The Effect of Adherence of a Soul Food Diet for African Americans with Osteoarthritis.

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“We the undersigned declare that this protocol is original, and does not contain text taken from another protocol or source, unless indicated.

Our signatures confirm that each author has made a significant contribution to the protocol, has read the entire protocol and agrees with its content.

Signed by all authors as follows:”

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1. ***Background***

Osteoarthritis (OA) is the most common form of arthritis and occurs when protective cartilage cushioning the ends of bones wear down over time, most commonly as a result of aging[1]. OA can cause joint pain, stiffness, inflammation, and overall, hindrance of ease of everyday activities[1]. According to the US Census released in June 2022, the US overall continues to age with an increase of median age for most states increasing over the last two decades while also continuing to be more diverse[2]. It is important to note that OA cannot be reversed, but improved, as symptoms can be reduced through preventative measures and lifestyle adjustments. One of the leading arthritis organizations, the Arthritis Foundation, lists the Mediterranean diet as 'The Ultimate Arthritis Diet' to combat inflammation symptoms [3,4]. With an increasingly aging and diverse population, it is necessary to obtain a wider, and better understanding of how to decrease symptoms of inflammation with diets, ingredients, and cuisines that parallel the increasingly diverse population. With the Mediterranean diet, widely considered and known as the 'healthiest and best diet', it's based on European focused food/cuisines which can play into stigmatization of other culture's cuisines, such as soul food, to be seen as unhealthy[5]. This includes soul food, a cuisine predominantly eaten by African Americans and includes beans, greens, cornmeal, and meat[6]. When describing soul food and its deep history, Chef Millie Peartree noted, "it's important that you highlight origins, feel and embrace the culture…food tells stories and sometimes the history makes you appreciate certain cuisine a little more"[1]. This profound value around cuisines act as a foundation for the study as the food plays a large role in cultural identity.

Although principles of the Mediterranean diet such as fresh vegetables and lean protein can be applied and are included in other cuisines, there is little to no information on this and leaves a large gap in the US public health communications portfolio.

According to the CDC, six in ten adults have a chronic disease and four in ten have two or more diseases in the US[7]. This contributes to the country's $4.1 trillion annual healthcare costs[7]. US adults with arthritis are expected to increase over time up to 78 million in 2040 [8] OA can be a debilitating disease and it has been found that those with OA experience lower employment than those without OA[9]. OA is also the most financially burdensome condition for privately insured patients in the US, over $6.3 billion in health expenses [10]. Specifically examining OA, there is very little information on racial disparities of the disease in the US. Also, the COVID-19 pandemic has only exacerbated economic and health disparity within the African American community[11]. By studying the preventative methods of OA, this can not only aid patients' health, but also, the financial burden of treatment and care [11]. From a report called, 'Arthritis in the Black Community' published by the Arthritis Foundation, it is stated that OA affects Black Americans more than whites and that Black patients tend to have a higher severity of pain and disability as a result but are less likely to obtain care and treatment [12]. There is little data on other ethnicity prevalences of OA which do not mirror the increasingly diverse population of the US.

Although there is data and studies on the effectiveness of the Mediterranean diet on relief and improvement of OA symptoms, this is not inclusive of other cultures and races that are too burdened by this chronic disease. Thus, it is not only important to

solely study OA symptoms, but also the diverse demographics OA affects, and inclusive prevention methods.

According to Medical News Today, there are eight foods that are recommended for OA symptom reduction: oily fish, oils, dairy, dark leafy greens, broccoli, green tea, garlic, nuts[4]. The Mediterranean diet includes a variety of fruits and vegetables, whole grains, legumes, healthy fats like olive oil and nuts, moderate amounts of seafood, low amounts of dairy and red meat, red wine in moderation, similar ingredients to the eight recommended foods[11]. Hence, the most recommended diet for osteoarthritis is the Mediterranean diet[4]. However, a single diet cannot satisfy everyone with OA that come from different cultures, ergo, eating habits and diets. The eight recommended ingredients can be applied and are present in other cultures' cuisines but there is a disparity in the research and literature in contrast to the Euro-centric Mediterranean diet. The principles of this diet such as consuming leafy greens, legumes, and lean protein can be integrated into any diet, such as soul food, not just a Euro-centric diet. Therefore, it is necessary to look at diets from different cultures, not only to represent the diversity of osteoarthritis patients, but also for potential eating habits that might also benefit osteoarthritis patients.

Previous studies have been conducted looking at how diet affects OA outcomes. For example, in an article called '*Mediterranean diet and knee osteoarthritis outcomes: A longitudinal cohort study'*, it was found that in a long term cohort study, higher adherence to Mediterranean diet was associated with a significantly lower risk of pain worsening and symptomatic knee OA[13]. Also, in another study, '*Adherence to a Mediterranean diet is associated with lower prevalence of osteoarthritis: Data from the*

osteoarthritis initiative', it showed that participants with the highest adherence to Mediterranean diet had a significantly reduced probability of knee OA[14]. Although there is lots of concrete evidence that a Mediterranean diet can prevent and reduce OA, there are no studies on other diets aside from the heavily Euro-centric, Mediterranean diet, which does not benefit the need for culturally competent care and does not mirror the diverse populations affected and need treatment for OA.

When it comes to the safety, efficacy, and dosing- it is particularly important to understand the nutritional value of the Mediterranean diet. The Mediterranean Diet is a diet that is primarily plant based with an emphasis on healthy fats, fruits, legumes, and the preferred animal proteins being fish and seafood[15]. Whilst studies have been conducted to show the effectiveness and feasibility of The Mediterranean diet on different ailments there has not been many studies on the safety and dosing of the diet itself.

As the diet is specified in different categories that are suggested to eat versus specific proportioned intake, the exact dosing of the diet is up to the individual. However in the past, different Food Pyramids have been produced in order to suggest dosage of the different categories of food groups that the diet promotes [16,17]. Some studies have been performed to assess the safety of the Mediterranean Diet alone such as in *Risk assessment of exposure to pesticides through dietary intake of vegetables typical of the Mediterranean diet in the Basque Country.* However the lack of study data or information on the direct safety and dosing of the Mediterranean Diet calls for more information and further studies on the diet's effectiveness in relation to other diets [18].

Question/Objective/Hypothesis

The understanding of increased severity and pain from OA for black patients and financial burden versus white patients coupled with an increasingly diverse and aging population in the United States flows into the necessity for more specialized methods,culturally competent treatments that reflect the diverse population with the disease, not just one demographic. This study will strive to answer the question of: does a culturally sensitive diet, soul food, help African Americans with osteoarthritis (OA) improve/increase diet adherence in comparison with the current American standard diet, the Mediterranean diet? This will be a randomized control trial with participants randomized to 1 of 2 total interventions, (1) Mediterranean diet, and (2) soul food.

2. ***Methods***

Subject Population

The participants were recruited from 4 sites including Emory University Hospital, Howard University Hospital, Johns Hopkins Hospital, and Detroit Medical Center. These four sites were chosen due to these hospitals being operated by a Historically Black College or University, or being a hospital within a city with a large African-American population. Inclusion criteria were self identifying as black, being 40–65 years old,has diagnosed osteoarthritis , having a sedentary lifestyle (<30 min p/week of formal exercise for the past 6 months), being able to eat by mouth, having no high risks of choking, being able to understand English or Spanish language, and sign a written consent by themselves. As osteoarthritis is more common as people age, the study intends to work with participants that are in the age range most likely affected by

osteoarthritis, as many start having symptoms or are diagnosed around 50 years[19]. Participants do not have to have an interest in soul food, but will be told that the diet will be inspired by Soul food. A sedentary lifestyle for participants is chosen as this lifestyle is more at risk for OA and regular exercise may skew results of inflammation[19].

Exclusion criteria were having a specific restricted diet, being allergic/intolerant or avoids specific foods that will be in the meal plan, has another form of bone-degenerative disease, is already following a strict meal plan due to disease, is not able to prepare their own foods, has inflammation in another body part/organ and cannot take food by mouth, choking when consuming the products, All participants will sign their written informed consents prior to data collection. Their identities will be protected, following guidelines.

Primary/Secondary Endpoints

Primary endpoint in this study will be adherence to the diet (randomly) allocated to the participant. This will be measured by bi-weekly questionnaires that take into account levels of satisfaction, and osteoarthritis symptoms and overall, will give researchers an understanding of any outcomes that may arise from a specialized diet to the respective population. This study will therefore analyze if consuming soul food will result in a higher adherence than consuming Mediterranean diet for the study population. According to a Harvard Business Review article, it takes about 21 days to form a habit[20]. Also, with food holding cultural and identity values, a higher adherence to soul food diet could act as one of the remedies for osteoarthritis symptoms such as inflammation, instead of a Mediterranean diet which mirrors the diets of European

descendant/ white individuals. A secondary outcome for this study is inflammation levels. Specifically, decreased inflammation levels from the diets. It is already known from many studies that the Mediterranean diet is the “best” for decreasing inflammation in osteoarthritis patients. However, there are no studies on culturally sensitive diets, soul food, decreasing inflammation in African American populations with osteoarthritis.

Study Arms

There will be two study arms: (1) the intervention, soul food and (2) the control, Mediterranean diet. Meal delivery service will be utilized and participants will receive a journal to write in and their meal kits weekly. Meal kits will contain ingredients, recipe, and nutritional value information. The meals for both arms will highlight ingredients to reduce inflammation. For example, legumes can help to reduce inflammation, for the Mediterranean diet, this would include chickpeas and for soul food, this would include black eyed peas. Participants will receive weekly meal kit deliveries and will also be given a food journal to detail what they ate for the week. The meal kit will either be a culturally sensitive diet or Mediterranean diet. Every two weeks, there will be a member of the research team to observe and conduct an inflammatory report. Audio-Taping may be used for the research team. The journal will include what participants ate as well as overall reaction to the meals daily, in terms of taste satisfaction (1-10, 10 being highly satisfactory),and if they would make the meal again in their regular life (yes or no). Participants will also go to monthly doctor appointments for blood test work to be sent to the research team to monitor overall health and look at inflammation.

Randomization and Blinding

This study will be a blinded, randomized clinical trial. Participant pool will be about 264 people. These eligible participants will be randomly selected in block size 8 then simply randomized to one of the two groups. The participants will not know what group they have been allocated to and neither will the investigators. Clinicians will also be blinded as standard and the same medical procedures will be conducted monthly for all participants, no matter their group assignment. However, the vendor assembling and shipping the meal kits will only know where specific kits, soul food or Mediterranean diet, will be shipped to in terms of address, not name of participant.

Study Procedures

The participants were recruited from 4 sites including Emory University Hospital, Howard University Hospital, Johns Hopkins Hospital, and Detroit Medical Center. At baseline, they will receive assessments in inflammation, which will be repeated at every follow-up visit, including tests for adherence and normal procedures (i.e. blood pressure) in order to prevent the occurrence of adverse events. All participants will be randomly assigned to one of the two study groups. The primary outcome measure will be adherence.The secondary outcome measure is inflammation levels. Throughout the study, all participants will daily record their use of the meals and overall reaction to the meals if any in the subject diaries to ensure adherence to the intervention protocol. Any adverse events such as nausea, vomiting, and diarrhea will also be recorded.

Safety Monitoring

There are no known risks associated with research participation,other than possible weight-loss. Throughout the study, all participants are asked to be in contact

bi-weekly with their assigned researcher to record their use of the meal plan to ensure adherence to the intervention protocol, and to monitor for adverse events if any.

Statistical Analyses

A two sample t-test for primary outcome will be applied. The primary outcome of the study is participants' adherence, which is scaled by the rate of how much research delivered meals and the number of meals that participants ate during the 6 months. Hence the hypothesis is H_0: $\mu_{soul\ food} = \mu_{Mediterranean\ diet}$ vs. H_A: $\mu_{soul\ food} \neq \mu_{Mediterranean\ diet}$. We assume that this is a two-sided test and equal allocation. With the significance level 0.05 and 90% power, then we can get $z_{1-\alpha/2=}1.96$, $z_{1-\beta}=1.28$. Besides, we need to know mean of soul food: $\mu_{soul\ food}$, standard deviation of soul food: $\sigma_{soul\ food}$, mean of Mediterranean diet: $\mu_{Mediterranean\ diet}$,standard deviation of mediterranean diet: $\sigma_{Mediterranean\ diet}$, measure of true population difference: $\Delta = \mu_{soul\ food} - \mu_{Mediterranean\ diet}$ to get the sample size. Then we plug the number into equation 1 to get the final group population. Suppose we have $\Delta=0.4$, $\sigma_{soul\ food} =1.1$, $\sigma_{Mediterranean\ diet}=0.9$. Then plug the value into equation 1 we can get the sample size per group is 132. Since we have two groups in the study, the total sample size is 264.

$$n_{per/group} = \frac{\left(\sigma_1^2 + \sigma_2^2\right)\left(z_{1-\alpha/2} + z_{1-\beta}\right)^2}{\Delta^2}$$

Equation 1

The secondary outcome measures consisted of objective inflammation scores by using at-home inflammation tests observed by a research team member. A two-sample

t-test will also be used to test whether there's difference in the mean of inflammation scores between soul food group and Mediterranean food. Since the primary outcome is about participants adherence, there's no need to perform Intention-to-Treat and/or Per protocol analysis. An interim analysis will not be planned to monitor for study as the study will only last 6 months.

3. ***Consent***

Consent will be obtained by guiding the participants through a consent process, with a member of the research team. The consent form will be given to the participants to read alongside a member of the research team. Consent will be given in the form of a written signature. All of the consent forms will be IRB-approved. The investigator will explain the study to the participant and if the participant has any questions, will answer any questions that the participant may have. Participants will be reviewed on their relation to participating in the study including the reasoning and all possible risks for the study. All participants are allowed to review the consent form and ask any questions that they may have prior to signing. All participants will also have the chance to discuss the study and think about it before they decide on whether they would like to participate. Only once the consent form is signed, will any procedures in regards to the study occur. The participant may withdraw their consent at any time. The participant may also keep their copy of the consent form.

Risk- Benefit Assessment

The research involves no more than minimal risk to subjects. The potential benefits gained by the study are that of potential knowledge and possible reduction of inflammation to the participant due to a diet change.

Recruitment of Women & Minorities

All individuals must meet all the inclusion criteria in order to be eligible to participate in the study. Women and members of minority groups will be included in accordance with the NIH Policy on Inclusion of Women and Minorities as Participants In Research Involving Human Subjects. The study intends to recruit at least 50% women within the study. As the study population is a minority group, the study intends to have more than 90% of participants be members of a minority group.

Conflicts of Interest

We have no conflicts of interest to disclose.

IRB Review

The trial will be conducted in accordance with the ICH E6, the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and the <NIH IC> Terms of Award. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel

involved in the conduct of this study have completed Human Subjects Protection Training.

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TITLE OF STUDY

The Effect of Adherence of a Soul Food Diet for African Americans with Osteoarthritis.

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PURPOSE OF STUDY

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

The purpose of this study is to understand if diets that are more similar to someone's identifying culture aid with keeping down osteoarthritis symptoms versus the traditional Mediterranean diet.

Participant's Initials ____

STUDY PROCEDURES

1. When participants enter the study, there will be an inflammatory report conducted at the beginning of the study.
2. Participants will receive a meal kit each week and a food journal that the participants will detail what they ate for the week. The meal kit will either be a culturally sensitive diet or the Mediterranean diet.
3. Every two weeks, participants will complete questionnaires measuring the levels of satisfaction of meals and there will be a member of the research team to observe and conduct an inflammatory report. Audio-Taping may be used for the research team.
4. Participants are asked to record what meals they ate and their overall reaction to the meals daily.
5. Participants must to go to the doctor monthly to have blood tests done, which will be sent to the research team.

SUBJECT PARTICIPATION

We estimate that 264 participants, 132 per group, who are recruited from 4 sites including, Emory University Hospital, Howard University Hospital, John Hopkins Hospital, and Detroit Medical Center, self-identifying as black, 40 – 65 years old and has diagnosed OA. Participants must live a sedentary lifestyle (<30 minutes per week of formal exercise for the past 6 months), be able to eat by mouth, have no high risks of choking, be able to understand English or Spanish language, and sign a written consent by themselves.

Participant's Initials ____

RISKS

There are no known risks associated with research participation, other than possible weight-loss, and the risks associated with cooking. The research team will be responsible for making sure that the food arrives safely.

You may decline to answer any or all questions and you may terminate your involvement at any time if you choose. If any potential risk or discomforts arise, please contact the study managers. If an immediate issue or emergency of health arises, please call 911.

BENEFITS

Some benefits that will be achieved from this research are the possibility of creating new knowledge for how our diets affect osteoarthritis and lowering your own

osteoarthritis inflammatory symptoms. The participant will also not have to cook meals during the research period, as all meals will be delivered to the participant.

Participant's Initials ____

CONFIDENTIALITY

Your responses to this trial will be anonymous. Please do not write any identifying information on your trial. For the purposes of this research study, your comments will not be anonymous. Every effort will be made by the researcher to preserve your confidentiality including the following:

- Assigning code names/numbers for participants that will be used on all research notes and documents
- Keeping notes, interview transcriptions, and any other identifying participant information in a locked file cabinet in the personal possession of the researcher.
- Encrypting all files that belong to the participant and that hold identifying information.

Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse and suicide risk.

AUTHORIZATION

I, _____ (print name), authorize the use of my records, any observations, and findings found during the course of this study for education, publication, and/or presentation.

Participant's Initials ____

COMPENSATION

Subjects will be compensated for participation in this study for expenses such as transportation to and from medical exams and meal delivery service. Subjects will receive $50 and a $100 gift card to their nearest grocery store at the conclusion of the study.

CONTACT INFORMATION

If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Primary Investigator, please contact the Institutional Review Board at (865) 354-3000, ext. 4822.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

Participant's Initials ____

CONSENT

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____

HHS.gov

U.S. Department of Health & Human Services

Office for Human Research Protections

Informed Consent Checklist (1998)

§46.116 (/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116) Informed Consent Checklist – Basic and A onal Elements

Feedback

- ✓ A statement that the study involves research
- ✓ An explanation of the purposes of the research
- ✓ The expected duration of the subject's participation
- ✓ A description of the procedures to be followed
- ✓ Identification of any procedures which are experimental
- ✓ A description of any reasonably foreseeable risks or discomforts to the subject
- ✓ A description of any benefits to the subject or to others which may reasonably be expected from the research
- ✓ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- ✓ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- ✓ For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- ✓ **Research, Rights or Injury:** An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- ✓ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

Additional Elements as Appropriate

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- ✓ Any additional costs to the subject that may result from participation in the research
- ✓ The consequences of a subject's decision to withdraw from the research and procedures f derly termination of participation by the subject
- ✓ A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- ✓ The approximate number of subjects involved in the study

Feedback

§46.117 Documentation of Informed Consent Checklist

a. Except as provided in paragraph "c" of this section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Written

The consent form may be either of the following:

1. ✓ A **written consent** document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.

Done Orally

2. ✓ A **short form written consent** document, stating that the elements of informed consent required by §46.116 have been presented **orally** to the subject or the subject's legally authorized representative. When this method is used, there shall be a **witness** to the oral presentation. Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

Waiver of Requirement for Signed Form