CArdiovascular Risk assEssment for patients with Rheumatoid Arthritis (CARE RA) Protocol

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1. SUMMARY

This is a 5-week, single-blinded, randomized trial to pilot test the efficacy of a behavioral intervention (CARE RA), a peer coach program, in increasing cardiovascular disease (CVD) risk assessment and self-efficacy in patients with rheumatoid arthritis (RA). Peer coaches are patients who themselves have the targeted condition (e.g., diabetes, RA) and have been trained to help others with the same condition in following treatment recommendations from their providers, social support, and improving self-efficacy, which translates into healthy behaviors. They are not physicians, nor other health professionals, and do not provide any medical advice to the patients they are coaching. We will explore their potential role to guide other patients with RA to obtain adequate CVD risk assessment, the most common cause of death in patients with RA.

The study population will consist of individuals with RA between the ages of 40-75 who have no history of established CVD and are not receiving a statin. The study duration will be 18 weeks, including a 6-week intervention period, starting from baseline enrollment and ending with the 3-month follow-up contact. Eligible subjects will be randomized to either a self-administered online learning arm or to the CARE RA arm, also called the peer coach arm. The self-administered online learning arm will include a tutorial on how to use the Patient Activated Learning System (PALS) followed by self-driven completion of the CARE RA curriculum within the PALS. The peer coach arm will include the same tutorial on the use of the PALS but will also include contacts with a peer coach for 5 weeks to reinforce key points in the CARE RA curriculum within the PALS. Each week, the peer coaches will have a 30 to 45-minute call with their assigned participant(s) during which they will discuss concepts about RA, CVD and RA, the importance of cardiovascular risk assessment, how to better communicate with your doctors, and how to request cardiovascular risk assessment from your doctor.

The primary objective is to increase the number of subjects who receive CVD risk assessment at their upcoming physician's appointment at the end of the 5-week intervention. Since some subjects might not have this test done by their physician by the end of the intervention, but may have it later on, we will also examine this outcome 3 months after the intervention is completed. We will also examine at that point if they met criteria to initiate a statin medication.

Secondary outcomes will be:

1. Change in Routine Assessment of Patient Index Data (RAPID3) score from baseline to the end of the study between arms.
2. Change in Social Support Survey Score from baseline to the end of the study between arms.
3. Change in Patient Activation Measure (PAM) score from baseline to the end of the study between arms. In order to utilize this measure, subject data will be shared with the licensing agency to help continue to improve the measure.
4. Change in Patient Health Questionnaire – 8 (PHQ-8) score from baseline to the end of the study between arms. Subjects who score a 10 or higher on the PHQ-8 at baseline data collection will be referred to mental health resources and counseling (websites, links,

educational materials) by the study team. Peer coaches will be trained to direct subjects who express depressed thoughts and feelings during the course of the program to the mental health resources and counseling and will report such instances to the research team.

5. Change in General Self-Efficacy (GSF) score from baseline to the end of the study between arms.
6. Change in Medication Understanding and Use Self-Efficacy Scale (MUSE) score from baseline to the end of the study between arms.

2. INTRODUCTION

CVD is the most common cause of death among patients with RA. Several studies showed a 50-60% increased risk of death from myocardial infarction and stroke in patients with RA compared with the general population, with the standardized mortality ratio attributable to CVD ranging from 1.13-5.15.[1-6] Aggressive treatment of RA decreases CVD morbidity and mortality, but there is evidence that many patients do not benefit from the "treat to target" paradigm and do not in fact receive sufficiently aggressive RA treatment. Thus, CVD risk assessment through cholesterol testing among patients with RA remains an important CVD risk reduction strategy.[7-11].

Several studies have reported that the prevalence of hyperlipidemia in patients with RA is lower than in those without RA. However, the relationship between lipids, RA, and CVD risk is complicated by RA therapies that have been associated with increased lipid levels.[12,13] We have reported previously that three different combination therapies were associated with increased lipid levels after 6 months of treatment.[12] Nevertheless, the American Heart Association/American College of Cardiology recommend following their guidelines applicable to the general population for CVD risk assessment, including cholesterol testing.

Although primary care physicians (PCPs) test RA patients' lipids more frequently than rheumatologists, overall testing remains suboptimal, with only 44% or fewer patients with RA tested, compared with 79% of patients with diabetes mellitus (DM), another CVD risk factor that is more widely appreciated by PCPs. A significant knowledge gap has been reported among PCPs regarding RA as a CVD risk factor, with 68% of PCPs frequently failing to identify RA as a CVD risk factor,[14] suggesting that specific interventions for these patients may be warranted.

One such intervention may be peer coaching. Peer coaching interventions are gaining traction for chronic disease self-care. Peer coaches have been shown to improve medication adherence for human immunodeficiency virus (HIV), asthma, diabetes, and cancer screening.[15-22] Peer coaches are lay individuals who themselves have the targeted chronic condition and who receive minimal training. They provide social and emotional support to the patient and could be used to help patients complete an educational program that includes decision support for CVD risk reduction strategies. However, peer coaches have not been used in RA, and have not been evaluated for CVD risk reduction in this population. Volunteer peer coaching programs are especially attractive in the context of patient communities, such as the online research community of >28,000 patients with arthritis enrolled in ArthritisPower. In preliminary discussions with my patients, several expressed interest in having contact with someone also living with arthritis to guide them through an educational program on CVD risk, ultimately helping them to discuss CVD risk reduction with their physician.

This study will use Bandura's Social Cognitive Theory to develop an online CVD risk reduction intervention for patients with RA. This theory proposed that experiential learning helps people to overcome their fears and impediments and can serve as a facilitator for behavioral change. Social support is also very important and can be achieved by interacting with others who have had similar experiences.

3. STUDY OBJECTIVES AND OUTCOMES

3.1 Primary Objective

The primary objective is to test the difference in the proportion of subjects who receive cardiovascular risk assessment or learning from their healthcare provider that they already had one in the past year, between subjects randomized to the peer coaching condition and subjects randomized to the self-administered online learning condition.

3.2 Secondary objectives:

To determine whether the CARE RA program is effective in improving the following patient generated health data compared to subjects in the self-administered online learning arm.

1. Change in Routine Assessment of Patient Index Data (RAPID3) score from baseline to the end of the study between arms.
2. Change in Social Support Survey Score from baseline to the end of the study between arms.
3. Change in Patient Activation Measure (PAM) score from baseline to the end of the study between arms.
4. Change in Patient Health Questionnaire – 8 (PHQ-8) score from baseline to the end of the study between arms. Subjects who score a 10 or higher on the PHQ-8 at baseline data collection will be referred to mental health resources and counseling (websites, links, educational materials) by the study team. Peer coaches will be trained to direct subjects who express depressed thoughts and feelings during the course of the program to the mental health resources and counseling and will report such instances to the research team.
5. Change in General Self-Efficacy (GSF) score from baseline to the end of the study between arms.
6. Change in Medication Understanding and Use Self-Efficacy Scale (MUSE) score from baseline to the end of the study between arms.
7. We will examine the feasibility of the intervention by having 80% or more of the subjects complete the intervention.

4. STUDY DESIGN

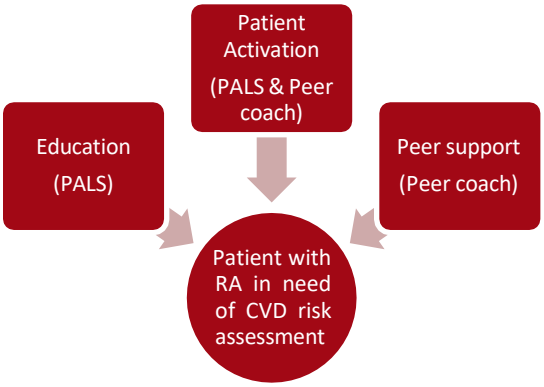
4.1 Study description

This is a single-blinded randomized trial to pilot test the effectiveness of the CARE RA intervention with self-administered online learning. The CARE RA intervention consists of 3 components: peer

support, patient activation, and online education via the PALS (Figure 1). It consists of weekly one-on-one telephonic sessions with a peer coach (a person with RA who has been trained on delivering the content of the CARE RA intervention to another person with RA) for five weeks. The intervention will begin at least 6 weeks before the subject's next appointment with a rheumatologist or other physician on their care team. During the intervention, subjects will learn how RA can affect their heart and receive training on how to better communicate with their physician so that they can obtain appropriate CVD risk assessment.

The peer coaches will be recruited and trained before deployment of the intervention. The recruitment and training of peer coaches for the CARE RA program is described below.

Figure 1: Components of the CARE RA Intervention



4.2 Peer Coaches

Peer Coach Recruitment

Peer coaches are individuals with RA who will be community member consultants in the study. Peer coaches are not health professionals but individuals who have RA. They will be trained in motivational interviewing, basics of communication, goal setting, and the PALS educational materials for the study. Peer coaches will complete a 7-week study protocol training led by Dr. Iris Navarro-Millán with support from the study research team.

Peer coaches are recruited by 2 methods:

1. ArthritisPower, our collaborator, will identify candidates who they believe would be good peer coaches based on their leadership and experience within the online arthritis community.

2. Dr. Iris Navarro-Millán will also identify patients from her own rheumatology practice who would be suitable candidates.

Peer Coach Screening

After an individual is referred, a research assistant will assess if the candidate meets the following inclusion criteria:

- Have RA

    - Patient should provide the RA medications (DMARDs) prescribed to them in order to meet criteria as having RA.
- Speaks English
- ≥ 40 and ≤75 years of age
- Taking a statin OR had a cholesterol test within the last 2 years
- Willing to have a cholesterol test if they have not yet been tested
    - This means that during training to become a peer coach, the potential peer coach would then need to have a cholesterol test done and a cardiovascular risk assessment done. This only applies to potential peer coaches who have not had a cholesterol test within the last 2 years or are not taking a statin.
- Willing to become a peer coach and discuss with peers' aspects about RA and CVD risk
- Have internet access
- Have a phone
- Express interest in helping others with RA
- Resides or lives in the US

After screening, the principal investigator and research study team will meet to review and discuss each candidate.

- If the candidate is not asked to move forward to be trained, the reason is documented. These individuals will be notified by the research assistant.
- If the individual is considered to be a good candidate, but is unavailable for the scheduled training, permission is obtained from the individual to contact them for future programs.
- Individuals who are considered a good candidate to be a peer coach will be scheduled for an upcoming training.

Peer Coach Training

Groups of 4-8 peer coaches will be scheduled for online training meetings. The peer coaches will be part of the research team that will be conducting this study and will be considered community member consultants. There will be a total of 7 group web conference training sessions via Zoom over 2 months. At the first meeting, peer coaches will be introduced to the CARE RA intervention schedule (Table 3). Over the course of training, the research team will review each chapter of the Peer Coaches' manual to teach the activities that the peer coach will need to complete throughout the intervention. Frequently asked questions (FAQs) are included that will help peer coaches manage various situations that may arise with their client.

During each online group training meeting, the following activities will occur:

- Review of learning materials on PALS
- Review of Peer Coach Manual (each week's session calls will be scripted in these manuals)
- Didactic training in motivational interviewing skills
- Practice of motivational interviewing skills

Group web conferences will be supplemented by 2 motivational interviewing (MI) training sessions on zoom with the PI and/or research assistant and only two coaches. During these smaller MI

sessions, peer coaches will practice MI skills with reinforcement by the PI and/or research assistant. During each MI training session, the following activities will occur:

- Practice of motivational interviewing skills by each peer coach, using role-play scripts and alternating roles between coach and subject under the supervision of the PI and/or the research assistants of the study
- Reinforcement of skills in real-time with encouragement of peer coaches to critique each other's skills

Group training sessions will be accompanied by paired practice sessions. Each coach will be paired with another coach. They will be asked to listen to the PI and/or research assistant delivering each session to a mock subject on audio recordings. They will then each practice delivering the intervention session in turn to their partner. Each coach in training will be encouraged to critique their partner's performance based on MI skills learned earlier in training. If coaches do not feel confident that they have mastered a session, they will be encouraged to continue to practice with their partner. Once each coach feels confident, they will schedule a separate one-on-one certification session with the PI and/or research assistant. At this session the PI and/or research assistant will play the role of the subject and the coach will deliver the session. The PI and/or research assistant will use a checklist to assess proficiency. Each coach will be certified on each session separately. If needed, additional training can be scheduled until each coach reaches the minimum level of proficiency. Only those that pass all the certification sessions will be allowed to work with subjects in the study.

Peer Coach Retention

Retention activities consist of the following:

- Ensure timely payment for work
- Provide ongoing support and continuing education/retraining with opportunities for practicing skills
  - Weekly group conference calls to assess process measures and monitor progress of the intervention
  - Provide group problem-solving for challenges encountered
  - Provide emotional support
  - Build group identity and pride
- Allowing each coach to determine their workload, increasing or decreasing according to life demands
- Be respectful of peer coaches' time and schedules
  - Keep mandatory conference calls and individual calls on time, short as possible, and reschedule only if necessary.
  - Provide assistance as needed in scheduling sessions with subjects

4.3 Patient Activated Learning System (PALS)

The PALS is a publicly available educational and empowerment resource designed to provide engaging, easily understood, and well-researched facts for people who want to know more about health, medicines, and diseases. PALS was developed at Weill Cornell Medicine Division of General Internal Medicine where its content is developed and curated (www.palsforhealth.com). The content in the PALS is evidence-based and peer reviewed. This content is translated into

patient-facing text in plain language, aiming for a sixth-grade reading level. Content is accompanied by visuals or short videos to reinforce the single learning objective for each module, known in the PALS parlance as a renewable knowledge object (RKO). Each RKO includes an assessment question about the information that they just reviewed. The PALS is based on Adult Learning Theory and Bandura's Social Cognitive Theory, informed by Bartell's Taxonomy of online interactions types.

The educational material of CARE RA will be posted on the PALS platform and clients can access it as many times as they want. Each session of the CARE RA curriculum is tied to several PALS RKOs that clients are asked to view ahead of their discussion with the peer coach. Subjects in the self-administered learning arm of the study will be given the complete list of these same PALS RKOs to view on their own.

4.4 Intervention Mapping

CARE RA is a behavioral intervention with the goal of increasing activation and self-efficacy in individuals with RA to participate in their own care. A theoretical framework maps a causal relationship between a problem and the factors contributing to it, while identifying modifiable factors that can enable behavioral change.

Table 1: Intervention Mapping to Social Cognitive Theory

Theoretical Construct	Targeted Barrier	Intervention Activity	Corresponding Session
Self-Efficacy	Feeling isolated Lack of understanding of CVD risk Lack of understanding of the effects of RA systemically Lack of understanding of the value of having a PCP	Education (PALS), Coaching, Motivational Interviewing (MI), Empowerment	Sessions 1, 2, 3 *Learn More* modules
Outcome Expectation	Unrealistic expectations about the goals for RA disease control Unrealistic expectations about CVD risk Unrealistic expectations that because they ask for a cholesterol test, that the doctor will order it Fear of need to take another medication	Education, Action planning, MI,	Sessions 2, 3, 4, 5 *Learn More* modules
Socio-Cultural Factors	No resources to learn from about CVD No guidance of how to engage in healthy behaviors (e.g. healthy diet, regular exercise, take medications) Disruptive social support (e.g. family preference for unhealthy diet, preference for junk food over healthy food) Lack of understanding of CVD risk	Supportive coaching, Action planning, Education (PALS)	Session 2, 3, 4, 5 *Learn More* modules
MI = motivational interviewing; CVD = Cardiovascular Disease; PCP= Primary Care Provider.			

5. STUDY POPULATION

5.1 Study population

Inclusion Criteria

- Have RA
- Age between 40 and 75 years (inclusive)

- Provide a date of their next appointment with their rheumatologist or other physician on their care team
- Willing to work with a peer coach
- Speaks English
- Have a phone
- Has access to the internet
- Resides or lives in the US

Exclusion criteria

- Do not have RA
- Younger than age 40 or older than age 75
- Taking a statin
- Known history of diabetes.
- Known history of CVD defined by:
    - Open heart surgery
    - Coronary angioplasty
    - History of heart failure
    - History of heart attack or stroke

Participants will be screened using a REDCap screening survey. If participants answer yes to any of the exclusion criteria questions, the survey skips to the end, and participants will be informed that they are not eligible. The age range for the inclusion criteria reflects the age range of the current AHA guidelines for risk assessment for CVD. The exclusion of established CVD reflects differences in national guidelines on the management of patients with established CVD vs. preventing CVD. The overall goal of this research is to discover effective strategies to prevent CVD, therefore we focus here on primary prevention.

5.2 Study duration

The study duration will be a maximum of 18 weeks from baseline enrollment to final follow up at 3 months after enrollment. The duration of the intervention is 5 weeks (Figure 2 and Table 2).

5.3 Planned number of subjects

We plan to enroll 128 subjects into this study. We will recruit patients from the ArthritisPower Patient Powered Research Network (PPRN), the Bendcare patient network, Dr. Michael Malekan's practice at New York Presbyterian – Brooklyn, and social media using Twitter. We will also be recruiting participants using flyers created by a company (BuildClinical). These flyers will be posted online and interested participants will be referred to us. The PPRN has over 28,000 patients with arthritis throughout the United States and territories. In order to enroll this number of subjects, it is expected that approximately 180 subjects will be screened. This takes into account an estimate of at least a 20% screen failure rate between Screening and Baseline. We will monitor the actual screen failure rate to make estimates for the planned larger study to follow this one.

- First subject's first enrollment: Q1 2021
- Last subject's last encounter/call: Q2 2022

5.4 Recruitment

Figure 2 outlines the workflow of this study from recruitment to final data collection.

Recruitment

We will send out invitations to participate in CARE RA to members of the ArthritisPower registry and the Bendcare patient network via email messages in several waves. We will send out 200-400 invitations at a time and continue to send out invitations based on the response and on peer coach capacity. Bendcare will also reach out to their patients to determine their interest in this study. Bendcare will screen patients for eligibility. Eligible patients will be consented by Bendcare and transferred to the research team for randomization. Bendcare will provide access to this REDCap database used to screen and consent Bendcare patients to the WCM research team within their secure network. We will also be recruiting participants using flyers created by a company (BuildClinical). These flyers will be posted online and interested participants will be referred to us. If the patient clicks on the online flyer, they'll be prompted to complete the BuildClinical screening survey based on our eligibility criteria.

We will post a recruitment video on Twitter through the PI's professional account. The recruitment video will briefly detail the CARE RA study and invite people to fill out an interest survey through REDCap if they would like to be contacted by the research team for more information. Once an individual completes the interest survey, the research team will reach out to them.

We will further increase recruitment through the patient list of Dr. Michael Malekan, Dr. Yevgeniya Gartshteyn, Dr. Jon Giles, Dr. Teja Kapoor, Dr. Rabia Iqbal, and Dr. Ayat Abdelgadir. All physicians have provided our team with authorization to contact their patients whom our team will identify using EPIC. To help streamline the process of identifying patients, we will use the EHR Data and Reporting system TRAC to extrapolate patients that meet the eligibility criteria. We will not reach out to patients who marked in EPIC their wish not to be contacted for research. We will reach out to patients through doximity.

Once a person consented to participate in the study, all data collected will follow those stipulated by the study. These recruitment processes will be in place until 128 subjects are recruited.

Screening

Individuals who are interested in participating will respond to the research assistant's contact information on the invitations for ArthritisPower, the survey that Bendcare is administering, and BuildClinical flyers and corresponding survey., An unblinded research assistant from WCM will respond to direct emails from interested individuals to schedule a screening telephone call. The WCM research assistant will also call patients that have indicated on the Bendcare survey, the Twitter REDCap survey, or patients of Dr. Michael Malekan, Dr. Yevgeniya Gartshteyn, Dr. Jon Giles, Dr. Teja Kapoor, Dr. Rabia Iqbal, and Dr. Ayat Abdelgadir who have not marked in EPIC their wish not to be contacted for research. Before the research assistant calls the participants, they will text them from a secure number through Doximity to let them know that they will be calling them shortly. During this phone call, the study will be explained in full. Prior to any study activities, subjects will be screened for eligibility and if eligible, they will review with the unblinded WCM research assistant the Informed Consent form approved by WCM Institutional Review Board (IRB) and which complies with regulatory requirements. Subjects will be given adequate

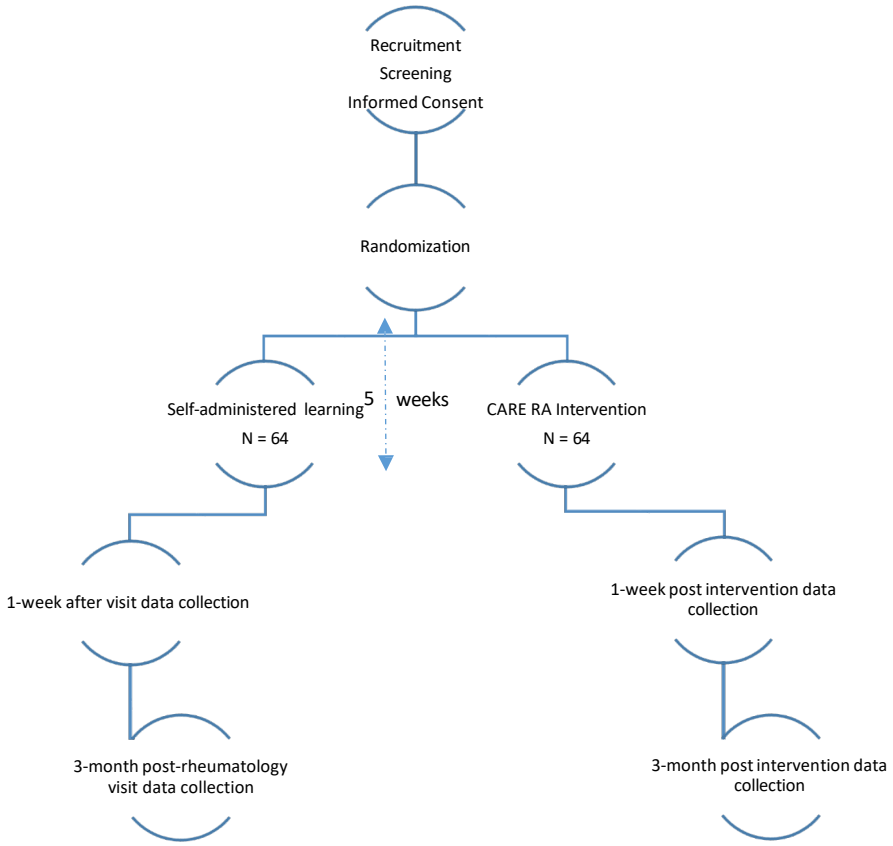
time to consider any information concerning the study given to them by the Investigator or designee. As part of the Informed Consent process, subjects will be given the opportunity to ask the Investigator any questions regarding potential risks and benefits of participation in the study. This informed consent process will be voice recorded during the screening telephone call in the secure HIPAA protected server of WCM Division of General Internal Medicine.

Enrollment and Randomization

We will randomize subjects by a computer-generated random allocation list. The unblinded research assistant will call the subject to complete the enrollment and randomization in the study. The call will consist of the following activities:

- The subject will need to provide the date of their next appointment with their rheumatologist or other physician on their care team .
- The intervention will begin at least 6 weeks before their next appointment and the first data collection point will be at that time.
- Once a subject is enrolled and randomized, the unblinded research assistant will inform the subject the arm they have been assigned to (CARE RA vs self-administered online learning) by phone.
- During the call, the unblinded research assistant will instruct the subject on how to complete the baseline data form on the WCM REDCap that they will receive by email before initiating the intervention or at least 6 weeks before their appointment with their rheumatologist or other physician on their care team .
- During this call, all subjects regardless of arm assignment will go through a PALS tutorial with the unblinded research assistant. This training will be over the phone/Zoom by the unblinded research assistant on how to access and navigate the PALS (e.g. finding the website, searching for articles, viewing the patient-facing text, watching the videos, completing the self-assessment question for each PALS RKO). We will make available also a video tutorial on the PALS to all participants.
- All participants will receive a phone call from a blinded research assistant to make sure that they have completed all the items in the data collection form at the timepoints established for the study.
- If assigned to the CARE RA arm of the study, the unblinded research assistant will provide the subject with information about how to they will be matched with their peer coach. After the subject is matched with a peer coach, the subject will be notified that their name and phone number has been shared with their peer coach and their peer coach will be in contact with them to schedule their first call. The first call between peer coaches and subjects should occur around 5-6 weeks before their next physician appointment. Subjects will receive a copy of the CARE RA Activity Book, the Intervention Schedule, and PALS tutorial by email. A hard copy of the CARE RA Activity Book will be available upon request by the subject. The unblinded research assistant will also ensure that the subjects have received all intervention materials.
- If assigned to the self-administered online learning arm, the unblinded research assistant will provide the PALS training as described above, the curriculum of the CARE RA program in the PALS and schedule the first data collection call around 5-6 weeks before their next physician visit.

Figure 2: Diagram of the workflow of the study



5.5 Schedule of study assessments

Table 2: Schedule of study assessments

	Baseline	**1 week after Intervention completed/1 week after doctor's appointment**	**3 months after intervention completed**	**Lost to Follow-Up/Dropouts**
Demographics	X			
Medications and comorbidities	X			
Surveys				
RAPID3	X	X	X	
Social Support Survey	X	X	X	
Patient Activation Measure (PAM)	X	X	X	
Patient Health Questionnaire – 8 (PHQ- 8)	X	X	X	

Medication Understanding and Use Self-Efficacy Scale (MUSE)	X	X	X	
The General Self-Efficacy Scale (GSF)	X	X	X	
Outcomes				
Cholesterol test		X	X	
Initiating lipid lowering therapy		X	X	
Program Evaluation				
Evaluation Survey		X		X
Focus Group/Interview		X		X

6. STUDY TREATMENTS

6.1 CARE RA arm

- Subjects in the CARE RA arm will have a Zoom call with the unblinded research assistant to review the study procedures relevant to the study arm one week before their Session 1 call with the peer coach. The subject will have an opportunity to ask any questions that they might have before initiating the program.
- The unblinded research assistant will remind the subject about the call with their assigned peer coach for Session 1.
- The unblinded research assistant will call the subject twice over the 5-week intervention period to check on them and to remind the subject of the second data collection point one week after the intervention has ended. These calls will also serve as intervention fidelity checks to assure that the sessions are occurring as scheduled and that the peer coach is interacting with the subject in a manner concordant with training. We will also remind subjects that they can call the study telephone number or contact the research team by email with questions.

6.2 Self-administered online learning arm

- Subjects will receive the same tutorial on the PALS by an unblinded research assistant (via phone/Zoom) on how to access and navigate the PALS (e.g. searching for articles, viewing the evidence summary, watching the videos, completing the self-assessment question after each PALS module).
- They will receive the list of PALS RKOs that correspond to the CARE RA curriculum by email. The mailing will include reminders of how to access the PALS and find the CARE RA PALS RKOs.
- The unblinded research assistant will call the subject twice over the next 5 weeks to remind them that they are in the study, give an opportunity to ask any questions, and remind them of the upcoming assessment points. The research assistant will avoid discussing the PALS unless the subject has specific questions to assure that these retention calls are not interventions.

7. STUDY PROCEDURES AND SCHEDULE

7.1 Intervention fidelity measures

A careful assessment of intervention implementation can provide insights into which aspects of the intervention were particularly effective. We will use several strategies to monitor intervention fidelity.

First, we will ask peer coaches to use Zoom teleconference calls for intervention delivery and record the weekly sessions between peer coaches and subjects. The goal of these recordings is to monitor fidelity of the intervention and monitor duration of the calls. These secure calls will be recorded and stored in the secure and HIPAA compliant server of the WCM Division of GIM. Study staff will review each session and use a checklist to assess intervention fidelity for each session.

Second, the peer coaches will have a checklist that they will have to complete as they go through the call of all the activities and topics that they have to cover in each session, which will ensure that these are completed by the end of each call. We will collect these checklists and compare the self-assessment of the coach to those of the study team based on their review of the Zoom call recordings. In the future larger trial, we will use these comparisons to plan for how to monitor intervention fidelity.

Third, we will monitor intervention implementation on an ongoing basis through weekly teleconferences with peer coaches, and weekly outreach to each peer coach individually throughout the intervention period. We will provide updates on the progress of the study, collaboratively troubleshoot problems, and provide ongoing advice, which often stems from other peers. At these calls, coaches will be asked to report on their clients and progress, giving the opportunity to reinforce the study protocol and MI skills.

Fourth, the research team will contact each subject twice over the 5-week intervention period to check on how the intervention is unfolding from the subject perspective.

7.2 Data collection:

All subjects will receive a baseline telephone call, the post-intervention follow up call, and the 3-month/final follow up call from the study team (Table 2). Subjects who are lost to follow-up or drop out of the study before completion will be contacted to complete the program evaluation portions of the intervention.

We will use REDCap to collect the data at baseline, post-intervention, and final follow up. The subject will receive a REDCap link via email that they will click to access the surveys at each data collection point. A blinded research assistant from WCM will follow up by phone with those subjects that have not completed or partially completed the surveys to minimize missing data.

Session	Objectives	Activity/Assignment	PALS - Renewable Knowledge Objects (RKOs)
1. "Introduction to the CARE RA Program"	1. Get to know each other 2. Introduce the CArdiovascular Risk assEssment Program for Rheumatoid Arthritis *(CARE RA)* program 3. Introduce the client to the Patient Activated Learning System (PALS)	A. Verify contact information and receipt of Activity Book B. Get to know each other C. Introduce the *CARE RA* program D. Introduce the PALS E. Rules and Responsibilities F. Sign contract G. PALS assignments (RKOs) for Session 2 H. Schedule Session 2 call	None for Session 1
2. "RA and My Heart"	1. Learn how RA affects your heart 2. Learn why a cholesterol test is needed to assess risk for heart attack and stroke	A. Greetings between coaches and clients B. Verify the client has reviewed the RKOs and introduction to Session 2 C. Review of PALS assignments for Session 2 D. *CARE RA* Highlights of Session 2 E. Plans for Session 3 F. PALS assignments for Session 3 G. Schedule Session 3 call	*Required:* - How can rheumatoid arthritis (RA) affect my body and my health? - What does atherosclerotic cardiovascular disease (ASCVD) risk mean? - How does rheumatoid arthritis (RA) affect my heart? - How can I lower my risk of heart disease if I have rheumatoid arthritis (RA)? - What is cholesterol? - Do I need a cholesterol test if I have rheumatoid arthritis (RA)? *Learn more:* - What is rheumatoid arthritis (RA)? - How is rheumatoid arthritis (RA) treated? - What medicines are used to treat rheumatoid arthritis (RA)?
3. "The Different Doctors Caring for People Living with Rheumatoid Arthritis (RA)"	1. Learn the difference between a rheumatologist and a primary care provider. 2. Learn how important is to have a primary care provider in addition to a rheumatologist if you have rheumatoid arthritis (RA)	A. Greetings between coaches and clients B. Verify that client has reviewed the RKOs and introduction to Session 3 C. Review of PALS assignments for Session 3 D. *CARE RA* Highlights of Session 3 E. Making a plan F. Plans for Session 4 G. PALS assignments for Session 4 H. Schedule Session 4 call	*Required:* - What is a rheumatologist? - What is a primary care provider (PCP)? - Do I need to see a primary care provider (PCP) if I already see a rheumatologist for my rheumatoid arthritis (RA)? - What can a primary care provider (PCP) do for me? - Which doctor should check my cholesterol levels if I have rheumatoid arthritis (RA)? *Learn more:* - What is a specialist or specialty doctor? - True or False: A primary care provider performs sick visit, injury, routine wellness care, and chronic disease management. A specialist focuses on treating specific conditions or organs.

4. "Requesting a Cholesterol Test"	1. To describe the importance of having a cholesterol test in order to learn what your risk is for heart attacks and strokes 2. To learn about how to communicate with your doctor about getting your cholesterol checked 3. To provide an overview of the medications used to lower your risk for heart attacks and strokes	A. Greetings between coaches and clients B. Verify that client has reviewed the RKOs and introduction to Session 4 C. Review of PALS assignments for Session 4 D. *CARE RA* Highlights of Session 4 E. <u>Making a plan:</u> A. Getting cholesterol test - Rheumatologist? - Primary Care Physician? B. Doing something with the results - Who will assess the CVD risk? - Who will manage cholesterol if CVD is high? C. Once you find out you have a test (feasibility): - Make a plan for determining 10-year CVD risk - Make decision for initiation of statins F. Rehearse script to request a cholesterol test G. Plans for Session 5 H. PALS assignments for Session 5 I. Schedule Session 5 call	<u>*Required:*</u> - How can I talk with my doctor if they are in a rush? - What medications are used to treat high cholesterol? - Do statins lower my chances of blood pressure related problems like heart disease and stroke? - When do I have to start taking medicine to treat high cholesterol? - Can rheumatoid arthritis (RA) medications lower my risk for heart attacks and stroke? - Do I need to prepare for a cholesterol test? <u>*Learn more*</u>*:* - Can I take my rheumatoid arthritis (RA) medication with statins? - What are some common side effects of statins?
5. "How Did it Go?"	1. To discuss how the encounter with the rheumatologist or other physician on their care team was regarding having a cholesterol test done 2. To learn more about how exercise and diet can help people with RA lower their cholesterol. 3. To establish plans for follow up with a primary care physician for possible initiation of statins	A. Greetings between coaches and clients B. Verify that client has reviewed the RKOs and introduction to Session 5 C. Review of PALS assignments for Session 5 D. *CARE RA* Highlights of Session 5 E. Discussion about the visit with the doctor F. Emphasize importance of following up with PCP G. Final questions and closure <u>Note:</u> Client should have completed the form with all the information for the 10-year pooled cohort risk equation.	<u>*Required:*</u> - What foods can help lower my cholesterol? - What is a healthy diet or eating pattern? - Can exercise help my rheumatoid arthritis (RA)? - Does exercise lower my risk for heart attacks and stroke if I have rheumatoid arthritis (RA)? - How can I exercise when I am in pain? - What should I expect when I receive the results of a cholesterol test? <u>*Learn more*</u>*:* - Can exercise make my rheumatoid arthritis (RA) symptoms worse? - What foods can help improve my rheumatoid arthritis (RA)? - What are the benefits of exercise?

7.3 Baseline telephone call (All subjects in the study)

The blinded research assistant will perform this call. Assessments at this phone call will include:

- Verify that subjects have completed the baseline data collection forms sent via email through REDCap:
    - Demographic data including gender, and race and ethnicity
    - RA history
    - General medical history
    - Surgical history
    - Surveys
        - RAPID3
        - Social Support Survey
        - Patient Activation Measure (PAM)
        - Patient Health Questionnaire – 8 (PHQ- 8)
        - The General Self-Efficacy Scale (GSF)
        - Medication Understanding and Use Self-Efficacy Scale (MUSE)

7.4 Post-intervention completion data collection point (All subjects in the study)

This call will take place around a week after completing the intervention by the blinded research assistant. This is a data collection call for all subjects in the study.

- **Surveys**
    - RAPID3
    - Social Support Survey
    - Patient Activation Measure (PAM)
    - Patient Health Questionnaire – 8 (PHQ- 8)
    - The General Self-Efficacy Scale (GSF)
    - Medication Understanding and Use Self-Efficacy Scale (MUSE)
- **Outcomes**
    - Cholesterol test
    - Initiating lipid lowering therapy
- **Program Evaluation**
    - Evaluation Survey
    - Focus Group/Interview

7.10 3-month post-intervention completion data collection point (All subjects in the study)

This call will take place around 3 months from completing the intervention by the blinded research assistant. This is a data collection call for all subjects in the study.

- **Complete patient generated health data (PGHD)**
    - RAPID3
    - Social Support Survey
    - Patient Activation Measure (PAM)
    - Patient Health Questionnaire – 8 (PHQ- 8)
    - The General Self-Efficacy Scale (GSF)
    - Medication Understanding and Use Self-Efficacy Scale (MUSE) Outcomes

- **Outcomes**
    - Cholesterol test
    - Initiating lipid lowering therapy

8. ANALYSIS AND STATISTICS

8.1 Power Calculations and Sample Size

The primary outcome measure is the percentage of patients in each arm that had a lipid panel checked or initiated LLT. Assuming 80% of the subjects in the intervention group have their lipids checked within the 3 months of the study, and 60% of the subjects in the control group have their lipid checked N=64 subjects per group would have at least 80% power to detect a margin difference of 20%, for a one-sided test and significance level of 0.05. We recognize that the sample of 128 subjects is modest, which reflects the pilot nature of the study in the context of a training grant. We will use data from this pilot study to design a more definitive trial powered to detect smaller differences in the primary outcome, and to compare usual care with the intervention.

8.2 Data Analysis

To analyze the data, descriptive analyses (means, medians, standard deviations, proportions, and frequency distributions) and correlation analyses (Spearman/Pearson rank correlations) will be conducted to assess and describe the cohort. Baseline comparability between study arms will be assessed with parametric and nonparametric analyses including two sample t-tests, Wilcoxon Rank Sum, and Chi-Square tests of proportions. Every effort will be made to keep subjects in the study for the entire follow-up. Analysis will be based on intention-to-treat, regardless of whether the subject completed the intervention program. The primary outcome is the percentage of patients with lipids checked (available now through national laboratory chain) or that reported having their lipids checked. Secondary outcomes include the percentage of subjects that reported initiating LLT, self-efficacy, and patient activation as described above. We will determine these outcomes in each group (self-administered online learning program and the CARE RA arm) as well as differences in these outcomes between the groups. Two-sided t-tests will be used to calculate differences and P values ≤ 0.05 will be considered statistically significant. We will examine differences in socio-demographics, disease severity, and depressive symptoms. These characteristics will be included in a multivariable logistic regression model to determine their association with the outcome (lipids being checked) and potentially increase the statistical power of the test of group differences.

9. PROGRAM EVALUATION

We will use the RE-AIM Framework for the evaluation of the program. The investigators of CARE RA will use these set of questions within Table 4 to evaluate the CARE RA program with the participants of the program and to guide the approach that investigators will follow to evaluate the reach, effectiveness, adoption, implementation, and maintenance of the program. This will help in the expansion of the program for a larger clinical trial.

Table 4: RE-AIM Evaluation Dimensions for the Cardiovascular Risk Reduction Program for Patients with Rheumatoid Arthritis.

Dimension*	Level
REACH	**Individual Level** -What percentage of potentially eligible subjects decided not to participate? -What percentage of potentially eligible subjects were excluded? -What percentage of potentially eligible subjects were enrolled in the program? -How representative of the target population were the subjects that were enrolled? -What proportion of subjects agreed to participate out of the total number of those that were invited and met criteria? -What factors contributed to the participation/non-participation of the subjects? -What might have been done to get more of the target population to participate? REACH will be assessed using our REDCap enrollment data, surveys, and focus groups or interviews. Through REDCap, we will be able to determine how many subjects were contacted through ArthrisPower, screened, and enrolled, compared to the overall number of subjects that completed the program. Surveys, focus groups, and interviews will allow us to determine factors that contributed to the use of the program. Through the surveys, focus groups, and interviews, we will conduct a qualitative analysis with subjects in the program so that we can obtain feedback on the reason's subjects chose to participate initially in the program, barriers they faced in enrolling in the program, and reasons why they chose to join or not to join the program.
EFFECTIVENESS	**Individual Level** -How many subjects in the CARE RA arm received a cholesterol test during the program compared to the control arm? -How many subjects in the CARE RA arm received a cholesterol test by 1-week post intervention follow up compared to the control arm? -How many subjects in the CARE RA arm received a cholesterol test by 3-months post intervention follow up compared to the control arm? -How many subjects in the CARE RA arm initiated a statin, if indicated, after completion of the program in each arm? - See statistical analysis section for details. -How many subjects saw an improvement in their secondary outcomes (RAPID3, SSS, PHQ-8, PAM, MUSE, and GSE) from baseline to 1-week and 3-month post intervention data collection between arms? -Were you able to understand the program information? -Do you believe the program information is valuable to living a healthy life?
ADOPTION	**Organization Level** -What factors contributed to ArthritisPower and its members, and the Bendcare network, to taking up the intervention? -What barriers interacted with the intervention to prevent adoption within ArthritisPower and the Bendcare patient network? ADOPTION will be assessed upon completion of the trial through talking with members of the ArthritisPower community and the Bendcare patient network.

IMPLEMENTATION	**Individual Level** -To what extent were the intervention components delivered as intended in the protocol? -How was the intervention implemented? By whom and when? -How was the program adapted or modified over time? -What was it like to deliver this program to individuals with rheumatoid arthritis? -What do you think was most successful? What were the major barriers in implementing this program? -What was it like to conduct the weekly sessions? -Would you do anything to revise the program? -Does the program improve my ability to deal with life's challenges to my health. -Does using the program makes it easier to live a healthier life? -Is the program useful in my life? -How satisfied are you with the program? -Was participating in the program difficult for you? -Would you recommend the program to people you know? This dimension will be assessed through surveys and focus groups/interviews with the subjects.
MAINTENANCE	**Organizational and Individual Level** - What was the attrition rate; were drop-outs representative of the target population? - How did attrition impact conclusions about effectiveness? - Is this intervention being implemented (and adapted) after the pilot study is completed? - What elements of the program are sustained for continuation of the program and why? - What elements of the program are discontinued for continuation of the program and why? - What elements of the program are modified for continuation of the program and why? - How do certain elements, such as using peer coaches instead of licensed professions and internet delivery, impact program continuation? This dimension will be assessed through surveys and focus groups/interviews with the subjects.

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