

The Design and Implementation of a Heart Disease Reversal Program in the Veterans Health Administration: Before and During the COVID-19 Pandemic

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Background: Heart disease continues to be the leading cause of death in the US, and the number of people with cardiovascular disease (CVD) is rising. CVD is more prevalent among military veterans than nonveterans, and veteran status is associated with higher risk of incident heart disease after controlling for socioeconomic status, other medical diseases, depression, and lifestyle. Many patients seeking care in the Veterans Health Administration, including those who undergo cardiac catheterization, meet the criteria for multimorbidity (defined as ≥ 2 chronic diseases).

Observations: The Heart Disease Reversal Program (HDRP) is a novel interdisciplinary, multicomponent lifestyle program at the US Department of Veterans Affairs (VA) Sacramento VA Medical Center. This program is a streamlined adaptation of

behavioral/lifestyle interventions aimed at promoting partial reversal (regression) of atherosclerotic heart disease and achievement of comprehensive cardiovascular risk reduction. HDRP was developed and implemented within a VA behavioral medicine clinic and successfully adapted for delivery through videoconferencing during the COVID-19 pandemic. Patient satisfaction survey data indicate a very high level of patient acceptability. We found direct-to-patient clinical outreach an effective method for launching a disease reversal program.

Conclusions: Beyond the clinical benefits to patients, there is significant value and benefit added to the health care system by offering an intervention within the disease reversal paradigm. Efforts of the health care team to reverse a disease can be considered the highest aim of medicine and health care.

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While cardiovascular mortality rates have declined, heart disease continues to be the leading cause of death in the US, and the number of people with cardiovascular disease (CVD) is rising.¹ CVD is more prevalent among military veterans than it is among nonveterans aged ≥ 25 years, and veteran status is associated with higher risk of incident heart disease after controlling for socioeconomic status, other medical diseases, depression, and lifestyle.²⁻⁴ Combat exposure, posttraumatic stress disorder (PTSD), and Purple Heart commendation are associated with higher rates of CVD, including adverse cardiovascular events.⁵⁻⁷ Many patients seeking care in the Veterans Health Administration (VHA), including those who undergo cardiac catheterization, meet the criteria for multimorbidity (defined as having ≥ 2 chronic diseases⁸), which is common among veterans.^{9,10} Multimorbidity presents a challenge for lifestyle intervention, as different diets may be prescribed to treat different conditions, such as Dietary Ap-

proaches to Stop Hypertension, and low-glycemic diet for diabetes mellitus (DM). Veterans with CVD are often clinically complex and may require more multifaceted secondary prevention programs.

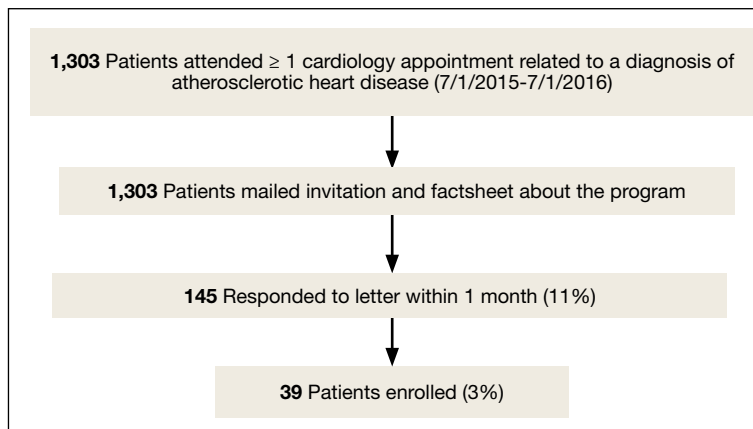
During the coronavirus 2019 (COVID-19) pandemic, effective secondary prevention intervention is needed more than ever. Older age, CVD, and common comorbidities, including hypertension, DM, and obesity, place patients at the highest risk for severe COVID-19 infection.¹¹ COVID-19 social distancing encourages vulnerable populations to stay home, which can make engaging in any levels of physical activity more challenging. The International Food Council found that 85% of adults have made a change to their food consumption pattern, including eating more, during the COVID-19 pandemic.¹² Thus, secondary CVD prevention programs for veterans need to provide treatment that addresses these specific challenges and can be delivered via telehealth for continuity of care after disruption of traditional services.

Clinical practice guidelines for the treatment of patients with recent cardiovascular

adverse events (AEs) include a referral to cardiac rehabilitation (CR).¹³ CR emphasizes exercise as the main intervention, along with coaching to promote multiple risk reduction. The most comprehensive CR program is intensive CR (ICR), including the Ornish ICR program.¹⁴ ICR includes 4 components: vegetarian diet, exercise, stress management (yoga, meditation), and group support. Ornish ICR has been shown to be efficacious in randomized controlled trials (RCTs).¹⁵⁻¹⁷ Three effectiveness studies, with 5,372 participants, demonstrated the real-world effectiveness of Ornish ICR in US hospitals.^{14,18,19} The program also was adapted successfully for the active-duty military and veteran population.^{20,21} Yet Ornish ICR is time intensive, and there are no certified VHA ICR Ornish sites. Furthermore, there is no formal strategy for targeting people with atherosclerotic CVD who no longer meet the criteria for CR or ICR. While Ornish ICR is highly effective for patients who are eligible and have access, a more effective and streamlined approach is needed for targeting many patients.

Nutrition may be the most powerful Ornish ICR component. The initial RCT conducted by Ornish and colleagues included only stress management training and a whole-food, plant-based (WFPB) diet, including grains, legumes, vegetables, fruits, nuts, and seeds. The trial found 91% of participants experienced reduced angina after only 24 days.¹⁵ The only single-component intervention study resulting in partial reversal of atherosclerosis was a WFPB diet-only study, which documented regression of atherosclerotic plaques after 5 years, using coronary angiography in 73% of participants, with arrested progression in the other 27%.²² Participants reported no cardiovascular AEs after 12 years.²³ Furthermore, a number of other recent studies have demonstrated the benefits of WFPB diet-only interventions for type 2 DM (T2DM), hypertension, and obesity.²⁴⁻²⁷ The Heart Disease Reversal Program (HDRP) was developed to create an interdisciplinary lifestyle intervention that emphasized nutrition for a broad population of veterans with atherosclerotic CVD, of varying levels of functional ability, to promote comprehensive CVD risk reduction and bring heart disease reversal intervention into routine clinical practice.

FIGURE Outreach to Determine Patient Interest in the Heart Disease Reversal Program



PROGRAM DESCRIPTION

The Mental Health, Cardiology, and Nutrition and Food services all approved the launch of HDRP. We contacted veterans by mail, and 11% expressed interest (Figure). Among patients who received the initial mailed letter (prior to our accepting staff referrals), only 5% of patients who enrolled in HDRP reported previously being told about or prescribed a WFPB diet by any health care provider (HCP). Currently, patients are primarily referred to HDRP by Cardiology, Primary Care, and Mental Health services.

Design

HDRP is an adaptation of interdisciplinary lifestyle interventions that have resulted in regression of atherosclerotic blockages confirmed with invasive coronary angiography.^{15-17,22,28} HDRP currently is offered in a Behavioral Medicine Clinic at the Sacramento US Department of Veterans Affairs (VA) Medical Center (VAMC) in California. Program staff include a clinical health psychologist who organizes, coordinates, and act as the lead facilitator of the program; registered dietitians; clinical pharmacists; and a consulting physician. Patients engage in the 4-month core HDRP program in small cohorts (ie, 6-10 patients), and spouses/partners are highly encouraged to attend all sessions.

Components

Telephone screening. Patients are screened for the inclusion and exclusion criteria

TABLE 1 Criteria for Patients Participating in Heart Disease Reversal Program

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> • Diagnosis of atherosclerotic heart disease • Myocardial infarction, or coronary artery bypass graft grafting surgery, or percutaneous cardiac intervention • Patient expresses interest in engagement in a behavioral/lifestyle intervention 	<ul style="list-style-type: none"> • Chronic kidney disease (stages 4-5) • History of bariatric surgery • Recent hospitalization due to CHF exacerbation • Pattern of repeat CHF-related hospitalizations in the past 6 months • Dementia • Behavioral flag (category 1) for recent disruptive behavior at Veterans Health Administration appointments

Abbreviation: CHF, congestive heart failure.

(Table 1). Patients engaging in a traditional CR program are included in the screening. Patients are informed that the program consists of lifestyle intervention, including emphasis on following a WFPB diet.

Health assessment. Once approved, all patients are instructed to complete baseline laboratory tests and questionnaires. Along with an electronic health record (EHR) review, a psychosocial assessment is completed by a licensed clinical health psychologist who assesses CVD history, eating behavior, exercise/physical activity, sleep, mental health, substance use, and social history, with the aim of enhancing our ability to help the patient to benefit from HDRP.²⁹ The patient data are used to develop a case conceptualization (ie, integrated understanding of the particular patient's psychiatric and medical diagnoses, behavioral patterns, social supports, lifestyle habits, strengths and weaknesses, and their interrelationships with each other and the patient's environment), resulting in an individualized plan. Patients are encouraged to ask questions about the program, and those who are still interested are invited to attend a seminar. A request for medical clearance to participate in the program is initiated through the EHR or by patients scheduling an appointment with their HCP. All patients are medically cleared by their HCP for participation. Safe exercise recommendations also are provided and guide patient goals.

CVD risk profile. Patients complete psychosocial questionnaires and fasting laboratory tests to produce a tailored CVD risk profile. Laboratory tests include fasting lipid, fasting glucose, hemoglobin A_{1c} (HbA_{1c}) C-reactive protein, vitamin B12, and vita-

min D. The same tests (excluding HbA_{1c}) are completed 1 month later (after completing 4 group sessions) and again posttreatment (including HbA_{1c}). Self-reported questionnaires are completed at the same time points, which include the Rate Your Plate dietary composition questionnaire, CHAMPS physical activity questionnaire for older adults, Beck Depression Inventory-II, and the Perceived Stress Scale.

Seminar. A 2-hour seminar provides patients and families with an opportunity to meet HDRP program staff, learn the background and rationale for chronic disease reversal, obtain a summary of the program, and hear a patient testimonial. Patients are asked to make a commitment, and the informed consent process includes all patients signing a behavioral contract.

Assessment and feedback. A licensed clinical health psychologist provides feedback to patients on their comprehensive CVD risk profile, using motivational interviewing.^{30,31} Smokers are encouraged to quit, and those interested are referred to their HCP and/or facility smoking cessation program.

Group sessions. Twelve weekly group sessions cover nutrition education and cooking, physical activity and exercise, stress management training, and medication reconciliation and adjustment. The nutrition component is the centerpiece of HDRP and is delivered by registered dietitians (Table 2). Patients are instructed to use the 3-week period between the HDRP seminar and the first core group session to try new recipes and prepare their kitchens, pantries, and mind-set to adopt the HDRP diet with 100% adherence. The WFPB diet used is consistent with the current guidelines of Caldwell Esselstyn, MD, and Dean Ornish, MD.³²⁻³⁴

A psychologist delivers the physical activity component. Patients are encouraged to meet the American Heart Association/American College of Cardiology recommendations for aerobic exercise (at least 150 minutes of moderate intensity physical activity per week) through a walking program.³⁵ Patients with medical contraindications (eg, severe pain, mobility restrictions) are encouraged to follow the exercise/activity recommendations they had been given by their primary care provider (PCP), physical therapist, or other HCP.

TABLE 2 Components of the Whole-Food, Plant-Based Nutrition Program

Topics	Guidelines	Education	Cooking	Common Modifications
Components	<ul style="list-style-type: none"> • Only eat whole unprocessed vegetables, fruit, whole grains, legumes, 1-2 tablespoons ground flaxseed, or 2 whole walnuts • Consume foods from each food group every day (legumes, grains, vegetables, fruit, nuts/ seeds) • Emphasis on more nutrient-dense plant foods • Emphasis on daily dark green leafy vegetable intake • Avoidance of animal-based foods (beef, poultry, fish, shellfish, dairy products) • About 10% of daily calories from fat, achieved through avoidance of added oils • Ad libitum (ie, eat to fullness) • No calorie counting • Vitamin B12 supplement for all participants (required for vegan diets) • Vitamin D3 supplement (if blood level is low) 	<ul style="list-style-type: none"> • Example meals, snacks, and beverages • Protein, vitamin, and mineral needs • Acceptable sweeteners • Debunking common dietary myths • Eating while traveling, in restaurants, and in social settings • Review of research on common diet fads and alternate diets 	<ul style="list-style-type: none"> • Knife skills and chopping/cutting technique • Oil free sauté/dry sauté • Steaming technique • Roasting technique • Using herbs and spices • Buying and storing foods 	<ul style="list-style-type: none"> • Limiting sugar and fruit intake in type 2 diabetes mellitus • Fluid restriction in congestive heart failure • Restricting high-purine foods for gout • Increasing calorie intake in near-underweight patients

A psychologist provides evidence-based cognitive behavioral stress management (CBSM) training, adapted from models developed for patients with stable ischemic heart disease, HIV/AIDS, and cancer.³⁶⁻³⁸ CBSM is a psychotherapy grounded in stress/coping theory and cognitive behavioral theory of psychopathology that integrates cognitive restructuring, coping skills training, communication/assertiveness training, anger management, and mindfulness/acceptance-based approaches. Additional emphasis is placed on assisting patients' adjustment to the lifestyle challenges for following a plant-based diet, dealing with food cravings and emotional eating, and connecting lifestyle change to patients' deepest values and goals.

A clinical pharmacist conducts a medication reconciliation for each patient at baseline. The pharmacist consults with each patient's PCP, cardiologist, and HDRP consulting physician, as needed, to ensure safe adjustments to medications. Pharmacists also provide education on medications at group sessions.

After completion of the 12-week core program, graduates are encouraged to attend the monthly graduates' group indefinitely, and as often as they desire to promote maintenance of the disease reversal lifestyle. Patients are encouraged to complete our recommended fasting laboratory work every 3 to 6 months to facilitate maintenance of treatment gains.

PROGRAM EVALUATION

Patients frequently reported that the group format was vital to their success. Patients re-

quested a cooking class, yet we lacked a full teaching kitchen. Integrating plant-based meal samples at every session and cooking videos helped. Patients reported that 100% adherence to the WFPB diet led to significant changes in their food preferences, including a loss of interest in meat.³⁹ Patients encouraged us to keep the "disease reversal" language and focus. One veteran stated: "Disease reversal, that is the reason I called you when I got your letter." Showing before and after images of coronary angiograms and cardiac positron emission tomography scans depicting regression of atherosclerotic plaque and restored myocardial perfusion were described as highly motivating and generated willingness to commit to a more aggressive lifestyle change.³¹

Patients routinely stated that they lacked understanding of their laboratory test results, which HDRP remedied. Some patients reported their adult children followed a plant-based diet, and our program resulted in a new commonality and source of bonding that was highly valued. Some patients reported that HDRP was helpful for controlling their COVID-19 anxiety and feeling in control of their health. Satisfaction surveys were completed by participants at the end of the core program, which demonstrated very high satisfaction with and acceptability of HDRP (Table 3).

The program also has received positive feedback from HCPs when we alert them to improvements in outcome measures for their patients. These HCPs expressed satisfaction

TABLE 3 Patient Satisfaction Survey (N = 40)

Survey Questions	Response
Rate your HDRP satisfaction, mean (SD) ^a	98.5 (5.8)
Rate the quality of the HDRP, mean (SD) ^a	97.4 (5.5)
Indicate how closely are you currently following the whole-food, plant-based, no-oil diet, mean (SD) ^a	89.6 (11.6)
Confidence in ability to follow the whole-food, plant-based, no-oil diet closely, mean (SD) ^a	94.3 (9.0)
Respondents indicating that they do not miss or crave animal-based foods (eg, meat, dairy), %	75
Respondents indicating that HDRP helped them feel more in control of their health, %	100

Abbreviation: HDRP, Heart Disease Reversal Program.

^aUsing a 100-point scale.

with having a program to refer patients to that can help with chronic illness in more depth.

COVID-19 Response

Face-to-face group appointments were converted to videoconferencing as a result of the COVID-19 pandemic. While HDRP always promoted the use of technology and mHealth tools, the pandemic led us to develop novel technology-based interventions.⁴⁰ One cohort transitioned from in-person to videoconferencing sessions, and 2 cohorts recently started this format and are ongoing. We have successfully used videoconferencing with Cisco Webex, the VA-approved backup platform, as we encountered technical barriers when using VA Video Connect. Program materials were shared electronically, and participants sent blood pressure/sugar logs by secure messaging. Guidance for online grocery shopping with home delivery was provided, and research on the benefits of the HDRP lifestyle on immune function was incorporated.

The stress management component incorporated coping with COVID-19, including normalizing common emotional difficulties with sheltering-in-place and quarantine, acknowledging and processing fear and anxiety related to being at very high risk for severe COVID-19. We presented heart disease reversal as an urgent and feasible goal during the pandemic both reducing risk of premature death and major adverse cardiovascular events in the long-term and also reducing personal risk of severe COVID complications. The new VA COVID Coach app was also presented as a resource. Reputable sources of COVID-19 and public health

information were shared. Walking continued to be the primary recommended form of exercise, while indoor home exercise options were promoted during the periods of very poor air quality due to the widespread California fires and smoke.

Considering the research suggesting benefits of our intervention for treating T2DM, promoting sustained weight loss, and promoting comprehensive cardiometabolic risk reduction, we have begun accepting referrals for patients with any type of atherosclerotic CVD (eg, peripheral artery disease, carotid artery disease), patients with T2DM (without CVD), and patients with only a history of ischemic stroke or transient ischemic attack.²⁴⁻²⁷ Vascular surgery has become a new referral source, primarily for patients with peripheral and carotid artery diseases. Finally, we are leveraging videoconferencing and accepting referrals across the VA Northern California Health Care System (VANCHCS) catchment (from the California-Oregon state border to the San Francisco Bay Area). This also helps address a longstanding problem with reaching the many rural veterans who live far from a VA clinic. We successfully implemented a consult/referral process within the EHR that is available to providers across VANCHCS.

DISCUSSION

The efficacy and effectiveness of reversal programs are well established in intensive programs (eg, ICR), yet such programs have yet to be streamlined and disseminated broadly into routine clinical care. HDRP has endeavored to address this by emphasizing nutrition relative to other program components. We

have learned that the words “disease reversal” are very often the reason patients initially reach out or accept referral to our program.

Consistent with past research on plant-based nutrition interventions, the group format was indispensable.⁴¹ Individual sessions with a clinical health psychologist enabled tailored feedback and education on how behavior changes could impact laboratory results and how certain psychosocial factors could support success. Participants reported that seeing significantly favorable laboratory results was highly motivating and confirmed the power of their lifestyle changes. Furthermore, a psychosocial health assessment with individual sessions promoted a tailored treatment plan with targeted clinical interventions, such as behavioral health education, motivational interviewing, and advanced methods, including cognitive behavioral therapy and techniques drawn from dialectical behavior therapy and acceptance and commitment therapy.

Veterans with multimorbidity face the difficult task of learning and maintaining a complex disease self-management program and implementing a lifestyle approach that is feasible, effective, promotes weight loss, and treats multiple conditions. HDRP is a model approach for this population, as demonstrated by a recent case report of a 65-year-old male veteran with atherosclerotic CVD, T2DM, hypertension, and myasthenia gravis who had 2 heart attacks within 2 months.⁴² His neurologic disease precluded significant physical activity. Although he achieved some initial weight loss through lifestyle changes, he continued to have daily angina despite optimal and aggressive cardiology management. After enrolling in HDRP and adopting the WFPB diet, the patient reported almost complete resolution of angina within 1 month, similar to that found in other studies.¹⁵

The literature suggests that concern over the acceptability of plant-based diets and patients’ ability to adhere to them long-term may be misplaced. A review paper on dietary interventions lasting > 1 year found that 51 to 61% of vegetarian and vegan study participants had maintained dietary adherence, while 20 to 55% of omnivorous diet intervention participants adhered to their study diets.⁴³ Remarkably, there were no statistically significant differences in the acceptability

of the vegan, vegetarian, or omnivorous diets in the studies reviewed.⁴³ Recent dietary research also suggests that providing patients with higher goals (eg, adopting a vegan diet instead of only moderate dietary changes) results in greater weight loss and maintenance.²⁶ HDRP provides training on consumption of whole plant foods, which may offer patients a unique advantage for maximizing results and higher adherence over time.

Limitations

Hands-on cooking instruction was not provided at our VAMC. The total time of the intervention was significantly less in HDRP (25 hours) than it was for the Ornish ICR program (72 hours), which may hinder long-term adherence. Without an exercise facility, we were not able to provide more detailed exercise instruction and supervised exercise.

Program Improvements Planned

There are a number of improvements that are planned for HDRP. First, the program anticipates requesting medical clearance at the telephone screening stage for self-referred patients. Second, HDRP will provide regular presentations on the program to VAMC clinics and community-based outpatient clinics, including reminders about inclusion/exclusion criteria and the referral process, and to solicit feedback on processes. Third, we hope to routinely provide education and address common questions and concerns of HCPs, including expected results. Fourth, we would like to lengthen the patient commitment to HDRP (eg, 1- to 2-year commitment to the graduate group), consistent with other HDRPs.²⁸ Fifth, we hope to further integrate technology-based components to promote behavior change/maintenance, such as automated text messaging.

CONCLUSIONS

Although our patient population was self-selected for participation, early program evaluation demonstrates high acceptability. Very few patients had ever been told about a heart disease reversing lifestyle, and we found direct-to-patient clinical outreach an effective method for launching a disease reversal program (optimally timed with HCP presentations). Furthermore, the program

is adaptable to current restrictions on in-person appointments due to the COVID-19 pandemic, and much more convenient for rural veterans who live far from any VA clinic. Being able to offer sustainable health care for individuals during unexpected public health crises is critically important. Additionally, treating veterans who are most vulnerable to pandemic illness due to existing medical conditions, such as CVD, should be a high priority. Last, HDRP also may represent a novel integrated treatment for COVID-19 anxiety and secondary CVD prevention, as lifestyle habits are optimized to improve chronic diseases that elevate risk for severe COVID-19 infection and mortality, as well as including coping strategies consistent with evidence-based psychotherapies for anxiety disorders.⁴⁴

We believe that beyond the clinical benefits to patients, there is significant value and benefit added to the health care system by offering an intervention within the “disease reversal” paradigm. Efforts of the health care team to reverse a disease can be considered the highest aim of medicine and health care.⁴⁵

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Disclaimer

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