ISRCTN48381929 https://doi.org/10.1186/ISRCTN48381929

Acupuncture for overactive bladder symptoms

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
11/02/2020

Overall study status
Completed

Last Edited
13/09/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Overactive bladder (OAB) affects 1 in 6 people. The symptoms of OAB are a strong urge to urinate, passing urine more frequently, and for some people, urinary incontinence. Current treatment for OAB includes lifestyle measures, medication and surgery. These measures can be invasive, expensive or have unwanted side effects. One study has shown acupuncture to be as effective as one type of medication with fewer side effects. Further high-quality research is needed to establish acupuncture's treatment effect before it is accepted as a treatment for OAB. Before investing in a large clinical trial looking at the effect of acupuncture on OAB, the aim of this study is to establish the feasibility of the study design.

Who can participate?
Adults with OAB.

What does the study involve?
Thirty participants will be recruited over a 15 month period, from the gynaecology and urology departments of Newcastle upon Tyne Hospitals Trust. They will be randomly allocated to one of two groups: a standard care group who will receive current conservative measures delivered during two study appointments, or a standard care plus acupuncture group who will receive, in addition, 6 weekly acupuncture treatments. Standard care includes a discussion of bladder habits, fluid intake and bladder retraining techniques. Acupuncture involves the insertion of fine needles into the skin, at specified points, which remain in place for approximately 30 minutes. All participants will be asked to complete a bladder diary and two questionnaires at their initial appointment, at 8 weeks and 14 weeks after enrolling onto the study. The research team will collect data on the length and ease of recruitment, completion of outcome measures, and the number of people who do not complete the study.

What are the possible benefits and risks of participating?
Data analysis will inform the design of ACASO II, a larger study which will test the treatment effect of acupuncture for the symptoms of OAB. Participating in the study may reduce overactive bladder symptoms, but this is not guaranteed. Taking part will help to investigate if acupuncture could become an option for treatment in the future. There are some side effects associated with having acupuncture. Documented side effects include: pain on needle insertion, minor bleeding on needle removal, dizziness, nausea and/or vomiting, fainting, headache, tiredness. In addition, the study team has identified that standard treatment may have the

drawbacks listed below: embarrassment regarding discussion of incontinence, questions that participants may find intrusive, and the study may require lifestyle changes that impact on patient's current habits.

Where is the study run from?
The Newcastle Upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2018 to September 2020

Who is funding the study?
1. Chartered Society of Physiotherapy Charitable Trust (UK)
2. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mrs Emma Hargreaves
emma.hargreaves1@nhs.net

Contact information

Type(s)
Scientific

Contact name
Mrs Emma Hargreaves

ORCID ID
https://orcid.org/0000-0002-7091-919X

Contact details
Physiotherapy Dept, Level 2
New Victoria Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP
+44 (0)191 2825484
emma.hargreaves1@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
241138

Protocol serial number
CPMS 38879, IRAS 241138

Study information

Scientific Title
Acupuncture in addition to standard conservative treatment for overactive bladder; a feasibility study for a randomised controlled trial (the ACASO study)

Acronym
ACASO

Study objectives
Overactive bladder (OAB) affects 1 in 6 people. The symptoms of OAB are; a strong urge to urinate, passing urine more frequently, and for some people, urinary incontinence. Current treatment for OAB includes lifestyle measures, medication and surgery. These measures can be invasive, expensive or have unwanted side effects. One study has shown acupuncture to be as effective as one type of medication with fewer side effects. Further high-quality research is needed to establish acupuncture's treatment effect before it is accepted as a treatment for OAB. Before investing in a large clinical trial looking at the effect of acupuncture on OAB, the aim of this study is to establish the feasibility of the study design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/08/2018, North East – Newcastle & North Tyneside 1 Research Ethics Committee (HRA Newcastle, Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048084; nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net), ref: 18/NE/0215

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Other specified disorders of bladder

Interventions
The ACASO study will be conducted on a single site, the Newcastle upon Tyne Hospitals NHS Foundation Trust. It is a feasibility study involving NHS patients with overactive bladder symptoms, and it seeks to demonstrate that the study design can be delivered in a clinical setting. The study employs a two-group design, comparing current first-line standard care with standard care plus acupuncture. This design was chosen as it provides a control group without denying care to any participant. The aim of the study is to address feasibility rather than the effect of treatment, and as such requires only a small number of participants.

Recruitment will take place in the gynaecology and urology departments of the Trust. Potential participants will be identified from the GP referral letters. The referral letters will be screened by the research team, those who may potentially be suitable for the study will be identified and a screening form placed on their medical notes. This will act as both a reminder to clinical staff to assess the patient against the inclusion/exclusion criteria, and also as a means of recording the screening data.

Clinical staff will discuss the study with potential participants who meet the inclusion criteria and provide them with a copy of the patient information sheet. Those that are interested in taking part in the study will be asked to indicate their preferred contact method i.e. telephone or email and asked to provide contact details so research staff can contact them within one working week. The conversation with the research staff is an opportunity for the potential participant to ask questions and seek clarification if required. If the potential participant is happy to proceed, an appointment for taking written informed consent will be made. Once consent has been taken, randomisation will take place

The study will recruit 30 participants who will be randomly assigned to one of two groups, using an online simple randomisation tool from sealedenvelope.com:
1. Standard treatment n=15
2. Standard treatment plus acupuncture n=15

It is estimated there are 12 new patients per week presenting with OAB symptoms in the two clinics identified for recruitment. This gives a possible pool of 720 patients during the 60-week recruitment period.

Standard care (Control)
Participants will be asked to complete a 3-day bladder diary prior to their first study visit and bring this with them when they attend, as per standard practise. Research staff will ask the participant to complete the ICIQ and ICECAP A measures after taking consent.
The care given by the specialist nurse will be guided by NICE guideline 171 which recommends the following lifestyle and behavioural interventions:
1. Review of 3-day bladder diary
2. Modification of high or low fluid intake
3. Reduction of caffeine intake if relevant
4. A bladder retraining programme
5. Weight reduction if BMI is greater than 30
The specialist nurse will discuss these topics with the participant and suggest ways to improve their symptoms of OAB. The participant is at liberty to choose whether they put this advice into action. Standard care will be delivered during a 30-minute appointment in the Women's Health Unit at the Royal Victoria Infirmary. A letter giving details of the intervention will be sent to the participants' GP and a copy placed in the medical records.
A second appointment will be arranged for 8 weeks (+/- 7 days) following the first appointment. The participant will be asked to complete a second 3-day bladder diary prior to this appointment and research staff will complete the ICIQ and ICECAP A measures with them during the 2nd visit. The third set of outcome measures will be sent to the participant by research staff at week 14 along with the exit questionnaire – they will be asked to complete these at home and return to the CI in a prepaid envelope.

Acupuncture group (Intervention)
This group will receive the same standard care documented above and in addition will have 6 weekly treatments of acupuncture based on western acupuncture principles(1). If possible the 1st and 6th acupuncture treatments will coincide with the standard care appointments to

minimise the need for repeated study visits.
All acupuncture treatments will take place in the Women's Health physiotherapy department at the RVI. All participants will receive acupuncture in accordance with the standard operating policy. A record of the treatment will be recorded using the acupuncture treatment form and stored in the participants study record.

The recruitment process and conduct of the study will be overseen by the Trial Steering Committee (TSC). This group will consist of the CI, academic supervisor, medical advisor, nurse specialist and patient representative. It will meet at four designated points during the study:
1. Prior to the start of the study to ensure all procedures and study materials are in place - projected date early September 2018
2. After 6 months of recruiting to review the recruitment rate and process – projected date early April 2019
3. Once all treatment components are completed to review the data collection process and initial analysis – projected date early March 2020
4. Once all data has been analysed and study report writing has begun, to discuss dissemination plans – projected date early August 2020

Intervention Type
Other

Primary outcome(s)
1. Participants' willingness to enter the trial, measured by the ratio between those who consented to participate and those who were eligible and approached
2. Participants acceptability of study design, measured by the completion rate of participants in each group and the degree of completeness of the three outcome measures selected (3DBD, ICIQ, and ICECAP A)
3. Participants' feedback on their experience of the study assessed using a questionnaire
4. Participant recruitment rate, measured by the number of patients randomised divided by the recruitment period. The recruitment period is defined as the date of the first patient first visit (FPFV) until the last patient first visit (LPFV). Anticipated recruitment rate is 2 per month giving a projected recruitment period of 15 months to recruit 30 participants
5. Study attrition rate, measured as the number of participants who failed to complete all aspects of the study
Timepoint(s): End of the study

Key secondary outcome(s))
At Baseline, at 8 weeks after starting treatment and at 14 weeks after starting treatment:
1. Three-day bladder diary - documenting frequency of voids, frequency of bladder leakage and episodes of nocturia
2. ICIQ-SF questionnaire to document bladder symptoms in the last 4 weeks
3. ICECAP-A - documenting the participants genral wellbeing over the past 4 weeks

Completion date
24/02/2020

Eligibility

Key inclusion criteria
1. Adults with a clinical diagnosis of idiopathic OAB syndrome - diagnosis is made by history taking and physical examination

2. Absence of other active urinary symptoms
3. Willingness to take part in the study protocol, ability to complete outcome measures and give informed consent
4. Acupuncture not contra-indicated i.e. no history of unstable heart conditions, unstable epilepsy or diabetes, bleeding disorders

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Evidence of other pathology that may be contributing to OAB symptoms i.e. urinary tract infection or a neurological condition. Treatment specific for these conditions should be offered to these individuals
2. Pregnancy - transient urinary symptoms can be present during pregnancy and often resolve spontaneously following delivery. There are some acupuncture points that are contraindicated in pregnant women
3. Unable to comprehend and retain the trial information i.e. poor understanding of English - the cost of employing interpreters to facilitate inclusion of patients who do not speak fluent English is beyond the financial scope of this feasibility study

Date of first enrolment
29/10/2018

Date of final enrolment
11/11/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Freeman Hospital
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Road

High Heaton
Newcastle-upon-Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Chartered Society of Physiotherapy Charitable Trust; Grant Codes: PRF/17/B17

Alternative Name(s)
CSP Charitable Trust, The Chartered Society of Physiotherapy Charitable Trust, The CSP Charitable Trust, Chartered Society of Physiotherapy, The Chartered Society of Physiotherapy, CSPCT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Emma Hargreaves (emma.hargreaves1@nhs.net). The data is held as an Excel file, it is anonymised and contains both quantitative and qualitative data. The file will be available from the date of publication until 24/02/2027, when it will be destroyed in line with the consent given by participants. Anyone wishing to view the data should contact Emma Hargreaves stating the purpose of the request. Sharing will be subject to an agreement re data usage and a secure method of data transfer.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2021	13/09/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V1.1		11/02/2020	No	Yes
Protocol file	version V1.1		11/02/2020	No	No