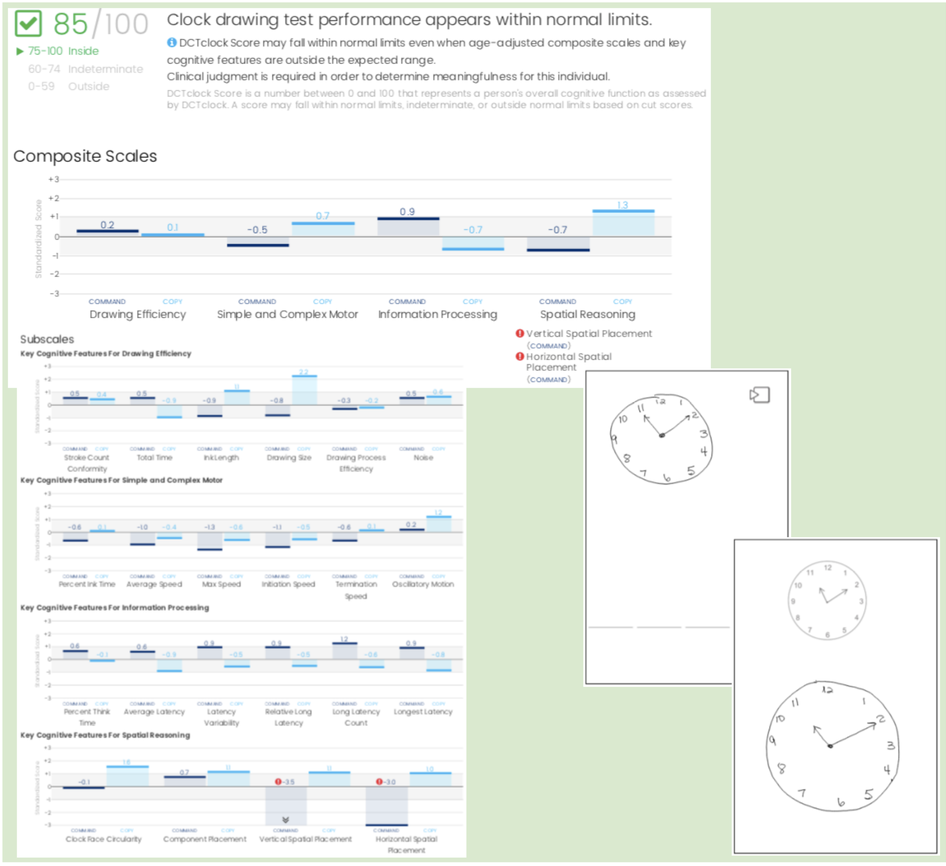
Each person serves as their own control, first drawing a clock from memory and then copying that same clock from a provided drawing using a special pen. The pen contains accelerometers and a camera that records and samples the drawing 75 times a second. Scoring is done almost instantaneously via a computerized algorithm that yields a numerical composite score of 0 to 100; the lower the score the greater the impairment, distilling the results of four domains of cognitive functioning into a standardized scale. Global terms are used to categorize memory as "within the normal range" (75 or above) or "outside the normal range" (below 60) are helpful, while scores between 60 and 74 are called "indeterminate".

Further insight is provided by four subscales. Each subscale is broken down into six different standardized scales allowing for more clinical analysis to be possible.

Example #1



Example #2



Additional Thoughts

1. Minimizing or eliminating barriers is critical to the recruitment process. Consenting subjects for testing the value of the DCTclock, via a study, was an impediment to the testing of our hypothesis. The DCTclock does not require it but its incorporation into a study did. Subjects were reluctant to sign the consent for a study regardless of explanation.
2. Scores labeled as "Indeterminate", those between 60 and 74, are confusing to subjects and failed to provide meaningful feedback. A more detailed or definitive result was wanted. Minor impairments are noted when reviewing individual sub-scores. It is suggested this term, be changed to "suggestive of mild memory changes" to promote further inquiry, without being seen as overly threatening.

Possible areas for future study

The DCTclock is FDA approved for the identification of people with dementia. At least six pharmaceutical firms are exploring the use of these drawings in identifying cognitive changes associated with a drug trial. Other areas for identifying and rating changes include:

- Comparing the DCTclock and AVLT results, since both instruments are sensitive to minor memory impairments.
- Developing scoring algorithms to detect residual sleepiness, impaired driving, the occurrence of head injuries in sports, response times in critical job areas.
- Developing scoring algorithms to detect and measure changes in symptoms of schizophrenia and movement disorders.

References

1. Lovato et al. *Control Clin Trials.* 1997 Aug;18(4):328-52
2. Kadam et al. *Perspect Clin Res.* 2016 Jul-Sep; 7(3): 137–143