

Methodological challenges across WW-FINGERS Studies: Impact of COVID-19 pandemic on statistical design and analysis plans for multidomain RCTs

Mark A Espeland¹ | Susanne Roehr^{2,3} | Hidenori Arai⁴ | Francesca Mangialasche⁵ |
Markku Peltonen⁶ | Rema Raman⁷ | Steffi G Riedel-Heller⁸ | Heather M Snyder⁹ |
Maria C Carrillo⁹ | Tiia Ngandu⁵ | Miia Kivipelto⁵

¹ Wake Forest School of Medicine, Winston-Salem, NC, USA

² Institute of Social Medicine, Occupational Health and Public Health (ISAP), Faculty of Medicine, University of Leipzig, Leipzig, Germany

³ Trinity College, Dublin, Ireland

⁴ The National Center for Geriatrics and Gerontology, Obu, Japan

⁵ Karolinska Institutet, Stockholm, Sweden

⁶ Finnish Institute for Health and Welfare, Helsinki, Finland

⁷ Alzheimer's Therapeutic Research Institute, University of Southern California, San Diego, CA, USA

⁸ Leipzig University, Leipzig, Germany

⁹ Alzheimer's Association, Chicago, IL, USA

Correspondence

Mark A Espeland, Wake Forest School of Medicine, Winston-Salem, NC, USA
Email: mespelan@wakehealth.edu

Abstract

Background: The coronavirus disease-19 (COVID-19) pandemic presents challenges to the conduct of randomized clinical trials of lifestyle interventions.

Method: World-Wide FINGERS is an international network of clinical trials to assess the impact of multidomain lifestyle intervention on cognitive decline in at-risk adults. Individual trials are tailoring successful approaches from the Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability (FINGER) to local cultures and environments. The network convened forums for researchers to discuss statistical design and analysis issues they faced during the pandemic. We will provide an updated report on experiences of trials that, at various stages of conduct, altered designs and analysis plans to navigate these issues. We provide recommendations for future trials to consider as they develop and launch behavioral intervention trials.

Result: The pandemic led researchers to change recruitment plans, interrupt timelines for assessments and intervention delivery, and move to remote intervention and assessments protocols. The necessity of these changes add emphasis to the importance, in study design and analysis, of intention to treat approaches, flexibility, within site stratification, interim power projections, and sensitivity analyses.

Conclusion: Robust approaches to study design and analysis are critical to negotiate issues related to the intervention. The World Wide Network of similarly oriented clinical trials will allow us to evaluate the effectiveness of responses to the pandemic across cultures, local environments, and phases of the pandemic.