PARTICIPANT INFORMATION SHEET


Research team:
Principal Investigator: Professor Keith Petrie
Student Researcher: Chiara Gasteiger
Co-Investigator: Professor Nicola Dalbeth

Project description and invitation

You are invited to take part in a study examining how healthcare professionals can explain biosimilars to patients. Some rheumatology patients in New Zealand may be asked to change from their bio-originator treatment to biosimilars in the near future. However, some physicians are unsure how to explain biosimilars to patients. You are invited to participate in a study investigating how to communicate changing to a biosimilar to people and their companion. This study is aiming to recruit 52 participants and 52 companions to assess a healthcare professional’s delivery of information about biosimilars. This letter contains an overview of the study to help you make an informed decision as to whether you would like to take part in this research.

This study is being carried out by Chiara Gasteiger, a PhD candidate from the Department of Psychological Medicine, and Professors Keith Petrie (Psychological Medicine) and Nicola Dalbeth (School of Medicine) who are supervising the project.

What does the study involve?

To take part in this research you must be 18 years of age or older, be able to read and write in English and have a companion who is willing to take part with you. Your companion can be a friend, family member or romantic partner, who is fluent in English, 18 years of age or older and who you have known for at least six months. You must both be able to attend one approximate 40-minute session at the Clinical Research Centre (Grafton Campus) together.

If you and your companion are eligible and choose to participate in this study, the researcher will arrange a time for you both to complete one in-person study session at the Clinical Research Centre, University of Auckland Grafton Campus. At this session, you will both be asked to complete a questionnaire covering your demographics and various measures such as your preferences for shared decision-making. Following this, you will receive some information on bio-originators and a clinic letter together. You will then be asked to attend a mock consultation, where a healthcare provider will give you some information about a medication called a biosimilar. During this mock consultation, it is important that you act as you would during a normal medical appointment, attending with a companion (support person). You may be asked to
briefly discuss the medication and make a hypothetical treatment decision together. After the mock consultation, you will both be asked to complete another questionnaire.

You will not be asked to take any treatments during this consultation or disclose any private health information. Your data will not affect any decisions made in your future health care. This study is based on a hypothetical medical scenario.

If you and your companion have consented, you may both be invited to take part in a brief (5 to 10 minute) audio-recorded interview together. You may be able to take part immediately after the study session, otherwise we can arrange a time that suits you both. You may refuse to answer any questions and are free to leave the interview without having to give a reason. However, because of the nature of the interview, the recording device cannot be turned off during the discussion and, if you withdraw from the research, information you have contributed up to that point cannot be withdrawn. Taking part in this interview gives you the choice to enter a draw to receive a $50 shopping voucher as a thank you for your extra time.

**Benefits and risks**

There are no expected risks or discomforts associated with this study. By taking part in this study, you can help us understand what information patients and their whānau may want to know about changing to biosimilars. The findings from this study may help develop future patient communication strategies.

**Who pays for the study?**

You will not incur any financial costs due to participation in this study. To thank participants for their contribution to the research, you will both receive a $40 voucher (Westfield/MTA gift cards). This research is funded by the Department of Psychological Medicine at the University of Auckland as part of a PhD in Health Psychology.

**Your rights as a participant**

Participation in the study is entirely voluntary. Whether or not you participate in this study will not affect your relationship with the researchers. If you are a student of the researchers, we give our assurance that your participation or non-participation in this study will have no effect on your grades or relationship with the University and that you may contact your Head of Department should you feel that this assurance has not been met.

If you choose to participate, you can change your mind at any time without any negative consequences. You can withdraw from the study at any time without giving a reason and withdraw any data traceable to you up until one week following your completion of the study. You will be given a copy of this document to keep. If you withdraw you will still receive a gift card.

All personal information will remain confidential and no material that could personally identify you will be used in any report on this study. Participant names will only appear on the consent form, which will be coded with a participant identification number so that your identity is kept confidential on all questionnaires. After completion of the study, all confidential data, including computer data files, recordings and transcriptions, will be stored for a minimum period of six years to allow for publication and re-analysis, after which time it will be securely and confidentially...
disposed of. Research publications and presentations from the study will not contain any information that could identify you.

What will happen after the study?

All data will be stored by the researcher in electronic format: in a password protected data file on a University of Auckland computer. Paper consent forms will be stored in a locked filing cabinet in the researcher’s office at the University. Data and consent forms will be kept for a period of six years. You will be given the option of requesting a summary of the results of this study. If you select on the Consent Form that you would like to receive a summary, it will be sent to you via email once the study has been completed. As it takes some time to analyse the results of studies, it may be more than a year after your participation that you receive this information.

We appreciate the time you have taken to read this information. If you have any questions please contact:

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Māori cultural support:
If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324.

If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

AHREC Chair contact details:
For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 ext 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

This study has been approved by the Auckland Health Research Ethics Committee (AHREC) on 23/07/2021 for three years (ref: AH22772).