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Nature hiking for Veterans with posttraumatic stress disorder: Pilot study design and findings

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ABSTRACT

Objectives: To evaluate feasibility and acceptability of a group-based nature recreation intervention (nature hiking) and control condition (urban hiking) for military Veterans with post-traumatic stress disorder (PTSD).

Design and setting: A pilot randomized controlled trial conducted in the U.S. Pacific Northwest.

Participants: Veterans with PTSD due to any cause.

Interventions: Twenty-six participants were randomized to a 12-week intervention involving either six nature hikes (n=13) or six urban hikes (n=13).

Primary and secondary outcome measures: Feasibility was assessed based on recruitment, retention and attendance. Questionnaires and post-intervention qualitative interviews were conducted to explore intervention acceptability. Questionnaires assessing acceptability and outcomes planned for the future trial (e.g., PTSD symptoms) were collected at baseline, 6-, 12- (immediately after the final hike) and 24-weeks follow-up.

Results: Of 415 people assessed for eligibility/interest, 97 were interested and passed preliminary eligibility screening, and 26 were randomized. Mean completion of all questionnaires was 91% among those in the nature hiking group and 68% in those in the urban hiking group. Over the course of the intervention, participants in the nature and urban groups attended an average of 56% and 58%, respectively, of scheduled hikes. Acceptability of both urban and nature hikes was high; over 70% reported a positive rating (i.e., good/excellent) for the hike locations, distance, and pace. Median PTSD symptom scores (PTSD Checklist-5) improved more at 12- and 24-weeks among those in the nature vs. urban hiking group.

Conclusions: This pilot study largely confirmed the feasibility and acceptability of nature hiking as a potential treatment for Veterans with PTSD. Adaptations will be needed to improve recruitment and increase hike attendance for a future randomized controlled trial to effectively test and isolate the ways in which nature contact, physical activity, and social support conferred by the group impact outcomes.

Trial registration: Clinicaltrials.gov (NCT03997344)

Key words: posttraumatic stress disorder, Veterans, nature, hiking, pilot randomized controlled trial

Strengths and limitations of the study

- The intervention, nature hiking is highly acceptable, and has the potential to be scaled, providing additional and/or alternative treatment options for individuals with PTSD.
- This randomized controlled pilot trial included an active control group (urban hiking) that could permit, in a future large-scale trial, distinguishing benefits due to physical activity and social cohesion (present in both interventions) from the environment (which differs between the interventions).
- We used population-based recruitment methods to understand eligibility in a population selected because of presumed PTSD based on medical record data.
- Because of its small size and focus on feasibility, the trial was not designed to be large enough to determine the effectiveness of nature hiking on outcomes.

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Competing interests: The authors have no competing interests to report.

Introduction

Posttraumatic Stress Disorder (PTSD) is a common, chronic mental health condition that affects up to 30% of military Veterans (1–3). PTSD is frequently comorbid with anxiety, depression, and substance misuse. It increases the risk of suicide as well as obesity, physical inactivity, and cardiovascular and metabolic disorders (1–12).

Clinical practice guidelines recommend treatment with several evidence-based psychotherapies and medications (13), but many patients who need PTSD treatment do not receive it (14). Barriers to obtaining treatment include concerns about medication side effects, desire for self-management approaches, stigma about receiving mental health care, and a lack of confidence in mental health treatment in general (14–17). These and other factors adversely impact engagement, contributing to low initiation of (14,18–22) and high drop-out rates from treatment (20,23,24). Furthermore, while the recommended PTSD treatments improve PTSD symptoms *on average*, approximately 60% of patients still have symptoms at or above diagnostic thresholds for PTSD (25). Thus, identifying a wider range of approaches that are acceptable and effective is key to reducing the burden PTSD places on individuals and their communities.

An increasing number of organizations encourage nature contact ("green prescriptions") to promote psychological well-being and treat symptoms of mental health disorders (26), though rigorous evidence supporting a benefit is lacking. A number of studies have evaluated the effects of nature-based recreation in populations composed of adults primarily or exclusively with PTSD (27–34). The interventions evaluated vary in content, duration, and structure (35). Though quantitative and qualitative data suggest improvements, methodological issues, including inconsistent outcome measures, low retention for follow-up, absence of control groups, and insufficient statistical power make it difficult to attribute benefits to the program or to understand the mechanisms underlying apparent benefits (36). Adequately powered studies designed to

distinguish between benefits due to physical activity (PA) and those due to the physical and social environment (e.g., nature) are needed.

Nature hiking may offer therapeutic value for people with PTSD, as it involves PA, nature contact, and, when done with others, the potential for forming social connections. Research suggests that each of these elements could improve outcomes in people with PTSD. PA improves anxiety and depression, stress regulation, sleep, and cognitive functioning (10,11,37). PA also decreases pain interference and may desensitize individuals to the physiologic arousal of PTSD. Benefits that have been observed in non-PTSD samples have prompted interest in evaluating the impact of PA in people with PTSD (37–43). Findings in patients with PTSD have generally been positive, but only eight studies have involved randomized controlled trial designs (4,40,43–49), and five of the RCTS were pilot studies or included fewer than 30 people (40,43–45,49). The types of PA studied (yoga, aerobic activity, strength training, or a combination), the primary etiology of the PTSD (sexual trauma, combat, other or a combination), the duration of treatment (ranging from 2 to 12 weeks), sample characteristics (female-only vs. predominantly men) and whether PA was studied as a stand-alone treatment or as an adjunct to evidence-based psychotherapies have varied widely across studies. Notably, no studies explicitly investigated the PA setting as a component of treatment, with many using facility-based PA or failing to specify the location of the PA.

This is an important omission, because the environment in which PA takes place may play an important role in the benefits it provides. PA in natural settings improves subjective well-being; decreases stress, anxiety, and depression; and promotes adaptive shifts in emotion regulation (35,50–52). Attention Restoration Theory (ART) and Stress Recovery Theory (SRT) provide a theoretical foundation for the observed benefits of nature contact on health (53,54). ART theorizes that nature contact improves cognitive function through a replenishment of “directed attention”, a capacity that is overly taxed in urban environments due to the need to block out distracting stimuli (e.g., noise) to focus on a specific task or cognitive process. This depleted attention capacity

can be restored in natural environments through the engagement of "soft fascination", with implications for both cognitive and emotional well-being. SRT posits that many types of nature exposure enhance psychological well-being through an activation of the parasympathetic nervous system in ways that reduce stress and sympathetic nervous system arousal (55,56).

In addition to PA and the physical environment in which it takes place, social factors may also play a role in the benefits of nature hiking. Recent research suggests that increased social cohesion and connectedness may mediate benefits of nature-based recreation (57). Social support forged through group activity could be particularly relevant for Veterans, as camaraderie and solidarity are critical components of military culture, and ones that are frequently lost in the return to civilian life (58). Social support is associated with reduced PTSD symptoms and improved treatment response (59), and may directly impact stress response, by increasing personal resources (60), and/or may indirectly impact PTSD symptom severity and response to treatment through buffering the potentially harmful impacts of stressful events (61).

Guided by prior research and gaps in the literature, our goal was to design and conduct a pilot study to test the feasibility and acceptability of a nature-based PA intervention for PTSD symptoms in military Veterans, regardless of PTSD etiology. The intervention (nature hiking) and the active control (urban hiking) were group-based and involved similar amounts of PA, to ensure control of the potential benefits of the group-based social support and of PA. Figure 1 depicts our conceptual model. This paper describes the results of the initial pilot study designed to emulate important elements of the future envisioned full-scale randomized trial.

Methods

Ethics approval

This study was approved by the institutional review boards at the VA Puget Sound Health Care System (MIRB 01738) and the University of Washington (6951) and registered at Clinicaltrials.gov (NCT03997344). Figure 2 presents an overview of the study, including timing of assessments.

Patient involvement

Patients were involved in the design and conduct of this study. This study question and design were informed by a Veteran with PTSD who served as a co-investigator. Study design and messaging for this pilot were also informed by a focus group of patients/Veterans who participated in a prior unpublished feasibility study.

Inclusion/Exclusion Criteria

Inclusion criteria included being a U.S. military Veteran and having PTSD (PTSD-checklist-5 (62) score≥33). To ensure safety, we excluded those with a hospitalization in the prior 3 months (self-report); a diagnosis of schizophrenia, bipolar disorder, or other psychotic disorder (self-report); inability to perform unsupervised exercise safely (based on the Physical Activity Readiness Questionnaire (63) and provider approval if any conditions were present), drug abuse in past year (Drug Abuse Screening Test-10 (64) score <3); alcohol disorder/dependence (current/past year; Alcohol Use Disorders Identification Test-10 (65) score>16); and moderate/severe suicidality (past month; MINI Suicidality module (66) score≥5). Patients also needed to express an ability/willingness to comply with study procedures (e.g., complete questionnaires, wear and sync an activity monitor, drive to hikes, and walk at least 2 hours at an easy/moderate pace over uneven terrain).

Recruitment

We used active and passive methods to recruit participants. For active recruitment, we mailed invitation letters to VA enrollees (identified using Department of Veterans Affairs (VA) electronic medical records) with at least one encounter with a diagnosis of PTSD in the prior two years and a zip code in one of three Seattle-Tacoma

area counties (King, Snohomish, and Pierce) (n=1001). We followed the mailing with up to three phone calls until we met recruitment targets. For passive recruitment, we placed study recruitment flyers in clinics in the VA Puget Sound and mailed flyers to four local organizations and clinics serving Veterans.

Screening

Individuals were first screened over the phone. Those who passed initial screening were mailed consent forms and given a link to complete a more extensive screening questionnaire online. Via the online screening questionnaire, PTSD symptoms, drug use, alcohol misuse, and suicidality were assessed, and a final determination of eligibility was made. Those who were eligible based on the two steps and returned signed consents were considered enrolled in the study.

Randomization

The random 1:1 allocation sequence was generated using simple randomization in random blocks of 2, 4 and 6. Randomization assignments were placed in opaque sequentially numbered envelopes. Once an individual was determined to be eligible, the study coordinator selected the next envelope to determine the individual's group assignment.

Blinding

We did not blind participants, the study coordinator, or the study statistician to group assignment.

Interventions, hike leaders, and incentives

The study included two arms: group nature and urban hiking. Both the nature and urban hikes followed the same schedule -- 6 hikes, held every other week on Sunday mornings (12 weeks total) from August through October 2019. The standard structure for hikes was: 1) "ice breakers" (short, guided conversations), 2) overview

of the planned hike, including distance, unique features, and planned stops, 3) hike, and 4) post-hike debrief and administration of questionnaires.

Hike durations increased gradually to account for anticipated increases in participants' physical fitness. Initial hikes were 60-90 minutes (2-3 miles), and later hikes were 2-3 hours (5-6 miles). To ensure safety and inclusion, one hike leader was in sight and hearing of the first participant and a second leader accompanied the last participant. The group stopped at least every 30 minutes to keep everyone together and offer opportunities to rest, regroup, and inquire about and address any issues or concerns arising since the last check-in.

Two non-clinicians (including at least one woman) co-led each nature and urban hike. Leaders were trained to handle physical and mental health emergencies. The same hike leaders led both nature and urban hikes to control for hike-leader effects.

To reduce barriers to attendance, a $35 incentive was provided to defray parking costs. We provided a rain jacket and technical shirt as well as well as an activity monitor (Garmin vivosmart 4) at the participant's first hike.

Selecting hike routes

The criteria used to select the hikes (which applied to both nature and urban hikes) included duration, elevation change, availability of facilities (e.g., toilets and water), distance from participants' homes, and access to parking. Nature hikes were held in State Parks, National Wildlife Refuges, and Natural Resources Conservation areas. Urban hikes were held in primarily built environments, avoiding urban parks or primarily residential neighborhoods with substantial greenery or water features. Urban hikes comprised areas that included sports stadiums, urban art, and retail establishments and were mainly on sidewalks rather than separated

bike/pedestrian paths/rail-trails. It was not feasible to match nature and urban hikes on elevation change; instead, we aimed to have similar hike durations to match total exertion. Generally, nature hikes were shorter and included more elevation gain/loss.

Baseline and follow-up assessments

We conducted assessments online using commercial software (QuestionPro) at baseline (before hikes began), and each week after the first hike for 12 weeks (after the 6th hike), and then at week 24; questionnaires completed immediately after the hikes were completed on paper. See Figure 2 for an overview and Supplemental Table 1 for measures at each time point. Questionnaires at weeks 6, 12, and 24 took approximately 30 minutes to complete. Questionnaires administered at weeks 1-5 and 7-11 took 5-10 minutes to complete. Participants received gift cards worth $10 for questionnaires completed in weeks 1-5 and 7-11, $20 for the 6-week questionnaire, and $50 for the 12- and 24-week questionnaires.

Measures

Feasibility measures

To evaluate feasibility, we assessed recruitment statistics (the proportion of individuals who were contacted, eligible, and enrolled, as well as reasons for ineligibility), retention (questionnaire completion), hike attendance, and safety (e.g., adverse events). We aimed to recruit 36-45 participants (12-15 people allocated to each of the three groups - nature hiking, urban hiking, and a no-hiking control group) and complete enrollment by July (3-4 months after recruitment initiation) due to concerns about weather for hikes later in the fall. Due to lower-than-anticipated recruitment numbers, in late June, we decided to eliminate the no-hiking control group. At this time, only one person was randomized to the no-hiking control group and informed of their group assignment; that person was re-randomized after this decision was made. The target for retention and attendance was 70%.

Acceptability measures

We included questions on acceptability of the hikes (e.g., distance, pace, terrain, and locations) and satisfaction with the study (e.g., communication) in the 6- and 12-week questionnaires. These questionnaires also included open-ended questions for participants to report what they thought went well and what could have been better. Additionally, after the final hike, the lead author conducted semi-structured telephone interviews, with a goal to interview 10-15 participants. To include a range of perspectives, we purposively sampled participants from both arms, aimed to include men and women, and participants who varied in terms of hike attendance. Questions inquired about participants' impressions of the hikes, including difficulty, location, length of time, distance from home, hike leaders, and reasons hikes were missed (if applicable); study communications; enrollment process; assessments; and other thoughts/impressions. All interviews were recorded; the interviewer also took notes during interviews. For both the comments shared via open-ended questions on the questionnaire and comments shared orally during the interviews, we conducted inductive content analysis, which involves open coding of data, organizing codes and data into categories, and comparing data across participants to identify patterns and themes in the data (67).

Outcome (efficacy) measures

Supplemental Table 1 details the measures and instruments that were assessed at each time point. The primary outcome of the future planned study is the PTSD-Checklist-5 (PCL-5), a 20-item instrument that assesses PTSD symptoms in the past month (range 0 to 80). Higher scores indicate greater symptom severity. The primary purpose of the extensive data collection was to evaluate feasibility of data collection rather than to estimate effect sizes because estimating effect sizes from small pilot studies is inherently imprecise (68). Thus, instead of conducting hypothesis tests for which we were underpowered, we present descriptive statistics (e.g., medians and interquartile ranges) for the PCL-5 only.

Results

Participants

The mean age of participants was 47 years (range 25-65), 7 (27%) were women, 42% were non-white race/ethnicity, and 14 (54%) were currently married (Table 1). Thirty percent had a college degree or more. Less than half worked full time and 46% had 100% VA service-connected disability, indicating severe impairment in ability to work. Nearly two-thirds of participants had served in combat and 68% had depressive symptoms based on the PHQ-8. Based on self-report nearly 70% met or exceeded PA guidelines of at least 75 minutes per week of vigorous-intensity activity or 150 minutes per week of moderate-intensity activity, or an equivalent combination of the two. At baseline (prior to study initiation), 81% of participants reported hiking at least one time and 27% completed 7 or more hikes in the prior year.

Feasibility

Recruitment statistics

Recruitment took place between April and August 2019 (16 weeks total). Of the 1001 patients mailed an invitation letter, we were unable to assess interest or eligibility in 586 (because they did not respond to the mailings and/or answer the phone when called; see Figure 3 for CONSORT diagram). Of the 415 with whom we made contact, 159 were not interested, 102 had health conditions that limited their walking/hiking, 36 had time conflicts (e.g., work or church on Sundays or travel that would prevent participation), and 37 had other reasons that they were unable to participate (e.g., moving out of the area, travel plans, did not have PTSD, etc.). Of the 97 (81 from letters + 16 from passive recruitment) interested who passed the preliminary eligibility review, 48 completed the online screening questionnaire. Twenty individuals were not eligible, 2 decided that they did not wish to participate, and 26 were eligible and randomized. Of the 20 who were not eligible, 13 were ineligible because of a moderate/high risk of suicide or skipping the question on suicidality, and 6 did not meet the threshold for PTSD.

Retention (questionnaire completion)

Mean completion of all questionnaires was 91% in the nature hiking group and 68% in the urban hiking group. Completion rates were similar for the shorter weekly questionnaires and the longer questionnaires.

Hike attendance

Over the course of the intervention, participants in the nature and urban groups attended an average of 56% and 58%, respectively, of scheduled hikes. In the nature group, one person attended no hikes, four (31%) attended 1-2 hikes, one attended 3 hikes, and seven (54%) attended 4-6 hikes. In the urban group, one person attended no hikes, 4 (31%) attended 1-2 hikes, no one attended only 3 hikes, and 8 (62%) attended 4-6 hikes. Attendance was lower among women in the nature group (n=5, mean: 43%) than among women in the urban group (n=2, 67%), whereas among men, hike attendance was similar in the two groups (65% vs. 56%). Common reasons for missing hikes included work, childcare, and prior plans.

Safety/Adverse events

One participant in the urban hiking arm reported increased anxiety/PTSD symptoms in connection with hiking in the urban environment and withdrew from the study.

Acceptability

Quantitative findings

Acceptability of both the urban and nature hikes was high. Over 70% reported a positive rating (i.e., good or excellent vs. very poor/inadequate, inadequate, or adequate) for the hike locations, distance, and pace.

Qualitative findings

Overall, qualitative interviews indicated that most participants felt positively about their experience. Veterans wanted to find more ways of connecting with one another socially during hikes as well as outside of hikes (Table 2). Hike logistics were noted as potential barriers to attendance.

Efficacy measures

Median PCL-5 scores decreased from baseline to week 12 and 24 for those in the nature (baseline=41, 12-weeks = 32, 24 weeks=31) but not among those in the urban hiking group (baseline=48, 12-weeks = 43, 24 weeks=47) (Supplemental Figure 1). We did not test the statistical significance of the changes because this pilot study was not designed to answer this question (70).

Discussion

This study was an important step to establishing feasibility and acceptability and identifying changes to consider in the development of a rigorous, fully-powered study to evaluate the impact of nature hiking on PTSD symptoms. The results of this pilot study were largely positive. Participants reported high acceptability, enjoyment, and value, based on quantitative and qualitive data. Most participants completed most hikes, regardless of treatment arm. Feedback about improving the social component supports the hypothesis that social connection is an important aspect of these hikes, indicating a need to continue to study group interventions like this one. Additionally, the decrease in median scores on the PCL-5 among those in the nature group immediately after the 12-week hiking intervention, and 12 weeks later (week 24) is promising. This preliminary finding should be investigated more thoroughly in future, larger-scale versions of our study. The indication that improvements may persist after the conclusion of the intervention is especially compelling given the current unknowns regarding the duration of effects of nature interventions.

Nevertheless, several issues need to be considered related to feasibility and acceptability for the next iteration of this research.

Feasibility of recruitment

We fell short of our goal of recruiting at least 36 people over 4 months. Failing to meet recruitment goals in the planned timeframe is a common problem in randomized controlled trials (71). Barriers to recruitment included unexpected delays, insufficient resources, and an inefficient recruitment process. Regarding delays, we had to wait weeks for IRB approval for each proposed modification to recruitment materials/protocol. Our pilot experience allowed us to pre-test materials and processes, but modifications will likely be needed, so having a plan that can accommodate a slow start or interruptions would be helpful. Regarding resources, we only had 20 hours per week of paid staff time for recruitment. The addition of two volunteers in the final two months helped to accelerate enrollment, but more resources earlier in recruitment would have been necessary to meet our goal.

One contributor to inefficiency in recruitment was the broad, population-based approach we employed for active recruitment. To identify patients for the introductory mailing, the only inclusion criteria were having a single encounter in VA's electronic medical record with a PTSD diagnosis and living in one of three Puget Sound counties. The only exclusionary factor was a diagnosis of schizophrenia, bipolar disorder, or other psychotic disorder. Likely in part because of this broad approach, approximately a quarter of contacted individuals reported a health condition that impaired their walking. Burdensome study procedures may have also impacted recruitment. About half of interested participants failed to complete the online screening questionnaire and numerous people had trouble completing the online questionnaire. Restructuring the recruitment process to make it faster and easier for potential participants may be necessary.

Restrictive eligibility criteria and accessibility of the intervention may have also impacted recruitment. In addition to being able to walk over uneven ground for at least two hours, participants also had to be available during the times selected, have low suicide risk, and be free from physical conditions such as high blood pressure (or obtain their primary care provider's permission) among several other criteria. Changing inclusion criteria (e.g., eliminating restrictions related to suicidality) would require tradeoffs related to safety that must be considered carefully.

Lastly, about 38% (159/415) of those for whom we were able to assess eligibility and interest declined participation. While some of these people may have declined because of the additional burdens of a research study, this statistic indicates that hiking may only appeal to a segment of the population, just as psychotherapy and pharmacotherapy only appeal to subsets of the population (25). Because of differences in treatment preferences, offering options is important, and nature hiking merits consideration so that we can rigorously assess its efficacy.

Retention

Retention varied by group and was poorer for the wrist-worn activity monitor than for the questionnaires. The activity monitor had a substantial amount of missing data, which is a common problem for activity monitors (72), and may have been related to the number of technical steps required for setting up the watch and syncing it, as many participants needed additional help to troubleshoot problems. Providing more support to set up the watch and incentives to wear and sync it may help to obtain more complete data. While overall questionnaire completion was high, it was higher in the nature hiking group (91%) than in the urban hiking group (68%). Though the small sample and our inability to conduct interviews with those who did not complete follow-up measures makes inference difficult, the retention differences could be a marker of commitment to the study. Future studies should pay careful attention to marketing the study to ensure that both interventions are

perceived as helpful. The difference in incentives provided for questionnaire completion vs. the other aspects of the study may also have played a role in retention for different study aspects. However, many participants shared that they participated to help fellow Veterans, indicating altruistic/intrinsic motivators for participation, reinforcing the importance of understanding drivers of participation, and reducing barriers and enhancing facilitators.

Acceptability of the hiking interventions

Hike attendance (56%) was lower than our target (70%) and women had lower attendance in the nature hiking group than men. While we were unable to ascertain reasons for missing hikes for each person, some reasons reported (e.g., other plans, work) were hard to avoid, while others (driving distance to hikes) could be addressed in the future by restricting the geographic area of recruitment and hikes and/or organizing small groups at different times to accommodate individuals' schedules. A history of military sexual trauma, which is common among women Veterans (73), may have impacted some women participants' comfort and perception of safety of hiking in nature with a majority male group. Ensuring a greater proportion of female participants in each group or organizing women-only groups could address this concern. These changes, would, however, result in additional costs and tradeoffs that would need to be carefully considered.

Conclusions

This pilot study provided useful information related to feasibility and acceptability, including common factors that resulted in exclusion; resources and procedures needed for recruitment; factors to consider for selection of nature and urban hikes; and barriers and facilitators to achieving high completion in follow-up assessments and the hikes. These insights can be harnessed to increase participation and rigor in future, scaled-up iterations of the study, and ensure that environments are safe (i.e., non-triggering). Future studies with larger sample sizes

are needed to isolate the ways nature contact, PA, and social support conferred by the group impact outcomes to develop and provide well-tailored interventions.

List of abbreviations

ART	Attention Restoration Theory
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
PA	Physical activity
PCL-5	PTSD Checklist for Diagnostic and Statistical Manual 5
PTSD	Posttraumatic stress disorder
SRT	Stress Recovery Theory
VA	Department of Veterans Affairs

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Contributors: AJL, GNB, CCE, JCF, KL, JB, and HF conceptualized the study and contributed to the intervention development and design. AJL and GNB oversaw the conduct of the trial all the authors contributed to the ongoing management of the trial. AJL, GNB, MM, AP, and CK oversaw data collection and data analysis. The manuscript was drafted by AJL. All the authors contributed to the interpretation of the findings and revised and reviewed the paper.

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Figure 1. Conceptual model

Figure 2. Depiction of study design and assessments

Figure 3. CONSORT diagram

Table 1. Baseline characteristics of Veterans in the urban and nature hiking groups

Characteristic	Total (n=26)		Nature (n=13)		Urban (n=13)	
	N or mean	% or SD	N or Mean	% or SD	N or Mean	% or SD
Age (years)						
<30	2	8	1	8	1	8
30-39	5	19	2	15	3	23
40-49	6	23	4	31	2	15
50-59	11	42	6	46	5	38
≥60	2	8	0	0	2	15
Gender						
Male	19	73	8	62	11	85
Female	7	27	5	38	2	15
Race/ethnicity						
Asian/Pacific Islander, NH	3	12	2	15	1	8
Black, NH	2	8	0	0	2	15
Hispanic	3	12	1	8	2	15
Native American, NH	2	8	0	0	2	15
Other	1	4	0	0	1	7.7
White, NH	15	58	10	77	5	38
Marital status						
Single, never married	4	15	3	23	1	8
Married currently	14	54	7	54	7	54

Characteristic	Total (n=26)		Nature (n=13)		Urban (n=13)	
	N or mean	% or SD	N or Mean	% or SD	N or Mean	% or SD
Separated/divorced	8	31	3	23	5	38
Education						
High school degree or equivalent	4	15	1	8	3	23
Some college, no degree	10	38	7	54	3	23
Associate degree	4	15	1	8	3	23
Bachelor's degree	4	15	2	15	2	15
Masters, doctorate, or professional degree	4	15	2	15	2	15
Annual household income						
$25,000-$49,999	7	27	4	31	3	23
$50,000-$74,999	11	42	4	31	7	54
$75,000-$99,999	2	8	1	8	1	8
$100,000 or more	4	15	3	23	1	8
Prefer not to answer	2	8	1	8	1	8
Employment status						
Full-time	12	46	6	46	6	46
Part-time	1	4	1	8	0	0
Not employed (disabled, retired, not looking for work, homemaker, other)	13	50	6	46	7	54
Highest military rank						

Characteristic	Total (n=26)		Nature (n=13)		Urban (n=13)	
	N or mean	% or SD	N or Mean	% or SD	N or Mean	% or SD
Enlisted (E1-E4)	9	35	4	31	5	38
Non-commissioned officer (E5-E9)	15	58	8	62	7	54
Officer (O1-O4)	2	8	1	8	1	8
VA disability rating*†						
No rating	2	8	0	0	2	15
30-60%	2	8	2	15	0	0
70-90%	8	31	4	31	4	31
100%	12	46	6	46	6	46
Self-reported health						
Excellent/very good	9	35	3	23	6	45
Good	11	42	7	54	4	31
Fair (no one reported poor)	6	23	3	23	3	23
PCL-5 score‡						
Mean, SD	47.1	10.9	46.0	11.4	48.2	10.8
Served in combat [yes]	17	65	8	62	9	69
Combat Exposure Score; mean (SD)* †	16.6	7.9	15.6	8.2	17.7	7.9
Patient Health Questionnaire-8 score*						
<10 (no depression)	8	32	4	33	4	31
10-19 (major depression)	14	56	7	58	7	54
≥20 (severe major depression)	3	12	1	8	2	15

Characteristic	Total (n=26)		Nature (n=13)		Urban (n=13)	
	N or mean	% or SD	N or Mean	% or SD	N or Mean	% or SD
Physical activity level						
Low	8	31	5	38	3	23
Moderate	3	12	1	8	2	15
High	15	58	7	54	8	62
Times gone hiking for 1+ hrs in last year						
Never	5	19	3	23	2	15
1-3	9	35	4	31	5	38
4-6	5	19	2	15	3	23
7+	7	27	4	31	3	23
Outdoor / nature-based activity experience						
None (no experience in the outdoors)	0	0	0	0	0	0
Casual (done some day hiking on maintained trails and car camping)	10	38	5	38	5	38
Amateur (have experience with backpacking)	11	42	6	46	5	38
Expert (substantial backcountry experience)	5	19	2	15	3	23

Abbreviations: NH, Non-Hispanic; PCL-5, Post-traumatic stress disorder checklist for Diagnostic and Statistical Manual 5; PTSD, post-traumatic stress disorder; SD, standard deviation

* Missing response for 1 nature participant

† Missing response for 1 urban participant

‡ One person in the nature hiking group had a PCL-5 of 32 (below the eligibility threshold of 33) due to an undetected error in initial scoring.

Table 2. Key themes and findings from qualitative data

Themes	Findings
A positive experience	• Both nature hiking group members ("All expectations were exceeded") and urban study participants ("LOVE THE GROUP") provided positive feedback.
Perceived benefits	• Participants reported on how the hikes helped them to be more active, lose weight, reduce stress, and feel more connected to others.
Hike logistics	• Participants suggested that prior to hikes, we ensure parking access, availability of toilets, and locate the hikes closer to participants' homes. • Others suggested that we consider organizing carpools and/or covering gas/mileage costs
Difficulty of hikes	• Most found the difficulty just right. • Some felt that the hikes were too short/easy.
Location of hikes	• Nature group: One participant wished that there was more of a "reward" ("like a waterfall", "when you have a view, it seems more profound"), because some were just "walks through the woods." • Urban group: One person noted that some neighborhoods were "sketchy" and they were "constantly walking around garbage" for one hike. Others noted that they really enjoyed exploring different neighborhoods, areas around sports stadium, and learning about the history of areas.

Group composition	• A few participants suggested that we enroll more women or organize women-only groups and/or groups for survivors of sexual assault.
Incentives for completing questionnaires	• Participants suggested that we offer the option to receive a single gift card that accumulated value instead of separate ones each time a questionnaire was completed.
Assessments	• Several participants had trouble with the online software (e.g., getting "kicked out" of the survey mid-way through); • Some participants reported that they would have liked text prompts instead of email, since they did not regularly check their email. • Some participants found some questions to be difficult to answer (e.g., the Perceived Cohesion Scale) or they were confused by differences in the time frame for different instruments (e.g., on the weekly questionnaires, some questions asked participants how they felt "right now" while others asked about the prior week).
Activity monitors	• Several participants noted having problems programming and syncing the activity monitor.
Fostering interaction/connections between participants in a group	• Participants suggested facilitating more structured ways to get to know other members of the group, including a social gathering prior to the initial hike, re-introductions before each hike, gathering for lunch or other meal after hikes, and organizing a social media group.

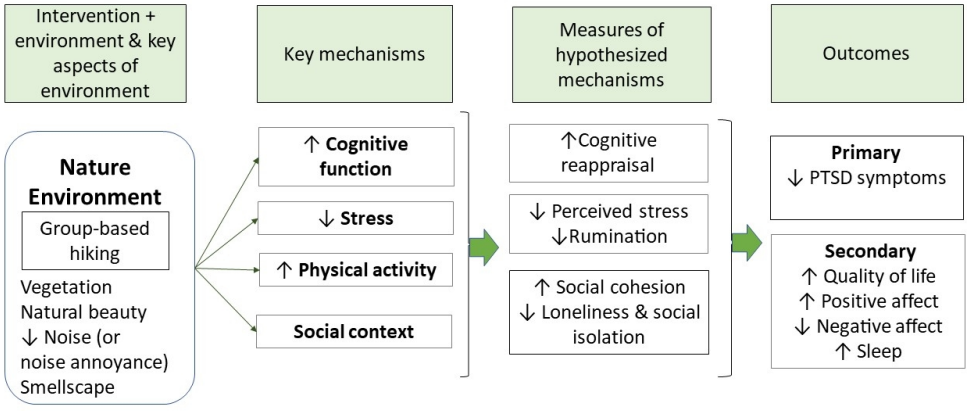


Figure 1. Conceptual model

338x190mm (96 x 96 DPI)

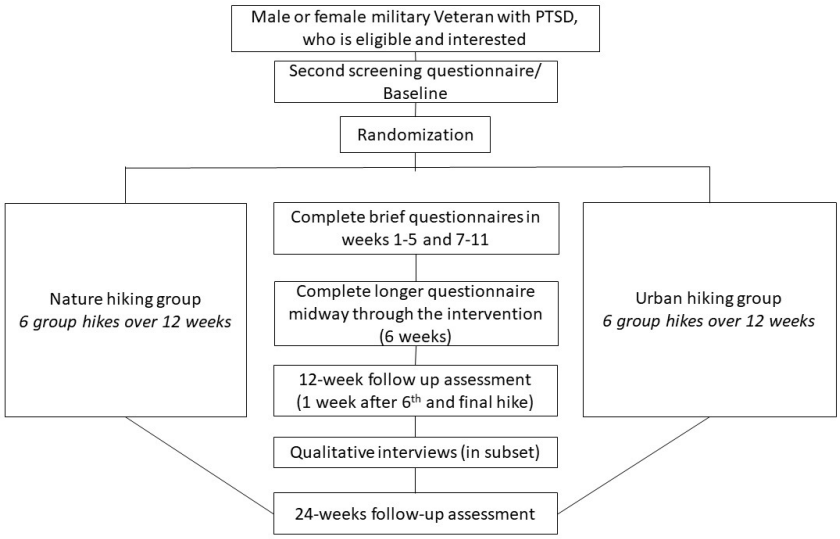


Figure 2. Depiction of study design and assessments

338x190mm (96 x 96 DPI)

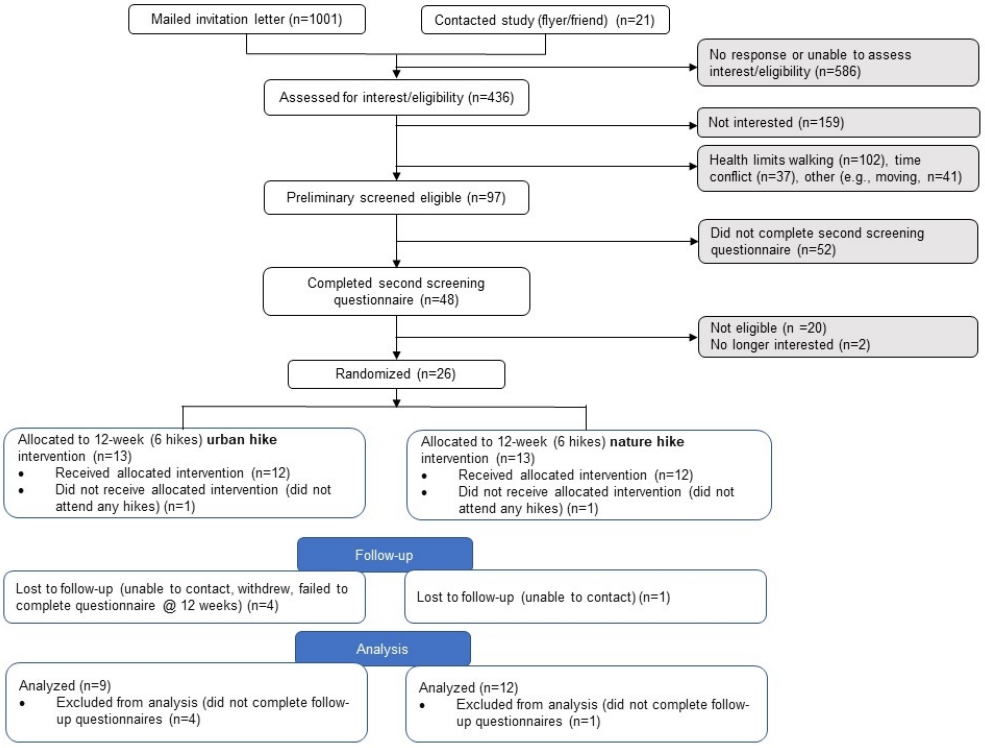


Figure 3. CONSORT diagram

254x190mm (96 x 96 DPI)

Supplemental Table 1. Constructs, instruments, and timing of assessments

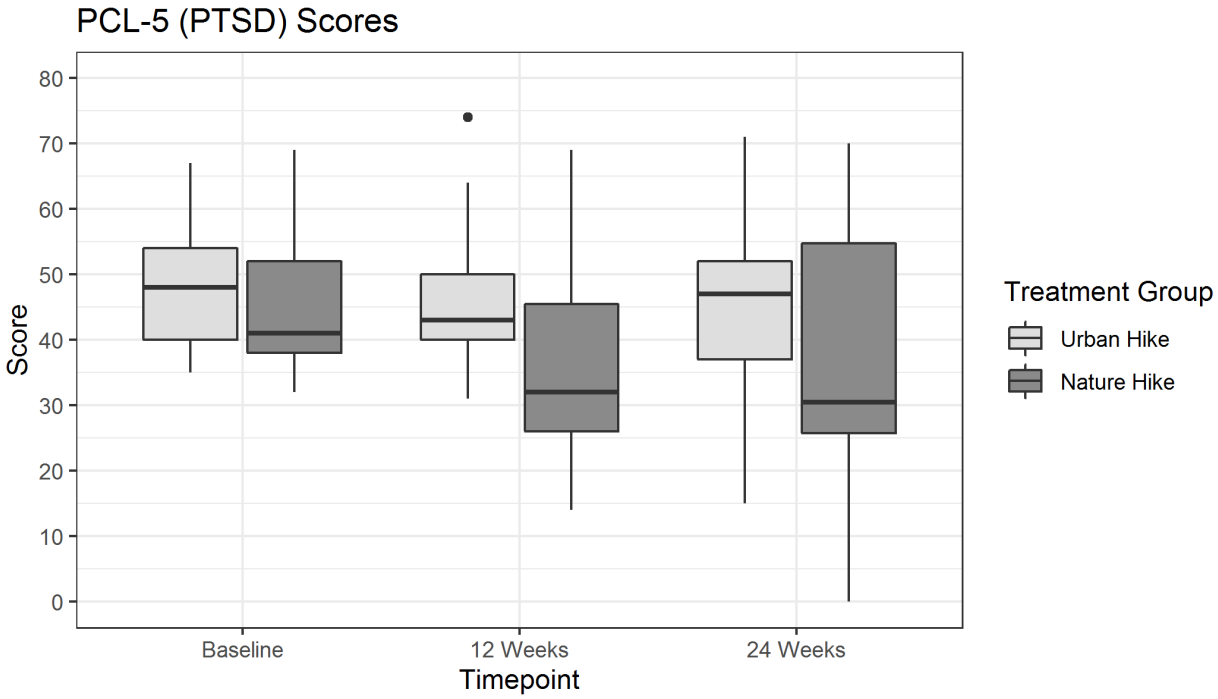
Constructs	Instrument
Demographics	n/a (Age, gender, race/ethnicity, education, service-connected disability, etc.)
Combat exposure	First two questions of the PTSD Diagnostic Scale-5 (73) and Combat Exposure Scale (74)
Ability to safely perform unsupervised physical activity	Physical Activity Readiness Questionnaire (PAR-Q) (62)
Suicidal ideation	MINI Suicidality module (65)
QoL/well-being	Satisfaction with Life Scale (75)
Physical health	14-item Physical Health Questionnaire (76)
PTSD symptoms	PTSD Checklist for DSM- 5 (61)
Depression	Personal Health Questionnaire (PHQ)-8 (77)
Perceived Stress	4-item Perceived Stress Scale (PSS) (78,79)
Affect	20-item Positive and Negative Affect Schedule (PANAS) (80,81) 10-item PANAS
Loneliness	3-item UCLA loneliness scale (82)
Social connectedness	First four items of the 6-item Perceived Cohesion Scale (83)
Anxiety	20-item Stress and Anxiety Scale (STAI) – state level 6-item STAI
Sleep	Full (19-item) Pittsburgh Sleep Quality Index (PSQI) (84) Shortened (5-item) PSQI
Nature connection	Connectedness to Nature Scale (6-items) (85)
Rumination	Full (12-item) state rumination (brooding subscale of Rumination Reflection Scale [RRS]) Shortened (8-item) state rumination (brooding subscale of RRS) (86)
Cognitive reappraisal	4-item state emotion regulation questionnaire (ERQ) (87)
Physical activity – self report	9-item International Physical Activity Questionnaire (IPAQ) short form (68)

Constructs	Instrument
Physical activity monitor	Wrist worn activity monitor (Garmin Vivosmart 4)
Alcohol consumption	10-item Alcohol Use Disorders Identification Test (AUDIT) (64) 3-item (AUDIT-C) (88)
Drug-related problems	Drug Abuse Screening Test-10 (63)
PTSD treatments	n/a
Preference for treatment, hiking frequency and expectation about treatment	n/a
Acceptability of hikes	n/a

‡Timing of assessment: S/B: screening/baseline, WK: weekly – weeks 1-5 and 7-11, FU: 6-, 12-, and 24-week follow-ups

†A, acceptability; CO, covariate (including moderators); E, eligibility (to assess inclusion/exclusion criteria); M, mediator P, primary outcome; S, secondary outcome

Figure 1. PTSD Checklist scores at baseline, 12- and to 24-weeks follow-up



CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4-7
	2b	Specific objectives or research questions for pilot trial	6-7
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	10-11
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7,9-10
	4c	How participants were identified and consented	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	10-11
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	n/a
Sample size	7a	Rationale for numbers in the pilot trial	10-11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	9-10
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	10-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 3
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 3
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Figure 2, page 10-11
	14b	Why the pilot trial ended or was stopped	11
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 3
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Supplemental Figure 1
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Table 2
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13-14
	19a	If relevant, other important unintended consequences	n/a
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	15-18
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	15-18
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	18
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	15-18
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	3
Protocol	24	Where the pilot trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	3
	26	Ethical approval or approval by research review committee, confirmed with reference number	7

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*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Nature vs. urban hiking for Veterans with posttraumatic stress disorder: a pilot randomized trial conducted in the Pacific Northwest United States

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Nature vs. urban hiking for Veterans with posttraumatic stress disorder: a pilot randomized trial conducted in the Pacific Northwest United States

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ABSTRACT

Objectives: To evaluate feasibility and acceptability of a group-based nature recreation intervention (nature hiking) and control condition (urban hiking) for military Veterans with post-traumatic stress disorder (PTSD).

Design and setting: A pilot randomized controlled trial conducted in the U.S. Pacific Northwest.

Participants: Veterans with PTSD due to any cause.

Interventions: Twenty-six participants were randomized to a 12-week intervention involving either six nature hikes (n=13) or six urban hikes (n=13).

Primary and secondary outcome measures: Feasibility was assessed based on recruitment, retention and attendance. Questionnaires and post-intervention qualitative interviews were conducted to explore intervention acceptability. Questionnaires assessing acceptability and outcomes planned for the future trial (e.g., PTSD symptoms) were collected at baseline, 6-, 12- (immediately after the final hike) and 24-weeks follow-up.

Results: Of 415 people assessed for eligibility/interest, 97 were interested and passed preliminary eligibility screening, and 26 were randomized. Mean completion of all questionnaires was 91% among those in the nature hiking group and 68% in those in the urban hiking group. Over the course of the intervention, participants in the nature and urban groups attended an average of 56% and 58%, respectively, of scheduled hikes. Acceptability of both urban and nature hikes was high; over 70% reported a positive rating (i.e., good/excellent) for the hike locations, distance, and pace. Median PTSD symptom scores (PTSD Checklist-5) improved more at 12- and 24-weeks among those in the nature vs. urban hiking group.

Conclusions: This pilot study largely confirmed the feasibility and acceptability of nature hiking as a potential treatment for Veterans with PTSD. Adaptations will be needed to improve recruitment and increase hike attendance for a future randomized controlled trial to effectively test and isolate the ways in which nature contact, physical activity, and social support conferred by the group impact outcomes.

Trial registration: Clinicaltrials.gov (NCT03997344)

Key words: posttraumatic stress disorder, Veterans, nature, green exercise, pilot randomized controlled trial

Strengths and limitations of the study

- The intervention, nature hiking (green exercise), is attractive because it has the potential to be a low stigma PTSD treatment option with physical and mental health benefits.
- By using group-based urban hiking as a comparison group to control for the effects of physical activity and social cohesion (present in both interventions), this study was designed to isolate benefits specifically due to the environment (which differed between the interventions).
- We used population-based recruitment methods to enroll a representative sample of Veterans with PTSD.
- Because of its small size and focus on feasibility, the study was not large enough to determine the effectiveness of nature hiking on outcomes.

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Competing interests: The authors have no competing interests to report.

Data availability statement: Data are available upon reasonable request. Due to legal and ethical restrictions, we are unable to share data publicly because the data contain potentially identifying and/or sensitive patient information. Subject to IRB approval, de-identified data will be released to a local Department of Veterans Affairs (VA) Puget Sound Health Care System and/or national VA research data repository for release to non-VA protocols. The VA research data repository administrator will be responsible for reviewing and responding to requests to release data to non-VA requestors. A data use agreement compliant with Veterans Health Administration Handbooks 1200.12 and 1605.1 will be required between Veterans Health Administration and

the requestor. Review and approval by VA privacy officer is required prior to disclosure. Data access requests will be reviewed by the IRB of the VA Puget Sound Health Care System (contact via Dr. Littman – alyson.littman@va.gov), via mail address: 1660 S Columbian Way, Building 101 – 5W41, Seattle, WA 98108.

Introduction

Posttraumatic Stress Disorder (PTSD) is a common, chronic mental health condition that affects up to 30% of military Veterans and is frequently comorbid with anxiety, depression, and substance misuse (1–3). PTSD increases the risk of suicide as well as obesity, physical inactivity, and cardiovascular and metabolic disorders (1–12). Clinical practice guidelines recommend treatment with several evidence-based psychotherapies and medications (13), but many Veterans who need PTSD treatment do not receive it (14). Barriers to obtaining treatment include concerns about medication side effects, desire for self-management approaches, stigma about receiving mental health care, and a lack of confidence in mental health treatment in general (14–17). These and other factors adversely impact engagement, contributing to low initiation of (14,18–22) and high drop-out rates from treatment (20,23,24). Identifying a wider range of approaches that are acceptable and effective is key to reducing the burden PTSD places on individuals and their communities.

There is growing interest in nature contact as a potential therapy for Veterans with PTSD and robust evidence that nature contact improves physical and psychological health, among healthy individuals and those with mental health disorders (25). Nature contact has been shown to increase subjective well-being; decrease stress, anxiety, depression, and negative affect; and promote adaptive shifts in emotion regulation (25,26). Benefits of nature contact are generally posited to occur based on two theories: Attention Restoration Theory (ART) and Stress Recovery Theory (SRT) (27,28). ART theorizes that nature contact improves cognitive function through a replenishment of “directed attention”, a capacity that is overly taxed in urban environments due to the need to block out distracting stimuli (e.g., noise) to focus on a specific task or cognitive process. This depleted attention capacity can be restored in natural environments through the engagement of “soft fascination”, with implications for both cognitive and emotional well-being. SRT is based on psycho-evolutionary principles, and posits that many types of nature exposure enhance psychological well-being through a pre-cognitive, positive

affective response and activation of the parasympathetic nervous system in ways that reduce stress and sympathetic nervous system arousal (26,29,30).

Like nature contact, physical activity (PA) is considered to be a promising approach to improve outcomes for individuals with PTSD. PA reduces anxiety and depression and improves stress regulation, sleep, and cognitive functioning in the general population (10,11,31), and in people with PTSD, though only eight studies have involved randomized controlled trial (RCT) designs (4,32–39), and five of the RCTs were pilot studies or included fewer than 30 people (32,33,35,38,39). Furthermore, we are aware of only one RCT focused on Veterans (39). Group-based PA interventions may be particularly well-suited for military Veterans, due to 1) proportionally higher rates of PTSD among Veterans (40), 2) consistency of PA interventions with values cultivated during military service, and 3) benefits of social interaction with Veteran peers (41). To our knowledge, no PA interventions in those with PTSD investigated the PA environment as a component of treatment. This is an important omission, because the environment in which PA takes place may play an important role in its benefits (42).

Green exercise, defined as activity that takes place in natural environments, is a burgeoning area of research (43–48). A number of studies have documented benefits from green exercise in Veteran populations and among individuals with PTSD (45–55). The specific interventions studied (from care farming to river rafting), dose/duration, and inclusion of additional, explicit therapeutic components vary substantially among studies. A 2019 systematic review that examined evidence for the proposed additive effects of exercise in the presence of nature observed some benefits (e.g., lower perceived exertion and enjoyment), the authors concluded that there was a high risk of bias across trials and an overall low quality of evidence (44). Thus, uncertainty about the duration and impacts of green exercise remains due to methodological issues and because most interventional studies tested only a single bout of exercise (43,44). Furthermore, in the studies including Veterans, important

limitations include low retention for follow-up, absence of control groups, and insufficient statistical power (52–58).

In addition to nature contact and PA, a third important component of many green exercise interventions includes a group component. Some recent research suggests that increased social cohesion and connectedness may mediate benefits of green exercise (59), but findings are inconsistent (60). Social support forged through group activity could be particularly relevant for Veterans, as camaraderie and solidarity are critical components of military culture, and ones that are frequently lost in the return to civilian life (61). Social support is associated with reduced PTSD symptoms and improved treatment response (62) and may directly impact stress response by increasing personal resources (63), and/or may indirectly impact PTSD symptom severity and response to treatment through buffering the potentially harmful impacts of stressful events (64).

Adequately powered studies involving ongoing green exercise that are designed to distinguish between benefits due to PA and those due to the physical (e.g., nature) and social (e.g., group cohesion) environment are needed. Thus, our goal was to design and conduct a pilot study to test the feasibility and acceptability of a green exercise intervention for PTSD symptoms in military Veterans, regardless of PTSD etiology. The intervention (nature hiking) and the active control (urban hiking) were group-based and involved similar amounts of PA, to ensure control of the potential benefits of the group-based social support and of PA. Figure 1 depicts our conceptual model. This paper describes the results of the initial pilot study designed to emulate important elements of the future envisioned full-scale randomized trial.

Methods

Identification and recruitment of participants

We used active and passive methods to identify and recruit Veterans to participate. While receiving care at a Department of Veterans Affairs (VA) health care facility was not an inclusion criterion, we used VA electronic medical records as a key source to identify potentially eligible Veterans. We identified VA enrollees (identified using electronic medical records) with at least one encounter with a diagnosis of PTSD in the prior two years; a zip code in one of three Seattle-Tacoma area counties (King, Snohomish, and Pierce); no hospitalizations in the prior 3 months; and no diagnoses of schizophrenia, bipolar disorder, or other psychotic disorder. We randomly selected 1001 individuals who met these criteria from a total of approximately 7000 and mailed them a letter informing them about the study and inviting them to participate. We followed the mailing with up to three phone calls until we met recruitment targets, or the recruitment period ended, whichever happened first. We also placed study recruitment flyers in clinics in the VA Puget Sound and mailed flyers to four local organizations and clinics serving Veterans. Individuals who expressed an interest were mailed an invitation letter.

We initially screened all Veterans who expressed an interest in participating for eligibility over the phone; inclusion criteria assessed included a history of PTSD, ability/willingness to comply with study procedures (e.g., complete questionnaires, wear and sync an activity monitor, drive to hikes, and walk at least 2 hours at an easy/moderate pace over uneven terrain). Exclusion criteria assessed included a diagnosis of schizophrenia, bipolar disorder, or other psychotic disorder; hospital admission in the prior 3 months, and inability to perform unsupervised physical activity based on the Physical Activity Readiness Questionnaire (65). We invited those who passed all criteria except for the Physical Activity Readiness Questionnaire to obtain approval to participate from their primary care provider. Though some of this information was available in VA medical records, because we also included Veterans who did not have VA medical records, we employed methods that allowed us to evaluate eligibility without medical record access. Those who passed initial screening were mailed consent forms and given a link to complete a more extensive screening questionnaire online. Via the online screening

questionnaire, PTSD symptoms, drug use, alcohol misuse, and suicidality were assessed. PTSD was determined based on a PTSD-checklist-5 (66) score ≥33. We excluded those with drug abuse in past year (Drug Abuse Screening Test-10 (67) score <3); alcohol disorder/dependence (current/past year; Alcohol Use Disorders Identification Test-10 (68) score>16); and moderate/severe suicidality (past month; MINI Suicidality module (69) score≥5). Those who were eligible and returned signed consents were considered enrolled in the study.

Study design

We conducted a two-arm randomized controlled feasibility trial. The two interventions were group nature and group urban hiking. The random 1:1 allocation sequence was generated using simple randomization in random blocks of 2, 4 and 6. Randomization assignments were placed in opaque sequentially numbered envelopes. Once an individual was determined to be eligible, the study coordinator selected the next envelope to determine the individual's group assignment. We did not blind participants, the study coordinator, or the study statistician to group assignment. This study was registered at Clinicaltrials.gov (NCT03997344). Figure 2 presents an overview of the study, including timing of assessments.

Description of hike locations and amenities

The criteria used to select the hike locations (which applied to both nature and urban hikes) included duration, elevation change, availability of facilities (e.g., toilets and water), distance from participants' homes, and access to parking. Nature hikes were held in State Parks, National Wildlife Refuges, and Natural Resources Conservation areas in the US Pacific Northwest. The nature hikes were in forest habitat, including old growth forest, saltwater shoreline, waterfalls, and alpine lakes. Elevations ranged from sea level to 2200 feet above sea level. Urban hikes were held in primarily built environments, avoiding urban parks or primarily residential neighborhoods with substantial greenery or water features. Urban hikes comprised areas that included sports stadiums, urban art, and retail establishments and were mainly on sidewalks rather than separated bike/pedestrian paths/rail-

trails. It was not feasible to match nature and urban hikes on elevation change; instead, we aimed to have similar hike durations to match total exertion. Generally, nature hikes involved somewhat shorter distances but included more elevation gain/loss.

Hiking intervention

A total of 6 hikes over 12 weeks (one every other week) were offered between August and October 2019. We chose to offer 6 hikes (vs. more or fewer) because this number was thought to be feasible and would be sufficient to assess feasibility and acceptability. The standard structure for hikes was: 1) "ice breakers" (short, guided conversations), 2) overview of the planned hike, including distance, unique features, and planned stops, 3) hike, and 4) post-hike debrief and administration of questionnaires. There were no additional group/therapeutic activities.

Hike durations increased gradually to account for anticipated increases in participants' physical fitness. Initial hikes were 60-90 minutes (2-3 miles), and later hikes were 2-3 hours (5-6 miles). To ensure safety and inclusion, one hike leader was in sight and hearing of the first participant and a second leader accompanied the last participant. The group stopped at least every 30 minutes to keep everyone together and offer opportunities to rest, regroup, and inquire about and address any issues or concerns arising since the last check-in.

The same hike leaders, who were non-clinicians, led both nature and urban hikes to control for hike-leader effects. On every hike, at least one of the leaders was a woman. Leaders were experienced outdoor educators who were employed by a Seattle-based outdoor organization that provides outdoor recreation activities for people with disabilities. While the leaders were not Veterans, the organization received grants from the VA as part of the Adaptive Sports Program (70) and had previously led programs for Veterans. Leaders were trained to

handle physical and mental health emergencies by the PIs (AJL and GNB) and a co-I who is a licensed clinical psychologist (KL). AJL and GNB supervised the hike leaders during the study.

To reduce barriers to attendance, a $35 incentive was provided to defray parking costs. We provided a rain jacket and technical shirt as well as well as an activity monitor (Garmin vivosmart 4) at the participant's first hike.

Outcomes

The primary outcomes of interest were feasibility and acceptability. **Feasibility** was assessed based on recruitment statistics (the proportion of individuals who were contacted, eligible, and enrolled, as well as reasons for ineligibility), retention (questionnaire completion), hike attendance, and safety (e.g., adverse events). We aimed to recruit 36-45 participants (12-15 people allocated to each of the three groups - nature hiking, urban hiking, and a no-hiking control group) and complete enrollment by July 2019 (approximately 3 months after recruitment began) due to concerns about weather for hikes later in the fall. Because of lower-than-anticipated recruitment numbers, in late June, we decided to eliminate the no-hiking control group. At this time, only one person was randomized to the no-hiking control group and informed of their group assignment; that person was re-randomized after this decision was made. The target for retention and attendance was 70%.

To assess **acceptability**, in the 6- and 12-week questionnaires, we included questions about distance, pace, terrain, and locations of hikes and pre-hike and trailhead information and communication. These questions were created for the study and asked participants to rate their perceptions on a 5- or 6-point Likert scale (e.g., from very poor to excellent). We also included open-ended questions for participants to report what they thought went well and what could have been better. Additionally, after the final hike, the lead author (AJL) conducted semi-structured telephone interviews, with a goal to interview 10-15 participants. To include a range of

perspectives, we purposively sampled participants from both arms, aimed to include men and women, and participants who varied in terms of hike attendance. Questions inquired about participants' impressions of the hikes, including difficulty, location, length of time, distance from home, hike leaders, and reasons hikes were missed (if applicable); study communications; enrollment process; assessments; and other thoughts/impressions.

Determination of **efficacy** was not a goal of this pilot RCT. The primary outcome of the future planned study is PTSD symptoms, assessed by the PTSD-Checklist-5 (PCL-5), a 20-item instrument that assesses PTSD symptoms in the past month (range 0 to 80, with higher scores indicating greater symptom severity). Other outcome measures of interest for the future planned study, which are detailed in Supplemental Table 1, include quality of life (71), positive and negative affect (72,73), sleep (74), rumination (75), and cognitive reappraisal (76).

Baseline and follow-up assessments

We conducted assessments online using commercial software (QuestionPro) at baseline (before hikes began), each week after the first hike for 12 weeks (after the 6th hike), and then at week 24; questionnaires completed immediately after the hikes were completed on paper. See Figure 2 for an overview and Supplemental Table 1 for measures at each time point. Questionnaires at weeks 6, 12, and 24 took approximately 30 minutes to complete. Questionnaires administered at weeks 1-5 and 7-11 included fewer measures and/or shortened versions and took 5-10 minutes to complete. Participants received gift cards worth $10 for completing questionnaires in weeks 1-5 and 7-11, $20 for the 6-week questionnaire, and $50 for the 12- and 24-week questionnaires. In addition to questionnaires, to obtain objective information about PA (a potential mechanism of benefit, which we would want to measure precisely in a future study), we asked participants to wear a wrist worn-activity monitor (Garmin vivosmart 4) every day, for at least 10 hours per day, for the first 12 weeks of the study. No incentives were provided for wearing or synching the watch.

Data analysis

Quantitative analysis

The primary purpose of the extensive data collection was to evaluate feasibility of data collection rather than to estimate effect sizes because estimating effect sizes from small pilot studies is inherently imprecise (77). Thus, instead of conducting hypothesis tests for which we were underpowered, we present descriptive statistics (e.g., medians and interquartile ranges) for the primary outcome (PCL-5) only.

Qualitative analysis

All interviews were recorded, and the interviewer took notes during interviews. For both the comments shared via open-ended questions on the questionnaire and comments shared orally during the interviews, we conducted inductive content analysis, which involves open coding of data, organizing codes and data into categories, and comparing data across participants to identify patterns and themes in the data (78).

Patient and public involvement

Patients were involved in the design and conduct of this study. The study question and design were informed by a Veteran with PTSD who served as a co-investigator. The design and messaging for this pilot study were also informed by a focus group of patients/Veterans who participated in a prior unpublished feasibility study.

Ethics approval

This study was approved by the institutional review boards at the VA Puget Sound Health Care System (MIRB 01738) and the University of Washington (6951).

Results

Feasibility

Recruitment statistics

Recruitment took place between April and August 2019 (16 weeks total). Of the 1001 patients mailed an invitation letter, we were unable to assess interest or eligibility in 586 (because they did not respond to the mailings and/or answer the phone when called; see Figure 3 for CONSORT diagram). Of the 415 with whom we made contact, 159 were not interested, 102 had health conditions that limited their walking/hiking, 36 had time conflicts (e.g., work or church on Sundays or travel that would prevent participation), and 37 had other reasons that they were unable to participate (e.g., moving out of the area, did not have PTSD, etc.). Of the 97 (81 from letters + 16 from passive recruitment) interested who passed initial screening, 48 completed the online screening questionnaire. Twenty individuals were not eligible, 2 decided that they did not wish to participate, and 26 were eligible and randomized. Of the 20 who were not eligible, 13 were ineligible because of a moderate/high risk of suicide or skipping the question on suicidality, and 6 did not meet the threshold for PTSD. Compared to those contacted and not randomized, a greater proportion of those randomized were women (27% randomized vs. 15% of those contacted), white (73% vs. 63%), and Hispanic (8% vs. 6%). Additionally, those who were randomized were younger (mean age = 47, range 25-65) than those not randomized (mean age = 52, range: 21-95).

Table 1 presents characteristics of Veterans who were randomized and includes self-reported race/ethnicity, which differed from race/ethnicity in the electronic medical record (reported above). Specifically, 42% of those randomized self-reported being white, whereas the electronic medical record data indicated that 73% were white. Thirty percent had a college degree or more. Less than half worked full time and 46% had 100% VA service-connected disability, indicating severe impairment in ability to work. Nearly two-thirds of participants had served in combat and 68% had depressive symptoms based on the PHQ-8. Based on self-report, nearly 70% met or exceeded PA guidelines of at least 75 minutes per week of vigorous-intensity activity or 150 minutes per

week of moderate-intensity activity, or an equivalent combination of the two. At baseline (prior to study initiation), 81% of participants reported hiking at least one time and 27% completed 7 or more hikes in the prior year.

Retention (questionnaire completion)

Mean completion of all questionnaires was 91% in the nature hiking group and 68% in the urban hiking group. Completion rates were similar for the shorter weekly questionnaires and the longer questionnaires.

Hike attendance

Over the course of the intervention, participants in the nature and urban groups attended an average of 56% and 58%, respectively, of scheduled hikes. In the nature group, one person attended no hikes, four (31%) attended 1-2 hikes, one attended 3 hikes, and seven (54%) attended 4-6 hikes. In the urban group, one person attended no hikes, four (31%) attended 1-2 hikes, no one attended only 3 hikes, and eight (62%) attended 4-6 hikes. Attendance was lower among women in the nature group (n=5, mean: 43%) than among women in the urban group (n=2, 67%), whereas among men, hike attendance was similar in the two groups (65% vs. 56%). Common reasons for missing hikes included work, childcare, and prior plans.

Safety/Adverse events

One participant in the urban hiking arm reported increased anxiety/PTSD symptoms in connection with hiking in the urban environment and withdrew from the study.

Acceptability

Quantitative findings

Acceptability of both the urban and nature hikes was high. Over 70% reported a positive rating (i.e., good or excellent vs. very poor/inadequate, inadequate, or adequate) for the hike locations, distance, and pace. Additionally, on average, pre-hike information, pre-hike communication, and trailhead communication were rated as good to excellent. Scores (minimum=1, maximum=5) were similar in the urban and nature hike groups at 6 weeks, but were lower in the urban hiking arm at 12 weeks (pre-hike information, mean scores: nature=4.4, urban=3.6; pre-hike communication: nature=4.6, urban=3.8; trailhead communication: nature=4.6, urban=4.1)

Qualitative findings

In response to the open-ended question on the questionnaire ("What went well so far?"), participants shared positive comments such as "This group seems to mesh really well", "all expectations were exceeded", and "good planning, leadership, and execution." In response to the question, "What do you think we can do better?", suggestions included having regional groups, closer hikes or paying for gas; weekly (instead of every other week) hikes; more team building and opportunities to socialize with others; and including more women and/or women-only groups. Key themes from the qualitative interviewers, which are presented in Table 2, echoed, and elaborated on themes shared in the questionnaire. Most participants felt positively about their experience in the study. As noted above, they liked getting to know other Veterans and having a "mission." Veterans wanted to find more ways of connecting with one another socially during hikes as well as outside of hikes. Hike logistics (e.g., distance from home) were noted as potential barriers to attendance.

Efficacy measures

Median PCL-5 scores decreased from baseline to week 12 and remained at the 12-week level at week 24 for those in the nature hiking group (baseline=41, 12-weeks = 32, 24 weeks=31). Among those in the urban hiking group, PCL-5 scores decreased from baseline to 12 weeks but increased nearly back to baseline levels at 24

weeks (baseline=48, 12-weeks = 43, 24 weeks=47) (Supplemental Figure 1). We did not test the statistical significance of the changes because this pilot study was not designed to answer this question (79).

Discussion

This study was an important step in establishing feasibility and acceptability and identifying changes to consider in the development of a rigorous, fully-powered study to evaluate the impact of nature hiking on PTSD symptoms. The results of this pilot study generally supported feasibility and acceptability. Participants reported high acceptability, enjoyment, and value, based on quantitative and qualitive data. In both arms, more than half of participants completed most hikes. Qualitative feedback about improving the social component supports the hypothesis that social connection is an important aspect of hikes, indicating a need to further develop the social component and continue to study group interventions like this one. Additionally, the decrease in median scores on the PCL-5 among those in the nature group after the 12-week hiking intervention, and 12 weeks later (week 24) is promising. This preliminary finding should be investigated more thoroughly in future, larger-scale versions of our study. The indication that improvements may persist after the conclusion of the intervention is especially compelling given the current unknowns regarding the duration of effects of nature interventions.

Nevertheless, several issues need to be considered related to feasibility and acceptability for the next iteration of this research.

Feasibility of recruitment

We fell short of our goal of recruiting at least 36 people over 4 months. Failing to meet recruitment goals in the planned timeframe is a common problem in randomized controlled trials (80). Barriers to recruitment included unexpected delays, insufficient resources, and an inefficient recruitment process. Regarding delays, we had to

wait weeks for IRB approval for each proposed modification to recruitment materials/protocol. Regarding resources, we only had 20 hours per week of paid staff time for recruitment. The addition of two volunteers in the final two months helped to accelerate enrollment, but more resources earlier in recruitment would have been necessary to meet our goal.

One contributor to inefficiency in recruitment was the broad, population-based approach we employed for active recruitment. To identify patients for the introductory mailing, the only inclusion criteria were having a single encounter in VA's electronic medical record with a PTSD diagnosis and living in one of three Puget Sound counties. The only exclusion criteria were a diagnosis of schizophrenia, bipolar disorder, or other psychotic disorder. Likely in part because of this broad approach, which did not include upper age limits, approximately one quarter of contacted individuals reported a health condition that impaired their walking. Burdensome study procedures may have also impacted recruitment. About half of interested participants failed to complete the online screening questionnaire and others informed us that they had trouble completing the online questionnaire. Imposing an upper age limit (e.g., 65 years) and restructuring the recruitment process to make it faster and easier for potential participants may be necessary.

Accessibility of the intervention and restrictive eligibility criteria may have also impacted recruitment. In addition to being able to walk over uneven ground for at least two hours, participants also had to be available during the times selected, have low suicide risk, and be free from physical conditions such as high blood pressure (or obtain their primary care provider's permission) among several other criteria. Changing inclusion criteria (e.g., eliminating restrictions related to suicidality) would require tradeoffs related to safety that must be considered carefully.

Lastly, about 38% (159/415) of those for whom we were able to assess eligibility and interest declined participation. While some of these people may have declined because of the additional burdens of a research study, this statistic indicates that hiking may only appeal to a segment of the population, just as psychotherapy and pharmacotherapy only appeal to subsets of the population (81). Because of differences in treatment preferences, offering options is important, and nature hiking merits consideration so that we can rigorously assess its efficacy.

Retention

Retention varied by group and was poorer for the wrist-worn activity monitor than for the questionnaires. The activity monitor had a substantial amount of missing data, which is a common problem for activity monitors (82), and may have been related to the number of technical steps required for setting up the watch and syncing it, as many participants needed additional help to troubleshoot problems. Providing more support to set up the watch and incentives to wear and sync it may help to obtain more complete data. While overall questionnaire completion was high, it was higher in the nature hiking group (91%) than in the urban hiking group (68%). Though the small sample and our inability to conduct interviews with those who did not complete follow-up measures makes inference difficult, the retention differences could be a marker of commitment to the study. Future studies should pay careful attention to marketing the study to ensure that both interventions are perceived as helpful. Enhancing the social aspects of the interventions may help achieve that goal. The difference in incentives provided for questionnaire completion vs. the other aspects of the study may also have played a role in retention for different study aspects. However, many participants shared that they participated to help fellow Veterans, indicating altruistic/intrinsic motivators for participation, reinforcing the importance of understanding drivers of participation, and reducing barriers and enhancing facilitators.

Acceptability of the hiking interventions

Hike attendance (56%) was lower than our target (70%) and women had lower attendance in the nature hiking group than men. While we were unable to ascertain reasons for missing hikes for each person, some reasons reported (e.g., other plans, work) were hard to avoid, while others (driving distance to hikes) could be addressed in the future by restricting the geographic area of recruitment and hikes and/or organizing small groups at different times to accommodate individuals' schedules. Our study, unfortunately, does not shed light on the optimal hike "dose." We suspect that 8-12 hikes (similar to a standard psychotherapy course) may be optimal for achieving clinically meaningful results. Additional research will be necessary to examine this important question. There were also an indication of lower acceptability/ratings for information sharing in the urban hiking vs. the nature hiking groups. While we aimed to share information about the urban area, we did not provide an exact route, which may have made it more difficult for participants to research urban vs. nature hikes, where we listed a trail. Providing a map of the route might help participants feel prepared. Regarding differences in attendance by gender, a history of military sexual trauma, which is common among women Veterans (83), may have impacted some women participants' comfort and perception of safety of hiking in nature with a majority male group. Ensuring a greater proportion of women in each group or organizing women-only groups (as was suggested by some participants) could address this concern. These changes, would, however, result in additional costs and tradeoffs that would need to be carefully considered.

Conclusions

This pilot study provided useful information related to feasibility and acceptability, including common factors that resulted in exclusion; resources and procedures needed for recruitment; factors to consider for selection of nature and urban hikes; and barriers and facilitators to achieving high completion in follow-up assessments and the hikes. These insights can be harnessed to increase participation and rigor in future, scaled-up iterations of the study, and ensure that environments are safe (i.e., non-triggering). Future studies with larger sample sizes

are needed to isolate the ways nature contact, PA, and social support conferred by the group impact outcomes to develop and provide well-tailored interventions.

List of abbreviations

ART	Attention Restoration Theory
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
PA	Physical activity
PCL-5	PTSD Checklist for Diagnostic and Statistical Manual 5
PTSD	Posttraumatic stress disorder
SRT	Stress Recovery Theory
VA	Department of Veterans Affairs

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Figure 1. Conceptual model

Figure 2. Depiction of study design and assessments

Figure 3. CONSORT diagram

Table 1. Baseline characteristics of Veterans in the urban and nature hiking groups

Characteristic	Total (n=26)		Nature (n=13)		Urban (n=13)	
	N or mean	% or SD	N or Mean	% or SD	N or Mean	% or SD
Age (years)						
<30	2	8	1	8	1	8
30-39	5	19	2	15	3	23
40-49	6	23	4	31	2	15
50-59	11	42	6	46	5	38
≥60	2	8	0	0	2	15
Gender						
Male	19	73	8	62	11	85
Female	7	27	5	38	2	15
Race/ethnicity						
Asian/Pacific Islander, NH	3	12	2	15	1	8
Black, NH	2	8	0	0	2	15
Hispanic	3	12	1	8	2	15
Native American, NH	2	8	0	0	2	15
Other	1	4	0	0	1	7.7
White, NH	15	58	10	77	5	38
Marital status						
Single, never married	4	15	3	23	1	8
Married currently	14	54	7	54	7	54

Characteristic	Total (n=26)		Nature (n=13)		Urban (n=13)	
	N or mean	% or SD	N or Mean	% or SD	N or Mean	% or SD
Separated/divorced	8	31	3	23	5	38
Education						
High school degree or equivalent	4	15	1	8	3	23
Some college, no degree	10	38	7	54	3	23
Associate degree	4	15	1	8	3	23
Bachelor's degree	4	15	2	15	2	15
Masters, doctorate, or professional degree	4	15	2	15	2	15
Annual household income						
$25,000-$49,999	7	27	4	31	3	23
$50,000-$74,999	11	42	4	31	7	54
$75,000-$99,999	2	8	1	8	1	8
$100,000 or more	4	15	3	23	1	8
Prefer not to answer	2	8	1	8	1	8
Employment status						
Full-time	12	46	6	46	6	46
Part-time	1	4	1	8	0	0
Not employed (disabled, retired, not looking for work, homemaker, other)	13	50	6	46	7	54
Highest military rank						

Characteristic	Total (n=26)		Nature (n=13)		Urban (n=13)	
	N or mean	% or SD	N or Mean	% or SD	N or Mean	% or SD
Enlisted (E1-E4)	9	35	4	31	5	38
Non-commissioned officer (E5-E9)	15	58	8	62	7	54
Officer (O1-O4)	2	8	1	8	1	8
VA disability rating*†						
No rating	2	8	0	0	2	15
30-60%	2	8	2	15	0	0
70-90%	8	31	4	31	4	31
100%	12	46	6	46	6	46
Self-reported health						
Excellent/very good	9	35	3	23	6	45
Good	11	42	7	54	4	31
Fair (no one reported poor)	6	23	3	23	3	23
PCL-5 score‡						
Mean, SD	47.1	10.9	46.0	11.4	48.2	10.8
Served in combat [yes]	17	65	8	62	9	69
Combat Exposure Score; mean (SD)* †	16.6	7.9	15.6	8.2	17.7	7.9
Patient Health Questionnaire-8 score*						
<10 (no depression)	8	32	4	33	4	31
10-19 (major depression)	14	56	7	58	7	54
≥20 (severe major depression)	3	12	1	8	2	15

Characteristic	Total (n=26)		Nature (n=13)		Urban (n=13)	
	N or mean	% or SD	N or Mean	% or SD	N or Mean	% or SD
Physical activity level						
Low	8	31	5	38	3	23
Moderate	3	12	1	8	2	15
High	15	58	7	54	8	62
Times gone hiking for 1+ hrs in last year						
Never	5	19	3	23	2	15
1-3	9	35	4	31	5	38
4-6	5	19	2	15	3	23
7+	7	27	4	31	3	23
Outdoor / nature-based activity experience						
None (no experience in the outdoors)	0	0	0	0	0	0
Casual (done some day hiking on maintained trails and car camping)	10	38	5	38	5	38
Amateur (have experience with backpacking)	11	42	6	46	5	38
Expert (substantial backcountry experience)	5	19	2	15	3	23

Abbreviations: NH, Non-Hispanic; PCL-5, Post-traumatic stress disorder checklist for Diagnostic and Statistical Manual 5; PTSD, post-traumatic stress disorder; SD, standard deviation

* Missing response for 1 nature participant

† Missing response for 1 urban participant

‡ One person in the nature hiking group had a PCL-5 of 32 (below the eligibility threshold of 33) due to an undetected error in initial scoring.

Table 2. Key themes and findings from qualitative data

Themes	Findings
A positive experience	• Both nature ("All expectations were exceeded") and urban study participants ("LOVE THE GROUP") provided positive feedback.
Perceived benefits	• Participants reported on how the hikes helped them to be more active, lose weight, reduce stress, and feel more connected to others.
Hike logistics	• Participants suggested that prior to hikes, we ensure parking access, availability of toilets, and locate the hikes closer to participants' homes. • Others suggested that we consider organizing carpools and/or covering gas/mileage costs
Difficulty of hikes	• Most found the difficulty just right. • Some felt that the hikes were too short/easy.
Location of hikes	• Nature group: One participant wished that there was more of a "reward" ("like a waterfall", "when you have a view, it seems more profound"), because some were just "walks through the woods." • Urban group: One person noted that some neighborhoods were "sketchy" and they were "constantly walking around garbage" for one hike. Others noted that they really enjoyed exploring different neighborhoods, areas around sports stadium, and learning about the history of areas.

Group composition	• A few participants suggested that we enroll more women or organize women-only groups and/or groups for survivors of sexual assault.
Incentives for completing questionnaires	• Participants suggested that we offer the option to receive a single gift card that accumulated value instead of separate ones each time a questionnaire was completed.
Assessments	• Several participants had trouble with the online software (e.g., getting "kicked out" of the survey mid-way through); • Some participants reported that they would have liked text prompts instead of email, since they did not regularly check their email. • Some participants found some questions to be difficult to answer (e.g., the Perceived Cohesion Scale) or they were confused by differences in the time frame for different instruments (e.g., on the weekly questionnaires, some questions asked participants how they felt "right now" while others asked about the prior week).
Activity monitors	• Several participants noted having problems programming and syncing the activity monitor.
Fostering interaction/connections between participants in a group	• Participants suggested facilitating more structured ways to get to know other members of the group, including a social gathering prior to the initial hike, re-introductions before each hike, gathering for lunch or other meal after hikes, and organizing a social media group.

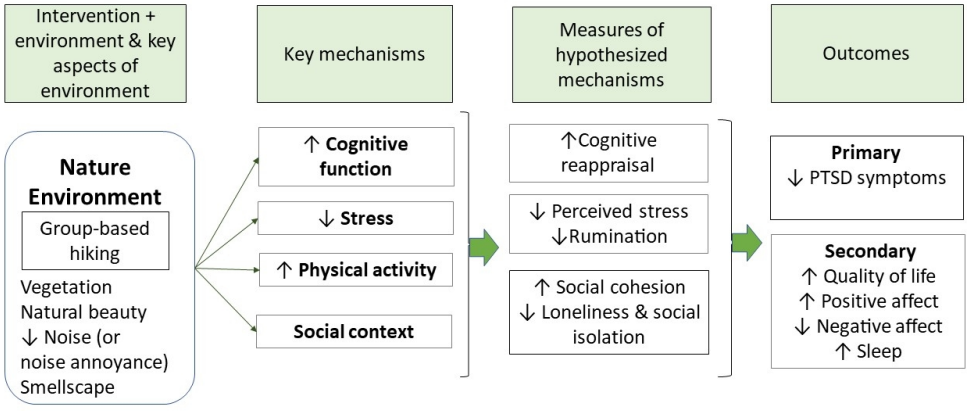


Figure 1. Conceptual model

338x190mm (96 x 96 DPI)

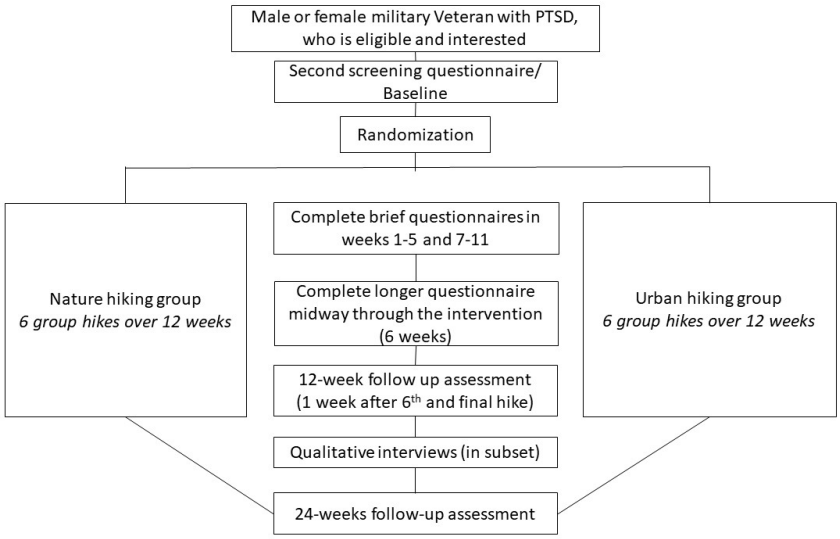


Figure 2. Depiction of study design and assessments

338x190mm (96 x 96 DPI)

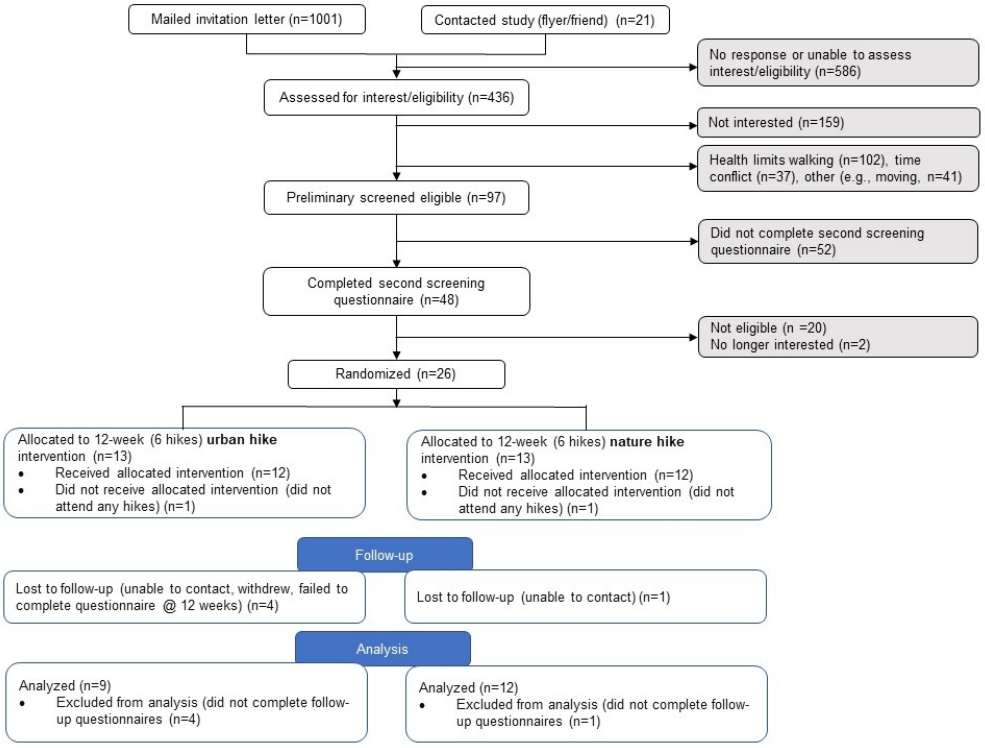


Figure 3. CONSORT diagram

254x190mm (96 x 96 DPI)

Supplemental Table 1. Constructs, instruments, and timing of assessments

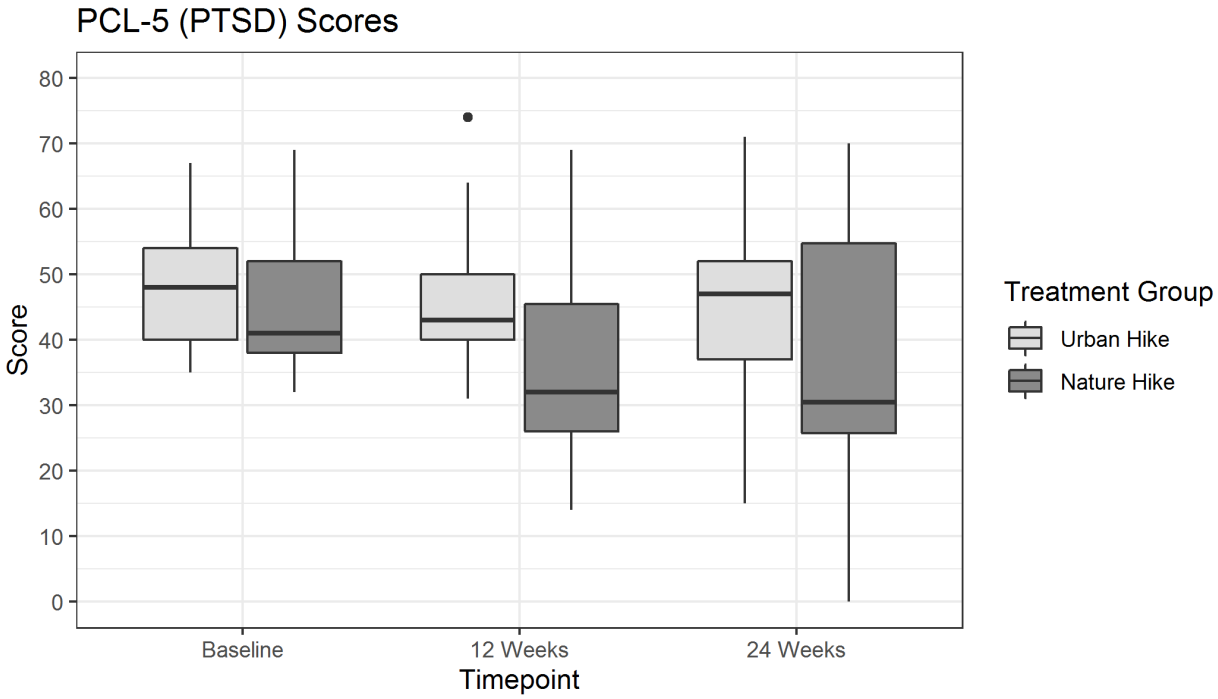
Constructs	Instrument
Demographics	n/a (Age, gender, race/ethnicity, education, service-connected disability, etc.)
Combat exposure	First two questions of the PTSD Diagnostic Scale-5 (73) and Combat Exposure Scale (74)
Ability to safely perform unsupervised physical activity	Physical Activity Readiness Questionnaire (PAR-Q) (62)
Suicidal ideation	MINI Suicidality module (65)
QoL/well-being	Satisfaction with Life Scale (75)
Physical health	14-item Physical Health Questionnaire (76)
PTSD symptoms	PTSD Checklist for DSM- 5 (61)
Depression	Personal Health Questionnaire (PHQ)-8 (77)
Perceived Stress	4-item Perceived Stress Scale (PSS) (78,79)
Affect	20-item Positive and Negative Affect Schedule (PANAS) (80,81) 10-item PANAS
Loneliness	3-item UCLA loneliness scale (82)
Social connectedness	First four items of the 6-item Perceived Cohesion Scale (83)
Anxiety	20-item Stress and Anxiety Scale (STAI) – state level 6-item STAI
Sleep	Full (19-item) Pittsburgh Sleep Quality Index (PSQI) (84) Shortened (5-item) PSQI
Nature connection	Connectedness to Nature Scale (6-items) (85)
Rumination	Full (12-item) state rumination (brooding subscale of Rumination Reflection Scale [RRS]) Shortened (8-item) state rumination (brooding subscale of RRS) (86)
Cognitive reappraisal	4-item state emotion regulation questionnaire (ERQ) (87)
Physical activity – self report	9-item International Physical Activity Questionnaire (IPAQ) short form (68)

Constructs	Instrument
Physical activity monitor	Wrist worn activity monitor (Garmin Vivosmart 4)
Alcohol consumption	10-item Alcohol Use Disorders Identification Test (AUDIT) (64) 3-item (AUDIT-C) (88)
Drug-related problems	Drug Abuse Screening Test-10 (63)
PTSD treatments	n/a
Preference for treatment, hiking frequency and expectation about treatment	n/a
Acceptability of hikes	n/a

‡Timing of assessment: S/B: screening/baseline, WK: weekly – weeks 1-5 and 7-11, FU: 6-, 12-, and 24-week follow-ups

†A, acceptability; CO, covariate (including moderators); E, eligibility (to assess inclusion/exclusion criteria); M, mediator P, primary outcome; S, secondary outcome

Figure 1. PTSD Checklist scores at baseline, 12- and to 24-weeks follow-up



CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	5-7
	2b	Specific objectives or research questions for pilot trial	7
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	9
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	11
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8-10
	4c	How participants were identified and consented	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8, 11-12
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	n/a
Sample size	7a	Rationale for numbers in the pilot trial	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	9-10
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 3
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 3
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Figure 2, page 11-12
	14b	Why the pilot trial ended or was stopped	12
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 3
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Supplemental Figure 1
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Table 2
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	15
	19a	If relevant, other important unintended consequences	n/a
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	17-21
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	17-21
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	17-21
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	17-21
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	3
Protocol	24	Where the pilot trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2, 9
	26	Ethical approval or approval by research review committee, confirmed with reference number	13

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Nature versus urban hiking for Veterans with posttraumatic stress disorder: a pilot randomized trial conducted in the Pacific Northwest United States

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Nature versus urban hiking for Veterans with posttraumatic stress disorder: a pilot randomized trial conducted in the Pacific Northwest United States

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ABSTRACT

Objectives: To evaluate feasibility and acceptability of a group-based nature recreation intervention (nature hiking) and control condition (urban hiking) for military Veterans with post-traumatic stress disorder (PTSD).

Design and setting: A pilot randomized controlled trial conducted in the U.S. Pacific Northwest.

Participants: Veterans with PTSD due to any cause.

Interventions: Twenty-six participants were randomized to a 12-week intervention involving either six nature hikes (n=13) or six urban hikes (n=13).

Primary and secondary outcome measures: Feasibility was assessed based on recruitment, retention and attendance. Questionnaires and post-intervention qualitative interviews were conducted to explore intervention acceptability. Questionnaires assessing acceptability and outcomes planned for the future trial (e.g., PTSD symptoms) were collected at baseline, 6-, 12- (immediately after the final hike) and 24-weeks follow-up.

Results: Of 415 people assessed for eligibility/interest, 97 were interested and passed preliminary eligibility screening, and 26 were randomized. Mean completion of all questionnaires was 91% among those in the nature hiking group and 68% in those in the urban hiking group. Over the course of the intervention, participants in the nature and urban groups attended an average of 56% and 58%, respectively, of scheduled hikes. Acceptability of both urban and nature hikes was high; over 70% reported a positive rating (i.e., good/excellent) for the hike locations, distance, and pace. Median PTSD symptom scores (PTSD Checklist-5) improved more at 12- and 24-weeks among those in the nature versus urban hiking group.

Conclusions: This pilot study largely confirmed the feasibility and acceptability of nature hiking as a potential treatment for Veterans with PTSD. Adaptations will be needed to improve recruitment and increase hike attendance for a future randomized controlled trial to effectively test and isolate the ways in which nature contact, physical activity, and social support conferred by the group impact outcomes.

Trial registration: Clinicaltrials.gov (NCT03997344)

Key words: posttraumatic stress disorder, Veterans, nature, green exercise, pilot randomized controlled trial

Strengths and limitations of the study

- By using group-based urban hiking as a comparison group to control for the effects of physical activity and social cohesion (present in both interventions), this study was designed to isolate benefits specifically due to the environment (which differed between the interventions).
- We used population-based recruitment methods to enroll a representative sample of Veterans with PTSD.
- Because of its small size and focus on feasibility, the study was not large enough to determine the effectiveness of nature hiking on outcomes.

Funding: This work was funded by Recreational Equipment, Inc. (REI; Award/Grant number is not applicable) and supported by equipment and outfitting contributions from Outdoor Research.

Competing interests: The authors have no competing interests to report.

Data availability statement: Data are available upon reasonable request. Due to legal and ethical restrictions, we are unable to share data publicly because the data contain potentially identifying and/or sensitive patient information. Subject to IRB approval, de-identified data will be released to a local Department of Veterans Affairs (VA) Puget Sound Health Care System and/or national VA research data repository for release to non-VA protocols. The VA research data repository administrator will be responsible for reviewing and responding to requests to release data to non-VA requestors. A data use agreement compliant with Veterans Health Administration Handbooks 1200.12 and 1605.1 will be required between Veterans Health Administration and the requestor. Review and approval by VA privacy officer is required prior to disclosure. Data access requests

will be reviewed by the IRB of the VA Puget Sound Health Care System (contact via Dr. Littman – alyson.littman@va.gov), via mail address: 1660 S Columbian Way, Building 101 – 5W41, Seattle, WA 98108.

Introduction

Posttraumatic Stress Disorder (PTSD) is a common, chronic mental health condition that affects up to 30% of military Veterans and is frequently comorbid with anxiety, depression, and substance misuse (1–3). PTSD increases the risk of suicide as well as obesity, physical inactivity, and cardiovascular and metabolic disorders (1–12). Clinical practice guidelines recommend treatment with several evidence-based psychotherapies and medications (13), but many Veterans who need PTSD treatment do not receive it (14). Barriers to obtaining treatment include concerns about medication side effects, desire for self-management approaches, stigma about receiving mental health care, and a lack of confidence in mental health treatment in general (14–17). These and other factors adversely impact engagement, contributing to low initiation of (14,18–22) and high drop-out rates from treatment (20,23,24). Identifying a wider range of approaches that are acceptable and effective is key to reducing the burden PTSD places on individuals and their communities.

There is growing interest in nature contact as a potential therapy for Veterans with PTSD and robust evidence that nature contact improves physical and psychological health, among healthy individuals and those with mental health disorders (25). Nature contact has been shown to increase subjective well-being; decrease stress, anxiety, depression, and negative affect; and promote adaptive shifts in emotion regulation (25,26). Benefits of nature contact are generally posited to occur based on two theories: Attention Restoration Theory (ART) and Stress Recovery Theory (SRT) (27,28). ART theorizes that nature contact improves cognitive function through a replenishment of “directed attention”, a capacity that is overly taxed in urban environments due to the need to block out distracting stimuli (e.g., noise) to focus on a specific task or cognitive process. This depleted attention capacity can be restored in natural environments through the engagement of “soft fascination”, with implications for both cognitive and emotional well-being. SRT is based on psycho-evolutionary principles, and posits that many types of nature exposure enhance psychological well-being through a pre-cognitive, positive

affective response and activation of the parasympathetic nervous system in ways that reduce stress and sympathetic nervous system arousal (26,29,30).

Like nature contact, physical activity (PA) is considered to be a promising approach to improve outcomes for individuals with PTSD. PA reduces anxiety and depression and improves stress regulation, sleep, and cognitive functioning in the general population (10,11,31), and in people with PTSD, though only eight studies have involved randomized controlled trial (RCT) designs (4,32–39), and five of the RCTs were pilot studies or included fewer than 30 people (32,33,35,38,39). Furthermore, we are aware of only one RCT focused on Veterans (39). Group-based PA interventions may be particularly well-suited for military Veterans, due to 1) proportionally higher rates of PTSD among Veterans (40), 2) consistency of PA interventions with values cultivated during military service, and 3) benefits of social interaction with Veteran peers (41). To our knowledge, no PA interventions in those with PTSD investigated the PA environment as a component of treatment. This is an important omission, because the environment in which PA takes place may play an important role in its benefits (42).

Green exercise, defined as activity that takes place in natural environments, is a burgeoning area of research (43–48). A number of studies have documented benefits from green exercise in Veteran populations and among individuals with PTSD (45–55). The specific interventions studied (from care farming to river rafting), dose/duration, and inclusion of additional, explicit therapeutic components vary substantially among studies. A 2019 systematic review that examined evidence for the proposed additive effects of exercise in the presence of nature observed some benefits (e.g., lower perceived exertion and enjoyment), the authors concluded that there was a high risk of bias across trials and an overall low quality of evidence (44). Thus, uncertainty about the duration and impacts of green exercise remains due to methodological issues and because most interventional studies tested only a single bout of exercise (43,44). Furthermore, in the studies including Veterans, important

limitations include low retention for follow-up, absence of control groups, and insufficient statistical power (52–58).

In addition to nature contact and PA, a third important component of many green exercise interventions includes a group component. Some recent research suggests that increased social cohesion and connectedness may mediate benefits of green exercise (59), but findings are inconsistent (60). Social support forged through group activity could be particularly relevant for Veterans, as camaraderie and solidarity are critical components of military culture, and ones that are frequently lost in the return to civilian life (61). Social support is associated with reduced PTSD symptoms and improved treatment response (62) and may directly impact stress response by increasing personal resources (63), and/or may indirectly impact PTSD symptom severity and response to treatment through buffering the potentially harmful impacts of stressful events (64).

Adequately powered studies involving ongoing green exercise that are designed to distinguish between benefits due to PA and those due to the physical (e.g., nature) and social (e.g., group cohesion) environment are needed. Thus, our goal was to design and conduct a pilot study to test the feasibility and acceptability of a green exercise intervention for PTSD symptoms in military Veterans, regardless of PTSD etiology. The intervention (nature hiking) and the active control (urban hiking) were group-based and involved similar amounts of PA, to ensure control of the potential benefits of the group-based social support and of PA. Figure 1 depicts our conceptual model. This paper describes the results of the initial pilot study designed to emulate important elements of the future envisioned full-scale randomized trial.

Methods

Identification and recruitment of participants

We used active and passive methods to identify and recruit Veterans to participate. While receiving care at a Department of Veterans Affairs (VA) health care facility was not an inclusion criterion, we used VA electronic medical records as a key source to identify potentially eligible Veterans. We identified VA enrollees (identified using electronic medical records) with at least one encounter with a diagnosis of PTSD in the prior two years; a zip code in one of three Seattle-Tacoma area counties (King, Snohomish, and Pierce); no hospitalizations in the prior 3 months; and no diagnoses of schizophrenia, bipolar disorder, or other psychotic disorder. We randomly selected 1001 individuals who met these criteria from a total of approximately 7000 and mailed them a letter informing them about the study and inviting them to participate. We followed the mailing with up to three phone calls until the recruitment period ended. We also placed study recruitment flyers in clinics in the VA Puget Sound and mailed flyers to four local organizations and clinics serving Veterans. Individuals who expressed an interest were mailed an invitation letter.

We initially screened all Veterans who expressed an interest in participating for eligibility over the phone; inclusion criteria assessed included a history of PTSD, ability/willingness to comply with study procedures (e.g., complete questionnaires, wear and sync an activity monitor, drive to hikes, and walk at least 2 hours at an easy/moderate pace over uneven terrain). Exclusion criteria assessed included a diagnosis of schizophrenia, bipolar disorder, or other psychotic disorder; hospital admission in the prior 3 months, and inability to perform unsupervised physical activity based on the Physical Activity Readiness Questionnaire (65). We invited those who passed all criteria except for the Physical Activity Readiness Questionnaire to obtain approval to participate from their primary care provider. Though some of this information was available in VA medical records, because we also included Veterans who did not have VA medical records, we employed methods that allowed us to evaluate eligibility without medical record access. Those who passed initial screening were mailed consent forms and given a link to complete a more extensive screening questionnaire online. Via the online screening

questionnaire, PTSD symptoms, drug use, alcohol misuse, and suicidality were assessed. PTSD was determined based on a PTSD-checklist-5 (66) score ≥33. We excluded those with drug abuse in past year (Drug Abuse Screening Test-10 (67) score <3); alcohol disorder/dependence (current/past year; Alcohol Use Disorders Identification Test-10 (68) score>16); and moderate/severe suicidality (past month; MINI Suicidality module (69) score≥5). Those who were eligible and returned signed consents were considered enrolled in the study.

Study design

We conducted a two-arm randomized controlled pilot trial. The two interventions were group nature and group urban hiking. The random 1:1 allocation sequence was generated using simple randomization in random blocks of 2, 4 and 6. Randomization assignments were placed in opaque sequentially numbered envelopes. Once an individual was determined to be eligible, the study coordinator selected the next envelope to determine the individual's group assignment. We did not blind participants, the study coordinator, or the study statistician to group assignment. This study was registered at Clinicaltrials.gov (NCT03997344). Figure 2 presents an overview of the study, including timing of assessments.

Description of hike locations and amenities

The criteria used to select the hike locations (which applied to both nature and urban hikes) included duration, elevation change, availability of facilities (e.g., toilets and water), distance from participants' homes, and access to parking. Nature hikes were held in State Parks, National Wildlife Refuges, and Natural Resources Conservation areas in the US Pacific Northwest. The nature hikes were in forest habitat, including old growth forest, saltwater shoreline, waterfalls, and alpine lakes. Elevations ranged from sea level to 2200 feet above sea level. Urban hikes were held in primarily built environments, avoiding urban parks or primarily residential neighborhoods with substantial greenery or water features. Urban hikes comprised areas that included sports stadiums, urban art, and retail establishments and were mainly on sidewalks rather than separated bike/pedestrian paths/rail-

trails. It was not feasible to match nature and urban hikes on elevation change; instead, we aimed to have similar hike durations to match total exertion. Generally, nature hikes involved somewhat shorter distances but included more elevation gain/loss.

Hiking intervention

A total of 6 hikes over 12 weeks (one every other week) were offered between August and October 2019. We chose to offer 6 hikes (versus more or fewer) because this number was thought to be feasible and would be sufficient to assess feasibility and acceptability. The standard structure for hikes was: 1) "ice breakers" (short, guided conversations), 2) overview of the planned hike, including distance, unique features, and planned stops, 3) hike, and 4) post-hike debrief and administration of questionnaires. There were no additional group/therapeutic activities.

Hike durations increased gradually to account for anticipated increases in participants' physical fitness. Initial hikes were 60-90 minutes (2-3 miles), and later hikes were 2-3 hours (5-6 miles). To ensure safety and inclusion, one hike leader was in sight and hearing of the first participant and a second leader accompanied the last participant. The group stopped at least every 30 minutes to keep everyone together and offer opportunities to rest, regroup, and inquire about and address any issues or concerns arising since the last check-in.

The same hike leaders, who were non-clinicians, led both nature and urban hikes to control for hike-leader effects. On every hike, at least one of the leaders was a woman. Leaders were experienced outdoor educators who were employed by a Seattle-based outdoor organization that provides outdoor recreation activities for people with disabilities. While the leaders were not Veterans, the organization received grants from the VA as part of the Adaptive Sports Program (70) and had previously led programs for Veterans. Leaders were trained to

handle physical and mental health emergencies by the PIs (AJL and GNB) and a co-I who is a licensed clinical psychologist (KL). AJL and GNB supervised the hike leaders during the study.

To reduce barriers to attendance, a $35 incentive was provided to defray parking costs. We provided a rain jacket and technical shirt as well as well as an activity monitor (Garmin vivosmart 4) at the participant's first hike.

Outcomes

The primary outcomes of interest were feasibility and acceptability. **Feasibility** was assessed based on recruitment statistics (the proportion of individuals who were contacted, eligible, and enrolled, as well as reasons for ineligibility), retention (questionnaire completion), hike attendance, and safety (e.g., adverse events). We aimed to recruit 36-45 participants (12-15 people allocated to each of the three groups - nature hiking, urban hiking, and a no-hiking control group) and complete enrollment by July 2019 (approximately 3 months after recruitment began) due to concerns about weather for hikes later in the fall. Because of lower-than-anticipated recruitment numbers, in late June, we decided to eliminate the no-hiking control group. At this time, only one person was randomized to the no-hiking control group and informed of their group assignment; that person was re-randomized after this decision was made. The target for retention and attendance was 70%, a commonly cited standard for trials (71,72).

To assess **acceptability**, in the 6- and 12-week questionnaires, we included questions created for the study about the difficulty of the hikes' distance, pace, and the terrain (rated on a 5-point scale from extremely difficult to effortless), and satisfaction with the locations of hikes (rated on a 5-point scale from extremely unsatisfied to very satisfied). Lastly, pre-hike and trailhead information and communication were assessed on a 5-point scale (e.g., from very poor (1) to excellent (5)). We also included open-ended questions for participants to report what

they thought went well and what could have been better. Additionally, after the final hike, the lead author (AJL) conducted semi-structured telephone interviews, with a goal to interview 10-15 participants. To include a range of perspectives, we purposively sampled participants from both arms, aimed to include men and women, and participants who varied in terms of hike attendance. Questions inquired about participants' impressions of the hikes, including difficulty, location, length of time, distance from home, hike leaders, and reasons hikes were missed (if applicable); study communications; enrollment process; assessments; and other thoughts/impressions.

Determination of **efficacy** was not a goal of this pilot RCT. The primary outcome of the future planned study is PTSD symptoms, assessed by the PTSD-Checklist-5 (PCL-5), a 20-item instrument that assesses PTSD symptoms in the past month (range 0 to 80, with higher scores indicating greater symptom severity). Other outcome measures of interest for the future planned study, which are detailed in Supplemental Table 1, include quality of life (73), positive and negative affect (74,75), sleep (76), rumination (77), and cognitive reappraisal (78).

Baseline and follow-up assessments

We conducted assessments online using commercial software (QuestionPro) at baseline (before hikes began), and then weekly for 12 weeks, starting with the week of the first hike and ending the week after the 6th hike, and finally at week 24; questionnaires completed immediately after the hikes were completed on paper. See Figure 2 for an overview and Supplemental Table 1 for measures at each time point. Questionnaires at weeks 6, 12, and 24 took approximately 30 minutes to complete. Questionnaires administered at weeks 1-5 and 7-11 included fewer measures and/or shortened versions and took 5-10 minutes to complete. Participants received gift cards worth $10 for completing questionnaires in weeks 1-5 and 7-11, $20 for the 6-week questionnaire, and $50 for the 12- and 24-week questionnaires. In addition to questionnaires, to obtain objective information about PA (a potential mechanism of benefit, which we would want to measure precisely in a future study), we asked

participants to wear a wrist worn-activity monitor (Garmin vivosmart 4) every day, for at least 10 hours per day, for the first 12 weeks of the study. No incentives were provided for wearing or synching the watch.

Data analysis

Quantitative analysis

The primary purpose of the extensive data collection was to evaluate feasibility of data collection rather than to estimate effect sizes because estimating effect sizes from small pilot studies is inherently imprecise (79). Thus, instead of conducting hypothesis tests for effectiveness outcomes for which we were underpowered, we present descriptive statistics (e.g., medians and interquartile ranges) for the primary outcome (PCL-5) only. For acceptability measures related to communication, we categorized responses as positive if respondents chose one of the two most favorable response options (e.g., satisfied/very satisfied; good/excellent) and not positive if they chose one of the other response options (extremely unsatisfied/unsatisfied/ neither satisfied or unsatisfied; inadequate/very poor/adequate). We then calculated the proportion of urban and nature participants with favorable responses for each question. In addition to proportions, we also calculated the mean scores for hike locations, distance, pace, pre-hike information, pre-hike communication, and trailhead communication by group.

Qualitative analysis

All interviews were recorded, and the interviewer took notes during interviews. For both the comments shared via open-ended questions on the questionnaire and comments shared orally during the interviews, we conducted inductive content analysis, which involves open coding of data, organizing codes and data into categories, and comparing data across participants to identify patterns and themes in the data (80).

Patient and public involvement

Patients were involved in the design and conduct of this study. The study question and design were informed by a Veteran with PTSD who served as a co-investigator. The design and messaging for this pilot study were also informed by a focus group of patients/Veterans who participated in a prior unpublished feasibility study.

Ethics approval

This study was approved by the institutional review boards at the VA Puget Sound Health Care System (MIRB 01738) and the University of Washington (6951).

Results

Feasibility

Recruitment statistics

Recruitment took place between April and August 2019 (16 weeks total). Of the 1001 patients mailed an invitation letter, we were unable to assess interest or eligibility in 586 (because they did not respond to the mailings and/or answer the phone when called; see Figure 3 for CONSORT diagram). Of the 415 with whom we made contact, 159 were not interested, 102 had health conditions that limited their walking/hiking, 36 had time conflicts (e.g., work or church on Sundays or travel that would prevent participation), and 37 had other reasons that they were unable to participate (e.g., moving out of the area, did not have PTSD, etc.). Of the 97 (81 from letters + 16 from passive recruitment) interested who passed initial screening, 48 completed the online screening questionnaire. Twenty individuals were not eligible, 2 decided that they did not wish to participate, and 26 were eligible and randomized. Of the 20 who were not eligible, 13 were ineligible because of a moderate/high risk of suicide or skipping the question on suicidality, and 6 did not meet the threshold for PTSD. Compared to those contacted and not randomized, a greater proportion of those randomized were women (27% randomized versus 15% of those contacted), white (73% versus 63%), and Hispanic (8% versus 6%).

Additionally, those who were randomized were younger (mean age = 47, range 25-65) than those not randomized (mean age = 52, range: 21-95).

Table 1 presents characteristics of Veterans who were randomized and includes self-reported race/ethnicity, which differed from race/ethnicity in the electronic medical record (reported above). Specifically, 42% of those randomized self-reported being white, whereas the electronic medical record data indicated that 73% were white. Thirty percent had a college degree or more. Less than half worked full time and 46% had 100% VA service-connected disability, indicating severe impairment in ability to work. Nearly two-thirds of participants had served in combat and 68% had depressive symptoms based on the PHQ-8. Based on self-report, nearly 70% met or exceeded PA guidelines of at least 75 minutes per week of vigorous-intensity activity or 150 minutes per week of moderate-intensity activity, or an equivalent combination of the two. At baseline (prior to study initiation), 81% of participants reported hiking at least one time and 27% completed 7 or more hikes in the prior year.

Retention (questionnaire completion)

Mean completion of all questionnaires was 91% in the nature hiking group and 68% in the urban hiking group. Completion rates were similar for the shorter weekly questionnaires and the longer questionnaires.

Hike attendance

Over the course of the intervention, participants in the nature and urban groups attended an average of 56% and 58%, respectively, of scheduled hikes. In the nature group, one person attended no hikes, four (31%) attended 1-2 hikes, one attended 3 hikes, and seven (54%) attended 4-6 hikes. In the urban group, one person attended no hikes, four (31%) attended 1-2 hikes, no one attended only 3 hikes, and eight (62%) attended 4-6 hikes. Attendance was lower among women in the nature group (n=5, mean: 43%) than among women in the

urban group (n=2, 67%), whereas among men, hike attendance was similar in the two groups (65% versus 56%). Common reasons for missing hikes included work, childcare, and prior plans.

Safety/Adverse events

One participant in the urban hiking arm reported increased anxiety/PTSD symptoms in connection with hiking in the urban environment and withdrew from the study.

Acceptability

Quantitative findings

Acceptability of both the urban and nature hikes was high. Over 70% reported a positive rating for the hike locations, distance, and pace; ratings were similar in the urban and nature hiking groups. Additionally, on average, pre-hike information, pre-hike communication, and trailhead communication were rated as good to excellent. Scores related to communication were similar in the urban and nature hike groups at 6 weeks, but were lower in the urban hiking arm at 12 weeks (pre-hike information, mean scores: nature=4.4, urban=3.6; pre-hike communication: nature=4.6, urban=3.8; trailhead communication: nature=4.6, urban=4.1)

Qualitative findings

In response to the open-ended question on the questionnaire ("What went well so far?"), participants shared positive comments such as "This group seems to mesh really well", "all expectations were exceeded", and "good planning, leadership, and execution." In response to the question, "What do you think we can do better?", suggestions included having regional groups, closer hikes or paying for gas; weekly (instead of every other week) hikes; more team building and opportunities to socialize with others; and including more women and/or women-only groups. Key themes from the qualitative interviewers, which are presented in Table 2, echoed, and elaborated on themes shared in the questionnaire. Most participants felt positively about their experience in the

study. As noted above, they liked getting to know other Veterans and having a "mission." Veterans wanted to find more ways of connecting with one another socially during hikes as well as outside of hikes. Hike logistics (e.g., distance from home) were noted as potential barriers to attendance.

Efficacy measures

Median PCL-5 scores decreased from baseline to week 12 and remained at the 12-week level at week 24 for those in the nature hiking group (baseline=41, 12-weeks = 32, 24 weeks=31). Among those in the urban hiking group, PCL-5 scores decreased from baseline to 12 weeks but increased nearly back to baseline levels at 24 weeks (baseline=48, 12-weeks = 43, 24 weeks=47) (Supplemental Figure 1). We did not test the statistical significance of the changes because this pilot study was not designed to answer this question (81).

Discussion

This study was an important step in establishing feasibility and acceptability and identifying changes to consider in the development of a rigorous, fully-powered study to evaluate the impact of nature hiking on PTSD symptoms. The results of this pilot study generally supported feasibility and acceptability. Participants reported high acceptability, enjoyment, and value, based on quantitative and qualitive data. In both arms, more than half of participants completed most hikes. Qualitative feedback about improving the social component supports the hypothesis that social connection is an important aspect of hikes, indicating a need to further develop the social component and continue to study group interventions like this one. Additionally, the decrease in median scores on the PCL-5 among those in the nature group after the 12-week hiking intervention, and 12 weeks later (week 24) is promising. This preliminary finding should be investigated more thoroughly in future, larger-scale versions of our study. The indication that improvements may persist after the conclusion of the intervention is especially compelling given the current unknowns regarding the duration of effects of nature interventions.

Nevertheless, several issues need to be considered related to feasibility and acceptability for the next iteration of this research.

Feasibility of recruitment

We fell short of our goal of recruiting at least 36 people over 4 months. Failing to meet recruitment goals in the planned timeframe is a common problem in randomized controlled trials (82). Barriers to recruitment included unexpected delays, insufficient resources, and an inefficient recruitment process. Regarding delays, we had to wait weeks for IRB approval for each proposed modification to recruitment materials/protocol. Regarding resources, we only had 20 hours per week of paid staff time for recruitment. The addition of two volunteers in the final two months helped to accelerate enrollment, but more resources earlier in recruitment would have been necessary to meet our goal.

One contributor to inefficiency in recruitment was the broad, population-based approach we employed for active recruitment. To identify patients for the introductory mailing, the only inclusion criteria were having a single encounter in VA's electronic medical record with a PTSD diagnosis and living in one of three Puget Sound counties. The only exclusion criteria were a diagnosis of schizophrenia, bipolar disorder, or other psychotic disorder. Likely in part because of this broad approach, which did not include upper age limits, approximately one quarter of contacted individuals reported a health condition that impaired their walking. Burdensome study procedures may have also impacted recruitment. About half of interested participants failed to complete the online screening questionnaire and others informed us that they had trouble completing the online questionnaire. Imposing an upper age limit (e.g., 65 years) and restructuring the recruitment process to make it faster and easier for potential participants may be necessary.

Accessibility of the intervention and restrictive eligibility criteria may have also impacted recruitment. In addition to being able to walk over uneven ground for at least two hours, participants also had to be available during the times selected, have low suicide risk, and be free from physical conditions such as high blood pressure (or obtain their primary care provider's permission) among several other criteria. Changing inclusion criteria (e.g., eliminating restrictions related to suicidality) might improve recruitment and generalizability, but would require tradeoffs related to safety and retention that must be considered carefully.

Lastly, about 38% (159/415) of those for whom we were able to assess eligibility and interest declined participation. While some of these people may have declined because of the additional burdens of a research study, this statistic indicates that hiking may only appeal to a segment of the population, just as psychotherapy and pharmacotherapy only appeal to subsets of the population (83). Because of differences in treatment preferences, offering options is important, and nature hiking merits consideration so that we can rigorously assess its efficacy.

Retention

Retention varied by group and was poorer for the wrist-worn activity monitor than for the questionnaires. The activity monitor had a substantial amount of missing data, which is a common problem for activity monitors (84), and may have been related to the number of technical steps required for setting up the watch and syncing it, as many participants needed additional help to troubleshoot problems. Providing more support to set up the watch and incentives to wear and sync it may help to obtain more complete data. While overall questionnaire completion was high, it was higher in the nature hiking group (91%) than in the urban hiking group (68%). Though the small sample and our inability to conduct interviews with those who did not complete follow-up measures makes inference difficult, the retention differences could be a marker of commitment to the study. Future studies should pay careful attention to marketing the study to ensure that both interventions are

perceived as helpful. Enhancing the social aspects of the interventions may help achieve that goal. The difference in incentives provided for questionnaire completion versus the other aspects of the study may also have played a role in retention for different study aspects. However, many participants shared that they participated to help fellow Veterans, indicating altruistic/intrinsic motivators for participation, reinforcing the importance of understanding drivers of participation, and reducing barriers and enhancing facilitators.

Acceptability of the hiking interventions

Hike attendance (56%) was lower than our target (70%) and women had lower attendance in the nature hiking group than men. While we were unable to ascertain reasons for missing hikes for each person, some reasons reported (e.g., other plans, work) were hard to avoid, while others (driving distance to hikes) could be addressed in the future by restricting the geographic area of recruitment and hikes and/or organizing small groups at different times to accommodate individuals' schedules. Our study, unfortunately, does not shed light on the optimal hike "dose." We suspect that 8-12 hikes (similar to a standard psychotherapy course) may be optimal for achieving clinically meaningful results. Additional research will be necessary to examine this important question. There were also an indication of lower acceptability/ratings for information sharing in the urban hiking versus the nature hiking groups. While we aimed to share information about the urban area, we did not provide an exact route, which may have made it more difficult for participants to research urban versus nature hikes, where we listed a trail. Providing a map of the route might help participants feel prepared. Regarding differences in attendance by gender, a history of military sexual trauma, which is common among women Veterans (85), may have impacted some women participants' comfort and perception of safety of hiking in nature with a majority male group. Ensuring a greater proportion of women in each group or organizing women-only groups (as was suggested by some participants) could address this concern. These changes, would, however, result in additional costs and tradeoffs that would need to be carefully considered.

Conclusions

This pilot study provided useful information related to feasibility and acceptability, including common factors that resulted in exclusion; resources and procedures needed for recruitment; factors to consider for selection of nature and urban hikes; and barriers and facilitators to achieving high completion in follow-up assessments and the hikes. These insights can be harnessed to increase participation and rigor in future, scaled-up iterations of the study, and ensure that environments are safe (i.e., non-triggering). Future studies with larger sample sizes are needed to isolate the ways nature contact, PA, and social support conferred by the group impact outcomes to develop and provide well-tailored interventions.

List of abbreviations

ART	Attention Restoration Theory
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
PA	Physical activity
PCL-5	PTSD Checklist for Diagnostic and Statistical Manual 5
PTSD	Posttraumatic stress disorder
SRT	Stress Recovery Theory
VA	Department of Veterans Affairs

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Figure 1. Conceptual model

Figure 2. Depiction of study design and assessments

Figure 3. CONSORT diagram

Table 1. Baseline characteristics of Veterans in the urban and nature hiking groups

Characteristic	Total (n=26)		Nature (n=13)		Urban (n=13)	
	N or mean	% or SD	N or Mean	% or SD	N or Mean	% or SD
Age (years)						
<30	2	8	1	8	1	8
30-39	5	19	2	15	3	23
40-49	6	23	4	31	2	15
50-59	11	42	6	46	5	38
≥60	2	8	0	0	2	15
Gender						
Male	19	73	8	62	11	85
Female	7	27	5	38	2	15
Race/ethnicity						
Asian/Pacific Islander, NH	3	12	2	15	1	8
Black, NH	2	8	0	0	2	15
Hispanic	3	12	1	8	2	15
Native American, NH	2	8	0	0	2	15
Other	1	4	0	0	1	7.7
White, NH	15	58	10	77	5	38
Marital status						
Single, never married	4	15	3	23	1	8
Married currently	14	54	7	54	7	54

Characteristic	Total (n=26)		Nature (n=13)		Urban (n=13)	
	N or mean	% or SD	N or Mean	% or SD	N or Mean	% or SD
Separated/divorced	8	31	3	23	5	38
Education						
High school degree or equivalent	4	15	1	8	3	23
Some college, no degree	10	38	7	54	3	23
Associate degree	4	15	1	8	3	23
Bachelor's degree	4	15	2	15	2	15
Masters, doctorate, or professional degree	4	15	2	15	2	15
Annual household income						
$25,000-$49,999	7	27	4	31	3	23
$50,000-$74,999	11	42	4	31	7	54
$75,000-$99,999	2	8	1	8	1	8
$100,000 or more	4	15	3	23	1	8
Prefer not to answer	2	8	1	8	1	8
Employment status						
Full-time	12	46	6	46	6	46
Part-time	1	4	1	8	0	0
Not employed (disabled, retired, not looking for work, homemaker, other)	13	50	6	46	7	54
Highest military rank						

Characteristic	Total (n=26)		Nature (n=13)		Urban (n=13)	
	N or mean	% or SD	N or Mean	% or SD	N or Mean	% or SD
Enlisted (E1-E4)	9	35	4	31	5	38
Non-commissioned officer (E5-E9)	15	58	8	62	7	54
Officer (O1-O4)	2	8	1	8	1	8
VA disability rating*†						
No rating	2	8	0	0	2	15
30-60%	2	8	2	15	0	0
70-90%	8	31	4	31	4	31
100%	12	46	6	46	6	46
Self-reported health						
Excellent/very good	9	35	3	23	6	45
Good	11	42	7	54	4	31
Fair (no one reported poor)	6	23	3	23	3	23
PCL-5 score‡						
Mean, SD	47.1	10.9	46.0	11.4	48.2	10.8
Served in combat [yes]	17	65	8	62	9	69
Combat Exposure Score; mean (SD)* †	16.6	7.9	15.6	8.2	17.7	7.9
Patient Health Questionnaire-8 score*						
<10 (no depression)	8	32	4	33	4	31
10-19 (major depression)	14	56	7	58	7	54
≥20 (severe major depression)	3	12	1	8	2	15

Characteristic	Total (n=26)		Nature (n=13)		Urban (n=13)	
	N or mean	% or SD	N or Mean	% or SD	N or Mean	% or SD
Physical activity level						
Low	8	31	5	38	3	23
Moderate	3	12	1	8	2	15
High	15	58	7	54	8	62
Times gone hiking for 1+ hrs in last year						
Never	5	19	3	23	2	15
1-3	9	35	4	31	5	38
4-6	5	19	2	15	3	23
7+	7	27	4	31	3	23
Outdoor / nature-based activity experience						
None (no experience in the outdoors)	0	0	0	0	0	0
Casual (done some day hiking on maintained trails and car camping)	10	38	5	38	5	38
Amateur (have experience with backpacking)	11	42	6	46	5	38
Expert (substantial backcountry experience)	5	19	2	15	3	23

Abbreviations: NH, Non-Hispanic; PCL-5, Post-traumatic stress disorder checklist for Diagnostic and Statistical Manual 5; PTSD, post-traumatic stress disorder; SD, standard deviation

* Missing response for 1 nature participant

† Missing response for 1 urban participant

‡ One person in the nature hiking group had a PCL-5 of 32 (below the eligibility threshold of 33) due to an undetected error in initial scoring.

Table 2. Key themes and findings from qualitative data

Themes	Findings
A positive experience	• Both nature ("All expectations were exceeded") and urban study participants ("LOVE THE GROUP") provided positive feedback.
Perceived benefits	• Participants reported on how the hikes helped them to be more active, lose weight, reduce stress, and feel more connected to others.
Hike logistics	• Participants suggested that prior to hikes, we ensure parking access, availability of toilets, and locate the hikes closer to participants' homes. • Others suggested that we consider organizing carpools and/or covering gas/mileage costs
Difficulty of hikes	• Most found the difficulty just right. • Some felt that the hikes were too short/easy.
Location of hikes	• Nature group: One participant wished that there was more of a "reward" ("like a waterfall", "when you have a view, it seems more profound"), because some were just "walks through the woods." • Urban group: One person noted that some neighborhoods were "sketchy" and they were "constantly walking around garbage" for one hike. Others noted that they really enjoyed exploring different neighborhoods, areas around sports stadium, and learning about the history of areas.

Group composition	• A few participants suggested that we enroll more women or organize women-only groups and/or groups for survivors of sexual assault.
Incentives for completing questionnaires	• Participants suggested that we offer the option to receive a single gift card that accumulated value instead of separate ones each time a questionnaire was completed.
Assessments	• Several participants had trouble with the online software (e.g., getting "kicked out" of the survey mid-way through); • Some participants reported that they would have liked text prompts instead of email, since they did not regularly check their email. • Some participants found some questions to be difficult to answer (e.g., the Perceived Cohesion Scale) or they were confused by differences in the time frame for different instruments (e.g., on the weekly questionnaires, some questions asked participants how they felt "right now" while others asked about the prior week).
Activity monitors	• Several participants noted having problems programming and syncing the activity monitor.
Fostering interaction/connections between participants in a group	• Participants suggested facilitating more structured ways to get to know other members of the group, including a social gathering prior to the initial hike, re-introductions before each hike, gathering for lunch or other meal after hikes, and organizing a social media group.

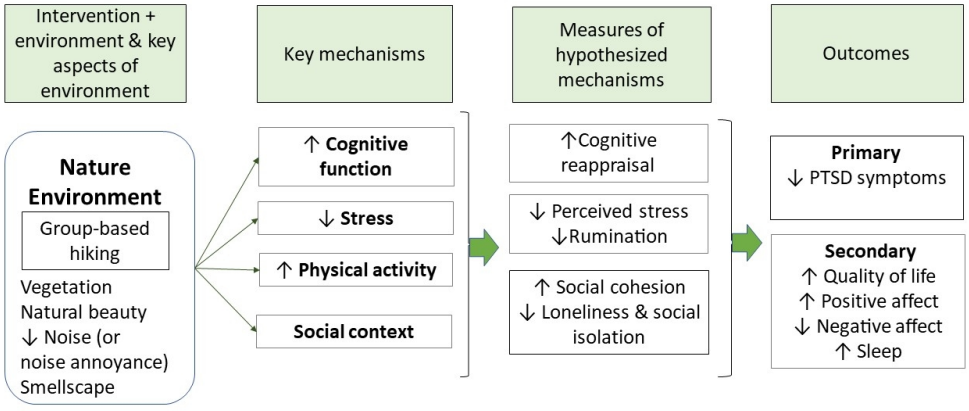


Figure 1. Conceptual model

338x190mm (96 x 96 DPI)

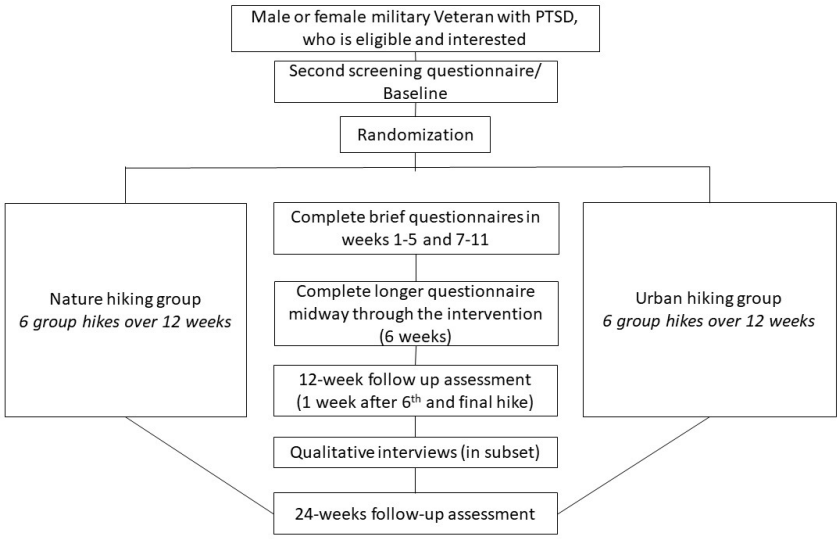


Figure 2. Depiction of study design and assessments

338x190mm (96 x 96 DPI)

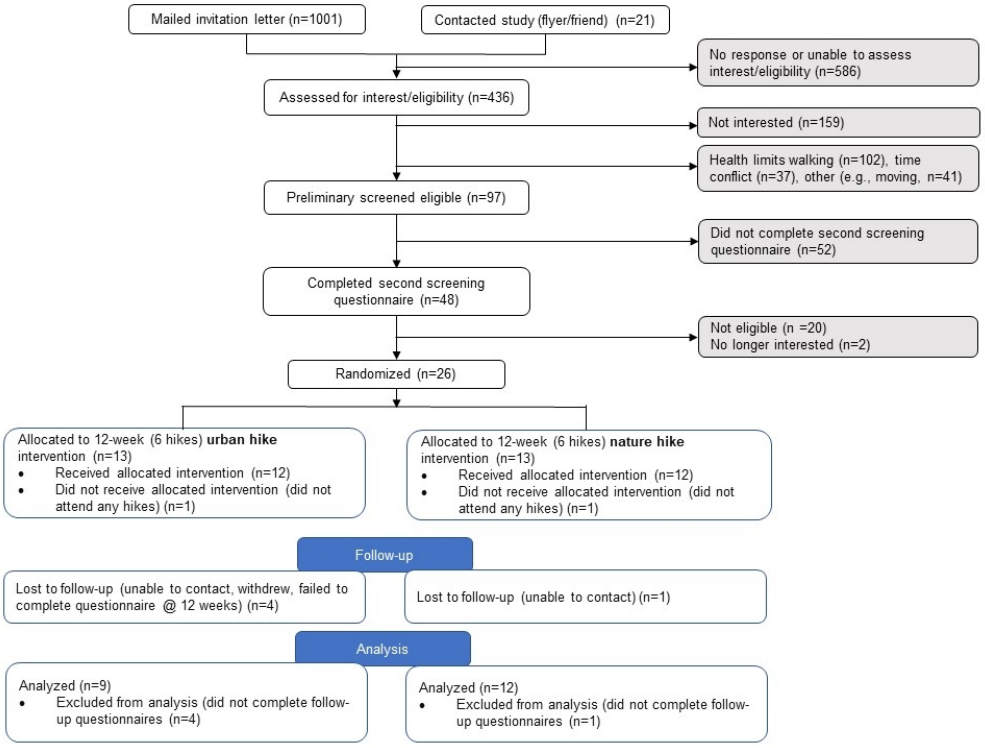


Figure 3. CONSORT diagram

254x190mm (96 x 96 DPI)

Supplemental Table 1. Constructs, instruments, and timing of assessments

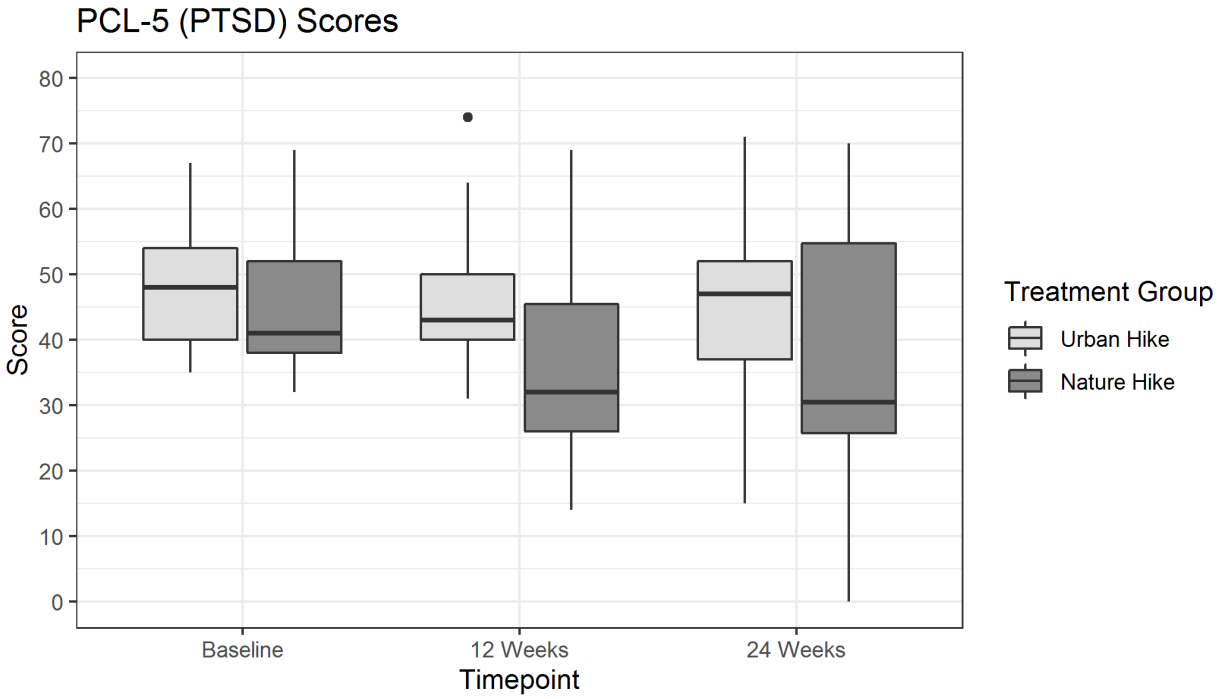
Constructs	Instrument
Demographics	n/a (Age, gender, race/ethnicity, education, service-connected disability, etc.)
Combat exposure	First two questions of the PTSD Diagnostic Scale-5 (73) and Combat Exposure Scale (74)
Ability to safely perform unsupervised physical activity	Physical Activity Readiness Questionnaire (PAR-Q) (62)
Suicidal ideation	MINI Suicidality module (65)
QoL/well-being	Satisfaction with Life Scale (75)
Physical health	14-item Physical Health Questionnaire (76)
PTSD symptoms	PTSD Checklist for DSM- 5 (61)
Depression	Personal Health Questionnaire (PHQ)-8 (77)
Perceived Stress	4-item Perceived Stress Scale (PSS) (78,79)
Affect	20-item Positive and Negative Affect Schedule (PANAS) (80,81) 10-item PANAS
Loneliness	3-item UCLA loneliness scale (82)
Social connectedness	First four items of the 6-item Perceived Cohesion Scale (83)
Anxiety	20-item Stress and Anxiety Scale (STAI) – state level 6-item STAI
Sleep	Full (19-item) Pittsburgh Sleep Quality Index (PSQI) (84) Shortened (5-item) PSQI
Nature connection	Connectedness to Nature Scale (6-items) (85)
Rumination	Full (12-item) state rumination (brooding subscale of Rumination Reflection Scale [RRS]) Shortened (8-item) state rumination (brooding subscale of RRS) (86)
Cognitive reappraisal	4-item state emotion regulation questionnaire (ERQ) (87)
Physical activity – self report	9-item International Physical Activity Questionnaire (IPAQ) short form (68)

Constructs	Instrument
Physical activity monitor	Wrist worn activity monitor (Garmin Vivosmart 4)
Alcohol consumption	10-item Alcohol Use Disorders Identification Test (AUDIT) (64) 3-item (AUDIT-C) (88)
Drug-related problems	Drug Abuse Screening Test-10 (63)
PTSD treatments	n/a
Preference for treatment, hiking frequency and expectation about treatment	n/a
Acceptability of hikes	n/a

‡Timing of assessment: S/B: screening/baseline, WK: weekly – weeks 1-5 and 7-11, FU: 6-, 12-, and 24-week follow-ups

†A, acceptability; CO, covariate (including moderators); E, eligibility (to assess inclusion/exclusion criteria); M, mediator P, primary outcome; S, secondary outcome

Figure 1. PTSD Checklist scores at baseline, 12- and to 24-weeks follow-up



CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	5-7
	2b	Specific objectives or research questions for pilot trial	7
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	9
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	11
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8-10
	4c	How participants were identified and consented	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8, 11-12
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	n/a
Sample size	7a	Rationale for numbers in the pilot trial	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	9-10
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 3
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 3
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Figure 2, page 11-12
	14b	Why the pilot trial ended or was stopped	12
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 3
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Supplemental Figure 1
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Table 2
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	15
	19a	If relevant, other important unintended consequences	n/a
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	17-21
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	17-21
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	17-21
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	17-21
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	3
Protocol	24	Where the pilot trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2, 9
	26	Ethical approval or approval by research review committee, confirmed with reference number	13

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.