The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

Participant Information Sheet and Consent Form

Acupuncture in **a**ddition to **s**tandard conservative treatment for **o**veractive bladder; a feasibility trial for a randomised controlled study (the **ACASO** study)

My name is Emma Hargreaves. I am a clinical specialist physiotherapist in Women's Health working for Newcastle upon Tyne Hospitals NHS Foundation Trust. I would like to invite you to take part in a research study that I am carrying out as part of my Doctor of Philosophy (PhD) studies. Before you decide if you would like to take part in the study I would like you to understand why the research is being done and what it would involve for you.

Part 1
What is this study about?
Overactive bladder symptoms (OAB) affect 1 in 6 people in the UK. Current treatments do not always relieve the symptoms, can be invasive, have side effects, and can incur considerable cost to the NHS. There is evidence that acupuncture may be an effective, alternative form of treatment for some people, but it is not an established treatment offered widely in the NHS.

A large study to test if acupuncture has a part to play in the treatment of OAB is planned. The study you are being asked to take part in is designed to test if it is possible to run and complete the larger study in a hospital setting. This study does not aim to demonstrate if acupuncture is effective in the treatment of OAB; it will look at whether patients are willing to take part in the study, how long it takes to recruit enough patients, how many participants complete the study, how completely the measurement tools are filled in, and will gather participants views on the process of taking part in the research. All this information is vital in planning for the larger study. This study is a small scale "dry run" of the larger project to understand and improve on the processes involved.

Why have I been invited?
You have been invited because you have overactive bladder symptoms and are seeking treatment for this. You will be able to take part in this trial if you are experiencing any of the following symptoms:

- A sudden and strong desire to pass urine – known as urgency
- Passing urine more than 8 times in 24 hours
- Voiding more than once at night
- Urinary incontinence relating to urgency

You would also need to:

- Be willing to take part in the study and be able to complete the measurement tools

A member of the research team will discuss the study with you and ensure that you are able to meet the criteria set out above.

What am I being asked to do?

If you consent to take part in the study, you will be randomly allocated to standard treatment or standard treatment plus acupuncture. Standard treatment means the treatment that you would normally receive for the complaint of overactive bladder symptoms. Standard treatment will involve a minimum of 2 appointments with a specialist nurse where you will be given advice on symptom management. This will include a review of your voiding habits, fluids management advice, and if applicable, weight management advice. The standard treatment plus acupuncture group will have the same standard treatment plus 6 weekly acupuncture treatments. The randomisation process will be completed using an online service, this means that results of the study are less likely to be affected by bias, but it does mean that you may not receive acupuncture as part of your treatment.

If you are in the group which will receive acupuncture as part of your treatment, this will mean that you have to attend 6 extra appointments at the hospital as part of the study. Funds have been reserved to reimburse you for these extra travel costs.

What is acupuncture?

Acupuncture is a form of therapy in which fine needles are inserted into specific points on the body. The points are chosen for their effect on bladder symptoms. They include points on the abdomen, calf and ankle.

Is acupuncture safe?

Acupuncture is generally very safe. Serious side effects are very rare – less than one per 10,000 treatments.

Does acupuncture have side effects?

You need to be aware that:

- Drowsiness occurs in a small number of people, if affected, you are advised not to drive immediately after treatment until the drowsiness has worn off
- Minor bleeding or bruising occurs after acupuncture in about 3% of acupuncture sessions;
- Pain during acupuncture occurs in about 1% of acupuncture sessions;
- Fainting can occur in certain people, particularly at the first acupuncture session.

Is there anything the acupuncturist needs to know?

Acupuncture cannot be performed on people with certain health problems.

Please check that you do not suffer from any of the following:

- Unstable diabetes
- Unstable epilepsy

- Bleeding disorders which mean that your blood does not clot normally
- Unstable heart conditions
- Heart valve replacements
- A recent stroke
- A recent diagnosis or treatment for cancer
- Swelling affecting the limbs (lymphoedema)
- Poor skin condition
- Allergy to metals

It is important that you let me know:

- If you have ever experienced a fit, faint or funny turn;
- If you have a pacemaker or any other electrical implants;

A member of the research team will check with you that you do not have any of the complaints listed above.

What are the measurement tools?

Your symptoms of OAB will be measured using 3 assessment tools

- A 3 -day bladder diary – this logs the frequency of voiding, the episodes of urinary leakage and episodes of waking at night to pass urine
- A short questionnaire about your bladder symptoms and how much they bother you
- A short questionnaire about your general level of well being

You will be asked to complete all three measures on 3 occasions, at the beginning of treatment, after 8 weeks of treatment and after 14 weeks of treatment.

At the end of the study you will also be asked to complete a questionnaire asking about your experiences of participating in the research.

Do I have to take part?

No, it is up to you if you take part. If you decide not to take part, your treatment will not be affected. You can leave the study at any time without giving reason. You can decide whether to take part after reading this information sheet and /or discussing it with me. If you would like to take part I will ask you to sign a consent form, although you can still decide to leave the study at any time. If, having read this information sheet, you have questions you would like to discuss with me please contact me by telephone or email, contact details are at the end of this leaflet.

What are the possible benefits of taking part?

I cannot promise the study will help you with overactive bladder symptoms, but you may experience an improvement in symptoms. By taking part you will be helping to investigate if acupuncture could be become an option for treatment in the future.

What will happen to me after the study?

Any data collected will be kept anonymous. The study findings are likely be published in a research journal and presented at conferences. If you have found the treatment you have

had during the study to be beneficial there will be an opportunity to continue treatment if you wish to do so.

What if there is a problem?
Any complaint about the way you have been treated during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part be confidential?
Yes. The research team will follow ethical and legal practice and all information about you will be handled in confidence. What you say may be published, but this will be anonymised. You will be asked to consent to your GP being informed that you are taking part in the study.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2
What will happen if I do not want to carry on with the study?
Simply contact me to let me know. Understanding the reasons why participants do not complete the study is important when it comes to designing a larger study in the future so I will ask you why you do not wish to continue in the study, you are not obliged to answer this if you do not want to say why. I can be contacted
By phone: 0191-2825484
By email: emma.hargreaves@nuth.nhs.uk

What if there is a problem?
If you have a concern about any aspect of the study, you can ring me, and I will do my best to answer any questions. My telephone is 0191 2825484. If you remain unhappy and wish to complain, you can do this by contacting Dr Carl Clarkson, the research supervisor on 0191 215 6113.
In the event that you suffer harm, and this is due to somebody's negligence, you may have grounds for a legal claim and compensation from Newcastle upon Tyne Hospitals NHS Foundation Trust, although you may have to pay legal costs.

General Data Protection Regulation (GDPR)
Newcastle upon Tyne Hospitals Foundation NHS Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Newcastle upon Tyne Hospitals Foundation NHS Trust will keep identifiable information about you for 7 years after the study has finished.
Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already

obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
You can find out more about how we use your information by contacting the study Chief Investigator (CI) Emma Hargreaves.

Newcastle upon Tyne Hospitals Foundation NHS Trust will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Newcastle upon Tyne Hospitals Foundation NHS Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The research team will pass these details to Newcastle upon Tyne Hospitals Foundation NHS Trust along with the information collected from you and your medical records. The only people in Newcastle upon Tyne Hospitals Foundation NHS Trust who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.
Newcastle upon Tyne Hospitals Foundation NHS Trust will keep identifiable information about you from this study for 7 years after the study has finished.

How will my data be kept confidential?
All information that will be used in the study will be kept secure in a locked filing cabinet in a room with a keypad within the physiotherapy department at the Royal Victoria Infirmary and kept strictly confidential. All data will be kept anonymous throughout the study. The research team are the only people who will view this data. Once the study is completed the data will be kept for 7 years after the end of the study and then destroyed. Data is stored in a secure offsite facility. Keeping data allows for it to be revisited and reviewed if necessary.

What will happen to the research results of this study?
The results of this study will be presented at Physiotherapy UK – this is the annual conference of Chartered Physiotherapists. It may also be published in a research journal. Any research results will be anonymous. All study participants and people who have helped in the setting up and running of the study will be invited to a presentation of the study results once completed. It is likely this will be towards the end of 2020.

Who is organising and funding this study?
The study has been funded by the Chartered Society of Physiotherapy Charitable Trust.
I am responsible for the organisation and delivery of the study.

Who has reviewed this study?
This study has been read and passed favourably by the North East – Newcastle &North Tyneside 1 Research Ethics Committee.

Further contact details

If you would like to know more about this study, please contact me on telephone 0191 2825484, or my academic supervisor Dr. Carl Clarkson 0191 2156113. If you have any concerns about this study, please contact me on the details below.

If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advise and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:
Telephone: 0191 223 1382 or 0191 223 1454
Email: patient.relations@nuth.nhs.uk
Address: Patient Relations Department
The Newcastle upon Tyne Hospitals NHS Foundation Trust
The Freeman Hospital
Newcastle upon Tyne
NE7 7DN

Please note:

If I contact you during the study, it is likely to be from a withheld number, this is how calls from the Trust appear on call monitoring systems. If this is a problem for you, let me know and I will make arrangements to call you with the number displayed.

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