

# BMJ Open Hardiness and Outcome of Self-catheterisation Training (HOST): protocol for an observational study exploring the effects of personality traits in women on ability to learn clean intermittent self-catheterisation

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#### ABSTRACT

**Introduction:** Clean intermittent self-catheterisation (CISC) is the recommended first-line management of voiding dysfunction; however, psychological factors involved in acceptance and take up are often neglected. There is a tendency to discuss the success of CISC in relation to factors that affect teaching and learning, with subsequent success or failure being attributed to these. There is limited research investigating what extent, personality traits impact on a woman's willingness to learn CISC and subsequent mastery of the technique.

**Method and analysis:** All women attending a tertiary urogynaecology department as eligible for CISC will be invited to participate in the study. Over the 14-month recruitment period, an estimated 130 women will be involved. The participants will complete a series of self-reported questionnaires. Personality types will be assessed using The Hardiness Scale and State-Trait Anxiety Inventory. The impact of urinary symptoms and CISC on quality of life (QoL) will be measured using an electronic pelvic-floor assessment questionnaire (ePAQ). Success and mastery will be measured by recording the number of hospital appointments and the length of time taken to learn. Confidence will be measured using the Likert scale. A sample of 20 women will be invited to participate in semi-structured in-depth interviews to explore women's views and experiences of CISC.

**Ethics and dissemination:** Regulatory approvals will be in place prior to the start of the study. Good clinical practice guidelines will be followed throughout. Eligibility and training for CISC will be undertaken in accordance to individualised care plans in line with unit protocol and will not be influenced by the study. Trial data will be anonymised and participant confidentiality will be maintained. The Study findings will be disseminated through publications in relevant journals and will be presented at multiprofessional conferences and scientific meetings.

#### INTRODUCTION

Female voiding dysfunction is a complex disorder of the lower urinary tract, which is poorly understood and often difficult to manage.<sup>1</sup> Most of the research works on lower urinary tract symptoms do not address the voiding phase of urinary dysfunction and therefore there are wide variations in prevalence estimates ranging from 5% to 24%. Groutz and Bhivas<sup>2</sup> suggested that these variations are due to the lack of a clear and standardised definition. Indeed, in a recent study, the prevalence rate was reported to be as high as 39%.<sup>3</sup> Voiding difficulties, which may result in urinary retention, are commonly managed with clean intermittent self-catheterisation (CISC). The majority of research to date explores complication rates such as urinary tract infection or the use of different types of catheters.<sup>4</sup> The success of CISC is often discussed in relation to factors that affect teaching and learning with subsequent success or failure, being attributed to these factors.<sup>5</sup>

There are several reports<sup>6,7</sup> providing anecdotal qualitative information from continence advisors and most of our current quantitative information is limited to small projects and audit.<sup>8</sup> However, there is a paucity in research investigating the extent to which personality variables impact on a woman's willingness to learn CISC and her subsequent mastery of the technique. In a study by Logan *et al*,<sup>9</sup> attempts were made to explore the patient perspective of CISC. Anxiety, embarrassment, technical difficulties and interpersonal skills, as well as the role of the nurseteaching CISC, affected the process

of learning the technique. Practical difficulties that patients may face, expectations and fears, as well as the motivation of the trainer and the patient, have been found to affect the learning of CISC.<sup>6</sup> Doherty<sup>5</sup> identified similar factors including patient understanding, manual dexterity and motivation. Although social, sexual and psychological aspects of learning CISC are discussed; neither Bennett<sup>6</sup> nor Doherty<sup>5</sup> explores this topic in any depth. Several authors reported that CISC improves quality of life (QoL) due to improved underlying symptoms such as a reduction in urinary tract infections, urgency and frequency.<sup>7–10</sup> Shaw<sup>11</sup> and associates explored the effects of CISC on QoL and reported that their research would help healthcare professionals to identify factors likely to influence responses to CISC and act as a tool to identify those patients who may have difficulty complying with the treatment. However, in view of their small sample size and the inclusion of many variables, their results should be interpreted with extreme caution. A recent study<sup>12</sup> used a series of semi-structured and in-depth interviews to explore the experiences and emotional responses of female patients learning CISC; a framework method was used where six recurrent themes including grief and loss, lack of knowledge, negative associations and stigma, psychological aversion and embarrassment, nursing approaches and coping mechanism were identified. The authors acknowledged that, their sample size was very small, with only five patients, and sampling and collection methods were subject to bias, limiting the interpretation of the themes identified. However, they concluded that the manner in which CISC is introduced to the patient and the experiences they have when learning how to perform CISC may either predispose them to pursue the option of learning CISC or to abandon it, and its potential benefits. These findings provide some valuable qualitative evidence but also reinforce the need to explore some of these issues further.

### Rationale for Hardiness and Outcome of Self-catheterisation Training

Within the field of urogynaecology, the current continence questionnaires do not explore women's personalities as a potential predictor of willingness to learn, and CISC management outcome. Hardiness and Outcome of Self-catheterisation Training (HOST) is designed to assess the effect of an individual's personality on CISC training and the impact of this, if any, on QoL using validated questionnaires and qualitative measures of semi-structured interviews to provide a narrative of women's experiences. It is an area where there is little or no research to direct healthcare professionals with quality evidence supporting the best practice.

### Method/design

HOST is a single centre, prospective observational study. HOST will utilise mixed methodology to investigate the

extent to which individual personality affects the success of CISC training and the impact of CISC on QoL.

Quantification of variables will be broadened and enriched by an in-depth, qualitative investigation of women's experiences of self-catheterisation. With no reported studies investigating hardiness, stress, coping among patients who are required to learn CISC, the study will provide novel information on the association between personality traits and coping abilities, and will, potentially, enable healthcare professionals to individualise CISC training to patient needs. If associations between hardiness and CISC training outcome are found, it is possible that healthcare professionals can adapt training for women with low hardiness scores to learn the required skills that improve coping,<sup>13</sup> and reduce stress<sup>14</sup> aided through mechanisms of social support,<sup>15</sup> to improve performance.<sup>16</sup> HOST will provide information to assist clinicians and managers to personalise CISC-related healthcare delivery, providing guidelines for the number and duration of hospital appointments based on individual characteristics and needs.

### Setting

The study will be conducted within a tertiary urogynaecology department in Birmingham, UK.

### Participants

The majority of women referred to the urogynaecology department present with pathology relating to the lower urinary tract. Participants will include women who have pre-existing voiding difficulties or, are at risk of developing voiding difficulties due to this pathology and/or the proposed treatment. Women are occasionally referred to the department with a neurological cause for their voiding dysfunction; these women will also be approached to take part in the study.

Inclusion criteria for participation in the research include all the following:

1. Women aged  $\geq 18$
2. *Actual* or *potential* urinary retention deemed suitable for nurse-led CISC training
3. Valid consent

Exclusion criteria include either of the following:

1. Women with significant physical or learning disability requiring that intermittent catheterisation be undertaken by the patient carers.
2. Women who do not have adequate understanding of the study or questionnaires as their first language is not English (due to questionnaire validity).

### Consent

Women eligible for the study will be provided with the study information leaflet, by members of the nursing or medical team within the urogynaecology department. They will be provided time to ensure that they understand the information and have opportunity to clarify and ask questions. Participation or non-participation in the study will not affect clinical care.

A written consent will be obtained from the women who wish to participate. The participants will have the right to withdraw from the study at any stage; the clinical care will not be affected if the participants choose to withdraw from the study.

## DATA COLLECTION

### Baseline

At the time of entering the study, baseline information will be recorded (age, socioeconomic grouping, ethnicity, urogynaecological issue requiring the teaching of CISC, problems that may arise from not learning CISC, willingness to learn and factors affecting QoL).

Women will be asked to complete the following self-report measures:

1. The Hardiness Scale
2. State-Trait Anxiety Inventory
3. electronic pelvic-floor assessment questionnaire (ePAQ)

### After completion of CISC

Training CISC will be delivered as per unit protocol. After the training period, success or failure of mastering CISC will be assessed by the Likert scale questions used to assess confidence level in undertaking the procedure. The number of visits required for teaching and the time taken will be recorded. Case notes will be accessed to identify the willingness to learn. Routine follow-up occurs around 1–4 weeks following the completion of training. This can be conducted over the telephone or face-to-face in a clinic.

As per the routine practice within the department, all women who attempt to learn CISC or have a procedure where they are at risk of developing urinary retention will be asked to repeat the ePAQ after the treatment.

### Qualitative analysis

A purposive sample of 20 women will be invited back to attend a semistructured interview to obtain a more detailed picture of their experiences. We will choose women of different age groups, social background and culture, with the aim of capturing information from a diverse population of women who need to learn CISC. Women who attempt to learn CISC will be made aware that the interview will not be undertaken by the same nurse who has taught the procedure so as to minimise any effects on responses provided by the research participants.

## MEASURES

### The Hardiness Scale

Bartone *et al*<sup>17</sup> suggest that compared with low scorers, hardy people have less depression, anxiety and suspiciousness of others and fewer health problems. Hardy personalities cope far more effectively with stressful events and tend to be more assertive and independent than low scorers. Hardiness is 'a constellation of personality characteristics that function as a resistance resource

in the encounter with stressful life events'<sup>18</sup> The questionnaire comprises of 15 questions which explore the facets of commitment, control and challenge.

### State-trait anxiety inventory Spielberger

Freud proposed a critical role for anxiety in everyone's personality.<sup>19 20</sup> In Spielberger's<sup>19</sup> refinement, he describes trait anxiety as a relatively stable and enduring disposition in a person's character while state anxiety is more situation-specific, transient and easier to manage or ameliorate. An individual who is highly trait-anxious will find much in life to feel threatened especially by, according to Spielberger,<sup>19</sup> any novel situation. The state-anxious individual, however, will recover more quickly under conditions of threat and, in general, find novel situations easier to manage. We might therefore expect that high trait-anxious women will be less likely to master CISC than those who are either low trait-anxiety scorers or those who only report state-anxiety in anticipation of CISC. Trait and state anxiety are measured on a 20-item Likert scales.

### Electronic pelvic-floor assessment questionnaire

The impact of urinary symptoms and CISC on QoL will be measured using ePAQ. This questionnaire is used widely within the field of urogynaecology as a validated symptom-based assessment tool.<sup>21</sup> It comprises of four domains which explore symptoms related to the bladder, bowel, vaginal and sexual components of pelvic floor dysfunction, scoring each domain in relation to the effects on QoL. The questionnaire also gives a bothersome score and as such it allows extensive comparison of symptoms before and after treatment enabling us to assess the outcomes of treatment.

### Semistructured in depth interviews

The interview protocol will be developed from the constructs represented in the questionnaires and literature reviews and following analysis of the quantitative data. Therefore, although comparatively arduous analytically, narratives are vital in explaining the findings from the quantitative measures. A mixed methods approach enables the researcher to provide a better understanding of the phenomenon under investigation and through a process which integrates outcome results can be compared for agreement and disagreement in relation to the phenomenon.<sup>22</sup> Inconsistencies in findings from the different methods can provide opportunity to explore multiple meanings that would have been lost in a single designed study. Flemming<sup>23</sup> suggests that to explore complex phenomena and understanding the impact of health problems can only be achieved using a mixed methods approach. This approach allows opportunity to describe and develop an understanding and insight into a phenomenon in relation to testing the null hypothesis that personality differences expressed through hardiness and state trait anxiety do not influence the success in CISC nor impact on QoL of women

undertaking CISC. Thematic analysis will be conducted with the help of a qualitative researcher and having an adequate understanding of the phenomena context through previous clinical practice and an understanding of the relevant literature will allow the researchers to make meaningful inferences.<sup>24</sup> The number to be interviewed will depend on saturation level, namely the point at which no new information is being derived.

### Confidence in CISC procedure

Likert-type questions will be used to assess the women's ability to perform CISC confidently and independently.

### Population/sample size

Women, with actual or potential urinary retention (due to prospective procedure) needing to learn CISC, will be considered eligible to participate in the HOST study. Based on the time frame of the study and the number of women currently seen in our CISC clinics and having treatments which have a risk of voiding difficulties attached to them, we expect to recruit 130 women. This figure is based on the number of women who attended a nurse-led clinic to learn CISC over the previous 12 months and treatments that have a risk of voiding difficulties attached to them.

The study will recruit over a 14-month period. It is estimated that 130 women will consent to the study, and of these, 130 women over 50% will be willing to learn CISC.

For the qualitative aspect of this project, we will aim to recruit a purposive sample which will include five women from each of the following four groups, a maximum of 20 women in total:

1. Women not willing to undergo a procedure due to risk of voiding difficulties.
2. Women willing to have a procedure but do not develop voiding difficulties.
3. Women who attempt CISC and attain mastery of the skill.
4. Women who attempt CISC and do not attain mastery of the skill.

Primary outcome measure

- Success of mastering CISC procedure.

Secondary outcome measures

- Willingness to learn CISC.
- Problems caused by not performing CISC (need for indwelling catheterisation, length of hospital stay and urinary tract infections).
- QoL.

### Statistical plan/analysis

Data will be stored in a database that is password protected. External reviewers will conduct an audit of analysis of data for agreement or disagreement to check its validity.

Baseline data will be tabulated according to CISC mastery status and willingness to learn, displaying appropriate summary statistics. If numbers allow, unadjusted

and adjusted logistic regression models will then be fitted to provide ORs of CISC mastery by hardiness for patients willing to learn CISC, state trait anxiety and ePAQ values and patient characteristics. The patient case notes will be used to identify willingness to learn CISC and logistic regression models will be used to identify the associations with willingness to learn and hardiness, state trait anxiety and ePAQ values and patient characteristics.

The number and length of appointments will be analysed by mastery status. Problems emerging by not performing CISC will be identified and also reported.

Statistical analyses will be carried out in SPSS. Thematic analysis of textual data will be analysed using NVivo.

### Patient involvement

Development of the HOST study as a research topic was discussed at the set-up phase with our continence patient and public involvement (PPI) group at the Birmingham Women's Hospital. Further PPI into its development included it being discussed at a recent quality improvement initiative which included patients who had been users of our service and stakeholders ranging from clerical, administration staff through to managers, medics, nurses, midwives and allied health-care professionals. It was concluded that this was an idea worth exploring further and the development of the research proposal has been designed with feedback from these patients.

## DISCUSSION

The psychological factors involved in the acceptance and take up of CISC can often be neglected. Patients are often faced with a life changing event, either short-term or long-term, but are given little time and support to manage their needs which should be assessed on an individual basis. This study aims to explore the lack of evidence on the personality differences and how these may affect the outcomes. It has the potential to be adapted to other areas of medicine and can have a significant impact on improving an individual's experience and our ability to offer patient-centred care that is relevant and appropriate to the need of our patients.

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