HUMAN POTENTIAL CENTRE
AN AUT UNIVERSITY RESEARCH CENTRE

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Participant Information Sheet

Study title:
The effect of the autoimmune protocol diet
in people with Rheumatoid Arthritis

	Ethics committee ref.:
Locality: Auckland University of Technology	21/NTB/55
Lead investigator: Julianne Taylor	Contact phone number:
Project Supervisor: Caryn Zinn PhD	021 680703

Invitation to participate

My name is Julianne Taylor, and I am studying a master's degree at the Auckland University of Technology (AUT).

I am inviting you to take part in a research project to investigate the effects of the autoimmune protocol (AIP) diet on rheumatoid arthritis (RA). Whether or not you take part is your choice. If you decide to take part, I thank you. If you decide not to take part, you do not need to give a reason, and there will be no disadvantage to you for not participating, and I thank you for considering taking part. If you want to take part now, but change your mind later, you can withdraw from the study at any time.

This Participant Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 9 pages long, including the Consent Form. Please make sure you have read and understood all the pages. If you have any questions please contact Julianne Taylor, the primary researcher.

Voluntary participation and withdrawal from this study

Your participation in this study is voluntary, and you are free to decline to participate, and if you are already in the study, you are also free to remove yourself at any stage, without any costs, repercussions, or disadvantages.

What is the purpose of the study?

Past research suggests diet changes can help reduce symptoms of RA. Indeed, many people with RA are interested to know if a diet will help them. A number of people with RA have said that a diet called the autoimmune protocol (AIP) has helped them, however it has not yet been tested in a clinical study. The purpose of this study is to test the AIP diet to see what effect it has on quality of life and RA symptoms. We also want to find out how easy or difficult it is for people to put into practice.

How is the Study designed?

This study is a pilot study, which is a small test study, with 10 participants.

The study takes place over 12 weeks, the first 4 weeks with no change in participants' usual diet, the last 8 weeks involve making diet changes; eliminating certain foods and alcohol.

During the study, participants will attend 4 appointments at AUT Millennium in Albany to have measurements recorded, including height, weight and waist circumference, blood pressure, and grip strength.

Weekly online questionnaires will assess quality of life measures such as levels of pain, fatigue, emotional wellbeing, sleep quality, and ability to carry out everyday activities.

A daily diet checklist will be filled in to monitor the foods eaten, and any extra pain relief required.

A three-day food diary will be filled in at 4 weekly intervals for a dietary analysis. This includes taking photos of your meals on your phone using an app.

At the end of the study participants will be interviewed for about 45 minutes, in person or by video conference, to find out about their experience of using the diet, things like its difficulty or ease, cost and time changes from their usual diet, and managing the diet in places outside the home.

Who can take part in this study?

You have been identified as eligible to participate in this study as you fulfil the following criteria:

- ✓ Eighteen years old or over
- ✓ Have clinically confirmed RA for more than 6 months and will provide medical support documents confirming this.
- ✓ You have been on stable medication and supplements for 8 weeks or more.
- ✓ You are currently eating a diet that does not restrict any type of food
- ✓ You are not pregnant, breast feeding, and do not have any of the following: diabetes mellitus, renal impairment, liver disease or other serious illness.
- ✓ You are able to access and use a smart phone and computer and are conversant in English.
- ✓ You can attend 4-weekly appointments at AUT in Albany, Auckland.
- ✓ You can commit fully to participating in the study for 12 weeks, which includes 8 weeks of diet change where you will be asked to exclude certain foods; grains, nuts, seeds, legumes, nightshade plants, eggs, dairy, and alcohol.

Please ask Julianne Taylor if you are unsure about any of these requirements.

What will my participation in the study involve?

Your participation involves taking part in the diet study that is 12 weeks long. The first 4 weeks you will be eating your usual diet, for the following 8 weeks you will be eating the study diet. You will meet with the primary researcher, Julianne Taylor, who is also a registered nutritionist and be given all the information you need; foods to eat and foods to avoid, shopping lists and meal recipes. The study diet restricts you from eating a number of foods, grains, nuts, seeds, legumes, nightshade plants, eggs, dairy and alcohol. You will be supported throughout the study as needed, as well as have the optional opportunity to join a secret Facebook group that includes other study members. Unless you use a pseudonym, other members of the group will be able to identify you.

During the 12 weeks you will be asked to fill in a weekly short (less than 5 minutes) online questionnaire to monitor your RA symptoms, and a daily checklist (less than 1 minute) to ensure your foods are in line with the diet plan. At the beginning of the study and every 4 weeks you will be asked to come into AUT for a number of measurements including your weight, waist circumference, blood pressure, and grip strength, and to meet with the registered nutritionist. A three-day food diary will be filled in at 4 weekly intervals, this includes taking photos of your meals on your phone using an app.

After the study is completed, some participants, the first 3 to start the study, and others if a wider range of experience is needed, will take part in an interview to find out about their experience following the diet plan, any challenges encountered, and how these were managed. The interview will be recorded and take 30 – 45 minutes. If you are interviewed, you do not have to answer any questions you feel uncomfortable answering.

Study timeline:

Week 1: You will have approximately a 1.5-hour appointment at AUT for measurements and instruction. Measurements include height, weight and waist circumference, blood pressure, and grip strength. You will be given a demonstration of online forms to fill out, as well as instructions for filling in a food diary, and take photos of meals.

Week 1-4: Fill in weekly online forms, and a daily checklist, while eating your usual diet with no change.

End week 4: Appointment at AUT to have repeat measurements taken and be given detailed verbal and written instructions from the researcher on the study diet. Fill in the 3- day food diary online, take photos of your meals on your phone.

Week 5 – 12: You will be eating the study diet and continue to fill in the online questionnaire and daily checklist. Support for following the diet will be given weekly as needed from the researcher as well as via the private Facebook group.

Week 8: Appointment at AUT doing repeat measurements. Fill in the 3- day food diary online and take photos of your meals.

End week 12: Appointment at AUT doing repeat measurements. Fill in 3-day food diary online, and take photos of meals. Interview with researcher for approximately 45 minutes on your experience of following the diet programme, either in person at AUT, or via video conference.

What are the time requirements of participating in this research?

The time commitment is approximately 10 hours over the course of the study. This will comprise of:

- Four appointments at AUT for measurements at commencement of study and 4 weekly (4 visits to AUT, 1 hour each plus travel).
- Dietary education of 1 hour.
- Online forms – weekly, time commitment about 5 minutes.
- Food diaries 4 times which take around 30 minutes to complete over 3 days.
- Daily checklist – approximately 1 minute each day.
- Interview at completion of study. Allow 1 hour.

There may be a time cost with regards to food preparation as most meals will need to be prepared from scratch.

What are the possible discomforts or risks of this study?

We do not anticipate any discomfort to you during your participation in this study. You may however experience some temporary side effects from the change in diets, such as gut symptoms or a headache. These are likely to be temporary and easily rectified. The researcher or supervisor is available to discuss your concerns with regards to any physical side-effects you might encounter.

Should any new information with respect to adverse effects of the diet intervention become available during the study that may have an impact on your health, this will be made available to you.

If you, however, do experience any discomfort or distress while participating in the study, the AUT Counselling service can be contacted for a consultation, there is no cost to you for this.

What are the possible benefits of this study?

You will have instruction and support from a registered nutritionist who will guide you through the autoimmune protocol diet, at no cost to you. A possible key benefit of this diet is a reduction in RA symptoms. You may also gain understanding of how certain foods affect your health.

What are the alternatives to taking part?

An alternative to taking part in this research is to seek out dietary advice of this nature in a proactive manner.

Will any costs be reimbursed?

There is no financial commitment required, except for transport costs to and from AUT 4 times during the study. A koha will be given to all participants to assist with this cost. Food eaten in the diet plan may, but not necessarily, be more expensive than your usual diet. Extra food costs are not able to be reimbursed if they are higher than normal.

What if something goes wrong?

It is unlikely that anything will go wrong from a dietary perspective, and the worst that can happen is the change in diet might make symptoms worse, in that case the researcher will be available to advise. If you were injured in this study, for example during data collection, like a grip strength strain, you would

be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

What will happen to my information?

During this study, the researcher Julianne Taylor will record information about you and your study participation. This includes the results of any study assessments. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only researchers (primary researcher, Julianne Taylor and her supervisors Dr Caryn Zinn, Dr Gael Mearns and Dr Rebecca Grainger) will have access to your identifiable information.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researcher. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed. The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Any data collected will not be used beyond this study.

Security and Storage of Your Information

Your identifiable information is held at AUT in a locked cabinet during the study. At the end of the study all information is de-identified. Information is held on a password protected computer in accordance with AUT's data management guidelines. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Consent forms will be kept in a locked cabinet at AUT for 10 years, and thereafter shredded.

Management of interview recordings

Interviews will be recorded on a password protected mobile phone or laptop, and saved as MP4s, and transferred to a password protected AUT computer. They will be deleted from the phone or laptop. Transcripts are identified only by a code, and any information which is likely to identify you (names, locations, etc.) will be obscured. Once the study and associated publications are completed, the recordings will be deleted from the computer.

Risks

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information about you, you should ask the researcher.

Rights to Withdraw Your Information

You may withdraw your consent for the collection and use of your information at any time, by informing your Study Researcher.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

Use of New Technologies

The QuestionPro platform will be used for online questionnaires. Questionnaires will be identified by your ID number only. The information from the questionnaire, and your email address is solely owned by the survey administrator and cannot be shared by any third party. It is password protected and can only be accessed by the survey administrator, researcher Julianne Taylor.

What happens after the study or if I change my mind?

If you change your mind, you may withdraw from the study at any time, without disadvantage, and we will maintain your anonymity.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

If you have questions about any aspect of the study, or if you wish to withdraw, you can contact Julianne Taylor or her supervisors at any time (contact details below).

Following your participation in the study there is no further requirement from you.

Can I find out the results of the study?

Yes, on the consent form you can request a copy of the results. In that case, you will be given a summary of the research within 6 months of the completion of this study.

Who is funding this study?

This study is funded by AUT postgraduate funding.

Who has approved this study?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northern A HDEC has approved this study.

How do I agree to participate in this research?

Please complete and submit the attached consent form.

Will the study results be published?

Yes, we expect the results of the study will be published as an article in an international journal. They will be published as part of Julianne Taylor's Masters' thesis

Where can I get more information, and what it I have concerns about the study?

If you have any questions, concerns or complaints about the study at any stage you can contact:

Julianne Taylor, lead researcher and MPhil student on juliannetaylor@xtra.co.nz or 021 680703.

Caryn Zinn, PhD, the primary study supervisor caryn.zinn@aut.ac.nz

Gael Mearns, PhD, supervisor gael.mearns@aut.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz

Website: https://www.advocacy.org.nz/

For Maori health support please contact :

Name, position Dr Lily Fraser, GP, Turuki Health, Mangere
Telephone number *(09)2755788*
Email *lfraser@thc.org.nz*

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

PARTICIPANT CONSENT FORM

The effect of the auto-immune protocol diet in people with rheumatoid arthritis.

Lead investigator: Julianne Taylor
Project supervisor: Dr Caryn Zinn

Please tick to indicate you consent to the following

I have read in my first language, and I understand the information provided in the Participant Information Sheet.	☐	
I have been given sufficient time to consider whether or not to participate in this study	☐	
I have had the opportunity to use a legal representative, whanau/family support or a friend to help me ask questions and understand the study	☐	
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	☐	
I have had an opportunity to ask questions regarding the study and have them answered to my satisfaction	☐	
I understand that taking part is voluntary (my choice) and that I may withdraw myself from this study at any time, without being disadvantaged in any way	☐	
I consent to the research staff collecting and processing my information, including information about my health.	☐	
If I decide to withdraw from the study, I agree that the information collected about me up to the point I withdraw may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study GP's contact details (optional) Name: Practice: Address: Phone: Email:	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.	☐	
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	☐	
I have answered the questions regarding my health, diet, medication, and supplement use to the best of my ability	☐	

I understand the compensation provisions in case of injury during the study.	☐	
I understand I may take part in an interview at the completion of the study.	☐	
I agree/do not agree to the interview being sound recorded.		
I agree/do not agree to the interview being image recorded.		
I know who to contact if I have any questions about the study in general	☐	
I understand my responsibilities as a study participant and agree to comply with the study requirements.	☐	
I wish to receive a summary of the results from the study	Yes ☐	No ☐

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Declaration by the participant:

I hereby consent to take part in this study.

Signature: ..... **Date:** .....

Full Name - printed .....

Contact Details .....

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____