HEALTH & BIOSECURITY
www.csiro.au

SAHMRI North Tce, Adelaide SA 5000
PO Box 10097, Adelaide SA 5000
ABN 41 687 119 230

Gold Kiwifruit and Psychological Health (GoKiPH)

PARTICIPANT INFORMATION SHEET

HUMAN RESEARCH ETHICS COMMITTEE NUMBER: 2022_008_HREC

INTRODUCTION

Each year CSIRO perform a number of research projects involving human participants. We examine the effect of different diets, nutrients, and supplements on diseases and various aspects of our health.

Gold kiwifruit contains a range of micronutrients that contribute to health and wellbeing. Maintaining adequate levels of some these micronutrients has been associated with improved mood, feelings of vitality and bowel health. This study will help examine if consuming gold kiwifruit can lead to improvements in psychological health in adults currently experiencing symptoms of depression and anxiety.

This project is being conducted by Michael Billows (PhD candidate). This research will form a part of the degree of Doctor of Philosophy at the University of Adelaide under the supervision of Dr Ian Zajac, Dr Naomi Kakoschke and Dr Paul Blatchford. The study is being partly funded by CSIRO industry partner, Zespri International Ltd. Zespri International Ltd are supplying the gold kiwifruit to be used in the study.

WHAT IS THE AIM OF THIS STUDY?

The aim of the study is to examine whether daily consumption of gold kiwifruit leads to improvements in psychological health by increasing dietary intake of certain micronutrients found in kiwifruit.

HOW WILL THE STUDY BE CARRIED OUT?

Who can take part in the study?

To be eligible to take part in the study, there are a few criteria you must meet. Have a look through the basic Inclusion Criteria and Exclusion Criteria outlined below and read on if you are keen to take part.

Inclusion Criteria

- male or female, 18-60 years of age inclusive at phone screen
- non-smoker (i.e., no history of smoking, vaping or nicotine replacement therapy within the last six months prior to baseline)*
- responses to test items on a questionnaire that assesses psychological wellbeing that identifies either a mild or moderate level of symptoms of depression and anxiety
- fluent in English and willing to provide written informed consent
- a current email address/service

Exclusion Criteria

- aversion and/or allergy/intolerance to kiwifruit and/or latex*
- needle phobia or fainting due to fear of needles*
- taking vitamin C supplements within the last three months of the commencement date of the study and not willing to abstain for the duration of the study*
- consumption of gold kiwifruit within 14 days prior to baseline*
- not prepared to abstain from consumption of gold kiwifruit (other than study product) for the duration of the trial*
- currently enrolled in any other dietary intervention study
- previously enrolled in dietary intervention studies at CSIRO involving kiwifruit
- Diabetes Mellitus or bleeding disorders (e.g., haemophilia)*
- previous or current diagnosis of iron deficiency*
- previous or current diagnosis of hypothyroidism or hyperthyroidism*
- taking prescription medications or probiotics for the treatment and management of gastrointestinal disorders (e.g., Irritable Bowel Syndrome) within last three months of the commencement date of the study and not be willing to abstain for the duration of the study*
- initiation of, or alterations to, a course of anti-depressants, anti-anxiety or anti-psychotic medication within last 6 months from commencement date of the study*

*Inclusion/exclusion criteria will be assessed via self-report
Note – other eligibility criteria exist and will be assessed during the screening process.

What can I expect during the screening process?
If you are eligible and decide to take part in this study, you will be asked to sign a Consent Form before completing a Medical Screening Questionnaire which will take around 10 minutes to complete. The questionnaire asks you to provide information about your medical history and current medication/supplement use.

If you are still deemed eligible following review of the questionnaire, you will be invited to take part in a telephone screening which should take about 15 minutes. During the telephone screening, you will be asked questions about your psychological wellbeing.

If you are still deemed eligible following the telephone screening, you will be invited to attend an appointment at the CSIRO Research Clinic at the South Australian Health & Medical Research Institute (North Terrace, Adelaide) to enrol and commence your participation in the study.

What can I expect during the study?

Your ongoing participation in the study involves attending the CSIRO clinic on 6 occasions. The 6 visits will be scheduled at fortnightly intervals from the date of enrolment in the study. Each visit will require a time commitment of approximately 60 minutes, during which you will be asked to respond to some online questions via a secure link and provide a blood sample. For the purposes of the blood sample, you will need to fast for at least 10 hours prior to your appointment (nothing to eat or drink - only water is permitted). You will be assigned a unique study identification number so that the information you provide is not linked to your name and is de-identified. You will be asked questions about your psychological wellbeing, gut and bowel health, and dietary intake.

At the first visit, you will be randomly allocated to one of two groups. Participants in the first group will be asked to consume 2 gold kiwifruit each day for the following 28 days. Participants in the second will be asked to maintain their typical dietary intake for 28 days. At the end of the 28 days, there is a 2-week interval before the two groups swap over and the first group consumes their typical diet whilst the second group consume kiwifruit for 28 days. We will provide you with enough gold kiwifruit for the duration of the study at no cost to you.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THE STUDY?

You may not benefit directly from participation in this study, but you will be providing a valuable contribution to the scientific knowledge in this field. Your personal results will be provided to you upon request, and you will be informed of the overall outcome of the study.

If you meet the eligibility criteria and are selected to participate in the study, you will be paid **$240.00** for attending all six visits to the clinic and participating in the study. If you choose to withdraw from the study at any time, you will be paid (at a rate of $40.00 per visit) only for the visits you attended up to the date of your withdrawal. Payment for participation in the study will occur after the completion of the final visit.

ARE THERE ANY RISKS INVOLVED?

The study involves providing blood samples on 6 occasions. There is a very minor risk of bruising from venous blood sampling. Bloods will be taken by trained and experienced CSIRO staff. You will be informed of any incidental findings that arise during the study and (with your permission), we will notify your doctor of any results that warrant further investigation.

A small portion of the population have a known allergic reaction to kiwifruit. Allergic reactions range from mild localised swelling/irritations in the mouth to more severe reactions (including anaphylaxis). If you already consume kiwifruit without experiencing an allergic reaction, then it is unlikely you would experience an allergic reaction when consuming kiwifruit as part of this study.

We will also ask you questions about your psychological wellbeing. We understand that some people feel uncomfortable with talking about their psychological wellbeing, so this is another risk to be aware about.

All human research undertaken by the CSIRO must comply with the values, principles, governance and review process specified in the *NH&MRC National Statement on Ethical Conduct in Human Research* (2007, Updated 2018). A copy of the National Statement can be found at https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

HOW WILL MY PRIVACY BE PROTECTED?

Your personal information is protected by the *Privacy Act 1988* (Cth) (Privacy Act). CSIRO will handle your personal information in accordance with this Act and the National Health & Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2007, updated 2018)), or as otherwise required by law.

CSIRO is collecting your personal information, including your name, address, telephone number, date of birth and signature, for the purposes of the Gold Kiwifruit and Psychological Health study and related scientific research. CSIRO may also collect your sensitive information, including information about your health and any medical conditions, for the purposes outlined above. Where you provide the personal or sensitive information of third parties to CSIRO, such as details related to your emergency contact or relatives, you must have consent from these individuals to do so. Where you do not have consent, please do not provide this information.

CSIRO may disclose your personal information to third parties including project partners, university staff and students, health professionals and any third-party service providers involved in the project, for the purposes outlined above. CSIRO may disclose sensitive information, including medical and health information, to your nominated GP or another medical professional, but only with your consent to do so.

CSIRO may disclose information collected about you to CSIRO's industry research partner for this project, Zespri International Ltd for the purposes outlined above, but any such information will be de-identified prior to disclosure so it will not identify you. (Zespri International Ltd is supplying the gold kiwifruit to be used in the study.)

CSIRO is using a third-party platform, Alchemer, to collect information about you on CSIRO's behalf. CSIRO has also engaged Clinpath Pathology (Clinpath) to analyse all blood samples collected during the study. CSIRO will allocate a unique ID number to you before information about you is collected via Alchemer and Clinpath, so that none of your personal information (i.e. information that identifies you) will be intentionally passed on to either third party. You should not provide any identifiable information in your survey responses via the Alchemer platform.

For further information about how Alchemer handles personal information please refer to their privacy policy at: https://www.alchemer.com/privacy/.

Clinpath uses information servers based in Australia and its privacy policy can be found here: www.clinpath.com.au/patients/patient-privacy/. We note that all blood samples you provide will be destroyed following analysis.

CSIRO and/or the industry partner, Zespri International Ltd will publish study results and data in research publications and press releases, however, CSIRO will de-identify any personal information contained in the data and results so that you cannot be identified.

The CSIRO Privacy Policy available at https://www.csiro.au/en/About/Access-to-information/Privacy outlines how your personal information will be handled, including details about how you can seek access or correction of the personal information we hold about you, how you can complain about a breach of the APPs and how CSIRO will deal with the complaint. If you require further information on how your personal information will be handled, please contact privacy@csiro.au.

ALTERNATIVES TO PARTICIPATION

Participation in this research is voluntary and is not your only option. Given the nature of this research, you may wish to make a personal appointment to discuss the appropriateness of this research study for you with your usual GP or healthcare practitioner, who has knowledge of your medical history, prior to deciding whether or not to take part in this research project**.**

WHAT IF I WISH TO WITHDRAW?

You are free to withdraw from the study at any time. If you choose to withdraw, your personal details will be retained along with any data you provide up to the date of your withdrawal. Your details and the data you have provided are an important part of the data set for analytical purposes. It is also important to understand that we can choose to end your participation, too. That decision would be made if we decided that the study is not in your best interest, if you are unable to follow the protocol of the study, or if the study is discontinued.

WHAT ARE MY OBLIGATIONS AS A PARTICIPANT?

You will need to inform a study staff member of any changes in your health (including initiation of, or changes to medications) as some changes could influence your participation in the study. You must also be able to attend all visits and undertake all relevant procedures during the study period.

IF YOU HAVE FURTHER QUESTIONS

Please email, Michael Billows at kiwifruitstudy@csiro.au or phone 8305 0675; or email the Principal Investigator, Dr Ian Zajac at ian.zajac@csiro.au (please mention that you are enquiring regarding the kiwifruit study).

This study has been approved by the CSIRO Human Research Ethics Committee. If you would like to speak with someone with respect to ethical matters or wish to register a formal complaint about the conduct of this research, please contact the Secretary of the Committee via email at chmhrec@csiro.au or phone on (07) 3833 5693.

I have read and understand this Participant Information Sheet.

Name (please print)……

Signature: ..... Date: / /