

# BMJ Open The QuickWee trial: protocol for a randomised controlled trial of gentle suprapubic cutaneous stimulation to hasten non-invasive urine collection from infants

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**To cite:** Kaufman J, Fitzpatrick P, Tosif S, *et al*. The QuickWee trial: protocol for a randomised controlled trial of gentle suprapubic cutaneous stimulation to hasten non-invasive urine collection from infants. *BMJ Open* 2016;**6**:e011357. doi:10.1136/bmjopen-2016-011357

► Prepublication history for this paper is available online. To view these files please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2016-011357>).

Received 1 February 2016  
Revised 31 May 2016  
Accepted 22 July 2016



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## ABSTRACT

**Introduction:** Urinary tract infections (UTIs) are common in young children. Urine sample collection is required to diagnose or exclude UTI; however, current collection methods for pre-continent children all have limitations and guidelines vary. Clean catch urine (CCU) collection is a common and favoured non-invasive collection method, despite its high contamination rates and time-consuming nature. This study aims to establish whether gentle suprapubic cutaneous stimulation with cold fluid-soaked gauze can improve the rate of voiding for CCU within 5 min in young pre-continent children.

**Methods and analysis:** This study is a randomised controlled trial of 354 infants (aged 1–12 months) who require urine sample collection, conducted in a single emergency department in a tertiary paediatric hospital in Melbourne, Australia. After standard urogenital cleaning, patients will be randomised to either a novel technique of suprapubic cutaneous stimulation using cold saline-soaked gauze in circular motions or no stimulation. The study period is 5 min, after which care is determined by the treating clinician if a urine sample has not been collected. Primary outcome: whether the child voids within 5 min (yes/no). Secondary outcomes: parental and clinician satisfaction with the method, success in catching a urine sample if the child voids, and sample contamination rates. This trial will allow the definitive assessment of this novel technique, gentle suprapubic cutaneous stimulation with cold saline-soaked gauze, and its utility to hasten non-invasive urine collection in infants.

**Ethics and dissemination:** The study has hospital ethics approval and is registered with the Australian New Zealand Clinical Trials Registry—ACTRN12615000754549. The results of the study will be published in a peer-reviewed journal.

**Trial registration number:** ACTRN12615000754549; Pre-results.

## INTRODUCTION

Urinary tract infections (UTIs) in young children are common affecting 5–7% of febrile

## Strengths and limitations of this study

- Simple, gentle, easily replicable, non-invasive technique for urine collection in young children.
- Randomised controlled trial informed by prospective baseline and pilot feasibility studies.
- Pragmatic technique and trial methodology which reflect the busy clinical environment.
- Clinicians and parents cannot be blinded to the intervention.

children under 2 years of age,<sup>1 2</sup> but the clinical signs of UTI can be non-specific. Urine collection is required for diagnosis of clinically suspected UTI or to determine the potential source of fever in the absence of a clear clinical focus. Limitations and ongoing debate exist with current invasive and non-invasive methods of obtaining urine samples from young pre-continent children.<sup>3 4</sup>

The decision on the method of urine sampling balances invasiveness (and hence pain and distress), reliability, speed and contamination rates. Clean catch urine (CCU) is often favoured for being non-invasive and requiring less technical expertise, in hospital and community-based settings,<sup>5</sup> and has lower contamination rates than other non-invasive methods such as urine collection bags.<sup>6</sup> Suprapubic aspiration and catheter specimens have lower contamination rates than CCU; however, these methods involve pain and distress for the child and require technical expertise and equipment.

Guidelines from the UK (National Institute for Health and Care Excellence),<sup>7</sup> USA (American Academy of Pediatrics)<sup>8</sup> and our local Royal Children's Hospital<sup>9</sup> have differing recommendations for the use of CCU for urine collection from febrile infants with

suspected UTI. Contamination rates in CCU are high and variable, reported as between 7.8% and 35%.<sup>6 10–12</sup>

CCU also ties up valuable resources in clinical settings due to its time-consuming nature, and parents report that obtaining a CCU is time consuming and messy.<sup>13</sup> This may result in increased urine contamination rates due to difficulty preventing accidental contamination of the genital area or collection jar, or CCU being abandoned by the parent or clinician. One previous study found that 58% of children waited longer than 1 hour to pass urine with CCU, with a mean time of 71 min to either pass urine or leave the department without a sample.<sup>14</sup>

We conducted an initial prospective baseline study to determine success in obtaining CCU with current practice, in pre-continent children aged 1–48 months. A timer was used to measure time to void after standard urogenital cleaning (without any additional stimulation). In preliminary results from the first 113 children, 13 children (11.5%) voided within 5 min.<sup>12</sup> Of the 57 patients who were aged <12 months, 12 patients (21%) voided within 5 min.

Previous studies have examined novel methods to obtain more rapid CCU in pre-continent children. These include vibrating bladder stimulator in infants and toddlers (not effective)<sup>14</sup> and lumbar/sacral stimulation in neonates (effective but limited age group).<sup>15 16</sup> An effective method to expedite CCU would reduce time to diagnosis, reduce the need for clinicians to instigate painful invasive urine collection methods, reduce urine culture contamination rates and likely improve parent and clinician satisfaction with the CCU method.

In animals such as rats, the mother stimulates bladder emptying by licking the perigenital skin of her newborn pups, triggering the perigenital-bladder reflex.<sup>17</sup> Animal model studies have also shown that mechanical and electrical perigenital skin stimulations can excite perigenital-to-bladder spinal reflexes and stimulate bladder contractions in cats with chronic spinal cord injury.<sup>18</sup>

In humans, suprapubic stimulation is proposed to trigger parasympathetic detrusor contraction via the exteroceptive somato-bladder reflex mechanism.<sup>19</sup> We hypothesise that a simple intervention of gentle suprapubic stimulation using cold fluid-soaked gauze may hasten bladder voiding, by triggering cutaneous reflexes which are present at birth and suppressed later in development.

We conducted a pilot feasibility study to test if additional suprapubic cutaneous stimulation with saline-soaked gauze was a feasible and acceptable intervention, and if this method may help to obtain CCU within 5 min in children aged 1–24 months in the paediatric emergency department (ED).<sup>20</sup> This was tested on 20 children using cold saline (7/20 successful, 35%) and 20 children using room temperature saline (5/20 successful, 25%). Most successful voids were from infants aged 1–12 months (12/12, 100%), so we chose 1–12

months as the participant age group for the definitive trial. CCU is not a recommended method of urine collection in neonates (<1 month) for investigation of UTI in our institution.

Our primary objective is to examine whether a simple and easily followed technique (additional suprapubic cutaneous stimulation with cold fluid-soaked gauze) increases the rate of voiding within 5 min in pre-continent children, compared to using standard urogenital cleaning alone. Secondary objectives are to study whether this method can reduce the number of urine voids that are ‘missed catches’, and reduce the need to use invasive urine sampling techniques in some circumstances.

## METHODS AND ANALYSIS

### Study aims

To determine if suprapubic cutaneous stimulation with cold fluid-soaked gauze increases the rate of urine voiding within 5 min in children aged 1–12 months in the paediatric ED, where a urine sample is required and the clinician has determined that CCU is an appropriate method of collection.

### Study design and setting

A prospective randomised controlled trial (RCT) will be undertaken to compare the rate of urine voiding within 5 min using standard urogenital cleaning and CCU alone, compared with standard urogenital cleaning and CCU with additional suprapubic cutaneous stimulation with cold saline-soaked gauze.

The population to be studied is children aged 1–12 months in a single paediatric ED at the Royal Children’s Hospital, Melbourne, Australia.

### Eligibility criteria

Eligibility criteria for the study are listed in [box 1](#).

### Interventions

Study procedures are as follows ([figure 1](#)).

#### Box 1 Eligibility criteria

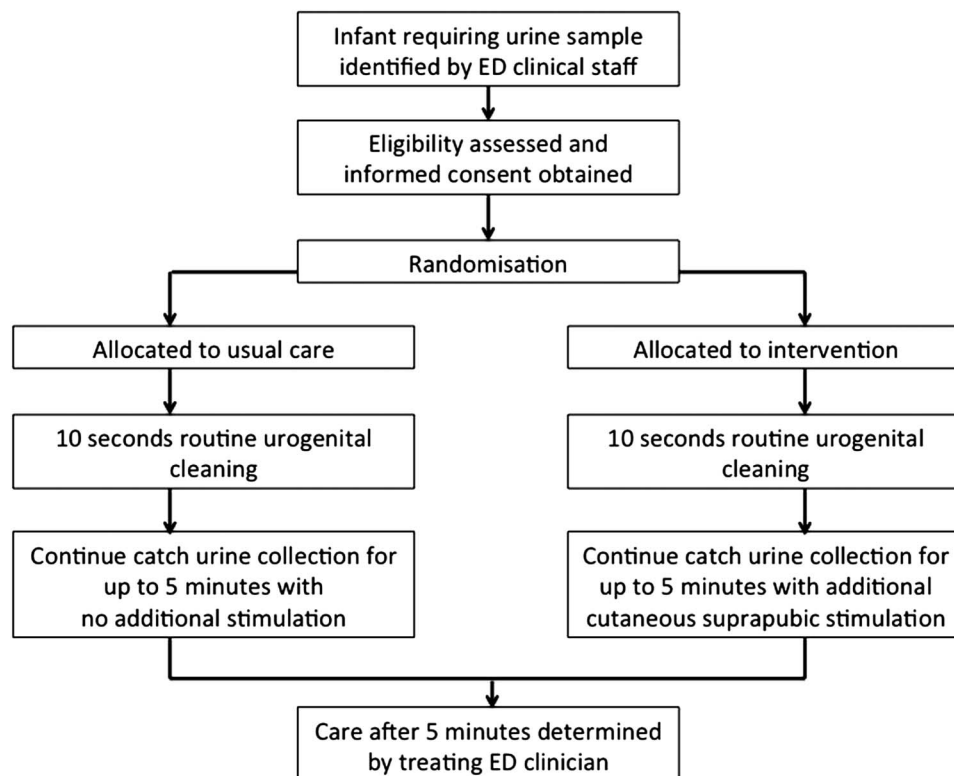
Inclusion criteria—all of the following:

- ▶ Aged 1 month (28 days of age) to 12 months (365 days of age), corrected for prematurity if <36 weeks gestation,
- ▶ Not able to void urine on request (pre-continent),
- ▶ Appropriate for and require clean catch urine sample collection, as determined by the treating clinician.

Exclusion criteria—any of the following:

- ▶ Children <1 month of age (<28 days of age),
- ▶ Children >12 months of age (>365 days of age),
- ▶ Need for immediate urine sample via sterile method as determined by treating clinician,
- ▶ Anatomical or neurological abnormality affecting voiding or sensation.

**Figure 1** Study flow chart in the ED. ED, emergency department.



The clinician provides a parent information handout, verbally explains the procedure and obtains verbal consent from parents. The child is offered a bottle/breast feed prior to attempted CCU if appropriate (routine practice).

Nursing or medical staff prepare the child for attempted CCU, open the opaque randomisation envelope, remove the nappy and start the timer. A parent, carer or staff member prepares to catch a urine sample if the child voids, and the genital orifice is cleaned for 10 s (standard practice). If randomised to the usual care arm, the parent, carer or staff member waits for the child to void spontaneously, until CCU is obtained or the timer reaches 5 min. If randomised to the intervention arm, the staff member (or parent/carer with supervision) additionally rubs the suprapubic area of child with cold saline-soaked gauze held by disposable plastic forceps in a circular pattern, until CCU is obtained or the timer reaches 5 min (see figure 2).

The timer is stopped if the child voids and CCU obtained and time to void recorded. Alternatively, a missed catch, failure to void at 5 min or reason for abandoning procedure is recorded as well as parent and clinician satisfaction with the method. Children who have been randomised and void during the 10 s cleaning phase will be included in the intention-to-treat analysis.

Standard urogenital cleaning for both groups will be performed using a designated standard cleaning pack with room temperature fluid for cleaning.

Additional suprapubic cutaneous stimulation will be performed using a designated pack containing



**Figure 2** QuickWee method of suprapubic cutaneous stimulation with saline-soaked gauze.

disposable plastic forceps and gauze, and study-labelled cold fluid, 10 mL of 0.9% saline ampoules. The cold fluid will be stored in a designated study refrigerator with a temperature of 2.8°C (checked monthly to ensure temperature range  $\pm 1^\circ\text{C}$ ). Clinicians will be advised to start using the cold fluid within 2 min after taken out from the refrigerator to ensure that it remains as close as possible to the designated temperature.

When CCU is not obtained within the 5 min trial period, the clinician will make the decision on the ongoing method of urine collection (continue CCU, catheter, SPA, abandon urine collection).

## Outcomes

The primary outcome measure is voiding of urine within 5 min (binary yes/no outcome).

Secondary outcome measures will be (1) parental and clinician satisfaction with the urine collection technique in each group (satisfaction rating scale 1–5: very satisfied, satisfied, neutral, unsatisfied, very unsatisfied); (2) if the child voids, whether a urine sample is successfully caught in the specimen jar or if the void is missed (binary yes/no outcome: CCU caught if child voids); and (3) contamination rate of CCU samples obtained within 5 min (binary yes/no outcome: urine culture contamination as per hospital laboratory definition).

## Sample size

A sample size of 354 patients (177 in each group) will be included in the study.

In preliminary data from the preceding baseline study measuring time to void for children requiring CCU using standard urogenital cleaning alone, 12 (21%) of 57 patients aged 1–12 months voided within 5 min. We surveyed a panel of 20 expert clinicians (Paediatric Emergency Medicine Physicians and Paediatricians at consultant level) who reported an increase in success rate of ~15% would suggest that this technique should be incorporated into their clinical practice. Data from the pilot feasibility study suggest that this is a reasonable estimate of the likely treatment effect.

With a sample size of 322 patients (161 in each group), the study would have 80% power to detect a difference of 21% (non-intervention arm) vs 35% (intervention arm) success rate of infants voiding within 5 min. Power and sample size calculations were completed using Stata (Statacorp 2015, Texas, USA) using an estimated total sample size for a two-sample proportions test (Pearson's  $\chi^2$  test).

An additional 10% of patients (16 in each group) will be recruited in the sample size to account for a small percentage of loss to follow-up of primary outcome results.

## Recruitment

ED nursing and medical staff will be trained to recruit patients and implement the intervention with face-to-face education sessions and written instructions available in the ED. They will identify potentially suitable patients requiring urine sample collection and make a decision about the appropriate method of urine sample collection on clinical grounds (independent of this research project), at the point of triage or during clinical assessment. Patients that clinical staff consider suitable for inclusion in the study will be recruited consecutively. The parent/carer will be provided with a verbal explanation and written study information sheet, and verbal consent will be obtained to participate in the study. Recruitment began in 2015, and it is anticipated that recruitment will be completed within 12 months.

## Allocation

Study participants will be randomly assigned, in a 1:1 ratio, to the intervention (additional suprapubic cutaneous stimulation with cold saline-soaked gauze) or standard care. A statistician not directly involved in the analysis of the study results prepared the randomisation schedule using random permuted blocks with at least three different block sizes to ensure concealment of allocation.

ED medical and nursing staff will enrol participants. A paper-based system, using opaque envelopes containing the allocation, will be used to assign the intervention in the ED. The allocation envelopes will be within sealed individual study packs contained in a locked study box, from which packs can only be taken sequentially. Owing to the obvious nature of the intervention, participants, clinicians and the research team analysing the data will not be blinded after randomisation and assignment to intervention.

## Data collection methods

The data will be recorded by ED clinicians on paper-based case record forms (CRF), and then entered by the research team using the REDcap (Research Electronic Data Capture) electronic database hosted at the Murdoch Childrens Research Institute on the research computer server with the following parameters.

Demographic and patient data to be recorded include age and sex of patient, relevant medical comorbidities, previous UTI, known anatomical or neurological abnormality affecting voiding or sensation, reason for presentation based on triage code and clinical indication for urine collection as recorded by clinician, and reasons for exclusions and refusals.

Clinical data to be recorded include whether the child voided within 5 min and time taken to void, successful catch of urine sample (child voids and urine sample obtained), person performing standard cleaning and/or suprapubic stimulation technique (parent, doctor, nurse), person catching urine (parent, doctor, nurse), whether CCU was abandoned before 5 min and reason for abandoning procedure, and parental and clinician satisfaction with the urine collection technique.

Clinical data to be collected subsequently (by linking with laboratory data from hospital records) include whether a urine sample is collected after the 5 min study period in the ED, positive and contaminated urine culture results, admission to hospital and initiation of antibiotic therapy.

## Data management and access to data

Any paper study records will be kept in locked storage cabinets. All electronic participant study records will be stored in the password-protected computer study database, accessible to the researchers only.

All study participants will be assigned a unique study number (Participant ID) for the study so that the stored data have identifiers removed but are re-identifiable.

All data entered into the study database will be checked by two members of the research team.

In accordance with state guidelines, all health information will be kept until participants reach 25 years of age, as per the Health Records Act 2001 (Vic).

### Statistical methods

Data analysis for the study will be performed by statisticians at the Clinical Epidemiology and Biostatistics Unit at the Murdoch Childrens Research Institute. Statistical analysis will follow standard methods for RCTs.

The primary analysis will be performed by intention-to-treat including all randomised participants where primary outcome data are available, consistent with the CONSORT guidelines for intention-to-treat analysis.<sup>21 22</sup>

The primary outcome measure is a binary yes/no outcome of voiding urine within 5 min. We will report the absolute difference between the two groups for the percentage of successful CCU, together with the 95% CI for the difference of percentages, and calculate p values using a  $\chi^2$  test. A p value of <0.05 will be considered significant.

Secondary outcome measures are parental and clinician satisfaction with the urine collection technique in each group, whether there is a successful CCU caught in each group and contamination rate of CCU samples in each group.

For each secondary outcome, we will describe the rates of successful CCU and contamination for each group with percentages and 95% CIs. The appropriate difference between groups will be estimated (difference of proportions for categorical outcomes, difference of means for continuous outcomes), together with the 95% CI for the difference. The p values will be estimated using  $\chi^2$  test for categorical variables and t-test or Wilcoxon's rank-sum tests for continuous variables.

In addition to the unadjusted analysis, all treatment comparisons for primary and secondary outcomes will also be presented adjusted for age and sex to account for any chance imbalance between the treatment groups with respect to these potentially confounding factors using linear and logistic regression models for continuous and binary outcomes, respectively.

### Data monitoring and auditing

No interim analysis will be undertaken: recruitment will continue until enrolment is completed. A data monitoring committee is not required for this low-risk study.

### Harms

There are no foreseeable additional risks to patients or their families by participating in this study.

Should any adverse events occur, they will be recorded on the CRF and intervention can be discontinued by the treating clinician. Minor temporary discomfort to the child can be caused by cold saline cutaneous stimulation. Crying and mild distress commonly occur with

routine CCU and will not be regarded as an adverse event, consistent with previous studies.<sup>14–16</sup>

### Outlook and significance

This single-centre randomised trial will allow the definitive assessment of the utility of this novel technique to hasten non-invasive urine collection in infants. If there is a clinically significant increase in voiding success within 5 min, this low-cost simple method could be adopted widely to hasten urine collection and reduce wait times in acute care settings, and potentially reduce specimen contamination rates.

### Limitations

As this is a non-blinded trial, there is the potential for the investigator to unintentionally introduce measurement or reporting bias. Owing to the nature of the intervention, it is not possible in this trial to blind the treating clinicians or study investigators.

### Current status

Study enrolment has started, and recruitment and data analysis are expected to be completed by December 2016.

## DISSEMINATION

### Protocol amendments

Protocol amendments will be updated and freely available on the Australian New Zealand Clinical Trials Registry website.

### Consent or assent

Parents will be given a parent/guardian information sheet (PGIS). Participation in the study will be discussed with the clinician and/or researcher. This will happen in the ED. The study investigators and research officer may be involved as clinicians in the clinical care of the patient.

Parents/participants will be assured that if they do not wish to participate, this will not affect their care. This is also stated in the PGIS. Verbal consent obtained from the parent/guardian (prior to undertaking sample collection) will be documented by nursing and medical staff. Refusal of consent will be recorded.

### Confidentiality

Confidentiality will be ensured by storing data in a password-protected database for which only the research team will have the password, and paper-based record forms will be stored in a locked cupboard.

Any patient data published will not allow personal identification: only group data will be published.

### Dissemination policy

Results will be published in a peer-reviewed publication and thesis chapter.

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**Acknowledgements** The authors thank the families and clinical staff participating in this trial.

**Contributors** JK was responsible for identifying the research question, drafting this paper and finalising the manuscript. All authors contributed to the study design and development of the protocol, provided comments on the drafts, and have read and approved the final version.

**Funding** This study is funded by a project grant from the Shepherd Foundation. JK has been funded in part by an Avant Doctor in Training Research Scholarship and Royal Australasian College of Physicians Basser Research Entry Scholarship. FEB is supported in part by a National Health and Medical Research Council Centre of Excellence Research Grant for paediatric emergency medicine (GNT 1058560) and a Royal Children's Hospital Foundation Grant, Melbourne, Australia. The Royal Children's Hospital Melbourne receives infrastructure support from the Victorian Government's Infrastructure Support Program, Melbourne, Australia. Minor incidental expenses will be supported by the Murdoch Childrens Research Institute Emergency Research Group. Assistance with the study design, data management, analysis and interpretation of data for this study will be provided by the Murdoch Childrens Research Institute and the Melbourne Children's Trial Centre. Royal Children's Hospital Emergency Department staff will assist with participant recruitment.

**Competing interests** None declared.

**Ethics approval** The trial has full ethics approval from the Royal Children's Hospital Human Research Ethics Committee, HREC reference number 35083A.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** Results will be published in a peer-reviewed publication and thesis chapter.

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