Informed Consent

Official Title: Effects of Coffee Versus Hibiscus Tea Consumption During Prolonged Sitting on Blood Pressure and Heart Rate

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KSU-IRB Form 005-E_INFORMED CONSENT FOR MEDICAL & CLINICAL STUDIES
King Saud University – Riyadh, Kingdom of Saudi Arabia Version
4.0 dated 30 March 2022

PART 1: INFORMATION SHEET

Study Title:	**Effects of Coffee Versus Hibiscus Tea Consumption During Prolonged Sitting on Blood Pressure and Heart Rate**
IRB Project Number/ Sponsor Study Code:	**No. E-25-9503**
Principal Investigator:	Not applicable
Principal Investigator Office Address:	King Saud University, College of Sport Sciences and Physical Activity, Department of Exercise Physiology, Building B69
Telephone (Mobile No):	+966540916188
Email:	445206448@student.ksu.edu.sa
Funding Details:	Study Funded? ☐ Yes ☑ No Funding Source:

SECTION A: INTRODUCTION

Dear Participant,

You are being invited to take part voluntarily in this local above-mentioned research study. A member of the research team will explain/inform you what is involved in this study and how it will affect you.

Prior to signing this form, please read carefully all the study aspects (the study procedures, the risks and benefits of participation, and how your confidentiality) to make an informed decision.

Please take your time to ask questions and feel comfortable making a decision whether to participate or not.

If you decide to participate in this study, you will be asked to sign this form and will be given a copy for your records. As part of the consenting process, we will keep you updated with any new findings that might affect your decision to continue with the trial.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You may choose either to 'take part' *or* 'not to take part' in the study. You may leave the study at any time during your participation (withdrawal). No matter what decision you make, there will be no penalty to you and you will not lose any of your

regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from KSUMC. However, *Ms. Hadeel Mohammed Almalki* may use information that was collected prior or after your leaving the study for research purpose only.

For further information regarding your rights as participant, you may call the office of Institutional Review Board, King Saud University at (+966-11) 469-1529 to 31.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Before you agree to be in this study, one of the study team member will talk to you and explain to you everything regarding the study. You can ask questions about any aspect of the research.
If you have further questions about the study, you may ask them at any time. You may call *Ms.* **Hadeel Mohammed Al-Malki** – Phone: **+966540916188**

WHAT IS EXPECTED OF ME DURING THE STUDY? WHAT ARE MY RESPONSIBILITIES?

Your participation in this study is totally voluntary, and you will always have the right to withdraw at any time without mentioning the reasons and without affecting your healthcare benefits or your relationship with the study staff. Signing this informed consent form does not mean that you waive your legal rights, yet you will still have the following responsibilities:

1. Read the informed consent form and seek understanding of the study. Participants will consume **3-4 cups of coffee and 3 cups of hibiscus drink**, which are within the daily safe consumption limits according to research, and will be subjected to **3 hours of continuous sitting**.
2. Ask questions and understand your rights.
3. Follow carefully all directions pertaining to drug dosing, tests and procedures, and appear for the study visits as scheduled i.e. Be on time for the labs, clinic, and if you have any circumstances that prevent you from being on time please inform your study staff.
4. Inform your family physician or the emergency room physician that you are participating in this study
5. Promptly report any apparent/potential adverse drug reaction to the study staff.
6. In case your family physician has to prescribe a new medication to you, please inform him/ her that you are participating in this study. Consult the study investigator about this new medication.
7. As long as you are on this trial and for the follow up period, you cannot participate in other studies without getting back to the study investigator.
8. Return all used drug containers (Boxes).
9. Ensure receiving the new drug containers (Boxes) and its usage instructions before finishing each visit.
10. If applicable, please ensure completing all life assessment questionnaire or study diaries on time.

SECTION B: STUDY DETAILS AND SUBJECT PARTICIPATION INFORMATION

1- **WHAT IS THE PURPOSE OF THE STUDY?** This study aims to examine and understand the effects of consuming coffee versus hibiscus drink during prolonged sitting on **blood pressure, heart rate, and heart rate variability** .

2- **HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?** The sample consists of 15 males and 15 females, including a 10% addition to account for potential data loss or incomplete responses.

3- **STUDY LOCATION?** The study will be conducted **at King Saud University**.

4- **HOW LONG WILL I BE IN THE STUDY?** If you agree to participate, you will be asked to come to the lab twice.

5- **WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?**

Visit 1: Screening and Initial Procedures

- You will sign the informed consent form.
- You will visit the **Exercise Physiology Laboratory at King Saud University** for initial assessments, including: ○ **Age, education level, physical activity level, smoking status, and medical conditions** to determine eligibility.
- Participants will be randomly assigned to consume either **coffee or hibiscus drink** first.
- You will sit continuously for **3 hours** after consuming the drink.
- Measurements (blood pressure, heart rate variability) will be taken **5 times**:
  - **Before drinking (baseline)
  - one hour after drinking
  - After 1 hour of sitting
  - After 2 hours of sitting
  - After 3 hours of sitting**

Visit 2:

- Participants will consume the **other drink** (opposite of Visit 1).
- The same prolonged sitting period (**3 hours**) and measurements will be conducted.
- An additional **reaction time test** will be included.

Sitting continuously for three hours is considered a globally standardized method in prolonged sitting research.

6- **WHAT OTHER OPTIONS ARE THERE?** You may choose not to participate or discontinue at any time.

7- CAN I STOP BEING IN THE STUDY?

You can decide to stop taking part in the study at any time. If you decided not to take part in this study, you will be receiving the utmost standard of care utilized at our site to treat similar conditions. Please inform the study investigator about your decision, he/she will guide you if there are any rules and guidelines, for your safety, with the alternate treatment for you or physician taking in charge for your illness treatment. No one will try or coerce you to continue the participation.

(NOTE: The procedures for safe and orderly termination of participation by the participant, should the participant decides to withdraw from the study before it is completed e.g. follow-up visits, etc. should be mentioned).

8- ARE THERE RISKS IF I STOP BEING IN THE STUDY? Not applicable.

9- WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY? Prolonged sitting may cause **temporary slight increases in blood pressure, fatigue, or lower back discomfort**, but these can be alleviated by light physical activity.

- **Blood pressure measurements** may cause mild bruising at the measurement site.
- **Coffee or hibiscus consumption** may cause mild effects like **insomnia or increased heart rate**, though doses will be controlled.
- A physician will be present during all measurements for safety.

There also may be other side effects or discomforts that we cannot predict, especially to a fetus or embryo. Because the drugs in this study may affect an unborn baby, you should not become pregnant or father a baby while on this study. The study investigator will discuss this with you. You should not breast-feed a baby while on this study.

10- ARE THERE BENEFITS TO TAKING PART IN THE STUDY? Participants will receive **precise cardiovascular health assessments**.

- They will be provided with the latest **physical activity recommendations**.
- Participants can request their individual health assessment results after data analysis.

11- WHAT IF I WILL TRAVEL OUTSIDE (Away from the study site) WHILE IN THE STUDY? If you travel and cannot complete a visit, you should notify the researchers. Your visits can be rescheduled upon return.

12- WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY? Immediately inform the **Principal Investigator (Hadeel Mohammed AlMalki, +966540916188)**. If necessary, participants may be withdrawn from the study for safety reasons.

13- WHAT ARE THE COSTS OF TAKING PART IN THE STUDY? No, all study procedures are free.

14- **WILL I BE PAID FOR MY TAKING PART IN THIS STUDY?** No financial compensation will be provided.

15- **WILL MY INFORMATION BE KEPT PRIVATE?** All the information collected in subject's records belong to King Saud University, and the study Sponsor. Your records will remain strictly confidential and will not be made publicly available. Scientific data from this research project may be presented or published in the journal but your personal identity will always remain protected. In some situations, if study requires, your information could be provided to the relevant personnel or permitted by the regulations of SFDA/FDA/KSU IRB or law within the limitations and boundaries of Saudi Arabia national, Sharia and ethical laws.

PART 2: CERTIFICATE OF CONSENT

Subject's Statement of Consent:

The research and procedures have been explained to me. I have been allowed to ask any questions and all my questions have been answered. I have read the consent and have had time to think about participating. I can ask any additional questions I may think of later. I may refuse to participate in the study, and I may quit being in the study at any time without any penalty and without affecting my health care.

- ☐ I have given permission for the study doctor and sponsor to use and disclose my personal health information.
- ☐ I will receive a signed copy of this consent form.
- ☐ I agree to participate in this study. My agreement is voluntary. I do not have to sign this form if I do not want to be part of this research study.
- ☐ I consent for my biosamples to be sent to Central Laboratory/Company (Local/Abroad). *(provide name and details of the laboratory)*

  I consent that my biosamples will be used for genetic testing. ☐ Yes ☐ No

  I consent that my biosamples will be used for second (future ☐ Yes ☐ No research) by the same Investigator or any other Investigator.

Participant's Name:	
Signature:	
Date:	
Time: (AM☐ PM☐)	

Person Obtaining Consent:

I have explained the nature and purpose of the study and the risks involved. I have answered and will answer questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Name of Person Obtaining Consent:	
Role In The Study:	☐ Principal Investigator ☐ Co-Investigator ☐ Other
Signature:	
Date:	
Time: (AM ☐ PM ☐)	

STOP! Do not use the following signature lines unless third party consent is being requested. (For subjects who are unable to give consent).

For Participants Unable to Consent:

Name of Participant:	
Name of Legally Authorized Representative/Guardian:	
Signature:	
Date:	
Person Obtaining Consent:	
Role of in the study:	☐ Principal Investigator ☐ Co-Investigator ☐ Other
Signature:	
Date:	

For Children Who Cannot Give Consent:

The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.

Name of Participant (child):	
Name of Parent or Legal Guardian:	
Signature of Parent or Legal Guardian"	
Person Obtaining Consent:	
Role in the study:	☐ Principal Investigator ☐ Co-Investigator ☐ Other
Signature:	
Date &Time: (AM☐ PM☐)	

IMPARTIAL WITNESS: In case when subject is unable to read and/or understand the text and nature of the ICF and the study, a witness is required.

Witness name:	
Relation (if any) with subject:	
Signature:	
Date:	
Person Obtaining Consent:	
Role in the study	☐ Principal Investigator ☐ Co-Investigator ☐ Other
Date:	