Cover letter

August 6, 2021

Dear Participant,

You are being invited to take part voluntarily in the clinical trial which I lead entitled "**Effect of Multi-Strain Probiotics as an anti-obesity among overweight and obese Saudi adults**". A member of the research team will explain what is involved in this study and how it will affect you. Prior to signing this form, please read carefully all the study aspects to make an informed decision. This consent form describes the study procedures, the risks and benefits of participation, and how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. 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. Throughout the course of this study, you will have the right to ask any questions regarding the study or your medical condition. As a part of the consenting process, we will keep you updated with any new findings that might affect your decision to continue with the trial.

Sincerely,

Prof. Hanan Alfawaz
Principal Investigator

INFORMED CONSENT FOR MEDICAL & CLINICAL STUDIES
KSU-IRB Form 005-E
King Saud University, Riyadh, Kingdom of Saudi Arabia

SECTION A:

STUDY INFORMATION

Study Title:	Effect of Multi-Strain Probiotics as an Anti-Obesity among Overweight and Obese Saudi Adults
Protocol Number/Study Code:	E-20-5503
Principal Investigator:	**Prof. Hanan A Alfawaz**
Principal Investigator Address:	Department of Food Science and Nutrition College of Food & Agriculture Sciences
Telephone:	0118055800
Email:	halfawaz@ksu.edu.sa
Sponsor/Non-Commercial Funding/NA:	Non funded

SECTION B:

WHAT IS THE PURPOSE OF THE STUDY?

1. Evaluate the anti-obesity effect of multi-Strain probiotic supplementation
2. Investigate the effect of probiotics on reducing Lipopolysaccharides LPS.
3. Determine the effect of probiotics on liver functions.
4. Study the association between probiotics and food intake.
5. Evaluate the role of gender difference in response to probiotic.

1. HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

The total number of participates in this study will be *90 in total 45 in control group and 45 treatment group.*

STUDY LOCATION? *Occupational Clinic, First Floor, King Khalid University Hospital.*

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

The study is a 12-week, double-blind, randomized, placebo-controlled clinical trial. The study population will be 90 participants adult male and female, 19-40 years. They will be recruited at Occupational Clinic, First Floor, King Khalid University Hospital.
All participants will be divided randomly, using randomization software, into two groups:

- *A first group is an active group, which will receive the probiotic supplementation and a menu of a norm caloric diet and guidelines for healthy eating.*

- *A second group is a control group, which will receive the placebo and a menu of a norm caloric diet and guidelines for healthy eating.*

Both groups will also be instructed to maintain their usual exercise program for the entire study. Blood analysis, 24-hour dietary recall, and physical activity will be recorded at the beginning and the end of the intervention

2.1. During the course of this study, you will go through the following visits/ procedures. *There will be two visits, in the beginning and at the end of the study. Additionally,* regular following up with all participants will be applied to reinforce instructions through phone calls and social media, WhatsApp.

3. Baseline visit or/ Screening procedures:

First visit: Participants are expected to provide blood samples at baseline. A train phlebotomist will withdraw (5ml) from arm veins using single-use sterile syringe and needle. Participants are also expected to fill a questionnaire which include questions pertaining to the demographics, anthropometric measurements (height, weight, waist and, hips), 24-hour recall, as well as physical activity.

4. Study Procedures/Treatment period: 3 months.

4.1. **Follow up/Study end period**

Second visit, after 3 months, participants are expected to provide blood samples, fill 24-hour recall, as well as physical activity.

5. HOW LONG WILL I BE IN THE STUDY?

6. If you agree to take part in this study, your involvement will last approximately *3 months.* You will be asked to return to the lab two times. Each visit will take approximately *20* minutes

7. 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:

i) Read the informed consent form and seek understanding of the study.
ii) Ask questions and understand your rights.
iii) 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.
iv) Inform your family physician or the emergency room physician that you are participating in this study
v) Promptly report any apparent/potential adverse drug reaction to the study staff.

vi) 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.
vii) 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.
viii) Return all used drug containers (Boxes).
ix) Ensure receiving the new drug containers (Boxes) and its usage instructions before finishing each visit.
x) If applicable, please ensure completing all life assessment questionnaire or study diaries on 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 outmost standard of care utilized at our site to treat similar conditions. Please inform to the doctor/study investigator about your decision of stopping your study participation. Your doctor will guide you how to stop in the study, 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**.**

Once you are off the study you *will not* be allowed to take part in this study again. If your condition improved on the study medication and on the sponsor discretion you might continue to receive the study drug for free until the study drug is available on the market.

8. ARE THERE RISKS IF I STOP BEING IN THE STUDY?

There aren't any risks, only changes such as flatulence, diarrhea or mild constipation may occur.

9. WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

Changes such as flatulence, diarrhea or mild constipation may occur.

10. ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Taking part in this study may help you reduce your weight.

Note: Taking part in this study may reduce your weight. While investigator hopes that the results of this study may increase understanding for the obesity or lead to better diagnosis or treatment, there is no proof of this yet. You will make some tests free.

11. WHAT OTHER OPTIONS ARE THERE?

Exclusion any participant who doesn't want to complete, also any participant with the right to withdraw at any stage.

12. WHAT IF I WILL TRAVEL OUTSIDE THE KINGDOM OR ABROAD WHILE IN THE STUDY?

For your safety, you need to notify the investigator about any planning to travel.

13. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

You should inform your study investigator immediately about any discomforts/ illness / injuries during this study. Moreover, upon the principal investigator's decision that this injury / illness is study related, then all treating procedures, follow-ups, hospitalization will be covered by *King Saud university.* This information of your sickness/injury will be collected, documented and reported as adverse event(s) with confidentiality.

Note: **It is important that you tell investigator** Prof. Hanan A Alfawaz **if you feel physically or mentally sick, are injured physically or mentally, are compromised socially, after taking part (after signing the informed consent form) in this study. You can tell the doctor in person or call him/her at *(011 805 5890)*. Treatment, including the investigational tests will be provided to you, in case if it is applicable. This information of your sickness/ injury will be collected, documented and reported as Adverse Event(s) with confidentiality.**

14. WHAT ARE THE COSTS OF TAKING PART IN THE STUDY?

You will not be asked to pay for participation or any procedure, drug, and laboratory test related to the study.

15. WILL I BE PAID FOR MY TAKING PART IN THIS STUDY?

You *will not* be compensated for your time spent for study, effort and travel expenses.

16. WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

Yes. All the information collected in subjects' records belong to King Saud University. Your records will remain strictly confidential and will not be made publicly available. However, in some situations as 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. Scientific data from this research project may be presented or published in the journal but your personal identity will always remain protected.

SECTION C:

NOTE: Fill this section in case subject's biospecimens are required as part of the study

17. I am being asked to give my biosamples(s) as per study protocol along my clinical data.

Yes you will be asked to provide fasting blood samples only.

18. I am asked for the biosamples(s) listed with the mentioned condition(s).

You are expected to provide (5ml) of blood sample at baseline and after 3 months, (before the start and after end the study) .

SECTION D:

19. 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. 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, the investigator Prof. Hanan Alfawaz may use information that was collected prior or after your leaving the study.

In case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

For further information regarding your rights as participant, you may call the office of Institutional Review Board, King Saud University at −966114691530 −966114691529) (966114691532 −966114691531

20. WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Before you agree to be in this study, you will talk to a study team member qualified to tell you about this 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 investigator Prof. Hanan A Alfawaz ***011 805 5890***

SECTION E:

SUBJECT'S 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) I have been given permission for the study doctor and sponsor to use and disclose my personal health information.

ii) I will receive a signed copy of this consent form.

iii) 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.

iv) I consent for my biosamples to be sent to Central Laboratory, of Chair for Biomarkers of Chronic Diseases (CBCD)KSU

v) I consent that my biosamples will be used for genetic testing. YES/ NO

Subject 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.

Signature of Person Obtaining Consent:	
Date:	
Time: (AM ☐ PM ☐)	
Principal Investigator:	Prof. Hanan Abdullah Alfawaz
Signature of Principal Investigator:	
Date:	
Time: (AM ☐ PM ☐)	

SECTION F:

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

For subjects unable to consent:

Legally Authorized Representative:	
Date:	
Person Obtaining Consent:	
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.

Parent or Legal Guardian:	
Date:	

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:	
Date:	

Principal Investigator:	**Prof. Hanan A Alfawaz**
Signature	
Date:	
Time (AM ☐ PM ☐)	

*For more information, please visit the website of the Research Ethics Committee in King Saud University (*http://dsrs.ksu.edu.sa/ar/comm_Policies