
CONFERENCE ABSTRACT

A randomized clinical trial for remote telemonitoring into an integrated care program for high complexity patients. Atlan-TIC project.

16th International Conference on Integrated Care, Barcelona 23-25 May 2016

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Introduction: The use of Information and Communication Technologies (ICT) is a promising development in the XXI century medicine. Its employment has already demonstrated significant benefits in areas such as dermatology or telematic control of hypertension and diabetes in young outpatients. Telemedicine applied in highly complex patients with advanced cardiac and respiratory disease, has shown an improvement in perceived satisfaction but its effectiveness, safety and cost-effectiveness has not been convincingly established. There are several factors that characterize the care needs of these patients: elderly, high demand for healthcare by the presence of frequent exacerbations, significant disability and need for primary caregivers. We believe that the implementation of ICT for telemonitoring high complex patients with advanced heart and/or respiratory disease require an integrated care model adapted and focused on their specific needs, with an established care circuits and responses. Currently Andalusian Public Health System (SSPA) is a prime setting to perform this rigorous evaluation.

Material and methods: We have designed a multicenter clinical trial, randomized, parallel group, in adult patients with advanced heart and / or respiratory disease. Participating hospitals are Virgen del Rocío Hospital, Virgen Macarena Hospital and Serranía de Ronda Hospital, so it has been included urban and/as well as rural populations. Inclusion criteria are the presence of heart failure with basal dyspnea NYHA \geq III degree and / or chronic respiratory failure with dyspnea \geq III of the MRC and / or O₂ saturation $<$ 90% and / or home oxygen therapy; presence heart failure or respiratory failure with dyspnea basal level $<$ III but have presented 2 or more income in the last year; achieve a score in the PALIAR score between 0 and 7 points; and submit one of the following situations care: hospitalization, hospital at home or palliative care teams and outpatient follow-up by the internal medicine department.

Efficiency and cost-effectiveness of incorporating telemonitoring into an integrated clinical care program between Primary Care and Hospital Care (Telepac arm) versus that standard integrated care (Pac arm) will be analyzed. Primary efficacy is defined as the reduction in the percentage of patients with hospital requirements and / or visits to the emergency room

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(hospital and / or primary care). High efficiency is measured by the number of hospital admissions, number of income-hospital emergency visits, number of visits to the emergency room for primary care, mortality, number of days of hospital stay, total cost per patient in Euros. In addition an analysis of safety, quality of life related to health (HRQOL), quality of care and satisfaction perceived by patients and cost-effectiveness will take place.

Sample size is calculated in 510 patients, 255 assigned for each arm. The inclusion period is defined in 12 months and each patient has six months follow up.

The intervention is divided into two arms: PAC arm: All patients in this arm apply the optimal standard of care issued by the SSPA plan of care for patients with chronic diseases and multimorbidity patients. This is based on a shared integrated clinical care between Primary Care and Hospital Care (Internal Medicine) and it includes a call-center (Centro de Información y Servicios Salud Responde for SSPA) to activate the patient clinical destabilization signal. Telepac arm: they apply the same care protocol by adding monitoring equipment constants automatically recorded to a virtual health notebook. This notebook is available in real time to the care team by telematic road of data transfer and accessible software system health. The telemonitoring system incorporates a range for preset values. Out of these preset values an alarm signal is notified to Call Center, which phones the patient to assess the real severity using a structured clinical interview. Depending on severity, Call Center proceeds performing a dietary or therapeutic recommendation and scheduling a face to face appointment with primary care physician (low severity), internist (mild severity) or sending home care devices (high severity). If a failure of adherence to technology is detected, social services for SSPA are activated.

Progress Report: Currently, this study has not started patient recruitment yet. It will begin in January 2016.

Conclusion: Application of telemonitoring patients with complex diseases requires further investigation and this should be done within a framework of comprehensive health care with inter-level coordination and organization to prove its usefulness in clinical practice care.

Keywords: randomized clinical trial; high complex patients; telemonitoring
