CLEAR Center Webinar

"Placebo and Contextual Effects in Clinical Trials for Osteoarthritis: Lessons from the TeMPO Trial"

Speakers:

Dr. Jeffrey Katz,

Professor of Medicine and Orthopaedic Surgery at Harvard Medical School and Professor of Epidemiology at Harvard School of Public Health. Clinical Director of the Orthopaedic and Arthritis Center for Outcomes Research in the Department of Orthopaedic Surgery at Brigham and Women's Hospital, and Director of Research in the Department of Orthopedic Surgery at BWH.

Dr. Jamie Collins,

Associate Professor of Orthopaedic Surgery at Harvard Medical School and Associate Director of the Orthopaedic and Arthritis Center for Outcomes Research at Brigham and Women's Hospital in Boston, USA. Director of the Biometry Consultancy Unit in the Department of Orthopaedic Surgery at Brigham and Women's Hospital and Director of the Data Management & Analysis Core of the Brigham Coordinating Center for the Arthritis Foundation's Osteoarthritis Clinical Trials Network.

Monday December 8, 2025 11 AM-12 PM PST

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Summary of talk: The Treatment of Meniscal Tear in Osteoarthritis (TeMPO) Trial was a four-arm multi-center randomized controlled clinical trial designed to establish the comparative efficacy of two in-clinic physical therapy (PT) interventions (one focused on strengthening (Standard PT) and one containing placebo (Sham PT)) and two protocolized home exercise programs. The results of the trial showed that subjects assigned to in-clinic PT (Standard or Sham) had similar improvement in pain between baseline and three months and slightly greater improvement at 6 months compared to those assigned to home exercises with no in-clinic PT. Pain scores in the Standard PT and Sham PT arms were virtually identical across all time points. In this talk, we will discuss the design, results, and clinical policy implications of the TeMPO trial, with emphasis on the rationale for and implementation of the Sham PT arm. We will also discuss placebo and contextual effects more broadly, including the implications of these effects for the design, interpretation, and translation of clinical trials in musculoskeletal disease.

Speaker Bio: Jeffrey N. Katz, MD, MS graduated from Princeton University in 1980, attended Yale Medical School, and completed a medical internship and residency at Yale-New Haven Hospital and a Rheumatology fellowship at Brigham and Women's Hospital. He received a Master's Degree in 1990 at Harvard School of Public Health. Dr. Katz is currently Professor of Medicine and Orthopaedic Surgery at Harvard Medical School and Professor of Epidemiology at Harvard School of Public Health.

Dr. Katz has focused his research on the evaluation and outcomes of musculoskeletal disorders including carpal tunnel syndrome, lumbar spinal

stenosis, osteoarthritis, meniscal tear, and surgeries for these conditions. He has developed measures of functional status and symptom severity for several conditions including carpal tunnel syndrome and lumbar spinal stenosis. He has led studies documenting the influence of surgeon and hospital volume on outcomes of total joint replacement. Dr. Katz is Principal Investigator of two NIH funded multicenter clinical trials that address treatment outcomes for individuals with knee osteoarthritis and meniscal tear: the MeTeOR Trial of surgical vs. rehabilitative approaches to meniscal tear in the setting of osteoarthritis, and the TeMPO Trial of four different nonoperative approaches including a sham intervention in this patient population.

Dr. Katz is Clinical Director of the Orthopaedic and Arthritis Center for Outcomes Research in the Department of Orthopaedic Surgery at Brigham and Women's Hospital, and Director of Research in the Department of Orthopedic Surgery at BWH. He lives in Brookline, MA with his wife Susan Zeiger, PhD, a 20th Century American historian.

Speaker Bio: Dr. Jamie E. Collins is Associate Professor of Orthopaedic Surgery at Harvard Medical School and Associate Director of the Orthopaedic and Arthritis Center for Outcomes Research at Brigham and Women's Hospital in Boston, USA. She is the Director of the Biometry Consultancy Unit in the Department of Orthopaedic Surgery at Brigham and Women's Hospital and Director of the Data Management & Analysis Core of the Brigham Coordinating Center for the Arthritis Foundation's Osteoarthritis Clinical Trials Network. She received her master's degree in mathematics and PhD in Biostatistics from Boston University.

Her research interests include the analysis of multilevel and correlated data, missing data and informative dropout, risk prediction, and machine learning methods for clustering and disease phenotyping. She oversees data collection and analysis for a number of NIH and foundation funded randomized controlled trials in OA and rheumatology. Dr. Collins is the lead statistician for the FNIH OA Biomarkers Consortium, an international collaboration that aims to identify novel knee osteoarthritis biomarkers with the greatest utility for predicting disease progression and treatment response in clinical trials.