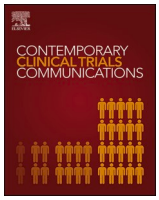
Contemporary Clinical Trials Communications 33 (2023) 101147

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc



Stepped care versus center-based cardiopulmonary rehabilitation for older frail adults living in rural MA: Design of a feasibility randomized controlled trial

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A B S T R A C T

Background: Cardiac and pulmonary rehabilitation programs are grossly underutilized, and participation is particularly low in rural regions.
Methods: We are conducting a 2-arm, randomized controlled feasibility trial. Eligible participants include older frail adults with cardiac or pulmonary disease living in a predominantly rural county in western Massachusetts. Participants are randomized 1:1 to treatment as usual or stepped care. Patients randomized to treatment as usual participate in twice weekly center-based rehabilitation sessions over eight weeks and are encouraged to exercise at home in between sessions. Patients randomized to the stepped-care arm are offered/enrolled in the center-based rehabilitation program followed by possible step up to three interventions based on prespecified non-response criteria: 1) Transportation-assisted center-based rehabilitation, 2) Home-based telerehabilitation, and 3) Community health worker-supported home-based telerehabilitation. The primary feasibility outcomes are average number of eligible patients randomized per month, baseline measure completion, proportion attending at least 70% of the prescribed sessions, average number of sessions attended in the stepped-care arm, and proportion in the stepped-care arm completing patient reported outcome measures. Each of these process indicators is evaluated by preset "Stop" and "Go" thresholds.
Conclusion: The proposed stepped-care model is an efficient, patient-centered, approach to expanding access to cardiac and pulmonary rehabilitation. Meeting the "Go" thresholds for the prespecified process indicators will justify conducting a definitive full-scale randomized controlled trial to compare the effectiveness and value (cost-effectiveness) of stepped-care versus center-based rehabilitation in older frail adults living rural counties.

Cardiac and pulmonary rehabilitation (PR) are multicomponent customized programs comprising education, emotional support, and exercise. Consistent high-quality evidence has demonstrated that patients participating in cardiac rehabilitation (CR) and PR experience significant benefits including improved exercise capacity, physical function, mental health and quality of life compared to no exercise controls [1–3]. Some studies have also shown a positive impact of CR and PR on readmission rates and mortality [1,2,4].

Although considered standard of care, the benefits of CR and PR are not realized in the U.S. because both are exceedingly underutilized. Survey data indicate that approximately 20%, and less than 5%, of eligible patients participate in CR [5,6] and PR [7–9], respectively. Several barriers to uptake and/or completion of CR and PR have been repeatedly identified. Distance to the rehabilitation center, inadequate transportation, and low perceived benefit influence both initial uptake and completion [10–13]. Lack of support from referring clinicians, anticipated disruption to usual routine, and restricted program hours decrease enrollment rates; while smoking, depression, symptom burden, and comorbidities decrease completion rates [10–12]. Low self-efficacy, fear that exercise will exacerbate symptoms, lack of experience exercising and/or general dislike of exercise may also decrease willingness to participate [11,12]. These barriers are particularly problematic for isolated older adults living in rural regions where lack of transportation is a critical barrier to access.

Despite extremely low rates of utilization, there is little to no evidence supporting specific strategies to optimize implementation of CR or PR in older adults living in rural regions. In this paper, we describe the design and rationale of a feasibility randomized controlled trial (RCT) designed to examine the potential value of a stepped care model to increase uptake and adherence to CR and PR in older adults living in rural regions, a significantly understudied population in which the uptake of both CR and PR is very low [7,8].

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https://doi.org/10.1016/j.conctc.2023.101147
Received 11 January 2023; Received in revised form 13 April 2023; Accepted 21 April 2023
Available online 23 April 2023

This feasibility trial will focus on older adults with levels of frailty enabling safe participation in a home-based rehabilitation program, namely persons who are vulnerable, mildly or moderately frail. In this context, frailty refers to a geriatric syndrome characterized by age-associated decreases in physiologic reserve and physical function. It is an independent risk factor for disability and all-cause mortality [14]. Frailty exists on a spectrum ranging from robust to terminally ill and can be measured using rapid screening tools. A scoping review of the literature supports implementing rehabilitation programs in this population [15]. CR and PR may have added benefits in frail older adults, such as reduction in sarcopenia and falls [16]. Additionally, because hospitalizations accelerate functional decline and increase the risk of institutionalization [17,18], the potential impact of CR and PR on reducing admissions and readmissions is particularly important in this population.

1. Rationale for stepped-care model

Stepped-care is a model in which care is tailored to patient needs. In this context, patients begin with the least resource intensive treatment. Those failing to respond advance to more resource intensive treatment options; thus, stepped-care enables a patient-centered approach by matching how care is delivered with individual patient needs. This model is particularly appealing to rural hospital systems with limited resources because it prevents over-servicing for those with lower levels of need and under-servicing for people with higher levels of need. In this study, patients randomized to stepped-care are enrolled in traditional center-based rehabilitation and based on prespecified non-response criteria, step up to three services: 1) Transportation-assisted center-based rehabilitation, 2) Home-based telerehabilitation, and 3) Community health worker (CHW) supported home-based telerehabilitation (Fig. 1). Unlike traditional stepped-care models, the initial treatment in this model, i.e., center-based rehabilitation, is not the least resource intensive. Center-based rehabilitation was chosen as the initial therapy because it is currently considered the standard of care.

2. Study aim

The objective of this study is to assess the feasibility of conducting a full-scale RCT to examine whether stepped-care improves adherence to CR and PR in older frail adults living in rural regions. We will randomize 120 participants to stepped-care or treatment as usual (treatment as usual). We hypothesize that the feasibility trial will meet prespecified process criteria justifying a full-scale RCT. The study has been registered at clinicaltrials.gov NCT05562037. The Berkshire Medical Center Institutional Review Board study approval number is 2022–003.

2.1. Setting

We are recruiting patients living in Berkshire County, the second most rural county in Massachusetts. There are few public transportation options available in this region, and travel is further hampered by several months of hazardous winter driving conditions. Compared to the state average, residents in Berkshire County are older, have a lower median household income, and rates of tobacco use are more than twice the state average [19]. Health outcomes (life expectance and quality of life) are among the lowest in the state [19].

2.2. Eligibility

Adults 60 years of age or older living in a rural area who have a condition qualifying for reimbursement (by government or private insurance) for CR or PR and have a score between 4 and 6 on the telephone version of the Clinical Frailty Scale [20,21] (corresponding to vulnerable, mildly frail, and moderately frail) are eligible to participate. Exclusion criteria include patients who qualify for CR because of cardiac bypass or valve replacement surgery (as they have much better uptake and adherence rates that those with non-surgical indications) as well as conditions which would preclude safe participation in home- or center-based CR or PR (see Table 1). Additional exclusion criteria

Table 1
Eligibility criteria.

Inclusion Criteria
Older adults (greater than 65 years of age)
Condition qualifying for reimbursement (by government or private insurance) for cardiac or pulmonary rehabilitation
Score of 4, 5 or 6 on the Clinical Frailty Scale (corresponding to vulnerable, mildly frail, and moderately frail)
Exclusion Criteria
Resting pulse oximetry <85% on room air or while breathing the prescribed level of supplemental oxygen
Unstable asthma with hospital admission or emergency department visit within previous three months
Severe exercise-induced hypoxemia, not correctable with oxygen supplementation
Acute systemic illness or fever
Complex ventricular arrhythmias
Resting systolic blood pressure greater than 200 mmhg
Resting diastolic blood pressure greater than 100 mmhg
Orthostatic blood pressure drop of >20 mm Hg with symptoms
History of arrhythmia with syncope severe symptomatic valvular disease unstable angina
Uncontrolled atrial or ventricular arrhythmias
Uncontrolled sinus tachycardia (>120 beats per minute)
Uncompensated congestive heart failure
Third degree heart block without a pacemaker
Active pericarditis or myocarditis
Acute cor pulmonale
Severe pulmonary hypertension
Resting ST displacement > 2 mm
Uncontrolled diabetes (blood glucose >400 mg/dl)
Conditions other than pulmonary or cardiac that prohibit exercise
Planned surgery or transplantation

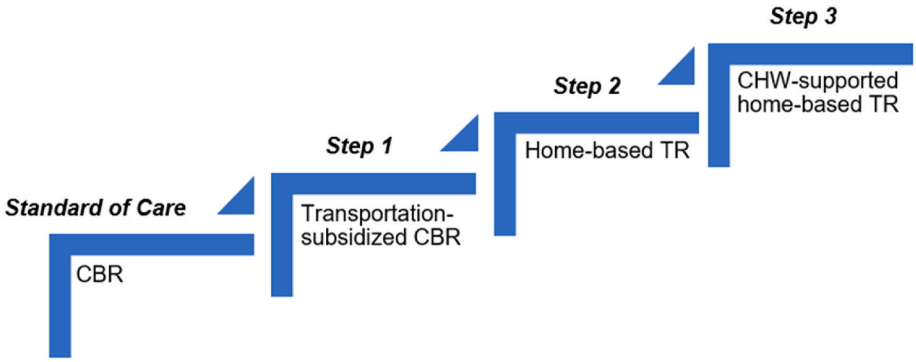

Fig. 1. Stepped care.

include hearing impairment limiting ability to participate in data collection by telephone, life expectancy less than one year as well as significant cognitive deficit and/or psychiatric illness that interferes with ability to provide consent, follow directions, or adhere to study procedures.

2.3. Recruitment and enrollment

The study population for the proposed feasibility study is drawn from referrals to PR and CR, patients identified by the pulmonary function laboratory with chronic obstructive pulmonary disease GOLD Stage 2–4, and those with ICD-10 codes for coronary artery disease and congestive heart failure.

A research assistant performs a targeted chart review to determine initial eligibility, and subsequently mails a letter to those meeting initial eligibility criteria informing them of the purpose of the study. The letter notifies potential subjects that they will be telephoned by an research assistant and offers them the opportunity to refuse this contact by calling an answering machine and leaving a message. The research assistant telephones all patients who do not "opt out." The research assistant obtains initial verbal consent and uses the telephone version of the Clinical Frailty Scale to determine eligibility for those interested in participating. Eligible patients are then enrolled. The research assistant collects baseline data, retrieves the randomization code from REDCap, and subsequently randomizes patients. Written consent is obtained for patients who attend an initial intake evaluation. In the unlikely event that a patient is referred to both CR and PR, the patient's primary care doctor is contacted to determine which should take priority.

2.4. Randomization

Patients are randomly allocated to treatment as usual or stepped-care using a 1:1 ratio. The randomization scheme was generated to create 12 random permuted blocks of size 4, 9 blocks of size 6, and 7 blocks of size 8 by an independent data programmer who is not otherwise participating in recruitment, data collection or data analyses. The assignment of treatment is automatically generated through REDCap made once baseline demographic, clinical, and patient reported outcome measures have been collected.

2.5. Study interventions

2.5.1. Treatment as usual

Patients participate in either center-based CR or PR. Both programs include an initial intake session. The purpose of this initial session is to obtain the data required to design an individualized effective and safe rehabilitation program. It is performed by a certified rehabilitation nurse or therapist and includes a medical history, physical examination, and baseline testing. Exercise capacity is measured in metabolic equivalents using a standardized formula for the 6-min walk test.

Once the intake evaluation is complete, a rehabilitation nurse or therapist develops an individualized treatment plan with each participant. Treatment plans include tailored education, nutritional guidance, smoking cessation counseling, risk-factor counseling (diabetes/hyperlipemia/hypertension) as appropriate, self-management skills, and emotional support. All CR and PR plans include exercise. Patients are asked to exercise to a level associated with moderate dyspnea using the modified Borg scale (rate of perceived exertion = 3) [22] and are monitored to ensure oxygen saturation levels remain above 90%. Strength training exercises are designed to achieve intensities of 70% or greater of 1 repetition maximum [23]. Breathing training (pursed lip breathing and diaphragmatic respiration) is provided for participants with chronic obstructive pulmonary disease. Patients attend two sessions per week over eight weeks and are encouraged to exercise between sessions. Upon completion of the 8-week program, patients are reevaluated to measure and document progress.

2.5.2. Stepped care

Participants randomized to the stepped-care arm are offered center-based CR or PR and subsequently stepped up to transportation-assisted center-based CR or PR, home-based CR or PR, and CHW-supported home-based telerehabilitation (CR or PR) based on prespecified non-response criteria. Non-response criteria cover refusal to enroll as well as, lack of, or poor adherence. The specific non-response criteria are.

1 Refuse the rehabilitation option offered.
2 Agree to enroll in the rehabilitation option offered, but do not show up for, or reschedule, the initial intake evaluation visit within two weeks.
3 Participate, but subsequently decline to continue participation.
4 Participate, but attend less than one session per week for two consecutive weeks.

Initial care. Patients are initially enrolled in center-based rehabilitation. Those meeting a non-response criterion are stepped up to transportation-assisted center-based rehabilitation.

Step 1. Transportation-Assisted Center-Based Rehabilitation.Transportation is provided, free of cost to the participant, to and from the initial intake evaluation, biweekly sessions, and formal reassessment.

Step 2. Home-Based Telerehabilitation.Patients participate in an 8-week home-based telerehabilitation program supported by Chanl Health. Chanl Health includes a mobile app for patients, a web dashboard for care managers to setup, view, and manage patient care, a hosted server and database system to store and manage data, integration with hospital electronic health records and with 3rd party monitoring devices. The platform also supports video calls to enable synchronous exercise monitoring. Once a personalized care plan is configured for the patient through the dashboard, the app converts each patient's care plan into an easy-to-follow set of daily tasks, provides reminders and tracks medication adherence, exercise sessions, clinical assessments, and completion of assigned education materials/modules.

Step 3. CHW-Supported Home-Based Telerehabilitation.The CHW-supported home-based telerehabilitation program supplements the home-based telerehabilitation program with biweekly in-person visits by a trained CHW. The CHW helps participants use the mobile app, participate in the video sessions, access educational materials, clarify educational content, and exercise.

2.6. Fidelity

In accordance with the NIH's Behavioral Change Consortium [24], we include strategies at the level of the study protocol, training, treatment delivery and receipt to enhance fidelity [25–27]. We have hired a CHW with the required skills, and have provided her with additional training in CR and PR. We will prevent skill drift via interim skill re-assessment at monthly intervals to ensure training fidelity. In addition, the CHW is supervised by a certified rehabilitation therapist throughout the intervention. We will use audiotaping to monitor fidelity of the CHW support component of the program. The CHW will audiotape all sessions (to prevent systematic changes in behavior related to selective recording); however, only a subset will be reviewed. A rehabilitation therapist will review the first two sessions using a standardized checklist and provide the CHW with feedback. The rehabilitation therapist will subsequently review a random sample of at least two sessions every two weeks using the same checklist and continue to provide the CHW with regular feedback.

3. Data collection

Data collection procedures are described in Table 2. Baseline data are collected by telephone prior to randomization. We will attempt to

Table 2
Data collection measures.

Timing	Week prior to intake evaluation	Intake evaluation	Formal Reassessment	Week following completion of program
Setting	Telephone	Rehabilitation Center	Rehabilitation Center	Telephone
Personnel	Unblinded Research Assistant	Rehabilitation Nurse or Therapist	Rehabilitation Nurse or Therapist	Research Assistant
Baseline Variables				
Demographic characteristics	X			
Clinical characteristics	X	X	X	
Lifestyle factors	X	X	X	
Outcome Measures				
Feasibility Outcomes				
Quantitative feasibility	Throughout Trial			
Qualitative feasibility				X*
Clinical outcomes				
PROMIS patient reported outcome measures	X			X
Euroqol-5D-5L	X			X
Cigarettes/day	X			X
Physical activity	X			X
6-min walk		X	X	
Physical function + mobility		X	X	
Adverse events		Throughout Intervention Period		
Emergency department visits, hospital admissions and readmissions		Throughout Intervention Period		
Costs		Throughout Intervention Period		

perform an exit interview and measure outcomes for patients withdrawing from the study prior to completing the formal reassessment. Patient reported outcomes are collected by telephone by a blinded research assistant who is not otherwise participating in the study.

3.1. Baseline variables

3.1.1. Demographic and clinical characteristics

The research assistant records age, sex, ethnicity, maximum level of education, employment status, living arrangements (living with a spouse, another person, or alone), ownership of a car and driving status, social support, and use of home services. Social support is measured using the PROMIS Instrumental Support – Short Form 8a [28]. Travel distance to the rehabilitation center is obtained via Google maps. The area deprivation index, a measure of socioeconomic status disadvantage is calculated using the Neighborhood Atlas mapping function created by the University of Wisconsin [29,30]. The research assistant also records clinical characteristics (medications, comorbidities), and lifestyle factors (cigarette and alcohol use).

3.2. Outcome measures

3.2.1. Feasibility outcomes

Feasibility to conduct a full-scale randomized efficacy trial is the primary outcome of this study and will be assessed using a mixed-methods approach.

3.3. Quantitative feasibility data

The primary feasibility outcomes reflect those most likely to impact the success of a large scale RCT (Table 3). For each criterion, a 'Stop' and 'Go' threshold is specified. A Stop threshold indicates that the outcome was not met and argues against proceeding with the planned full-scale RCT. Meeting the Go threshold signifies that the feasibility outcome was met and supports proceeding to the full-scale RCT. Results falling between the Stop and Go thresholds indicate that the relevant trial procedure(s) should be modified (e.g., reducing the number of outcome measures, modifying eligibility criteria) prior to proceeding to the full-scale trial [31]. We will conclude that a full-scale RCT is not feasible if one or more process criteria meet the Stop threshold. The 95% Confidence Intervals (CI) around each point estimate assume a sample size of 120.

Table 3
Process indicators and criteria.

Outcome	Process Indicators	Threshold	Process Criteria	Point Estimate (95% CI)
Recruitment	Average number of eligible patients randomized per month	**Stop**	Less than 2	2 (0.73, 3.27)
		Go	More than 5	5 (3.73, 6.27)
Burden of data collection	Baseline measure completion	**Stop**	Less than 60%	0.60 (0.51, 0.69)
		Go	More than 80%	0.80 (0.72, 0.87)
Adherence	Proportion attending at least 70% of prescribed sessions in SC arm	**Stop**	Less than 25%	0.25 (0.17, 0.33)
		Go	More than 45%	0.45 (0.36, 0.54)
Adherence	Average number of sessions attended in SC arm	**Stop**	Less than 6	6 (4.73, 7.27)
		Go	More than 11	11 (9.73, 3.27)
Retention	Proportion in SC arm completing patient reported outcome measures	**Stop**	Less than 25%	0.25 (0.15, 0.38)
		Go	More than 70%	0.70 (0.61, 0.78)

Secondary feasibility outcomes include the proportion of patients approached meeting eligibility criteria (i.e., number needed to screen), the proportion of patients meeting prespecified non-response criteria at each Step, the proportion agreeing to advance to each Step, and the average number of days spent at each Step. We will monitor the number of sessions cancelled by either the patient, hospital personnel, or and/or CHW and all protocol deviations. These data may lead to revisions in the protocol by identifying opportunities to increase recruitment, retention, and/or adherence.

3.4. Qualitative feasibility data

The research assistant will attempt to conduct semi-structured telephone interviews with all participants meeting prespecified non-response criteria at each Step. In addition, we will perform exit

interviews with a random sample of 15 participants completing the stepped-care intervention. Telephone interviews will be audiotaped (after obtaining consent) using TapeACall Pro and subsequently transcribed using a 3rd party HIPAA compliant service. We use a standardized interview guide including both open-ended questions and prompts to elicit participants' views and experiences with all aspects of the intervention including personnel, components of the rehabilitation program, and data collection procedures. The interviews will prompt participants to describe their likes and dislikes about the stepped-care program, and when relevant, reasons for non-adherence. Whenever possible, we will perform exit interviews with participants dropping out of the trial. The research assistant will also interview the CHW to determine the factors that facilitated or impeded the delivery of the intervention and to identify procedures in the protocol which could be improved upon for the full-scale trial. Lastly, the research assistant will use a similar approach to ascertain feedback from the rehabilitation center staff.

3.5. Clinical outcomes

Though not powered to detect significant changes across the two groups, we measure outcomes for the planned full-scale RCT to assess responsiveness to change, floor or ceiling effects, variability, and participant burden. These data will inform the parameters needed for a realistic sample size calculation for the full-scale RCT. Adherence is the planned primary outcome for the full-scale trial as the benefits of CR and PR cannot be realized without improving adherence. The average number of sessions attended and the proportion of patients completing the final reassessment will be reported as secondary outcomes.

Because we are including patients with both cardiac and pulmonary disease, outcome measures must be relevant to both conditions. We use the NIH PROMIS computer adaptive tests to assess dyspnea severity, dyspnea functional limitation, physical function, social isolation, anxiety, and depression/sadness [28]. Physical activity is measured using the Physical Activity Scale for the Elderly [32]. Health-related quality of life is measured using the EuroQol-5D-5L [33]. EuroQol-5D-5L scores will be used to calculate utilities for the cost-effectiveness analyses planned for the full-scale trial. Smoking is assessed by self-report (number of cigarettes smoked per day). Functional exercise capacity is measured using the 6-min walk test [34,35]. Physical function and mobility are measured using the Short Physical Performance Battery [36,37].

Emergency department visits, hospital admissions and readmissions are measured by querying the electronic health record. We capture medical costs through the cost accounting system used by the hospital. We include costs related to emergency department visits, hospital admissions and readmissions, outpatient visits (primary care, pulmonary and cardiology), medication, laboratory and imaging costs. For program costs, we will monitor subscription, data plan, equipment, patient transportation, and labor (including training, salary, and mileage reimbursement) costs. Indirect and research costs will not be considered.

4. Adverse events

Adverse events are recorded by a rehabilitation therapist, research assistant or CHW weekly and, when applicable, verified by electronic health record review. We classify adverse events by organ system and grade each for severity using the Common Terminology Criteria For Adverse Events (v.5). Development of a severe or life-threatening adverse event results in early termination. However, all subjects are followed until the end of the study period. All unexpected and serious adverse events are reported to the Human Subjects Committee within 24 h.

4.1. Sample size Justification

This is a feasibility trial, and it is not designed or powered to detect a statistically significant difference in efficacy between the two interventions. A target sample size of 120 (n = 60 in the stepped-care arm) enables us to generate reasonable 95% confidence intervals (CIs) around the pre-specified process criteria (see Table 3). CI calculations for proportions were calculated using a 95% two-sided exact distribution. Using a two-sided 95% CI for a mean with unknown standard deviation (i.e., *t*-test), an estimated standard deviation of 3 and approximately 24 months of enrollment, would generate a margin of error of 1.27.

4.2. Analyses

4.2.1. Quantitative analyses

All analyses will be reported in accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines for feasibility trials [38]. Analyses will be performed by a statistician blinded to group assignment. Given the objectives of this feasibility study, the analyses will be primarily descriptive. No formal interim analyses are planned. The participant flow will be described using the CONSORT flow diagram. We will summarize the distributions of the baseline and outcome measures for each arm of the feasibility trial. We will also summarize completeness of the baseline and outcome assessments and the missing data patterns. Means and standard deviations will be used to describe continuous variables and counts, and percentages will be used for categorical variables. Each adverse event will be counted once per participant. We will report the frequency of each adverse event. We will estimate 95% cis for all measures using exact methods for proportions, t-tests for means, and chi-square tests for variances. Non-parametric tests will be used for variables with skewed distributions. We plan to conduct stratified comparisons for baseline covariates (sex, smoking status, level of frailty, and referral to CR or PR) to 1) determine whether we should stratify the full-scale trial by any of these covariates, and 2) identify which heterogeneity of treatment effect analyses should be incorporated into the statistical plan of future full-scale RCT. All analyses will be conducted in SAS version 9.4 or the latest version of R.

4.3. Qualitative analyses

Qualitative analysis of the transcripts will be focused on identifying themes to improve the design, content, and delivery of both interventions. The analyses of the transcripts will be based on Framework Analysis. This approach is well suited towards qualitative studies focused on answering specific questions over a relatively short time-period. The analyses will proceed over five steps [39,40]: 1) Familiarization: To familiarize themselves with the data and become aware of key ideas, an investigator (LF) and the rehabilitation therapist responsible for monitoring fidelity will each read and reread one third of the transcripts. 2) Identification of a thematic framework: They will meet after having coded four purposefully sampled transcripts separately to discuss how they interpreted the data and their initial set of themes and specific codes. They will continue to code the transcripts in parallel and meet regularly to revise and update the coding scheme as required. 3) Indexing: The final coding scheme will subsequently be applied to the complete set of transcripts by mapping relevant sections to the appropriate code. 4) Charting: Data mapped during the index phase will then be organized into charts by theme and specific codes. 5) Mapping and Interpretation: Lastly, investigators will review the key points described in the charts and record the specific changes recommended to improve the design, content, and delivery of the interventions.

4.3.1. Withdrawals

Participants are free to withdraw from participation in the study at any time upon request. Protocol deviations do not lead to withdrawal unless the participant is no longer appropriate for the study as judged by

the principal investigators based on non-adherence with the requirements for participation or safety concerns. A participant is considered to have withdrawn from the study with a primary reason of lost to follow-up if study staff are unable to contact the participant after three attempts, despite reaching out to designated contacts. The rehabilitation therapist will attempt to contact participants who miss a session, reschedule the missed session within one week, counsel the participant on the importance of maintaining the assigned visit schedule, and ascertain if the participant wishes to and/or should continue in the study. For patients who must temporarily withdraw from the program due to illness, a delay in up to two weeks is permitted. Patients who are not cleared to resume rehabilitation after two weeks are withdrawn. Replacement of participants who withdraw or discontinue early will not be made.

5. Discussion

There is an urgent need to improve enrollment, adherence and completion of CR and PR. The National Heart, Lung, and Blood Institute, the Agency for Healthcare Research and Quality, and Million Hearts Campaign have all developed resources to improve utilization of rehabilitation programs. However, a national survey conducted by Pack et al. [41] found that relying on expansion of hospital-based programs, even under the most optimistic scenarios, is insufficient to meet demand. Thus, new strategies must be developed. The proposed stepped-care model is an efficient, patient-centered, approach to expanding access to both CR and PR. Meeting the "Go" thresholds for the process indicators specified for this feasibility trial will justify conducting a definitive full-scale RCT to compare the effectiveness and value (cost--effectiveness) of stepped-care versus treatment as usual (center-based rehabilitation) in older frail adults living rural counties.

This study design builds on evidence-based interventions and features several innovative features. First, to the best of our knowledge, this will be the first trial to examine the potential value of a stepped-care approach to improve utilization of CR and PR concurrently. Second, unlike traditional stepped-care models, the sequence of treatment options was chosen to ensure that all patients are first offered the standard of care. While the interventions included in the stepped-care model do not address all known barriers, they do target several factors which have been repeatedly cited as limiting uptake of both CR and PR and are particularly relevant for a rural population. Third, this trial will focus on frail older adults. Attending hospital-based CR or PR programs can be burdensome for frail older adults living in rural communities, and home-based programs may be of significant benefit to this demographic group. Fourth, this will be one of the first trial to explicitly address adherence to PR. Fifth, while the trial is designed to examine whether stepped-care increases participation in CR and PR compared to treatment as usual, it will also generate data required to inform future interventions including the proportion of patients who benefit/or fail to respond to each sequential treatment option.

There are also limitations to the design. An alternative approach would be to offer patients accommodations based on their individual preferences. For example, while our program does allow patients to refuse center-based rehabilitation (with or without transportation provided) prior to enrolling in telerehabilitation, it does not allow patients to first try telerehabilitation and then to revert back to center-based rehabilitation. Home-based rehabilitation programs typically deliver less intensive exercise training. However, we anticipate that frail older adults' exercise requirements can be met with minimal equipment in a home environment [42]. Although walking programs are effective, they were not felt to be appropriate in our region, in large part because of the prolonged winter and icy conditions. We considered limiting the proposal to a single condition. But, given the frequent co-occurrence of chronic heart and lung disease in older adults, and the similarities between home-based CR and PR programs, including both maximizes the impact of the intervention. Weather in the northeast and car problems may impact the CHW's ability to reach participants. Moreover, participant illness may also impact the delivery of the intervention. Programs will be able to be lengthened by up to two weeks to account for these potential interruptions. It is possible that patients may withdraw consent between the verbal and written consent procedures. The research assistant will try to minimize the chance of this occurring by ensuring that patients understand the protocol and the requirements for participation. The number of withdrawals will be monitored and is included as a feasibility outcome. Rehabilitation programs are dose dependent. We recognize that the duration of program included in this feasibility trial may be short for some patients. An 8-week program was chosen because PR and CR programs at BHS average eight weeks for low to moderate risk patients. If found to be feasible, future implementation studies will be able to incorporate longer programs depending on individual patient needs.

Research resources generated with funds from this grant will be freely distributed, as available, to qualified academic investigators for non-commercial research in adherence with the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources.

Ethics approval and consent to participate

This study was approved by Institutional Review Board at the Berkshire Medical Center. We are obtaining written informed consent from all subjects willing and eligible to participate.

Availability of data and materials

Not applicable.

Funding

This study was supported by NHLBI Award #R34 HL156920-01A1.

Authors' contributions

All authors were involved in the study conception and design. All authors were involved in drafting the manuscript and approved the final manuscript.

Disclaimer

The opinions expressed here are those of the authors and do not represent the official policy or position of the NHLBI.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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