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| A patient information leaflet for adults with hallux valgus  The following researchers will be conducting the study: | | |
| **Role** | **Name** | **Organisation** |
| Principal Investigator | Dr Matthew Cotchett | School of Allied Health, Discipline of Podiatry, La Trobe University |
| Co-investigator | Steven Edwards | School of Allied Health, Discipline of Podiatry, La Trobe University |
| Co-Investigator | Dr Rebecca Jessup | School of Allied Health, Discipline of Podiatry, La Trobe University |
| Co-investigator | Professor Hylton Menz | School of Allied Health, Discipline of Podiatry, La Trobe University |
| **Research funder** | This research receives in kind support from La Trobe University. | |

1. **What is the study about?**

You are invited to participate in a study which is designed to develop a patient information leaflet for people with hallux valgus (also known as a bunion). We hope to learn about your beliefs and expectations about what a patient information leaflet should include for people with this condition.

Your contact details were obtained from a database of people who have been attending the La Trobe University Podiatry Clinic for foot-related treatment or you might have responded to an advertisement posted at La Trobe University or of the clinic of a health professional.

1. **Do I have to participate?**

Being part of this study is voluntary. If you want to be part of the study we ask that you read the information below carefully and ask us any questions.

You can read the information below and decide at the end if you do not want to participate. If you decide not to participate this won’t affect your relationship with La Trobe University or any other listed organisation.

1. **Who is being asked to participate?**

You have been asked to participate because:

* you are over the age of 18 and have had a painful hallux valgus for the past 3 months, or
* you are a health professional that currently manages people with hallux valgus

1. **What will I be asked to do?**

If you want to take part in this study, you will be asked to attend two focus groups. The first focus group will involve talking about your preferences for the content and design of a patient information leaflet for people with hallux valgus. The second focus group will involve providing feedback on a leaflet that was designed based on your input from the first focus group.

Each focus group will take approximately 60 minutes to complete.

| Example procedures | Assessment/task | Online Screening  Time: 5 minutes | Focus Group One  Time: 60 minutes | Focus Group Two (four weeks after Focus Group One)  Time: 60 minutes |
| --- | --- | --- | --- | --- |
| Eligibility | X | X | X |

Observational notes and audio recordings will be collected from the focus groups.

1. **What are the benefits?**

All participants will be provided with a $50 shopping voucher for their participation in the study. In addition, information gathered by participants in this study will be used to guide and develop a patient information sheet for people with hallux valgus. It is envisaged that this resource will help people with hallux valgus to make mor informed decisions about the treatment of hallux valgus as well as supporting clinicians who manage this condition.

1. **What are the risks?**

With any study there are (1) risks we know about, (2) risks we don’t know about and (3) risks we don’t expect. If you experience something that you aren’t sure about, please contact us immediately so we can discuss the best way to manage your concerns.

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| **Name/Organisation** | **Position** | **Telephone** | **Email** |
| Dr Matthew Cotchett | Chief Investigator | 5444 7213 | m.cotchett@latrobe.edu.au |

We do not foresee any risks associated with this study.

1. **What will happen to information about me?**

We will collect information about you in ways that will reveal who you are

We will **store** information about you in ways that will not reveal who you are.

We will **publish** information about you in ways that will not be identified in any type of publication from this study.

We will **keep** your information for 7 years after the project is completed. After this time we will destroy all of your data.

The storage, transfer and destruction of your data will be undertaken in accordance with the [Research Data Management Policy](https://policies.latrobe.edu.au/document/view.php?id=106/) <https://policies.latrobe.edu.au/document/view.php?id=106/>.

The personal information you provide will be handled in accordance with applicable privacy laws, any health information collected will be handled in accordance with the Health Records Act 2001 (Vic). Subject to any exceptions in relevant laws, you have the right to access and correct your personal information by contacting the research team.

1. **Will I hear about the results of the study?**

We will let you know about the results of the study on request. This may entail mailing a summary of the results (which will not be identifiable) to your home residence. If you prefer, a discussion with Dr Matthew Cotchett can occur in person”.

1. **What if I change my mind?**

You can choose to no longer be part of the study at any time until [four weeks] following the collection of your data. You can let us know by:

1. Completing the ‘Withdrawal of Consent Form’ (provided at the end of this document);
2. Calling us; or
3. Emailing us

Your decision to withdraw at any point will **not** affect your relationship with La Trobe University or any other organisation listed.

When you withdraw we will stop asking you for information. Any identifiable information about you will be withdrawn from the research study. However, once the results have been analysed we can only withdraw information, such as your name and contact details. If results haven’t been analysed you can choose if we use those results or not.

1. **Who can I contact for questions or want more information?**

If you would like to speak to us, please use the contact details below:

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| --- | --- | --- | --- |
| **Name/Organisation** | **Position** | **Telephone** | **Email** |
| Dr Matthew Cotchett | Chief Investigator | 5444 7213 | m.cotchett@latrobe.edu.au |

1. **What if I have a complaint?**

If you have a complaint about any part of this study, please contact:

|  |  |  |  |
| --- | --- | --- | --- |
| **Ethics Reference Number** | **Position** | **Telephone** | **Email** |
| HEC22353 | Senior Research Ethics Officer | +61 3 9479 1443 | [humanethics@latrobe.edu.au](mailto:humanethics@latrobe.edu.au) |

**Consent Form – Declaration by Participant**

I (the participant) have read (or, where appropriate, have had read to me) and understood the participant information statement, and any questions have been answered to my satisfaction. I agree to participate in the study, I know I can withdraw at any time until [four weeks] following the collection of my data. I agree information provided by me or with my permission during the project may be included in a thesis, presentation and published in journals on the condition that I cannot be identified.

**[DELETE - Option/s that are irrelevant to the study]**

I would like my information collected for this research study to be:

Only used for this specific study;

Used for future related studies;

Used for any future studies

**[INSERT/DELETE - Applicable statements]**

I agree to have my interview audio recorded

I agree to have biospecimens collected

I would like to receive a copy of the results via email or post. I have provided my details below and ask that they only be used for this purpose and not stored with my information or for future contact.

|  |  |  |
| --- | --- | --- |
| **Name** | **Email (optional)** | **Postal address (optional)** |
|  |  |  |

**Participant Signature**

I have received a signed copy of the Participant Information Statement and Consent Form to keep

|  |  |
| --- | --- |
| Participant’s printed name |  |
| Participant’s signature |  |
| Date |  |

**Declaration by Researcher**

I have given a verbal explanation of the study, what it involves, and the risks and I believe the participant has understood;

I am a person qualified to explain the study, the risks and answer questions

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| --- | --- |
| Researcher’s printed name |  |
| Researcher’s signature |  |
| Date |  |

\* All parties must sign and date their own signature

**Withdrawal of Consent**

I wish to withdraw my consent to participate in this study. I understand withdrawal will not affect my relationship with La Trobe University of any other organisation or professionals listed in the Participant Information Statement. I understand the researchers cannot withdraw my information once it has been analysed, and/or collected as part of a focus group.

**I understand my information will be withdrawn as outlined below:**

* Any identifiable information about me will be withdrawn from the study
* The researchers will withdraw my contact details so I cannot be contacted by them in the future studies unless I have given separate consent for my details to be kept in a participant registry.
* The researchers cannot withdraw my information once it has been analysed, and/or collected as part of a focus group

*\*\*if you have consented for your contact details to be included in a participant registry you will need to contact the registry staff directly to withdraw your details.*

I would like my already collected and unanalysed data

Destroyed and not used for any analysis

Used for analysis

**Participant Signature**

|  |  |
| --- | --- |
| Participant’s printed name |  |
| Participant’s signature |  |
| Date |  |

**Please forward this form to:**

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| --- | --- |
| CI Name | Dr Matthew Cotchett |
| Email | m.cotchett@latrobe.edu.au |
| Phone | (03) 5444 7213 |
| Postal Address | Kingsbury Drive, Bundoora, Victoria, Australia, 3086 |