

EP18.07

Multi-PAP trial: How can we improve drug prescription in patients with multimorbidity and polypharmacy in primary care?. Study protocol

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Background & Aim: Objective: The Multi-PAP project aims to determine whether the use of a complex intervention in young-old patients with multimorbidity and polypharmacy is more effective than usual care in improving physician drug prescription in primary care, measured by means of the Medication Appropriateness Index (MAI)-score at six 6 and 12 months. Potential improvements in health services utilization, quality of life, and drug safety and adherence will also be assessed.

Methods: Design: pragmatic randomized clinical trial by clusters with 12 months follow-up (0, 6 and 12 months). Unit of randomization: general practitioner, Unit of analysis: patient. Setting: Health Centres in three different Spanish Autonomous Communities (Aragón, Madrid, Andalucía). Population: patients 65-74 years of age with multimorbidity (≥ 3 chronic diseases) and polypharmacy (≥ 5 drugs taken for at least three months). Sample size: 500 patients (250 in each arm, 7 patients per physician) will be recruited by 120 general practitioners before randomization. Intervention: complex intervention based on the ARIADNE principles with two main components: 1) training of physicians, 2) shared decision-making with patients. Variables: MAI, health care utilization, quality of life (EuroQol 5D-5L), drug therapy and adherence (Morisky-Green, Haynes-Sackett), clinical and socio-demographic factors. Primary outcome: difference in MAI-Score 6 months from baseline with its corresponding 95%CI. Analysis: adjustment by main confounding and prognostic factors will be performed through a multilevel analysis. All analyses will be carried out adhering to the intention-to-treat principle. A cost-utility analysis will also be performed. Funding: Instituto de Salud Carlos III, Madrid, Spain (PI15/00572, PI15/00276, PI15/00996). Project co-financed with fundings FEDER.

This proposal is integrated in the 'Red Temática de Investigación Cooperativa de Investigación en Servicios y Enfermedades Crónicas (REDISSEC)' from Instituto de Salud Carlos III (<http://redisecc.com/es/>).