ABSTRACT

Objectives:

The vaginal use of cones or balls aims to increase muscle performance and thereby prevent or treat urinary incontinence. To date, no systematic review has focused on the effectiveness of these devices specifically during the postpartum period. The objectives of this review were: to compare the effectiveness of vaginal cones or balls for improvement of pelvic floor muscle performance and urinary continence in the postpartum period to no treatment, placebo, sham treatment or active controls; to gather information on effect on perineal descent or pelvic organ prolapse, adverse effects and economical aspects.

Design:

Quantitative systematic review

Data Sources:

14 scientific databases (including PubMed and CINAHL) and the world-wide web; experts were contacted for published and unpublished data.

Review Methods:

Studies had to be randomised/quasi-randomised trials and have female participants up to one year after childbirth. The intervention is compared to no treatment, placebo, sham treatment or active controls. Outcome measures relate to pelvic floor muscle performance or urinary incontinence. Studies were selected, “risk of bias” assessed, and data extracted by two reviewers independently with inter-reviewer agreement.

Main Findings:

One study met the inclusion criteria; its original data were re-analysed. In an intention-to-treat analysis, compared with the control group, the cone group showed a statistically significant lower rate of urinary incontinence; compared with the exercise group, the prevalence was similar. However, the validity of the analysis is limited.

Conclusions and implications:

The evidence gained from this systematic review is very limited. The use of cones may be helpful for urinary incontinence after childbirth, but further research is needed.

Keywords:

health promotion, pelvic floor, postpartum period, review, urinary incontinence

INTRODUCTION

Background

Pelvic floor muscle training should be a routine recommendation to all women during postpartum care (Abrams et al., 2010, The Joanna Briggs Institute, 2011). An alternative pelvic floor muscle rehabilitaton method consists in the vaginal use of cones or balls. To date, no systematic review has focused on the use of these devices specifically during the postpartum period. A Cochrane review looked into the effectiveness of cones or balls for urinary incontinence and included postpartum women (Herbison and Dean, 2013). Another Cochrane review by Boyle et al. (2012) and a systematic review by Mørkved and Bø (2014) looked into the effectiveness of pelvic floor muscle training during and after pregnancy and included cones amongst

other forms of training. Urinary incontinence was used as a primary outcome in all three reviews; studies having solely considered pelvic floor muscle strength as an outcome in continent women were excluded from the Cochrane reviews, whereas the use of this outcome is not made explicit in Mørkved and Bø (2014). Pelvic floor muscle strength in continent women as an outcome was used in a systematic review on the prevention of pelvic floor dysfunction around childbirth by Harvey (2003). However, this review also only included cones amongst other pelvic floor muscle rehabilitation methods, it excluded studies on the treatment of urinary incontinence, and it would now be useful to search for more recent articles to update this review's findings.

Thus, a systematic review was needed which focused on (1) the vaginal use of cones or balls as a pelvic floor muscle rehabilitation method (2) in the postpartum period, and (3) used both pelvic floor muscle performance and urinary (in)continence as primary outcomes to estimate effectiveness of device use.

Objectives and research question

The objective was to compare the effectiveness of vaginal balls or cones for improvement of pelvic floor muscle performance and urinary continence in the postpartum period to no treatment, placebo, sham treatment or active controls (e.g. pelvic floor muscle exercises). A secondary objective was to gather information on effect on perineal descent or pelvic organ prolapse, adverse effects, and economic aspects.

The research question was developed using the PICO (population – intervention – comparison – outcome)-framework outlined by O'Connor et al. (2011): *Does the vaginal use of cones or balls by women in the postpartum period improve performance of the pelvic floor muscles and urinary continence, compared to no treatment, placebo, sham treatment or active controls?* Randomised and quasi-randomised studies have been considered to answer this question.

METHODS

Review protocol and registration

The review was registered at *PROSPERO – International prospective register of systematic reviews* in health and social care on 16 January, 2014, under the number CRD42014006165 (Oblasser et al., 2014a). Minor modifications to the protocol have been made during the review; details including the rationale can be seen under the *PROSPERO* registration link. The final protocol pre-specifiying the detailed methodology of the review has been published (Oblasser et al., 2014b). The review kept to the published protocol; however, as a meta-analysis was not possible, reanalyses of the raw data were performed instead to meet the primary study objective.

Design

This is a quantitative systematic review on the basis of the guidance on systematic reviews of interventions by the Cochrane Collaboration (Higgins et al., 2011b).

Eligibility criteria

Inclusion and exclusion criteria were developed on the basis of the PICOS (PICO plus study design)-scheme of the PRISMA Statement (Liberati et al., 2009). The types of participants, interventions, comparisons, outcome measures and study designs, and report characteristics included in and excluded from this systematic review are listed in the following.

Types of studies

Randomised and quasi-randomised controlled trials with individual or cluster randomisation and parallel design were included. Blinding of participants is not possible for this intervention.

Types of participants

- Women up to one year after childbirth at the time of beginning the intervention, of any parity, mode of birth and birth injuries, with or without urinary incontinence, were included.
- Pregnant women, women with anal incontinence or major genitourinary/pelvic morbidity were excluded.

Types of interventions

Vaginal use of cones or balls.

Inclusion criteria:

- cone or ball use of any frequency and duration, and of any method (combined with exercises or not)
- cones or balls of any form, size, weight or brand
- with any method of instruction (advised by any health practitioner or self-taught by information material).

Types of comparison

Comparison could be made with physiological restitution (no device or treatment) or any form of pelvic floor muscle training, e.g. physiotherapy individually or in group, or pelvic floor muscle exercises at home.

Types of outcome measures

Outcomes should be measured immediately after the intervention, or be longer-term follow-up data.

Primary outcomes

Either one or both of these:

- pelvic floor muscle performance (e.g. strength, endurance), determined using a valid and reliable measure, e.g. vaginal squeeze pressure or participant reported improvement
- urinary (in)continence, determined using a valid and reliable measure, e.g. quantified symptoms or urodynamics.

Secondary outcomes

- perineal descent or pelvic organ prolapse as assessed by standardised clinical methods
- adverse effects, e.g. discomfort or pain during or after the intervention, or vaginitis, as determined in each of the included studies
- health economics, e.g. cost of interventions or teaching time, as determined in each of the included studies.

Report characteristics

There were no language, publication period or publication status restrictions.

Search methods

The searches took take place between 26 February and 28 September 2014. Studies were searched and selected by the first (CO) and second (JC) reviewer independently screening titles and abstracts of the citations found in searches. Studies were included if they fulfilled the above defined PICOS criteria. Disagreements were resolved by consensus. Search protocols were recorded and retained.

Electronic searches

Bibliographic databases searched can be seen in table 1. The search strategy used for PubMed (the most complex database), comprising searches for synonymous textwords and subject headings and their combination by Boolean operators, is given in table 2. In addition to the focus on cones and balls, search terms for the intervention have been collected with a wider view on pelvic floor muscle exercises in general. This was done not to miss articles mentioning the relevant terms only in their full text as some articles were found not to have relevant terms in the title or abstract (and in any other of the fields searched by an [all fields]-search in PubMed) when preliminary searches were undertaken as part of search strategy development work. For the same reason, study design is not included in the search strategy. This PubMed search strategy was adapted according to the search functions and complexity of each database.

Citation searching was performed via SCOPUS, web of science and the “cited by”-link in databases. The Bielefeld Academic Search Engine (BASE) and Google Scholar helped search the world-wide web, and the web sites of the International Continence Society (ICS) and cone or ball manufacturers were screened.

Searching other resources

References of similar reviews and trial reports identified for data extraction were screened to identify further relevant studies. Authors of these reports were asked if they knew of relevant work.

Data collection and analysis

Study selection

Titles and abstracts of records identified by the searches were screened. For the articles considered potentially eligible, full-texts were purchased. Both reviewers checked eligibility.

Data extraction and management

Data were extracted from selected studies using a piloted standard data extraction form adapted from the data extraction form templates of the The Cochrane Pregnancy and Childbirth Group (n.y.) and The Cochrane Editorial Resources Committee (2013). This included specific details on study characteristics concerning methodology, participants, intervention, comparison and analysis, as well as results and conclusions. Attempts were made to contact the authors of studies for clarification of incomplete information or to obtain any missing data. Data were extracted by the lead reviewer and cross-checked by the second reviewer.

Assessment of risk of bias in included study

Risk of bias was assessed by the first and second reviewer independently using the "Risk of bias assessment tool" of the Cochrane Collaboration (Higgins et al., 2011a). Assessment within domains was made for each outcome and judged into the

categories low, unclear and high risk of bias. Assessments made by reviewers were compared and disagreements were resolved by consensus.

Measures of treatment effect

Relative risks (RR) with 95% confidence intervals (CI) were calculated for dichotomous data, and differences in means (MD) with standard deviations (SD) for continuous data.

Unit of analysis issues

The unit of analysis was individuals.

Data synthesis

As only one study was included, a data synthesis by meta-analysis was not possible and a narrative review was undertaken as planned in the protocol. However, a secondary analysis of raw data enabled to directly address the question of this systematic review.

Data were analysed using an online percentage calculator (LISSWORX, 2014) and the computer programmes *MedCalc 12.5* (Software, 2014) and *SPSS 21 and 22* (IBM Corporation, 2012/13); power calculations were performed via *G*Power 3.1* (Faul et al., 2007, Buchner et al., 2013). Comparative analyses used the chi-squared test for dichotomous data, and Mann-Whitney and independent t-tests for continuous data. Intention-to-treat analysis was performed with available data, with the main analysis for the primary outcome urinary incontinence and exploratory analyses for the outcomes pad test and perineometric measurements. A sensitivity analysis with a best/worse case scenario (single imputation) for urinary incontinence was performed to help determine the robustness of the results.

RESULTS

Description of studies

Results of the search

By the search techniques used, 37 potentially useful articles were identified out of 1324 records screened. The PRISMA flow chart (Liberati et al., 2009) documents the literature assessment and selection process in figure 1.

Included study

Only one study (Wilson and Herbison, 1998) met the inclusion criteria and was included in the review, its characteristics are described in table 3. The set of cones used consisted of nine cones of identical shape and volume but of increasing weight from 20 to 100g. Each participant, starting with the heaviest weight she could retain without voluntary holding, was instructed to keep the cone in her vagina for 15 minutes twice a day. Once she was successful on two consecutive occasions she proceeded to the next heaviest cone (Wilson and Borland, 1990).

Excluded records

36 records were excluded; seven (Spreafico, 1992, Cox, 1995, Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women, 2009, Bø, 2011, Duffin, 2012, Rathfisch and Kızılkaya Bejı, 2012, Freeman, 2013) because they were not primary studies, and 24 (Sleep and Grant, 1987, Dougherty et al., 1989, 1998, Glazener et al., 2001, Meyer et al., 2001, Sanlorenzo et al., 2001, Chiarelli and Cockburn, 2002, Chiarelli et al., 2004, Dumoulin, 2004, Dumoulin et al., 2004, Gorbea Chavez et al., 2004, Erratum, 2005, Ewings et al., 2005, Glazener et al., 2005, Lee and Choi, 2006, Citak et al., 2010, Sheeba et al., 2011, Kim et al., 2012, Ahlund et al., 2013, Assis et al., 2013,

Dumoulin et al., 2013, Hilde et al., 2013, Peirce et al., 2013, Glazener et al., 2014) because they did not research the use of cones or balls but the usual pelvic floor exercises without device. Fischer and Baessler (1996) and Fischer et al. (1996) (same study) was not a randomised controlled trial; in Jonasson et al. (1992), women were at least two years post partum. Two studies corresponding to the PICOS criteria were excluded during data extraction: Jonasson et al. (1989) used a method for measuring pelvic floor muscle strength later shown to be of questionable validity (Hahn et al., 1996) and not in use any more; Norton and Baker (1990) was an only abstract which did not provide enough information to be reviewed, and the attempts to contact the authors for clarification of incomplete information were unsuccessful.

Risk of bias in included study

The risks of bias of the included study are presented in table 4. There is a high risk for performance, detection, and attrition bias, an uncertain risk of selection bias for uncertain allocation concealment, and otherwise a low risk of bias.

Secondary analysis

In the included study (Wilson and Herbison, 1998), the authors had compared usual pelvic floor care after childbirth with an intervention group comprising three different interventions, one of them being the use of cones. They kindly provided the raw data set and thus, reanalyses could be performed by the review authors to compare the cone group to the specific groups of interest.

Effects of interventions

The results of the reanalysis are shown in table 5. Compared to the control group, the cone group shows a statistically significant lower rate of the primary outcome urinary incontinence at 12 months post partum (RR 0.63, p = 0.022), but an almost same rate of urinary incontinence in the cone group cannot be excluded (95% CI 0.40-0.998). Exploratory analyses of pad test and perineometry measurements do not support the difference found for urinary incontinence (all p-values > 0.05). Compared to the exercise group, the prevalence of urinary incontinence in the cone group is similar (RR 1.01, p = 1.000), but a prevalence of urinary incontinence half or almost twice as high in the cone group cannot be excluded (95% CI 0.52-1.93). Exploratory analyses of pad test and perineometry measurements support these findings (all p-values > 0.05 showing no statistically significant difference between cone and exercise group).

This study had a high dropout rate, therefore it was important to consider the potential impact of dropout on the findings. The possible impact of dropout was re-calculated as originally presented by Wilson and Herbison (1998). If all the participants who were not followed up were assumed to be incontinent, then the prevalence of urinary incontinence would have been 81% in the control group, 69% in the cone group, and 74% in the exercise group. The group comparisons would then give the following results: cone group versus control group RR (95% CI) = 0.86 (0.68-1.08) (x^2 = 1.607, df = 1, p = 0.205), not showing any difference and effect of cone use; cone group versus exercise group RR (95% CI) = 0.93 (0.70-1.24) (x^2 = 0.047, df = 1, p = 0.829), not showing any difference between the treatments. If the participants who were not followed up were all assumed to be continent, then the prevalence of urinary incontinence would have been 59% in the control group, 28%

in the cone group, and 23% in the exercise group. The group comparisons would then give these results: cone group versus control group RR (95% CI) = 0.47 (0.27-0.81) (x^2 = 9.5, df = 1, p = 0.002), showing a greater effect of cone treatment than the complete case analysis; cone group versus exercise group RR (95% CI) = 1.20 (0.55-2.62) (x^2 = 0.041, df = 1, p = 0.840), not showing any difference between the treatments.

After 24-44 months and in women without further pregnancy or treatment, urinary incontinence shows a prevalence of 54% in the control group, 68% in the cone group, and 50% in the exercise group, whereby only 33% (32/53/51%) of the original participants could be followed up. The cone group versus control group comparison gives a RR (95% CI) of 1.27 (0.83-1.94) (x^2 = 0.56, df = 1, p = 0.455), while the cone group versus exercise group comparison gives a RR (95% CI) of 1.37 (0.80-2.33) (x^2 = 0.71, df = 1, p = 0.399), not showing any differences between the groups.

Secondary outcomes

There was no statistically significant difference found in total teaching time (not applicable to control group) between the cone and exercise groups: cone group 114 minutes (SD 14.62), exercise group 120 minutes (SD 15.43); MD 6.00 (95% CI -3.16-15.16), t = 1.32, df = 42, p = 0.193.

DISCUSSION

Main findings

Only one study fitted the criteria and is included in this systematic review. Its data were reanalysed to provide distinct comparisons between the interventions of interest according to the aims of this review. Compared to the control group, the cone group shows a statistically significant lower rate of the main outcome urinary incontinence at 12 months post partum. When compared to the exercise group, the prevalence of urinary incontinence in the cone group is similar. Not all exploratory and sensitivity analyses support the results of the main analysis. Table 6 gives an overview of the different analyses performed and their results.

24-44 months after birth, no difference in urinary incontinence prevalence between groups can be identified, but the follow-up rates were low. Teaching time is the only secondary outcome reported, not showing a difference between relevant groups.

Strengths and limitations

Considering the extensive search strategy of this review, there is a high likelihood that all relevant studies were identified; reporting bias may be present nevertheless. Two studies corresponding to the PICOS criteria had to be excluded, one for a questionable method of measurement, the other for lack of information. Consequently, only one study was included, and only urinary incontinence was analysed as a main outcome.

A secondary intention-to-treat analysis was performed on Wilson and Herbison´s (1998) data in order to meet the systematic review objective. Its validity however, is limited by its low post hoc power, being 65% and 3% for prevalence of urinary incontinence in the comparisons cone vs. control and cone vs. exercise group, respectively. There was a high rate of withdrawals, especially in the cone and exercise groups, potentially leading to attrition bias. Also, comparing the cone and control group in the way the reanalysis does carries a new high risk for performance bias (which does not apply to the original study with a different aim and analysis): in addition to using cones as a different method of muscle rehabilitation, the cone group (as one of the enforced exercise regimen groups) received four sessions with a physiotherapist that were not part of the usual pelvic floor muscle care of the control group. The statistically significant effect found in the main analysis is not large, and all the results show (very) wide confidence intervals.

Further limitations at review level equal those on study and outcome level. The nature of the intervention makes blinding of participants to group allocation impossible, potentially leading to performance bias by device users themselves or to detection bias (under- or overestimation of effect) in self-rating by users. Performance bias could also have been introduced by the higher amount of adherence in the enforced regimen groups compared to the control group; even the cone group participants reported doing pelvic floor muscle exercises although this was not part of the protocol. The repeatability, reliability and sensitivity of short pad tests are critically discussed (Moore and Karantanis, 2008, National Collaborating Centre for Women´s and Children´s Health, 2013), as issues are raised around the validity and reliability of perineometric measurements (Bø and Sherburn, 2005, Bø et al., 2007). Information about harm was not obtained.

Interpretation

The available evidence consists of one study with 192 relevant participants. Key methodological limitations of this study are a high risk for performance and attrition bias for all outcomes, a high risk for detection bias for the outcome urinary incontinence, and an additional high risk for performance bias in the cone vs. control group comparisons. According to Higgins et al. (2011a, table 8.7.a), this amount of bias has to be interpreted as “plausible bias that seriously weakens confidence in the results”.

Considering the comparison of cone vs. control group, where an effect of cone use and thus a difference between the groups is desired, the difference shown in the main analysis is supported by the sensitivity analysis assuming overall continence. However, the better outcome of the cone group could not only be caused by the use of cones itself but also by the performance bias introduced in this comparison by the additional professional support in the cone group compared to the control group. The exploratory analyses and the sensitivity analysis assuming overall incontinence do not support this result, and do not find any difference even with this potential performance bias towards cones.

Considering the comparison of cone vs. exercise group (in this comparison a difference is not necessarily desired as equal performance can provide options for postnatal women), the lack of a difference detected between the groups in the main analysis is supported by exploratory and sensitivity analyses. However, the power of this comparison is only 3%, and a true difference could exist which was not found as this comparison was underpowered. Likewise, the low follow-up rates at 24-44 months suggest a strong possibility of underpowered comparisons.

Nevertheless, the results of this review are in agreement with the results of the Cochrane review by Herbison and Dean (2013), which included but did not focus on postpartum interventions. These authors provided some evidence that weighted vaginal cones are more useful than no active treatment for urinary incontinence (not specifically post partum), and might be of similar effectiveness to pelvic floor muscle exercises.

CONCLUSION

The novel aspect of this systematic review lies in being, to the authors´ knowledge, the first one to look at the vaginal use of balls or cones specifically during the postpartum period, and with both pelvic floor muscle performance and urinary continence as intended primary outcomes to estimate effectiveness of device use. The information gained from this systematic review is useful to help with promotion of pelvic floor health and of concern to health professionals working in the field of obstetrics and gynaecology, women after childbirth, and researchers. If cones or balls were shown to be effective in the postpartum period, women in this period of life would have more evidence-based options regarding pelvic floor muscle rehabilitation. The scientific evidence gained from this systematic review is very limited, as only one study met the inclusion criteria, and a reanalysis of the raw data from this study had to be performed to obtain the desired information. This reanalysis is limited by different kinds of bias inherent in the data available, which means its results cannot be considered robust. The body of evidence identified for this systematic review therefore was not sufficient to answer the review question satisfactorily.

Implications for practice

The available results suggest that the use of vaginal cones might be helpful for urinary incontinence after childbirth. However, the findings of this review alone are not robust enough on which to base a recommendation for or against the use of cones. No information regarding other devices than the cones used in the only included study can be given.

Implications for research

This systematic review points to the need for further research to determine the effectiveness of vaginal balls or cones for improvement of pelvic floor muscle performance and urinary continence in the postpartum period compared to no treatment, placebo, sham treatment or active controls. High quality randomised controlled trials are the desirable research design, although the potential for high study dropout rates must be considered.

REFERENCES

Reference to the study included in this review

Wilson, P. D., Herbison, G. P., 1998. A randomized controlled trial of pelvic floor muscle exercises to treat postnatal urinary incontinence. International Urogynecology Journal 9(5), 257 -264.

References to records excluded from this review

Ahlund, S., Nordgren, B., Wilander, E. L., Wiklund, I., Friden, C., 2013. Is home-based pelvic floor muscle training effective in treatment of urinary incontinence after birth in primiparous women?

A randomized controlled trial Pelvic floor muscle training in urinary incontinence. Acta Obstetricia et Gynecologica Scandinavica 92(8), 909 -915.

Assis, T. R., Sá, A. C. A. M., Amaral, W. N., Batista, E. M., Formiga, C. K. M. R., Conde, D. M., 2013. Efeito de um programa de exercícios para o fortalecimento dos músculos do assoalho pélvico de multíparas [The effect of an exercise program to strengthen pelvic floor muscles in multiparous women]. Revista Brasileira de Ginecologia e Obstetrícia 35⁀1⁀, 10-15.

Bø, K., 2011. Evidence for pelvic floor muscle training during pregnancy and after childbirth: to do or not to do? Australian & New Zealand Continence Journal 17(4), 121 -122.

Chiarelli, P., Cockburn, J., 2002. Promoting urinary continence in women after delivery: randomised controlled trial. BMJ 324(7348), 1241 -1244.

Chiarelli, P., Murphy, B., Cockburn, J., 2004. Promoting urinary continence in postpartum women: 12-month follow-up data from a randomised controlled trial. International Urogynecology Journal 15(2), 99 -105.

Citak, N., Cam, C., Arslan, H., Karateke, A., Tug, N., Ayaz, R., Celik, C., 2010. Postpartum sexual function of women and the effects of early pelvic floor muscle exercises. Acta Obstetricia et Gynecologica Scandinavica 89(6), 817 -822.

Cox, S., 1995. Kegel exercises. International Journal of Childbirth Education 10(1), 34 -36.

Dougherty, M. C., Bishop, K. R., Abrams, R. M., Batich, C. D., Gimotty, P. A., 1989. The effect of exercise on the circumvaginal muscles in postpartum women. Journal of Nurse-Midwifery 34(1), 8 -14.

Duffin, C., 2012. Postnatal exercise improves muscle tone and relieves back pain. Primary Health Care 22(10), 7 -8.

Dumoulin, C., 2004. Efficacité des traitements physiotherapiques pour l'incontinence urinaire d'effort chez la femme en période postnatale [Effectiveness of physiotherapeutic treatments for stress urinary incontinence in women post partum]. PhD Thesis. Université de Montréal, Montréal (Canada).

Dumoulin, C., Lemieux, M., Bourbonnais, D., Gravel, D., Bravo, G., Morin, M., 2004. Physiotherapy for persistent postnatal stress urinary incontinence: a randomized controlled trial. Obstetrics and Gynecology 104(3), 504 -510.

Dumoulin, C., Martin, C., Elliott, V., Bourbonnais, D., Morin, M., Lemieux, M. C., Gauthier, R., 2013. Randomized controlled trial of physiotherapy for postpartum stress incontinence: 7-year follow-up. Neurourology and Urodynamics 32(5), 449 -454.

Erratum. 2005. Journal of Obstetrics & Gynaecology 25(8), 834 -835.

Ewings, P., Spencer, S., Marsh, H., O'Sullivan, M., 2005. Obstetric risk factors for urinary incontinence and preventative pelvic floor exercises: cohort study and nested randomized controlled trial. Journal of Obstetrics & Gynaecology 25(6), 558 -564.

Fischer, W., Baessler, K., 1996. Postpartum pelvic floor conditioning using vaginal cones: not only for prophylaxis against urinary incontinence and descensus. International Urogynecology Journal and Pelvic Floor Dysfunction 7(4), 208 -214.

Fischer, W., Baessler, K., Linde, A., 1996. Beckenbodenkonditionierung mit Vaginalgewichten ' post partum und bei Harninkontinenz [Pelvic floor conditioning with vaginal weights ' post partum and in urinary incontinence]. Zentralblatt für Gynäkologie 118⁀1⁀, 18-28.

Freeman, R. M., 2013. Can we prevent childbirth-related pelvic floor dysfunction? BJOG 120(2), 137-140.

Glazener, C. M., Herbison, G. P., MacArthur, C., Grant, A., Wilson, P. D., 2005. Randomised controlled trial of conservative management of postnatal urinary and faecal incontinence: six year follow up. BMJ 330(7487), 337.

Glazener, C. M., Herbison, G. P., Wilson, P. D., MacArthur, C., Lang, G. D., Gee, H., Grant, A. M., 2001. Conservative management of persistent postnatal urinary and faecal incontinence: randomised controlled trial. BMJ 323(7313), 1 -5.

Glazener, C. M., MacArthur, C., Hagen, S., Elders, A., Lancashire, R., Herbison, G. P., Wilson, P. D., 2014. Twelve-year follow-up of conservative management of postnatal urinary and faecal incontinence and prolapse outcomes: randomised controlled trial. BJOG 121(1), 112 -120.

Gorbea Chavez, V., Velazquez Sanchez Mdel, P., Kunhardt Rasch, J. R., 2004. Efecto de los ejercicios del piso pelvico durante el embarazo y el puerperio en la prevencion de la incontinencia urinaria de esfuerzo [Effect of pelvic floor exercise during pregnancy and puerperium on prevention of urinary stress incontinence]. Ginecologia y Obstetricia de Mexico 72(12), 628 -636.

Hilde, G., Staer-Jensen, J., Siafarikas, F., Ellström Engh, M., Bø, K., 2013. Postpartum pelvic floor muscle training and urinary incontinence: A randomized controlled trial. Obstetrics and Gynecology 122(6), 1231 -1238.

Jonasson, A., Fianu, S., Larsson, B., 1992. Vagitrim - nytt, enkelt jhälpmedel för effektiv träning av bäckenbottenmuskulatur [Vagitrim - a new, simple aid for effective training of pelvic floor muscles]. Lakartidningen 89(36), 2820.

Jonasson, A., Larsson, B., Pschera, H., 1989. Testing and training of the pelvic floor muscles after childbirth. Acta Obstetricia et Gynecologica Scandinavica 68(4), 301 -304.

Kim, E. Y., Kim, S. Y., Oh, D. W., 2012. Pelvic floor muscle exercises utilizing trunk stabilization for treating postpartum urinary incontinence: randomized controlled pilot trial of supervised versus unsupervised training. Clinical Rehabilitation 26(2), 132 -141.

Lee, I. S., Choi, E. S., 2006. Pelvic floor muscle exercise by biofeedback and electrical stimulation to reinforce the pelvic floor muscle after normal delivery. Taehan Kanho Hakhoe Chi 36(8), 1374-1380.

Meyer, S., Hohlfeld, P., Achtari, C., De Grandi, P., 2001. Pelvic floor education after vaginal delivery. Obstetrics and Gynecology 97(5 Pt 1), 673 -677.

Norton, P., Baker, J., 1990. Randomized prospective trial of vaginal cones vs. Kegel exercises in postpartum primiparous women. Neurourology and Urodynamics 9(4), 434 -435.

Peirce, C., Murphy, C., Fitzpatrick, M., Cassidy, M., Daly, L., O'Connell, P., O'Herlihy, C., 2013. Randomised controlled trial comparing early home biofeedback physiotherapy with pelvic floor exercises for the treatment of third-degree tears (EBAPT trial). BJOG 120(10), 1240 -1245.

Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women. 2009. Midwifery News (52), 32.

Rathfisch, G., Kızılkaya Beji, N., 2012. Protection of continence in pregnancy, labor and postpartum periods. International Journal of Urological Nursing 6(3), 100 -106.

Sampselle, C. M., Miller, J. M., Mims, B. L., Delancey, J. O., Ashton-Miller, J. A., Antonakos, C. L., 1998. Effect of pelvic muscle exercise on transient incontinence during pregnancy and after birth. Obstetrics and Gynecology 91(3), 406 -412.

Sanlorenzo, O., Stagnozzi, R., Santarsiero, G., Bovicelli, L., 2001. Training dei muscoli perineali: Valutazione a tre mesi dal parto [Training of the perineal muscles: Evaluation three months after delivery]. Urogynaecologia International Journal 15(1 SUPPL.), 42 -45.

Sheeba, T. T., Raddi, S. A., Ballad, M. B., 2011. A hospital based randomized controlled trial to evaluate the effectiveness of Kegel's exercise on postpartum perineal laxity. Journal of the South Asian Federation of Obstetrics and Gynecology 3(3), 157 -159.

Sleep, J., Grant, A., 1987. Pelvic floor exercises in postnatal care. Midwifery 3(4), 158 -164.

Spreafico, L., 1992. La rieducazione nel post-partum [Re-education during post-partum]. Europa Medicophysica 28(2), 85 -88.

Additional references

Abrams, P., Andersson, K. E., Birder, L., Brubaker, L., Cardozo, L., Chapple, C., Cottenden, A., Davila, W., de Ridder, D., Dmochowski, R., Drake, M., DuBeau, C., Fry, C., Hanno, P., Hay Smith, J., Herschorn, S., Hosker, G., Kelleher, C., Koelbl, H., Khoury, S., Madoff, R., Milsom, I., Moore, K., Newman, D., Nitti, V., Norton, C., Nygaard, I., Payne, C., Smith, A., Staskin, D., Tekgul, S., Thuroff, J., Tubaro, A., Vodusek, D., Wein, A., Wyndaele, J. J., 2010. Fourth international consultation on incontinence recommendations of the international scientific committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. Neurourology and Urodynamcis 29(1), 213 -240.

Bø, K., Berghmans, B., Mørkved, S., Van Kampen, M. (Eds.), 2007. Evidence-Based Physical Therapy for the Pelvic Floor. Churchill Livingstone, Edinburgh.

Bø, K., Sherburn, M., 2005. Evaluation of female pelvic-floor muscle function and strength. Physical Therapy 85(3), 269 -282.

Boyle, R., Hay-Smith, E. J., Cody, J. D., Mørkved, S., 2012. Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women. Cochrane Database of Systematic Reviews (10), CD007471. DOI: 10.1002/14651858.CD007471.pub2.

Buchner, A., Erdfelder, E., Faul, F., Lang, A.-G., 2013. G*Power for Windows (Version 3.1) . Available at: http://www.gpower.hhu.de/ (Accessed: 17 Jan 2014).

Faul, F., Erdfelder, E., Lang, A.-G., Buchner, A., 2007. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior Research Methods 39(2), 175 -191.

Hahn, I., Milsom, I., Ohlsson, B. L., Ekelund, P., Uhlemann, C., Fall, M., 1996. Comparative assessment of pelvic floor function using vaginal cones, vaginal digital palpation and vaginal pressure measurements. Gynecologic and Obstetric Investigation 41(4), 269 -274.

Harvey, M. A., 2003. Pelvic floor exercises during and after pregnancy: a systematic review of their role in preventing pelvic floor dysfunction. Journal of Obstetrics and Gynaecology Canada 25(6), 487 -498.

Herbison, P. G., Dean, N., 2013. Weighted vaginal cones for urinary incontinence. Cochrane Database of Systematic Reviews (7), CD002114. DOI: 10.1002/14651858.CD002114.pub2.

Higgins, J. P. T., Altman, D. G., Sterne, J. A. C., 2011a. Assessing risk of bias in included studies. In: Higgins, J.P.T., Green, S. (Eds.), Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). Chapter 8. Available at: www.cochrane-handbook.org (Accessed: 22 Feb 2014).

Higgins, J. P. T., Green, S., (Eds.) 2011b. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 201 1). The Cochrane Collaboration. Available at: www.cochrane-handbook.org (Accessed: 22 Feb 2014).

IBM Corporation, 2012/13. IBM SPSS Statistics for Windows (Version 21.0 and 22.0) [Computer program].

Liberati, A., Altman, D. G., Tetzlaff, J., Mulrow, C., Gøtzsche, P. C., Ioannidis, J. P. A., Clarke, M., Devereaux, P. J., Kleijnen, J., Moher, D., 2009. The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Health Care Interventions: Explanation and Elaboration, PLoS Medicine 6(7), pp. e1000100. DOI: 10.1371/journal.pmed.1000100.

LISSWORX, 2014. Online Prozentrechner. Available at: http://www.prozentrechner.net/ (Accessed: 16 Oct 2014).

Moore, K. H., Karantanis, E., 2008. Outcome Measures in Pelvic Floor Rehabilitation. In: Baessler, K., Schüssler, B., Burgio, K.L., Moore, K.H., Norton, P.A. & Stanton, S.L. (Eds.), Pelvic Floor Re-education, 2nd ed. Springer, London. pp. 162-174.

Mørkved, S., Bø, K., 2014. Effect of pelvic floor muscle training during pregnancy and after childbirth on prevention and treatment of urinary incontinence: a systematic review. British Journal of Sports Medicine 48(4), 299 -310.

National Collaborating Centre for Women´s and Children´s Health, 2013. Urinary Incontinence in Women: the Management of Urinary Incontinence in Women, 2nd edn. London: Royal College of Obstetricians and Gynaecologists. Available at: http://www.nice.org.uk/guidance/cg171/evidence/cg171-urinary-incontinence-in-women-full-guideline3 (Accessed: 27 March 2015).

O'Connor, D., Green, S., Higgins, J. P. T., 2011. Defining the review question and developing criteria for including studies. In: Higgins, J.P.T., Green, S. (Eds.), Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). Chapter 5. Available at: http://handbook.cochrane.org/ (Accessed: 22 Feb 2014).

Oblasser, C., Christie, J., McCourt, C., 2014a. Vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum: a quantitative systematic review, PROSPERO, CRD42014006165. Available at: http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014006165#.VHDpHcl0CCc (Accessed: 27 March 2015).

Oblasser, C., Christie, J., McCourt, C., 2014b. Vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women postpartum: a quantitative systematic review and meta-analysis protocol. Journal of Advanced Nursing 71(4), 933 -941.

Software, M., 2014. MedCalc for Windows (Version 14.10.2) . Available at: http://www.medcalc.org/calc/relative_risk.php (Accessed: 28 Oct 2014).

The Cochrane Editorial Resources Committee, 2013. Data Collection Form (V2) . Available at: http://training.cochrane.org/authors/resources/checklists-and-forms (Accessed: 8 Nov 2014).

The Cochrane Pregnancy and Childbirth Group, n.y. Data Extraction Form. Available at: http://pregnancy.cochrane.org/author-resources-new-reviews (Accessed: 1 Nov 2014).

The Joanna Briggs Institute, 2011. The Joanna Briggs Institute Best Practice Information Sheet: The effectiveness of pelvic floor muscle exercises on urinary incontinence in women following childbirth. Nursing and Health Sciences 13(3), 378 -381.

Torgerson, D., 2014. Sources of Bias in Randomised Controlled Trials [Power Point Presentation]. York Trials Unit, York.

Wilson, P. C., Borland, M., 1990. Vaginal cones for the treatment of genuine stress incontinence. Australian and New Zealand Journal of Obstetrics and Gynaecology 30(2), 157 -160.

Table 1: Databases searched

For published reports:

- Cochrane Central Register of Controlled Trials (CENTRAL)
- PubMed
- Embase
- Maternity and Infant Care Database
- CINAHL
- PEDro
- POPLINE
- AMED
- Index Medicus for the South-East Asian Region (IMSEAR)

For grey literature:

- Conference Proceedings Citation Index
- ProQuest Dissertations & Theses Full Text

For citation searching:

- SCOPUS
- Web of Science
- “cited by”-link in databases

For ongoing studies:

- WHO International Clinical Trials Registry Platform (ICTRP)

Table 2: PubMed search strategy

Filter: Humans

1. post part* OR postpart* OR post natal* OR postnatal* OR "lying in" OR puerper* OR childbirth* OR birth* OR deliver* OR "Postpartum Period"[Mesh:NoExp]
2. cone* OR ball OR balls OR beads OR Kegel exerciser* OR weight* OR device* OR aid OR “aids” OR "Resistance Training"[Mesh]

   (beads and Kegel exerciser are synonyms found for balls, weight is sometimes used for cone/ball)
3. "pelvic floor" OR "pelvic hammock" OR pelvic muscle* OR "pelvic musculature" OR vaginal muscle* OR "vaginal musculature" OR circumvaginal muscle* OR "circumvaginal musculature" OR perivaginal muscle* OR "perivaginal musculature" OR levator OR pubococcyge* OR "pelvic diaphragm" OR perine* OR Kegel OR "Pelvic Floor"[Mesh] OR "Perineum"[Mesh]
4. train* OR exercis* OR educat* OR re-educat* OR reeducat* OR rehabilitat* OR restor* OR conditioning OR "Exercise"[Mesh:NoExp] OR "Exercise Therapy"[Mesh:NoExp] OR “Rehabilitation"[Mesh:NoExp] OR "Education"[Mesh:NoExp]
5. 3 AND 4
6. 2 OR 5
7. "pelvic floor" OR "pelvic hammock" OR pelvic muscle* OR "pelvic musculature" OR vaginal muscle* OR "vaginal musculature" OR circumvaginal muscle* OR "circumvaginal musculature" OR perivaginal muscle* OR "perivaginal musculature" OR levator OR pubococcyge* OR "pelvic diaphragm" OR perine* OR "Pelvic Floor"[Mesh] OR "Perineum"[Mesh]
8. performance OR strength* OR “pressure” OR endurance OR tone OR toning

OR tonus OR function* OR “activity” OR force OR “power” OR contraction* OR contractility OR stiffness OR "Muscle Strength"[Mesh:NoExp] OR "Physical Endurance"[Mesh:NoExp] OR "Muscle Tonus"[Mesh] OR "Muscle Contraction"[Mesh:NoExp]

9. 7 AND 8
10. “urinary stress incontinence” OR “stress urinary incontinence” OR urinary incontinen* OR stress incontinen* OR effort incontinen* OR “involuntary urination” OR “leaking of urine” OR “leakage of urine” OR urinary leak* OR urine leak* OR urinary continen* OR "Urinary Incontinence"[Mesh]
11. 9 OR 10
12. 1 AND 6 AND 11

Explanation:

- unless indicated as search for a Medical Subject Heading by [Mesh], terms are searched as textwords by [all fields]
- NoExp = no explosion used for Medical Subject Heading
- * = truncation
- speech marks are used to prompt a phrase search and an only [all fields]-search respectively

Figure 1: PRISMA flow chart [11]

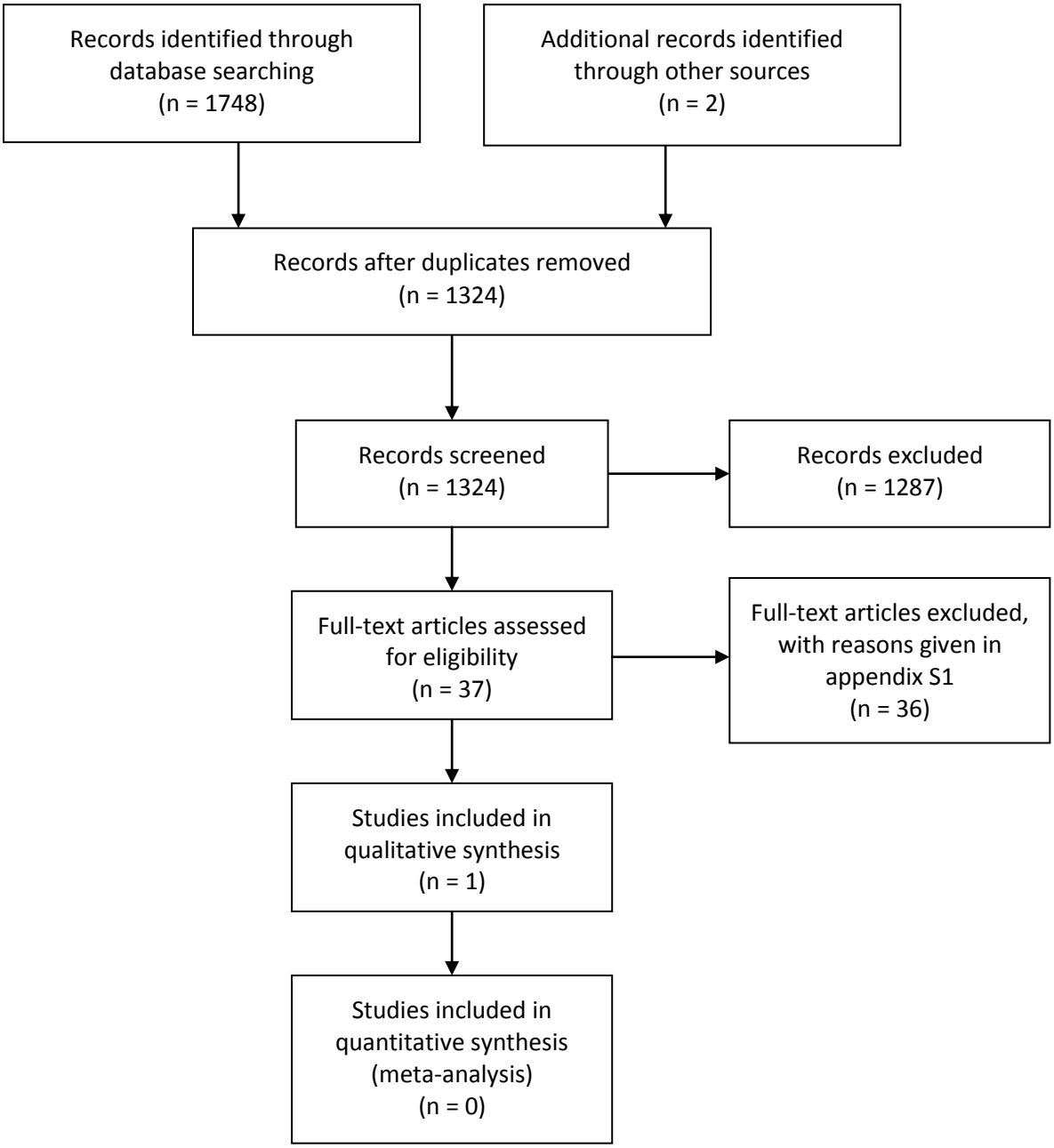

Table 3: Characteristics of included study

Methods	– Randomised controlled trial – 2 parallel study arms (one arm with 3 subgroups) with women who had incontinence 3 months postpartum
Participants	– 230 women with symptoms of incontinence 3 months post partum – New Zealand hospital maternity centre
Interventions	– Control (comparison) group (n = 117): standard postpartum pelvic floor care/muscle exercises: daily instruction by physiotherapist on pelvic floor muscle exercises in small groups (approximately 6 women) from the second postnatal day, or an audiotape at weekends, during hospital stay – Intervention groups (n = 113): enforced exercise regimen with physiotherapist with 1 training session and 3 follow-up visits at 3, 6, and 9 months post partum; factorial design with 3 subgroups: (1) Pelvic floor muscle exercises (n = 39): fast and slow contractions with aim of 100/day (2) Cones (n = 36): use of cones as described in text (3) Both (n = 38): both use of cones and pelvic floor muscle exercises
Outcomes	Outcomes measured at 12 months post partum: – Self-reported urinary incontinence – Pelvic floor muscle strength (maximum and sustained

	value by perineometry measurements) – 1-hour home pad test – Teaching time – Frequency and amount of pelvic floor muscle exercises – Self-reported faecal incontinence – Feelings of general wellbeing – Sexual satisfaction Outcomes measured at 24-44 months post partum: – Self-reported urinary incontinence – Frequency and amount of pelvic floor muscle exercises

Table 4: Risk of bias in included study

Domain	Support for judgement	Review authors' judgement
Selection Bias		
Random sequence generation	"Assignment was by means of a computer program that used files stored in computer-readable form to produce the next assignment. The assignment was stratified by parity […], number of incontinent episodes […] and type of delivery […], and was blocked to produce even numbers after every 6 subjects in each of the strata. Those in the intervention group were further randomized in a similar manner to subgroups doing [pelvic floor muscle exercises] only, vaginal cones only, and both [pelvic floor muscle exercises] and cones".	Low risk

	The authors confirmed that a random sequence generation was used.	
Allocation concealment	"Assignment was by means of a computer program that used files stored in computer-readable form to produce the next assignment. The assignment was […] blocked to produce even numbers after every 6 subjects in each of the strata. Those in the intervention group were further randomized in a similar manner to subgroups […]". Blocked randomisation with even blocks makes an allocation sequence partly predictable.	Uncertain risk
Performance Bias		
Blinding of participants and personnel	Participants cannot be blinded with these interventions. Blinding of personnel has not been reported. Outcomes are likely to be influenced by	High risk

	lack of blinding.	
Detection Bias		
Blinding of outcome assessment: Participant reported outcomes External assessment	 Urinary incontinence: Participants cannot be blinded with these interventions. Perineometry “was recorded [...] by a second physiotherapist, blinded to the group allocation.” Pad test: was performed by a different, blinded physiotherapist (personal information from author).	 High risk Low risk Low risk
Attrition Bias		
Incomplete outcome data	There was a large number of withdrawals with no outcome data, and reason for missing outcome data is likely to be related to true outcome with an imbalance in numbers for missing data across	High risk

	intervention groups. Number of withdrawals: – control group: 26/117 – exercise group: 20/39 – cone group: 15/36 – exercise + cone group: 24/38	
Reporting Bias		
Selective reporting	All outcomes of all groups, and all cases (withdrawals included) were reported. A study protocol was not available, but the authors confirmed that as far as they can remember they reported everything, and “certainly did not change primary and secondary outcomes”.	Low risk
Other Bias		
Other sources of bias	No important concern about bias not addressed in the other domains in the tool.	Low risk

	Forms of bias considered according to Higgins et al. (2011a) and Torgerson (2014). Forms of bias of cross-over and cluster-randomised trials do not apply.	

Table 5: Results of reanalysis

Outcome	Cone group	Control group	Exercise group	Cone group versus control group	Cone group versus exercise group
After 12 months					
	Prevalence			**RR (95% CI)**	
Urinary incontinence (yes/no)	n/N=10/21 48%	n/N=69/91 76%	n/N=9/19 47%	0.63 (0.40-0.998) p = 0.022 x^2 = 5.25 df = 1	1.01 (0.52-1.93) p = 1.000 x^2 = 0.00 df = 1
	Mean (SD)			**MD (95% CI)**	
Pad test (g)	N=20 0.60 (1.142)	N=82 2.63 (11.539)	N=18 2.11 (5.051)	-2.03 (-7.18-3.11) p = 0.34 U = 718.5	-1.51 (-3.86-0.84) p = 0.63 U = 163,5
Pelvic floor muscle strength (perineometry maximum value) (cm H_2O)	N=19 12.663 (9.611)	N=79 13.106 (8.2318)	N=19 13.589 (8.4046)	-0.44 (-4.76-3.87) p = 0.84 t = 0.20 df = 96	-0.93 (-6.87-5.01) p = 0.75 t = 0.32 df = 36
Pelvic floor muscle strength (perineometry sustained value) (cm H_2O)	N=19 7.821 (7.6800)	N=79 6.682 (6.0824)	N=19 7.874 (5.9252)	1.14 (-2.11-4.39) p = 0.49 t = -0.70 df = 96	-0.05 (-4.57-4.46) p = 0.98 t = 0.024 df =36
After 24-44 months					
	Prevalence			**RR (95% CI)**	
Urinary incontinence	n/N=13/19 68%	n/N=20/37 54%	n/N=10/20 50%	1.2658 (0.8266-1.9383) P = 0.455 x^2 = 0.56 df = 1	1.3684 (0.8021-2.3347) P = 0.399 x^2 = 0.71 df = 1

Table 6: Statistical differences between groups found in analyses

Analysis	Cone group versus control group	Cone group versus exercise group
Main analysis (complete case analysis)	Significant	Not significant
Exploratory analyses	Not significant	Not significant
Sensitivity analysis assuming overall incontinence of dropout	Not significant	Not significant
Sensitivity analysis assuming overall continence of dropout	Significant	Not significant