Heart failure disease management interventions: time for a reappraisal

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Heart failure disease management interventions: time for a reappraisal

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Introduction

It is over two decades since the first publications of heart failure (HF) disease management trial results and both useful and timely to consider progress and lessons in this field of health services research. The early program trials have undoubtedly been influential. For example, a trial of a nurse-directed multidisciplinary intervention for elderly patients with congestive heart failure (n=282) found reductions in readmissions for HF and medical costs with improvements in quality of life at 90 days [1]. A trial of a multidisciplinary, home-based intervention of a single home visit by a cardiac nurse one to two weeks after discharge for patients with chronic congestive HF (n=200) found fewer unplanned readmissions plus out-of-hospital deaths and associated days in hospital and reduced hospital-based costs at six months and improvements in quality of life at three months [2]. Another trial of a specialist nurse intervention for patients with HF due to left ventricular systolic dysfunction (n=165) found fewer: deaths or readmissions with HF, all-cause readmissions and admissions and days in hospital for HF [3]. Cumulatively, these three trials alone have received around 4000 citations and historically formed the impetus for over 60 subsequent trials, over a dozen meta-analyses [4] and a movement towards multi-disciplinary disease management programs for other chronic conditions.

What can be concluded from trials of HF disease management interventions?

Yet, the sizeable positive results of these early trials of extremely brief interventions have struggled to be replicated consistently since, even with considerably larger and more complex interventions [5] and meta-analyses [4]. This influence derived from an overwhelming focus on 'headline' positive effects – to the neglect of key design weaknesses, including atypically healthy populations, vaguely described interventions, and non-described

comparison group found in these and other trials and meta-analyses [4]. Proponents for HF disease management interventions, even currently, retrospectively gloss over the possibilities of bias created by these important design flaws [4, 5], continuing to label HF disease management interventions as 'proven' [6].

The positive results of these early trials are curious. Indeed, the early trials [1-3] could be expected to have worse findings than subsequent trials, which could draw upon and harness insights from the previous ones. The difficult challenges of daily HF disease management are now much better understood: over 100 subsequent qualitative research studies in the years since have identified both the immense daily complexity of maintaining effective disease management and the consistently very poor knowledge, skills and confidence that the vast majority of HF patients and families possess to do so both before and after specialist consultations [7]. Yet, the interventions of these trials were briefer, focused only on patients, and more rudimentary than subsequent trials [4].

Why would early findings be so much more positive than subsequent results?

Over the past decade, we [8, 9] and others [10-13] have suggested that the risk of publication bias remains high in this field because researchers have considerable vested career interests in publishing and championing interventions with positive findings. Current labelling of the interventions as being 'proven' also risks confirmatory bias: the tendency to search for, interpret, favor, and recall information to affirm one's prior beliefs or hypotheses. Indeed, larger studies of HF disease management interventions performed by *independent* investigators with no career or personal interest in results have had inconsistent and negative results [5, 14].

Casting these past interventions as 'proven', proponents now call for a nuanced approach to HF management [6]. Indeed, we identified these weaknesses over a decade ago, including a plea that appeared on the cover of the Lancet including the recognition that 'Management programs for heart failure have been championed on the basis of limited high-quality evidence' [15].

Future research priorities

In terms of approaches, now, as before, we call for more independent and nuanced, high quality evidence [4, 15-17] into understanding the outcomes of HF disease management interventions. Learning from negative trial results is useful and important but has been uncommon [18]. As complex interventions, concerted efforts are needed to both describe and understand the nature and effects of programmes and heterogeneity [4] and how outcomes are influenced by both context [19] and intervention mechanisms [7, 20, 21].

Simplistic questions regarding 'which interventions work?' [22] – often associated with catchy study acronyms - should be replaced by research which examines how factors associated with programmes, people and places interact to influence outcomes; in short to address 'what works for whom, when and why?' [15-17, 19]. This more nuanced evidence base, if it is to address more nuanced questions, should utilize multiple quantitative and qualitative methods [4, 15-21]. It is high time we acknowledged the limitations and weaknesses inherent in contemporary HF management interventions and used more creative and sensitive approaches to designing, implementing and evaluating them.

Moving from simple approaches – interventions working versus not working – and dismissing inconsistencies as always being about interventions, not about population variations, will require a paradigm shift in research approaches to HF management programs [19]. It will prove to be a challenge. For example, although research into intervention mechanisms is large and growing in research volume [23], review approaches [24], frameworks [25] and methods [26], there is an absence of detailed primary studies. Mechanisms are the 'black box' between an intervention's inputs and outputs [27] and as such are causal, often unobservable and may be associated with benefits or harms. Mechanisms can also be considered as complex systems that affect outcomes through the interaction of various intervention parts [28].

Using the PICO approach, there is an urgent need for better described and targeted populations, systematically theorized and well described Interventions, driven by theories of change, comprehensively described fair Comparisons of typical HF care and more appropriate patient-centred Outcomes (and experiences) that are measured and explained. Adopting this approach explicitly is likely to help identify factors such as the crucial characteristics of a program [29], and determinants of issues such as self-care [30, 31] as well as context, settings and possible mechanisms.

Patient care

Of course, a one size fits all approach to HF management is untenable and it is incumbent on clinicians to not only apply these interventions to the right people at the right time but also to consider issues such as patient (and partner, family, caregiver) choice and preferences. Most HF interventions have been designed, driven and evaluated by clinicians and researchers with their primary outcomes invariably survival and hospital readmission.

But where are the patients in all of this and are these the most appropriate outcomes? Why are we not advocating and designing with patients these interventions and asking them about which outcomes are most desirable for them? We suspect that for patients, partners, families and caregivers, outcomes such as health-related quality of life and wellbeing will take precedence over survival and hospital resources. Also, consideration of other important issues such as satisfaction with and experiences of their care is essential. Too often clinicians still adopt a 'we know what's best' attitude to HF management when in fact the patient is the expert in their disease and its management.

Navigating science and advocacy

The boundaries between science and advocacy are blurred around HF disease management programs. Too often those advocating disease management approaches have either ignored negative findings or dismissed them as resulting from factors that serve to 'mask' otherwise effective interventions [6].

While advocates of programs remain eager to cast current evidence as 'proof', this continues to risk confirmatory bias: a tendency which influences professionals in situations in which they seek to appear more knowledgeable and credible than justified in ambiguous situations [32]. In addition to bias, as with other fields, blurring the lines between advocacy and science increases the risk of unethical attempts to falsely 'create' research success and impact. From the use of questionable research practices (such as merging outcomes or statistical manipulation to produce more impactful results, to the outright fabrication of data and study results), there remains an ongoing need for independent and more dispassionate evaluations of HF disease management programs free from actual or perceived conflicts of interest.

Contributors

Both authors wrote and approved the final version of the manuscript.

Declaration of interests

We declare no competing interest.

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