Participant Information Sheet

(for the primary participant)

Exploring brain-to-brain synchrony between individuals in love.

Formal study title: Neural Correlates of Love: An EEG-based Hyperscanning Study.

Sponsor: University of Otago, Otago Medical School.

Lead investigator(s): Prof. Dirk De Ridder & Dr. Divya Adhia

Contact phone number: 03 470 9337

Study site: Dunedin hospital, Otago Medical School, University of Otago, NZ.

Ethics committee ref: H21/105

As the "primary participant", you are invited to take part in a study exploring the brain-to-brain synchrony between two individuals in love, compared to two close friends, and two strangers. 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, and it won't affect the care you receive. 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 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 10 pages long, including the Consent Form. Please make sure you have read and understood all the pages well.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THE STUDY

- **Your participation in this study is voluntary and you can decline to participate.**
- **You may withdraw from this project at any time and without any disadvantage to you of any kind. The study researcher may decide to withdraw you from the study if there are any side effects from the procedure or if they have any other concerns.**

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to identify the brain regions that synchronise while looking into each other's eyes, between romantic lovers when compared to between friends and strangers using a non-invasive brain scanning technique [electroencephlography (EEG)-based hyperscanning].

The results obtained from this study will help us to develop new brain stimulation treatments for improving health outcomes in individuals diagnosed with brain disorders like social phobia, autism, schizophrenia, chronic anxiety, major depressive disorders, and personality disorders by altering their functional brain networks.

HOW IS THE STUDY DESIGNED?

This study will involve simultaneously recording the electrical activity of the brains of two participants at a time on separate days. The participants will be divided into three groups:

- Pair who are in romantic love (i.e., Primary participant and their partner)
- Pair who are in close friendship (i.e., Primary participant and their partner)
- Pair who don't know each other (i.e., Primary participant and a stranger)

The primary participant will be in all the three groups and their scanning session with the other participant (i.e., their partner, their friend, or a stranger) will be randomised to be conducted on separate days.

WHO CAN TAKE PART IN THE STUDY?

We are seeking approximately 80 healthy participants in total:

- 20 couples in romantic love, for at least one month and a maximum of 12 months.
- 20 friends (one each) of the primary participant and of opposite sex
- 20 age matched strangers of opposite sex

The couples will mutually agree and decide on who will be the primary participant for the study. The primary participant will be required to invite a close friend who is not in love (and of opposite sex) for participating in the study.

We are asking you to take part as the primary participant.

You are not eligible to participate if you:

- Are left dominant.
- Have a history of epilepsy or seizures, or substance abuse.
- Have history of neurological conditions (e.g., stroke, multiple sclerosis, spinal cord injury), cognitive impairments (e.g., dementia, Alzheimer's disease), or psychiatric disorders (e.g., schizophrenia, bipolar disorder, or other psychotic illness).
- Have previously had brain surgery.
- Have any electronic implants (i.e., pacemaker or defibrillator), or metal implant in your body (particularly head and neck).
- Are currently pregnant or had a recent pregnancy (i.e., in the last 6 months).

- Have any current severe acute or chronic medical illnesses, dyslipidaemia, hyperacusis, uncontrolled or untreated hypertension, or are currently undergoing any therapy for any medical condition.

Screening: You will be screened by the study investigator for your eligibility to participate in this study. You will need to complete an online screening questionnaire.

Your partner will also complete questionnaires about love and friendship individually, and their responses to the questionnaires **will not be shared** with you.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

As the primary participant for this study, you will be required to attend four testing sessions.

Each session will take ~1.5 hour at the Dunedin hospital (6th floor, Room 626). The following procedures will be conducted after obtaining written informed consent.

Session 1: Baseline testing session

This session will take ~1 hour at the Dunedin hospital (6th floor, Room 626). The following procedures will be conducted after obtaining written informed consent.

- **Questionnaires:** You will be asked to complete a short questionnaire about your demographics (age, sex, ethnicity, etc). You will also complete questionnaires about love and friendship before and after the brain wave testing session. Your responses to the questionnaires **will not be** shared with any other participant.

- **Brain wave testing:** In the baseline session you will be asked to wear a cap with electrodes attached to it (see Picture 1). According to the Tikanga Māori, the head is considered sacred “he tapu te upoko”. The researcher will obtain permission from you before touching your head. A pair of electrodes will be placed on your chest and your fingers to record your heart activity and skin response, respectively. Your brain activity will be recorded (for 10 minutes) while you rest in a comfortable chair, with your eyes open.

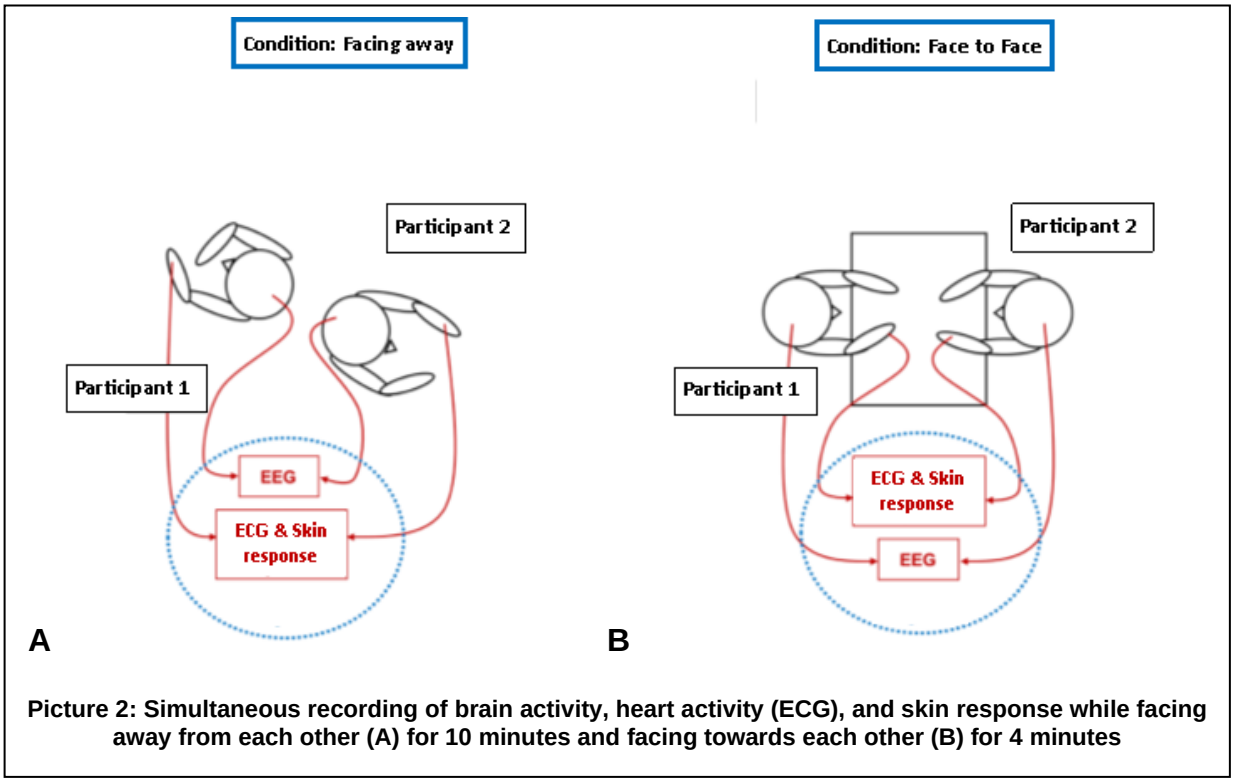
Picture 1. Brain wave testing cap with electrodes

- **Randomisation:** Following the baseline testing session, your next session will be randomly assigned to record your brain activity with either:
  1. Your partner or
  2. Your friend or
  3. A stranger

  The testing session will be required to be at the same time of the day, as your baseline testing session.

- **Session 2 to Session 4: Simultaneous Brain wave testing:** You and another participant (partner, friend or stranger) will be asked to wear a cap with electrodes attached to it (see Picture 1). The researcher will obtain permission from you before touching your head. A pair of electrodes will be placed on your chest and your fingers to record your heart

activity and skin response respectively. Your brain activity will simultaneously be recorded (for 10 minutes) with the second person, while you both rest in a comfortable chair with your eyes open and while you face away from each other (See Picture 2A). Following this, you and the second person will be asked to look into each other eyes and your brain activity, heart activity (ECG), and skin response will simultaneously be recorded for an additional 4 minutes (See Picture 2B).



Picture 2: Simultaneous recording of brain activity, heart activity (ECG), and skin response while facing away from each other (A) for 10 minutes and facing towards each other (B) for 4 minutes

WHAT I CAN AND CANNOT DO DURING THE STUDY PHASES?

As the electrical activity of the brain activity can be affected by various factors, we request you ***avoid*** the following **before the testing session**:

- Eating large meals for 2 hours before the session (light snacking is OK).
- Drinking alcohol for 24 hours before the session.
- Smoking for 4 hours before the session.
- Consuming caffeinated drinks an hour before the session.
- Applying any hair products (oil, gel) before the session.

You will be provided with some refreshments (e.g., crackers, tea, or juice) after each session.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF THIS STUDY?

- Previous studies have demonstrated that this type of simultaneous recording of the brain activity is a safe procedure. There should not be any side effects but if there are any, they should be mild and disappear soon after.
- You will be closely monitored for your responses during all the testing procedures, and sufficient rest will be provided between each test. Any side effects will be formally recorded and addressed if medical attention is required.

- The brain activity recordings may possibly reveal unusual findings. If this is the case, we discuss the findings with you, inform your GP/current healthcare provider, and make referrals to appropriate treatment providers.
- There are no direct benefits to you from participating in this study. However, this study will help advance the understanding of brain responses during social interaction and will help develop new treatments for disorders of social interaction (e.g., depression, chronic pain, autism, and schizophrenia).

WILL ANY COSTS BE REIMBURSED?

There will be no costs to you for participating in the study.

You (as the primary participant) will receive a $20 petrol voucher as a reimbursement for your travel and parking expenses, for attending each testing session (total for the four sessions will be $80).

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 research staff will record information about you and your study participation. This includes the results of various measures (e.g., ratings about love, friendship, brain activity, heart activity) by way of questionnaires, and assessments. If needed, information from your hospital records and your GP may also be collected. 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 involved in the research program will have access to your identifiable information. Identifiable information will be destroyed at the end of the project.

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 in an international scientific journal or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information:

If you agree, your coded information may be used for future research related to the brain-to-brain synchrony. If you agree, your coded information may also be used for other medical and/or scientific research that is unrelated to the current study.

This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.

You will not get reports or other information about any research that is performed using your information.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use once your information has been shared for future research.

Security and Storage of Your Information:

Your identifiable information is held at the University of Otago during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

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 brain scan tests during the study. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study's scientific integrity.

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 Doctor.

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.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you change your mind, you can withdraw from the study at any time by informing the study doctor.

After the study is completed, the data will be securely stored in a locked filing cabinet and only those involved in the research program will have access to it. Personal information such as contact details and names will be destroyed at the end of the project. Data on which the results of the study depend will be kept in secure storage for ten years, after which it will be destroyed.

The study results will be published in an international scientific journal. Only a summary of the data will be mentioned in the research publication. The data included in the publication will in no way be linked to any specific person, and your identity will not be recorded with the data. At the testing session, you will be given a unique identification code, and your data will be linked to that code only. You are most welcome to request a copy of the study results. These will be available in approximately June 2023.

All the data will be de-identified and linked to a unique identification study number, and no personal information about the participants will be shared.

WHO IS FUNDING THE STUDY?

This study has been funded by internal funds from the Otago Medical School.

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 University of Otago Human Ethics Committee has approved this study (Ref: H21/105).

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:

Name: Dr. Paul Turner **Position**: Assistant Research Fellow **Department:** Department of Surgical Sciences, University of Otago, Dunedin.	**Phone number:** 03 470 9337 **Email**: paul.turner@otago.ac.nz
Name: Dr. Divya Adhia **Position**: Research Fellow **Department:** Department of Surgical Sciences, University of Otago, Dunedin.	**Phone number:** 03 470 9337 **Email**: divya.adhia@otago.ac.nz
Name: Professor Dirk De Ridder **Position**: Chair, Neurosurgery **Department:** Department of Surgical Sciences, University of Otago, Dunedin.	**Phone number:** 03 470 9337 **Email**: dirk.deridder@otago.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 :

If you require Māori cultural support talk to your whānau in the first instance.

To ensure ongoing cultural safety the Maori Research Review Committee of the University of Otago and Southern District Health Board encourage those who identify themselves as Maori and who are participating in health research or clinical trials to seek cultural support and advice from either Mo Wai Te Ora – Maori Health Services or their own Kaumatua or Whaea.

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

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

Consent Form

Exploring brain-to-brain synchrony between individuals in love.

By signing this form, you indicate your consent to the following:

I have read, or have had read to me, 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 pull out 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.		
I understand the risks associated with the testing procedure, which are explained in the Participant Information Sheet.		
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics 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 know that I will be given petrol voucher to reimburse the travel costs associated with participating in the study.		
I understand the compensation provisions in case of injury during the study.		
I know whom to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
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 ☐
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 wish to receive a summary of the results of the study.	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by a member of the 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:
