Role description of lay panel member for the NESIC Trial Management Group (TMG) / Trial Steering Committee (TSC)

For further details about this project – please contact, Laura Burgess l.burgess@imperial.ac.uk (0203 311 5208) Francine Heatley f.heatley@imperial.ac.uk (0203 311 7371) or Rebecca Lawton r.lawton@imperial.ac.uk (0203 311 5204)

Role Description for:

Sydney Chapple, Trial Management Group / Trial Steering Group lay member for the NESIC Research Project

NESIC Study Summary:

The NESIC study proposes to assess a Neuromuscular Electrical Stimulation (NMES) device to treat symptoms arising from reduced blood flow to the leg muscles caused by Peripheral Arterial Disease (PAD). Intermittent Claudication (IC), or pain in the lower legs on exercise that settles with rest, affects approximately 5% of the UK population between 55 and 74 years. Patients may require bypass surgery or angioplasty (using a balloon to widen a narrowed artery) to restore blood flow, which is expensive and carries significant risks. Non-invasive management includes medication and exercise.

Nationally adopted guidelines (NICE) recommend all IC patients should undertake Supervised Exercise Therapy (SET), undergoing a circuit of exercises under the supervision of a healthcare professional. SET can improve the walking distances before the onset of symptoms and quality of life. However, due to lack of funding and resources, SET is only available to a minority of patients and therefore many patients are given exercise advice (EA) only.

NMES devices are an emerging technology for treating circulation problems in the legs. These readily available devices lack robust evidence of their benefit. A pilot study of 20 patients with IC using a device called the Revitive Medic, over a 6-week period, significantly improved the distance walked before limitation due to pain and quality of life. This portable device is useable at the patient's convenience.

The proposed study assesses the added benefit of NMES to locally available therapy (SET or BMT only). Eligible patients will be randomly allocated to a control group (local therapy) or an intervention group (local therapy + NMES). Measures include a treadmill test, questionnaires and blood flow assessment to the legs at the beginning of the study and subsequently at 3, 6 and 12 months. Analysis of the differences in these measures between the groups may indicate a beneficial and cost-effective role for NMES in the first line management of IC patients.

Purpose of steering group:

The role of the Trial Steering Committee is to provide advice, through its Chair, to the research team on all appropriate aspects of the trial and in particular that the rights, safety and well-being of the

trial participants are the most important considerations and should prevail over the interests of science and society.

Other roles include:

- monitoring the progress of the trial, adherence to the protocol, participant safety and the consideration of new information of relevance to the research question
- to ensure appropriate ethical and other approvals are obtained in line with the project plan
- to agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments
- to provide advice to the investigators on all aspects of the trial

Why involve you in the steering committee?

We are inviting you to be a member of the NESIC TMG/ TSC as we believe public involvement is an essential part of the development of modern health and social care services. Research that reflects the needs and views of the public is more likely to produce results that can be used to improve health and social care.

The TSC Committee Members:

The TSC chair:

Prof Andrew Bradbury, Sampson Gamgee Professor of Vascular Surgery, Solihull Hospital, Birmingham

Other committee members:

- Prof Jonathan Beard, Consultant Vascular Surgeon and Honorary Professor of Surgical Education at Royal College of Surgeons, *Sheffield* Vascular Institute
- Dr Louise Brown, Senior Statistician, MRC Clinical Trials Unit at UCL
- Mr Sydney Chapple, PPI representative

Other members who may attend the meetings:

- Professor Alun Davies, Chief investigator
- Laura Burgess, Trial Manager
- Francine Heatley, Trial Manager
- Rebecca Lawton, Trial Manager
- Natalia Klimowska- Nassar, Operations Manager Imperial College Trials Unit (ICTU)
- Sponsor representative if requested
- NIHR EME (funding body) representative if requested

We have found from experience that also involving the PPI representative in the Trial Management Group (TMG) discussions can be beneficial for both the rep and research team. The TMG consists of the smaller, immediate project team, consisting of the Chief Investigator, Trial Manager and statistician. This group discusses more of the day to day problems faced by the trial which you may be asked to help advice on using your experience as a patient.

The Imperial Research Team:

The NESIC Chief Investigator is Professor Alun Davies. The trial manager is Laura Burgess.

Professor Alun Davies:

Professor Alun Davies Professor of Vascular Surgery at Imperial College London and a Consultant Surgeon whose NHS practice is based at Charing Cross and St Mary's Hospital, London. Professor Davies trained in Cambridge, Oxford, Plymouth, Boston (USA) and Bristol, prior to taking up a Consultant appointment in Charing Cross in 1994. Professor Davies is regarded as a world expert in the management of venous disorder. He has also written extensively on many aspects of vascular disease, writing over 370 peer reviewed manuscripts and runs a large research group.

Laura Burgess Trial Manager:

Laura Burgess is a Trial Manager at the UKCRC registered Imperial Clinical Trials Unit (ICTU) in the School of Public Health within the Faculty of Medicine at Imperial College. She is a Biomedical Science graduate from the University of Warwick and currently studying for an MSc in Clinical Trials at the University of Edinburgh. She has over 5 years' experience of conducting clinical research across therapeutic areas including cardiovascular, oncology and infectious diseases.

Confidentiality:

As a representative of the NESIC trial TSC you are asked not to share confidential information you may have received as a result of your position.

Roles and responsibilities of user representative:

We would like you to:

- Attend the TSC meetings in person or by phone as per your preference. These will usually be held annually, although if a major issue is identified they may be held more regularly.
- Represent the patient/lay user views of the NESIC Research Project at selected TMG meetings. These are usually held bimonthly but we would only expect your input periodically and can arrange a teleconference if preferred.
- To contribute to the discussion within the TMG/TSC and help us solve any problems we are facing with the study from your perspective.

Essential Criteria:

- Understanding or experience of the issues relating to intermittent claudication or peripheral arterial disease, NMES and SET
- Be able to maintain confidentiality
- Have the time to attend meetings in person or by phone

Desirable Criteria:

It would be helpful if you have access to a computer and e-mail and have a basic understanding of the NHS and research processes although this is not required.

Remuneration:

Travel expenses and out-of-pocket expenses will be reimbursed and refreshments will be provided where appropriate.

Support:

You are able to access support and advice from the Trial Manager (contact emails at the top of this document). Please do not hesitate to ask if you don't understand something; research is full of acronyms and sometimes we forget to say the terms in full.

Further information on public involvement can be found here:

NIHR HTA Information on lay member reps: ***http://www.nets.nihr.ac.uk/ppi***

INVOLVE information on public involvement in research: ***http://www.invo.org.uk/wp-content/uploads/2011/12/PIP1whatisitallabout.pdf***

Many thanks for contributing to the NESIC research trial. We really do appreciate your involvement to help us improve the quality of the study!