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Trends in the Recruitment of Older Adults in Clinical Trials on Low Back Pain

PAULO ROBERTO CARVALHO DO NASCIMENTO (Paulo Nascimento) - UNIVESITY OF OTTAWA - pnasc030@uottawa.ca, Stéphane Poitras - University of Ottawa, Martin Bilodeau - University of Ottawa and Bruyère Research Institute

Introduction: The burden of low back pain (LBP) is high especially for older adults who experience a higher number of years living with a disability. Despite the negative impact of LBP in older adults, this population is not being well represented in clinical trials.

Objectives: This study aims to analyze the International Clinical Trial Registry Platform (ICTRP) database from the World Health Organization (WHO) to verify the future trend in the participation of older adults between registered clinical trials on LBP.

Methods: We performed a cross-sectional review of the ICTRP searching for registered clinical trial (CT) protocols that were planning interventions for LBP with the registration date from January 2015 through March 2018. One investigator (PN) performed a search using the term "low back pain" in the WHO platform, which contains the trial registration data sets provided by several countries (i.e., Australia, New Zealand, United States of America, European Union, Brazil, India, Netherlands, South Korea, Germany, Cuba, Ira, Japan, Africa, Sri Lanka, Thailand, and Peru), providing one single point of access to all registered clinical trials globally. From the eligible studies protocols, we extracted those planning to include older adults.

Results: A total of 166 CTs protocols for LBP were planning to recruit participants older than 65 years old. However, only five registries (3,01%, pooled sample = 169 participants) were designed targeting specifically participants older than 65 years old. In addition, the protocols planning to recruit older adults did not provide information about how to guarantee their engagement and thus, representativeness or analysis of subgroup. The exclusion of older participants was not justified and imposed through an arbitrary upper-age limit in 93.6% of the protocols. Most of the protocols are from single-center studies, and a greater number are planned to be carried out in developed regions. Higher interest was in pharmacological interventions, devices/technology, and physical rehabilitation respectively.

Conclusions: Older adults with LBP will continue to be under-investigated in CTs for LBP in the near future. In general, ongoing trials are small, planned to occur in developed regions and proposing pharmacological interventions to deal with the LBP. More efforts to guarantee the participation and increase the number of CTs targeting older people are necessary to provide evidence-based interventions and the acknowledgment of adverse events.

Keywords: ageism; low back pain; clinical trial.