WESTERN SYDNEY
UNIVERSITY

Participant Information Sheet

Project Title: *Miracle Berries for Taste Alteration (Dysgeusia) in Cancer Patients*

Project Summary:

You are invited to participate in a research study being conducted by Dr Suzanne Grant, Senior Research Fellow, NICM Health Research Institute. The research is designed to test the feasibility and effectiveness of miracle berries for the treatment of taste alteration also known as dysgeusia.

What is dysgeusia? Dysgeusia is a change or impaired sense of taste, an unpleasant alteration of taste sensation, or a distortion or perversion of the sense of taste. This taste may be metallic, bitter, sour, salty, or, more rarely, sweet taste sensations. This change of taste may not be there all the time but may be triggered by eating. It is a common side effect of cancer patients who are treated with chemotherapy.

Miracle berries are a food that some people have found help them with this taste alteration. We are seeking people who have undergone or are currently undergoing chemotherapy and are experiencing taste alteration to use the miracle berries for a seven day period. This project will test whether our proposed research methodology is feasible and acceptable, and whether the miracle berries help with the taste, improve quality of life and other symptoms you may experience such as poor appetite or nausea.

Participants may be invited to be part of a TV series that will have an episode about the miracle berries. This may involve being filmed and interviewed about your experience before and after using the miracle berries. A separate consent and information about the filming will be provided to you should you choose to take part.

How is the study being paid for?

This study is being supported by Western Sydney University.

What will I be asked to do?

To confirm your eligibility, we will need to ask you more questions before you start. This is performed using the short Screening Questions which can be administered over the telephone by the Research Assistant. You may self-screen using the online survey. If you are eligible, you are asked to provide contact details (name, and two telephone numbers, and an email address). The research assistant will then contact you initially by email, providing you with details of the next steps, the patient information consent form, and contact details. The research assistant will also call you to arrange a baseline clinic visit.

Fresh miracle berries will be supplied to you. You will be asked to consume 1 whole berry (excluding the pip) 15 minutes before each main meal for 7 days. Participants will be provided with a supply of 24 berries. This is adequate to enable to the participant to eat one berry before breakfast, lunch and dinner, 3 times per day. There is no known risk to consuming more berries but 3 berries per day is a suitable dosage for our study.

Berries will be stored in a container supplied by the Investigators. Participants will be asked to store the berries in their freezer. Participants will be required to attend the Westmead centre twice to complete a questionnaire and undergo a taste sensation test at baseline and completion of the study. During this test, a taste strip is placed at the middle of the tongue and you will be asked to report the

taste perceived (salty, sour, sweet, bitter, or nothing) by pointing at the corresponding word on a response chart.

How much of my time will I need to give?

You will need to be able to attend two clinic visits.

Will I be reimbursed for my travel costs?

You will be reimbursed $50 in total for your travel costs. At your second and final clinic visit, you will be offered the opportunity to claim a maximum of $50. The payment will be made by a $50 voucher given at the second study visit.

What benefits will I, and/or the broader community, receive for participating?

The study aims to further our medical knowledge about miracle berries and may improve future treatment of taste alteration in people who have chemotherapy.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

We do not anticipate that the Miracle Berries or the taste test that we will conduct will cause the participant any discomfort. Most people find the taste of the berries pleasant, however if you find the taste unpleasant and are unable to eat them you may withdraw from the study at any time.

How do you intend to publish or disseminate the results?

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, such as tables and graphs showing the overall information. Raw data is sometimes made available to a journal as part of their requirements, any data will be de-identified and provided in such a way that you cannot be identified.

If you would like to receive notification about the results of the study please let the Study Coordinator know when you complete your consent form.

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Will the data and information that I have provided be disposed of?

Please be assured that only the researchers will have access to the raw data you provide. However, your data may be used in other related projects for an extended period of time Please note that minimum retention period for data collection is five years post publication. The data and information you have provided will be securely disposed of. In accordance with the Australian privacy and other relevant laws, you have the right to request access to your information that we have collected and stored by the research team. Please contact the chief investigator, Dr Suzanne Grant, s.grant@westernsydney.edu.au, 0419 126 209, if you would like access to your information.

We will store all information collected for this study securely and destroy it 15 years after the results are published in accordance with university policy and the Australian Code for the Responsible Conduct of Research.

Can I withdraw from the study?

Participation is entirely voluntary, and you are not obliged to be involved. If you do participate you can withdraw at any time. If you withdraw, you can advise us that you do not consent for us to use the data we collected up until your withdrawal. We will only use the information that you give consent for us to use. Whatever your decision, it will not affect your treatment or your relationship with the research or medical staff.

Can I tell other people about the study?

Yes, you can tell other people about the study by providing them the contact details of the Chief Investigator, Dr Suzanne Grant, s.grant@westernsydney.edu.au, 0419 126 209, to discuss their participation in the research project and obtain a copy of the information sheet. You can also send the online survey link to other people.

If you would like your doctor to be notified of your participation in the study, please advise the Chief Investigator. The Chief Investigator will send a letter will be sent to your doctor stating the nature of the study, treatments, expected benefits.

What if I require further information?

Please contact *Dr Suzanne Grant* should you wish to discuss the research further before deciding whether or not to participate.

Dr Suzanne Grant, Senior Research Fellow, NICM Health Research Institute

Email: s.grant@westernsydney.edu.au

Phone: 0419 126 209

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee The Approval number is HREC12946.