Ischemic heart disease (IHD) is the most important cause of death within cardiovascular disease (CVD), which in turn is the leading cause of death in Canada. The number of IHD survivors is increasing, enhancing the importance of secondary prevention services. The current cardiac rehabilitation program (CRP) model in Canada is an evidence-based, cost-effective intervention that encompasses a multidisciplinary team to modify IHD risk factors and lifestyle behaviours. However, their use is limited due to hospital's and patient's barriers. Standard CRP (sCRP) require an attendance of two to three in-hospital exercise/educational sessions per week for three to four months, each session holding a restricted number of patients, limiting the program's overall intake capacity. Although these programs include primary and secondary prevention patients, all receive a similar intervention in a “one size fits all” fashion. Additionally, attendees face the challenges of distance, transportation and lack of time since these sessions are held during regular working time, which explains the program's high drop-out rates of 25-40%. Patients at low and moderate risk, may be treated with more flexible programs, allowing them a more flexible schedule and increasing the hospital's patient intake capacity enabling crucial resources to be directed to those at high risk that need in-hospital supervision the most.

Home-based CRP have been compared to in-hospital CRP in an attempt to diversify program delivery. They have reported better sustainability of exercise capacity, which might be explained by the possibility that those who achieve healthy behavioural changes within their own environment are able to better maintain these gains. However, these interventions have focused on low-risk patients only and exercise-based outcomes with minimal assessment of metabolic variables (of critical importance for patients with IHD).

Our purpose is to investigate whether a reduced CRP (rCRP), which in the same period of time requires a lower number of supervised sessions, is as effective or better than the sCRP for improving exercise capacity, adherence and IHD risk factors immediately after completion and at one-year. The following questions will be addressed: 1) Is the rCRP “not worse” or better than the sCRP for improving exercise capacity and IHD risk factors at four and 16 months following baseline? 2) Will the rCRP have better adherence than the sCRP?

### Study Methods

This is a two group randomized controlled trial. Primary and secondary prevention patients referred to the St. Paul's Hospital CRP were screened for eligibility. Those at high risk, according to the American Association of Cardiovascular and Pulmonary Rehabilitation risk stratification criteria were excluded (i.e., heart failure, poor exercise capacity). Eligible and consenting patients signed an informed consent and underwent a baseline assessment of medical history, exercise capacity, lipid profile, blood pressure (bp), anthropometric measurements, lifestyle behaviours and psychosocial measures. Patients were randomized to either the sCRP or the rCRP following their first cardiac rehabilitation (CR) class. The same assessment was done at program graduation (4 months) and again one-year later to assess the immediate and sustainable effects, respectively (Figure 1).

The sCRP is a four-month intervention, with an initial evaluation by a cardiologist, nurse, exercise specialist and dietitian. Patients attend 32, twice weekly in-hospital exercise/educational sessions, nutritional counselling, medical care, psychological screening and smoking cessation if needed. The rCRP only differs from the sCRP in the number of in-hospital exercise sessions during the same program duration (10 sessions in four months). In an attempt to compensate for the decreased in-class information and motivation, rCRP...
Figure 1: Recruitment and follow-up algorithm

- **CRP Intake Clinic Recruitment**
- **Consented: NO**
  - Standard CRP
- **Consented: YES**
  - Randomization
  - **Standard CRP**
    - Months 1-4
      - In-hospital exercise sessions twice/week
        - 32 sessions total
  - **Reduced CRP**
    - 1st Month
      - 1st and 2nd week: 2 exercise sessions/week
        - 3rd and 4th week: 1 exercise session/week
    - 2nd Month
      - 6th and 8th week: 1 exercise session/week
    - 3rd Month
      - 12th week: 1 exercise session/week
    - 4th Month
      - 16th week: 1 exercise/week
    - 4-Month exit assessment
    - 16-Month assessment
    - 16-Month assessment
participants received a package that provided educational information, and a logbook to record their exercise sessions which would serve as a self-motivation/self-monitoring system. The CRP clinical staff had the discretion to move patients in the rCRP to the sCRP in cases of patient safety only following a pre-designed algorithm (not shown).

The primary outcome is the difference in exercise capacity measured as total time in the treadmill from baseline to program completion and at 16 months compared between the two groups, assessed by a symptom limited stress test using the Bruce protocol. Secondary outcomes include fasting glucose, lipids, bp, body mass index, waist circumference, global CVD risk, lifestyle (physical activity, diet), psychosocial measures (quality of life, self-efficacy) and CRP adherence (percent attendance and leisure time physical activity). These outcomes were measured at CRP intake (baseline), at CRP completion (4 months) and will be measured at 16 months following baseline. Changes for continuous and categorical variables between the two groups will be tested using a two by three repeated measures ANOVA and Pearson chi square, respectively. Using a non-inferiority power calculation, based on preliminary data on the primary outcome and considering a 25% drop-out rate, the sample size was calculated as a total of 118 participants.

Current Status

Recruitment lasted 42 months and was finalized on May, 2010. A total of 2016 charts were screened of which 65% (1310 patients) were non-eligible. The main reason for non-eligibility was a history of or current congestive heart failure and low baseline exercise capacity. From the 706 eligible patients, 75% refused to participate and 15% consented but did not show up to the first class, therefore were not randomized. The main reasons for refusal to randomization were: 1) a preference to be in the standard program (60%) due to anxiety and/or a perceived “lack of self-discipline” and 2) a preference to be in the reduced program (40%) due to time restraint or geographical barriers. With 25 participants still to complete their 1-year follow-up assessment, data collection will be complete in September of 2011.

Conclusion

Given the importance of providing CR for the growing population of CVD patients it is imperative to achieve higher hospital intake, while having flexible programs for the diverse population of potential CRP attendees. Currently, there is a mismatch between the types of CRP offered and demand. The reduced CRP aims to maintain the comprehensive nature of a standard program, providing much needed support for patients to achieve and maintain behavioural changes with less hospital supervision, allowing to increase CRP openings for high risk patients. Of relevance is that 40% of patients refused to be randomized due to a preference for a reduced program, which exposes a gap in the current CRP model.

References