Study title: Improving Experiences of People with Myeloproliferative Neoplasms associated Splanchnic Vein Thrombosis: A Co-Design Approach

Chief Investigator: Dr Vicki Tsianakas

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

Summary

Myeloproliferative Neoplasms associated Splanchnic Vein Thrombosis (MPN-SVT) is a rare health condition. MPN-SVT is when blood clots form in abdominal veins (SVT) due to chronic bone-marrow cancer (MPN). Often, people do not know they have an MPN until after the SVT is diagnosed. Management of MPN-SVT is complex and involves different medical and nursing teams, usually in more than one healthcare setting. People with MPN-SVT also experience a range of symptoms relating to MPN-SVT and the side effects of medications used to treat this health condition.

We recently carried out a study to explore the views and experiences of people living with MPN-SVT and the specialist healthcare professionals (HCPs) involved in their care. Findings from this research powerfully demonstrated the need to develop new care processes and/or resources to improve the experiences of people with MPN-SVT. With their consent, a film was produced by editing together extracts from participants' filmed interviews. The film will be shown to you during this study.

We are now inviting you to take part in the next stage of this research, which will bring people with MPN-SVT (Service-Users) and HCPs (Service-Providers) together to develop new resources and care processes. The aim is to improve service-users' experiences. The study relies on the involvement of service-users, who are experts with lived experience of the health condition being studied. If you choose to take part, you will work closely with other people who have MPN-SVT, HCPs, and researchers. This is called 'co-design,' because the people taking part in the study work together to 'design' new or better ways to support people with MPN-SVT. Our learning from the previous study will be shared with all participants as a springboard for this 'co-design' process.

Please do get in touch with the research team at King's College London if:

- You have any questions after reading this leaflet – we want to make sure you fully understand what this research study is about before you decide whether or not to take part;
- You are interested in taking part in the study – we can then explain more about the study, answer your questions and, if you wish to proceed, ask you for your consent to participate.

Dr Vicki Tsianakas (Study Lead) & Dr Freya Brown (Researcher)

King's College London

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Table of Contents

Why am I being invited to take part?

You are being invited to take part because you are an adult (≥18 years-old) who has MPN-SVT, and you currently live in England. You may or may not have taken part in the previous study described above. Either way, your insights and knowledge of MPN-SVT means that you would be a valuable member of the 'co-design' research team.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw from the study at any time, without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What would taking part involve?

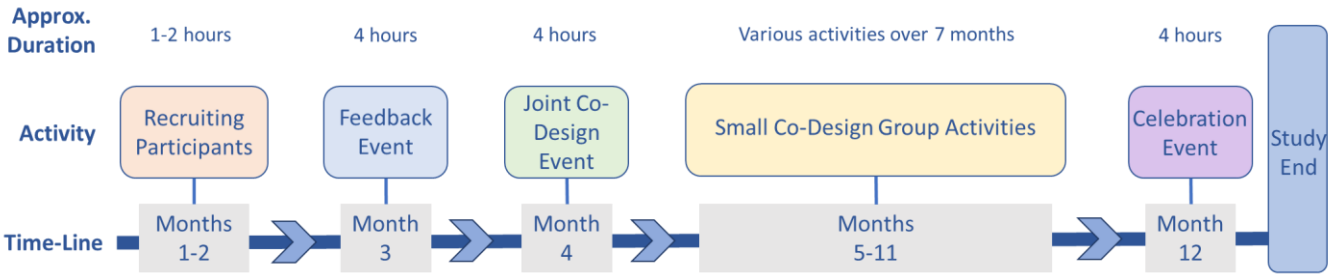
This study will take place over one year. We aim to recruit 8-16 service-users (people with MPN-SVT), 8-16 specialist HCPs, and 2-4 generalist HCPs to take part in the study. Some of the HCPs may work in the clinic you attend. If you consent to take part, you will be invited to attend a series of events and activities that will be spread out over 12 months. We will also ask you to complete two short anonymous online questionnaires: 1) A questionnaire asking about you, including what type of MPN you have, diagnosis dates, your age, gender, ethnicity, employment, family/household (please see section '**Information on the Use of Data**' for more information); and 2) A questionnaire at the end of the study, asking about your experience of taking part and your views on the resources and care processes that we develop together. Your name will not be included in either questionnaire.

Participants in the study will work together to improve information and healthcare for people with MPN-SVT. For example, this might involve 'co-designing' an information leaflet, an animation, or infographics. It might involve developing a way to provide people diagnosed with MPN-SVT with better psychological, emotional and/or social support. In addition, we will think together about:

- How and where to offer healthcare for people with MPN-SVT so that it is effective and acceptable;
- How to tell other people (service-users, friends and family, specialist and generalist healthcare professionals etc.) about the new resources and care processes we develop;
- How the new resources and care processes we develop can be used in practice;
- How to evaluate these new resources and care processes to find out how helpful and effective they are.

Please see below for a study timeline and more details about each stage of the study.

Study Timeline



Feedback Event (4 hours):

First, you will be invited to an event with other people who have MPN-SVT. We will show you the film developed during the previous study which includes extracts from interviews with people living with MPN-SVT. This will act as a springboard for discussion about improvements that could be made to healthcare services for people with MPN-SVT. The aim of the event will be to agree priorities for improving MPN-SVT care and resources. A similar feedback event will be held separately for participating HCPs.

Joint Co-design Event (4 hours):

All participants (people with MPN-SVT and HCPs) will then be invited to a Joint Co-design Event. We will show the film again, and priorities agreed at both the service-user and HCP Feedback Events will be presented and discussed. The purpose of this event will be:

- To reach a consensus on the top 3-4 priority areas for improvement;
- To come up with different ideas for improving the experiences of people with MPN-SVT in these priority areas;
- To agree which of these ideas to take forward and develop in the next stage of the study.

Small Co-Design Group Activities (Spread over 7 months):

Three or four smaller co-design working groups of approximately 5-7 people will be formed. Each group will include service-users, HCPs and at least one researcher. Over the next 7 months, members of each group will work together to develop one of the prioritised resources or care processes. This will be co-ordinated and facilitated by the researcher. Group members will decide how (virtually or face-to-face) and when to meet. They will also agree on other ways to communicate and work with each other over the 7 months. It is not possible to know in advance how many meetings will be required, but a maximum of 7 months will be allocated to this phase of the study. We will remain flexible in our approach to ensure inclusion of all participants at these meetings. If you do not wish to attend a group meeting (virtual or face-to-face), you will be able to contribute to the process in other ways (for example, individual phone call or visit with the researcher, or by email or post). Any input from you during this phase will be extremely helpful. The researcher will monitor progress and support each group to achieve their aim.

Final Celebration Event (4 hours):

At the end of the study, all participants will be brought together once again to share and celebrate progress and discuss the next steps for this work. This will include thinking about how to tell other people about the resources and care processes we have developed. We will also think about ways to find out how helpful and effective the outputs from this study are.

We will invite people from key charities and organisations with an interest in MPN-SVT to this celebration event. You will also be able to bring one person to this event if you want to (for example, a partner, spouse, adult child or good friend).

Important Information about Participation:

We expect the Feedback Event, Joint Co-Design Event, and the final Celebration Event to be held face-to-face. However, we will be guided by the participants if there is a strong preference for these to be held virtually. These events will be facilitated by researchers and a member of the research team with lived experience of MPN-SVT. We expect the Small Co-Design Group activities to be virtual but, again, it will be up to the group members how they choose to communicate.

For face-to-face events, all reasonable travel expenses will be reimbursed, so please keep receipts/tickets. We will also pay up to £10 per hour towards any childcare costs you have due to attending face-to-face events. Refreshments and lunch will be provided. We will ask in advance if you have any allergies or other dietary requirements.

At the end of the study, you will receive a £50 voucher as compensation for your time and a certificate to evidence your role as a co-designer on this research study.

What are the possible benefits of taking part?

There are no direct benefits to you taking part in this study, but the results from this study might help to improve healthcare for people with MPN-SVT in the future. We hope that participating in this study will be rewarding for all involved.

The results of this study may be used for the future development of a new healthcare intervention and/or resources. Your participation in this study will not entitle you to benefit financially from the commercial development of any interventions or resources. However, if you want and with your consent, you will be credited for your contribution to developing any study outputs.

What are the possible disadvantages and risks of taking part?

We do not expect there to be any serious physical risks from participation in this study, but we will be discussing some potentially upsetting issues. If you do find any of the discussions upsetting, you can leave the meeting at any time. Researchers will be there to support you and to signpost you to additional sources of support if needed.

We will request that all involved in the study respect each other's confidentiality outside of the group sessions, but the researchers will not be able to guarantee this. Therefore, we will ask that people think carefully about what they feel comfortable sharing with other participants, and to only share information if they are happy to do so.

Taking part in this study will involve giving up some of your time to attend the events and engage with small co-design group activities. We appreciate that many people are extremely busy with work, family, social and other commitments. We also understand that fatigue is a common symptom of MPN-SVT. You will still be able to participate in the study if you are unable to attend face-to-face events. We will aim to make it possible for people to contribute to the co-design process in many different ways to enable a diverse group of people to take part. If you find that participation in the study is requiring too much from you, you will be able to discuss this with a researcher and we will do our best to find alternative, less intensive ways for you to stay involved. You can also withdraw completely from the study at any time without giving a reason and without your healthcare or legal rights being affected.

Further supporting information

What will happen if I don't want to carry on with the study?

You can withdraw your active participation in the study at any stage without giving a reason. Because this research is collaborative and involves group discussions, it will not be possible to withdraw any data generated during the co-design process. If you complete an online questionnaire for the study, it will not be possible to withdraw these data either. This is because your name will not be included in the questionnaire, and it will not be possible to identify which questionnaire is yours. Therefore, if you withdraw from the study, all data already collected with consent would be retained and used in the study. However, the data will be pseudonymised (which means that your name and any other identifying information will be removed). Your name and contact details would be deleted from our records. Your consent document (emailed consent form or video recorded consent) will be archived with the study data and deleted five years after the study end date in line with King's College London guidelines. If you withdraw, no further data would be collected.

If you withdraw from the study early, you will still receive a voucher, providing you have engaged in some research activities, as follows:

- If you withdraw before the Feedback Event, you will not receive a voucher;
- If you participate in the Participant Feedback Event and/or the Joint Co-Design Event, but withdraw from the study before engaging in the small co-design group work, you will receive a £25 voucher at the point you withdraw;
- If you do start engaging in the small co-design group work, but withdraw before the study end, you will receive the full £50 voucher at the point you withdraw.

What will happen to the results of the research study?

The results will be written up in the final study report and made available to you upon request. They will also be published in a professional journal, presented at healthcare conferences, and shared online. Study participants will be involved in deciding how we share the study results and with who. Some participants may also want to help us tell others about the results (see also below section on how we will use information about you).

Who is organising and funding this study?

This study is sponsored by King's College London (KCL). It is funded by Royal Free London NHS Foundation Trust.

How have people with MPN-SVT been involved in this study?

Two people with MPN-SVT formed an Advisory Group for the previous study, providing invaluable advice to researchers on study design and procedures. They also helped to analyse anonymised data from the study and were co-authors on the study report. They will continue to work with King's College London researchers on this next 'co-design' stage of the research. To date, they have advised on our funding applications and the wording of this information sheet. Their role is to ensure that the experiences of people with MPN-SVT remain central to this research.

What to expect during the consent process

We do not want you to feel any pressure to take part in this study – it is entirely up to you. Whatever you decide, your healthcare and legal rights **will not** be affected. If you have any questions for the researcher before deciding, please do get in touch.

People who took part in the previous MPN-SVT study and consented to be contacted again:

If you took part in the previous study and consented to be contacted about future research relating to MPN-SVT, a member of the King's College London research team will contact you to share this information sheet with you. You will be given at least 48 hours and opportunity to ask questions before you decide whether or not to take part.

People who are new to this MPN-SVT research project:

If you hear about this study via MPN Voice, and contact our research team to find out more, we will share this information sheet with you. You will be given at least 48 hours and opportunity to ask questions before you decide whether or not to take part.

Providing consent to participate:

If you decide you would like to take part in this co-design study, you will be given a choice about how you wish to provide consent (formal agreement) to participate in the study:

- You can provide verbal consent during a video-recorded call which would involve the researcher reading the consent form to you;

OR

- The researcher will email you the consent form for you to print off, complete and sign. You would then email the researcher a scanned copy of the signed form. If you choose this way to provide consent, the researcher will also call you by telephone to confirm that it was you who emailed the completed form and that you want to participate.

Electronic consent forms and video-recorded consent files will be stored securely for the duration of the study. Only the Chief Investigator and lead researcher will have access to stored data. The consent files will then be archived for 5 years in a King's College London secure, time-managed electronic archiving system. They will be destroyed 5 years after the study end date (by 01/09/2030).

Information on the Use of Data

How will we use information about you?

We will need to use information from you for this research project.

The information we will collect about you will include your name and contact details, which will be necessary to do the research.

We want to invite a diverse group of people to take part in this study. Therefore, we will also ask you to complete an anonymous online questionnaire with the following information:

- Information about your MPN-SVT diagnosis (what type of MPN you have, when you were diagnosed with MPN and when you were diagnosed with SVT);
- Any MPN-SVT symptoms or medication side-effects you have;
- Your gender;
- Your ethnicity;
- Your age;
- Your employment;
- Information about your family/household.

This electronic questionnaire will be hosted on the Qualtrics platform. The information collected via this questionnaire will only be used to give us an idea about how successful we were in recruiting a diverse group of people. You will not enter your name or any other identifying information on the electronic questionnaire. The King's College London researchers will be the only people who can access completed questionnaires. This information will not be linked to your name or to any other information that identifies you. However, as there will only be a small number of people with MPN-SVT participating in this study (8-16), it may be possible for the King's College London researchers to identify you from your answers on this questionnaire. At the end of the study the information from all completed questionnaires will be download and deleted from Qualtrics. The downloaded files will be stored securely and destroyed after the archiving period of 5 years (see below).

We will also ask you if you have any dietary requirements to make sure we cater for everyone attending the face-to-face events. In addition, to reimburse you for any travel or childcare expenses, we will need you to share your bank details with us. This information will be stored securely at King's College London, only used for the purposes set out above, and deleted when no longer needed.

We will ask all participants for consent to audio-record the group events and audio- or video-record the small co-design meetings. The recordings of these meetings will not be shared with anyone. They will be saved to the secure study SharePoint site. They will not be transcribed, but the researcher will listen to them and make notes. The researcher will also take notes during the group sessions. This is to ensure we keep an accurate record of the research activities, co-design objectives and agreed schedules. Any audio and video recordings of meetings will be deleted before the study end date.

Because this research study involves group work your identity will be known to the other participants, researchers, and facilitators with lived experience of MPN-SVT. We will ask everyone to respect the confidentiality of others outside of the group sessions, but the researchers cannot guarantee this.

We will keep all information about you safe and secure. All the study information, including information about you, will be stored on a secure SharePoint site that can only be accessed by King's College London researchers working on this study. Information about you may also be shared with research auditors. It is their job to ensure that we are carrying out the research properly. Anything that identifies you will be removed from information about you that is stored on the SharePoint site. Your name will be removed and replaced with a random Study ID Number or a pretend name. Any other identifying information, such as place names, will also be removed or replaced. Once we have finished the study, we will keep some of the data so we can check the results. Data collected during the study will be archived for 5 years in a King's College London secure, time-managed electronic archiving system, in line with the King's College London '*Schedule of Retention Periods for Research Data*'. All data will be destroyed 5 years after the study end date (by 01/09/2030).

We will write our reports in a way that no-one can work out that you took part in the study. However, you may want to be acknowledged for your contribution to developing the study outputs. For example, you may want your name to appear as a co-producer at the end of an animated film or on the bottom of a leaflet. You may also want to help tell others about what we have done. For example, you may want to be a co-author on a journal or magazine article, or to help present information about our study at a meeting. If you do, we will ask you to sign another consent form to waive your right to confidentiality for the specific purpose set out in the form. We recommend you discuss this in detail with the researchers if it is something you are interested in.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you share something with us that makes us concerned about your (or another person's) safety, we have a professional responsibility to tell someone else. If this happens, we will talk to you about it in private, and we will only tell people who can help you to stay safe.

If you agree to take part in this study, you will also have the option to allow the research team (within King's College London) to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to determine if you are interested in taking part in another research study. Your verbal consent may then be sought to pass your contact details to another research team within King's College London. Agreeing to be contacted does not oblige you to participate in further studies.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- By asking one of the research team (contact details included below)
- By contacting the Data Protection Officer for KCL: Olenka Cogias, info-compliance@kcl.ac.uk.

What if I have further questions, or if something goes wrong?

If this project has harmed you in any way or if you wish to make a complaint about the conduct of the project, you can contact King's College London using the details below for further advice and information:

The Chair, PNM Research Ethics Panel, rec@kcl.ac.uk

Who is organising the study?

The study was developed by expert clinicians (Royal Free Hospital), researchers (University of Surrey and King's College London) and people with lived experience of MPN-SVT. Researchers at King's College London will be responsible for organising the study and running the research activities.

Who has reviewed the study?

The study has been reviewed by King's College London Research Ethics Committee (Ref: LRS/DP-23/24-42250).

Researcher Contact Details:

If you have any further questions about the study, please contact the researcher, Freya Brown, on 020 7848 2303 or email: mpn-svt@kcl.ac.uk.

Thank you for taking the time to read this participant information sheet and please keep a copy for your records.