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Version 2

Personalized Outreach for Equitable Treatment in Rheumatology
Full Study Proposal

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BACKGROUND

In 2023, the City of Vancouver's annual Homelessness Count identified 2,420 individuals as homeless, defined as being unsheltered or accessing emergency shelter facilities.¹ This does not capture over 3,000 individuals who are provisionally housed in transitional housing or single room occupancy hotels, which are generally lacking in safety and long-term stability.² Although the root causes of homelessness are diverse and unique to each individual, there is a convergence towards extreme poverty, instability, and a gradual accumulation of barriers to reclaiming one's life.³ Over time, these individuals face accelerated development of chronic illness, driven by poor physical conditions and toxic stress; our healthcare system has historically and presently been inadequate to care for their needs, often inflicting trauma instead.⁴

Rheumatic diseases such as inflammatory arthritis represent a substantial cause of pain and disability among the general population, and they are a known cause of problematic opioid use as an attempt at self-management.⁵ Although there are no published epidemiologic studies of rheumatic diseases in those living with extreme poverty, the rate of Rheumatoid Arthritis and Spondyloarthritis in the general Canadian adult population is estimated to be 1.2% and 0.9% respectively,^{6,7} with rates being at least 2-3 times higher among Indigenous peoples.⁸ More severe, functionally-debilitating disease is seen in those of lower socioeconomic status.⁹ In the City of Vancouver alone, where 39% of individuals who are homeless identify as Indigenous, one can conservatively estimate at least 100 individuals living with inflammatory arthritis among those who are homeless or precariously housed.¹

The management of those who live with both rheumatic disease and extreme poverty is predictably fraught with challenges. The most effective disease-modifying therapies are immunosuppressing and require regular monitoring bloodwork, posing difficulties for those with unpredictable lives with frequent infectious exposures. As of 2024, the only published descriptions of rheumatology care for homeless individuals comes from a single centre in Los Angeles, who report far less disease-modifying anti-rheumatic drug (DMARD) use, more reliance on corticosteroids, and higher disease activity in a retrospective cohort when compared to a matched cohort of general Rheumatoid Arthritis patients.^{10,11} To our understanding, these studies were done from a general academic rheumatology centre without specific structural adaptations for patients experiencing homelessness.

Despite these challenges, we believe that the treatment of rheumatic disease in those experiencing extreme poverty, when done appropriately, can have benefits beyond pain and disease outcomes. DMARD use has been shown to reduce long-term opioid use in those with inflammatory arthritis,¹² and lead to functional improvements that may empower social mobility. When paired with accessible supports, caring for a rheumatic disease may add structure and organization to a person's life, and seeing symptomatic improvement can build trust between patients, their providers, and the healthcare system.

PROGRAM OVERVIEW

Our study aims to enhance the existing twice-monthly rheumatology clinic at the Pender Community Health Centre with a rheumatology-specific outreach service for patients with inflammatory arthritis. This service will be provided by a rheumatology subspecialty trainee under the supervision of two attending rheumatologists. This will consist of biweekly phone calls, text messages, or home visits as per the patient's preference, at times flexible to patient needs. This will be in addition to monthly in-person assessment and bloodwork monitoring with adjustment as clinically indicated by their treating rheumatologist. Outreach services will include management of medications and side effects, proactive screening for infections, coordination of rheumatologic and general healthcare with their Primary Care Provider, social service navigation, and reminders for appointments and lab monitoring. All participants will be provided with a \$20 honorarium for each in-person assessment they attend as part of the program.

We will aim to enroll 20 patients between July 2025 and October 2025. Participants will be randomized to either **honorarium with outreach** or **honorarium alone** arms in a 1:1 fashion, stratified by housing status (unhoused and emergency sheltered in one strata, provisionally accommodated and stably housed in the second strata).

All enrolled patients will receive a \$20 honorarium for each in-person assessment with completed monitoring bloodwork as requested by the treating rheumatologist. The program will last 6 months for each patient from time of enrolment, or until a patient chooses to leave the program, whichever is sooner. At baseline, participants will complete two surveys: one on their general health status, and one specific to their rheumatic disease. At the 3-month and 6-month visits, these surveys will be repeated, and a semi-structured interview will be completed to obtain feedback on the pilot program. Participants will receive a \$50 rather than a \$20 honorarium for their additional time at these extended 3-month and 6-month visits.

The outcomes of this pilot program will inform how we can better care for those who live with inflammatory arthritis and are also marginalized by extreme poverty and/or housing instability. We plan on disseminating and discussing results with our participants, community members, inner city physicians, and rheumatologists. If there are specific positive themes or outcomes from the pilot, we will advocate for additional resources to permit long-term implementation and further study to confirm results, make further improvements to our program, and improve generalizability.

STUDY TEAM

- Pender rheumatologists (Dr. B. Ohata and Dr. D. Choudhary)
- Pender outreach (Dr. A. Yu)
- Pender Clinic Patient Advisors (Ms. S. McMillan and Ms. M. Alec)
- Pender Clinic leadership (Dr. G. Montesano)
- ID expert clinician (Dr. M. Kestler)
- Urban health expert clinician (Dr. A. Palepu)
- Non-clinical interviewer for patient feedback (Dr. N. Saleh)
- Mary Pack Arthritis Centre (Funding support)

INCLUSION AND EXCLUSION CRITERIA

INCLUSION CRITERIA:

Referred patients must:

- Have a diagnosis of an autoimmune inflammatory arthritis with peripheral involvement (ex Rheumatoid arthritis, psoriatic arthritis, peripheral spondyloarthritis, arthritis associated with a connective tissue disease)
- Be attached to one of the Vancouver Coastal Health Community Health Centres (VCH CHC; Pender, Downtown, Ravensong, Heatley, Three Bridges)
- Be willing to attend in-person appointments at Pender Community Health Centre
- Be at least 18 years of age and capable of consenting to participation
- Be able to receive medical care in English.

EXCLUSION CRITERIA:

- Have cognitive impairment or an untreated psychiatric condition that would severely impair ability to engage with outreach or treatment
- Have no reasonably reliable method of contact (phone, email, social media, etc.)

STUDY PROTOCOL

INVITATION TO PARTICIPATE:

A letter communicating the existence and purpose of the Pender Rheumatology clinic that includes details about the study will be sent to all Primary Care Providers at VCH CHCs, as well as all Rheumatologists practicing in Vancouver (Appendix 1.1). The letter will invite Primary Care Providers and Rheumatologists to refer patients they feel would benefit from assessment at the Pender Rheumatology clinic, and also inform them about this study. Primary Care Providers and Rheumatologists will also receive a letter for patients that they can choose to distribute to those whom they feel may be suitable for the study (Appendix 1.2). No contact information for potential participants will be forwarded directly to the study PIs for the purposes of enrolment into the study, however standard referrals for Rheumatology assessment will need to be forwarded to the Pender Rheumatology clinic. An index appointment will be scheduled for them at the Pender Rheumatology clinic, where eligible participants will be invited to speak to a team member for more information and possible study enrolment.

INDEX VISIT:

At the index visit, a Rheumatology specialist physician (BO or DC) will assess and determine the likelihood of inflammatory arthritis. Those with a confirmed diagnosis of inflammatory arthritis based on expert rheumatology opinion and meet our inclusion criteria will receive an offer to hear more about the study. Those who do not meet inclusion criteria or decline to participate will still receive the standard of care at the Pender Rheumatology clinic if they wish. AY will explain the study and consent form in a separate room from the treating rheumatologist.

After consent is obtained, patients will be stratified by their housing status for randomization. We will have two groups; one with participants who are unsheltered or accessing emergency shelter systems, and one with participants who are provisionally or permanently accommodated, such as those in transitional housing, living in a single-room occupancy hotel, supportive housing, or market housing. The stratification by housing status is designed to account for differences in baseline needs and challenges, supporting equitable comparison of intervention effects. Random sequences will be generated for each stratum by a computer-based random sequence generator such that each block of 4 will contain two participants in each of the intervention (Honorarium and Outreach) and control (Honorarium alone) groups. Randomization sequences will be stored in sealed, opaque envelopes prepared prior to participant enrollment. Each envelope will be labeled with the corresponding stratum and assigned a sequential number for use in order of participant enrollment. The next sequential envelope will be opened by AY to reveal the participant's group assignment.

At the first study visit, the consenting participant will complete a baseline survey on their health, disease understanding, and functional status (Appendix 3), and AY will also perform a standardized chart review to determine their baseline comorbidities and healthcare utilization (Appendix 4). The participant's treating rheumatologist will also document a baseline disease activity score using the Clinical Disease Activity Index (CDAI). This score has been validated for research use to track clinical response to

treatment and is widely used in almost all trials of inflammatory arthritis. Use of disease activity scores is standard of care for many rheumatologists, although such regular documentation of disease activity scores is more typical for research purposes.

All participants will be assigned a study ID to facilitate de-identified survey responses. We will also collect contact information including phone number and email to facilitate outreach (Appendix 5). Participants will have the option to provide other forms of contact such as social media handles or outreach workers to help facilitate outreach, but these will not be mandatory.

OUTREACH VISITS:

Outreach will be provided to all participants in the “Outreach and Honoraria” arm of the study. Outreach will be provided by AY, a clinical fellow in rheumatology in their 5th year of postgraduate medical training, and second year of rheumatology fellowship. AY has previous work and research experience providing outreach to residents in Vancouver’s Downtown Eastside. The frequency of outreach contacts will be a maximum of once per week and a minimum of once per 4 weeks, flexible to the needs of the participant. Outreach will be provided in the form of phone calls, text/direct messages, video calls, or home visitations depending on the needs and preferences of the participant. The frequency, duration, and content of outreach will be documented in field notes by AY. All medical advice given via outreach will be discussed with either BO or DC for rheumatologic concerns, or MK for infectious concerns. AY will not advise or manage medical issues outside of inflammatory arthritis and its complications, other than to recommend review by a participant’s primary care provider or the emergency department if deemed necessary. AY will not independently prescribe any medications via outreach but can recommend an expedited assessment by a Pender Clinic Rheumatologist if necessary. AY will document any assessment and advice provided to each participant.

We anticipate potential reasons for outreach to include:

- Providing education on patient’s rheumatic diagnosis
- Providing education around patient medications
- Managing symptoms of disease or side effects of medications
- Providing advice of holding immunomodulatory medications during acute infections or seeking care for infectious complications of treatment, with remote advice provided by MK
- Connecting patients with appropriate resources from the Arthritis Society or the Mary Pack Arthritis Centre
- Providing reminders for bloodwork or appointment times
- Providing support for attending appointments or investigations (with allocated funding for subsidizing transportation if necessary)

A collection of sample texts can be found in the Supplementary Appendix. Texts and calls will be made through a phone dedicated for the purpose of this study, and all participant information on this phone will be password protected. Standard text and call services will be provided by TELUS, and charged to the study team if the participant has a pay-as-you-go plan. Participants can expect to receive texts between 0800 and 2000 HRS at most once per week, and can expect a response to their questions by text within 48 hours.

FOLLOW-UP VISITS:

The frequency of follow-up visits will be determined by the participant's treating rheumatologist (BO or DC). Follow-up visits will be done in-person at the Pender Community Health Centre unless there are extenuating circumstances and the participant consents to telehealth. The follow-up frequency, counselling, treatments, and investigations provided will all represent the standard of care for the participant's rheumatic disease, degree of disease severity, and comorbidities. The Pender Rheumatology clinic runs every second Wednesday, and although participants will be given an appointment time, there is substantial flexibility for the time and duration of their appointments beyond what standard rheumatology practices can offer.

We anticipate most participants will require monthly visits. The treating rheumatologist will document relevant disease activity scores every 3 months. The patient will complete a survey on their health, disease understanding, and functional status every 3 months (Appendix 3).

CHART REVIEWS:

All prospective participants will be asked to provide signed consent for the research team to access their medical records for the purpose of the study. The patient's baseline and 6-month comorbidities will be collected based on a standardized list that tracks the Charleson Comorbidity Index. We will also collect data on healthcare utilization including the number of ED visits and hospitalization days in the 6-month study period, and compare this to the 6-month period prior to study enrolment. Data will be abstracted from CST Cerner and the patient's referral letter.

PATIENT INTERVIEWS:

At the 3-month and 6-month mark, participants remaining in the study will be asked to take part in a semi-structured interview to provide feedback on the program, which will be tailored to whether they are in the "Outreach and Honoraria" or "Honoraria Only" arms (Appendix 6A/B). To maintain an arm's length between the feedback process and the treating clinicians, these interviews will be carried out confidentially by a member of the research team who will not be a part of their care team (NS). Interviews will be scheduled by NS with the participants directly, and can be held at Pender clinic, a separate site, or occur over the phone. Participants will be asked for permission to record their interview for the purposes of transcription. All recordings will be deleted within 7 days of transcription. Participants who do not consent to recording will have their interviews summarized in real-time. The recording device will be a dedicated study device that will be purchased for the use of this study.

STATISTICAL ANALYSIS:

The primary outcome of the study will be the rate of adherence to follow-up over 6 months, as measured by the ratio of scheduled in-person appointments that were attended versus not attended. This will be compared to the historical rate of attendance among patients followed at the Pender Rheumatology Clinic with a diagnosis of inflammatory arthritis from Jan 2023 to June 2025. This range is

to provide an adequate sample of visits with the current clinic structure during a period after all the British Columbian COVID-19 isolation and masking protocols were lifted. Based on previous attendance trends at this clinic, enrolling 10 patients in each arm of the study will provide 80% power to detect a 15% difference in attendance rate at a p value of 0.05.

Secondary exploratory outcomes will include the change from baseline in the Clinical Disease Activity Index (CDAI), number of tender and swollen joints, participant self-rated arthritis-related pain and function, self-rated understanding of disease, rates of emergency department visits and total hospitalization days, number of serious infections, and qualitative feedback from semi-structured interviews.

At the conclusion of the study, attendance will be analyzed as a categorical variable using the Fisher's exact test. Continuous variables among the secondary outcomes, such as disease activity scores, will be compared to baseline values with the Wilcoxon signed-rank test, and compared between groups with the Mann Whitney U test. Qualitative data will be transcribed and reviewed independently by two researchers (AY and NS) to code and identify relevant themes among study participants as guided by the study objectives. AY and NS will then meet to discuss patterns and discrepancies before re-coding the transcripts to produce a single report. Attendance data for the primary outcome will be analyzed in an intention-to-treat fashion, however, patients who are lost to follow-up prior to 3 months of the study period will not be included in the analysis of secondary outcomes.

HONORARIA:

All participants will receive a \$20 cash honorarium, along with a small gift of tea and a thank-you note, for each in-person appointment they attend with completed monitoring bloodwork. There is on-site phlebotomy at the Pender Community Health Clinic, and the research team will provide the participant with an honorarium if they complete their bloodwork on the same day as their visit, even if results are not available. Each participant will provide a signed record of receipt when they collect their honorarium. All participants will receive a \$50 cash honorarium if they complete their 3-month and 6-month study visits, which will include a repeat of the baseline survey, as well as a semi-structured interview as documented above, after completing their standard clinical visit and bloodwork.

COMMUNITY CONSULTATION

We acknowledge that research and programming in the Downtown Eastside community has had mixed effects, with the potential to misrepresent or become traumatic to participants. We have done our best to meaningfully integrate the recommendations laid out by Boilevin and colleagues in their Manifesto on Research in the Downtown Eastside.¹³ We also acknowledge that this is a disproportionate representation of Indigenous individuals living both in the Downtown Eastside, and with Inflammatory Arthritis, and have taken steps to ensure Indigenous perspectives are included in this work.

The research protocol has been reviewed and approved by our patient advisors who have lived experience with arthritis and living in the Downtown Eastside. Our advisors (SM and MA) will be compensated for their work and appropriately acknowledged in all knowledge translation efforts. They have generously offered to be involved throughout the course of the study, through the design, implementation, review of participant feedback, and design of data sharing and knowledge translation processes. We are committed to holding ourselves accountable to our patient advisors and participants throughout the study.

We acknowledge that there is an overrepresentation of Indigenous peoples both in those living in the Downtown Eastside, as well as those living with inflammatory arthritis. Both of our patient advisors are Indigenous and have provided input on how to communicate about arthritis and autoimmunity from an Indigenous lens. All patient facing members of the study (BO, DC, AY, and NS) have completed additional training in Indigenous Cultural Safety (San'yas 23-24 Indigenous Cultural Safety Course) and Trauma Informed Care (UBC Trauma and Violence Informed Care Foundations).

We have also formally consulted with the VCHRI Indigenous Health Research Unit (Dr. Gabrielle Legault and Ms. Sandra Fox) who have provided input and support for the study.

STUDY RISKS AND MITIGATION STRATEGIES

This is not a study of new therapeutics or treatment strategies. All participants will be treated for their inflammatory arthritis as per standard of care by a licensed rheumatologist. In higher risk cases, treatment decisions will be made via shared decision making between the rheumatologist and the participant, and study participation will in no way determine the type of medical treatment the participant receives.

We also acknowledge that participants may have had negative experiences in the past with the healthcare system or health research. Surveys and questionnaires may ask questions that make a participant uncomfortable or invoke a previously traumatic experience. Our clinicians and team members have all completed courses on cultural safety and trauma-informed care and will make every effort to create a safe environment for our participants.

Our mitigation strategies for risks associated with providing general rheumatology care within the context of this study include:

- On-demand and flexible outreach support from outreach worker, who will be a rheumatology trainee with previous outreach experience in the Downtown Eastside
- Honorarium for attending in-person appointments and labs
- All study procedures have been reviewed by patient advisors with lived experience in the Downtown Eastside and with inflammatory arthritis

- Remote ID clinician support for advice on wound care and infection prophylaxis
- Low threshold to initiate antibiotic prophylaxis or medication rescue strategies
- Short prescription durations with witnessed ingestion/injection whenever available, contingent on adherence to follow-up and monitoring
- Coordination of rheumatologic and general healthcare with primary care physician
- Engaging with low-barrier labs and pharmacies to support adherence

KNOWLEDGE TRANSLATION

Our knowledge translation strategy will consist of three elements: Communication of results to the community, communication of results to providers and professional organizations, and advocacy for change.

We plan to work with our patient advisors to create a community research summary in accessible language that will be distributed to all study participants via mail or email. This summary will take the form of a visual abstract, and will be vetted by study participants and our patient advisors prior to finalization and distribution. Any study participants who do not have an address or an email will be contacted via phone if possible with an offer to discuss the results of the study. We will also share this summary during in-person visits with study participants after the study is completed. All study participants will have an open invitation to discuss their reflections on the results directly with one of the study team members.

We will also produce a research summary for inner city providers (physicians and nurse practitioners) as well as professional arthritis organizations including Arthritis Research Canada, the Mary Pack Arthritis Program, and the BC Society of Rheumatologists. As a part of this communication, we will invite these groups to provide feedback and offer their support for our advocacy efforts.

Our ultimate goal for this research is to expand our capacity to provide the best possible care to those living with inflammatory arthritis and face extreme poverty. Depending on the results, we will advocate for ongoing support at the level of the Health Authority, Ministry, and relevant foundations to support what has worked in the study. We may also design further studies based on the results and participant feedback from POET Rheum to confirm results, study new strategies, and improve generalizability.

PROGRAM MEASURES

- Primary Outcome: Adherence to in-person follow-up measured by the ratio of appointments attended to appointments scheduled, both between the two intervention groups, and as compared to the historical rate of attendance from June 2022 – June 2025.
- Secondary Outcomes:

- Adherence to laboratory monitoring
 - Disease activity measures appropriate for their disease
 - ED visit or hospitalization through chart review
 - Participant self-rated understanding of disease and medications
 - Participant qualitative feedback
- Disease activity measures at 3 and 6 months after enrolment in the program include
- Patient qualitative feedback will consist of 3-month and 6-month semi-structured interviews which will be done and analyzed by a member of the team that is not actively involved in the patient's clinical care or outreach team
 - Patient reported survey of arthritis-related pain, function, and understanding of disease will also be collected at baseline and at 3 and 6 months
 - Participants will receive a \$50 honorarium for completing these follow-up interviews along with the 3-month and 6-month surveys

BUDGET

Participant honoraria for appointments: \$20 per appointment x 20 participants x 6 visits = \$2,400

Participant honoraria for interview completion: \$100 x 20 participants = \$2,000

Cost of temporary phone and plan for outreach: \$25 x 12 months = \$300

Cost of recording device = \$80

Total: \$4,780

TIMELINE

October 2024 – December 2024: Obtain necessary pre-approvals and oversight from key stakeholders for the project including:

- Pender rheumatologists (Dr. B. Ohata and Dr. D. Choudhary)
- Patient Advisors (Ms. S. McMillan and Ms. M. Alec)
- Pender Clinic leadership and office manager (Dr. G. Montesano and K. St. Claire)
- ID expert clinician (Dr. M. Kestler)
- Social medicine expert clinician (Dr. A. Palepu)
- Non-clinical interviewer for patient feedback (Dr. Navid Saleh)
- Community health centre clinicians
- Pender laboratory and VCH CHC Wound Care teams
- Mary Pack Arthritis Centre

December 2024 – May 2025:

- Finalize program with stakeholders
- Create program materials including consent form, data collection tools, qualitative feedback surveys, and invitations to participate
- Go through Ethics Process at UBC

May 2025 – July 2025:

- Reach out to Vancouver Community Health Centres and Rheumatologists with invitation to refer eligible patients to participate
 - AY to visit CHCs and discuss project with clinic managers
- Enrolment begins

July 2025 – ~April 2025

- Study period

~April 2025 – July 2025

- Data analysis and presentation of results to participants, inner city physician groups, rheumatologists, and other relevant stakeholders

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