MASSEY UNIVERSITY
COLLEGE OF SCIENCES
TE WĀHANGA PŪTAIAO

CHAMP Participant Information Sheet

Formal Study title: **Effects of collagen hydrolysate and milk protein on enhancing joint comfort and improving skin appearance**

Sponsor: Massey University, Palmerston North

Funded by: High Value Nutrition Ko Ngā Kai Whai Painga, a New Zealand National Science Challenge

Lead Researcher: Prof Jane Coad

Study Site: Massey University, Palmerston North

Contact phone number: 06 951 6321

Ethics committee ref.: 2022 EXP 12925

You are invited to take part in a study on the effects of collagen and milk protein on joint comfort and skin appearance. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason. If you do want to take part now, but change your mind later, you can pull out of 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. Please feel free to do this.

If you agree to take part in this study, you will be asked to sign a Consent Form at your first visit which is identical to 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 10 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

Participation in this study is completely voluntary. You are under no obligation to accept this invitation. If you decide to participate, we respect your right to:

- Refuse to answer any particular questions
- Bring a support person to the research visits
- Withdraw from the study at any time, without explanation
- Ask further questions about the study at any time while you are taking part
- Provide information on the understanding that it is completely confidential to the researchers. All information will be collected confidentially; it will not be possible to identify you on any reports prepared from the study.
- Be given access to a summary of the research findings when it is concluded.

What is the purpose of the study?

As people get older, they often experience knee pain, which may progress to degenerative joint changes leading to osteoarthritis (OA). OA is a common form of joint disease which can be painful and affect movement and other activities. It is associated with damage to the structure of the joint and related inflammation. There is no cure and treatment of OA usually focuses on management of pain or surgery. Although OA is affected by genes and environmental factors, emerging research suggests diet and lifestyle may also be important.

Collagen supplements are becoming increasingly popular for a range of reasons. They are often marketed as anti-ageing products to enhance skin appearance. There is also some evidence that collagen may affect symptoms of OA or metabolic conditions linked to inflammation, such as metabolic syndrome, but many studies have had inconclusive results.

The aim of this study is to investigate the effects of a novel collagen protein (Suprosol™), extracted from cow hide, on age-related knee pain, skin appearance and inflammatory markers and compare it to milk protein or placebo. Changes in markers of metabolic syndrome will also be assessed because there is an association between these and inflammatory conditions such as OA.

The findings of this study may be important in understanding the causes and identifying new approaches for reducing knee pain and improving OA, a condition which affects over 1 in 10 adults in New Zealand. The results of the study will help to clarify whether collagen supplements are a useful part of the treatment of knee pain.

How is the study designed?

This study will recruit 100 postmenopausal women aged 50 years and over. Participants will be randomly assigned to one of 3 groups; to consume collagen supplements or milk protein supplements or placebo each day for 4 months. Participants will take part in an online or telephone screening questionnaire to check eligibility. If eligible they will visit the Human Nutrition Research Unit (HNRU) at Massey University, for two visits, 4 months apart.

The study will require participants to take the provided supplements for 4 months. Prior to starting the supplements, participants will be asked to record their diet for a period of 4 days, including everything they eat and drink. At the beginning and end of the study, during visits to HNRU, blood samples will be drawn, and a urine sample collected, to assess any

changes in biomarkers of joint health and inflammation. Participants will also have body composition measured and undergo a series of quick and painless tests to assess skin and hair quality, as well as mobility changes. Participants will be asked to provide information about their knee pain and medication use throughout the period of supplement, through online or posted questionnaires completed once a month.

WHO CAN TAKE PART IN THE STUDY?

This study will recruit 100 postmenopausal women (5+ years after last menstrual period) aged 50 years and over with no history of surgery or trauma to the knees; no medically diagnosed heart/renal/hepatic disease, gout or rheumatoid arthritis and other autoimmune inflammatory disorders; not taking prescribed medication for osteoarthritis, other than over the counter pain relief (such as paracetamol); not lactose intolerance or a strict vegetarian (collagen is sourced from animals). Participants will have a BMI below 40 and cannot be heavy smokers or high alcohol consumers

Participants will be selected on the basis of having self-reported knee pain and early signs of osteoarthritis from their score from their answers to the KOOS (Knee injury and Osteoarthritis Outcome Score) questionnaire about knee pain. You must be willing to stop taking dietary supplements from 4 weeks before and during trial.

Participants must be willing to consume a supplement made from milk protein or bovine collagen (or placebo) each day for a 4-month period.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If you decide to take part in this study, after having had time to read the information sheet and ask questions, you will be required to complete the screening questionnaire which will assess whether you meet the selection criteria. This involves answering a few questions related to the inclusion/exclusion criteria and about your knee pain. The screening questionnaire can be completed online or by telephone and takes about 20 minutes.

If you meet the requirements for taking part, you will be randomly assigned to one of 3 groups; to consume either collagen supplements, milk protein supplements or placebo each day. These will be provided to you as powder sealed in foil sachets. In addition, all participants will be provided with multi-vitamin tablets to consume daily throughout the supplement period. You and the researchers will be “blinded” which means not knowing which supplement you will be taking until the study is completed. Randomisation and blinding are required to reduce any bias of the participants and researchers.

A member of the research team will make an appointment with you to visit the Human Nutrition Research Unit on the Massey Palmerston North campus for 2 visits, 4 months apart. You will come to these visits fasted (not having eaten or drunk anything other than water from 9pm the night before). We will provide a light breakfast when the tests have been completed. You should not exercise on the morning you visit the research unit.
The total time involved should be no more than 7 hours over a 4-month period. You will be reimbursed for your travel ($40 voucher at the end of the second visit to the research unit).

Before you come to your first appointment, we will ask you to complete a 4-day diet diary so we have information about your normal diet which we would like you to continue throughout the study. You will be provided with instructions and a template to complete this on.

At the first appointment, you will have the opportunity to ask any questions, after which you will be asked to sign the consent form.
During this visit, which will take about 2-3 hours, we will ask you to:

- Complete a questionnaire about your health, demographic information, normal diet and physical activity, self-assessment of your skin condition, experience of knee pain and use of medication.
- Have your body composition measured using DXA, BodPod and BIA. We are using 3 different machines for these measurements because they provide slightly different information and we can compare the results. As part of the body composition data collection, we will record your weight and height and waist and hip circumferences.
- Have two finger prick blood tests which use tiny amounts of blood to measure your fasting blood glucose level and lipid profile.
- Have a blood sample of about 16mL (equivalent to about 3 teaspoons) taken by an experienced and qualified phlebotomist. This will be used to measure markers of inflammation (such as such as C-reactive protein and interleukins) and markers of cartilage synthesis and breakdown (such as N-terminal type I collagen pro-peptide, C-terminal telopeptide of type II collagen and cartilage oligomeric matrix protein precursor).
- Provide a urine sample (which we will use to measure a marker of collagen breakdown and various nutrients).
- Have assessments of the skin on your upper arms and face which we do by touching your skin with a pen-like probe.
- Provide us with 4 hairs from your head and a couple of finger- or toenail-clippings so we can assess their tensile strength.
- Undertake a series of tests which are standard measurements of knee function, mobility and muscle strength including a Timed Up and Go (TUG) Test, Stair Climb Test (SCT), 30-Second Chair Stand Test (30-CST), 2-Minute Walk Test, and 40-Metre Fast-Paced Walk Test (40-FPWT).
- Review your diet diary with one of the research team who may have some questions.
- Discuss how to incorporate the supplement into your normal diet and collect sachets of powder for the next 4 months. We will provide a table for you to record how and when you consumed the supplement and any side-effects you may have experienced.

We will ask you to complete online questionnaires about your knee pain and medication use at the end of the first, second and third month.
We will make an appointment for you to come back to the HNRU after you have been taking the supplement for 4 months.
We will ask you to collect information about your daily diet before you come back for your final study visit.
At the final visit, we would like you to have fasted overnight as you did before the first visit. We will repeat all the measurements; the visit will take about 2-3 hours.
We will ask you to return any unused sachets of supplement.

Time	Time Involvement	Activity
Before the study starts (screening)	20 minutes	Screening questionnaire: health screen, weight and height measurements (will be done over the phone or through email/online questionnaire)
4 weeks before the study starts	N/A	Stop taking dietary supplements which may interfere with the intervention
1 week before you start	1 hour	Record what you eat and drink for 4 days
Visit 1	2-3 hours	Body composition assessments; blood samples; urine sample; skin and hair assessment; mobility assessment; questionnaire about knee pain and medication use
After 1 month	20 minutes	Complete online or postal questionnaire about your knee pain and medication use
After 2 months	20 minutes	Complete online or postal questionnaire about your knee pain and medication use
After 3 months	20 minutes	Complete online or postal questionnaire about your knee pain and medication use
1 weeks before your final visit	1 hour	Record what you eat and drink for 4 days
Visit 2 (final visit): at 4 months	2-3 hours	Same as for Visit 1 Return any unused supplements

WHAT WILL HAPPEN TO MY BLOOD AND URINE SAMPLES?

When we have taken your blood samples, we will label them with your unique identification code (not your name or other personal information). The blood is spun-down and small volumes of the separated plasma will be transferred into small tubes, all labelled with your unique identification code for later analysis. Some of the measurements will be carried out in our laboratories at Massey and some will be undertaken by a commercial medical laboratory in Christchurch. We measure and send samples in batches so your samples will probably be stored in our secure freezers for several months before being analysed.

The results of the tests will be sent to the research team who will enter the data into coded and password-protected spreadsheets.

Usually, any remaining blood and urine samples will be destroyed after analysis. You may have beliefs about the sacred value of tissue/blood samples. These cultural issues should be discussed with your whanau and family as appropriate. There are a range of views held by Māori in relation to these issues. Some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research studies where this occurs. It is acknowledged that individuals have the right to choose. There will be opportunity for a karakia or prayer if you would like.

All participants have the right to withdraw their samples during the trial.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The supplement powders are commonly consumed as part of a normal diet and are usually well tolerated. It is possible that a participant may experience side-effects such as mild abdominal discomfort. All side-effects should be recorded so the research team can assess them.

Some people dislike having blood taken. Occasionally blood draws can cause bruising. The staff who will take your blood are experienced and it is not expected that this will happen.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

The supplement powders are rich in nutrients which may enhance your health and positively affect your joints and skin. It is possible that you may experience less pain or require less pain relief medication. Indirect benefits include enhanced well-being and mobility. But it is also possible that you may not receive any benefit in taking part on the study. The test results may be beneficial in identifying any abnormal result that you can ask your medical practitioner to investigate further or in reassuring you about your health if all is normal.

WILL ANY COSTS BE REIMBURSED?

The participants will not incur any direct costs.

The participants will be given a gift voucher (Pak-n-Save) to the value of $40 at the end of the second visit to Massey to contribute to travel costs.

The sachets of supplements will be provided by the research study.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, 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 won't affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study, the researcher 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 the study coordinators 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 research team or any study information sent to the sponsor. 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 could identify you.

Security and Storage of Your Information.

Your identifiable information is held at Massey University during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, which is standard practice in research studies, then destroyed. Your coded information will be entered into electronic databases.

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.

Please ask if you would like to access the results of your blood tests during the study.

If you have any questions about the collection and use of information about you, you should ask a member of the research team.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing a member of the research team.

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

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

If you decide that you no longer wish to participate in this study, you need to inform a member of the study team. We will ask you if the data we have already collected from you can still be used for analysis. Your blood samples will be destroyed.
Once all participants have completed the study, we can tell you which treatment group you were allocated to. We cannot provide further supplements.

CAN I FIND OUT THE RESULTS OF THE STUDY?

All participants can request a lay summary of the study findings; we will contact you after the data have been analysed to ask whether you would like the summary of the results. The study is registered with Australia New Zealand Clinical Trials Registry where you can also find out further information; the trial registration number is ACTRN12622000779774p.

WHO IS FUNDING THE STUDY?

The study is funded by High Value Nutrition, one of the 11 National Sciences Challenges. High Value Nutrition is under the supervision of the Ministry of Business, Innovation and Employment (MBIE).

WHO HAS APPROVED THE 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 Health and Disability Ethics Committee has approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

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

Professor Jane Coad, professor of nutrition and study leader
Telephone: 06 9516321
Email: j.coad@massey.ac.nz

Dr Janet Weber, senior lecturer in nutrition and principal investigator
Telephone: 06 9517562
Email: j.l.weber@massey.ac.nz

Katie Schraders, study coordinator
Telephone: 06 9516228
Email: k.schraders@massey.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/

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

Consent Form

Your letterhead

Please tick to indicate you consent to the following

I have read or have had read to me in my first language, and I understand 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 understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
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 when 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.	Yes ☐	No ☐
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 understand the compensation provisions in case of injury during the study.		
I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

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: _____