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The design and rationale of a multi-center randomized clinical trial comparing one avocado per day to usual diet: The Habitual Diet and Avocado Trial (HAT)

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ABSTRACT

Excess visceral adiposity is associated with increased risk of diabetes and cardiovascular disease. In the U.S. approximately 60% of adults have visceral obesity. Despite high calorie and fat, small, well-controlled clinical studies suggest that avocado consumption has favorable effects on body weight and visceral adiposity. Additionally, short-term studies also suggest that consuming avocados increases satiety, hence, may decrease overall energy intake. The Habitual Diet and Avocado Trial HAT is a multi-center, randomized, controlled trial designed to test whether in a large, diverse cohort providing one avocado per day for consumption for six months compared to a habitual diet essentially devoid of avocados, will result in a decrease in visceral adiposity as measured by magnetic resonance imaging (MRI) in individuals with an increased waist circumference (WC). Additional outcome measures include hepatic lipid content, plasma lipid profiles, blood pressure and high sensitivity C-reactive protein. Inclusion criteria were increased WC and not currently eating more than two avocados per month. Major exclusion criteria were not eating or being allergic to avocados, and not willing or able to undergo MRI scans.

From June 27, 2018 to March 4, 2020, 1008 participants were randomized at 4 clinics. The cohort was 72% women, 53% Non-Hispanic White, and had a mean age of 50 years. Follow-up was completed in October 2020 when 936 participants had final MRI scans. HAT will provide information on the effects of avocado consumption on visceral fat adiposity and cardiometabolic disease risk in a diverse sample of participants.

1. Introduction

In the U.S., approximately 60% of adults have abdominal obesity, defined as a waist circumference of ≥ 40 in. for women and ≥35 in. for men [16,22]. Intra-abdominal adiposity, or visceral adiposity, is associated with increased risk of type 2 diabetes, cardiovascular disease (CVD) events, and all-cause mortality [23,37,43]. Excess energy expenditure is stored in adipose tissue as visceral fat, as well as in the liver, pancreas and skeletal muscle as ectopic fat. This excess adipose tissue accumulation results in insulin resistance and systemic inflammation [30]. To reduce the burden of CVD and type 2 diabetes, strategies are needed to reduce visceral adiposity.

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Observational evidence suggests higher consumption of avocados is associated with a lower risk of excess body fat and rates of overweight/obesity. An NHANES analysis (2001−2012) showed avocado consumers weighed less (−3.4 kg) and had smaller waist circumferences (−1.2 cm) than non-consumers [26]. In addition, avocado consumers had lower odds of overweight/obesity (OR 0.67) and elevated waist circumferences (OR 0.68). These findings are consistent with an NHANES analysis using datasets from 2001 to 2008 that showed avocado consumers have lower body weight, BMI and waist circumference compared to non-consumers, and lower odds of metabolic syndrome (OR 0.50) [13]. To determine whether relationships between avocado consumption and adiposity are due to a direct effect of avocado consumption or a marker for healthy lifestyle and diet requires a randomized controlled trial.

Postprandial studies show that consuming avocado as part of a meal increases satisfaction and satiety and reduces desire to eat. In a randomized study of overweight adults, consumption of a lunch meal with half an avocado increased meal satisfaction by 23% and reduced desire to eat over the subsequent 5-h by 28% compared to a control meal without avocado [42]. In a 12-week randomized controlled weight loss study, intake of one avocado per day as part of a hypocaloric diet decreased body weight, BMI, total body fat, and visceral adipose tissue to the same extent as a hypocaloric diet without avocado [18]. Despite a similar weight loss on the hypocaloric diet, the group without avocado had decreased satiety compared to baseline from 2 to 12 weeks, whereas satiety did not change in the avocado group. Thus there is evidence that avocado intake increases subjective and objective measures of satiety, and facilitates weight loss as part of hypocaloric diet without decreasing satiety. Research conducted in diverse populations, under less controlled conditions, for longer durations, and with more rigorous adiposity outcomes is needed.

The Habitual Diet and Avocado Trial (HAT) will determine whether providing one avocado per day over a six-month period influences visceral adiposity measured by magnetic resonance imaging (MRI), compared to habitual diet in individuals with abdominal obesity. Secondary outcomes include hepatic lipid content, plasma lipid profiles, blood pressure and plasma high sensitivity C-reactive protein (hsCRP) concentrations. The focus of this paper is to describe the HAT design.

2. Study organization

A Steering Committee consisting of Principal Investigators at four clinical centers and a coordinating center oversees the trial. Participating sites include Pennsylvania State University (with a subsite at Hershey Medical Center), PA; Loma Linda University, CA; University of California at Los Angeles, CA; Tufts University (Jean Mayer USDA Human Nutrition Research Center on Aging), MA; and a coordinating center at Wake Forest University Health Sciences, NC. The four clinical centers were responsible for recruitment and follow-up of participants, and the coordinating center was responsible for overall trial coordination, data entry, management and analysis. In addition, there is a central lab (Tufts), MRI reading center (LLU), and two diet assessment centers (LLU and Tufts). The Hass Avocado Board sponsored the trial and provided avocados but did not have access to unblinded data while the trial was ongoing.

Study procedures, including written informed consent from all participants, were approved by each center's Institutional Review Board. Wake Forest University Health Sciences serves as the Central IRB. A separate consent form describing possible future use of blood samples was offered to all participants. The storage of the blood samples for future testing was optional and did not affect eligibility. The protocol is available at hat.phs.wakehealth.edu and the trial is registered in clinicaltrials.gov (NCT 03528031).

2.1. Design

HAT is a 2 group, randomized, controlled, multicenter clinical trial. The primary aim is to determine whether providing one avocado per day for six months will produce changes in visceral adiposity measured by MRI compared to a habitual diet group in individuals with an elevated waist circumference. The secondary aim is to assess whether providing one avocado per day for six months will result in differences in hepatic lipid content and plasma hsCRP concentrations as compared to the habitual diet. Additional aims are to assess effects on plasma insulin, total cholesterol and LDL-C concentrations, red blood cell fatty acid profiles, diet quality, fiber intake, quality of life and perceptions of health, and sleep quality.

3. Screening and eligibility

The HAT cohort is intended to reflect a population of adults with abdominal obesity. PIs or study personnel had one-on-one interviews with the potential volunteers during the screening visit to assess eligibility and likelihood of compliance and gauge their commitment and ability to comply with the study demands. Efforts were made to select volunteers showing high levels of commitment and interest. Volunteers were screened using the inclusion and exclusion criteria listed in Table 1. All randomized participants had a waist circumference of ≥35 in. for women or ≥ 40 in. for men, were ≥ 25 years old at screening, and not currently eating more than 2 avocados per month (habitual intake in U.S.). The HAT cohort excluded participants who do not eat avocados, who were allergic to avocados, or who were not willing to undergo MRI scans. Eligible participants were assigned to groups in a 1:1 ratio using permuted block randomization with varying block sizes of 4 and 8 and stratification by clinic. Eligibility was confirmed using the web-based data entry system, which also performed randomization. Neither participants nor clinic staff were blinded to intervention assignment; however, the MRI reading center and Central Lab staff were blinded.

A total of 2513 volunteers were screened, and 1008 were randomized. A table showing reasons for exclusion appears in the Supplement.

4. Intervention

Participants in the intervention arm were instructed to follow their usual diet and lifestyle, provided with enough fresh Hass avocados to allow consumption of 1 per day over 6 months, and with simple usage ideas and resources on how to choose, store and ripen avocados. No additional nutrition guidance was provided. Participants in the intervention group picked up fresh avocados from their study site every two weeks with minimal interaction with study personnel. Participants in

Table 1
HAT inclusion criteria.

Inclusion Criteria
• Increased waist circumference defined as ≥35 in. for women, ≥40 in. for men [38] (NCEP ATP III 2005)
• At least 25 years old at screening
• Not currently eating more than 2 avocados per month (habitual intake in U.S.)
Exclusion Criteria
• Does not eat avocados
• Sensitive/allergic to avocados
• Allergies to latex or oral allergy syndrome
• Not willing or unable to undergo MRI scans
• Unstable medical condition such as on dialysis for renal disease, cardiac, gastrointestinal, or hepatic disease, cancer (non-melanoma skin cancer >5 years ago acceptable, any cancer site >10 yrs. without recurrence).
• Pregnant, lactating, intention of pregnancy
• Lost or gained 10 lbs. of body weight in last year
• Following restricted or weight loss dietary patterns
• Unstable anti-anxiety/anti-depressive/anti-psychotic medication use defined as dose change within last 6 months
• Oral steroid use within the last 6 months longer than 7 days
• Elevated alcohol intake (7+ drinks/week females; 14+ drinks/week males)
• Participation in another clinical intervention trial within 30 days of baseline
• PI judgment

the habitual diet arm were instructed to follow their usual diet and lifestyle and limit their avocado intake to 2 avocados or less per month. No avocados were provided to the habitual diet arm.

Adherence to the intervention protocol was assessed using 4 random 24–hour dietary recalls by trained research dietitians. The Nutrition Data System for Research (NDSR) was used for dietary analysis. Adherence was quantified by measuring the frequency and amount of avocado consumption in the intervention and control groups. Compliance visits were conducted monthly post-randomization; study personnel had conversations with all participants to assess their compliance and discuss any barriers preventing them from complying with the protocol. Retention was enhanced by providing a welcoming environment for participants, providing reminder messages the day prior to a scheduled visit and contacting those who missed appointments to reschedule. Gift cards and small gifts, along with an honorarium were provided to the participants.

5. Measurement, ascertainment, and follow-up

The schedule and examination components at each visit are shown in Table 2. Post-randomization study visit schedules were similar between groups with the exception that participants in the avocado group picked-up avocados from their site. Visits included the following measures: blood pressure, body weight, height and waist circumference, visceral and hepatic fat by MRI, and fasting blood samples collected for measurement of cardiometabolic risk factors and red blood cell (RBC) fatty acid profile. Details of each assessment are provided below.

5.1. MRI

MRI was performed to assess the volume of visceral adipose tissue (VAT) and the hepatic fat fraction (HFF). The non-contrast MRI protocol at each site was consistent with the Manual of Procedures (MOP). Blinded staff completed the MRI assessments. All participants underwent a non-contrast abdominal MRI on a 3 T Siemens MR scanner. Two phantoms were scanned at all sites to verify consistent data across all sites and over time: two ex-vivo preserved human livers, and a fat/water phantom. The ex-vivo livers were formalin fixed, one chosen from an individual with no history of liver pathology, and one with a history of non-alcoholic fatty liver disease. The fat/water phantom was an approximately 4 L container that contained about 3.2Ls of 5% agarose gel with 0.03% sodium azide, and 0.8 L of lard. A DIXON axial vibe two-echo sequence was used for measuring volume of VAT. Slice coverage was enough to cover 4 cm above the dome of the liver to 7 cm below the top of the iliac crest. Parameters were approximately: slices 96, FOV 400 mm, slice thickness 3.5 mm, TR 5 ms, TE (1.23, 2.46 ms), flip angle 9°. Subcutaneous fat was manually segmented and excluded using sliceOmatic and a watershed algorithm. Fat images were thresholded using an implementation of the Otsu algorithm from ImageJ. MR spectroscopy was used to measure HFF, using a PRESS sequence. Spectra were processed with LCModel version 6.3 using lipid quantification settings, and T1 and T2 correction were applied [7]. Data were anonymized and sent to the MRI Reading Center for processing.

5.2. Biosample collection

Trained phlebotomists drew fasting blood. A maximum of thirty milliliters (mL) was drawn at each visit. Serum, plasma and RBCs were separated and aliquoted on site. Samples were shipped to and analyzed at the Central Lab for: fasting total cholesterol, triglyceride, high density lipoprotein-cholesterol (HDL—C), glucose, insulin and high sensitivity C reactive protein (hsCRP) concentrations, and RBC fatty acid profiles. Low density lipoprotein (LDL)-cholesterol was calculated using the Friedewald equation [12]. Additional specimens, including buffy coat, serum, plasma and RBC aliquots are archived from participants who consent to bio banking. DNA will be extracted from whole blood samples collected at randomization. Analytes and methods are shown in Table 3. At the UCLA site, fecal samples were collected for microbiome analysis.

5.3. Blood pressure

Seated blood pressure was measured at each visit utilizing automated devices. Three measurements were taken after a 5-min rest period, 1 min apart and the last two averaged for analysis.

5.4. Anthropometric measures

Height, body weight and waist circumference were measured using standardized protocols across sites. Height was measured at baseline only using a stadiometer. Weight was measured at Visits 2, 5, and 8

Table 2
Data collection schedule.

Measurement	Visit 1 (−2 to 0 wks)	Visit 2[a,b] (0 wks)	Visit 3 (4 wks)	Visit 4 (8 wks)	Visit 5 (12 wks)	Visit 6 (16 wks)	Visit 7 (20 wks)	Visit 8 (26 wks)
Screening interview	x							
Health and Demographics		x						x
Blood Pressure		x	x	x	x	x	x	x
Height		x						
Weight		x			x			x
Waist Circumference	x	x			x			x
Visceral adiposity, MRI	x							x
Hepatic fat, MRI	x							x
Triglycerides		x			x			x
Cholesterol		x			x			x
Fasting glucose		x			x			x
Fasting insulin		x			x			x
hsCRP		x			x			x
RBC fatty acid profile		x			x			x
Buffy coat DNA		x						
Stored Serum, Plasma and RBC		x			x			x
24 h diet recall[d]	x			x		x		x
Diet, Food & Avocado Satisfaction[e]		x			x			x
Quality of Life (SF-36)		x			x			x
Quality of Life (SF-20)[f]			x	x		x	x	
Sleep quality		x			x			x
Contact Information	x	x	x	x	x	x	x	x
Compliance visit			x	x	x	x	x	

Table 3
Laboratory method principles by analyte.[a]

Fasting Analyte	Matrix	Method Principle
Triglycerides	EDTA Plasma	Enzymatic, colorimetric, endpoint (Glycerol Phosphate Oxidase)
Total Cholesterol	EDTA Plasma	Enzymatic,colorimetric,endpoint (Aminoantipyrene/Phenol/Peroxidase)
HDL-cholesterol	EDTA Plasma	Enzymatic,colorimetric,endpoint(Cholesterol oxidase/Peroxidase/DSBmT/Cholesterol esterase)
LDL-cholesterol	Serum	Derived using Friedewald equation*
Glucose	EDTA Plasma	Enzymatic, kinetic (Hexokinase-UV/NAD)
hsCRP	Serum	solid-phase, two-site chemiluminescent immunometric
Insulin	Serum	solid-phase, two-site chemiluminescent immunometric
RBC fatty acid profile	RBC	Friedewald equation

[a] If triglycerides >300 mg/dL then direct LDL-cholesterol measurement was performed using a two reagent colorimetric enzymatic homogenous procedure.

using a digital scale. Waist circumference was measured at visits 1, 2, 5 and 8. Measurements were taken against the skin at the approximate midpoint between the lower margin of the last palpable rib and the top of the iliac crest [41]. These measures were performed in duplicate and averaged.

5.5. Questionnaires

Study personnel obtained a medical history, demographic data and information about eating habits and physical activity. Other questionnaires included the Diet, Food & Avocado Satisfaction and the Pittsburg Sleep Quality Index questionnaire [4].

5.6. Quality of life

All participants completed the RAND 36-Item Health survey at visits 2, 5 and 8 [36]. Participants in the control group also completed the RAND 20-Item Health survey at visits 3, 4, 6 and 7.

5.7. Dietary assessment tools

Four 24-h dietary recalls were conducted for each study participant during the course of the study. Recalls were collected by phone prior to randomization, and then within 1 to 2 weeks around visits 4, 6 and 8 with a goal of 2 weekdays and 1 weekend day during the intervention or control period. The two diet assessment centers were each responsible for collecting 50% of the 24-h recalls across all study sites. Dietary intake data were collected using NDSR software versions 2017 and 2018 [33,34]. The sites followed a standardized manual of procedures for dietary data collection and dietary data management. Outcome data from NDSR includes daily estimated energy and nutrient intake.

6. Data quality, entry and management

The Coordinating Center lead protocol development and amendments; developed and distributed forms and the MOP; trained personnel in data collection; generated and distributed reports; provided rapid feedback to the clinics, Central Lab, MRI Reading Center and diet assessment sites on data quality; developed and maintained databases and a central website; managed and analyzed trial data; and provided statistical expertise as required for presentations and manuscripts. The web-based system developed for HAT created participant and visit-specific form sets dynamically. It included checks as the data were entered directly using tablet devices, verification of eligibility prior to randomization, and range and logic checks on individual data items. Data were checked on form submission and any data queries were presented to the data entry staff for immediate resolution, if possible. Entered data were immediately available for dynamic reports and study management.

7. Statistical analysis, sample size, and power considerations

The sample size estimate assumed an overall mean VAT volume of 5 L at baseline and a difference 0.5 L at 6 m favoring the intervention arm compared to the control arm. A two sample *t*-test with 80% power for an effect of 0.5 L when the SD is 2.5 would require about $n = 800$ total participants with both baseline and follow-up scans; 85% power would require about 900, and 90% power about 1050. A target of 1000 randomizations was selected, which allowed for 85% power with dropout of 10% or less.

Based on published results in overweight/obese cohorts similar to HAT [3,6,11,14,24,25,31,39], we expected VAT means between 4 and 6 L and a cross-sectional standard deviation (SD) between 2 and 3 L within sites, but 3.5 L overall accounting for site-to-site variation. The HAT primary outcome is a pre-post difference, with a variance that depends on the within participant correlation, conservatively estimated to be between 0.6 and 0.8. Under these assumptions the SD for the 6-month in HAT change would be in the range 1.4 to 2.8 L. An effect of 10 to 15% in the pre-post difference seemed plausible for six months of an effective intervention.

The primary hypothesis is that compared to a habitual diet, provision of one avocado per day for six months will result in a decrease in visceral adiposity. To test the primary hypothesis, we will compare the estimated mean change from baseline to follow-up in the two randomized groups, with all tests of group differences performed according to intention to treat. A linear regression model of change from baseline to follow-up on intervention assignment and clinic (which stratified the randomization) will be the primary analysis. The two-sided 0.05 level test of the hypothesis that the intervention effect is zero from this model will be used to determine whether or not the intervention was effective. Baseline characteristics in the randomized groups will be compared, and in secondary analyses any baseline variables found to have differences that are clinically significant will be added to the linear regression as post-stratification factors. For the secondary hypotheses, we will take a similar approach, extending the regression model to linear mixed effects models for those outcomes that are measured repeated over time. These analyses will be considered exploratory with no adjustment for multiple comparisons.

Subgroup analyses will be performed by adding a categorical subgroup indicator to the linear regression model and an interaction term for intervention by subgroup. The significance of the interaction term adjusted for multiple comparisons will be used to test for subgroup effects. Subgroups will be defined by:

- Sex (male vs. female)
- Ethnicity/Race (non-Hispanic white vs. other)
- Baseline visceral adiposity volume (median split)
- Baseline HEI2015 (median split)
- Baseline Kcal intake (% contribution of avocado to the diet, median split)

All these groups were chosen for their potential to modify response to the intervention. Sex and Ethnicity/Race are known to correlate with dietary habits. Changes in VAT could correlate with baseline VAT. Similarly, diet quality (HEI) and total calorie intake could account for some heterogeneity in the intervention effect.

Two sensitivity analyses will be conducted to account for missing values on the primary outcome. The first will be an analysis of covariance predicting follow-up values after controlling for baseline, plus variables for intervention assignment and clinic effects. The second will be a within-participant repeated measures analysis with an unrestricted structure on the variance-covariance matrix of the residuals. Both of

these models produce valid estimates if the data are missing at random. If inferences from these models are consistent with the model specified for the primary analysis, this will be noted when reporting results. If inferences are not consistent, results from both the primary analysis and the sensitivity analyses will be reported.

8. Safety and safety monitoring

The HAT protocol and interventions were designed to minimize occurrence of any untoward effects. Safety management in HAT was intended to 1) minimize the occurrence of adverse events, especially those related to the intervention, and 2) manage adverse events (AE) related to the study.

Avocados are generally recognized as safe for consumption in the general population. Avocado allergies, while uncommon, have been reported and staff were trained to refer participants to their primary care physician if stuffy nose, wheezing, coughing or edema was reported. In order to avoid injuries involved with cutting and pitting an avocado, staff provided participants with written instructions describing how to cut, remove the pit and peel an avocado. Events related to these risks were reported.

Other risks associated with this study such as obtaining blood samples represent a minor increase over minimal risk. For participants randomized to the intervention, there were also risks of weight gain from the increased caloric intake that may result from consuming avocados. Participants were advised to see a health care provider regarding abnormal results from a clinical or laboratory evaluation depending on the severity.

9. Results

From June 27, 2018 to March 4, 2020, 1008 participants were randomized (Fig. 1). The randomized cohort includes 730 (72%) women, 543 (54%) non-Hispanic whites, and had a mean age of 50 years (Table 4). The last participant visits occurred in October 2020, and over 90% of the cohort attended the follow-up MRI scan.

Recruitment was significantly impacted by media attention. In August 2018, as part of an effort to promote recruitment, a press release from one site mentioned that participants would receive free avocados and other incentives. Unexpectedly, the release was picked up by a variety of news outlets and an information website emphasizing a "get paid to eat avocados for science" message that was quickly disseminated worldwide. While this increased recruitment (Fig. 1), sites were overwhelmed with inquiries about the trial from interested individuals, many of them not eligible.

After reaching the randomization target but before follow-up was complete, shutdowns due to COVID-19 affected in-person visit scheduling starting in mid-March 2020 for some of the last randomized participants. The trial adopted three priorities in response to this crisis: first, ensure the safety of participants; two, prepare to obtain follow-up MRIs

Table 4
Baseline characteristics, presented as N (%) or mean (SD).

	Control ($N = 503$)	Avocado ($N = 505$)
Age in years	50.4 ± 13.8	50.1 ± 14.3
Female %	374 (74.4%)	356 (70.5%)
Non-Hispanic White	265 (52.7%)	292 (57.8%)
Mean Waist Circumference [cm]	109.3 ± 13.2	109.3 ± 13.1
Mean BMI [kg/m2]	32.5 ± 5.3	32.3 ± 5.2

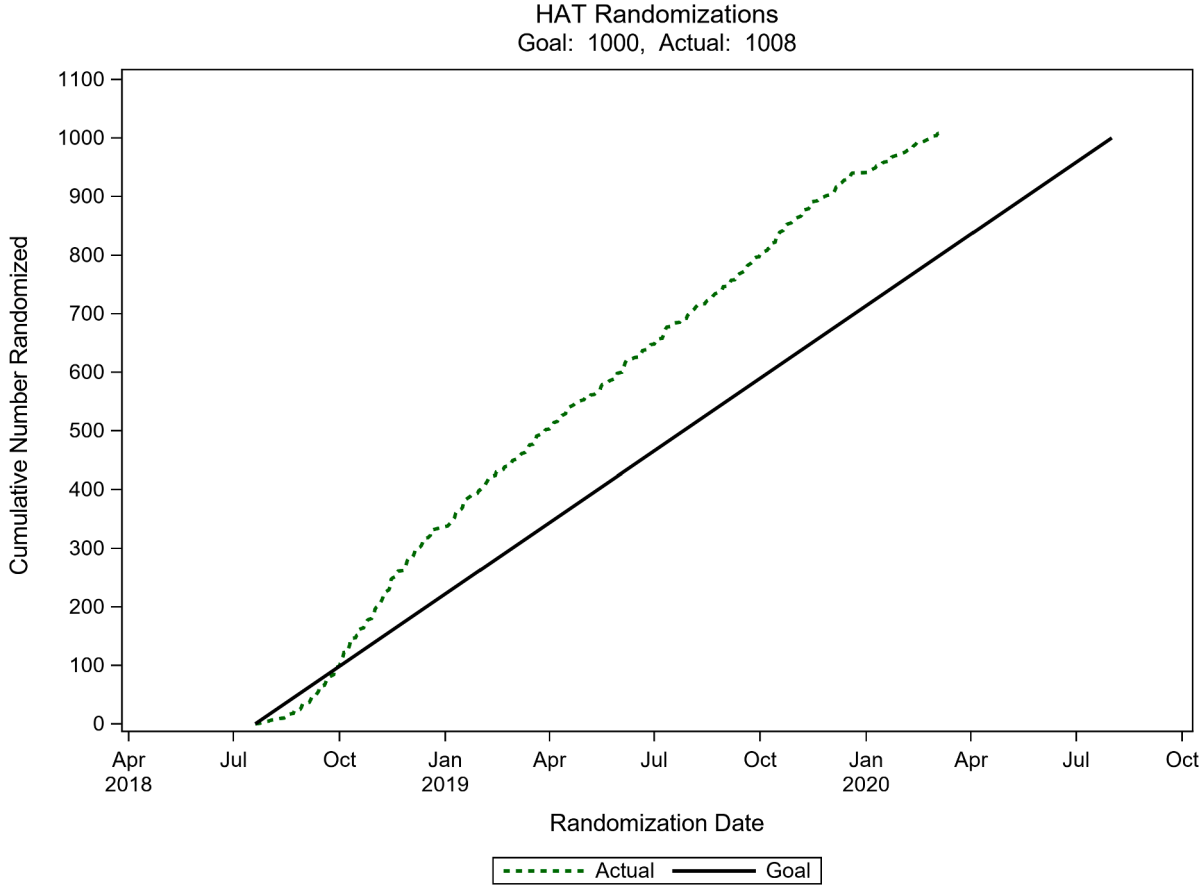

Fig. 1. Overall cumulative recruitment in HAT.

when they could be done safely even if delayed beyond 6 months; three, continue to provide avocados to participants in the intervention group. All sites maintained contact with their active participants in both the intervention and control arms. Distribution of avocados was maintained and all sites resumed operations at least partially, including collecting remaining endpoint samples from participants and performing follow-up MRI scans. A total of 216 participants were due for an MRI during the shutdown. Sites were able to obtain 182, of which 120 were within the window for 6-month follow-up. Pre-shutdown only 5% of final MRIs were not obtained, compared to 16% during the shutdown. About a third of MRIs during the shutdown were beyond the 6-month window compared to less than 1% pre-shutdown. Timely implementation of amendments to existing protocols and assessment tools ensured participant safety during data collection while maintaining compliance and reducing attrition.

10. Discussion

The success of recruitment and better than expected retention suggests that the HAT trial will have adequate statistical power to test its primary hypothesis: whether providing one avocado per day for six months generates a favorable change in visceral adiposity compared to habitual consumption of two or less per month. Evidence from the HAT trial will provide a rigorous test of whether consumption of 1 avocado/day reduces visceral adiposity and whether it may have other health effects on cardiometabolic risk factors, liver fat, and diet quality.

Obesity, and visceral obesity in particular, is a major public health problem, contributing to chronic diseases such as diabetes, cardiovascular disease and hypertension. Daily exercise can decrease visceral adiposity but this is already well known and widely recommended: new, evidence-based effective strategies for decreasing visceral adiposity could greatly impact public health. Simple dietary changes that are effective for this and easy to implement would be a breakthrough.

The HAT study has several strengths. This is the largest randomized controlled clinical trial to date evaluating the effect of avocado consumption on visceral adiposity in adults with abdominal obesity, a group likely benefit from targeted dietary strategies. The randomized design of the study and the success of recruitment, adherence, and better than expected retention suggests that the HAT trial will have adequate statistical power to robustly test its primary hypothesis. The multi-center nature of the study with participants being recruited from sites in different geographical locations with variations in background diet and lifestyle habits increases external validity. HAT will also further our understanding of the role of the intervention in relation to other health outcomes through ancillary studies, and future investigations of multiple clinical, biochemical, and genetic hypotheses. The availability of dietary data as well as biospecimens will enable modeling of biological systems—an opportunity to predict dietary responses and design targeted dietary interventions in the future.

An unavoidable limitation of this trial is the inability to blind participants to the intervention. Also, the recruitment strategies may have enrolled participants who are in overall better health than the general population, or are otherwise less representative. Another challenge was the COVID-19 pandemic which interrupted delivery of the intervention and study assessments at all sites. Given the possibility of changes in dietary pattern due to COVID-19, we will analyze data from the additional dietary questionnaire to capture these changes. In summary, the results of HAT are expected to inform individual dietary choices, clinical recommendations, and public health guidelines regarding the impact of avocado consumption on visceral fat adiposity and cardiometabolic disease risk in a clinically relevant/high risk population.

Declaration of interests

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

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2021.106565.

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