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Phase 2 Clinical trial success: Association with statistical decision-making in preceding rodent experiments

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OBJECTIVES/GOALS: In neurological animal research, statistical misapplication may lead to overoptimism in a therapy's potential for successful translation. This pilot study investigated whether human clinical trials that fail have higher prevalence of statistical misapplication in preceding animal experiments, compared to human trials that succeed. METHODS/STUDY POPULATION: Phase 2 clinical trials for 3 neurological conditions were identified on ClinicalTrials.gov and classified as successful or failed based on advancement to Phase 3 and/or preplanned efficacy test results. PRISMA guideline methods were used to systematically search for preclinical animal experiments (same indication and intervention) preceding the start of the human trial. Data were gathered from animal articles by collectors blinded to human trial outcome and included items describing reporting transparency, experimental design and sample sizes, and statistical tests applied. Statistical mistakes were coded based on mismatch between test and design. Rates of mistakes were compared between articles preceding successful and non-successful human trials using weighted point estimates and 95% confidence interval. RESULTS/ANTICIPATED RESULTS: The final sample included 24 trials (16 successful) and 70 associated animal studies. Transparency was poor, with infrequent reporting of group allocation method (39%), sample sizes adequate to evaluate attrition (DISCUSSION/SIGNIFICANCE OF IMPACT: Statistical misapplication is common in animal research, and this pilot study has demonstrated that preclinical statistical mistakes may indeed occur more frequently prior to failed human trials. Mistakes and lack of transparency may lead to overoptimism in preclinical experimental findings, with consequences for subsequent human translation.

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Sleeping safely? Examining changes in infant sleep practices during and after illness

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OBJECTIVES/GOALS: Unsafe sleep practices contribute to sleep-related infant mortality, a leading cause of preventable sudden unexplained infant death (SUID). Infant illness represents a risk for SUID. However, the mechanism behind this increased risk is unknown. The objective of this study was to measure changes to safe sleep practices during infant illness. METHODS/STUDY POPULATION: We performed a prospective cohort survey study of infants aged 0–12 months presenting to the pediatric emergency department. We assessed sleep practices prior to illness, during illness, and 2 weeks and 1 month following illness. We assessed adherence to American Academy of Pediatrics safe sleep recommendations at each point in time. Wilcoxon sign rank test was used to examine changes between time points. Regression models compared caregivers who reported a change to unsafe sleep practices with those who did not. RESULTS/ANTICIPATED RESULTS: Of enrolled participants (n = 142), 110 (77%) completed all three follow-up surveys. For those with complete follow-up, 62.4% were female, 60.3% were Black, non-Hispanic, 25.7% were White, non-Hispanic. The most common chief complaint was respiratory illness (35.7%), followed by fever (22.7%), and 70.3% of patients were discharged home. Across all sleep behaviors surveyed, caregivers reported, on average, a 12% change to unsafe sleep practices during illness. These changes were sustained at the 2-week and 1-month follow-ups. Factors associated with a change to unsafe sleep practice were parental age. DISCUSSION/SIGNIFICANCE OF IMPACT: Over 10% of infants experienced a change to unsafe sleep practices during illness, sustained at 2-week and 1-month follow-ups. This may explain the association of infant illness with SUID. Interventions promoting safe sleep adherence during illness are key to decreasing sleep-related infant mortality.

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Correlation between gait performance and global cognitive functions in senior adults: A systematic review

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OBJECTIVES/GOALS: Gait performance (GP) and global cognitive functions (GCF) are both critical for maintaining independence and quality of life in senior adults. Recent studies have explored the potential link between GP and GCF, encompassing executive functions. METHODS/STUDY POPULATION: PRISMA guidelines will govern this systematic review. This systematic review synthesizes published research from 2000 to 2024, including peer-reviewed articles, pilot studies, and randomized controlled trials, to examine the relationship between GP (how a person walks and stands) and GCP in older adults. The exclusion criteria will be based on studies focused on physical activities unrelated to balance, meta-analysis, and systematic reviews and those published in languages other than English or Spanish. RESULTS/ANTICIPATED RESULTS: Our preliminary data indicate that gait, or walking speed, is significantly correlated with GCP in older adults, with slower walking associated with poorer global cognition. Specifically, gait speed during dual-task walking shows a strong correlation with working memory ($p < .001$) and processing speed ($p < .05$) in individuals aged over 60 years. Gender differences were observed, with women over 80 walking slower than men over 85 years, who walked faster, and women exhibited poorer global cognition than men. DISCUSSION/SIGNIFICANCE OF IMPACT: Overall, a gait slowing between 0.68 and 1.1 m per second could predict a marker for the risk of developing dementia, indicating that monitoring gait speed in older adults may provide early warning signs, allowing for timely interventions. Enhancing GP and GCF can improve the quality of life and independence in older adults. Acknowledgments: Research supported by NIH: Award Number HCTRECD R25MD007607 from the NIMHD.

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