

Using pilot studies to inform health services

Jenny A Stewart Williams, Julia M Lowe and Paula M Candlish

Abstract

A pilot study was conducted at the John Hunter Hospital, Newcastle, Australia in 1998–99 to inform a randomised controlled trial (RCT) for a cardiac rehabilitation intervention for patients with congestive heart failure (CHF). Although the RCT did not proceed, the pilot study results raised a number of issues. In this paper, the pilot is used to demonstrate how estimates of population benefit need to take into account patient eligibility, consent and adherence, and also how non-clinical data can inform the planning and development of health service interventions.

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THE AIM OF THE PILOT STUDY was to investigate potential recruitment and participation issues for a cardiac rehabilitation program for patients with congestive heart failure (CHF). It was originally intended that the pilot, conducted in the Hunter Region of New South Wales, Australia, would inform a randomised controlled trial (RCT) to evaluate the effectiveness of the program; however, the program was established without the RCT.

The intervention consisted of an education and self-management program run by a multidisciplinary team including a cardiac rehabilitation nurse consult-

What is known about the topic?

There are often different perspectives in regard to the utility of pilot studies — they may be seen as an unnecessary delay to a new program or as a valid first step in program development.

What does this paper add?

A pilot study conducted for a cardiac rehabilitation program facilitated greater understanding of the potential barriers for the target consumers of the new program.

What are the implications for practitioners?

Pilot studies can contribute to health services planning and development by checking the generalisability and applicability of research interventions and estimates of population benefit. The experience described here suggests pilot studies can result in more realistic expectations and more effective implementation.

ant, a specialist heart failure nurse, a social worker, a physiotherapist and a dietitian. Primary diagnosis of CHF was a prerequisite for study enrolment, which took place between 1 May and 31 October, 1998.

The pilot comprised qualitative and quantitative components. The quantitative component was a prospective, single arm, open study of patients over 18 years of age who were admitted to the John Hunter Hospital with a primary diagnosis of CHF. Eligible patients were offered the cardiac rehabilitation intervention. The qualitative component followed the quantitative component, and comprised focus groups with participating patients, their carers, and staff involved with the program.

Outcomes

Box 1 shows, for the 184 available patients, the numbers and reasons for exclusion at each successive stage, with only 37 patients (20.1%) finishing the program. A total of 75 (40.8%) patients were ineligible: seven were excluded by their specialist; 13 did not have a confirmed diagnosis of CHF; 14 were not fluent in English; six required surgery; ten were referred to other programmes and 25 had serious comorbidities. Fifty-nine (32.1%) consented to join

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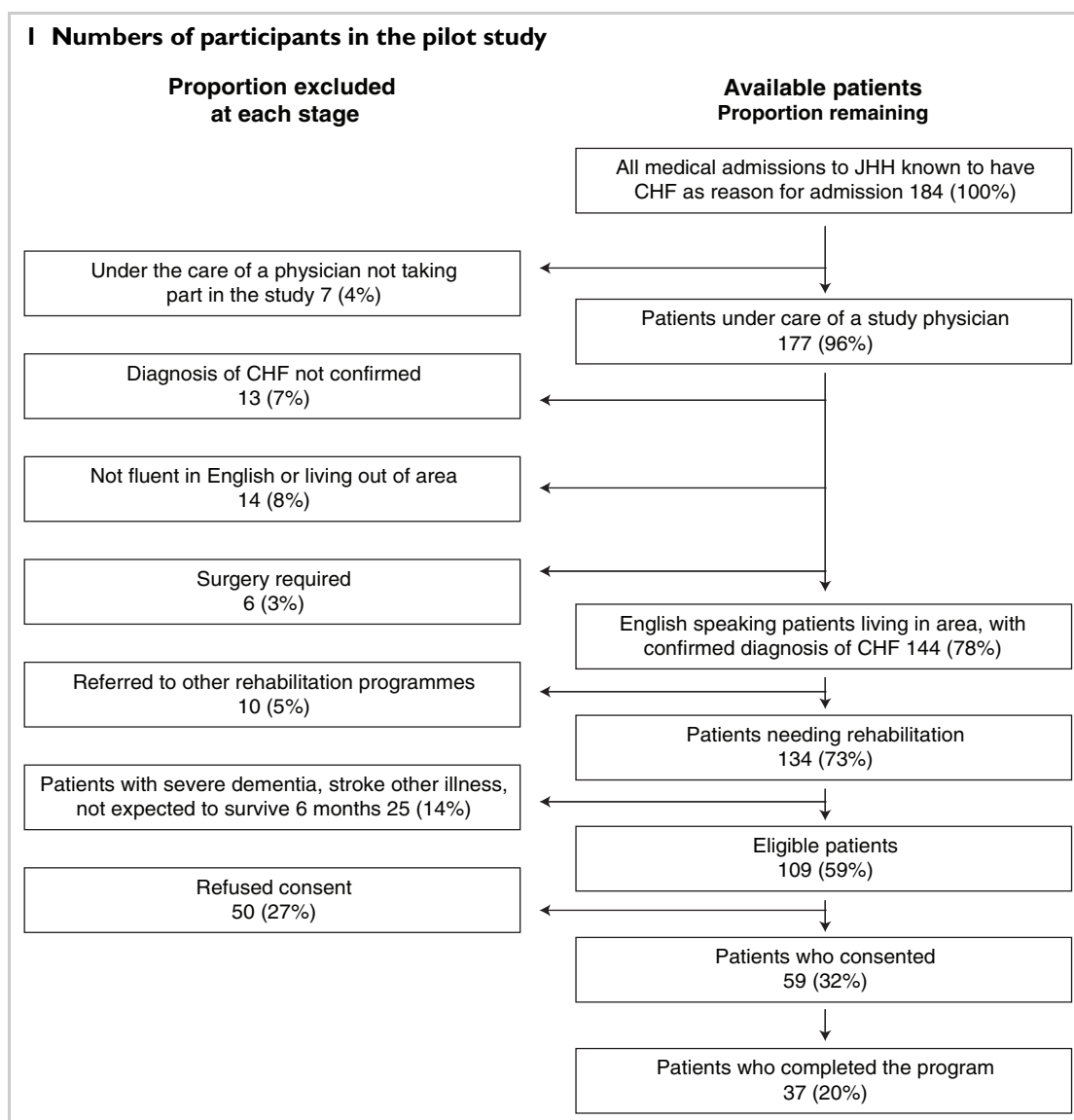
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the pilot and 50 (27.2%) refused consent. While ethical consideration precluded a formal investigation of the reasons for refusal, the overwhelming impression of staff was that these patients and their families felt that they were either too old or frail to take part. Many women who refused commented voluntarily that they could not, or would not, impose upon their families to join the program.

Box 2 gives a profile of the pilot population. Subjects are grouped into those who consented (n=59), refused (n=50) and were excluded (n=48).

This latter group comprised patients excluded by their specialist, patients requiring surgery, patients referred to other programs and patients with comorbidities.

In the focus groups the nursing and allied health staff identified the following issues: rescheduling more clinic visits in the last 12 weeks of the program; holding exercise classes with fewer participants; improving the venue for the education sessions; revisiting the clinical pathways to identify patients for referral to the program; actively recruiting subjects



through specialists; ensuring all subjects received a home visit; providing a transportation service for subjects to attend the program; and providing accessible parking for those who preferred to use private transport. Informal feedback from medical staff supported these views.

Participants in the patient and carer focus groups were very positive about the benefits of the pilot cardiac rehabilitation program. In addition to providing education and practical sessions on diet and exercise, they said the program fostered a supportive collegiate environment, and many friendships evolved out of the program. Participants also acknowledged the importance of family support for their adherence to the lifestyle advice. There was general recognition that lack of transport was a major deterrent for many people to attend the hospital-based sessions. Program participants, like staff, saw the provision of a free transportation service as crucial to the success of the program.

The quantitative data show that a higher proportion of females than males refused consent. The proportion of unplanned CHF readmissions (at both 28 days and 6 months) was higher for those who did not join the study, and mortality at 28 days was also higher. The mortality data only included in-hospital deaths and therefore may underestimate the total number of deaths. This pattern is consistent with the impression of staff that it was the older and sicker patients who refused to take part in the pilot. The differences were even more marked when patients with comorbidities were compared with participants. A similar study in the United Kingdom identified the reasons for non-participation as perceptions of being too old, too unwell or too busy.¹

Implications

Although the potential effects of the intervention on non-consenters and non-eligible subjects is unknown, and the numbers in this pilot study are too small to demonstrate significant differences, the data describe characteristics in the sub-groups which may or may not be systematically related to the effectiveness of the pilot intervention. This highlights the need for caution when translating the results of research into practice. This study demonstrated how estimates of population benefit from systematic application of clinical trial results may be inaccurate. Less than two-thirds of the patients initially identified were finally eligible, and nearly half of these refused to take part in the program.

Using the hospitalisation rate of 783 per 100 000 from our previous paper² applied to the number of people aged over 60 in NSW in 2001 would suggest 8554 hospital admissions for CHF. Piepoli et al³ suggested the number needed to treat (NNT) of 17 people completing a heart failure exercise rehabilitation program to prevent one death. Combining the two suggests that 503 lives could be saved. However, because participation and adherence rates are lower than ideal, it is likely that fewer lives would be saved. For example, using the estimate of 503 and applying a consent rate of 32% suggests 161 lives saved, and applying an adherence rate of 20% suggests 101 lives saved. It is important to draw these distinctions when estimating NNT.

While there is extensive literature on the impact of losses to clinical trials before randomisation, and while most RCTs recognise the importance of maximising the recruitment of eligible patients, few report on even the demographic characteristics of those who either refuse or are ineligible to take part.⁴⁻⁶ In a systematic review of the effectiveness of exercise

2 Profile of subjects

Characteristic	Consenters (n=59)	Refusals (n=50)	Exclusions/comorbidities (n=48)
Male	54%	36%	50%
Mean age in years (range)	71 (46–98)	79 (60–95)	80 (57–91)
Mean length of hospital stay in days	7.6	8.1	12.6
Mortality at 28 days (%[no.])	3.3% (2)	6% (3)	10% (5)
Mortality at 6 months (%[no.])	13% (8)	14% (7)	27% (13)
Unplanned CHF re-admission at 28 days (%[no.])	3.3% (2)	14% (7)	21% (10)
All cause unplanned re-admission at 6 months (%[no.])	20% (12)	30% (15)	na

na = not applicable

training and CHF, completion rates were not recorded for five studies, compliance rates were not recorded for 15 of the studies, and the characteristics of patients who were not recruited were not described.⁷

The quantitative component of the pilot study helped identify reasons for non-participation and ineligibility, as well as patient outcomes for consenters, refusals and exclusions, and the qualitative component provided feedback on the pilot intervention. The results were used to further develop the John Hunter Hospital Cardiac Rehabilitation Program which has actively recruited CHF patients since 2000. The transport barrier was addressed with programs established at four sites instead of one to reduce travelling. The resistance shown by patients, carers and staff to the idea of the benefit of exercise for older people with heart failure was addressed in information sessions for staff and carers by explaining the benefits.

Although not the original intent of the pilot, these results were used to inform a Hunter Health proposal to the NSW Department of Health to implement an area-wide chronic and complex care program. This program, which commenced operation in 2000, focuses on heart failure, chronic obstructive pulmonary disease, and cancer care, with recurrent funding provided by the NSW Department of Health. As a result of identification of transport as a major barrier to participation, the program was offered at five sites, minimising travel time and parking problems for patients and their families. This also made the selection of better venues possible and reduced class size. Patient information (both written and oral) was changed to address perceptions that age and frailty preclude exercise. The heads of general medicine and cardiology accompanied the cardiac rehabilitation staff to promote the program as it was introduced at each site.

Results from the program in October 2002 showed that 187 of 510 eligible patients (36%) had completed the program, comparing favourably with the NSW Health benchmark of 10%, suggesting that some of the lessons learned from this pilot study had been well applied.

Conclusions

Working practices have often evolved over the years, and there can be many different layers acting as barriers to a smooth patient journey through the health system. These barriers include communication

and administration or paperwork processes, and often involve a number of organisations or departments. A pilot study can provide opportunities to bring together multidisciplinary teams from primary, secondary, tertiary and social care, and from within this team of professionals create a culture of ownership, responsibility and accountability for a new program. It can give managers and staff an overview of the complete process — helping staff to understand, often for the first time, how complicated systems can be for patients, which in turn can enable modification before a program is rolled out to a wider area. While managers may see a pilot as an unnecessary delay to a new program, this experience shows it can result in more realistic expectations and more effective implementation.

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Competing interests

The authors declare that they have no competing interests.

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