



## Results of a prospective cardiovascular disease prevention program

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### ARTICLE INFO

#### Keywords:

Cardiovascular disease  
Cardiovascular risk  
Prevention  
Behavioral intervention  
Therapeutic lifestyle change

### ABSTRACT

The Cardiovascular Health Program (CHP) Registry is a 12-month, prospective study of therapeutic lifestyle change (TLC). Adult participants received comprehensive assessment of health behaviors and cardiovascular disease (CVD) risk factors. Personalized TLC action plans addressed modifiable health behaviors for diet, exercise, stress management, and sleep. Participants attended a half-day interactive workshop and met face-to-face with certified health coaches four times over 6 months. Monthly telephonic coaching for 6 more months completed the intervention. Measured outcomes included adherence to behavioral prescriptions, anthropometrics, CVD-relevant laboratory tests, and for a subset of participants, carotid intima-media thickness (CIMT). Of 965 participants, 648 (67%) completed the program and were included in the analysis. Participants were of mean age  $55.4 \pm 12.5$  years, 57% women, and racially diverse. Adherence to prescribed TLC was substantial: dietary behaviors at goal rose from 53% to 86%, exercise 44% to 66%, perceived stress 65% to 79%, and sleep quality 28% to 49%. For participants with abnormal anthropometrics at baseline, there were improvements in body mass index in 63%, waist circumference (men 71%, women 74%), systolic BP 69%, and diastolic BP 71%. For participants with abnormal laboratory values at baseline, there were improvements in total cholesterol in 74%, LDL-cholesterol 65%, triglycerides 86%, fasting glucose 72%, and insulin resistance 71%. Improvements were not driven by prescribed medications. CIMT improved or showed no change in 70% of those measured, associated with significant improvements in sleep quality and longer total sleep time. Longer trials incorporating controls and major adverse CVD events are warranted.

### 1. Introduction

Cardiovascular disease (CVD) is the leading cause of death in Western societies (Benjamin et al., 2019). Timely diagnosis of CVD and immediate lifesaving therapy have been the mainstay of cardiovascular care, but more recently CVD prevention has become a major strategy embraced by medical societies (Eckel et al., 2014; Arnett et al., 2019). CVD prevention begins with careful assessment of risk factors, especially those risk factors that can be modified by therapeutic lifestyle change

(TLC). Such lifestyle changes include the adoption of a heart healthy diet, regular exercise, stress management techniques, proper amounts of healthy sleep, and smoking cessation (Eckel et al., 2014; Arnett et al., 2019; Vongpatanasin, 2007; Pearson et al., 2002). TLC is especially appealing because it has potential to reverse the prevalence of CVD in a safe and cost-effective manner (Gaudet, 1998; Khera et al., 2016).

Experts agree that TLC can reduce CVD risk but the incorporation of preventive strategies into practice remains a formidable challenge (David, 2002; Ebrahim et al., 2006; Dunton, 2018). To date, there are

**Abbreviations:**  $\alpha$  Blocker, alpha blocker; ACEi, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker;  $\beta$  blocker, beta blocker; BMI, body mass index in kg/m<sup>2</sup>; BP, blood pressure; CCB, calcium channel blocker; CHP, Cardiovascular Health Program; CIMT, carotid intima-media thickness; CLIA, Clinical Laboratory Improvement Amendments; Dias BP, diastolic blood pressure in mm Hg; DPP4, mdeipeptidyl peptidase 4 inhibitor; ESS, Epworth Sleepiness Scale; FBG, fasting blood glucose in mg/dL; HOMA-IR, homeostatic model assessment for insulin resistance; IPAQ, International Physical Activity Questionnaire; IRB, institutional review board; LDL, low density lipoprotein; MACE, major adverse cardiovascular events; NDRI, nicotine and dopamine reuptake inhibitor; NP, nurse practitioner; PSQI, Pittsburgh Sleep Quality Index; PSS, Perceived Stress Scale; RYP, Rate-Your-Plate; SD, standard deviation; SARI, serotonin antagonist and reuptake inhibitor; SNRI, serotonin-norepinephrine reuptake inhibitor; SPSS, Statistical Package for the Social Science; SSRI, selective serotonin reuptake inhibitor; Statin, HMG-CoA reductase inhibitor; Sys BP, systolic blood pressure in mm Hg; TCA, tricyclic antidepressant; TLC, therapeutic lifestyle change; Tot Chol, total cholesterol in mg/dL; Trig, triglycerides in mg/dL; WC, waist circumference in cm.

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<https://doi.org/10.1016/j.pmedr.2021.101344>

Received 25 November 2020; Received in revised form 2 February 2021; Accepted 22 February 2021

Available online 12 March 2021

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few published reports of prevention models demonstrating improvement in outcomes that will ultimately translate into sustainable results (Hedbäck et al., 1993; Ornish et al., 1998; Espinosa Caliani et al., 2004; Edelman et al., 2006; Wood et al., 2008; Kadda et al., 2015; Gysan et al., 2017). There is a need to improve the integration of TLC into clinical practice (Li et al., 2018; Spring et al., 2014). With specialists in a variety of disciplines working together to identify CVD risks and empower patients with sustainable strategies to improve those risks, integrative medicine has shown promising results (Gaudet, 1998; Dunton, 2018). However, the full benefit of this type of systematic team-based intervention has yet to be realized.

It is noteworthy that sleep evaluation and sleep improvement have not been routinely incorporated into CVD risk assessment strategies or integrative medicine efforts to improve CVD risk. In view of epidemiological evidence of the association of sleep perturbations and incident CVD (Gottlieb et al., 2010; Hla et al., 2015; Geovanini et al., 2018; Javaheri et al., 2017), sleep parameters deserve to be included in a CVD risk reduction program.

The objectives of this Cardiovascular Health Program (CHP) Registry study were to evaluate a systematic, integrative model for cardiovascular wellness by measuring CVD risk factors and their response to the 12-month TLC intervention. The specific aims were to measure 1) changes in lifestyle behaviors of diet, exercise, stress management and sleep in response to the TLC intervention, 2) assess changes in CVD risk factors from study intake to study completion, and 3) measure change in carotid intima-media thickness (CIMT) before and after the intervention.

## 2. Methods

The CHP Registry study was a prospective, single-armed, before and after intervention trial that enrolled participants from 2006 to 2015. Study participants were comprised of adults eligible for care in the military health care system who were self-referred or referred by a provider for CVD risk reduction. Participants received the 12-month intervention—on-site health coaching over approximately 6 months followed by off-site telephonic coaching over approximately 6 months. The CHP Registry protocol was approved by the local IRB and was registered in clinicaltrials.gov (ID NCT01975181). All participants gave written, informed consent to be part of this research study. The study was performed in accordance with the principles of the Declaration of Helsinki.

Inclusion criteria included age of at least 18 years, confirmed military health care system eligibility, and an ability to understand and complete health questionnaires. Exclusion criteria were inability or unwillingness to give informed consent for the CHP Registry study, suspected or known pregnancy or plans to become pregnant during the subsequent year, previous participation in a comprehensive TLC-type program, and known diagnosis with life expectancy less than 5 years. Latter diagnoses considered to be exclusionary were assessed somewhat subjectively but included conditions such as neoplasms unresponsive to further therapy or life-limiting conditions entering the terminal phase of

their expected course.

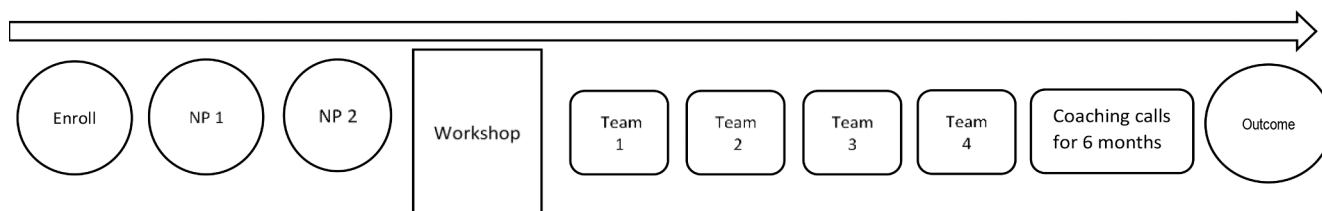
Participants completed questionnaires to gather information on demographics and lifestyle behaviors regarding diet, exercise, perceived stress, and sleep. See Fig. 1. Since all participants received care in the military health care system, their electronic health records were accessible to nurse practitioners of the CHP to survey for conditions previously diagnosed by a health care provider. During a first face-to-face appointment with the NP (NP1), the lifestyle behavior health questionnaires were reviewed with the participants for completeness and accuracy. Participants also underwent focused physical examination with anthropometrics, and cardiovascular-relevant laboratory tests during the first NP appointment. The physical examination included routine vital signs, a head to toe survey not including genitalia or rectum. Blood pressure measurements were taken with the patient seated after resting for at least 5 min and repeated 5 to 10 min later. The two blood pressure values were then averaged for the purposes of the study. Height was measured with shoes off. Weight was measured with street clothes on, shoes off, and pockets emptied.

A subset of participants (2012 to 2015) also underwent carotid ultrasound for measurement of CIMT. Participants and their primary care providers were made aware of all results of these evaluations. The NP established a collaborative relationship with the participants and determined each participant's personal TLC goals in the program.

Recognizing that behavioral interventions that have a theoretical foundation are more likely to be effective than those without such an underpinning, the CHP utilized principles of Social Cognitive Theory (SCT) which describes the interaction between personal factors, behaviors and the environment (Bandura, 1986). People learn through their own experiences and their observations of others' experiences by seeing the results of their actions. Through observational learning and reinforcement, people learn self-control, self-efficacy, usefulness of goal setting and self-monitoring.

The integrative approach to the CHP was based on four pillars of optimal health: diet, exercise, stress management and sleep improvement. After a comprehensive assessment of patient risk factors and the identification of any pre-clinical chronic disease, an individualized integrative action plan was developed by the multi-disciplinary team of a nurse practitioner, nutritionist, exercise physiologist, stress management counselor, sleep specialist and cardiologist. The integrative action plans were focused on guiding participants to make realistic, personalized, and practical behavior/lifestyle changes linked to clinically-relevant outcomes. The integrative action plans were an adjunct to usual interventions of the primary care providers and were intended to augment existing medical care by assisting participants to reach widely-accepted goals for optimal health. The integrative action plans incorporated guidelines from the American Heart Association (Arnett et al., 2019), Academy of Nutrition and Dietetics (Millen et al., 2014), American College of Sports Medicine (Haskell et al., 2007), and Centers for Disease Control and Prevention (2017).

During a second meeting with the NP, anthropometric and laboratory test results were reviewed with the participant. The NP also



**Fig. 1.** Pictorial flow of the 12 month CHP Registry Intervention. At enrollment, patients complete demographic and health behavior questionnaires. Questionnaires are reviewed at first visit with nurse practitioner (NP1) and CV pertinent physical exam is performed. Between NP1 visit and NP2 visit, an integrative team meets to develop a personalized TLC plan. At NP2, results of tests and TLC plan are reviewed with the patient. The half day workshop includes education and experiential sessions with healthy cooking and stress reduction. At monthly intervals, team appointments are held with certified motivational coaches to maintain patient investment and to manage impediments to TLC. After 6 months of the intervention, patients enter 6-month phase of coaching calls to maintain their improvements.

presented the integrative action plan highlighting a roadmap for achieving their personal goals. Participants then attended a half-day interactive, educational workshop which focused on providing actionable and practical information on the four pillars of health. Participants were referred for more detailed testing or consultation when further evaluation was indicated by findings of the questionnaires or lab test results. Such referrals included cardiac stress testing, polysomnography, or consultation with other specialists (e.g. endocrinology, psychiatry).

Over 4 to 6 months following the workshop, the intervention consisted of a series of 4 team appointments with the health coaches who were subject matter experts in dietetics, exercise, stress management, and sleep. These subject matter experts were certified motivational coaches who implemented and reinforced specific lifestyle prescriptions with the participants. After the 4 on-site team coaching appointments, the intervention continued with monthly motivational telephone calls with the NP and health coaches to solidify gains made during the on-site portion of the intervention.

The prescriptions for lifestyle change reflected recommendations of major medical societies. For diet, patients were encouraged to embrace a Mediterranean style of eating with emphasis on whole grains, vegetables, fruit, and nuts with limited red meat, limited sodium and saturated fat, and modest intake of alcohol (de Lorgeril et al., 1999; Rees et al., 2019). Participants who were overweight or obese were further urged portion control, attention to stress eating, and being mindful of hunger and satiety cues (Javaheri et al., 2017). Exercise prescriptions offered a balance between aerobic and strength-based exercise, aiming for at least 150 min of moderate-intensity exercise per week and selected by the individual participant to be sustainable (Haskell et al., 2007). Stress management techniques were taught and subsequently reinforced with an expert instructor who encouraged techniques of visual imagery, diaphragmatic breathing, and progressive muscle relaxation that were enhanced by playing recorded audio programs with verbal instruction or calming music. Participants were also taught the use of a “tension tamer”, a 5 to 10 min stress reduction technique to be employed as needed for particularly stressful periods of the participant’s day (Kashani et al., 2012). Sleep prescriptions were individually tailored to address the environment and timing of sleep to include a “power-down period” before bed, regularity of bed and wake times, and planning adequate time for sleep. The sleep prescriptions utilized principles outlined in cognitive-behavioral therapy for insomnia.

At study end, participants repeated the completion of questionnaires on lifestyle behaviors regarding diet, exercise, perceived stress, and sleep. Participants also underwent repeat anthropometrics, had cardiovascular-relevant laboratory tests and repeated CIMT measurement. Outcome measures included changes in lifestyle behaviors, CVD risk factors, and CIMT between entry to and completion of the CHP Registry study. Changes in prescribed medications were also recorded.

The time commitment by staff members of the integrative CVD prevention team included tasks to prepare for participant visits as well as conducting the face-to-face appointments. The NPs generally required 3 h of preparation time and 4 h of face-to-face appointment time for each participant over the course of the year-long intervention. Each of the four team appointments (See Fig. 1) included an hour each with the dietitian, exercise coach, and stress management/sleep coach. Participation by staff members in the interactive workshop included 40 min presentations and a 90 min heart-healthy lunch demonstration by the dietitian. The follow-up motivational coaching calls were conducted by the NP or the specialty health coaches and required up to 20 min per call, once per month for the 6 month follow-up period.

## 2.1. Questionnaire tools utilized

### 2.1.1. Diet

The Rate-Your-Plate (RYP) questionnaire (Gans et al., 2000) is a simplified food-frequency questionnaire focusing on foods contributing the most fat, saturated fat, and cholesterol to the American diet. RYP was

developed in the late 1980s and has been updated several times to reflect changes in national dietary recommendations. This dietary assessment questionnaire consists of 26 questions about weekly eating habits that are scored as: 3 points for healthy choices, 2 points for choices that indicate there are some ways to make eating habits healthier, and 1 point to indicate that there many ways to make eating habits healthier. Summed points range from a least healthy score of 26 to a most healthy score of 78 points. This questionnaire was used with permission of the copyright owner.

### 2.1.2. Exercise

A modification of the International Physical Activity Questionnaire (IPAQ) (Hallal and Victora, 2004) was utilized. Participants were asked, “How many minutes of intentional exercise (in continuous ten minute increments) do you average per week? Examples include—brisk walking, jogging, swimming, biking, exercise class, or aerobic equipment such as treadmill, elliptical, or bike.”

### 2.1.3. Stress

The Perceived Stress Scale (PSS) (Cohen et al., 1983) is a validated 14-item questionnaire asking the subject how often certain experiences of stress occurred in the last month and is designed to measure the degree to which situations in one’s life are appraised as stressful. With item responses from 0 to 4, the range of possible scores is 0 to 56 with higher scores correlating with higher stress. The PSS is designed for use in members of the community who have at least a junior high school education. The items are easy to understand and the response alternatives are simple to grasp. The questions are quite general in nature and relatively free of content specific to any particular group. Scores in the low 20’s reveal moderate stress levels, whereas scores approaching 30 are substantial.

### 2.1.4. Sleep quality

The Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989) is a self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. Nineteen individual items generate seven component scores whose sum yields one global score with a range of 0 to 21. The psychometric and clinical properties of the PSQI suggest its utility in both clinical practice and research activities. A global score of greater than 5 indicates a poor sleeper. Sleep perturbations can be categorized by scores: 0 to 5 is a good sleep score, 6 to 10 shows mild sleep difficulty, 11 to 15 moderate sleep difficulty, and 16 to 21 severe sleep difficulty.

### 2.1.5. Sleepiness

The Epworth Sleepiness Scale (ESS) (Johns, 1992) is the most widely used tool to estimate the subjective symptom of daytime sleepiness. Subjects are asked to use a scale of 0 to 3 to estimate their likelihood of dozing in eight different situations in recent weeks. The individual scores are summed and possible scores range from 0 to 24. Sleepy subjects score 11 or higher and sleepiness can be categorized by scores: 11 to 14 mild sleepiness, 15 to 19 moderate sleepiness, and 20 to 24 severe sleepiness. This questionnaire was used with permission of the copyright owner.

### 2.1.6. Fatigue

The visual numeric Fatigue Scale (Fatigue Visual Numeric Scale, 2020) is available in the public domain. The Fatigue Scale asks subjects to express their experience of fatigue from 0 to 10 for the previous 2-week period. Subjects who circle 5 to 6 express mild fatigue, 7 to 8 moderate fatigue, and 9 to 10 severe fatigue.

### 2.1.7. Sleep apnea

The well-validated Berlin Questionnaire (Netzer et al., 1999) assesses persistent and frequent symptoms that suggest high risk for sleep apnea. Questions about symptoms demonstrated internal consistency

(Cronbach correlations, 0.86–0.92). With a positive Berlin Questionnaire, the sleep apnea was predicted with a sensitivity of 0.86, a specificity of 0.77, a positive predictive value of 0.89, and a likelihood ratio of 3.79. This questionnaire was used with permission of the copyright owner.

## 2.2. Laboratory measurements

All blood tests were performed in the CLIA-certified laboratory of our associated medical center laboratory. Blood was drawn for testing after confirming with participants that they had fasted since the evening meal on the previous night. As noted in Table 4, cutoffs for normal lipid values included <200 mg/dL for total cholesterol, <100 mg/dL for LDL cholesterol, and <150 mg/dL for triglycerides. Cutoffs for normal glucose metabolism were <100 mg/dL for fasting blood glucose and <2.8 for the homeostatic model assessment for insulin resistance or HOMA-IR. The HOMA-IR was calculated by the equation (glucose in mmol/L × insulin in mIU/mL)/22.5) with values ≥2.8 indicating insulin resistance.

## 2.3. Anthropometric measurements

Blood pressure values equal to or less than 120 mmHg systolic and 80 mmHg diastolic (120/80) were considered to be normal, while values equal to or greater than 140/90 were assessed as hypertensive. Blood pressures in the intermediate zone were labeled prehypertension (National High Blood Pressure Education Program, 2004).

Body mass index (BMI) was calculated as the weight in kilograms divided by the square of the measured height in meters. BMI values of less than 18.5 kg/m<sup>2</sup> are considered to be underweight. Values of 18.5 to 24.9 are categorized as normal weight, while values from 25.0 to 29.9 are called overweight, and 30.0 and higher are termed obese (CDC, 2020).

Waist circumferences were normalized by sex. For women, a waist circumference greater than 89 cm and for men, greater than 102 were considered to be abnormally increased (CDC, 2020).

## 2.4. CIMT measurement

Images were obtained by a sonographer on a single ultrasound machine (SonoSite MicroMaxx 3.4.3: Bothell, Washington) using a linear array 5 to 10 MHz transducer with standardized image settings, such as resolution mode, depth of field, gain, and transmit focus. The sonographer was blinded to other clinical data at the time of the sonogram imaging and interpretation. All sonograms were obtained with the participant in the supine position and head facing the contralateral side. Simultaneous electrocardiograms were recorded. The sonographer, also expert in the measurement of CIMT, used commercially available software (Sonocalc IMT, Bothell, Washington) for analyses. Intima-media thickness was determined from images of the far wall of the distal common carotid arteries (immediately proximal to the carotid bulb) and reported as the mean value for the bilateral measurements. The near (intima-luminal interface) and far (media-adventitial interface) field arterial wall borders were manually traced for measurement and averaged for mean CIMT (millimeters) across a 10-mm arterial segment. A mean CIMT measurement of greater than the 75th percentile cutoff value, based upon age and sex, in at least one carotid vessel was defined as an abnormal CIMT, as proposed by the American Society of Echocardiography Carotid Intima-Media Thickness Task Force (Stein et al., 2008). This cutoff value has been used in a prior large atherosclerosis outcomes study as its main outcome measure (Taylor et al., 2009).

## 2.5. Statistics

As the purpose of this study was to create a data registry to enable research on patients at risk for CVD, a sample size determination was not

performed. Descriptive statistics were performed using means ± standard deviations, and medians with ranges as appropriate. Changes in main outcome variables were evaluated using paired *t*-test for continuous variables and chi-square test for categorical variables. All tests were two-tailed and *p* values <0.05 were assumed to represent statistical significance. When multiple outcomes were measured simultaneously, Bonferroni correction was performed to account for multiple comparisons. Data were analyzed using Statistical Package for the Social Sciences (SPSS) and Excel (Microsoft Office 2013).

## 3. Results

Participants eligible for enrollment in the CHP Registry study included active duty military service members, their dependents, military service retirees and their dependents. Therefore a full range of ages, races, and both sexes were represented. Participants were majority women, majority white, and on average obese. A substantial number of participants had a family history of CVD as well as comorbid illnesses, especially dyslipidemia and hypertension. Only a modest number of participants had diabetes mellitus and coronary artery disease (Table 1).

Of 965 participants enrolled, 648 participants (67%) completed the program intervention. The 317 participants who opted out of the program were somewhat younger and had a higher BMI but opt outs were not significantly different by sex or by race (see Table 2). Reasons for opting out of the CHP Registry study were dominated by the category “Lost to Follow-Up” (41%), followed by geographical access (18%), lack of time (18%), and intercurrent medical issues (10%).

At baseline, a large majority of participants were overweight, had increased waist circumference, and had elevated blood pressure. Substantial numbers had elevated total cholesterol and LDL cholesterol, prediabetes, and insulin resistance (Tables 3 and 4). A small minority of participants (28, 4%) were active tobacco smokers who were referred for smoking cessation intervention offered by local medical resources.

After program intervention, a majority of participants showed that they were able to adhere to their integrative action plan, especially regarding diet, exercise, and stress reduction. However, only a minority of participants improved their total sleep time (Table 5). Of the participants who smoked at study onset (28 participants of 648 enrolled or 4%), only 12 (2%) continued to smoke tobacco at study completion. Due to the small numbers of smokers, further statistical assessment of

**Table 1**  
Demographics and Comorbid Illnesses.

	All subjects n = 648	Men n = 276 (43%)	women n = 372 (57%)	<i>p</i> value*
Age ± SD, years	55.4 ± 12.5	56.6 ± 12.8	54.5 ± 12.2	0.03
Race				
White	62%	69%	57%	0.43
African-American	29%	23%	34%	
Hispanic	4%	4%	4%	
Asian	2%	1%	2%	
Other	3%	3%	3%	
Family History of CVD	75%	73%	77%	0.38
Active Smoker	4%	6%	3%	0.17
Comorbid Illnesses				
Dyslipidemia	71%	81%	65%	0.054
Hypertension	49%	55%	45%	0.09
Obstructive Sleep Apnea	25%	38%	15%	0.001**
Depression	23%	20%	27%	0.96
Anxiety	21%	17%	25%	0.78
Diabetes Mellitus	11%	10%	12%	0.83
Coronary Artery Disease	11%	20%	5%	0.001**
Stroke	2%	3%	2%	0.46

\**p*-value for *t*-test between men and women.

\*\*statistically significant after correction for multiple comparisons.

**Table 2**  
Comparison of Baseline Characteristics for Program Completers vs Those Opting Out.

	Age (years)	Race (%)	Women (%)	BMI (kg/m <sup>2</sup> )
Program Completers (n = 648)	55.4 ± 12.5	62 W,29B,4L,2A,3O	57%	30.5 ± 5.5
Program Opt Outs (n = 317)	48.3 ± 13.3	59 W,28B,6L,3A,3O	51%	31.0 ± 5.7
p value	<0.001	0.95	0.48	0.01

BMI = body mass index, for race W = white, B = black, L = Latino, A = Asian, O = other.

**Table 3**  
Anthropometric Data at Baseline and Program Completion.

	all BMI n = 648	all WCmen n = 276	all WCwomen n = 372	all Sys BP n = 648	all Dias BP n = 648
Baseline, mean ± SD	30.5 ± 5.5	102.6 ± 12.6	97.6 ± 14.1	128 ± 14	80 ± 9
Completion, mean ± SD	29.4 ± 5.4	101.0 ± 11.9	95.0 ± 14.0	125 ± 14	78 ± 9
p value*	<0.001	<0.001	<0.001	<0.001	<0.001
#, % improved	391, 60%	173, 63%	262, 70%	370, 57%	356, 55%
BMI ≥ 25	n = 535, 83%	WCmen > 102, n = 126, 46%	WCwomen > 89, n = 231, 62%	Sys BP > 120, n = 440, 68%	Dias BP > 80, n = 290, 45%
Baseline, mean ± SD	31.5 ± 4.8	113.6 ± 8.9	105.9 ± 10.6	135 ± 11	88 ± 4
Completion, mean ± SD	30.8 ± 4.9	110.8 ± 8.9	102.7 ± 11.3	129 ± 13	82 ± 8
p value*	<0.001	<0.001	<0.001	<0.001	<0.001
#, % improved	335, 63%	89, 71%	170, 74%	305, 69%	205, 71%
#, % now normal	34, 6%	19, 15%	31, 13%	130, 30%	129, 44%

Baseline and completion values are expressed as mean ± standard deviation. \*p value for comparisons between values at baseline and program completion. All tests remain statistically significant after correction for multiple comparisons.

BMI = body mass index in kg/m<sup>2</sup>, WC = waist circumference in cm, Sys BP = systolic blood pressure in mm Hg, Dias BP = diastolic blood pressure in mm Hg.

tobacco use was not addressed.

Because the study was implemented as an adjunct to usual medical care, patients and their care providers were made aware of all questionnaire and laboratory test results. As a result, changes in medications were prescribed for various medical conditions. Careful documentation of medication changes showed that new medications and increased doses of medications occurred in only a very small proportion of participants: 7% of participants for dyslipidemia, 5% for blood pressure, 3% for diabetes or prediabetes, and 3% for depression (Tables 6–9).

At the completion of the intervention, substantial majorities of participants were documented to have objective improvements in body mass index, waist circumference, systolic and diastolic blood pressure, total cholesterol, LDL cholesterol, triglycerides, fasting blood glucose, and insulin resistance (Tables 3 and 4). When analyzing only subjects with abnormal findings at baseline, a greater proportion of participants showed objective improvements. The proportion of participants who converted to normal values was approximately 50% or less (Tables 3 and 4).

In order to obtain an objective, quantitative measure of atherosclerotic burden, CIMT was planned for each participant before and after the intervention. However, of 648 participants, CIMT was accomplished in only a subset consisting of 156 consecutive participants (24%) due to

**Table 4**  
Laboratory Data at Baseline and Program Completion.

	all Tot Chol n = 648	all LDL n = 648	all Trig n = 648	all FBG** n = 574	all HOMA** n = 574
Baseline, mean ± SD	187.0 ± 42.8	111.2 ± 34.8	116.6 ± 79.7	93.6 ± 10.1	2.7 ± 1.9
Completion, mean ± SD	180.6 ± 38.9	105.5 ± 32.8	104.59 ± 5	92.4 ± 10.4	2.6 ± 2.0
p value*	<0.001	<0.001	<0.001	=0.002	=0.013
#, % improved	362, 56%	354, 55%	377, 58%	300, 52%	320, 56%
<b>Tot Chol ≥ 200 n = 246, 38%</b>		<b>LDL ≥ 100 n = 389, 60%</b>	<b>Trig ≥ 150 n = 134, 21%</b>	<b>FBG ≥ 100 n = 141, 22%</b>	<b>HOMA ≥ 2.8 n = 211, 33%</b>
Baseline, mean ± SD	229.1 ± 29.7	133.0 ± 25.3	225.9 ± 111.8	106.8 ± 7.2	4.7 ± 1.9
Completion, mean ± SD	206.7 ± 35.7	119.0 ± 29.3	165.2 ± 84.9	100.7 ± 10.1	3.9 ± 2.9
p value*	<0.001	<0.001	<0.001	<0.001	<0.001
#, % improved	181, 74%	251, 65%	115, 86%	102, 72%	149, 71%
#, % now normal	105, 43%	90, 23%	73, 54%	72, 51%	74, 35%

Baseline and completion values are expressed as mean ± standard deviation. \*p value for comparisons between values at baseline and program completion. \*\*patients with diabetes excluded. Tot Chol = total cholesterol in mg/dL, LDL = low density lipoprotein in mg/dL, Trig = triglycerides in mg/dL, FBG = fasting blood glucose in mg/dL, HOMA = homeostatic model assessment for insulin resistance.

**Table 5**  
Changes in Behaviors and Associated Symptoms for all Participants (n = 648).

	Baseline (mean score, % at goal)	Completion (mean score, % at goal)	p value*	% of Subjects Improved from Baseline
<b>Rate-Your-Plate Dietary Score</b> (26 to 78 points)	60.9 ± 7.4 (53%)	66.6 ± 6.2 (86%)	<0.0001	85%
<b>Exercise Time</b> (≥150 min/week)	150.2 ± 138.4 (44%)	223.7 ± 182.4 (66%)	<0.0001	65%
<b>Perceived Stress Score</b> (0 to 56 points)	20.9 ± 8.7 (65%)	17.4 ± 8.1 (79%)	<0.0001	64%
<b>Pittsburg Sleep Quality Index</b> (0 to 21 points)	7.1 ± 3.9 (28%)	2.9 ± 3.6 (49%)	<0.0001	61%
<b>Sleep Duration</b> (hours/night)	6.3 ± 1.3 (41%)	6.6 ± 1.2 (50%)	<0.0001	44%
<b>Epworth Sleepiness Score</b> (0 to 24 points)	8.8 ± 4.9 (64%)	7.4 ± 4.6 (77%)	<0.0001	57%
<b>Fatigue Score</b> (0 to 10 points)	4.3 ± 2.4 (53%)	3.4 ± 2.3 (70%)	<0.0001	53%

\*Comparisons by paired t-test between means at baseline and completion. All tests remain statistically significant after correction for multiple comparisons.

difficulty hiring an ultrasonography technician. Of the 156 participants with CIMT measures, 132 (85%) were found to have CIMT above the 75th percentile and were therefore considered to be abnormal for age and sex. Of the 156 participants with CIMT measures, 91 (58%) showed regression of atherosclerosis, 18 (12%) showed stability in the CIMT measurement, and 47 (30%) showed worsening CIMT measurement.

Comparisons were made between the group with improved or stable CIMT and the group with worsened CIMT. There were no between group

**Table 6**  
Antihypertensive Medications in All Patients (n = 648).

Any BP Medication (n = 310 of 648, 52%)	BP Medications Taken	n (%)	
One Agent (n = 126, 41%)	Diuretic	37 (29%)	
	ACEi	32 (25%)	
	β Blocker	23 (18%)	
	ARB	16 (13%)	
	α Blocker	9 (7%)	
	Other	9 (7%)	
	Two Agents (n = 106, 34%)	Diuretic-ACEi	20 (19%)
		Diuretic-ARB	17 (16%)
		Diuretic- blocker	14 (13%)
		Diuretic-CCB	6 (6%)
ACEi-β blocker		10 (9%)	
ACEi-CCB		7 (7%)	
ARB-Other		16 (15%)	
Other		14 (13%)	
Three Agents (n = 60, 19%)		Diuretic-ACEi-β blocker or Diuretic-ARB-CCB	60 (19%)
		Usually α Blocker added	18 (6%)

During the 12 month intervention, 597 of 648 patients (92%) had no changes in BP medication; 19 (3%) decreased or stopped BP medication; 32 (5%) increased or started BP medication.

BP = blood pressure, ACEi = angiotensin converting enzyme inhibitor, β blocker = beta blocker, ARB = angiotensin receptor blocker, α Blocker = alpha blocker, CCB = calcium channel blocker.

**Table 7**  
Dyslipidemia Medications in All Patients (n = 648).

Any Lipid Medication (n = 248 of 648, 38%)	Lipid Medications Taken	n (%)
One Agent (n = 205, 83%)	Statin	193 (94%)
	Niacin	5 (2%)
	Fibrate	4 (2%)
	Other	3 (1%)
	Two Agents (n = 39, 16%)	Statin-ezetimibe
Statin-niacin		16 (41%)
Statin-fibrate		4 (10%)
Statin- ezetimibe-niacin		4 (1%)

During the 12 month intervention, 584 of 648 patients (90%) had no changes in lipid medication; 18 (3%) decreased or stopped lipid medication; 46 (7%) increased or started lipid medication.

Statin = HMG-CoA reductase inhibitor.

differences in improvements in diet score (p = 0.49), exercise minutes (p = 0.63), or perceived stress (p = 0.84). However, the group with improved/stable CIMT did show significantly greater improvements in sleep quality with PSQI improving 3.0 points while the group with worsened CIMT improved PSQI by only 0.8 points (p = 0.03). The change in sleep quality score was due to increased total sleep time in the stable/improved CIMT group who increased total sleep time by nearly an hour compared to the worsened CIMT group who increased total sleep by only 12 min (p = 0.05). See [supplemental Table 11](#).

To assess the effect of medications on the objective outcomes of the intervention, re-analysis of the outcomes data were performed on the subgroup of participants (n = 505) who had no change in prescribed medications. The outcomes were virtually identical to the larger group of all participants implying that the healthful changes in outcomes for weight, blood pressure, lipids, and glucose metabolism should not be

**Table 8**  
Diabetes Medications in All Patients (n = 648).

Any Diabetes Medication (n = 56 of 648, 9%)	Diabetes Medications Taken	n (%)
One Agent (n = 31, 55%)	Metformin	25 (81%)
	Pioglitazone	3 (10%)
	Glipizide	1 (3%)
	Insulin	1 (3%)
	DPP4	1 (3%)
Two Agents (n = 19, 34%)	Metformin-glipizide	9 (47%)
	Other	10 (53%)
Three Agents (n = 6, 11%)	Multiple regimens	na

During the 12 month intervention, 626 of 648 patients (97%) had no changes in diabetes medication; 4 (1%) decreased or stopped diabetes medication; 18 (3%) increased or started diabetes medication.

DPP4 = dipeptidyl peptidase 4 inhibitor.

**Table 9**  
Antidepressant Medications in All Patients (n = 648).

Any Antidepressant Medication (n = 100 of 648, 15%)	Antidepressant Medications Taken	n (%)	
One Agent (n = 74, 74%)	SSRI	30 (41%)	
	SNRI	12 (16%)	
	TCA	12 (16%)	
	SARI	6 (8%)	
	NDRI	6 (8%)	
	Other	3 (4%)	
	Two Agents (n = 21, 21%)	SSRI-plus other	na
	Three Agents (n = 5, 5%)	Various regimens	na

During the 12 month intervention, 618 of 648 patients (95%) had no changes in antidepressant medication; 10 (2%) decreased or stopped antidepressant medication; 20 (3%) increased or started antidepressant medication.

SSRI = selective serotonin reuptake inhibitor, SNRI = serotonin-norepinephrine reuptake inhibitor, TCA = tricyclic antidepressant, SARI = serotonin antagonist and reuptake inhibitor, NDRI = nicotine and dopamine reuptake inhibitor.

attributed to medication changes but rather to the intervention ([Table 10](#)).

#### 4. Discussion

The chief findings of the CHP Registry study were that TLC, implemented with an integrative, personalized action plan including behavioral prescriptions and supported by an interactive, educational workshop, and face-to-face coaching for six months, followed by six months of telephonic coaching, resulted in substantial improvements in CVD risk factors. The effect sizes of the TLC were impressive in view of the large majorities of participants who showed improvements and that up to 50% of participants reverted abnormal findings to normal. These results are especially noteworthy since the effects of medication changes in the study were found to be negligible.

Major factors that makes the CHP Registry study unique were its comprehensive evaluation with assessments by the multidisciplinary team to formulate action plans addressing a full array of CVD risk factors and health behaviors. The nurse practitioner utilized a systematic and reproducible protocol to incorporate the patient's family history information into risk stratification enhancing CVD risk assessment to identify previously unidentified patients at risk and identifying appropriate targets for therapy ([Kashani et al., 2015](#)). The CHP Registry study utilized an integrative, evidence-based, and patient-centric approach to empower and engage participants to reach their personal health goals. The CHP Registry model considered each participant's individual health, lifestyle, and psychosocial profile in the development of

**Table 10**  
Blood Pressure, Lipids, Glucose, HOMA for Patients with No Change in Medication during Intervention.

	all Sys BP n = 505	all Dias BP n = 505	all Tot Chol n = 505	all LDL n = 505	all Trig n = 505	all FBG* n = 456	all HOMA* n = 456
Baseline	127 ± 13	79 ± 9	186.8 ± 41.5	111.2 ± 34.91	114 ± 82.1	96.5 ± 17.8	2.9 ± 2.2
Completion	125 ± 13	77 ± 9	181.2 ± 38.9	105.6 ± 32.1	104 ± 60.2	94.9 ± 17.2	2.7 ± 2.3
p value	=0.002	<0.001	0.0001	<0.0001	=0.0001	=0.01	=0.002
#, % improved	296, 59%	284, 56%	282, 56%	271, 54%	285, 56%	269, 53%	286, 57%
	<b>Sys BP &gt; 120</b> n = 343, 68%	<b>Dias BP &gt; 80</b> n = 217, 43%	<b>Tot Chol ≥ 200</b> n = 188, 37%	<b>LDL ≥ 100</b> n = 307, 61%	<b>Trig ≥ 150</b> n = 99, 20%	<b>FBG ≥ 100*</b> n = 109, 24%	<b>HOMA ≥ 2.8*</b> n = 165, 36%
Baseline	135 ± 10	88 ± 6	229.1 ± 24.7	132.4 ± 26.0	217.1 ± 68.9	107.3 ± 7.0	4.6 ± 1.9
Completion	129 ± 13	82 ± 8	209.1 ± 34.2	119.4 ± 28.9	161.7 ± 80.7	100.6 ± 10.5	3.6 ± 1.8
p value	<0.001	<0.001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
#, % improved	242, 71%	159, 73%	137, 73%	195, 64%	84, 85%	79, 72%	118, 72%
#, % now normal	104, 30%	102, 47%	73, 39%	65, 21%	52, 53%	55, 50%	62, 38%

\* p value for comparisons between intervention values at baseline and program completion.

\*\*patients with diabetes excluded.

Sys BP = systolic blood pressure in mm Hg, Dias BP = diastolic blood pressure in mm Hg, Tot Chol = total cholesterol in mg/dL, LDL = low density lipoprotein in mg/dL, Trig = triglycerides in mg/dL, FBG = fasting blood glucose in mg/dL, HOMA = homeostatic model assessment for insulin resistance.

customized interventions.

In contrast, prior studies using TLC interventions have frequently limited the scope of their interventions (Saffi et al., 2014; Blumenthal et al., 2016; Alharbi et al., 2016; Dougherty et al., 2017). The most frequent interventions have focused solely on diet and exercise. In a meta-analysis of 14 studies measuring the effect of diet and exercise on coronary and carotid atherosclerosis (Jhamnani et al., 2015), results favored a reduction in atherosclerotic burden including a 34% decrease in coronary artery stenosis. A randomized 9-month trial of TLC including diet, exercise, and stress management showed no difference in plaque burden over the course of the study even while improvements in risk factors (BMI, blood pressure, lipids) and subjective well-being did improve (Elkoustaf et al., 2019). Prior studies have also limited the scope of their outcome measures, often focusing on a single parameter such as blood pressure (Appel et al., 2003). Previously published studies

that incorporated multiple modalities to reduce CVD risk have shown successes though these successes are difficult to summarize succinctly because of heterogeneous methods and varying metrics. These studies are summarized in Table 11.

A second factor making the CHP Registry study unique is the inclusion of measures to evaluate sleep behaviors and symptoms so that prescriptions for sleep improvement could be implemented. Sleep improvement is an area that has been largely ignored in other cardiovascular risk reduction programs.

A strength of the CHP Registry study was the systematic use of a standardized registry model applied to each participant for risk assessment, multidisciplinary clinical review, development of customized action plans, appointment flow, and data collection before and after the intervention. The standardized model of the registry was bolstered by the use of pre-specified measures using well-validated questionnaires

**Table 11**  
Published CVD prevention studies that utilize multiple interventions.

Author, Journal, Year	Study Design	Intervention Group (INT)	Usual Care Controls (CON)	Interventions	Outcomes
Hedbäck B, et al. Eur Heart J 1993	Prospective, observational, controlled intervention	147 patients after myocardial infarction	158 patients after myocardial infarction	Diet, exercise, smoking cessation, and psychological support	At 10 years, INT group had 15% fewer total deaths, 11% fewer cardiac deaths (p < 0.01).
Ornish D, et al. JAMA 1998	Prospective, randomized, controlled, intervention	28 patients with CHD	20 patients with CHD	Vegan diet, exercise, stress management, group psychosocial support	At 5 years, INT group had 8% regression in stenoses, controls had 28% worsening. RR for MACE 2.47 for controls.
Espinosa Caliani S, et al. Rev Esp Cardiol 2004	Prospective, observational, controlled intervention	133 patients with low-risk myocardial infarction	40 patients with low-risk myocardial infarction	Health education and psychological evaluation, exercise, smoking cessation, cardiovascular risk control	At 1 year, INT group had more quit smoking, lower BMI, better quality of life, greater exercise capacity, and more frequent return to work (p < 0.05).
Edelman D, et al. J Gen Intern Med 2006	Prospective, randomized, controlled, intervention	77 outpatients over age 45 y, with at least one CV risk factor	77 outpatients over age 45 y, with at least one CV risk factor	Personalized health plan with coaching, mindfulness meditation, relaxation training, stress management, motivational techniques.	At 10 months, INT group had significantly lower 10-year CHD risk (p = 0.04), more exercise, and lower weight compared to usual care controls.
EuroAction, Wood DA, et al. Lancet 2008	Prospective, matched, cluster-randomized, controlled trial	1589 with CHD, 1189 at high risk	1499 with CHD, 1128 at high risk	15-week (75 hrs) health education, exercise, smoking cessation, CBT-based stress management plus pharmaco-therapy	At 1 year, INT group had improvements in diet, BP, and cholesterol compared to usual care controls (p < 0.05).
Kadda O, et al. J Clin Nurs. 2015	Prospective, randomized, controlled, intervention	250 patients after open heart surgery for CHD	250 patients after open heart surgery for CHD	Diet, exercise, and smoking cessation	At 1 year, INT group had 0.56 risk for nonfatal CV event (p = 0.03), improved diet and exercise.
PreFord Study, Gysan DB, et al. Eur J Prev Cardiol 2017	Prospective, randomized, controlled, intervention	224 Ford employees at high risk	223 Ford employees at high risk	15-week multi-modal behavioral intervention, diet, exercise	At 36 months, intervention group had 19% less increase in risk score, HR 0.51 for MACE compared to usual care controls.

CHD = coronary heart disease, CON = controls, CV = cardiovascular, CVD = cardiovascular disease, INT = intervention group, MACE = major adverse cardiovascular events, BP = blood pressure.

and data collection tools. The pre-specified measures and use of validated questionnaires lend credibility to the findings and allow for valid comparisons of the findings with other studies past and future.

A second strength of the study was that the population included men and women of a variety of races and a broad age spectrum. The characteristics of the study participants make the findings broadly generalizable to other settings. Alternatively, characteristics of the study participants may also limit the generalizability of the results in that participants were active duty service members, retirees, or their dependents implying that all participants belonged to a household that benefited from employment or retirement income. Accordingly, the findings of the study may not pertain to a population with disadvantaged socioeconomic circumstances.

There are limitations to the CHP Registry study design that must be acknowledged. First was the lack of a control group which makes the improvements in lifestyle behaviors and the improvements in risk factors difficult to interpret. A true effect size of the intervention without data from controls, is impossible to estimate with certainty. During the process of study design for the CHP, enrolling a control group was given careful consideration but was believed to be unworkable in view of the strong expectations our participants had to be enrolled in an active TLC intervention. Furthermore, it was felt to be questionable from an ethical point of view to enroll participants in a control arm when the CVD risks of those participants were enriched by a variety of personal factors such as strong family history of CVD or a family history of premature CVD.

A second limitation of the CHP Registry study was that it did not use major cardiovascular events (MACE) as the primary outcome measure. Indeed, behavioral outcomes measured in this study were based upon self-report which are less credible than objectively measured data such as MACE and laboratory results. Furthermore, while blood pressure was measured with an automated device improving its objectivity, other anthropometrics were measured without blinding the technicians to the order of the visit (baseline versus outcome). This is an additional source of bias. Unfortunately, measurement of MACE requires a much larger sample size and much longer study duration than was mandated by the study's budget and other resources. In retrospect it was a missed opportunity not to track participants for a longer period to assess the durability of their lifestyle behavior changes and the effects of those changes on other measures of CV health. However, the CHP Registry study was able to incorporate CIMT for approximately one quarter of participants, providing an objective measure of atherosclerotic burden in a substantial subset of participants. It must also be acknowledged that limiting the study period to a 12-month interval may not afford adequate time for all objective measures (such as body mass index) to show a robust response. Medical problems and risk factors that were gradually accreted over a lifetime may not be responsive to quick fixes.

Third, the completion rate of the 12-month program was disappointing (648 of 965 enrolled, 67%) which may limit the generalizability of the findings. Future studies may find it advisable to look for ways to decrease the duration if not the intensity of the intervention to keep participants engaged.

Fourth, the study sample was comprised of active duty service members, military retirees, and their dependents who may be more committed to health and fitness than members of the general population, creating a bias that makes the results of the study less generalizable. On the other hand, members of the military and their families are often described in health terms as "a slice of the pie from the general population", such that the only way to understand similarities and differences between these populations would be to conduct a comparative trial. There have been ongoing discussions with civilian and corporate entities to consider implementation of the CHP in other settings though there are no firm plans to do so at this time.

A fifth limitation of the CHP Registry study was an inability to diagnose and implement treatment for obstructive sleep apnea in a timely manner. While the effect of treating sleep apnea on CVD outcomes remains controversial (Yu et al., 2017; Javaheri and Campos-Rodriguez,

2017), the inability to assess for and manage sleep apnea expeditiously in our participants is a confounding factor of unknown consequences.

A sixth limitation was the reliance on subjective self-reports to measure adherence to therapeutic lifestyle change prescriptions. The same questionnaires that were used at baseline during the intake to the CHP were used again at program completion allowing for comparisons to be made before and after the intervention. Regrettably, behavioral questionnaires being subjective self-reports are likely to be biased by patient recall with optimistic estimates as well as a desire to please the investigators and coaches. During the design phase of the investigation, it was proposed to employ objective measuring devices such as wearable bio-recording devices (actigraphs) to obtain objective estimates of exercise and sleep. These options were explored and were found to be too costly. A suggestion to use digital photographs of selected meals sent by patients to dietitians was felt to be too unwieldy and fraught with inaccuracy. For objective measurement of stress levels, the investigators considered measuring salivary cortisol levels but a search of the peer-reviewed literature revealed a lack of standardization for collection and interpretation of results. In the intervening years, it appears that wearable bio-recording devices have become remarkably more affordable and reliable such that it would be advisable for future studies to fold in such data collection as an objective check on self-reported behaviors for exercise and sleep. It is also urged that future studies be planned for a longer duration to determine the durability of results and to capture hard outcomes such as major adverse cardiovascular events.

In summary, the CHP Registry study adhered to recommendations of the ACC/AHA guidelines on the primary prevention of CVD by using a team-based, multi-disciplinary, patient-centered protocol that performed a comprehensive CVD risk assessment and implemented collaborative therapeutic lifestyle changes incorporating social determinants of health. Participants showed that they were largely able to adhere to lifestyle prescriptions over the course of a year. Objective outcome measures showed remarkable improvements in CVD risks in the domains of diet, exercise, stress management, and sleep. A strong majority (70%) of participants who had CIMT measurements showed improved or stable intima-media thickness that was associated with substantially improved sleep quality and increased total sleep time. The success of the CHP Registry model of CVD prevention deserves further study to determine its scalability, cost-effectiveness, and effects on MACE.

#### CRediT authorship contribution statement

**Arn Eliasson:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Supervision, Validation, Writing - original draft, Writing - review & editing. **Mariam Kashani:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. **Marina Vernalis:** Conceptualization, Funding acquisition, Project administration, Resources, Supervision, Writing - review & editing.

#### Declaration of Competing Interest

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

#### Acknowledgements

The study was funded by a research grant from the US Army's Telemedicine & Advanced Technology Research Center, an office of the headquarters of the US Army Medical Research and Materiel Command in Fort Detrick, Maryland. The funding was administered by the Henry M. Jackson Foundation for the Advancement of Military Medicine,



Rockville, Maryland. "The views expressed in this article are those of the author and do not reflect the official policy of the Department of Army/Navy/Air Force, Department of Defense, or U.S. Government."

## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.pmedr.2021.101344>.

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