

Can study subjects who malingering be identified with the Epworth Sleepiness Scale?

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Methodological Question Being Addressed: Whether a subject's sleep hygiene as measured by the Epworth Sleepiness Scale can be used to identify and eliminate malingering study subjects from being randomized.

Introduction: When a non-creditable presentation of a disease is conscious and with the purpose of personal gain, it is referred to as malingering. Malingers affect the public's perception of disease as well as the treatments. Another consequence of malingering is the cost on society for unnecessary assessments and treatments. In clinical research, by providing inaccurate information, malingers may be inappropriately randomized and could contribute to placebo response resulting in larger sample sizes along with the commensurate costs. In the literature, rates of malingering range from 8-48%. The Epworth Sleepiness Scale (ESS) questionnaire was developed to measure components of daytime sleepiness, which have developed across weeks, months and years rather than independent changes from day to day. It is not a measure of acute symptoms. Therefore the responses should be relatively unchanged across days or a week between surveys. ESS has been used extensively with high test-retest reliability ranging from 0.82-0.93 when tested weeks to months apart. With high test-retest reliability, malingering identification could be based on low reproducibility within 24 to 48 hours after initial screening.

Methods: The objective of this study was to determine whether the computerized version of ESS can identify malingers when administered twice over a short period of time. 36 subjects were randomized to one of two arms. Each subject was coached in malingering techniques and took both a baseline test and then a repeat test at either 24 hour or 48 hours.

Results: Subjects were unable to consistently reproduce their responses in either arm, 24 or 48-hours. When compared to the results of the in-clinic validation study performed by the developer of the ESS, the malingers had higher baseline scores, as well as inconsistent standard deviations and correlations (0.62 for 24 hour, 0.57 for 48 hour, 0.82 for 5 months in-clinic patients) that were very different than patients scores from the validity study.

Conclusion: As such, serial ESS testing is a tool that may identify malingering and assist in preventing malingers from being randomized.

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