

DOTTORATO DI RICERCA IN SCIENZE INFERMIERISTICHE E SANITA' PUBBLICA

XXXV CICLO - Anno Accademico 2021/2022

Dottorando: Dott. Gabriele Caggianelli

Tutor: Prof. Ercole Vellone

Titolo tesi: Effectiveness of Motivational Interviewing in Improving Self-Care of Patients with Heart Failure:

Results of the MOTIVATE-HF study

ABSTRACT

Background: Heart failure (HF) consists of a clinical syndrome determined by structural and/or functional abnormalities of the heart. HF is a common chronic condition affecting approximately 26 million people worldwide. According to the latest research, the growth rate is steady, mainly due to an aging population and medical innovations. Despite significant progress in the treatment of HF, outcomes continue to be poor. In fact, HF is associated with high rates of mortality and hospitalization, resulting in high medical costs. Although its beneficial effects are well known, many patients with HF find it difficult to perform self-care. Investigators are studying interventions to improve these behaviors and indirectly reduce the negative effects. Recent evidence shows that one of the possible interventions is motivational interviewing (MI), a patient-centered counseling technique that has been used to engage and motivate clients to change their behavior through self efficacy. To date, only a few studies have been conducted in this field, and the results have been mixed. In addition, previous studies have not involved informal caregivers, although their benefit is known to be substantial. Patients with HF experience a variety of physical symptoms that are perceived as burdensome and, as such, negatively affect their quality of life. These symptoms are the reason why patients seek emergency room assistance or re-hospitalization. However, self-care has been shown to improve the outcomes of patients with HF (e.g the use of health care services, mortality, and symptoms).

Objective: The objective of this doctoral program was (a) to evaluate whether MI improves patients' self-care maintenance and management as well as confidence (or self-efficacy); (b) to evaluate whether MI is effective in improving health service utilization and mortality rates; and (c) to evaluate whether MI is effective in improving physical symptom burden in patients with HF.

Methods: The study was a three-arm, multicenter randomized controlled trial. Patients with HF and their informal caregivers were enrolled and randomly divided into three arms: Arm 1: MI administered to patients; Arm 2: MI administered to patients and caregivers; Arm 3: standard of care. Participants were enrolled from three Italian HF specialty centers. Patients were included only if they had HF in NYHA functional class II to IV and excluded if they had a recent coronary event, lived in a residential setting, or had severe cognitive impairment. Informal caregivers were identified by the patients as the people who were mainly responsible for their care. The intervention consisted of one face-to-face MI session followed by three telephone contacts within two months from enrollment to buster the initial intervention. Data were collected at baseline and at 3, 6, 9 and 12 months after enrollment.

In the first study, self-care was evaluated through the Self-Care of HF Index. This includes the self-care maintenance, management and confidence scales. For each scale, the score ranged from 0 to 100, with higher scores indicating better self-care and a value above 70 being considered adequate.



DOTTORATO DI RICERCA IN SCIENZE INFERMIERISTICHE E SANITA' PUBBLICA

The second and the third studies were planned secondary analyses. For the second study, data were analyzed with descriptive statistics, and a longitudinal generalized mixed model and a Cox proportional-hazard model were fitted to compare rates of health care services use and mortality among the three study arms during follow-ups. In the third study, symptoms' burden was assessed with the Heart Failure Somatic Perception Scale (HFSPS) with the dimensions of dyspnea, chest discomfort, early and subtle and edema. Higher scores at the HFSPS and its dimensions indicate worse physical symptoms.

Results: A sample of 510 patients (median 74 years, 58% male) and their caregivers (median 55 years, 75.5% female) were randomized to Arm 1 (n=155), Arm 2 (n=177) and Arm 3 (n=178). In the first study, at three months, self-care maintenance improved 6.99, 7.42 and 2.58 points in Arm 1, 2 and 3, respectively (p=0.028). Self-care maintenance appeared adequate in 18.4%, 19.4% and 9.2% of patients in Arm 1, 2 and 3 respectively (p=0.016). During the period of one year, self-care maintenance, management and confidence in Arms 1 and 2 were significantly higher than in Arm 3 in several follow-ups. During the same period, Arm 2 had the best scores in self-care management. In the second study, at 12 months, 16.1%, 17% and 11.2% of patients used health-care services at least once in Arms 1, 2 and 3, respectively, without significant difference (p > 0.05). At 3 months, 1.9%, 0.6% and 5.1% of patients died in Arms 1, 2 and 3, respectively. Mortality was lower in Arm 2 vs Arm 3 at 3 months [hazard ratio (HR)=0.112, 95% CI 0.014-0.882, p=0.04]; no difference was found in subsequent follow-ups. Mortality was lower in Arm 1 vs Arm 3 at 3 months but did not reach statistical significance (HR=0.38, 95% CI 0.104-1.414, p=0.15). In the third study, at 12 months, Chest Discomfort improved in Arms 1 and 2 vs Arm 3 (Δ : -8.13, 95%CI: -14.61; -1.65, p=0.0142). Dyspnea improved in Arms 1 and 2 vs Arm 3 both at 9 and 12 months (Δ: -7, 95%CI: -13.18; -0.82, p=0.0266 and -6.78, 95%CI: -13.19; -0.38, p=0.0380); HFSPS total score improved in Arm 1 and Arm 2 vs Arm 3 at 9 months (Δ: -4.55, 95%CI: -9.05; -0.05, p=0.0475). Over 1 year, Chest Discomfort and HFSPS total score in Arm 2 improved compared to Arm 3 (β = -2.61, 95%CI: -4.21; -1.00, P = 0.0015 and β =-1.35, 95%CI: -2.50; -0.21, P = 0.02).

Conclusion: This doctoral program offers new insights regarding the effectiveness of psycho-educational interventions aimed at strengthening and improving self-care behaviors as well as supporting the role of the caregiver.

This body of work demonstrated that the MI approach performed by a trained nurse is helpful in improving self-care. In addition, it was found that MI is effective in reducing all-cause mortality but not effective enough in limiting the use of health care services. The findings of this body of work also indicate that MI may be effective in reducing the burden of physical symptoms, probably as a result of improved behaviors in performing adequate self-care. Finally, it was consistently found in these three studies that caregiver involvement may enhance the effect of MI.

MI interventions could be a viable and a cost-effective way to improve outcomes for patients with HF. ClinicalTrial.gov, identifier: NCT02894502.

Keywords: Motivational interviewing, heart failure, self-care, hospitalization, mortality, health service use, symptoms