A Pilot Nutrition Intervention to Reduce Cardiovascular Disease Risk Using a Mediterranean Diet in the Southeastern U.S. (HHP)

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Research Location:
Auburn University Main Campus
Auburn University Pharmaceutical Care Clinic (AUPCC)
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Auburn University, AL 36849

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COLLEGE OF HUMAN SCIENCES
DEPARTMENT OF NUTRITION, DIETETICS,
AND HOSPITALITY MANAGEMENT

INFORMED CONSENT

For a Research Study entitled:

"The Healthy Hearts Program: a pilot nutritional intervention to reduce cardiovascular disease risk factors"

You are invited to participate in a research study to help determine the impact of nutrition interventions on cardiovascular disease risk factors. The study is being conducted by Amy Willis, MS, RD, LD, under the direction of Michael Greene, PhD, from the Department of Nutrition, Dietetics, and Hospitality Management, and Kimberly Braxton Llyod, PharmD, in the Auburn University Pharmaceutical Care Center (AUPCC). You were selected as a possible participant because you are 19 years or older and meet one of following:

- A previous diagnosis of high blood pressure, total cholesterol, or pre-diabetes OR
- Lab results for your blood pressure, cholesterol, blood glucose or BMI were elevated in the past

Your involvement in this study will not in any way affect Healthy Tigers participation or any insurance deduction benefit derived as a result of Healthy Tigers participation.

What will be involved if you participate? If you decide to participate in this research study, you will be asked to participate in a 12-week nutrition education program that includes:

Education: Throughout the study, you will have access to the following:

- Seven on-line nutrition education modules
- Recipes, shopping lists, and menu planning tips and techniques
- An individual session with a registered dietitian
- Contact information to a registered dietitian to answer questions

Assessments: At three different points throughout this study, you will be asked to visit the AUPCC and participate in the following assessments:

- Questionnaires for diet analysis and knowledge and energy expenditure assessment. 2 questionnaires will be completed during your visits at the AUPCC and one will be web-based and will be completed from your personal computer. Instructions for the web-based questionnaire will be given during your first visit.
- Blood work to assess:
  - Blood sugar
  - Blood lipids/cholesterol
  - Inflammation
  - Diet analysis
- Urine analysis for diet analysis

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- Height, weight, blood pressure, waist circumference, body composition

How much time will I need to invest throughout the study? Throughout the 12-week study, your total time commitment will be approximately 5 ½ hours (not including travel to and from the AUPCC). You will be asked to come the the AUPCC for 4 visits (approximately 45 minutes each). You will also be asked to complete web-based tasks (education modules and questionnaires) that will range from 10-30 minutes each.

Are there risks or discomforts?

Confidentiality: A risk associated with participating in this study is a breach of confidentiality. To minimize these risks, we will securely store all of your personal information and remove all identifying information during data collection.

Blood Draws: There are also risks associated with a venipuncture blood draw. You will have approximately 10 mL of blood taken 3 times over the course of 12 weeks from your arm. The total amount of blood taken for the whole study will be approximately 2 tablespoons (30 ML). Risks include: pain or discomfort at the site of puncture; bruising at point of blood draw; redness and swelling for the vein; rarely an infection; and, uncommonly, faintness from the procedure. To minimize risks, all blood will be drawn by phlebotomy trained clinicians who will inform and monitor you before, during, and after the procedure.

Participation: Participation in this study result in a perceived social risk due to participation. Participation in the Healthy Hearts Program will not affect Healthy Tigers participation or any insurance deduction benefit derived as a result of Healthy Tigers participation.

Are there any benefits to yourself or others? If you choose to participate, you will receive free enrollment in a 12-week nutrition program and receive free health assessments, diet plans, recipes, nutrition education, and medication check-ups throughout the 12-week challenge. You will learn important information on dietary ways to reduce cardiovascular disease risk factors.

Will you receive compensation for participating? All participants who complete all nutrition education components will be entered into a lottery for a chance to win a $50.00 gift card, participants have a 1 in 30 chance of being selected to win. You may also be randomized into a group that receives free olive oil and nuts as a part of your dietary plan. Participants have a 1 in 2 chance of being randomized into this group.

If you change your mind about participating, you can withdraw at any time during the study. Your participation in every aspect of this study is completely voluntary. If you choose to withdraw, your data can be withdrawn as long as it is identifiable. Your decision about whether or not to participate or stop participating will not jeopardize your future relations

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with Auburn University, the AU Pharmaceutical Care Clinic, or the Department of Nutrition, Dietetics, and Hospitality Management.

Your privacy will be protected. Any information obtained in connection with this study will remain anonymous (*or confidential*). Information obtained through your participation may be presented at a professional meeting or published in a journal.

If you have questions about this study, *please ask them now* OR contact Amy Willis at awillis@auburn.edu. A copy of this document will be given to you to keep.

If you have questions about your rights as a research participant, you may contact the Auburn University Office of Research Compliance or the Institutional Review Board by phone (334) 844-5966 or e-mail at IRBadmin@auburn.edu or IRBChair@auburn.edu

HAVING READ THE INFORMATION PROVIDED, YOU MUST DECIDE WHETHER OR NOT YOU WISH TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES YOUR WILLINGNESS TO PARTICIPATE.

_____	_____
Participant's signature Date	Investigator obtaining consent Date
_____	_____
Printed Name	Printed Name
	_____
	Co-Investigator Date
	_____
	Printed Name

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