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Title Page (With Author Information)

Does acupuncture improve overactive bladder symptoms? A protocol for a qualitative study to explore patient experiences of receiving acupuncture for OAB symptoms

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Figure

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Abstract

Overactive bladder (OAB) affects around 12% of the adult population and is the subject of thousands of studies. Qualitative studies of OAB are less common and the patient voice is rarely heard. This protocol outlines the theoretical framework underpinning the study and defines the methodology that will be used to investigate the lived experience of OAB and choices regarding treatment options. This study will reference the patient experience of receiving acupuncture for OAB symptoms, a novel treatment with a growing evidence base. This is the first study to address patient experience related to acupuncture for OAB and may produce information of use to people with OAB, clinicians and those developing new pathways of care.

1.Introduction

1.1 Background

Overactive bladder (OAB) has been the subject of a multitude of research studies. The ICS classification of OAB symptoms[1] is accepted world-wide as urgency, frequency and nocturia with or without associated incontinence in the absence of other explanatory causes. Large scale epidemiology studies [2] [3]have established a prevalence of approximately 12% of the adult population, which increases with age[4] A number of Cochrane Reviews have been conducted studying the effects of interventions for OAB, namely anti-cholingeric medications[5], sacral nerve modulation[6] botulinum toxin injections[7], and bladder retraining techniques[8] and acupuncture[9].

In addition, the cost of treatments has been explored[10] [11] and an association between OAB symptoms and depression has been established [12]. A multitude of symptom measurement tools have been validated[13] [14] suggesting that no one measure is accepted as best practise. These measures focus on documentation of symptoms of OAB, although more recent measures seek to include elements regarding patient satisfaction with treatment[15].

Acupuncture has been suggested as alternative treatment modality for OAB and two large RCTs have demonstrated that the effect can be comparable to anti-cholingeric medication[16, 17]. Acupuncture is used by physiotherapists and other healthcare professionals as an adjunct to conservative management of OAB, and its feasibility in an NHS setting in the United Kingdom has been demonstrated[18]. However, acupuncture is not widely offered in the NHS currently.

The lived experience of OAB is under-reported in the literature. A systematic review conducted in 2010[19] addressed quality of life for urinary incontinence and OAB sufferers. Most of the papers reviewed related to global urinary incontinence, only 4 papers focussed solely on OAB. This review sought to quantify the types of symptoms that caused distress rather than the consequences of that distress on the way people lived their lives.

A qualitative study by Anger[20] carried out focus groups with 33 women regarding their symptoms, treatment options and outcomes. Four major themes emerged from the study including impact of OAB on quality of life, strategies to control wetness, medications and side effects, and triggers. Again, this paper's focus was on the types of symptoms that bothered women, but it did not explore in any depth how this impacted on their lives.

Nicholson[21] highlighted the devastating consequences for many OAB sufferers in terms of their physical, social, and emotional lives and also focused on the hidden nature of the condition with many people feeling shame and hopelessness regarding their condition. This in turn deterred them from seeking help for the condition.

Rantell[22] explored patient-orientated treatment goals using the Self-assessment Goal Achievement (SAGA) Questionnaire and reported that themes emerged relating to OAB symptoms, psychological wellbeing, work, and sex. The SAGA process allows for a measure of satisfaction with treatment as it is applied before and after intervention to assess to what degree the goals set have been achieved. This process emphases patient-centred goals as measures of treatment success that is lacking in other measures.

1.2 Rationale and theoretical framework

This study aims to provide specific insight regarding the experience of OAB sufferers of having acupuncture to treat their symptoms. To provide context to these experiences it is

important to understand the impact OAB has on their lives and their experiences with conventional treatments. This study will be the first to address these research questions in relation to acupuncture as a treatment.

We will conduct semi-structured interviews with people who have experience of both OAB symptoms and acupuncture to treat these. A choice of interview formats will be offered. Interviews will be recorded, transcribed and thematic analysis conducted using NVivo software [QSR International version 12 released March 2020], to identify emerging themes. This study relies on a constructivist paradigm[23], the participants are viewed as individuals with their own realities and the methods chosen will allow for this reality to be explored. As this study is addressing a new area of practise, theoretical frameworks do not exist currently.

The interviews will be transcribed and the six step process of thematic analysis applied as described by Braun and Clarke[24]. This allows for understanding of a set of experiences, thoughts, and behaviours across a dataset. It will be an inductive process, with themes emerging from the interviews[25]

This paradigm acknowledges that the values of the research team will have an influence on the outcome of the study. This influence will be evaluated with the use of a reflexive log as described by Creswell [23]completed in tandem with interviews, to understand how the researchers' experiences and role may influence the interpretation of the study findings

1.3 Study aims

- Explore the experiences of people with OAB having acupuncture for their symptoms
- Understand what informed the decision to have acupuncture
- Explore the essence of living with OAB (as this will help to understand if this informed the decision and impact of having acupuncture)
- Understand the implications of this decision making for researchers developing acupuncture and treatment pathways for OAB

2. Methods

2.1 Design

We collect data by conducting semi-structured interviews. We will use an interview schedule based on the study aims and previous studies in related fields (see appendix 1). All participants will be asked the same questions; however, interviewers can explore areas that are important to individuals.

2.2 Study Setting

The study will be conducted on a single site at a large NHS Foundation Trust. Participants can choose to conduct the interview in person, via telephone or via Microsoft Teams virtual platform. Some participants may wish to combine the interview with a treatment visit.

2.3 Participants

This study will draw from a small distinct participant population of people who have experienced both symptoms of OAB and acupuncture as a treatment. As acupuncture is not widely practised in the UK for OAB, it was not possible to identify a group of possible participants who were unknown to the research team. The corresponding authors' NHS

clinic has pioneered the use of acupuncture in an NHS setting and this clinic was used to identify possible participants.

A purposive sampling process will be used to target participants who can inform the research questions posed by this study. The research team wish to include participants who have found acupuncture to be a useful treatment and those who did not and will strive to invite equal numbers. It is anticipated that those who did not find acupuncture to be beneficial may be more reluctant to participate. Recruitment strategy and response will be discussed in the study report.

2.4 Sample size

Formal sample size calculation in qualitative studies is the subject of debate[26]. The concept of Information Power as discussed by Malterud et al [27] has been utilised in this study as the population studied is specific and the quality and depth of information is a key component. The team have chosen to pre-state the expected number of participants based on:

- Knowledge regarding the size of the population likely to fit the study inclusion criteria
- Expected willingness to participate

To our knowledge, this is the first study to address the research questions we are asking, therefore there are no other papers to base a sample size on. There are other studies addressing the lived experience of OAB. The sample sizes in these studies vary between 4[28], 18[21], and 33[20], although the inclusion criteria were wider than the proposed study. A sample size of up to 15 has been chosen to guide recruitment, however recruitment may be halted early if the data reaches saturation[29].

2.5 Inclusion/Exclusion criteria

Details are given in Table 1.

2.6 Consent

Informed consent will be discussed with the participant prior to enrolment in the study using a study consent form. The possible participant will have received the PIS and had time to read it prior to the consent /interview appointment. Each point on the form will be individually discussed with the possible participant and they will have an opportunity to ask questions and receive answers. As some interviews will be conducted virtually or by telephone, ethical permission has been agreed for verbal consent to be used in this study. Participants will be asked to confirm their consent prior to starting the interview and this will be recorded and transcribed as part of the interview for audit purposes. Those undertaking in person interviews will be asked to sign a consent form.

2.7 Withdrawal

Participants may choose to withdraw at any stage of the study by contacting the named research supervisor. They do not have to give a reason for withdrawal, however if they wish to discuss reasons for withdrawal these may be of relevance to the research findings and will be recorded.

Progression through the study is shown in Figure 1.

2.8 Data Collection

Participants will be given a choice regarding how interviews are conducted

- Face to face interviews
- Telephone interviews
- Virtual interviews using Microsoft Teams platform

The interview will be led by a member of the research team with academic and/or clinical experience of interviewing, it is predicted that between 30 minutes to one hour will be sufficient to explore the questions in the interview schedule. The interview will be recorded. The participants will only be interviewed on one occasion. On completion of the interview, participants are eligible to receive a gift voucher to the value of £30 to compensate them for their time and as a contribution towards travel expenses or use of WIFI for virtual interviews. Research team members will concurrently complete a log, detailing reflections on their influence and experiences during interviews.

2.9 Data analysis

A data protection impact assessment (DPIA) has been conducted and agreed with the sponsoring organisation. Study IDs will be used to identify the audio files. Audio files will be securely transferred to a 3rd party for transcription of the interview verbatim.
Transcribed interviews will be uploaded to NVivo software [QSR International version 12 released March 2020] for data analysis. The six step process of thematic analysis described by Braun and Clarke[24] will be followed, namely:

- Familiarising with the data
- Generating initial codes
- Searching for themes
- Reviewing themes
- Defining and naming themes
- Production of the study report

This process is not linear and may involve circling back as more data is added from subsequent interviews. Data analysis will start concurrently with the interview process and will involve at two members of the research team to validate emerging themes. The first three steps will be conducted independently, with the final three steps being a collaborative process. The reflexive logs of all interviewers will be considered when producing the study report.

2.10 Ethical and regulatory considerations

The interview schedule devised to guide discussions with participants includes topics that some may find of a personal nature, embarrassing or distressing. The research team are experienced interviewers and clinicians and will take an empathetic approach and conduct the interviews at a pace that suits the individual.
If there is concern regarding the mental wellbeing of the participant, they will ask permission to involve the participants' GP or other relevant health professionals to mitigate harm to the participant or other people.

This study has been granted a favourable ethical opinion and has the required permissions in place to begin the study

3. Discussion

3.1 Study advantages

To our knowledge, this is the first qualitative study to focus on the experience of people with OAB symptoms who choose to have acupuncture as a treatment. It will add a human dimension to the growing body of quantitive evidence regarding the efficacy of acupuncture as a treatment modality and may uncover emergent themes that inform future research designs.

It is anticipated that many of the individuals who choose to take part in this study will be doing so from an altruistic standpoint as there is no significant personal gain from participation. The research team expect that people with OAB may welcome the opportunity to have their voice heard and to contribute to health care professionals understanding of the condition.

3.2 Study limitations

The inclusion of participants who are known to the research team could be viewed as a limitation and lead to concerns regarding coercion. The research team sought to use an alternative population of OAB sufferers, contacting other clinics and patient support groups, but were unable to identify suitable people to approach. The design requires introduction to the study by an independent clinician and participants are not known to the researchers' conducting interviews. Furthermore, a researcher has been designated as the point of contact for withdrawals and complaints. This individual will not have any other role during data collection and can be viewed as independent of the process. Along with the use of a reflexive log to document the influence of the interviewer on process, it is hoped to mitigate the possibility of coercion.

4. Study timescales

Ethical permission to conduct the study was granted on 13/09/2022 by North-West Greater Manchester West Research Ethics Committee. Permission to begin recruitment was granted by the sponsoring organisation on 17/10/2022. Data collection and analysis will begin in early 2023 and it is anticipated that the results of the study will be submitted for publication by June 2023.

References

1. Abrams P, C.L., Wagg A, Wein A (Eds), *Incontinence 6th Edition.* 2017.
2. Tubaro, A., *Defining overactive bladder: epidemiology and burden of disease.* Urology, 2004. **64**(6 Suppl 1): p. 2-6.
3. Irwin, D.E., et al., *Population-based survey of urinary incontinence, overactive bladder, and other lower urinary tract symptoms in five countries: results of the EPIC study.* European urology, 2006. **50**(6): p. 1306-1315.
4. Sexton, C.C., et al., *Prevalence and Effect on Health-Related Quality of Life of Overactive Bladder in Older Americans: Results from the Epidemiology of Lower*

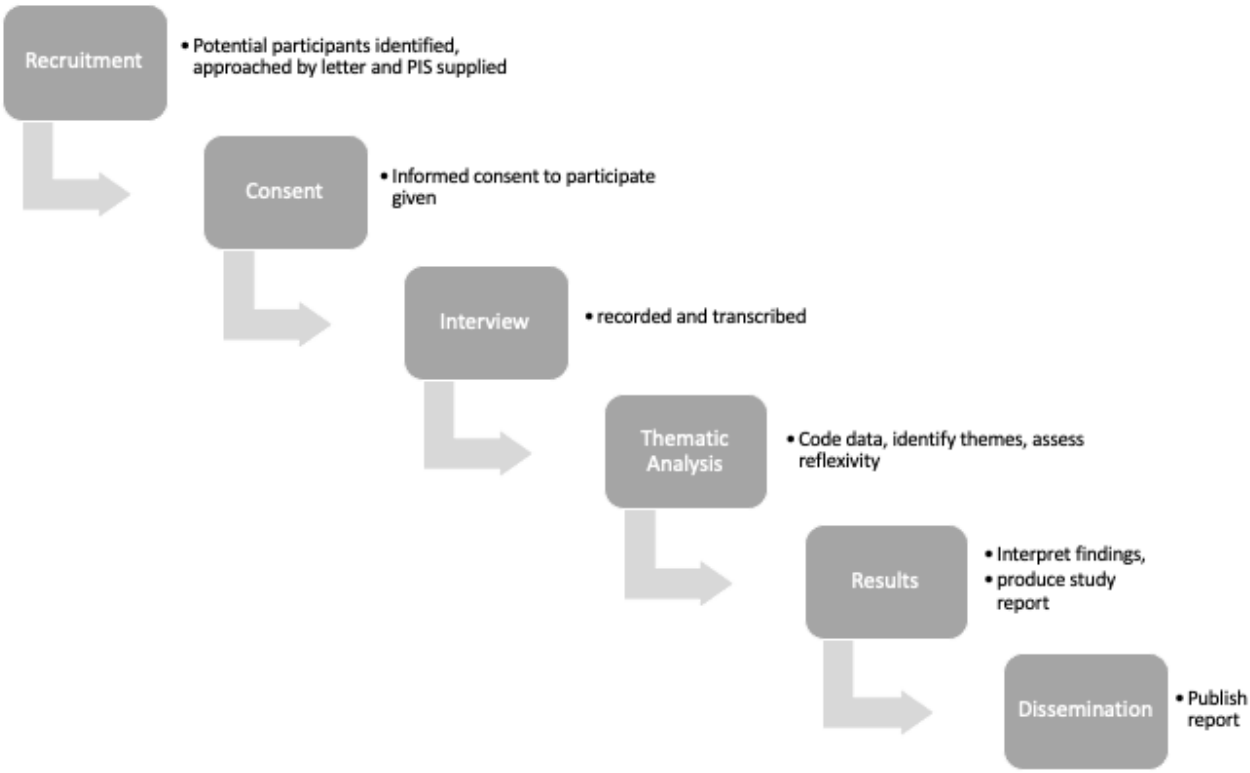
Urinary Tract Symptoms Study. Journal of the American Geriatrics Society, 2011. **59**(8): p. 1465-1470.
5. Madhuvrata, P., et al., *Which anticholinergic drug for overactive bladder symptoms in adults.* The Cochrane database of systematic reviews, 2012. **1**(3): p. CD005429-CD005429.
6. Herbison, G.P. and E.P. Arnold, *Sacral neuromodulation with implanted devices for urinary storage and voiding dysfunction in adults.* The Cochrane database of systematic reviews, 2009(2): p. CD004202-CD004202.
7. Duthie, J.B., et al., *Botulinum toxin injections for adults with overactive bladder syndrome.* The Cochrane database of systematic reviews, 2011(12): p. CD005493.
8. Wallace, S.A., et al., *Bladder training for urinary incontinence in adults.* Cochrane Database of Systematic Reviews, 2004(1).
9. Hargreaves, E., et al., *Acupuncture for treating overactive bladder in adults.* Cochrane Database Syst Rev, 2022. **9**: p. CD013519.
10. Hu, T.-W., et al., *Estimated economic costs of overactive bladder in the United States.* Urology, 2003. **61**(6): p. 1123-1128.
11. Ganz, M.L., et al., *Economic Costs of Overactive Bladder in the United States.* Urology, 2010. **75**(3): p. 526-532.e18.
12. Vrijens, D., et al., *Affective symptoms and the overactive bladder - a systematic review.* J Psychosom Res, 2015. **78**(2): p. 95-108.
13. Avery, K., et al., *ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence.* Neurourology and Urodynamics: Official Journal of the International Continence Society, 2004. **23**(4): p. 322-330.
14. Homma, Y., et al., *Symptom assessment tool for overactive bladder syndrome—overactive bladder symptom score.* Urology, 2006. **68**(2): p. 318-323.
15. Kelleher, C., et al., *Development of an overactive bladder assessment tool (BAT): A potential improvement to the standard bladder diary.* Neurourology and urodynamics, 2018.
16. Yuan, Z., et al., *Acupuncture for overactive bladder in female adult: a randomized controlled trial.* World journal of urology, 2015. **33**(9): p. 1303-1308.
17. Liu, B., et al., *Electroacupuncture Versus Pelvic Floor Muscle Training Plus Solifenacin for Women With Mixed Urinary Incontinence: A Randomized Noninferiority Trial.* Mayo Clinic Proceedings, 2019. **94**(1): p. 54-65.
18. Hargreaves, E., C. Harding, and C. Clarkson, *Acupuncture in addition to standard conservative treatment for overactive bladder; a feasibility trial for a randomized controlled study.* Neurourol Urodyn, 2021.
19. Bartoli, S., G. Aguzzi, and R. Tarricone, *Impact on quality of life of urinary incontinence and overactive bladder: a systematic literature review.* Urology, 2010. **75**(3): p. 491-500.
20. Anger, J.T., et al., *Women's experience with severe overactive bladder symptoms and treatment: insight revealed from patient focus groups.* Neurourol Urodyn, 2011. **30**(7): p. 1295-9.
21. Nicolson, P., et al., *It's just the worry about not being able to control it! A qualitative study of living with overactive bladder.* Br J Health Psychol, 2008. **13**(Pt 2): p. 343-59.
22. Rantell, A., L. Cardozo, and V. Khullar, *Personal goals and expectations of OAB patients in the UK.* Neurourology and urodynamics, 2017. **36**(4): p. 1194-1200.

23. Creswell, J.W., *30 essential skills for the qualitative researcher*. Second edition / John W. Creswell, Johanna Creswell Báez.. ed, ed. J. Creswell Báez. 2021: Los Angeles : SAGE.
24. Braun, V. and V. Clarke, *Using thematic analysis in psychology.* Qualitative research in psychology, 2006. **3**(2): p. 77-101.
25. Kiger, M.E. and L. Varpio, *Thematic analysis of qualitative data: AMEE Guide No. 131.* Med Teach, 2020. **42**(8): p. 846-854.
26. Sim, J., et al., *Can sample size in qualitative research be determined a priori?* International journal of social research methodology, 2018. **21**(5): p. 619-634.
27. Malterud, K., V.D. Siersma, and A.D. Guassora, *Sample Size in Qualitative Interview Studies: Guided by Information Power.* Qual Health Res, 2016. **26**(13): p. 1753-1760.
28. Kinsey, D., et al., *When is better really better? Individuals' experiences of treatment for OAB with anticholinergic medication.* International Journal of Urological Nursing, 2017. **11**(1): p. 42-51.
29. Fusch, P.I. and L.R. Ness, *Are we there yet? Data saturation in qualitative research.* The qualitative report, 2015. **20**(9): p. 1408-1416.

Highlights

- Lived experience of overactive bladder symptoms
- Use of acupuncture as a treatment modality
- Qualitative investigation of treatment choices

Figure



Table

Table 1 Inclusion and exclusion criteria.

Inclusion criteria	***Exclusion criteria***
Aged over 18 years of age	Under 18 years of age
Male or female	Symptoms do not conform to ICS definition of OAB
A working diagnosis of OAB that meets the ICS definition[1]	No experience of acupuncture for OAB
Completed a minimum of a 4-week acupuncture trial for OAB symptoms	Unwilling or unable to give informed consent to participation
Informed consent to participate	Unwilling or unable to give informed consent to interview being recorded for transcription purposes
Informed consent for interview to be recorded for transcription purposes	

Declaration of interests

☒ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☐ The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: