Consent Form for Participants Able to Give Consent

V1.0, 20 March 2024
Centre name: University College of Osteopathy, London, UK
Study Protocol number: N/A

Full Title of Project: A Multimodal Manual Therapy-Based Intervention for People with Painful Diabetic Neuropathy: Feasibility of a Randomised Controlled Trial (NeuOst)

Name of Principal Investigator: Dr David Hohenschurz-Schmidt
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Please initial boxes to indicate your consent to individual items.

1. I confirm that I have read and understand the participant information sheet version 1.0 dated 20 March 2024 for the research project titled 'NeuOst: A Multimodal Manual Therapy-Based Intervention for People with Painful Diabetic Neuropathy: Feasibility of a Randomised Controlled Efficacy Trial' and have had the opportunity to ask questions which have been answered to my satisfaction. 2. **(Consent required for participation.)**	
3. I understand that my participation is voluntary, and I am free to withdraw at any time, without giving any reason and without my legal rights nor treatment / healthcare being affected. **(Required for participation.)**	
4. I understand that sections of any of my medical notes may be looked at by responsible individuals from University College of Osteopathy, London, or from regulatory authorities where it is relevant to my taking part in this research. **(Required for participation.)**	
5. I understand that data collected from me are a gift donated to University College of Osteopathy and that I will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication treatment, product or service. **(Required for participation.)**	
6. I consent to the open sharing of any data collected during this trial that cannot be traced back to me. **(Required for participation.)**	
7. I consent to take part in the research project titled 'NeuOst: A Multimodal Manual Therapy-Based Intervention for People with Painful Diabetic Neuropathy: Feasibility of a Randomised Controlled Efficacy Trial'. **(Required for participation.)**	

8. I give consent for unidentifiable information collected from me to be used to support other research or in the development of a new test, medical device or treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which University College of Osteopathy has ensured will keep this information secure). **(Optional item. Only initial the box if you agree.)**	
9. I give consent to my treatment sessions being audio- and video-recorded for quality assurance purposes. **(Optional item. Only initial the box if you agree.)**	
10. I give consent to my treatment sessions being observed by medical or research staff (in addition to the treating osteopath) for quality assurance purposes. **(Optional item. Only initial the box if you agree.)**	
11. I give consent to being contacted at the end of the study about the possibility to take part in interviews with the research team about my experiences in the present study. **(Optional item. Only initial the box if you agree.)**	
12. I give consent to being contacted about the possibility to take part in any other research studies. **(Optional item. Only initial the box if you agree.)**	

Please note that while you can withdraw your consent for data collection and study participation at any time, this will not preclude the collection of information about serious health-related events, which we will be required to collect for several months after study initiation for legal purposes.

☐ I would like to receive a summary of the study results.

_____	_____	_____
Name of participant	Signature	Date

_____	_____	_____
Name of person taking consent (if different from Principal Investigator)	Signature	Date

1 copy for participant; 1 copy for Principal Investigator; 1 copy for clinical notes

To ensure confidence in the process and minimise risk of loss, all consent forms must be printed, presented, and stored in double sided format.