



## Opinion Article

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# Could Pragmatic Clinical Trials be Effective in the Management of Patients with Heart Failure?

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## Introduction

Pragmatic Clinical Trials (PCT) seem to be popular nowadays and can be used to test the effectiveness of health interventions avoiding the restrictions associated with traditional explanatory randomized clinical trials. The pragmatic methodology design is promising for chronic diseases like Heart Failure (HF) and comorbidities. HF has been mentioned as the most malignant type of Cardiovascular-Disease (CVD) and has the same aggravation of symptoms and survival rates, as the most types of cancer [1,2]. It is a syndrome characterized by symptoms that persist; breathlessness, fatigue and swelling of ankles. All these symptoms affect the Health-Related Quality of Life (HR-QoL) and the ability of the patients to maintain self-care management [3-5]. HF in diabetic patients is an important health problem and DM is a major risk factor in HF and vice versa [6,7]. HF and DM most of the time occur together, aggravating each condition and exacerbates patient outcomes [8,9].

### The Benefits of Pragmatic Methodology in HF Management

In previous RCTs (Randomized Clinical Trials) a standardized approach has been used in the intervention's approaches related to the management of HF patients [10]. In the RCT 'Support Heart' the pragmatic methodology that has been used, tested the effectiveness of a supportive care management program for patients with HF and DM, had an intensive intervention, started rapidly in early stages based on a patient-centred approach and was rapidly accepted by the patients in the Intervention Group (IG) [11]. The intervention of the 'Support Heart' research study that was based in pragmatic methodology, improved the HR-QoL, symptoms and acute events of HF patients with the comorbidity of DM [12]. From a patient perspective, a comprehensive point of view of any intervention is fundamental and real-world effectiveness is important,

based on patients' needs at the time of the intervention. The word pragmatism originates from the Greek word "pragma", that means action that is the central factor of pragmatism [13]. Human actions can never be separated from the beliefs, values and previous experiences of people. Human thoughts and believes are related to human action and the results of the actions can be used or rejected by humans in the future (self-management actions on improving signs and symptoms) [14]. A pragmatic study focuses on an individual decision-making in a real-world situation like patients with HF and the comorbidity of DM. Patients with HF and DM have to deal everyday with various difficult and complex factors; follow a specific type of lifestyle and optimize specific health behaviors e.g., physical activity, more complex diet, blood glucose checking, daily weight and adherence to complex medications for both diseases, which may interact with each other causing serious side effects to the patients, as well as they deal with acute and chronic complications of HF or DM [15].

Most of the times, patients' education is not effective for the development of self-care skills in patients with HF and DM and their caregivers [16]. So, it makes it necessary to find more effective ways of coping for patients, family and caregivers [17] based on their needs. The pragmatic methodology investigates reality and different ways and approaches to investigate a research problem; so, it could be better understood and managed. It enables researchers to conduct research in an innovative and dynamic way to find solutions to a research problem. A pragmatic study is based on an individual decision maker in a real-world situation like chronic patients with HF and DM experienced [17]. The aim of pragmatic trials is to recruit a more heterogeneous population in a real world compared with RCTs so the sample reflects the patient population that can utilize the intervention in everyday life [18]. Pragmatic methodol-

ogy could be easily applied in general population and at low cost, since it did not use specific strategy like other clinical trials, but has an individualized patient centre-approach based on each need of the patient that differs in each time point and for each patient [19]. On the other hand, RCTs have become progressively large, more expensive and more complex and cannot be applied in a real-world situation [20].

### The Limitations of Pragmatic Methodology in HF Management

Despite the fact that pragmatic clinical trials are promising and encouraging in the population of HF patients and other chronic conditions, it is important to recognize and address limitations. The studies that are based in pragmatic methodology and pragmatic trials do not most of the times have constraints on patients and clinicians; between patients and health professionals/clinicians a 'bond' and a relationship may be created between them since they focused on patients' needs and have a patient-centred approach for each patient; but this may lead to inconsistent or missing data [21]. Also, a team of health care specialists in managing HF population, is needed covering the whole spectrum, for the proper implementation of interventions based on pragmatic methodology and meets patients' needs; the need of each patient may differ in each time since the intervention for supporting patients is individualized. Although a unique strength of pragmatic methodology is the generalization in a real-world setting, the pragmatic trials have not yet been conducted in global or multinational settings, limiting geographic generalizability [22].

### Future Recommendations

A new approach is necessary to manage chronic conditions. Studies based in pragmatic methodology design, on the 'real world' and on the 'real needs' of HF patients with/without comorbidities which focused on a patient-centred approach, that was missing from previous studies and previous management programs, seems to be promising and effective in the management for chronic diseases. Managing programs based on pragmatic methodology can be easily adopted by the Health Care Systems in each country for chronic diseases and not only for patients with HF and DM.

### Acknowledgments

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### Conflict of Interest

None.

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