

A. OVERALL COVER PAGE

Project Title: Lifestyle intervention to reduce body weight and systemic inflammation among World Trade Center responders with PTSD: Pilot Randomized Control Trial	
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Change of Contact PD/PI: NA	
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Human Subjects: NA	Vertebrate Animals: NA
hESC: No	Inventions/Patents: No

B. OVERALL ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Aim 1: To develop and assess the feasibility and acceptability of a pilot nutrition intervention (MedDiet) with a PA component to reduce body weight, MetS, prevent/reduce systemic inflammation among World Trade Center responders with PTSD.

Aim 2: To assess within and between group changes in dietary intake (MedDiet) score and PA.

Exploratory Aim: To assess within and between group changes in body weight, inflammatory biomarkers and prevalence of MetS; and assess if a change in inflammatory biomarkers, is moderated by changes in MetS, body weight, or MedDiet score.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

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B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

No

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

Dissemination of Findings

The key findings of this study have been published to a peer reviewed journal (see list below). We presented our findings in various competitive domestic and international conferences as oral and poster presentations. The PI (Arcan) was invited to present our key findings at the Greek Alzheimer's Disease Association in 2/2023 in Thessaloniki, Greece. The PI was also invited to present the project and findings at the seminar series of the Departments of Endocrinology and Family Medicine of Virginia Commonwealth University. Most importantly, other research studies have been developed and funded using our nutrition intervention in its totality focusing on lifestyle interventions to reduce cancer risk and inflammation. Recently, a Center was funded by NCI (one of four in the US) focusing on social drivers of health (SDOH) through multi-level interventions to reduce cancer risk within underserved communities through community engagement. The PI (Arcan) is the co-lead of the SDOH signature project (5 year R01 level) focusing on multi-level nutrition and physical activity changes within income based housing communities across Virginia. The individual-level nutrition component adapted all the modalities of the WTC-Nutrition project.

Grant details

National Cancer Institute (U19CA291433)

MPI: Fuemmeler, LaRose & Sheehan

Arcan: Co-lead (Lead PI) for the R01-level Social Drivers of Health (SDOH) Signature project

Title: The Virginia Advancing Cancer Control Engagement Research Through Transformative Solutions (VA-ACCERT) Center (One

of four Centers awarded in the US)

The PI (Arcan) serves as a Co-I in the CDC/NIOSH funded grant (1 R21OH012630-01-00; PI Ginex, Stony Brook University) entitled Effectiveness and Implementation of a Brief Motivational Intervention to Increase Physical Activity for World Trade Center Health Program Cancer Survivors.

Additionally, more collaborations of the PI with other investigators resulted in submission of grants focusing on testing anti-inflammatory diets to improve mental health and other behaviors of youth involved in gun related violence and injuries; this study is under review by CDC investigators.

Peer reviewed publication

Arcan C, Hou W, Hoffman K, Reichardt A, Yang X, Clouston SAP, Bromet EJ, Luft B. Mediterranean diet intervention among World Trade Center responders with post-traumatic stress disorder: Feasibility and outcomes of a pilot randomized controlled trial. Obesity science & practice. 2024 February;10(1):e725. PubMed PMID: 38263989; PubMed Central PMCID: PMC10804354; DOI: 10.1002/osp4.725.

Invited Presentation

Arcan, C. Mediterranean diet intervention to reduce body weight and systemic inflammation among World Trade Center responders with Post Traumatic Stress Disorder: Pilot Randomized Controlled Trial.

13th Panhellenic Conference, Alzheimer's Disease & 5th Mediterranean Conference on Neurodegenerative Disease, Thessaloniki, Greece, February 9-12, 2023.

Please scroll to the end of the left column to see the list of my presentation:

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Peer reviewed oral presentations

Arcan C, Esse Foka, Wang X, Hughes, K, Reichardt A, Clouston S, Luft B. Association between change in dietary intake with change in body mass index and waist circumference among World Trade Center responders with PTSD participating in a nutrition intervention. International Society for Behavioral Nutrition and Physical Activity (ISBNPA); June 20-23, 2024, Omaha, NE

Arcan C, Hou W, Wang X, Hughes, K, Reichardt A, Clouston S, Luft B. Nutrition Intervention to Reduce Body Weight and Systemic Inflammation Among World Trade Center Responders with Post Traumatic Stress Disorder: Randomized Controlled Trial; International Society for Behavioral Nutrition and Physical Activity (ISBNPA); May 18-21, 2022; Phoenix, AZ

Peer reviewed poster presentations

Esse Noudegbessi, Wei Hou, Kathryn Hughes, Amanda Reichardt, Sean A. P. Clouston, Benjamin J. Luft, Chrisa Arcan. Changes in nutrition knowledge, home food availability, and sedentary behaviors with changes in body mass index and waist circumference among World Trade Center Responders with PTSD participating in a nutrition intervention. Society for Behavioral Medicine, Philadelphia, PA, March 13-16, 2024.

Chrisa Arcan, Esse Noudegbessi, Kathryn Hoffman, Amanda Reichardt, Sean A. P. Clouston, Benjamin J. Luft. Nutrition Knowledge and Eating Behaviors of World Trade Center Responders with PTSD Participating in a Nutrition Intervention, ISBNPA, Uppsala, Sweden, June 14-17, 2023

Chrisa Arcan, Wei Hou, Xiaohua Yang, Kathryn Hughes, Amanda Reichardt, Sean A. P. Clouston, Benjamin J. Luft. Nutrition Knowledge and Eating Behaviors of World Trade Center Responders with PTSD Participating in a Nutrition Intervention, Society for Behavioral Medicine, Phoenix, AZ, April 26-29, 2023.

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Not Applicable

Title: Lifestyle intervention to reduce body weight and systemic inflammation among World Trade Center responders with PTSD: Pilot Randomized Control Trial

ABSTRACT

Background

Responders who worked on the rescue and recovery efforts of the World Trade Center (WTC) disaster on September 11, 2001 (9/11) suffer from multiple morbidities. While post-traumatic stress disorder (PTSD) is the most common mental health condition, obesity and metabolic disorders are also prevalent posing a challenge to medical interventions alone. There is also evidence for poor dietary intake, inactivity and disturbed sleep patterns. Healthful lifestyle interventions including diet and physical activity (PA) hold promise for the prevention/development of chronic diseases such as diabetes, cardiovascular, cancer and dementia. It was, therefore, imperative that we enriched the therapeutic choices for the aging WTC responders by providing a lifestyle medicine approach along with the excellent clinical care. Therefore, a pilot randomized-controlled trial (RCT) was implemented to test the feasibility and preliminary efficacy of a Mediterranean Diet (MedDiet) intervention with a physical activity component among WTC responders with overweight, obesity, and PTSD.

Methods

Sixty-two members (males: 87%; age 45-65 years) from the WTC Health Program (WTC-HP) at Stony Brook University's two clinics were randomized to MedDiet intervention (n=31) or control (usual nutrition counseling) (n=31) conditions. The MedDiet group received 10-weeks online nutrition and physical activity program delivered through a study website, weekly reminder and motivational mobile text messages, and goal setting; both groups had three in-person counseling sessions. Baseline, post-intervention and 3-month follow-up (FU) data collected (blood biomarkers, anthropometrics, psychosocial surveys, MedDiet questionnaire, dietary intake, and PTSD checklist score). Descriptive statistics (frequencies/percent) of demographics at baseline and study feasibility (participant recruitment, retention and satisfaction) were calculated (Aim 1). Statistical comparisons of MedDiet score by condition at three measurement times were calculated (Aim 2) and within and between group changes in body weight, inflammatory biomarkers, prevalence of MetS, and PTSD were assessed (Exploratory aim); for continuous outcomes, nonparametric Wilcoxon rank sum tests for between-group comparisons and Wilcoxon signed rank tests for pre-post within-group comparisons were conducted.

Results

A total of 58 (94%) participants completed the post-intervention and 46 (74%) completed all follow-up measurements. Among MedDiet participants, more than 85% watched the weekly videos and responded to teach back questions, 83% (20/24) reported being satisfied and very satisfied with the program, 96% (23/24) would participate again, and 100% (24/24) would recommend it to other WTC-HP members. Both groups experienced an increase in the MedDiet score by 4 points at post intervention and by 3 points at follow-up (baseline was 6 points out of 14 points maximum). Compared to control, the MedDiet group had significant reductions in HbA1c, $\omega 6/\omega 3$, and hsCRP. Both groups experienced significant reduction in waist circumference (WC), but the MedDiet group had larger reduction at both times. Both groups experienced a significant reduction in PCL scores and in oxidized LDL (oxLDL) and total cholesterol.

Conclusion

In both groups, nutrition intervention has contributed to a significant decrease in anthropometrics, MedDiet score, oxLDL, total cholesterol and PTSD symptoms; the MedDiet group had higher reductions in metabolic and inflammatory markers. Larger RCTs are needed to confirm the findings and elucidate mechanism of action.

Section 1: Key Findings

The WTC-Nutrition study was a 10-week **high dose** pilot randomized controlled trial testing a Mediterranean Diet (MedDiet) with a physical activity component among WTC first responders with overweight, obesity and diagnosed PTSD. Sixty-two participants were randomized to MedDiet group (n=31) and usual care (n=31), with an overall goal of improving eating behaviors, reduce systemic inflammation, improve metabolic health and manage body weight. The study was conducted during COVID-19 and lasted a year from 12/1/2020 through 11/30/2021. The nutrition intervention included evidence-based behavioral strategies mainly delivered remotely through a study website with embedded videos, recipes, tips, goal setting, and group experiential cooking session, augmented with weekly motivational text messages and minimal individual coaching (three times during the study). Due to ethical reasons, the control group included usual care which was in-person individual nutrition counseling.

Key Findings of the Study

Aim 1 included the development and assessment of the feasibility and acceptability of the pilot nutrition intervention. The study successfully recruited and retained 62 participants; a 100% of participants completed the 10-week intervention, 94% completed the post-intervention and 74% completed the 3-month follow-up assessments. Participant satisfaction was high (83%) and 100% reported that they would recommend it to other WTC-Health Program members. The majority of MedDiet participants expressed a high degree of satisfaction with the program and the weekly education materials and unanimously reported that they would recommend it to other clinic patients. A total of 212 WTC-HP participants met initial eligibility criteria within the past year based on their medical records; the main reasons for refusal to participate were either the COVID-19 pandemic, lack of interest, time, or travel plans. Seventy-one members consented to participate and completed baseline measures; nine participants dropped out prior to randomization due to concerns about COVID-19, work schedule, or tech privacy, resulting in 62 randomized participants. A total of 58 (94%) participants completed the post-intervention and 46 (74%) completed all follow-up measurements.

Aim 2 included assessment of within and between group changes in dietary intake (MedDiet score) and physical activity (daily steps). The 14-item Mediterranean diet survey was used to assess compliance with the MedDiet reporting on habitual consumption of foods/beverages. Possible scores ranged from 0 to 14 and a higher score represents higher adherence to the MedDiet. Both intervention and control groups experienced a similar increase in the MedDiet score; at baseline, the median MedDiet score was 6.0 (1.0-11.0) and increased by 4 (-1.0-8.0; $p<0.0001$) and 3 points (-2.0-7.0; $p<0.0001$) at post-intervention and follow-up, respectively.

Daily steps were measured using a Fitbit. The participants were asked to wear the instrument for a week and at least three days (two weekly and one weekend) of complete recording was sufficient for analysis. On average the participants recorded about 7,300 steps per day without significant changes within or between groups over the study period. Through a survey we also assessed the participants' sedentary activities; at baseline, the participants reported spending 6.5 hours/day watching TV; at post-intervention, hours spent watching TV decreased by 1.5 hours/day. Similarly, at baseline they reported spending on average 180 minutes/day engaging in moderate physical activity and this increased by 60 minutes a week at follow-up. While the within and between group changes were not statistically significant, they indicate the interventions' potential to positively impact the participants' lifestyle behaviors.

Exploratory Aim included assessment of within and between group changes in anthropometrics, inflammatory and oxidative biomarkers and prevalence of MetS. The findings indicate that overall nutrition counseling positively impacted the participants' diet, anthropometrics, some lipid and oxidative biomarkers and PTSD symptoms. There were also significant between group improvement in the MedDiet group in **HbA1c**, **ω6/ω3**, and **hsCRP**. Both groups experienced significant reduction in waist circumference (WC), however, the reduction was higher in the intervention group [(MedDiet: WC: -1.75inches (-9.75-0.50) vs. Control: WC: -1.00 inches (-13.0-1.30)] at post intervention and at follow-up the intervention group experienced even higher reduction in WC [MedDiet: WC: -2.5inches (-9.5-0.7) vs. Control: WC: -1.65 inches (-15.0-1.8)]; **$p<0.0001$** for all changes. The baseline median BMI was 33.2; in the entire sample the BMI was reduced at post-intervention by -0.68 (-4.61-2.09; $p<0.0001$) and at follow-up by -0.60 (-6.91-3.59; $p<0.0009$) without significant differences between the two groups. At post-intervention the MedDiet group experienced a reduction in **HbA1c** of -0.10% (-1.00-0.30; $p=0.009$) while the control group had no change 0.00 (-1.20-0.60); **between group $p=0.019$ at post intervention**. At baseline, in the entire sample, the average **ω6/ω3** was 14.4 which is representative of the Western dietary pattern (lower is preferred). There was a significant average decrease of -1.69 (-8.84-6.72; **$p=0.003$**) at post intervention. The MedDiet group had a significant decrease of -2.71 (-8.84-6.72; **$p=0.002$**) while the control group had only -0.29 (-7.53-4.56; $p=0.307$) decrease, with a significant between group difference (**between group $p=0.029$**) at post-intervention. At baseline the average **hsCRP** was 1.80 mg/L (0.30-9.40) for the entire sample. At 3-month follow-up there was a significant between group difference (**$p=0.025$**) because the MedDiet group experienced a decrease of -0.18 mg/L, while the control group experienced an increase of 0.25 mg/L compared to baseline.

There were significant improvements in total cholesterol and oxLDL at post-intervention and follow-up for the entire sample. Each group experienced a reduction in their oxLDL at post-intervention and at follow-up; for the total sample, the baseline median oxLDL was 48.50 U/L (19.00-570.00) and was reduced by -12.5 (-352.00-82.00 $p<0.0001$) at post-intervention and by -24.00 (-391.00-130.00; $p<0.0001$) at follow-up. At baseline, total cholesterol was 200.50 mg/dL (100.00-293.00) and was reduced by -9.00 mg/dL (-93.00-51.00; $p=0.007$) and -13.90 mg/dL (-110.00-73.00; $p=0.031$) at post- and follow-up, respectively; only the MedDiet group experienced a significant decrease of -8.5 mg/dL (-88.00-38.00; $p=0.035$) at post-intervention. MetS was reduced by an

average of 15% in each group. Although assessment of PTSD symptoms was not included in the proposed study aims, changes in the PCL scores were reported. Each group experienced a reduction in PCL scores. In both groups combined, the average median PCL score was 52.0 (25.0-74.0) at baseline; the score was reduced by -13 (-37.00-11.00) points at post-intervention and by and -8 (-61.00-14.00) points at follow-up (**p <0.0001 in both**).

Translation of Findings

Following completion of the intervention and after receiving positive feedback from the participants, the WTC-HP at Stony Brook University implemented the complete 12-week program as part of the Health & Wellness lifestyle program for weight loss and overall health. This online program follows the same modalities as the intervention with a tailored individual counseling by a dietitian. All the intervention materials are available online to other researchers and to the public. After implementing the program, the Clinic dietitians found that the most important benefit of this program was the study timeline. The three in-person visits, as part of the program, within 3-4 months followed by a 3 month follow up has been very helpful to keep the patients motivated between their annual visits. This indicates that regular contact with patients who may have challenges in keeping annual appointments may be one way to keep them motivated and responsive the health messages.

(<https://wtcnutrition.wixsite.com/website/weeklywellnessprogram>).

Discussion of Key Outcomes

The study was feasible and the majority of MedDiet participants expressed a high degree of satisfaction with the program and the weekly education materials and unanimously reported that they would recommend it to other clinic patients. While intervention effectiveness was not a primary aim of the study, intent-to-treat analyses indicated that both groups showed significant improvements in physical and mental health during the study period. Both groups improved adherence to the MedDiet, experienced improvements in their PTSD symptoms, reduced WC and BMI. Additionally, both groups saw an improvement in oxLDL and total cholesterol, while the MedDiet group, compared to control, had additional improvements in HA1c, $\omega 6/\omega 3$, and hsCRP at either post-intervention or at follow-up. Despite lack of significant change in hsCRP in either group, the group difference that was driven by a decrease in the MedDiet and an increase in the control groups may provide support for the anti-inflammatory properties of the MedDiet. It is also noteworthy that both groups experienced a significant reduction in PCL scores at a level representing a clinically meaningful change. While potential factors could have contributed to these changes including but not limited to nutrition counseling serving as psychotherapy due to individualized attention and promotion of self-care. Or, it could be due to positive changes in weight and various inflammatory and oxidative biomarkers, all risk factors for PTSD.

Based on participant surveys, they reported improvements in weekly minutes of moderate activity and reduction in minutes of TV watching. However, many of the participants did not properly wear the Fitbit, thus within and between group comparisons were not feasible due to missing values. In interpreting the results of this study, it is important to consider that the control group (usual care) consisted of nutrition counseling with healthful dietary recommendations; additionally, the small sample size due to being a pilot may have contributed to lack of more significant between-group differences. A larger study with WTC responders with a passive control could confirm these findings and explore the underlying mechanisms.

Section 2: Scientific Report

Brief WTC-Nutrition Intervention Description

A pilot randomized controlled trial was conducted to test the feasibility of a nutrition intervention with a physical activity component focusing on the Mediterranean Dietary pattern (MedDiet) to improve eating behaviors and reduce weight and systemic inflammation among World Trade Center (WTC) responders with overweight/obesity and active diagnosis of chronic post-traumatic stress disorder (PTSD). The intervention adopted principles of Social Cognitive Theory (SCT) emphasizing behavior (healthy eating and physical activity) within the inclusion of social context (family/friend support) in a dynamic and reciprocal interaction between the person (study participant) and the environment (home food availability/family meals). Utilizing several previously tested intervention modalities, including individual nutrition counseling, a group meeting, and education through smart phone and the Web, we tested the feasibility and acceptability of a 10-week **high dose** nutrition intervention with a physical activity component with a total of 62 participants (31 MedDiet and 31 usual nutrition counseling); and assessed within and between group changes in dietary intake, MedDiet score, body weight,

waist circumference, inflammatory, oxidative stress, and lipid biomarkers, physical activity, and PTSD symptoms. The control group received three in-person nutrition counseling sessions focusing on ways to maintain an overall healthy diet and reduce saturated fat intake. The findings of this lifestyle intervention can inform the WTC-HP's extensive research and clinical efforts with the potential to provide an excellent preventive care model to reduce inflammation and weight among WTC responders with PTSD. Additionally, the study provided many lessons that can guide the development of a full-scale lifestyle intervention (Figure 1).

The MedDiet intervention arm included the following components:

- ◆ Weekly (10-weeks) web based WTC-Nutrition study curriculum including a 'eating' and 'fit' tip, recipes, videos, and other useful handouts.
- ◆ Three counseling meetings (one hour each) including information on the MedDiet, gradual behavior/habit changes, promote family support, anticipated barriers, and motivators.
- ◆ Weekly text message with the link to the study's website weekly session, and a text message with teach-back questions on the video and weekly goal setting and motivational and reminder messages (3 times/week).
- ◆ Experiential group cooking skills (three in-person group cooking and taste testing events were planned but due to COVID-19, one synchronous remote cooking demo was conducted; participants were following and cooking along in their kitchens).

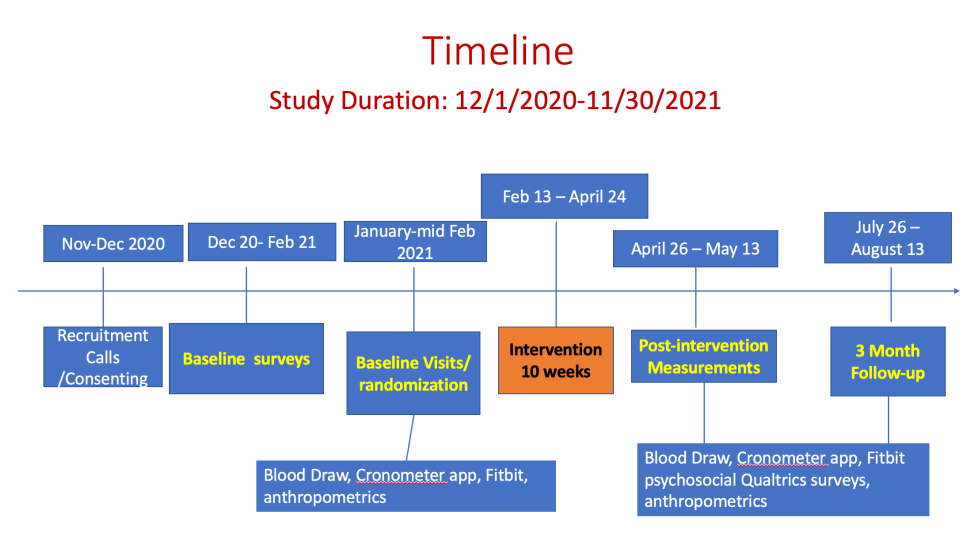


Figure 1. Study Timeline

The study included the following specific aims:

Aim 1: To develop and assess the feasibility and acceptability of a pilot nutrition intervention (MedDiet) with a PA component to reduce body weight, MetS, prevent/reduce systemic inflammation among World Trade Center responders with PTSD.

Aim 2: To assess within and between group changes in dietary intake (MedDiet) score and PA.

Exploratory Aim: To assess within and between group changes in body weight, inflammatory biomarkers and prevalence of MetS; and assess if a change in inflammatory biomarkers, is moderated by changes in MetS, body weight, or MedDiet score.

Participants' Sociodemographic characteristics

The average age of participants was 54 years (range: 42-64), 87% male, 58% Caucasian, 5% African American, 5% Asian/other/multiracial, and 32% refused to answer/unknown; more than one half of participants had some college education and 20% had a bachelor's degree or grad school; close to 60% worked in law enforcement,

35% worked full time, and 40% were retired. The two groups were not significantly different in demographic characteristics (Table 1).

Table 1 Participant Characteristics (N= 62)

Characteristics	Total N=62	Intervention N=31	Control N=31	p value
Race (n, %)				
White or Caucasian	36 (58.06%)	16 (25.81%)	20 (32.26%)	0.740
Black or African-American	3 (4.84%)	2 (3.23%)	1 (1.61%)	
Asian/Other/Multi-racial	3 (4.84%)	2 (3.23%)	1 (1.61%)	
Gender: Male	54 (87.10%)	27 (43.55%)	27 (43.55%)	1.00
Age (mean; SD)	54.24 (5.80)	54.90 (6.14)	53.58 (5.46)	0.313
Range	42.00-64.00	42.00-64.00	43.00-64.00	
Education (n, %)				
High School Graduate	12 (21.82%)	5 (9.09%)	7 (12.73%)	0.669
Associate, some college, tech school	30 (54.54%)	16 (27.28%)	15 (27.27%)	
Bachelor's Degree/Grad School	11 (20.00%)	8 (14.55%)	5 (9.09%)	

Key Findings for Aim 1

The study successfully recruited and retained a sample of 62 participants, of whom 94% completed all post-intervention and 74% completed all follow-up assessments. The majority of MedDiet participants expressed a high degree of satisfaction with the program and the weekly education materials and unanimously reported that they would recommend it to other clinic patients. Figure 1 shows a flowchart of recruitment, randomization, and data collection. A total of 212 WTC-HP participants met initial eligibility criteria within the past year based on their medical records; the main reasons for refusal to participate were either the COVID-19 pandemic, lack of interest, time, or travel plans. Seventy-one members consented to participate and completed baseline measures; nine participants dropped out prior to randomization due to concerns about COVID-19, work schedule, or tech privacy, resulting in 62 randomized participants. A total of 58 (94%) participants completed the post-intervention and 46 (74%) completed all follow-up measurements (Figure 2).

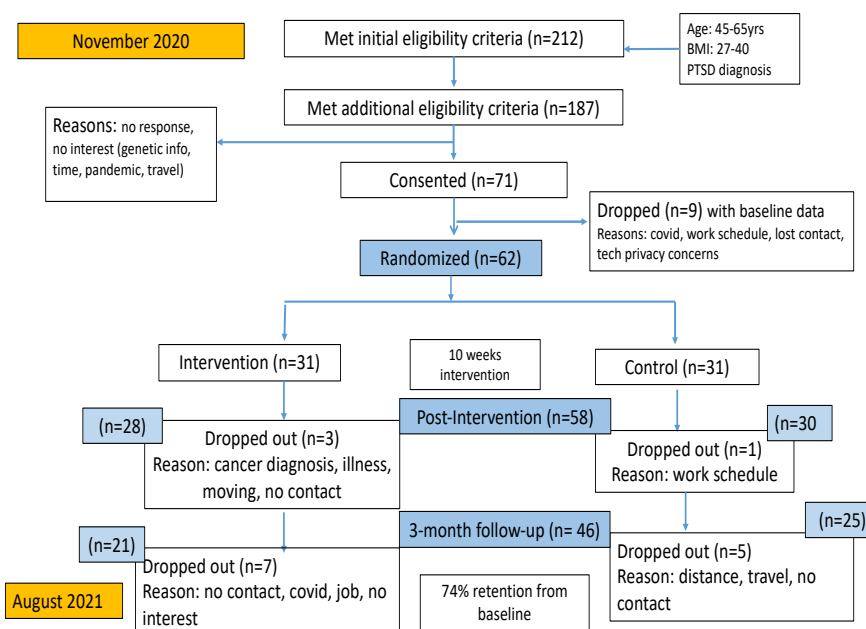


Figure 2 Flowchart of recruitment, randomization and data collection of the WTC-Nutrition Pilot randomized controlled trial

Participant Satisfaction with the Intervention

The participant satisfaction results indicated a high degree of satisfaction with the intervention. Among the MedDiet intervention participants, more than 85% watched the weekly videos and responded to teach back questions related to the video content and set a weekly goal; out of those who set goals, 41% fully completed and 21% partially completed their goals (made a few changes toward the set goal); 83% (20/24) reported being satisfied and very satisfied with the program, 96% (23/24) would participate again, and 100% (24/24) would recommend it to other WTC-HP patients. More than 90% were satisfied with the individual components (e.g., website, recipes, videos), 95% (23/24) were satisfied and very satisfied with the PA tips, while 92% (22/24) would like to have more cooking demonstrations in the future; 92% of MedDiet participants reported that receiving the can of olive oil at baseline helped increase intake and motivated them to purchase more.

Key Findings for Aim 2**Dietary Intake (MedDiet Score)**

The 14-item Mediterranean diet survey was used to assess compliance with the MedDiet reporting on habitual consumption of foods/beverages. Response categories are 1 or 0 (total range 0-14) representing participants' adherence to each food category in predetermined frequencies, including servings of fruit and vegetables, sweet desserts, breads/starches (refined versus whole grains), ocean fish, and beverages. A higher score represents higher adherence to the MedDiet.

Both intervention and control groups experienced an increase in the MedDiet score; at baseline, the median MedDiet score was 6.0 (1.0-11.0) and increased by 4 (-1.0-8.0; $p<0.0001$) and 3 points (-2.0-7.0; $p<0.0001$) at post-intervention and follow-up, respectively (Table 2).

Physical Activity and Sedentary Behaviors

Daily steps were measured with Fitbit that the participants were instructed to wear for seven consecutive days; the device can be clipped to the waistband or a front pocket and measures motion through an internal accelerometer aggregating into data as daily step count or time (minutes) spent in physical activity. A minimum of three days, including one weekend day of recorded data was accepted for analysis. On average the participants recorded about 7,300 steps per day without significant changes within or between groups over the study period. At baseline, the participants reported spending 6.5 hours/day watching TV; at post-intervention, hours spent watching TV decreased by 1.5 hours/day. Similarly, at baseline they reported spending on average 180 minutes/day engaging in moderate physical activity and this increased by 60 minutes a week at follow-up. While these within group changes were not statistically significant, they indicate the potential to positively impact the participants' lifestyle behaviors through this type of an intervention.

Post-traumatic Stress Disorder (PTSD)

Although assessment of PTSD symptoms was not included in the proposed study aims, it was measured and changes in the PCL scores were reported. Post-traumatic stress disorder symptoms were measured with PCL-5, a 17-item self-report validated measure of current (past month) PTSD symptom severity based on the DSM-5 criteria. Participants were asked to rate problems they were bothered by in the past month "in relation to 9/11" on a scale of 1=not at all to 5=extremely (range 17-85). A minimum of 5 points suggests mild response to treatment; 5-10 points moderate, reliable change (e.g. change not due to chance); and a minimum of 10 points represents clinically meaningful change (e.g. transition toward "symptoms closer to non-PTSD"; 10-20 points clinically significant change "no-PTSD". Each group experienced a reduction in PCL scores. In both groups combined, the average median PCL score was 52.0 (25.0-74.0) at baseline; the score was reduced by -13 (-37.00-11.00) points at post-intervention and by -8 (-61.00-14.00) points at follow-up (Table 2).

Table 2 Baseline to post-intervention and 3-month follow up changes in the Mediterranean Diet score and PCL score of study participants (N=62)

Outcome Measures	Total	Intervention N=31	Control N=31	
	Median (min,max) p-value	Median (min,max) p-value [#]	Median (min,max) p-value [#]	Between group p-value
Mediterranean Diet score^{&}				
Baseline	6.00 (1.00 - 11.00)	6.00 (1.00 - 11.00)	6.00 (1.00 - 10.00)	
Difference baseline to post	4.00 (-1.00 - 8.00) p <0.0001	4.00 (-1.00 - 8.00) p<0.0001	3.00 (-1.00 - 7.00) p<0.0001	0.099
Difference baseline to 3-month follow up	3.00 (-2.00 - 7.00) p <0.0001	4.00 (-1.00 - 6.00) p<0.0001	3.00 (-2.00 - 7.00) p<0.0001	0.986
PCL Score*				
Baseline	52.00 (25.00 - 74.00)	52.00 (31.00 - 71.00)	50.00 (25.00 - 74.00)	0.927
Difference baseline to post	-13.00 (-37.00 - 11.00) p <0.0001	-11.50 (-37.00 - 6.00) p<0.0001	-13.00 (-30.00 - 11.00) p<0.0001	1.00
Difference baseline to 3-month follow up	-8.00 (-61.00 - 14.00) p<0.0001	-6.50 (-61.00 - 14.00) P=0.001	-9.50 (-25.00 - 10.00) p<0.0001	0.741

[&] Mediterranean Diet Score Range: 1-14 (higher score indicates more adherence to the Mediterranean Diet (response Yes=1; No=0))

[#] p-values indicate within group significant changes

*Possible PCL Score Range: 17-85 (higher score indicates more severe PTSD symptoms)

Key Findings for the Exploratory Aim

Waist Circumference and body mass index

Since the entire sample included only participants with overweight or obesity, at baseline, the median waist circumference (WC) was 43 inches, which is higher than the recommended cut off. Both groups experienced significant reduction in WC; however, the reduction was higher in the intervention group [(MedDiet: WC: -1.75inches (-9.75-0.50) vs. Control: WC: -1.00 inches (-13.0-1.30)] at post intervention and at follow-up the intervention group experienced even higher reduction in WC [MedDiet: WC: -2.5inches (-9.5-0.7) vs. Control: WC: -1.65 inches (-15.0-1.8)]. The baseline median BMI was 33.2; among the entire sample the BMI was reduced at post-intervention by -0.68 (-4.61-2.09; p<0.0001) and at follow-up by -0.60 (-6.91-3.59; p<0.0009) without significant differences between the two groups (Table 3).

Table 3 Waist circumference and body mass index among participants in the WTC-Nutrition study (N=62)

Outcome variables	Total N=62	Intervention N=31	Control N=31	
	Median (min,max) p-value	Median (min,max) p-value	Median (min,max) p-value	Between group p-value
Waist Circumference (in)				
Baseline	43.00 (35.5-59.30)	43.00 (35.50-59.30)	43.17 (37.25-56.00)	0.897
Difference baseline to post	-1.50 (-13.00-1.30) p <0.0001	-1.75 (-9.75-0.50) p<0.0001	-1.00 (-13.00-1.30) <0.0001	0.168
Difference	-1.75	-2.5	-1.65	0.466

baseline to 3-month follow up	(-15.00-1.80) p <0.0001	(-9.50-0.75) p<0.0001	(-15.00-1.80) <0.0001	
BMI*				
Baseline	33.20 (27.5-41.75)	33.61 (28.32-40.53)	32.75 (27.50-41.75)	0.387
Difference Pre vs. post	-0.68 (-4.61-2.09) p<0.0001	-0.82 (-3.78-2.09) p=0.0001	-0.49 (-4.61-1.34) p=0.010	0.173
Difference baseline to 3-month follow up	-0.60 (-6.91-3.59) p=0.0009	-0.59 (-4.63-3.59) p=0.06	-0.75 (-6.91-1.35) P=0.007	0.982

Inclusion criteria were BMI ≥ 27 to ≤ 40

There were treatment differences in HbA1c, $\omega 6/\omega 3$, and hsCRP. At baseline **HbA1c** was 5.9% and 5.6% in the MedDiet and the control group, respectively. At post-intervention the MedDiet group experienced a reduction in HbA1c of -0.10% (-1.00-0.30; p=0.009) while the control group had no change 0.00 (-1.20-0.60); **between group p=0.019 at post intervention.**

At baseline, among the entire sample, the average $\omega 6/\omega 3$ was 14.4 which is representative of the Western dietary pattern (lower is preferred). There was a significant average decrease of -1.69 (-8.84-6.72; **p=0.003**) at post intervention. The MedDiet group had a significant decrease of -2.71 (-8.84-6.72; **p=0.002**) while the control group had only -0.29 (-7.53-4.56; p=0.307) decrease, with a significant between group difference (**between group p=0.029**) (Figure 3) at post-intervention. While not significant, at 3-month follow up the MedDiet group still experienced a decrease of -1.52 (-7.88-5.07; p=0.092) while the control group experienced an increase of 0.03 (-3.67-12.22; p=0.990).

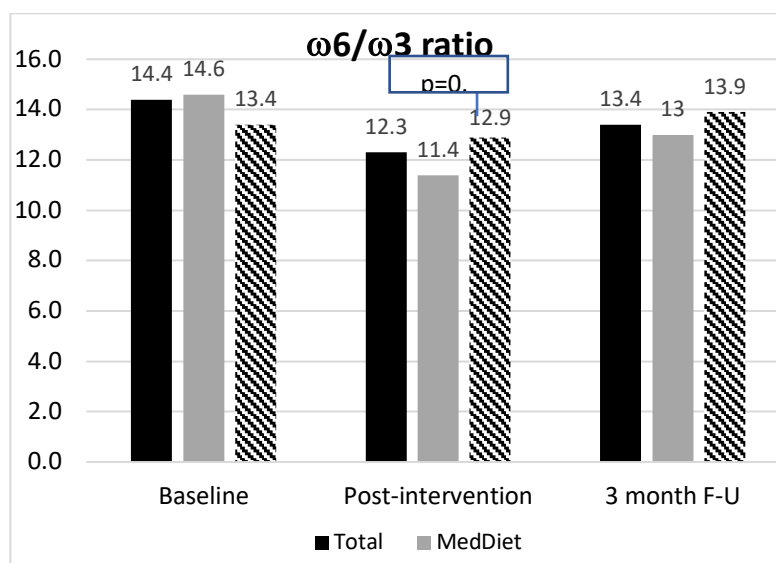


Figure 3. omega 6/omega 3 significant treatment effect between Mediterranean Diet and Control groups at post-intervention (p=0.029).

At baseline the average hsCRP was 1.80 mg/L (0.30-9.40) for the entire sample. While not significant, compared to baseline, there was a decrease of -0.3 mg/L (-2.60-3.00) in the MedDiet group and an increase of 0.25 mg/L (-2.60-2.60) in the control group at post intervention. However, at 3-month follow-up there was a significant between group difference (**p=0.025**) because the MedDiet group experienced a decrease of -0.18 mg/L, while the control group experienced an increase of 0.25 mg/L (Figure 4) compared to baseline.

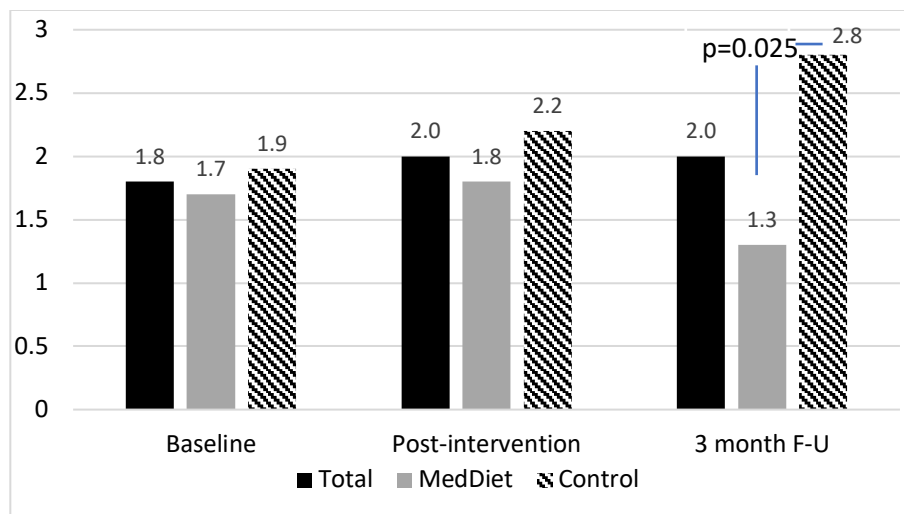


Figure 4. hsCRP significant treatment effect between Mediterranean Diet and Control groups at 3-month follow-up ($p=0.025$)

There were significant improvements in total cholesterol and oxLDL at post-intervention and follow-up for the entire sample. Both groups experienced a reduction in their oxLDL at post-intervention and at follow-up; at baseline, median oxLDL was 48.50 U/L (19.00-570.00) for the entire sample, and was reduced by -12.5 (-352.00-82.00 $p<0.0001$) at post-intervention and by -24.00 (-391.00-130.00; $p<0.0001$) at follow-up.

At baseline, total cholesterol was 200.50 mg/dL (100.00-293.00) and was reduced by -9.00 mg/dL (-93.00-51.00; $p=0.007$) and -13.90 mg/dL (-110.00-73.00; $p=0.031$) at post- and follow-up, respectively; only the MedDiet group experienced a significant decrease from baseline of -8.5 mg/dL (-88.00-38.00; $p=0.035$) at post-intervention. At baseline, the average CHOL/HDL for all participants was 4.05; only the MedDiet group had an average decrease at follow-up of -0.40 (-6.60-1.00; $p=0.032$) (Table 4).

Table 4 Baseline to post-intervention and 3-month follow up changes in blood biomarkers of hsCRP and HA1c, lipids, and fatty acid ratio for participants in the pilot WTC-Nutrition study (N=62)

Outcome variables	Total N=62	Intervention N=31	Control N=31	
	Median (min,max) p-value [#]	Median (min,max) Within group p-value [#]	Median (min,max) Within group p-value [#]	Between group p-value
Oxidized LDL (U/L)				
Baseline	48.50 (19.00-570.00)	40.0 (19.0-570.0)	68.00 (21.00-470.00)	0.119
Difference baseline to post	-12.50 (-352.0-82.00) p<0.0001	-5.00 (-352.0-31.00) 0.027	-16.00 (-286.0-82.00) <0.0001	0.117
Difference baseline to 3-month follow up	-24.00 (-391.0-130.00) p<0.0001	-20.0 (-391.0-130.0) 0.002	-26.00 (-287.0-12.00) <0.0001	0.638
hs-CRP (mg/L)				
Baseline	1.80 (0.30-9.40)	1.70 (0.3-9.4)	1.90 (0.70-7.0)	0.680
Difference baseline to post	0.00 (-2.60-3.00) p=0.76	-0.3 (-2.60-3.00) 0.255	0.25 (-2.60-2.60) 0.167	0.101
Difference	0.20 (-4.30-3.90)	-0.18 (-4.30-2.20)	0.25 (-1.90-3.90)	0.025

baseline to 3-month follow up	p=0.471	0.238	0.059	
Hemoglobin A1c (%)				
Baseline	5.70 (4.80-11.70)	5.90 (4.80-7.70)	5.60 (5.00-11.70)	0.158
Difference baseline to post	0.00 (-1.20-0.60) p=0.069	-0.10 (-1.00-0.30) 0.009	0.00 (-1.20-0.60) 0.757	0.019
Difference baseline to 3-month follow up	0.05 (-1.20-2.70) p=0.518	0.10 (-1.20-1.20) 0.790	0.00 (-0.90-2.70) 0.647	0.657
Total Cholesterol (mg/dL)				
Baseline	200.5 (100.0-293.0)	200.00 (100.00-293.00)	201.00 (138.00-270.00)	0.811
Difference baseline to post	-9.0 (-93.00-51.00) p=0.007	-8.50 (-88.00-38.00) p=0.035	-9.00 (-93.00-51.00) p=0.092	0.907
Difference baseline to 3-month follow up	-13.9 (-110.0-73.0) P=0.031	-8.00 (-110.0-55.00) p=0.107	-16.00 (-102.0-73.00) p=0.142	0.683
CHOL/HDL ratio				
Baseline	4.05 (2.20-10.40)	4.00 (2.20-10.40)	4.20 (2.80-7.60)	0.844
Difference baseline to post	-0.10 (-6.40-1.50) P=0.132	-0.15 (-6.40-0.80) p=0.231	-0.10 (-3.10-1.50) p=0.353	0.803
Difference baseline to 3-month follow up	-0.25 (-6.60-1.40) p=0.015	-0.40 (-6.60-1.00) p=0.032	-0.20 (-2.40-1.40) p=0.170	0.396
Triglycerides				
Baseline	129.50 (55.00-702.00)	130.00 (60.00-702.00)	129.00 (55.00-357.00)	0.741
Difference baseline to post	-19.00 (-569.0-124.00) p=0.012	-16.50 (-569.0-124.00) p=0.212	-21.50 (-170.0-64.00) p=0.022	0.768
Difference baseline to 3-month follow up	-12.00 (-572.0-97.00) p=0.062	-15.00 (-572.0-97.00) p=0.154	-3.00 (-145.0-91.00) p=0.184	0.825
ω6/ω3 ratio				
Baseline	14.38 (6.85-25.24)	14.57 (6.85-22.86)	14.32 (7.88-25.24)	0.994
Difference baseline to post	-1.69 (-8.84-6.72) p=0.003	-2.71 (-8.84-6.72) p=0.002	-0.29 (-7.53-4.56) p=0.307	0.029
Difference baseline to 3-month follow up	-0.97 (-7.88-12.22) P=0.263	-1.52 (-7.88-5.07) p=0.092	0.03 (-3.67-12.22) p=0.990	0.152

p-values indicate within group significant changes

Normal range:

Oxidized LDL (U/L) <60 U/L

hs-CRP (mg/L): 1.0-3.0 mg/L

Hemoglobin A1c (%): prediabetes range 5.7% to 6.4% based on the specific lab

Total Cholesterol (mg/dL): <200 mg/dL

CHOL/HDL ratio: <=3.5 indicate low-risk for CVD

Triglycerides: <150 mg/dL

ω 6/ ω 3: Lower ratio indicate a less inflammatory state (desirable)

Metabolic Syndrome

Metabolic syndrome is defined by presence of three or more of its components. The following components are included in the definition of MetS:

- ◆ Waist Circumference: Women \geq 88cm; Men \geq 102cm
- ◆ Triglycerides: \geq 150mg/dL
- ◆ Low HDL chol: Women <40 mg/dL; Men <50 mg/dL
- ◆ Blood pressure: \geq 130mm Hg/ \geq 85 mm Hg
- ◆ Fasting glucose \geq 100 mg/dL

In this study the change of the MetS prevalence (\geq 3 of components) from baseline to post-intervention and follow-up was assessed for the entire sample; at baseline the prevalence was 53.23%. From baseline to post intervention ($p=0.012$) and to follow-up ($p=0.052$) the net decrease in prevalence was almost the same at about 15.2%.

Findings on intake of certain foods and knowledge

Dietary intake was also measured through the Dietary Screener Questionnaire (DSQ), assessing the frequency of 26 foods and beverages consumed in the past month. In this study a few food groups were assessed, including intake (times/week) of red meat, fruits, and vegetables. Participants reported consuming red meat on average 1.76 times/week; only the intervention group significantly reduced consumption by -0.80 times (-1.22 -0.38; $p=0.0002$). Similarly, only the intervention group experienced significant increase in vegetable intake; at baseline the participants reported having vegetables on average 3.34 times/week. At post intervention, only among the MedDiet group intake increased by 1.25 times (0.38-2.12; $p=0.005$). Prevalence of fruit intake was low with an overall intake of 3.66 times a week; both intervention and control groups significantly increased their intake by 1.34 times ($p=0.05$) and 1.86 times ($p=0.006$) at post intervention. Not significant group differences were observed.

Conclusion

This pilot study successfully recruited and retained a sample of 62 participants, of whom 94% completed all post-intervention and 74% completed all follow-up assessments. Additionally, since the study was conducted during a period marked by efforts to reduce exposure to COVID-19, this delivery method allowed the study to continue given the required restrictions. In interpreting the results of this study, it is important to consider that due to ethical reason the WTC-HP at Stony Brook University decided to also provide nutrition counseling with healthful dietary recommendations to the control group (usual care). While intervention effectiveness was not a primary aim of the study, intent-to-treat analyses indicated that both groups showed significant improvements in physical and mental health during the study period. This indicates that the WTC responders with overweight and obesity and diagnosed PTSD who are members of the WTC-HP can strongly benefit from receiving an intense and multimodal nutrition program that also includes goal setting as in this study.

Both groups improved adherence to the MedDiet, experienced improvements in their PTSD symptoms, reduced WC and BMI. Additionally, both groups saw an improvement in oxLDL and total cholesterol, while the MedDiet group, compared to control, had additional improvements in HA1c, ω 6/ ω 3, and hsCRP at either post-intervention or at follow-up. Despite lack of significant change in hsCRP in either group, the group difference that was driven by a decrease in the MedDiet and an increase in the control groups may provide support for the anti-inflammatory properties of the MedDiet.

Program implementation

Following completion of the intervention and after receiving positive feedback from the participants, the WTC-HP at Stony Brook University implemented the complete 12-week program as part of the Health & Wellness lifestyle program for weight loss and overall health. This online program follows the same modalities as the intervention with a tailored individual counseling by a dietitian. All the intervention materials are available online to other researchers and to the public. After implementing the program, the Clinic dietitians found that the most important benefit of this program was the study timeline. The three in-person visits, as part of the program, within 3-4 months followed by a 3 month follow up has been very helpful in keeping the patients motivated between

their annual visits. This indicates that regular contact with patients who may have challenges in keeping annual appointments may be one way to keep them motivated and responsive to the health messages.

(<https://wtcnutrition.wixsite.com/website/weeklywellnessprogram>).

Cumulative Inclusion Enrollment Table (Please see the Table that is included within this report below)

There was a total of 62 participants at baseline. All the participants were adults and the majority of them were male (n=54; 87%) and White (n=36; 58%), consistent with the characteristics of the overall WTC responder population. There were 3 (about 5%) African American and 3 (about 5%) participants in Asian/Other/Multiracial category. However, there was a large number of participants that refused to answer/unknown (n=20; 32%).

Dissemination of Findings

The key findings of this study have been published to a peer reviewed journal (see list below). We presented our findings in various competitive domestic and international conferences as oral and poster presentations. The PI (Arcan) was invited to present our key findings at the Greek Alzheimer's Disease Association in 2/2023 in Thessaloniki, Greece. The PI was also invited to present the project and findings at the seminar series of the Departments of Endocrinology and Family Medicine of Virginia Commonwealth University. Most importantly, other research studies have been developed and funded using our nutrition intervention in its totality focusing on lifestyle interventions to reduce cancer risk and inflammation. Recently, a Center was funded by NCI (one of four in the US) focusing on social drivers of health (SDOH) through multi-level interventions to reduce cancer risk within underserved communities through community engagement. The PI (Arcan) is the co-lead of the SDOH signature project (5 year R01 level) focusing on multi-level nutrition and physical activity changes within income based housing communities across Virginia. The individual-level nutrition component adapted all the modalities of the WTC-Nutrition project.

Grant details

National Cancer Institute (U19CA291433)

MPI: Fuemmeler, LaRose & Sheehan

Arcan: Co-lead (Lead PI) for the R01-level Social Drivers of Health (SDOH) Signature project

Title: The Virginia Advancing Cancer Control Engagement Research Through Transformative Solutions (VA-ACCERT) Center (One of four Centers awarded in the US)

The PI (Arcan) serves as a Co-I in the CDC/NIOSH funded grant (1 R21OH012630-01-00; PI Ginex, Stony Brook University) entitled Effectiveness and Implementation of a Brief Motivational Intervention to Increase Physical Activity for World Trade Center Health Program Cancer Survivors.

Additionally, more collaborations of the PI with other investigators resulted in submission of grants focusing on testing anti-inflammatory diets to improve mental health and other behaviors of youth involved in gun related violence and injuries; this study is under review by CDC investigators.

Peer reviewed publication

Arcan C, Hou W, Hoffman K, Reichardt A, Yang X, Clouston SAP, Bromet EJ, Luft B. Mediterranean diet intervention among World Trade Center responders with post-traumatic stress disorder: Feasibility and outcomes of a pilot randomized controlled trial. Obesity science & practice. 2024 February;10(1):e725. PubMed PMID: 38263989; PubMed Central PMCID: PMC10804354; DOI: 10.1002/osp4.725.

Invited Presentation

Arcan, C. Mediterranean diet intervention to reduce body weight and systemic inflammation among World Trade Center responders with Post Traumatic Stress Disorder: Pilot Randomized Controlled Trial.

13th Panhellenic Conference, Alzheimer's Disease & 5th Mediterranean Conference on Neurodegenerative Disease, Thessaloniki, Greece, February 9-12, 2023.

Please scroll to the end of the left column to see the list of my presentation:
https://drive.google.com/drive/folders/1XgaswdlkdbO7QP7N__nJ0e0IU0irVqAY

Peer reviewed oral presentations

Arcan C, Esse Foka, Wang X, Hughes, K, Reichardt A, Clouston S, Luft B. Association between change in dietary intake with change in body mass index and waist circumference among World Trade Center responders

with PTSD participating in a nutrition intervention. International Society for Behavioral Nutrition and Physical Activity (ISBNPA); June 20-23, 2024, Omaha, NE

Arcan C, Hou W, Wang X, Hughes, K, Reichardt A, Clouston S, Luft B. Nutrition Intervention to Reduce Body Weight and Systemic Inflammation Among World Trade Center Responders with Post Traumatic Stress Disorder: Randomized Controlled Trial; International Society for Behavioral Nutrition and Physical Activity (ISBNPA); May 18-21, 2022; Phoenix, AZ

Peer reviewed poster presentations

Esse Noudegbessi, Wei Hou, Kathryn Hughes, Amanda Reichardt, Sean A. P. Clouston, Benjamin J. Luft, **Chrisa Arcan**. Changes in nutrition knowledge, home food availability, and sedentary behaviors with changes in body mass index and waist circumference among World Trade Center Responders with PTSD participating in a nutrition intervention. Society for Behavioral Medicine, Philadelphia, PA, March 13-16, 2024.

Chrisa Arcan, Esse Noudegbessi, Kathryn Hoffman, Amanda Reichardt, Sean A. P. Clouston, Benjamin J. Luft. Nutrition Knowledge and Eating Behaviors of World Trade Center Responders with PTSD Participating in a Nutrition Intervention, ISBNPA, Uppsala, Sweden, June 14-17, 2023

Chrisa Arcan, Wei Hou, Xiaohua Yang, Kathryn Hughes, Amanda Reichardt, Sean A. P. Clouston, Benjamin J. Luft. Nutrition Knowledge and Eating Behaviors of World Trade Center Responders with PTSD Participating in a Nutrition Intervention, Society for Behavioral Medicine, Phoenix, AZ, April 26-29, 2023.

Cumulative Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.


Study Title:

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More Than One Race										
Unknown or Not Reported										
Total										

ORIGINAL ARTICLE

Mediterranean diet intervention among World Trade Center responders with post-traumatic stress disorder: Feasibility and outcomes of a pilot randomized controlled trial

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Abstract

Objective: Responders of the World Trade Center (WTC) disaster suffer from comorbidities. A Mediterranean Diet (MedDiet) nutrition intervention with physical activity was implemented among WTC responders with overweight/obesity and post-traumatic stress disorder (PTSD).

Methods: WTC Health Program members ($N = 62$), 45–65 years, males 87%, body mass index (BMI) 27–45 kg/m² randomized to MedDiet ($n = 31$) or usual nutrition counseling ($n = 31$). The 10-week intervention included online nutrition education, text messages, and group experiential cooking; both groups had three in-person individual nutrition counseling. Anthropometrics, serum biomarkers, psychosocial factors, MedDiet score, and PTSD symptoms were assessed at baseline, post-intervention, and 3-months (follow-up). The primary outcome was intervention feasibility and secondary outcomes were within- and between-group changes of all measures at post-intervention and follow-up. Nonparametric Wilcoxon rank sum tests for between-group comparisons and Wilcoxon signed rank tests for pre-post within-group comparisons.

Results: A total of 58(94%) and 46(74%) participants completed the post-intervention and follow-up measurements, respectively. Both groups experienced significant improvements in anthropometrics, MedDiet score, oxidized low-density lipoprotein, and PTSD symptoms. Baseline median (range) were weight 100.42 (73.66–135.17) kg, BMI 33.20 (27.50–41.75) kg/m², and Waist circumference (WC) 109.22 (90.17–150.62) cm. Median % weight loss at post-intervention was MedDiet: –3% (–11%–7%), $p = 0.0002$; Control: –1% (–13%–4%), $p = 0.008$ and at follow-up MedDiet: –2% (–14%–12%), $p = 0.07$; Control: –2% (–20%–3%), $p = 0.006$. The overall BMI was reduced by –0.68 kg/m² (–4.61–2.09) kg/m² $p < 0.0001$ at post-intervention and by –0.60 kg/m² (–6.91–3.39) kg/m², $p < 0.0009$ at follow-up. Overall, median WC was reduced ($p < 0.0001$); post-intervention –3.81 cm

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(−33.00–3.30)cm and follow-up −4.45(−38.10–4.57)cm. There were group differences in HbA1c ($p = 0.019$) and serum $\omega 6/\omega 3$ ($p = 0.029$) at post-intervention.

Conclusion: Online intervention with personal counseling was feasible in this population. Improvements in anthropometrics, MedDiet score, selected serum biomarkers and PTSD symptoms were found in both groups; group differences in HbA1c and serum $\omega 6/\omega 3$. A larger study with a delayed control is needed to better assess intervention effects.

KEYWORDS

body mass index, Mediterranean diet, post traumatic stress disorder, systemic inflammation, waist circumference, WTC responders

1 | INTRODUCTION

Twenty years after the terrorist attacks of 11 September 2001 on the World Trade Center (WTC) in New York City, the rescue workers and other responders who helped with the clean-up continue to bear the burden of multiple co-morbidities mainly due to environmental exposure and psychological trauma.^{1–3} Trauma-exposed WTC responders experience high prevalence of inflammation-related conditions such as metabolic syndrome (MetS), cardiovascular disease, and chronic obstructive pulmonary disease.¹ The average body mass index (BMI) among WTC responders is in the obesity range (i.e., $>30 \text{ kg/m}^2$)⁴ and nearly one-third have at least three of the MetS factors with hypertension and abdominal obesity occurring most frequently.⁵ Post-traumatic stress disorder (PTSD) is a psychiatric condition that can develop after a traumatic event and manifests in various psychological, biological, and behavioral outcomes⁶ that carry severe societal and economic consequences. One in five WTC responders who aided in the initial recovery operations suffer from PTSD.⁷

Evidence to date has shown the co-occurrence of obesity and obesity-related chronic diseases, such as type 2 diabetes, insulin resistance, and cardiovascular disease with PTSD.^{8–10} Moreover, individuals with PTSD have poorer dietary behaviors and have more difficulty achieving weight loss compared to individuals without PTSD.^{11–13} While the multimorbidity of obesity, MetS and PTSD^{14,15} often poses challenges to medical interventions,^{16,17} it also emphasizes the importance for lifestyle modification interventions incorporating diet and Physical Activity (PA) to reduce systemic inflammation, metabolic comorbidities, and weight in individuals with PTSD.^{18,19}

A systematic review of intervention trials involving anti-inflammatory rich diets and exercise have shown to protect against low-grade inflammation and attenuate inflammatory biomarkers.²⁰ However, there is a scarcity of lifestyle modification interventions focusing on nutrition and PA among participants who suffer from PTSD.²¹ The Mediterranean Dietary pattern (MedDiet) is characterized by healthy dietary fats and antioxidant- and polyphenol-rich foods derived mainly from plant-based sources like fruits, vegetables, olive oil, beans, nuts, legumes, herbs, spices, and whole grains.²² In part, the benefits of a MedDiet are thought to emerge from its focus on meal combinations and foods that work synergistically to reduce

postprandial inflammatory and oxidative risks.^{23,24} Regular adherence to the MedDiet has been shown to have beneficial effects in primary and secondary prevention of cardiovascular disease, metabolic disorders, and breast cancer and to provide a neuroprotective effect.^{19,25–28} Emerging evidence points to the protective effect of the MedDiet through lipid reduction, protection against oxidative stress and inflammation, modification of hormone and growth factors linked to cancer pathogenesis, and gut microbiota influencing metabolic health.²⁹

Lifestyle modification interventions delivered remotely utilizing the Internet and mobile technology have shown great promise in improving lifestyle behaviors including dietary intake, PA, and behavioral modification.^{30–33} Here, we report results from the WTC-Nutrition Study, a 10-week prospective randomized control trial implementing the MedDiet with a PA component to improve eating behaviors among WTC responders with overweight and obesity and an active diagnosis of chronic PTSD. The intervention was mainly delivered using the Internet and a mobile technology with minimal in person counseling. This manuscript describes findings on study feasibility and on secondary outcomes, including anthropometrics, MedDiet score, PTSD symptoms (PCL score), and selected blood biomarkers.

2 | MATERIALS AND METHODS

2.1 | Study design and setting

The WTC-Nutrition pilot study was a two-arm randomized controlled trial conducted at the WTC Health Program (WTC-HP) at Stony Brook University in Long Island, New York from December 2020 through November 2021. A total of 62 participants were randomized to intervention (MedDiet $n = 31$) and control (Usual care $n = 31$). The sample size was based on available budget and was also informed by other feasibility studies involving behavior change nutrition interventions and the home food environment.^{34,35} The primary aim of the study was to assess the feasibility of the intervention and the secondary aims were that by the end of the intervention and at 3-months post intervention (follow-up) the MedDiet group compared

to the control group would have had higher MedDiet score indicating higher intake of food representative of the Mediterranean dietary pattern, more favorable anthropometric measures, and improvements in lipid profile and inflammatory biomarkers.

The study participants were members of the WTC-HP. In 2002, the Centers for Disease Control and Prevention established a monitoring and treatment program for 9/11 rescue and recovery workers. Stony Brook University has two WTC-HP clinics and provides monitoring, treatment, and mental health services to a little more than 13,000 responders primarily residing on Long Island, NY. Overall, the participants at the program were mainly male (92%) and worked in law enforcement (71.5%) during the 9/11 disaster.³⁶

2.2 | Participant recruitment and screening

The screening and recruitment of study participants were conducted by the WTC-HP registered dietitians who also served as study dietitians and by other clinic staff. Three recruitment methods were utilized: (1) in person during scheduled annual monitoring visits, (2) physician referrals for nutrition counseling within the past year, and (3) calling clinic members who met initial inclusion criteria and had signed prior informed consent agreeing to be contacted for future studies. The initial goal was to recruit participants with obesity (BMI ≥ 30 kg/m²), however due to the limited number of individuals meeting all the inclusion criteria, the decision was made to also include participants with BMI ≥ 27 kg/m²). Thus, the final inclusion criteria were BMI ≥ 27 to ≤ 40 kg/m², age 40–65 years, diagnosed PTSD with a Checklist (PCL-5) score ≥ 40 in the past year, and willingness to attend and provide a blood sample at baseline, follow-up, and post-intervention data collection visits. The specific age range was selected because the average age of WTC-HP members was 53 years. Exclusion criteria included, active malignant cancer (except non-melanoma skin cancer) and/or history of malignancy within the last three years for gastrointestinal-related cancer, autoimmune disorders (associated with increased inflammatory markers), history of surgical weight loss, and evidence of cognitive impairment with Montreal Cognitive Assessment ≤ 22 in the past year, previous or current nutrition counseling by WTC-HP dietitians or participation in another lifestyle intervention, unwillingness or lack of ability to follow the recommended diet, physical difficulties that impair walking, inability to read and speak English, and not having a smartphone or unwilling to utilize text messaging services. All study procedures, including data collection and materials, were approved by Stony Brook University's Institutional Review Board. This trial was registered on clinicaltrials.gov NCT05138198 (11/29/2021).

Once recruitment was completed and participants signed the informed consent, a baseline meeting with the RDs was scheduled within 2 weeks in either of the two Stony Brook WTC-HP clinics. One day prior to the meeting, participants received a reminder email, call, or a text message with an attachment of the "pre-visit intake form" via Qualtrics to collect information on salient health behaviors, such as smoking, food preferences, readiness for behavioral change,

medication and supplement use, and diabetes and mental health history; they also received instructions on how to download the Cronometer and Fitbit apps on their smart phones.

During the baseline visit that lasted about 60 min, the participants received information about study procedures, had their blood pressure, height, weight, and Waist circumference (WC) measured and their blood drawn by a clinic phlebotomist or a nurse; participants were instructed to be fasting from midnight to the time of their appointment. They received their personal Fitbit and were shown how to wear and sync it with their smartphones. Instructions on how to record their daily food intake on Cronometer app were also provided. Following the baseline visit, the participants received electronic surveys in batches via text messages with Qualtrics link to be completed over 1 week. The surveys included the 14-question Mediterranean diet questionnaire, 26-question Dietary Screener Questionnaire, and questions assessing the participants' nutrition knowledge, eating habits, weight history, social support, sleeping habits, and their home food environment.

After baseline measurements, the participants were randomized to MedDiet or control (usual nutrition counseling) groups using a computer-generated randomization procedure. The participants were blinded to their study status. To promote adherence to measurements and retention, various incentives were provided, including a container of extra virgin olive oil (MedDiet only) or \$25 gift card (control only) at baseline, \$50 gift-cards after each post-intervention and follow-up assessment, and \$50 to cover transportation costs to/from the clinics. Participants were able to keep their Fitbit watch (Inspire HR model)³⁷ as an incentive. After the group cooking session, a raffle was drawn, and one participant received a \$50 air fryer.

2.3 | Intervention modules (treatment arm: Mediterranean diet with physical activity tips)

The intervention adopted principles of Social Cognitive Theory,³⁸ emphasizing behavior (healthy eating and PA) within the inclusion of social context (family/friend support) in a dynamic and reciprocal interaction between the participants and their environment (home food availability/family meals) and was informed by elements of the "Feeding America's Bravest" study.³⁹ The three individual counseling meetings included addressing questions about the MedDiet, behaviors and habits, family support, anticipated barriers, and motivators.^{39–41}

The WTC-Nutrition intervention emphasized a higher consumption of foods rich in antioxidant and anti-inflammatory components and lower consumption of foods with inflammatory potential. The goal was toward gradually increasing intake of a variety of vegetables, fruits, whole grains, seafood/fish, legumes, and white meat (poultry/turkey) and reducing the intake of red meat, processed meat, sugary beverages, chips, fried foods, and sweets. Extra virgin olive oil was recommended as the fat of choice.

The intervention was delivered using a multimodal approach to ensure high intervention dose by meeting the previously reported

barriers to participation including the possibility of boredom and irregular work schedule.⁵ The main mode of intervention delivery was through the study website and mobile phones (text messages). Weekly content included a mix of psychoeducation and behavioral skills and strategies (e.g., goal setting, skills building and self-efficacy to prepare and consume healthy meals, knowledge about the Med-Diet, social support, mitigating barriers to change, and providing positive reinforcement). Each week the participants received a text message with the link to the study's website weekly session with content including a "food" and "fit" tips, recipes, and short videos with nutrition education and experiential skills development. Based on the theme/topic of each week, the participants received additional reminder and motivational text messages, as well as a text message with teach back questions following the videos and a prompt to set personal weekly goals. The weekly nutrition topics and activities are

shown in Table 1. One live session of group experiential cooking was conducted remotely due to COVID-19 imposed social isolation. Additionally, both the MedDiet and control groups received three in-person counseling sessions during each of the measurement times.

2.4 | Control group (usual care)

The control group received three in-person individual counseling sessions with their assigned dietitian. The dietitian provided medical nutrition therapy, a specific application of the Nutrition Care Process in clinical settings that focuses on the management of diseases (e.g., diabetes, heart disease, etc.). Specific dietary recommendations were based on the Bull's Eye Food Guide used by Stony Brook University Hospital for outpatient nutrition counseling.⁴²

TABLE 1 Overview of the WTC-nutrition intervention weekly sessions.

Topics (Weeks)	Nutrition and PA themes
1. Introduction to the study: Live healthy to lose weight	<ul style="list-style-type: none"> • Healthy habit building and meals and snacks to get started • Setting realistic goals; importance of PA • Family meals and social support
2. Med not meds	<ul style="list-style-type: none"> • Introduction of MedDiet and increase minutes of exercise • Introduction of olive oil and how to gradually increase consumption
3. Label lingo	<ul style="list-style-type: none"> • Label reading education and portion control recommendations; guide to increase daily steps
4. Prep, plan, and save	<ul style="list-style-type: none"> • Introduction to meal preparation and grocery store tour (virtual) • Importance of making a grocery list, purchasing more produce (fruits, vegetables) and more seafood; PA choices to overcome challenges
5. Facts on fats and inflammation	<ul style="list-style-type: none"> • Chronic inflammation education; sources for healthy fat intake • Healthy fat sources: Nuts (including peanuts) and seeds
6. Eat the rainbow	<ul style="list-style-type: none"> • Fighting inflammation with food and the importance of fruits and vegetables; fighting inflammation with PA • Ways to increase intake of fruits and vegetables; consider challenges and opportunities
7. Bittersweet? Carbs, beverages and ways to reduce sugar intake	<ul style="list-style-type: none"> • Carbohydrate education and importance of whole grains; importance of strength training • Sugar-sweetened beverages and simple carbs; ways to increase whole grains
8. How to balance a meal (emphasize olive oil for fat) and dining out Mediterranean + snacking & fast food	<ul style="list-style-type: none"> • How to balance a meal and ways to dine out and snack healthfully • Choose unsaturated fats over butter & cheese; choose grilled instead of fried options when dining; read the label or menu ahead of time • Explore healthy food swaps for cravings when they arise
9. "Eat food, not a lot, mostly plants"	<ul style="list-style-type: none"> • Importance of a plant-based diet and plant-based proteins in the diet • Ways to increase meatless meals per week
10. Healthy for life	<ul style="list-style-type: none"> • Tips for time management and sustainable habits • Maintain my physical activity routine; be mindful about my food choices in various occasions; increase social support in eating and PA

Note: The intervention themes were delivered through a study website, motivational and reminder text messages, videos, goal setting (weekly). Abbreviation: PA, Physical Activity.

2.5 | Measures

Data collection occurred at three time points: baseline (11/2020–2/2021), post-intervention (5/2021; 3 months from baseline), and follow-up (8/2021; 6 months from baseline) to assess the sustainability of behaviors. Study feasibility was assessed through careful recording of participant recruitment and retention process, the completion of measurements in three time points, compliance of weekly video review through teach-back responses and goal setting/compliance, and responses to a process evaluation survey at the end of the study. Sociodemographic characteristics were collected only at baseline.

2.6 | Anthropometry

Study RDs measured the participants' height, weight, and WC using standardized procedures. Height (cm) was measured to the nearest 0.1 cm using a portable stadiometer (Perspective Enterprises, Portage); weight was measured to the nearest 100 g using an Omron Scale with participants wearing light indoor clothing and no shoes. Body mass index (BMI) [(weight (kg)/height (m)²] was calculated. Waist circumference was measured using a tape measure snugly fitted around each participant's waist at the level of the iliac crest and measuring the circumference after expiration.

2.7 | Dietary intake

The 14-item Mediterranean diet survey was used to assess compliance with the MedDiet reporting on habitual consumption of foods/beverages. Response categories are 1 or 0 (total range 0–14) representing participants' adherence to each food category in pre-determined frequencies, including servings of fruit and vegetables, sweet desserts, breads/starches (refined vs. whole grains), ocean fish, and beverages. A higher score represents higher adherence to the MedDiet.^{43,44}

2.8 | Physical activity

Daily steps were measured using a Fitbit that the participants were instructed to wear for seven consecutive days; the device can be clipped to the waistband or a front pocket and measure motion through an internal accelerometer aggregating into data as daily step count or time (minutes) spent in PA. A minimum of 3 days, including one weekend day of recorded data, was accepted for analysis.

2.9 | Post-traumatic stress disorder

Post-traumatic stress disorder symptoms were measured using PCL-5, a 17-item self-report validated measure of current (past month) PTSD symptom severity based on the DSM-5 criteria. Participants were

asked to rate problems they were bothered by in the past month "in relation to 9/11" on a scale of 1 = not at all to 5 = extremely (range 17–85). A minimum of 5 points suggests mild response to treatment; 5–10 points moderate, reliable change (e.g., change not due to chance); and a minimum of 10 points represents clinically meaningful change (for example, transition toward "symptoms closer to non-PTSD"; 10–20 points clinically significant change "no-PTSD".⁴⁵

2.10 | Blood biomarkers

A total of up to 60 mL of blood was collected at baseline, post-intervention, and follow-up. Small aliquots of participant plasma samples were frozen and stored at –80°C at the WTC research facility located at Stony Brook University Hospital until all samples from the same group were collected and could be analyzed on the same day. Biomarkers included a detailed lipid panel [oxidized low-density lipoprotein (oxLDL), calcLDL, high-density lipoprotein, triglycerides], omega-3 and omega-6, Hemoglobin A1c (HbA1c), and high sensitivity C-reactive protein; 10 inflammatory cytokines (IFN γ , IL-1 β , IL-4, IL-5, IL-6, IL-8, IL-10, IL-12p70, IL-22 and TNF α) were analyzed by Quanterix (CorPlex Cytokine profile).

2.11 | Statistical analysis

To assess the study's primary aim, participant recruitment and retention were calculated. The number of participants who read the in-app messages via their responses and compliance with goal setting were assessed. Descriptive statistics (frequencies/percent) of demographics at baseline and statistical comparisons of secondary outcomes (i.e., MedDiet score and blood biomarkers) by condition at three measurement times were calculated. Because the study was not powered for intervention efficacy, the sample size was limited and outcome variables did not follow a Gaussian distribution, between-group comparisons were conducted for continuous outcomes using nonparametric Wilcoxon rank sum tests; pre-post within-group comparisons were conducted using Wilcoxon signed rank tests. It was also examined whether analytic choices might change the results using linear mixed models that were fitted for outcome measures with the inclusion of all three time points in adjusting for age and gender. While this method provides the flexibility to account for within-subject correlation for repeated measures, it resulted in similar levels of significance as non-parametric methods mentioned above; thus, the results in this study reflect the median values derived from nonparametric tests.

3 | RESULTS

The average age of participants was 54 years (range: 42–64), 87% male, 58% Caucasian, 5% African American, 5% Asian/other/multi-racial, and 32% refused to answer/unknown; more than one half of

the participants had some college education and 20% had a bachelor's degree or grad school; close to 60% worked in law enforcement, 35% worked full time, and 40% were retired. The two groups were not significantly different in demographic characteristics (Table 2).

Figure 1 shows a flowchart of recruitment, randomization, and data collection. A total of 212 WTC-HP members met initial eligibility criteria within the past year based on their medical records; the main reasons for refusal to participate were either the COVID-19 pandemic, lack of interest, time, or travel plans. Seventy-one members consented to participate and completed baseline measures; nine participants dropped out prior to randomization due to concerns about COVID-19, work schedule, or tech privacy, resulting in 62 randomized participants. A total of 58 (94%) participants

completed the post-intervention and 46 (74%) completed all follow-up measurements. More than 85% of MedDiet participants watched the weekly videos and responded to teach back questions related to the video content and set a weekly goal; out of those who set goals, 41% fully completed and 21% partially completed their goals (made a few changes toward the set goal); 83% (20/24) reported being satisfied and very satisfied with the program, 96% (23/24) would participate again, and 100% (24/24) would recommend it to other WTC-HP members. More than 90% were satisfied with the individual components (e.g., website, recipes, videos), 95% (23/24) were satisfied and very satisfied with the PA tips, while 92% (22/24) would like to have more cooking demonstrations in the future; 92% of MedDiet participants reported that receiving the can of olive oil

TABLE 2 Characteristics of participants in the WTC-Nutrition study (N = 62).

Characteristics	Total N = 62	Intervention N = 31	Control N = 31	p-value
Race (n, %)				
White or Caucasian	36 (58.06%)	16 (25.81%)	20 (32.26%)	0.740
Black or African-American	3 (4.84%)	2 (3.23%)	1 (1.61%)	
Asian/Other/Multi-racial	3 (4.84%)	2 (3.23%)	1 (1.61%)	
Gender: Male	54 (87.10%)	27 (43.55%)	27 (43.55%)	1.00
Age (mean; SD)	54.24 (5.80)	54.90 (6.14)	53.58 (5.46)	0.313
Age Range	42.00–64.00	42.00–64.00	43.00–64.00	
Education (n, %)				
High school graduate	12 (21.82%)	5 (9.09%)	7 (12.73%)	0.669
Associate, some college, tech school	30 (54.54%)	16 (27.28%)	15 (27.27%)	
Bachelor's Degree/Grad school	11 (20.00%)	8 (14.55%)	5 (9.09%)	

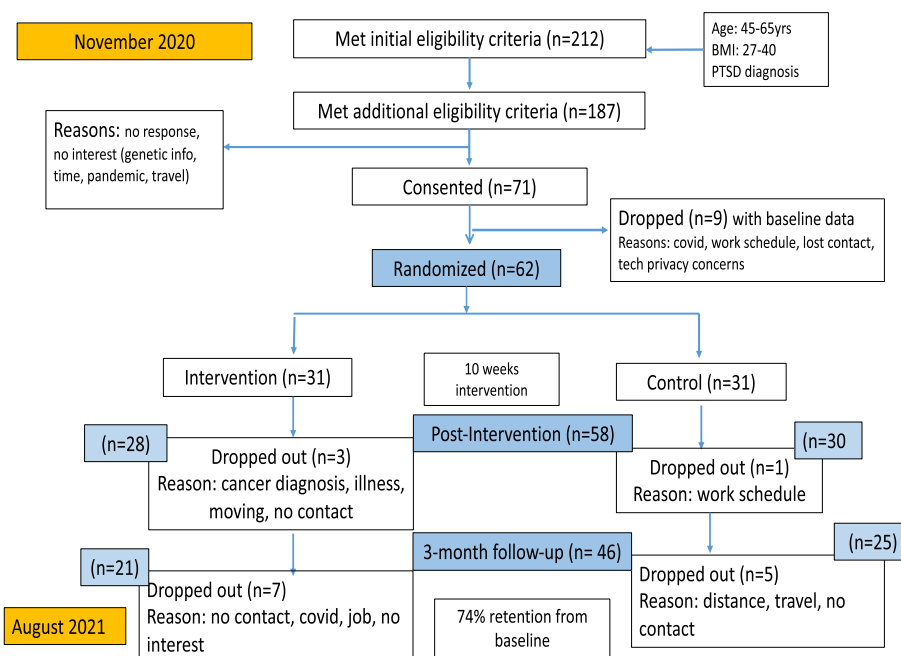


FIGURE 1 Recruitment, randomization, and data collection for the WTC-Nutrition pilot randomized controlled trial.

at baseline helped increase intake and motivated them to purchase more.

Both groups experienced a significant drop in the median weight, BMI, and WC at post intervention and at follow-up. Overall, at baseline the median (range) weight was 100.4 (73.7–135.2) kg, BMI 33.2 (27.5–41.8) kg/m², and WC 109.2 (90.2–150.6) cm. At post-intervention, there was a drop in median weight by [MedDiet –3% (–11%–7%) $p = 0.0002$ versus Control –1% (–13%–4%), $p = 0.008$] and at follow-up by [MedDiet –2% (–14%–12%), $p = 0.07$ versus Control –2% (–20%–3%), $p = 0.006$]. Overall, there was a reduction in BMI at post-intervention by –0.68 (–4.61–2.09) kg/m², $p < 0.0001$ and at follow-up by –0.60 (–6.91–3.59) kg/m², $p = 0.0009$. There was also a reduction in WC in both groups ($p < 0.0001$) by –3.1 (–33.0–3.1) cm and by –4.4 (–38.1–4.6) cm at post-intervention and follow-up (Table 3).

Both groups experienced an increase in the MedDiet score; at baseline, the median MedDiet score was 6.0 (1.0–11.0) and increased by 4 points (–1.0–8.0, $p < 0.0001$) and 3 points (–2.0–7.0, $p < 0.0001$) at post-intervention and follow-up, respectively. Among all participants, the median PCL score at baseline was 52.00 (25.00–74.00) and decreased by –13 points (–37.00–11.00), $p < 0.0001$ and by –8 points (–61.00–14.00) $p < 0.0001$ at post-intervention and follow-up, respectively (Table 4).

Table 5 shows changes in oxLDL and other lipid biomarkers; oxLDL was reduced in both groups without significant group differences. For the total sample, the baseline median (range) oxLDL was 48.5 (19.0–570.0) U/L and was reduced by –12.50 (–352.0–82.0) U/L, $p < 0.0001$ at post-intervention and by –24.00 (–391.00–130.00) U/L, $p < 0.0001$ at follow-up. Only the MedDiet group experienced a significant drop in median total cholesterol at

TABLE 3 Changes in weight, body mass index, and waist circumference (WC) among participants in the WTC-Nutrition study ($N = 62$).

Outcome variables	Total $N = 62$ Median (min, max) p -value	Intervention $N = 31$ Media (min, max) p -value ^a	Control $N = 31$ Median (min, max) p -value ^a	Between group p -value
Weight (kg)				
Baseline	100.42 (72.66–135.17)	98.88 (80.10–135.17)	100.65 (72.66–130.09)	0.905
Median % weight change (baseline to post)	–2% (–13%–7%) $p < 0.0001$	–3% (–11%–7%) $p = 0.0002$	–1% (–13%–4%) $p = 0.008$	0.222
Median % weight change (baseline to 3-month follow up)	–2% (–2%–12%) $p = 0.0008$	–2% (–14%–12%) $p = 0.07$	–2% (–20%–3%) $p = 0.006$	0.982
BMI (kg/m ²)				
Baseline	33.20 (27.50–41.75)	33.61 (28.32–40.53)	32.75 (27.50–41.75)	0.387
Difference baseline to post-intervention	–0.68 (–4.61–2.09) $p < 0.0001$	–0.82 (–3.78–2.09) $p = 0.0001$	–0.49 (–4.61–1.34) $p = 0.010$	0.173
Difference baseline to 3-month follow up	–0.60 (–6.91–3.59) $p = 0.0009$	–0.59 (–4.63–3.59) $p = 0.06$	–0.75 (–6.91–1.35) $p = 0.007$	0.982
Waist circumference (cm) ^b				
Baseline	109.22 (90.17–150.62)	109.22 (90.17–150.62)	109.6 (94.61–142.24)	0.897
Difference baseline to post-intervention	–3.81 (–33.00–3.30) $p < 0.0001$	–4.45 (–24.76–1.27) $p < 0.0001$	–2.54 (–33.02–3.30) < 0.0001	0.168
Difference baseline to 3-month follow up	–4.45 (–38.10–4.57) $p < 0.0001$	–6.35 (–24.13–1.90) $p < 0.0001$	–4.19 (–38.10–4.57) < 0.0001	0.466

Note: Inclusion criteria were BMI ≥ 27 to ≤ 40 . The bolded values indicate statistically significant improvement in the values where the p -value is lower than 0.05.

Abbreviation: BMI, Body mass index (kg/m²).

^a p -values indicate within group changes.

^bLow risk: Women: < 80 cm (31.5 in); Men: < 94 cm (37 in).

TABLE 4 Changes in the Mediterranean diet score and PCL score among participants in the WTC-Nutrition study (N = 62).

Outcome variables	Total N = 62 Median (min, max) <i>p</i> -value ^b	Intervention N = 31 Median (min, max) <i>p</i> -value ^b	Control N = 31 Median (min, max) <i>p</i> -value ^b	Between group <i>p</i> -value
Mediterranean diet score ^a				
Baseline	6.00 (1.00–11.00)	6.00 (1.00–11.00)	6.00 (1.00–10.00)	
Difference baseline to post-intervention	4.00 (–1.00–8.00) <i>p</i> < 0.0001	4.00 (–1.00–8.00) <i>p</i> < 0.0001	3.00 (–1.00–7.00) <i>p</i> < 0.0001	0.099
Difference baseline to 3-month follow up	3.00 (–2.00–7.00) <i>p</i> < 0.0001	4.00 (–1.00–6.00) <i>p</i> < 0.0001	3.00 (–2.00–7.00) <i>p</i> < 0.0001	0.986
PCL score ^c				
Baseline	52.00 (25.00–74.00)	52.00 (31.00–71.00)	50.00 (25.00–74.00)	0.927
Difference baseline to post-intervention	–13.00 (–37.00–11.00) <i>p</i> < 0.0001	–11.50 (–37.00–6.00) <i>p</i> < 0.0001	–13.00 (–30.00–11.00) <i>p</i> < 0.0001	1.00
Difference baseline to 3-month follow up	–8.00 (–61.00–14.00) <i>p</i> < 0.0001	–6.50 (–61.00–14.00) <i>p</i> = 0.001	–9.50 (–25.00–10.00) <i>p</i> < 0.0001	0.741

Note: The bolded values indicate statistically significant improvement in the values where the *p*-value is lower than 0.05.

^aMediterranean Diet Score Range: 1–14 (higher score indicates more adherence to the Mediterranean Diet (response Yes = 1; No = 0).

^b*p*-values indicate within group changes.

^cPossible PCL Score Range: 17–85 (higher score indicates more severe PTSD symptoms).

post-intervention; at the baseline, the median total cholesterol was 200.00 (100.00–293.00) mg/dL and was reduced by –8.5 (–88.00–38.00) mg/dL, *p* = 0.035.

There were treatment differences in HbA1c, $\omega 6/\omega 3$, and hsCRP; the MedDiet group experienced reduction in HbA1c [MedDiet: –0.10% (–1.00–0.30), *p* = 0.009 versus Control: 0.00% (–1.20–0.60); *p* = 0.757; between group diff. *p* = 0.019] and in $\omega 6/\omega 3$ [MedDiet: –2.7 (–8.84–6.72, *p* = 0.002) versus Control: –0.29 (–7.53–4.56; *p* = 0.307); between group *p* = 0.029] at post-intervention (Figure 2).

While hsCRP did not significantly decrease in the total sample, at follow-up there was a significant treatment difference (*p* = 0.025) because the MedDiet group experienced a decrease of –0.18 mg/L, while the control group experienced an increase of 0.25 mg/L (Figure 3). On average, the participants recorded about 7300 steps per day without significant changes within or between groups over the study period (data not shown). There were no significant within or between group changes in inflammatory cytokines thus results were not presented here.

4 | DISCUSSION

To address the perceived gap in lifestyle interventions among WTC responders who suffer from both somatic and mental issues, the WTC-Nutrition pilot intervention was conducted in a group of WTC

responders with overweight and obesity and chronic PTSD. The study met the primary outcome of feasibility and acceptability, having successfully recruited and retained a sample of 62 participants. The majority of MedDiet participants expressed a high degree of satisfaction with the program and the weekly education materials and unanimously reported that they would recommend it to other clinic patients.

In interpreting the secondary outcomes of this study, it is important to consider that the control group (usual care) consisted of nutrition counseling with healthful dietary recommendations. While intervention effectiveness was not the primary aim of the study,⁴⁶ intent-to-treat analyses indicated that both groups showed significant and sustained improvements in body weight, WC, BMI, oxLDL and total cholesterol, while the MedDiet group, compared to control, had additional improvements in HA1c, $\omega 6/\omega 3$, and hsCRP at either post-intervention or at follow-up. Despite the lack of significant change in hsCRP in either group, the group difference that was driven by a decrease among the MedDiet group and an increase in the control group may provide support for the anti-inflammatory properties of the MedDiet.²⁶ Additionally, both groups experienced improvements in their PTSD symptoms.

In this 10-week pilot intervention the participants experienced an overall median weight reduction of 2%; while it was lower than the clinical significance threshold of >5%, the results were similar to a large study among 60,000 U.S veterans with overweight/obesity and

TABLE 5 Changes in blood biomarkers of hsCRP and HA1c, lipids, and fatty acid ratio among participants in the WTC-Nutrition study (N = 62).

Outcome Variables	Total N = 62 Median (min, max) p-value ^a	Intervention N = 31 Median (min, max) Within group p-value ^a	Control N = 31 Median (min, max) Within group p-value ^a	Between group p-value
Oxidized LDL (U/L)				
Baseline	48.50 (19.00–570.00)	40.00 (19.0–570.0)	68.00 (21.00–470.00)	0.119
Difference baseline to post-intervention	–12.50 (–352.0–82.00) p < 0.0001	–5.00 (–352.0–31.00) 0.027	–16.00 (–286.0–82.00) <0.0001	0.117
Difference baseline to 3-month follow up	–24.00 (–391.00–130.00) p < 0.0001	–20.00 (–391.00–130.0) 0.002	–26.00 (–287.00–12.00) <0.0001	0.638
hs-CRP (mg/L)				
Baseline	1.80 (0.30–9.40)	1.70 (0.3–9.4)	1.90 (0.70–7.0)	0.680
Difference baseline to post-intervention	0.00 (–2.60–3.00) p = 0.76	–0.30 (–2.60–3.00) 0.255	0.25 (–2.60–2.60) 0.167	0.101
Difference baseline to 3-month follow up	0.20 (–4.30–3.90) p = 0.471	–0.18 (–4.30–2.20) 0.238	0.25 (–1.90–3.90) 0.059	0.025
Hemoglobin A1c (%)				
Baseline	5.70 (4.80–11.70)	5.90 (4.80–7.70)	5.60 (5.00–11.70)	0.158
Difference baseline to post-intervention	0.00 (–1.20–0.60) p = 0.069	–0.10 (–1.00–0.30) 0.009	0.00 (–1.20–0.60) 0.757	0.019
Difference baseline to 3-month follow up	0.05 (–1.20–2.70) p = 0.518	0.10 (–1.20–1.20) 0.790	0.00 (–0.90–2.70) 0.647	0.657
Total cholesterol (mg/dL)				
Baseline	200.50 (100.0–293.0)	200.00 (100.00–293.00)	201.00 (138.00–270.00)	0.811
Difference baseline to post	–9.00 (–93.00–51.00) p = 0.007	–8.50 (–88.00–38.00) p = 0.035	–9.00 (–93.00–51.00) p = 0.092	0.907
Difference baseline to 3-month follow up	–13.9 (–110.0–73.0) p = 0.031	–8.00 (–110.0–55.00) p = 0.107	–16.00 (–102.0–73.00) p = 0.142	0.683
CHOL/HDL ratio				
Baseline	4.05 (2.20–10.40)	4.00 (2.20–10.40)	4.20 (2.80–7.60)	0.844
Difference baseline to post	–0.10 (–6.40–1.50) p = 0.132	–0.15 (–6.40–0.80) p = 0.231	–0.10 (–3.10–1.50) p = 0.353	0.803
Difference baseline to 3-month follow up	–0.25 (–6.60–1.40) p = 0.015	–0.40 (–6.60–1.00) p = 0.032	–0.20 (–2.40–1.40) p = 0.170	0.396

(Continues)

TABLE 5 (Continued)

Outcome Variables	Total N = 62 Median (min, max) <i>p</i> -value ^a	Intervention N = 31 Median (min, max) Within group <i>p</i> -value ^a	Control N = 31 Median (min, max) Within group <i>p</i> -value ^a	Between group <i>p</i> -value
Triglycerides				
Baseline	129.50 (55.00–702.00)	130.00 (60.00–702.00)	129.00 (55.00–357.00)	0.741
Difference baseline to post	–19.00 (–569.0–124.00) <i>p</i> = 0.012	–16.50 (–569.0–124.00) <i>p</i> = 0.212	–21.50 (–170.0–64.00) <i>p</i> = 0.022	0.768
Difference baseline to 3-month follow up	–12.00 (–572.0–97.00) <i>p</i> = 0.062	–15.00 (–572.0–97.00) <i>p</i> = 0.154	–3.00 (–145.0–91.00) <i>p</i> = 0.184	0.825
$\omega 6/\omega 3$ ratio				
Baseline	14.38 (6.85–25.24)	14.57 (6.85–22.86)	14.32 (7.88–25.24)	0.994
Difference baseline to post	–1.69 (–8.84–6.72) <i>p</i> = 0.003	–2.71 (–8.84–6.72) <i>p</i> = 0.002	–0.29 (–7.53–4.56) <i>p</i> = 0.307	0.029
Difference baseline to 3-month follow up	–0.97 (–7.88–12.22) <i>p</i> = 0.263	–1.52 (–7.88–5.07) <i>p</i> = 0.092	0.03 (–3.67–12.22) <i>p</i> = 0.990	0.152

Note: Normal range: Oxidized LDL (U/L) < 60 U/L. hs-CRP (mg/L): 1.0–3.0 mg/L. Hemoglobin A1c (%): prediabetes range 5.7%–6.4% based on the specific lab. Total Cholesterol (mg/dL): <200 mg/dL. CHOL/HDL ratio: ≤ 3.5 indicate low-risk for CVD. Triglycerides: <150 mg/dL. $\omega 6/\omega 3$: Lower ratio indicates a less inflammatory state (desirable). The bolded values indicate statistically significant improvement in the values where the *p*-value is lower than 0.05.

^a*p*-values indicate within group changes.

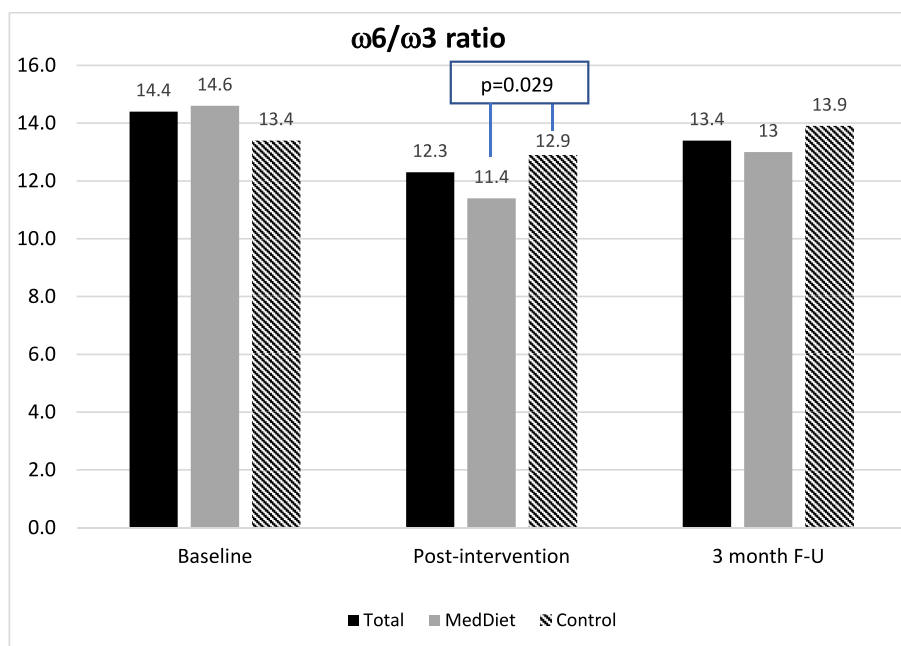


FIGURE 2 Serum omega 6-to-omega 3 ratio significant treatment effect between Mediterranean Diet and Control groups at post-intervention, *p* = 0.029.

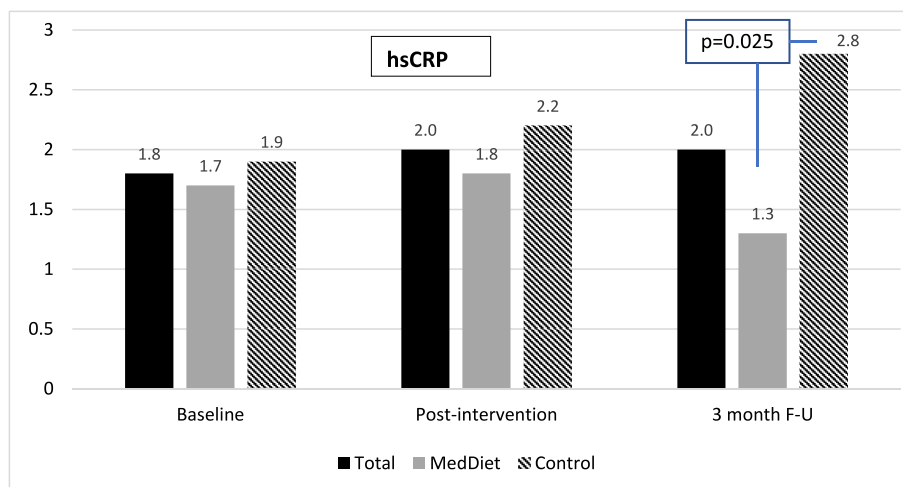


FIGURE 3 Serum hsCRP significant treatment effect between the Mediterranean Diet and Control groups at 3-month follow-up, $p = 0.025$.

PTSD; in the study reporting 6-month outcomes of the VA MOVE!, a multidisciplinary weight management program, the overall mean percent change in weight was -1.9 .⁴⁷ In contrast, a weight loss counseling study by Haas and colleagues that was delivered through a mobile phone app among 43 adults with overweight and obesity found median weight loss of -4.6% , reduction in BMI of -1.4 , and WC reduction of -3.5 cm (1.4 inches).⁴⁸ In the present WTC-Nutrition study the MedDiet group experienced a larger drop in the WC of -1.75 inches at post intervention and -2.5 inches at 3-month follow up. While both studies used a mobile technology, the study by Haas used a mobile app with tailored counseling and feedback.⁴⁸ Other notable differences were that the Haas study included participants with lower BMI ($26-33$ kg/m²) and without mental health issues. Nevertheless, considering the consistent findings that individuals with PTSD participating in weight loss programs have lower rates of success,⁴⁹ the anthropometric improvements of this WTC-Nutrition pilot study were encouraging.

Favorable changes in the self-reported MedDiet score from a median of 6 to 10 (out of 14) indicate compliance with the recommended dietary changes. Furthermore, the dietary improvement coupled with the reduction of serum omega-6/omega-3 ratio, especially in the MedDiet group, further confirmed the increase in the anti-inflammatory diet. While both omega 3 and 6 are essential fatty acids, they have different effects on disease risk.⁵⁰ Based on research to date, within an overall healthy diet, a recommended ratio of about 4:1 has shown to have a favorable impact on inflammation and health promotion.⁵¹ At baseline, study participants had a median ratio of 14.4 which was consistent with the average Western diet.⁵² The results of this study suggest that a multidomain lifestyle intervention with a focus on the MedDiet can improve the omega-6/omega-3 ratio in patients with overweight and obesity and comorbid PTSD.

While improvement in PTSD symptoms was not an aim of this study, it is noteworthy that both groups experienced a significant reduction in PCL scores. A 13.0-point reduction at post-intervention was within the clinically meaningful change, indicating a transition

toward non-PTSD. Various potential factors could have contributed to these changes, including but not limited to nutrition counseling serving as psychotherapy due to individualized attention and promotion of self-care; or it could be due to positive reduction in weight and various inflammatory and oxidative biomarkers, supporting prior findings on the interconnection of weight, atherogenic lipid profile, and systemic inflammation, all risk factors for PTSD.^{14,15,53,54} Trials among military and veteran populations with PTSD have shown that first-line psychotherapy approaches have high dropout rates and many patients remain highly symptomatic post treatment.⁵⁵ Having high participant retention, compliance, and satisfaction in this study, nutrition programming might be an indirect method for providing some relief for PTSD symptoms. Emerging evidence of the association between combat-related PTSD and higher levels of pro-inflammatory cytokines further supports lifestyle interventions to address both the psychiatric and somatic aspects of PTSD.^{56,57}

While a larger study is needed to confirm the current findings, the significant improvements in oxLDL are promising, as oxLDL plays a primary role in MetS-related diseases leading to numerous pro-inflammatory and pre-carcinogenic effects. This study, therefore, adds to a growing body of research examining the effects of diet, especially MedDiet, on oxLDL levels.⁵⁸⁻⁶¹ The reduction of total cholesterol among the MedDiet group is in agreement with findings from other randomized studies.^{61,62} Additionally, numerous studies have indicated the protective effect of the MedDiet on the cardiovascular and vascular health.^{25,28,63,64} A study comparing the diets of individuals with acute ischemic stroke with healthy controls indicated a higher prevalence of stroke and worse clinical profile among those with low adherence to MedDiet.⁶⁵

There were strengths and limitations to this study. In addition to limitations inherent to every pilot study (e.g., limited power), this study included WTC responders, a predominantly white male population exposed to a unique circumstance who also work in a small number of response-focused occupations; thus, the findings may not be generalizable. In addition, study participants may be more eager to

make lifestyle changes, thus positively contributing to the study's success. The relatively low rate of participants who achieved their personal goals will need further investigation in future studies.

Yet, this study also had several strengths. To the authors' knowledge, this was the first nutrition intervention implemented among the WTC responders with overweight and obesity and diagnosed PTSD and has the potential to serve as a guide in augmenting treatment activities among the WTC responders. The primary study aim was successfully met by demonstrating successful recruitment in the WTC-HP clinics, engaging the participants throughout the intervention, and retaining them across all three assessments; however, the summer season may have partially contributed to slightly lower participation in follow-up measurements. Using a multimodal approach to intervention delivery, mainly the Internet and mobile phones and augmented by individual counseling, might have significantly contributed to the improvement of eating behaviors and health outcomes as it has been shown in other studies.^{66,67} Most MedDiet participants responded to the weekly educational sessions with high compliance in answering the teach back questions. The study utilized objective measures such as serum biomarkers and validated measures to assess dietary intake.

5 | CONCLUSION

The WTC-Nutrition intervention implemented MedDiet, that has been extensively researched and established as a heart healthy diet shown to decrease systemic inflammation and risk for cardiovascular disease. The intervention was mostly delivered digitally that has allowed for enhanced communication frequency and concomitant increased intervention dose, as well as convenience among those with shift-related occupations. Additionally, since the study was conducted during a period marked by efforts to reduce exposure to COVID-19, this delivery method allowed the study to continue given the required restrictions. Despite the remote delivery, the results were consistent with previous studies showing that nutritional interventions can effectively reduce metabolic risk factors.^{26,28} Furthermore, when accompanied by regular contact and individual goal setting, as in this study, nutritional interventions can potentially improve weight and mental health in participants with comorbid overweight and obesity and mental health conditions. In summary, the study successfully met its aims and provided valuable lessons that can be used to guide the development of a full-scale trial, while components of the intervention can be implemented in clinics serving populations with comorbid physical and mental health issues.

AUTHOR CONTRIBUTIONS

Chrisa Arcan conceived the study and led the development of the manuscript; Wei Hou analyzed data; Kathryn Hoffman and Amanda Reichardt served as study dietitians, developed the study materials, and assisted in study coordination; Xiaohua Yang advised and coordinated blood collection, specimen storage and quality control of blood analysis results; Sean A. P. Clouston advised on study design;

Benjamin Luft directed all study activities within the Clinic operations and insured smooth study completion; all authors critically reviewed the manuscript and had final approval of the submitted manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

CLINICAL TRIAL REGISTRATION

www.clinicaltrials.gov: NCT05138198.

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C. OVERALL PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

Yes

Publications Reported for this Reporting Period

Public Access Compliance	Citation
N/A: Not NIH Funded	Arcan C, Hou W, Hoffman K, Reichardt A, Yang X, Clouston SAP, Bromet EJ, Luft B. Mediterranean diet intervention among World Trade Center responders with post-traumatic stress disorder: Feasibility and outcomes of a pilot randomized controlled trial. Obesity science & practice. 2024 February;10(1):e725. PubMed PMID: 38263989; PubMed Central PMCID: PMC10804354; DOI: 10.1002/osp4.725.

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

NOTHING TO REPORT

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period? No

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization? No

C.5 OTHER PRODUCTS AND RESOURCE SHARING

NOTHING TO REPORT

D. OVERALL PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Commons ID	Sr/Key	Name	Degree(s)	Role	Cal	Aca	Sum	Foreign Org	Country	SS
CARCAN	Y	Arcan, Chrisa	AB,MPH,MBA,PHD	PD/PI	1.2	0.0	0.0			NA
	Y	Bromet, Evelyn J	PHD, MPhil	Co-Investigator	0.1	0.0	0.0			NA
	Y	Matkovic, Mara	MD	Co-Investigator	0.1	0.0	0.0			NA
	N	Sicoli, Jonathan		Information Technology	4.0	0.0	0.0			NA
	Y	Yang, Xiaohuayang	MS	Co-Investigator	1.0	0.0	0.0			NA
	Y	Clouston, Sean A.P.	PHD, MA	Co-Investigator	0.5	0.0	0.0			NA
	N	Reichardt, Amanda Jacqueline	MS, RDN, CDN, CPT	Dietitian	4.2	0.0	0.0			NA
	N	Hoffman, Katherine	MS RDN CDN CDCES	Study Dietitian	4.2	0.0	0.0			NA
	Y	Hou, Wei	PhD	Co-Investigator	1.0	0.0	0.0			NA
	Y	Luft, Benjamin J	MD	Co-Investigator	0.4	0.0	0.0			NA

Glossary of acronyms:

Sr/Key - Senior/Key

Cal - Person Months (Calendar)

Aca - Person Months (Academic)

Sum - Person Months (Summer)

Foreign Org - Foreign Organization Affiliation

SS - Supplement Support

RS - Reentry Supplement

DS - Diversity Supplement

OT - Other

NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Not Applicable

D.2.b New Senior/Key Personnel

Not Applicable

D.2.c Changes in Other Support

Not Applicable

D.2.d New Other Significant Contributors

Not Applicable

D.2.e Multi-PI (MPI) Leadership Plan

Not Applicable

E. OVERALL IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

NOTHING TO REPORT

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

Not Applicable

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

NOTHING TO REPORT

G. OVERALL SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND NOTICE OF FUNDING OPPORTUNITIES REPORTING REQUIREMENTS

NOTHING TO REPORT

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS**G.4.a Does the project involve human subjects?**

Not Applicable

G.4.b Inclusion Enrollment Data

File(s) uploaded:

CumulativeInclusionEnrollmentReport_3.25.25.pdf

G.4.c ClinicalTrials.gov

Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

NOT APPLICABLE

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

No foreign component

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

Cumulative Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

Study Title:

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More Than One Race										
Unknown or Not Reported										
Total										

I. OVERALL OUTCOMES

I.1 What were the outcomes of the award?

The WTC-Nutrition, a pilot randomized-controlled trial (RCT) was implemented to test the feasibility and preliminary efficacy of a Mediterranean Diet (MedDiet) intervention with a physical activity component among WTC responders with overweight, obesity, and PTSD. Compared with Usual Care (nutrition counseling) control, the study aimed to improve eating behaviors, anthropometrics, post-traumatic stress disorder (PTSD) symptoms and related inflammatory and lipid biomarkers. The 10-week nutrition intervention included evidence-based behavioral strategies mainly delivered remotely through a study website with embedded videos, recipes, tips, goal setting, and group experiential cooking session, augmented with weekly motivational text messages and minimal individual coaching.

The study successfully recruited and retained 62 participants all of whom completed the 10-week intervention; 94% completed the post-intervention and 74% completed the 3-month follow-up assessments. The intervention participants were highly satisfied with the program (83%) and 100% of them reported that they would recommend it to other WTC-Health Program members. The findings indicate that overall nutrition counseling positively impacted the participants' diet, anthropometrics, some lipid and oxidative biomarkers and PTSD symptoms.

We found that the participants' Mediterranean Diet (MedDiet) score increased at post intervention and at 3 months follow-up; from 6 points at baseline to 10 points at post intervention (possible range 0-14 points). The participants experienced improvements in their PTSD symptoms, indicated by a reduction of -13 points and -8 points in the DSM-V PCL-5 score at post intervention and at follow-up, respectively, compared to baseline (52 points). While both groups reduced their waist circumference, the MedDiet group had a larger reduction of -1.75 inches and -2.5 inches from baseline (43 inches) at post intervention and at follow-up, respectively. Similarly, both groups had a decrease in body mass index (BMI), however, the intervention group had a larger decrease by -0.82 points compared to -0.49 points in the control group (baseline average BMI 33.2). There were significant improvements in total cholesterol and oxidized LDL (oxLDL) at post-intervention and follow-up in both samples. In the total sample, oxLDL was reduced by -12.5 U/L and -24 U/L at post post-intervention and follow-up, respectively. Total cholesterol decreased only in the MedDiet group by -8.0 mg/dL at post intervention. Similarly, the Chol/HDL ratio decreased only in the intervention group by -0.40 at follow-up. The MedDiet group had additional reduction in serum Hemoglobin A1c (HbA1c) by -0.10% and in serum omega 6/omega 3 by -2.71 (lower ratio is desirable) compared to the control group. At baseline the average hsCRP was 1.80 mg/L for the entire sample. While not significant, compared to baseline, there was a decrease of -0.3 mg/L in the MedDiet group and an increase of 0.25 mg/L in the control group at post intervention. However, at 3-month follow-up there was a significant difference between the intervention and control groups because the MedDiet group experienced a decrease of -0.18 mg/L, while the control group experienced an increase of 0.25 mg/L compared to baseline.