RADIANT STUDY

THE UNIVERSITY OF SYDNEY

PARTICIPANT INFORMATION STATEMENT

Title	The efficacy and safety of a supplement combination for hand osteoarthritis pain: an internet-based randomised placebo-controlled trial
Short Title	The RADIANT study
Project Sponsor	The University of Sydney
Principal Investigator	Professor David Hunter
Associate Investigators	Dr Xiaoqian Liu, Dr Sarah Robbins, Dr Jillian Eyles, Tatyana Fedorova, Sonika Virk, Leticia Goncalves, Varshini Ravi, Dr Leticia Alle Deveza, Professor Andrew McLachlan

(1) What is this study about?

You have been invited to take part in a research project from the Institute of Bone and Joint Research (IBJR), The University of Sydney. This project is an internet-based study aiming to compare a supplement combination with placebo for people with hand osteoarthritis.

Currently, dietary supplements are widely used by patients with osteoarthritis. Some commonly used supplements such as glucosamine and chondroitin have been proven to be ineffective in reducing osteoarthritis symptoms. However, some lesser-known supplements such as the four listed below have demonstrated promising results in clinical trials, but further research is needed.

- ***Boswellia serrata* extract:** also known as Indian Frankincense, comes from the Indian Boswellia serrata tree. Its natural anti-inflammatory properties may help reduce osteoarthritis symptoms.
- **Pine bark extract:** comes from the inner bark of the Pinus pinaster tree, most commonly found in Europe. It is rich in bioflavonoids that have both antioxidant and anti-inflammatory effects.
- **Methylsulfonylmethane (MSM):** a popular dietary supplement made from organic sulphur, used to treat many symptoms and conditions. One of the most common uses of MSM is to decrease joint or muscle pain.
- **Curcumin:** the active ingredient in Turmeric. It has a potent combination of antibiotic, anti-inflammatory, analgesic and antioxidant effects.

We have developed a new product combining the four supplements above to test its efficacy in people with hand osteoarthritis. This Participant Information Statement tells you more about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this document carefully and ask questions about anything that you don't understand or want to know more about.

(2) Who is running the study?

The study is being carried out by the following researchers:

- Professor David Hunter, Principal Investigator, PhD primary supervisor

  Rheumatology Department, Royal North Shore Hospital, Northern Clinical School, Faculty of Medicine and Health, The University of Sydney; Institute of Bone and Joint Research, Kolling Institute of Medical Research, The University of Sydney.

- Dr Xiaoqian Liu, PhD candidate, Study Physician

  Rheumatology Department, Royal North Shore Hospital, Northern Clinical School, Faculty of Medicine and Health, The University of Sydney; Institute of Bone and Joint Research, Kolling Institute of Medical Research, The University of Sydney.

- Dr Sarah Robbins, Project Manager

  Rheumatology Department, Royal North Shore Hospital, Northern Clinical School, Faculty of Medicine and Health, The University of Sydney; Institute of Bone and Joint Research, Kolling Institute of Medical Research, The University of Sydney.

- Ms Leticia Goncalves, Research Assistant

  Northern Clinical School, Faculty of Medicine and Health, The University of Sydney.

- Ms Varshini Ravi, Research Assistant

  Rheumatology Department, Royal North Shore Hospital, Northern Clinical School, Faculty of Medicine and Health, The University of Sydney; Institute of Bone and Joint Research, Kolling Institute of Medical Research, The University of Sydney.

- Tatyana Fedorova, Senior Research Coordinator

  Rheumatology Department, Royal North Shore Hospital, Northern Clinical School, Faculty of Medicine and Health, The University of Sydney; Institute of Bone and Joint Research, Kolling Institute of Medical Research, The University of Sydney.

- Sonika Virk, Research Coordinator

  Rheumatology Department, Royal North Shore Hospital, Northern Clinical School, Faculty of Medicine and Health, The University of Sydney; Institute of Bone and Joint Research, Kolling Institute of Medical Research, The University of Sydney.

- Dr Leticia Alle Deveza, Rheumatologist

  Rheumatology Department, Royal North Shore Hospital, Northern Clinical School, Faculty of Medicine and Health, The University of Sydney; Institute of Bone and Joint Research, Kolling Institute of Medical Research, The University of Sydney.

- Dr Jillian Eyles, Research Fellow, PhD co-supervisor

  Rheumatology Department, Royal North Shore Hospital, Northern Clinical School, Faculty of Medicine and Health, The University of Sydney; Institute of Bone and Joint Research, Kolling Institute of Medical Research, The University of Sydney.

- Professor Andrew McLachlan, PhD co-supervisor

  School of Pharmacy, Faculty of Medicine and Health, The University of Sydney

Student declaration

Xiaoqian Liu is conducting this study as part of her degree of Doctor of Philosophy at The University of Sydney under the supervision of Professor David Hunter.

Funding declaration

This study is being funded by a grant from the National Health and Medical Research Council (NHMRC). All the money being paid by the sponsor to run the trial will be deposited into an account managed by The University of Sydney. No money is paid directly to individual researchers.

(3) What will the study involve for me?

The study will be a randomised, placebo-controlled, double-blind, 12-week, internet-based trial without any study visits. All procedures will be conducted online and over the telephone.

"Randomised trial": Sometimes doctors don't know the best way of treating patients with a condition, so comparisons need to be made between different treatments. Study participants are placed into groups and given different treatments; then, the results are compared to see whether one treatment is better than the other. To ensure the groups are similar to start with, a computer allocates each study participant into their group randomly, like the flip of a coin. Neither the doctor nor the study participant can decide which treatment the participant receives.

"Blind trial": In a "blind trial" the study participants do not know which treatment group they are in. If the trial is "double-blind", neither the researcher nor the study participant knows which treatment the participant is receiving (although, if the researcher needs to find out, he/she can do so).

"Placebo": A placebo is a dummy treatment that looks like genuine medicine but contains no active ingredient.

Online Screening

If you are interested in this trial, you will be asked to complete an online screening survey to assess if you are suitable for this study. You will be required to read this Patient Information Statement in its entirety before completing the survey.

In the final section of the screening survey, the system will assess your potential suitability automatically, using criteria we have set up in advance. If you are considered unsuitable for the study, you will receive an automatic message at the end of the online screening informing you of that. We will also send you an email listing the reason(s) for exclusion. If you are potentially suitable for this study, you will be asked to provide pictures of both of your hands so that the investigators can assess your hand osteoarthritis. You will need assistance from a friend or family member to take a picture of your hands in the correct position. You will receive instructions on how to take and upload the image into the online survey. For identification purposes, you will also be requested to take and upload a second picture of your hands next to your face.

X-ray Assessment

As part of the online screening, you will be asked if you have had a recent hand x-ray taken (within 36 months) and for your permission to access the x-ray at the imaging facility where it was taken. If the facility does not make the x-ray available digitally, but you possess a hard-copy of it, we will provide you with a pre-paid envelope containing an x-ray bag addressed to us. After the x-ray has been reviewed, we will return it to you. If you have not had a recent hand x-ray within 36 months, we will provide you with a referral letter requesting one. Before sending you the referral, we will need to collect your informed consent (please refer to the section Consenting Checklist and Participant Consent Form for more details).

Within one week of receiving your referral, you will need to have your x-ray taken at one of the Castlereagh Imaging centres which are located throughout greater Sydney region. The x-ray cost will be covered by the study. You will not be allowed to use Medicare to cover the x-ray cost as it is considered a study procedure. We will not reimburse you for any other costs such as travelling to and from the imaging centre. No other x-rays or laboratory tests will be necessary for this study.

After the assessments of your hand photo and x-ray are complete, we will determine your suitability for the study. If you are not suitable, we will contact you by telephone or email. If you are suitable for this study, the study coordinator will give you a call to proceed with a consenting checklist.

Consenting Checklist and Participant Consent Form

The study coordinator will explain the research project and all of the study procedures to you and answer any questions you might have to ensure you fully understand the whole process before you sign the consent form.

Additionally, the study coordinator will instruct you on the medication *"wash-out period"* if required for the study (e.g., if you are taking any anti-inflammatory drugs, opioids or supplements containing the ingredients being studied, you will be asked to stop taking them for at least one week before the study starts or 2 months in case of the supplement). During the study, you will only be allowed to use paracetamol such as Panadol, or Panadol Osteo® as rescue medication for any exacerbation in your symptoms. A maximum of 3000 mg of paracetamol per day will be allowed, that is, if the tablet you are taking contains 500 mg of paracetamol, you will be permitted to take a maximum of six tablets in one day. You will need to record when you take paracetamol and how much. We will collect this information via weekly online surveys. You will be asked to stop taking any paracetamol for one week before your main assessments (weeks 2, 6 and 12). You will be reminded of this on REDCap when completing your monitoring survey at week 1, 5 and 11.

Once you understand the purpose, procedures, benefits and risks of the study, you will be sent a link to the electronic consent form. For identification and safety purposes, you will need to provide the contact details of two next-of-kin before electronically signing the consent form. You will be able to sign the document with your mouse (if using a computer) or with your finger (if using a tablet or smartphone). After signing the form, you will receive a PDF copy of the signed document for your records via email.

After you have provided consent (and undergone the medication wash-out period if needed), you will be invited to complete the baseline survey. The study coordinator might contact you to ask about your hand pain intensity in the one week before you complete the baseline survey.

Baseline Survey

During the baseline survey, you will be asked to provide further information on your demographic characteristics, medical history, previous treatments, medications in use, weight and height. You will also be asked to complete some questionnaires on your pain intensity, hand function, quality of life, use of technology, work productivity, activity impairment and personality traits.

Randomisation

After we have received your completed baseline survey, you will be randomised by a computer to either the active or placebo group. We will then post you a participant information pack, including participant instructions, participant information booklet, and a participant identification card. We will send you a text message advising of when we shipped your information pack.

Active treatment group

If you are allocated to the active group, there will be two different capsules to take daily:

- 1. Combined supplement (blue capsule) containing *Boswellia serrata* extract 250 mg/day, Pine bark extract 100 mg/day, Methylsulfonylmethane 1500 mg/day. Dosage: two blue capsules in the morning and one blue capsule in the evening taken orally with water after meals for 12 weeks.
- 2. Curcumin (red capsule) 168 mg/day. Dosage: two red capsules in the morning and two red capsules in the evening taken orally with water after meals for 12 weeks.

Placebo Group

If you are allocated to the placebo group, there will be two different capsules to take daily:

- 1. Placebo combined supplement (blue capsule) containing microcrystalline cellulose USP. Dosage: two blue capsules in the morning and one blue capsule in the evening taken orally with water after meals for 12 weeks.
- 2. Placebo curcumin (red capsule) containing sunflower seed oil. Dosage: two red capsules in the morning and two red capsules in the evening taken orally with water after meals for 12 weeks.

Study Kit Shipment

Your study kit containing your supplements will be delivered to you by a courier through a company called Pharmaceutical Packaging Professionals (PPP) Pty Ltd. We will need to share your address and contact details with PPP for this purpose.

We will send you a text message when your study kit has been dispatched. You should receive your study kit within 48 to 72 hours of dispatch. You will be asked to notify us by replying the text message (or via email) as soon as you receive your study kit.

Each study kit will be composed of:

- Two white bottles each containing 135 blue capsules of the combined supplement (active or placebo). There will be 270 of these capsules in total.
- Two white bottles each containing 180 red capsules of the curcumin (active or placebo). There will be 360 of these capsules in total.

There are 18 blue and 24 red spare capsules in your study kit to cover any unexpected events (e.g., if you drop one dose on the floor accidentally).

Scheduling Day 1

When you notify us that you have received your study kit, one of our researchers will call you to confirm that you have the correct kit, instruct you on how to take your supplements and to schedule the start date for the study – Day 1.

Follow-up Surveys

You will be required to complete weekly surveys for 12 weeks scheduled from Day 1 assessing supplement compliance, the occurrence of adverse events and the use of rescue medication. At weeks 2, 6 and 12, you will be asked to provide information on your hand symptoms and quality of life. You will be prompted to fill out these online surveys by email. Automatic reminders will be sent in case you don't complete the survey on the scheduled date.

Study Completion

At the end of the week 12 survey, you will be required to complete the work productivity and activity impairment questionnaire, report your treatment satisfaction and provide a capsule count of the remaining supplements, and you will be instructed on how to dispose of them.

After submitting your survey, your treatment allocation (active or placebo) will display on your screen. Please do not reveal your treatment allocation to the study coordinator as she needs to remain blinded to your study treatment group until all of the participants complete the study. You will also receive an automatic email with your treatment allocation and a PDF copy of the disposal instructions.

We will post a gift card to you, which will be blocked for security reasons. You will be instructed to contact us via email (radiant.study@sydney.edu.au) when you receive your gift card so we can activate it for you.

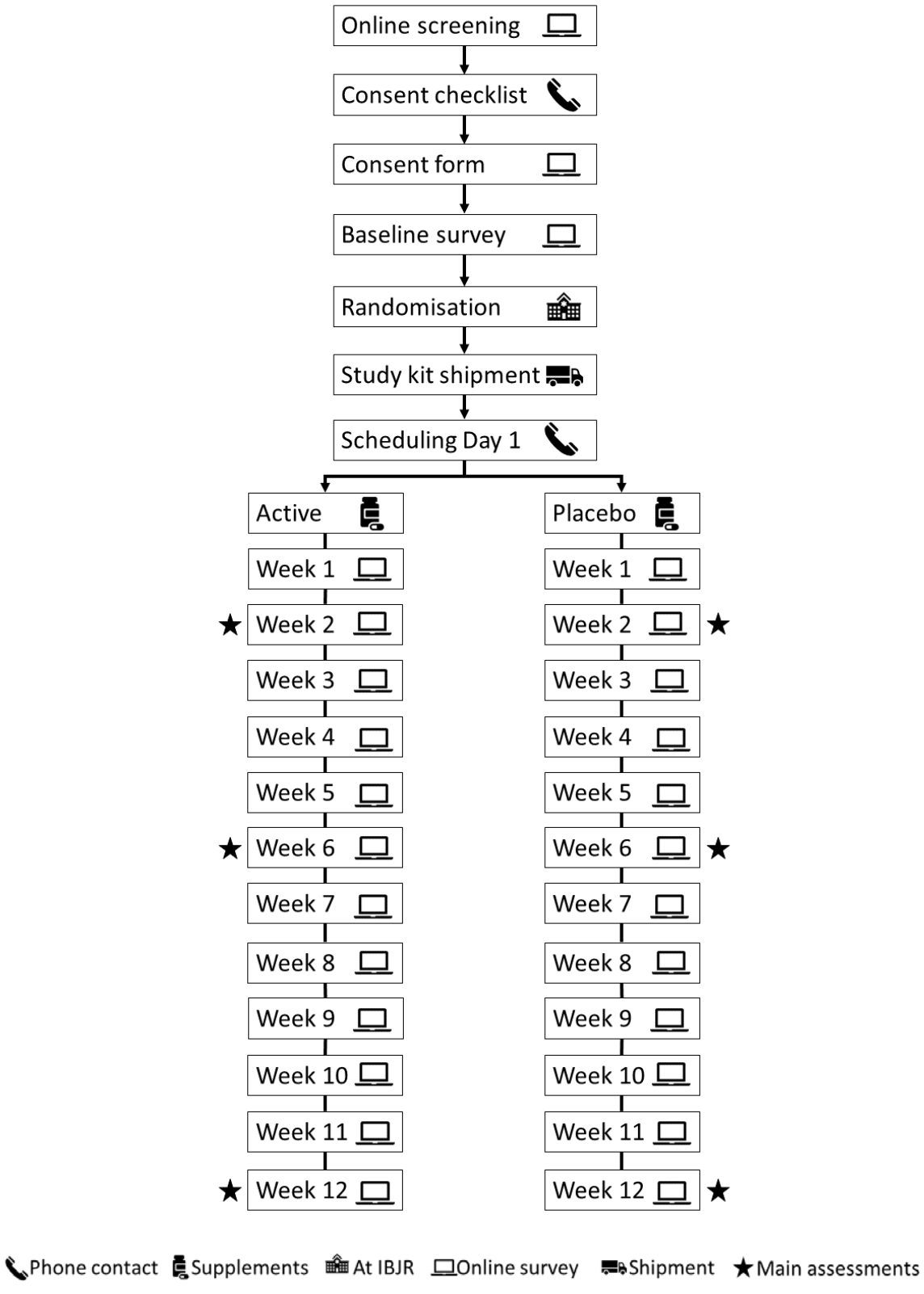
(4) How much of my time will the study take?

This is a 12-week internet-based study. Thus, you will need to be committed to the study for 12 weeks from Day 1 (the day you start taking the supplements). During the study, you will be asked to complete 15 surveys including online screening, consent form, baseline survey and weekly follow-up surveys for 12 weeks.

The online screening will take you around 20 minutes to complete; the consent form might take you 5 minutes, and you will need to allow for up to 1 hour to complete the baseline survey, but you can save it and resume it later at any time. You will be given a "return code" so you can log in later to resume the survey if needed. Please make a note of the return code.

From Day 1, you will be asked to complete weekly surveys which should take you 5-10 minutes to complete, except for weeks 2, 6 and 12, which might take you around 10-15 minutes. There will be no right or wrong answers, and you should complete it as spontaneously as possible.

Please see the study flow chart:



(5) Who can take part in the study?

You might be suitable for this study if you:

- Are an Australia resident
- Are able and willing to participate in the study
- Have an active e-mail account and have access to the internet
- Have at least functional English
- Are 40 years old or older
- Have a clinical diagnosis of hand osteoarthritis
- Have had hand pain due to osteoarthritis for at least half the days in the past month
- Have functional impairment of your hand (i.e., you have difficulties in performing daily tasks such as turning a key, using knife and scissors, clenching your fist)
- Have a digital or hard copy of a hand x-ray taken in the past 36 months, or you are willing to undergo a hand x-ray and are able to travel to a Castlereagh Imaging centre if you haven't had one within 36 months
- Are willing to avoid starting any new treatments for your hand osteoarthritis during the study

You might not be suitable for this study if you:

- Are unable to be reached after completing your screening survey
- Are a woman who is pregnant or breastfeeding, or of childbearing potential but not willing to use contraceptive methods for the duration of the study
- Have any history of inflammatory arthritis (e.g., gout, rheumatoid arthritis)
- Are suffering any painful syndrome of the upper limb contributing to hand pain which may interfere with the evaluation (e.g., joint infection, cubital tunnel syndrome, diabetic neuropathy)
- Had a significant injury in your most symptomatic hand that led to an important loss of function or surgery in the past six months such as fracture, joint dislocation, trauma, laceration or nerve damage
- Have any clinically significant acute or ongoing chronic medical conditions (e.g., uncontrolled diabetes) that could compromise your safety, limit your ability to complete the study, and/or compromise the objectives of the study
- Are currently taking medications known to have potential pharmacological interaction with one or more supplements being tested:
    - antiplatelet/ anticoagulant drugs (e.g. warfarin)
    - immunosuppressants (e.g. prednisone)
    - antidiabetic medication (e.g. metformin, insulin)
    - sulfasalazine, midazolam or norfloxacin
    - chemotherapy drugs (e.g. docetaxel, etoposide)

  - antiretroviral (anti-HIV) drugs (e.g. saquinavir)
- Are allergic to any ingredients of the study products
- Are taking centrally acting analgesics (e.g. opioids, duloxetine and pregabalin) regularly
- Are using anti-inflammatory drugs (oral or topical) on a regular or occasional basis or if you are using centrally acting analgesics on an occasional basis, but you are unable to undergo a 1-week wash-out and/or are not willing to stop these medications for the duration of the study
- Have been taking supplements containing any ingredients of the active study products (i.e., curcumin, *Boswellia serrata* extract, pine bark extract or MSM) and/or are not willing to undergo a 2-month wash-out and to stop using it for the duration of the study
- Underwent a hand surgery in the last 12 months or are planning to have hand surgery in the next six months
- Had any intra-articular injections in your hand of hyaluronic acid in the past six months, corticosteroid in the past months or autologous blood product in the past 12 months
- Are participating in another clinical trial and/or received treatment with any investigational product within 30 days before study initiation

(6) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary, and you do not have to take part in it. Your decision about whether to participate will not affect your current or future relationship with the researchers or anyone else at The University of Sydney. If you decide not to participate, it will not affect the treatment you receive now or in the future. Your decision will not affect your relationship with the staff caring for you.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by contacting the study coordinator on phone number 02 9926 7821 or email radiant.study@sydney.edu.au and signing the withdraw form. If you decide not to take part in the study, you must discuss treatment alternatives with your doctor.

What data CAN and CAN'T be withdrawn

If you decide to withdraw from the study, please notify the study coordinator and/or a member of the research team before you withdraw. This notice will allow the study physician to discuss any health risks or special requirements linked to withdrawing. If you do withdraw your consent during the research project, we will not collect any more information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with the law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want us to do this, you must tell the study coordinator and/or a member of the research team before you join the research project.

(7) Are there any risks or costs associated with being in the study?

The ingredients of the supplement combination used in this study are dietary 'nutraceuticals'. We do not expect that there will be any major risks associated with the supplements; however, the combination of the supplements has not been tested yet in clinical trials. Although this study is of nutraceuticals, these are being given in unnatural dosages as a medicine. There is a possible risk of an interaction between curcumin and anticoagulant (blood-thinning) medications. The risk in pregnancy is unclear. There have not been any major side effects reported for the other supplements used in the study.

The possible side-effects that may occur following use of the supplements include diarrhoea, bloating, abdominal pain, nausea, reflux, dizziness, low blood pressure, headache, fatigue, trouble sleeping, increased risk of bleeding and bruising, itching or worsening of allergy symptoms and a possible decrease in blood sugar levels.

This research study might involve exposure to a very small amount of radiation (if you require a hand x-ray). As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a radiation dose of about two millisieverts (mSv) each year. The effective dose from this study is about 0. 001mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal.

Participation in this study will not cost you anything financially. If you need to have a new x-ray taken, we will cover the cost.

(8) What happens if I suffer injury or complications as a result of the study?

If you suffer any injuries or complications as a result of this study, you should contact the study coordinator as soon as possible, who will assist you in arranging appropriate medical treatment. You are advised to use emergency services by dialling "000" in case of any severe injury or complications.

You will be provided with a Participant Information Card (PIC) stating that you are taking part in a clinical trial, the contact details of the study coordinator, and what to do in emergencies. You will be required to keep this card with you at all times during the study duration so that any physician can note your involvement with the study. This may be useful in the case of any complications that may arise, related or unrelated to the study.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the supplements or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from the compensation received.

If you are not eligible for compensation for your injury or complication under the law but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

(9) Are there any benefits associated with being in the study?

You will be reimbursed for your time and participation with a $50 gift card after the study completion. This study will enhance medical knowledge and may improve the future treatment of hand osteoarthritis; however, it may not directly benefit you.

(10) What will happen to information about me that is collected during the study?

Your personal information will be collected and managed by the Research Electronic Data Capture (REDCap) designed to help researchers for building and managing online surveys, which is hosted at The University of Sydney server.

The answers you give on the personality questionnaire in the baseline survey will be shared with Tools4Patient, an innovative company dedicated to exploring the placebo effect in different patients and conditions. Your information (e.g., medical history, medications in use, age, weight and height) will be anonymised before being shared. Tools4Patient is located in Belgium, thus part of the European Union. There are very strict rules applying to privacy and security of electronic data; by law, Tools4patient must comply with those legal requirements.

Additionally, we will share your details (name, date of birth, postal address and contact number) with PPP so they can dispense and ship your study kit to you. This information will be sent using encrypted files and only the PPP staff receiving this document will have access to your information.

Your information will be stored securely, and your identity will be kept strictly confidential, except as required by law. Only the researchers involved in the study, the PPP staff and the Human Research Ethics Committee (HREC) for monitoring purposes will have access to your details.

All electronic study files will be password-protected. The privacy, security and ownership of all research data will be maintained by The University of Sydney and will not be stored or accessible by another organisation. Physical documents containing identifiable information be stored in a locked cabinet throughout the study. Any files containing identifiable information will be encrypted before being shared with another organisation (e.g., PPP).

The study findings may be published in PhD thesis, journal publications, conference presentations, and other reports, but you will not be individually identified in these publications. You may request access to your results from the study.

We will keep the information we collect for this study, and we may use it in future projects related or not to this project. By providing your consent, you are allowing us to use your anonymised information in future projects. We don't know at this stage what these other projects will involve. These future projects will seek ethical approval before using the information from this study.

Three years after we perform the study close-out, we will publish all collected data in a data repository to share it with other researchers around the world. All information published will be de-identified, and it will be impossible for anyone to identify your data.

(11) What will happen to my treatment when the study is finished?

The products in this study will not be available after the study finishes. You will need to consult with your GP about the most appropriate treatment for you at that time.

(12) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(13) What if I would like further information about the study?

When you have read this information, our study coordinator will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact the study coordinator (Sonika Virk) on phone number 02 9926 7821 or via email radiant.study@sydney.edu.au.

(14) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. This feedback will be in the form of *one-page lay summary.* You will receive this feedback after the study is finished by all participants, and the results have been analysed.

(15) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called the Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of The University of Sydney (protocol number: 2018/766). As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, The University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** human.ethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep

RADIANT STUDY

THE UNIVERSITY OF SYDNEY

e-PARTICIPANT CONSENT FORM (REDCap)

Participant's declaration

- ✓ I have read the Participant Information Statement, and I understand the purpose of the study and any risks/benefits involved.
- ✓ I have had the opportunity to ask questions, and I am satisfied with the answers I have received.
- ✓ I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.
- ✓ I understand that I will be given a copy of this document to keep.
- ✓ I agree to share my postal address with Pharmaceutical Packaging Professionals for shipment purposes

For identification and safety purposes, please provide the contact details of two next-of-kin.

1) Full name: _____ Phone number: _____

2) Full name: _____ Phone number: _____

Your full name: _____

Signature: _____ Date: ____/____/_____

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THE UNIVERSITY OF SYDNEY

WITHDRAWAL OF CONSENT FORM

Title	The efficacy and safety of a supplement combination for hand osteoarthritis pain: an internet-based randomised placebo-controlled trial
Short Title	The RADIANT study
Project Sponsor	The University of Sydney
Principal Investigator	Professor David Hunter
Associate Investigators	Dr Xiaoqian Liu, Dr Sarah Robbins, Dr Jillian Eyles, Tatyana Fedorova, Sonika Virk, Leticia Goncalves, Varshini Ravi, Dr Leticia Alle Deveza, Professor Andrew McLachlan

Participant's declaration

I wish to WITHDRAW my consent to participate in the study described above and understand that such withdrawal WILL NOT affect my routine care or my relationships with the researchers at The University of Sydney. I further understand that any information that has already been collected before I withdrew my permission will be kept and, where the law allows, my personal health information, will continue to be used by the study investigator.

Full name: _____

Signature: _____

Date: ___/___/_____

The completed form should be forwarded to **Sonika Virk** by post or email:

Email: radiant.study@sydney.edu.au

Telephone: 02 9926 7821

Address: Rheumatology Department, Royal North Shore Hospital

Level 7, Clinical Administration 7

St Leonards, NSW 2065