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Update on RFA Increasing Use of Cardiac and Pulmonary Rehabilitation in Traditional and Community Settings NIH-Funded Trials

ADDRESSING CLINICAL TRIAL CHALLENGES PRESENTED BY THE COVID-19 PANDEMIC

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We previously reported on an initiative to increase the uptake of cardiac rehabilitation (CR) and pulmonary rehabilitation (PR) in traditional and community settings funded by the National Heart, Lung, and Blood Institute (and the National Institute on Aging [NIA]).¹ The overall objectives of the initiative and those reflected in the funded research projects are to (1) test strategies that will lead to increased use of CR and PR in the US population who are eligible based on current 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 administered by traditional center-based or new models, is accompanied by improvements in relevant clinical and patient-centered outcomes. The NIA funding opportunity announcement addressed one or more specific age-related factors.

At the time of our previous report, the six funded projects (four CR and two PR) had successfully met milestones for the initial grant year and had transitioned into the second year, most having begun participant recruitment. At the initial investigator meeting in October 2019, principal investigators from all six trials presented their progress and exchanged valuable feedback. Summaries of the respective research projects published in 2020 highlight the features of the research studies.¹ The October 2020 investigator meeting focused on the effects of the novel coronavirus (COVID-19) pandemic on the projects, trial adaptations

to address related challenges, lessons learned, and potential paths forward.

On March 11, 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic.² Most hospitals and clinics suspended nonemergent procedures, surgical procedures, and appointments, including center-based CR and PR sessions. Other overarching factors affected the conduct and progression of clinical research, including fear of contracting COVID-19 among potential study participants and researchers, stay-at-home orders issued by local governments, and the need for clinician researchers to shift their responsibilities solely to the inpatient clinical setting, notably pulmonary and critical care medicine. In most areas of the US, the temporary suspension of in-person clinical services was in place from March to May 2020, with gradual partial reopenings beginning in May.³

At the onset of the pandemic, the National Institutes of Health issued guidance outlining flexibilities for studies impacted by the COVID-19 public health emergency. Grant recipients were encouraged to consult with their institutional review boards and institutions about potential measures to protect participants and research staff. Concurrently, the Centers for Medicare & Medicaid Services expanded access to telehealth visits for Medicare beneficiaries and to many behavioral health and education services delivered via telehealth and audio-only communications.^{3,4}

For this CR/PR initiative, the COVID-19-related shutdowns and suspension of services required the study teams to quickly submit revised protocols to ensure the safety of participants and research staff. Sites modified interventions, assessments, and data collection to minimize direct participant contact (Table). Psozka and colleagues⁵ discuss these types of changes in end point collection, functional and exercise measures, and statistical analysis in expert consensus recommendations for clinical trials in the COVID-19 age. The specific approaches taken to address the COVID-19-related challenges for each funded trial are summarized next.

PROJECT UPDATES

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

The primary aim of the iATTEND trial is to assess the efficacy of hybrid CR (HYCR) on attendance. The primary hypothesis is that patients randomized to HYCR will

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The contents of this article are solely the responsibility of the authors and do not necessarily represent official views of the National Heart, Lung, and Blood Institute, the National Institute on Aging, the National Institutes of Health, or the United States Department of Health and Human Services.

The authors declare no conflicts of interest.

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Table

COVID-19-Related Study Changes in This CR/PR Collaborative Initiative

CR/PR Project	Primary End Point(s)	Secondary End Point(s)	Statistical Analysis Plan	Recruitment Status at Time of Suspension of Services	Protocol	Other
iATTEND	Number of sessions attended, percentage of patients completing 36 visits (hybrid vs traditional). 26 participants affected by suspension	Included data from the 26 patients affected by trial suspension	For primary end point, DSMB considering how to include data from the 26 participants impacted by trial suspension	78 patients enrolled, with 26 participants actively participating in CR randomized before suspension. No recruitment mid-March to mid-May. Enrollment resumed in June	Revised during suspension. In-person sessions temporarily changed to synchronized telehealth visits and phone calls.	CR hybrid-program telehealth model enhanced from a one-on-one patient-to-staff encounter to a WebEx platform, allowing for simultaneous virtual engagement of three to five patients during a 45-min period
HeLP	Attendance at CR. Data collected for remote sessions during suspension		No change anticipated	65 participants recruited and 15 still participating in CR. No recruitment between March 16, 2020, and June 7, 2020	In-person interventions changed to remote (phone, e-mail, postal mail)	Anticipate need for 4-mo extension
ERA Nudge	Participation in CR. Will count logging exercise into app and phone calls as participation during suspension	Exercise capacity originally assessed by METs on treadmill. Changed to 6MWT	No change anticipated	112 patients enrolled, 21 were active in center-based program and 10 active in home-based program March to May.	Center-based CR changed to fully remote March to May. Some outdoor in-person sessions began in May.	Added messaging for all patients regarding precautions for COVID-19. During inclement weather, limited use of gym for in-person sessions.
MACRO	Changed from SPPB that requires direct supervision to self-reported AM-PAC-CAT Basic Mobility Domain	Accelerometry elevated into a more prioritized end point and integrated with the AM-PAC-CAT as a complementary performance measure	No change anticipated	43 enrolled prior to suspension. Stopped by the DSMB on March 16, 2020, and resumed (with protocol changes approved by the IRB) on September 21, 2020	Significantly revised to facilitate remote processes. Changes approved on July 10, 2020. Sample size reduced from 480 to 374.	Overall shift from site-vs-home-based CR to home- and hybrid-based models.
Increasing Adherence to PR After COPD-Related Hospitalizations	Percentage of patients that initiate and complete PR after a COPD-related hospitalization—unchanged	Patient choice of home-based vs on-site PR—unchanged	Original intent-to-treat analyses retained. Two secondary analyses added.	Recruitment deferred during suspension. Sample size increased to 240 (from 150) as it is now noninferiority study.	Revised to have no contact enrollment	The study transitioned to allow the individuals referred to the PR center to have the choice of either on-site PR or telehealth home-based PR program.
CHIEF-PR	Completion rate of PR after acute COPD exacerbation—unchanged	To assess exercise capacity at patient homes, 6MWT replaced by 1-min sit-to-stand test. Surveys and questionnaires collected remotely using NIH Toolbox for PROs.	No change anticipated	Recruitment postponed until mid-June; no participants affected by suspension. Increased enrollment rates after June—currently on track	Revised to Online Patient Enrollment Network	The study transitioned to a remote assessment of exercise capacity at patient homes.

Abbreviations: AM-PAC-CAT, Activity Measure for Post-Acute Care with Computerized Adaptive Testing; COPD, chronic obstructive pulmonary disease; CR, cardiac rehabilitation; DSMB, Data and Safety Monitoring Board; IRB, institutional review board; MET, metabolic equivalent; NIH, National Institutes of Health; PR, pulmonary rehabilitation; PRO, patient-reported outcome; 6MWT, 6-min walk test; SPPB, Short Physical Performance Battery.

complete significantly more CR sessions than patients randomized to clinic-based CR alone. Secondary aims are to assess the effect of HYCR on exercise capacity and quality of life. In mid-March 2020, all outpatient clinical and research activities were suspended at Henry Ford Hospital. This policy impacted 26 patients actively engaged in either the standard CR (S-CR) or hybrid CR (combined clinic- and home-based using video synchronized telehealth) arms of the trial. Regardless of study group assignment, for these 26 patients, the number of CR sessions attended at the time CR operations were suspended was used as their total number of sessions completed for the trial (Table). The COVID-19-related suspension directly impacted assessment of the primary trial end points, and the Data and Safety Monitoring Board (DSMB) is evaluating how to include the data from these 26 patients in the statistical analysis. For example, one trial whose primary end point was impacted by COVID-19 excluded all affected participant-related data from their primary analysis but included such data in secondary analyses.⁶ In June 2020, new patient enrollment resumed using COVID-19-specific procedures (eg, wearing a mask during CR, individual vs group education).

Due to COVID-19, the findings from iATTEND take on increasing importance because the trial evaluates the delivery of CR outside the facility-based setting.⁷ Additionally, because of COVID-19, health systems are now better prepared to assist CR programs by adding telehealth-based HYCR programs to their services. To leverage these system-level advances within Henry Ford Health System, in February 2021, the CR hybrid program switched its telehealth model from a one-on-one patient-to-staff encounter^{8,9} to a WebEx platform (Cisco) that allows simultaneous and virtual engagement of three to five patients in a real-time manner during a 45-min period, with the goal of at least 30 min of supervised exercise for each person. The autumn 2020 surge in COVID cases in Michigan did not necessitate appreciable alterations in trial operations.

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).

The goal of the HeLP trial is to test the impact of two interventions: case management and incentives on participation in CR among Medicaid enrollees of low socioeconomic status.^{1,10} On March 16, 2020, trial recruitment was suspended, and the CR facility ceased normal operations due to the COVID-19 outbreak. At this time point, the study had recruited 65 participants, of whom 15 were still participating in CR.

The CR program transitioned from in-person visits to weekly telehealth phone calls for currently enrolled patients. Accordingly, the study pivoted to encouraging remote attendance. To maintain a consistent target of encouraging or incentivizing 2-3 visits/wk, at-home exercise sessions were included. For each of these sessions, CR staff set a patient-specific step goal, and objective measures of step counts were obtained with pedometers (Omron).^{11,12} Study interventions switched to completely remote delivery, with case management conducted by phone and incentives delivered by email or mail, to encourage participation in weekly telehealth visits and complete step goals. The trial continued to operate fully remotely for 8 wk before the CR program began a phased reopening in May. While COVID-19 surges have occurred in late 2020 to early 2021, infection rates have remained low in Vermont, and the clinic has not been required to reduce operations.

The main outcome for this trial is attendance at CR. As the team was able to continue data collection and CR sessions remotely, investigators anticipate using data from this time and do not foresee a need for changes to the statistical plan. However, to account for the cessation of recruitment for 11 wk due to research restrictions, they may need to extend trial recruitment by 4 mo.

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 goal of ERA Nudge is to increase adherence to and completion of CR in a diverse, low socioeconomic status population. The study is testing the choice of home versus hospital-based rehabilitation and behavioral nudge messages.^{13,14} All patients receive an application (app) on their smartphone that allows them to access information, chat with staff, and receive educational information.^{15,16} On March 13, 2020, all in-person research activities were suspended due to COVID-19, and the in-person clinical CR program was closed. At that time, 112 patients had been enrolled, 21 were active in the center-based program, and 10 were active in the home-based program.

In response to this situation, the team moved to a fully remote program, with patients who were enrolled in center-based CR receiving phone calls on the days of their previously scheduled classes. Participants received teaching and exercise coaching. Those who were enrolled in the home-based program continued to receive one phone call/wk as per the protocol. The collection of survey data was by phone, and assessment of exercise capacity was delayed. The team continued to deliver nudge messaging with added messages for all participants regarding precautions for COVID-19. For example, the messages encouraged them to use mail pharmacies, prescription delivery, or have friends or family members pick up medication refills to avoid exposure to COVID-19. Recruitment was suspended for approximately 6 wk. In early May, the investigators were able to reopen center-based classes and resume enrollment, with approval from the hospital to hold classes in the park next to the hospital, with an option for indoor sessions with two to three participants/class on inclement weather days. This outdoor model was developed based on experience in Toronto.¹⁷

The primary outcome of the trial remains CR participation. When no in-person visits were allowed, participation was counted as logging exercise into the app and participating in phone calls. No changes are anticipated in the statistical analysis. Exercise capacity is a secondary outcome, which was originally assessed as metabolic equivalents (METs) on the treadmill but switched to 6-min walk test (6MWT) due to COVID-19 (Table).

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

Modified Application of Cardiac Rehabilitation for Older Adults (MACRO) is a randomized controlled multisite trial in which precepts of cardiology and geriatrics are merged. A coaching intervention is employed by MACRO that aims to increase function in older adults hospitalized with cardiac disease by increasing their participation in CR. The MACRO coaches use behavioral prompts to better motivate patient interests in CR programs and facilitate options for site-based, home-based, and hybrid (site-based transitioning to home-based) formats of CR to best match

circumstances and preferences for each patient. The pre-COVID-19 MACRO protocol relied heavily on face-to-face assessments. The pre-COVID-19 primary end point was the Short Physical Performance Battery,¹⁸ a performance measure of gait, balance, and strength that requires direct supervision to maintain safety and fidelity.

When the COVID-19 pandemic was declared, the trial was suspended by the DSMB, as the direct engagements required by the protocol were no longer feasible. The 43 pre-COVID-19 enrollees were released from the trial and their data removed from the analysis. The study team had to extensively revise the protocol to achieve practical, sensitive, and safe methods without face-to-face encounters. The primary end point was changed to the Activity Measure for Post-Acute Care with Computerized Adaptive Testing Basic Mobility Domain,¹⁹ a self-reported measure of physical function that can be administered by phone. The sample size was reduced from 480 to 374.

In addition to the Activity Measure for Post-Acute Care with Computerized Adaptive Testing, remotely facilitated accelerometry was prioritized as a complementary performance measure.²⁰ Despite these significant changes, great efforts were made to preserve the original primary goal (ie, improving functional capacity by facilitating CR).

The MACRO study was initially designed to study trade-offs between site-based and home-based CR. However, as a pragmatic trial, it has shifted focus since the pandemic to home-based and hybrid CR models because these have become more common options of care. As a pragmatic trial, MACRO will be able to track the utility of these novel approaches to CR, which may better serve older, complex, and/or frail patients who could not easily attend site-based programs even before COVID was a concern.

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

The goal of this clinical trial is to compare adherence to PR after referral to either a centralized home-based PR program²¹ or a center-based program that offers on-site PR after a chronic obstructive pulmonary disease (COPD)-related hospitalization. Centralized home-based PR involves delivery of all home PR program materials virtually and/or remotely. The center can take referrals from any provider, and provide home PR to any patient in the country, facilitating use by small hospitals, rural hospitals, or hospitals with low resources to deliver home PR. The randomized trial was slated to start in March 2020, but was delayed because of the COVID-19 pandemic.

In response to the COVID-19 public health emergency, the Centers for Medicare and Medicaid Services added PR services to the Medicare telehealth reimbursement list. Due to this change, PR centers can now offer telehealth PR. Thus, the study transitioned to allow the individuals referred to the PR center to choose either on-site PR or the telehealth home-based PR program. The changes made in the context of a public health emergency will provide the study with generalizable and practical results while respecting the original goals as funded:

1. The investigators will still learn the percentage of patients who initiate and complete PR after a COPD-related hospitalization to compare to the current dismal <2% PR initiation in the same setting²² found in a large study of Medicare beneficiaries.
2. The team will learn about patient choice of home-based versus on-site PR after a COPD hospitalization.

The primary outcome of this study, completion of the 3-mo PR program, will continue to be based on intention-to-treat analysis, wherein comparisons will be made between the two randomization groups: referral to centralized home-based PR versus referral to a PR center. Because of the COVID-19-related changes, two secondary analyses also will be performed: a per-protocol analysis combining participants in the centralized home-based PR arm with those in the PR center arm that chose home-based telehealth versus hospital-based PR, and an analysis comparing three participant arms: those randomized to home-based PR, those randomized to hospital PR who chose home-based telehealth PR, and those randomized to hospital PR who chose on-site PR. The sample size will increase from 150 to 240 patients, and the design will change to a noninferiority study.

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).

The Comprehensive Health Informatics Engagement Framework for Pulmonary Rehabilitation (CHIEF-PR) aims to facilitate PR referrals, initial assessments, completion rates, and maintenance using an innovative multipronged approach. The goal of this trial is to demonstrate that the CHIEF-PR is effective in increasing the use of PR in patients after an acute exacerbation of COPD, and improving clinical and patient-reported outcomes as compared with routine clinical care. The CHIEF-PR is a multipronged integrated trial, which addresses barriers for PR uptake and completion using integrated multilevel information technology solutions at the health care, provider, and patient levels. Recruitment into the clinical trial was supposed to commence in March 2020 but was postponed until mid-June due to the COVID-19 pandemic. Thus, the study participants were not affected by the clinical trial shutdown.

During the trial shutdown, the investigators refined their enrollment and follow-up procedures to ensure sufficient social distancing and participant protection from COVID-19 risks. Initial patient contact is now carried out by hospital staff providing interested patients with access to an electronic consenting platform via their smartphone or tablet.²³ The entire study is conducted at participant homes after discharge from a hospital. An individualized exercise program is prescribed after remote assessment of exercise capacity using a validated telehealth system.²⁴ To assess exercise capacity at participant homes, the team replaced the 6MWT with a 1-min sit-to-stand test, which was previously demonstrated to be a reliable alternative to the 6MWT.²⁵ As originally planned, participants in the intervention group follow their exercise plan daily using a home-based telerehabilitation system. In comparison, those in the control group receive only printed materials provided after the initial assessment. Physical activity assessment was planned using Fitbit devices. However, the team found that Fitbit accuracy depended on pace and sensor location,²⁶ which may bias estimates in older adults. Additionally, the number of steps may be affected by social isolation during a lockdown. These considerations resulted in using the Physical Functioning Scale of the Short-Form 36, whose internal consistency and validity in older adults have been well established²⁷ (Table).

The sample size and primary outcome of the CHIEF-PR trial, and the completion rate of PR after acute COPD exacerbation, have not changed. The team has increased patient enrollment rates to address the initial delay in the trial

commencement, and the current CHIEF-PR accrual to date has reached initially planned milestones.

SUMMARY AND FUTURE DIRECTIONS

The overall objectives of this CR/PR initiative include using new models to increase the uptake of CR/PR in both traditional and community settings. Thus, several of the research projects already employed virtual and/or remote components as part of their original protocols before the COVID-19 pandemic. With the onset of this public health emergency, a rapid shift to new and more extensive uses of telehealth, remote monitoring and assessment, and virtual oversight/supervision approaches were initiated to ensure patient and research staff safety and maintain study integrity to the extent possible (Table). Central to the investigator ability to address trial shutdown challenges was ongoing supportive guidance by the National Institutes of Health staff.

The research questions addressed by these projects have become more critical in light of the pandemic. It is crucial to understand whether safe, effective, and efficient CR/PR programs can be delivered remotely and/or virtually in home-based and hybrid settings. In a post-COVID world, hospitals and clinics may add or enhance remote and/or virtual components to their CR/PR programs to establish safe, effective hybrid programs. Overall, the research projects underwent numerous adaptations and revisions to address the considerable challenges posed by COVID-19. Despite these challenges, the trials may provide even more valuable, generalizable, and practical results in a post-COVID-19 world in which innovative approaches are likely to remain at the forefront of CR/PR delivery. Study adaptations, including early contingency planning and risk management protocols, are needed for the future to address potential public health emergencies, natural disasters, travel or communication disruptions, policy changes, and social and demographic factors in target populations.

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