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Increasing Use of Cardiac and Pulmonary Rehabilitation in Traditional and Community Settings

OPPORTUNITIES TO REDUCE HEALTH CARE DISPARITIES

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Although both cardiac rehabilitation (CR) and pulmonary rehabilitation (PR) are recommended by clinical practice guidelines and covered by most insurers, they remain severely underutilized. To address this problem, the National Heart, Lung, and Blood Institute (NHLBI), in collaboration with the National Institute on Aging (NIA), developed Funding Opportunity Announcements (FOAs) in late 2017 to support phase II clinical trials to increase the uptake of CR and PR in traditional and community settings. The objectives of these FOAs were to (1) test strategies that will lead to increased use of CR and PR in the US population who are eligible based on clinical guidelines; (2) test strategies to reduce disparities in the use of CR and PR based on age, gender, race/ethnicity, and socioeconomic status; and (3) test whether increased use of CR and PR, whether by traditional center-based or new models, is accompanied by improvements in relevant clinical and patient-centered outcomes, including exercise capacity, cardiovascular and pulmonary risk factors, and quality of life. Five NHLBI grants and a single NIA grant were funded in the summer of 2018 for this CR/PR collaborative initiative. A brief description of the research to be developed in each grant is provided.

Key Words: cardiac rehabilitation • health disparities • pulmonary rehabilitation

Clinical practice guidelines recommend cardiac rehabilitation (CR) for the nearly 2 million people in the United States who experience an acute coronary event or undergo a revascularization procedure each year, and for millions more who have a chronic cardiac condition (class 1A recommendation). Cardiac rehabilitation is covered by Medicare and most insurers after acute myocardial infarction, percutaneous coronary intervention, coronary artery bypass surgery, valvular heart surgery, cardiac transplantation, chronic stable angina, and chronic heart failure with reduced ejection fraction. Traditional CR is typically delivered at a center (hospital or clinic) and consists of up to 36 1-hr sessions in a group setting within 12 mo after hospital discharge. A substantial body of evidence demonstrates the benefits of CR, including a reduction in cardiovascular (CV) morbidity and mortality and improved quality of life (QoL) and functional status. Recent studies have shown that CR participation resulted in a 20-30% reduction in hospital readmissions and a similar decrease in CV deaths.[1] However, <25% of eligible patients participate in CR, and the proportion completing the recommended 36 sessions is even smaller.

Pulmonary rehabilitation (PR) is a multidisciplinary intervention for symptomatic patients with chronic respiratory diseases, particularly chronic obstructive pulmonary disease (COPD). Pulmonary rehabilitation aims to reduce symptoms, decrease disability, increase participation in physical and social activities, and improve QoL for these patients. Over 700 000 patients are hospitalized annually in the United States for COPD. Many of these patients qualify for PR, but only 2.7% of those qualifying participated in these programs within 12 mo after discharge.[2] Although a survival benefit remains under investigation, clinical trials of PR show a reduction in hospitalizations and emergency department or physician office visits,[3] as well as improvement in exercise capacity and QoL.[4] Medicare will typically pay for 36 sessions of PR per lifetime but may pay up to 72 sessions if clinicians document that extended PR services are medically necessary.

Despite the clear benefits on clinical and patient-centered outcomes, both CR and PR remain severely underutilized. Participation is particularly low in the groups that are at the highest risk for morbidity and mortality, including women, older adults, minorities, persons of lower socioeconomic status (SES), and rural populations.[5] Multiple factors contribute to low CR and PR participation rates including a lack of referral or strong recommendation from a physician and inadequate follow-up or facilitation of enrollment after referral. Financial issues such as limited or absent health insurance coverage and the inability to afford copayments, even when insured, also limit CR/PR participation as do conflicting work and home responsibilities and distance and transportation difficulties. Social and cultural factors, including the lack of gender and racial diversity among CR/PR staff, language and cultural barriers, and lack of program availability and access are additional challenges that impact the poor rates of participation for CR and PR.[2,6] Many eligible patients are also commonly perceived as

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too frail for CR and PR when in reality they might benefit most.[7] Newer delivery models for health care such as telemedicine and treatment in non-health care settings (eg, home and community center) address some of these patient and provider barriers and lower costs for CR and PR participation. However, the efficacy of the latest approaches has been demonstrated predominantly in low-to-moderate risk patients, with limited data regarding their benefits and safety for high-risk CR/PR candidates.

Inspired by the Million Hearts Cardiac Rehabilitation Collaborative[8] and a review of existing research, the National Heart, Lung, and Blood Institute (NHLBI) developed a Funding Opportunity Announcement (FOA) to support phase II single-site clinical trials to increase the uptake of CR and PR in traditional and community settings. The objectives of this FOA (RFA-HL-18-019) were to (1) test strategies that will lead to increased use of CR and PR in the US population who are eligible based on clinical guidelines; (2) test strategies to reduce disparities in the use of CR and PR based on age, sex, race/ethnicity, and SES; and (3) test whether increased use of CR and PR, whether by traditional center-based or new models, is accompanied by improvements in relevant clinical and patient-centered outcomes, including exercise capacity, CV and pulmonary risk factors, and QoL.

In discussion with NHLBI staff, National Institute on Aging (NIA) staff recognized that issues beyond CR recruitment and enrollment barriers existed for older adults. Specifically, the overall goals and components of traditional CR programs, intended to safely guide patients back to their normal activities and reduce future CV events, required modification for most real-world older adults, many of whom have baseline comorbidities and disabilities. Thus, NIA decided to issue a separate FOA (RFA-AG-18-016) to fund one R01 multicomponent clinical study to address one or more specific age-related factors including (1) patient-related issues, (2) CR program goals and components, and (3) CR program setting-related aspects. This FOA sought to determine specific aspects of novel CR programs that may be better suited to medically complex and vulnerable older adults, such as broader entry criteria, patient-directed goals, regimens modified for disabilities/adaptive equipment, hybrid venues including home and telehealth-based, and outcomes, including physical/cognitive function, independence, reduced falls and disability, and improvement in QoL.

The NHLBI FOA was released in September 2017, utilizing a biphasic, milestone-driven R61/R33 Exploratory/Developmental Phased Award mechanism consisting of a start-up phase (R61) and a full enrollment and clinical trial execution phase (R33). Shortly thereafter the NIA released their FOA to fund a single R01 focusing on CR in older adults. Five NHLBI grants and a single NIA grant were funded in the summer of 2018 for this CR/PR collaborative initiative. A brief description of the research to be developed in each grant follows in the text and the Table.

FUNDED GRANTS

Project Title: Improving ATTENDance to Cardiac Rehabilitation (iATTEND). Principal Investigator: Steven J. Keteyian, PhD, Henry Ford Hospital, Detroit, MI (HL 143099).

Although center-based cardiac rehabilitation (CBCR) represents guideline-based care for patients with CV disease, <25% complete the maximum 36 sessions typically allowed by most third-party insurance payers.[5] As such, many patients may not be receiving the full clinical benefit ascribed to CR, and among African Americans, participation and attendance in CR and adoption of healthier lifestyle changes are even less likely.[6,9,10]

iATTEND is a single-site phase II clinical trial that is randomizing 270 patients to CBCR only or hybrid CR (HYCR), which combines CBCR and remote, home-based CR using telemedicine.[11] Both groups are targeted to attend 36 CR sessions within 6 mo. The primary aim of the iATTEND trial is to assess the efficacy of HYCR on attendance. The primary hypothesis is that patients randomized to HYCR will complete significantly more CR sessions than patients randomized to CBCR alone. Secondary aims are to assess the effect of HYCR on exercise capacity and QoL. Patient assessments are conducted at baseline, within 10 d after completing CR, and 6 mo after completing CR.

The iATTEND trial is unique because it focuses on patients residing within or proximal to Detroit, MI, representing a predominantly African American (79%) at-risk cohort that often cannot regularly attend CR due to social and economic challenges. This trial provides an opportunity to examine the adoption of a model that mimics traditional CBCR in terms of (*a*) delivering the same secondary prevention elements and (*b*) measuring common program outcomes in a high-risk understudied population.

Project Title: Improving Participation in Cardiac Rehabilitation Among Lower-Socioeconomic Status Patients: Efficacy of Early Case Management and Financial Incentives. The Healthy Lifestyle Program (HeLP) Study. Principal Investigator: Diann Gaalema, PhD, University of Vermont, Burlington, VT (HL 143305).

Lower SES is a robust predictor of CR nonparticipation.[6,12] There is growing recognition of the need to increase CR among economically disadvantaged patients, but there are almost no evidence-based interventions available for doing so. In the present study, we are examining the efficacy of using early case management and financial incentives for increasing CR participation among lower-SES patients. Case management has been effective at promoting attendance at a variety of health-related programs (eg, treatment for diabetes, HIV, asthma, and cocaine dependence)[13] as well as reducing hospitalizations. Financial incentives are also highly effective in altering health behaviors such as smoking during pregnancy and weight loss among disadvantaged populations, including CR participation in our prior trial.[14,15] In this trial, 200 CR-eligible lower-SES patients will be randomized to one of the following four treatment groups: (1) case manager facilitation of CR attendance and coordination of cardiac care; (2) financial incentives contingent on the initiation of and continued attendance at CR sessions; (3) a combination of these two interventions, or (4) standard CR. Participants in all four groups will complete pre- and post-treatment assessments, comparing attendance at CR and end-of-intervention improvements in fitness, executive function, and health-related QoL. The cost-effectiveness of the interventions will also be examined. Furthermore, we will model the value of the interventions based on increases in participation rates, intervention costs, long-term medical costs, and health outcomes after a coronary event. This systematic examination of promising interventions will allow us to test the efficacy and cost-effectiveness of approaches that have the potential to increase CR participation substantially and significantly improve health outcomes among cardiac patients of lower SES.

Project Title: Enhancing Cardiac Rehabilitation Adherence Through Home-Based Rehabilitation and Behavioral Nudges (ERA Nudge). Principal Investigator: Pamela Peterson, MD, MSPH, Denver Health Medical Center, Denver, CO, and University of Colorado Anschutz Medical Campus, Aurora, CO (HL 143324).

The overarching goal of ERA Nudge is to increase adherence and completion of CR in a diverse population of

Table

Projects Funded by RFA: Increasing Use of Cardiac and Pulmonary Rehabilitation in Traditional and Community Settings

Project Title	Principal Investigator and Site	Cardiac or Pulmonary Rehabilitation	Primary Outcome	Sample Size and Characteristics	Intervention
The Improving ATTENDance to Cardiac Rehabilitation (iATTEND) Trial	Steven Keteyian, PhD; Henry Ford Hospital Detroit, MI	Cardiac	Effect of remote/home-based CR on attendance	n = 270, age ≥18 yr, with focus on at-risk, urban residents of Detroit, MI	Remote CR delivered with the assistance of telemedicine
Enhancing Cardiac and Pulmonary Rehabilitation Adherence Through Home-Based Rehabilitation and Behavioral Nudges (ERA Nudge)	Pamela N. Peterson, MD MSPH; Denver Health Medical Center	Cardiac	Effect of home vs hospital-based CR and nudge messages on adherence	n = 400, age ≥18 yr English and Spanish Focus on a safety net population in urban Denver	Home-based CR and nudge messages delivered via cellphone-based application
Improving Participation in Cardiac Rehabilitation among Lower-Socioeconomic Status Patients: Efficacy of Early Case Management and Financial Incentives. Healthy Lifestyle Program (HeLP)	Diann E. Gaalema, PhD; University of Vermont Medical Center	Cardiac	Effect of financial incentives and/or case management on CR attendance	n = 200, age ≥ 18 yr, lower socioeconomic status patients in Vermont	Early case management and financial incentive to improve CR attendance in underrepresented populations
Modified Application of Cardiac Rehabilitation for Older Adults (MACRO)	Daniel E. Forman, MD, University of Pittsburgh, Pittsburgh, VA, Washington U.	Cardiac	Effect of CR on Short Physical Performance Battery	n = 480, aged ≥70 yr, hospitalized with cardiovascular disease	Tailoring CR to needs of elders, goal-directed, adaptive regimen, hybrid model, deprescribing
Increasing Adherence to Pulmonary Rehabilitation After COPD-Related Hospitalizations	Roberto Benzo, MD, Mayo Clinic Rochester, MN	Pulmonary	Adherence and effectiveness of home-based PR	n = 150, frail adults after COPD hospitalization	Home-based PR for frail COPD patients
Comprehensive Health Informatics Engagement Framework for Pulmonary Rehabilitation (CHIEF-PR)	Joseph Finkelstein, MD, Mt Sinai Hospital, New York, NY	Pulmonary	Percentage of eligible COPD patients completing 3-mo PR	n = 120, adults after COPD exacerbation	Home PR using multifaceted computer-based intervention

Abbreviations: COPD, chronic obstructive pulmonary disease; CR, cardiac rehabilitation; PR, pulmonary rehabilitation.

low SES. This single-site trial is conducted at Denver Health Medical Center, a large, integrated urban safety-net health system. The project uses a multipronged approach to increase enrollment, adherence, and completion. The study is testing the choice of home-based versus hospital-based CR and behavioral "nudge" messages. The acceptability and uptake of a home-based program among a safety-net population are unknown. Behavioral nudges utilize principles from the fields of behavioral economics and cognitive psychology and have the potential to augment the impact of messaging interventions to modify behavior and enhance adherence.[16-19] In the first year of the project, qualitative work was performed to tailor nudge messages for English and Spanish speakers. In addition, a tool was developed to present information on the pros and cons of the hospital-based and home-based CR for those randomized to the choice intervention. In the R33 phase of this project, a randomized trial of 400 CR-eligible patients will compare: (1) hospital-based CR and generic messaging; (2) hospital-based CR and nudge messaging; (3) choice of hospital- or home-based CR and generic messaging; and (4) choice of hospital- or home-based CR and nudge messaging. All patients are provided with a mobile phone-based application, which is used to deliver generic and nudge messaging and home-based rehabilitation. The primary outcomes of the trial are the enrollment in and completion of CR. The interventions will also be assessed using the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) implementation research framework.[20]

Project Title: Modified Application of Cardiac Rehabilitation for Older Adults (MACRO). Principal Investigator: Daniel Forman, MD, University of Pittsburgh, Pittsburgh, PA (AG 060499).

Cardiovascular disease (CVD) is endemic in today's rapidly expanding population of older adults. Treatment of CVD in older adults often entails significant clinical challenges from multimorbidity issues (ie, concurrent CVD and non-CVD, polypharmacy, functional decline—physical and cognitive—frailty, falls, depression, and other health care issues).[21,22] Although CR has purported utility for adults of any age,[23] most older candidates do not participate.[24] Age-related impediments relate to logistics and the common misperception that CR lacks priority or value amidst other life and illness travails. The current project, MACRO, is a pragmatic randomized controlled trial to test modifications of CR that are designed to better meet the needs of older adults.[25]

The MACRO protocol tests an additional layer of clinical coaching and support to amplify existing CR infrastructures and to supplement them with innovative adjuncts that address the specific needs of older adults. Elemental MACRO precepts are: (1) enhanced transitions (ie, from inhospital management to outpatient CR), to long-term active and healthy lifestyle thereafter, utilizing the medical site, home, and hybrid models of outpatient CR, and home assessments to better ensure success; (2) enhanced risk assessments, integrating functional, and psychosocial domains with CVD risks to better guide shared decisions and clinical care; (3) embedded engagement and motivational techniques to achieve personal motivations for each patient participating in CR; and (4) deprescribing components to remove/reduce sedating medications to potentially lessen fatigue, falls, and cognitive impairment.

In MACRO, 480 older (≥70 yr) hospitalized adults with CR-eligible CVD will be randomized across three sites to a MACRO coaching/support intervention or standard CR. The primary outcome of MACRO is performance at 3 mo on the Short Physical Performance Battery (SPPB), a general measure of physical function.[26] Additional assessments at 3, 6, and 12 mo include changes in physical activity (self-reported and evaluated with accelerometry), handgrip, SPPB, depression, cognition, frailty, self-efficacy, and QoL. Other measures are CR participation, patient-reported satisfaction, falls, and rehospitalization.

Project Title: Increasing Adherence to Pulmonary Rehabilitation After COPD-Related Hospitalizations. Principal Investigator: Roberto Benzo MD, MS, Mayo Clinic, Rochester, MN (HL 142933).

Despite proven benefits, the current model of a center-based PR program fails to address the needs of many patients with COPD.[27] The most common patient barrier to attendance is travel to center-based programs, particularly for frail patients with more severe COPD who need transportation assistance. Home-based, unsupervised PR has been proposed as an alternative model to hospital-based programs and has been found to be safe and effective. Although PR post-COPD hospitalization has been reported as the most effective intervention to prevent hospital readmission,[3] the reality is that only 4% of eligible individuals attend PR after hospital discharge for multiple reasons.[28] Many of these 700 000 annual COPD hospitalizations, which account for a large proportion of the annual direct medical costs of COPD, are potentially preventable.

In this project, we will refine and test a simple system of remote PR that uses off-the-shelf technology that may fill the practice gap based on our previous work[29] with the addition of Health Coaching to promote a behavior change that we have shown to be highly effective in decreasing COPD rehospitalizations and sustainably improving QoL.[30] The proposed system is compliant with currently approved Medicare billing codes for remote monitoring.

A pilot study will refine the already developed home-based PR program for frail COPD patients in the post-hospitalization period. After incorporation of the necessary changes informed by the pilot study, the adherence, the clinical effectiveness, and the cost-effectiveness of traditional center-based PR and home-based PR will be compared in a well-powered phase 2 clinical trial of 150 patients. The proposed study will provide data to further refine, implement, and support the coverage of home-based PR.

Project Title: Comprehensive Health Informatics Engagement Framework for Pulmonary Rehabilitation (CHIEF-PR). Principal Investigator: Joseph Finkelstein, MD, PhD, Icahn School of Medicine at Mount Sinai, New York, NY (HL 143317).

Based on our previous successful experience in implementation of health information technologies supporting guideline-concordant care,[31] we developed the Comprehensive Health Informatics Engagement Framework for Pulmonary Rehabilitation (CHIEF-PR), aimed to facilitate PR referrals, initial assessments, completion rates, and maintenance using an innovative multipronged approach.[32] The goal of this trial is to demonstrate that CHIEF-PR is effective in the increasing use of PR in patients after acute exacerbation of COPD and improves clinical and patient-reported outcomes as compared with routine clinical care.

CHIEF-PR is a multipronged integrated computer-mediated intervention aimed at facilitating PR at the patient, provider, and health care levels. CHIEF-PR consists of three major components: clinical decision support to facilitate referrals and heighten provider awareness about PR, interactive computer-mediated patient engagement app to convey benefits of PR[33] and help with enrollment,[34] and home-automated telemanagement[35] to support individualized PR at home.[36] Since successful patient PR completion and maintenance is predicated on adequate referral and

baseline assessment rate, contemporaneous implementation of all three CHIEF-PR components is necessary to ensure persistent improvements in PR use.

CHIEF-PR will be evaluated in a randomized, controlled, parallel 2-group prospective trial with blinded outcome assessment. Overall, 120 patients will be randomized to the intervention or to standard-of-care PR within 4 wk after an emergency department visit or hospitalization due to acute COPD exacerbation. The primary hypothesis is that the introduction of CHIEF-PR will be associated with a significant increase in the completion of the PR program by patients after acute COPD exacerbation as compared with current practice. The primary outcome is the percentage of eligible COPD patients who complete a comprehensive 3-mo PR program. The impact of CHIEF-PR on exercise capacity, QoL, self-efficacy and illness perception, and reduction in perceived breathlessness and urgent care utilization will also be explored.

CURRENT STATUS AND FUTURE DIRECTIONS

At the first investigator meeting on October 30, 2019, the principal investigators from all six trials presented their progress and exchanged valuable feedback. All five NHLBI-funded trials have successfully transitioned from the R61 development phase to the definitive R33 phase. The single NIA trial, funded as an R01, has made similar progress. NHLBI and NIA program staff are pleased with the scope of the trials, including both CR and PR, and the focus on improving the participation rates of older adults, women, minorities, and individuals of lower SES. It is our goal to use the results of these innovative interventions to inform the design of large multicenter trials in the general population to increase PR participation and fulfill the Million Hearts Initiative mission to increase CR participation to 70% by 2022.[8]

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- Project Title: Improving ATTENDance to Cardiac Rehabilitation (iATTEND). Principal Investigator: Steven J. Keteyian, PhD, Henry Ford Hospital, Detroit, MI (HL 143099)—NHLBI
- Project Title: Improving Participation in Cardiac Rehabilitation Among Lower-Socioeconomic Status Patients: Efficacy of Early Case Management and Financial Incentives. The Healthy Lifestyle Program (HeLP) Study. Principal Investigator: Diann Gaalema, PhD, University of Vermont, Burlington, VT (HL 143305)—NHLBI
- Project Title: Enhancing Cardiac Rehabilitation Adherence Through Home-Based Rehabilitation and Behavioral Nudges (ERA Nudge). Principal Investigator: Pamela Peterson, MD, MSPH, Denver Health Medical Center, Denver, CO, and University of Colorado Anschutz Medical Campus, Aurora, CO (HL 143324)—NHLBI
- Project Title: Modified Application of Cardiac Rehabilitation for Older Adults (MACRO). Principal Investigator: Daniel Forman, MD, University of Pittsburgh, Pittsburgh, PA (AG 060499)—NIA
- Project Title: Increasing Adherence to Pulmonary Rehabilitation After COPD-Related Hospitalizations. Principal Investigator: Roberto Benzo, MD, MS, Mayo Clinic, Rochester, MN (HL 142933)—NHLBI
- Project Title: Comprehensive Health Informatics Engagement Framework for Pulmonary Rehabilitation (CHIEF-PR). Principal Investigator: Joseph Finkelstein, MD, PhD, Icahn School of Medicine at Mount Sinai, New York, NY—NHLBI

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