Contemporary Clinical Trials Communications 15 (2019) 100395

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

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

Older Veterans EmpoweRed To Use Regular Exercise (OVERTURE) II: Design and methods of a randomized controlled trial among older veterans with chronic health conditions

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1. Introduction

There are physical and mental health benefits associated with regular physical activity across the life span [1]; however, individuals are less likely to engage in regular physical activity with advancing age. Recent statistics from the Federal Interagency Forum on Aging Related-Statistics (FIFA-RS) [2] suggest that only 12% of adults 65 years and older engage in regular physical activity that meets the Federal guidelines for physical activity. The guidelines recommend that U.S. adults engage in at least 150 min of moderate-intensity aerobic activity weekly and two to three alternating days of muscle-strengthening activities [3,4]. The guidelines further recommend that older adults with chronic health conditions strive to be as physically active as possible.

Among older adults, veterans represent a special population that may not be able to meet the Federal government's guidelines for physical activity. As a result of military service, older veterans who once were considered to be in optimal physical and mental condition as active duty service members, often live with multiple chronic conditions (MCCs) that may limit physical activity [5,6]. For example, older veterans receiving care through the Veterans Affairs (VA) often report a high degree of functional limitations and mental health issues [5,6], such as chronic knee and back pain [7], major depression [8], and post-traumatic stress disorder [8]. Consequentially, the presence of MCCs increases the risk for poor quality of life (QOL) [9,10] and wellbeing (WB) [11] and limits physical activity.

In spite of the evidence that physical activity is beneficial to QOL [9] and WB [11], there is scant evidence in the research literature of exercise interventions for older adults with MCCs, specifically for older veterans. Older adults, regardless of veteran status, who have MCCs are often excluded from exercise interventions [12]. OVERTURE II endeavors to determine the feasibility of an exercise intervention that may promote QOL and WB among older veterans with MCCs.

2. Methods

2.1. Ethical approval

The study commenced upon approval from the University of Alabama at Birmingham (UAB) Institutional Review Board (Protocol #00001897) and registration in clinicaltrials.gov NCT03580551.

2.2. Specific aims

The specific aims for the study are: (1) to further assess the feasibility of the exercise intervention; (2) to utilize data from the feasibility study to estimate an effect of the exercise intervention's ability to improve outcome measures; and (3) to assess whether further changes will be necessary to improve the intervention based on post-intervention focus groups.

2.3. Study design

The proposed study will examine the feasibility of Older Veterans EmpoweRed To Use Regular Exercise (OVERTURE) II, which is a short-term (8-weeks), unsupervised, homebased DVD chair exercise program for physically inactive older Black and White veterans with three or more chronic health conditions, such as type 2 diabetes, hypertension, major depression, and anxiety. A mixed-method, quantitative-qualitative sequential design with focus groups will be adopted for this study.

For incentives, participants will receive Season 13 of the exercise program, which includes 4 DVDs, a DVD player, two 2- pound hand weights, a 10" exercise ball, a small handball, and a 6-pound resistance exercise band. Focus group participants will receive a check for $25.The first part of the study will take place in the private residences of each participant. The second part of the study, which is the focus groups, will take place at UAB. The procedures for the study are provided in Fig. 1.

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https://doi.org/10.1016/j.conctc.2019.100395
Received 8 February 2019; Received in revised form 24 May 2019; Accepted 7 June 2019
Available online 28 June 2019

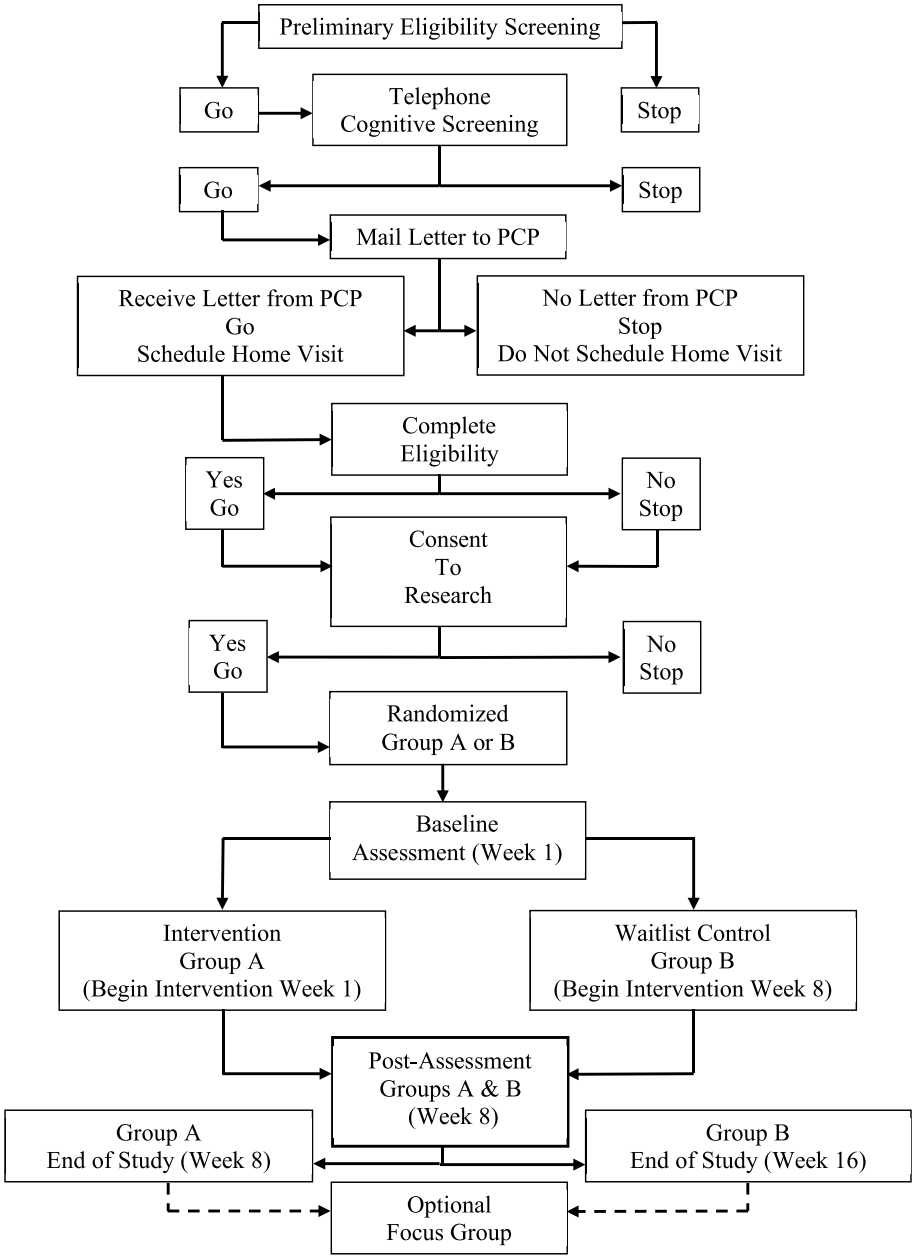

Fig. 1. Flowchart of procedures.

2.4. Eligibility criteria

Inclusion will be restricted to individuals who can (1) provide proof of veteran status, such as discharge documentation, military identification, Veteran Affairs Health identification card, or pictures in official government uniform, (2) self-reported race or ethnicity as Black/African American or White/Caucasian, (3) at least 65 years of age or older, (4) self-report less than 30 min of daily physical activity, (5) receive a passing score on the Six-Item Screener to Identify Cognitive Impairment [13], which was selected based on validity and reliability, as well as easy of administration, (6) obtain primary care physician approval, (7) verified three or more chronic health conditions, (8) systolic blood pressure lower than 180, (9) diastolic blood pressure lower than 100, (10) resting heart rate of 90 or lower, (11) own a sturdy stand-alone chair, and (12) possess an operable television. Individuals who do not meet the inclusion criteria will not be invited to participate in the study.

2.5. Recruitment and enrollment

Potential participants will be identified based on age and regional demographics using the UAB Edward R. Roybal Center for Research on Applied Gerontology database. A total of 2000 brochures describing the study will be mailed. Recruitment activities will also take place at local and surrounding veteran organizations, such as the Veterans of Foreign Wars, the American Legion, and Vietnam Veterans of America. Preliminary eligibility will take place over the telephone. Interested individuals will contact the study personnel by telephone for additional information about the study and preliminary eligibility.

2.6. Sample

Forty participants will be recruited for this study. However, given the former US draft policy and age of participants (65 years and older), we anticipate recruiting more males than females. Twenty participants

from each racial group (Black and White) will be randomly assigned to either the intervention group (Group A) or the waitlist control group (Group B) based on a random allocation sequence selected by a statistical software program (SAS for Windows v9.3.1.) [14].

3. Intervention

Sit and Be Fit^{TM} [15] is a nationally recognized fitness program selected as the intervention. The exercise program includes endurance, strength, flexibility, and balance activities, which are key components of physical activity programs for older adults [28]. However, the program has not been previously evaluated for feasibility among any population of older adults. Fig. 1 is a flowchart of the procedures for the study.

3.1. Exercise intervention (group A)

After the baseline assessments, participants in the intervention group (Group A) will be instructed to complete an assigned exercise session once a day (approximately 30 min), five days a week (Monday through Friday) for 8-weeks, and to complete an activity log that includes the date and the start/stop time for each exercise session. As a measure of feasibility, participants will also be instructed to rate their satisfaction for each exercise session. If participants encounter issues with the use of the DVD, they will receive a DVD player troubleshooting guide and the telephone number for the research team.

A member of the research team will ensure that the DVD player and television are properly setup and that the DVD is queued to the first exercise session. The DVD exercise sessions are numbered. Participants will be instructed on how to read the sessions number on the DVD and on their television screen. To ensure safety of participant and the proper operation of the DVD player, a member of the research team will observe the participant sitting in a chair at the start of the exercise program for approximately 5 min. The research team member will ask the participant to stop and re-start the DVD session.

After the observation, the home visit will conclude. Participants will not have any contact with the research team, unless it was to troubleshoot the DVD or answer questions over the telephone. The research coordinator will contact participants at week 6 to schedule the return visit at the end of week 8. At the posttest visit, participants in the intervention group will be asked to repeat the baseline assessments, excluding the assessment for comorbidity. Participants in the intervention group will have the option to participate in one of three focus groups.

3.2. Waitlist control (group B)

The waitlist control group will complete all baseline measures during the first visit at week 1. At 8 weeks, the waitlist control group will complete the post-assessments. After the post-assessment at 8 weeks, the waitlist control group (Group B) will receive the intervention instructions, equipment and materials. At week 9, participants in the waitlist control group will begin the identical process as the intervention group. At the end of week 14, the study staff will contact the waitlist control group to schedule a visit at the end of 16 weeks to collect the exercise log and the satisfaction survey. The waitlist control group will not receive an additional post-assessment at the end of week 16. Following the last visit at 16 weeks, the waitlist control group will have the option to participate in one of three focus groups.

3.3. Primary measures of feasibility

Feasibility will be evaluated based on the four metrics identified by Learmonth and Motl [16], which includes process, resources, management, and scientific outcomes. Table 1 describes the feasibility metrics for this study. Additionally, the table describes our data collection methods, approach to the assessment of quantitative and qualitative

Table 1
Feasibility Metrics for OVERTURE II

Metric	Reason	Method	Importance
Process	Recruitment	Mass mailing using Center's research database Recruitment activities at local and surrounding organizations for veterans (e.g., Veterans of Foreign Wars)	Can be used to determine the most effective approach to recruitment for Phase II and III studies.
	Retention	Ratios and proportions to determine the percentage of participants retained for the study.	
	Attrition	Ratios and proportions to determine the percentage of participants dropped from study and reasons for withdrawal.	
	Adherence	Assess adherence based on participants' adherence logs.	
Resources	Participant communication	Evaluate the cost of establishing and maintaining communication with participants through mail, telephone, and in-person	Determine the most effective method for communicating with participants, which will be adopted for future studies.
	Incentives	Evaluate the cost of the all incentives	Can be used to estimate the cost of large Phase II and Phase III studies.
	Program costs	Evaluate the overall program's financial costs from pre-study to post-study	
Management	Obtain IRB approval	Assess the length of time and personnel efforts in the preparation and approval of the IRB	Can provide insight on the time and effort required to start the next phase of the study
	Clinical Trial registration	Registration of the trial in the Federal government's database for clinical trials. Determine the length of time and personnel effort	
	Training of staff	Determine the amount of time required to train all staff	Can provide insight on the time and effort required to start the next phase of the study
	Travel time	Determine the amount of travel time to and from each visit	
	Administration of Informed Consent	Record the start and stop time of the administration of the informed consent	
	Administration of Baseline Assessments	Record the start and stop time of the baseline assessments	
	Adverse events	Evaluation of minimal risk	Follow established Federal guidelines for reporting
Scientific	Participants' experience	Use statistical methods, such as ratios and proportions, and qualitative methods, specifically focus groups, to evaluate aspects of participants' experience, adherence, and satisfaction	Quantitative findings can assist with power calculations and effect size for future studies Qualitative data can be used to modify the intervention for future studies
	Participant adherence		
	Participants' satisfaction		
	Overall feasibility	Summarize quantitative and qualitative feasibility.	Use overall findings to inform Phase II and Phase III studies
	Effect size	Calculated based on $\geq$ 0.5 standard deviations	
	Qualitative content analysis	Directed content analysis will be used to ascertain codes about feasibility. Program modifications will also be evaluated for feasibility.	

Table 2
Assessments for OVERATURE II.

Measures	Pre-Assessment (Baseline)	Post-Assessment
36-item Medical Outcomes scale SF-36 [15]	X	X
Subjective Wellbeing Scale[17] (Modified) [19]	X	X
Physical Activity Scale for the Elderly (PASE) [20]	X	X
Charlson Comorbidity Index (CCI) [22]	X	
Body Mass Index (BMI) [23]	X	X
Blood Pressure	X	X
Short-Physical Performance Battery (SPPB) [24]	X	X
Handgrip Strength [25]	X	X

data, and the importance of each feasibility metric for future Phase II and III studies.

3.4. Secondary outcome measures

Secondary outcome measures will be assessed as pre- and post tests for this study. The measures for this study were selected because they have demonstrated validity and reliability among older adults [17–21], as well as because they are important aspects of health in older adults. Table 2 provides the administration guide for all secondary outcome measures.

Quality of Life (QOL). The 36-item Medical Outcomes Scale SF-36 [18] will be administered to assess physical and mental health-related QOL. Scores on the mental health composite and physical health composite of the SF-36 range from 0 to 100 and have population average of 50. A high score would indicate a high level of QOL on each composite as measured by the scale.

Subjective Wellbeing (SWB). SWB [19], which is related to how individuals rate their general feelings of happiness, will be measured using a modified SWB [20,21]. The scale consists of 4 items that assess overall happiness. Scores on the scale range from 4 to 28. A high score would indicate a high degree of perceived happiness.

Physical Activity. The Physical Activity Scale for the Elderly (PASE) [22] will be used to evaluate subjective levels of physical activity. Scores range from 0 to 360. A high score would indicate a high level of physical activity.

Comorbidity. The 18-item Charlson Comorbidity Index (CCI) [23] will be administered during baseline to assess self-report of co-occurring chronic health conditions. Individual chronic conditions will be assigned a score based on severity and averaged. A high score of 6 would suggests greater risk of mortality.

Body Mass Index (BMI). Pre- and posttest BMI will be assessed based on standard calculation of weight (kilograms) divided by the square of height (meters) [24]. High BMI may indicate a high proportion of body fatness [24].

Blood Pressure. Systolic and diastolic blood pressures and pulse will be evaluated at baseline and post test using a standard blood pressure cuff and heart rate monitor.

Physical Function. The Short Physical Performance Battery (SPPB) [25] assesses lower-extremity function and mobility in older adults. Performance measures include gait, balance (tandem, semi-tandem and side-by-side), and strength (repeated standing unassisted from a straight-backed chair with arms folded over chest). Scores range from 0 to 12. A score below 10 may indicate limitations in mobility, as well as predict premature mortality.

Handgrip Strength. Handgrip strength will be measured using a handgrip dynamometer [26]. Handgrip strength has been correlated with poorer functional, psychological and social health outcomes [27]. Participants will be asked to complete the handgrip strength assessments, which will measure handgrip strength in pounds and kilograms. A high handgrip strength measured by pounds/kilograms will be considered favorable.

3.5. Focus groups

At the end of the intervention, all participants will be invited to participate in one of three focus groups at UAB. Focus groups will be conducted to explore feasibility of the study, participants' perceptions and feelings about the exercise program, as well as to explore facilitators and barriers to completing the intervention. Results from the focus groups will be used to modify the intervention, if necessary.

4. Data analysis plan

Descriptive statistics, such as means (standard deviations) and frequencies (proportions), will be used to describe the characteristics of the participants.

4.1. Process

Recruitment. Methods used to recruit participants will be evaluated for effectiveness based on the mass mailing and recruitment activities. Percentages will be used to determine the recruitment rate for both methods.

Retention. Ratios and proportions will be used to determine the percentage of participants retained for the study.

Attrition. Similar to retention, ratios and proportions will be used to determine the percentage of participants that withdraw from the study. Additionally, the reasons for withdrawal will be examined based on qualitative findings.

Adherence. Participants' exercise logs will be used to calculate adherence based on the number of self-reported sessions completed.

4.2. Resources

Communication. The cost of establishing and maintaining the most effective method for communicating with participants and providers will be calculated.

Incentives. Focus groups will be used to evaluate the effectiveness of the incentives for recruitment and program adherence.

Program costs. The overall cost of the program will be evaluated based on the total costs of program supplies, including the purchases of all equipment and ancillary supplies, recruitment activities, and mass mailings, as well as administrative costs of the program.

4.3. Management

Obtain IRB approval. Estimate the length of time and personnel efforts in the preparation, faculty review, submission, and approval of the initial review by the UAB Institutional Review Board.

Clinical Trial registration. Estimate the length of time and personnel effort for the training, registration, and approval in ClinicalTrial.gov.

Training of staff. Estimate the amount of time required to train all staff.

Administration of documents. Evaluate the amount of time required to administer all instruments, including the informed consent, pre- and post tests.

Adverse events. Evaluate the applicability of minimal risk for the study.

4.4. Scientific

Participants' experience. Participants' overall experience will be evaluated using quantitative methods, which will include satisfaction surveys, and qualitative data from focus groups.

Participants' adherence. Participants' exercise logs will be used to evaluate adherence to the exercise program, as well as qualitative data from focus groups.

Participants' satisfaction. Similar to adherence, participants' satisfaction surveys, as well as qualitative data from focus groups will be used to evaluate participants' satisfaction.

Internal consistency. The reliability of multiple item scales (QOL [18] and SWB [17]) will be assessed by calculating Cronbach's alpha for each scale. Good internal consistency will be assessed by using a criteria of Cronbach's alpha ≥ 0.80.

Effect size and power calculations. The changes and related 95% confidence intervals of pre- and post-intervention data QOL [18], SWB [17], BMI [24], physical activity [22], physical function [25], and handgrip strength [26] will be used to assess clinical significance of the intervention. We expect to find an improvement in physical activity, mental health-related QOL and physical health-related QOL greater than or equal to 0.5 standard deviation units [29]. These improvements will be converted to effect sizes and used to compute power calculations for a larger trial. If the improvements are not as expected, the research team will re-evaluate the intervention content and delivery.

Qualitative content analysis. Directed content analysis will be used to ascertain codes about the feasibility of the exercise program. Qualitative content analysis will also be used to assess whether changes made to the intervention from preliminary studies improved the feasibility of the modified intervention, and whether additional modifications are warranted based on post-intervention focus groups that explore attitudes and feelings about the home-based DVD exercise program, and facilitators and barriers to the exercise program.

5. Discussion

To the best of our knowledge, this study is novel because it is the first examination of a popular exercise program for feasibility, particularly in a sample of older veterans with MCC. Currently, there is a dearth of research on older adults with MCCs and even more so older veterans with MCCs [30]. Although the US Department of Health and Human Services (HHS) recognizes the need to expand research in the area of older adults with MCCs, little progress has been made in this area [30–32]. Recently, the National Institute on Health mandated the inclusion of older adults with MCC in clinical trials [32]. The American Geriatrics Society (AGS) has been at the forefront of the change in research inclusion criteria [33,34]. Regardless of the changes to clinical trials inclusion criteria, AGS continues to advocate for the inclusion of older adults with MCC in exercise intervention research to better inform the health and health care services for this growing population [33].

This study focuses on a growing population of older adults that report high functional limitations [5], musculoskeletal conditions [7], and mental health issues [8], all of which individually or collectively, increases risk for poor QOL [18] and SWB [17]. Veterans over the age of 65 will continue to constitute a substantial percentage of the population in the United States and Puerto Rico. By 2020, the male veteran population is expected to be approximately 9 million, with the largest proportion of growth seen in the oldest-old category (85 years and older) [2]. Female veterans in the oldest-old category will also increase, although less dramatically [2].

This study uses research-grade measures of scientific end-points, rather than clinical measures. In the future, it will be important to include frequently used clinical measures that are part of the Annual Medicare Wellness Visits (AMWV) [35]. Such measures may provide a more robust clinical cognitive measure, a depression screening, and a clinical measures for physical function and safety.

5.1. Limitations

A potential limitation of this study is the recruitment criteria for participants with three or more MCCs. It is plausible that participants will encounter barriers to exercise program adherence, such as chronic pain and physician visits. Lastly, given the sample size of the study, the findings are not generalizable to the broader population.

6. Conclusions

Quantitative and qualitative preliminary findings suggest that the exercise program may prove feasible and demonstrate trends toward improvement in QOL [18]. An additional measure, specifically subjective wellbeing [17,19], has been added to better inform the study about QOL [18]. Based on qualitative feedback from participants, other improvements have also been incorporated, such as an increase in the weight of hand weights, stronger resistance bands, and a smaller exercise ball.

The proposed study is of low cost with high potential for feasibility. If the exercise program proves feasible, future Phase II and Phase III studies could be implemented and evaluated for efficacy and effectiveness without substantial financial burden to the Federal government.

Equally important, the incorporation of clinical measures would be of great value to the veterans and primary care providers because the measures will align with the AMWV [35]. Lastly, this study may inform the development of an exercise program within the VA and community-based organizations from which older veterans receive health care and social services.

Funding acknowledgements and Clinical Trial Registration

This study was supported by the National Institutes of Health/National Insistute on Aging Edward R. Roybal Center award number P30 AG022838 and the National Center for Advancing Translational Research of the National Institutes of Health under award number UL1TR003096. Clinical Trials Registration NCT03580551.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2019.100395.

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