Lifestyle interventions for the treatment of urinary incontinence in adults (Review)

Imamura M, Williams K, Wells M, McGrother C



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[Intervention Review]

Lifestyle interventions for the treatment of urinary incontinence in adults

Mari Imamura¹, Kate Williams², Mandy Wells³, Catherine McGrother⁴

¹Academic Urology Unit, University of Aberdeen, Aberdeen, UK. ²Department of Health Sciences, University of Leicester, Leicester, UK. ³Integrated Bladder and Bowel Care Services, NHS Devon, Exeter, UK. ⁴Dept of Health Sciences, University of Leicester, Leicester, UK

Contact address: Mari Imamura, Academic Urology Unit, University of Aberdeen, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD, UK. m.imamura@abdn.ac.uk.

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ABSTRACT

Background

Low cost, non-invasive alterations in lifestyle are frequently recommended by healthcare professionals or those presenting with incontinence. However, such recommendations are rarely based on good evidence.

Objectives

The objective of the review was to determine the effectiveness of specific lifestyle interventions (i.e. weight loss; dietary changes; fluid intake; reduction in caffeinated, carbonated and alcoholic drinks; avoidance of constipation; stopping smoking; and physical activity) in the management of adult urinary incontinence.

Search methods

We searched the Cochrane Incontinence Group Specialised Register, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and MEDLINE in process, and handsearching of journals and conference proceedings (searched 3 July 2013), and the reference lists of relevant articles. We incorporated the results of these searches fully in the review. We undertook an updated search of the Specialised Register, which now includes searches of ClinicalTrials.gov and WHO ICTRP, on 27 October 2014; potentially eligible studies from this search are currently awaiting classification.

Selection criteria

Randomised and quasi-randomised studies of community-based lifestyle interventions compared with no treatment, other conservative therapies, or pharmacological interventions for the treatment of urinary incontinence in adults.

Data collection and analysis

Two authors independently assessed study quality and extracted data. We collected information on adverse effects from the trials. Data were combined in a meta-analysis when appropriate. We assessed the quality of the evidence using the GRADE approach.

Main results

We included 11 trials in the review, involving a total of 5974 participants.

Four trials involving 4701 women compared weight loss programmes with a control intervention. Low quality evidence from one trial suggested that more women following weight loss programmes reported improvement in symptoms of incontinence at six months (163/214 (76%) versus 49/90 (54%), risk ratio (RR) 1.40, 95% confidence interval (CI) 1.14 to 1.71), and this effect was sustained at 18 months (N = 291, 75% versus 62%, RR not estimable, reported P value 0.02). No data were available for self-reported cure and quality of life. One of the weight loss trials involving 1296 women reported very low quality evidence for a reduction in weekly urinary incontinence a mean of 2.8 years after following a lifestyle weight loss intervention that had been compared with a pharmacological weight loss intervention.

Three trials involving 181 women and 11 men compared change in fluid intake with no change. Limited, very low quality evidence suggested that symptom-specific quality of life scores improved when fluid intake was reduced, although some people reported headaches, constipation or thirst. A further three trials involving 160 women and nine men compared reduction in caffeinated drinks with no change, and one trial involving 42 women compared a soy-rich diet with soy-free diet. However, it was not possible to reach any conclusions about the effects of these changes, due to methodological limitations, that resulted in very low quality evidence.

Adverse effects appeared relatively uncommon for all interventions studied.

All included studies had a high or unclear risk of bias across all bias parameters, but most notably for allocation concealment. The main factors for our downgrading of the evidence were risk of bias, indirect evidence (less than 12 months of follow-up; and not all participants having confirmed urinary incontinence at baseline in some studies), and imprecise results with wide confidence intervals.

Other interventions such as reduction in consumption of sweetened fizzy or diet drinks; reduction in alcohol consumption; avoiding constipation; smoking cessation; restricting strenuous physical forces; or reducing high levels of, or increasing low levels of, physical activity, could not be assessed in this review, as no evidence from randomized controlled trials or quasi-randomised trials was available.

Authors' conclusions

Evidence for the effect of weight loss on urinary incontinence is building and should be a research priority. Generally, there was insufficient evidence to inform practice reliably about whether lifestyle interventions are helpful in the treatment of urinary incontinence.

PLAIN LANGUAGE SUMMARY

Lifestyle interventions for the treatment of urinary incontinence in adults

Background

Urinary incontinence imposes a considerable burden on individuals and on society. Although a range of treatments is available, alterations in lifestyle are frequently recommended for the treatment of urinary incontinence, as they are relatively low in cost and have few unwanted side-effects. Advice commonly given includes losing weight, changes in diet, adjusting volume of fluid intake, decreasing caffeine or alcohol consumption, avoiding constipation and straining (when passing faeces), stopping smoking, and being more physically active - though restricting excessive heavy activity.

What we wanted to find out

We (a team of Cochrane researchers) wanted to see whether lifestyle interventions have a beneficial effect on any type of urinary incontinence in adults

What we did

We searched the medical literature extensively up to July 2013 for studies that compared the effects of community-based lifestyle alterations with either no treatment, or other non-surgical treatments, or medical (medicine) treatment, on urinary incontinence in adults.

What we found

We identified 11 studies, with 5974 participants (nearly all women, only 20 were men), that investigated the effect of lifestyle alterations on urinary incontinence. Four investigated weight loss; one compared a soy-rich diet with a soy-free diet; three investigated changes in

volume of fluid intake; and three investigated the effect of reducing caffeine intake. We identified no trials that investigated reducing alcohol intake, avoiding constipation and straining, stopping smoking or levels of physical activity.

Findings from four studies suggested that weight loss may reduce incontinence among overweight women and this merits further research. However, it should be noted that a large proportion of the participants contributing to this result were part of two diabetes studies that, while they recorded the effect of weight loss on urinary incontinence, did not record how many participants suffered from it at the start of the study. The duration of the weight loss programmes in these studies ranged from three to 12 months.

A small amount of very low quality evidence from the studies that investigated volume of fluid intake suggested that symptoms of urinary incontinence may reduce when fluid intake is reduced, although some participants in the studies reported headaches, constipation or thirst.

We could not combine the findings from other studies that investigated a similar treatment (e.g. caffeine reduction) because they measured their results in different ways, and/or were of poor quality, which means their results may be unreliable. Much more well-designed research is needed, so that lifestyle recommendations for the treatment of incontinence can be based on good evidence. At present there is not enough evidence to establish whether any lifestyle treatments work.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Weight loss compared to control for the treatment of urinary incontinence in adults

Patient or population: adults with urinary incontinence Settings: Intervention: weight loss

| Comparison: control | | | | | | |
|--|--|---|------------------------------|---------------------------------|------------------------------------|---|
| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% Cl) | No of participants (studies) | Quality of the evidence (GRADE) | Comments |
| | Assumed risk | Corresponding risk | | | | |
| | Control | Weight loss | | | | |
| Cure rates by patient ob- servation (all UI types) - not reported | | | Not estimable | - | | |
| Improvement rates by patient observation (all UI types) Follow-up: 6 months | 544 per 1000 | 762 per 1000 (621 to 931) | RR 1.4 (1.14 to 1.71) | 304 (1 study) | ⊕⊕⊖⊖ low ^{1,2} | |
| Condition-specific qual- ity of life In- continence Impact Ques- tionnaire. Scale from: 0 to 400. Better quality of life indicated by lower values. Follow-up: 3 months | The median condition- specific quality of life in the control groups was 89 points | The median condition- specific quality of life in the intervention groups was 52 lower (95% CI not estimable) | | 40 (1 study) | ⊕⊕⊖⊖ low ^{1,2} | |
| Adverse effects Follow-up: 3 months | | | Not estimable | 48 (1 study) | | The study reported that the intervention had 'few side effects' |

| Cure rates by symp- tom quantification (all UI types) Follow-up: 12 months | 315 per 1000 | 350 per 1000 (287 to 431) | RR 1.11 (0.91 to 1.37) | 738 (1 study) | ⊕⊕⊖⊖ Iow ^{1,3,4} |
|---|--------------|-------------------------------------|-------------------------------|---------------------|---|
| Improvement rates by symptom quantification (all UI type) Follow-up: 12 months | 325 per 1000 | 393 per 1000 (332 to 468) | RR 1.21 (1.02 to 1.44) | 1032 (2 studies) | $\oplus \oplus \bigcirc \bigcirc$ low ^{1,3,4} |
| Prevalence of weekly UI (all UI type) Follow-up: 12 months | 286 per 1000 | 252 per 1000 (223 to 286) | RR 0.88 (0.78 to 1) | 2739 (1 study) | $\oplus \bigcirc \bigcirc$ very low ^{1,3,4,5} |

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; RR: risk ratio; UI: urinary incontinence

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ Risk of bias: We downgraded the evidence by one level because blinding of participants and personnel was unlikely.

 2 Indirectness: We downgraded the evidence by one level because of short follow-up <12 months

³ Risk of bias: We downgraded the evidence by one level because the authors did not report or provide a description of an allocation concealment method in one study (Phelan 2012).

⁴ Missing outcome data in 7%-10% of the participants in one study (Phelan 2012).

Indirectness: We downgraded the evidence by one level because data include a sub-study of a trial (Phelan 2012) for diabetes that included continent as well as incontinent patients; only 27% had weekly urinary incontinence at baseline.

BACKGROUND

Description of the condition

Urinary symptoms pose a considerable health care burden with 200 million people suffering from incontinence worldwide (Abrams 2005). The Leicestershire Medical Research Council (MRC) incontinence study, which was the largest comprehensive study of urinary symptoms in a UK general population, reported that 29% of men and 34% of women aged 40 years or over experience clinically significant incontinence or voiding symptoms (McGrother 2004), with substantial impact on quality of life. This represents a financial burden to the National Health Service (NHS) of 1% of its annual budget (Turner 2004). Overall prevalence and service needs will continue to grow as the population ages.

Lifestyle factors may play a role in either in the improvement, or maintenance, of continence. While published literature about lifestyle factors and incontinence is sparse (Hannestad 2004), alterations in lifestyle are frequently recommended by both healthcare professionals and lay people in the belief that they will decrease urine leakage. For example, advice is commonly given to lose weight, increase or decrease fluid intake, stop using caffeinated drinks, reduce alcohol consumption, or to be more physically active - but restrict excessive heavy activities that put pressure on the pelvic floor, such as aerobics or lifting - to stop smoking and avoid constipation and straining. Such recommendations are rarely based on evidence from clinical trials, but on the basis that there are plausible explanations for why these changes might work, and that they are unlikely to cause harm.

Theoretically, the potential for diet and lifestyle to impact upon incontinence is wider than factors currently identified from a purely empirical viewpoint. It is generally recognised that nutritional and metabolic mechanisms impinge upon all systems of the body including the urinary tract. In practice, incontinence is more commonly observed in patients with specific morbidities such as cerebrovascular disease, dementia, depression and diabetes, and this is supported by scientific evidence (McGrother 2007). In these chronic conditions, diet and lifestyle factors have been identified as probably causal: for example, high saturated fat, low fatty fish/ omega-3 fat, low fibre, high glycaemic index, low vegetable and high salt intakes (Chowdhury 2012; He 2006; Baumgart 2015; Ortega 2012; Skerrett 2010). More generally, the WHO and statutory guidance in the UK and USA currently recognize the importance of poor diet, physical inactivity, excess alcohol and sugary drinks plus smoking in the prevention of such chronic conditions. On this basis, modifications to such diet and lifestyle factors may prevent or reduce bladder dysfunction.

A wide range of interventions and treatments has been used in the management of urinary incontinence, including conservative interventions such as physical therapies: a review by Dumoulin and colleagues broadly supported the recommendation for pelvic floor muscle training in women (Dumoulin 2010); and Herbison and colleagues reported that the evidence tentatively supported the use of vaginal cones in women who find them acceptable (Herbison 2002). In the area of behavioural training, Wallace and colleagues identified that there was limited evidence on the use of bladder training (Wallace 2004), but it was unlikely to do harm. The Lipp 2011 review on anti-incontinence devices identified insufficient evidence for the use of devices and suggested further well designed trials in the area. The Nabi 2006 review on pharmaceutical interventions, e.g. anticholinergics, reported statistically significant improvements in symptoms, while for surgical interventions, the Ogah 2009 review reported that minimally invasive surgery was as effective as traditional surgery. For absorbent products, Fader and colleagues identified minimal evidence (Fader 2007; Fader 2008), although there was sufficient evidence to support the use of some pads over others. However, this review specifically focuses on the use of lifestyle interventions for the treatment of urinary incontinence.

Description of the intervention

I) Weight loss

Both obesity and urinary incontinence are common problems in women and men. Obese women have higher intra-abdominal pressure than non-obese women, and it is thought that this chronically elevated pressure may predispose to incontinence by weakening pelvic floor support structures. In recent years, a number of trials (Hunskaar 2008; Subak 2002; Subak 2009a) including three which specifically reported on weight loss by obese or overweight adults compared to no treatment (Brown 2006a; Subak 2005a; Subak 2009b) have reported an association between increased weight and urinary incontinence.

2) Dietary factors

Dietary factors are recognised as contributing to the maintenance of good health, which is strongly related to low levels of incontinence (McGrother 2007). Indications from epidemiological data suggest that poor diet may play a specific role in urinary incontinence. The prospective Leicestershire MRC Incontinence Study, which examined food items and nutrients in relation to incidence of urinary incontinence, found associations between 1) stress urinary incontinence and low intake of bread plus high saturated fat, zinc and Vitamin B12, and 2) overactive bladder and low intakes of bread, vegetables, chicken, protein, vitamin D and potassium in women (Dallosso 2003; Dallosso 2004a; Dallosso 2004b). Overactive bladder was associated only with high potato intake in men (Dallosso 2004c). The ratio of high saturated fat to polyunsaturated fat intake has also been related to the severity of incontinence in women (Maserejian 2010).

3) Fluids

Worsening of urinary urgency, frequency and incontinence is often reported after consuming caffeine, alcohol, fizzy (carbonated) drinks, sweetened diet drinks (Cartwright 2007), or excessive fluids. In a large prospective cohort study, fizzy drinks was the only type of fluid intake independently associated with incontinence in women (Dallosso 2003), whereas in men, beer intake appeared to be protective (Dallosso 2004c). In a study of urinary symptoms in younger men, caffeine, exercise and tobacco were all associated with worse symptoms in the lower urinary tract (Moon 1997). Caffeine may increase bladder muscle contractility (Creighton 1990), whereas alcohol or excessive fluids may have a diuretic effect, while it has been hypothesised that some sweeteners lead to increased detrusor overactivity (Dasgupta 2006). Sugary fizzy drinks have a high glycaemic index, which worsens control of diabetes and related neuro-muscular functions. These factors are also recognised as potential hazards to general health, which is predictive of urinary incontinence.

4) Constipation and straining

Some evidence suggests that the chronic straining associated with constipation may be a risk factor in the development of urinary incontinence (Moller 2000), and may increase the latency time of the pudendal nerve (Kiff 1984). This nerve supplies the muscles responsible for pelvic support, which is why it has been suggested that constipation may result in, or worsen, urinary incontinence. Poor diet and lack of fibre in the diet can also lead to constipation.

5) Smoking cessation

Several trials have suggested that smokers are more likely than non-smokers to report urinary incontinence (Dallosso 2003; Tampakoudis 1995).

6) Physical activity

Prospective cohort evidence suggests that moderate physical activity decreases the risk of onset of urinary incontinence in middle-aged and older women (Danforth 2007; McGrother 2012; Townsend 2008).

7) Physical forces

It is likely that weakened pelvic floor support structures and raised intra-abdominal pressure caused by heavy lifting and strenuous activity such as aerobics may affect incontinence. Strenuous activity alone may also lead to incontinence in the short term (Nygaard 2006).

Why it is important to do this review

This review aimed to evaluate the effects of these types of lifestyle interventions on improving incontinence and related symptoms by assessing the evidence available from randomized controlled trials. Such interventions are cheap to deploy, have few side effects, are broadly acceptable and may improve the overall health of adults with and without urinary incontinence. This review will enable us to better understand the effect such interventions have on urinary incontinence.

OBJECTIVES

The objective of the review was to determine the effectiveness of specific lifestyle interventions (i.e. weight loss; dietary changes; fluid intake; reduction in caffeinated, carbonated and alcoholic drinks; avoidance of constipation; stopping smoking; and physical activity) in the management of adult urinary incontinence (UI).

METHODS

Criteria for considering studies for this review

Types of studies

Randomised trials or quasi-randomised trials (that use some assignment rule such as alternation, or hospital or clinic record number).

Types of participants

Adults with urinary incontinence, diagnosed either by symptom classification (stress Ulurinary incontinence (SUI); urgency urinary incontinence (UUI); mixed urinary incontinence (MUI)) or by urodynamic investigation (urodynamic stress incontinence (USI); idiopathic detrusor overactivity (IDO)). Due to the small number of studies available, we made a pragmatic decision after the review commenced, to include all studies if some of the participants had UI. An example would include studies primarily concerned with people with overactive bladder (OAB): OAB describes a clinical problem - that encompasses urgency and urgency UI (usually with frequency and nocturia) - from a symptomatic perspective (Abrams 2002). The review excluded studies where all participants explicitly had overactive bladder without UI (socalled 'OAB-dry'). Otherwise we included studies with overactive bladder with the assumption that some participants (regardless of the proportion) had UI (so-called 'OAB-wet'). We also made the post hoc decision to include studies that reported prevalence of UI as an outcome. Here the identified studies were from diabetes trials

where not all participants had UI at baseline. Given that obesity is amongst the most clearly established risk factors for UI in women (Abrams 2013), we assumed that some study participants had UI at baseline. We excluded studies where all participants were continent at baseline.

Types of interventions

One arm of the trial had to be allocated to a community-based lifestyle intervention following a standardised (within trial) protocol. Any of the following lifestyle interventions alone or in combination were included: advice given to lose weight, change diet, adapt the amount or type (e.g. caffeine) of fluid intake, and moderate alcohol consumption, as well as advice given to avoid constipation and straining, stop smoking, and be more physically active whilst restricting excessive heavy physical activity.

Comparison interventions included no (active) treatment, other conservative physical therapies such as pelvic floor muscle training (PFMT) or bladder training, or pharmacological therapies.

We did not consider interventions such as leaflet-only lifestyle advice, without a standardised (within trial) protocol, to be eligible active treatments.

Types of outcome measures

The International Continence Society recommends five outcome categories: the individual's observation (reported symptoms), quantification of symptoms (urine loss), the clinician's observation, and quality of life outcomes, namely, condition-specific, and generic and socioeconomic measures (Mattiasson 1998).

Primary outcomes

- Individual report of symptom cure/improvement.
- Condition-specific quality of life, e.g. ICIQ-Urinary
- Incontinence Form (Avery 2004).
 - Adverse effects.

Secondary outcomes

• Quantification of symptoms (e.g. diary, bladder chart):

 cure and improvement rates on diary or pad test in the short term (less than 12 months) and longer term (more than 12 months);

• number of incontinent episodes in 24 hours.

- Generic quality of life measures e.g. Short Form 36 (Ware 1993).
 - Socio-economic measures:
 - costs of interventions;
 - cost-effectiveness of interventions;
 - resource implications.

• Non-specified outcomes judged important when

performing the review. As the search identified trials in people with diabetes that reported prevalence of UI at follow-up, post hoc decisions were made to include prevalence as an outcome only for the assessment of weight loss interventions.

Main outcomes for 'Summary of findings' table

Main outcomes for the 'Summary of findings' table were (in order of importance):

- symptom cure based on individual report;
- symptom improvement (including cure) based on individual report;
 - condition-specific quality of life;
 - adverse effects;
 - symptom cure based on quantification of symptoms;
 - symptom improvement (including cure) based on
- quantification of symptoms;
 - number of incontinent episodes in 24 hours.

For the assessment of weight loss interventions only, prevalence at follow-up was included in place of the number of incontinent episodes. Main outcomes for weight loss interventions thus were (in order of importance):

- symptom cure based on individual report;
- symptom improvement (including cure) based on individual report;
 - condition-specific quality of life;
 - adverse effects;
 - symptom cure based on quantification of symptoms;
 - symptom improvement (including cure) based on

quantification of symptoms;

• prevalence of UI at follow-up.

The timeframe chosen for these outcomes was at 12-month followup.

Search methods for identification of studies

We did not impose any language or other restrictions on the searches.

Electronic searches

This review drew on the search strategy developed for the Cochrane Incontinence Group. We identified 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, and MEDLINE in process, and handsearching of journals and conference proceedings. Most of the trials in the Cochrane Incontinence Group Specialised Register are also contained in CENTRAL. The date of the search was 3 July 2013; the results of these searches are fully incorporated into the review.

We completed an additional search of ClinicalTrials.gov on 28 November 2013 - this search is detailed in Appendix 1. The results of this search have not been fully incorporated into the review we have placed potentially eligible studies into Studies awaiting classification.

We undertook a further updated search of the Specialised Register on 27 October 2014 the results of which we assessed, and added potentially eligible studies to Studies awaiting classification (the Specialised Register now includes searches of ClinicalTrials.gov and WHO ICTRP).

The terms used to search the Incontinence Group Specialised Register were:

(({DESIGN.CCT*}

OR {DESIGN.RCT*}) AND ({INTVENT.LIFESTYLE*}) AND {TOPIC.URINE.INCON*})

(All searches were of the keyword field of Reference Manager 2012).

Searching other resources

We searched the references lists of relevant articles.

Data collection and analysis

Selection of studies

Two review authors independently screened eligible studies for inclusion. We resolved any disagreements by discussion. We listed excluded trials with reasons for their exclusion.

Data extraction and management

Two review authors extracted data from published reports independently, and resolved any disagreements by discussion. Where there was insufficient information in the published report, we planned to seek clarification from the trialists, but this was not required.

For studies where not all participants had UI at baseline, we preferred the data from a subgroup of people with UI, if these were reported separately. If such data were not available, we extracted data from the whole study but recorded the proportion of people with UI at baseline where possible.

Assessment of risk of bias in included studies

Two review authors evaluated all relevant studies independently for their potential risk of bias.

We undertook assessment of methodological quality using the Cochrane 'Risk of bias' tool to include assessment of: random sequence generation; allocation concealment; blinding of participants and personnel; blinding of outcome assessment; incomplete outcome data; selective reporting; and other sources of bias. We resolved any differences of opinion related to the 'Risk of bias' assessment by discussion. We planned sensitivity analysis using only the data from studies having a low risk of bias, but this was not possible due to lack of data.

Measures of treatment effect

We undertook quantitative synthesis if we identified more than one eligible study. We used a fixed-effect model to calculate pooled estimates of treatment effect across similar trials with their 95% confidence intervals. We combined dichotomous outcome data using the relative risk (RR) method. We intended to combine continuous outcomes using the Mantel-Haenszel weighted mean difference (WMD) method, but this was not done because the continuous outcome data available were either not reported as means with standard deviations (SD), or were not reported by more than one study. We calculated a mean difference for individual trials where possible.

We grouped trial data according to the type of incontinence when data were available. We planned other subgroup analyses (e.g. age, gender, severity of symptoms, methodological quality), but could not perform these due to insufficient data.

We did not perform quantitative synthesis for adverse events, because the included studies reported adverse events narratively and very few numerical data were available; instead we report the findings by a qualitative summary.

Unit of analysis issues

We analyzed trials with a parallel group design on the basis of individuals randomized.

The recommended approach for including cross-over trials in a meta-analysis is to perform a paired analysis taking into account the within-person differences (Elbourne 2002). However, the included cross-over trials tended to report all measurements after the active treatment period and all measurements after the control treatment period, and then compared these data as if they came from a parallel group trial. The trials also did not publish the mean and standard deviation values (for the within-person differences) required to perform paired analyses. We therefore presented data from these trials as reported, although this gives rise to a 'unit of analysis' error. These results should therefore be interpreted with caution.

Dealing with missing data

Where possible, we used data based on explicit intention-to-treat analysis. If this was unclear, we performed available case analysis. We collected data on dropout rates, and noted reasons for withdrawal and dropout reported by the trialists in the 'Characteristics of included studies' table when these appeared to be treatmentrelated.

Assessment of heterogeneity

We assessed heterogeneity across studies by visual inspection of plots of the data, the Chi² test for heterogeneity, and the I² statistic (Higgins 2003). We also explored potential sources of heterogeneity.

Assessment of reporting biases

We planned to create funnel plots of the intervention effect estimates against their standard errors using Review Manager (RevMan; RevMan 2014), but the number of studies included in the review was not sufficient for us to perform this assessment.

Sensitivity analysis

To assess the potential impact of widening the inclusion criteria of the review to include studies where not all of the participants had UI at baseline, we considered conducting sensitivity analyses in which we would exclude studies with mixed populations (with and without incontinence) from the meta-analysis of each outcome, however, we could not do this due to the low number of studies available.

Summary of findings table

We summarised results in 'Summary of findings' tables, following the standard methods described in Chapters 11 and 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011a; Schünemann 2011b). As the recommendation to generate 'Summary of findings' tables is relatively new and became prominent after the publication of the review protocol, we decided to undertake this exercise and determined main outcomes for these tables during the course of the review. We used no external information in the 'Assumed risk' column of the tables. The overall quality of evidence for each outcome was assessed using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (Guyatt 2008). In GRADE, there are four levels of quality of evidence: high, moderate, low and very low. Randomised studies begin as 'high' quality evidence, but may be rated downwards depending upon performance in one or more of five pre-defined categories: (i) limitation of study design (risk of bias), (ii) inconsistency (heterogeneity), (iii) indirectness, (iv) imprecision, and (v) other considerations (e.g. publication bias).

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Results of the search

The electronic searches retrieved a total of 338 records, from which we obtained 60 full text articles we assessed for eligibility. We considered 32 reports of 11 trials eligible for inclusion in the review, and identified one report of an eligible ongoing trial (Moholdt 2011).

Additionally, we completed assessment of 1151 records retrieved from ClinicalTrials.gov (28 November 2013) after the main search was fully incorporated into the review - details of four potentially relevant records are given in the Characteristics of studies awaiting classification table (Baker 2011; Heesakkers 2009; Huang 2012; Markland 2013). A further updated search of the Specialised Register on 27 October 2014 retrieved 101 records; we screened these and added three extra studies to the Studies awaiting classification section (Gozukara 2014; Seckin 2011; Wells 2014). The results of these latter two searches (ClinicalTrials.gov and the Specialised Register) have not been fully incorporated into the review. The flow of literature through the assessment process is shown in the PRISMA flowchart (Figure 1).





Included studies

Design

The review included a total of 32 reports of 11 trials: five parallel-arm randomized controlled trials (RCTs; Brown 2006b; Dowd 1996; Phelan 2012; Subak 2005; Subak 2009), four randomized cross-over trials (Hashim 2008; Manonai 2006; Swithinbank 2005; Wells 2011), and one quasi-randomised trial that used health record numbers as the basis for assigning people to interventions (Bryant 2002). We also identified one unpublished RCT with limited information (Miller 2007).

Participants

The included trials involved a total of 5974 participants, who were predominantly female (5954 women and 20 men). The average age (it was unclear if this was a mean or median) of the participants in the included trials ranged from 49 to 58 years, except for two trials with means of 62.7 years (Hashim 2008), and 70.25 years (Dowd 1996).

Sample size varied across trials. The majority of included trials had 60 or fewer participants (seven trials), however, two trials had more than 1000 participants and a further two trials had more than 100 participants Brown 2006b; Phelan 2012; Subak 2009; Swithinbank 2005).

In four trials, all trial participants had UI at baseline:

- Dowd 1996: 58 women with UI;
- Subak 2005: 48 women with SUI (6%), stress predominant MUI (40%), UUI (11%) and urgency predominant MUI (43%);
- Subak 2009: 338 women with SUI (8%), stress predominant MUI (25%), UUI (18%) and urgency predominant MUI (48%);

• Swithinbank 2005: 110 women with USI (57%) and IDO (43%).

Four trials included adults with OAB, leading to UUI in some of the trial participants:

• Bryant 2002: 9 men and 86 women with symptoms of urgency, frequency and/or UUI; 83% had UUI at baseline;

- Hashim 2008: 11 men and 13 women with OAB; 29% had UUI at baseline;
 - Miller 2007: 60 women with OAB;
 - Wells 2011: 14 women with OAB, with or without UI.

One trial included women with urogenital atrophy, leading to UI in some of the participants:

• Manonai 2006: 42 women with urogenital atrophy; 61% had SUI and 19% had UUI at baseline.

The other trials that contributed the largest numbers of participants were sub-studies of large diabetes trials of intensive weight loss programmes, namely the DPP (Diabetes Prevention Program; Brown 2006b), which focused on the prevention of diabetes, and Look AHEAD (Action For Health in Diabetes; Phelan 2012), which evaluated cardiovascular morbidity and mortality among individuals with type 2 diabetes. Not all of the trial participants in these trials had UI at baseline, but reported prevalence of UI at follow-up:

• Brown 2006b: 2191 women in a diabetes trial; no baseline measures of UI;

• Phelan 2012: 2994 women in a diabetes trial; 27% had weekly UI at baseline.

Interventions

Weight loss

Four trials assessed the effect of weight loss programmes on incontinence compared with a control intervention (Brown 2006b; Phelan 2012; Subak 2005; Subak 2009). All weight loss interventions included components of diet and physical activity.

Diet

The review identified one trial that examined dietary factors by comparing a soy-rich diet with a control diet (Manonai 2006).

Changing volume of fluid intake

Three trials assessed the effect of changing the volume of fluid intake (Dowd 1996; Hashim 2008; Swithinbank 2005).

Type of fluid intake

Three trials assessed the effect of reducing caffeinated drinks (Bryant 2002; Miller 2007; Wells 2011). No relevant trials were identified with respect to alcohol, sweetened fizzy drinks or diet drinks.

Constipation and straining, smoking cessation, physical activity and physical forces

The review identified no randomized trials addressing the effect of constipation and straining, smoking cessation, physical activity or physical forces on urinary incontinence.

Outcome

Quality of reporting of outcomes was generally poor. Not all specified outcomes were reported. Where reported, outcomes were reported using diverse measures, which made the results difficult to interpret. Meta-analysis was performed only for cure and improvement rates and UI prevalence from the weight loss interventions. All other outcomes were summarised narratively. We excluded 27 reports relating to 20 studies after full text screening; see Characteristics of excluded studies. For example, the review excluded studies where lifestyle change was implemented as part of a multi-faceted intervention, e.g. dietary change and constipation management with pelvic floor muscle training, because in such studies we could not separate the effects of lifestyle change from other factors.

Risk of bias in included studies

Excluded studies

The risk of bias of the included trials is summarised in Figure 2 and Figure 3.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies





Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

Allocation

Four of the 11 included trials described adequate methods of random sequence generation (Brown 2006b; Subak 2005; Subak 2009; Wells 2011), and of these, allocation was adequately concealed in two (Subak 2005; Subak 2009), but was unclear in the other two (Brown 2006b; Wells 2011). One trial used quasi-randomisation based on health record numbers and was therefore at high risk of selection bias (Bryant 2002). Other trials did not describe the methods used for random sequence generation and allocation concealment and so we judged them to be at unclear risk of bias for this domain.

Blinding

Blinding of participants and personnel was not feasible due to the nature of interventions; this may have biased self-reported outcomes such as cure, improvement and quality of life. Blinding of outcome assessment should be possible, but was done in only three trials (Phelan 2012; Subak 2005; Subak 2009), and was unclear in the others.

Incomplete outcome data

The percentage of participants followed up and included in analysis varied across trials as shown below:

- 100% (Hashim 2008);
- 90% or more (Phelan 2012);
- between 80% and 89% (Brown 2006b; Manonai 2006; Subak 2005; Subak 2009; Swithinbank 2005);
 - between 70% and 79% (Bryant 2002; Wells 2011);
 - 55% (Dowd 1996); and
 - not reported (Miller 2007).

Of these, four trials were considered to be at low risk of attrition bias (incomplete outcome data) because the trial reports stated that either there were no missing outcome data (Hashim 2008), or described use of imputation (Subak 2009), or confirmation that participants with missing data did not differ from participants with data in terms of demographic and clinical characteristics (Brown 2006b; Subak 2005). One trial (Dowd 1996), in which 26 (45%) of the 58 participants did not complete diaries and were excluded from analysis, was assessed as having a high risk of attrition bias. Reasons for missing outcome data were not clearly described in the other trials, and it was difficult to determine whether the extent of missing data was likely to induce clinically important bias. We therefore judged them to be at unclear risk of bias for this domain.

Selective reporting

All trials reported on the outcomes listed in their methods section but, as there was otherwise insufficient information to permit judgement of low or high risk of bias within published reports, we consider them to be at unclear risk of bias for this domain.

Other potential sources of bias

Two trials assessing fluid intake manipulation (Dowd 1996; Hashim 2008), and caffeine reduction (Miller 2007; Wells 2011), noted that compliance to the trial protocol was relatively poor. Apart from this factor, it was difficult to assess whether any other important risk of bias existed in these and the other trials.

Effects of interventions

See: Summary of findings for the main comparison Weight loss compared to control for the treatment of urinary incontinence in adults; Summary of findings 2 Soy-rich diet compared to control for the treatment of urinary incontinence in adults; Summary of findings 3 Decreasing fluids compared to increasing fluids for the treatment of urinary incontinence in adults; Summary of findings 4 Caffeine reduction compared to control for the treatment of urinary incontinence in adults; Summary of findings 5 Lifestyle weight loss compared to metformin weight loss for the treatment of urinary incontinence in adults

The results of the included studies, and the quality of the body of evidence for each outcome, are summarised in the 'Summary of findings' tables (Summary of findings for the main comparison; Summary of findings 2; Summary of findings 3; Summary of findings 4; and Summary of findings 5).

1) Weight loss by obese or overweight adults versus no active intervention

Description of studies

We identified four trials involving a total of 4701 participants that compared intensive lifestyle weight loss interventions with control or no active interventions in relation to incontinence (Brown 2006b; Phelan 2012; Subak 2005; Subak 2009). All participants in two of the included trials had UI (Subak 2005; Subak 2009). The other two trials were sub-studies of large diabetes trials (Brown 2006b; Phelan 2012), DPP and Look AHEAD, respectively, and contributed 4315 (92%) of the trial participants to the analysis. These trials did not recruit participants specifically with UI and therefore not all the participants had it. We extracted outcome data on cure and improvement (based on quantification of symptoms) from a subgroup of people with UI in the Look AHEAD trial (N = 738; Phelan 2012), and data on prevalence of UI at follow-

up from the whole (sub-)study (N = 2994). The trial authors reported the one-year results of a four-year intensive weight loss programme; the trialists planned that follow-up of this trial would run until 2014. The only relevant outcome from the DPP trial was prevalence at follow-up of UI from the whole (sub-)study (N = 1321; Brown 2006b); the proportion of people with UI at baseline was unknown (not reported).

All participants in the included trials were female. The weight loss groups were given a reduced-calorie diet and increased physical activity according to a structured and supervised protocol. The comparison groups received:

• no intervention (waiting list; Subak 2005);

• a structured education programme on weight loss (Subak 2009);

- diabetes support and education (Phelan 2012); or
- a placebo drug (Brown 2006b).

Duration of the interventions varied across trials. The intensive intervention phase lasted for:

• three months (Subak 2005);

• six months followed by a further randomisation in the intervention group (not the control group) to motivation-based or skill-based maintenance programmes for an additional 12 months (Subak 2009);

- six months with monthly follow-up thereafter for an average of 2.8 years (Brown 2006b); or
 - 12 months (Phelan 2012).

All four trials reported that women allocated to the intervention group achieved a statistically significant decrease in body weight from baseline compared with those in the control group.

Primary outcomes

Improvement rates based on women's perception (self-report) were reported in one trial (Subak 2009). The results showed that at six months women in the intervention group were more likely to report improvement than those in the control group at six months (163/214 (76%) versus 49/90 (54%), risk ratio (RR) 1.4, 95% confidence interval (CI) 1.14 to 1.71; Analysis 1.1), 12 months (298 women in analysis, 75% versus 68%, RR not estimable, reported P value 0.2) and 18 months (291 women in analysis, 75% versus 62%, RR not estimable, reported P value 0.02) after randomisation (Analysis 1.2). The reported P values suggest that the differences were statistically significant at six months and 18 months. No information was available on self-reported cure.

The intervention group also reported that incontinence had less adverse impact on their lives (median Incontinence Impact Questionnaire scores, 40 women in analysis, 37 versus 89, P value 0.01) and was less distressing (median Urogenital Distress Inventory scores, 40 women in analysis, 104 versus 195, P value < 0.0001) compared with the control group in one trial that reported these outcomes (Subak 2005; Analysis 1.3).

Adverse effects appeared to be relatively uncommon, with one trial reporting that the intervention had 'few side effects' (Subak 2005).

Secondary outcomes

Three trials reported cure and improvement rates based on quantification of symptoms (rather than women's perception; Subak 2005; Subak 2009; Phelan 2012; Analysis 1.4; Analysis 1.5; Analysis 1.6; Analysis 1.7). Depending on the trial, length of follow-up and type of incontinence, cure rates for the intervention group ranged from 7% to 35% and improvement rates ranged from 37% to 64%. In the control group cure rates ranged from0% to 32% of women, while improvement ranged from 0% to 62%. In general the intervention group had higher rates in terms of both cure and improvement compared with the control group when stress and urgency UI symptoms were considered together ('all UI'). For improvement rates, the difference between the groups was statistically significant at three months (7/19 (37%) versus 0/ 21 (0%), RR 16.50, 95% CI 1.01 to 270.78; Analysis 1.6), six months (88/214 (41%) versus 20/90 (22%), RR 1.85, 95% CI 1.22 to 2.81; Analysis 1.6) and 12 months (234/583 (40%) versus 146/449 (32%), RR 1.21, 95% CI 1.02 to 1.44; Analysis 1.6), although the effect was attenuated over time and was no longer statistically significant at 18 months (91/197 (46%) versus 36/90 (40%), RR 1.15, 95% CI 0.86 to 1.55; Analysis 1.6). The difference for cure rates did not reach statistical significance (Analysis 1.4).

Looking at different types of UI at each outcome time point, the Subak 2009 trial showed a similar pattern with a tendency towards greater improvement in the intervention group than in the control group among the subgroup of women who reported stress symptoms at six, 12 and 18 months (P values 0.01, 0.01 and 0.92, respectively) or urgency symptoms at six, 12 and 18 months (P values 0.04, 0.07 and 0.03, respectively; Analysis 1.7). In the same trial, cure rates by type of UI also favoured the intervention group for both SUI (P value 0.004) and UUI (P value 0.02) at six months, but no further follow-up was available (Analysis 1.5).

The prevalence of weekly (or more frequent) UI of any type (stress or urgency) was lower in the intervention group than in the control group in the two sub-studies of diabetes trials with a follow-up of between one and 2.8 years (Analysis 1.8). According to adjusted odds ratios (ORs) reported by trial authors, the intervention was associated with a statistically significant reduction in the odds of having UI by around 20% to 24% compared with the control group (in Phelan 2012, adjusted OR 0.80, 95% CI 0.65 to 0.98; in Brown 2006b, adjusted OR 0.76, 95% CI 0.61 to 0.95). The prevalence of weekly SUI was also lower in the intervention group compared with the control in both trials (in Phelan 2012, adjusted OR 0.73, 95% CI 0.55 to 0.96, Analysis 1.9; in Brown 2006b, adjusted OR 0.80, 95% CI 0.64 to 1.01) but no such difference was apparent for UUI (Analysis 1.9). The trial authors suggest that the reduction in the prevalence of overall weekly incontinence

may be due to differences in weekly SUI.

Compared with women in the control group, those in the intervention group had a greater percentage reduction from baseline in weekly incontinence episodes over the period of three to 18 months regardless of type of UI (all, stress or urgency; Analysis 1.10; Analysis 1.11). Differences between the groups for all UI and SUI episodes were reported to be statistically significant at three, six and 12 months but no longer significant at 18 months. The difference for UUI was not statistically significant at any point in time after three months.

General health-related quality of life was measured only in one small trial with 40 participants using SF-36 ((Subak 2005; Analysis 1.3). The median SF-36 Physical Component Score favoured the intervention group (55 versus 47, P value 0.003) but there was no significant difference between the groups in the Mental Component Score of the same instrument (48 versus 51, P value 0.09).

2) Dietary changes versus no active intervention

Description of study

We identified only one small trial that assessed the effect of dietary factors on UI (Manonai 2006). The trial used a randomized crossover design and compared a soy-rich diet with a control (soy-free) diet in 42 women who experienced at least one of urinary or genital symptoms owing to urogenital atrophy. At baseline around 61% and 63% of women in the intervention and control groups, respectively, had SUI episodes and 19% and 11%, respectively, had UUI episodes. Partcipants underwent two two-week treatment periods in random order with two four-week washout periods before and between treatments. The trial authors found compliance to the diet to be satisfactory on the basis of the elevation of serum levels of daidzein and genistein during the soy-rich diet period. Outcome data were available for 36 women who completed the trial. As data subgrouped by incontinence status were not available, the extracted data were from the whole study.

Primary outcomes

The trial did not address self-reported cure and improvement rates, condition-specific quality of life and adverse effects.

Secondary outcomes

The trial did not address cure and improvement rates based on quantification of symptoms, number of UI episodes and generic quality of life. The available data suggest that the percentage of women with UUI episodes in the control group increased from baseline during the control diet period (N = 36, from 11% to 22%, P value not reported; Analysis 2.1). Correspondingly, symptom scores (mean, SD) of UUI significantly increased during the

control diet period (N = 36, from 0.14 (0.35) to 0.25 (0.50), P value < 0.05; Analysis 2.2), although the difference was small.

3) Change in fluid intake versus no treatment

Description of studies

We identified three trials that examined altering the level of fluid intake (Dowd 1996; Hashim 2008; Swithinbank 2005).

One RCT allocated 58 women with UI to one of three groups that increased fluid intake by 500 (Dowd 1996). The trial provided a five-week programme with randomisation in the second week. The trial reported that adherence to the fluid manipulation was poor, which made results difficult to interpret.

Another randomized cross-over trial with 84 women with UI reported outcome data for the 69 women (39 with USI and 30 with IDO) who completed the trial (Swithinbank 2005). The trial lasted four weeks. In the first week participants drank normally (week 1, baseline) and in the second week drank normally, but only caffeine-free fluids (week 2, caffeine-free baseline). Participants were then randomized in the order in which they either increased fluids to 3 litres daily, or decreased fluids to 750 ml daily, in the third and fourth weeks while maintaining caffeine restriction (i.e. only drinking caffeine-free fluids). Adherence to fluid intake protocols seemed fair, with a mean fluid intake of 1639 ml for Week 1, 1630 ml for Week 2, 2673 ml for the week of increasing fluids and 872 ml for the week of decreasing fluids.

In another cross-over trial with 24 participants (11 men and 13 women) with OAB (Hashim 2008), only seven (29%) participants had UUI at baseline. Participants were randomized into two groups and asked to either increase or decrease their fluid intake from baseline. As outcome data specific to a subgroup of people with UI were not reported separately, the extracted data applied to the whole study. Group I was asked to drink at < 25% of baseline for four days, followed by two days' normal drinking, four days' at < 50%, two days' normal drinking, four days at > 25%, two days' normal drinking, and then four days at > 50%. Group II did the reverse. The trial reported that participants had difficulty in either increasing or decreasing fluids by 50%.

Primary outcomes

One cross-over trial assessed quality of life using the Bristol Female Lower Urinary Tract Symptoms questionnaire (Swithinbank 2005). Quality of life improved when fluid intake was decreased compared with baseline in women with USI (N = 39, P value < 0.003) or IDO (N = 30, P value < 0.003) but the women reported no significant difference in the impact of incontinence symptoms on their daily life before and after treatment (no further data were available).

Regarding adverse effects, the same cross-over trial reported that, with decreasing fluids, 'side effects such as constipation and thirst

were troublesome' (Swithinbank 2005). Another cross-over trial with 24 participants reported that adverse events observed were mild and tolerable: four participants felt thirsty and two had headaches, constipation or concentrated urine when fluid intake was decreased by 50% from baseline; and one had headache when intake was reduced by 25% (Hashim 2008).

No information was available regarding self-reported cure or improvement.

Secondary outcomes

The number of daily incontinent episodes was reported by three trials that used different measures. A four-week cross-over trial stratified results by type of UI at baseline (Swithinbank 2005; Analysis 3.1). Among 39 women with USI, the week of decreasing fluid intake (with caffeine restriction) was associated with a statistically significant reduction in the median number of daily incontinent episodes compared with the week of increasing fluid intake (with caffeine restriction; 0.5 versus 0.7, P value 0.006). Daily incontinent episodes after decreasing fluid intake (with caffeine restriction) were also statistically significantly fewer compared with the baseline week when participants drank normally (week 1, 0.5 versus 1.6, P value 0.006), but there was no significant difference when compared with the caffeine-free baseline week in which participants maintained a similar fluid intake from baseline, but substituted caffeine-free drinks for caffeine-containing drinks (week 2, 0.5 versus 0.8, P value 1.000). The week of increasing fluid intake (no caffeine) did not differ significantly from the caffeinefree baseline week (week 2, 0.7 versus 0.8, P value 0.426) in terms of daily incontinent episodes. For 30 women with IDO, drinking less fluid (no caffeine) had no statistically significant effect on daily incontinent episodes (0.5 versus 0.6, P value not significant) when compared with the caffeine-free baseline, but drinking more fluid (no caffeine) resulted in a significant worsening (increase) of the symptom (1.1 versus 0.6, P value < 0.003).

In the other cross-over trial participants were asked to increase or decrease their fluid intake by 25% and 50% from baseline in random order (Hashim 2008). There was no statistically significant difference in the mean number of daily incontinent episodes between the baseline period and each of the fluid manipulation periods, although it should be noted that only seven (29%) of the 24 participants had UUI at baseline (Analysis 3.2).

The Dowd 1996 trial randomized participants to three groups (maintain, increase or decrease fluid), but the authors reported that adherence to the fluid manipulation protocol was poor and that results were inconclusive (Analysis 3.3).

We identified three trials that assessed the effects of a reduction in caffeine intake on incontinence (Bryant 2002; Miller 2007; Wells 2011).

In Bryant 2002, 95 participants (86 women, 9 men) with OAB (83% had UUI at baseline) were randomized by use of health record numbers (quasi-randomised) to caffeine reduction education or control (continued caffeine intake). In addition, both groups received bladder training and were followed up for four weeks. Caffeine intake in the intervention group was reduced significantly from baseline compared with the control group (58% versus 11%, P value < 0 000.1)

Wells 2011 was a randomized cross-over trial in which 14 women with OAB (with or without UI) underwent two two-week periods of caffeinated or caffeine-free fluids intake with a 14-day washout period between treatments. It was a feasibility trial and identified only in abstract form. Data were available for the 11 women who completed the trial. Two participants did not comply with caffeine substitution.

The third trial, Miller 2007, was an unpublished two-arm RCT that evaluated the effect of restricting 'irritating' beverages (caffeinated or non-caffeinated). In this trial around 60 women with OAB (it was unclear if some or all participants were incontinent) were asked to substitute 'irritating' beverages with milk or water, but to maintain a similar volume of fluid from baseline. The request to stop drinking irritating beverages was associated with an improvement in OAB symptoms, but the trial author noted that the findings were confounded by a significant reduction in overall fluid intake in the intervention group from baseline (email communication from the trial author to the Cochrane Incontinence Group). No further information was available regarding this trial. The remainder of this section therefore focuses on the first two trials.

In all three trials, outcome data were extracted from the whole study, as data specific to the UI subgroup of the trial population were not reported separately.

Primary outcomes

The Wells 2011 trial reported condition-specific quality of life using ICIQ Overactive Bladder (ICIQ-OAB) and ICIQ Overactive Bladder Symptoms Quality of Life (ICIQ-OABqol) questionnaires among 11 of the 14 women who completed the trial. Overall, women had lower (better) scores during the period of caffeine substitution (when drinking caffeine-free fluids) compared with the caffeine exposure period, but the difference in total scores for the ICIQ-OABqol was not statistically significant (mean 54 versus 68, P value 0.065; Analysis 4.1). No information was available regarding self-reported cure and improvement, or adverse effects.

4) Caffeine reduction versus continued caffeine intake

Description of studies

Secondary outcomes

There was no evidence of a difference in incontinence episode frequency between the caffeine reduction and caffeine exposure

groups. The Bryant 2002 trial reported a mean difference of 0.2 episodes per day (Analysis 4.2: mean difference (MD) -0.20, CI - 1.02 to 0.62), whereas the Wells 2011 trial reported 'no difference' with no numerical data provided. No information was available for cure and improvement rates based on quantification of symptoms or generic quality of life.

5) Reduction in sweetened fizzy or diet drinks versus no treatment

We found no trials that compared a reduction in sweetened fizzy or diet drinks with no treatment.

6) Reduction in alcohol consumption versus no treatment

We found no trials that compared a reduction in alcohol consumption with no treatment.

7) Avoiding constipation versus no treatment

We found no trials that compared avoidance of constipation with no treatment.

8) Smoking cessation versus no treatment

We found no trials that compared stopping smoking with no treatment.

9) Restricting strenuous physical forces versus no treatment

We found no trials that compared restricting strenuous physical forces with no treatment.

10) Reducing high levels of, or increasing low levels of, physical activity versus no treatment

We found no trials that compared a reduction in high levels of physical activity, or increasing low levels of physical activity, with no treatment.

11) Any lifestyle interventions, either alone or in combination, versus other lifestyle interventions or pharmacological and other conservative therapies

One trial was identified that compared a lifestyle weight loss intervention versus metformin. This trial was a sub-study of a large DPP trial for diabetes described above (Brown 2006b), which compared different weight loss programmes: an intensive lifestyle intervention or a pharmacological intervention (metformin). This comparison included 1296 women.

The only relevant outcome for this review was the effect of weight loss on the prevalence of weekly or more frequent UI at a mean follow-up of 2.8 years. The results showed that women allocated to the lifestyle group (N = 659) had a significantly lower prevalence of UI (any UI) compared with those in the comparison group (252/ 659 (38%) versus 306/635 (48%), RR 0.79, 95% CI 0.70 to 0.90; Analysis 5.1.1). The results hold for the prevalence of both weekly SUI symptoms (206/659 (31%) versus 252/635 (40%), RR 0.79, 95% CI 0.68 to 0.91; Analysis 5.1.2), and UUI symptoms (156/ 659 (24%) versus 182/635 (29%), RR 0.83, 95% CI 0.69 to 0.99; Analysis 5.1.3).

| a intervention | oy-rich diet compared to control for the treatment of urinary incontinence in adults | | | | | | |
|------------------|---|--|--------------------|-----------------------------|---------------------------------|------------------------------------|----------|
| s for the treatm | Patient or population: add Settings: Intervention: soy-rich died Comparison: control | uits with urinary incont | inence | | | | |
| | Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments |
| | | Assumed risk | Corresponding risk | | | | |
| | | Control | Soy rich diet | | | | |
| | Cure rates by patient ob- servation (all UI types) - not reported | | | Not estimable | - | | |
| - | Improvement rates by patient observation (all UI types) - not reported | | | Not estimable | - | | |
| | Condition-specific qual- ity of life - not reported | | | Not estimable | - | | |
| | Adverse effects - not re- ported | | | Not estimable | - | | |
| | Cure rates by symp- tom quantification (all UI types) - not reported | | | Not estimable | - | | |

ADDITIONAL SUMMARY OF FINDINGS [Explanation]

| Improvement rates by symptom quantification (all UI types) - not re- ported | | Not estimable - | | | | |
|---|---|---|--|--|--|--|
| Incontinent episodes per week (all UI types) - not reported | | Not estimable - | | | | |
| *The basis for the assumed assumed risk in the compari CI: confidence interval; RR: | I risk (e.g. the median control group risk acrossion group and the relative effect of the interventisk ratio; UI: urinary incontinence | ss studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the ntion (and its 95% CI). | | | | |
| GRADE Working Group grades of evidence High quality: Further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate. | | | | | | |

| Patient or population: adults with urinary incontinence Settings: Intervention: decreasing fluids Comparison: increasing fluids | | | | | | | |
|--|--|--------------------|-----------------------------|---------------------------------|---|--|--|
| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments | |
| | Assumed risk | Corresponding risk | | | | | |
| | Increasing fluids | Decreasing fluids | | | | | |
| Cure rates by patient ob- servation (all UI types) - not reported | | | Not estimable | - | | | |
| Improvement rates by patient observation (all UI types) - not reported | | | Not estimable | | | | |
| Condition-specific qual- ity of life Follow-up: 1 weeks | See comment | See comment | Not estimable | 69 (1 study ¹) | ⊕○○○ very low ^{2,3,4,5,6} | Quality of life improved when fluid intake was de creased but the impact o incontinence on daily life did not differ significantly before or after the treatmen | |
| Adverse effects Follow-up: 1 weeks | See comment | See comment | Not estimable | 93 (2 studies ¹) | ⊕⊖⊖⊖ very low ^{2,3,5,6,7,8} | Reported adverse effects include constipation, thirst headache and concen trated urine with decreas ing fluids | |

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| Cure rates by symp- tom quantification (all UI types) - not reported | | | Not estimable | - | | |
|--|--|---|---|--|---|--|
| Improvement rates by symptom quantification (all UI types) - not re- ported | | | Not estimable | - | | |
| Incontinent episodes per week (all UI types) Follow-up: 1-4 weeks | See comment | See comment | Not estimable | 125 (3 studies ⁹) | ⊕○○○ very low ^{2,3,5,6,8,10,11} | Decreasing fluid intake sig- nificantly reduced inconti- nent episodes in one study, no difference was found in another study and the re- sults were inconclusive in the other study |
| *The basis for the assum assumed risk in the comp CI: confidence interval; UI | ned risk (e.g. the medi arison group and the re I: urinary incontinence | an control group risk acro elative effect of the interve | oss studies) is provided ention (and its 95% CI). | I in footnotes. The corres | ponding risk (and its 95% confid | dence interval) is based on the |
| GRADE Working Group gr High quality: Further rese Moderate quality: Further Low quality: Further resea Very low quality: We are | ades of evidence arch is very unlikely to r research is likely to ha arch is very likely to hav very uncertain about th | change our confidence in we an important impact or ve an important impact on e estimate. | the estimate of effect. 1 our confidence in the 6 our confidence in the e | estimate of effect and may stimate of effect and is lik | / change the estimate. ely to change the estimate. | |
| ¹ Randomised cross-over t ² Risk of bias: We downg probably not done and cou ³ Risk of bias: We downgr concealment method. ⁴ Missing outcome data in ⁵ Indirectness: We downgr participants included both | trial graded the evidence by Id introduce bias. raded the evidence by 18% of participants. raded the evidence by continent and incontine | one level because blindi one level because the aut two levels because of sho nt patients in one study (H | ng of participants, pers hors did not report or p ort follow-up <12 mon lashim 2008) | sonnel and outcome asse provide a description of ar ths in all studies and bec | essors was n allocation ause study | |

⁶ Imprecision: We downgraded the evidence by one level because confidence intervals for relative effect were not estimable.

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⁷ Missing outcome data in 18% of participants in one study (Swithinbank 2005), whereas the other study had no missing outcome data (Hashim 2008).

⁸ Inconsistency: We downgraded the evidence by one level because becuse of heterogenous interventions.

⁹ One RCT compared increasing versus decreasing versus maintaining fluid intake (Dowd 1996) and two randomized cross-over trials comparing increasing versus decreasing fluid intake (Hashim 2008; Swithinbank 2005).

¹⁰ Missing outcome data in 45% of participants in the RCT (Dowd 1996), 18% of participants in a cross-over trial (Swithinbank 2005),

whereas the other cross-over trial had no missing outcome data (Hashim 2008).

¹¹ Low adherence to the protocol was reported in two studies (Dowd 1996;Hashim 2008).

| Patient or population: adults with urinary incontinence Settings: Intervention: caffeine reduction Comparison: control | | | | | | | |
|--|--|--|-----------------------------|---------------------------------|---------------------------------------|----------|--|
| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments | |
| | Assumed risk | Corresponding risk | | | | | |
| | Control | Caffeine reduction | | | | | |
| Cure rates by patient ob- servation (all UI types) - not reported | | | Not estimable | - | | | |
| mprovement rates by patient observation (all Ul types) - not reported | | | Not estimable | - | | | |
| Condition-specific qual- ity of life CIQ Overactive Bladder Symptoms Quality of Life. Scale from: 25 to 160. Better quality of life indi- cated by lower values. Follow-up: 2 weeks | The mean condition-spe- cific quality of life in the control groups was 68.36 points | The mean condition-spe- cific quality of life in the intervention groups was 14.45 lower (95% CI not estimable) | Not estimable | 11 (1 study ¹) | ⊕○○○ very low ^{2,3,4,5,6} | | |
| Adverse effects - not re- ported | | | Not estimable | - | | | |
| Cure rates by symp- tom quantification (all UI types) - not reported | | | Not estimable | - | | | |

| symptom quantification (all UI types) - not re- ported | | | Not estimable | - | |
|---|---|--|---|--|---|
| Incontinent episodes per day (all UI types) Follow-up: 4 weeks | The mean number of in- continent episodes per day (all UI types) in the control groups was 1.4 | The mean number of in- continent episodes per day (all UI types) in the intervention groups was 0.2 lower (1.02 lower to 0.62 higher) | Not estimable | 74 (1 study ⁷) | ⊕)) very low ^{2,4,5,6,8} |
| *The basis for the assum assumed risk in the comp CI: confidence interval | ed risk (e.g. the median c arison group and the relativ | ontrol group risk across st e effect of the intervention | udies) is provided in foc (and its 95% CI). | tnotes. The correspon | ding risk (and its 95% confidence interval) is based on the |
| GRADE Working Group gra High quality: Further resea Moderate quality: Further Low quality: Further resea Very low quality: We are | ades of evidence arch is very unlikely to char research is likely to have a arch is very likely to have an very uncertain about the est | ge our confidence in the es n important impact on our c important impact on our c imate. | timate of effect. confidence in the estimat onfidence in the estimate | e of effect and may cha of effect and is likely t | ange the estimate. o change the estimate. |
| | | | | | |

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| Lifestyle weight loss compared to metformin weight loss for the treatment of urinary incontinence in adults | | | | | | | | |
|---|--|-----------------------|-----------------------------|---------------------------------|------------------------------------|----------|--|--|
| Patient or population: ad Settings: Intervention: lifestyle wei Comparison: metformin v | ults with urinary incontine ght loss veight loss | nce | | | | | | |
| Outcomes Illustrative comparative risks | | risks* (95% CI) | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments | | |
| | Assumed risk | Corresponding risk | _ | | | | | |
| | Metformin weight loss | Lifestyle weight loss | | | | | | |
| Cure rates by patient ob- servation (all UI types) - not reported | | | Not estimable | - | | | | |
| Improvement rates by patient observation (all UI types) - not reported | | | Not estimable | - | | | | |
| Condition-specific qual- ity of life - not reported | | | Not estimable | - | | | | |
| Adverse effects - not re- ported | | | Not estimable | - | | | | |
| Cure rates by symp- tom quantification (all UI types) - not reported | | | Not estimable | - | | | | |
| Improvement rates by symptom quantification (all UI types) - not re- ported | | | Not estimable | - | | | | |

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| (all UI types) Follow-up: mean 2.8 years | 482 per 1000 | 381 per 1000 (337 to 434) | RR 0.79 (0.7 to 0.9) | 1294 (1 study) | $\bigcirc \bigcirc \bigcirc$ very low ^{1,2,3,4} | |
|--|---|---|---|---|--|---------------------------|
| *The basis for the assum assumed risk in the comp CI : confidence interval; RF GRADE Working Group gr. High quality : Further rese Moderate quality : Further Low quality: Further rese | ed risk (e.g. the med arison group and the r risk ratio ades of evidence arch is very unlikely to research is likely to have | lian control group risk across relative effect of the intervent o change our confidence in th ave an important impact on o | s studies) is provided ir tion (and its 95% Cl). e estimate of effect. our confidence in the est ur confidence in the est | footnotes. The correspo | nding risk (and its 95% confidence | interval) is based on the |
| Very low quality: We are Risk of bias: We downgr mentioned and may intro ? Risk of bias: We downgr | aded the evidence by oduce bias. raded the evidence by | one level because blinding o one level because the autho | f participants, personne rs did not report or pro | and outcome assessors vide a description of an a | was not | |
| oncealment method. | 11% of participants. | ona laval bacquea data coma | from a sub study of a t | ial (Brown 2006) for diab | | |

DISCUSSION

This is the first systematic review to consider the effectiveness of specific lifestyle interventions in the management of adults with urinary incontinence.

Summary of main results

This review identified eleven trials that reported on the effect of weight loss (four trials), the intake of a soy-rich diet (one trial), change in fluid intake (three trials), reduction in caffeinated drinks (three trials), and lifestyle versus non-lifestyle interventions for weight loss (one trial). No trials were identified that investigated alcohol, sweetened fizzy drinks or diet drinks, constipation and straining, smoking cessation, physical activity or physical forces. Adverse effects appeared to be relatively uncommon for all interventions studied, although, with decreasing fluids, some participants experienced thirst, constipation, concentrated urine or headaches.

Is weight loss by obese or overweight adults more effective than no treatment?

Four trials investigated whether weight loss by obese or overweight adults was more effective than no treatment and included a total of 4701 women (Brown 2006b; Phelan 2012; Subak 2005; Subak 2009). It is important to note that two trials, which contributed over 90% of the women to this analysis, were primarily diabetes trials (N = 1321 and 2994, respectively; Brown 2006b; Phelan 2012).

There is 'low' quality evidence that, compared with the control interventions, weight loss programmes were associated with higher improvement rates based on women's self-report (primary outcome), and also higher cure and improvement rates based on quantifiable symptoms (secondary outcomes), although there was no information available on self-reported cure (primary outcome). The two diabetes trials also reported prevalence of urinary incontinence and identified a similar trend towards the weight loss groups having a greater reduction in the number of women with weekly incontinence episodes compared with the control groups ('very low' quality evidence). Only the smallest trial with 40 women measured disease-specific quality of life using the Incontinence Impact Questionnaire and the Urogenital Distress Inventory (Subak 2005), which showed statistically significant differences that favoured the weight loss group compared with the control group ('low' quality evidence).

This consistency of effect across a number of measured outcomes gives strength to the evidence. Overall, the differences in both cure and improvement when weight loss is compared to control suggest that weight loss interventions may be of interest to morbidly and moderately obese women and their clinicians. The degree of improvement in UI may be contingent upon the magnitude of the weight loss. A cohort analysis, Wing 2010, associated with one of the included trials (called the PRIDE study, N = 338 at baseline; Subak 2009) showed that women who lost 5% to 10% of their body weight (regardless of randomized treatment assignment) were two to four times more likely to achieve at least a 70% reduction in the number of total (i.e. stress or urgency) incontinence episodes per week compared with those who gained weight at follow-ups at six months (adjusted OR 3.7, 95% CI 1.6 to 8.2), at 12 months (adjusted OR 3.7, 95% CI 1.7 to 8.3) and at 18 months (adjusted OR 2.4, 95% CI 1.1 to 5.1). Weight losses greater than 10% did not result in greater improvements in incontinence outcomes (at 6 months, adjusted OR 3.8, 95% CI 1.5 to 9.6; at 12 months, adjusted OR 4.1, 95% CI 2.1 to 7.9; at 18 months, adjusted OR 3.3, 95% CI 1.7 to 6.4).

There is little evidence available concerning the potential mechanisms involved in the weight loss effect. There was inconsistency in the type of intervention provided that included various combinations of diet and physical activity. It was also unclear whether the dietary mechanism involved reduced calorie intake, or other change in the quality of the diet, or both. Some of the potential benefits of weight loss could also have been attributed to better glycaemic control rather than weight loss alone, in view of the substantial numbers of diabetics involved in the trials. Such results may not be entirely relevant to all people with obesity, although there was independent evidence for a weight loss effect in nondiabetics.

As might be expected, the benefit of the weight loss intervention diminished over time. This is clear from the forest plots for cure and improvement rates by quantification of symptoms and the number of incontinence episodes per week, which show that the point estimates move closer to the line of no effect from three months, through to 18 months. Maintenance of effect is rarely seen in long-term incontinence trials carried out years after intervention (Agur 2008; Glazener 2005), and therefore sustainability of weight loss and its long-term effect on incontinence would require further research.

Is dietary change more effective than no change?

One small trial investigated whether dietary change is more effective than no change (Manonai 2006); it included 42 women comparing a soy-rich diet with a soy-free diet. The only available outcome data for UI frequency found no evidence of a difference between the two diets ('very low' quality evidence). Other data were insufficient to draw any conclusions about the effect of the content of the diet on UI.

Is changing the volume of fluid intake more effective than no change in the volume of fluid intake?

Three trials investigated whether changing the volume of fluid intake is more effective than no change in the volume of fluid intake; these included 181 women and 11 men (Dowd 1996; Hashim 2008; Swithinbank 2005). Only one cross-over trial used

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disease-specific quality of life as the primary outcome and reported improvement in scores for the Bristol Female Lower Urinary Tract Symptoms questionnaire following decreased fluid intake (Swithinbank 2005). One trial reported poor adherence to the intervention protocol, which led to inconclusive results (Dowd 1996). Each trial used a different protocol detailing fluid manipulation and none of the trials reported improvement or cure. We ranked the quality of findings as 'very low'.

Is caffeine reduction more effective than no change in caffeine consumption?

Three trials investigated whether caffeine reduction is more effective than no change in caffeine consumption and included a total of160 women and nine men (Bryant 2002; Miller 2007; Wells 2011). One trial was reported exclusively via an author email (Miller 2007), and was insufficiently detailed for us to draw firm conclusions. Across the trials, there was inconsistency in outcomes used, limited data and insufficient reporting to enable an analysis of whether caffeine reduction is better than no change in consumption. The limited and 'very low' quality data available on disease-specific quality of life (ICIQ-OABqol) and incontinence episode frequency found no evidence of a difference between the groups.

Is any lifestyle intervention more effective than another intervention?

One trial investigated whether one lifestyle intervention is more effective than any another intervention and included 1296 women (Brown 2006b); this was a sub-study of a large diabetes trial that compared two weight loss programmes - an intensive lifestyle intervention or a pharmacological intervention (metformin). The only available outcome data were on the effect of weight loss on prevalence of weekly UI (a secondary outcome of 'very low' evidence quality). The results showed that women had a lower prevalence of weekly UI in the lifestyle group than in the metformin group at a mean of 2.8 years follow-up and this difference between the groups was statistically significant, favouring the lifestyle intervention.

Overall completeness and applicability of evidence

The majority of included trials had small sample sizes, with 60 or fewer participants, and short follow-up (i.e. less than 12 months). Five of the included trials were parallel-arm RCTs (Brown 2006b; Dowd 1996; Subak 2005; Subak 2009; Phelan 2012). The remainder included four randomized cross-over trials (Hashim 2008; Manonai 2006; Swithinbank 2005; Wells 2011), and one quasi-RCT (allocation made using health record numbers; Bryant 2002). We also included one unpublished trial, with limited information, from an author email (Miller 2007). Participants in the trials included in this review were predominantly female, with the average age (unclear if this was mean or median) ranging from 49 to 58 years, except for two trials with means of 62.7 years, Hashim 2008, and 70.25 years, Dowd 1996. The trial participants were also those resident in the community. Therefore, the applicability of findings to men and older age groups, and particularly frail elderly people in care home settings, is uncertain.

Random sequence allocation was adequately generated and concealed in only two trials (Subak 2005; Subak 2009); in other trials it was either inadequate or not described in sufficient detail. This may have introduced selection bias.

The percentage of participants followed up and included in analysis varied across the included trials. Only four trials had either no missing outcome data, imputed missing data, or stated that missing data were balanced across groups (Brown 2006b; Hashim 2008; Subak 2005; Subak 2009), while in one trial nearly half of the participants were excluded from analysis due to missing data (Dowd 1996). In the other trials, the numbers of and reasons for missing outcome data were not clearly described, which led to uncertainty about the degree of attrition bias present in these trials. Reported outcome data were heterogenous in a number of ways and this limited our ability to make comparisons across trials. For example, within each category of lifestyle intervention (weight loss, diet quality, fluid restriction and caffeine restriction), the trials used no outcomes consistently. There was no single outcome common to all trials, and even outcomes that were conceptually similar were measured in different ways. No primary outcome data were available for six of the trials included in the review (Brown 2006b; Bryant 2002; Dowd 1996; Manonai 2006; Miller 2007; Phelan 2012). In particular, quality-of-life outcomes were very poorly recorded. The importance of the inclusion of quality-of-life outcomes should not be underestimated, as they are likely to be the most keenly valued by patients themselves. More recent trials are likely to include quality-of-life measures, as they are increasingly identified as key outcomes, and use of recognised instruments for measuring them, such as the International Consultation on Incontinence Questionnaire (ICIQ), are becoming more widely used.

Quality of the evidence

We assessed the levels of evidence for each outcome measured at 12 months after the commencement of the treatment using the GRADE approach (Summary of findings for the main comparison; Summary of findings 2; Summary of findings 3; Summary of findings 4; and Summary of findings 5). Overall, the GRADE level of evidence for all outcomes was either 'low' or 'very low' across the different interventions. The main factors for downgrading the evidence included risk of bias (lack of blinding and unclear allocation concealment), indirect evidence (less than 12 months of follow-up) and imprecise results due to a small sam-

ple size with wide confidence intervals, or a lack of information (e.g. standard deviation) required to estimate confidence intervals. Evidence from studies where only some of the participants were incontinent was also downgraded for indirectness as described below.

Quality of outcome reporting was generally poor. We judged methodological quality (risk of bias) from the trial reports, and so our judgements may reflect the quality of reporting, rather than the actual methodological quality of the trials.

Potential biases in the review process

Due to the limited number of trials we identified that included only adults with UI, we made a post hoc decision to include data from trials where not all participants were incontinent when they entered the trial: the populations in these trials primarily had: overactive bladder (Hashim 2008; Miller 2007; Wells 2011); urgency and frequency (Bryant 2002); urogenital atrophy (Manonai 2006), or diabetes (Brown 2006b; Phelan 2012). Baseline incontinence ranged from 27% of the trial participants in Phelan 2012 to 83% in Bryant 2002, or was not reported but assumed (Brown 2006b). We extracted outcome data from the whole study for all trials except Phelan 2012, which provided subgrouped data specific to incontinence status.

We made another post hoc decision to include an outcome on the prevalence of UI at follow-up; this outcome was identified from the two weight loss trials in people with diabetes (Brown 2006b; Phelan 2012). Our literature search was systematic and designed to pick up any mention of UI, urinary leakage or overactive bladder in the title, abstract and controlled vocabulary. A more indepth search required to identify studies for all clinical conditions was, however, not feasible within the limited resources available. This may have introduced reporting bias, as a large or beneficial intervention effect on UI may be more likely to be reported in abstracts of published reports than data showing little or no effect, and so be more likely to be identified by our search. If this is the case, including prevalence data could have exaggerated intervention effects. The applicability of evidence for managing people with urinary incontinence may also be limited, as the extent to which the weight loss programmes served as prevention, rather than treatment, of urinary incontinence is unclear.

Although every effort was made to adhere to the review protocol to minimise bias, these post hoc decisions resulted in changes to the inclusion criteria of the review. As data from those studies with mixed populations (with and without incontinence) often constituted the only information available for some of the interventions assessed in the review, we chose to include these data to provide relevant, albeit indirect, evidence. We exercised caution when interpreting these findings, by downgrading the quality of the body of evidence for the outcomes based on the studies with mixed populations (with and without incontinence) by one level on the ground of indirectness. The review also encountered a problem associated with cross-over trials that did not report data in a standard way which would take into account the within-person differences (paired analysis). Instead, the included trials tended to report all measurements after completion of the treatment period and compared these data, as if they were a parallel group; some included trials also reported all measurements before and after intervention and compared these data within each treatment phase. The information required to perform paired analyses was not available from the published reports, which meant not only that the data from similar trials could not be incorporated into a meta-analysis, but also that the reported data presented a 'unit of analysis' error. These results should therefore be interpreted with caution.

The addition of the assessment of evidence quality using the GRADE approach and 'Summary of findings' tables was a relatively new development in the systematic review methods at the time of this review. While these methods were not specified in the protocol, we nevertheless attempted to incorporate them into the present review. Efforts were made to minimise bias in determining outcomes to be included in the tables and quality ratings for each outcome through careful discussion among the review authors. However, these steps may have been influenced by knowledge of the results of the research and may therefore carry some risk of bias.

Agreements and disagreements with other studies or reviews

We are unaware of other systematic reviews on this topic. However, a summary of the evidence in men and in women, including that from non-randomised studies, is provided in the 5th Edition of the International Consultation on Incontinence (Moore 2013).

AUTHORS' CONCLUSIONS

Implications for practice

The available data show that evidence for weight loss as a treatment to reduce urinary incontinence (UI) among morbidly and moderately obese women is building, and might be worth considering as an initial treatment prior to other standard treatments such as pelvic floor muscle training and surgery. However, there is insufficient evidence to inform practice reliably about the effectiveness of lifestyle interventions in general.

Implications for research

The evidence for lifestyle changes for UI is strongest for the effects of weight loss programmes, which should receive research priority. Weight loss interventions involving diet and fluid manipulation

require more well designed trials that using representative samples of cases. Priority should also be given to investigating dietary mechanisms for weight loss effects, such as calorie reduction, specific food or drink items and nutrient content as well as the role of physical activity. Where specific evidence of effectiveness exists, as in weight loss, lifestyle interventions should be further evaluated as first-line treatments.

The review identified a complete lack of randomized trials for lifestyle factors that are generally supposed to increase incontinence, such as the intake of alcohol, sweetened fizzy or diet drinks, smoking, physical forces, or clinical constipation and straining. The widespread use of such lifestyle advice to moderate these factors in the hope of reducing UI, and the observational evidence we identified, suggest a need for further research in these areas.

There is a need for separate consideration of the components of multi-faceted lifestyle interventions in trials. Combining a number

of individual interventions, whose efficacy has not been evaluated independently, in trials makes it impossible to determine which factors affect change. Ideally, the initial research focus should be on those areas where evidence is building (e.g. weight loss) or where healthcare advice often promotes lifestyle interventions in the absence of evidence (e.g. caffeine consumption). The results of such trials could then feed into a multi-faceted lifestyle intervention trial that would reflect common practice and be rooted in a sound evidence base.

It is expected that more recent trials are likely to have fewer methodological problems. Ongoing improvements in the quality of reporting, and incorporation of consistent use of CONSORT (Consolidated Standards of Reporting Trials, http://www.consortstatement.org/), should impact on the inclusion of trials in subsequent systematic reviews, ensuring that the most robust evidence contributes to clinical recommendations.

REFERENCES

References to studies included in this review

Brown 2006b {published data only}

* Brown JS, Wing R, Barrett-Connor E, Nyberg LM, Kusek JW, Orchard TJ, et al. Lifestyle intervention is associated with lower prevalence of urinary incontinence: the Diabetes Prevention Program. *Diabetes Care* 2006;**29**(2):385–90. [: sr–incont21588]

Diabetes Prevention Program Research Group. The Diabetes Prevention Program (DPP): description of lifestyle intervention. *Diabetes Care* 2002;**25**(12):2165–71. [: sr–incont45301]

Diabetes Prevention Program Research Group. The Diabetes Prevention Program: design and methods for a clinical trial in the prevention of type 2 diabetes. *Diabetes Care* 1999;**22**(4):623–34. [: sr–incont45300]

Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New England Journal of Medicine* 2002;**346**(6):393–403. [: sr–incont45299]

Bryant 2002 {published data only}

Bryant CM, Dowell CJ, Fairbrother G. A randomised trial of the effects of caffeine upon frequency, urgency and urge incontinence (Abstract number 96). Neurourology and Urodynamics. 2000; Vol. 19(4), issue 4:501–2. [: sr–incont9985]

* Bryant CM, Dowell CJ, Fairbrother G. Caffeine reduction education to improve urinary symptoms. British Journal of Nursing 2002; Vol. 11, issue 8:560–5. [: sr–incont14625] Bryant CM, Dowell CJ, Fairbrother G. Final results of a randomised trial of a caffeine reduction intervention and descriptive analysis of caffeine behaviours (Abstract number 303). Proceedings of the International Continence Society (ICS), 31st Annual Meeting; 2001 Sept 18-21: Seoul, Korea. 2001. [: sr–incont14382]

Dowd 1996 {published data only}

Dowd TT, Campbell JM, Jones JA. Fluid intake and urinary incontinence in older community-dwelling women. *Journal of Community Health Nursing* 1996;**13**(3):179–86. [: sr–incont4875]

Hashim 2008 {published data only}

Hashim H, Abrams P. How should OAB patients manipulate their fluid input? (Poster abstract 1187). *Journal* of Urology 2007;**177**(4 Suppl S):391–2. [: sr–incont31881] * Hashim H, Abrams P. How should patients with an overactive bladder manipulate their fluid intake? *BJU International* 2008;**102**(1):62–6. [: sr–incont27614] Sivanandam A, Bhandari M. How should patients with an overactive bladder manipulate their fluid intake? [comment]. *BJU International* 2008;**102**(7):903; author reply 903-4. [: sr–incont27443]

Manonai 2006 {published data only}

Manonai J, Songchitsomboon S, Chanda K, Hong JH, Komindr S. The effect of a soy-rich diet on urogenital atrophy: a randomized, cross-over trial. *Maturitas* 2006;**54** (2):135–40. [: sr–incont21878]

Miller 2007 {unpublished data only}

Miller JM. Overactive bladder and potentially "irritating" beverage intake: a randomized controlled trial. http:// www.nursing.umich.edu/faculty/miller'janis.html (accessed 10 Dec 2007) 2007. [: sr–incont29636]

Phelan 2012 {published data only}

Phelan S, Kanaya AM, Subak LL, Hogan PE, Espeland MA, Wing RR, et al. Prevalence and risk factors for urinary incontinence in overweight and obese diabetic women:

action for health in diabetes (Look AHEAD) study. *Diabetes Care* 2009;**32**(8):1391–7. [: sr–incont32095]

* Phelan S, Kanaya AM, Subak LL, Hogan PE, Espeland MA, Wing RR, et al. Weight loss prevents urinary incontinence in women with type 2 diabetes: results from the Look AHEAD trial. *Journal of Urology* 2012;**187**(3): 939–44. [: sr–incont44588]

Ryan DH, Espeland MA, Foster GD, Haffner SM, Hubbard VS, Johnson KC, et al. Look AHEAD (Action for Health in Diabetes): design and methods for a clinical trial of weight loss for the prevention of cardiovascular disease in type 2 diabetes. *Controlled Clinical Trials* 2003;**24**(5):610–28. [: sr–incont45302]

Subak 2005 {published data only}

Subak LL, Whitcomb E, Shen H, Saxton J, Vittinghoff E, Brown JS. Weight loss: a novel and effective treatment for urinary incontinence. *Journal of Urology* 2005;**174**(1): 190–5. [: sr-incont20655]

Subak 2009 {published data only}

Grady D, Subak L, Kusek J, Nyberg L. PRIDE program to reduce incontinence by diet and exercise. www.controlled-trials.com (accessed 17 January 2005) and http://clinicaltrials.gov/show/NCT00091988 (accessed 28 November 2013) 2004. [: sr-incont19516; : sr-incont49826]

Huang AJ, Stewart AL, Hernandez AL, Shen H, Subak LL, for the Program to Reduce Incontinence by Diet and Exercise. Sexual function among overweight and obese women with urinary incontinence in a randomized controlled trial of an intensive behavioral weight loss intervention. *Journal of Urology* 2009;**181**(5):2235–42. [: sr–incont31149]

Huang AJ, Subak LL, Wing R, West DS, Hernandez AL, Macer J, et al. An intensive behavioral weight loss intervention and hot flushes in women. *Archives of Internal Medicine* 2010;**170**(13):1161–7. [: sr–incont40225] Myers DL, Sung VW, Richter HE, Creasman J, Subak LL. Prolapse symptoms in overweight and obese women before and after weight loss. *Female Pelvic Medicine & Reconstructive Surgery* 2012;**18**(1):55–9. [: sr–incont44558] Pinto AM, Kuppermann M, Nakagawa S, Vittinghoff E, Wing RR, Kusek JW, et al. Comparison and correlates of three preference-based health-related quality-of-life measures among overweight and obese women with urinary incontinence. *Quality of Life Research* 2011;**20**(10): 1655–62. [: sr–incont44597]

Pinto AM, Subak LL, Nakagawa S, Vittinghoff E, Wing RR, Kusek JW, et al. The effect of weight loss on changes in health-related quality of life among overweight and obese women with urinary incontinence. *Quality of Life Research* 2012;**21**(10):1685–94. [: sr–incont45862]

* Subak L, Wing R, West D, Franklin F, Vittinghoff E, Creasman JM, et al. Weight loss to treat urinary incontinence in overweight and obese women. *New England Journal of Medicine* 2009;**360**(5):481–90. [: sr-incont29651]

Subak LL, Marinilli Pinto A, Wing RR, Nakagawa S, Kusek

JW, Herman WH, et al. Decrease in urinary incontinence management costs in women enrolled in a clinical trial of weight loss to treat urinary incontinence. *Obstetrics & Gynecology* 2012;**120**(2 Pt 1):277–83. [: sr–incont45146] Subak LL, Wing R, Smith West D, Franklin F, Vittinghoff E, Creasman J, et al. A behavioral weight loss program significantly reduces urinary incontinence episodes in overweight and obese women (Abstract 1). *Journal of Pelvic Medicine & Surgery* 2007;**13**(5):223–4. [: sr–incont31081] West DS, Gorin AA, Subak LL, Foster G, Bragg C, Hecht J, et al. A motivation-focused weight loss maintenance program is an effective alternative to a skill-based approach. *International Journal of Obesity* 2011;**35**(2):259–69. [: sr–incont40994]

Wing RR, Creasman JM, West DS, Richter HE, Myers D, Burgio KL, et al. Improving urinary incontinence in overweight and obese women through modest weight loss. *Obstetrics & Gynecology* 2010;**116**(2 Pt 1):284–92. [: sr–incont39918]

Wing RR, West DS, Grady D, Creasman JM, Richter HE, Myers D, et al. Effect of weight loss on urinary incontinence in overweight and obese women: results at 12 and 18 months. *Journal of Urology* 2010;**184**(3):1005–10. [: sr–incont40041]

Swithinbank 2005 {published data only}

* Swithinbank L, Hashim H, Abrams P. The effect of fluid intake on urinary symptoms in women. *Journal of Urology* 2005;**174**(1):187–9. [: sr–incont20656]

Swithinbank LV, Rogers CA, Yang Q, Shepherd AM, Abrams P. Does the amount and type of fluid intake effect urinary symptoms in women? (Abstract number 104). Neurourology and Urodynamics. 1999; Vol. 18(4), issue 4: 371–2. [: sr–incont9946]

Wells 2011 {published data only}

Wells M, Green S, Jamieson K, Markham T, Rogers P, Getliffe K, et al. An investigation of the effect of drinking caffeinated versus decaffeinated fluids on symptoms of overactive bladder syndrome: a feasibility trial (Abstract 700). Proceedings of the 41st Annual Meeting of the International Continence Society (ICS); 2011 Aug 29-Sept 2; Glasgow, Scotland. 2011. [: sr–incont42229]

References to studies excluded from this review

BE-DRI {published data only}

Mueller ER, Litman H, Zimmern PE, Norton P, Goode P. Impact of fluid management on fluid intake and urge incontinence in the BE-DRI trial for OAB in women [Abstract 1530]. *Journal of Urology* 2009;**181**(4 Suppl): 547–8.

The Urinary Incontinence Treatment Network (UITN). Design of the Behavior Enhances Drug Reduction of Incontinence (BE-DRI) study. *Contemporary Clinical Trials* 2007;**28**(1):48–58. [: SR–INCONT22573] Zimmern P, Litman H, Mueller E, Norton P, Goode P. Impact of fluid management on fluid intake and urge incontinence in the BE-DRI trial for OAB in women

(Abstract: Podium #30). *Neurourology and Urodynamics* 2009;**28**(2):163.

* Zimmern P, Litman HJ, Mueller E, Norton P, Goode P, for the Urinary Incontinence Treatment Network. Effect of fluid management on fluid intake and urge incontinence in a trial for overactive bladder in women. *BJU International* 2010;**105**(12):1680–5. [: SR–INCONT39953]

Bird 2005 {published data only}

Bird ET, Parker BD, Kim HS, Coffield KS. Caffeine ingestion and lower urinary tract symptoms in healthy volunteers. *Neurourology and Urodynamics* 2005;**24**(7): 611–5.

Brown 2007 {published data only}

Brown CT, Emberton M. Self-management for men with lower urinary tract symptoms. *Current Urology Reports* 2009;**10**(4):261–6.

* Brown CT, Yap T, Cromwell DA, Rixon L, Steed L, Mulligan K, et al. Self management for men with lower urinary tract symptoms: randomised controlled trial. *BMJ* 2007;**334**(7583):25–8.

Yap TL, Brown C, Cromwell DA, Van Der Meulen J, Emberton M. The impact of self-management of lower urinary tract symptoms on frequency-volume chart measures. *BJU International* 2009;**104**(8):1104–8.

Dougherty 2002 {published data only}

Dougherty MC, Dwyer JW, Pendergast JF, Boyington AR, Tomlinson BU, Coward RT. A randomized trial of behavioral management for continence with older rural women. *Research in Nursing & Health* 2002;**25**(1):3–13. [: SR–INCONT12933]

Dumoulin 2011 {published data only}

Dumoulin C, Sran M, Lieblich P, Wilson P. Physiotherapy significantly reduces leakage in postmenopausal women with osteoporosis and urinary incontinence: result of a parallel randomised controlled trial (Abstract 130). *Neurourology and Urodynamics* 2011;**30**(6):985–6.

Glazener 2001 {published data only}

Glazener CM, Herbison GP, MacArthur C, Grant A, Wilson PD. Randomised controlled trial of conservative management of postnatal urinary and faecal incontinence: six year follow up. *BMJ* 2005;**330**(7487):337–40. Glazener CM, Herbison GP, Wilson PD, MacArthur C, Lang GD, Gee H, et al. Conservative management of persistent postnatal urinary and faecal incontinence: randomised controlled trial. BMJ. England, 2001; Vol. 323, issue 7313:593–6. [: SR–INCONT 12122]

* Glazener CM, Herbison GP, Wilson PD, MacArthur C, Lang GD, Gee H, et al. Conservative management of persistent postnatal urinary and faecal incontinence: randomised controlled trial [Extended electronic version]. eBMJ. England, 2001; Vol. 323:1–5. [: SR–INCONT12123]

Herschorn 2003 {published data only}

Herschorn S, Becker D, Miller B, Thompson M, Forte L. The impact of a simple health education intervention in overactive bladder patients (Abstract). Proceedings of the International Continence Society (ICS), 33rd Annual Meeting; 2003 Oct 5-9; Florence Italy. 2003:352–3.

Herschorn 2004 {published data only}

Herschorn S, Becker D, Miller E, Thompson M, Forte L. Impact of a health education intervention in overactive bladder patients. *Canadian Journal of Urology* 2004;**11**(6): 2430–7. [: SR–INCONT20194]

Hofbauer 1990 {published data only}

Hofbauer J, Preisinger F, Nurnberger N. [The value of physical therapy in genuine female stress incontinence]. [German] [Der Stellenwert der Physikotherapie bei der weiblichen genuinen Stress–inkontinenz]. Zeitschrift Fur Urologie Und Nephrologie 1990;**83**(5):249–54. [: SR–INCONT350]

Kim 2011a {published data only}

Kim H, Yoshida H, Suzuki T. The effects of multidimensional exercise treatment on communitydwelling elderly Japanese women with stress, urge, and mixed urinary incontinence: a randomized controlled trial. *International Journal of Nursing Studies* 2011;**48**(10): 1165–72. [: SR–INCONT42657]

Kim 2011b {published data only}

Kim H, Yoshida H, Suzuki T. Effects of exercise treatment with or without heat and steam generating sheet on urine loss in community-dwelling Japanese elderly women with urinary incontinence. *Geriatrics and Gerontology International* 2011;**11**(4):452–9. [: SR–INCONT42661]

Kincade 2007a {published data only}

Kincade JE, Dougherty MC, Carlson JR, Wells EC, Hunter GS, Busby-Whitehead J. Factors related to urinary incontinence in community-dwelling women. *Urologic Nursing* 2007;**27**(4):307–17. [: SR–INCONT23858]

Kincade 2007b {published data only}

Kincade JE, Dougherty MC, Carlson JR, Hunter GS, Busby-Whitehead J. Randomized clinical trial of efficacy of self-monitoring techniques to treat urinary incontinence in women. *Neurourology and Urodynamics* 2007;**26**(4): 507–11. [: SR–INCONT23537]

Li 2001 {published data only}

Li FZ, Harmer P, McAuley E, Duncan TE, Duncan SC, Chaumeton N, et al. An evaluation of the effects of Tai Chi exercise on physical function among older persons: a randomized controlled trial. *Annals of Behavioral Medicine* 2001;**23**(2):139–46.

Parker 2005 {published data only}

Parker B, Bird E, Coffield S. Randomized prospective study of caffeine's effect on lower urinary tract symptoms in healthy human subjects (Poster 7). *Neurourology and Urodynamics* 2005;**24**(2):167–8.

Ree 2007 {published data only}

Ree ML, Nygaard I, Bo K. Muscular fatigue in the pelvic floor muscles after strenuous physical activity. *Acta Obstetricia et Gynecologica Scandinavica* 2007;**86**(7):870–6.

Schauss 2006 {published data only}

Schauss DA, Spiller DG. Reducing the symptoms of overactive bladder and urinary incontinence: results of a
two-month randomized, double-blind, placebo-controlled clinical trial (Abstract 300). Proceedings of the International Continence Society (ICS), 36th Annual Meeting; 2006 Nov 27-Dec 1; Christchurch, New Zealand. 2006.

Tomlinson 1999 {published data only}

Tomlinson BU, Dougherty MC, Pendergast JF, Boyington AR, Coffman MA, Pickens SM. Dietary caffeine, fluid intake and urinary incontinence in older rural women. *International Urogynecology Journal and Pelvic Floor Dysfunction* 1999;**10**(1):22–8.

Van Hespen 2006 {published data only}

Van Hespen ATH, Tak ECPM, Van Dommelen P, Hopman-Rock M. Evaluation of the urinary incontinence training programme, INCondition, for women living in homes for the elderly. *Nederlands Tijdschrift voor Fysiotherapie* 2006; **116**(6):136–42.

Wagg 2007 {published data only}

Wagg AR, Barron D, Kirby M, Stott D Corlett K. A randomised partially controlled trial to assess the impact of self-help vs. structured help from a continence nurse specialist in women with undiagnosed urinary problems in primary care. *International Journal of Clinical Practice* 2007; **61**(11):1863–73. [: SR–INCONT23948]

References to studies awaiting assessment

Baker 2011 {published data only}

Baker J. Mindfulness-Based Stress Reduction Techniques and Yoga for treatment of urinary urge incontinence (MBSR-Yoga) (Trials registry number: NCT01470560). ClinicalTrials.gov (http://clinicaltrials.gov/show/ NCT01470560) 2011. [: sr-incont49230]

Gozukara 2014 {published data only}

Gozukara YM, Akalan G, Tok EC, Aytan H, Ertunc D. The improvement in pelvic floor symptoms with weight loss in obese women does not correlate with the changes in pelvic anatomy. *International Urogynecology Journal* 2014;**25**(9): 1219–25. [: sr–incont62552]

Heesakkers 2009 {published data only}

Heesakkers J. Prospective intervention study of drink advice in overactive bladder syndrome (OAB) (Trials registry number: NCT00982241). ClinicalTrials.gov (http:// clinicaltrials.gov/show/NCT00982241) 2009 (accessed 2 December 2013). [: sr-incont49231]

Huang 2012 {published data only}

Huang A. Lessening Incontinence by Learning Yoga (LILY) (Trials registry number: NCT01672190). ClinicalTrials.gov (http://clinicaltrials.gov/show/NCT01672190) 2012 (accessed 28 November 2013). [: NCT01672190; : TrialID.LILY;; sr-incont49228]

Huang AJ, Jenny HE, Chesney MA, Schembri M, Subak LL. A group-based yoga therapy intervention for urinary incontinence in women: a pilot randomized trial. *Female Pelvic Medicine & Reconstructive Surgery* 2014; **20**(3):147–54. [: NCT01672190; : TrialID.LILY.; : sr–incont60608]

Markland 2013 {published data only}

Markland AD, Shanks JL. Vitamin D supplementation in older adults with urinary incontinence (Trial registry number: NCT01971801). ClinicalTrials.gov (http:// clinicaltrials.gov/show/NCT01971801) 2013 (accessed 28 November 2013). [: sr–incont49229]

Seckin 2011 {published data only}

Seckin B, Kulaksizoglu H, Cakmakci E. The effects of pelvic floor muscle targeted Pilates versus regular aerobic exercise on urinary incontinence (Abstract UP-03.170). *Urology* 2011;**78**(3 Suppl 1):S400–1. [: sr–incont61934]

Wells 2014 {published data only}

Wells MJ, Jamieson K, Markham TC, Green SM, Fader MJ. The effect of caffeinated versus decaffeinated drinks on overactive bladder: a double-blind, randomized, crossover study. *Journal of Wound, Ostomy, & Continence Nursing* 2014;**41**(4):371–8. [: sr–incont62569]

References to ongoing studies

Moholdt 2011 {published data only}

Moholdt TT, Salvesen K, Ingul CB, Vik T, Oken E, Morkved S. Exercise Training in Pregnancy for obese women (ETIP): study protocol for a randomised controlled trial. *Trials [Electronic Resource]* 2011;**12**:154. [: sr–incont41703]

Additional references

Abrams 2002

Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, et al. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. *American Journal of Ostetrics and Gynecology* 2002;**187**(1): 116–26.

Abrams 2005

Abrams P, Cardozo L, Khoury S, Wein A. *Incontinence: 3rd International Consultation on Incontinence, 2004, Volume 1: Basics and Evaluation.* 2005. France: Health Publication Ltd, 2005.

Abrams 2013

Milsom I, Altman D, Cartwright R, Lapitan MC, Nelson R, Sillén U, et al. Epidemiology of urinary incontinence (UI) and other lower urinary tract symptoms (LUTS), pelvic organ prolapse (POP) and anal incontinence (AI) (Comittee 1). In: Abrams P, Cardozo L, Khoury S, Wein A editor(s). Incontinence: 5th International Consultation on Incontinence. Recommendations of the International Scientific Committee: evaluation and treatment of urinary incontinence, pelvic organ prolapse and faecal incontinence; 2012 Feb 23-25; Paris. Belgium: International Consultation on Urological Diseases (ICUD), 2013:15–107.

Agur 2008

Agur WI, Steggles P, Waterfield M, Freeman RM. The longterm effectiveness of antenatal pelvic floor muscle training: eight-year follow up of a randomised controlled trial. *British journal of obstetrics and gynaecology* 2008;**115**(8):985–990.

Avery 2004

Avery K, Donovan J, Peters T, Shaw C, Gotoh M, Abrams P. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. *Neurourology and Urodynamics* 2004;**23**(4):322–30.

Baumgart 2015

Baumgart M, Snyder HM, Carrillo MC, Fazio S, Kim H, Johns H. Summary of the evidence on modifiable risk factors for cognitive decline and dementia: a population based perspective. *Alzheimer's & Dementia* 2015;**11**: 718–726.

Brown 2006a

Brown JS, Wing R, Barrett-Connor E, et al. Lifestyle intervention is associated with lower prevalence of urinary incontinence. *Diabetes Care* 2006;**29**:385–90.

Cartwright 2007

Cartwright R, Srikrishna S, Cardozo L, Gonzalez J. Does Diet Coke cause overactive bladder? A 4-way crossover trial, investigating the effect of carbonated soft drinks on overactive bladder symptoms in normal volunteers (Abstract 19). *Neurourology and Urodynamics* 2007;**26**(5):626–7.

Chowdhury 2012

Chowdhury R, Stevens S, Gorman D, Pan A, Warnakula S, Chowdhury S, Ward H, Johnson L, Crowe F, Hu FB, Franco OH. Association between fish consumption, longchain omega 3 fatty acids and risk of cerebrovascular disease: a systematic review and meta-analysis. *BMJ (Clinical Research ed)* 2012;**345**:e6698.

Creighton 1990

Creighton SM, Stanton SL. Caffeine: does it affect your bladder?. *British Journal of Urology* 1990;**66**(6):613–4.

Dallosso 2003

Dallosso HM, McGrother CW, Matthews RJ, Donaldson MMK, and the Leicestershire MRC Incontinence Study Team. The association of diet and other lifestyle factors with overactive bladder and stress incontinence: a longitudinal study in women. *BJU International* 2003;**92**:69–77.

Dallosso 2004a

Dallosso HM, Matthew R, McGrother CM, Donaldson MMK and the Leicestershire MRC Incontinence Study Team. Diet as a risk factor for the development of stress urinary incontinence: a longitudinal study in women. *European Journal of Clinical Nutrition* 2004a;**58**(6):920–6.

Dallosso 2004b

Dallosso HM, Matthews RJ, McGrother CW, Donaldson MMK, Shaw C and the Leicestershire MRC Incontinence Study Team. The association of diet and other lifestyle factors with the onset of overactive bladder: a longitudinal study in men. *Public Health Nutrition* 2004b;7(7):885–91.

Dallosso 2004c

Dallosso HM, McGrother CM, Matthew R, Donaldson MMK and the Leicestershire MRC Incontinence Study Team. Nutrient composition of the diet and the development of overactive bladder: a longitudinal study in women. *Neurourology and Urodynamics* 2004;**23**(3): 204–10.

Danforth 2007

Danforth KN, Shah AD, Townsend MK, Lifford KL, Curhan GC, Resnick NM, et al. Physical activity and urinary incontinence among healthy, older women. *Obstetrics and Gynecology* 2007;**109**:721–7.

Dasgupta 2006

Dasgupta J, Elliott RA, Doshani A, Tincello DG. Enhancement of rat bladder contraction by artificial sweeteners via increased extracellular Ca2+ influx. *Toxicology and Applied Pharmacology* 2006;**217**(2):216–24.

Dumoulin 2010

Dumoulin C, Hay-Smith J. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2010, Issue 1. [DOI: 10.1002/14651858.CD005654.pub2; : CD005654]

Elbourne 2002

Elbourne DR, Altman DG, Higgins JP, Curtin F, Worthington HV, Vail A. Meta-analyses involving crossover trials: methodological issues. *International Journal of Epidemiology* 2002;**31**(1):140–9.

Fader 2007

Fader M, Cottenden AM, Getliffe K. Absorbent products for light urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2007, Issue 2. [DOI: 10.1002/ 14651858.CD001406.pub2; : CD001406]

Fader 2008

Fader M, Cottenden AM, Getliffe K. Absorbent products for moderate-heavy urinary and/or faecal incontinence in women and men. *Cochrane Database of Systematic Reviews* 2008, Issue 4. [DOI: 10.1002/14651858.CD007408; : CD007408]

Folstein 1975

Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. *Journal of Psychiatric Research* 1975;**12**(3):189–98.

Glazener 2005

Glazener CMA, Herbison GP, MacArthur C, Grant A, Wilson DP. Randomised controlled trial of conservative management of postnatal urinary and faecal incontinence: six year follow up. *BMJ* 2005;**330**(7487):337–9.

Guyatt 2008

Guyatt GH, Oxman AD, Kunz R, Vist GE, Falck-Ytter Y, Schünemann HJ, et al. What is "quality of evidence" and why is it important to clinicians?. *BMJ* 2008;**336**(7651): 995–8.

Hannestad 2004

Hannestad YS, Rortveit G, Daltveit AK, Hunskaar S. Are smoking and other lifestyle factors associated with female urinary incontinence? The Norwegian EPINCONT Study. *BJOG: An International Journal of Obstetrics and Gynaecology* 2004;**110**(3):247–54.

He 2006

He FJ, Nowson CA, MacGregor GA. Fruit and vegetable consumption and stroke: meta-analysis of cohort studies. *Lancet* 2006;**367**(9507):320–326.

Herbison 2002

Herbison GP, Dean N. Weighted vaginal cones for urinary incontinence. *Cochrane Database of Systematic Reviews* 2002, Issue 1. [DOI: 10.1002/14651858.CD002114; : CD002114]

Higgins 2003

Higgins JPT, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;**327**: 557–60.

Hunskaar 2008

Hunskaar S. A systematic review of overweight and obesity as risk factors and targets for clinical intervention for urinary incontinence in women. *Neurourology and Urodynamics* 2008;**27**(8):749–57.

James 1988

James JE, Paull I, Cameron-Traub E, Miners JO, Lelo A, Birkett DJ. Biochemical validation of self-reported caffeine consumption during caffeine fading. *Journal of Behavioral Medicine* 1988;**11**(1):15–30.

Kiff 1984

Kiff ES, Barnes PR, Swash M. Evidence of pudendal neuropathy in patients with perineal descent and chronic straining at stool. *Gut* 1984;**25**(11):1279–82.

Lipp 2011

Lipp A, Shaw C, Glavind K. Mechanical devices for urinary incontinence in women. *Cochrane Database* of Systematic Reviews 2011, Issue 7. [DOI: 10.1002/ 14651858.CD001756.pub5; : CD001756]

Maserejian 2010

Maserejian NN, Giovannucci EL, McVary KT, McGrother C, McKinlay JB. Dietary macronutrient and energy intake and urinary incontinence in women. *American Journal of Epidemiology* 2010;**171**(10):1116–25.

Mattiasson 1998

Mattiasson A, Djurhuus JC, Fonda D, Lose G, Nordling J, Stöhrer M. Standardization of outcome studies in patients with lower urinary tract dysfunction: a report on general principles from the Standardisation Committee of the International Continence Society. *Neurourology and Urodynamics* 1998;**17**(3):249–53.

McGrother 2004

McGrother CW, Donaldson MMK, Shaw C, Matthews RJ, Hayward TA, Dallosso HM, et al. Storage symptoms of the bladder: prevalence, incidence and need for services in the UK. *BJU International* 2004;**93**(6):763–9.

McGrother 2007

McGrother C, Donaldson M, Wagg A, Matharu G, Williams K, Watson J, et al. Continence. In: Stevens ARJ, Mant J, Simpson S editor(s). *Health Care Needs Assessment: the epidemiologically based needs assessment reviews*. 3rd Edition. Abingdon: Radcliffe Medical Press Ltd, 2007: 69–175.

McGrother 2012

McGrother CW, Donaldson MMK, Thompson J, Wagg A, Tincello DG, Manktelow BN. Etiology of overactive bladder: a diet and lifestyle model for diabetes and obesity in older women. *Neurourology and Urodynamics* 2012;**31**: 487–95.

Moller 2000

Moller L, Lose G, Jorgensen T. Risk factors for lower urinary tract symptoms in women 40-60 years of age. *Obstetrics and Gynecology* 2000;**96**:446.

Moon 1997

Moon TD, Hagen L, Heisey DM. Urinary symptomatology in younger men. *Urology* 1997;**50**(5):700–3.

Moore 2013

Moore K, Dumoulin C, Bradley C, Burgio K, Chambers T, Hagen S, et al. Adult conservative management (Chapter 12). In: Abrams P, Cardozo L, Khoury S, Wein A editor(s). *Incontinence: 5th International Consultation on Incontinence. Recommendations of the International Scientific Committee: evaluation and treatment of urinary incontinence, pelvic organ prolapse and faecal incontinence2012 Feb 23-25; Paris.* Belgium: International Consultation on Urological Diseases (ICUD), 2013:1101–227.

Nabi 2006

Nabi G, Cody JD, Ellis G, Hay-Smith J, Herbison GP. Anticholinergic drugs versus placebo for overactive bladder syndrome in adults. *Cochrane Database of Systematic Reviews* 2006, Issue 4. [DOI: 10.1002/14651858.CD003781.pub2; : CD003781]

Nygaard 2006

Nygaard I, Girts T, Fultz NH, Kinchen K, Pohl G, Sternfeld B. Is urinary incontinence a barrier to exercise in women?. *Obstetrics and Gynecology* 2005;**106**(2):307–314.

Ogah 2009

Ogah J, Cody JD, Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2009, Issue 4. [DOI: 10.1002/14651858.CD006375.pub2; : CD006375]

Ortega 2012

Ortega RM, Rodriguez-Rodriguez E, Lopez-Sobaler AM. Effects of omega 3 fatty acids supplementation in behavior and non-neurodegenerative neuro-psychiatric disorders. *British Journal of Nutrition* 2012;**107**:S261–S270.

Reference Manager 2012

Thomson Reuters. Reference Manager Professional Edition Version 12. New York: Thomson Reuters. New York: Thomson Reuters, 2012.

RevMan 2014

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

Schünemann 2011a

Schünemann HJ, Oxman AD, Higgins JPT, Vist GE, Glasziou P, Guyatt GH. Chapter 11: Presenting results

and 'Summary of findings' tables. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration 2011. Available from www.cochrane-handbook.org. The Cochrane Collaboration, Available from www.cochranehandbook.org.

Schünemann 2011b

Schünemann HJ, Oxman AD, Vist GE, Higgins JPT, Deeks JJ, Glasziou P, et al. Chapter 12: Interpreting results and drawing conclusions. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration 2011. Available from www.cochrane-handbook.org. The Cochrane Collaboration.

Skerrett 2010

Skerrett PJ, Willett WC. Essentials of healthy eating: a guide. *Journal of Midwifery & Women's Health* 2010;**55**(6): 492–501.

Subak 2002

Subak LL, Johnson C, Whitcomb E, et al. Does weight loss improve incontinence in moderately obese women? . *International Urogynecology Journal and Pelvic Floor Dysfunction* 2002;**13**(1):40–3.

Subak 2005a

Subak LL, Whitcomb E, Shen H, Saxton J, Vittinghoff E, Brown JS. Weight Loss: a novel and effective treatment for urinary incontinence. *Journal of Urology* 2005;**174**:190–5.

Subak 2009a

Subak LL, Richter HE, Hunskaar S. Obesity and urinary incontinence: epidemiology and clinical research update. *Journal of Urology* 2009;**182**(6 Suppl):S2–7. [: SR–INCONT39545]

Subak 2009b

Subak LL, Wing R, West DS, Franklin F, Vittinghoff E, Creasman JM, et al. PRIDE Investigators. Weight loss to treat urinary incontinence in overweight and obese women. *New England Journal of Medicine* 2009;**360**(5):481–90.

Tampakoudis 1995

Tampakoudis P, Tantanassis T, Grimbizis G, Papaletsos M, Mantalenakis S. Cigarette smoking and urinary incontinence in women? A new calculative method of estimating the exposure to smoke. *European Journal of Obstetrics, Gynecology, and Reproductive Biology* 1995;**63**(1): 27–30.

Townsend 2008

Townsend MK, Curhan GC, Resnick NM, Grodstein F. Body mass index, waist circumference, and incident urinary incontinence in older women. *Obesity* 2008;**16**:881–6.

Turner 2004

Turner DA, Shaw C, McGrother CW, Dallosso HM, Cooper NJ. The cost of clinically xignificant urinary storage symptoms for community dwelling adults in the UK. *BJU International* 2004;**93**(9):1246–52.

Wallace 2004

Wallace SA, Roe B, Williams K, Palmer M. Bladder training for urinary incontinence in adults. *Cochrane Database* of Systematic Reviews 2004, Issue 1. [DOI: 10.1002/ 14651858.CD001308.pub2; : CD001308]

Ware 1993

Ware JE, Snow KK, Kosinski M, Gandek B. *SF-36*® *Health Survey Manual and Interpretation Guide*. Boston, MA: New England Medical Center, The Health Institute, 1993.

Wing 2010

Wing RR, Creasman JM, West DS, Richter HE, Myers D, Burgio KL, et al. Improving urinary incontinence in overweight and obese women through modest weight loss. *Obstetrics and Gynecology* 2010;**116**(2 Pt 1):284–92.

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Brown 2006b

| Methods | Design: A sub-study of the Diabetes Prevention Program (DPP), an RCT with over- weight non-diabetic individuals, randomly allocated to the intensive lifestyle weight loss programme (Group I), metformin (Group II) or placebo (Group III). For the purpose of this sub-study, men were excluded from analysis Study centre: 27 centres in the USA Recruitment period: 1996-1999 Power calculation: performed for the original DPP trial |
|---------------|---|
| Participants | Number of (female) participants randomized: total = 2191 Number of (female) participants followed up: total = 1957; Group I = 660; Group II = 636; Group III = 661 Withdrawals/dropouts/lost to follow-up: total = 234 (11%) women with missing UI data were excluded from analysis Gender: female Mean age, years (SD): Group I: 49.3 (10.6); Group II: 49.9 (9.6); Group III: 49.5 (9.7) BMI mean (SD): Group I: 34.7 (6.9); Group II: 34.8 (6.9); Group III: 35.1 (7.0) Ethnicity: Group I: white = 343; African American = 138; Hispanic = 103; Native American = 51; Asian = 25 Group II: white = 333; African American = 148; Hispanic = 97; Native American = 45; Asian = 13 Group III: white = 355; African American = 144; Hispanic = 94; Native American = 51; Asian = 17 Education: not stated Employment status: not stated Severity of symptoms: not stated Prior incontinence surgery: not stated Inclusion criteria: age at least 25 years, BMI ≥ 24 kg/m ² , a fasting plasma glucose level 95-125 mg/dl, and a 2-h post challenge glucose level 140-199 mg/dl Exclusion criteria: people taking medications that could affect glucose tolerance or who had serious medical illness Diagnostic groups: not stated |
| Interventions | Group I: intensive lifestyle intervention. The goals were at least 7% weight loss and at least 150 minutes of moderate-intensity physical activity per week. A 16-lesson curricu- lum covering diet, exercise, and behaviour modification, taught by case managers during the first 24 weeks after enrolment, was "flexible, culturally sensitive, and individualized". Subsequent individual sessions (usually monthly) and group sessions with the case man- agers were also provided to reinforce the behavioural changes Treatment duration: 24 weeks with monthly follow-up thereafter Length of follow-up: average 2.8 (range 1.8-4.6) years Training provided by: case managers, with training in nutrition, exercise or behaviour modification, on a one-to-one basis Group II: metformin 850 mg twice daily with standard lifestyle intervention |

Lifestyle interventions for the treatment of urinary incontinence in adults (Review)

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| | Group III: placebo twice daily with standard lifestyle intervention The standard lifestyle intervention included written information and an individual meet- ing (20-30 minutes) that emphasized a healthy diet, reduced weight, increased activity levels and smoking cessation, at baseline and annually Co-interventions: not stated Compliance: Mean change in weight, kg (SD): Group I = -3.4 (8.2); Group II = -1.5 (7. 6); Group III = +0.5 (6.7); P value < 0.001 |
|----------|--|
| Outcomes | Weekly prevalence of UI by type (stress, urge or any UI) based on participant's report at the end-of-trial visit |
| Notes | The primary aim of the DPP trial was to evaluate whether an intensive lifestyle inter- vention with improved diet and increased physical activity or metformin therapy among overweight pre-diabetic men and women would prevent or delay the onset of type 2 diabetes. Not all participants had UI at baseline. The objective of the analysis included in this review was to assess whether these interventions were associated with a lower prevalence of incontinence in women, because weight loss may decrease incontinence, whereas increased physical activity may worsen incontinence, and incontinence may also be a barrier to exercise Funding: The DPP trial was supported by the following: The Diabetes Prevention Pro- gram, National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Child Health and Human Development, the National Institute on Aging, the Office of Research on Minority Health and Health Dis- parities, the Office of Women's Health, the Indian Health Service, the Centers for Disease Control and Prevention, the General Clinical Research Program, the National Center for Research Resources, the American Diabetes Association, Bristol-Myers Squibb, Lipha Pharmaceuticals, and Parke-Davis. LifeScan, Health O Meter, Hoechst Marion Rous- sel, Merck-Medco Managed Care, Merck, Nike Sports Marketing, and Slim Fast Foods. Quaker Oats donated materials, equipment, or medicines for concomitant conditions. McKesson ioServices, Matthews Media Group, and the Henry M Jackson Foundation provided support services under subcontract with the Co-ordinating Center |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Low risk | Quote: "Adaptive randomisation stratified by clinical centre" |
| Allocation concealment (selection bias) | Unclear risk | Not mentioned |
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Assignments to metformin and placebo were blinded but the lifestyle intervention was not |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Not mentioned |

| Incomplete outcome data (attrition bias) All outcomes | Low risk | Of the 2191 women enrolled in the 3 arms of the DPP, 234 (11%) women with miss- ing UI data were excluded from the analy- sis. The study stated that "women missing data on urinary incontinence did not differ in incident diabetes, mean weight change, or mean change in physical activity over- all or within treatment groups compared with women with completed urinary in- continence data" |
|--|---|---|
| Selective reporting (reporting bias) | Unclear risk | Insufficient information provided. The main outcome for this analysis was preva- lence of incontinence |
| Other bias | Unclear risk | The DPP trial was closed early after 2.9 years when lifestyle changes and metformin treatment had each reduced the incidence of diabetes |
| Bryant 2002 | | |
| Methods | Design: quasi-RCT. Participants were randomized by health record numbers and allo- cated to caffeine reduction education (Group I) or control (Group II) Study centre: 2 nurse-led continence clinics, Sydney, Australia Recruitment period: not stated Power calculation: performed Funding: not stated | |
| Participants | Number of participants randomized: total = 95; Group I = 48; Group II = 47 Number of participants followed up: total = 74; Group I = 36; Group II = 38 Withdrawals/dropouts/lost to follow-up: total = 21 (22%); Group I = 12; Group II = 9. Reasons: failure to return to follow-up (n = 14); anxiety or family problem (n = 4); hospital admission (n = 2); intercurrent illness (n =1) Gender (number and % female): Group I = 45 (94%); Group II = 41 (87%) Mean age, years (SD): Group I = 56 (18); Group II = 58 (16) Mean body weight, kg (SD): Group I = 69 (17); Group II = 68 (20) Ethnicity: not stated Education: not stated Severity of symptoms: mean number of leakage episodes per 24 hours (SD): Group I = 2.8 (3.2); Group II = 3.1 (3.9) Prior incontinence surgery: not stated Inclusion criteria: adults with symptoms of urgency, frequency and/or urge incontinence, and who routinely ingested caffeine at levels of 100 mg or more every 24 hours Exclusion criteria: significant cognitive impairment, pregnancy or symptoms of urinary tract infection | |

Diagnostic groups: 83% of the sample had urge UI, while 17% reported no UI at baseline

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Bryant 2002 (Continued)

| | (only frequency and urgency) | |
|--|---|--|
| Interventions | Group I: educational intervention (with bladder training) to reduce caffeine intake to < 100 mg a day. The intervention consisted of a thorough review (with participants) of their caffeine intake history, urinary symptoms and time/volume/caffeine charts for 3 randomly selected 24-hour periods, followed by a planned caffeine reduction interven- tion using a caffeine fading method (James 1988). This method decreases caffeine intake by one drink each day until the desired maximum intake of 100 mg caffeine a day is reached and the caffeinated drinks have been replaced by other fluids Treatment duration: participants were seen weekly for 4 weeks Length of follow-up: no follow-up after 4-week programme Training provided by: not stated Group II: continued usual daily caffeine intake of > 100 mg every 24 hours. Also received bladder training Co-interventions: not stated Compliance: mean caffeine intake reduction per 24 hours, (SD): Group I: 58%; Group II: 11%; P value < 0.0001 | |
| Outcomes | Number of incontinent episodes in 24 hours | |
| Notes | | |
| Risk of bias | | |
| Bias | Authors' judgement Support for judgement | |
| Random sequence generation (selection bias) | High risk | Quote: "Patients were randomized by health record number to two groups" |
| Allocation concealment (selection bias) | High risk | Quote: "Patients were randomized by health record number to two groups" |
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Not mentioned but unlikely |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Not mentioned |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | Data reported for 74 (78%) of 95 partic- ipants who completed the study. Reasons for withdrawal were reported but not sepa- rately for each group. The study states that caffeine levels did not differ between the completers and those who withdrew, but it is unclear if severity of incontinence dif- fered |

Bryant 2002 (Continued)

| Selective reporting (reporting bias) | Unclear risk | Insufficient information. Reported out- comes specified in the method section |
|--------------------------------------|--|--|
| Other bias | Unclear risk | Insufficient information provided |
| Dowd 1996 | | |
| Methods | Design: RCT. Participants were assigned randomly to increased fluid intake (Group I), decreased fluid intake (Group II) or maintained fluid intake (Group III) Study centre: USA Recruitment period: not stated Power calculation: not stated | |
| Participants | Number of participants randomized: total = 58; Group I = 20; Group II = 18; Group III = 20 Number of participants followed up: total = 32; Group I = 14; Group II = 10; Group III = 8 Withdrawals/dropouts/lost to follow-up: total = 26 (45%); Group I = 6; Group II = 8; Group III = 12. Reason: diaries were not sufficiently completed Gender: female Mean age, years (range): 70.25 (52-89) BMI: 19/32 participants with data had normal or below normal weight; 8/32 participants were obese Ethnicity: not stated Education: not stated Employment status: not stated Severity of symptoms (mean daily UI episodes per day): 0.6 (n = 32) Prior incontinence surgery: not stated Inclusion criteria: women over 50 years of age who had had UI for 6 months or more, were independent in self-care, scored over 20 on the Mini-Mental State Examination (Folstein 1975) and were English speaking Exclusion criteria: not stated Diagnostic groups: not stated | |
| Interventions | The first week served as the baseline, after which participants were assigned to 1 of th 3 groups. Participants were instructed in the detailed recording of intake using the sam measuring cups and glasses for the duration of the study and were instructed to keep intake and output diaries for 5 weeks Group I: increased fluid intake by 500 ml, total intake not to exceed 2400 ml per day Group II: decreased intake by 300 ml, total intake not to be less than 1000 ml per day Group III: maintained fluid intake at baseline level Treatment duration: 5 weeks (randomisation in second week) Length of follow-up: a 3-month telephone follow-up (n = 29) was undertaken for th entire cohort; no data were available for each randomized group Treatment provided by: registered nurses who were given in-service training on UI an oriented to the study procedures. They provided new data-collection sheets and responded to questions on a weekly basis Co-interventions: not stated | |

Dowd 1996 (Continued)

| | Compliance (mean daily fluid intake): Group I = fluid intake was increased until week 3 when they returned closer to the baseline level; Group II = intake was less than baseline through the first 4 weeks but increased in week 5; Group III = increased intake by approximately 170 ml in week 5; this suggests generally low compliance across the groups |
|----------|---|
| Outcomes | Number of incontinent episodes in 24 hours |
| Notes | The secondary aim of the study was to assess whether there was any relationship between caffeine intake and incontinence episodes Funding: Kidney Foundation of Summit County in Akron, Ohio, USA |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Quote: "The women were assigned ran- domly" |
| Allocation concealment (selection bias) | Unclear risk | Not mentioned |
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Not mentioned but unlikely |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Not mentioned |
| Incomplete outcome data (attrition bias) All outcomes | High risk | Data were presented for 32/58 (55%) of the women randomized who maintained the diaries for the entire study |
| Selective reporting (reporting bias) | Unclear risk | Insufficient information provided. The only outcome reported was the number of incontinence episodes, but this was accord- ing to the study aim |
| Other bias | High risk | The study reported that adherence to the fluid manipulation was poor and made re- sults difficult to interpret |

| Methods | Design: prospective 2-group cross-over trial. After a 4-day screening period (baseline), there were 4 phases of 4-day fluid manipulation and 2-day washout over the period of 4 weeks. Participants were randomly assigned to 1 of the 2 groups and asked either to increase or decrease their fluid intake first, from baseline Study centre: Bristol Urological Institute, Southmead Hospital, Bristol, UK Recruitment period: not stated Power calculation: performed |
|---------------|--|
| Participants | Number of participants randomized: 67 were contacted, 40 were recruited and 24 were randomized Number of participants followed up: 24 Withdrawals/dropouts/lost to follow-up: none Gender: male = 11; female = 13 Age (years): mean 62.7, median (range) 62.5 (42, 80) BMI: not stated Ethnicity: not stated Education: not stated Education: not stated Education: not stated Inclusion criteria: adult men and women (≥18 years old) with symptoms of OAB. Enrolled after a 4-day screening period (to establish baseline values) using frequency/ volume charts (FVC), completed daily, if they had a mean of 8 or more voids and 1 or more urgency and/or urgency incontinence episodes in 24 hours. Participants were identified from a database that included those who were contacted and/or participated in previous trials. They were initially screened by telephone to see if they would agree to take part in the trial and were eligible for it Exclusion criteria: participants were excluded from any part of the study if their increase/ decrease resulted in them drinking > 3 L or < 1 L of fluid, as drinking 3 L would be excessive and drinking < 1 L would cause symptoms of dehydration, e.g. headaches and constipation. People were also excluded if they were pregnant or breast-feeding; had haematuria, bacteriuria, pyuria, proteinuria, glucosuria or ketosuria on urine dipstick testing; had a residual volume of > 150 mL, as assessed by a bladder scan; had uncon- trolled hypertension, suspicion or evidence of clinically relevant cardiac failure, renal disease or hepatic disease; were diagnosed with or suspected of having diabetes insipidus/ primary polydipsia or diabetes mellitus; had neurogenic dysfunction of the lower urinary tract; were known alcohol or drug abusers; were scheduled to be admitted to hospital for inpatient surgery during the trial; had any history of clinically relevant psychiatric disorders within the last 24 months preceding enrolment in the trial; had a history of not complying with medical regimens or were not compliant with pr |
| Interventions | 4-day screening period with FVC to establish baseline drinking habits, prior to randomisation to Group I or IIGroup I:4 days drinking 25% less than baseline followed by 2 days normal drinking (i.e. a |

| | washout); followed by 4 days drinking 50% less than baseline followed by 2 days normal drinking; followed by 4 days drinking 25% more than baseline followed by 2 days normal drinking; followed by 4 days drinking 50% more than baseline | |
|---|---|---|
| | Group II: 4 days drinking 25% more than baseline fo by 4 days drinking 50% more than baseline fo by 4 days drinking 25% less than baseline follo 4 days drinking 50% less than baseline | llowed by 2 days normal drinking; followed llowed by 2 days normal drinking; followed wed by 2 days normal drinking; followed by |
| | Participants who drank > 3 L or < 1 L were in each part of the study, and the ICIQ-C period, to assess their quality of life for that Significance was analyzed by comparing eac of the study group (n = 24). The number of is presented for reference Treatment duration: 4 weeks Co-intervention: not stated Compliance: all 24 participants participate not all participated in the other parts of the i.e. their input was < 1 L or > 3 L when the fl output was approximately 289 ml higher the asked to drink 25% more than their normal more, and when asked to drink 50% more the respective groups with baseline. When as to drink 32% less than the baseline. The 25 | excluded. Patients completed a 4-day FVC AB questionnaire at the end of each 4-day period th intervention group to the overall baseline f participants differed in each period so this d in the period with a 25% reduction, but study because they did not fulfil the criteria, uid intake was manipulated. The mean fluid an the fluid intake. When participants were fluid input they only managed to drink 17% they managed 23% more, when comparing ked to drink 50% less, participants managed i% reduction was adhered to quite well |
| Outcomes | Condition-specific quality of life Adverse effects Number of incontinent episodes in 24 hours | |
| Notes | Funding: Bristol Urological Institute PA Research Fund | |
| Risk of bias | | |
| Bias | Authors' judgement | Support for judgement |
| Random sequence generation (selection bias) | Unclear risk | Quote: "randomized into one of the two groups" |
| Allocation concealment (selection bias) | Unclear risk | Not mentioned |
| Blinding of participants and personnel | High risk | Not mentioned but unlikely |

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(performance bias) All outcomes

Hashim 2008 (Continued)

| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Not mentioned |
|--|---|--|
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No missing outcomes |
| Selective reporting (reporting bias) | Unclear risk | Insufficient information available. The study described what was measured by fre- quency/volume charts in the method sec- tion |
| Other bias | High risk | The study reported that participants had difficulty in adhering to the study protocol when they were asked either to increase or decrease fluids by 50% |
| Manonai 2006 | | |
| Methods | Design: cross-over trial with 2 x 12-week diet periods and 2 x 4-week washout periods before and between treatments. Participants were randomly allocated to the order in which they followed an isocaloric soy-rich diet or a control diet Study centre: Mahidol University, Bangkok, Thailand Recruitment period: not stated Power calculation: not stated | |
| Participants | Number of participants randomized: 42 Number of participants followed up: 36 Withdrawals/dropouts/lost to follow-up = 6. Reasons: 5 withdrew from the study because of their inability to comply with the study; 1 lost to pelvic examination follow-up Gender: female Mean age, years: 52.5 (SD 5.11; range 40-59) BMI: not stated Ethnicity: not stated Education: not stated Education: not stated Employment status: not stated Severity of symptoms: not stated Inclusion criteria: healthy women whose periods had ceased at least 3 months previously, who were 45-70 years of age, not using hormone therapy and did not regularly consume a vegetarian diet. All women had experienced at least one type of urinary or genital symptoms owing to urogenital atrophy Exclusion criteria: presence or history of sex hormone-dependent malignancies; presence or history of liver or renal disorders; and pathology of urogenital tract Diagnostic groups: before soy-rich diet, 61% had SUI and 19% had UUI; and before control diet 63% had SUI and 11% had UUI. Some women may have had symptoms, e.g. vaginal dryness, but no UI | |

Manonai 2006 (Continued)

| Interventions | During both study periods, participants consumed self-selected diets with low-fat and low-cholesterol foods. Subjects were advised to maintain their physical activity consis- tently throughout the study and were instructed to avoid all additional soy products, herbal or vitamin and mineral supplements. They were also instructed to keep an accu- rate 3-day food record Intervention period I: isocaloriic soy-rich diet: Participants consumed 25 g soy protein in various forms containing > 50 mg per day of isoflavones, which was substituted for an equivalent amount of animal protein. All soy foods for the study were provided monthly Intervention period II: control diet Treatment duration: 2 x 12-week diet periods with 2 x 4-week washout periods before and between treatments Treatment provided by: the same nutritionist throughout the study Co-intervention: not stated Compliance: good compliance was shown by the significant elevation of serum levels of daidzein and genistein during the soy-rich diet period | |
|--|---|---|
| Outcomes | Number of women with incontinent episodes Incontinence symptom scores | |
| Notes | Funding: Thai Health Promotion Foundation | |
| Risk of bias | | |
| Bias | Authors' judgement | Support for judgement |
| Random sequence generation (selection bias) | Unclear risk | Quote: "The subjects were randomized into two groups" |
| Allocation concealment (selection bias) | Unclear risk | No information available |
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Not mentioned but unlikely |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Pelvic examination and vaginal pH test were performed by the same examiner who was blinded, but these outcomes were not relevant to this review. No mention of blinded assessment for the outcomes spec- ified in the review |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | Data are presented for 36 (86%) of 42 women who completed the study. Reasons for withdrawals and drop-outs were de- scribed but their incontinence severity was unclear and it was also unclear at what time point the withdrawals/drop-out occurred |

Manonai 2006 (Continued)

| Selective reporting (reporting bias) | Unclear risk | Insufficient information available. Re- ported outcomes were specified in the methods section | | |
|---|---|---|--|--|
| Other bias | Unclear risk | Insufficient information available | | |
| Miller 2007 | Miller 2007 | | | |
| Methods | Design: RCT with 2 groups Study centre: University of Michigan School of Nursing, USA Study period: 01 January 2007-31 December 2007 | | | |
| Participants | Number of participants: Group I = around 30; Group II = around 30 Gender: female Diagnostic groups: OAB (unclear if wet or dry) | | | |
| Interventions | Group I: reduced intake of 'irritating' beverages (caffeine or non-caffeine). Participants were instructed to maintain the overall volume of fluid intake by replacing the 'irritating' beverages with water or milk Group II: control (no details provided) Treatment duration: unclear | | | |
| Outcomes | The study found a significant reduction in OAB symptoms (not defined) in the interven- tion group. However, the author noted that findings were confounded by a significant reduction in overall fluid intake in the intervention group from baseline (by an average of 8 fluid oz (around 230 ml) per 24 hours). The author also notes that caffeine reduction was not associated with the OAB symptom reduction | | | |
| Notes | Unpublished trial. All information was obtained from an author email to the Cochrane Incontinence Group search co-ordinator (26 January 2009) Funding: Pfizer, GA6120A8 Detrol Competitive Grant | | | |
| Risk of bias | | | | |
| Bias | Authors' judgement | Support for judgement | | |
| Random sequence generation (selection bias) | Unclear risk | Insufficient information available | | |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information available | | |
| Blinding of participants and personnel | Unclear risk | Insufficient information available | | |

All outcomes
Blinding of outcome assessment (detection Unclear risk Insufficient information available bias)
All outcomes

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(performance bias)

Miller 2007 (Continued)

| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | Insufficient information available |
|--|--|---|
| Selective reporting (reporting bias) | Unclear risk | Insufficient information available |
| Other bias | High risk | The study author noted non-adherence to the protocol among study participants |
| Phelan 2012 | | |
| Methods | Design: a sub-study of the Look AHEAD (Action for Health in Diabetes) trial, an RCT with overweight or obese individuals with type 2 diabetes, randomly allocated to intensive lifestyle weight loss intervention (Group I) or a diabetes support and education control condition (Group II). For the purpose of this sub-study, men were excluded from analysis Study centre: 16 centres, USA Recruitment period: from 2001. Planned follow-up until 2014 Power calculation: performed | |
| Participants | Recruitment period: from 2001. Planned follow-up until 2014 Power calculation: performed Number of (female) participants randomized in Look AHEAD trial: 3063. Of these, 69 who did not complete baseline incontinence assessment were excluded from this sub- study Number of randomized participants in this sub-study: Group I = 1495; Group II = 1499 Number of participants followed up: Group I = 1385; Group II = 1354 Withdrawals/dropouts/lost to follow-up: Group I = 110; Group II = 145. Study com- pleters were more likely to be white (P value = 0.01) and to be never smokers (P value = 0.02) than non-completers, but no other significant differences were observed Gender: female Mean age, years (SD): Group I: 57.8 (6.7); Group II: 58.1 (6.9) Mean BMI (SD): Group I: 36.3 (6.2); Group II: 36.7 (6.0) Ethnicity: Group I: non-Hispanic white 56%, African-American 20%, Hispanic 15%, Native American/Alaskan native 6%, Other 3%; Group II: non-Hispanic white 55%, African-American 20%, Hispanic 15%, Native American/Alaskan native 7%, Other 3% Education: not stated Employment status: not stated Severity of symptoms: not stated Prior incontinence surgery: not stated Inclusion criteria: overweight and obese individuals (men and women) with type 2 diabetes, 45-76 years of age with a BMI of \geq 25 kg/m ² (> 27 kg/m ² if currently taking insulin) Exclusion criteria: \geq HbA1c 11%, blood pressure \geq 160/100 mmHg, triglycerides \geq 600 mg/dl, inadequate control of comorbid conditions, factors that may limit adherence to the interventions Diagnositic groups: at baseline 27% of participants reported weekly (or more frequent) | |

Phelan 2012 (Continued)

| | of UI was coded based on whether a participant reported a higher frequency of stress or urgency episodes. About 13% in each group reported predominant SUI and 10% reported predominant UUI. Only 2% of women were classified as having MUI (defined as frequency of SUI = frequency of UUI) |
|---------------|---|
| Interventions | Group I: intensive lifestyle intervention designed to promote an average of 7% or greater weight loss at 1 year. Participants were encouraged to consume a low calorie and low fat, portion controlled diet that included liquid meal replacements, and to achieve at least 175 minutes of physical activity weekly. The participants were seen weekly for the first 6 months and 3 times monthly for the next 6 months for a total of 44 sessions (Phase I, months 1-12) Treatment duration: the intensive intervention occurred in the first 4 years of the study period (e.g. Phase II, months 13-48; Phase III, months 49+) Length of follow-up: for the purpose of this sub-study, outcomes were assessed after 1 year of intervention Training provided by: lifestyle counsellor Group II: diabetes support and education: participants were invited to 3 group sessions during the year which focused on diet, physical activity or social support Co-interventions: not reported Compliance: Mean weight lost at 1 year, kg (SD): Group I: 7.7 (7.0); Group II: 0.7 (5. 0); P value < 0.0001 |
| Outcomes | Improvement (decrease of at least 2 episodes per week) and resolution (cure) in women who had weekly or more frequent incontinence episodes at baseline, assessed by validated self-report questions after 1 year of intervention Prevalence of UI (that occurred at least weekly) assessed by validated self-report questions after 1 year of intervention |
| Notes | The primary objective of the LOOK AHEAD trial was to assess the intervention effects on cardiovascular morbidity and mortality Funding: the Department of Health and Human Services. The following organizations have committed to make major contributions to Look AHEAD: FedEx Corp; Health Management Resources; LifeScan, Inc, a Johnson and Johnson Company; Optifast ® of Nestle HealthCare Nutrition, Inc; Hoffmann-La Roche Inc; Abbott Nutrition; and Slim-Fast Brand of Unilever North America |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Quote: "Partiicpants were randomly as- signed within centers to the ILI [inten- sive lifestyle intervention] or the DSE [di- abetes support and education] conditions with equal probability". "Randomisation is stratified by clinical center and blocked with random block sizes" |
| Allocation concealment (selection bias) | Unclear risk | No information available |

| Blinding of outcome assessment (detection bias) All outcomesLow riskQuote: "All measures were complete baseline and 1 year by assessors who masked to participant treatment groupIncomplete outcome data (attrition bias) All outcomesUnclear riskOf the 3063 women enrolled in the I AHEAD trial, 69 (2%) women with UI data at baseline were excluded of this sub-study. The 1-year follow-up | men- |
|---|--|
| Incomplete outcome data (attrition bias) Unclear risk Of the 3063 women enrolled in the I All outcomes Unclear risk Of the 3063 women enrolled in the I AHEAD trial, 69 (2%) women with UI data at baseline were excluded f this sub-study. The 1-year follow-up | ed at were p." |
| was 93% (1385/1495) in the interven group and 90% (1354/1499) for the o trol group. Survey completers were n likely to be white and non-smokers. implication for the incontinence outco is unknown | Look h no from rate ntion con- more The come |
| Selective reporting (reporting bias) Unclear risk Insufficient information available | |
| Other bias Unclear risk Insufficient information available | |

Subak 2005

| Methods | Design: RCT stratified by type of incontinence (either stress only and stress-predominate MUI or urge only and urge-predominate MUI), then randomly allocated to immediate (Group I) or delayed (Group II) enrolment in the weight reduction programme Study centre: University of California, USA Recruitment period: January 1999-March 2000 Power calculation: performed |
|--------------|--|
| Participants | Number of participants randomized: total = 48; Group I = 24; Group II = 24 Number of participants followed up: total = 40; Group I = 19; Group II = 21 Withdrawals/dropouts/lost to follow-up: total = 8; Group I = 5 (2 loss to follow-up for unknown reasons, 1 medical exclusion, 2 missing primary outcome data); Group II = 3 (2 lost to follow-up for unknown reasons, 1 withdrew from study due to death of spouse) Gender: female Median age, years (IQR): Group I = 50.5 (46-54); Group II = 57.5 (50-62); P value = 0.006 Median BMI (IQR): Group I = 34 (32-40); Group II = 36 (32-38) Ethnicity: Group I: white = 18; other 2; Group II: white = 17; other = 3 Education: not stated Employment status: not stated Severity of symptoms (number of women with 'severe' incontinence defined as > 10 episodes per week): Group I = 19; Group II = 20 Prior incontinence surgery (number of women): Group I = 1; Group II = 3 |

| | Inclusion criteria: a consecutive sample of women 18 to 80 years old with BMI between 25-45 kg/m ² , UI for at least 3 months and at least 4 incontinent episodes in a 7-day urinary diary. Prior incontinence therapies (including surgery) were not exclusions from study eligibility Exclusion criteria: pregnancy, urinary tract infection, significant medical condition, pelvic cancer, neurological condition possibly associated with incontinence, interstitial cystitis or potential inability to complete the study Diagnostic groups: Group I: stress alone = 3; stress-predominate MUI = 9; urge alone = 3; urge-predominate MUI = 9 Group II: stress alone = 0; stress-predominate MUI = 10; urge alone = 2; urge-predominate MUI = 11 |
|---------------|---|
| Interventions | Group I: a 3-month intensive group-based medical and behavioural weight loss pro- gramme. Participants were placed on a standard low calorie liquid diet (800 kcals per day or less), encouraged to increase physical activity gradually until they were exercising 60 minutes daily, and were taught standard cognitive and behavioural skills to assist in modifying eating and exercise habits. Participants met weekly in group sessions led by a nutritionist, exercise physiologist or behavioral therapist and followed a structured protocol Treatment duration: 3 months Length of follow-up: 3 and 6 months after completion of the 3-month programme for the entire cohort; no data were available for each randomized group Training provided by: nutritionist, exercise physiologist or behavioural therapist Group II: a waiting list control group had no intervention for 3 months and then entered the weight reduction programme Co-interventions: participants currently using incontinence therapy were included in the study, but were asked to not change treatment during study Compliance: median % weight improvement, (IQR): Group I: 16 (9-20); Group II: 0 (-2-2) |
| Outcomes | Condition-specific quality of life Adverse effects Cure rates based on quantification of symptoms (defined as number of women with a 100% reduction in weekly UI episodes recorded by 7-day diary) Improvement (including cure) rates based on quantification of symptoms (defined as number of women with a 75%-100% reduction in weekly UI episodes recorded by 7- day diary) Number of incontinent episodes per week Generic quality of life |
| Notes | Funding: Mount Zion Health Services Inc and University of California |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "The randomization codes were prepared by computer generated random numbers" |

Subak 2005 (Continued)

| Allocation concealment (selection bias) | Low risk | Quote: "sealed, opaque envelopes num- bered consecutively" |
|--|--------------|--|
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Quote: "Participants could not be blinded" |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: " research investigators assess- ing outcomes and statistical analysts were blinded" |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | The analysis was "by intent to treat". The study states that the "40 women (83%) who completed the first 3 months of the trial were similar in demographic and clinical characteristics to the 8 women (17%) who did not complete the first 3 months of the trial" |
| Selective reporting (reporting bias) | Unclear risk | Insufficient information available |
| Other bias | Unclear risk | Imbalance in age at baseline due to chance (P value = 0.006), the effect(s) on outcome are unknown |

Subak 2009

| Methods | Design: RCT stratified by clinical centre, then randomly allocated by 2:1 ratio to 6- month weight loss programme (Group I) or 4-session education programme (Group II) Study centre: multiple centres in Alabama, USA (PRIDE study) Recruitment period: 2004-2006 Power calculation: performed |
|--------------|---|
| Participants | Number of participants randomized: total = 338; Group I = 226; Group II = 112 Number of participants with data on incontinence at 6 months: total = 304; Group I = 214; Group II = 90 Withdrawals/dropouts/lost by 6 months: total = 34; Group I = 12 (5 discontinued; 3 were unwilling to follow the program, 1 had a medical reason and 1 had schedule conflicts; 7 did not fill diary); Group II = 22 (15 discontinued; 10 were unwilling to follow the programme, 3 had family problems, 1 was disappointed by the group assignment and 1 had schedule conflicts; 7 did not fill diary) Number of participants with data on incontinence at 12 months: total = 294; Group I = 207; Group II = 87 Number of participants with data on incontinence at 18 months: total = 287; Group I = 197; Group II = 90 Gender: female Mean age, years (SD): Group I = 53 (11); Group II = 53 (10) Mean BMI (SD): Group I = 36 (6); Group II = 36 (5) |

| | Ethnicity: Group I: white = 171; black = 47; other = 8; Group II: white = 91; black = 17; other = 4 Education (beyond high school): Group I = 200; Group II = 93 Employment status: not stated Severity of symptoms: not stated Prior incontinence surgery: none (see exclusion criteria) Inclusion criteria: women at least 30 years of age, BMI of 25-50, and at baseline reported 10 or more UI episodes in a 7-day diary of voiding. Previous medical therapy for incon- tinence or obesity did not affect eligibility Exclusion criteria: use of medical therapy for incontinence or weight loss within the previous month, current urinary tract infection or \geq 4 or more urinary tract infections in the previous year a history of incontinence of neurologic or functional origin (due |
|---------------|---|
| | to factors not involving the lower urinary tract, such as chronic impairment of physical or cognitive functioning), previous surgery for incontinence or urethral surgery, major medical or genitourinary tract conditions, pregnancy or parturition in the previous 6 months, type 1 or type 2 diabetes mellitus requiring medical therapy that increased the risk of hypoglycemia, and uncontrolled hypertension Diagnostic groups: Group I: stress alone = 8; stress-predominant (at least 2/3 of the total number of episodes were stress episodes) = 36; urge alone = 33; urge-predominant (at least 2/3 of the total number of episodes were urge episodes) = 71 MUI with no predominant type = 78; |
| | Group II: stress alone = 10; stress-predominant = 21; urge alone = 8; urge-predominant = 37; MUI with no predominant type = 36 |
| Interventions | At randomisation, all participants were given a self-help behavioural-treatment booklet with instructions for improving bladder control (including pelvic floor muscle training) . Incontinence was not discussed further with either group Group I: weight loss programme designed to produce an average loss of 7% to 9% of initial body weight within the first 6 months of the program, modelled after that used in 2 large clinical trials: the Look AHEAD (Action for Health in Diabetes), and the DPP (Diabetes Prevention Program). Participants met weekly for 6 months in groups of 10-15 for 1-hour sessions that were led by experts in nutrition, exercise, and behaviour change and were based on a structured protocol. Given a standard reduced-calorie diet (1200-1500 kcal per day), with a goal of providing no more than 30% of the calories from fat. To improve adherence, the participants were provided with sample meal plans and were given vouchers for a meal-replacement product (Slim-Fast) to be used for 2 meals a day during months 1-4 and for 1 meal a day thereafter. Encouraged to increase physical activity (brisk walking or activities of similar intensity) gradually until active for at least 200 minutes each week. Behavioural skills, including self-monitoring, stimulus control, and problem-solving, were emphasized Treatment duration: 6 months |
| | Follow-up (weight loss maintenance): On completion of the 6-month programme, par- ticipants underwent a second randomisation to a motivationally focused maintenance programme or a standard skills based maintenance approach and were followed for fur- ther 12 months. |
| | Iraining provided by: experts in nutrition, exercise, and behaviour change Group II: structured education programme (control): 4 education sessions at months 1, 2, 3, and 4. During these 1-hour group sessions, which included 10-15 women, general information was presented about weight loss, physical activity, and healthful |

Subak 2009 (Continued)

| | eating habits, according to a structured protocol Co-intervention: see exclusion criteria Compliance (mean weight, kg (SD)): Group I: baseline = 98 (17); 6 months = 90 (17); Group II: baseline = 95 (16); 6 months = 94 (17) Compliance (weight % change(95% CI)): Group I: 6 months = -8.0 (-9.0 to7.0); 12 months = -7.5 (-8.6 to6.4); 18 months = -5.5 (-6.7 to4.3); Group II: 6 months = -1.6 (-2.7 to0.4); 12 months = -1.7 (-3. 2 to0.2); 18 months = -1.6 (-3.4 to - 0.7) |
|----------|---|
| Outcomes | Improvement rates based on participant's report (women reported that overall leakage was better or much better) Cure rates based on quantification of symptoms (defined as number of women reporting a 100% reduction in weekly UI episodes recorded by 7-day voiding diary) Improvement rates based on quantification of symptoms (defined as number of women with a 70%-100% reduction in weekly UI episodes recorded by 7-day voiding diary) Change in the number of incontinent episodes per week |
| Notes | Funding:the National Institute of Diabetes and Digestive and Kidney Diseases and the Office of Research on Women's Health |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "Randomization was performed with the use of randomly permuted blocks of three or six, stratified according to clin- ical center" |
| Allocation concealment (selection bias) | Low risk | Quote: " random assignment [was] con- cealed in tamper-proof envelopes" |
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Quote: "The participants were aware of their treatment assignment" |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: " the staff members who collected the outcome data were not" aware of their treatment assignment |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | Quote: "Baseline variables, including age, race, parity, BMI, type of incontinence, frequency of incontinence episodes, and pad weight were not significantly associ- ated with the retention of participants at 6 months". Also, multiple imputation meth- ods were used for missing data The study stated that "Participants who |

| | | dropped out of the study had a higher number of baseline UI episodes than com- pleters but dropouts in the intervention and control groups did not differ" (Wing 2010b) |
|--------------------------------------|---|--|
| Selective reporting (reporting bias) | Unclear risk | Insufficient information available. Re- ported outcomes were specified in the methods section |
| Other bias | Unclear risk | Insufficient information available |
| Swithinbank 2005 | | |
| Methods | Design: cross-over trial with random allocation to the order in which participants in- creased or decreased decaffeinated fluids in weeks 3 or 4 Study centre: Bristol Urological Institute, Southmead Hospital, Bristol, UK Recruitment period: not stated Power calculation: performed | |
| Participants | Number of participants randomized: 110 women were approached to enter the study, 26 refused, the remaining 84 were included in the study (by incontinence type: USI = 48; IDO = 36) Number of participants followed up: total = 69; USI group = 39; IDO group 30 Withdrawals/dropouts/lost to follow-up: total = 15; USI group = 9 (19%); IDO group = 6 (17%). No reasons provided Gender: female Median age, years (range): 54.8 (31-76) BMI: not stated Ethnicity: not stated Education: not stated Education: not stated Severity of symptoms: not stated Prior incontinence surgery: not stated Inclusion criteria: women with USI or IDO: women in the IDO group had been re- ferred for investigation of symptoms of frequency, urgency and urgency incontinence, and women with USI had been referred because of leakage secondary to coughing and exercise; the USI group was naive to surgery Exclusion criteria: urinary tract infection, hepatic, cardiac or renal disease, diabetes mel- litus; those on anti-depressants, anticholinergics or diuretics Diamostic groups: USI = 48: IDO = 36 | |
| Interventions | Treatment duration: 4 weeks Week 1: participants drank normally (basel Week 2: all participants drank normally, bu Weeks 3 and 4: participants were random to 3 L (20 cups) per day for a week follow to 750 ml (5 cups) per day, or vice versa. decreased fluids were compared. Urine osm | ine) It only caffeine-free fluids ized to either increasing caffeine-free fluids ed by a week of reducing caffeine-free fluids Results from the weeks with increased and olality was measured at weekly clinic visit to |

Swithinbank 2005 (Continued)

| | assess compliance Detailed urinary diaries that included information concerning episodes of urgency and leakage were kept for each day of the 4-week study period. A reason for randomising the order of increased or decreased fluid intake was to counter the placebo effect (e.g. a bladder training effect) of keeping urinary diaries Co-interventions: not stated Compliance (mean fluid intake per day, ml; all women with USI or IDO): week 1 = 1639 ml; week 2 with caffeine-free fluids = 1630 ml; week increasing fluid = 2673 ml; week decreasing fluid: 872 ml |
|----------|---|
| Outcomes | Condition-specific quality of life Adverse effects Number of incontinent episodes in 24 hours |
| Notes | Funding: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Quote: "randomized in the order in which [participants] increased and decreased flu- ids" |
| Allocation concealment (selection bias) | Unclear risk | Not mentioned |
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Not mentioned but unlikely |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Not mentioned |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | Data not available for 15 (18%) of 84 par- ticipants enrolled. Reasons for this were not provided |
| Selective reporting (reporting bias) | Unclear risk | Insufficient information available. Re- ported outcomes were specified in the methods section |
| Other bias | Unclear risk | Insufficient information available |

| Random sequence generation (selection bias) | Low risk | Quote: " randomized via random number generator" |
|---|---|--|
| Bias | Authors' judgement | Support for judgement |
| Risk of bias | | |
| Notes | Available as abstract only Funding: not reported | |
| Outcomes | ICIQ-OAB; ICIQ-OABqol Number of incontinent episodes (3-day bladder diary) | |
| Interventions | All participants underwent 2 x 2-week periods of caffeinated and caffeine-free fluid intake with the 2 periods separated by a 14-day washout period. Before starting their assigned period, participants took part in a run-In period of caffeine withdrawal, during which they were requested to reduce their caffeine intake by substituting one cup of caffeinated tea or coffee with decaffeinated every other day Co-interventions: not reported Compliance: "2 participants did not comply with caffeine substitution" based on caffeine levels from saliva samples | |
| Participants | Number of participants randomized: total = 14 Number of participants followed up: 11 Withdrawals/dropouts/lost to follow-up: 3 withdrawals Gender: female Mean age, years (range): 52.1 (27-79) BMI: not reported Ethnicity: not reported Education: not reported Education: not reported Education: not reported Severity of symptoms: not reported Prior incontinence surgery: not reported Inclusion criteria: women aged > 18 years with newly diagnosed OAB, experiencing > 7 voids per day and > 2 episodes per night, self-rated urgency and/or UUI with or without stress incontinent symptoms, and consuming > 2 caffeinated drinks per day (minimum 60 mg caffeine per 24 hours) Exclusion criteria: stress incontinence only, smoking, taking oestrogen and/or medica- tions containing caffeine or interfere with caffeine metabolism, postvoid residual < 100 ml, history of frequent (> 3/6 months) [sic] urinary tract infections, pregnant, or unable to undertake a bladder diary Diagnositic groups: OAB with or without UI | |
| Methods | Design: cross-over trial with random allocat sumed caffeinated or caffeine-free fluids (fea Study centre: single centre, UK Recruitment period: not reported Power calculation: not reported | tion to the order in which participants con- asibility study) |

Wells 2011 (Continued)

| Allocation concealment (selection bias) | Unclear risk | No information available |
|--|--------------|---|
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Not mentioned but unlikely |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | No information available |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | 14 randomized and 11 completed the fol- low-up (79%). No further details |
| Selective reporting (reporting bias) | Unclear risk | Insufficient information |
| Other bias | High risk | 2 participants did not comply with caffeine substitution |

Abbreviations

BMI: body mass index DPP: Diabetes Prevention Program FVC: frequency volume charts HbA1c: glycated haemoglobin ICIQ-OAB: Internatioanal Consultation on Incontinence Questionnaire Overactive Bladder ICIA-OABqol:Internatioanal Consultation on Incontinence Questionnaire Overactive Bladder Symptoms Quality of Life IDO: idiopathic detrusor overactivity MUI: mixed urinary incontinence OAB: overactive bladder oz: (fluid) ounce RCT: randomized controlled trial SD: standard deviation SUI: stress urinary incontinence UI: urinary incontinence USI: urodynamic stress incontinence UUI: urgency urinary incontinence

Characteristics of excluded studies [ordered by study ID]

| Study | Reason for exclusion |
|--------|--|
| BE-DRI | Anticholinergic medications plus behavioural training versus anticholinergic medications alone. Behavioural training included specific fluid management as well as pelvic floor muscle control and exercises, urge suppression, and delayed voiding. Study conducted by the Urinary Incontinence Treatment Network (UITN). Complex interventions for which we could not separate the effect of lifestyle interventions |

(Continued)

| Bird 2005 | Not a relevant population. Healthy volunteers (N = 80). Caffeine tablet versus placebo. Outcome: perceived change in LUTS |
|----------------|--|
| Brown 2007 | Self-management plus standard care versus standard care. Self-management included lifestyle (fluid, caffeine, alcohol), bladder training and toileting. Complex intervention meant we could not separate the effect of lifestyle interventions |
| Dougherty 2002 | BMC versus control. BMC = lifestyle change, if needed; if lifestyle not needed, bladder training (BT); if BT not effective, PFMT + biofeedback (BF). Complex intervention meant we could not separate the effect of lifestyle interventions |
| Dumoulin 2011 | Physiotherapy versus control. Physiotherapy treatment combined 1) PFMT and other exercises with 2) dietary recommendations/changes and constipation management. We could not separate the effect of (2) from (1) |
| Glazener 2001 | Not a relevant intervention. PFMT (for all UI) plus bladder training (for urge UI) versus control |
| Herschorn 2003 | Tolterodine plus health education intervention versus tolterodine alone. $N = 84$. Abstract only, so no details of health education intervention available. Possibly related to Herschorn 2004 |
| Herschorn 2004 | Health education intervention plus tolterodine versus tolterodine alone. Participants received a behavioural modification information sheet with multiple components including: 1) fluid intake regulation, 2) caffeine limitation, 3) scheduled toileting, 4) bladder stretching, 5) PFMT, and 6) urge suppression. We could not separate the effect of 1) and 2) from the rest |
| Hofbauer 1990 | Not a relevant intervention. Electrical stimulation (ES) + 'gymnastic' versus 'gymnastic' versus ES versus sham ES. German publication |
| Kim 2011a | Multidimensional exercise treatment, consisting of stretching, PFMT and fitness exercises. Community-dwelling elderly Japanese women with SUI, UUI or MUI. We could not separate the effect of non-PFMT exercise |
| Kim 2011b | Exercise treatment with or without heat and steam generating sheet (HSGS). Exercise consisted of stretching, PFMT and fitness exercises. A 4-arm trial comparing: 1) exercise + HSGS, 2) exercise only, 3) HSGS only, and 4) education. Community-dwelling elderly Japanese women with stress, urge or mixed UI. We could not separate the effect of non-PFMT exercise |
| Kincade 2007a | Described the characteristics of women participating in 2 clinical trials and explored the relationships between demographic characteristics, caffeine and fluid intake, quality of life, and severity of urine loss. No usable data |
| Kincade 2007b | Self-monitoring including: 1) caffeine, 2) fluid intake, 3) PFMT, 4) voiding frequency, 5) constipation. We could not separate the effect of lifestyle change |
| Li 2001 | The study did not focus on UI, but assessed the effects of Tai Chi on physical function. The only incontinence- related outcome was use of toilet, as part of a composite measure of "eating, dressing, bathing or using the toilet" |
| Parker 2005 | Not a relevant population. Healthy volunteers (N = 64). Caffeine tablet versus placebo. Outcome: LUTS. Abstract only. Probably related to Bird 2005 |

(Continued)

| Ree 2007 | The study did not focus on UI, but examined whether strenuous physical activity could produce pelvic floor muscle fatigue among young nulliparous women with stress UI. No outcome data on UI |
|-----------------|---|
| Schauss 2006 | Not a relevant intervention. 'UroLogic' versus placebo. UroLogic is a nutritional supplement containing <i>Equi-</i> setum arvense and <i>Crataeva murvale</i> |
| Tomlinson 1999 | Complex intervention for which we could not separate the effect of lifestyle change. BMC versus control. The three phases of BMC were: 1) self-monitoring including fluid management and caffeine reduction; 2) bladder training; and 3) pelvic muscle exercise with biofeedback. 218 women were randomized into treatment or control. Analysis focused on 41 women who were randomized into the treatment and completed the first phase of BMC. No data were available for the control group |
| Van Hespen 2006 | Not a relevant population. RCT of the UI training programme, INCOndition, including training of pelvic floor muscles, bladder function and mobility, for women living in homes for the elderly. German with English abstract |
| Wagg 2007 | Lifestyle leaflet versus structured help in clinic (including BT and PFMT). Leaflet-only interventions, without a standardised (within trial) protocol, are not eligible |

Abbreviations

BF: biofeedback BMC: behavioural management for continence BT: bladder training ES: electrical stimulation LUTS: lower urinary tract symptoms MUI: mixed urinary incontinence PFMT: pelvic floor muscle training RCT: randomized controlled trial SUI: stress urinary incontinence UI: urinary incontinence UUI: urgency urinary incontinence

Characteristics of studies awaiting assessment [ordered by study ID]

Baker 2011

| Methods | RCT |
|---------------|---|
| Participants | Women with urgency incontinence |
| Interventions | Mindfulness-based stress reduction technique and yoga (MBSR-yoga) versus sham yoga |
| Outcomes | Change from baseline in mean number of urge incontinent episodes from pre treatment to post treatment |
| Notes | Estimated enrolment: 30 Study start date: February 2011 |

Baker 2011 (Continued)

Primary completion date: May 2012 (final data collection date for primary outcome measure)

Gozukara 2014

| Methods | RCT |
|---------------|--|
| Participants | Overweight/obese women with UI recorded in a 3-day diary |
| Interventions | Behavioural weight loss versus structured education programme |
| Outcomes | Change in voiding diary from baseline to 6 months in voiding diary parameters; Pelvic Floor Distress Inventory and POP-Q |
| Nata | |

Heesakkers 2009

| Methods | RCT |
|---------------|---|
| Participants | Patients with OAB |
| Interventions | Low versus normal versus high fluid intake |
| Outcomes | Urine osmolality; PPIUS (Perception of Intensity of Urgency Scale) urge-score |
| Notes | Enrollment: 0 Study start date: July 2009 Primary completion date: December 2010 (final data collection date for primary outcome measure) |

Huang 2012

| Methods | RCT |
|---------------|--|
| Participants | Women with UI or OAB |
| Interventions | Yoga therapy versus control |
| Outcomes | Change in the number of incontinence episodes over 7 days from pre treatment to post treatment |
| Notes | Enrollment: 20 Study start date: August 2012 Study completion date: December 2012 |

Markland 2013

| Methods | RCT |
|---------------|---|
| Participants | Older women with UI |
| Interventions | Vitamin D supplementation versus placebo |
| Outcomes | Change in the number of incontinent episodes on a 7-day bladder diary from the baseline evaluation to the final visit at 12-weeks |
| Notes | Estimated enrollment: 100 Study start date: January 2014 Estimated study completion date: November 2015 |

Seckin 2011

| Methods | RCT |
|---------------|---|
| Participants | Individuals with incontinence due to stress or OAB |
| Interventions | Aerobic pelvic floor muscle exercise versus targeted Pilates exercise group |
| Outcomes | Change in SEAPI quality of life score from baseline |
| Notes | Enrolment: 80 Poster only, minimal detail available |

Wells 2014

| Methods | Randomised cross-over trial |
|---------------|---|
| Participants | Women with newly diagnosed OAB and history of caffeine consumption |
| Interventions | Group A: 14-day caffeinated drink period followed by a 14-day decaffeinated drink period Group B: 14-day decaffeinated drink period followed by a 14-day caffeinated drink period (with a 14-day run-in period and 14-day wash-out period between group entry |
| Outcomes | Episodes of urgency and frequency, volume per void and incontinence recorded in a 3-day diary |
| Notes | Enrolment: 11 |

Abbreviations

OAB: overactive bladder POP-Q: Pelvic Organ Prolapse Quantification System RCT: randomized controlled trial SEAPI: stress-related leak (S), emptying ability (E), anatomy (A), protection (P), inhibition (I) UI: urinary incontinence

Characteristics of ongoing studies [ordered by study ID]

Moholdt 2011

| Trial name or title | Exercise Training in Pregnancy (ETIP) for obese women |
|---------------------|---|
| Methods | Design: randomised controlled trial with 2 parallel arms (intervention versus control) Study centre: the Norwegian University of Science and Technology and the St Olav's Hospital, Trondheim University Hospital |
| Participants | 150 previously sedentary, pregnant women with a pre-pregnancy BMI at or above 30 kg/m ² |
| Interventions | Intervention: organised exercise training 3 times per week Control: standard antenatal care |
| Outcomes | The main outcome measure will be weight gain from baseline to delivery Secondary outcomes include incontinence |
| Starting date | September 2010. Recruitment anticipated until the end of 2012 |
| Contact information | Trine T Moholdt, Department of Publich Health and General Practice, Norwegian University of Science and Technology, Trondheim, Norway. Email: trine.moholdt@ntnu.no |
| Notes | |

Abbreviation

BMI: body mass index

DATA AND ANALYSES

Comparison 1. Weight loss versus no active intervention

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|--|-------------------|------------------------|-------------------------------------|---------------------|
| 1 Improvement rates based on women's perception (all types UI) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 1.1 At 6 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 2 Improvement rates based on women's perception (all types UI) | | | Other data | No numeric data |
| 3 Quality of life and symptom scores | | | Other data | No numeric data |
| 4 Cure rates based on quantification of symptoms (all types UI) | 3 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 4.1 At 3 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | $0.0 \ [0.0, 0.0]$ |
| 4.2 At 6 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | $0.0 \ [0.0, 0.0]$ |
| 4.3 At 12 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | $0.0 \ [0.0, 0.0]$ |
| 5 Cure rates based on | | | Other data | No numeric data |
| quantification of symptoms (by type of UI) | | | | |
| 6 Improvement rates based on quantification of symptoms (all types UI) | 3 | | Risk Ratio (M-H, Fixed, 95% CI) | Subtotals only |
| 6.1 At 3 months | 1 | 40 | Risk Ratio (M-H, Fixed, 95% CI) | 16.5 [1.01, 270.78] |
| 6.2 At 6 months | 1 | 304 | Risk Ratio (M-H, Fixed, 95% CI) | 1.85 [1.22, 2.81] |
| 6.3 At 12 months | 2 | 1032 | Risk Ratio (M-H, Fixed, 95% CI) | 1.21 [1.02, 1.44] |
| 6.4 At 18 months | 1 | 287 | Risk Ratio (M-H, Fixed, 95% CI) | 1.15 [0.86, 1.55] |
| 7 Improvement rates based on quantification of symptoms (by type of UI) | | | Other data | No numeric data |
| 8 Prevalence of weekly urinary incontinence after intervention (all types UI) | 2 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 8.1 At 12 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | $0.0 \ [0.0, 0.0]$ |
| 8.2 At 2.8 years | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 9 Prevalence of weekly urinary incontinence after intervention (by type of UI) | | | Other data | No numeric data |
| 10 Incontinent episodes per week (% change from baseline; all UI types) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 10.1 At 6 months | 1 | | Mean Difference (IV. Fixed, 95% CI) | 0.0 [0.0. 0.0] |
| 10.2 At 12 months | 1 | | Mean Difference (IV. Fixed, 95% CI) | 0.0 [0.0. 0.0] |
| 10.3 At 18 months | 1 | | Mean Difference (IV, Fixed, 95% CI) | 0.0 [0.0, 0.0] |

Lifestyle interventions for the treatment of urinary incontinence in adults (Review)

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Comparison 2. Soy-rich diet versus control

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|--|-------------------|------------------------|--------------------|-----------------|
| 1 Number of women with UI episodes: soy-rich diet versus control | | | Other data | No numeric data |
| 2 Mean UI symptom scores (SD; 0 = none, 1 = mild, 2 = moderate, 3 = severe): soy-rich diet versus control | | | Other data | No numeric data |

Comparison 3. Increase in fluid intake versus decrease in fluid intake

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|-------------------|------------------------|--------------------|-----------------|
| 1 Median number of daily UI episodes (IQR) | | | Other data | No numeric data |
| 2 Median number of daily UI episodes (range) | | | Other data | No numeric data |
| 3 Mean number of daily UI episodes (any UI) | | | Other data | No numeric data |

Comparison 4. Caffeine reduction versus control

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size | |
|---|-------------------|------------------------|-------------------------------------|---------------------|--|
| 1 Mean quality of life scores | | | Other data | No numeric data | |
| 2 Mean number of UI episodes per 24 hours (SD) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected | |

Comparison 5. Lifestyle weight loss versus metformin

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|-------------------|------------------------|---------------------------------|----------------------|
| 1 Prevalence of weekly UI after intervention | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 1.1 All UI types at 2.8 years | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | $0.0 \ [0.0, \ 0.0]$ |
| 1.2 Stress UI at 2.8 years | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | $0.0 \ [0.0, \ 0.0]$ |
| 1.3 Urgency UI at 2.8 years | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | $0.0 \ [0.0, 0.0]$ |

Analysis I.I. Comparison I Weight loss versus no active intervention, Outcome I Improvement rates based on women's perception (all types UI).

Review: Lifestyle interventions for the treatment of urinary incontinence in adults

Comparison: I Weight loss versus no active intervention

Outcome: I Improvement rates based on women's perception (all types UI)

| Study or subgroup | Weight loss n/N | Control n/N | Risk Ratio M-H,Fixed,95% Cl | Risk Ratio M-H,Fixed,95% Cl |
|-----------------------------|--------------------|----------------|---|--------------------------------|
| l At 6 months Subak 2009 | 163/214 | 49/90 | -+- | 1.40 [1.14, 1.71] |
| | | | 0.005 0.1 10 200 Favours control Favours weight loss | |

Analysis I.2. Comparison I Weight loss versus no active intervention, Outcome 2 Improvement rates based on women's perception (all types UI).

Improvement rates based on women's perception (all types UI)

| Study | Outcome | Weight loss (number improved) | Weight loss (t otal N) | Weight loss (%) | Control (number improved) | Control (t otal N) | Control (%) | Reported P value |
|------------|------------------------------|-------------------------------------|---------------------------|--------------------|---------------------------------|-----------------------|----------------|---------------------|
| Subak 2009 | At 12 months (N = 298) | Not reported | Not reported | 75 | Not reported | Not reported | 68 | 0.2 |
| Subak 2009 | At 18 months (N = | Not reported | Not reported | 75 | Not reported | Not reported | 62 | 0.02 |

Lifestyle interventions for the treatment of urinary incontinence in adults (Review)

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Improvement rates based on women's perception (all types UI) (Continued)

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Analysis I.3. Comparison I Weight loss versus no active intervention, Outcome 3 Quality of life and symptom scores.

Quality of life and symptom scores

| Study | Outcome | Weight loss (to- tal N) | Weight loss, me- dian (IQR) | Control (total N) | Control, median (IQR) | Reported P value |
|------------|--|----------------------------|--------------------------------|----------------------|--------------------------|---------------------|
| Subak 2005 | 3 months | | | | | |
| Subak 2005 | Incontinence Im- pact Question- naire (score range 0-400 with lower score indicating better quality of life) | 19 | 37 (11 to 86) | 21 | 89 (56 to 136) | 0.01 |
| Subak 2005 | Urogenital Distress Inven- tory (score range 0-300 with lower scores indicating less distress) | 19 | 104 (67 to 122) | 21 | 195 (156 to 228) | <0.0001 |
| Subak 2005 | SF-36 physical component (higher scores in- dicate better quality of life) | 19 | 55 (49 to 58) | 21 | 47 (41 to 50) | 0.003 |
| Subak 2005 | SF-36 mental component (higher scores in- dicate better quality of life) | 19 | 48 (46 to 49) | 21 | 51 (48 to 54) | 0.09 |

Analysis I.4. Comparison I Weight loss versus no active intervention, Outcome 4 Cure rates based on quantification of symptoms (all types UI).

Review: Lifestyle interventions for the treatment of urinary incontinence in adults

Comparison: I Weight loss versus no active intervention

Outcome: 4 Cure rates based on quantification of symptoms (all types UI)

| Study or subgroup | Weight loss | Control | Risk Ratio | Risk Ratio |
|-------------------------------|-------------|---------|-------------------------------------|-----------------------|
| | n/N | n/N | M-H,Fixed,95% Cl | M-H,Fixed,95% CI |
| l At 3 months Subak 2005 | 3/19 | 0/21 | | 7.70 [0.42, 140.03] |
| 2 At 6 months Subak 2009 | 15/214 | 4/90 | | 1.58 [0.54, 4.62] |
| 3 At 12 months Phelan 2012 | 132/376 | 114/362 | * | 1.11 [0.91, 1.37] |
| | | | 0.01 0.1 10 100 | |
| | | | Favours control Favours weight loss | |

Analysis 1.5. Comparison I Weight loss versus no active intervention, Outcome 5 Cure rates based on quantification of symptoms (by type of UI).

Cure rates based on quantification of symptoms (by type of UI)

| Study | Outcome | Weight loss (number cured) | Weight loss (total N) | Weight loss (%) | Control (number cured) | Control (total N) | Control (%) | Reported P value |
|------------|---------------------------|----------------------------------|--------------------------|--------------------|------------------------------|----------------------|----------------|---------------------|
| Subak 2009 | Stress UI at 6 months | Not reported | Not reported | 27 | Not reported | Not reported | 15 | 0.004 |
| Subak 2009 | Urgency UI at 6 months | Not reported | Not reported | 19 | Not reported | Not reported | 11 | 0.02 |
Analysis I.6. Comparison I Weight loss versus no active intervention, Outcome 6 Improvement rates based on quantification of symptoms (all types UI).

Review: Lifestyle interventions for the treatment of urinary incontinence in adults

Comparison: I Weight loss versus no active intervention

Outcome: 6 Improvement rates based on quantification of symptoms (all types UI)

| Study or subgroup | Weight loss | Control | Risk Ratio | Weight | Risk Ratio |
|--|---|---------|----------------------|---------|------------------------|
| | 11/11 | 11/15 | 11-1 I,I IXed,75% CI | | 11-11,1 Xed,75% C1 |
| I At 3 months | | | | | |
| Subak 2005 | 7/19 | 0/21 | | 100.0 % | 16.50 [1.01, 270.78] |
| Subtotal (95% CI) | 19 | 21 | | 100.0 % | 16.50 [1.01, 270.78] |
| Total events: 7 (Weight loss) | , 0 (Control) | | | | |
| Heterogeneity: not applicabl | e | | | | |
| Test for overall effect: $Z = 1$. | .96 (P = 0.050) | | | | |
| 2 At 6 months | | | | | |
| Subak 2009 | 88/214 | 20/90 | | 100.0 % | 1.85 [1.22, 2.81] |
| Subtotal (95% CI) | 214 | 90 | • | 100.0 % | 1.85 [1.22, 2.81] |
| Total events: 88 (Weight loss Heterogeneity: not applicabl Test for overall effect: Z = 2. 3 At 12 months | s), 20 (Control) e .88 (P = 0.0039) | | | | |
| Phelan 2012 | 39/376 | 119/362 | - | 76.1 % | 1.12 [0.92, 1.37] |
| Subak 2009 | 95/207 | 27/87 | | 23.9 % | 1.48 [1.05, 2.09] |
| Subtotal (95% CI) Total events: 234 (Weight Io | 583 | 449 | • | 100.0 % | 1.21 [1.02, 1.44] |
| Heterogeneity: $Chi^2 = 1.81$, | $df = (P = 0.18); ^2 =$ | 45% | | | |
| Test for overall effect: $Z = 2$. | .17 (P = 0.030) | | | | |
| 4 At 18 months | . , | | | | |
| Subak 2009 | 91/197 | 36/90 | + | 100.0 % | 1.15 [0.86, 1.55] |
| Subtotal (95% CI) | 197 | 90 | * | 100.0 % | 1.15 [0.86, 1.55] |
| Total events: 91 (Weight loss | s), 36 (Control) | | | | |
| Heterogeneity: not applicable | e | | | | |
| Test for overall effect: $Z = 0$. | .96 (P = 0.34) | | | | |
| | | | | | |
| | | | 0.1 0.2 0.5 1 2 5 10 | | |

Favours control Favours weight loss

Analysis I.7. Comparison I Weight loss versus no active intervention, Outcome 7 Improvement rates based on quantification of symptoms (by type of UI).

| Study | Outcome | Weight loss (number cured) | Weight loss (total) | Weight loss (%) | Control (number cured) | Control (total) | Control (%) | Reported P value |
|------------|---------------------------------|----------------------------------|------------------------|--------------------|------------------------------|--------------------|----------------|---------------------|
| Subak 2009 | Stress UI at 6 months | Not reported | Not reported | 51 | Not reported | Not reported | 34 | 0.01 |
| Subak 2009 | Urgency UI at 6 months | Not reported | Not reported | 41 | Not reported | Not reported | 29 | 0.04 |
| Subak 2009 | Stress UI at 6 months | Not reported | Not reported | 51 | Not reported | Not reported | 34 | 0.01 |
| Subak 2009 | Urgency UI at 6 months | Not reported | Not reported | 41 | Not reported | Not reported | 29 | 0.04 |
| Subak 2009 | Stress UI at 18 months | Not reported | Not reported | 61 | Not reported | Not reported | 62 | 0.92 |
| Subak 2009 | Ur- gency UI at 18 months | Not reported | Not reported | 47 | Not reported | Not reported | 34 | 0.03 |

Improvement rates based on quantification of symptoms (by type of UI)

Analysis I.8. Comparison I Weight loss versus no active intervention, Outcome 8 Prevalence of weekly urinary incontinence after intervention (all types UI).

Review: Lifestyle interventions for the treatment of urinary incontinence in adults

Comparison: I Weight loss versus no active intervention

Outcome: 8 Prevalence of weekly urinary incontinence after intervention (all types UI)

| Study or subgroup | Weight loss | Control | F | Risk Ratio | Risk Ratio |
|-------------------|-------------|----------|---------------------|-----------------|---------------------|
| | n/N | n/N | M-H,Fix | ked,95% Cl | M-H,Fixed,95% CI |
| At 2 months | | | | | |
| Phelan 2012 | 350/1385 | 387/1354 | — · | - | 0.88 [0.78, 1.00] |
| 2 At 2.8 years | | | | | |
| Brown 2006b | 252/659 | 302/660 | _ | | 0.84 [0.74, 0.95] |
| | | | | | |
| | | | | · · · · · | |
| | | | 0.5 0.7 | 1 1.5 2 | |
| | | | Favours weight loss | Favours control | |

Analysis 1.9. Comparison I Weight loss versus no active intervention, Outcome 9 Prevalence of weekly urinary incontinence after intervention (by type of UI).

| Study | Outcome | Weight loss (num- ber with UI) | Weight loss (total N) | Weight loss (%) | Control (number with UI) | Control (total N) | Control (%) | Reported P value | Reported adjusted odds ratio (95% CI) |
|----------------|---------------------|---|-----------------------------|--------------------|--------------------------------|----------------------|-----------------|---------------------|--|
| Brown 2006b | SUI at 2.8 years | 206 | 659 | 31 | 242 | 660 | 37 | 0.04 | 0.80 (0.64 to 1.01) |
| Brown 2006b | UUI at 2.8 years | 156 | 659 | 24 | 169 | 660 | 26 | 0.41 | Not reported |
| Phelan 2012 | SUI at 1 year | 145 | 1385 | 11 | 173 | 1354 | 13 | 0.07 | 0.73 (0.55 to 0.96) |
| Phelan 2012 | UUI at 1 year | Not reported | Not reported | Not reported | Not reported | Not reported | Not reported | Not reported | 0.93 (0.70 to 1.23) |

Prevalence of weekly urinary incontinence after intervention (by type of UI)

Analysis 1.10. Comparison I Weight loss versus no active intervention, Outcome 10 Incontinent episodes per week (% change from baseline; all UI types).

Review: Lifestyle interventions for the treatment of urinary incontinence in adults

Comparison: I Weight loss versus no active intervention

Outcome: 10 Incontinent episodes per week (% change from baseline; all UI types)

| Study or subgroup | Weight loss N | Mean(SD) | Control N | Mean(SD) | | Dif IV,Fix | Mean ference ed,95% Cl | | Mean Difference IV,Fixed,95% Cl |
|------------------------------|------------------|---------------|--------------|---------------|------------|---------------|------------------------------|---------|---------------------------------------|
| l At 6 months Subak 2009 | 214 | -47 (51.9496) | 90 | -28 (62.0685) | | _+ | - | | -19.00 [-33.59, -4.41] |
| 2 At 12 months Subak 2009 | 207 | -57 (43.7854) | 87 | -45 (51.612) | | | _ | | -12.00 [-24.38, 0.38] |
| 3 At 18 months Subak 2009 | 197 | -62 (35.5848) | 90 | -55 (47.745) | | - | - | | -7.00 [-18.04, 4.04] |
| | | | | | | | | | |
| | | | | | -100 | -50 | 0 50 | 100 | |
| | | | | | Favours we | eight loss | Favours | control | |

Lifestyle interventions for the treatment of urinary incontinence in adults (Review)

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Analysis I.II. Comparison I Weight loss versus no active intervention, Outcome II Incontinence episodes per week (% change from baseline; by type of UI).

| Study | Outcome | Weight loss (to- tal N) | Weight loss (% change from baseline) | Control (total N) | Control (% change from baseline) | Reported P value |
|------------|---|----------------------------|--|----------------------|--|---------------------|
| Subak 2005 | All UI at 3 months, me- dian (IQR) | 19 | -60 (-89 to -30) | 21 | -15 (-25 to 9) | 0.0005 |
| Subak 2005 | Stress UI at 3 months, median (IQR) | 19 | -92 (-100 to -66) | 21 | 5 (-63 to 33) | 0.003 |
| Subak 2005 | Urgency UI at 3 months, median (IQR) | 19 | -70 (-100 to -16) | 21 | -11 (-67 to 69) | 0.03 |
| Subak 2005 | | | | | | |
| Subak 2005 | | | | | | |
| Subak 2005 | | | | | | |
| Subak 2005 | | | | | | |
| Subak 2005 | | | | | | |
| Subak 2005 | | | | | | |
| Subak 2009 | All UI at 6 months, mean (95% CI) | 214 | -47 (-54 to -40) | 90 | -28 (-41 to -13) | 0.01 |
| Subak 2009 | Stress UI at 6 months, mean (95% CI) | 214 | -58 (-67 to -46) | 90 | -33 (-50 to -9) | 0.02 |
| Subak 2009 | Urgency UI at 6 months, mean (95% CI) | 214 | -42 (-51 to -32) | 90 | -26 (-44 to -3) | 0.14 |
| Subak 2009 | All UI at 12 months, mean (95% CI) | 207 | -57 (-63 to -50) | 87 | -45 (-56 to -32) | 0.08 |

Incontinence episodes per week (% change from baseline; by type of UI)

| Incontinence episodes per week | (% change from | n baseline; by type of UI) | (Continued) |
|--------------------------------|----------------|----------------------------|-------------|
|--------------------------------|----------------|----------------------------|-------------|

| Subak 2009 | Stress UI at 12 months, mean (95% CI) | 207 | -66 (-71 to -59) | 87 | -45 (-59 to -27) | <0.001 |
|------------|--|-----|------------------|----|------------------|--------|
| Subak 2009 | Urgency UI at 12 months, mean (95% CI) | 207 | -50 (-59 to -39) | 87 | -48 (-63 to -29) | 0.87 |
| Subak 2009 | All UI at 18 months, mean (95% CI) | 197 | -62 (-67 to -55) | 90 | -55 (-65 to -43) | 0.3 |
| Subak 2009 | Stress UI at 18 months, mean (95% CI) | 197 | -69 (-76 to -61) | 90 | -62 (-73 to -48) | 0.32 |
| Subak 2009 | Urgency UI at 18 months, mean (95% CI) | 197 | -56 (-64 to -46) | 90 | -49 (-64 to -28) | 0.46 |

Analysis 2.1. Comparison 2 Soy-rich diet versus control, Outcome I Number of women with UI episodes: soy-rich diet versus control.

Number of women with UI episodes: soy-rich diet versus control

| Study | Outcome | Soy-rich diet (n/N) | Soy-rich diet (%) | Control diet (n/N) | Control diet (%) |
|--------------|------------------------------------|---------------------|-------------------|--------------------|------------------|
| Manonai 2006 | SUI episodes: before (baseline) | 22/36 | 61 | 23/36 | 63 |
| Manonai 2006 | SUI episodes: after | 22/36 | 61 | 18/36 | 51 |
| Manonai 2006 | UUI episodes: before (baseline) | 7/36 | 19 | 4/36 | 11 |
| Manonai 2006 | UUI episodes: after | 6/36 | 17 | 8/36 | 22 |

Analysis 2.2. Comparison 2 Soy-rich diet versus control, Outcome 2 Mean UI symptom scores (SD; 0 = none, 1 = mild, 2 = moderate, 3 = severe): soy-rich diet versus control.

Mean UI symptom scores (SD; 0 = none, 1 = mild, 2 = moderate, 3 = severe): soy-rich diet versus control

| Study | Outcome | Soy-rich diet (n = 36) | Soy-rich diet (n = 36) |
|--------------|---------------------------------|------------------------|------------------------|
| Manonai 2006 | SUI episodes: before (baseline) | 0.67 (0.68) | 0.75 (0.65) |
| Manonai 2006 | SUI episodes: after | 0.72 (0.66) | 0.72 (0.74) |

Lifestyle interventions for the treatment of urinary incontinence in adults (Review)

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| Mean | UI symptom scores | (SD; 0 = none, 1 | l = mild, 2 = | = moderate, 3 = | severe): soy-rich d | iet versus control | (Continued) |
|------|-------------------|------------------|---------------|-----------------|---------------------|--------------------|-------------|
|------|-------------------|------------------|---------------|-----------------|---------------------|--------------------|-------------|

| Manonai 2006 | Reported P value | > 0.05 | > 0.05 |
|--------------|---------------------------------|-------------|-------------|
| Manonai 2006 | UUI episodes: before (baseline) | 0.17 (0.38) | 0.14 (0.35) |
| Manonai 2006 | UUI episodes: after | 0.19 (0.47) | 0.25 (0.50) |
| Manonai 2006 | Reported P value | > 0.05 | < 0.05 |

Analysis 3.1. Comparison 3 Increase in fluid intake versus decrease in fluid intake, Outcome 1 Median number of daily UI episodes (IQR).

Median number of daily UI episodes (IQR)

| Study | Type of UI | Baseline | Caffeine-free baseline | Caffeine-free and increasing fluids | Caffeine-free and decreasing flu- ids |
|------------------|--|------------------|---------------------------|--|---|
| Swithinbank 2005 | Urodynamic stress incontinence (SUI), n = 39 | 1.6 (0.6 to 2.8) | 0.8 (0.1 to 1.9) | 0.7 (0.3 to 3) | 0.5 (0.2 to 2.1) |
| Swithinbank 2005 | Idiopathic detrusor overactivity (IDO), n = 30 | 0.9 (0.4 to 2) | 0.6 (0.2 to 1.8) | 1.1 (0.2 to 3) | 0.5 (0.2 to 1.2) |

Analysis 3.2. Comparison 3 Increase in fluid intake versus decrease in fluid intake, Outcome 2 Median number of daily UI episodes (range).

Median number of daily UI episodes (range)

| Study | Randomised group | N | Median (range) | Reported P value compared with baseline |
|-------------|------------------|----|----------------|--|
| Hashim 2008 | Baseline | 24 | 0 (0, 4.8) | |
| Hashim 2008 | 25% less fluid | 24 | 0 (0, 5.5) | 1.0 |
| Hashim 2008 | 50% less fluid | 12 | 0 (0, 4.5) | 0.69 |
| Hashim 2008 | 25% more fluid | 21 | 0 (0, 10.3) | 1.00 |
| Hashim 2008 | 50% more fluid | 14 | 0 (0, 12.8) | 0.69 |

Analysis 3.3. Comparison 3 Increase in fluid intake versus decrease in fluid intake, Outcome 3 Mean number of daily UI episodes (any UI).

Mean number of daily UI episodes (any UI)

| Study | Time period | Maintain fluid (N = 14) | Increase fluid (N = 10) | Decrease fluid (N = 8) |
|-----------|-------------------|----------------------------|-------------------------|------------------------|
| Dowd 1996 | Week 1 (baseline) | 0.48 | 0.6 | 0.54 |
| Dowd 1996 | Week 2 | 0.71 | 0.61 | 0.26 |
| Dowd 1996 | Week 3 | 0.81 | 0.67 | 0.17 |
| Dowd 1996 | Week 4 | 0.57 | 0.5 | 0.14 |
| Dowd 1996 | Week 5 | 0.48 | 0.55 | 0.07 |

Analysis 4.1. Comparison 4 Caffeine reduction versus control, Outcome I Mean quality of life scores.

Mean quality of life scores

| Study | Outcome | Caffeine substitution | Caffeine exposure | Reported P value |
|------------|--|-----------------------|-------------------|---------------------|
| Wells 2011 | ICIQ Overactive Bladder (ICIQ-OAB) total score (N = 11); 0-16 overall score with greater values indicating in- creased symptom severity | 4.64 | 6.55 | < 0.01 |
| Wells 2011 | ICIQ Overactive Bladder Symptoms Quality of Life (ICIQ-OABqol) score (N = 11); 25-160 overall score with greater values indi- cating increased impact on quality of life | | | |
| Wells 2011 | How regularly bladder symptoms interfered with the ability to get a good night's rest | 2.64 | 4.09 | < 0.01 |
| Wells 2011 | 2) How often bladder symp- toms caused anxiety or worry | 1.73 | 2.64 | < 0.05 |

Mean quality of life scores (Continued)

| Wells 2011 | 3) How much bladder symptoms interfered with everyday life overall | 3.73 | 5.64 | < 0.01 |
|------------|--|-------|-------|--------|
| Wells 2011 | 4) Total scores for the ICIQ- OABqol | 53.91 | 68.36 | 0.065 |

Analysis 4.2. Comparison 4 Caffeine reduction versus control, Outcome 2 Mean number of UI episodes per 24 hours (SD).

Review: Lifestyle interventions for the treatment of urinary incontinence in adults

Comparison: 4 Caffeine reduction versus control

Outcome: 2 Mean number of UI episodes per 24 hours (SD)

| Study or subgroup | Reduced caffeine | | Control | | Mean Difference | Mean Difference |
|-------------------|------------------|-----------|---------|-----------|------------------------------|-----------------------|
| | Ν | Mean(SD) | Ν | Mean(SD) | IV,Fixed,95% CI | IV,Fixed,95% CI |
| Bryant 2002 | 36 | 1.2 (1.9) | 38 | 1.4 (1.7) | + | -0.20 [-1.02, 0.62] |
| | | | | | | |
| | | | | | | |
| | | | | _ | -10 -5 0 5 | 10 |
| | | | | Favours | reduced caffeine Favours con | trol |
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Analysis 5.1. Comparison 5 Lifestyle weight loss versus metformin, Outcome 1 Prevalence of weekly UI after intervention.

Review: Lifestyle interventions for the treatment of urinary incontinence in adults Comparison: 5 Lifestyle weight loss versus metformin Outcome: I Prevalence of weekly UI after intervention

| Study or subgroup | Lifestyle weight loss | Metformin weight loss | Risk Ratio | Risk Ratio |
|-----------------------------|-----------------------|--------------------------|----------------------|---------------------|
| | n/N | n/N | M-H,Fixed,95% CI | M-H,Fixed,95% CI |
| I All UI types at 2.8 years | 252//50 | 20///25 | _ | |
| Brown 2006b | 252/659 | 306/635 | | 0.79 [0.70, 0.90] |
| 2 Stress UI at 2.8 years | | | | |
| Brown 2006b | 206/659 | 252/635 | + | 0.79 [0.68, 0.91] |
| 3 Urgency UI at 2.8 years | | | | |
| Brown 2006b | 156/659 | 182/635 | -+ | 0.83 [0.69, 0.99] |
| | | | | |
| | | | | |
| | | | 0.1 0.2 0.5 1 2 5 10 | |

Favours lifestyle Favours metformin

APPENDICES

Appendix I. Additional search of ClinicalTrials.gov

After the main searching for this review was completed, searching and assessment of 1151 records from ClinicalTrials.gov was completed (date of last search: 28 November 2013; via the Central Register of Studies (CRS) software) using the following search terms: Continent OR continence OR incontinent OR incontinence OR overactive OR overactivity (in the simple search command line) After screening 1151 records we identified four that were potentially eligible for this review. As this search was completed after the main search was completed (and its results had been fully incorporated into the review) these four trials were added to Studies awaiting classification so that they can be fully assessed for the next version of the review.

HISTORY

Protocol first published: Issue 1, 2002

Review first published: Issue 12, 2015

| Date | Event | Description |
|-------------|---|--------------------|
| 7 July 2010 | New citation required and minor changes | new review authors |
| 7 July 2010 | Amended | protocol amended |

CONTRIBUTIONS OF AUTHORS

All authors contributed to the initial design and writing of the protocol. MI and KW led study selection, data abstraction and analysis, and wrote the first draft. CM and MW provided critical revisions of the draft for important intellectual content. All authors provided final approval of the version to publish.

DECLARATIONS OF INTEREST

M Imamura: none known K Williams: none known M Wells: none known C McGrother: none known

SOURCES OF SUPPORT

Internal sources

• No sources of support supplied

External sources

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

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Selection criteria for Types of participants has been amended after the review commenced. The protocol stated that only adults with urinary incontinence (UI) would be considered for inclusion. Due to the limited number of studies that met this criterion, we also included data from trials where some, but not all, participants had UI at baseline regardless of the proportion of people with UI or availability of data subgrouped by incontinence status.

As the recommendation to assess the quality of evidence using the GRADE approach and also to include 'Summary of findings' tables became prominent during the course of the review, we attempted to undertake the assessment, even though this was not mentioned in the protocol. The GRADE and 'Summary of findings' outcomes were thus defined after the review commenced.

Searches of MEDLINE, EMBASE, CINAHL included in the specialised register, and searches of the reference lists of relevant articles, had been planned originally but were not spelt out in the protocol. Descriptions of these searches have been added to the review for the sake of clarity.

ClinicalTrials.gov has been searched in response to a comment from an external referee.