

THE 6-MINUTE WALK TEST AND OTHER CLINICAL ENDPOINTS IN DUCHENNE MUSCULAR DYSTROPHY: RELIABILITY, CONCURRENT VALIDITY, AND MINIMAL CLINICALLY IMPORTANT DIFFERENCES FROM A MULTICENTER STUDY

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ABSTRACT: Introduction: An international clinical trial enrolled 174 ambulatory males ≥ 5 years old with nonsense mutation Duchenne muscular dystrophy (nmDMD). Pretreatment data provide insight into reliability, concurrent validity, and minimal clinically important differences (MCIDs) of the 6-minute walk test (6MWT) and other endpoints. Methods: Screening and baseline

evaluations included the 6-minute walk distance (6MWD), timed function tests (TFTs), quantitative strength by myometry, the PedsQL heart rate–determined energy expenditure index, and other exploratory endpoints. Results: The 6MWT proved feasible and reliable in a multicenter context. Concurrent validity with other endpoints was excellent. The MCID for 6MWD was 28.5 and 31.7 meters based on 2 statistical distribution methods. Conclusions: The ratio of MCID to baseline mean is lower for 6MWD than for other endpoints. The 6MWD is an optimal primary endpoint for Duchenne muscular dystrophy (DMD) clinical trials that are focused therapeutically on preservation of ambulation and slowing of disease progression.

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Abbreviations: 6MWD, 6-minute walk distance; 6MWT, 6-minute walk test; AOS, American Thoracic Society; CNGR, Cooperative International Neuromuscular Research Group; CK, creatine kinase; DMD, Duchenne muscular dystrophy; EEI, energy expenditure index; HRQL, health-related quality of life; MCID, minimal clinically important difference; MPS, mucopolysaccharidosis; nmDMD, nonsense mutation DMD; NSAA, North Star Ambulatory Assessment; PedsQL, Pediatric Quality of Life Inventory; TFT, timed function test

Key words: 6-minute walk test; ambulation; Duchenne muscular dystrophy; energy expenditure index; muscular dystrophy; myometry; natural history; PedsQL; timed function test

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Additional Supporting Information may be found in the online version of this article.

*Collaborating authors are listed in Appendix 1. Other members of the PFC124-GD-007-DMD Study Group are listed in Appendix 2 in the Supporting Information.

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Reliability, Validity and MCID of 6MWT and other Endpoints in DMD

Duchenne muscular dystrophy (DMD) is a disabling and life-threatening X-linked genetic disorder caused by defects in the gene for dystrophin, a protein that stabilizes muscle cell membranes.¹ DMD is characterized by complete loss of dystrophin and is the most common neuromuscular disease of childhood. It affects 1 in 3800–6300 males, and there are an estimated 15,000 patients with the disease in the USA.^{2,3} There is no approved therapy that addresses the underlying cause of DMD.^{4,5} In $\sim 13\%$ of boys with nonsense mutation DMD (nmDMD), which represents ~ 1700 boys in the USA and ~ 2400 boys in Europe), the causative defect in the dystrophin gene is a nonsense mutation that truncates dystrophin protein production by introducing a premature stop codon into dystrophin mRNA.^{6–8}

THE NEED FOR CLINICALLY MEANINGFUL ENDPOINTS IN DMD

Given that several novel approaches to treatment of DMD have shown promise in preclinical and/or proof-of-concept clinical studies,^{9–12} the research community has faced the need to identify and develop clinically meaningful outcome measures for use in pivotal therapeutic trials. In boys with DMD, walking abnormalities are a major disease manifestation that has great importance to patients and

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Farm, Stock and Home ,1893 *Considering Class: Theory, Culture and the Media in the 21st Century* ,2017-11-06

Considering Class Theory Culture and Media in the 21st Century offers the reader international and interdisciplinary perspectives on the importance of class analysis in the 21st century Political economists sociologists educationalists ethnographers cultural and media analysts combine to provide a multi dimensional account of current class dynamics The crisis consists precisely in the gap between the objective reality and efficacy of class forces shaping international politics and the relative paucity of class consciousness at a popular level and appreciation of class as an explanatory optic at a theoretical level This important book shows why the process of reconstructing class consciousness must also take place on the ground of cultural and subjective formation where everyday values habits and media practices are in play Contributors are Anita Biressi

Joseph Choonara Maurizio Donato Danny Dorling Mark Gibson Craig Haslop Dave Hill Peter Jakobsson Marina Kabat Holly Lewis Catherine Lumby Lisa Mckenzie Tony Moore Adrian Murray Deirdre O Neill Jonathan Pratschke Michael Seltzer Eduardo Sartelli Fredrik Stiernstedt Roberto Taddeo Mike Wayne Milly Williamson Ferruh Y Imaz *Drinkology* Alexis Willett, 2019-11-07 SHORTLISTED FOR THE 2019 ANDR SIMON FOOD DRINK BOOK AWARDS Like a new Bill Bryson she offers an easy sharing of deep knowledge with humour where one learns things in a gentle way without it feeling like learning Dan Jago judge of the Andr Simon Food Drink Book Awards Hot or cold caffeinated alcoholic sweet or not this book provides a fascinating cultural history of our favourite drinks and explores the science or not underpinning their many health claims A wonderful read Dr Giles Yeo author of *Gene Eating* A truly engaging read By dispelling common health misconceptions and debunking bad science *Drinkology* arms us with information to make better choices about what we drink not just what we eat Ian Marber Very engaging and entertaining a clear guide to everything we need to know about drinks from water to milk tea alcohol and beyond Dr Willett dispels common myths and fads and sets the record straight allowing us to make fully informed choices A fascinating deep dive into the science behind everything we drink Elisabeth Cresta and Caroline Day founders of Fight the Fads Do you really know what you are drinking Are you sure We all consume many drinks every day often without thinking Perhaps we re just thirsty perhaps we need something to wake us up perhaps we need something to relax us at the end of the day But have you ever stopped to wonder what exactly is in that chai latte you re guzzling or just what those added electrolytes in your bottled water are supposed to do Whether it s a simple glass of water or early morning espresso the finest champagne or energy drink the morning after all drinks have an impact on our body in one way or another *Drinkology* distils the scientific evidence to see if we can get to the bottom of questions such as Is a regular glass of wine good for our health or not Should we worry about energy drinks Is fluoride in our tap water harmful How do non dairy milks compare with each other What s the secret to the perfect cup of tea Are fermented drinks and probiotics the answer to all our worries Is there such a thing as a superdrink Whether you want to discover the true benefits of wellness drinks find out if sulphites in wine really cause headaches or are just sick of the pseudoscience behind the marketing of what we consume this book is for you *Drinkology* is a scientific digest of many of the world s most popular beverages and may just change the way you drink

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