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Conservative treatment for functional daytime urinary incontinence in children (Protocol)

Buckley BS, Sanders CD, Kwong JSW, Kilpatrick KA, Anderson CA

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Conservative treatment for functional daytime urinary incontinence in children.
Cochrane Database of Systematic Reviews 2016, Issue 9. Art. No.: CD012367.
DOI: 10.1002/14651858.CD012367.

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[Intervention Protocol]

Conservative treatment for functional daytime urinary incontinence in children

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Editorial group: Cochrane Incontinence Group.
Publication status and date: Edited (no change to conclusions), published in Issue 10, 2016.

Citation: Buckley BS, Sanders CD, Kwong JSW, Kilpatrick KA, Anderson CA. Conservative treatment for functional daytime urinary incontinence in children. *Cochrane Database of Systematic Reviews* 2016, Issue 9. Art. No.: CD012367. DOI: 10.1002/14651858.CD012367.

ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To determine the effectiveness of conservative interventions (non-pharmacological and non-surgical) for functional daytime urinary incontinence in children.

Intervention comparisons may include:

- Individual conservative interventions (lifestyle, behavioural or physical) versus no treatment;
- Combined conservative interventions versus no treatment;
- One individual conservative interventions versus another individual or combined conservative intervention;
- Combined conservative interventions versus other combined conservative interventions;
- Individual conservative interventions versus non-conservative interventions (pharmacological or invasive) (combined or not with any conservative interventions);
- Combined conservative interventions versus non-conservative interventions (pharmacological or invasive) (combined or not with any conservative interventions).

BACKGROUND

Description of the condition

Functional daytime urinary incontinence in children is the term used to describe any leakage of urine while awake that is not caused

by some known underlying neurological or congenital anatomic cause.

The development of bladder control in early childhood is a complex process that is not fully understood. While there exist considerable individual, social and cultural variations, in general by the age of three years most children have achieved an adequate degree of continence thereby using the toilet for voiding. By five years of age most can void at will and postpone voiding, and involuntary wetting while asleep or awake becomes a problem that may require some therapeutic intervention (Milsom 2013).

Although in a large proportion of children with functional daytime urinary incontinence no cause is determined, a number of independent risk factors have been identified. These include stress, neglect or trauma, a paternal history of daytime wetting, and a history of daytime wetting in male siblings (Lai 2015; Milsom 2013). Some known physical factors are also known to contribute to daytime urinary incontinence, such as constipation, vesico-ureteric reflux and a history of urinary tract infection. Functional daytime urinary incontinence has been found in a significant number of children who had functional constipation and encopresis, and urinary symptoms improved when bowel symptoms were treated (Loening-Baucke 1997).

For children presenting with apparent functional incontinence, the International Children's Continence Society (ICCS) has created a classification system relating to abnormalities in the storage and voiding stages of the micturition cycle. These are urgency incontinence (often attributable to overactive bladder resulting from detrusor over-activity, but confirmation by cystometric evaluation is required before the label is formally applied), underactive bladder (a raise in intra-abdominal pressure, often produced by straining, is required to start, maintain or complete urination; often attributable to detrusor under-activity), voiding postponement (low micturition frequency, often with urgency and incontinence resulting from a full bladder), dysfunctional voiding (contraction of the urethral sphincter or pelvic floor during voiding), bladder outlet obstruction (mechanical or functional), stress incontinence, giggle incontinence, vaginal reflux (vesicovaginal pooling), daytime urinary frequency, and bladder neck dysfunction (impaired or delayed opening of bladder neck despite adequate detrusor contraction) (Austin 2014).

Determining the prevalence of functional daytime urinary incontinence in children from existing research is problematic for several reasons. Definitions of urinary incontinence have differed between studies (frequency and extent of leakage). In some settings increased reported prevalence may be attributed to greater public understanding of incontinence as a health issue and of treatments available as a result of awareness campaigns and information disseminated through health care, education and the media. Variations in reported prevalence may also result from societal norms and cultural differences. Limited access to or experience of health care may affect what degree of daytime wetting is perceived to constitute a health problem.

At seven years of age, studies have reported prevalence of daily daytime wetting ranging from 0.5% to 0.8% (Hansen 1997; Hellstrom 1990) and of wetting more than once per week from 0.9% to 2.5% (Hansen 1997; Hellstrom 1990; Joinson 2006; Swithinbank 2010). Estimates for the prevalence of daytime wetting more than once per month range from 3.9% to 9.0%, and combined daytime and nighttime wetting range from 6.3% to 9.0% (Joinson 2006; Kajiwara 2004; Lee 2000; Soderstrom 2004). At 11 to 13 years of age estimates for daytime and nighttime wetting more than once per month range from 1.1% to 4.2% (Kajiwara 2004; Lee 2000; Soderstrom 2004). At 15 to 17 years of age, estimates of daytime wetting more than once every three months range from 1.8% to 3.0% (Hellstrom 1995; Swithinbank 1998).

Overall, girls appear more likely to be affected by functional daytime urinary incontinence than boys, with this difference becoming more marked as children grow older. At seven years there is little clear difference: estimates of daytime and nighttime wetting more than once per month range from 5.8% to 8.9% in girls and from 6.8% to 9.2% in boys, and of more than once per week from 1.2% to 3.1% in girls and 0.7% to 3.8% in boys (Hellstrom 1995; Joinson 2006; Swithinbank 2010). However, at ages 11 to 13 girls are more likely to be affected and this difference becomes more marked as they grow older. At ages 11 to 13, estimates of daytime and nighttime wetting more than once per month range from 3.9% to 4.3% in girls and from 1.0% to 4.1% in boys (Kajiwara 2004; Soderstrom 2004). Regular daytime wetting has been reported by 16.6% of girls and 7.2% of boys aged 11 to 12 (Swithinbank 1998). By the ages of 15 to 17, estimates for daytime wetting range from 3.6% to 4.7% of girls and from 0.3% to 0.9% of boys (Hellstrom 1995; Swithinbank 1998).

Daytime urinary incontinence can create practical and social difficulties for both the child and their family, and can impact on a child's wellbeing in more serious ways, which highlights the importance of seeking help for the condition. Daytime urinary incontinence can impact on children's access and engagement with their education in both practical and performance aspects (Whale 2016). Research has indicated that children experiencing incontinence will have increased absenteeism, poorer academic performance, and potential social difficulties during the school years (Filce 2015). In a large study of more than 8000 children aged between 7 and 9 years, a higher rate of psychological and behavioural problems was observed in those who experienced daytime wetting. General anxiety, separation anxiety and sadness or depression were all approximately twice as common in children with daytime wetting than in those without. Externalising problems such as phobia, attention and activity problems, oppositional behaviours and conduct problems were also twice as common, and found to be more likely in children whose wetting was frequent (twice or more per week) (Joinson 2006; Lettgen 2002; von Gontard 2012). Psychological and behavioural problems in childhood have been found to be predictive of a range of personal, psychological and social

problems later in life (McCulloch 2000).

Description of the intervention

Conservative treatments of daytime functional urinary incontinence in children encompass a broad range of non-surgical and non-pharmacological interventions, which may be employed individually or in combinations.

The following sections outline some types of conservative treatment; others may be identified during the conduct of the review.

Lifestyle and behavioural interventions

Some simple lifestyle and behavioural interventions can be implemented by the child and parents with little input from healthcare professionals. Bladder diaries can be kept and are useful in establishing voiding patterns. Toilet plans and scheduled voiding can be used as initial, simple interventions. Incentives and rewards such as star charts may also be used to motivate children as well as provide positive reinforcement for changes to voiding and drinking schedules. Educational materials can be provided relating to diet and fluid intake and good posture when sitting on the toilet. Alarm devices, although primarily used in children with nocturnal enuresis, can also be useful for children with daytime UI by providing auditory signals on the occurrence of incontinence (Glazener 2005; NICE 2010).

More complex lifestyle and behavioural interventions may require greater involvement of healthcare professionals. Methods involving bladder training, double voiding and voiding postponement are commonly employed treatment options. Managing constipation is an important consideration as it can be a causative factor in children with urinary incontinence (Loening-Baucke 1997).

Conservative physical interventions

Physical therapies such as pelvic floor muscle training, abdominal muscle training and core stability exercises can be used to treat daytime functional urinary incontinence in children. Physical therapies can be used with or without biofeedback, which assists the children in learning good exercising or bladder emptying technique by means of visual or auditory feedback.

Transcutaneous electrical stimulation of the sacral root or tibial nerve can also be considered Bower 2003.

How the intervention might work

Conservative treatment options work in varying ways, targeting different pathological processes implicated in urinary incontinence.

Bladder diary-keeping aims to assess voiding patterns of the individual child and identify subsequent schedules for voiding. Scheduled voiding and toilet plans aim to retrain the bladder and the brain into a new pattern of micturition and so improve the child's ability to suppress urges to urinate. Star charts and other reward strategies are intended to use positive reinforcement to provide incentives to the child to reach achievable goals, such as improved voiding patterns or continence. There is limited evidence that such strategies can work in nocturnal enuresis (Caldwell 2013).

Good toileting posture is intended to develop and heighten awareness of correct voiding processes and to encourage children to take time to void. Modification of diet may reduce intake of agents that may aggravate urinary storage or voiding problems. Although reduction of fluid intake may in itself aggravate low functional bladder capacity, modification of fluid intake timing may reduce the need to void at times when incontinence typically occurs.

Alarms, more commonly used in nocturnal enuresis, are intended to provide auditory signals on occurrence of incontinence and increase the child's awareness of the wetting (Glazener 2005; NICE 2010).

Bladder training employs strategies such as delayed voiding with the intention of increasing functional bladder capacity, thereby reducing the need to void. Management of constipation and reduction of impaction can reduce pressure on the bladder which can subsequently improve urgency and wetting in some children. Behavioural therapies may also be combined with psychotherapy and/or family therapy or education, which aim to identify and address potential psychological causative factors and to modify the environment or emotional conditions that have led to or compound incontinence.

Physical therapy focuses on strengthening and relaxing the supportive muscles of the urinary system, primarily the pelvic floor muscles, and consequently improving continence. In younger children this can be in the form of 'stop-start' exercises undertaken during micturition. Abdominal muscle training and core stability exercises are likewise intended to improve the tone of muscles that, if not well controlled, can affect continence.

Biofeedback can also be a useful teaching and performance enhancing aid to improve patient's awareness of the physiological processes of micturition, in particular in identifying and using the pelvic floor muscles correctly, learning to understand good bladder emptying techniques. This can be achieved by auditory or visual signals using electromyography to identify contraction and relaxation of the pelvic floor muscles, thereby improving the effectiveness of the exercises.

Electrical stimulation involves either direct stimulation or transcutaneous stimulation of the sacral root or tibial nerve. Although the direct mechanism of action of electrical stimulation is unclear, it is thought to centre on alterations in the afferent and efferent nerve fibres to the lower urinary tract in children (Bower 2003).

Why it is important to do this review

Daytime urinary incontinence can result in practical, social and educational difficulties for children and their families and can

impact significantly on various psychosocial aspects of children's lives (Joinson 2006). Therefore, identifying effective treatments is particularly important both to alleviate symptoms and to improve the mental well-being of children affected.

Existing Cochrane systematic reviews relating to urinary incontinence in children all focus on the treatment of nocturnal enuresis (Caldwell 2013; Deshpande 2012; Glazener 2002; Glazener 2004; Glazener 2005; Huang 2011). Consequently there is a need for systematic reviews of treatments for daytime urinary incontinence in the same population. This review will focus on conservative interventions only, and a separate review will cover pharmacological treatment of daytime urinary incontinence in children.

OBJECTIVES

To determine the effectiveness of conservative interventions (non-pharmacological and non-surgical) for functional daytime urinary incontinence in children.

Intervention comparisons may include:

- Individual conservative interventions (lifestyle, behavioural or physical) versus no treatment;
- Combined conservative interventions versus no treatment;
- One individual conservative interventions versus another individual or combined conservative intervention;
- Combined conservative interventions versus other combined conservative interventions;
- Individual conservative interventions versus non-conservative interventions (pharmacological or invasive) (combined or not with any conservative interventions);
- Combined conservative interventions versus non-conservative interventions (pharmacological or invasive) (combined or not with any conservative interventions).

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised and quasi-randomised controlled trials and cluster-randomised trials.

Types of participants

Study participants eligible for inclusion will be aged 5 years or over and under 18 years with daytime urinary incontinence and no co-morbidities or conditions considered to be the cause. The lower cut-off age of 5 years has been selected because by this age the majority of children will have achieved continence, and beyond five years of age daytime urinary incontinence merits consideration for treatment.

Insofar as is possible, children with recognised treatable or untreatable causes of incontinence will not be included in main meta-analyses. These will include congenital or acquired neurogenic conditions, congenital anomalies or known current urinary tract infections. Children with only voiding symptoms such as hesitancy or straining will also not be included in main meta-analyses. Where studies include children both with and without known causes of their incontinence, or children with only voiding symptoms as well as children with storage symptoms or both, efforts will be made to retrieve data from authors relating only to those with incontinence with no known aetiologies. Where this is not possible, studies with small subgroups of children with known causes of incontinence or voiding symptoms alone may be included in meta-analyses, and sensitivity analyses conducted to determine whether their inclusion affects results.

Types of interventions

This systematic review will consider conservative treatment of daytime urinary incontinence. An intervention is considered conservative if it is a non-pharmacological and a non-surgical treatment. This includes lifestyle, behavioural and psychosocial interventions, physical interventions, and non-invasive feedback or stimulation interventions.

The types of interventions included will be determined by the studies identified. The following criteria will apply for inclusion or exclusion:

Lifestyle, behavioural and psychosocial interventions

Interventions that seek to address continence issues in children by assessing and altering their behaviours and habits or those of their carers. These may include: bladder diaries, toilet plans, timed voiding; rewards and incentives; constipation management; posture education; bladder training, double voiding and voiding postponement; dietary education and changes or drinking schedules. Ingestion of foods, drinks, herbal agents or supplements specifically aimed at treating urinary incontinence will not be included. A separate review of alternative, complementary and herbal treatments will include these.

Physical interventions

Interventions that seek to address continence issues in children through enhanced muscle control. These may include pelvic floor

muscle training, abdominal muscle training and core stability exercises, with or without biofeedback.

Non-invasive feedback or stimulation interventions

Interventions that seek to address continence issues in children by using devices or techniques to improve awareness of wetting, or to initiate or regulate voiding through stimulation of nerves or muscles transcutaneously. These may include: alarm devices or other techniques to improve awareness; transcutaneous stimulation using electrical or other methods.

Devices or techniques that involve any invasive element such as implants or needles will not be included. Interventions that involve the placement of needles might include tibial or sacral nerve management approaches, and have the capacity to cause distress with children. Both are invasive and the second involves placement under general anaesthetic. In addition to the potential for discomfort and distress in a paediatric population, there are few centres that treat representative numbers of children in these ways, and the variation globally in approach, technique, management and measurement of outcome is variable so that comparison could be flawed. Trials of acupuncture may be considered in a separate review of alternative and complementary therapies.

Types of outcome measures

Primary outcomes

Number of children no longer experiencing daytime urinary incontinence - child or carer reported

Secondary outcomes

Quantification of symptoms:

- Frequency of incontinence episodes, of pad or clothes changes
- Reduction of frequency of incontinence episodes, or of pad or clothes changes
- Objective measurement of volume of incontinent episodes (eg. pad tests)

Quality of life/psychosocial outcomes:

- Psychometric or behavioural measurements
- Quality of life measurements. The measurements considered will be dependent upon those reported in trials, but may include general paediatric quality of life tools such as PedQol or incontinence-specific tools developed for use by children (Bower 2006; Varni 2001).

Socio-economic measures:

- Cost of interventions, cost-effectiveness of interventions, resource implications (e.g. cost of incontinence management methods), missed schooldays

Adverse events or child- or parent-perceived harms associated with interventions reported by studies.

Other outcome measurements may be identified in eligible studies, and will be included in the review if deemed appropriate and robust.

Quality of evidence

The quality of evidence in the review will be assessed using the GRADE approach, and considering the following factors:

1. limitations in the study design (risk of bias);
2. inconsistency of results (heterogeneity);
3. indirectness of evidence (applicability);
4. imprecision (number of events and confidence intervals);
5. publication bias.

The GRADE working group recommends including no more that seven critical outcomes in a systematic review (Guyatt 2011a; Guyatt 2011b). In this review, the five outcomes for which the quality of evidence will be assessed are:

1. Number of children no longer experiencing daytime urinary incontinence - child or carer reported
2. Frequency of incontinence episodes
3. Objective measurement of volume of incontinent episodes (e.g. pad test)
4. Resource implications (cost of incontinence management methods)
5. Quality of life measurements
6. Adverse effects

Search methods for identification of studies

We will not impose any restrictions, for example language or publication status, on the searches described below.

Electronic searches

This review will draw on the search strategy developed for the Cochrane Incontinence Group. We will identify relevant trials from the Cochrane Incontinence Group Specialised Trials Register. For more details of the search methods used to build the Specialised Register please see the Group's module in the Cochrane Library. The register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, MEDLINE Epub Ahead of Print, CINAHL, ClinicalTrials.gov, the World Health Organisation's International Clinical Trials Registry Platform (WHO ICTRP), UK Clinical Research Network Portfolio and handsearching of journals and conference proceedings. Most of the trials in the Cochrane Incontinence Group Specialised Register are also contained in CENTRAL.

The terms that will be used to search the Cochrane Incontinence Group Specialised Register are given in Appendix 1.

The Specialised Register also contains trials identified in international clinical trial registries via the Cochrane Register of Studies search portal. However, the search terms used for the clinical trial registry searches are not as comprehensive as used in searches of the bibliographic databases. As it has been observed that academic papers on childhood incontinence may use different terms than are used in adult incontinence (such as "day wetting", "daytime wetting" and "toileting problems") supplementary electronic searches using a review-specific set of search terms will be conducted of international clinical trial registries via WHO ICTRP .

The WHO platform is a regularly updated database of trials registered in 16 international registries (China, European Union, Netherlands, ClinicalTrials.gov (USA), Japan, Australian & New Zealand, ISRCTN, Brazil, India, Korea, Cuba, Germany, Pan African, Sri Lanka, Thailand). Registries include much of the information needed to judge whether a trial may eligible for inclusion in a review: population, trial interventions and comparisons, methods, outcome measures and follow up, and sample size.

The search terms will encompass conditions but no intervention terms to ensure all potential interventions are included. No language or other limitations will be imposed.

The search strategy will be adapted for searching of the following Chinese language bibliographic databases: Chinese Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), and Wanfang (Xia 2008).

Searching other resources

In addition to electronic searches, the reference lists of the identified papers and any existing reviews will be handsearched to identify other papers for inclusion. Furthermore, attempts will be made to contact authors for additional results or clarification of methods within the study.

Data collection and analysis

Selection of studies

Trials identified from the electronic searches will be screened by two independent review authors for potential eligibility for inclusion. Titles and abstracts of trials identified in electronic databases of published trials will be screened, and titles and metadata of trials identified in trial registers.

Full-text reports will be sought for all potentially eligible trials. For trials identified in trial registries that are not duplicated in searches of bibliographic databases (unpublished trials), authors or institutions recorded in the registry will be contacted to request trial reports. The eligibility of trials for inclusion in the review will be determined from the full reports by two independent review authors according to predefined criteria. Differences will be resolved by discussion between the two authors and if necessary will be referred to a third author for arbitration.

A similar process will also be employed on screening of trials identified from the reference lists of included studies. Papers in languages other than English will be assessed by native speakers for eligibility and subsequently for data extraction.

Potentially eligible trials that are excluded and reasons for exclusion will be detailed in a 'Characteristics of excluded studies' table.

Similar selection processes will be conducted for Chinese language studies.

Data extraction and management

Data extraction will be carried out by two independent review authors using predefined data extraction forms. Differences will be resolved by discussion between the two authors and if necessary will be referred to a third author for arbitration. Where data from the study are not provided, the author(s) will be contacted requesting further information. Included trial data will be processed as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011).

Assessment of risk of bias in included studies

The risk of bias in eligible trials will be assessed independently by two authors using the Cochrane 'Risk of bias' tool. Factors considered will include quality of random allocation and concealment (where appropriate), description of dropouts and withdrawals and missing data, blinding during intervention and at outcome assessment (where appropriate), description of and protection against possible contamination (where appropriate), other biases. The risk of bias for each domain will be judged as 'low risk', 'unclear risk' or 'high risk'.

As per selection of studies and data extraction, two independent review authors will carry out 'Risk of bias' assessment. Differences will be resolved by discussion between the two authors and if necessary will be referred to a third author for arbitration. Data will be entered into RevMan5 software to produce 'Risk of bias' tables.

Measures of treatment effect

Risk ratios will be calculated for dichotomous data and mean differences with 95% confidence intervals for continuous data. If the same continuous outcome is measured using a different scale, the standardised mean difference will be used.

Unit of analysis issues

In the event that there are multiple treatment arms in a study, individual pairs of interventions will be considered separately. Furthermore, studies designed as cluster-randomised and cross-over

trials will be dealt with as described in the Cochrane Handbook Higgins 2011.

Cluster-randomised trials

If identified, cluster-randomised trials will be included in the analyses along with individually-randomised trials. The sample sizes of cluster-randomised trials will be adjusted using the methods described in the Cochrane Handbook for Systematic Reviews of Interventions using an estimate of the intra-cluster correlation coefficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If ICCs from other sources are used, this will be reported and sensitivity analyses conducted to investigate the effect of variation in the ICC. If both cluster-randomised trials and individually-randomised trials are identified, the data from both will be pooled using the sample size adjustment methods described above if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely. Heterogeneity in the randomisation unit will be considered and sensitivity analyses performed to investigate the effects of the randomisation unit.

Dealing with missing data

Levels of attrition will be noted for included studies and the impact of including studies with high levels of missing data assessed using sensitivity analysis. For all outcomes analyses will be conducted, insofar as is possible, on an intention-to-treat basis. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

Heterogeneity will be assessed using the Chi^2 and I^2 statistics. Heterogeneity will be regarded as substantial if the I^2 is greater than 50% or if the P value is less than 0.10 in the Chi^2 test.

Assessment of reporting biases

In order to consider whether there may be publication bias, funnel plots will be generated for any meta-analyses containing 10 or more studies. Asymmetry of the funnel plots will be assessed visually and formal tests for funnel plot asymmetry conducted as appropriate. For dichotomous outcomes the test proposed by Harbord will be used and for continuous outcomes that proposed by Egger (Egger 1997; Harbord 2006).

Electronic searching of trial registries will also be used to identify unpublished trials.

Data synthesis

A fixed-effect model will be used in meta-analysis unless significant heterogeneity is identified between studies, in which case a random-effects model will be used. We will use RevMan5 to carry out meta-analysis.

Subgroup analysis and investigation of heterogeneity

Planned subgroup analyses to be undertaken are by age (children 5 to 12 years and adolescents 13 to 18 years), sex and pathological cause of daytime urinary incontinence where possible.

Sensitivity analysis

Sensitivity analyses will be carried out for factors that may affect the results of meta-analyses. Studies for which a risk of selection bias is identified using the Cochrane 'Risk of bias' instrument will be included in main meta-analyses and subsequently excluded in sensitivity analyses to assess their effect, if any, on the overall results. Likewise studies that include subgroups of children with known causes of incontinence or of voiding symptoms alone will be included in main meta-analyses and subsequently excluded to assess their effect on the overall results.

ACKNOWLEDGEMENTS

We would like to thank the following Cochrane Incontinence editorial base staff members for their help and support with this review: Lyn Ajanaku, Aniruddh Deshpande, Suzanne Hagen, Suzanne Macdonald, Muhammad Imran Omar, Luke Vale, Sheila Wallace and Kate Williams.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Cochrane Incontince Group Specialised Register search terms

The terms that will be used to search the Incontinence Group Specialised Register are given below:
(({DESIGN.CCT*} OR {DESIGN.RCT*})
AND
({TOPIC.URINE.INCON.diurnal.} OR {TOPIC.URINE.ENURESIS.daytimewetting.} OR {TOPIC.URINE.OVERACTIVEbladder.children.} OR {topic.urine.incon.urge.children.} OR {TOPIC.URINE.NEUROGENIC.children.} OR {TOPIC.URINE.INCON.children*})
(All searches will be of the keyword field of Reference Manager 2012).

WHAT'S NEW

Date	Event	Description
1 October 2016	Amended	Contact details updated.

CONTRIBUTIONS OF AUTHORS

Brian Buckley, the contact person, drafted the protocol. All authors provided methodological and clinical inputs.

DECLARATIONS OF INTEREST

Brian S Buckley: none

Caroline D Sanders: none

Joey SW Kwong: none

Kirsty A Kilpatrick: none

Coral A Anderson: none

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- National Institute for Health Research (NIHR), UK.

This project was supported by the National Institute for Health Research, via Cochrane Infrastructure, Cochrane Programme Grant or Cochrane Incentive funding to the Incontinence Group. The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, National Health Service or the Department of Health.