TITLE: Increasing Cardiac Rehabilitation Participation among Medicaid Enrollees
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Statistical Analyses and Power:

Power: Sample size was determined based on having sufficient power to detect differences between treatment conditions corresponding to our primary hypotheses regarding CR participation outcomes. Results from our prior trials and the literature on financial incentives demonstrate that doubling or more of participation rates is a common outcome (e.g. Higgins, 1994; Lussier et al., 2006). Our preliminary data show that the CR participation rate in low-income groups in Chittenden County, Vermont is ~24%. We expect to at least double that rate, which would be equivalent to bringing the low-income participation rates up to the same level as the average participation rate of the rest of the population. Given these assumptions, an adequately powered study would require 63 participants per condition. As such, the proposed sample size of 130 subjects (65/condition) will result in greater than 80% power for a chi-square test to detect the difference between participation rates of 24% vs. 48% at end-of-intervention assessment. Based on prior incentive studies we expect a similar effect size for CR adherence over time as well. 65 subjects per condition will leave us adequately powered for both initial participation as well as longer-term adherence.

Thus, accrual of 140 participants (130 randomized and 10 pilot participants) over 3 years is necessary for the successful completion of this study. In our preliminary data gathering the number of CR-eligible patients over the past 16 months was assessed. We have realistically determined that a pool of over 100 Medicare or equivalent CR participants is available yearly. A recruitment yield of 140/*300 or* 47*%* is realistic, in that subjects potentially gain by the provision of the health benefits provided by CR participation, as well as by the financial remuneration involved in study participation. Based on our preliminary data, 24% of this population already participates in CR and one could reasonably assume that most of these individuals would also participate in the proposed study.

Data Analysis: Treatment conditions will be compared for differences in baseline characteristics using t-tests for continuous measures and chi-square tests for categorical variables. If specific characteristics differ significantly across treatment conditions, such as gender or age, and that are predictive of treatment outcomes, they will be considered as covariates in subsequent analyses. If the number of covariates appear somewhat large in number, a propensity score approach will be implemented to adjust comparisons between groups. Primary analyses will include all subjects randomized to treatment conditions independent of early dropout, non-adherence, etc., consistent with an intent-to-treat approach to randomized clinical trials (Armitage, 1983).

The primary outcome measures in this trial will be CR participation and will be compared between the intervention and control conditions. The number of participants who attend even a single session will be examined as well as the total number of sessions each participant completes (up to 36). Attendance rates will be compared across the treatment conditions using chi square tests or Fisher's Exact tests, if small expected cell frequencies are present. Logistic regression models to compare the two groups at each time point will be employed if covariates or the propensity scoring approach are implemented. A traditional 5% significance level will be employed.

Although this study is powered for our primary outcome of participation, we will also examine fitness (maximal exercise capacity), cognitive (BSI, BDI, Stroop, GNG, DD, TPQ), and quality of life (EuroQual and MacNew) gains at 4 and 12 months, both between the two conditions, as well as between those who do and do not attend CR. Changes in these scores will also be examined for possible gender interactions. Since multiple observations for each participant will be obtained, the general analytic approach will consist of a repeated measures analysis implemented using a linear mixed model. Formal testing will examine the group by time interaction term to assess differential time changes between the two conditions (intervention vs. usual care). Post-hoc comparisons between the two groups will be made if significant interactions are observed. Data management and analysis will be conducted using SAS (ver10).

Cost Effectiveness Data: We will collect the costs associated with program implementation from the clinical site and from participants at each follow-up interview (including travel costs). Operating costs under each arm will be collected through customizing our cost assessment tool used for cardiac rehabilitation and lifestyle modification (Lee & Shepard, 2009) and counseling services (Flynn, et al., 2009; Shepard, et al., 2003). To assess costs to participants (e.g. travel expenses, time spent, and out-of-pocket expenses), we will adapt the client DATCAP to this study (www.datcap.com/client.htm) The direct nonmedical and indirect costs include the value of time of participants attending the program, waiting, traveling, or exercising, and transportation expenses. The indicator of quality adjusted life years (QALYs) for each group will be calculated using the EuroQol quality of life measure (Oldridge, et al., 2005). The cost-effectiveness ratio of cost per

QALY (Zeckhauser & Shepard, 1976) will be modeled using meta-analysis data from randomized-controlled trials of CR after a coronary event (Taylor et al., 2004; Heran et al., 2011) to estimate the cost-effectiveness of monetary incentives to encourage CR use compared to standard CR. The cost-effectiveness model will also include hospitalization costs averted and possible increases in ambulatory costs if CR use, associated testing, and ambulatory services are increased by the incentives condition (Heran et al 2011). Similar to another recent cost-effectiveness study of CR, we will perform the analysis with two contrasting time perspectives—the period of follow up alone, and a lifetime perspective, based on a carefully calibrated model to project utilization and costs (Shepard et al. 2009). The former provides a more conservative, short-term analysis closely tied to the observed data. The latter provides a long-run perspective.