Personalized Outreach for Equitable Treatment in Rheumatology

Informed Consent Form

Participant Information and Consent Form

Study Title: Personalized Outreach for Equitable Treatment in Rheumatology

Who is conducting the study?
Principal Investigator: Brent Ohata, MD
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Co-Investigators:
Alec Yu, MD, Division of Rheumatology (UBC), alec.yu@vch.ca, 604-349-5817
Daksh Choudhary, MD, Division of Rheumatology (UBC), 778-776-2255

Study team members:
Navid Saleh, MD, Department of Medicine (UBC)
Galen Montesano, MD, Division of Family Practice (UBC)
Mary Kestler, MD, Division of Infectious Disease (UBC)
Anita Palepu, MD, MPH, Department of Medicine, Division of General Internal Medicine (UBC)
Sandra McMillan, Patient Advisor
Marilyn Alec, Patient Advisor

Study Sponsor: Mary Pack Arthritis Program

Why are we doing this study, and why should you take part?
Research shows that people who live with inflammatory arthritis, including rheumatoid arthritis or arthritis due to an autoimmune disease, can have difficulties attending regular follow-up visits. We are testing if regular outreach and support can improve care for people with inflammatory arthritis, especially those living in challenging circumstances. You are invited to take part in this study because you are living with inflammatory arthritis and receive care at a Vancouver Coastal Health community health centre. By joining this study, you may help us find better ways to manage autoimmune diseases for patients in your community. Your participation is voluntary, and you have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from this study at any time without negative changes to the medical care, education, or other services you are entitled to or are receiving now. A total of 20 participants will be recruited.

What happens if you say "Yes, I want to be in the study?"
If you say "Yes", here is how we will do the study:

- You will be randomly assigned to have either outreach with honorarium support, or honorarium support alone. Randomization means you are put into a group by chance (like the flip of a coin), and there is no way to predict which group you will be assigned to. You will have a 50% chance to be in either group.
- The outreach group will receive regular check-ins every 1-4 weeks by phone, text, or in-person to help with symptoms, medications, or side effects related to your arthritis.

- You can expect to get texts, a call, or a visit at most once per week, between the hours of 8am and 8pm. You will receive a response to your text or call within 48 hours. If you have a pay-as-you-go phone plan, our study will cover your costs for contacting us. We will collect your phone number and email for study purposes only, and you have the option of sharing social media handles if you prefer to be contacted via a social medial platform (ie. Facebook Messenger or Instagram). These will not be shared with anyone outside of the study.
- You will follow-up every month with a rheumatologist at the Pender clinic. Follow-ups will focus on how you are managing your arthritis and medications, as well as a physical examination. For each follow-up appointment where you complete any recommended bloodwork or imaging, you will receive a $20 honorarium in both groups. Bloodwork will be collected as per standard care.
- We will access your medical records to monitor your health and care outcomes for the 6 months prior and 6 months after the day you enter the study.
- You will be asked to share feedback about your experiences every 3 months with an interviewer who is not involved in your care team (Navid Saleh).
- The study will last for 6 months from the time you are enrolled. You can choose to leave the study at any time and still be a patient at the Pender Community Health Centre if you would like.

Who is conducting the study?
This study is being conducted by the rheumatologists and a rheumatology trainee at the Pender Community Health Centre. It is being funded by the Mary Pack Arthritis Program.

Who should not participate in this study?
You cannot participate in this study if you have no reliable way of being contacted, such as no regular access to a phone or internet. You cannot participate if you have a severe and untreated mental health condition, brain injury, or brain disease.

Is there any way this study could be bad for you?
The risks and side effects of the usual treatment of inflammatory arthritis will be explained to you as part of your standard care. If you are unclear about what is standard care and what is specifically part of this study, please discuss this with your study doctor.

You may have had negative experiences with the healthcare system or health researchers in the past. During this study, the doctors or researchers may ask questions about your health or experiences that you find uncomfortable. If this happens, you always have the right to not answer any question you are uncomfortable answering.

How will the results of the study be shared?
We will share what we learn with you after the study finishes. We will also share what we learn with other healthcare workers in Vancouver, as well as in research papers and presentations. Your personal information will always remain de-identified.

Will this study help you in any way?
There may not be direct benefit from taking part in this study. You will receive a $20 honorarium for every in-person visit with the rheumatologist with completed bloodwork. You will receive $50 for completing the 3-month and 6-month interviews for the study. You may also receive regular personalized advice and outreach with a member of our team. Outreach support will not apply to all participants due to randomization. Outreach may help improve your understanding of your condition and its treatment. The findings from this study may also help others receive better care in the future.

What happens if you decide to withdraw your consent to participate?
You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw later, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to you) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let the principal investigator of the study know.

How will we protect your privacy in this study?
Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or designate and by representatives of UBC's Clinical Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law. This will be on an encrypted document in a password protected computer that only the research team will have access to. Everything else that can be traced to you, including your forms and audio recordings, will be kept in a secure and locked filing cabinet until it can be transcribed, after which they will be destroyed within 7 days of transcription.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the study team.

Who can you contact if you have questions about the study?

If you have any questions or concerns about what we are asking of you, please contact Brent Ohata (604-453-0324) or Alec Yu (alec.yu@vch.ca; 604-349-5817).

What happens if something goes wrong?
By signing this form, you do not give up any of your legal rights and you do not release the principal investigator, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

Who can you contact if you have concerns or complaints about the study?
If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the UBC Office of Research Ethics at 604-822-8598 or if long distance e-mail RSIL@ors.ubc.ca or call toll free at 1-877-822-8598.

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My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I authorize access to my health records as described in this consent form.

I will receive a signed and dated copy of this consent form for my own records.
I consent to participate in this study.

_____	_____	_____
Participant's Signature	**Printed name**	**Date**

_____	_____	_____	_____
Signature of Person Obtaining Consent	**Printed name**	**Study Role**	**Date**