Study Title:

Effects of grape powder on psychological distress and gut microbiota in college students (FTGP2025)

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CONSENT TO TAKE PART IN RESEARCH

Title of Research: Effects of grape powder on psychological distress and gut microbiota in college students (FTGP2025)
Principal Investigator: Guojun Wu, Ph.D.

RESEARCH SUMMARY: This consent form is part of an informed consent process for research study, and it will provide information that will help you decide whether you want to take part in this **research**. It is your choice whether to take part or not.

P**URPOSE**: This study aims to determine the effects of freeze-dried table grape powder (FTGP) on psychological distress and gut microbiota in college students during exam period, and to explore the relationships between gut microbiota and psychological distress. If you take part in the research, you will be asked to complete a Dietary History Questionnaire, receive either FTGP or placebo powder for 4 weeks depending on a double-blind randomization group assignment. We will collect your stools samples and response to validated mental health questionnaire at 3 different time points. Your time in the research will take 45 minutes for consent and eligibility interview, 60 minutes for Dietary History Questionnaire. The study will last approximately five weeks, including the 4-week supplement intervention and sample collection during the exam period. Each survey and sample collection session will take around 10-15 minutes.

RISKS/BENEFITS: Possible harms or burdens of taking part in the study may be mild digestive discomfort due to the FTGP or placebo, allergic reaction to grape components, inconvenience for you and/or your family when you collect a stool sample at home. You will not receive any direct benefit from taking part in this study.

ALTERNATIVES: Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research?
Guojun Wu, Ph.D. is the Principal Investigator of this research. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Guojun Wu, Ph.D. may be reached at 848-932-6394, 61 Dudley Rd, New Brunswick, NJ 08901

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Research: California Table Grape Commission.

Why is this research being done?
This study is being done to find out if eating a freeze-dried grape powder can help reduce stress, anxiety and depression in college student during exams. The grape powder is made from real grapes. We also

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want to see how the grape powder affects beneficial and bad bacteria linked to stress and health. This study will examine whether consuming a freeze-dried grape powder, made from real grapes, can help reduce stress, anxiety, and depression in college students during exams. The study will also look at how the grape powder affects gut bacteria that are related to stress and overall health

Who may take part in this research and who may not?
You may take part in this research if you:
- Are between 18 and 30 years old.
- Can give written informed consent.
- Have a BMI between 18.5-24.9 kg/m2
- Healthy (self-reported)
- Can read and speak English

You may not take part in this research if you :
- Currently taking medications that interfere with polyphenol
- Currently using or have used antibiotics continuously for >3 days within 3 months prior to enrollment
- Have had surgery involving the intestinal lumen within the last 30 days
- Have a documented diagnosis of celiac disease or/and inflammatory bowel diseases
- Are pregnant or breastfeeding
- Have prediabetes and diabetes
- Have had bariatric surgery
- Are immunocompromised (e.g., cancer treatment, bone marrow/organ transplant, immune deficiency, or poorly controlled HIV/AIDS)
- Are unable to provide consent
- Are hospitalized,
- Have a history of current alcohol, drug, or medication abuse (self-reported),
- Have contraindication to any substance in the investigational product or who are currently enrolled in other interventional trials

Why have I been asked to take part in this research?
You are invited to take part in this study because you meet some of the criteria for this study.

How long will the research take and how many participants will take part?
We aim to recruit 50 participants to complete the entire study. For each participant it will take around 5 weeks to complete the study. Overall, we expect to complete this study in 1 year.

What will I be asked to do if I take part in this research?
If you take part in this research, you will be randomly assigned to one of the two groups. You will be randomly assigned to receive either a grape powder supplement or a placebo, both identical in packaging. You will not be told which one you receive to ensure the study remains fair and unbiased
You will be asked to:
- Complete a Dietary History Questionnaire
- Take the powder supplement daily for 4 weeks in the morning. You will mix the powder with 180 mL water (6 fl. oz.) and drink it. Instructions will be provided. You will be asked to record your supplement use each day in a daily log. You will not be informed of your group assignment during the intervention to maintain the integrity of the study's double-blind design. After the study is complete, data collection and data analysis are concluded, if you express interest in learning your assignment may be informed upon request.
- Complete 3 short online surveys (before the study, at week 4, and during your exam week). These surveys ask questions about your stress, anxiety, and mood. Each one takes about 10–15 minutes.

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- Provide 3 stool samples — one before the study, one at week 4, and one during your exam week. You will collect the samples at home using a kit we provide. You will drop them off or ship them to the research team.
- Check in with the research team once a week. A study team member will check your daily log and ask if you've had any side effects or problems.
- Maintain your usual diet and physical activity during the study and abstain from consuming a selection of foods that are typically rich in polyphenols, i.e. dark chocolate, red wine and grape juice, and to restrict consumption of tea and red fruit to a maximum of two servings per day each.

What are the risks of harm or discomforts I might experience if I take part in this research?
Collecting stool samples at home may impose inconvenience for you and your family. You may experience mild digestive discomfort.

Are there any benefits to me if I choose to take part in this research?
You may feel better, less stressed, or more focused by taking the grape supplement during the exam period. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this research?
There are no alternative treatments available. Your alternative is not to take part in this research.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the research, you will be updated about any new information that may affect whether you are willing to continue taking part in the research. If new information is learned that may affect you after the research or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. You will receive a one-page summary of the overall findings of the study when the final data analysis is complete.

Will there be any cost to me to take part in this study?
There are no costs to you for participating in this research.

Will I be paid to take part in this study?
In order to compensate you for your time and effort in participating in this study, you will be paid $30 for each visit that you complete, according to the schedule below:

- $30.00 after the completion of questionnaire and fecal sample collection and shipment at 1st visit.
- $30.00 after the completion of questionnaire and fecal sample collection and shipment at 2nd visit.
- $30.00 after the completion of questionnaire and fecal sample collection and shipment at 3rd visit.

Payment for participating in this study will be made using ClinCard, a pre-paid Visa card that works like a debit card. We will give you one card that will be used to pay you at each visit/in accordance with the schedule above for the duration of the study. Your ClinCard will come with an information sheet about how to use the card and who to call if you have any questions. You may use this card online or at stores that accept Visa. Please see the ClinCard Cardholder FAQ sheet or the Rutgers ClinCard Information Page: https://sites.rutgers.edu/clincard-users/ for important details about how to use the card, about fees that may apply and what to do if your card is lost or stolen.

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ClinCard is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study that you are participating in.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. A code will be assigned to every participant, and the collected data will be recorded using the participant's unique code for identification purposes. The Principal Investigators and research personnel who need to contact you will be the only one with access to the master code identifier. Participants' hard copy files will be kept in locked cabinets in a secured building. Electronic files will be stored in an encrypted password-protected file which is stored on the university's secure server and will only be accessible to authorized research personnel. The master code identifier and the data files will be kept in two separate locations. We will keep data in hard copies and the master code identifier for 6 years after study completion and then they will be permanently deleted from the server or shredded. Electronic data in de-identified form will be kept indefinitely

The research team may use or share your information collected or created for this research with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Food and Drug Administration
- The research team, including the Principal Investigators, study coordinators, and all other research staff at Rutgers University
- California Table Grape Commission, and any persons or companies working for or with California Table Grape Commission.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen to my information—data, recordings and/or images—and bio-specimens collected for this research after the research is over?

After information that could identify you has been removed, de-identified informed consent from you. information and biospecimens collected for this research may be used for other research we conduct without obtaining additional
We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

What will happen if I do not wish to take part in the research or if I later decide not to stay in the research?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

Any data that has already been collected cannot be withdrawn because there may not be any identifiers to link the data with you.

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At any time, the Principal Investigator can take you out of this research because it would not be in your best interest to stay in it. The Principal Investigator can stop treatment even if you are willing to stay in the research.

Who can I contact if I have questions?

If you have questions, concerns, or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator:
Guojun Wu, Ph.D.
Department of Biochemistry and Microbiology
61 Dudley Rd, New Brunswick, NJ 08901
Tel: +1 848-932-6394

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

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AGREEMENT TO TAKE PART IN RESEARCH

Participant Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this research have been answered. I agree to take part in this research.

Participant Name (Print):_____

Participate Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the research including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____

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If you would like to participate in the ClinCard reimbursement card program, please sign this consent form in the spaces provided below. Please take as much time as you like to decide. Please ask your study coordinator any questions you may have.

CONSENT TO PARTICIPATE IN THE CLINCARD REIMBURSEMENT CARD SERVICE
If you would like to participate in the ClinCard reimbursement card program, please sign this consent form in the spaces provided below.

By signing below, I agree that:

- I give permission to use and share my information about me as described in this form.
- I would like to participate in the ClinCard program and have read the disclosures and descriptions above.
- During the study I may change my mind, and I may choose not to use the ClinCard program for the study by telling the study coordinator. I will not be penalized or lose any benefits to which I am otherwise entitled.

Subject Name (Print): _____

Subject Signature: _____ Date: _____