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

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[Intervention Review]

Lifestyle interventions for the treatment of urinary incontinence in adults

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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% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Weight loss				
Cure rates by patient observation (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 quality of life Incontinence Impact Questionnaire. 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 symptom 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)	⊕⊕◯◯ **low**[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)	⊕⊕◯◯ **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)	⊕◯◯◯ **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

1) 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 UIurinary 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 (so-called '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 follow-up.

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 treatment-related.

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

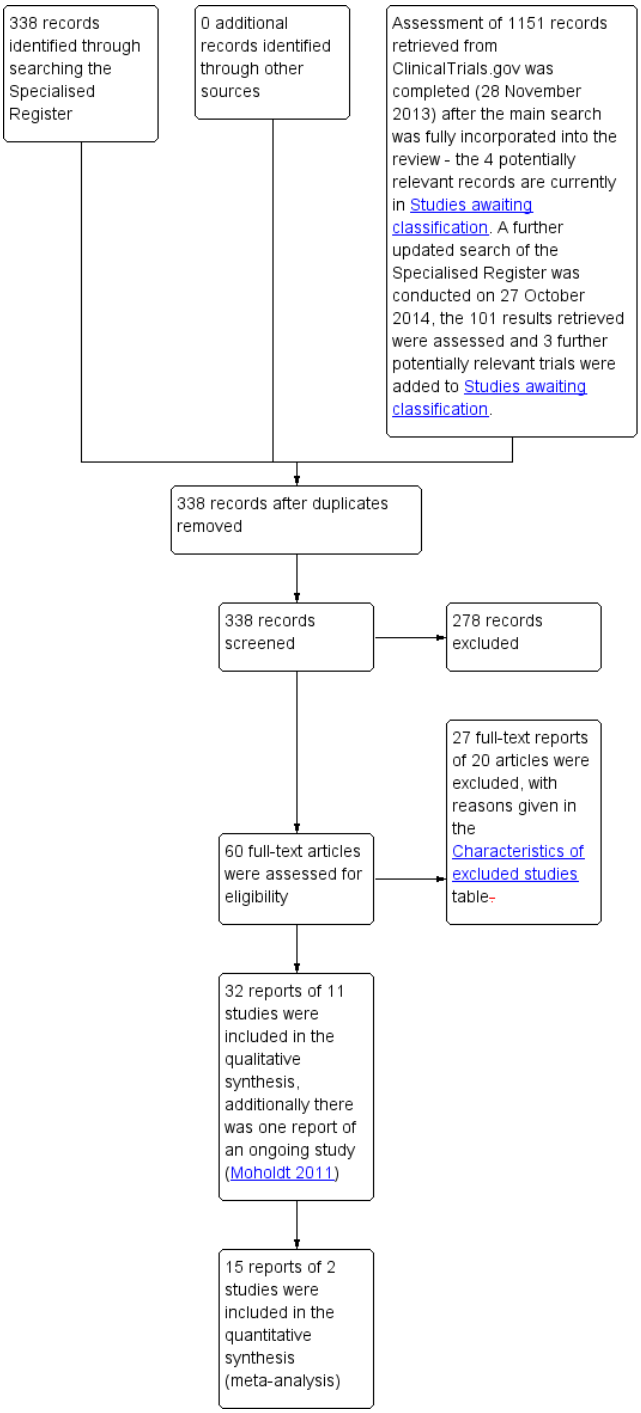
See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

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).

Figure 1. PRISMA study flow diagram



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.

Excluded studies

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

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

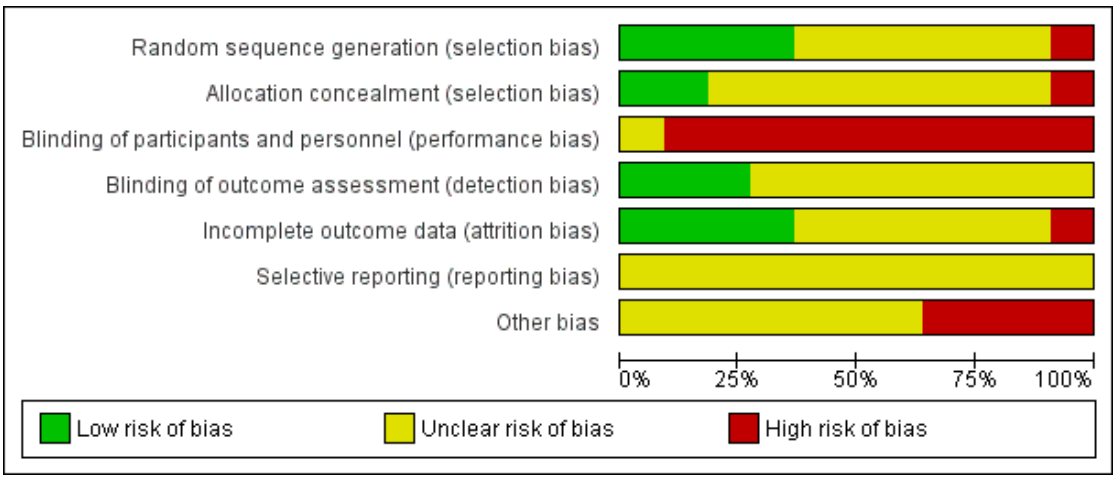
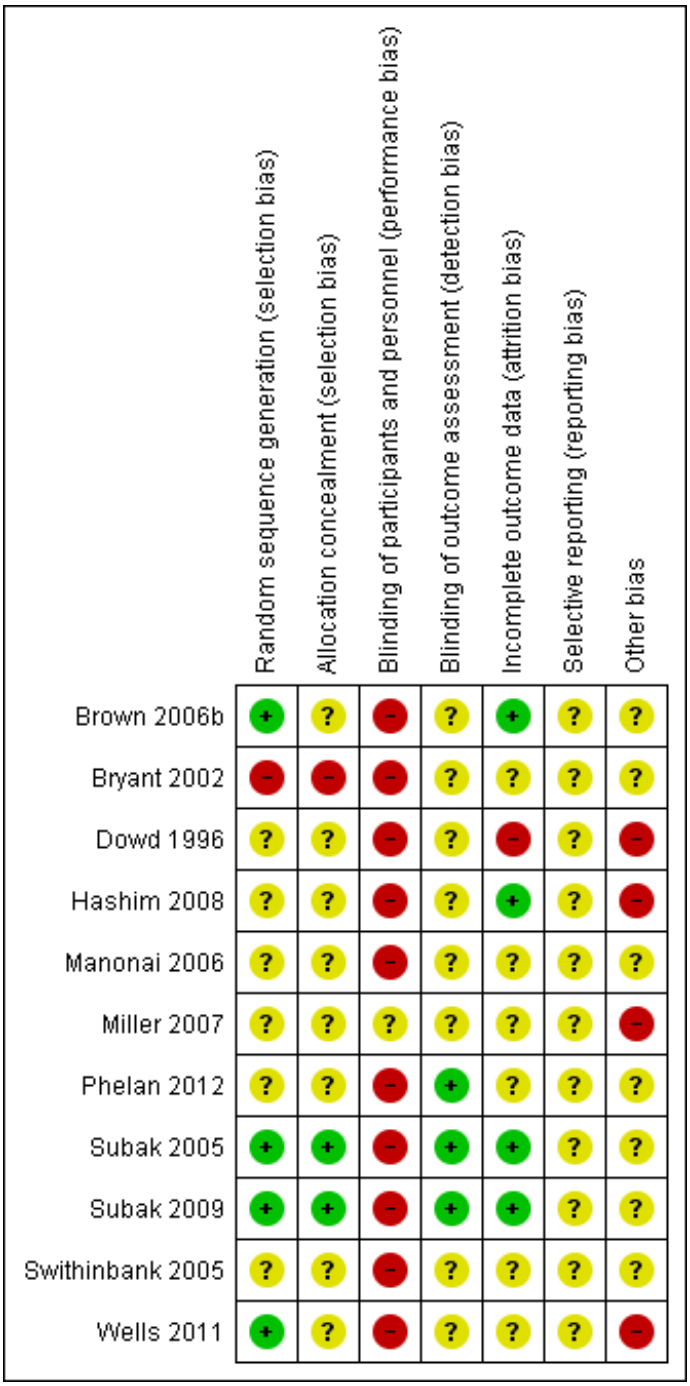


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study



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 cross-over 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 caffeine-free 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).

4) *Caffeine reduction versus continued caffeine intake*

Description of studies

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.

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).

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Soy-rich diet compared to control for the treatment of urinary incontinence in adults

Patient or population: adults with urinary incontinence
Settings:
Intervention: soy-rich diet
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	Soy rich diet				
Cure rates by patient observation (all UI types) - not reported			Not estimable	-		
Improvement rates by patient observation (all UI types) - not reported			Not estimable	-		
Condition-specific quality of life - not reported			Not estimable	-		
Adverse effects - not reported			Not estimable	-		
Cure rates by symptom quantification (all UI types) - not reported			Not estimable	-		

Improvement rates by symptom quantification (all UI types) - not reported		Not estimable	-
Incontinent episodes per week (all UI types) - not reported		Not estimable	-

*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.

Decreasing fluids compared to increasing fluids for the treatment of urinary incontinence in adults

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 observation (all UI types) - not reported			Not estimable	-		
Improvement rates by patient observation (all UI types) - not reported			Not estimable	-		
Condition-specific quality 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 decreased but the impact of incontinence on daily life did not differ significantly before or after the treatment
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 concentrated urine with decreasing fluids

Cure rates by symptom quantification (all UI types) - not reported			Not estimable	-		
Improvement rates by symptom quantification (all UI types) - not reported			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 significantly reduced incontinent episodes in one study, no difference was found in another study and the results were inconclusive in the other study

*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; **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] Randomised cross-over trial
[2] Risk of bias: We downgraded the evidence by one level because blinding of participants, personnel and outcome assessors was probably not done and could introduce bias.
[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.
[4] Missing outcome data in 18% of participants.
[5] Indirectness: We downgraded the evidence by two levels because of short follow-up <12 months in all studies and because study participants included both continent and incontinent patients in one study (Hashim 2008)
[6] Imprecision: We downgraded the evidence by one level because confidence intervals for relative effect were not estimable.

[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).

Caffeine reduction compared to control for the treatment of urinary incontinence in adults

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 observation (all UI types) - not reported			Not estimable	-		
Improvement rates by patient observation (all UI types) - not reported			Not estimable	-		
Condition-specific quality of life ICIQ Overactive Bladder Symptoms Quality of Life. Scale from: 25 to 160. Better quality of life indicated by lower values. Follow-up: 2 weeks	The mean condition-specific quality of life in the control groups was **68.36 points**	The mean condition-specific 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 reported			Not estimable	-		
Cure rates by symptom quantification (all UI types) - not reported			Not estimable	-		

Improvement rates by symptom quantification (all UI types) - not reported			Not estimable	-	
Incontinent episodes per day (all UI types) Follow-up: 4 weeks	The mean number of incontinent episodes per day (all UI types) in the control groups was **1.4**	The mean number of incontinent 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 **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

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] Randomised cross-over trial; feasibility study.
[2] Risk of bias: We downgraded the evidence by one level because blinding of participants, personnel and outcome assessors was probably not done.
[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.
[4] Missing outcome data in > 20% of participants.
[5] Indirectness: We downgraded the evidence by two levels because of short follow-up <12 months and because study participants included both continent and incontinent patients.
[6] Imprecision: We downgraded the evidence by one level because confidence intervals for relative effect were not estimable.
[7] A quasi-randomised controlled trial based on health record numbers.
[8] Risk of bias: We downgraded the evidence by one level because allocation concealment was inadequate (quasi-randomisation based on health record numbers).

Lifestyle weight loss compared to metformin weight loss for the treatment of urinary incontinence in adults

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

Outcomes	Illustrative comparative 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 observation (all UI types) - not reported			Not estimable	-		
Improvement rates by patient observation (all UI types) - not reported			Not estimable	-		
Condition-specific quality of life - not reported			Not estimable	-		
Adverse effects - not reported			Not estimable	-		
Cure rates by symptom quantification (all UI types) - not reported			Not estimable	-		
Improvement rates by symptom quantification (all UI types) - not reported			Not estimable	-		

Prevalence of weekly UI (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)	⊕○○○ **very low**[1,2,3,4]

*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

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, personnel and outcome assessors was not mentioned and may introduce bias.

[2] 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.

[3] Missing outcome data in 11% of participants.

[4] Indirectness: We downgraded the evidence by one level because data come from a sub-study of a trial (Brown 2006) for diabetes that included continent as well as incontinent patients.

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 non-diabetics.
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

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 in-depth 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.consort-statement.org/), should impact on the inclusion of trials in subsequent systematic reviews, ensuring that the most robust evidence contributes to clinical recommendations.

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* *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 overweight 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 $\geq$ 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 curriculum 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 managers 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

Brown 2006b (*Continued*)

	Group III: placebo twice daily with standard lifestyle intervention The standard lifestyle intervention included written information and an individual meeting (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 intervention 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 Program, 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 Disparities, 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 Roussel, 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

Brown 2006b (*Continued*)

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 missing UI data were excluded from the analysis. 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 overall or within treatment groups compared with women with completed urinary incontinence data"
Selective reporting (reporting bias)	Unclear risk	Insufficient information provided. The main outcome for this analysis was prevalence 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 allocated 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 Employment status: 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

	(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 intervention 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 participants who completed the study. Reasons for withdrawal were reported but not separately 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 differed

Bryant 2002 (*Continued*)

Selective reporting (reporting bias)	Unclear risk	Insufficient information. Reported outcomes 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 the 3 groups. Participants were instructed in the detailed recording of intake using the same 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 the entire cohort; no data were available for each randomized group Treatment provided by: registered nurses who were given in-service training on UI and 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 randomly"
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 according to the study aim
Other bias	High risk	The study reported that adherence to the fluid manipulation was poor and made results difficult to interpret

Hashim 2008

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 Employment status: not stated Severity of symptoms: not stated Prior incontinence surgery: 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 uncontrolled 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 protocol requirements or unable to keep a diary or perform the required volume measurements on their own; had significant pelvic organ prolapse (Stage III or IV) or had significant stress UI Diagnostic groups: OAB = 24 (100%). Only 7 (29%) participants had 1 or more urge UI episode at baseline
Interventions	4-day screening period with FVC to establish baseline drinking habits, prior to randomisation to Group I or II Group 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 followed by 2 days normal drinking; followed by 4 days drinking 50% more than baseline followed by 2 days normal drinking; followed by 4 days drinking 25% less than baseline followed by 2 days normal drinking; followed by 4 days drinking 50% less than baseline Participants who drank > 3 L or < 1 L were excluded. Patients completed a 4-day FVC in each part of the study, and the ICIQ-OAB questionnaire at the end of each 4-day period, to assess their quality of life for that period Significance was analyzed by comparing each intervention group to the overall baseline of the study group (n = 24). The number of participants differed in each period so this is presented for reference Treatment duration: 4 weeks Co-intervention: not stated Compliance: all 24 participants participated in the period with a 25% reduction, but not all participated in the other parts of the study because they did not fulfil the criteria, i.e. their input was < 1 L or > 3 L when the fluid intake was manipulated. The mean fluid output was approximately 289 ml higher than the fluid intake. When participants were asked to drink 25% more than their normal fluid input they only managed to drink 17% more, and when asked to drink 50% more they managed 23% more, when comparing the respective groups with baseline. When asked to drink 50% less, participants managed to drink 32% less than the baseline. The 25% 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 (performance bias) All outcomes	High risk	Not mentioned but unlikely

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 frequency/volume charts in the method section
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 Employment status: not stated Severity of symptoms: not stated Prior incontinence surgery: 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 of both SUI and UUI. Other women had frequency, urgency or other vaginal symptoms, e.g. vaginal dryness, but no UI

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 consistently 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 accurate 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 specified 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 described 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. Reported outcomes were specified in the methods section
Other bias	Unclear risk	Insufficient information available

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

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	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 completers 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/m² (> 27 kg/m² 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 intervention, and underlying disease likely to limit life span and/or affect safety of the interventions Diagnositic groups: at baseline 27% of participants reported weekly (or more frequent) urinary incontinence. The reference group was 'less than weekly'. Predominant type

	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 assigned within centers to the ILI [intensive lifestyle intervention] or the DSE [diabetes 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

Phelan 2012 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of patient and personnel not mentioned but unlikely
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "All measures were completed at baseline and 1 year by assessors who were masked to participant treatment group."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of the 3063 women enrolled in the Look AHEAD trial, 69 (2%) women with no UI data at baseline were excluded from this sub-study. The 1-year follow-up rate was 93% (1385/1495) in the intervention group and 90% (1354/1499) for the control group. Survey completers were more likely to be white and non-smokers. The implication for the incontinence outcome is unknown
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/m², 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 programme. 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 numbered 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 assessing 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 incontinence 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 ≥ 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, participants underwent a second randomisation to a motivationally focused maintenance programme or a standard skills based maintenance approach and were followed for further 12 months Training 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

	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 to - -7.0); 12 months = -7.5 (-8.6 to - -6.4); 18 months = -5.5 (-6.7 to - -4.3); Group II: 6 months = -1.6 (-2.7 to - -0.4); 12 months = -1.7 (-3.2 to - -0.2); 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 clinical center"
Allocation concealment (selection bias)	Low risk	Quote: "... random assignment [was] concealed 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 associated with the retention of participants at 6 months". Also, multiple imputation methods 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 completers ... but dropouts in the intervention and control groups did not differ" (Wing 2010b)
Selective reporting (reporting bias)	Unclear risk	Insufficient information available. Reported 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 increased 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 Employment status: 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 referred 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 mellitus; those on anti-depressants, anticholinergics or diuretics Diagnostic groups: USI = 48; IDO = 36
Interventions	Treatment duration: 4 weeks Week 1: participants drank normally (baseline) Week 2: all participants drank normally, but only caffeine-free fluids Weeks 3 and 4: participants were randomized to either increasing caffeine-free fluids to 3 L (20 cups) per day for a week followed by a week of reducing caffeine-free fluids to 750 ml (5 cups) per day, or vice versa. Results from the weeks with increased and decreased fluids were compared. Urine osmolality was measured at weekly clinic visit to

	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 fluids"
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 participants enrolled. Reasons for this were not provided
Selective reporting (reporting bias)	Unclear risk	Insufficient information available. Reported outcomes were specified in the methods section
Other bias	Unclear risk	Insufficient information available

Wells 2011

Methods	Design: cross-over trial with random allocation to the order in which participants consumed caffeinated or caffeine-free fluids (feasibility study) Study centre: single centre, UK Recruitment period: not reported Power calculation: not reported
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 Employment status: 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 medications 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
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
Outcomes	ICIQ-OAB; ICIQ-OABqol Number of incontinent episodes (3-day bladder diary)
Notes	Available as abstract only Funding: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "… randomized … via random number generator"

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 follow-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 *Equisetum arvense* and *Crataeva murvale*
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
Notes	Enrolment: 158 Study start date: June 2008

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 quantification of symptoms (by type of UI)			Other data	No numeric data
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]

11 Incontinence episodes per week (% change from baseline; by type of UI)		Other data	No numeric data

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

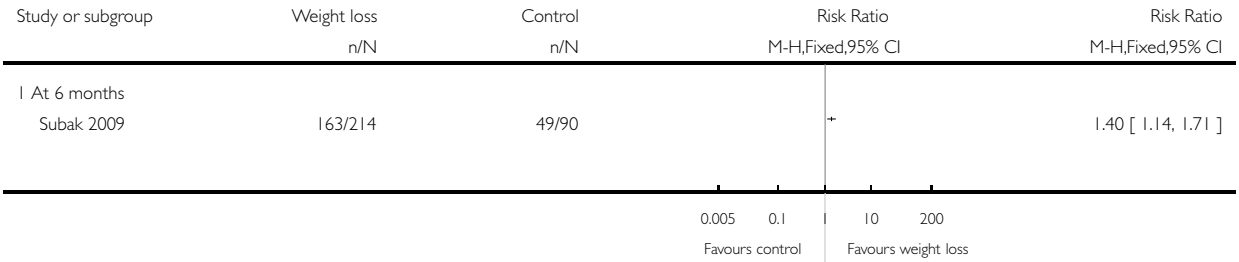
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Prevalence of weekly UI after intervention	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 All UI types at 2.8 years	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.2 Stress UI at 2.8 years	1		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 1.1. Comparison 1 Weight loss versus no active intervention, Outcome 1 Improvement rates based on women's perception (all types UI).

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

Comparison: 1 Weight loss versus no active intervention

Outcome: 1 Improvement rates based on women's perception (all types UI)



Analysis 1.2. Comparison 1 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

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

	291)							

Analysis 1.3. Comparison 1 Weight loss versus no active intervention, Outcome 3 Quality of life and symptom scores.

Quality of life and symptom scores

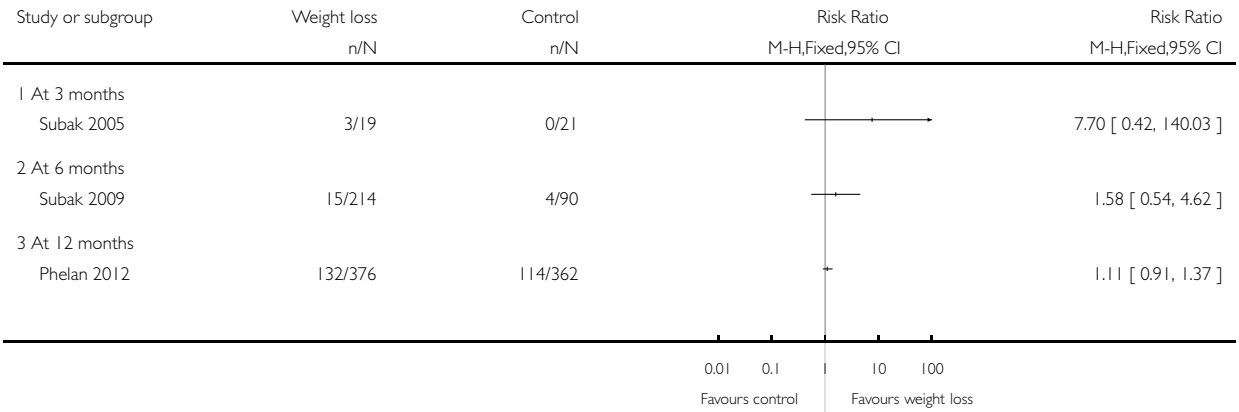
Study	Outcome	Weight loss (total N)	Weight loss, median (IQR)	Control (total N)	Control, median (IQR)	Reported P value
Subak 2005	3 months					
Subak 2005	Incontinence Impact Questionnaire (score range 0-400 with lower score indicating better quality of life)	19	37 (11 to 86)	21	89 (56 to 136)	0.01
Subak 2005	Urogenital Distress Inventory (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 indicate better quality of life)	19	55 (49 to 58)	21	47 (41 to 50)	0.003
Subak 2005	SF-36 mental component (higher scores indicate better quality of life)	19	48 (46 to 49)	21	51 (48 to 54)	0.09

Analysis 1.4. Comparison 1 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: 1 Weight loss versus no active intervention

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



Analysis 1.5. Comparison 1 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)

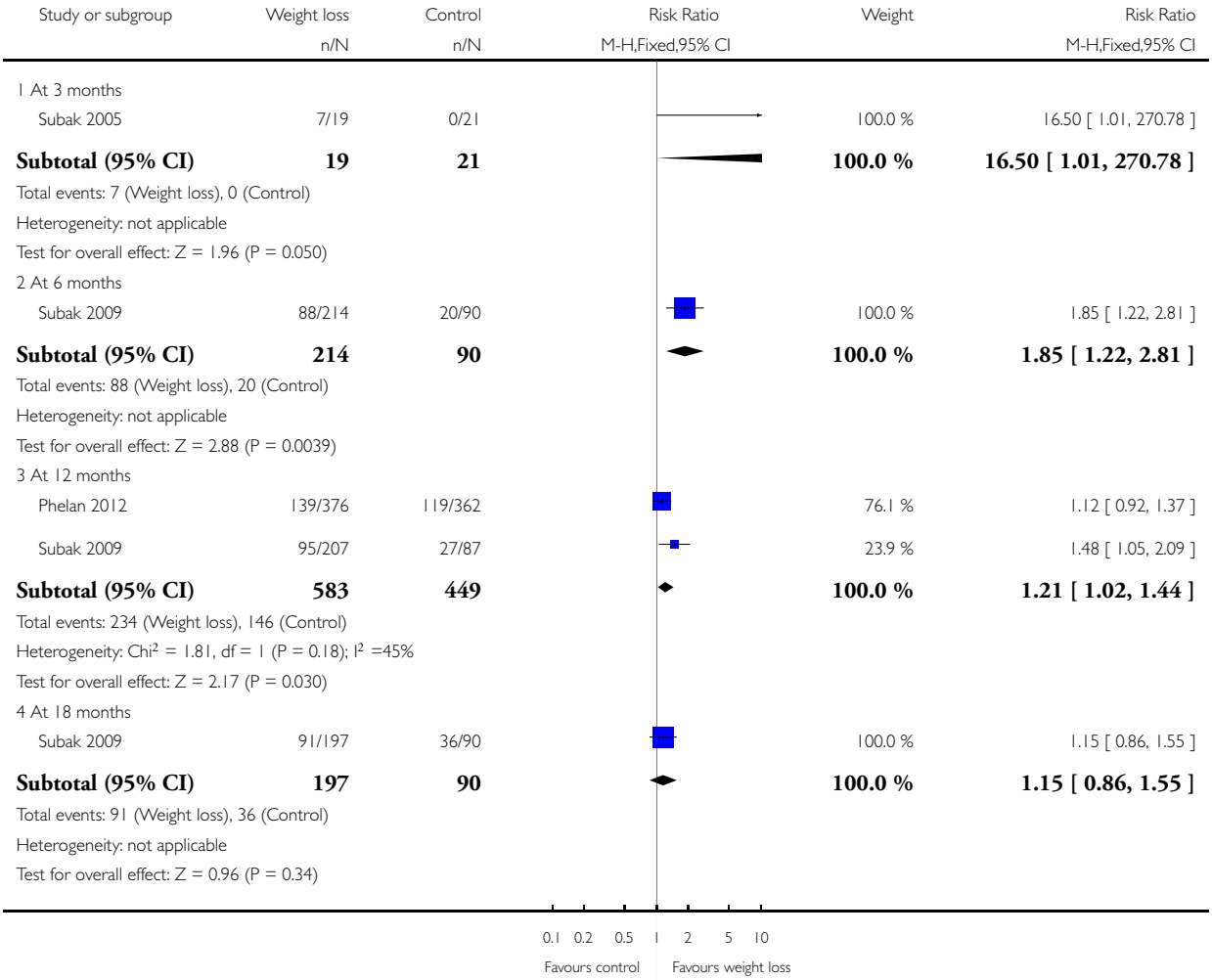
Study	Outcome	Weight loss (number cured)	Weight loss (total N)	Weight loss (%)	Control (number cured)	Control (total N)	Control (%)	Reported P value
Subak 2009	Stress UI at 6 months	Not reported	Not reported	27	Not reported	Not reported	15	0.004
Subak 2009	Urgency UI at 6 months	Not reported	Not reported	19	Not reported	Not reported	11	0.02

Analysis 1.6. Comparison 1 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: 1 Weight loss versus no active intervention

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



Analysis 1.7. Comparison 1 Weight loss versus no active intervention, Outcome 7 Improvement rates based on quantification of symptoms (by type of UI).

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

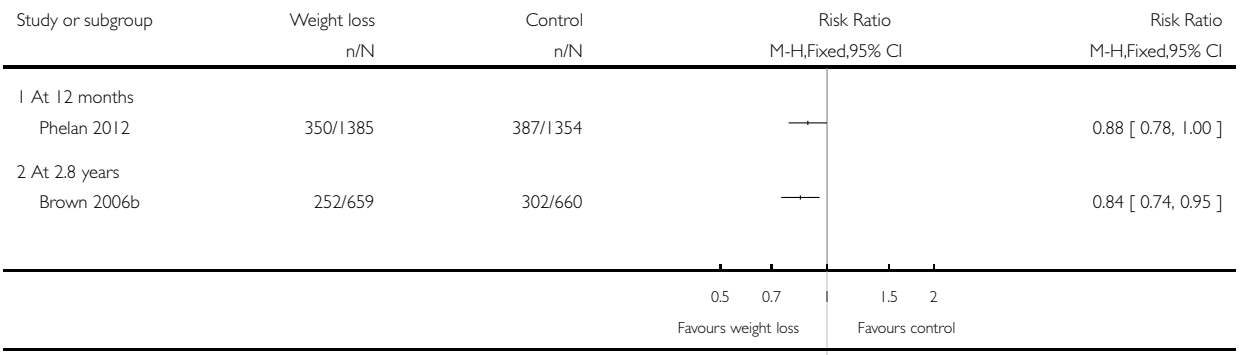
Study	Outcome	Weight loss (number cured)	Weight loss (total)	Weight loss (%)	Control (number cured)	Control (total)	Control (%)	Reported P value
Subak 2009	Stress UI at 6 months	Not reported	Not reported	51	Not reported	Not reported	34	0.01
Subak 2009	Urgency UI at 6 months	Not reported	Not reported	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	Urgency UI at 18 months	Not reported	Not reported	47	Not reported	Not reported	34	0.03

Analysis 1.8. Comparison 1 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: 1 Weight loss versus no active intervention

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



Analysis 1.9. Comparison 1 Weight loss versus no active intervention, Outcome 9 Prevalence of weekly urinary incontinence after intervention (by type of UI).

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

Study	Outcome	Weight loss (number 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)

Analysis 1.10. Comparison 1 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: 1 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)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 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]

Analysis 1.11. Comparison 1 Weight loss versus no active intervention, Outcome 11 Incontinence episodes per week (% change from baseline; by type of UI).

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

Study	Outcome	Weight loss (total N)	Weight loss (% change from baseline)	Control (total N)	Control (% change from baseline)	Reported P value
Subak 2005	All UI at 3 months, median (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) (*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 1 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)

Mean UI symptom scores (SD; 0 = none, 1 = mild, 2 = moderate, 3 = severe): soy-rich diet 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 fluids
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 1 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 increased 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 indicating increased impact on quality of life			
Wells 2011	1) 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 symptoms 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)

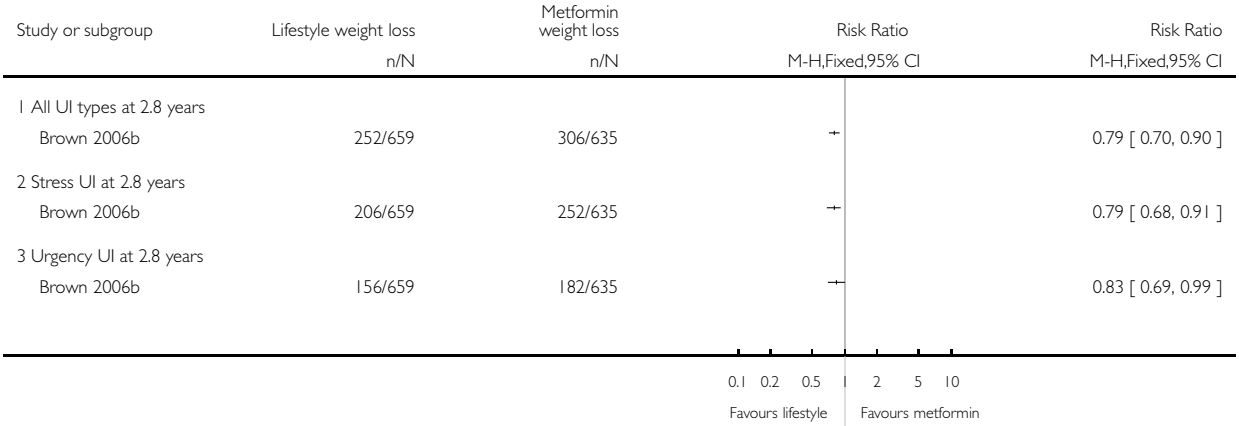
Study or subgroup	Reduced caffeine N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
Bryant 2002	36	1.2 (1.9)	38	1.4 (1.7)		-0.20 [-1.02, 0.62]

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: 1 Prevalence of weekly UI after intervention



APPENDICES

Appendix 1. 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

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- 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.