Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: A randomised controlled feasibility trial

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Content

Appendix A: Historical traces of vaginal weights

The following is a nonsystematic collection of sources and hints to the devices' origin which were come across and followed up during the research.

Nonvibrating devices

In the Chinese Taoist (Daoist) healing tradition, exercising the pelvic floor muscles can be traced back 6000 years (Chang, 1990). This tradition also recommends a device: a stone egg (Chia, 1986). This is an egg shaped piece of a gemstone (e.g. jade), either carried around in the vagina or used to perform exercises by moving it inside the vagina or lifting weight (Chia, 1986, Cremer, no date). The practice also includes energetic work according to the Taoist theory (Chia, 1986). In a contemporary leaflet (Cremer, no date), larger (and thus heavier) eggs are recommended for parous women, smaller (and thus lighter) ones for women with an already trained pelvic floor.

The German gynaecologist Buchheit (1985, p. 152) reported, without giving sources for his statements, that in "many African peoples" it would be custom to put pebbles into young women's vaginas to educate them to train their pelvic floor muscles regularly; likewise, women of the Indian subcontinent would wear two stacked pebbles. He theorised that these stones would exert pressure on vaginal acupuncture points (of which he claims to be the discoverer), thus protecting the carrier from many health disorders.

Vibrating balls

Chia (1986, p. 187) also mentions a two eggs technique for, among other exercises, "banging them together to achieve a vibration that will stimulate the inside organs". Citing Cheng (1970), Buchheit (1985) reported that contemporary Japanese women would use double balls called ri-no-tama (Ri-no-tama is still a current term for vaginal balls (Wikipedia, 2018)). They would probably originate from Myanmar, from where they would have spread all over East Asia many centuries ago. Buchheit (1985) described that these hollow balls originally had been of gold, silver, or less precious metal, filled by mercury (citing Li (1965a)). When contracting the pelvic floor muscles, a rhythmical stimulus and pressure would be exerted on certain points of the vaginal wall and soft electric impulses on these points would result from the bimetal electricity (he again cites Cheng (1970)). Buchheit described the then (1985) contemporary balls as double balls of plastic containing smaller balls of iron.

Only the Sheng (1963) and Sheng (1966) editions (and not the Cheng (1970) edition cited by Buchheit (1985)) were available to the author to verify the citations. In these, Cheng wrote about a Burmese ball, a hollow metal ball with birdseed inside, used by women for masturbation and by men to please their partner by attaching it to their penis. He then mentioned the Japanese rin-to-tama [sic] (in using the plural but not the word "double") as a form of the Burmese origin ball, containing mercury, which at body temperature would give exciting electrical impulses. He goes on to describe balls of gold, silver or lead which are inserted under the skin, but he never explicitly mentions vaginal use.

The reference made by Buchheit (1985) to Li (1965a) was also followed up. However, no hint could be found to the balls, neither in Li (1965a) nor in the German edition (Li, 1965b).

Appendix B: Research team

Claudia Oblasser MA RM, Research Student (PhD Midwifery), School of Health Sciences, City, University of London, UK and Baden, Austria:
Principal investigator in the sense of trial execution: responsible for trial planning, research protocol, organising recruitment, participant information, data collection, analysis; thesis author, academic author

Christine McCourt BA PhD, Professor of Maternal and Child Health, Centre for Maternal and Child Health Research, Division of Midwifery and Radiography, School of Health Sciences, City, University of London, UK:
First PhD supervisor; co-author

Engelbert Hanzal MD, Associate Professor of Obstetrics and Gynaecology, Medical University of Vienna, Austria:
Principal investigator (responsibility) according to Austrian law on medical devices which requests a MD as principal investigator (Bundeskanzleramt Rechtsinformationssystem, 1996); local advisor to research student; blinded assessor for physiologic pelvic floor measurement; co-author

Edona Berisha BSc MSc MSc RM, then Staff Midwife at the AKH Vienna, Austria:
Blinded assessor for physiologic pelvic floor measurement; co-author

Sabine Clauss MD, then Medical University of Vienna, Austria:
Blinded assessor for physiologic pelvic floor measurement; co-author

Shashivadan P. Hirani BSc MSc PhD, Senior Lecturer in Health Services Research, Division of Health Services Research, School of Health Sciences, City, University of London, UK:
Second PhD supervisor 2015-2018; co-author

Janice Christie BSc PgCert PgDip MA PhD RN RSCPHN, Senior Lecturer Nursing, School of Nursing, Midwifery and Social Work, University of Manchester, UK:
Second PhD supervisor 2013/14; co-author

Hanns Helmer MD, Associate Professor of Obstetrics and Gynaecology, Medical University of Vienna, Austria:
Supporting recruitment as medical lead of the postnatal wards at the AKH Vienna

Team of the Section of Medical Statistics (IMS) of the Medical University of Vienna, Austria:
Statstical support

Wolfgang Peter CEng, Data Engineering & Statistics, Innsbruck, Austria:
Statstical support

Appendix C: Registrations, papers and presentations arising from this thesis

Registrations

1. Systematic review protocol registration *:*
   Oblasser, C., Christie, J. and McCourt, C. (2014) '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: 17 September 2018).

2. Research protocol registration:
   Oblasser, C. (2015) 'Vibrating Vaginal Balls After Childbirth', *ClinicalTrials.gov* (NCT02355327). Available at: https://www.clinicaltrials.gov/ct2/show/NCT02355327 (Accessed: 17 September 2018).

Papers

1. Systematic review protocol journal article*:*
   Oblasser, C., Christie, J. and McCourt, C. (2014) '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), pp. 933-941.

2. Systematic review journal article:
   Oblasser, C., Christie, J. and McCourt, C. (2015) 'Vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum: A quantitative systematic review', *Midwifery,* 31(11), pp. 1017-1025.

3. Research protocol journal article:
   Oblasser, C., McCourt, C., Hanzal, E. and Christie, J. (2016) 'Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: A protocol for a randomised controlled feasibility trial', *Journal of Advanced Nursing,* 72(4), pp. 900-914.

4. Conference abstract:
   Oblasser, C., McCourt, C., and Hanzal, E. (2016) 'Vibrierende Beckenbodenkugeln zur Verbesserung der Beckenbodenmuskulatur nach der Geburt: Erste Ergebnisse zu Rekrutierung und Survey eines Machbarkeits-RCT [Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: Preliminary results (recruitment and survey) of a randomised controlled feasibility trial]' [Abstract] (from the Proceedings of the 3rd international meeting of the German Society of Midwifery Science (DGHWi), Fulda, 12 February 2016), *Zeitschrift für Hebammenwissenschaft (Journal of Midwifery Science)* 4(Suppl.01), pp. S10-11.

Parallel online publication:
Oblasser, C., McCourt, C., and Hanzal, E. (2016) 'Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: preliminary results (recruitment and survey) of a randomised controlled feasibility trial' [Abstract], *3rd international meeting of the German Association of Midwifery Science (DGHWi)*, Fulda, 12 February. Available at: http://www.egms.de/static/en/meetings/dghwi2016/16dghwi03.shtml (Accessed: 14 Feb 2018).

5. Conference abstract:
   Oblasser, C. (2016) 'Vaginalkugeln zur Beckenbodenaktivierung nach der Geburt RCT [Vaginal balls to activate the pelvic floor in women after childbirth]' [Abstract] (from the Proceedings of the 26. Jahrestagung der MKÖ, Linz, 21-22 October 2016), *Journal für Urologie und Urogynäkologie*, 23(Sonderheft 4), p. 7.

Oral presentations

1. January 2015: School of Health Sciences Research Seminar Series, City University London, London/UK: “Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: a randomised controlled feasibility trial”

2. March 2015: 5th Annual Postgraduate Research Symposium, City University London, London/UK: “Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: a randomised controlled feasibility trial”

3. June 2015: Normal Birth Conference, Grange-over-Sands/UK, oral presentation of poster “Vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum: A quantitative systematic review”

4. June 2015: Normal Birth Conference, Grange-over-Sands/UK, Pecha Kucha presentation: “Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: a randomised controlled feasibility trial”

5. February 2016: 3rd international meeting of the German Society of Midwifery Science (DGHWi), Fulda/Germany: “Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: Preliminary results (recruitment and survey) of a randomised controlled feasibility trial”

6. March 2016: 3MT® (3 Minute Thesis Competition), City University London, London/UK: “Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: a randomised controlled feasibility trial” (2nd prize award)

7. March 2016: 6th Annual Postgraduate Research Symposium, City University London, London/UK: “Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: a randomised controlled feasibility trial” (1st prize award for best paper)

8. July 2016: School of Health Sciences Research Seminar Series, City University London, London/UK: “Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: a randomised controlled feasibility trial – decisions in the research process”

9. September 2016: Maternal Health Research Group – Monthly Seminar, King’s College, London/UK: “Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: a randomised controlled feasibility trial”

10. October 2016: 26th Annual Meeting of the Medizinische Kontinenzgesellschaft Österreich (MKÖ, Medical Continence Society Austria), Linz/Austria: “Vaginalkugeln zur Beckenbodenaktivierung nach der Geburt” [Vaginal balls for pelvic floor activation after childbirth]

11. May 2017: School of Health Sciences Research Seminar Series, City, University of London, London/UK: “Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: a randomised controlled feasibility trial – selected findings and research implications for a full RCT”

Poster presentations

1. November 2014: Annual Conference of the Royal College of Midwives, Telford/UK: “Vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum: A quantitative systematic review”

2. June 2015: Normal Birth Conference, Grange-over-Sands/UK: “Vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum: A quantitative systematic review”

3. December 2016: 5th European Midwives Association Education Conference, London/UK: “Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: a randomised controlled feasibility trial”

4. May 2017: 4th International Clinical Trials Methodology Conference (ICTMC), Liverpool/UK: “Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: a randomised controlled feasibility trial”

5. September 2018: IX. Internationaler Dialog, Vienna/Austria: “Vibrierende Beckenbodenkugeln zur Verbesserung der Beckenbodenmuskulatur nach der Geburt: ein randomisiert-kontrollierter Machbarkeits-RCT” [Vibrating vaginal balls to enhance pelvic floor muscle performance after childbirth: a randomised controlled feasibility RCT]

Awards

1. 2nd prize at the 3MT® (3 Minute Thesis Competition) March 2016, City University London, London/UK
2. 1st prize for best paper at the 6th Annual Postgraduate Research Symposium, March 2016, City University London, London/UK

Reprint of systematic review protocol in Journal of Advanced Nursing

Oblasser, C., Christie, J. and McCourt, C. (2014) '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), pp. 933-941.

JAN
Informing Practice and Policy Worldwide through Research and Scholarship

PROTOCOL

Vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women postpartum: a quantitative systematic review and meta-analysis protocol

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OBLASSER C., CHRISTIE J. & MCCOURT C. (2015) 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. **doi: 10.1111/jan.12566**

Abstract

Aim. To identify, critically appraise and synthesize the best current evidence on the use of vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum.

Background. The vaginal use of cones or balls is a pelvic floor muscle training method that aims to enhance muscle performance and thereby prevent or treat urinary incontinence. Nonetheless to date, no systematic review has focused on the effectiveness of these devices specifically during the postpartum period.

Design. Quantitative systematic review with potential meta-analysis.

Methods. The review will be undertaken by searching 14 scientific databases (including PubMed and CINAHL, without date restriction) and the world-wide web; experts will also be contacted for published and unpublished data. Included studies must be randomized or quasi-randomized trials and have female participants until 1 year after childbirth. The intervention will be compared with no treatment, placebo, sham treatment or active controls. Outcome measures will relate to pelvic floor muscle performance or urinary incontinence. Studies will be selected, 'risk of bias' assessed and data extracted by two reviewers independently. Following inter-reviewer agreement of included studies, data will be checked after entry into systematic review processing software. If appropriate, data will be synthesized by meta-analysis; if this is not possible, a narrative review only will be undertaken.

Discussion. The information gained from this systematic review will help midwives, nurses, other health professionals and women after childbirth decide how to promote female pelvic floor health and in defining further areas of study.

Keywords: health promotion, midwifery, nursing, pelvic floor, postnatal care, postpartum period, review, urinary incontinence

Why this systematic review is needed:

- As childbearing challenges pelvic floor integrity, postpartum pelvic floor health is an important issue in maternity health care
- The vaginal use of cones or balls by women post partum raises the question of their effectiveness and evidence about it
- This is the first systematic review to focus specifically on the use of vaginal cones for pelvic floor muscle training in the postpartum period

Introduction

Pelvic floor health is an important issue for childbearing women worldwide and the impact of postpartal pelvic problems on women's lives can be considerable. O'Reilly *et al.*'s (2009) and Buurman and Lagro-Janssen's (2012) interviewees felt distressed by and ashamed about their pelvic problems, which negatively affected their intimate relationships and social activities. As well as feeling uninformed and being reluctant to approach healthcare workers with their pelvic problems themselves, they described healthcare workers as not being sensitive enough to the topic. Midwives and nurses as key professionals in this period of a woman's life need to be able to deal effectively with this issue and thus, this systematic review aims to provide all healthcare workers with information to be more knowledgeable and proactive in promoting pelvic floor health.

The pelvic floor seals the inferior opening of the bony pelvis. It contributes to the body's voiding and continence mechanisms and, in the female, supports the pelvic organs (Ashton-Miller *et al.* 2001, Ashton-Miller & DeLancey 2007). It does so by its muscles (mainly the levator ani), nerves and connective tissue, and any impairment of these structures can lessen the pelvic floor's ability to accomplish the necessary tasks.

Childbearing challenges pelvic floor integrity. During pregnancy, the changes in the hormones progesterone and relaxin lead to tissue softening, and the growing uterus requiring space and the physiological weight gain lead to mechanical changes (Baessler & Schüssler 2008). During vaginal birth, the pelvic floor suffers mechanical trauma by (over)stretching and there might even be tissue rupture and/or biochemical (ischaemic) damage (DeLancey & Ashton-Miller 2007, Baessler & Schüssler 2008).

This pelvic floor impairment by childbearing may or may not lead to clinical symptoms (Baessler & Schüssler 2008). One symptom indicative of a deficient pelvic floor is stress urinary incontinence, an involuntary loss of urine on effort or physical exertion or on sneezing or coughing (International Continence Society (Publications & Communications Committee) 2013). Meyer *et al.* (1998) and Lukacz *et al.* (2006) give a prevalence of stress urinary incontinence after childbirth of 3–36% (depending on mode of delivery) and 15% respectively; other studies, not differentiating between types of urinary incontinence, give a prevalence of urinary incontinence after childbirth of 9·3–38% (Brown & Lumley 1998, Mørkved & Bø 1999, Glazener *et al.* 2001, Burgio *et al.* 2003). Other possible symptoms of pelvic floor impairment are perineal descent, pelvic organ prolapse or anal incontinence (Baessler *et al.* 2008).

Background

Pelvic floor muscle training is an effective conservative (non-surgical) treatment method for stress urinary incontinence due to impaired pelvic floor muscles generally (Dumoulin & Hay-Smith 2010) and also around the time of childbirth (Boyle *et al.* 2012). In the sense of secondary prevention, pelvic floor muscle training can also aim at enhancing performance of pelvic floor muscles in women after childbirth without urinary incontinence symptoms. It is then used to forego stress urinary incontinence (or other pelvic floor impairment symptoms) later in life. Therefore, pelvic floor muscle training should be a routine recommendation to all women during postpartum care (Abrams *et al.* 2010, The Joanna Briggs Institute 2011).

Training thereby means to learn to volitionally perform a correct pelvic floor muscle contraction (motor learning) and to enhance the pelvic floor muscles' strength and endurance (strength training) (Bø & Aschehoug 2007, Bø & Mørkved 2007, Laycock 2008). The theory behind this is twofold (Bø 2004). First, it is assumed that women learn to consciously pre- and co-counteract abrupt increases in intra-abdominal pressure by an effective contraction (called 'the knack' by Miller *et al.* 1998). This improves urethral closure pressure by bringing the urethra upwards and forward against the pubic symphysis, thereby clamping it by the increasing mechanical pressure and thus preventing leakage. Second, it has been suggested that strength training enhances hypertrophy (growth), tone and stiffness of the pelvic floor muscles and connective tissue, which in turn elevates these urethral support structures in the pelvis. This limits descent of urethra and bladder neck and facilitates a more effective automatic co-contraction during intra-abdominal pressure rises.

Different approaches to pelvic floor muscle training exist (Baessler *et al.* 2008). One pelvic floor muscle training method consists in the vaginal use of cones or balls. These

devices can be cylinders either conical at one end or rounded at both ends, or ball-shaped, and they come in different weights (to be increased during training) and sizes (Bø & Aschehoug 2007). According to Bø (2007), their assumed working mechanism consists of reflexive or voluntary contractions of the pelvic floor muscles to prevent the inserted cones/balls from slipping out, thus enhancing pelvic floor muscle strength. Additionally, sensory (by feeling pressure from the cone) and kinaesthetic (by feeling the cone move downwards) biofeedback teaches women to identify their pelvic floor muscles so they are enabled to contract them consciously (Chiarelli & Moore 2008). Vibrating vaginal balls give further stimulation by vibrations caused by a loose inner ball when the woman is moving (Glavind 2001). It is also possible to use the cones/balls as a resistance device during voluntarily contracting and releasing the pelvic floor muscles around them (Arvonen *et al.* 2001, Bø 2007).

Rationale

Although the effect of pelvic floor muscle training by cones or balls might differ in women after childbirth because of the physiological changes during the childbearing period, no systematic review to date has focused on the vaginal use of cones or balls specifically during the postpartum period. A Cochrane review looked into the effectiveness of cones or balls for urinary incontinence and included postpartum women (Herbison & 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 training 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 quantitative systematic review is needed which focuses on: (1) the vaginal use of cones or balls as a pelvic floor muscle training method; (2) in the postpartum period; and (3) uses both pelvic floor muscle performance and urinary (in)continence as primary outcomes to estimate effectiveness of device use. Such a systematic review is proposed here.

The review

Aim

The aim of this quantitative systematic review is to identify, critically appraise and synthesize the best current evidence on the use of vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum.

Objectives

The objective of this systematic review is 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. A secondary objective is to gather information on effect on perineal descent or pelvic organ prolapse, adverse effects and economical aspects.

Research question

The research question has been developed by using the PICO (population – intervention – comparison – outcome)-framework outlined by the Cochrane Collaboration (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 with no treatment, placebo, sham treatment or active controls?

Design/methodology

This is a quantitative systematic review with a potential meta-analysis on the basis of the guidance on systematic reviews of interventions by the Cochrane Collaboration (Higgins & Green 2011).

Inclusion/exclusion criteria

Inclusion and exclusion criteria have been 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 included in and excluded from this systematic review are listed in the following.

Types of participants

- Women up to 1 year after childbirth at the time of beginning the intervention, of any parity, mode of birth and birth injuries, with or without urinary incontinence, will be included.
- Pregnant women, women with anal incontinence or major genitourinary/pelvic morbidity will be excluded.

Types of intervention

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
- any method of instruction (advised by any health practitioner or self-taught by information material).

Types of comparison

Comparison could be done against physiological restitution (no device or treatment), placebo, sham 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

Primary

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

- perineal descent or pelvic organ prolapse as assessed by standardized 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.

Outcomes should be measured immediately after the intervention. If longer term follow-up data are available, these will also be analysed.

Types of study designs

Randomized and quasi-randomized controlled trials with individual or cluster randomization and parallel design will be included. Blinding of participants is not possible for this intervention.

Search methods

Databases, reports, experts and the world-wide web will be sources for published and unpublished data and for information on ongoing projects. Bibliographic databases to be searched can be seen in Table 1. The search strategy prepared for PubMed, comprising searches for synonymous text words 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 but not in title and abstract (and in any other of the fields searched by an [all fields]-search in PubMed), which was found to be the case for literature identified in preliminary searches. For the same reason, study design is not included in the search strategy. This PubMed search strategy will be adapted according to the search functions and complexity of each database.

The references of selected trial reports or similar reviews will be screened to identify further relevant studies. Authors of included studies will be asked if they know of relevant work. The Bielefeld Academic Search Engine (BASE) and Google Scholar will help search the world-wide web, and the web sites of the International Continence Society (ICS) and cone or ball manufacturers will be screened. There will be no language or publication period restrictions. Search protocols will be maintained. The search is planned to take place between 26 February–23 December 2014.

Studies will be searched and selected by the first (CO) and second (JC) reviewer independently screening titles and abstracts of the citations found in searches. Studies will be included if they fulfil the above defined PICOS. Disagreements will be resolved by consensus and if further clarification is needed, the third reviewer (CM) will be consulted. The PRISMA flow chart (Liberati *et al.* 2009) will be used to document the selection process.

Quality appraisal

Included studies will be assessed for risk of bias by the first and second reviewer independently using the 'Risk of bias assessment tool' of the Cochrane Collaboration (Higgins *et al.* 2011a). Domains to be considered are random sequence generation, allocation concealment, blinding of

Table 1 Databases to be 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)

personnel and outcome assessment (blinding of participants is not possible with this intervention), completeness of outcome data and reporting, and other sources of bias. Assessment within domains will be made for each main outcome. Possible bias will be described and judged into the categories low, unclear and high risk of bias, according to the criteria laid out by Higgins *et al.* (2011a). Specific to cluster-randomized trials, recruitment bias (individuals having been recruited to the trial after randomization of clusters), baseline imbalance and loss of clusters will be considered (Higgins *et al.* 2011b). Attempts will be made to contact the authors of studies for clarification of incomplete information. Assessments made by reviewers will be compared and disagreements will be resolved by consensus. If further clarification is needed, the third reviewer will be consulted.

Risk of bias will be presented in a table for each study and its outcomes and across studies by description in the results section and in a 'Summary risk of bias' graph and table. Sensitivity analysis will investigate risk of bias. Overall risk of bias will be summarized in a 'Summary of findings' table and magnitude and direction of possible bias for specific outcomes across studies will be discussed.

Data abstraction

Data will be extracted from selected studies using a piloted standard data extraction form adapted from the data extrac-

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 urine 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

tion form templates of The Cochrane Pregnancy and Childbirth Group (2013) and The Cochrane Editorial Resources Committee (2013). This will include specific details on study characteristics concerning methodology, participants, intervention, comparison and analysis, and results and conclusions. Attempts will be made to contact the authors of studies for clarification of incomplete information or to obtain any missing data. Data will be extracted by the lead reviewer and cross checked by the second reviewer.

Data synthesis

Quantitative analysis will be performed using the analysis software Review Manager (RevMan) 5.3.4 (The Cochrane Collaboration 2014), seeking appropriate statistical expert advice. To ensure correctness, all data will be entered into RevMan 5.3.4 by the lead reviewer and cross checked by the second reviewer. Data used will be at the aggregate (study) level. Unit of analysis will be the participating woman in individually randomized trials and any unit used in cluster-randomized trials.

Cluster-randomized trials will be analysed alongside individually randomized trials if the authors have used an appropriate method of data analysis to account for clustered data in their published analysis. If the authors have not analysed their data to account for clustering effects, a re-analysis will be performed, or, if the necessary information is not available, inflated standard errors will be calculated for such data prior to any meta-analysis undertaken during this review (as in accordance with Higgins *et al.* 2011b). Inclusion or exclusion of cluster-randomized trials in a sensitivity analysis will consider possible differences between the intervention effects as an effect of study design.

Effect sizes for dichotomous data will be expressed as either risk ratio (RR) or risk difference (RD) with corresponding 95% confidence intervals (CI) and by the number needed to treat (NNT) if there is a statistically significant reduction in RD. Effect sizes for continuous data will be expressed as differences in means (MD) or standardized differences in means (SMD) with their standard errors. Ordinal data will be either dichotomized and treated as dichotomous data, or treated as continuous data, depending on the data characteristics.

Studies will be examined for clinical heterogeneity (diversity in relation to participants, intervention, comparison) and for statistical heterogeneity. If the studies appear to be too clinically heterogenous (as assessed by professional judgement), no meta-analysis will be performed, but the study data will be descriptively discussed and presented. If clinically homogenous, statistical heterogeneity between studies will be assessed by visual inspection of the forest plot and by calculation of the χ^2 and I^2 statistic. Interpretation of the I² statistic will follow Deeks *et al.* (2011), judging $I^2 > 50–60\%$ as substantial heterogeneity.

The implications of these findings for the use of meta-analysis will be as follows:

- If quantitative data are found to be statistically sufficiently homogenous, the fixed effects model will be used for pooling in statistical meta-analysis.
- If data are found to be statistically heterogeneous, depending on the degree, there will be either (i) no pooling of data but the quantitative data will be discussed, with findings being presented in a descriptive form. Or (ii) the random effects model will be used for pooling and the source of heterogeneity will be assessed by identification of the methodological differences between studies and by sensitivity and subgroup analyses.

The following sensitivity analyses are planned (subject to available data):

- use of a fixed or random effects model to determine pooled effect measures
- comparing different ways of dealing with ordinal data
- comparing inclusion or exclusion of cluster-randomized trials
- comparing inclusion or exclusion of quasi-randomized trials
- comparing inclusion or exclusion of studies with different levels of risk of bias
- comparing inclusion or exclusion of studies with suspected selective outcome reporting bias thought to introduce serious bias (if missing outcome data could not be provided)
- deleting each single study in turn.

The following subgroup analyses are planned (subject to available data):

- women with urinary incontinence compared with women without urinary incontinence
- use of non-vibrating cones or balls compared with vibrating balls
- different duration of device use.

If at least ten (Sterne *et al.* 2011) trials are found, a funnel plot with visual inspection and possible use of statistical tests to evaluate the plot will be used to assess the possibility of publication bias.

Ethical considerations

No ethical issues are attached to this systematic review.

Validity and reliability/rigour

Criteria having been used in the compilation of this systematic review protocol and the present report correspond to the PRISMA Statement (Liberati *et al.* 2009). Methodological issues follow those laid out in the Cochrane Handbook (Higgins & Green 2011).

Discussion

There are some operational difficulties anticipated in performing this quantitative systematic review and possible meta-analysis. Amongst the issues to consider at study and outcome level are the limitations of measurement tools. Responsiveness, validity and reliability of different pelvic floor muscle performance or urinary incontinence measures are critically discussed by different authors (Bø & Sherburn 2005, Bø *et al.* 2007, Moore & Karantanis 2008). Lack of adherence to pelvic floor muscle training interventions is common (Alewijnse *et al.* 2007) and a high number of withdrawals has been identified as a challenge in studies on the topic (Herbison & Dean 2013). 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 (overestimation of effect) in self-rating by users.

Considering the review level, the available literature might be sparse, reporting bias may be present and studies found might be of small sample size. Reporting in the literature with respect to methodological details or data might be of insufficient quality and information seeking by contacting authors might not yield the desired result. Trials might be clinically heterogeneous in relation to participants, intervention and choice of comparison group. They might use different measurements of pelvic floor muscle performance or urinary continence which might render them difficult or impossible to compare. The identified issues might limit the practicability of performing a meta-analysis.

The novel aspect of this quantitative 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 primary outcomes to estimate effectiveness of device use. The information gained from this systematic review will be useful for midwives, nurses, other health practitioners and women after childbirth to help with promotion of pelvic floor health. It will also be useful for research to define further areas of study and in particular to design an experimental investigation into the topic by CO.

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Conflict of interest

Claudia Oblasser: Conclusions from the review will have an influence on the planning of a PhD research project. Janice Christie: none. Christine McCourt: none.

Author contributions

CO was responsible for the study conception and for drafting of the manuscript. JC and CM supervised the work, gave substantial contributions to conception and design, and critically revised the work for important intellectual content. All authors approved the final version of the article.

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/ethical_1author.html)]:

- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

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 Urodynamics* **29**(1), 213–240.

Alewijnse D., Mesters I., Metsemakers J.F.M. & van den Borne B. (2007) Strategies to enhance adherence and reduce drop out in conservative treatment. In *Evidence-Based Physical Therapy for the Pelvic Floor* (Bø K., Berghmans B., Mørkved S. & Van Kampen M., eds), Churchill Livingstone, Edinburgh, pp. 133–146.

Arvonen T., Fianu-Jonasson A. & Tyni-Lenné R. (2001) Effectiveness of two conservative modes of physical therapy in women with urinary stress incontinence. *Neurourology and Urodynamics* **20**(5), 591–599.

Ashton-Miller J.A. & DeLancey J.O. (2007) Functional anatomy of the female pelvic floor. In *Evidence-Based Physical Therapy for the Pelvic Floor* (Bø K., Berghmans B., Mørkved S. & Van Kampen M., eds), Churchill Livingstone, Edinburgh, pp. 19–33.

Ashton-Miller J., Howard D. & Delancey J. (2001) The functional anatomy of the female pelvic floor and stress continence control system. *Scandinavian Journal of Urology and Nephrology Supplement* **35**(207), 1–7.

Baessler K. & Schüssler B. (2008) The effects of pregnancy and childbirth on the pelvic floor. In *Pelvic Floor Re-education: Principles and Practice*, 2nd edn (Baessler K., Schüssler B., Burgio K.L., Moore K.H., Norton P.A. & Stanton S.L., eds), Springer, London, pp. 36–48.

Baessler K., Schüssler B., Burgio K.L., Moore K.H., Norton P.A. & Stanton S.L., eds (2008) *Pelvic Floor Re-education: Principles and Practice*, 2nd edn. Springer, London.

Bø K. (2004) Pelvic floor muscle training is effective in treatment of female stress urinary incontinence, but how does it work? *International Urogynecology Journal and Pelvic Floor Dysfunction* **15**(2), 76–84.

Bø K. (2007) Pelvic floor muscle training for stress urinary incontinence. In *Evidence-Based Physical Therapy for the Pelvic Floor* (Bø K., Berghmans B., Mørkved S. & Van Kampen M., eds), Churchill Livingstone, Edinburgh, pp. 171–187.

Bø K. & Aschehoug A. (2007) Strength training. In *Evidence-Based Physical Therapy for the Pelvic Floor* (Bø K., Berghmans B., Mørkved S. & Van Kampen M., eds), Churchill Livingstone, Edinburgh, pp. 119–132.

Bø K. & Mørkved S. (2007) Motor learning. In *Evidence-Based Physical Therapy for the Pelvic Floor* (Bø K., Berghmans B., Mørkved S. & Van Kampen M., eds), Churchill Livingstone, Edinburgh, pp. 113–119.

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

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

Boyle R., Hay-Smith E.J.C., 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.

Brown S. & Lumley J. (1998) Maternal health after childbirth: results of an Australian population based survey. *BJOG: An International Journal of Obstetrics and Gynaecology* **105**(2), 156–161.

Burgio K.L., Zyczynski H., Locher J.L., Richter H.E., Redden D.T. & Wright K.C. (2003) Urinary incontinence in the 12-month postpartum period. *Obstetrics and Gynecology* **102**(6), 1291–1298.

Buurman M.B.R. & Lagro-Janssen A.L.M. (2012) Women's perception of postpartum pelvic floor dysfunction and their help-seeking behaviour: a qualitative interview study. *Scandinavian Journal of Caring Sciences* **27**(2), 406–413.

Chiarelli P.E. & Moore K.H. (2008) Exercise, feedback and biofeedback. In *Pelvic Floor Re-education: Principles and Practice*, 2nd edn (Baessler K., Schüssler B., Burgio K.L., Moore K.H., Norton P.A. & Stanton S.L., eds), Springer, London, pp. 184–189.

Deeks J.J., Higgins J.P.T. & Altman D.G. (2011) Analysing data und undertaking meta-analyses. In *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0* [updated March 2011] (Higgins J.P.T. & Green S., eds), The Cochrane Collaboration, chapter 9. Retrieved from http://handbook.cochrane.org/ on 25 February 2014.

DeLancey J.O. & Ashton-Miller J.A. (2007) MRI of intact and injured female pelvic floor muscles. In *Evidence-Based Physical Therapy for the Pelvic Floor* (Bø K., Berghmans B., Mørkved S. & Van Kampen M., eds), Churchill Livingstone, Edinburgh, pp. 93–105.

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

Glavind K. (2001) Conservative treatment of stress incontinence with Geisha balls. *International Urogynecology Journal* **12**(4), 223–224.

Glazener C.P., Herbison G.D., Wilson P.C., MacArthur D., Lang G.H., Gee M. & Grant A. (2001) Conservative management of persistent postnatal urinary and faecal incontinence: randomised controlled trial. *BMJ (British Medical Journal)* **323**(7313), 593–596.

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 & Gynaecology Canada: JOGC* **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. & Green S. (eds) (2011) *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0* [updated March 2011]. The Cochrane Collaboration. Retrieved from http://handbook.cochrane.org/ on 22 February 2014.

Higgins J.P.T., Altman D.G. & Sterne J.A.C. (2011a) Assessing risk of bias in included studies. In *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0* [updated March 2011] (Higgins J.P.T. & Green S., eds), The Cochrane Collaboration, chapter 8. Retrieved from http://handbook.cochrane.org/ on 22 February 2014.

Higgins J.P.T., Deeks J.J. & Altman D.G. (2011b) Special topics in statistics. In *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0* [updated March 2011] (Higgins J.P.T. & Green S., eds), The Cochrane Collaboration, chapter 16. Retrieved from http://handbook.cochrane.org/ on 22 February 2014.

International Continence Society (Publications & Communications Committee) (2013) ICS Fact Sheets: A Background to Urinary and Faecal Incontinence. Retrieved from http://www.ics.org/Documents/Documents.aspx?DocumentID=2172 on 29 December 2013.

Laycock J. (2008) Concepts of neuromuscular rehabilitation and pelvic floor muscle training. In *Pelvic Floor Re-education: Principles and Practice*, 2nd edn (Baessler K., Schüssler B.,

Burgio K.L., Moore K.H., Norton P.A. & Stanton S.L., eds), Springer, London, pp. 177–183.

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), e1000100. doi:10.1371/journal.pmed.1000100.

Lukacz E.S., Lawrence J.M., Contreras R., Nager C.W. & Luber K.M. (2006) Parity, mode of delivery and pelvic floor disorders. *Obstetrics & Gynecology* **107**(6), 1253–1260.

Meyer S., Schreyer A., Grandi P.D. & Hohlfeld P. (1998) The effects of birth on urinary continence mechanisms and other pelvic-floor characteristics. *Obstetrics and Gynecology* **92**(1), 613–618.

Miller J., Ashton-Miller J.A. & DeLancey J.O. (1998) A pelvic muscle precontraction can reduce cough-related urine loss in selected women with mild SUI. *Journal of the American Geriatrics Society (JAGS)* **46**(7), 870–874.

Moore K.H. & Karantanis E. (2008) Outcome measures in pelvic floor rehabilitation. In *Pelvic Floor Re-education: Principles and Practice*, 2nd edn (Baessler K., Schüssler B., Burgio K.L., Moore K.H., Norton P.A. & Stanton S.L., eds), Springer, London, pp. 162–174.

Mørkved S. & Bø K. (1999) Prevalence of urinary incontinence during pregnancy and postpartum. *International Urogynecology Journal and Pelvic Floor Dysfunction* **10**(6), 394–398.

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.

O'Connor D., Green S. & Higgins J.P.T. (2011) Defining the review question and developing criteria for including studies. In *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0* [updated March 2011] (Higgins J.P.T. & Green S., eds), The Cochrane Collaboration, chapter 5. Retrieved from http://handbook.cochrane.org/ on 22 February 2014.

O'Reilly R., Peters K., Beale B. & Jackson D. (2009) Women's experiences of recovery from childbirth: focus on pelvis problems that extend beyond the puerperium. *Journal of Clinical Nursing* **18**(14), 2013–2019.

Sterne J.A.C., Egger M. & Moher D. (2011) Addressing reporting biases. In *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0* [updated March 2011] (Higgins J.P.T. & Green S., eds), The Cochrane Collaboration, chapter 10. Retrieved from http://handbook.cochrane.org/on 22 February 2014.

The Cochrane Collaboration (2014) Review Manager (RevMan) Version 5.3.4 for Windows [Computer programme]. Retrieved from http://www.cochrane.org/editorial-and-publishing-policy-resource/review-manager-revman on 08 October 2014.

The Cochrane Editorial Resources Committee (2013) Data Collection Form (V2). Retrieved from http://training.cochrane.org/authors/resources/checklists-and-forms on 8 November 2013.

The Cochrane Pregnancy and Childbirth Group (2013) Data Extraction Form. Retrieved from http://pregnancy.cochrane.org/author-resources-new-reviews on 1 November 2013.

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.

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Vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum: A quantitative systematic review

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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.

Contents

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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 prespecifiying 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 and Green, 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

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.

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 (Higins 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 χ^2 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 Fig. 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 100 g. 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,

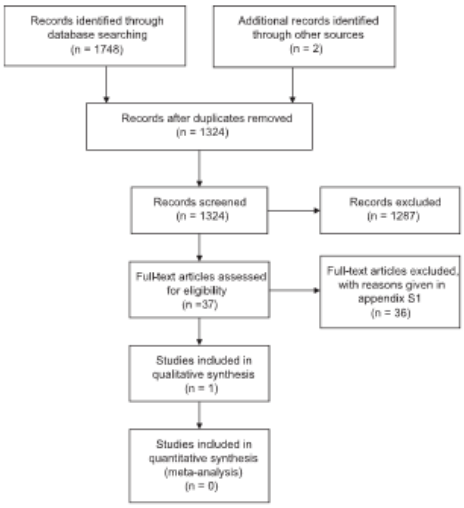

Fig. 1. PRISMA flow chart (according to Liberati et al., 2009).

Table 3
Characteristics of included study.

Methods	– Randomised controlled trial – Two parallel study arms (one arm with three subgroups) with women who had incontinence three months postpartum
Participants	– 230 women with symptoms of incontinence three 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 six women) from the second postnatal day, or an audiotape at weekends, during hospital stay – Intervention groups ($n=113$): enforced exercise regimen with physiotherapist with one training session and three follow-up visits at three, six, and nine months post partum; factorial design with three 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) – One-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

2009; Bø, 2011; Duffin, 2012; Rathfisch and Kızılkaya Beji, 2012; Freeman, 2013) because they were not primary studies, and 24 (Sleep and Grant, 1987; Dougherty et al., 1989; Sampselle et al., 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) ($\chi^2=1.607$, 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) ($\chi^2=0.047$, 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

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'. The authors confirmed that a random sequence generation was used.	Low risk
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 lack of blinding.	High risk
Detection bias		
Blinding of outcome assessment		
Participant reported outcomes	Urinary incontinence: Participants cannot be blinded with these interventions.	High risk
External assessment	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).	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 intervention groups. Number of withdrawals: – Control group: 26/117 – Exercise group: 20/39 – Cone group: 15/36 – Exercise + cone group: 24/38	High risk
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. Forms of bias considered according to Higins et al. (2011a) and Torgerson (2014). Forms of bias of cross-over and cluster-randomised trials do not apply.	Low risk

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) (χ^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) (χ^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) (χ^2 = 0.56, df = 1, p = 0.455), whereas the cone group versus exercise group comparison gives a RR (95% CI) of 1.37 (0.80–2.33) (χ^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.

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 χ^2 = 5.25 df = 1	1.01 (0.52–1.93) p = 1.00 χ^2 = 0.00 df = 1
	Mean (SD)			**MD (95% CI)**	
Pad test (g)	N = 20 0.60 (1.14)	N = 82 2.63 (11.54)	N = 18 2.11 (5.05)	−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 12.66 (9.61)	N = 79 13.11 (8.23)	N = 19 13.59 (8.40)	−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 7.82 (7.68)	N = 79 6.68 (6.08)	N = 19 7.87 (5.93)	1.14 (−2.11–4.39) p = 0.49 t = −0.70 df = 96	−0.05 (−4.57–4.46) p = 0.98 t = 0.02 df = 36
After 24–44 months					
	Prevalence			**RR (95% CI)**	
Urinary incontinence (yes/no)	n/N = 13/19 68%	n/N = 20/37 54%	n/N = 10/20 50%	1.27 (0.83–1.94) p = 0.46 χ^2 = 0.56 df = 1	1.37 (0.80–2.33) p = 0.40 χ^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

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 versus control and cone versus 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 versus control group comparisons. According to Higins 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 versus 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 versus 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.

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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. Int. Urogynecol. J. 9, 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 Obstet. Gynecol. Scand. 92, 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]. Rev. Bras. Ginecol. Obstet. 35, 10–15.

Bø, K., 2011. Evidence for pelvic floor muscle training during pregnancy and after childbirth: to do or not to do? Aust. N. Z. Cont. J. 17, 121–122.

Chiarelli, P., Cockburn, J., 2002. Promoting urinary continence in women after delivery: randomised controlled trial. Br. Med. J. 324, 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. Int. Urogynecol. J. 15, 99–105.

Citak, N., Cam, C., Arslan, H., et al., 2010. Postpartum sexual function of women and the effects of early pelvic floor muscle exercises. Acta Obstet. Gynecol. Scand. 89, 817–822.

Cox, S., 1995. Kegel exercises. Int. J. Childbirth Educ. 10, 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. J. Nurse-Midwifery 34, 8–14.

Duffin, C., 2012. Postnatal exercise improves muscle tone and relieves back pain. Prim. Health Care 22, 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]. „ Université de Montréal, Montréal, Canada (Ph.D. thesis).

Dumoulin, C., Lemieux, M., Bourbonnais, D., Gravel, D., Bravo, G., Morin, M., 2004. Physiotherapy for persistent postnatal stress urinary incontinence: a randomized controlled trial. Obstet. Gynecol. 104, 504–510.

Dumoulin, C., Martin, C., Elliott, V., et al., 2013. Randomized controlled trial of physiotherapy for postpartum stress incontinence: 7-year follow-up. Neurourol. Urodyn. 32, 449–454.

Erratum, 2005. J. Obstet. Gynaecol. 25, 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. J. Obstet. Gynaecol. 25, 558–564.

Fischer, W., Baessler, K., 1996. Postpartum pelvic floor conditioning using vaginal cones: not only for prophylaxis against urinary incontinence and descensus. Int. Urogynecol. J. Pelvic Floor Dysfunct. 7, 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, 18–28.

Freeman, R.M., 2013. Can we prevent childbirth-related pelvic floor dysfunction? BJOG 120, 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. Br. Med. J. 330, 337.

Glazener, C.M., Herbison, G.P., Wilson, P.D., et al., 2001. Conservative management of persistent postnatal urinary and faecal incontinence: randomised controlled trial. Br. Med. J. 323, 1–5.

Glazener, C.M., MacArthur, C., Hagen, S., et al., 2014. Twelve-year follow-up of conservative management of postnatal urinary and faecal incontinence and prolapse outcomes: randomised controlled trial. BJOG 121, 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]. Ginecol. Obstet. Mexico 72, 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. Obstet. Gynecol. 122, 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, 2820.
Jonasson, A., Larsson, B., Pschera, H., 1989. Testing and training of the pelvic floor muscles after childbirth. Acta Obstet. Gynecol. Scand. 68, 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. Clin. Rehab. 26, 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, 1374–1380.
Meyer, S., Hohlfeld, P., Achtari, C., De Grandi, P., 2001. Pelvic floor education after vaginal delivery. Obstet. Gynecol. 97, 673–677.
Norton, P., Baker, J., 1990. Randomized prospective trial of vaginal cones vs. Kegel exercises in postpartum primiparous women. Neurourol. Urodyn. 9, 434–435.
Peirce, C., Murphy, C., Fitzpatrick, M., et al., 2013. Randomised controlled trial comparing early home biofeedback physiotherapy with pelvic floor exercises for the treatment of third-degree tears (EBAPT trial). BJOG 120, 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. Int. J. Urol. Nurs. 6, 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. Obstet. Gynecol. 91, 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]. Urogynaecol. Int. J. 15, 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. J. South Asian Fed. Obstet. Gynecol. 3, 157–159.
Sleep, J., Grant, A., 1987. Pelvic floor exercises in postnatal care. Midwifery 3, 158–164.
Spreafico, L., 1992. La rieducazione nel post-partum [Re-education during post-partum]. Eur. Medicophys. 28, 85–88.

Additional references

Abrams, P., Andersson, K.E., Birder, L., et al., 2010. Fourth international consultation on incontinence recommendations of the international scientific committee: evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. Neurourol. Urodynam., 29; , pp. 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. Phys. Ther. 85, 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 Syst. Rev., CD007471. http://dx.doi.org/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 January 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. Behav. Res. Methods 39, 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. Gynecol. Obstet. Invest. 41, 269–274.
Harvey, M.A., 2003. Pelvic floor exercises during and after pregnancy: a systematic review of their role in preventing pelvic floor dysfunction. J. Obstet. Gynaecol. Can. 25, 487–498.
Herbison, P.G., Dean, N., 2013. Weighted vaginal cones for urinary incontinence. Cochrane Database Syst. Rev., CD002114. http://dx.doi.org/10.1002/14651858.CD002114.pub2.
Higins, 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 February 2014).
Higgins, J.P.T., Green, S., (Eds.) 2011b. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration. Available at: ⟨www.cochrane-handbook.org⟩ (accessed 22 February 2014).
IBM Corporation, 2012/13. IBM SPSS Statistics for Windows (Versions 21.0 and 22.0) [Computer program].
Liberati, A., Altman, D.G., Tetzlaff, J., et al., 2009. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. PLoS Med. 6, e1000100. http://dx.doi.org/10.1371/journal.pmed.1000100.
LISSWORX, 2014. Online Prozentrechner. Available at: ⟨http://www.prozentrechner.net/⟩ (accessed 16 October 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 edn. 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. Br. J. Sports Med. 48, 299–310.
National Collaborating Centre for Womens and Children's Health, 2013. Urinary Incontinence in Women: The Management of Urinary Incontinence in Women, 2nd edn. 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 February 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. J. Adv. Nurs. 71, 933–941.
Software, M., 2014. MedCalc for Windows (Version 14.10.2). Available at: ⟨http://www.medcalc.org/calc/relative_risk.php⟩ (accessed 28 October 2014).
The Cochrane Editorial Resources Committee, 2013. Data Collection Form (V2). Available at: ⟨http://training.cochrane.org/authors/resources/checklists-and-forms⟩ (accessed 8 November 2014).
The Cochrane Pregnancy and Childbirth Group, n.y. Data Extraction Form. Available at: ⟨http://pregnancy.cochrane.org/author-resources-new-reviews⟩ (accessed 1 November 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. Nurs. Health Sci. 13, 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. Aust. N. Z. J. Obstet. Gynaecol. 30, 157–160.

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PROTOCOL

Vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth: a protocol for a randomised controlled feasibility trial

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Abstract

Aim. This paper presents a feasibility trial protocol the purpose of which is to prepare for a future randomised controlled trial to determine the effectiveness of vibrating vaginal pelvic floor training balls for postpartum pelvic floor muscle rehabilitation.

Background. Vibrating vaginal pelvic floor training balls are available in Austria to enhance women's pelvic floor muscles and thus prevent or treat urinary incontinence and other pelvic floor problems following childbirth. Nonetheless, there is currently little empirical knowledge to substantiate their use or assess their relative effectiveness in comparison to current standard care, which involves pelvic floor muscle exercises.

Design. Single blind, randomised controlled feasibility trial with two parallel groups.

Methods. It is planned to recruit 56 postpartum women in Vienna, who will be randomised into one of two intervention groups to use either vibrating vaginal balls or a comparator pelvic floor muscle exercises for 12 weeks. As this is a feasibility study, study design features (recruitment, selection, randomisation, intervention concordance, data collection methods and tools) will be assessed and participants' views and experiences will be surveyed. Tested outcome measures, collected before and after the intervention, will be pelvic floor muscle performance as reported by participants and measured by perineometry. Descriptive and inferential statistics and content analysis will serve the preparation of the future trial.

Discussion. The results of this feasibility trial will inform the design and conduct of a full randomised controlled trial and provide insight into the experiences of women regarding the interventions and study participation.

Keywords: feasibility studies, midwifery, pelvic floor, perineal care, postnatal care, postpartum period, RCT, resistance training, urinary incontinence, vaginal balls/cones

Why this study is needed?

- Vibrating vaginal balls are used with little scientific evidence on their effectiveness.
- If effective, vibrating vaginal balls could enhance pelvic floor muscle training choices for women after childbirth.
- A robust randomised controlled trial needs careful preparation and will be informed by the proposed feasibility trial.

Introduction

Pelvic floor health is an important issue for women worldwide and the impact of pelvic problems on women's lives can be considerable. Pelvic problems impair women's quality of life, women feel in a vulnerable situation and experience powerlessness in living with an unpredictable body; this negatively affects their intimate relationships, work and social activities (Margalith *et al.* 2004, Hägglund & Ahlström 2007, O'Reilly *et al.* 2009).

Pregnancy and childbirth have been identified as etiological factors of pelvic floor problems in a woman's life (Koelbl *et al.* 2013). In the first 3 months postpartum, 33% of women are reported to experience urinary incontinence, with small changes over the first year post partum (Thom & Rortveit 2010). Faecal and flatal incontinence were reported by 10% and up to 24% of women respectively at 6 weeks after delivery (Hall *et al.* 2003, Borello-France *et al.* 2006) and by 1% and 26% of women at 9 months after vaginal delivery (Zetterstrom *et al.* 1999); pelvic organ prolapse stage ≥II was found to have a prevalence between 7·7% and 56% in the 3-6 months after birth (Diez-Itza *et al.* 2011a,b, Wai *et al.* 2011).

The described pelvic floor problems are assumed to be associated with suboptimal pelvic floor muscle performance. Several studies found that the pelvic floor muscles of urinary continent women performed better than those of incontinent women (Hahn *et al.* 1996, Bø 2003, Mørkved *et al.* 2004, Baracho *et al.* 2012, Hilde *et al.* 2013). Pelvic floor muscle weakness may also be a factor contributing to anal incontinence and pelvic organ prolapse (Bø & Frawley 2007, Mørkved 2007, Sahlin & Berner 2007, Koelbl *et al.* 2013).

Irrespective of pelvic floor symptoms, a reduced pelvic floor muscle performance after vaginal delivery was demonstrated in the short (Marshall *et al.* 2002, Baytur *et al.* 2007, Sigurdardottir *et al.* 2011, Hilde *et al.* 2013) and long-term (Friedman *et al.* 2012). Therefore, in combination with the correlations described above, pelvic floor muscle training is recommended as a standard intervention to all women in postpartum care (Abrams *et al.* 2010). Training in women without symptoms aims at enhancing pelvic floor muscle performance as secondary prevention of stress urinary incontinence or other pelvic floor muscle impairment symptoms later in life. However, Koelbl *et al.* (2013) temper this statement by recommending that health providers should carefully consider the cost/benefit of population based approaches to health professional taught pelvic floor muscle training to all postpartum women regardless of their continence status. Midwives and nurses as key professionals in this period of high pelvic floor vulnerability in a woman's life need to be knowledgeable and proactive in promoting pelvic floor health and thus, the proposed study aims to provide all health care workers with useful information for pelvic floor care.

Background

To promote pelvic floor health in women after childbirth, the commonly recommended intervention to treat and prevent pelvic floor problems is instructing women to perform pelvic floor muscle exercises (Boyle *et al.* 2012, Mørkved & Bø 2014). An alternative pelvic floor muscle rehabilitation method consists in the vaginal use of cones or balls. These devices can be cylinders either conical at one end or rounded at both ends, or ball-shaped, and they come in different weights (to be increased during training) and sizes (Bø & Aschehoug 2007). According to Bø (2007), their assumed working mechanism consists of reflexive or voluntary contractions of the pelvic floor muscles to prevent the inserted cones/balls from slipping out, thus enhancing pelvic floor muscle performance. Additionally, sensory (by feeling pressure from the cone) and kinesthetic (by feeling the cone move downwards) biofeedback teaches women to identify their pelvic floor muscles so they are enabled to contract them consciously (Chiarelli & Moore 2008). Vibrating vaginal balls are considered to provide further stimulation by vibrations caused mechanically by a loose inner ball when the woman is moving with the ball inserted (Glavind 2001).

A systematic review (Oblasser *et al.* 2015) showed a dearth of evidence on the effectiveness of vibrating balls to enhance pelvic floor muscle performance or urinary continence in the postpartum period. A secondary analysis of original data of the only included study (Wilson & Herbison 1998) in the aforementioned systematic review suggests that use of non-vibrating weighted vaginal cones might be helpful for urinary incontinence after childbirth but the evidence was limited. Glavind (2001) studied the

associated outcomes of vibrating vaginal ball use in women with stress urinary incontinence in a clinical trial but this was not specific to the postpartum period. Within the methodological limits of only ten women in a single group, the study showed encouraging results and the author recommended further research on ball effectiveness. Thus, all available data correspond with the results of a Cochrane review on non-vibrating weighted vaginal cones (including balls) for women with urinary incontinence (not specifically post partum) which provided some evidence that weighted vaginal cones are more useful than no active treatment for urinary incontinence and might be of similar effectiveness to pelvic floor muscle exercises. This review recommended larger, high-quality trials to reach a more firm conclusion on their effectiveness (Herbison & Dean 2013).

Thus, while pelvic floor care is an important issue for all women after childbirth, there is limited evidence to evaluate the use of vibrating vaginal balls. Such vibrating balls are available for sale in Austria (see e.g. Fun Factory no date) and seem to be known and accepted among women as an option to strengthen the pelvic floor muscles after childbirth; also women and professionals provide anecdotal evidence about their effectiveness. Such a device which helps to rehabilitate the pelvic floor muscles effectively without deliberate exercise would be practical and time saving and give women more choice about pelvic floor care. Conversely, it is important not to recommend and spend money on an ineffective device. Research can scientifically examine whether these devices are effective and thereby further evidence-based practice.

The best research design to determine the effectiveness of an intervention is a randomised controlled trial (RCT) (OCEBM Levels of Evidence Working Group 2011). As a full RCT needs careful preparation and more basic research on the intervention is needed, a feasibility trial is proposed here. The novelty of the proposed research lies in the particular suggested working mechanism of the balls, pelvic floor muscle performance as an outcome measure, the greater intended number of participants than in Glavind's (2001) genitive study, the targeted use for women after childbirth and in its methodological purpose.

The study

Aims

The proposed study aims to assess practical issues and feasibility for good design of a future full RCT which will determine the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth. Furthermore, the feasibility trial will monitor any potential harms of the experimental intervention; explore women's perspectives on and experiences with the interventions and the trial.

Research questions

- How can an RCT on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance after childbirth be prepared and performed best?
- How many participants would be needed for a full trial to test effectiveness?
- What are women's perspectives on and experiences with the interventions and the trial?
- Is there any harm associated with the experimental intervention?

Objectives

- Determine feasibility of a future full trial
- Explore different recruitment strategies
- Test appropriate outcome measures
- Determine descriptive characteristics of the future RCT's outcome measures
- Explore effect sizes
- Increase clinical experience with the experimental intervention
- Collect harms-related data of the experimental intervention
- Increase knowledge on the theoretical basis of the experimental intervention
- Investigate women's perspectives on and experiences with the interventions and the trial
- Determine concordance with the interventions and identify any adaptations needed to increase this
- Assess staff, time and budget necessary for a full RCT

Design/methodology

The study will be a single blind, randomised controlled feasibility trial with two parallel groups (use of vibrating vaginal ball versus pelvic floor muscle exercises).

Sample

The opportunity and volunteer sample in Vienna will be hospital and community based. The inclusion and exclusion criteria, selected to include healthy women, control for confounding factors, minimise the risk of infection and for

pragmatic and ethical reasons, are shown in Table 1. Recruitment will be explored via different routes:

- Postnatal wards of Vienna General Hospital
- Delivery suite of Vienna General Hospital
- Community midwives
- Practices of obstetrician-gynaecologists
- Midwifery Centre Vienna (Hebammenzentrum Wien) and Nanaya (parenting centre)
- Relevant websites (e.g. the Austrian Midwifery Board website, or facebook)

Professionals at the different sites will approach eligible women, or leaflets will be placed. If possible, a potential participant's phone number is noted so that CO can actively approach her, otherwise women have to approach the researcher themselves. Web recruitment also relies on self recruitment of women. If a woman's interest and eligibility is confirmed at an initial contact with CO (mostly a phone call), she is sent an information/consent form via e-mail or mail in case she does not have it yet (this depends on recruitment route). Not earlier than 7-10 days after she has received the form, the potential participant is called to ask if she is still interested and to answer possible questions. If interested in participation, a personal meeting between her and CO on the venue of her choice (her home, hospital or a public place where sufficient privacy can be obtained) is arranged, earliest after the 6 weeks postpartum check by her obstetrician-gynaecologist. At this meeting, the study will be fully explained and details can be clarified. If applicable, the participant information/consent form will be signed and data collection will start.

56 women from the accessible population are planned to be recruited from February 2015–February 2016. This sample size was based on the following rationales for feasibility and pilot studies:

- A sample size of 55 is recommended for pilot studies by Sim and Lewis (2012) to determine descriptive characteristics of outcome measures for calculation of sample size for the main trial.
- Using the formula for calculating sample sizes to be able to determine feasibility proportions by Hooper (no date), the determination of a rate of ≥80% with a 95% CI from 70-90 (the lowest feasibility rate in this trial, see feasibility criteria in Table 2) requires a sample size of 56.

Treatment assignment. Allocation of participants to trial groups will be done by randomisation in blocks of different

Table 1 Inclusion and exclusion criteria.

Inclusion criteria
• Women from 6 weeks to 6 months after vaginal childbirth (at beginning of intervention)
• Term birth, i.e. 37+ 0 or more weeks of gestation
• 6 weeks postpartum check by obstetrician-gynaecologist performed and woman discharged from postpartum care with diagnostic findings appropriate to this period after childbirth
• Lochia have ceased
• Over the age of 18 with capacity to consent
• Sufficient knowledge of written and spoken German to be able to participate in the study
• Baby alive/not seriously ill
Exclusion criteria
• Currently enrolled in pelvic floor muscle training with physiotherapist, midwife or fitness trainer
• Status post perineal tear 3rd or 4th degree at most recent birth
• Status post continence surgery
• Current pelvic floor or gynaecological surgery
• Current infection of genitourinary tract
• Recurrent (>5 infectious episodes during last 12 months) or chronic (>3 weeks duration of single episode in last 12 months) vaginal infections
• Neuromuscular conditions influencing pelvic floor muscle function (e.g. multiple sclerosis)
• Major medical condition influencing infectious risk (diabetes, immune suppressive therapy, HIV infection etc.)
• Currently on medication that could interfere with treatment or evaluation
• Currently enrolled in any other research study
• Pregnancy (also commencing during participation) or pregnancy planned within the study period
• Retention of ball is impossible
• Inability to perform the proposed procedures

Table 2 Feasibility criteria: the full trial will deemed to be feasible if all of the following criteria are met.

Recruitment:
• ≥10% of eligible persons give consent to participate in the trial (can only be calculated for recruitment where professionals will note the number of eligible women).
Pre intervention data collection:
• At least 50 of the 56 or ≥90% (95% CI = 80-100) of participants attend the first pelvic floor muscle measurement within 3 weeks of consenting to take part in the trial.
Completion and concordance:
• At least 50 of the 56 or ≥90% (95% CI = 80-100) of participants start with the intervention within 4 days of the initial pelvic floor muscle measurement by perineometry.
• At least 45 of the 56 or ≥80% (95% CI = 70-90) of enrolled participants keep to the assigned intervention group and adhere adequately to the intervention.
Post intervention data collection:
• At least 45 of the 56 or ≥80% (95% CI = 70-90) of enrolled participants have the final data collection within 2 weeks of ending the intervention.

size. Blocked randomisation promotes an even distribution of participants, especially in small samples where only part of the intended sample size may be recruited as in the proposed study; different size of blocks will help prevent selection bias by keeping the investigator masked to the size of each block and thus unable to predict allocation (Efird 2011). To obtain more information about the experimental intervention (Duan 2013), the allocation ratio is skewed towards the ball group with two-thirds (37) of participants allocated to the experimental and one-third (19) to the comparison arm.

The allocation sequence will be produced via an appropriate computer programme accessible only to a research administrator. Opaque sealed envelopes serially numbered with the participant identification numbers and containing the codes generated by the computer programme will be prepared in advance. Each time a participant is randomised following consent by CO, the envelope with her participant identification number will be opened.

Interventions. The experimental intervention is the use of the EC licensed pelvic floor muscle training ball Laselle Kegel Exerciser 28 g (Intimina 2014). The ball is inserted into the vagina and left for 15 minutes daily in the first week and if well tolerated 30 minutes daily from the second week onwards. To achieve the vibrating effect, the balls are worn while moving – performing everyday tasks or going for a walk. The balls are not to be worn during menstruation or intercourse, other contraindications are covered in the exclusion criteria (Table 1). Detailed instructions for use are given to participants in the information/consent form and explained verbally by CO before signing. The participants will neither be prohibited nor encouraged to do the pelvic floor muscle exercises they have been recommended by their health practitioners.

Comparison will be made to basic usual care after childbirth in Austria, which is the routine recommendation to do pelvic floor muscle exercises. Although courses for supervised pelvic floor muscle training for women after childbirth are available, many women do not attend and if they do, costs are not defrayed by the health insurance system. Participants will be asked to continue/start the pelvic floor muscle exercises they routinely were recommended by customary written instructions from their health professionals after birth. If women have not been given an instruction sheet, they will be given one designed for this study and the techniques will be explained to them. There are no contraindications to this intervention.

Duration of the interventions is projected for 12 weeks, in accordance with the recommended pelvic floor muscle training duration for urinary incontinence in the UK NICE guidelines (National Collaborating Centre for Women's and Children's Health 2013) and with Glavind (2001). To chart concordance, participants will be asked to keep a training diary to note if/how long the ball was worn or if/how often the exercises were performed. Concordance is defined as adequate when at least 80% (in days) of the prescribed exercise sessions have been completed. This diary is also likely to enhance participants' retention in the study and concordance with the intervention, as well as planned phone calls for adverse events monitoring.

Data collection. Table 3 summarises which data will be collected when and how. All except one of the data collection tools have been designed specifically for this study. The questionnaire to collect participant reported pelvic floor outcome measures contains a self-designed section with measures of pelvic floor muscle performance and vaginal/bowel symptoms taken from the pelvic floor questionnaires by Dietz *et al.* (2012), Thibault-Gagnon *et al.* (2014)

Table 3 Summary of data collection.

Variable(s)	Timepoint	Method of collection
Feasibility variables (see criteria in Table 2)	Throughout study and at the end of trial data collection	Calculation
Staff, time, and budget necessary	Throughout study	Noting down in a list, calculation
Baseline variables	Before the intervention	Structured interview
Participant reported pelvic floor outcome measures	Before and after the intervention	Structured questionnaire to be completed by participant
Technically assessed pelvic floor muscle performance	Before and after the intervention	Physiological measurement by perineometry
Women's perspectives and experiences	Before and after the intervention OR after the intervention	Structured interview OR structured anonymous questionnaire
Concordance	Throughout study	Training diary
Adverse events/harm	Throughout study	Phone interviews, question in final interview/survey, self-reporting by participants

and Bässler and Kempkensteffen (2009) (consent from authors obtained). Original questions were adapted to suit the purpose of this study, in consideration of patient and public involvement (PPI, see below) input and to enable a consistent questionnaire design. It also includes the validated German International Consultation on Incontinence Modular Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF) (Avery *et al.* 2004). Perineometric measurements comprise vaginal resting pressure, maximum pressure and endurance. Correctly performed in a standardised manner, they have been shown to be valid and reliable (Bø *et al.* 1990a,b, Hundley *et al.* 2005, Frawley *et al.* 2006). Study documents will be made available with the report of the study itself.

Blinding (masking) of participants, personnel and outcome assessors is recommended to avoid risk of bias in clinical trials (Higgins *et al.* 2011). To avoid detection bias, the assessor measuring pelvic floor muscle performance will be masked in this study by withholding allocation information by asking participants not to reveal their intervention during measurement. Masking of participants (by withholding information about the alternative options) would make the trial flow more complicated with this intervention and there is a large risk of unmasking as mothers might meet and talk to each other. Therefore, participants are not masked. CO, assigning participants to interventions, explaining procedures, doing baseline data and participant reported outcome data collection and interviews, as well as analysis, will not be masked.

Table 4 shows the study flow from a participant's view. 18 women of the vaginal ball group and 10 of the exercises group will be interviewed by structured interviews before the intervention to examine their views on the intervention and the trial and after the intervention to gain their perspectives on and now experiences with the intervention and their participation in the trial. From these interviews, a questionnaire will be developed to anonymously survey the following participants and to pilot it for the main trial.

The 28 survey participants will be offered the questionnaire to complete after their last meeting with the researcher. If the participant has Internet access, she will be given the online link to complete the electronic version of the questionnaire. Otherwise, it will be handed out in paper form with an addressed and stamped envelope and expected to be sent back via mail. Two global text message reminders will be sent 1 and 2 weeks later to enhance response rate (QuestionPro Survey Software 2015). Feasibility variables will be calculated according to the criteria in Table 2. Any woman who does not wish to participate or asks to withdraw from the study will be given an opportunity to give her reasons for doing so.

Data management and analysis. Data will be collected on paper or via online forms created via *formAssembly* at City University London and will subsequently be entered into a computer database. To avoid entry errors, data will be double-checked on a later day. Data will be processed and analysed using the currently available versions of Excel and/or SPSS (IBM Corporation 2012/13), with support from a statistical advisor.

Feasibility criteria and resources calculation will be analysed descriptively, as well as baseline data, concordance and pelvic floor outcome measures. Groups will be compared by appropriate tests in a superiority analysis. Due to the nature of a feasibility trial, there will be no hypothesis testing (Eldridge 2013, *Feasibility and Pilot Studies* no year) and the results from statistical tests are not planned to be published except in the doctoral thesis. For continuous data, these will be repeated measures analysis of variance (ANOVA) or independent t-test for parametric and linear regression analysis or Mann-Whitney U test for nonparametric data respectively. For dichotomous data, these will be logistic regression or Fisher's exact test. If a large imbalance between groups is found for a confounding factor, statistical adjustment will be made by using ANCOVAs for the planned ANOVAs, or by using stratified analyses for the other tests. The intention-to-treat analysis will exclude participants who are found to be ineligible after randomisation. Missing values will be dealt with according to their nature and with the technique appropriate to the reason why they are missing. The findings from these group comparisons are intended to refine hypotheses and better understand the needs of a full trial in terms of best primary outcome measure and sample size calculation.

Qualitative data will be processed and analysed following the principles of processing qualitative survey data given by Oppenheim (2000). They will thus be either precoded, or content analysis will create codes for answers to open questions and categorise answers into these codes to condense information.

Ethical considerations

The ethical principles (according to the World Medical Association 2013) of doing no harm, participants' right to autonomy, information and data protection, as well as safety of the researcher were considered. The study was approved by the relevant ethics committees (Table 5). The trial will be conducted in accordance with the research protocol and any

Table 4 Schedule of enrolment, interventions, and assessments.

	Study period									
	Enrolment			Allocation	Post-allocation				Close-out	
	−t3	−t2 7-10 days after −t3	−t1 not before six weeks after birth	0 = −t1	t1 = −t1/0	t2 within 2 weeks of t1	t3-t7	t8 within 2 weeks after ending the intervention	t9 within 2 weeks after ending the intervention
1. Enrolment									
Recruitment	Via different routes								
Recruitment Initial eligibility screen		Phone call (15 min.) (for those concerned)							
Eligibility screen			a						
Informed consent			a						
2. Allocation				a					
3. Interventions						Starts after perineometry	× (12 weeks)		
4. Assessments									
Baseline variables collection					a				
Participant reported outcome variables collection					a			c	
Perineometry						b			b
Interviews OR questionnaire					a			c OR after c (15-20 min)	
Adverse events monitoring							5 phone calls (à 5-10 min)	c	

a = personal meeting of CO with the potential participant, on the venue most suitable to the participant (her home, hospital room or public place where sufficient privacy can be obtained). Estimated duration: 2 hours.

b = by masked assessor (EH); Participants have to travel to Vienna General Hospital. Estimated duration of contact: 15 minutes. Travel time according to participant.

c = personal meeting of CO with the participant, on the venue most suitable to the participant (her home, hospital room or a public place where sufficient privacy can be obtained). Estimated duration: 1-1.5 hours.

Table 5 Items from the World Health Organization trial registration data set.

Primary registry and trial identifying number	www.clinicaltrials.gov NCT02355327
Date of registration in primary registry	January 2015
Secondary identifying numbers	Lead Ethics Committee: Ethics Committee of the Medical University of Vienna, 1704/2014 (October 2014) Ethics Committee: Senate Research Ethics Committee of City University London, SREC 14-15 02 D 02 12 2014 (January 2015)
Source(s) of monetary or material support	City University London Northampton Square London EC1V 0HB United Kingdom Medizinische Universität Wien (Medical University of Vienna) Spitalgasse 23 1090 Wien Austria
Primary sponsor	City University London Northampton Square London EC1V 0HB United Kingdom
Secondary sponsor	Medizinische Universität Wien (Medical University of Vienna) Spitalgasse 23 1090 Wien Austria
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Contact for scientific queries	As above
Public title	Feasibility study on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth [translated from German]
Scientific title	Feasibility trial on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth
Country of recruitment	Austria
Health condition or problem studied	Pelvic floor health after childbirth
Interventions	• Experimental device: Laselle Kegel Exerciser Participants use a vibrating pelvic floor muscle training ball for 12 weeks. The ball is inserted into the vagina and left for 15 minutes daily in the first week, and if well tolerated 30 minutes daily from the second week onwards. To achieve the vibrating effect, the ball is worn while moving – performing everyday tasks or going for a walk. • Active behavioural control: Pelvic floor muscle exercises Participants get usual care after childbirth, which is the routine recommendation of pelvic floor muscle exercises. Participants will be asked to continue/start the pelvic floor muscle exercises they routinely were recommended by customary written instructions from their health professionals after birth. • Intervention duration for this study is 12 weeks.
Key inclusion and exclusion criteria	See Table 1
Study type and design	Study type: interventional Allocation: randomised Intervention Model: parallel assignment Masking: single blind (outcome assessor) Purpose: feasibility trial

Table 5 (*Continued*).

Date of first enrollment	February 2015
Target sample size	56
Recruitment status	Recruiting
Primary outcomes	• Feasibility as measured by recruitment rate (Timepoint: within 4 weeks of ending recruitment) • Feasibility as measured by pre intervention pelvic floor muscle measurement attendance rate (Timepoint: within 4 weeks of ending data collection) • Feasibility as measured by start of intervention rate (Timepoint: within 4 weeks of ending data collection) • Feasibility as measured by concordance rate (Timepoint: within 4 weeks of ending data collection) • Feasibility as measured by retention rate (Timepoint: within 4 weeks of ending data collection) • Feasibility as measured by post intervention data collection attendance rate (Timepoint: within 4 weeks of ending data collection) • Feasibility as measured by staff necessary (Timepoint: within 4 weeks of ending data collection) • Feasibility as measured by time necessary (Timepoint: within 4 weeks of ending data collection) • Feasibility as measured by budget necessary (Timepoint: within 4 weeks of ending data collection)
Key secondary outcomes	• Participant reported pelvic floor muscle outcomes as measured by structured questionnaire (Timepoint: within 3 weeks before the intervention) • Participant reported pelvic floor muscle outcomes as measured by structured questionnaire (Timepoint: within 2 weeks after the intervention) • Pelvic floor muscle performance as measured by perineometry (Timepoint: within 4 days before the intervention) – by masked assessor • Pelvic floor muscle performance as measured by perineometry (Timepoint: within 2 weeks after the intervention) – by masked assessor • Women's perspectives and experiences as measured by structured interviews (Timepoint: within 3 weeks before the intervention) – 28 of 56 women • Women's perspectives and experiences as measured by structured interviews (Timepoint: within 2 weeks after the intervention) – same 28 of 56 women as for previous outcome measure • Women's perspectives and experiences as measured by structured anonymous questionnaire (Timepoint: within 3 weeks after the intervention) – 28 of 56 women (those not included in the two previous outcome measures) • Concordance to interventions as measured by training diary (Timepoint: at time of intervention (12 weeks)) • Type, severity and number of adverse events as measured by active and passive surveillance (interview, self-report) (Timepoint: at time of intervention (12 weeks)) • Type, severity and number of adverse events as measured by active and passive surveillance (interview/questionnaire, self-report) (Timepoint: up to 1 year after end of intervention) – first 28 of 56 women: interview, second 28 of 56 women: questionnaire

amendments if needed, will be clarified with the ethics committees and communicated at the trial registry.

Participants must provide written informed consent. This will be obtained by CO in a personal meeting with each prospective participant, after having allowed her enough time to read the information/consent form and to reflect about participation and after thorough discussion of all unclear issues. The consent form was created according to the template by the lead ethics committee and is kept in lay language. Confidential secure handling of personal data is regulated by the Austrian Data Protection Act (Bundeskanzleramt Österreich 2015) and by City University London's requirements for retention, access and storage of the data.

Safety of medical devices used

Laselle Kegel Exercisers by Intimina/LELO are of body-safe, phthalate-free FDA-approved silicone and ABS (Intimina 2014) and they are a EU/EEC licensed medical device class 1 (Council Directive 93/42/EEC), as is the vaginal measurement probe. The handheld microprocessor of the measurement device Peritron™ (from Laborie) does not have a CE mark. However, the Peritron™ has already been used in other studies.

Adverse effects of interventions

The use of vaginal pelvic floor balls seems to be a safe method of training. In the studies that mention adverse effects of balls or cones, these are rare and not serious. In a German pharmaceutic consumer survey on the Laselle Kegel Exercisers (Test-Club-Bericht 2013), no adverse effects were reported (cave: consumer journal). Glavind (2001), using another (double) model of vibrating vaginal balls, described a slight vaginal irritation in one of her ten participants. In their systematic review on weighted vaginal cones, Herbison and Dean (2013) mention discomfort and bleeding as reasons for women dropping out of treatment. Another adverse effect identified with cones is occasional muscle soreness at the beginning of the training (Fischer *et al.* 1996), and Bø *et al.* (1999) reported one woman with abdominal pain and two with vaginitis (out of 29). However, Glavind (2001) and Bø *et al.* (1999) included women up to 59 and 70 years, respectively, which might influence adverse effects. An Austrian physiotherapist having been working with pelvic floor training balls since 15 years confirms that some women have experienced bleeding, but she never has seen a case of vaginal infection (Udier 2014).

Pelvic floor muscle exercises seem to be a safe method of training, although the majority of studies do not consider reporting adverse effects (Boyle *et al.* 2012, National Collaborating Centre for Women's and Children's Health 2013). In one study with 107 participants, pain (once) and an uncomfortable feeling during exercise (three times) were identified as adverse effects (Lagro-Janssen *et al.* 1992). The pelvic floor measurement performed for this study is not known to carry any risks and there is no report about pain in any of the studies reviewed using this device.

Adverse events

Expected adverse events in the experimental group are discomfort, slight muscle soreness or pain (from too much training), slight vaginal bleeding (rarely), vaginal irritation (very rarely) or infection (very rarely). Expected adverse events in the comparison group are an uncomfortable feeling during exercise (rarely) or pain (very rarely). A policy of active and passive surveillance will be applied to monitor expected and unexpected adverse events after uptake of the assigned intervention:

- Participants will be informed in oral and written form about potential adverse effects and their warning signs.
- To check for adverse events, participants will be phoned at fixed intervals. The content of the call is standardised and the contacts will be documented.
- Adverse events assessment is part of the final interview and survey questionnaire.

Transfer to necessary care will be arranged should the need arise, and termination of participation will be recommended to a participant when there is vaginal infection, occurrence of repeated bleeding, or pregnancy. Adverse events recording will comprise type, severity and number of all events for all participants and will be reported according to interventions. Serious adverse events (SAEs), as defined by the guidance for clinical safety data management (European Medicines Agency 1995) and urgent safety measures will be reported to both research ethics committees.

Patient and public involvement

In planning the methodological features of this feasibility trial, six women having given birth were consulted as part of the recommended PPI process (National Institute for Health Research no date). The ethnic background of these women was Somali, British White and Austrian White. Consultation meetings were held between March and July 2014. Study issues in question at the time of meeting were discussed with the women, such as where best to recruit participants, their potential worries, number and kind of study contacts, or acceptability of the experimental intervention and outcome measurements. Their suggestions were e.g. to stress the importance of the research to potential participants, that Muslim women might not want to use a vaginal ball, to ask a female person for pelvic floor muscle measurement, or to prepare a paper questionnaire for women who do not have Internet access. Two women checked the appropriateness and comprehensibility of study documents for participants.

Validity and reliability/rigour

As advised for the chosen design (Eldridge 2013, *Feasibility and Pilot Studies* no year, Williams & Lecouturier no year), the study has clear feasibility aims and pre-defined progression criteria and there will be no hypothesis testing.

A scientifically justified calculation of the sample size for pilot/feasibility studies (Sim & Lewis 2012, Hooper no date) determined the appropriate number of participants, who are specified via inclusion and exclusion criteria. The key elements ensuring validity and reliability of the future randomised controlled trial – random group allocation, allocation concealment and masked assessment (Meinert 2012) – are applied. Even if the participants and researcher will be aware of group allocation, allocation can be concealed from the masked outcome assessor. The use of two methods of data collection – participant reported pelvic floor outcomes and technical measurement – in the same study and the same research approach will enhance outcome information on the variable pelvic floor muscle performance by methodological triangulation (Denzin 2009). The ICIQ-UI SF is a validated questionnaire and the perineometric measurements are valid and reliable. The quantitative research results will be complemented by qualitative data to take into account participants' points of view and experiences. Instruments developed for this study were submitted to a PPI process and will be tested further during the current study. PPI work also informed the other features in the preparation of the study. Data entered manually from collection forms into the computer database will be checked on a later day to avoid entry errors. Confounding variables will be controlled for by considering them as co-variables in the analysis. As this is a feasibility trial, a data monitoring committee is not needed. The compilation of this trial protocol and the present report correspond to the SPIRIT guidelines (Chan *et al.* 2013).

Registration, reporting and dissemination

The trial was registered based on the protocol version 2 from 19 October 2014. The registration items from the World Health Organization Trial Registration Data Set (WHO 2015) are presented in Table 5. Reporting and dissemination of the results is planned via completion of the thesis, professional conferences, publications in appropriate journals and to (PPI) participants. Authorship eligibility guidelines as recommended by the International Committee of Medical Journal Editors (2015) will apply.

Discussion

The proposed feasibility trial will collect information to prepare a future RCT. The novel aspect of this study, as far as known, is that the proposed study is the first one to look at the use of vibrating vaginal balls specifically during the postpartum period. The quantitative and qualitative information gained from this feasibility trial will be useful for midwives, nurses, other health practitioners and women after childbirth to help with promotion of pelvic floor health. By testing the planned processes it will also be useful for research in setting the basis and enhancing the rigour of the confirmatory future RCT to determine the effectiveness of the device of interest.

Limitations

A limitation inherent in the proposed research design is that no results about the effectiveness of the device researched will be available after completion of this study. The planned non-probability sampling approach of an opportunity and volunteer sample at a single city will reduce generalisibility of the results. Participants cannot be masked for the researched interventions and contamination of interventions might be found. 12 weeks may proof an intervention period too long for participants and concordance thus may be difficult to achieve.

Conclusion

The results of this trial will provide information about the features and feasibility of a future RCT concerning issues of trial design, recruitment, interventions, methods of measurement, data collection and data analysis. They will also provide information about any potential harms and participants' views of and experiences with the interventions and participating in a trial of it.

The interpretation and discussion will focus on feasibility, taking into account the stated feasibility criteria (Table 2), sources of potential bias or imprecision, and barriers or facilitators to participation and concordance. It will be concluded that the planned full RCT to determine the effectiveness of vibrating vaginal pelvic floor muscle training balls is feasible as planned, feasible with modifications or not feasible. If not feasible, the realisation of a full RCT must be abandoned. If feasible with modifications, necessary protocol alterations for the full scale trial based on the results of the feasibility trial will be clearly stated. If feasibility is shown, funding for the full trial will be sought.

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Conflict of interest

CO: The planned trial is CO's PhD research project. CM: none. EH: none. JC: none.

Author contributions

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/recommendations/)]:

- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

References

Abrams P., Anddersson 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.

Avery K., Donovan J., Peters T.J., Shaw C., Gotoh M. & Abrams P. (2004) ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. *Neurourology and Urodynamics* **23**(4), 322–330.

Baracho S.M., Barbosa da Silva L., Baracho E., da Silva L., Filho A., Sampaio R.F. & Mello de Figueiredo E. (2012) Pelvic floor muscle strength predicts stress urinary incontinence in primiparous women after vaginal delivery. *International Urogynecology Journal and Pelvic Floor Dysfunction* **23**(7), 899–906.

Bässler K. & Kempkensteffen C. (2009) Validierung eines umfassenden Beckenboden-Fragebogens für Klinik, Praxis und Forschung [Validation of a comprehensive pelvic floor questionnaire for clinical practice and research]. *Gynäklogisch-geburtshilfliche Rundschau* **49**(4), 299–307.

Baytur Y.B., Serter S., Tarhan S., Uyar Y., Inceboz U. & Pabuscu Y. (2007) Pelvic floor function and anatomy after childbirth. *Journal of Reproductive Medicine* **52**(7), 604–610.

Bø K. (2003) Pelvic floor muscle strength and response to pelvic floor muscle training for stress urinary incontinence. *Neurourology and Urodynamcis* **22**(7), 654–658.

Bø K. (2007) Pelvic floor muscle training for stress urinary incontinence. In *Evidence-Based Physical Therapy for the Pelvic Floor* (Bø K., Berghmans B., Mørkved S. & Van Kampen M., eds), Churchill Livingstone, Edinburgh, pp. 171–187.

Bø K. & Aschehoug A. (2007) Strength training. In *Evidence-Based Physical Therapy for the Pelvic Floor* (Bø K., Berghmans B., Mørkved S. & Van Kampen M., eds), Churchill Livingstone, Edinburgh, pp. 119–132.

Bø K. & Frawley H. (2007) Pelvic floor muscle training in prevention and treatment of POP. In *Evidence-Based Physical Therapy for the Pelvic Floor* (Bø K., Berghmans B., Mørkved S. & Van Kampen M., eds), Churchill Livingstone, Edinburgh, pp. 240–248.

Bø K., Kvarstein B., Hagen R. & Larsen S. (1990a) Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: I. Reliability of vaginal pressure measurements of pelvic floor muscle strength. *Neurourology and Urodynamics* **9**(5), 471–477.

Bø K., Kvarstein B., Hagen R.R. & Larsen S. (1990b) Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: II. Validity of vaginal pressure measurements of pelvic floor muscle strength and the necessity of supplementary methods for control of correct contraction. *Neurourology and Urodynamics* **9**(5), 479–487.

Bø K., Talseth T. & Holme I. (1999) Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones and no treatment in management of genuine stress incontinence in women. *BMJ* **318**(7182), 487–493.

Borello-France D., Burgio K.L., Richter H.E., Zyczynski H., Fitzgerald M.P., Whitehead W., Fine P., Nygaard I., Handa V.L., Visco A.G., Weber A.M. & Brown M.B. (2006) Fecal and urinary incontinence in primiparous women. *Obstetrics and Gynecology* **108**(4), 863–872.

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.

Bundeskanzleramt Österreich (2015) *Datenschutzgesetz 2000*. Retrieved from https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=bundesnormen&Gesetzesnummer=10001597 on 03 January 2015.

Chan A.W., Tetzlaff J.M., Gotzsche P.C., Altman D.G., Mann H., Berlin J.A., Dickersin K., Hrobjartsson A., Schulz K.F., Parulekar W.R., Krleza-Jeric K., Laupacis A. & Moher D. (2013) SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* **346**, e7586.

Chiarelli P.E. & Moore K.H. (2008) Exercise, feedback, and biofeedback. In *Pelvic Floor Re-education: Principles and Practice*, 2nd edn. (Baessler K., Schüssler B., Burgio K.L., Moore K.H., Norton P.A. & Stanton S.L., eds), Springer, London, pp. 184–189.

Denzin N. (2009) *The Research Act: A Theoretical Introduction to Sociological Methods*. Aldine Transaction, New Brunswick.

Dietz H.P., Shek K.L., Chantarasorn V. & Langer S.E.M. (2012) Do women notice the effect of childbirth-related pelvic floor trauma? *Australian and New Zealand Journal of Obstetrics and Gynaecology* **52**(3), 277–281.

Diez-Itza I., Arrue M., Ibanez L., Paredes J., Murgiondo A. & Sarasqueta C. (2011a) Influence of mode of delivery on pelvic organ support 6 months postpartum. *Gynecologic and Obstetric Investigation* **72**(2), 123–129.

Diez-Itza I., Arrue M., Ibanez L., Paredes J., Murgiondo A. & Sarasqueta C. (2011b) Postpartum impairment of pelvic floor muscle function: factors involved and association with prolapse. *International Urogynecology Journal* **22**(12), 1505–1511.

Duan N. (2013) From pilot studies to confirmatory studies. *Shanghai Archives of Psychiatry* **25**(5), 325–328.

Efird J. (2011) Blocked randomization with randomly selected block sizes. *International Journal of Environmental Research and Public Health* **8**(1), 15–20.

Eldridge S. (2013) '*What is a Pilot Study and How Do I Do A Good One?*' [PowerPoint Presentation]. London.

European Medicines Agency (1995) *Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95)*. Retrieved from http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002749.pdf on 20 July 2014.

Feasibility and Pilot Studies (no year) Retrieved from https://www.uclan.ac.uk/research/explore/groups/assets/Feasibility_and_pilot_studies.pdf on 26 December 2014.

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.

Frawley H.C., Galea M.P., Phillips B.A., Sherburn M. & Bø K. (2006) Reliability of pelvic floor muscle strength assessment using different test positions and tools. *Neurourology and Urodynamics* **25**(3), 236–242.

Friedman S., Blomquist J.L., Nugent J.M., McDermott K.C., Munoz A. & Handa V.L. (2012) Pelvic muscle strength after childbirth. *Obstetrics and Gynecology* **120**(5), 1021–1028.

Fun Factory (no date) *Smartball uno*. Retrieved from https://www.funfactory.com/en/smartballs/smartball-uno/on 20 October 2014.

Glavind K. (2001) Conservative treatment of stress incontinence with Geisha balls. *International Urogynecology Journal* **12**(4), 223–224.

Hägglund D. & Ahlström G. (2007) The meaning of women's experience of living with long-term urinary incontinence is powerlessness. *Journal of Clinical Nursing* **16**(10), 1946–1954.

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.

Hall W., McCracken K., Osterweil P. & Guise J.M. (2003) Frequency and predictors for postpartum fecal incontinence. *American Journal of Obstetrics and Gynecology* **188**(5), 1205–1207.

Herbison G.P. & Dean N. (2013) Weighted vaginal cones for urinary incontinence. *Cochrane Database of Systematic Reviews* (7), CD002114.

Higgins J.P.T., Altman D.G. & Sterne J.A.C. (2011) Assessing risk of bias in included studies. In *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0* [updated March 2011] (Higgins J.P.T. & Green S., eds), The Cochrane Collaboration, chapter 8. Retrieved from http://handbook.cochrane.org/on 22 February 2014.

Hilde G., Staer-Jensen J., Siafarikas F., Engh M.E., Braekken I.H. & Bø K. (2013) Impact of childbirth and mode of delivery on vaginal resting pressure and on pelvic floor muscle strength and endurance. *American Journal of Obstetrics and Gynecology* **208** (1), 50.e1-7.

Hooper R. (no date) *Justifying Sample Size for a Feasibility Study*. Research Design Service, London. Retrieved from http://www.rdslondon.co.uk/RDSLondon/media/RDSContent/copy/Justifying-Sample-Size-for-a-Feasibility-Study.pdf on 28 April 2014.

Hundley A.F., Wu J.M. & Visco A.G. (2005) A comparison of perineometer to brink score for assessment of pelvic floor muscle strength. *American Journal of Obstetrics and Gynecology* **192** (5), 1583–1591.

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

International Committee of Medical Journal Editors (2015) Defining the Role of Authors and Contributors. Retrieved from http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html on 03 February 2015.

Intimina (2014) *Laselle Kegel Exercisers*. Retrieved from http://www.intimina.com/en/kegel-exercisers-laselle.php on 21 July 2014.

Koelbl H., Igawa T., Salvatore S., Laterza R.M., Lowry A., Sievert K.D. & Sultan A. (2013) Pathophysiology of urinary incontinence, faecal incontinence and pelvic organ prolapse. In *Incontinence*, 5th edn (Abrams P., Cardozo L., Khoury S. & Wein A., eds), ICUD-EAU, no place, pp. 263–359.

Lagro-Janssen A.L.M., Debruyne F.M.J., Smits A.J.A. & Van Weel C. (1992) The effects of treatment of urinary incontinence in general practice. *Family Practice* **9**(3), 284–289.

Margalith I., Gillon G. & Gordon D. (2004) Urinary incontinence in women under 65: quality of life, stress related to incontinence and patterns of seeking health care. *Quality of Life Research* **13** (8), 1381–1390.

Marshall K., Walsh D. & Baxter G. (2002) The effect of a first vaginal delivery on the integrity of the pelvic floor musculature. *Clinical Rehabilitation* **16**(7), 795–799.

Meinert C.L. (2012) *Clinical Trials: Design, Conduct and Analysis, Monographs in Epidemiology and Biostatistics*, 2nd edn. Oxford University Press, Oxford.

Mørkved S. (2007) Physical therapy for fecal incontinence. In *Evidence-Based Physical Therapy for the Pelvic Floor* (Bø K., Berghmans B., Mørkved S. & Van Kampen M., eds), Churchill Livingstone, Edinburgh, pp. 309–315.

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.

Mørkved S., Salvesen K.A., Bø K. & Eik-Nes S. (2004) Pelvic floor muscle strength and thickness in continent and incontinent nulliparous pregnant women. *International Urogynecology Journal and Pelvic Floor Dysfunction* **15**(6), 384–390.

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

National Institute for Health Research (no date) *Patient and Public Involvement in Health and Social Care Research: A Handbook for Researchers by Research Design Service London*. Retrieved from http://www.rdslondon.co.uk/RDSLondon/media/RDSContent/copy/RDS_PPI-Handbook_web.pdf on 01 July 2014.

Oblasser C., Christie J. & McCourt C. (2015) Vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum: a quantitative systematic review. *Midwifery* **31**(11), 1017–1025.

OCEBM Levels of Evidence Working Group (2011) *The Oxford 2011 Levels of Evidence*. Retrieved from http://www.cebm.net/wp-content/uploads/2014/06/CEBM-Levels-of-Evidence-2.1.pdf on 21 July 2014.

Oppenheim A.N. (2000) *Questionnaire Design, Interviewing and Attitude Measurement*, 2nd edn. Pinter Publishers Ltd., London.

O'Reilly R., Peters K., Beale B. & Jackson D. (2009) Women's experiences of recovery from childbirth: focus on pelvis problems that extend beyond the puerperium. *Journal of Clinical Nursing* **18**(14), 2013–2019.

QuestionPro Survey Software (2015) *10 Easy Ways to Increase Response Rates for your Online Survey*. Retrieved from http://www.questionpro.com/a/showArticle.do?articleID=deploy01 on 18 May 2015.

Sahlin Y. & Berner E. (2007) Fecal incontinence. In *Evidence-Based Physical Therapy for the Pelvic Floor* (Bø K., Berghmans B., Mørkved S. & Van Kampen M., eds), Churchill Livingstone, Edinburgh, pp. 304–309.

Sigurdardottir T., Steingrimsdottir T., Arnason A. & Bø K. (2011) Pelvic floor muscle function before and after first childbirth. *International Urogynecoly Journal* **22**(12), 1497–1503.

Sim J. & Lewis M. (2012) The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *Journal of Clinical Epidemiology* **65**(3), 301–308.

Test-Club-Bericht (2013) Intimina Laselle Vaginalkugeln zur Stärkung der Beckenbodenmuskulatur [Intimina Laselle vaginal balls for pelvic floor muscle strengthening]. *Gesunde Medizin* (5), 38–39.

Thibault-Gagnon S., Yusuf S., Langer S., Wong V., Sheck K.L., Martin A. & Dietz H.P. (2014) Do women notice the impact of childbirth-related levator trauma on pelvic floor and sexual function? Results of an Observational Ultrasound Study *International Urogynecology Journal* **25**(10), 1389–98. doi:10.1007/s00192-014-2331-z.

Thom D.H. & Rortveit G. (2010) Prevalence of postpartum urinary incontinence: a systematic review. *Acta Obstetetrica et Gynecologica Scandinavica* **89**(12), 1511–1522.

Udier E. (2014) *Skype Conversation with CO*. 14 May.

Wai C.Y., McIntire D.D., Atnip S.D., Schaffer J.I., Bloom S.L. & Leveno K.J. (2011) Urodynamic indices and pelvic organ prolapse quantification 3 months after vaginal delivery in primiparous women. *International Urogynecology Journal and Pelvic Floor Dysfunction* **22**(10), 1293–1298.

WHO (2015) WHO Data Set. Retrieved from http://who.int/ictrp/network/trds/en/on 10 February 2015.

Williams M. & Lecouturier J. (no year) Pilot and Feasibility Studies. Retrieved from http://www.themedcalls.nihr.ac.uk/__data/assets/pdf_file/0019/114175/LTC-CYP-Pilot-and-Feasibility-studies.pdf on 08 January 2015.

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.

World Medical Association (2013) *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. Retrieved from http://www.wma.net/en/30publications/10policies/b3/ on 17 March 2015.

Zetterstrom J.P., Lopez A., Andzen B., Dolk A., Norman M. & Mellgren A. (1999) Anal incontinence after vaginal delivery: a prospective study in primiparous women. *BJOG* **106**(4), 324–330.

Appendix D: Systematic review search strategies

Table 1 Cochrane Central Register of Controlled Trials (CENTRAL)

Search interface	Ovid
Search strategy	1. (post part* or postpart* or post natal* or postnatal* or "lying in" or puerper* or childbirth* or birth* or deliver*).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] 2. Postpartum Period/ 3. 1 or 2 4. (cone* or ball or balls or beads or Kegel exerciser* or weight* or device* or aid or aids).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] 5. resistance training/ 6. 4 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 Kegel).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] 8. Pelvic Floor/ 9. Perineum/ 10. 7 or 8 or 9 11. (train* or exercis* or educat* or re-educat* or reeducat* or rehabilitat* or restor* or conditioning).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] 12. exercise/ 13. exercise therapy/ 14. Rehabilitation/ 15. 11 or 12 or 13 or 14 16. 10 and 15 17. 6 or 16 18. (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*).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] 19. 8 or 9 or 18 20. (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).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] 21. muscle strength/ 22. Muscle Tonus/ 23. Muscle Contraction/ 24. physical endurance/ 25. 20 or 21 or 22 or 23 or 24 26. 19 and 25 27. (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*).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] 28. exp Urinary Incontinence/ 29. 27 or 28 30. 26 or 29 31. 3 and 17 and 30

Table 2 PubMed

Search interface	https://www.ncbi.nlm.nih.gov/pubmed/
Search strategy	“all fields” ((((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])))) AND ((((cone* OR ball OR balls OR beads OR Kegel exerciser* OR weight* OR device* OR aid OR “aids” OR "Resistance Training"[Mesh])))) OR ((((("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]))) AND ((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])))))) AND ((((((("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]))) AND ((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]))))) OR ((“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]))) Filters: Humans

Table 3 Embase

Search interface	Ovid
Search strategy	1. (post part* or postpart* or post natal* or postnatal* or lying in or puerper* or childbirth* or birth* or deliver*).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword] 2. puerperium/ 3. 1 or 2 4. (cone* or ball or balls or beads or Kegel exerciser* or weight* or device* or aid or aids).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword] 5. resistance training/ 6. 4 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 Kegel).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword] 8. pelvis floor/ 9. perineum/ 10. 7 or 8 or 9 11. (train* or exercis* or educat* or re-educat* or reeducat* or rehabilitat* or restor* or conditioning).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword] 12. 10 and 11 13. pelvic floor muscle training/ 14. 12 or 13 15. 6 or 14 16. (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*).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword] 17. 8 or 9 or 16 18. (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).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword] 19. muscle strength/ 20. muscle tone/ 21. muscle contraction/ 22. endurance/ 23. 18 or 19 or 20 or 21 or 22 24. 17 and 23 25. (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*).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword] 26. urine incontinence/ or mixed incontinence/ or stress incontinence/ or urge incontinence/ 27. 25 or 26 28. 24 or 27 29. 3 and 15 and 28 30. limit 29 to (human and exclude medline journals)

Table 4 Maternity and Infant Care Database

Search interface	Ovid
Search strategy	1. (post part* or postpart* or post natal* or postnatal* or lying in or puerper* or childbirth* or birth* or deliver*).mp. [mp=abstract, heading word, title] 2. Puerperium.de. 3. Postnatal period.de. 4. 1 or 2 or 3 5. (cone* or ball or balls or beads or Kegel exerciser* or weight* or device* or aid or aids).mp. [mp=abstract, heading word, title] 6. (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).mp. [mp=abstract, heading word, title] 7. Pelvic floor.de. 8. 6 or 7 9. (train* or exercis* or educat* or re-educat* or reeducat* or rehabilitat* or restor*).mp. [mp=abstract, heading word, title] 10. Exercise.de. 11. 9 or 10 12. 8 and 11 13. Pelvic floor exercises.de. 14. Kegel exercises.de. 15. 5 or 12 or 13 or 14 16. (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*).mp. [mp=abstract, heading word, title] 17. 7 or 16 18. (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).mp. [mp=abstract, heading word, title] 19. Physical endurance.de. 20. 18 or 19 21. 17 and 20 22. (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*).mp. [mp=abstract, heading word, title] 23. Urinary incontinence.de. 24. 22 or 23 25. 21 or 24 26. 4 and 15 and 25

Table 5 CINAHL

Search interface	EBSCO host
Search strategy	• Limiters: Human • Search modes: Boolean/Phrase S1: (“post part*” OR postpart* OR “post natal*” OR postnatal* OR "lying in" OR puerper* OR childbirth* OR birth* OR deliver*) OR ((MH "Puerperium") OR (MH "Postnatal Period"))

	S2: (cone* OR ball OR balls OR beads OR “Kegel exerciser*” OR weight* OR device* OR aid OR aids) OR (MH "Resistance Training") S3: ("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) AND (train* OR exercis* OR educat* OR re-educat* OR reeducat* OR rehabilitat* OR restor* S4: (MH "Kegel Exercises") S5: S2 OR S3 OR S4 S6: ("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 ((MH "Pelvic Floor Muscles") OR (MH "Perineum")) S7: (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 ((MH "Muscle Strength") OR (MH "Muscle Tonus") OR (MH "Muscle Contraction") OR (MH "Physical Endurance")) S8: S6 AND S7 S9: (“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 (MH "Urinary Incontinence+") S10: S8 OR S9 S11: S1 AND S5 AND S10 S12: S1 AND S5 AND S10

Table 6 PEDro

Search interface	https://search.pedro.org.au/advanced-search
Search strategy	• Body part: perineum or genito-urinary system • Subdiscipline: continence and women’s health • Method: clinical trial <u>Abstract&Title search for each of these terms:</u> post part*, postpart*, post natal*, postnatal*, "lying in", puerper*, *birth, Birth*, deliver*

Table 7 POPLINE

Search interface	http://www.popline.org/advancedsearch
Search strategy	**TITLE**: cone OR ball OR beads OR Kegel OR weight OR weight* OR device OR aid OR "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* **AND** **KEYWORD**: pelvis = one search vagina = a second, separate search postpartum women = a third, separate search

Table 8 AMED

Search interface	Ovid
Search strategy	1. (post part* or postpart* or post natal* or postnatal* or lying in or puerper* or childbirth* or birth* or deliver*).mp. [mp=abstract, heading words, title] 2. (cone* or ball or balls or beads or Kegel exerciser* or weight* or device* or aid or aids).mp. [mp=abstract, heading words, title] 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).mp. [mp=abstract, heading words, title] 4. Pelvic floor/ 5. perineum/ 6. 3 or 4 or 5 7. (train* or exercis* or educat* or re-educat* or reeducat* or rehabilitat* or restor* or conditioning).mp. [mp=abstract, heading words, title] 8. Exercise/ 9. Exercise therapy/ 10. Rehabilitation/ 11. 7 or 8 or 9 or 10 12. 6 and 11 13. 2 or 12 14. (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*).mp. [mp=abstract, heading words, title]

	15. 4 or 5 or 14 16. (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).mp. [mp=abstract, heading words, title] 17. Muscle strength/ 18. Muscle tonus/ 19. Muscle contraction/ 20. physical endurance/ 21. 16 or 17 or 18 or 19 or 20 22. 15 and 21 23. (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*).mp. [mp=abstract, heading words, title] 24. Urinary incontinence/ 25. 23 or 24 26. 22 or 25 27. 1 and 13 and 26

Table 9 Index Medicus for the South-East Asian Region (IMSEAR)

Search interface	http://imsear.li.mahidol.ac.th/
Search strategy	**Browse by subject:** • Cones and balls: Separate search for each of these terms: cone, ball, balls, bead, beads, Kegel, weight, weights, device, devices, aid, aids • Pelvic floor exercises: Separate search for each of these terms: pelvic, pelvis, vaginal, circumvaginal, perivaginal, levator, pubococcyge*, perine* **Title search in „Search all of IMSEAR Institutional Repository“:** • Cones or balls: Separate search for each of these terms: cone OR cone*, ball OR balls, beads, Kegel, “vaginal weight*”, “vaginal device*”, “vaginal aid” OR “vaginal aids” • Pelvic floor: Separate search for each of these terms: “pelvic floor”, “pelvic hammock", “pelvic muscle*”, "pelvic musculature", "pelvic diaphragm", “vaginal muscle*”, "vaginal musculature", circumvaginal, perivaginal, levator, pubococcyge*, perine*

Table 10 Conference Proceedings Citation Index

Search interface	Via City University London
Search strategy	• Indexes=CPCI-S • Timespan=All years #1: TS=(“post part*” OR postpart* OR “post natal*” OR postnatal* OR "lying in" OR puerper* OR *birth* OR deliver*) #2: TS=(Cone OR ball OR beads OR “Kegel exerciser*” OR weight* OR device* OR aid) #3: TS=(("pelvic floor" OR "pelvic hammock" OR “pelvic musc*” OR “*vaginal musc*” OR levator OR pubococcyge* OR "pelvic diaphragm" OR perine* OR Kegel) AND (train* OR exercis* OR educat* OR re-educat* OR reeducat* OR rehabilitat* OR restor* OR conditioning)) #4: #2 OR #3 #5: TS=(("pelvic floor" OR "pelvic hammock" OR pelvic musc* OR *vaginal musc* OR levator OR pubococcyge* OR "pelvic diaphragm" OR perine*) AND (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)) #6: TS=(“urinary stress incontinence” OR “stress urinary incontinence” OR “urinary *continen*” OR “stress incontinen*” OR “effort incontinen*” OR “involuntary urination” OR “leak* of urine” OR “urin* leak*”) #7: #5 OR #6 #8: #1 AND #4 AND #7

Table 11 ProQuest Dissertations & Theses Full Text

Search interface	Via City University London
Search strategy	• Textword-search (all(cone OR ball OR beads OR weight OR device OR aid) OR (all("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) AND (all(train* OR exercis* OR educat* OR re-educat* OR reeducat* OR rehabilitat* OR restor* OR conditioning) OR su.Exact("physical education" OR "exercise" OR "rehabilitation")))) AND (all("post part*" OR postpart* OR "post natal*" OR postnatal* OR "lying in" OR puerper* OR childbirth* OR birth* OR deliver*) OR su.Exact("postpartum period" OR "births")) AND ((all("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*) AND (all(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 su.Exact("pressure" OR "pressure measurement" OR "power"))) OR (all("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 su.Exact("urinary incontinence")))

Table 12 SCOPUS and Web of Science

Search for Wilson and Herbison (1998)			
Source	**Access via**	**Wilson and Herbison (1998) found in database**	**Search strategy**
Scopus	City University London	Yes	Screening “cited by”-list
Web of Science	City University London (Web of knowledge)	No	n.a.

Table 13 “Cited by”-link in databases

Search for Wilson and Herbison (1998)		
Source	**Wilson and Herbison (1998) found in database**	**Search strategy**
CENTRAL	Yes	“Find citing articles”
Embase	No	n.a.
Midirs	No	n.a.
Amed	No	n.a.
CPCI-S	No	n.a.
ProQuest Dissertations & Theses Global: Health & Medicine	No	n.a.

Table 14 WHO International Clinical Trials Registry Platform (ICTRP)

Search interface	http://apps.who.int/trialsearch/
Search strategy	• Recruitment status: ALL • All countries Condition: post part* OR postpart* OR post natal* OR postnatal* OR lying in OR puerper* OR childbirth* OR birth* OR deliver* **AND** Intervention: cone* OR ball OR balls OR beads OR Kegel exerciser* OR weight* OR device* OR aid OR aids OR 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

Appendix E: Systematic review data collection form

Systematic review data collection form – part 1

Data extraction form for: inclusion/exclusion

Name of person extracting data	
Date form completed *(day.month.year)*	
Notes:	

General information

Report citation	
Location of study	
Report ID *(created by me)*	
Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)*	
Publication type *(e.g. full report, abstract, letter)*	
Report ID of other reports of this study including errata or retractions *(additional reports of the same study should be grouped under the same study identifier (study ID))*	
Notes	

Study eligibility (PICOS)

Study characteristics	Eligibility criteria	Eligibility criteria met? If unclear please note: not reported vs reported unclearly Yes No Unclear
Types of intervention	*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 and balls of any form, size, weight or brand* *• with any method of instruction (advised by any health practitioner or self-taught by information material).*	☐ ☐ ☐
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 stress incontinence, will be included.* *Pregnant women, women with anal incontinence or major genitourinary/pelvic morbidity will be exluded.*	☐ ☐ ☐
Primary outcome measures	*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*	☐ ☐ ☐
Study Design	*Randomised or quasi-randomised (alternation, date of birth...) controlled trial with parallel design*	☐ ☐ ☐
Types of comparison	*Comparison could be done against physiological restitution (no device or treatment) or any form of pelvic floor muscle strength training, e.g. physiotherapy individually or in group, or pelvic floor exercises at home.*	☐ ☐ ☐
INCLUDE ☐	EXCLUDE ☐	
Reason for exclusion		
Notes:		

Systematic review data collection form – part 2

Data extraction form for each included study

Name of person extracting data	
Date form completed *(day.month.year)*	
Notes:	

Include here: Data extraction form for: inclusion/exclusion

Instruction

- 1. fill in this form, 2. screen study report to see if everything relevant is in this form
- State “reported unclearly” if so, or “NR” for not reported for the “unclear”-field
- n.a. = not applicable
- Make clear: direct citations (by speech marks) and changes in direct citations
- Make clear: personal assumption/calculation by writing in this darker blue

Characteristics of study

Methodology/ethics

	Descriptions as stated in report/paper	Location in source *(pg & quadrant/fig/table/other)*
Aim of study *(including e.g. efficacy, equivalence, pragmatic)*		
Research question		
Research hypothesis		
Unit of allocation *(individuals or clusters/groups)*		
Start date *(=start of recruitment)*		
End date *(=end of data collection)*		
Duration of study *(end-start)*		
Ethical approval obtained for study	☐ ☐ ☐ Yes No Unclear	
Study funding sources *(including role of funders)*		
Conflicts of interest for study authors *(e.g. funding)*	Stated: Potential?:	
Notes:		

Participants

		Description *Include comparative information for each intervention or comparison group if applicable and available*	Location in source *(pg & quadrant/fig/table/other)*
Population description *(from which study participants are drawn)*			
Setting *(including country, location and social context)*			
Inclusion criteria			
Exclusion criteria			
Sampling method *(e.g. convenience sample, stratified)*			
Method of recruitment of participants *(e.g. phone, mail, clinic patients)*			
Sample description	Age		
	Parity		
	Birth injuries		
	Weeks/months post partum		
	Breastfeeding		
	Continence status with diagnostic criteria		
	Ethnicity		

	Other relevant sociodemographics		
	Other		
Subgroups measured		☐ None ☐ UI vs non-UI ☐ Vibrating balls vs non-vibrating balls or cones ☐ Different duration of device use	
Subgroups reported		☐ None ☐ UI vs non-UI ☐ Vibrating balls vs non-vibrating balls or cones ☐ Different duration of device use	
Informed consent obtained		☐ Yes ☐ No ☐ Unclear	
Total no. randomised			
Clusters *(if applicable; no., type, no. people per cluster)*			
Baseline equality imbalances between groups If so, detail and record any rationale given		☐ Yes ☐ No ☐ Unclear	
Duration of participation *(from recruitment to last follow-up)*			

Equality imbalance between groups with regards to intervention uptake or attrition If so, detail and record any rationale for imbalance reported	Intervention uptake: ☐ ☐ ☐ Yes No Unclear Attrition: ☐ ☐ ☐ Yes No Unclear	
Are any outcome subgroup analyses provided for equality criteria?	☐ ☐ ☐ Yes No Unclear	
Notes:		

Intervention group

	Description as stated in report/paper	Location in source *(pg & quadrant/fig/table/other)*
Group name		
No. randomised to group		
Device description		
Method of use		
Timing	Frequency: Duration of each episode:	
Duration of treatment period		

Theoretical basis for *(include in-text key references)*	Device used: Method of use: Timing: Duration of treatment period:	
Is an original instigator/ source of the intervention given?	Yes ☐ No ☐ Who/reference:	
Method of instruction *(e.g. by which health practitioner, self-taught)*		
Any standardisation applied regarding implementation of the intervention? Which?	☐ ☐ ☐ Yes No Unclear	
Co-intervention(s)? Which?	☐ ☐ ☐ Yes No Unclear	
Integrity of delivery		
Adherence, incl. measurement and reason for non-adherence		
Notes:		

Comparison group(s)

Copy and paste table for each comparison group

	Description as stated in report/paper	Location in source *(pg & quadrant/fig/table/other)*
Group name		

No. randomised to group		
Description *(include sufficient detail for replication, e.g. content, dose, components)*		
Timing	Frequency: Duration of each episode:	
Duration of treatment period		
Theoretical basis for *(include in-text key references)*	Timing: Duration of treatment period:	
Is an original instigator/ source of the intervention given?	Yes ☐ No ☐ Who/reference:	
Method of instruction *(e.g. by which health practitioner, self-taught)*		
Any standardisation applied regarding implementation of the intervention? Which?	☐ ☐ ☐ Yes No Unclear	
Co-intervention(s)? Which?	☐ ☐ ☐ Yes No Unclear	
Integrity of delivery		
Adherence, incl. measurement and reason for non-adherence		
Notes:		

Primary outcome(s)

Copy and paste table for each primary outcome

	Description as stated in report/paper		Location in source *(pg & quadrant/fig/table/other)*
Outcome name			
Outcome definition *(with diagnostic criteria if relevant)*			
Time points measured *(specify whether from start or end of intervention)*			
Time points reported			
Is the length between end of intervention and outcome measurement described? If so, what is it? Is it likely to be adequate? Why?	☐ ☐ ☐ Yes No Unclear		
Outcome measurement tool			
Is validity and reliability of outcome tool adressed?	☐ ☐ ☐ Yes No Unclear How: Reviewer comments: Is/are the relevant outcome(s) reliable/valid measure(s)?		
Person measuring/ reporting; blinded?	Person:	Blinded: ☐ ☐ ☐ Yes No Unclear	

Any training of person measuring? Which training was provided?	☐ ☐ ☐ Yes No Unclear	
Is data collection likely to affect intervention? *(e.g. pretest or repeated measures)* Has this been considered?	☐ ☐ ☐ Yes No Unclear How?: ☐ ☐ ☐ Yes No Unclear How?:	
Are confounding variables identified? Which ones?	☐ ☐ ☐ Yes No Unclear	
Has confounding been adequately controlled for?	☐ ☐ ☐ Yes No Unclear How?:	
Unit of measurement *(if relevant)*		
Scales: upper and lower limits *(indicate whether high or low score is good)*		
Power *(e.g. power & sample size calculation)*	Power calculation undertaken prior to study: ☐ Yes ☐ No ☐ Unclear Planned power: Calculated sample size: Sample size “measurement available": → Power achieved: Why was desired sample size not achieved?	
Notes:		

Risk of bias assessment (adapted from Cochrane tool)

Domain	Support for judgement	Review authors' judgement
Selection bias		
Random sequence generation.	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence. ☐ ☐ ☐ High Risk Low Risk Unclear Risk
Allocation concealment.	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment. ☐ ☐ ☐ High Risk Low Risk Unclear Risk
Performance bias		
Blinding* of personnel *Assessments should be made for each main outcome (or class of outcomes).* **Adapted to no blinding of participants*	Describe all measures used, if any, to blind study personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated interventions by personnel during the study. ☐ ☐ ☐ High Risk Low Risk Unclear Risk

Detection bias		
Blinding of outcome assessment *Assessments should be made for each main outcome (or class of outcomes).*	Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Detection bias due to knowledge of the allocated interventions by outcome assessors. ☐ High Risk ☐ Low Risk ☐ Unclear Risk
Attrition bias		
Incomplete outcome data *Assessments should be made for each main outcome (or class of outcomes).*	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis, as well as loss of clusters*. State whether attrition, loss of clusters* and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors. **adapted to cluster RCTs*	Attrition bias due to amount, nature or handling of incomplete outcome data. ☐ High Risk ☐ Low Risk ☐ Unclear Risk
Reporting bias		
Selective reporting.	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Reporting bias due to selective outcome reporting. ☐ High Risk ☐ Low Risk ☐ Unclear Risk

Other bias		
Other sources of bias.	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were prespecified in the review's protocol, responses should be provided for each question/entry.	Bias due to problems not covered elsewhere in the table. ☐ High Risk ☐ Low Risk ☐ Unclear Risk

Analysis

1. **Primary outcomes – main analysis** (subgroup analysis below)

- *Copy and paste the appropriate (dichotomous, continous, ordinal) table for **each outcome** and **time point.***
- *Delete unnecessary tables.*

Imputation of missing data *(e.g. assumptions made for ITT analysis)*	☐ Yes ☐ No ☐ Unclear	

***Dichotomous** outcome:*			
	Description as stated in report/paper		Location in source *(pg & quadrant/fig/table/other)*
Comparison			
Number of time points recorded and time points			
Time point *(specify whether from start or end of intervention)*			
Unit of analysis *(individuals, cluster/groups)*			
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*	Used: Appropriate:		
Intention to treat analysis?	☐ Yes ☐ No ☐ Unclear		
Results	Intervention n=	Comparison n=	

Unadjusted	No. with event	No. participants measured	No. with event	No. participants measured	
Results adjusted, for what					
Any other results reported *(e.g. odds ratio, risk difference, CI or P value)*					
No. missing participants *(=randomised-measured)*					
Reasons missing					
No. participants moved from other group					
Reasons moved					
Reanalysis required? *(specify, e.g. correlation adjustment)*	☐ Yes ☐ No ☐ Unclear				n.a
Reanalysis possible?	☐ Yes ☐ No ☐ Unclear				
Reanalysed results					
Notes:					

Continuous *outcome:*		
	Description as stated in report/paper	Location in source *(pg & quadrant/fig/table/other)*

Comparison							
Number of time points recorded and time points							
Time point *(specify whether from start or end of intervention)*							
Only post-intervention or change from baseline?							
Unit of measurement							
Unit of analysis *(individuals, cluster/groups)*							
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*	Used: Appropriate:						
Intention to treat analysis?	☐ Yes ☐ No ☐ Unclear						
Results unadjusted	Intervention n=			Comparison n=			
	Mean	SD *(or other variance, specify)*	No. participants measured	Mean	SD *(or other variance, specify)*	No. participants measured	
Results adjusted, for what							

Any other results reported *(e.g. mean difference, CI, P value)*			
No. missing participants *(=randomised-measured)*			
Reasons missing			
No. participants moved from other group			
Reasons moved			
Reanalysis required? *(specify, e.g. correlation adjustment)*	☐ Yes ☐ No ☐ Unclear		n.a.
Reanalysis possible?	☐ Yes ☐ No ☐ Unclear		
Reanalysed results			
Notes:			

Ordinal *outcome:*		
	Description as stated in report/paper	Location in source *(pg & quadrant/fig/table/other)*
Comparison		
Number of time points recorded and time points		

Time point *(specify whether from start or end of intervention)*			
Only post-intervention or change from baseline?			
Scale			
Unit of analysis *(individuals, cluster/groups)*			
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*	Used: Appropriate:		
Intention to treat analysis?	☐ ☐ ☐ Yes No Unclear		
Results Unadjusted	Intervention n=	Comparison n=	
	No. participants measured	No. participants measured	
	Results:	Results:	
Results adjusted, for what			
Any other results reported *(e.g. odds ratio, risk difference, CI or P value)*			
No. missing participants *(=randomised-measured)*			
Reasons missing			
No. participants moved from other group			

Reasons moved			
Reanalysis required? *(specify, e.g. correlation adjustment)*	☐ Yes ☐ No ☐ Unclear		n.a
Reanalysis possible?	☐ Yes ☐ No ☐ Unclear		
Reanalysed results			
Notes:			

2. **Primary outcomes – subgroup analyses** (urinary continent vs incontinent participants, vibrating vs non-vibrating devices, different duration of device use)

- *Copy and paste the appropriate (dichotomous, continuous, ordinal) table for **each subgroup and outcome** and **time point** as required.*
- *Delete unnecessary tables.*

Imputation of missing data *(e.g. assumptions made for ITT analysis)*	☐ Yes ☐ No ☐ Unclear	

Subgroup:		
***Dichotomous** outcome:*		
	Description as stated in report/paper	Location in source *(pg & quadrant/fig/table/other)*
Comparison		
Number of time points recorded and time points		
Time point *(specify whether from start or end of intervention)*		

Unit of analysis *(individuals, cluster/groups)*					
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*	Used: Appropriate:				
Intention to treat analysis?	☐ Yes ☐ No ☐ Unclear				
Results unadjusted	Intervention n=		Comparison n=		
	No. with event	No. participants measured	No. with event	No. participants measured	
Results adjusted, for what					
Any other results reported *(e.g. odds ratio, risk difference, CI or P value)*					
No. missing participants *(=randomised-measured)*					
Reasons missing					
No. participants moved from other group					
Reasons moved					
Reanalysis required? *(specify, e.g. correlation adjustment)*	☐ Yes ☐ No ☐ Unclear				n.a.
Reanalysis possible?	☐ Yes ☐ No ☐ Unclear				

Reanalysed results		
Notes:		

Subgroup:		
Continuous *outcome:*		
	Description as stated in report/paper	Location in source *(pg & quadrant/fig/table/other)*
Comparison		
Number of time points recorded and time points		
Time point *(specify whether from start or end of intervention)*		
Only post-intervention or change from baseline?		
Unit of measurement		
Unit of analysis *(individuals, cluster/groups)*		
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*	Used: Appropriate:	

Intention to treat analysis?	☐ Yes ☐ No ☐ Unclear						
Results unadjusted	Intervention n=			Comparison n=			
	Mean	SD *(or other variance, specify)*	No. participants measured	Mean	SD *(or other variance, specify)*	No. participants measured	
Results adjusted, for what							
Any other results reported *(e.g. mean difference, CI, P value)*							
No. missing participants *(=randomised-measured)*							
Reasons missing							
No. participants moved from other group							
Reasons moved							
Reanalysis required? *(specify, e.g. correlation adjustment)*	☐ Yes ☐ No ☐ Unclear						n.a.
Reanalysis possible?	☐ Yes ☐ No ☐ Unclear						
Reanalysed results							
Notes:							

Subgroup:			
Ordinal *outcome:*			
	Description as stated in report/paper		Location in source *(pg & quadrant/fig/table/other)*
Comparison			
Number of time points recorded and time points			
Time point *(specify whether from start or end of intervention)*			
Only post-intervention or change from baseline?			
Scale			
Unit of analysis *(individuals, cluster/groups)*			
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*	Used: Appropriate:		
Intention to treat analysis?	☐ ☐ ☐ Yes No Unclear		
Results unadjusted	Intervention n=	Comparison n=	
	No. participants measured	No. participants measured	
	Results:	Results:	

Results adjusted, for what			
Any other results reported *(e.g. odds ratio, risk difference, CI or P value)*			
No. missing participants *(=randomised-measured)*			
Reasons missing			
No. participants moved from other group			
Reasons moved			
Reanalysis required? *(specify, e.g. correlation adjustment)*	☐ Yes ☐ No ☐ Unclear		n.a
Reanalysis possible?	☐ Yes ☐ No ☐ Unclear		
Reanalysed results			
Notes:			

3. Secondary outcomes

If no or unclear, go to next secondary outcome.

Intervention group		
	Description as stated in report/paper	Location in source *(pg & quadrant/fig/table/other)*
1. Perineal descent or pelvic organ prolapse	☐ Yes ☐ No ☐ Unclear *If yes, take outcome template from primary outcome tables*	

Risk of bias?		
2. Adverse effects	☐ ☐ ☐ Yes No Unclear	
Time point of data collection		
How was data collected?		
Results		
Risk of bias?		
3. Women's experiences and opinion	☐ ☐ ☐ Yes No Unclear	
What was recorded?		
Time point of data collection		
How was data collected?		
No. participants asked and number presenting views	Asked: Presenting views:	
Characteristics of participants; who is asked/not asked to participate?		
Research approach adopted		
How was data analysed? Is this appropriate?	How: Appropriate:	
Any subgroup analysis? Which?	☐ ☐ ☐ Yes No Unclear	

Any rigour criteria applied/identified? Which?	☐ Yes ☐ No ☐ Unclear	
Results		
Any discordant/differing views recorded? Which?	☐ Yes ☐ No ☐ Unclear	
Risk of bias?		
4. Resource requirements *(e.g.health care personnel, staff numbers, equipment)*	☐ Yes ☐ No ☐ Unclear	
Results		
Risk of bias?		
5. Economic information *(i.e. time necessary, intervention cost, changes in other costs as result of intervention)*	☐ Yes ☐ No ☐ Unclear	
Results		
Risk of bias?		

Comparison group(s) *Copy and paste table for each comparison group*		
	Description as stated in report/paper	Location in source *(pg & quadrant/fig/table/other)*

1. Perineal descent or pelvic organ prolapse	☐ ☐ ☐ Yes No Unclear *If yes, take outcome template from primary outcome tables*	
2. Adverse effects	☐ ☐ ☐ Yes No Unclear	
Time point of data collection		
How was data collected?		
Results		
Risk of bias?		
3. Women's experiences and opinion	☐ ☐ ☐ Yes No Unclear	
What was recorded?		
Time point of data collection		
How was data collected?		
No. participants asked and number presenting views	Asked: Presenting views:	
Characteristics of participants; who is asked/not asked to participate?		
Research approach adopted		
How was data analysed? Is this appropriate?	How: Appropriate:	
Any subgroup analysis? Which?	☐ ☐ ☐ Yes No Unclear	

Any rigour criteria applied/identified? Which?	☐ Yes ☐ No ☐ Unclear	
Results		
Any discordant/differing views recorded? Which?	☐ Yes ☐ No ☐ Unclear	
Risk of bias?		
4. Resource requirements *(e.g.health care personnel, staff numbers, equipment)*	☐ Yes ☐ No ☐ Unclear	
Results		
Risk of bias?		
5. Economic information *(i.e. time necessary, intervention cost, changes in other costs as result of intervention)*	☐ Yes ☐ No ☐ Unclear	
Results		
Risk of bias?		

Other information

	Description as stated in report/paper	Location in source *(pg & quadrant/fig/table/other)*
Key conclusions of study authors		
Miscellaneous comments from study authors		
Were there any unexpected benefits for anyone?	☐ Yes ☐ No ☐ Unclear Which?	
References to other relevant studies according to PICOS		
References to other relevant studies according to search strategy		
References to other relevant articles about vaginal cones or balls		
References to other relevant articles with reason for relevance		
Study author contact details *(will be filled in only if necessary)*		

Additional information requested	Yes ☐ No ☐ Information requested (content): From: Date: Response:
Notes:	

Exclusion after data extraction

Reasons for exclusion: (study design? participants? interventions/outcomes? attrition? bias?)

Date entered into RevMan and by whom?

Date data entered into RevMan checked and by whom?

Definitions

Assumed risk estimate	An estimate of the risk of an event or average score without the intervention, used in Cochrane 'Summary of findings tables'. If a study provides useful estimates of the risk or average score of different subgroups of the population, or an estimate based on a representative observational study, you may wish to collect this information.
Bias	A systematic error or deviation in results or inferences from the truth. In studies of the effects of health care, the main types of bias arise from systematic differences in the groups that are compared (selection bias), the care that is provided, exposure to other factors apart from the intervention of interest (performance bias), withdrawals or exclusions of people entered into a study (attrition bias) or how outcomes are assessed (detection bias). Reviews of studies may also be particularly affected by reporting bias, where a biased subset of all the relevant data is available.
Change from baseline	A measure for a continuous outcome calculated as the difference between the baseline score and the post-intervention score.
Clusters	A group of participants who have been allocated to the same intervention arm together, as in a cluster-randomised trial, e.g. a whole family, town, school or patients in a clinic may be allocated to the same intervention rather than separately allocating each individual to different arms.
Co-morbidities	The presence of one or more diseases or conditions other than those of primary interest. In a study looking at treatment for one disease or condition, some of the individuals may have other diseases or conditions that could affect their outcomes.
Compliance	Participant behaviour that abides by the recommendations of a doctor, other health care provider or study investigator (also called adherence or concordance).
Contemporaneous data collection	When data are collected at the same point(s) in time or covering the same time period for each intervention arm in a study (that is, historical data are not used as a comparison).

Exclusions	Participants who were excluded from the study or the analysis by the investigators.
Imputation	Assuming a value for a measure where the true value is not available (e.g. assuming last observation carried forward for missing participants).
Integrity of delivery	The degree to which the specified procedures or components of an intervention are delivered as originally planned.
Post-intervention	The value of an outcome measured at some time point following the beginning of the intervention (may be during or after the intervention period).
Power	In clinical trials, power is the probability that a trial will obtain a statistically significant result when the true intervention effect is a specified size. For a given size of effect, studies with more participants have greater power. Note that power should not be considered in the risk of bias assessment.
Providers	The person or people responsible for delivering an intervention and related care, who may or may not require specific qualifications (e.g. doctors, physiotherapists) or training.
Quasi-randomised controlled trial	A study in which the method of allocating people to intervention arms was not random, but was intended to produce similar groups when used to allocate participants. Quasi-random methods include: allocation by the person's date of birth, by the day of the week or month of the year, by a person's medical record number, or just allocating every alternate person.
Reanalysis	Additional analysis of a study's results by a review author (e.g. to introduce adjustment for correlation that was not done by the study authors).

Report ID	A unique ID code given to a publication or other report of a study by the review author (e.g. first author's name and year of publication). If a study has more than one report (e.g. multiple publications or additional unpublished data) a separate Report ID can be allocated to each to help review authors keep track of the source of extracted data.
Sociodemographics	Social and demographic information about a study or its participants, including economic and cultural information, location, age, gender, ethnicity, etc.
Study ID	A unique ID code given to an included or excluded study by the review author (e.g. first author's name and year of publication from the main report of the study). Although a study may have multiple reports or references, it should have one single Study ID to help review authors keep track of all the different sources of information for a study.
Theoretical basis	The use of a particular theory (such as theories of human behaviour change) to design the components and implementation of an intervention
Unit of allocation	The unit allocated to an intervention arm. In most studies individual participants will be allocated, but in others it may be individual body parts (e.g. different teeth or joints may be allocated separately) or clusters of multiple people.
Unit of analysis	The unit used to calculate N in an analysis, and for which the result is reported. This may be the number of individual people, or the number of body parts or clusters of people in the study.
Unit of measurement	The unit in which an outcome is measured, e.g. height may be measured in cm or inches; depression may be measured using points on a particular scale.
Validation	A process to test and establish that a particular measurement tool or scale is a good measure of that outcome.
Withdrawals	Participants who voluntarily withdrew from participation in a study before the completion of outcome measurement.

Appendix F: Literature on the use of vaginal cones post partum excluded from the systematic review

Three studies having researched the use of nonvibrating weighted cones for routine post partum pelvic floor muscle rehabilitation were excluded from the systematic review. They are presented in chronological order, together with the reasons for their exclusion.

Jonasson et al. (1989) studied the use of cones with 84 women of any parity and without postpartum complications at eight weeks after childbirth. For 12 weeks, the women either did pelvic floor muscle exercises or used cones. Thereafter, pelvic floor muscle strength was measured by the cone weight a woman could keep inside the vagina, which showed a statistically significant greater increase in pelvic floor muscle strength in women using cones. However, held cone weight later was detected not to be a valid scientific pelvic floor muscle strength measure (Hahn et al., 1996, Kerschan-Schindl et al., 2002). According to Newman and Laycock (2008), held cone weight is only to be used as an adjunct assessment tool in clinical practice. Attempts to contact Jonasson et al. (1989) for further information on the study, particularly on the use of other pelvic floor muscle strength measurements, were unsuccessful. This study was therefore excluded for not having used a valid and reliable measure of pelvic floor muscle strength.

Norton and Baker (1990) performed an RCT with continent and incontinent primiparous women starting six weeks after term vaginal delivery. They compared a cone group with a Kegel exercise group and a group which was only taught body mechanics (which the cone and exercise group were also taught). After four intervention weeks with adherence diaries, perineometry showed a statistically significant improvement in introital and lower vaginal pressure in the cone group. In the Kegel exercise group, introital but not lower vaginal pressure improved, the control group showed no improvement. Resting tone did not change statistically significantly in any group. The sample was small (60 women), study power was not discussed and accounted for. The published abstract envisages further data collection to determine outcomes after six months, but a corresponding publication could not be found. According to the contacted author, this was so because the sample was underpowered and the study seen as preliminary work with the three groups arriving at the same endpoint by six months (Norton, 2014). As this study was published as an abstract only and no further information could be obtained from the authors, it had to be excluded from the systematic review.

Fischer and Baessler (1996) and Fischer et al. (1996) (same study) studied the use of cones from six to eight weeks after birth. They compared four to six weeks of cone use in 71 women after spontaneous birth to 20 women doing pelvic floor muscle exercises (and eight nulliparae doing cone training). The comparisons showed only a small difference in contraction pressure raise by manometric assessment between the postpartum cone and exercise groups. The limitation of this study is the nonrandomised generation of the comparison groups (leading to participants in the exercise group having higher initial values) which was the reason to exclude it from the systematic review.

Appendix G: Statistical formulae

Sample size calculation for feasibility trial (Eldridge and Kerry, 2012, Hooper, no date)

$$p \pm 1.96 \sqrt{\frac{p(1-p)}{n}} \quad (1)$$

$$n = \frac{1.96^2\, p(1-p)}{\mathrm{CI}^2} \quad (2)$$

p = proportion of interest
n = required sample size
CI = confidence interval

Criterion for approximate normality (Jovanovic and Zalenski, 1997)

$$CAN = \frac{\mathrm{x}\,(n - \mathrm{x})}{n} \quad (3)$$

x = number of adverse events
n = sample size

Appendix H: Recruitment form health professionals (generic)

This form was adapted to the professional group and context. Variable information is enclosed in [].

CITY UNIVERSITY LONDON

MEDIZINISCHE UNIVERSITÄT WIEN

Machbarkeits-RCT zur Wirksamkeit von vibrierenden Beckenbodenkugeln zur Verbesserung der Beckenbodenmuskulatur nach der Geburt

Sehr geehrter/liebe [Berufsgruppe bzw. Anrede],

Bitte sprechen Sie eine [Wöchnerin/Frau/Patientin] an, wenn sie die folgenden Kriterien erfüllt:

- Termingeburt (ab 37+0)
- Vaginale Geburt
- Kein Dammriss Grad III oder IV bei der gerade stattgefundenen Geburt
- Ausreichende mündliche und schriftliche Kenntnisse der deutschen Sprache, um an der Studie teilnehmen zu können
- Mindestens 18 Jahre alt, mündig
- Keine neuromuskuläre Erkrankung, die die Funktion der Beckenbodenmuskeln beeinflussen kann (z.B. Multiple Sklerose)
- Keine Erkrankung, die das Infektionsrisiko beeinflussen kann (z.B. Diabetes, immunsuppressive Therapie, HIV-Infektion etc.)
- Kind lebt/ist nicht schwer erkrankt

Diese Kriterien werden entsprechend dem Kontext der Rekrutierung eingesetzt:

- [Frauen von 6 Wochen bis 5 Monate nach der Geburt]
- [6-Wochen-Untersuchung durch Gynäkologen durchgeführt, aus postpartaler Betreuung mit einem dem Zeitpunkt nach der Geburt entsprechenden Befund entlassen]
- [Derzeit nicht schwanger, während der Studienzeit (16 Wochen) keine Schwangerschaft geplant]
- [Nimmt derzeit an keinem Beckenbodentrainig mit Physiotherapeutin, Hebamme oder Fitnesstrainerin teil]
- [Derzeit keine gynäkologischen Operationen bzw. Operationen im Bereich des Beckenbodens]
- [Wiederkehrende (>5 Episoden während der letzten 12 Monate) oder chronische (>3 Wochen Dauer einer einzelnen Episode während der letzten 12 Monate) vaginale Infektionen]

Die folgenden Elemente werden nur bei denjenigen Rekrutierungspersonen eingefügt, die sich bereit erklären, die Angaben zu notieren:

Ablehnungen:
Bitte für jede Frau, die ihre Telefonnummer nicht eingetragen haben möchte, ein Stricherl machen (dies dient der Feststellung der Rekrutierungsrate).

Gründe für Nicht-Teilnahme:
Bitte für jede Frau, die nicht teilnehmen möchte, die angegebenen Gründe eintragen.

Ist mit Anruf einverstanden:

Datum	Name	Telefon	Kriterien erfüllt

Appendix H(e): Recruitment form health professionals (generic) – English translation

This form was adapted to the professional group and context. Variable information is enclosed in [].

Feasibility trial on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth

Dear [health professional or name],

please approach a [parturient/woman/patient] if she fulfils the following criteria:

- Term birth (37+0 or more weeks of gestation)
- Vaginal birth
- No 3rd or 4th degree perineal tear at this birth
- Sufficient knowledge of written and spoken German to be able to participate in the study
- Over the age of 18, with capacity to consent
- No neuromuscular condition influencing pelvic floor muscle function (e.g. MS)
- No major medical condition influencing infectious risk (diabetes, immune suppressive therapy, HIV infection etc.)
- Baby alive/not seriously ill

These criteria will be included according to the context of recruitment:

- [Women from 6 weeks to 5 months post partum]
- [6 weeks postpartum check by obstetrician performed and woman discharged from postpartum care with diagnostic findings appropriate to this period after childbirth]
- [Currently not pregnant and no pregnancy planned within the study period (16 weeks)]
- [Currently not enrolled in pelvic floor muscle training with physiotherapist, midwife or fitness trainer]
- [No current pelvic floor or gynaecological surgery]
- [Recurrent (> 5 episodes during last 12 months) or chronic (> 3 weeks duration of single episode in last 12 months) vaginal infections]

The following elements will be inserted only for the professionals willing to note the information:

Refusals:
Please make a line for each woman who does not want to have her phone number noted (this serves to find out the recruitment rate).

Reasons for not wanting to participate:
Please insert the reasons given by each woman not wanting to participate.

Gives permission to be called:

Date	Name [Date of delivery]	Phone number	Criteria checked

Appendix I: Recruitment phone call eligibility checklist

Criterion	Fulfilled
Inclusion	
Between 6 weeks and 5 months after childbirth	
Vaginal delivery	
Birth at 37+0 or more weeks of gestation	
Over the age of 18 with capacity to consent	
Sufficient knowledge of written and spoken German to be able to participate in the study	
Baby alive/not seriously ill	
6 weeks postpartum check by obstetrician performed and woman discharged from postpartum care with diagnostic findings appropriate to this period after childbirth	
Lochia ceased	
Currently not pregnant	
Exclusion	
Currently enrolled in pelvic floor muscle training with physiotherapist, midwife or fitness trainer	
Perineal tear 3rd or 4th degree at most recent birth	
Status post continence surgery	
Current pelvic floor or gynaecological surgery	
Current infection of genitourinary tract	
Recurrent (> 5 infectious episodes during last 12 months) or chronic (> 3 weeks duration of single episode in last 12 months) vaginal infections	
Neuromuscular conditions influencing pelvic floor muscle function (e.g. MS)	
Major medical condition influencing infectious risk (diabetes, immune suppressive therapy, HIV infection etc.)	
Currently on medication that could interfere with treatment or evaluation	
Currently enrolled in any other research study	
Current pregnancy or pregnancy planned within the study period (16 weeks)	
Inability to perform the proposed procedures	

Appendix J: Information/consent/initial study meeting schedule

Name: **Baby name:**

Date of birth:

Date:

Time:

Venue:

- Check eligibility

Criterion	**Fulfilled**	**Confirmed by**
Inclusion		
Between 6 weeks and 5 months after childbirth		Maternity notes
Vaginal delivery		Maternity notes
Birth at 37+0 or more weeks of gestation		Maternity notes
Over the age of 18, with capacity to consent		Maternity notes; capacity to consent assumded, enquiry if in doubt
Sufficient knowledge of written and spoken German to be able to participate in the study		Conversation
Baby alive/not seriously ill		Participant
6 weeks postpartum check by obstetrician-gynaecologist performed and woman discharged from postpartum care with diagnostic findings appropriate to this period after childbirth		Participant
Lochia have ceased		Participant
Exclusion		
Currently enrolled in pelvic floor muscle training with physiotherapist, midwife or fitness trainer		Participant
Perineal tear 3rd or 4th degree at most recent birth		Maternity notes
Status post continence surgery		Participant
Current pelvic floor or gynaecological surgery		Participant
Current infection of genitourinary tract		Participant
Recurrent (> 5 infectious episodes during last 12 months) or chronic (> 3 weeks duration of single		Participant

episode in last 12 months) vaginal infections		
Neuromuscular conditions influencing pelvic floor muscle function (e.g. MS)		Participant
Major medical condition influencing infectious risk (diabetes, immune suppressive therapy, HIV infection etc.)		Participant
Currently on medication that could interfere with treatment or evaluation		Participant
Currently enrolled in any other research study		Participant
Current pregnancy, pregnancy planned within the study period (16 weeks), pregnancy commencing during participation		Participant
Inability to perform the proposed procedures		Participant

- Study fully explained and questions clarified
- Gone through information/consent form
- Pelvic floor clarified (with pictures and explanations)
- Woman not interested in participation: Why?
  ➔ end process here
- Consent form signed
- Participant ID attributed
- Baseline data collected
- Participant reported outcome measurements collected
- Initial interview performed
- Randomisation performed
- Intervention explained
- Adherence chart explained
- Perineometry explained, incl. appointment
- Latex allergy No Yes
- Informed about next contact (phone calls)

Appendix K: Participant information and consent form

Information und Einwilligungserklärung zur Teilnahme an der Studie

Machbarkeitsstudie zur Wirksamkeit von vibrierenden Beckenbodenkugeln zur Verbesserung der Beckenbodenmuskulatur nach der Geburt

(Wissenschaftlicher Titel: Machbarkeits-RCT zur Wirksamkeit von vibrierenden Beckenbodenkugeln zur Verbesserung der Beckenbodenmuskulatur nach der Geburt)

Sehr geehrte Interessentin an der Studie,

ich lade Sie ein, an der oben genannten Studie teilzunehmen. Bevor Sie einer Teilnahme zustimmen, lesen Sie bitte die folgende Information genau durch, zögern Sie nicht, um genauere Informationen zu fragen und sprechen Sie mit anderen darüber. Die Aufklärung über die Studie erfolgt in einem ausführlichen Gespräch mit Hebamme Claudia Oblasser M.A.

Ihre Teilnahme an dieser Studie erfolgt freiwillig. Falls Sie teilnehmen möchten, müssen Sie ein Einwilligungsformular unterschreiben. Sie können jederzeit ohne Angabe von Gründen aus der Studie ausscheiden oder Teile der Studie nicht durchführen (z.B. einzelne Fragen nicht beantworten). Die Ablehnung der Teilnahme oder ein vorzeitiges Ausscheiden aus dieser Studie hat keine nachteiligen Folgen für Ihre gesundheitliche Betreuung.

Studien sind notwendig, um verlässliche neue Forschungsergebnisse zu gewinnen. Unverzichtbare Voraussetzung für die Durchführung einer Studie ist jedoch, dass Sie Ihr Einverständnis zur Teilnahme schriftlich erklären.

Bitte unterschreiben Sie die Einwilligungserklärung nur

- wenn Sie Art und Ablauf der Studie vollständig verstanden haben,
- wenn Sie bereit sind, der Teilnahme zuzustimmen und
- wenn Sie sich über Ihre Rechte als Teilnehmerin an dieser Studie im Klaren sind.

Zu dieser Studie, sowie zur Information und Einwilligungserklärung wurde von den zuständigen Ethikkommissionen eine befürwortende Stellungnahme abgegeben.

1. Was ist der Zweck dieser Studie?

Wir wissen, dass regelmäßige Beckenbodenübungen den Zustand des Beckenbodens und Beckenbodenbeschwerden (z.B. unfreiwilligen Harnverlust) verbessern. Die Verwendung von vibrierenden Beckenbodenkugeln kann eine Alternative zu Beckenbodenübungen sein. Eine vorhandene Studie zeigte vielversprechende Erfolge, aber es wurde noch nicht untersucht, ob die Kugeln für Frauen nach der Geburt hilfreich sind. Wir nehmen an, dass Frauen, die die Beckenbodenkugeln verwenden, einen gesundheitlichen Nutzen daraus ziehen könnten, aber bis zur Durchführung einer geeigneten klinischen Prüfung können wir uns dessen nicht sicher sein. Der Zweck dieser Machbarkeitsstudie ist, genügend Informationen zu sammeln, um die Durchführung einer zukünftigen aussagekräftigen klinischen Prüfung zur Wirksamkeit von vibrierenden Beckenbodenkugeln nach der Geburt vorzubereiten. Die Studie ist ein Doktoratsprojekt von Hebamme Claudia Oblasser M.A.

2. Welche anderen Behandlungsmöglichkeiten gibt es?

Zur Regeneration des Beckenbodens nach der Geburt stehen **stattdessen auch** die folgenden Möglichkeiten zur Verfügung: Beckenbodenübungen mit Physiotherapeutin, Hebamme oder Fitnesstrainerin in Gruppe oder Einzelarbeit.

3. Wie läuft die Studie ab?

Diese Studie wird an der medizinischen Universität Wien durchgeführt, und es werden insgesamt 56 Personen daran teilnehmen.

Vor Aufnahme in diese Studie müssen Sie Ihre ärztliche Mutter-Kind-Pass-Untersuchung 6 Wochen nach der Geburt erledigt haben und mit einem dem Stadium nach der Geburt entsprechenden Befund aus der nachgeburtlichen Betreuung entlassen worden sein, und der Wochenfluss muss aufgehört haben.

Im Rahmen dieser Studie wird die Verwendung von vibrierenden Beckenbodenkugeln mit der Durchführung von Beckenbodenübungen zu Hause verglichen (einer üblichen Behandlung zur Stärkung des Beckenbodens nach der Geburt). Sie werden per Zufallsverfahren einer der zwei Gruppen zugeteilt – die Zufallszuteilung zur Gruppe (=Randomisierung) erfolgt über ein Computerprogramm. Sie werden gemeinsam mit Claudia Oblasser das Kuvert öffnen, in dem Ihre Gruppe genannt wird. Die Wahrscheinlichkeit, in die Gruppe „Beckenbodenkugel“ oder „Beckenbodenübungen“ zu kommen, steht im Verhältnis 2 zu 1.

Sie werden für die Dauer von 12 Wochen entweder die vibrierenden Beckenbodenkugeln verwenden ODER Beckenbodenübungen zu Hause durchführen.

Ihre gesamte Teilnahme an dieser Studie wird voraussichtlich etwa 14-16 Wochen dauern.

Folgende Maßnahmen werden aus Studiengründen unter Wahrung der Intimsphäre durchgeführt:

- Erhebung von persönlichen Informationen (z.B. Beruf, Körpergrösse) sowie der Vorgeschichte Ihrer Schwangerschaften und Geburten (an einem Ort Ihrer Wahl, 15 Minuten).
- Je ein Fragebogen über den Zustand Ihres Beckenbodens zu Beginn und am Ende der Studie (an einem Ort Ihrer Wahl, 10 Minuten).
- Je ein strukturiertes Interview über Ihre Erfahrung mit und Meinung zu Ihrer Art des Beckenbodentrainings und zur Studie am Beginn und am Ende der Studie ODER ein Fragebogen am Ende der Studie (ob Interview oder Fragebogen ist abhängig davon, wie weit die Studie fortgeschritten ist) (an einem Ort Ihrer Wahl, Interview 30-40 Minuten ODER Fragebogen 20 Minuten).
- Messung der Beckenbodenstärke (Perineometrie) zu Beginn und am Ende der Studie: Für diese Messung werden Sie gebeten, zweimal in das AKH zu kommen. Bevor gemessen wird, wird festgestellt, ob Sie Ihren Beckenboden korrekt anspannen können. Dafür lässt die messende Person Sie Ihre Beckenbodenmuskeln um einen ca. 5cm tief in die Scheide eingeführen Finger anspannen. Für die Messung selbst wird eine Silikonsonde (26(33)mm Durchmesser) einige cm tief in Ihre Scheide eingeführt und Sie werden mehrmals gebeten, Ihre Beckenbodenmuskeln möglichst fest bzw. lang anzuspannen. Die Person, die Ihre Beckenbodenstärke messen wird, weiss nicht, welcher Gruppe Sie zugeteilt sind. Sie darf dies auch nicht erfahren, um die Messung nicht zu beeinflussen. Die Messung selbst dauert ca. 5-10 Minuten.
- Sie werden gebeten, während der 12 Trainingswochen jeden Tag in einem Formular zu notieren, ob Sie die Kugeln so wie vorgesehen verwendet/die Übungen so wie vorgesehen durchgeführt haben.
- Sie werden 5-mal angerufen (in Einzelfällen eventuell etwas häufiger) und gefragt, wie es Ihnen geht oder ob Sie irgendetwas brauchen.

Die Einhaltung der Besuchstermine und der Studienvorgaben ist von großer Bedeutung für den Erfolg dieser Studie.

4. Wie funktioniert die Verwendung einer vibrierenden Beckenbodenkugel?

Sie müssen die Kugel in der ersten Woche einmal täglich für 15 Minuten, ab der 2. Woche einmal täglich für 30 Minuten in der Scheide tragen, während Sie in Bewegung sind, z.B. bei der Hausarbeit oder beim Spazierengehen. Die genaue Anleitung zur Verwendung finden Sie in Anhang 1.

Bitte verwenden Sie die Kugel nicht während der Monatsblutung, bei Geschlechtsverkehr, bei Entzündungen, Erkrankungen, Operationen oder Schmerzen im Genitalbereich, und während einer Schwangerschaft.

5. Wie werden Beckenbodenübungen zu Hause durchgeführt?

Sie müssen die beschriebenen Beckenbodenübungen 3x täglich durchführen. Die genaue Anleitung zur Durchführung finden Sie in Anhang 2.

6. Wer kann an der Studie teilnehmen?

An der Studie teilnehmen können Frauen zwischen 6 Wochen und 6 Monaten (zu Beginn des Trainings) nach einer Geburt durch die Scheide nach der 37. Schwangerschaftswoche. Sie dürfen während der Studienzeit an keinem anderen Beckenbodentraining und keiner anderen Studie teilnehmen. Sie dürfen keine schweren Erkrankungen haben. Sie dürfen derzeit nicht schwanger sein und auch während der Studie keine Schwangerschaft planen.

7. Worin liegt der Nutzen einer Teilnahme an der Studie?

Mit der Anwendung von Beckenbodenkugeln oder -übungen kann möglicherweise Ihr Beckenboden gestärkt werden, oder es können Beckenbodenbeschwerden gebessert werden. Durch die Teilnahme an der Studie erhalten Sie auch zweimal durch die Beckenbodenmessung Auskunft über die Stärke Ihres Beckenbodens aus der Sicht von Fachpersonal. Durch die intensive Beschäftigung mit dem Beckenboden rückt seine Wahrnehmung und die Wichtigkeit seiner Gesundheit mehr in Ihr Bewusstsein, was langfristig zu Ihrer Beckenbodengesundheit beitragen könnte. Falls sich während der Studie zeigt, dass Sie Probleme mit dem Beckenboden haben, kann Ihnen eine entsprechende Vorgangsweise empfohlen werden.

Es ist jedoch auch möglich, dass Sie durch Ihre Teilnahme an dieser Studie keinen direkten persönlichen Nutzen für Ihre Gesundheit ziehen. Unabhängig von Ihrem persönlichen Nutzen werden die Ergebnisse dieser Studie dazu beitragen, Erkenntnisse zu gewinnen, um eine zukünftige klinische Prüfung optimal durchführen zu können, die zur bestmöglichen Beratung von Frauen nach der Geburt beitragen soll.

8. Gibt es unerwünschte Wirkungen oder Risiken?

Die Verwendung von Beckenbodenkugeln ist eine sichere Methode. *Laselle* Beckenbodenkugeln der Firma *Intimina/LELO* sind ein in der EU zugelassenes Medizinprodukt, in Apotheken oder über das Internet erhältlich, und erfüllen europäische Sicherheitsstandards. Dieses Produkt wird gegenwärtig zur Vorbeugung oder Behandlung von Beckenbodenschwäche und Harninkontinenz verwendet.

Die Verwendung von Beckenbodenkugeln kann zu geringen Nebenwirkungen oder Risiken führen. Die bislang beobachteten Nebenwirkungen und Beschwerden umfassen: unangenehmes Gefühl, leichte Muskelschmerzen (Muskelkater), leichte vaginale Blutung (selten), leichte Reizung der Scheide (sehr selten) oder Infektion (sehr selten). Bisher unbekannte Nebenwirkungen sind nicht zu erwarten.

Die Durchführung von Beckenbodenübungen kann zu geringen Nebenwirkungen oder Risiken führen: unangenehmes Gefühl oder Schmerzen (beides sehr selten). Bisher unbekannte Nebenwirkungen sind nicht zu erwarten.

Die im Rahmen dieser Studie durchgeführte Beckenbodenmessung ist schmerzlos und birgt keine bekannten Risiken, ebensowenig die Interviews und Fragebögen.

9. Was ist zu tun beim Auftreten von Beschwerden?

Sollten im Verlauf der Studie irgendwelche Beschwerden oder Symptome auftreten, müssen Sie diese mitteilen; bei schwerwiegenden Begleiterscheinungen umgehend, ggf. telefonisch. Bitte melden Sie sich bei einer der folgenden Personen/Stellen, entsprechendes weiteres Vorgehen wird dann organisiert:

Claudia Oblasser unter 0676 301 94 86 oder Claudia.oblasser.1@city.ac.uk
falls dringend: Geburtsbereich an der Universitätsklinik für Frauenheilkunde: 01 40400 29380
Professor Engelbert Hanzal unter 01 40400 29150
Professor Hanns Helmer unter 01 40400 29380

Mögliche Zeichen, bei denen Sie mit einer der genannten Personen/Stellen Kontakt aufnehmen sollen: größere als einem Muskelkater entsprechende Schmerzen, Blutung, vermehrter Ausfluss.

10. Eintritt einer Schwangerschaft während der Studie

Sollten Sie während der Studie schwanger werden oder den Verdacht haben, dass Sie schwanger geworden sind, informieren Sie bitte umgehend Claudia Oblasser und beenden Sie als Vorsichtsmaßnahme die Verwendung der Kugeln (falls Sie diese verwenden). Die Beckenbodenübungen allein können auch in der Schwangerschaft durchgeführt werden.

11. Wer organisiert diese Studie?

Die Studie ist ein Doktoratsprojekt der Hebamme Claudia Oblasser M.A. Sie führt das Projekt unter Supervision von Christine McCourt (Professorin zur Gesundheit von Mutter und Kind an der City University London) durch, mit Unterstützung von Engelbert Hanzal (Professor für Geburtshilfe und Gynäkologie, Medizinische Universität Wien). Die Verantwortung für die Studie liegt laut österreichischem Medizinproduktegesetz bei Professor Hanzal. Insgesamt wird das Projekt voraussichtlich bis Oktober 2016 dauern.

12. Wer hat diese Studie genehmigt?

Diese Studie wurden von den Ethikkommittees der Medizinischen Universität Wien und der City University London (Senate REC) begutachtet und genehmigt. Ethikkommittees sorgen dafür, dass die Rechte und die Gesundheit von StudienteilnehmerInnen gewahrt werden.

13. Wann wird die Studie vorzeitig beendet?

Sie können jederzeit auch ohne Angabe von Gründen Ihre Teilnahmebereitschaft widerrufen und aus der Studie ausscheiden, oder einzelne Teile nicht durchführen (z.B. Fragen, die Ihnen zu persönlich sind, nicht beantworten), ohne dass Ihnen dadurch irgendwelche Nachteile für Ihre weitere gesundheitliche Betreuung entstehen.

Es ist aber auch möglich, dass Ihr Forschungsteam entscheidet, Ihre Teilnahme an der Studie vorzeitig zu beenden, ohne vorher Ihr Einverständnis einzuholen. Die Gründe hierfür können sein:

a) Sie können den Erfordernissen der Studie nicht (mehr) entsprechen.
b) Ihr Studienteam hat den Eindruck, dass eine weitere Teilnahme an der Studie nicht in Ihrem Interesse ist.
c) Die Studie wird vorzeitig beendet.

Sofern Sie sich dazu entschließen, vorzeitig aus der Studie auszuscheiden, oder Ihre Teilnahme aus einem der oben genannten Gründe vorzeitig beendet wird, ist es für Ihre eigene Sicherheit wichtig, dass Sie sich zu einem Telefonat einige Zeit nach Beendigung der Teilnahme bereit erklären, in dem erhoben werden soll, ob es Ihnen gut geht.

14. In welcher Weise werden die im Rahmen dieser Studie gesammelten Daten gespeichert und verwendet?

Ihre Informationen werden vertraulich behandelt. Zu den vertraulichen Daten, in denen Sie namentlich genannt werden („personenbezogene" Daten), hat nur das Studienteam Zugang. Weiters können Beauftragte von in- und ausländischen Gesundheitsbehörden und der zuständigen Ethikkommissionen die Richtigkeit der Aufzeichnungen überprüfen. Diese Personen unterliegen einer gesetzlichen Verschwiegenheitspflicht.

Die Weitergabe der Daten im In- und Ausland erfolgt ausschließlich zu statistischen Zwecken in verschlüsselter (nur „indirekt personenbezogener") oder nicht personenbezogener („anonymisierter") Form, das heißt, Sie werden nicht namentlich genannt.

Die Daten werden 10 Jahre geschützt aufbewahrt und danach vertraulich vernichtet.

Das Studienteam unterliegt im Umgang mit den Daten den Bestimmungen des österreichischen Datenschutzgesetzes 2000 in der jeweils geltenden Fassung.

Wenn Sie Ihre Einwilligung zurückziehen und damit Ihre Teilnahme vorzeitig beenden, werden keine neuen Daten mehr über Sie erhoben. Auf Grund gesetzlicher Dokumentationspflichten (Medizinproduktegesetz) kann jedoch weiterhin für einen gesetzlich festgelegten Zeitraum eine Einsichtnahme in Ihre personenbezogenen Daten zu Prüfzwecken durch autorisierte, zur Verschwiegenheit verpflichtete Personen erfolgen.

Die vorhergehenden Informationen treffen auch zu, falls die Studie vorzeitig beendet wird.

Die Ergebnisse dieser Studie werden in Claudia Oblassers Doktorarbeit (PhD Thesis) verschriftlicht, auf Tagungen und Konferenzen präsentiert sowie in Fachjournalen veröffentlicht werden. Ihre persönlichen Daten können dabei nicht identifiziert werden.

Ausgenommen von der vertraulichen Behandlung sind dem Forschungsteam bekannt werdende Umstände, in denen zum Schutz des Kindeswohls eine gesetzliche Handlungspflicht besteht.

15. Entstehen für die Teilnehmer Kosten? Gibt es einen Kostenersatz oder eine Vergütung?

Durch Ihre Teilnahme an dieser Studie entstehen für Sie Fahrtkosten zur Beckenbodenmessung im AKH Wien. Sie erhalten für Ihre Teilnahme an dieser Studie zu Beginn jeder Messung 2 Einzelfahrscheine der Wiener Verkehrsbetriebe ausgehändigt.

16. Möglichkeit zur Diskussion weiterer Fragen und Vorgehen bei einem Problem

Für weitere Fragen im Zusammenhang mit dieser Studie steht Ihnen Claudia Oblasser gerne zur Verfügung. Auch Fragen, die Ihre Rechte als Teilnehmerin an dieser Studie betreffen, werden Ihnen gerne beantwortet, ebenso wie Sie Ihre Sorgen vorbringen oder sich über einen Aspekt der Studie beschweren können.

Mo-Fr 9-18 Uhr erreichbar unter: 0676 301 94 86
Jederzeit erreichbar unter: Claudia.oblasser.1@city.ac.uk

Ebenso können Sie sich wenden an:
Professor Engelbert Hanzal: Mo-Fr 9-14 Uhr erreichbar unter: 01 40400 29150
Jederzeit erreichbar unter: engelbert.hanzal@meduniwien.ac.at

Professor Christine McCourt: Mo-Fr 10-17 Uhr erreichbar unter: 00 44 207 040 5863
Jederzeit erreichbar unter: Christine.McCourt.1@city.ac.uk

17. Was mache ich wenn ich einen unabhängigen Rat will?

Falls Sie mit einer unabhängigen Stelle sprechen möchten, kontaktieren Sie bitte die Wiener Pflege-, Patientinnen- und Patientenanwaltschaft unter 01 587 12 04 oder per email: post@wpa.wien.gv.at; oder das Sekretariat der Ethikkommission der City University London:

Anna Ramberg (Secretary to Senate Research Ethics Committee)
Research Office, E214
City University London
Northampton Square
London EC1V 0HB
Tel: 00 44 20 7040 3040
E-mail: Anna.Ramberg.1@city.ac.uk

18. Sollten andere behandelnde Ärzte von der Teilnahme an der klinischen Prüfung informiert werden?

Sollten Sie während Ihrer Teilnahme an dieser Studie ärztliche Hilfe (egal aus welchem Grund) in Anspruch nehmen, informieren Sie bitte Ihren Arzt/Ihre Ärztin über Ihre Studienteilnahme.

Alle persönlichen Daten werden streng vertraulich behandelt. Die Teilnahme an dieser Studie erfolgt freiwillig und kann jederzeit widerrufen werden.

Bitte lesen Sie die gesamte Teilnehmerinformation sorgfältig durch!

19. Einwilligungserklärung

Name der Teilnehmerin in Druckbuchstaben: .....

Geb.Datum: .....

Ich erkläre mich bereit, an der *Machbarkeitsstudie zur Wirksamkeit von vibrierenden Beckenbodenkugeln zur Verbesserung der Beckenbodenmuskulatur nach der Geburt* teilzunehmen.

Ich bin von Frau Claudia Oblasser ausführlich und verständlich über die Verwendung von *Intimina Laselle* Beckenbodenkugeln oder Beckenbodenübungen, mögliche Belastungen und Risiken, sowie über Wesen, Bedeutung und Tragweite der Studie, die bestehende Versicherung sowie die sich für mich daraus ergebenden Anforderungen aufgeklärt worden. Ich habe darüber hinaus den Text dieser Teilnehmeraufklärung und Einwilligungserklärung, die insgesamt 10 Seiten (plus 2 Seiten Anhang) umfasst, gelesen. Aufgetretene Fragen wurden mir von Claudia Oblasser verständlich und ausreichend beantwortet. Ich hatte genügend Zeit, mich bezüglich meiner Teilnahme zu entscheiden. Ich habe zurzeit keine weiteren Fragen mehr.

Ich werde den Erfordernissen, die für die Durchführung der Studie erforderlich sind, Folge leisten, behalte mir jedoch das Recht vor, meine freiwillige Mitwirkung jederzeit zu beenden oder einzuschränken, ohne dass mir daraus Nachteile für meine gesundheitliche Betreuung entstehen.

Ich bin zugleich damit einverstanden, dass meine im Rahmen dieser Studie ermittelten Daten gespeichert werden. Mir ist bekannt, dass zur Überprüfung der Richtigkeit der

Datenaufzeichnung Beauftragte der zuständigen Behörden und der Ethikkommissionen bei Claudia Oblasser Einblick in meine personenbezogenen Studiendaten nehmen dürfen.

Sollte ich meine Teilnahme an dieser Studie widerrufen oder wird meine Teilnahme an der Studie von Seiten des Forschungsteams vorzeitig beendet, so willige ich ein, dass die bis zu diesem Zeitpunkt erhobenen Daten weiterhin verwendet werden dürfen, soweit dies erforderlich ist, um

a) sicherzustellen, dass meine schutzwürdigen Interessen nicht beeinträchtigt werden und

b) den gesetzlichen Dokumentationspflichten zu entsprechen.

Beim Umgang mit den Daten werden die Bestimmungen des Datenschutzgesetzes 2000 beachtet.

Für den Fall, dass ich aus der Studie ausscheide, bin ich einverstanden, dass meine Daten weiterhin aufbewahrt und analysiert werden, wie in dieser Information beschrieben:
☐ ja ☐ nein

Ich möchte nach Beendigung der Studie über die Ergebnisse informiert werden:
☐ ja ☐ nein ☐ ich bin nicht sicher – gebe später Bescheid

Eine Kopie dieser Teilnehmerinformation und Einwilligungserklärung habe ich erhalten. Das Original verbleibt bei Claudia Oblasser.

.....
(Datum und Unterschrift der Teilnehmerin)

.....
(Datum, Name und Unterschrift Claudia Oblasser)

Anhang 1: Anleitung zur Verwendung der Beckenbodenkugel

- Waschen Sie Ihre Hände.
- Geben Sie, falls Sie möchten, für ein leichteres Einführen eine kleine Menge wasserlösliches Gleitgel (wird Ihnen zur Verfügung gestellt) auf die saubere Kugel.
- Nehmen Sie eine bequeme Position ein (Rückenlage, Seitenlage, hockend, stehend mit einem Bein hochgestellt). Atmen Sie entspannt und führen Sie die Kugel sanft und mit stetigem Druck in die Scheide ein. Achten Sie darauf, dass sich das Rückholbändchen außerhalb des Körpers befindet. Die Kugel muss nicht tief eingeführt werden, sie sollte bequem ca. 2 cm tief in der Scheide liegen, das ist weniger hoch als ein Tampon.
- Bewegen Sie sich mit der eingeführten Kugel, z.B. bei einem Spaziergang oder während der Hausarbeit. Während des Bewegens sollten Sie die Vibrationen spüren. Verwenden Sie die Kugel für 15 Minuten täglich in der ersten Woche, und für 30 Minuten täglich ab der zweiten Woche, insgesamt für 12 Wochen. Es sollte Ihnen nicht viel Anstrengung bereiten, die Kugel drinnen zu halten – tragen Sie die Kugel nur so lange wie es Ihnen leicht fällt, eventuell also kürzer als 15 bzw. 30 Minuten. Falls Sie die Kugel gar nicht halten können, setzen Sie sich bitte mit Claudia Oblasser in Verbindung.
- Richtig sitzende Beckenbodenkugeln verursachen kein Ziehen im Unterleib, drücken nicht auf das Gesäß und üben keinen Druck nach unten aus. Zu Beginn der Anwendung kann es jedoch zu **leichten** Schmerzempfindungen („Muskelkater") im Beckenbereich kommen.
- Zum Entfernen ziehen Sie zuerst sanft und bei Bedarf mit stärkerem Druck am 7 cm langen Rückholbändchen. Sollte die Kugel nicht leicht zu entfernen sein, entspannen Sie sich und ziehen etwas fester.
- Reinigen Sie die Kugel nach jedem Gebrauch (falls Sie sie länger nicht verwendet haben auch davor) mit Wasser und der Ihnen zur Verfügung gestellten antibakteriellen Seife. Benutzen Sie keine Reinigungsmittel mit Alkohol, Benzin oder Aceton, da diese Inhaltsstoffe Ihre Scheidenflora negativ beeinflussen und auch die Silikon-Außenhülle der Vaginalkugeln beschädigen können. Trocknen Sie die Kugeln mit einem fusselfreien Tuch und bewahren Sie sie in der mitgelieferten antibakteriellen Aufbewahrungstasche auf.
- Wahrscheinlicher ist eine Wirkung, wenn Sie die Kugel konsequent verwenden.

Bitte verwenden Sie die Kugel nicht während der Monatsblutung, bei Geschlechtsverkehr, bei Entzündungen, Erkrankungen, Operationen oder Schmerzen im Genitalbereich, und während einer Schwangerschaft.

Grundsätzliche Empfehlung zur Vermeidung von Inkontinenz:
Spannen Sie Ihre Beckenbodenmuskeln vor und während jeder für den Beckenboden belastenden Aktivität an, z.B. wenn Sie Ihr Kind hochheben, husten oder niesen.

Anspannen des Beckenbodens:
Stellen Sie sich vor, dass Sie Harn oder Winde zurückhalten. Spannen Sie die Muskeln um die Scheide an und heben Sie sie an, indem Sie die drei Öffnungen für Darmausgang, Scheide und Harnröhre schließen und nach innen (und etwas nach vorne) hochziehen.

Anhang 2: Anleitung zur Durchführung der Beckenbodenübungen

Anspannen des Beckenbodens:
Stellen Sie sich vor, dass Sie Harn oder Winde zurückhalten. Spannen Sie die Muskeln um die Scheide an und heben Sie sie an, indem Sie die drei Öffnungen für Darmausgang, Scheide und Harnröhre schließen und nach innen (und etwas nach vorne) hochziehen. Beginnen Sie vorsichtig und rhythmisch. Ihre Gesäß-, Bauch- und Beinmuskeln sollten nicht mitarbeiten.

- Langes Anspannen:
  Halten Sie die Anspannung für ein paar Sekunden und entspannen Sie danach für ein paar Sekunden; atmen Sie. Steigern Sie Dauer und Anzahl, bis Sie die Anspannung bis zu 10 Sekunden halten können, und das bis zu 8-10x hintereinander.

- Schnelles Anspannen:
  Spannen Sie die Beckenbodenmuskeln so stark und schnell hintereinander wie möglich an; atmen Sie währenddessen und entspannen Sie danach. Tun Sie dies bis zu 8-10x hintereinander.

Versuchen Sie die Übungen in verschiedenen Positionen (liegend, sitzend, stehend) und machen Sie sie zur Routine, z.B. jedes Mal, wenn Sie Ihr Kind füttern.

Damit die Übungen wirksam sind, müssen Sie konsequent üben und beide Arten von Übungen mindestens 3x täglich durchführen.

Grundsätzliche Empfehlung zur Vermeidung von Inkontinenz:
Spannen Sie Ihre Beckenbodenmuskeln vor und während jeder für den Beckenboden belastenden Aktivität an, z.B. wenn Sie Ihr Kind hochheben, husten oder niesen.

Anleitung angelehnt an: Association of Chartered Physiotherapists in Women´s Health (2013a und 2013b) und National Collaborating Centre for Women's and Children's Health (2013)

Appendix K(e): Participant information and consent form – English translation

Version submitted to City University London Ethics Committee

Information and consent form for participation in a study

Feasibility study[1] on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth

Scientific title: Feasibility-RCT on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth

Dear person interested in the study,

I invite you to take part in the above named study. Before you agree to participate, please read the following information carefully, don´t hesitate to ask for more detailed information, and speak with others about it. Further information about the study will be provided in a detailed talk with midwife Claudia Oblasser M.A.

Your participation in this study is voluntary. If you want to participate, you must sign a consent form. You can withdraw participation at any time without giving a reason, or refuse to participate in parts of the study (e.g. not answer single questions). If you do not want to participate or withdraw from participation early, this has no disadvantage for your health care.

Studies are necessary to gain reliable new research results. However, an indispensable requirement for a study is that you agree to participate in written form.

Please sign this consent form only if

- you fully understand kind and process of the study,
- you agree to participate and
- your rights as participant in this study are clear to you.

This study and the information and consent form have been approved by the appropriate ethics committees.

1. What is the purpose of this study?

We know that regularly practising pelvic floor muscle exercises improves pelvic floor muscle performance and symptoms (e.g. urinary incontinence). The use of vibrating pelvic floor training balls may be an alternative to pelvic floor muscle exercises. A previous study showed a promising effect, but it has not yet been tested whether the balls are helpful for women after childbirth. We anticipate women who use the pelvic floor training balls may have some health benefits but cannot be sure until the completion of an appropriate clinical trial. The purpose of this feasibility study is to gather enough information to prepare a future effective clinical trial to test the effectiveness of vibrating vaginal pelvic floor training balls after childbirth. The study is a PhD project of midwife Claudia Oblasser M.A.

[1] Translation comment: The English term *feasibility trial* cannot be translated exactly into German. The best translation for scientific purposes is *feasibility-RCT*, and for lay people *feasibility study*. As this is a translation from German to English to inform you as Ethics Committee, the terms used in German have been translated.

2. Which other treatment options are there?

To rehabilitate the pelvic floor after childbirth, there are also the following possibilities **instead**: pelvic floor muscle exercises with physiotherapist, midwife or fitness trainer in groups or individually.

3. How is the study performed?

This study will take place at the Medical University of Vienna with 56 participants.

Before being included into this study, you must have had your 6 weeks check performed by your obstetrician and habe been discharged from postpartum care with findings appropriate to this period after childbirth, and your postpartum vaginal discharge must have ceased.

In this study, the use of vibrating vaginal pelvic floor training balls will be compared to performing pelvic floor exercises at home (a usual intervention to strengthen the pelvic floor after childbirth). You will be assigned by chance to one of these two groups – the chance allocation (called randomisation) is done via a computer programme. Together with Claudia Oblasser you will open the envelope which contains your allocation information. The probability of being assigned to the group "pelvic floor ball" will be 2:1 compared to being assigned to the group "exercises".

For a duration of 12 weeks, you will use the pelvic floor training balls OR do the pelvic floor muscle exercises at home.

Your total participation in this study is expected to take 14-16 weeks.

<u>The following interventions will be performed confidentially as part of the study:</u>

- The collection of personal information (such as profession, height) and your obstetric history (at a site of your choice, 15 minutes).
- A questionnaire about your pelvic floor health at the beginning and the end of the study (at a site of your choice, 10 minutes).
- A structured interview about your experiences with and opinion about your method of pelvic floor muscle training and the study at the beginning and the end of the study OR a questionnaire at the end of the study (if interview or questionnaire depends on study progress) (at a site of your choice, interview 30-40 minutes OR questionnaire 20 minutes).
- Measurement of pelvic floor muscle performance (perineometry) at the beginning and the end of the study. For this measurement you will be asked to come to Vienna General Hospital twice. Before measurement, it is checked if you are able to squeeze your pelvic floor muscles correctly. For this, the measuring person lets you squeeze your pelvic floor muscles around a finger which is inserted about 5cm into the vagina. For the measurement, a silicone probe (26(33)mm diameter) will be inserted into your vagina and you will be asked to squeeze your pelvic floor muscles a few times as firm as possible and as long as possible. The person measuring your pelvic floor muscle performance does not know the group you are allocated to. He/she must not hear about it to avoid an influence on the measurement. The measurement itself takes about 5-10 minutes.
- During the 12 training weeks, you will be asked to note down each day in a form if you have used the balls/performed the exercises as planned.
- You will be called by telephone 5 times (in single cases maybe more frequently) and asked how you are or if you need something.

Keeping to the study appointments and requirements is of high importance for the success of this study.

4. How is a pelvic floor training ball used?

The ball is worn vaginally once daily for 15 minutes during the first week, and for 30 minutes daily from the second week onwards; wear the ball when you are moving, e.g. when doing housework or going for a walk. You find the detailed instruction about ball use in Appendix 1.

Please do not use the ball during menstruation and intercourse, and when having inflammations, diseases, operations or pain in the genital area, and during pregnancy.

5. How do I perform pelvic floor muscle exercises at home?

You must perform the pelvic floor exercises 3 times a day. You find the detailed instruction about how to do pelvic floor exercises in Appendix 2.

6. Who can participate in the study?

Women between 6 weeks and 6 months (at the beginning of training) after vaginal birth after 37 completed weeks of pregnancy can participate in the study. During the study, you must not participate in another kind of pelvic floor muscle training or another study. You must not suffer from a serious disease. You must not be pregnant or plan a pregnancy during the study period.

7. What is my benefit of participating in this study?

By using pelvic floor training balls or doing pelvic floor muscle exercises, your pelvic floor could be strengthened or pelvic floor symptoms could be enhanced. By participating in the study, you get two pelvic floor measurements and information about your pelvic floor performance from the view of a health professional. By the intensive preoccupation with the pelvic floor, you might become more conscious about its perception and the importance of its health, which could contribute to your pelvic floor health in the long term. If problems with your pelvic floor become clear during the study, you can be referred to appropriate health care.

It is also possible that you will not draw any direct personal benefit for your health from participating in this study. Independent from your personal benefit, the results of this study will teach us lessons to be able to undertake a future clinical trial effectively to provide better advice to women after childbirth.

8. Are there any unwanted effects or risks?

The use of pelvic floor training balls is a safe method. Laselle pelvic floor training balls of *Intimina/LELO* are a EC licensed medical device sold in pharmacies or available via the world-wide web, and they fulfil European safety standards. This product is presently used to prevent or treat pelvic floor weakness or urinary incontinence.

The use of pelvic floor training balls can lead to minor side effects or risks. The side effects and complaints observed so far comprise: discomfort, slight muscle soreness or pain (like from too much training), slight vaginal bleeding (rarely), slight vaginal irritation (very rarely) or infection (very rarely). Hitherto unknown side effects are not expected.

The performance of pelvic floor muscle exercises can lead to minor side effects or risks: uncomfortable feeling or pain (both very rarely). Hitherto unknown side effects are not expected.

The pelvic floor measurement performed for this study is painless and does not carry any known risks, neither do the interviews and questionnaires.

9. What do I have to do if I experience discomfort?

In case you experience any discomfort or symptoms during the study, you must report them; in serious cases immediately, if necessary by phone. Please notify one of the following persons/sites, appropriate proceeding will then be organised:

Claudia Oblasser at 0676 301 94 86 or Claudia.oblasser.1@city.ac.uk
if urgent: delivery suite at Vienna General Hospital: 01 40400 29380
Professor Engelbert Hanzal at 01 40400 29150
Professor Hanns Helmer at 01 40400 29380

Possible signs which should make you contact one of the named persons/sites: pain exceeding pain to be expected from too much muscle training, bleeding, increased vaginal discharge.

10. If you get pregnant during the study

In case you get pregnant or suspect to be pregnant during the study, please inform Claudia Oblasser promptly and terminate the use of the vaginal balls as a safety measure (in case you use them). The pelvic floor muscle exercises alone can also be performed during pregnancy.

11. Who is organising this study?

The study is a PhD project of midwife Claudia Oblasser MA. She is conducting the project with supervision by Christine McCourt (Professor of Maternal and Child Health[2] at City University London), and with support by Engelbert Hanzal (Professor of Obstetrics and Gynaecology, Medical University of Vienna). According to the Austrian law on medical devices, responsibility for the study lies with Professor Hanzal. Duration of the project is planned until October 2016.

12. Who has approved this study?

This study has been reviewed and approved by the Ethical committees of the Medical University of Vienna and of City University London (Senate REC). Ethics committees make sure that the rights and health of study participants are protected.

13. When will the study be terminated early?

You can withdraw from the study at any time without giving reasons, or refuse to participate in parts of the study (e.g. not answer questions which you find too personal). This will not have any disadvantage for your health care.

It is also possible that your research team decides to terminate your participation in the study early without asking for your consent. Reasons for this can be:

a) You do not correspond (any more) to the requirements of the study.
b) Your study team has the impression that your further participation in the study is not in your interest.
c) The study is terminated early.

In case you decide to withdraw from the study early, or your participation is terminated early for one of the above reasons, it is important for your own safety that you agree to a phone call some time after cessation of participation, to ascertain your well-being.

[2] translated into German

14. How will data collected for this study be stored and used?

Any information you provide will be kept confidential. Only the researchers involved in the study will have access to your personal data. Also, delegates from the Ethics Committees or Austrian or international health regulatory agencies are allowed to examine the correctness of the documentation. These persons are subject to a legal obligation to confidentialty.

Circulation of data nationally and internationally is done exclusively for statistical purposes in encrypted (only indirect personal) or not personal (anonymised) form – this means your name is not circulated.

Data will be stored securely for ten years and then confidentially destroyed.

Concerning data handling, the study team is subject to the Austrian law on data protection from the year 2000 in its most recent version.

If you withdraw your consent and thereby terminate your participation early, no new data will be collected about you. Due to legal documentation duties (law on medical devices), authorised persons with an obligation to confidentialty have a right of access to your personal data for control purposes for a legally determined timeframe.

The aforementioned information also applies in case the study is terminated early.

The results of this study will be written down in Claudia Oblasser´s PhD thesis, presented at conferences and published in academic journals. It will thereby not be possible to trace back your personal information.

The research team is exempt from its obligation to confidentialty if becoming aware of circumstances which legally require to act in the best interest of the child.

15. Are there any costs for the participant? Is there any refund?

Through your participation in this study you incur costs for travelling to the pelvic floor measurement at Vienna General Hospital. Therefore, you will be handed 2 single tickets of the Wiener Verkehrsbetriebe (*"transport for Vienna"*) at the beginning of each measurement for your participation in this study.

16. Possibility to discuss further questions and what to do if there is a problem

Claudia Oblasser is happy to answer further questions about this study and about your rights as participant in this study. You can contact her also if you find any concern or worries, or if you would like to complain about any aspect of this study.

Mo-Fr 9-18 on: 0676 301 94 86
Anytime on: Claudia.oblasser.1@city.ac.uk

You can also contact:
Professor Engelbert Hanzal: Mo-Fr 9-14 on: 01 40400 2915
Anytime on: engelbert.hanzal@meduniwien.ac.at

Professor Christine McCourt: Mo-Fr 10-17 on: 00 44 207 040 5863
Anytime on: Christine.McCourt.1@city.ac.uk

17. What if I want independent advice?

In case you want to talk with an independent person, please contact the Wiener Pflege-, Patientinnen- und Patientenanwaltschaft[3] on 01 587 12 04 or via email: post@wpa.wien.gv.at; or the Secretary to Senate Research Ethics Committee of City University London:
Anna Ramberg
Secretary to Senate Research Ethics Committee
Research Office, E214
City University London
Northampton Square
London
EC1V 0HB
Fon: 00 44 20 7040 3040
Email: Anna.Ramberg.1@city.ac.uk

18. Should other medical doctors be informed about your participation in this clinical trial?

In case you consult a doctor for medical help during your participation in the study (for whatever reason), please inform her or him about your participation in the study.

All personal data will be treated confidentially. Participation in this study is voluntary and you can withdraw at any time.

Please read all of the participant information carefully!

19. Consent form

Name of participant in capital letters: .....

Date of birth: .....

I agree to take part in the *feasibility study on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth*.

I have been informed in detail and understandably by Claudia Oblasser about the use of *Intimina Laselle* pelvic floor training balls or pelvic floor exercises, potential side effects and risks, as well as the nature, significance and consequences of this study, the insurance and the thereof resulting requirements. I also have read the text of this participant information and consent form of 10 pages

[3] Translation comment: This is an independent institutional complaint service for all health service patients in Vienna

(plus 2 pages appendix[4]). Arising questions have been answered comprehensibly and sufficiently by Claudia Oblasser. I had enough time to decide about my participation. I have no further questions at the moment.

I will follow the requirements necessary for the realisation of this study, but will keep my right to withdraw or limit my voluntary participation at any time, without experiencing any disadvantage for my health care.

I agree that my data collected in the context of this study are stored. I know that delegates from the Ethics Committees or appropriate health regulatory agencies are allowed access to my personal study data with Claudia Oblasser to examine correctness of documentation.

Should I withdraw my participation in the study or should my participation in this study be terminated early from the side of the research team, I agree that data collected to this point in time may (if necessary) be used further to

a) make sure that my protected interests are not affected and

b) correspond to the legal documentation obligations.

In data handling, the study team has to follow the regulations laid down in the Austrian law on data protection from the year 2000.

In case I terminate the study early, I agree to storage and analysis of my data as described in this information:

☐ Yes ☐ No

I would like to be informed about the results of the study:

☐ Yes ☐ No ☐ I am not sure – I want to tell you later

I have received a copy of this participant information and consent sheet. The original stays with Claudia Oblasser.

.....

(Date and signature of participant)

.....

(Date and signature of Claudia Oblasser)

[4] Translation comment: corresponding to the German version

Appendix 1: Instruction for using pelvic floor training balls

- Wash your hands.
- Apply, if desired, a small amount of water-based lubricant (will be provided) onto your clean pelvic ball for ease of insertion.
- Position your body comfortably (lying on your back or side, squatting, standing with one leg elevated). Breathe for relaxation and insert the ball gently and with steady pressure into your vagina. Make sure the retraction cord is outside of the body. The ball does not have to be inserted deeply, it should lie comfortably about 2cm deep in the vagina, this is not as high as a tampon.
- Move with the ball inside, e.g. during a walk or doing housework. You should feel the vibrations when you move. Use the ball for 15 minutes daily in the first week, and for 30 minutes daily from the second week onwards, altogether for 12 weeks. It should not take you a great effort to keep the ball inside – wear the ball only as long as it is easy for you, even if this possibly means less than 15 or 30 minutes, respectively. If you cannot keep the ball inside at all, please contact Claudia Oblasser.
- Correctly placed vaginal balls do not cause any dragging in the lower abdomen, do not push at the buttocks and do not exert downward pressure. However, you can experience **slight** muscle soreness (like from too much muscle exercising) in the pelvis at the beginning of training.
- To take the ball out, draw gently initially and if needed firmer on the 7 cm long retraction cord. If you cannot take the ball out easily, relax and draw firmer.
- Clean the ball after each use (if you have not used it for some time, clean it also before use) with water and the antibacterial soap provided for the study. Do not use cleansing agents with alcohol, benzine or acetone, as these substances can influence you vaginal flora negatively and can also destroy the outer silicone layer of the ball. Dry the ball with a fuzz free cloth and keep them in the provided antibacterial bag.
- An effect is more likely if you use the ball consequently.

Please do not use the ball during menstruation and intercourse, and when having inflammations, diseases, operations or pain in the genital area, and during pregnancy.

General recommendation (to prevent leakage):
Contract your pelvic floor muscles before and during each activity requiring effort from the pelvic floor, e.g. when you are lifting your baby, coughing or sneezing.

Contracting the pelvic floor:
Imagine that you are trying to stop yourself passing urine or wind. Squeeze the muscles around the vagina and lift them by closing and drawing up (and a little bit forward) inside the 3 passages for the anus, vagina and urethra.

Appendix 2: Instruction for doing pelvic floor muscle exercises

Contracting the pelvic floor:
Imagine that you are trying to stop yourself passing urine or wind. Squeeze the muscles around the vagina and lift them by closing and drawing up (and a little bit forward) inside the 3 passages for the anus, vagina and urethra. Start gently and rhythmically. Your buttocks, legs and tummy should not move when doing the exercise.

- Long contractions:
  Hold the squeeze for a few seconds, and then relax for a few seconds; breathe. Increase the time and the number that you do until you can hold the squeeze for up to 10 seconds and repeat up to 8-10 times.

- Fast contractions:
  Tighten the pelvic floor muscles as quickly and strongly as you can, breathe, and then relax. Do this up to 8-10 times.

Try exercising in different positions (lying, sitting, standing) and establish a routine, such as every time you feed your baby.

For the exercises to be effective you need to persevere and do the two types of exercise at least 3 times a day.

General recommendation (to prevent leakage):
Contract/tighten your pelvic floor muscles before and during each activity requiring effort from the pelvic floor, e.g. when you are lifting your baby, coughing or sneezing.

Instruction according to: Association of Chartered Physiotherapists in Women´s Health (2013a and 2013b) and National Collaborating Centre for Women's and Children's Health (2013)

Appendix L: Recruitment contact documentation

Active recruitment

Name	Phone number	Call date/time	Source	Eligible?	Result: - wants to participate - more time - … - no interest - why not?	Date of meeting	Place of meeting	Other

Passive recruitment

Name	First contact call/mail +date	Further contacts	Phone number/ mail address	Where did you hear about the study?	Eligible? Yes/no +reason	**Result:** - wants to participate - more time - … - no interest - why not?	Date of meeting	Place of meeting

Appendix M: Recruitment details

Active recruitment paths

Postnatal wards of the AKH Vienna

Recruitment started after an information presentation held as part of a routine staff morning meeting on 27 February 2015. As neither contact dates for women had been obtained by mid May 2015 nor did the participant information sheet seem to have been distributed, recruitment efforts via this route were stopped in May 2015.

Delivery suite of the AKH Vienna

Recruitment started after an information meeting with midwifery staff on 4 March 2015. No contact dates for women were obtained via this route. However, one interested woman called the researcher the day after she had been given the participant information sheet. Recruitment via this route was terminated in January 2016 after completed recruitment.

Community midwives in Vienna

Twenty-one midwives were approached by phone calls between January and July 2015. They were selected because they were personally known to the author or named by a colleague. A selection criterion was that they should not offer postpartum exercise classes because it was assumed that their clients would attend their classes and midwives therefore would not have access to a large eligible population; neither should there arise competition between recruitment for the trial and their business. Three of the 21 midwives could not be reached or did not get back to CO, and seven declined to support recruitment for this feasibility trial.

Eleven midwives started recruitment between February and July 2015. During the recruitment period, one went into maternity leave and a few had prolonged absences; one midwife who initially had agreed to contribute later withdrew because of private problems. The number of contacts provided by midwives varied between 0 and 10 (1x10, 1x9, 1x7, 1x6, 2x5, 2x2, 3x0). Recruitment was terminated in January 2016 after its completion. All midwives were then sent an e-mail to thank them for their support. They were also asked the number of and reasons why women had not been interested in the trial, and how many women had been interested but not wished to give their phone number away (this

information had originally been planned to be collected in the professionals' recruitment form; as this did not prove feasible, the midwives were asked for it in this last e-mail).

It could be observed that each midwife had her own recruitment style. One recruited very cautiously and approached her clients months after birth when it was clear that they would not attend a postpartum exercise class. One provided names and phone numbers to CO but seemed to not have passed on the participant information sheets. One obviously recommended women to participate in the trial (participant quote: "My midwife said I should participate"). A common pattern was that names were provided at the beginning of the collaboration but not any more later on during the recruitment year.

Obstetricians' surgeries in Vienna

Thirty-one obstetricians were approached between February and September 2015. They were personally known to the author or recommended by other recruitment helpers. Contacted via their e-mail addresses identified from the Internet, all were sent an initial invitation e-mail with one reminder a few weeks later when applicable. Fourteen of the 31 contacted obstetricians did not reply, four declined to support recruitment for this feasibility trial. Another one withdrew her/his willingness to participate at the personal meeting when she/he had heard that a particular one of his/her colleagues was contributing to recruitment.

Ten obstetricians started with recruitment between February and September 2015, of whom one soon withdrew because of a technical housing damage and the resulting stress in her surgery. One obstetrician agreed to put recruitment sheets in the waiting area. The number of contacts provided by obstetricians varied between 0 and 28 (1x28, 1x7, 1x5, 1x2, 6x0). Recruitment was terminated in January 2016 after its completion. All obstetricians were then sent an e-mail to thank them for their support. They were also asked the number of and reasons why women had not been interested and how many women had been interested but did not want to give their phone number away (this information had originally been planned to be collected in the professionals' recruitment form. As this did not prove to be feasible, the obstetricians were asked for it in the last e-mail).

Passive recruitment paths

Midwifery Centre Vienna (Hebammenzentrum Wien)

Recruitment sheets were laid out at the centre's information corner and possibly distributed by midwives in groups from February 2015 onwards. Recruitment was cancelled in January 2016 when it was complete.

Parenting centres

Nanaya (private parenting centre): Recruitment sheets were taken to the class by course leaders for postnatal exercise groups at their last course unit (course terminated twice a month) from February 2015 until January 2016. Course leaders were informed about the trial and could recommend it to women. Recruitment was cancelled in January 2016 when it was complete.

Parenting centre of the City of Vienna: Recruitment sheets were laid out at the centre's information corner in April 2015.

World Wide Web

The recruitment text (as on the recruitment sheet in Appendix 13 a/b of the research protocol [Appendix N]) was put on

- a facebook page created for this purpose from February 2015 to January 2016 (https://www.facebook.com/Studie-zum-Beckenbodentraining-nach-der-Geburt-1518209895112706/?ref=bookmarks), and on
- the website of the Austrian Midwifery Board in February 2015 and left until May 2015 (approximate dates), and again from November 2015 until January 2016.

To enhance recruitment, a parent and supportive psychologist colleague opened a discussion thread at parents.at (an Austrian online discussion forum for parents) in February 2015, which was continued once in April 2015 by a friend who had opened an account there to support the trial.

Parenting magazine *Eltern*

A new recruitment route arose during the trial: In their Austrian supplement, the German parenting magazine *Eltern* published a note on the trial which the team obviously had discovered when screening the news section of the homepage of the Austrian midwives board (Eltern Magazin Österreich, 2015).

Table 15 Recruitment paths with efforts and success

Recruitment route	Names provided	Of these contacted	Of these recruited	Contacting women	Of these recruited	Recruited women
Recruitment via recruitment professionals (with oral information and participant information sheet being handed out)						
Community midwives	46[a]	45	20	3[a]	1	21
Obstetricians	42	42	19	0	0	19
AKH Vienna delivery suite	0	0	0	1	1	1
Sum	**88**	**87**	**39**	**4**	**2**	**41**
	91 contacts via this route					
[a]Of the 46 names provided by community midwives, only 45 women were contacted as one contacted the author herself. Within the contacting women (community midwives) she is one of three, the two others also came from recruitment midwives but their names had not been provided.						
Recruitment via recruitment sheet/text or word-of-mouth						
Parenting centres	n.a.	n.a.	n.a.	8	3	3
Midwifery Centre Vienna	n.a.	n.a.	n.a.	1	1	1
Facebook	n.a.	n.a.	n.a.	5	2	2
Parents.at	n.a.	n.a.	n.a.	3	2	2
Homepage Austrian Midwifery Board	n.a.	n.a.	n.a.	3	0	0
Magazine *Eltern*				5	3	3
Via other participant	3	3	1	7	2	3
Other (from)	1 (friend)	1	1	3	0	1
				(a midwife)		0
				4 (unknown)	0	0
Sum	**4**	**4**	**2**	**39**	**13**	**15**
	43 contacts via this route					
Overall sum	n.a.	**91**	**41**	**43**	**15**	**56**

Appendix N: Research protocol

CITY UNIVERSITY LONDON AND MEDICAL UNIVERSITY OF VIENNA

Research Protocol

Feasibility trial on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth

Claudia Oblasser

Version 2 of 19 October 2014

Abstract

Background:
Pelvic floor muscle training after childbirth is recommended to prevent or treat urinary incontinence and other pelvic floor problems. A device that is sometimes recommended to women in Austria to enhance their pelvic floor muscles are vibrating vaginal pelvic floor training balls. To date, only a small study on vibrating balls exists, and it researched women with urinary incontinence and not women after childbirth. Therefore, research is needed to scientifically objectify the popular claim of these balls´ effectiveness in the postpartum period and further evidence based practice.

Aims:
This feasibility trial aims at assessing practical issues and feasibility of a future randomised controlled trial (RCT) to determine the effectiveness of vibrating vaginal pelvic floor training balls for postpartum pelvic floor muscle rehabilitation, at monitoring harms of the experimental intervention, and at exploring women´s perspectives on and experiences with the interventions and the trial.

Methodology:
The 56 participants of this feasibility trial in Vienna will be randomised into one of two intervention groups: the vibrating vaginal ball group or the usual pelvic floor muscle exercises group (each intervention is planned to be used for 12 weeks). The tested study features comprise

- recruitment strategies: invitation at the obstetric department of Vienna General Hospital, by community midwives and via obstetrician´s practices, at relevant venues for mothers (e.g. parent centres), and via the world-wide web,
- inclusion and exclusion criteria for women from six weeks until six months post partum,
- the necessary number of participants determined by power calculation,
- the randomisation procedure by computer generated numbers,
- the interventions themselves: best use of vibrating pelvic floor training balls, and their safety, compared to pelvic floor muscle exercises,
- concordance and retention measures: diaries and phone contact,
- data collection via physiologic measurement, interviews and questionnaires,
- effectiveness outcomes: participant reported outcomes and technical measurement by perineometry,
- a survey of women's views of and experiences with the interventions and the trial,
- analysis: statistics and content analysis.

Results:
The results of this trial will inform the features and feasibility of a future full RCT. It will be concluded that a full RCT to determine the effectiveness of vibrating vaginal pelvic floor training balls post partum is feasible as planned, feasible with modifications or not feasible. If considered feasible, the results will enable the full study to be planned correctly.

Version 2 of 19 October 2014

Content

Background

Research problem

As childbearing challenges the pelvic floor, pelvic floor muscle training is recommended as a routine measure after childbirth to prevent incontinence or perineal descent and pelvic organ prolapse later in life (Abrams *et al.*, 2010). A device recommended and used in Austria to strengthen the pelvic floor muscles after childbirth are vibrating pelvic floor training balls. When inserted into the vagina, the ball causes vibrations through the woman´s movements by a loose inner ball. This vibration together with contraction of the pelvic floor muscles to prevent the ball from slipping out is purported to strengthen the pelvic floor muscles (Glavind, 2001).

Literature review

An ongoing systematic review (Oblasser, Christie and McCourt, 2014) shows a dearth of evidence on the effectiveness of vibrating balls to enhance pelvic floor muscle strength or urinary continence in the post partum period. The only study on vibrating vaginal balls by Glavind (2001) with 10 participants in a single intervention group included women with stress urinary incontinence and not specifically in the post partum period. Within its methodological limits, the study showed encouraging results and the author recommended further research.

A systematic review on non-vibrating weighted vaginal cones (including balls) for women with urinary incontinence showed that larger, high-quality trials are needed to reach a more firm conclusion on their effectiveness (Herbison and Dean, 2013). There also is a need for more basic research to understand the unclear theoretical mechanism of the cones (Bø, 1995).

Relevance of the topic and rationale for the research

Pelvic floor care is an important issue for all women after childbirth. The vibrating balls are available for sale, seem well known and accepted among women in Austria, and there is reassuring anecdotal evidence about their effectiveness. A device which helps to train the pelvic floor muscles effectively without deliberate exercise would be practical and time saving. It might thus lead to a higher training concordance than the standard care pelvic floor muscle exercises which only show low concordance (Bø, Owe and Nystad, 2007). Therefore, it may pragmatically be seen to be more effective, even if standard care pelvic floor muscle exercises may technically be more beneficial. On the other hand, it is important not to recommend and spend money on an ineffective training device. Research can scientifically examine the popular claim of effectiveness and thereby further evidence-based practice.

The best research design to determine the effectiveness of an intervention is a randomised controlled trial (RCT) (OCEBM, 2011). As a full RCT needs careful preparation and more basic research on the intervention is needed, a feasibility trial is proposed here. The novelty of the proposed research lies in the particular suggested working mechanism of the balls, the greater intended number of participants than in Glavind´s (2001) study, the targeted use for women after childbirth, and in its methodological purpose.

Research strategy

Purpose of the research

Research aims

- Assess practical issues and feasibility of a future full RCT
- Monitor harms of the experimental intervention
- Explore women´s perspectives on and experiences with the interventions and the trial

Research questions

- How can an RCT on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance after childbirth be prepared and performed best?
- How many participants would be needed for a full trial to test effectiveness?
- What are women´s perspectives on and experiences with the interventions and the trial?
- Is there any harm associated with the experimental intervention?

Study objectives

- Determine feasibility of a future full trial
- Explore different recruitment strategies
- Determine descriptive characteristics of the outcome measures
- Explore effect sizes
- Increase clinical experience with the experimental intervention
- Collect harms-related data of the experimental intervention
- Increase knowledge on theoretical basis of the experimental intervention
- Investigate women´s perspectives on and experiences with the interventions and the trial
- Determine concordance with the interventions and identify any adaptations needed to increase this
- Assess staff, time, and budget necessary for a full RCT

Research design

Parallel arm, single blind feasibility trial with two groups

Participants

Sample specification

Inclusion criteria:

- Women from 6 weeks to 6 months after vaginal childbirth (at beginning of intervention)
- Term birth, i.e. 37+0 or more weeks of gestation
- 6 weeks postpartum check by obstetrician-gynaecologist performed and woman discharged from postpartum care with diagnostic findings appropriate to this period after childbirth
- Lochia have ceased
- Over the age of 18 with capacity to consent

- Sufficient knowledge of written and spoken German to be able to participate in the study
- Baby alive/not seriously ill

Exclusion criteria:

- Currently enrolled in pelvic floor muscle training with physiotherapist, midwife or fitness trainer
- Status post perineal tear 3rd or 4th degree at most recent birth
- Status post continence surgery
- Current pelvic floor or gynaecological surgery
- Current infection of genitourinary tract
- Recurrent (>5 infectious episodes during last 12 months) or chronic (>3 weeks duration of single episode in last 12 months) vaginal infections
- Neuromuscular conditions influencing pelvic floor muscle function (e.g. multiple sclerosis)
- Major medical condition influencing infectious risk (diabetes, immune suppressive therapy, HIV infection etc.)
- Currently on medication that could interfere with treatment or evaluation
- Currently enrolled in any other research study
- Pregnancy (also commencing during participation) or pregnancy planned within the study period
- Retention of ball is impossible
- Inability to perform the proposed procedures

Eligibility criteria checklists for recruiting professionals, the recruitment phone call and for the first personal meeting (including how criteria will be confirmed) are included as appendices 14 a+b, 16 and 17.

Sampling method

Hospital and community based convenience sample, with random allocation to groups

Recruitment

Recruitment will be explored via different routes and organised by Claudia Oblasser:

a) Postnatal wards of Vienna General Hospital (AKH)
b) Delivery suite of Vienna General Hospital (AKH)
c) Community midwives in Vienna
d) Practices of obstetrician-gynaecologists in Vienna
e) Midwifery Centre Vienna (Hebammenzentrum Wien) and Nanaya (parenting centre)
f) World-wide websites

Details of recruitment via each route can be found in appendix 1. If a woman´s interest and eligibility is confirmed at an initial contact with Claudia Oblasser (mostly a phone call), she is sent an information/consent form via e-mail or mail in case she does not have it yet (this depends on recruitment route). Not earlier than 7-10 days after she has received the form, the potential participant is called to ask if she is still interested and to answer possible questions. If interested in participation, a personal meeting between her and Claudia Oblasser on the venue of her choice (her home, hospital or a public place where sufficient privacy can be obtained) is arranged, earliest after the six weeks postpartum check by her obstetrician-gynaecologist. At this meeting, the study will be fully explained and details can

be clarified. If applicable, the participant information/consent form will be signed, and data collection will start. Appendix 17 shows the content of this information/consent/first study meeting.

Sample size

56 women from the accessible population will be recruited. This sample size was calculated to correspond to the study objectives:

i. Using the formula for calculating sample sizes to be able to determine feasibility proportions by Hooper (n.y.), the determination of a rate of ≥ 80% with a 95%CI from 70-90 (the lowest feasibility rate in this trial, see feasibility criteria in appendix 2) requires a sample size of 56.
ii. Sample sizes between 24 and 55 are recommended for pilot studies by Sim and Lewis (2012) and Julious (2005) respectively to determine descriptive characteristics of outcome measures for calculation of sample size for the main trial.

Method of treatment assignment

Allocation of participants to trial groups will be done by randomisation in blocks of different size. These will be produced via an appropriate computer programme by a research administrator and accessible only to her/him. Opaque sealed envelopes serially numbered with the participant identification numbers and containing the codes generated by the computer programme will be prepared for Claudia Oblasser. Each time a participant is to be randomised after consent, the envelope with the next number will be opened. To obtain more information about the experimental intervention, two thirds (37) of participants will be allocated to the experimental and one third (19) to the comparison arm.

Interventions

Experimental intervention

Participants use the EC licensed pelvic floor muscle training ball *Laselle Kegel exerciser* 28g (*Intimina/LELO*). The ball is inserted into the vagina and left for 15 minutes daily in the first week, and if well tolerated 30 minutes daily from the second week onwards. To achieve the vibrating effect, the balls are worn while moving – performing everyday tasks or going for a walk. The balls are not to be worn during menstruation, other contraindications are covered within the exclusion criteria. Detailed instructions for use are given to participants in the information/consent form and explained verbally by Claudia Oblasser, and they can be found in appendix 3. Safety information about the intervention is provided in appendix 8 (ethical issues).

Comparison intervention

Comparison will be made to standard care after childbirth, which is the routine recommendation of pelvic floor muscle exercises. Participants will be asked to continue/start the pelvic floor muscle exercises they routinely were recommended by customary written instructions from their health professionals after birth. If women have not been given an instruction sheet, they will be given and explained the instruction in the information/consent form, which can also be found in appendix 4. There are no contraindications to this intervention; safety information about the intervention is provided in appendix 8 (ethical issues).

Duration of the interventions is projected for 12 weeks, in accordance with the recommended pelvic floor muscle training duration for urinary incontinence in the NICE guidelines (National Collaborating Centre for Women's and Children's Health, 2013) and with Glavind (2001). To chart concordance, participants will be asked to keep a training diary to note if/how long the ball was worn (appendix 23a+b) or if/how often the exercises were performed (appendix 24a+b). This diary is also likely to enhance participants' retention within the study and concordance with the intervention, as well as the phone calls for adverse events monitoring (see corresponding sections).

Measurement and data collection

Data to be collected

Table 1 summarises which data will be collected when, how and by whom. More information about the data collection tools can be found in Appendix 5.

Table 1: Summary of data collection

Variable(s)	Timepoint	Method of collection	Person collecting	Data collection tool
Baseline variables	Before the intervention	Structured interview	Claudia Oblasser	Appendix 19
Participant reported pelvic floor outcome measures	Before and after the intervention	Structured questionnaire to be filled out by participant	Claudia Oblasser	Appendices 20a+b
Externally assessed pelvic floor muscle performance	Before and after the intervention	Physiological measurement by perineometry	Engelbert Hanzal (blinded)	Appendix 22
Women´s perspectives and experiences	Before and after the intervention OR after the intervention	Structured interviews OR structured anonymous questionnaire	Claudia Oblasser	Appendices 21a+b and 26a+b OR 27a+b and 28a+b
Concordance	Throughout study	Training diary	Participant	Appendices 23a+b, 24a+b
Adverse events/harm	Throughout study	Phone interviews, question in final interview/survey, self-reporting by participants	Claudia Oblasser	Appendix 25
Staff, time, and budget necessary	Throughout study	Noting down in a list, calculation	Claudia Oblasser	Appendix 12
Feasibility variables (see criteria in appendix 2)	Throughout study and at the end of trial data collection	Calculation	Claudia Oblasser	--

Blinding

- The external assessor measuring pelvic floor muscle performance will be blinded.
- Blinding of participants (by withholding information about the alternative options) would make the trial flow more complicated with this intervention, and there is a large risk of unblinding as mothers might meet and talk to each other. Therefore, participants are not blinded.
- Caregivers are not expected to be involved as women have been discharged from postpartum care. If a caregiver gets consulted outside of the study, she or he will be informed by the participant about participation in the study and intervention used.
- Claudia Oblasser, allocating participants to groups, explaining procedures, doing baseline data and participant reported outcome data collection and interviews, is not blinded.

Process

A table showing study flow from a participant´s view is included as appendix 6. 18 women of the vaginal ball group and 10 of the exercises group will be interviewed by structured interviews (Claudia Oblasser) before the intervention to examine their views on the intervention and the trial, and after the intervention to gain their perspectives on and now experiences with the intervention and their participation in the trial. From these interviews, a questionnaire will be developed (by Claudia Oblasser) to anonymously survey the following participants and to pilot it for the main trial. For the interview schedule/questionnaire after the intervention, different versions will be used according to group (appendices 27a+b and 28a+b).

For the participants who get the survey questionnaire: At the end of the last meeting, after otherwise completed data collection, the survey questionnaire will be provided. If the participant has Internet access, she will be given the online link to complete the electronic version of the questionnaire. Otherwise, it will be handed out in paper form with an addressed and stamped envelope and expected to be sent back via mail. Two global text message reminders will be sent one and two weeks later.

Women not wanting to participate and any participant withdrawing from the study will be asked for their reasons, whenever possible.

Data management, analysis and presentation

Data management and protection

Data will be collected on paper forms or via online forms created via *formAssembly* at City University London. Collected data will be entered into a computer database by Claudia Oblasser, on her office computer at City University London and on her private Laptop. Handling of data is regulated by the Austrian Data Protection Act (Austria. Datenschutzgesetz 2000). Detailed information on data protection can be found in appendix 8.

Data processing and analysis

Data will be processed and analysed using the currently available versions of Excel and/or SPSS. Details of data processing are given in appendix 7. All data analyses will be performed by Claudia Oblasser, with support from a statistical advisor.

Feasibility criteria and resources calculation will be analysed descriptively, as well as baseline data, concordance and pelvic floor outcome measures. Groups will be compared on an intention-to-treat basis by appropriate tests in a pilot analysis. For continuous data, these will be repeated measures analysis of variance (ANOVA) or independent t-test for parametric, and linear regression analysis or Mann-Whitney U test for nonparametric data respectively. For dichotomous data, these will be logistic regression or Fisher´s exact test. If a large imbalance between groups is found for a confounding factor, statistical adjustment will be made by using ANCOVAs for the planned ANOVAs, or by using stratified analyses for the other tests. Missing values will be dealt with the technique appropriate to the reason why they are missing. The findings from these group comparisons are intended to better understand the needs of a full trial in terms of sample size calculation and best primary outcome measure. Due to the nature of a feasibility trial, there will be no hypothesis testing, and the results from statistical tests will not be published.

Qualitative data will be processed and analysed by content analysis. This will follow the principles of processing qualitative survey data given by Oppenheim (1992).

Presentation of results

Results will provide information about the features and feasibility of an RCT concerning issues of trial design, recruitment, intervention, method of measurement, data collection, and data analysis. They will also provide information about harms of the interventions, and participants´ views of and experiences with the interventions and participating in a trial of it.

Interpretation, discussion and conclusion

The interpretation and discussion will focus on feasibility, taking into account the stated feasibility criteria (see appendix 2), sources of potential bias or imprecision, and barriers or facilitators to participation and concordance.

It will be concluded that the planned full RCT to determine the effectiveness of vibrating vaginal pelvic floor muscle training balls is feasible as planned, feasible with modifications or not feasible. If not feasible, the performance of a full RCT must be abandoned. If feasible with modifications, necessary protocol alterations for the full scale trial based on the results of the feasibility trial will be clearly stated. If feasibility is shown, funding for the full trial will be sought.

Further issues

Patient and public involvement

In planning the methodological features of this feasibility trial, five women having given birth were consulted by Claudia Oblasser as part of the recommended patient and public involvement (PPI) process (National Institute for Health Research, n.y.). Ethnic background of these women was Somali, British White, and Austrian White. Meetings were held between March and July 2014. Study issues in question at the time of meeting were discussed with the women, such as where best to recruit participants, their potential worries, number and kind of study contacts, or acceptability of the experimental intervention and outcome measurements. Their suggestions were e.g. to stress the importance of the research to potential participants, that Muslim women might not want to use the balls, to ask a female person for pelvic floor muscle measurement, or to use a paper questionnaire for women as not everybody has Internet access. Two women checked the appropriateness and comprehensibility of study documents for participants. PPI participants will be kept informed about study results.

Ethical considerations

Ethical approval will be sought through the Research Ethics Committee of the Medical University of Vienna and City University London Senate Research Ethics Committee. Relevant ethical principles (according to the World Medical Association, 2008) are listed in appendix 8, together with information on how they will be addressed. Safety/harm of the intervention is considered in particular in appendix 9 on adverse events monitoring, recording and reporting. Potential benefits and risks for participants can be found in appendix 8 on ethical issues, appendix 9 on adverse events, and in the participant information/consent sheet. Once approved, the trial will be conducted in accordance with the research protocol (any amendments if needed will be clarified with the Ethics Committees) and the applicable ethical guidelines. An annual progress report and a summary final report will be sent to the Research Ethics Committees by Claudia Oblasser.

Claudia Oblasser`s interest in the topic stems from selling pelvic floor training balls in the past, however she is not affiliated with the company and therefore declares no conflict of interest.

Registration, reporting and dissemination

After ethics approval, the study will be registered at clinicaltrials.gov. Reporting and dissemination of the results is planned via completion of the thesis, professional conferences and publications in appropriate journals.

Timeplan, resources and costing

The study timetable is enclosed as appendix 10. Main sponsor is City University London, by supporting Claudia Oblasser with a PhD scholarship until September 2016. The Medical University of Vienna contributes with outcome assessments (Engelbert Hanzal), and by offering a recruitment possibility. Costs and their payment are outlined in appendix 11.

Research team and venue

Claudia Oblasser MA RM, Research Student (PhD Midwifery) at City University London, Baden, Austria:
Principal investigator in the sense of study execution: responsible for study planning, research protocol, organising recruitment, participant information, most data collection, analysis; academic author

Christine McCourt BA PhD, Professor of Maternal and Child Health, City University London, UK:
PhD supervisor; co-author

Engelbert Hanzal MD, Associate Professor of Obstetrics and Gynaecology, Medical University of Vienna, Austria:
Principal investigator (responsibility) according to Austrian law on medical devices; local advisor to research student; blinded assessor for physiologic pelvic floor measurement; co-author

Hanns Helmer MD, Associate Professor of Obstetrics and Gynaecology, Medical University of Vienna, Austria:
Supporting recruitment as medical lead of the postnatal wards at Vienna General Hospital

Vienna General Hospital (AKH) acts as the clinical centre of the Medical University of Vienna.

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. and 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', *Neurouology and Urodynamcis,* 29(1), pp. 213-240.

Association of Chartered Physiotherapists in Women´s Health (ACPWH) (2013a) Fit and safe to exercise in the childbearing year (Advice for physiotherapists and other health professionals). [Online]. Available at: http://pogp.csp.org.uk/publications (Accessed: 15 August 2014).

Association of Chartered Physiotherapists in Women´s Health (ACPWH) (2013b) *Fit for the Future: Essential advice and exercises following childbirth*. [Online]. Available at: http://pogp.csp.org.uk/publications?page=1 (Accessed: 15 August 2014).

Austria (1996) *Bundesgesetz betreffend Medizinprodukte (Medizinproduktegesetz - MPG)*. [Online]. Available at: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003 (Accessed: 11 August 2014).

Austria (2000) *Bundesgesetz über den Schutz personenbezogener Daten (Datenschutzgesetz 2000 - DSG 2000)*. [Online]. Available at: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=bundesnormen&Gesetzesnummer=10001597 (Accessed: 11 August 2014).

Avery, K., Donovan, J., Peters, T. J., Shaw, C., Gotoh, M. and Abrams, P. (2004) 'ICIQ: A Brief and Robust Measure for Evaluating the Symptoms and Impact of Urinary Incontinence', *Neurourology and Urodynamics*, 23, pp. 322-330.

Baessler, K. and Kempkensteffen, C. (2009) 'Validierung eines umfassenden Beckenboden-Fragebogens für Klinik, Praxis und Forschung', *Gynäklogisch-geburtshilfliche Rundschau*, 49, pp. 299-307.

Bø, K. (1995) 'Vaginal weight cones. Theoretical framework, effect on pelvic floor muscle strength and female stress urinary incontinence', *Acta Obstetricia et Gynecologica Scandinavica,* 74, pp. 87-92.

Bø, K., Owe, K. M. and Nystad, W. (2007) 'Which women do pelvic floor muscle exercises six months' postpartum?', *American Journal of Obstetrics and Gynecology,* 197(1), pp. 49-51.

Bø, K., Talseth, T. and Holme, I. (1999) 'Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women', *BMJ (British Medical Journal)*, 318, pp. 487-493.

Boyle, R., Hay-Smith, E. J. C., Cody, J. D. and 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). doi: 10.1002/14651858.CD007471.pub2.

Dietz, H. P., Shek, K. L., Chantarasorn, V. and Langer, S. E. M. (2012) 'Do women notice the effect of childbirth-related pelvic floor trauma?', *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 52, pp. 277-281.

European Medicines Agency (1995) *Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95)*. [Online]. London: EMEA. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002749.pdf (Accessed: 20 July 2014).

Fischer, W., Baessler, K. and 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, pp. 18-28.

Frawley, H. C., Galea, M. P., Phillips, B. A., Sherburn, M. and Bø, K. (2006) 'Reliability of Pelvic Floor Muscle Strength Assessment Using Different Test Positions and Tools', *Neurourology & Urodynamics*, 25, pp. 236-242.

Gameiro, M. O., Moreira, E. H., Gameiro, F. O., Moreno, J. C., Padovani, C. R. and Amaro, J. L. (2010) 'Vaginal weight cone versus assisted pelvic floor muscle training in the treatment of female urinary incontinence. A prospective, single-blind, randomized trial', *International Urogynecology Journal,* 21, pp. 395-399.

Glavind, K. (2001) 'Conservative treatment of stress incontinence with Geisha balls', *International Urogynecology Journal*, 12(4), pp. 223-224.

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

Hooper, R. (n.y.) *Justifying sample size for a feasibility study: Research Design Service London*. [Online]. Available at: http://www.rdslondon.co.uk/RDSLondon/media/RDSContent/copy/Justifying-Sample-Size-for-a-Feasibility-Study.pdf (Accessed: 28 April 2014).

Intimina (2014) *Laselle Kegel Exercisers*. Available at: http://www.intimina.com/en/kegel-exercisers-laselle.php (Accessed: 21 July 2014).

Julious, S. A. (2005) 'Sample size of 12 per group rule of thumb for a pilot study', *Pharmaceutical Statistics*, 4, pp. 287-291.

Lagro-Janssen, A. L. M., Debruyne, F. M. J., Smits, A. J. A. and Van Weel, C. (1992) 'The effects of treatment of urinary incontinence in general practice', *Family Practice* 9(3), pp. 284–289.

National Collaborating Centre for Women's and Children's Health (2013) *Urinary incontinence in women: the management of urinary incontinence in women*. 2nd ed. London: Royal College of Obstetricians and Gynaecologists.

National Institute for Health Research (n.y.) *Patient and Public Involvement in Health and Social Care Research: A Handbook for Researchers by Research Design Service London*. [Online]. London: Research Design Service. Available at: http://www.rdslondon.co.uk/RDSLondon/media/RDSContent/copy/RDS_PPI-Handbook_web.pdf (Accessed: 1 July 2014).

Oblasser, C., Christie, J. and McCourt, C. (2014) 'Vaginal cones or balls to improve pelvic floor muscle performance and urinary continence in women post partum: A quantitative systematic review and meta-analysis protocol'. [Ongoing, online]. Available at: http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014006165 (Accessed: 18 August 2014).

OCEBM Levels of Evidence Working Group (2011) *The Oxford 2011 Levels of Evidence*. [Online]. Available at: http://www.cebm.net/wp-content/uploads/2014/06/CEBM-Levels-of-Evidence-2.1.pdf

Oppenheim, A. N. (1992) *Questionnaire Design, Interviewing and Attitude Measurement*. New ed. London: Pinter Publishers Ltd.

Reilly, E. T. C., Freeman, R. M., Waterfield, M. R., Waterfield, A. E., Steggles, P. and Pedlar, F. (2002) 'Prevention of postpartum stress incontinence in primigravidae with increased bladder neck mobility: a randomised controlled trial of antenatal pelvic floor exercises', *BJOG: an international journal of obstetrics and gynaecology*, 109, pp. 68-76.

Sim, J. and Lewis, M. (2012) 'The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency', *Journal of Clinical Epidemiology*, 65, pp. 301-308.

Test-Club-Bericht (2013) 'Intimina Laselle Vaginalkugeln zur Stärkung der Beckenbodenmuskulatur', *Gesunde Medizin*, (5), pp. 38-39.

Thibault-Gagnon, S., Yusuf, S., Langer, S., Wong, V., Sheck, K. L., Martin, A. and Dietz, H. P. (2014) 'Do women notice the impact of childbirth-related levator trauma on pelvic floor and sexual function? Results of an observational ultrasound study', *International Urogynecology Journal*. doi: 10.1007/s00192-014-2331-z.

Udier, E. (2014). Skype conversation with Claudia Oblasser. 14 May.

World Medical Association (2008) *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. [Online]. Available at: http://www.wma.net/en/30publications/10policies/b3/17c.pdf (Accessed: 21 July 2014).

Appendix 1: Recruitment details

Recruitment will take place via different routes:

a) Postnatal wards of Vienna General Hospital (AKH):
At discharge, eligible women are offered the participant information/consent sheet by medical doctors.

b) Delivery suite of Vienna General Hospital (AKH):
Eligible women discharged directly from the delivery suite are offered the participant information/consent sheet by midwives.

c) Community midwives in Vienna:
10 midwives will be approached to give appropriate clients the participant information/consent form. If recruitment shows to be difficult, more midwives will be approached.

d) Practices of obstetrician-gynaecologists in Vienna:
10 obstetricians will be approached to give appropriate clients the participant information/consent form. If recruitment shows to be difficult, more obstetricians will be approached.

a-d) If a woman accepts the leaflet, she is asked her for her verbal consent to pass her name and telephone number to Claudia Oblasser (recruitment form for professionals see appendices 14a+b). Not earlier than 7-10 days later, Claudia Oblasser will call the woman to introduce herself, ask her if she is interested in taking part, and answer possible questions.

e) Midwifery Centre Vienna (Hebammenzentrum Wien), Nanaya (parenting centre):
Eligible women are informed by course leaders (who mention the study but do not note the phone number) or by Claudia Oblasser (who notes the phone number and procedes as described in a-d. Additionally, recruitment leaflets are left at the centres´ information board and/or "leaflet corner". If recruitment shows to be difficult, similar centres will be approached.

f) World-wide web:
- via putting the text of the recruitment leaflet on websites relevant to women after childbirth:
  - Austrian Midwifery Board (Österreichisches Hebammengremium, www.hebammen.at)
  - Midwifery Centre Vienna (Hebammenzentrum Wien, www.hebammenzentrum.at) – website under construction; can only be clarified in October when new website is completed
- If comparable websites are discovered during the study, it is intended to add them.
- via placing the text of the recruitment leaflet at facebook and using contacts therein to make it known, e.g. with Geburtsallianz (Austrian consumer movement around childbirth)

Appendix 2: Feasibility criteria

The full trial will deemed to be feasible if all of the following criteria are met.

Recruitment:

- ≥ 10% of eligible persons give consent to participate in the trial (can only be calculated for recruitment where professionals will note the number of eligible women).

Pre intervention data collection:

- At least 50 of the 56 (90%) or ≥ 90% (95%CI=80-100) of participants attend the first pelvic floor muscle measurement within 3 weeks of consenting to take part in the trial.

Completion and concordance:

- At least 50 of the 56 (90%) or ≥ 90% (95%CI=80-100) of participants start with the intervention within 4 days of the initial pelvic floor muscle measurement by perineometry.
- At least 45 of the 56 (80%) or ≥ 80% (95%CI=70-90) of enrolled participants keep to the assigned intervention group and adhere adequately to the intervention.

Post intervention data collection:

- At least 45 of the 56 (80%) or ≥ 80% (95% CI=70-90) of enrolled participants have the final data collection within 2 weeks of ending the intervention.

Appendix 3: Instruction for using pelvic floor training balls

- Wash your hands.
- Apply, if desired, a small amount of water-based lubricant (will be provided) onto your clean pelvic ball for ease of insertion.
- Position your body comfortably (lying on your back or side, squatting, standing with one leg elevated). Breathe for relaxation and insert the ball gently and with steady pressure into your vagina. Make sure the retraction cord is outside of the body. The ball does not have to be inserted deeply, it should lie comfortably about 2cm deep in the vagina, this is not as high as a tampon.
- Move with the ball inside, e.g. during a walk or doing housework. You should feel the vibrations when you move. Use the ball for 15 minutes daily in the first week, and for 30 minutes daily from the second week onwards, altogether for 12 weeks. It should not take you a great effort to keep the ball inside – wear the ball only as long as it is easy for you, even if this possibly means less than 15 or 30 minutes, respectively. If you cannot keep the ball inside at all, please contact Claudia Oblasser.
- Correctly placed vaginal balls do not cause any dragging in the lower abdomen, do not push at the buttocks and do not exert downward pressure. However, you can experience **slight** muscle soreness (like from too much muscle exercising) in the pelvis at the beginning of training.
- To take the ball out, draw gently initially and if needed firmer on the 7 cm long retraction cord. If you cannot take the ball out easily, relax and draw firmer.
- Clean the ball after each use (if you have not used it for some time, clean it also before use) with water and the antibacterial soap provided for the study. Do not use cleansing agents with alcohol, benzine or acetone, as these substances can influence you vaginal flora negatively and can also destroy the outer silicone layer of the ball. Dry the ball with a fuzz free cloth and keep them in the provided antibacterial bag.
- An effect is more likely if you use the ball consequently.

Please do not use the ball during menstruation and intercourse, and when having inflammations, diseases, operations or pain in the genital area, and during pregnancy.

General recommendation (to prevent leakage):
Contract your pelvic floor muscles before and during each activity requiring effort from the pelvic floor, e.g. when you are lifting your baby, coughing or sneezing.

Contracting the pelvic floor:
Imagine that you are trying to stop yourself passing urine or wind. Squeeze the muscles around the vagina and lift them by closing and drawing up (and a little bit forward) inside the 3 passages for the anus, vagina and urethra.

Appendix 4: Instruction for doing pelvic floor muscle exercises

Contracting the pelvic floor:
Imagine that you are trying to stop yourself passing urine or wind. Squeeze the muscles around the vagina and lift them by closing and drawing up (and a little bit forward) inside the 3 passages for the anus, vagina and urethra. Start gently and rhythmically. Your buttocks, legs and tummy should not move when doing the exercise.

- Long contractions:
  Hold the squeeze for a few seconds, and then relax for a few seconds; breathe. Increase the time and the number that you do until you can hold the squeeze for up to 10 seconds and repeat up to 8-10 times.

- Fast contractions:
  Tighten the pelvic floor muscles as quickly and strongly as you can, breathe, and then relax. Do this up to 8-10 times.

Try exercising in different positions (lying, sitting, standing) and establish a routine, such as every time you feed your baby.

For the exercises to be effective you need to persevere and do the two types of exercise at least 3 times a day.

General recommendation (to prevent leakage):
Contract/tighten your pelvic floor muscles before and during each activity requiring effort from the pelvic floor, e.g. when you are lifting your baby, coughing or sneezing.

Instruction according to: Association of Chartered Physiotherapists in Women´s Health (2013a and 2013b) and National Collaborating Centre for Women's and Children's Health (2013)

Appendix 5: Data collection tools

- Baseline data collection form (appendix 19): created by Claudia Oblasser

- Participant reported pelvic floor outcome questionnaire (appendices 20a+b): created by Claudia Oblasser

  This questionnaire contains the following elements:
  - measures of pelvic floor muscle strength: question 1 with a reported high test-retest reliability taken from Dietz *et al.* (2012); question 2 taken and adapted from Thibault-Gagnon *et al.*´s (2014, including Mr. Dietz) pelvic floor and birth questionnaire. Permission has been sought from Mr. Dietz to use these questions.
  - vaginal symptoms with a question adapted from Thibault-Gagnon *et al.* (2014), and a question from Baessler and Kempkensteffen (2009), a validated German pelvic floor questionnaire for practice and research. Permission has been sought from Ms. Baessler to use single questions of her questionnaire.
  - bowel symptoms with two questions (one adapted) from Baessler and Kempkensteffen (2009).
  - urinary incontinence symptoms measured with the ICIQ-UI Short Form (German) of the International Consultation of Urinary Incontinence (ICI). This is a standardised urinary incontinence questionnaire validated by Avery *et al.* (2004) and a validated translation by the ICI. Permission has been given by the ICI to use the questionnaire in its original form.

  Adaptations of original questions have been made to suit the purpose of this study, in consideration of patient and public involvement (PPI) input and to enable a consistent questionnaire design. The questionnaire is completed by the participant herself, but Claudia Oblasser will be present and explanations can be given if necessary.

- Outcome form for perineometry (appendix 22): created by Claudia Oblasser

  The device used for the physiologic measurement of pelvic floor muscle performance will be the perineometer *Peritron™ PRN09301* (or *cat 9300V*), with a vaginal sensor and a collar to control depth of insertion from Laborie (http://laborie.com/products/pelvic-muscle-rehabilitation/biofeedback-and-stimulation/peritron/). For safety details see Appendix 8.

- Initial and final interview schedules (appendices 21a+b and 26a+b): created by Claudia Oblasser

- Concordance charts (appendices 23a+b and 24a+b): created by Claudia Oblasser

- Adverse events monitoring form (appendix 25): created by Claudia Oblasser

- Survey (draft) questionnaire (appendices 27a+b and 28a+b): created by Claudia Oblasser

- Staff, time, and budget documentation form (appendix 12): created by Claudia Oblasser

Forms being administered to study participants have been reviewed by two women as part of the patient and public involvement (PPI) process. Piloting of forms is part of the proposed feasibility design.

Appendix 6: Schedule of enrolment, interventions, and assessments

	Study period								
	Enrolment			Allocation	Post-allocation			Close-out	
	-t3	**-t2** 7-10 days after –t3	**-t1** not before six weeks after birth	**0** = -t1	**t1** = -t1/0	**t2** within 2 weeks of t1	**t3-t7**	**t8** within 2 weeks after ending the intervention	**t9** within 2 weeks after ending the intervention
1. Enrolment									
Recruitment	Via different routes								
Recruitment Initial eligibility screen		Phone call (15 min.) (for those concerned)							
Eligibility screen			a						
Informed consent			a						
2. Allocation				a					
3 .Interventions						Starts after perineometry	x (12 weeks)		
4. Assessments									
Baseline variables collection					a				
Participant reported outcome variables collection					a			c	
Perineometry						b			b
Interviews OR questionnaire					a			c OR after c (15-20 min.)	
Adverse events monitoring							5 phone calls (à 5-10 min.)	c	

a = personal meeting of Claudia Oblasser with the potential participant, on the venue most suitable to the participant (her home, hospital room or public place where sufficient privacy can be obtained). Estimated duration: 2 hours. The content of the meeting can be found in appendix 17.

b = by external (blinded) assessor (Engelbert Hanzal): Participants have to travel to Vienna General Hospital (AKH). Estimated duration of contact: 15 minutes. Travel time according to participant.

c = personal meeting of Claudia Oblasser with the participant, on the venue most suitable to the participant (her home, hospital room or a public place where sufficient privacy can be obtained). Estimated duration: 1-1.5 hours

Appendix 7: Data processing details

Data entering
Collected data will be entered into the computer database as soon as possible. To avoid errors when entering data manually from paper forms into the computer, entries will be checked on a later day. Data from electronic forms in *formAssembly* can be directly imported into the computer database.

Precoding
The baseline data collection form and interview schedules are precoded (see data collection forms in the appendix). The ICIQ-UI Short Form as part of the participant reported outcome questionnaire is also precoded. Data collection forms for patient reported outcomes and perineometry, and the survey questionnaire(s) will not be precoded to not to disturb their appearance.

Coding of quantitative data
Concordance is defined as adequate when at least 80% (in days) of the prescribed exercise sessions have been completed. Otherwise, it is considered inadequate.

Vaginal squeeze pressure maximum voluntary contraction during perineometry will be reported as the highest maximum contraction of 3 measurements and the mean of 3 maximum contraction measurements.

Coding of adverse events
Adverse events recording will comprise type, severity and number of all events for all participants and will be reported according to interventions.

Coding of qualitative data
From the answers received for each qualitative (open) question, coding frames with answering categories and their corresponding frequencies will be determined. Qualitative data thus become quantifiable and then follow the processing and analysis of quantitative data. The number and name of categories can only be decided after all or most answers have been collected.

Appendix 8: Ethical issues

Doing no harm

Safety of medical devices used

For the intervention: *Laselle Kegel Exercisers* by *Intimina*/*LELO* are of body-safe, phthalate-free FDA-approved silicone and ABS (Intimina, 2014), and they are a EU/EEC licensed medical device class 1 (Council Directive 93/42/EEC, declaration of conformity included as appendix 29).

For the measurement: The vaginal probe is a licensed class 1 medical device and has a CE mark (certificate included as appendix 30). The measuring device itself does not have a CE mark yet, but it has been confirmed by *Laborie* that this is expected for the upcoming September. However, the *Peritron*™ has already been used in other studies (e.g. in Reilly *et al*., 2002; Frawley *et al*., 2006; Gameiro *et al*., 2010).

Adverse effects of interventions

The use of vaginal pelvic floor balls seems to be a safe method of training. The reported adverse effects of balls or cones (a similar device) are rare and not serious. In a German pharmaceutic consumer survey on the *Laselle Kegel Exercisers* (Test-Club-Bericht, 2013), no adverse effects have been reported. Glavind (2001), using another (double) model of vibrating vaginal balls, describes a slight vaginal irritation in one of her 10 participants. In their systematic review on weighted vaginal cones, Herbison and Dean (2013) mention discomfort and bleeding as reasons for women dropping out of treatment. Another adverse effect identified with cones is occasional muscle soreness at the beginning of the training (Fischer, Baessler and Linde, 1996), and Bø, Talseth and Holme (1999) reported one woman with abdominal pain and two with vaginitis (out of 29). However, this is a biased selection of studies that mention adverse effects. Also, Glavind (2001) and Bø, Talseth and Holme (1999) included women up to 59 and 70 years, respectively, which might influence adverse effects. An Austrian physiotherapist having been working with pelvic floor training balls since 15 years confirms that some women have experienced bleeding, but she never has seen a case of vaginal infection (Udier, 2014).

Pelvic floor muscle exercises seem to be a safe method of training, although the majority of studies do not consider adverse effects (Boyle *et al*., 2012; National Collaborating Centre for Women's and Children's Health, 2013). In one study with 107 participants, pain (once) and an uncomfortable feeling during exercise (three times) have been identified as adverse effects (Lagro-Janssen *et al*., 1992).

The pelvic floor measurement performed for this study is painless and does not carry any known risks, as well as the interviews and questionnaires.

Adverse events monitoring, recording and reporting plans for this study can be found in appendix 9.

Further issues

- With respect to the special situation post partum, women can only take part in the study from 6 weeks post partum onwards, when an obstetrician-gynaecologist has

performed the six weeks check and discharged the woman from postpartum care with diagnostic findings appropriate to this period after childbirth.

- Lochia must have ceased.
- Women are given oral and written information about the potential risks of the interventions with the participant information/consent form.
- In the participant information/consent form, participants will be provided with written contact details of Claudia Oblasser, Engelbert Hanzal, Hanns Helmer and the delivery unit of Vienna General Hospital (AKH) for any urgent question or problem arising during and post-study.
- Transfer to necessary care will be arranged should the need arise.
- Termination of participation will be recommended to a participant when there is vaginal infection, occurrence of repeated bleeding, or pregnancy.
- Participants can withdraw their participation or refuse to participate in parts of the study anytime and will be informed about this in the participant information/consent form (this might be important as pelvic floor health is an intimate topic).
- The questions about womens´ reasons for not wanting to participate/wanting to withdraw will be asked in a neutral way so that women do not feel pressured to participate.
- Participants will get their travel fees within Vienna reimbursed (2 single tickets) when coming to the pelvic floor muscle assessments.
- A complaints policy is detailed within the participant information/consent form.

Personal benefits for participants

By using pelvic floor training balls or doing pelvic floor muscle exercises, participants´ pelvic floor muscles could be strengthened or pelvic floor symptoms could be enhanced. Participants get two pelvic floor measurements and information about the performance of their pelvic floor muscles from the view of a health professional. By the intensive preoccupation with the pelvic floor, participants might get a better perception of it and become more conscious about the importance of its health, which might contribute to their pelvic floor health in the long term. By having raised the topic of incontinence after childbirth, women with this problem might be identified and referred to appropriate treatment who otherwise might be (more) reluctant to seek health care.

Right to autonomy

- Claudia Oblasser will have no care dependency relationship with women interested in the study. Engelbert Hanzal might accidentially know interested women from his private medical practice or because he was involved in their care during birth. As he is not involved in recruitment and in giving preliminary information to potential participants, he is not in a position to exert pressure towards participation.
- Participation will be voluntary, no pressure (practical, moral or concerning time) will be exerted.
- Participants will be offered the possibility to withdraw at any time or to refuse parts of the study without negative sequelae.

Right to information

- In the participant information/consent form, participants are informed about the study.
- Participants give informed consent.
- Participants are given the information they require at any point during or after the study.

Right to data protection

Privacy will be kept during all data collection procedures. To maintain confidentiality of data, each participant will be assigned a participant identification number (participant ID) after consent (numbering will start with 1). The list with names and corresponding numbers will be stored electronically and kept in paper form. All paper data collection forms used by Claudia Oblasser (baseline data, participant reported outcomes and interviews) will be filled out with only the participant ID on them. Survey questionnaires at the end of the intervention will be anonymous (in paper and electronic form).

Personal information in paper form will be stored in a locked cupboard at Claudia Oblasser´s office at home or at City University London. Personal information on computers will be secured by the encryption software *truecrypt*. Electronic data submissions via *formAssembly* are securely processed and stored at City University London.

Electronic data collection forms for perineometry will need the participant´s name to be filled in, as participants cannot be expected to know their participant ID, and the outcome assessor does not have a list of names and corresponding numbers. Access to these perineometry data submitted via *formAssembly* is password protected and only possible to Claudia Oblasser. Data will be entered into the computer database and processed only by the participant ID after their arrival at Claudia Oblasser´s office.

Analysis and presentation of results will use de-identified data. Data will be securely stored and confidentially destroyed after ten years.

Safety of researcher

- Risk assessment according to City University London policy has been undertaken for Claudia Oblasser. To avoid dangers of lone working, a text message will be sent to a friend before and after she goes to a (potential) participant´s home.
- According to the Austrian Law about medical devices (Austria. Medizinproduktegesetz 1996), liability lies with the manufacturer if the device is used in the way it is registered for.
- The Research Committee of the Medical University of Vienna does not see the necessity of an insurance for the proposed research. Further insurance issues for Claudia Oblasser will be clarified with City University London.

Appendix 9: Adverse events monitoring, recording and reporting

An adverse event is "any unfavourable and unintended sign […], symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product" (European Medicines Agency, 1995, p. 3).

Expected adverse events (see also appendix 8)
Experimental group:

- Discomfort
- Slight muscle soreness or pain (from too much training)
- Slight vaginal bleeding (rarely)
- Vaginal irritation (very rarely) or infection (very rarely)

Comparison group:

- Uncomfortable feeling during exercise (rarely)
- Pain (very rarely)

Monitoring of adverse events
A policy of active and passive surveillance will be applied to monitor expected and unexpected adverse events after uptake of the assigned intervention:

- Participants will be informed in oral and written form about potential adverse effects and their warning signs.
- Participants will be given contact details of Claudia Oblasser, Engelbert Hanzal, Hanns Helmer and the delivery unit at Vienna General Hospital (AKH) in written form for any urgent question or problem arising during and post-study.
- To check for adverse events, participants will be phoned by Claudia Oblasser according to the following scheme:

  4 days after beginning the intervention (after perineometry)
  1 week later
  2 weeks later
  3 weeks later
  3 weeks later

  Duration of each phone call will be between 5 and 10 minutes. The content of the call is standardised (appendix 25) and the contacts will be documented. At each planned time point for a call, three calls are initiated to reach the participant. A voicemail will be left each time in case the participant does not answer the phone.
- Adverse events assessments is part of the final interview and survey questionnaire.
- Transfer to necessary care will be arranged should the need arise.
- Termination of participation will be recommended to a participant when there is vaginal infection or occurrence of repeated bleeding.

Recording and reporting of adverse events

Adverse events recording will comprise type, severity and number of all events for all participants and will be reported according to interventions. Serious adverse events (SAEs), as defined by the guidance for clinical safety data management (European Medicines Agency, 1995), and urgent safety measures will be reported by Claudia Oblasser to both Research Ethics Committees by the respective forms provided within 15 days of her becoming aware of the event.

Appendix 10: Study timetable

2014		2015												2016					
Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June -Sept
Recruitment																			
	Interventions																		
	Data collection																		
	Data analysis (interviews)																Data analysis		
Writing up																			

Appendix 11: Resources and costing

Human resources

Support needed for	Provided by	Projected cost	Paid or sponsored by
Randomisation procedure	Research administrator	--	City University London
Perineometry	Staff of Medical University of Vienna	--	Medical University of Vienna
Statistical support	To be confirmed	To be confirmed	PhD budget

Material

Item	Projected cost	Paid or sponsored by
Printed study material	--	City University London (office)
Randomisation cards + envelopes	--	City University London (office)
Pelvic floor training balls	37 balls à € 12,50 = € 462,50 (≈£ 370,00)	PhD budget
Lubricant	37 lubricants à € 13,95 = € 516,15 (≈£ 413,00)	PhD budget
Antibacterial soap	37 liquid soaps à € 1,15 = € 42,55 (≈£ 33,80)	PhD budget
Telephone	€ 15.-/month x 12 months = € 180,- (≈£ 142,56)	PhD budget
Postage to send participant information/consent forms	100 letters à € 0,90 = € 90,00 (≈£ 72,20)	PhD budget
Postage for sending survey questionnaire back	19 participants à € 0,62 = € 11,78 (≈£ 9,33)	PhD budget
Participant travel reimbursement	56 participants à 4 journeys à € 2,20 = € 492,80 (≈£ 390,29)	PhD budget
Perineometer with vaginal probe Collar for vaginal sensor to control depth of insertion	Canadian $ 1200,00 = € 820,00 (≈£ 650,00) + customs Canadian $ 18,19 = € 12,50 (≈£ 10,00) + customs	Engelbert Hanzal and Claudia Oblasser
Sum	€ 2212,03 (≈£1.766,86)	

Appendix 12: Staff, time, and budget documentation form

Staff

Person	Task	Time needed

Budget

Item	Quantity	à	Amount

Appendix 13a: Recruitment leaflet

School of Health Sciences City University London
Medizinische Universität Wien

Teilnehmerinnen für eine Studie zum Beckenbodentraining nach der Geburt gesucht

Als Teilnehmerin dieser Studie würden Sie in den Monaten nach der Geburt Ihres Kindes entweder Beckenbodenübungen durchführen oder vibrierende Beckenbodenkugeln verwenden. Dies soll der Stärkung der Beckenbodenmuskulatur dienen, um Problemen wie Harninkontinenz vorzubeugen.

Um eine mögliche Veränderung des Beckenbodens zu messen, würde ich Sie vor und nach 12 Wochen Training bitten, Fragebögen auszufüllen und zu einer schmerzlosen Messung der Beckenbodenstärke in die Universitätsklinik für Frauenheilkunde (AKH) zu kommen. Ausserdem bin ich mittels Interview oder Fragebogen an Ihrer Meinung zur Beckenbodenkugel/zu den Übungen und zur Studie interessiert.

Anfallende Fahrtkosten innerhalb Wiens werden ersetzt.

Für weitere Informationen über diese Studie, oder wenn Sie sich für eine Teilnahme interessieren, kontaktieren Sie bitte:
Hebamme Claudia Oblasser unter 0676 301 94 86
oder Claudia.Oblasser.1@city.ac.uk

Diese Studie wurde von den Ethikkommissionen der Medizinischen Universität Wien und der City University London begutachtet und genehmigt. Sie ist ein Doktoratsprojekt von Claudia Oblasser, unter Supervision von Professorin Christine McCourt (City University London), und mit Unterstützung durch Professor Engelbert Hanzal (Medizinische Universität Wien).

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Version 2 of 19 October 2014

Appendix 13b: Recruitment leaflet – English translation

School of Health Sciences City University London
Medical University of Vienna

Participants needed for a study about pelvic floor muscle training after childbirth

As a participant in this study, you would be asked to perform pelvic floor muscle exercises or use vibrating pelvic floor training balls in the months after the birth of your baby. This is supposed to strengthen the pelvic floor muscles to prevent problems such as urinary incontinence.

To determine a possible change in your pelvic floor, I would ask you to complete questionnaires and to come to Vienna General Hospital for a painless measurement of pelvic floor muscle strength before and after 12 weeks of training. I am also interested in your opinion about the ball/exercises and the study via interview or questionnaire.

Travel costs within Vienna will be reimbursed.

For further information about this study, or to volunteer for this study, please contact:
Midwife Claudia Oblasser on 0676 301 94 86 or Claudia.Oblasser.1@city.ac.uk

This study has been reviewed by, and received ethics clearance through the Research Committees of the Medical University of Vienna and of City University London. It is a PhD project by Claudia Oblasser, supervised by professor Christine McCourt (City University London), and supported by professor Engelbert Hanzal (Medical University of Vienna).

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Version 2 of 19 October 2014

Appendix 14a: Recruitment form health professionals (generic)

This form will be adapted to the professional group and context. Variable information is enclosed in [].

Machbarkeits-RCT zur Wirksamkeit von vibrierenden Beckenbodenkugeln zur Verbesserung der Beckenbodenmuskulatur nach der Geburt

Sehr geehrter/liebe [Berufsgruppe bzw. Anrede],

Bitte sprechen Sie eine [Wöchnerin/Frau/Patientin] an, wenn sie die folgenden Kriterien erfüllt:

- Termingeburt (ab 37+0)
- Vaginale Geburt
- Kein Dammriss Grad III oder IV bei der gerade stattgefundenen Geburt
- Ausreichende mündliche und schriftliche Kenntnisse der deutschen Sprache, um an der Studie teilnehmen zu können
- Mindestens 18 Jahre alt, mündig
- Keine neuromuskuläre Erkrankung, die die Funktion der Beckenbodenmuskeln beeinflussen kann (z.B. Multiple Sklerose)
- Keine Erkrankung, die das Infektionsrisiko beeinflussen kann (z.B. Diabetes, immunsuppressive Therapie, HIV-Infektion etc.)
- Kind lebt/ist nicht schwer erkrankt

Diese Kriterien werden entsprechend dem Kontext der Rekrutierung eingesetzt:

- [Frauen von 6 Wochen bis 5 Monate nach der Geburt]
- [6-Wochen-Untersuchung durch Gynäkologen durchgeführt, aus postpartaler Betreuung mit einem dem Zeitpunkt nach der Geburt entsprechenden Befund entlassen]
- [Derzeit nicht schwanger, während der Studienzeit (16 Wochen) keine Schwangerschaft geplant]
- [Nimmt derzeit an keinem Beckenbodentrainig mit Physiotherapeutin, Hebamme oder Fitnesstrainerin teil]
- [Derzeit keine gynäkologischen Operationen bzw. Operationen im Bereich des Beckenbodens]
- [Wiederkehrende (>5 Episoden während der letzten 12 Monate) oder chronische (>3 Wochen Dauer einer einzelnen Episode während der letzten 12 Monate) vaginale Infektionen]

Die folgenden Elemente werden nur bei denjenigen Rekrutierungspersonen eingefügt, die sich bereit erklären, die Angaben zu notieren:

Ablehnungen:
Bitte für jede Frau, die ihre Telefonnummer nicht eingetragen haben möchte, ein Stricherl machen (dies dient der Feststellung der Rekrutierungsrate).

Gründe für Nicht-Teilnahme: Bitte für jede Frau, die nicht teilnehmen möchte, die angegebenen Gründe eintragen.

Ist mit Anruf einverstanden:

Datum	Name	Telefon	Kriterien erfüllt

Appendix 14b: Recruitment form health professionals (generic) – English translation

This form will be adapted to the professional group and context. Variable information is enclosed in [].

Feasibility trial on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth

Dear [health professional],

please approach a [parturient/woman/patient] if she fulfils the following criteria:

- Term birth (37+0 or more weeks of gestation)
- Vaginal birth
- No 3rd or 4th degree perineal tear at this birth
- Sufficient knowledge of written and spoken German to be able to participate in the study
- Over the age of 18, with capacity to consent
- No neuromuscular condition influencing pelvic floor muscle function (e.g. MS)
- No major medical condition influencing infectious risk (diabetes, immune suppressive therapy, HIV infection etc.)
- Baby alive/not seriously ill

These criteria will be included according to the context of recruitment:

- [Women from 6 weeks to 5 months post partum]
- [6 weeks postpartum check by obstetrician-gynaecologist performed and woman discharged from postpartum care with diagnostic findings appropriate to this period after childbirth]
- [Currently not pregnant and no pregnancy planned within the study period (16 weeks)]
- [Currently not enrolled in pelvic floor muscle training with physiotherapist, midwife or fitness trainer]
- [No current pelvic floor or gynaecological surgery]
- [Recurrent (>5 episodes during last 12 months) or chronic (>3 weeks duration of single episode in last 12 months) vaginal infections]

The following elements will be inserted only for the professionals willing to note the information:

Refusals:
Please make a line for each woman who does not want to have her phone number noted (this serves to find out the recruitment rate).

Reasons for not wanting to participate: Please insert the reasons given by each woman not wanting to participate.

Gives permission to be called:

Date	Name	Phone number	Criteria checked

Appendix 15: Recruitment phone call documentation

Name	Phone number	Call date/time	Where did you hear about the study?	**Result:** - wants to participate - more time - … - no interest - why not?	Eligible?	Date of meeting	Place of meeting

Appendix 16: Recruitment phone call eligibility checklist

Name:

Telephone number:

Criterion	Fulfilled
Inclusion	
Between 6 weeks and 5 months after childbirth	
Vaginal delivery	
Birth at 37+0 or more weeks of gestation	
Over the age of 18 with capacity to consent	
Sufficient knowledge of written and spoken German to be able to participate in the study	
Baby alive/not seriously ill	
6 weeks postpartum check by obstetrician-gynaecologist performed and woman discharged from postpartum care with diagnostic findings appropriate to this period after childbirth	
Lochia ceased	
Currently not pregnant	
Exclusion	
Currently enrolled in pelvic floor muscle training with physiotherapist, midwife or fitness trainer	
Perineal tear 3rd or 4th degree at most recent birth	
Status post continence surgery	
Current pelvic floor or gynaecological surgery	
Current infection of genitourinary tract	
Recurrent (>5 infectious episodes during last 12 months) or chronic (>3 weeks duration of single episode in last 12 months) vaginal infections	
Neuromuscular conditions influencing pelvic floor muscle function (e.g. MS)	
Major medical condition influencing infectious risk (diabetes, immune suppressive therapy, HIV infection etc.)	
Currently on medication that could interfere with treatment or evaluation	
Currently enrolled in any other research study	
Current pregnancy or pregnancy planned within the study period (16 weeks)	
Inability to perform the proposed procedures	

Appendix 17: Information/consent/first study meeting schedule

Name:

Date:

Time:

Venue:

- Check eligibility

Criterion	Fulfilled	Confirmed by
Inclusion		
Between 6 weeks and 5 months after childbirth		Maternity notes
Vaginal delivery		Maternity notes
Birth at 37+0 or more weeks of gestation		Maternity notes
Over the age of 18, with capacity to consent		Maternity notes; capacity to consent assumded, enquiry if in doubt
Sufficient knowledge of written and spoken German to be able to participate in the study		Conversation
Baby alive/not seriously ill		Participant
6 weeks postpartum check by obstetrician-gynaecologist performed and woman discharged from postpartum care with diagnostic findings appropriate to this period after childbirth		Participant
Lochia have ceased		Participant
Exclusion		
Currently enrolled in pelvic floor muscle training with physiotherapist, midwife or fitness trainer		Participant
Perineal tear 3rd or 4th degree at most recent birth		Maternity notes
Status post continence surgery		Participant
Current pelvic floor or gynaecological surgery		Participant
Current infection of genitourinary tract		Participant
Recurrent (>5 infectious episodes during last 12 months) or chronic (>3 weeks duration of single episode in last 12 months) vaginal infections		Participant
Neuromuscular conditions influencing pelvic floor muscle function (e.g. MS)		Participant
Major medical condition influencing infectious risk (diabetes, immune suppressive therapy, HIV infection etc.)		Participant

Currently on medication that could interfere with treatment or evaluation		Participant
Currently enrolled in any other research study		Participant
Current pregnancy, pregnancy planned within the study period (16 weeks), pregnancy commencing during participation		Participant
Inability to perform the proposed procedures		Participant

- Study fully explained and questions clarified
- Pelvic floor clarified (with pictures and explanations)
- Gone through information/consent form
- Woman not interested in participation: Why?
  ➔ end process here
- Consent form signed
- Participant ID attributed
- Baseline data collected
- Participant reported outcome measurements collected
- Initial interview performed
- Randomisation performed
- Intervention explained
- Concordance chart explained
- Informed about appointment for perineomtry
- Informed about next contact (phone calls)

Appendix 18: Participant name-number translation form

Participant name Address Tel, mail	Participant identification number

Appendix 19: Baseline data collection form

Participant ID:

Demographics

Age (**Variable: age**)	
Ethnicity (**ethn**)	○ Austrian 1 ○ Other:... 2
Highest completed education (**educ**)	○ Pflichtschule (compulsory education) 1 ○ Lehre (apprenticeship) 2 ○ Berufsbildende mittlere Schule (vocational middle school) 3 ○ Matura (high school) 4 ○ Hochschulstudium (academic education) 5
Profession learned (**prof learn**)	
Current profession (**prof cur**)	○ Paid work:… 1 ○ Housewife 2 ○ Student 3
Partnership status (**partner**)	○ Living in partnership 1 ○ Living alone 2

Most recent birth

Date	
Completed weeks post partum (**weeks pp**)	
Parity (**parity**)	○ I 1 ○ II 2 ○ III 3 ○ IV or more 4
Birth mode (**mode**)	○ Spontaneous 1 ○ Ventouse 2 ○ Forceps 3
Gestational age (completed weeks+days) (**gest age**)	
Singleton (**singl**)	○ Singleton 1 ○ Multiple 2
Birth weight (g) (**weight baby**)	

Birth injury (**injur**)	○ None ○ Abrasion ○ Labial/clitoral tear ○ 1st degree perineal tear ○ 2nd degree perineal tear ○ Vaginal tear ○ Cervical tear ○ Episiotomy	1 2 3 4 5 6 7 8

Previous births (if applicable)

Birth mode(s) + at which birth (**mode past**)	○ Spontaneous ○ Ventouse ○ Forceps ○ Caesarean section	1 2 3 4
Birth injuries + at which birth (**injur past**)	○ None ○ Abrasion ○ Labial/clitoral tear ○ 1st degree perineal tear ○ 2nd degree perineal tear ○ 3rd or 4th degree tear ○ Vaginal tear ○ Cervical tear ○ Episiotomy	1 2 3 4 5 6 7 8 9
Birth weights of children (g) + at which birth (**weights babies**)		

Other variables

Breastfeeding (**breastf**)	○ Yes ○ No	1 2
Cigarettes smoking (**smok**)	○ Yes ○ No	1 2
Height (cm) (**height**)		
Weight (kg) (**weight**)		
Calculated BMI (**BMI**)		
Previous urinary incontinence (**UI**)	○ No ○ Yes, immediately after this birth ○ Yes, during recent pregnancy ○ Yes, before recent pregnancy ○ Can´t remember	1 2 3 4 5

Appendix 20a: Participant reported pelvic floor outcome questionnaire

CITY UNIVERSITY LONDON

MEDIZINISCHE UNIVERSITÄT WIEN

Teilnehmerinnennummer:

Bitte beantworten Sie die folgenden Fragen zu Ihrem Beckenboden:

(1) Beurteilen Sie die derzeitige Stärke Ihres Beckenbodens, verglichen mit vor der gerade stattgefundenen Geburt, und geben Sie sie als Prozentsatz an. D.h. wenn wir sagen würden, dass die Stärke Ihres Beckenbodens vor dieser Geburt 100% war, wieviel % Stärke würden Sie ihm nun geben?

Bitte notieren Sie den Prozentsatz (inklusive Zahl) in der Skala:

0----------50----------100----110

vor dieser Geburt

Die folgende Frage wird nur in den Fragebogen nach dem Training eingefügt:

(2) Bitte markieren Sie die entsprechende Antwort:

Wie kommen Ihnen jetzt nach dem Training verglichen mit vor dem Training Ihre Beckenbodenmuskeln vor?

viel stärker – stärker – kein Unterschied – schwächer – viel schwächer

Bitte kreuzen Sie bei allen folgenden Fragen das entsprechende Kästchen an:

(3) Denken Sie, dass Ihre Scheide zu schlaff oder weit ist?

- ☐ nein – niemals
- ☐ manchmal
- ☐ häufig
- ☐ immer

(4) Wie sehr stört Sie dieses Problem?

- ☐ nicht zutreffend – habe kein Problem

- ☐ überhaupt nicht
- ☐ ein wenig
- ☐ ziemlich
- ☐ stark

(5) Fühlen Sie einen Druck in Ihrer Scheide?

- ☐ nein – niemals
- ☐ manchmal
- ☐ häufig
- ☐ immer

(6) Wie sehr stört Sie dieses Problem?

- ☐ nicht zutreffend – habe kein Problem

- ☐ überhaupt nicht
- ☐ ein wenig
- ☐ ziemlich
- ☐ stark

(7) Entweichen Ihnen Winde oder Blähungen versehentlich, ohne dass Sie sie zurückhalten können?

- ☐ niemals
- ☐ manchmal – weniger als einmal pro Woche
- ☐ häufig – einmal oder mehr pro Woche
- ☐ meistens – täglich

(8) Wie sehr stört Sie dieses Problem?

- ☐ nicht zutreffend – habe kein Problem

- ☐ überhaupt nicht
- ☐ ein wenig
- ☐ ziemlich
- ☐ stark

(9) Verlieren Sie oder entweicht Ihnen versehentlich Stuhl?

- ☐ niemals
- ☐ manchmal – weniger als einmal pro Woche
- ☐ häufig – einmal oder mehr pro Woche
- ☐ meistens – täglich

(10) Wie sehr stört Sie dieses Problem?

- ☐ nicht zutreffend – habe kein Problem

- ☐ überhaupt nicht
- ☐ ein wenig
- ☐ ziemlich
- ☐ stark

ICIQ-UI Short Form (German)

Nummer des Teilnehmers/der Teilnehmerin | Initialen des Teilnehmers/der Teilnehmerin | **VERTRAULICH** | T T M M M J J **Heutiges Datum**

Viele Menschen haben gelegentlich Probleme mit unwillkürlichem Harnverlust. Wir versuchen zu ermitteln, wie viele Menschen ungewollt Harn verlieren, und wie sehr dies ein Problem für sie ist. Wir wären Ihnen sehr dankbar, wenn Sie die folgenden Fragen beantworten würden und dabei daran denken, wie es Ihnen in den vergangenen 4 Wochen gegangen ist.

1 Bitte tragen Sie Ihr Geburtsdatum ein: ☐☐ ☐☐☐ ☐☐ (TAG MONAT JAHR)

2 Sind Sie? *(Bitte ein Feld ankreuzen)*: weiblich ☐ männlich ☐

3 Wie häufig verlieren Sie Harn? *(Bitte ein Feld ankreuzen)*

niemals ☐	0
ungefähr 1 mal pro Woche oder weniger ☐	1
zwei oder drei mal pro Woche ☐	2
ungefähr 1 mal pro Tag ☐	3
mehrmals am Tag ☐	4
ständig ☐	5

4 Wir würden gerne wissen, wieviel Harn Sie Ihrer Meinung nach verlieren. Wieviel Harn verlieren Sie gewöhnlich? (unabhängig davon, ob Sie Vorlagen tragen oder nicht) *(Bitte ein Feld ankreuzen)*

kein Harnverlust ☐	0
eine kleine Menge Harn ☐	2
eine mittlere Menge Harn ☐	4
eine große Menge Harn ☐	6

5 Wie sehr beeinträchtigt generell der Harnverlust Ihren Alltag?
Bitte markieren Sie eine Zahl zwischen 0 (überhaupt nicht) und 10 (ein schwerwiegendes Problem)

0 1 2 3 4 5 6 7 8 9 **10**
überhaupt nicht — schwerwiegend

Summenscore der Fragen 3+4+5 ☐☐

6 Wann verlieren Sie Harn? *(Bitte kreuzen Sie alle Felder an, die zutreffen)*

- niemals – kein Harnverlust ☐
- Harnverlust vor dem Erreichen der Toilette ☐
- Harnverlust beim Husten oder Niessen ☐
- Harnverlust während des Schlafes ☐
- Harnverlust bei körperlicher Betätigung / sportlicher Aktivität ☐
- Harnverlust nach dem Wasserlassen und Wiederankleiden ☐
- Harnverlust ohne erkennbare Ursache ☐
- ständiger Harnverlust ☐

Vielen Dank für die Beantwortung der Fragen.

Appendix 20b: Participant reported pelvic floor outcome questionnaire – English translation

Participant ID:

Please answer the following questions concerning your pelvic floor:

(1) Rate the strength of your pelvic floor muscles now compared to before the most recent birth, using a percentage. This means: If we said that the strength of your pelvic floor muscles before this birth was 100%, how much would you rate its strength in % now?

Please note the percentage (including the number) in the scale:

0----------50----------100----110

before this birth

The following question will only be inserted in the questionnaire after training:

(2) Please mark the right answer:

How do your pelvic floor muscles feel now after the training compared to before?

a lot tighter – tighter – no difference – slacker – a lot slacker

Please tick the right box for all following questions:

(1) Do you think that your vagina is to loose or lax?

- ☐ no – never
- ☐ sometimes
- ☐ frequently
- ☐ always

(2) How much does this problem bother you?

- ☐ not applicable – I have no problem

- ☐ not at all
- ☐ a little
- ☐ quite
- ☐ very

(3) Do you feel pressure in your vagina?

- ☐ no – never
- ☐ sometimes
- ☐ frequently
- ☐ always

(4) How much does this problem bother you?

- ☐ not applicable – I have no problem

- ☐ not at all
- ☐ a little
- ☐ quite
- ☐ very

(5) Do you lose wind from your back passage without being able to hold it back?

- ☐ never
- ☐ sometimes – less than once a week
- ☐ frequently – once or more often a week
- ☐ usually – daily

(6) How much does this problem bother you?

- ☐ not applicable – I have no problem

- ☐ not at all
- ☐ a little
- ☐ quite
- ☐ very

(7) Do you accidentally lose stool from your back passage?

- ☐ never
- ☐ sometimes – less than once a week
- ☐ frequently – once or more often a week
- ☐ usually – daily

(8) How much does this problem bother you?

- ☐ not applicable – I have no problem

- ☐ not at all
- ☐ a little
- ☐ quite
- ☐ very

Initial number

ICIQ-UI Short Form

CONFIDENTIAL

DAY MONTH YEAR

Today's date

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1 Please write in your date of birth: DAY MONTH YEAR

2 Are you *(tick one)*: Female ☐ Male ☐

3 How often do you leak urine? *(Tick one box)*

never	0
about once a week or less often	1
two or three times a week	2
about once a day	3
several times a day	4
all the time	5

4 We would like to know how much urine you think leaks.
How much urine do you usually leak (whether you wear protection or not)?
(Tick one box)

none	0
a small amount	2
a moderate amount	4
a large amount	6

5 Overall, how much does leaking urine interfere with your everyday life?
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

ICIQ score: sum scores 3+4+5 ☐☐

6 When does urine leak? *(Please tick all that apply to you)*

never – urine does not leak	☐
leaks before you can get to the toilet	☐
leaks when you cough or sneeze	☐
leaks when you are asleep	☐
leaks when you are physically active/exercising	☐
leaks when you have finished urinating and are dressed	☐
leaks for no obvious reason	☐
leaks all the time	☐

Thank you very much for answering these questions.

Appendix 21a: Initial interview schedule

Participant ID:

Before randomisation

(1) Warum interessieren Sie sich für die Teilnahme an der Studie? **Variable: why interest**

(2) Haben Sie in Ihrem Leben schon Beckenbodenübungen gemacht? **Variable: ever done PFMX**

□ Ja **1**
In welchem Zusammenhang? (wann, warum, wie…): **Variable: context PFMX**

□ Nein **2**
□ Ich bin nicht sicher **3**

(3) Bitte beschreiben Sie (eventuelle) Veränderungen Ihres Beckenbodens seit der Geburt: **Variable: changes PF**

(4) Haben Sie nach dieser Geburt Informationen über Beckenbodenübungen bekommen? **Variable: given PFMX**

□ Ja, schriftlich **1**
→ Darf ich die bitte sehen?
□ gezeigt □ nicht gezeigt
Welche? **Variable: info written PFMX**

□ Ja, mündlich **2**
Welche? **Variable: info oral PFMX**

□ Nein **3**
□ Ich weiss nicht **4**

(5) Haben Sie die Übungen gemacht? **Variable: done PFMX**

□ Ja **1**
□ Manchmal **2**
□ Nein **3**
Warum nicht? **Variable: why not PFMX**

(6) Haben Sie je Beckenbodenkugeln verwendet? **Variable: used balls**
□ Ja **1**
□ Nein **2**

(7) Haben Sie, bevor Sie mit dieser Studie in Kontakt gekommen sind, schon mal von Beckenbodenkugeln gehört? **Variable: heard balls**

□ Ja **1**
□ Nein **2**
□ Ich bin nicht sicher **3**

(8) Was denken Sie über die Beckenbodenkugeln? **Variable: opinion balls**

(9) Würden Sie gern in eine bestimmte Gruppe kommen? **Variable: preference**

□ Ja **1**
In welche? **Variable: which preference**
□ Übungen **1**

□ Kugeln **2**

□ Nein **2**
□ Ich bin nicht sicher **3**

After randomisation

(10) Was sagen Sie nun zu Ihrer Gruppenzuteilung, wie fühlen Sie sich? **Variable: allocation opinion**

(11) Von 0-10, wie hoch ist Ihre Motivation, die [Intervention] 12 Wochen lang zu machen? **Variable: motivation**

(12) Möchten Sie noch etwas sagen/fragen? **Variable: other**

Appendix 21b: Initial interview schedule – English translation

Participant ID:

Before randomisation

(1) Why are you interested in participating in the study? **Variable: why interest**

(2) In your life, have you ever been doing pelvic floor muscle exercises? **Variable: ever done PFMX**

- □ Yes **1**
  - In what context? (when, why, how…): **Variable: context PFMX**
- □ No **2**
- □ I am not sure **3**

(3) Please would you describe changes (if any) associated with your pelvic floor since the birth?: **Variable: changes PF**

(4) Have you been given information about pelvic floor muscle exercises after this birth? **Variable: given PFMX**

- □ Yes, in written form **1**
  - → can I see them please?
    - □ shown □ not shown
  - Which ones? **Variable: info written PFMX**
- □ Yes, in oral form **2**
  - Which ones? **Variable: info oral PFMX**
- □ No **3**
- □ I don´t know **4**

(5) Have you been doing the exercises? **Variable: done PFMX**

- □ Yes **1**
- □ Sometimes **2**
- □ No **3**
  - Why not? **Variable: why not PFMX**

(6) Have you ever used pelvic floor training balls? **Variable: used balls**

- □ Yes **1**
- □ No **2**

(7) Have you, before getting into contact with this study, ever heard of pelvic floor training balls? **Variable: heard balls**

- □ Yes **1**
- □ No **2**
- □ I am not sure **3**

(8) What do you think about the pelvic floor training balls? **Variable: opinion balls**

(9) Do you have a preference for a group? **Variable: preference**

- □ Yes **1**
  - For which one? **Variable: which preference**
    - □ exercises **1**
    - □ balls **2**
- □ No **2**
- □ I am not sure **3**

After randomisation

(10) What do you say now about your group allocation, how do you feel? **Variable: allocation opinion**

(11) From 0-10, how high is your motivation to do the [intervention] for 12 weeks? **Variable: motivation**

(12) Anything else you want to say/ask? **Variable: other**

Appendix 22: Outcome form perineometry

Date will be automatically created

Participant name: .....

Tickets for public transport given: ☐

Oral consent for assessment given: ☐

Ability to contract checked by digital palpation: ☐

Vaginal resting pressure: ..... cm H_2O

Vaginal squeeze pressure maximum voluntary contraction:
Measurement 1 ..... cm H_2O
Measurement 2 ..... cm H_2O
Measurement 3 ..... cm H_2O

Average of 3 measurements:..... cm H_2O

Vaginal squeeze pressure endurance: ..... seconds

Appendix 23a: Concordance chart vibrating balls

CITY UNIVERSITY LONDON

MEDIZINISCHE UNIVERSITÄT WIEN

Bitte verwenden Sie dieses Blatt, um zu notieren, an welchen Tagen und wie viele Minuten Sie die Kugel verwendet haben (Eintrag z.B.: *30*)

- Sollten Sie die vorgegebene Verwendungsauer nicht erreichen, weil Ihr Trainingsmaximum vorher erreicht ist (=länger ist nicht möglich), schreiben Sie bitte *max* zur Minutenangabe. Andere Gründe für das Nicht-Erreichen bleiben unerwähnt.
- Während der Menstruation Kugel bitte nicht verwenden und M eintragen.

	MO	DI	MI	DO	FR	SA	SO
Woche 1 Datum:							
Woche 2 Datum:							
Woche 3 Datum:							
Woche 4 Datum:							
Woche 5 Datum:							
Woche 6 Datum:							
Woche 7 Datum:							
Woche 8 Datum:							
Woche 9 Datum:							
Woche 10 Datum:							
Woche 11 Datum:							
Woche 12 Datum:							

Teilnehmerinnennummer:

Appendix 23b: Concordance chart vibrating balls – English translation

Please use this sheet to record on which days and how many minutes you have used the balls (entry e.g.: *30*)

- Should you not reach the planned duration of use because your maximum training capability is reached earlier (=longer is not possible), please add *max* to the number of minutes. Other reasons for not reaching the planned duration are not mentioned.
- During menstruation, please do not use ball and write M.

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Week 1 Date:							
Week 2 Date:							
Week 3 Date:							
Week 4 Date:							
Week 5 Date:							
Week 6 Date:							
Week 7 Date:							
Week 8 Date:							
Week 9 Date:							
Week 10 Date:							
Week 11 Date:							
Week 12 Date:							

Participant ID:

Appendix 24a: Concordance chart pelvic floor muscle exercises

CITY UNIVERSITY LONDON

MEDIZINISCHE UNIVERSITÄT WIEN

Bitte verwenden Sie dieses Blatt, um zu notieren, an welchen Tagen und wie oft Sie die Übungsblöcke durchgeführt haben (Eintrag z.B. *3x*)

1x = 1 Übungsblock = Ziel: 8-10x kurz und 8-10x lange anspannen
Sollten Sie die geplante Anzahl bei einem Block nicht erreichen, weil Ihr Trainingsmaximum vorher erreicht ist (=öfter ist nicht möglich), können Sie den Block trotzdem als 1x werten. Bei Nicht-Erreichen aus anderen Gründen wird der Block nicht gezählt.

	MO	DI	MI	DO	FR	SA	SO
Woche 1 Datum:							
Woche 2 Datum:							
Woche 3 Datum:							
Woche 4 Datum:							
Woche 5 Datum:							
Woche 6 Datum:							
Woche 7 Datum:							
Woche 8 Datum:							
Woche 9 Datum:							
Woche 10 Datum:							
Woche 11 Datum:							
Woche 12 Datum:							

Teilnehmerinnennummer:

Appendix 24b: Concordance chart pelvic floor muscle exercises – English translation

Please use this sheet to record on which days and for how many blocks you have done the pelvic floor muscle exercises (entry e.g. *3x*)

1x = 1 block of exercises = aim: 8-10 short and 8-10 long contractions
Should you not reach the planned number of contractions for a block because your maximum training capability is reached earlier (=more often is not possible), you can still count this as 1x. If you do not reach the planned number for other reasons, the block is not counted.

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Week 1 Date:							
Week 2 Date:							
Week 3 Date:							
Week 4 Date:							
Week 5 Date:							
Week 6 Date:							
Week 7 Date:							
Week 8 Date:							
Week 9 Date:							
Week 10 Date:							
Week 11 Date:							
Week 12 Date:							

Participant ID:

Appendix 25: Adverse events monitoring form (incl. English translation)

Participant ID:

Initiating questions for call and message left:

- "Guten Tag Frau …, hier spricht Claudia Oblasser, ich wollte nachfragen, wie es mit der Studie bzw. mit Ihrer Teilnahme geht? Wie kommen Sie zurecht?"

Questions during call:

- Both groups: "Haben Sie irgendwelche Schwierigkeiten oder Probleme mit der [Intervention]?"
  "Haben Sie irgendwelche Schmerzen/unangenehmes Gefühl?"
  "Haben Sie unerwünschte Wirkungen/Nebenwirkungen?"
- Ball group only: "Haben Sie vermehrten Ausfluss oder Blutung?"
- Both groups: "Haben Sie irgendwelche Fragen?"

	Call 1 date/time, result	Call 2 date/time, result	Call 3 date/time, result	Content of call
4 days after beginning the intervention (after perineometry)				
1 week later				

2 weeks later				
3 weeks later				
3 weeks later				

English translation:

Initiating question for call and message left:
"Hello Ms …, here is Claudia Oblasser, I wanted to check how it is going with the study and your participation respectively? How are you getting on?"

Questions during call:
Both groups: "Do you have any difficulties or problems with the [intervention]?"
"Do you have any pain/uncomfortable feeling?"
"Do you have adverse effects/side effects?"
Ball group only: "Do you have any increased discharge or bleeding?"
Both groups: "Do you have any questions?"

Appendix 26a: Final interview schedule

Date:

Participant ID:

collect concordance chart

Both groups:

(1) Bitte beschreiben Sie Ihre Erfahrung mit der Studie – Wie war es, Studienteilnehmerin zu sein? **Variable: experience study**

(2) Bitte beschreiben Sie Ihre Erfahrung mit der [Intervention]: **Variable: experience intervention**

(3) Hat die [Intervention] gut in den Alltag gepasst? **Variable: daily life**

Ja **1**
Inwiefern: **Variable: why daily yes**

Nein **2**
Inwiefern nicht: **Variable: why daily no**

Ich bin nicht sicher **3**

(4) In welchen Alltagssituationen war es am leichtesten, die [Intervention] durchzuführen? **Variable: easy daily life**

(5) Haben Sie die [Intervention] so häufig gemacht, wie Sie wollten? **Variable: frequency**

□ Ja **1**
□ Nein **2**
Was hinderte Sie am Üben? **Variable: barriers**

□ Hab mir keine Gedanken darüber gemacht, wie oft ich die [Intervention] machen will **3**

Ball group:

(6) Wie verhält sich der Beckenboden, was tut er wenn die Kugel drin ist? **Variable: PF**

(7) Hatten Sie das Gefühl, dass die Kugel herausrutscht, dass Sie sie verlieren? **Variable: slipping out**

□ Ja **1**
□ Nein **2**
□ Anderes (**3**):

(8) Ist das eine lange andauernde Anspannung oder ein immer wiederholtes neues Anspannen? **Variable: contraction**

□ andauernd **1**
□ wiederholt **2**
□ Sonstiges (**3**):

(9) Wie war die Handhabung der Kugel (z.B. Reinigung, Aufbewahrung)? **Variable: handling**

(10) Könnte an der Kugel etwas verbessert werden? **Variable: enhance balls**

□ Ja **1**
Was?: **Variable: ball enhance idea**

□ Nein **2**

Exercise group:

(11) Haben Sie Interesse an den Kugeln? **Variable: interest**

□ Ja **1**
□ Nein **2**
□ Ich weiss nicht sicher **3**

(12) Haben Sie eine Kugel gekauft? **Variable: buy**

□ Ja **1**
□ Nein **2**

Both groups:

(13) Falls es welche gibt, beschreiben Sie bitte Veränderungen des Beckenbodens seit der [Intervention]: **Variable: changes PF**

(14) Würden Sie gern mit der [Intervention] weitermachen? **Variable: continue**

□ Ja **1**
Warum: **Variable: continue why**

□ Nein **2**
Warum nicht: **Variable: continue why not**

□ Ich bin nicht sicher **3**

(15) Hat Ihnen die Teilnahme an der Studie Vorteile gebracht? **Variable: advantage**

□ Ja **1**
Welche?: **Variable: advantage which**

□ Nein **2**
□ Ich bin nicht sicher **3**

(16) Hatten Sie irgendwelche unerwünschten Begleiterscheinungen, die Sie auf die [Intervention] zurückführen? **Variable: adverse events**

□ Ja **1**
Welche?: **Variable: adverse events which**

□ Nein **2**
□ Muskelkater? (probing) **3**

(17) Es wird behauptet, dass die [Intervention] der "Verbesserung des Empfindens beider Partner beim Intimverkehr" dienen – haben Sie Veränderungen festgestellt, die Sie der [Intervention] zuschreiben würden? **Variable: sexuality**

(18) Was könnte an der Studie verbessert werden? **Variable: enhance study**

(19) Möchten Sie noch etwas sagen oder fragen? **Variable: other**

Appendix 26b: Final interview schedule – English translation

Date:
Participant ID:

collect concordance chart

Both groups:

(1) Please describe your experience with the trial – How was it to be study participant? **Variable: experience study**

(2) Please describe your experience with the [intervention]: **Variable: experience intervention**

(3) Did the [intervention] fit well into daily life? **Variable: daily life**
- Yes **1**
  In what respect: **Variable: why daily yes**
- No **2**
  Why not: **Variable: why daily no**
- I am not sure **3**

(4) In which situations of daily life was it most easy to perform the [intervention]? **Variable: easy daily life**

(5) Did you practice as often as you wanted to? **Variable: frequency**
- Yes **1**
- No **2**
  What were your barriers to practising? **Variable: barriers**
- I did not think about how often I wanted to practice **3**

Ball group:

(6) How does the pelvic floor react, what is it doing when the ball is inside the vagina? **Variable: PF**

(7) Did it feel like the ball would slip out, like losing it? **Variable: slipping out**
- Yes **1**
- No **2**
- Other (**3**):

(8) Is this a long continuous contraction or a repeated contraction and bringing upwards of the ball? **Variable: contraction**
- continuous **1**
- repeated **2**
- other (**3**):

(9) How was handling of the ball (e.g. cleaning, storage)? **Variable: handling**

(10) Could the ball be enhanced? **Variable: enhance balls**

□ Yes **1**
How?: **Variable: ball enhance idea**
□ No **2**

Exercise group:

(11) Are you interested in the balls? **Variable: interest**
□ Yes **1**
□ No **2**
□ I don´t know for sure **3**

(12) Did you buy a ball? **Variable: buy**
□ Yes **1**
□ No **2**

Both groups:

(13) If there are any, please would you describe any changes associated with your pelvic floor since the [intervention]: **Variable: changes PF**

(14) Would you like to continue with the [intervention]? **Variable: continue**
□ Yes **1**
Why: **Variable: continue why**
□ No **2**
Why not: **Variable: continue why not**
□ I am not sure **3**

(15) Did you get any advantages from participating in the study? **Variable: advantage**
□ Yes **1**
Which?: **Variable: advantage which**
□ No **2**
□ I am not sure **3**

(16) Did you experience any adverse effects which you would attribute to the [intervention]? **Variable: adverse events**
□ Ja **1**
Which?: **Variable: adverse events which**
□ No **2**
□ Mucle soreness? (probing) **3**

(17) The [intervention] is also said to be useful for "sensory enhancement of both partners during sexual intimacy" – have you experienced any change which you would ascribe to the use of the [intervention]? **Variable: sexuality**

(18) How could the study be enhanced? **Variable: enhance study**

(19) Anything else you want to say or ask? **Variable: other**

Appendix 27a: Draft survey questionnaire ball group

As this is a provisional questionnaire which will be finalised during the study, the layout has not been fully considered here.

CITY UNIVERSITY LONDON

MEDIZINISCHE UNIVERSITÄT WIEN

Fragebogen zur Beckenbodenstudie

Bitte füllen Sie Ihre Antwort ein oder kreuzen Sie das passende Kästchen an. Falls nötig, nehmen Sie bitte ein weiteres Blatt Papier.

(1) Bitte beschreiben Sie Ihre Erfahrungen mit Ihrer Teilnahme an der Studie:

(2) Bitte beschreiben Sie Ihre Erfahrungen mit der Verwendung der Beckenbodenkugel:

(3) Waren Sie zufrieden mit Ihrer Gruppenzuteilung oder wären Sie gern in die andere Gruppe gekommen?

□ Zufrieden mit der Gruppenzuteilung
Warum?:

□ Wäre gern in die andere Gruppe gekommen
Warum?:

(4) Wie ist Ihre Meinung zum Beckenbodentraining mit der Kugel?

(5) Würden Sie die Beckenbodenkugel gern weiterhin verwenden?

□ Ja
Warum?:

□ Nein
Warum nicht?:

□ Ich bin nicht sicher

(6) Hat Ihnen die Teilnahme an der Studie Vorteile gebracht?

(7) Hat Ihnen die Teilnahme an der Studie Nachteile gebracht?

(8) Hatten Sie irgendwelche unerwünschten Begleiterscheinungen, die Sie auf die Verwendung der Beckenbodenkugel zurückführen?
□ Ja
Welche?:

□ Nein

(9) Es wird auch behauptet, das Beckenbodenkugeln der "Verbesserung des Empfindens beider Partner beim Intimverkehr" dienen – haben Sie Veränderungen festgestellt, die Sie der Verwendung der Beckenbodenkugel zuschreiben würden?

(10) Möchten Sie noch etwas mitteilen?

Appendix 27b: Draft survey questionnaire ball group – English translation

Questionnaire for pelvic floor study

Please fill your answer in or tick right answer. If necessary, please take an additional sheet of paper.

(1) Please describe your experiences with your participation in the study:

(2) Please describe your experiences with the use of the pelvic floor ball:

(3) Were you happy about your group allocation or would you have liked to be in the other group?
- □ Happy with group allocation
  Why?:
- □ Would have liked to be in the other group
  Why?:

(4) What is your opinion about pelvic floor training with the ball?

(5) Would you like to continue to use the pelvic floor ball?
- □ Yes
  Why?:
- □ No
  Why not?:
- □ I am not sure

(6) Did you get any benefits from participating in the study?

(7) Did you get any disadvantages from participating in the study?

(8) Did you experience any adverse effects which you would attribute to the use of the ball?
- □ Ja
  Which ones?:
- □ No

(9) It is said that the balls lead to "sensory enhancement of both partners during sexual intimacy" – did you realise any change that you would contribute to the ball?

(10) Would you like to communicate something else?

Appendix 28a: Draft survey questionnaire exercise group

As this is a provisional questionnaire which will be finalised during the study, the layout has not been fully considered here.

CITY UNIVERSITY LONDON

MEDIZINISCHE UNIVERSITÄT WIEN

Fragebogen zur Beckenbodenstudie

Bitte füllen Sie Ihre Antwort ein oder kreuzen Sie das passende Kästchen an. Falls nötig, nehmen Sie bitte ein weiteres Blatt Papier.

(1) Bitte beschreiben Sie Ihre Erfahrungen mit Ihrer Teilnahme an der Studie:

(2) Bitte beschreiben Sie Ihre Erfahrungen mit der Durchführung der Beckenbodenübungen:

(3) Waren Sie zufrieden mit Ihrer Gruppenzuteilung oder wären Sie gern in die andere Gruppe gekommen?

☐ War zufrieden mit der Gruppenzuteilung
Warum?:

☐ Wäre gern in die andere Gruppe gekommen
Warum?:

(4) Wie ist Ihre Meinung zum Beckenbodentraining mit den Beckenbodenübungen?

(5) Würden Sie die Beckenbodenübungen gern weiterhin durchführen?

☐ Ja
Warum?:

□ Nein
Warum nicht?:

□ Ich bin nicht sicher

(6) Hat Ihnen die Teilnahme an der Studie Vorteile gebracht?

(7) Hat Ihnen die Teilnahme an der Studie Nachteile gebracht?

(8) Hatten Sie irgendwelche unerwünschten Begleiterscheinungen, die Sie auf die Durchführung der Beckenbodenübungen zurückführen?
□ Ja
Welche?:

□ Nein

(9) Es wird auch behauptet, das Beckenbodenübungen der Verbesserung des Empfindens beider Partner beim Intimverkehr dienen – haben Sie Veränderungen festgestellt, die Sie den Beckenbodenübungen zuschreiben würden?

(10) Möchten Sie noch etwas mitteilen?

Appendix 28b: Draft survey questionnaire exercise group – English translation

Questionnaire for pelvic floor study

Please fill your answer in or tick right answer. If necessary, please take an additional sheet of paper.

(1) Please describe your experiences with your participation in the study:

(2) Please describe your experiences with performing the pelvic floor exercises:

(3) Were you happy about your group allocation or would you have liked to be in the other group?

- ☐ Happy with group allocation
  Why?:
- ☐ Would have liked to be in the other group
  Why?:

(4) What is your opinion about pelvic floor training with pelvic floor exercises?

(5) Would you like to continue to perform the pelvic floor exercises?

- ☐ Yes
  Why?:
- ☐ No
  Why not?:
- ☐ I am not sure

(6) Did you get any benefits from participating in the study?

(7) Did you get any disadvantages from participating in the study?

(8) Did you experience any adverse effects which you would attribute to performing pelvic floor exercises?

- ☐ Yes
  Which ones?:
- ☐ No

(9) It is said that pelvic floor exercises lead to sensory enhancement of both partners during sexual intimacy – did you realise any change that you would contribute to the exercises?

(10) Would you like to communicate something else?

Appendix 29: Licensing certificate for vaginal balls

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE 2007/47/EEC) CONCERNING MEDICAL DEVICES

MANUFACTURER:	Suzhou Armocon Technology Co., Ltd 3-5/F No.77 Suhong Middle Road, SIP, Jiangsu China 215027
MEDICAL DEVICE: Model:	Kegel exerciser Lasselle Intimina 28g, 38g, 48g
CLASSIFICATION - ANNEX IX:	Class I, Rule 5, point 1

WE, < Suzhou Armocon Technology Co., Ltd >., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 (INCLUDING DIRECTIVE 2007/47/CE) CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS

THIS DECLARATION IS BASED ON

TECHNICAL DOCUMENTATION SHOWING THE CONFORMITY OF THE PRODUCT OF THE ESSENTIAL REQUIREMENTS OF THE DIRECTIVE

Biological evaluation of medical Device ISO10993 -5/10;
The Polycyclic Aromatic Hydrocarbon Directive 2005/69/EC;
The Phthalate Directive 2005/84/EC;
Restriction of Hazardous Substance Directive 2002/95/EC;
Degress of Protection Provided by Enclosures - IPX-7;
Food and Drug Administration Regulation;
Product safe performance check : Pulling test, push test, boiling water test, salt water test.
hereby declare that:

Equipment: Lasselle Kegel Exercisers
Model: 28g, 38g, 48g

is in conformity with the applicable requirements of the following documents:

Ref. No.	Title	Edition/Date
ISO10993-5	Biological evaluation of medical devices Part 5 Tests in vitro cytotoxicity	2009
ISO10993-10	Biological evaluation of medical devices. Part 10:Tests for irritation and skin sensitization	2002
ZEK 01-08	Central Experience Exchange Office, ZEK. central authority announced ZEK's official website the01.2-08 document	2008
EN14372:2004	Child use and care articles — Cutlery and feeding utensils — Safety requirements and tests	2004
IEC62321:2008	Electro-technical products–Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers	2008
IEC60529:1989 +A1:1999	Degrees of protection provided by enclosures - IPX-7	1989+1999
SHAEC110682 7001	FDA 21 CRF 180.22 & 181.3; FDA 21 CRF 177.2600	2011
SH11111555-001	Quality test: Pulling test, push test, boiling water test, salt water test	2011
PRO-DG-0299	Lasselle Kegel Exercisers -28g Assembly drawing	2011
PRO-DG-0300	Lasselle Kegel Exercisers -38g Assembly drawing	2011
PRO-DG-0301	Lasselle Kegel Exercisers -48g Assembly drawing	2011
PRO-SP-0299	Semi-finished Inspection Specification	2011
PRO-SP-0294	Final Inspection Specification	2011

PRO-SP-0246	Assembly work instruction	2012
PRO-SP-0306	Packing work instruction	2011

IDENTIFICATION CLASS I

CE

EUROPEAN REPRESENTATIVE: LELOI AB
BIRGER JARLSGATAN 22 114 34 STOCKHOLM

EC REP

START OF CE-MARKING:

PLACE, DATE OF DECLARATION: November 21st, 2012, Suzhou, China

SIGNATURE: <SIGNATURE OF MANUFACTURER>
NAME: Paul Jaques
POSITION: General Manager

Appendix 30: Licensing certificate for vaginal perineometry probe

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 592088**

Issued To: **Laborie Medical Technologies Canada ULC**
6415 Northwest Drive, Unit 10
Mississauga
Ontario
L4V 1X1
Canada

In respect of:

The design and manufacture of: urodynamic diagnostic and therapeutic devices and sterile tubing; diagnostic uitrasound devices, sterile endoscopic needles and sterile accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **21 December 2012** Date: **02 May 2014** Expiry Date: **02 August 2017**

...making excellence a habit.

Page 1 of 1

Appendix O: Adherence chart vibrating vaginal balls

CITY UNIVERSITY LONDON

MEDIZINISCHE UNIVERSITÄT WIEN

Bitte verwenden Sie dieses Blatt, um zu notieren, an welchen Tagen und wie viele Minuten Sie die Kugel verwendet haben (Eintrag z.B.: *30*)

- Sollten Sie die vorgegebene Verwendungsauer nicht erreichen, weil Ihr Trainingsmaximum vorher erreicht ist (=länger ist nicht möglich), schreiben Sie bitte *max* zur Minutenangabe. Andere Gründe für das Nicht-Erreichen bleiben unerwähnt.
- Während der Menstruation Kugel bitte nicht verwenden und M eintragen.

Wochentag							
Woche 1 Datum:							
Woche 2 Datum:							
Woche 3 Datum:							
Woche 4 Datum:							
Woche 5 Datum:							
Woche 6 Datum:							
Woche 7 Datum:							
Woche 8 Datum:							
Woche 9 Datum:							
Woche 10 Datum:							
Woche 11 Datum:							
Woche 12 Datum:							

Teilnehmerinnennummer:

Appendix O(e): Adherence chart vibrating vaginal balls – English translation

CITY UNIVERSITY LONDON

MEDIZINISCHE UNIVERSITÄT WIEN

Please use this sheet to record on which days and how many minutes you have used the balls (entry e.g.: *30*)

- Should you not reach the planned duration of use because your maximum training capability is reached earlier (=longer is not possible), please add *max* to the number of minutes. Other reasons for not reaching the planned duration are not mentioned.
- During menstruation, please do not use ball and write M.

Day of week							
Week 1 Date:							
Week 2 Date:							
Week 3 Date:							
Week 4 Date:							
Week 5 Date:							
Week 6 Date:							
Week 7 Date:							
Week 8 Date:							
Week 9 Date:							
Week 10 Date:							
Week 11 Date:							
Week 12 Date:							

Participant ID:

Appendix P: Adherence chart pelvic floor muscle training

CITY UNIVERSITY LONDON

MEDIZINISCHE UNIVERSITÄT WIEN

Bitte verwenden Sie dieses Blatt, um zu notieren, an welchen Tagen und wie oft Sie die Übungsblöcke durchgeführt haben (Eintrag z.B. *3x*)

1x = 1 Übungsblock = Ziel: 8-10x kurz und 8-10x lange anspannen
Sollten Sie die geplante Anzahl bei einem Block nicht erreichen, weil Ihr Trainingsmaximum vorher erreicht ist (=öfter ist nicht möglich), können Sie den Block trotzdem als 1x werten. Bei Nicht-Erreichen aus anderen Gründen wird der Block nicht gezählt.

Wochentag							
Woche 1 Datum:							
Woche 2 Datum:							
Woche 3 Datum:							
Woche 4 Datum:							
Woche 5 Datum:							
Woche 6 Datum:							
Woche 7 Datum:							
Woche 8 Datum:							
Woche 9 Datum:							
Woche 10 Datum:							
Woche 11 Datum:							
Woche 12 Datum:							

Teilnehmerinnennummer:

Appendix P(e): Adherence chart pelvic floor muscle training – English translation

CITY UNIVERSITY LONDON

MEDIZINISCHE UNIVERSITÄT WIEN

Please use this sheet to record on which days and for how many blocks you have done the pelvic floor muscle exercises (entry e.g. *3x*)

1x = 1 block of exercises = aim: 8-10 short and 8-10 long contractions
Should you not reach the planned number of contractions for a block because your maximum training capability is reached earlier (=more often is not possible), you can still count this as 1x. If you do not reach the planned number for other reasons, the block is not counted.

Day of week							
Week 1 Date:							
Week 2 Date:							
Week 3 Date:							
Week 4 Date:							
Week 5 Date:							
Week 6 Date:							
Week 7 Date:							
Week 8 Date:							
Week 9 Date:							
Week 10 Date:							
Week 11 Date:							
Week 12 Date:							

Participant ID:

Appendix Q: Final interview schedule long form

Spacing of text in interview forms was reduced to save Appendix space.

Participant ID:

Date/time/venue:

(1) Bitte beschreiben Sie Ihre Erfahrung mit der [Intervention]: **Variable: experience intervention**

(2) Hat die [Intervention] gut in den Alltag gepasst? **Variable: daily life**
- □ Ja **1**
  Inwiefern: **Variable: why daily yes**
- □ Nein **2**
  Inwiefern nicht: **Variable: why daily no**
- □ Ich bin nicht sicher **3**

(3) In welchen Alltagssituationen war es am leichtesten, die [Intervention] durchzuführen? **Variable: easy daily life**

(4) Haben Sie die [Intervention] so häufig gemacht, wie Sie wollten? **Variable: frequency**
- □ Ja **1**
- □ Nein **2**
  Was hinderte Sie an der Durchführung? **Variable: barriers**
- □ Hab mir keine Gedanken darüber gemacht, wie oft ich die [Intervention] machen will **3**

<u>Ball group:</u>

(5) Wie verhält sich der Beckenboden, was tut er wenn die Kugel drin ist? **Variable: PF**

(6) Hatten Sie das Gefühl, dass die Kugel herausrutscht, dass Sie sie verlieren? **Variable: slipping out**
- □ Ja **1**
- □ Nein **2**
- □ Anderes (**3**):

(7) Ist das eine lange andauernde Anspannung oder ein immer wiederholtes neues Anspannen? **Variable: contraction**
- □ andauernd **1**

□ wiederholt **2**
□ Sonstiges **3**:

(8) Spüren Sie die Vibrationen? **Variable: vibrations**
□ Ja **1**
□ Nein **2**
□ Sonstiges **3**:

(9) Wie war die Handhabung der Kugel (z.B. Reinigung, Aufbewahrung)? **Variable: handling**

(10) Könnte an der Kugel etwas verbessert werden? **Variable: enhance ball**
□ Ja **1**
Was?: **Variable: enhance ball idea**
□ Nein **2**

(11) Haben Sie Beckenbodenübungen durchgeführt? **Variable: ball PFMX**
□ Ja **1**
□ Nein **2**
Näheres: **Variable: details**

Exercise group:

(12) Haben Sie Interesse an der Kugel? **Variable: interest ball**
□ Ja **1**
□ Nein **2**
□ Ich weiss nicht sicher **3**

(13) Haben Sie eine Kugel gekauft/verwendet? **Variable: buy ball**
□ Ja **1**
□ Nein **2**

Both groups:

(14) Hat die [Intervention] Nachteile? **Variable: disadvantage intervention**
□ Nein **2**
□ Ja **1**
➔ Welche? **Variable: disadvantage intervention which**

(15) Hatten Sie irgendwelche unerwünschten Begleiterscheinungen, die Sie auf die [Intervention] zurückführen? **Variable: adverse events**
□ Ja **1**

Welche?: **Variable: adverse events which**

□ Nein **2**

□ Muskelkater? Blutung? Ausfluss? (probing)

(16) Falls es welche gibt, beschreiben Sie bitte Veränderungen Ihres Beckenbodens seit der [Intervention]: **Variable: changes PF**

(17) Es wird behauptet, dass die [Intervention] der „Verbesserung des Empfindens beider Partner beim Intimverkehr“ dienen – haben Sie Veränderungen festgestellt, die Sie der [Intervention] zuschreiben würden? **Variable: sexuality**

(18) Würden Sie gern mit der [Intervention] weitermachen? **Variable: continue**

□ Ja **1**

Warum: **Variable: continue why**

□ Nein **2**

Warum nicht: **Variable: continue why not**

□ Ich bin nicht sicher **3**

(19) Bitte beschreiben Sie Ihre Erfahrung mit der Studie – Wie war es, Studienteilnehmerin zu sein? **Variable: experience study**

(20) Hat Ihnen die Teilnahme an der Studie Vorteile gebracht? **Variable: advantage participation**

□ Ja **1**

Welche?: **Variable: advantage participation which**

□ Nein **2**

□ Ich bin nicht sicher **3**

(21) Hat Ihnen die Teilnahme an der Studie Nachteile gebracht? **Variable: disadvantage participation**

□ Ja **1**

Welche?: **Variable: disadvantage participation which**

□ Nein **2**

□ Ich bin nicht sicher **3**

(22) Was könnte an der Studie verbessert werden? **Variable: enhance study**

(23) Haben Sie während der Studie irgendwelchen Sport betrieben (Yoga, Pilates, BB-Training etc.)? **Variable: sports**

(24) Möchten Sie noch etwas anmerken oder fragen? **Variable: other**

Appendix Q(e): Final interview schedule long form – English translation

Participant ID:

Date/time/venue:

(1) Please describe your experience with the [intervention]: **Variable: experience intervention**

(2) Did the [intervention] fit well into daily life? **Variable: daily life**
- □ Yes **1**
  In what respect: **Variable: why daily yes**
- □ No **2**
  Why not: **Variable: why daily no**
- □ I am not sure **3**

(3) In which situations of daily life was it most easy to perform the [intervention]? **Variable: easy daily life**

(4) Did you practice as often as you wanted to? **Variable: frequency**
- □ Yes **1**
- □ No **2**
  What were your barriers to practising? **Variable: barriers**
- □ I did not think about how often I wanted to practice **3**

<u>Ball group:</u>

(5) How does the pelvic floor react, what is it doing when the ball is inside the vagina? **Variable: PF**

(6) Did it feel like the ball would slip out, like losing it? **Variable: slipping out**
- □ Yes **1**
- □ No **2**
- □ Other (**3**):

(7) Is this a long continuous contraction or a repeated contraction? **Variable: contraction**
- □ continuous **1**
- □ repeated **2**
- □ other (**3**):

(8) Did you feel the vibrations? **Variable: vibrations**

□ Yes **1**
□ No **2**
□ Other (**3**):

(9) How was handling of the ball (e.g. cleaning, storage)? **Variable: handling**

(10) Could the ball be enhanced? **Variable: enhance balls**

□ Yes **1**
How?: **Variable: ball enhance idea**
□ No **2**

(11) Have you done pelvic floor muscle exercises? **Variable: ball PFMX**

□ Yes **1**
□ No **2**
Details: **Variable: details**

Exercise group:

(12) Are you interested in the balls? **Variable: interest**

□ Yes **1**
□ No **2**
□ I don´t know for sure **3**

(13) Did you buy a ball? **Variable: buy**

□ Yes **1**
□ No **2**

Both groups:

(14) Does the [intervention] have disadvantages? **Variable: disadvantage intervention**

□ No **2**
□ Yes **1**
➔ Which ones? **Variable: disadvantage intervention which**

(15) Did you experience any adverse effects which you would attribute to the [intervention]? **Variable: adverse events**

□ Yes **1**
Which?: **Variable: adverse events which**
□ No **2**

□ Mucle soreness? Bleeding? Discharge? (probing) **3**

(16) If there are any, please would you describe any changes associated with your pelvic floor since the [intervention]: **Variable: changes PF**

(17) The [intervention] is also said to be useful for “sensory enhancement of both partners during sexual intimacy“ – have you experienced any change which you would ascribe to the use of the [intervention]? **Variable: sexuality**

(18) Would you like to continue with the [intervention]? **Variable: continue**

□ Yes **1**

Why: **Variable: continue why**

□ No **2**

Why not: **Variable: continue why not**

□ I am not sure **3**

(19) Please describe your experience with the trial – How was it to be study participant? **Variable: experience study**

(20) Did you get any advantages from participating in the study? **Variable: advantage**

□ Yes **1**

Which?: **Variable: advantage which**

□ No **2**

□ I am not sure **3**

(25) Did you get any disadvantages from participating in the study? **Variable: disadvantage participation**

□ Yes **1**

Which?: **Variable: disadvantage participation which**

□ No **2**

□ I am not sure **3**

(21) How could the study be enhanced? **Variable: enhance study**

(22) Have you done any sports during the study (Yoga, Pilates, BB-Training etc.)? **Variable: sports**

(23) Anything else you want to say or ask? **Variable: other**

Appendix R: Final interview schedule short form

Participant ID:

Date/time/venue:

(1) Bitte beschreiben Sie Ihre Erfahrung mit der [Intervention]: **Variable: experience intervention**

(2) Hat die [Intervention] gut in den Alltag gepasst? **Variable: daily life**
- □ Ja **1**
  Inwiefern: **Variable: why daily yes**
- □ Nein **2**
  Inwiefern nicht: **Variable: why daily no**
- □ Ich bin nicht sicher **3**

(3) In welchen Alltagssituationen war es am leichtesten, die [Intervention] durchzuführen? **Variable: easy daily life**

(4) Haben Sie die [Intervention] so häufig gemacht, wie Sie wollten? **Variable: frequency**
- □ Ja **1**
- □ Nein **2**
  Was hinderte Sie an der Durchführung? **Variable: barriers**
- □ Hab mir keine Gedanken darüber gemacht, wie oft ich die [Intervention] machen will **3**

<u>Ball group:</u>

(5) Wie verhält sich der Beckenboden, was tut er wenn die Kugel drin ist? **Variable: PF**

(6) Hatten Sie das Gefühl, dass die Kugel herausrutscht, dass Sie sie verlieren? **Variable: slipping out**
- □ Ja **1**
- □ Nein **2**
- □ Anderes (**3**):

(7) Ist das eine lange andauernde Anspannung oder ein immer wiederholtes neues Anspannen? **Variable: contraction**

□ andauernd **1**
□ wiederholt **2**
□ Sonstiges **3**:

(8) Spüren Sie die Vibrationen? **Variable: vibrations**

□ Ja **1**
□ Nein **2**
□ Sonstiges **3**:

(9) Wie war die Handhabung der Kugel (z.B. Reinigung, Aufbewahrung)? **Variable: handling**

(10) Könnte an der Kugel etwas verbessert werden? **Variable: enhance ball**

□ Ja **1**
Was?: **Variable: enhance ball idea**
□ Nein **2**

(11) Haben Sie Beckenbodenübungen durchgeführt? **Variable: ball PFMX**

□ Ja **1**
□ Nein **2**
Näheres: **Variable: details**

Exercise group:

(12) Haben Sie Interesse an der Kugel? **Variable: interest ball**

□ Ja **1**
□ Nein **2**
□ Ich weiss nicht sicher **3**

(13) Haben Sie eine Kugel gekauft/verwendet? **Variable: buy ball**

□ Ja **1**
□ Nein **2**

Both groups:

(14) Hat die [Intervention] Nachteile? **Variable: disadvantage intervention**

□ Nein **2**
□ Ja **1**
➔ Welche? **Variable: disadvantage intervention which**

(15) Hatten Sie irgendwelche unerwünschten Begleiterscheinungen, die Sie auf die [Intervention] zurückführen? **Variable: adverse events**

□ Ja **1**

Welche?: **Variable: adverse events which**

□ Nein **2**

□ Muskelkater? Blutung? Ausfluss? (probing)

(16) Falls es welche gibt, beschreiben Sie bitte Veränderungen Ihres Beckenbodens seit der [Intervention]: **Variable: changes PF**

(17) Es wird behauptet, dass die [Intervention] der „Verbesserung des Empfindens beider Partner beim Intimverkehr“ dienen – haben Sie Veränderungen festgestellt, die Sie der [Intervention] zuschreiben würden? **Variable: sexuality**

(18) Würden Sie gern mit der [Intervention] weitermachen? **Variable: continue**

□ Ja **1**

Warum: **Variable: continue why**

□ Nein **2**

Warum nicht: **Variable: continue why not**

□ Ich bin nicht sicher **3**

(19) Haben Sie während der Studie irgendwelchen Sport betrieben (Yoga, Pilates, BB-Training etc.)? **Variable: sports**

(20) Möchten Sie noch etwas anmerken oder fragen? **Variable: other**

(21) Stillen Sie noch? **Variable: breastfeeding**

Appendix R(e): Final interview schedule short form – English translation

Participant ID:

Date/time/venue:

(1) Please describe your experience with the [intervention]: **Variable: experience intervention**

(2) Did the [intervention] fit well into daily life? **Variable: daily life**
- □ Yes **1**
  In what respect: **Variable: why daily yes**
- □ No **2**
  Why not: **Variable: why daily no**
- □ I am not sure **3**

(3) In which situations of daily life was it most easy to perform the [intervention]? **Variable: easy daily life**

(4) Did you practice as often as you wanted to? **Variable: frequency**
- □ Yes **1**
- □ No **2**
  What were your barriers to practising? **Variable: barriers**
- □ I did not think about how often I wanted to practice **3**

<u>Ball group:</u>

(5) How does the pelvic floor react, what is it doing when the ball is inside the vagina? **Variable: PF**

(6) Did it feel like the ball would slip out, like losing it? **Variable: slipping out**
- □ Yes **1**
- □ No **2**
- □ Other (**3**):

(7) Is this a long continuous contraction or a repeated contraction? **Variable: contraction**

□ continuous **1**
□ repeated **2**
□ other (**3**):

(8) Did you feel the vibrations? **Variable: vibrations**

□ Yes **1**
□ No **2**
□ Other (**3**):

(9) How was handling of the ball (e.g. cleaning, storage)? **Variable: handling**

(10) Could the ball be enhanced? **Variable: enhance balls**

□ Yes **1**
How?: **Variable: ball enhance idea**
□ No **2**

(11) Have you done pelvic floor muscle exercises? **Variable: ball PFMX**

□ Yes **1**
□ No **2**
Details: **Variable: details**

<u>Exercise group:</u>

(12) Are you interested in the balls? **Variable: interest**

□ Yes **1**
□ No **2**
□ I don´t know for sure **3**

(13) Did you buy a ball? **Variable: buy**

□ Yes **1**
□ No **2**

<u>Both groups:</u>

(14) Does the [intervention] have disadvantages? **Variable: disadvantage intervention**

□ No **2**
□ Yes **1**
➔ Which ones? **Variable: disadvantage intervention which**

(15) Did you experience any adverse effects which you would attribute to the [intervention]? **Variable: adverse events**

- □ Yes **1**
  - Which?: **Variable: adverse events which**
- □ No **2**
- □ Mucle soreness? Bleeding? Discharge? (probing) **3**

(16) If there are any, please would you describe any changes associated with your pelvic floor since the [intervention]: **Variable: changes PF**

(17) The [intervention] is also said to be useful for “sensory enhancement of both partners during sexual intimacy“ – have you experienced any change which you would ascribe to the use of the [intervention]? **Variable: sexuality**

(18) Would you like to continue with the [intervention]? **Variable: continue**

- □ Yes **1**
  - Why: **Variable: continue why**
- □ No **2**
  - Why not: **Variable: continue why not**
- □ I am not sure **3**

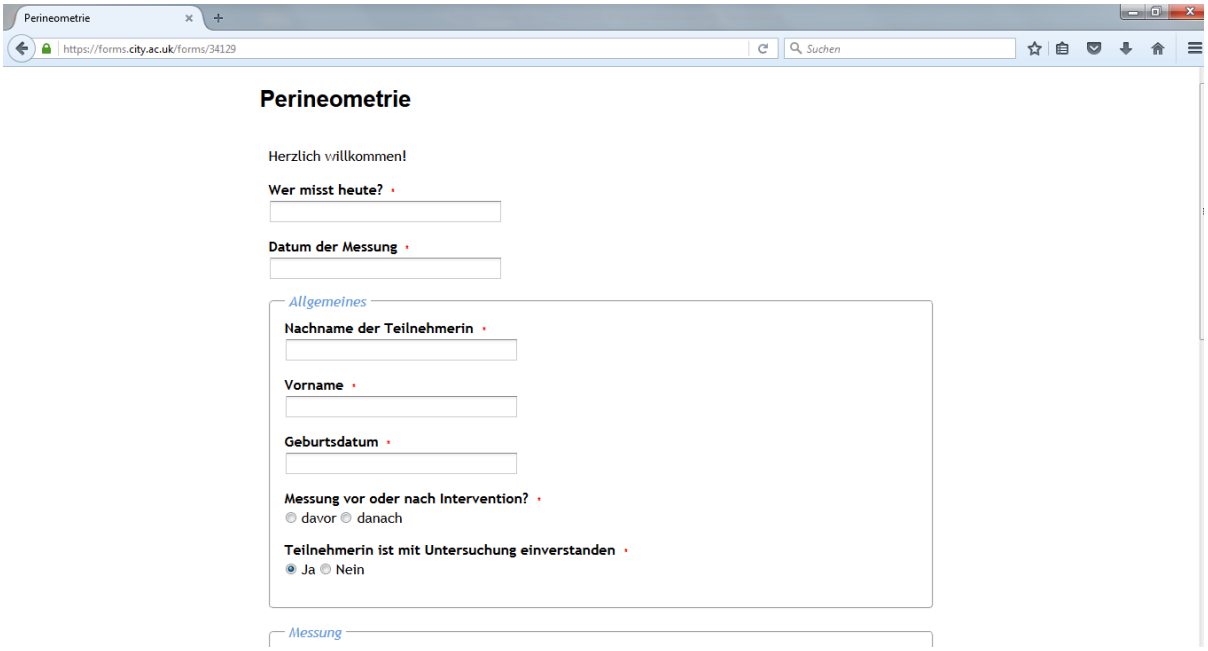
(19) Have you done any sports during the study (Yoga, Pilates, PF training etc.)? **Variable: sports**

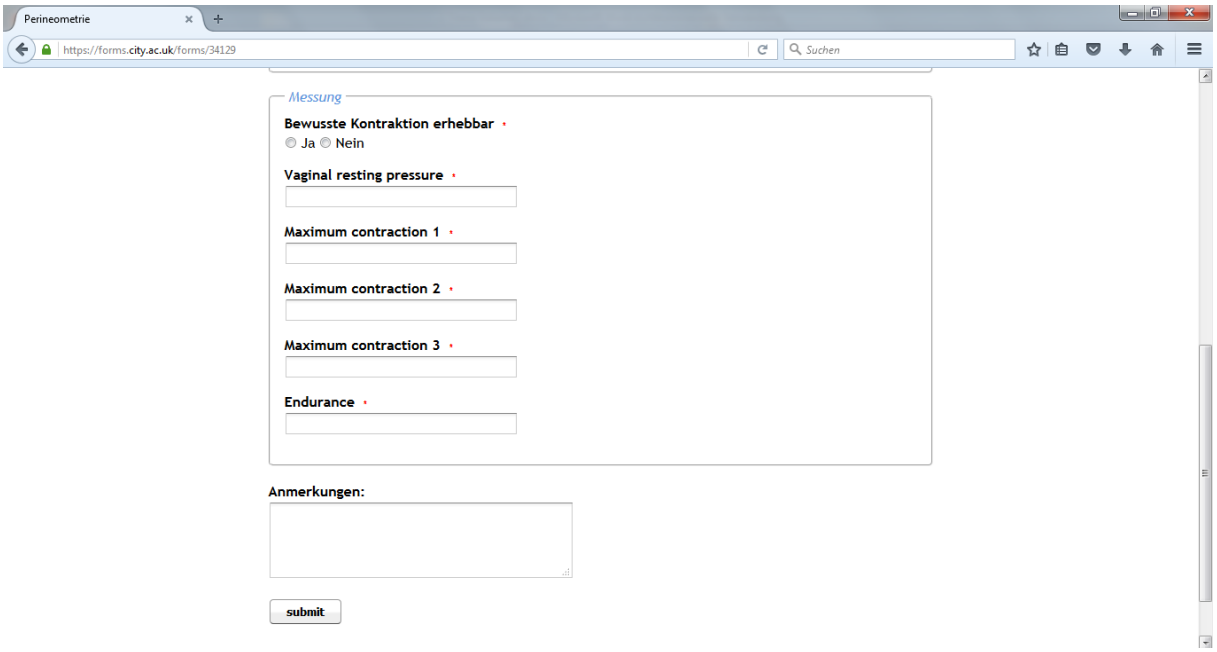
(20) Anything else you want to say or ask? **Variable: other**

(21) Are you still breastfeeding? **Variable: breastfeeding**

Appendix S: Outcome form perineometry

Final version





Appendix S(e): Outcome form perineometry – English translation

Final version

Perineometry

Welcome!

Who is measuring today? ……...

Date of measurement: ……

General information

Participant family name: ……
First name: ……
Date of birth: …….
Pre or post intervention measurement: pre – post
Participant consenting to measurement: yes – no

Measurement

Voluntary contraction palpable: yes – no
Vaginal resting pressure: ……...
Maximum contraction 1: ……
Maximum contraction 2: ……
Maximum contraction 3: …….
Endurance: ……..

Comments: ……..

Appendix T: Adverse events monitoring form

Participant ID:

Initiating questions for call and message left:

- „Guten Tag Frau …, hier spricht Claudia Oblasser, ich wollte nachfragen, wie es mit der Studie bzw. mit Ihrer Teilnahme geht? Wie kommen Sie zurecht?“

Questions during call:

- Both groups: „Haben Sie irgendwelche Schwierigkeiten oder Probleme mit der [Intervention]?”
  „Haben Sie irgendwelche Schmerzen/unangenehmes Gefühl?”
  „Haben Sie unerwünschte Wirkungen/Nebenwirkungen?“
- Ball group only: „Haben Sie vermehrten Ausfluss oder Blutung?“
- Both groups: „Haben Sie irgendwelche Fragen?”

Measurement date:

Intervention start date:

12 weeks completed at (date):

	Call 1 date/time, result	**Call 2 date/time, result**	**Call 3 date/time, result**	**Content of call**
4 days after beginning the intervention (after perineometry)				

1 week later				
2 weeks later				
3 weeks later				
3 weeks later				

Final call:
Date:

Content:

Appendix T(e): Adverse events monitoring form – English translation

Initiating question for call and message left:

“Hello Ms …, here is Claudia Oblasser, I wanted to check how it is going with the study and your participation respectively? How are you getting on?”

Questions during call:

Both groups: “Do you have any difficulties or problems with the [intervention]?”

“Do you have any pain/uncomfortable feeling?”

“Do you have adverse effects/side effects?”

Ball group only: “Do you have any increased discharge or bleeding?”

Both groups: “Do you have any questions?”

Appendix U: Initial interview schedule long form

Participant ID:

Before randomisation

(1) Warum interessieren Sie sich für die Teilnahme an der Studie? **Variable: why interest**

(2) Bitte beschreiben Sie (eventuelle) Veränderungen Ihres Beckenbodens durch die/seit der Geburt: **Variable: changes PF**

(3) Haben Sie in Ihrem Leben schon jemals Beckenbodenübungen gemacht? **Variable: ever done PFMX**

□ Ja **1**

In welchem Zusammenhang? (wann, warum, wie…): **Variable: context PFMX**

□ Nein **2**

□ Ich bin nicht sicher **3**

(4) Haben Sie nach dieser Geburt Informationen über Beckenbodenübungen bekommen? **Variable: given PFMX**

□ Ja, schriftlich **1**

→ Darf ich die bitte sehen? **Variable: shown PFMX**

□ gezeigt □ nicht gezeigt → Grund: **Variable: why not shown**

Welche? **Variable: info written PFMX**

□ Ja, mündlich **2**

Welche? **Variable: info oral PFMX**

□ Nein **3**

□ Ich weiss nicht **4**

(5) Haben Sie die Übungen gemacht? **Variable: done PFMX**

□ Ja **1**

□ Manchmal **2**

□ Nein **3**

Warum nicht? **Variable: why not PFMX**

(6) Was denken Sie über Beckenbodenübungen? **Variable: opinion exercises**

(7) Haben Sie je Beckenbodenkugeln verwendet? **Variable: used balls**

□ Ja **1**

□ Nein **2**

(8) Haben Sie, bevor Sie mit dieser Studie in Kontakt gekommen sind, schon mal von Beckenbodenkugeln gehört? **Variable: heard balls**

□ Ja **1**

□ Nein **2**

□ Ich bin nicht sicher **3**

(9) Was denken Sie über die Beckenbodenkugeln? **Variable: opinion balls**

(10) Würden Sie gern in eine bestimmte Gruppe kommen? **Variable: preference**

□ Ja **1**

In welche? **Variable: which preference**

□ Übungen **1**

□ Kugeln **2**

□ Nein **2**

□ Ich bin nicht sicher **3**

After randomisation

Gruppe: Übungen Kugel

(11) Was sagen Sie nun zu Ihrer Gruppenzuteilung, wie fühlen Sie sich? **Variable: allocation opinion**

(12) Von 0-10, wie hoch ist Ihre Motivation, die [Intervention] 12 Wochen lang zu machen? **Variable: motivation**

(13) Möchten Sie noch etwas sagen/fragen? **Variable: other**

Appendix U(e): Initial interview schedule long form – English translation

Participant ID:

Before randomisation

(1) Why are you interested in participating in the study? **Variable: why interest**

(2) Please would you describe changes (if any) associated with your pelvic floor since the birth?: **Variable: changes PF**

(3) In your life, have you ever been doing pelvic floor muscle exercises? **Variable: ever done PFMX**

□ Yes **1**

In what context? (when, why, how…): **Variable: context PFMX**

□ No **2**

□ I am not sure **3**

(4) Have you been given information about pelvic floor muscle exercises after this birth? **Variable: given PFMX**

□ Yes, in written form **1**

→ can I see them please?

□ shown □ not shown → Reason:

Variable: why not shown

Which ones? **Variable: info written PFMX**

□ Yes, in oral form **2**

Which ones? **Variable: info oral PFMX**

□ No **3**

□ I don´t know **4**

(5) Have you been doing the exercises? **Variable: done PFMX**

□ Yes **1**

□ Sometimes **2**

□ No **3**

Why not? **Variable: why not PFMX**

(6) What do you think about pelvic floor muscle exercises? **Variable: opinion exercises**

(7) Have you ever used pelvic floor training balls? **Variable: used balls**

- □ Yes **1**
- □ No **2**

(8) Have you, before getting into contact with this study, ever heard of pelvic floor training balls? **Variable: heard balls**

- □ Yes **1**
- □ No **2**
- □ I am not sure **3**

(9) What do you think about the pelvic floor training balls? **Variable: opinion balls**

(10) Do you have a preference for a group? **Variable: preference**

- □ Yes **1**

  For which one? **Variable: which preference**

  - □ exercises **1**
  - □ balls **2**
- □ No **2**
- □ I am not sure **3**

After randomisation

Group: Exercises Ball

(11) What do you say now about your group allocation, how do you feel? **Variable: allocation opinion**

(12) From 0-10, how high is your motivation to do the [intervention] for 12 weeks? **Variable: motivation**

(13) Anything else you want to say/ask? **Variable: other**

Appendix V: Initial interview schedule short form

Participant ID:

Before randomisation

(1) Haben Sie in Ihrem Leben schon jemals Beckenbodenübungen gemacht? **Variable: ever done PFMX**

□ Ja **1**

In welchem Zusammenhang? (wann, warum, wie…): **Variable: context PFMX**

□ Nein **2**

□ Ich bin nicht sicher **3**

(2) Haben Sie nach dieser Geburt Informationen über Beckenbodenübungen bekommen? **Variable: given PFMX**

□ Ja, schriftlich **1**

→ Darf ich die bitte sehen? **Variable: shown PFMX**

□ gezeigt □ nicht gezeigt → Grund: **Variable: why not shown**

Welche? **Variable: info written PFMX**

□ Ja, mündlich **2**

Welche? **Variable: info oral PFMX**

□ Nein **3**

□ Ich weiss nicht **4**

(3) Haben Sie die Übungen gemacht? **Variable: done PFMX**

□ Ja **1**

□ Manchmal **2**

□ Nein **3**

(4) Haben Sie je Beckenbodenkugeln verwendet? **Variable: used balls**

□ Ja **1**

□ Nein **2**

(5) Haben Sie, bevor Sie mit dieser Studie in Kontakt gekommen sind, schon mal von Beckenbodenkugeln gehört? **Variable: heard balls**

□ Ja **1**

□ Nein **2**

□ Ich bin nicht sicher **3**

(6) Würden Sie gern in eine bestimmte Gruppe kommen? **Variable: preference**

□ Ja **1**

In welche? **Variable: which preference**

□ Übungen **1**

□ Kugeln **2**

□ Nein **2**

□ Ich bin nicht sicher **3**

After randomisation

Gruppe: Übungen Kugel

(7) Was sagen Sie nun zu Ihrer Gruppenzuteilung, wie fühlen Sie sich? **Variable: allocation opinion**

(8) Von 0-10, wie hoch ist Ihre Motivation, die [Intervention] 12 Wochen lang zu machen? **Variable: motivation**

Appendix V(e): Initial interview schedule short form – English translation

Participant ID:

Before randomisation

(1) In your life, have you ever been doing pelvic floor muscle exercises? **Variable: ever done PFMX**

□ Yes **1**

In what context? (when, why, how…): **Variable: context PFMX**

□ No **2**

□ I am not sure **3**

(2) Have you been given information about pelvic floor muscle exercises after this birth? **Variable: given PFMX**

□ Yes, in written form **1**

→ can I see them please?

□ shown □ not shown → Reason:

Variable: why not shown

Which ones? **Variable: info written PFMX**

□ Yes, in oral form **2**

Which ones? **Variable: info oral PFMX**

□ No **3**

□ I don´t know **4**

(3) Have you been doing the exercises? **Variable: done PFMX**

□ Yes **1**

□ Sometimes **2**

□ No **3**

(4) Have you ever used pelvic floor training balls? **Variable: used balls**

□ Yes **1**

□ No **2**

(5) Have you, before getting into contact with this study, ever heard of pelvic floor training balls? **Variable: heard balls**

□ Yes **1**

□ No **2**

□ I am not sure **3**

(6) Do you have a preference for a group? **Variable: preference**

□ Yes **1**

For which one? **Variable: which preference**

□ exercises **1**

□ balls **2**

□ No **2**

□ I am not sure **3**

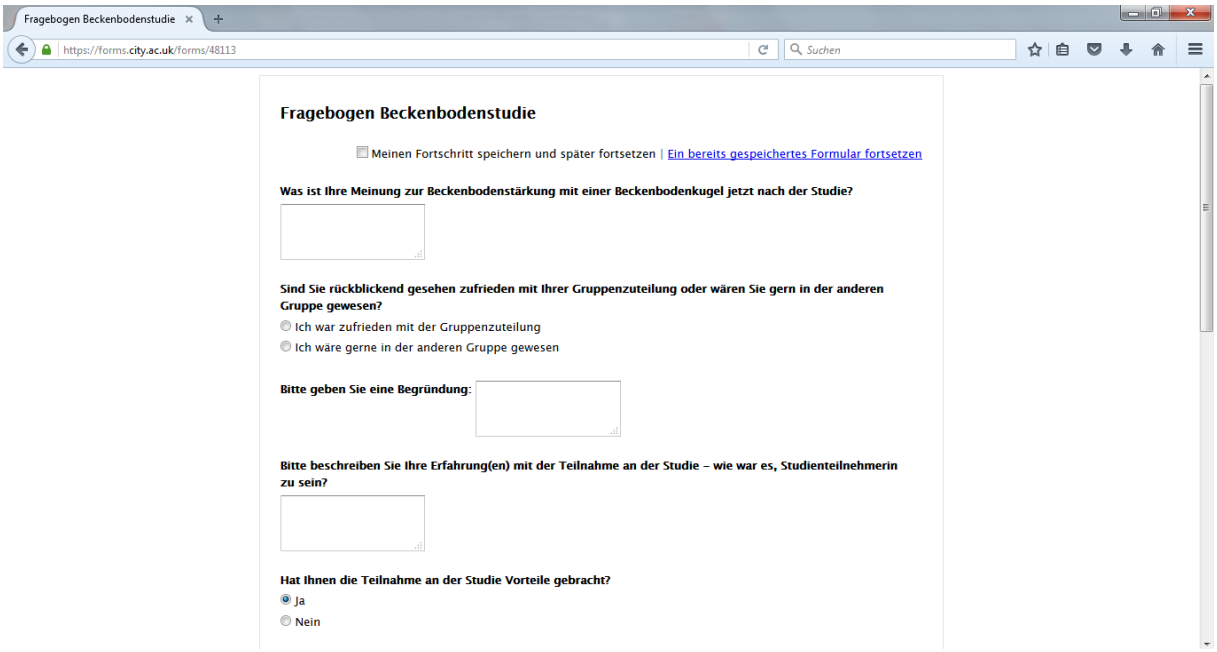
After randomisation

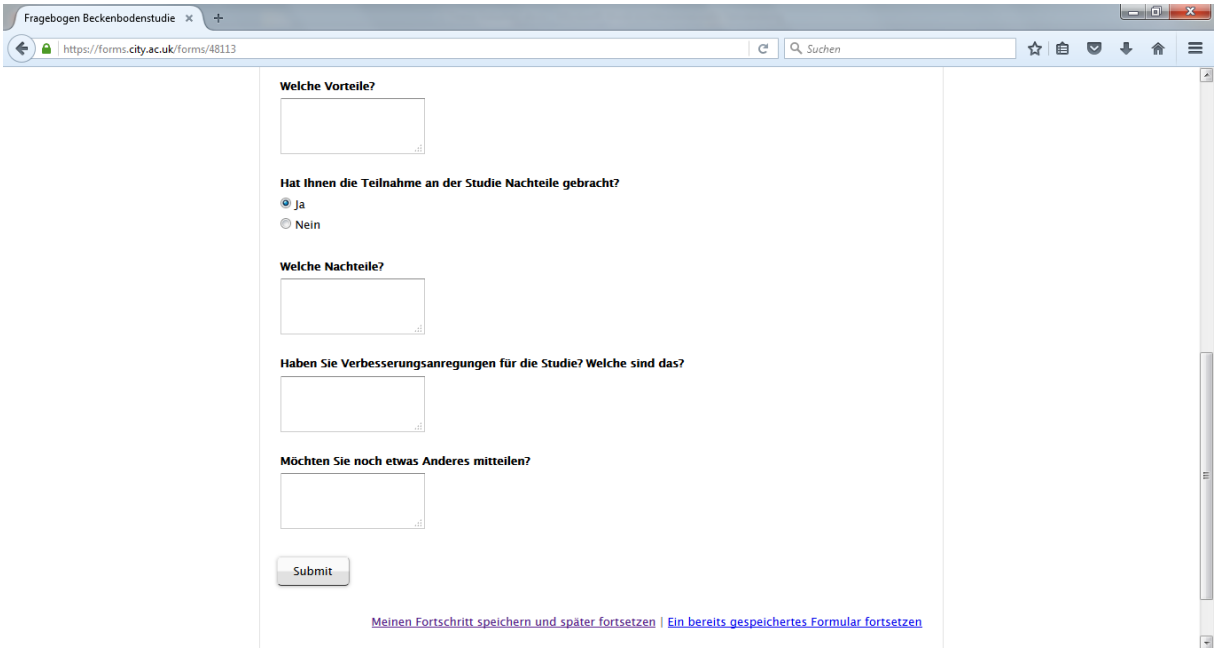
Group: Exercises Ball

(7) What do you say now about your group allocation, how do you feel? **Variable: allocation opinion**

(8) From 0-10, how high is your motivation to do the [intervention] for 12 weeks? **Variable: motivation**

Appendix W: Online survey questionnaire experimental group





Appendix W(e): Online survey questionnaire experimental group – English translation

(1) What is your opinion about pelvic floor muscle enhancement with a vaginal ball now after the study?

(2) Seen in retrospect, are you happy with your group allocation or would you have liked to be in the other group?

□ Happy with group allocation
Please state the reason:
□ Would have liked to be in the other group
Please state the reason:

(3) Please describe your experience(s) with your participation in the study – how was it to be a study participant?

(4) Did you get any benefits from participating in the study?

□ Yes
Which benefits?
□ No

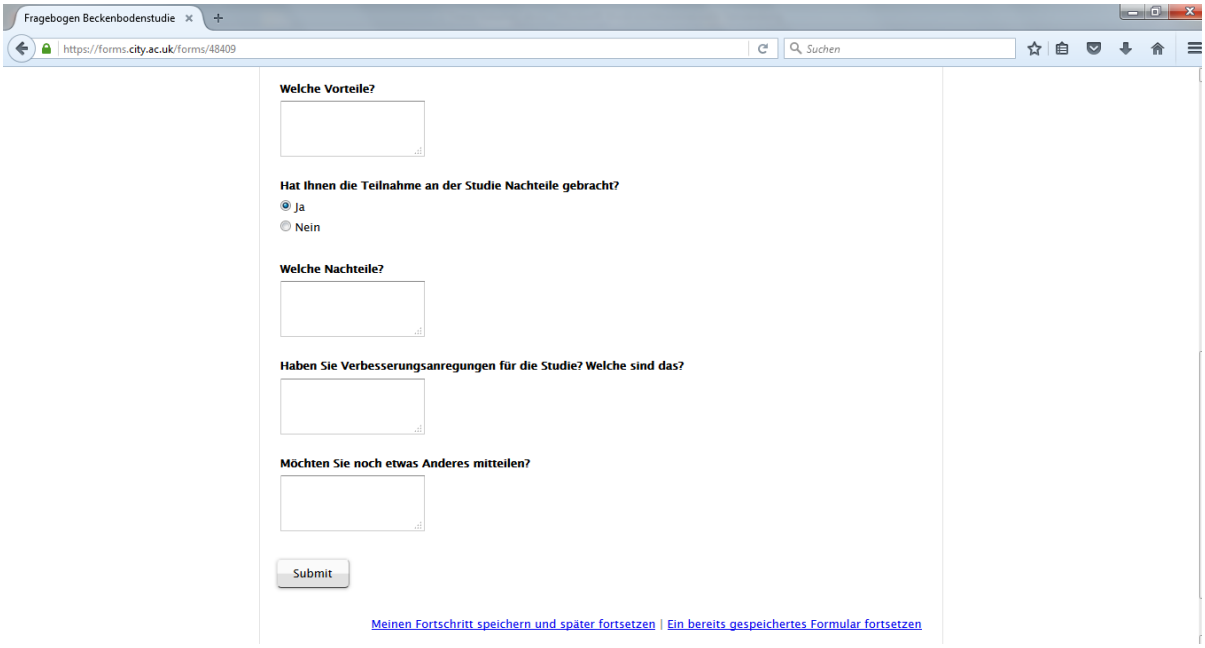
(5) Did you get any disadvantages from participating in the study?

□ Yes
Which disadvantages?
□ No

(6) Do you have suggestions to enhance the study? Which ones?

(7) Would you like to communicate something else?

Appendix X: Online survey questionnaire comparison group



Appendix X(e): Online survey questionnaire comparison group – English translation

(1) What is your opinion about pelvic floor muscle enhancement with pelvic floor exercises now after the study?

(2) Seen in retrospect, are you happy with your group allocation or would you have liked to be in the other group?

□ Happy with group allocation
Please state the reason:
□ Would have liked to be in the other group
Please state the reason:

(3) Please describe your experience(s) with your participation in the study – how was it to be a study participant?

(4) Did you get any benefits from participating in the study?

□ Yes
Which benefits?
□ No

(5) Did you get any disadvantages from participating in the study?

□ Yes
Which disadvantages?
□ No

(6) Do you have suggestions to enhance the study? Which ones?

(7) Would you like to communicate something else?

Appendix Y: Final study meeting schedule

- Hand out transport tickets
- Was there enough soap and lubricant?
- Collect and go through adherence chart
- Collect participant reported outcome measurements
- Perform final interview
- If applicable, amendments from first visit
- Discuss measurement values
- Study results in 2 years
- Ok to call 2 weeks later?
- Perineometry appointment
- Latex allergy No Yes
- Ok to send online survey questionnaire? E-mail?
- Vaginal infection (comparison group)

Appendix Z: Detailed origin of questions used in pelvic floor questionnaire

Question number in initial/final questionnaire	Question with response options	Source of question/response options
Measures of pelvic floor muscle strength		
1/1	Rate the strength of your pelvic floor muscles now, compared to before the most recent birth, using a percentage. This means: If we said that the strength of your pelvic floor muscles before this birth was 100%, how much would you rate its strength in % now? Please note the percentage (including the number) in the scale: 0----------50----------100----110 before this birth	Dietz et al. (2012) Original question adapted (wording) Answering scale designed by CO
n.a./2	How do your pelvic floor muscles feel now after the training compared to before? *a lot tighter – tighter – no difference – slacker – a lot slacker*	Thibault-Gagnon et al. (2014) Original question (number 45) adapted (wording) Original answering options adapted (style)
Measures for vaginal symptoms		
2/3	Do you think that your vagina is to loose or lax? □ no – never □ sometimes	Baessler and Kempkensteffen (2009) Original question (number 37) with original answering options used

	□ frequently □ always	
3/4	How much does this problem bother you? □ not applicable – I have no problem □ not at all □ a little □ quite □ very	Baessler and Kempkensteffen (2009) Original question (number 42) adapted to singular/wording Original answering options used
4/5	Do you feel pressure in your vagina? □ no – never □ sometimes □ frequently □ always	Thibault-Gagnon et al. (2014) Original question (number 39) used Answering options aligned with those from Baessler and Kempkensteffen (2009)
5/6	How much does this problem bother you? □ not applicable – I have no problem □ not at all □ a little □ quite □ very	Baessler and Kempkensteffen (2009) Original question (number 32) adapted to singular/wording Original answering options used
Measures for anal symptoms		
6/7	Do you lose wind from your back passage without being able to hold it back? □ never □ sometimes – less than once a week □ frequently – once or more often a week	Baessler and Kempkensteffen (2009) Original question (number 21) with original answering options used

	□ usually – daily	
7/8	How much does this problem bother you? □ not applicable – I have no problem □ not at all □ a little □ quite □ very	Baessler and Kempkensteffen (2009) Original question (number 27) adapted (wording) Original answering options used
8/9	Do you accidentally lose stool from your back passage? □ never □ sometimes – less than once a week □ frequently – once or more often a week □ usually – daily	Baessler and Kempkensteffen (2009) Original questions (number 23/24) adapted (combined) Original answering options used
9/10	How much does this problem bother you? □ not applicable – I have no problem □ not at all □ a little □ quite □ very	Baessler and Kempkensteffen (2009) Original question (number 27) adapted (wording) Original answering options used

Appendix AA: Perineometry details

Initial meeting participant information and instruction checklist for perineometry

- Venue and assessor
- Empty bladder before the appointment
- How to perform a pelvic floor muscle contraction
- Contraction check by palpation with one finger by assessor
- Clarification of latex allergy
- Description of vaginal probe
- Explanation of vaginal resting pressure, pressure strength and duration measurement
- Duration of appointment: 15 minutes
- Do not reveal group allocation to assessor

Supplementary technical details of perineometric measurement

- Women were carefully instructed on what they had to do.
- Not all women are capable of correct pelvic floor muscle contraction by verbal instruction only and without controlled guidance (Bø et al., 1988, Bump et al., 1991, Talasz et al., 2008, Hilde et al., 2012). Before taking the measurements, each participant's ability to contract her pelvic floor muscles therefore was assured by vaginal palpation as recommended in the literature (Bø et al., 1988, Bump et al., 1991, Chiarelli et al., 2003).
- During contractions, inward movement of the perineum had to be observed (Bø et al., 1990, Bø, 2015).
- A slight co-contraction of the deep abdominal muscles (lower transversus abdominis and internal oblique) with a pelvic floor muscle contraction is physiologic (Bø et al., 1990, Bø, 2015). For the measurement to be specific, co-contraction of the outer abdominal muscles (rectus abdominis [resulting in pelvic tilt] and external oblique), gluteal or hip adductor muscles is to be avoided and was checked for by the assessors (Bø, 2004, Madill and McLean, 2006, Bø, 2015).
- If necessary, the position of the probe was controlled by manual support from the assessor (Hahn et al., 1996, Peschers et al., 2001, Bø, 2015).
- Duration of strength contraction was not specified in this trial. There is no standard contraction duration for strength pressure measurement. In the more recent literature on perineometry reliability, strength contraction duration ranged from 2-3 to 5 seconds (Kerschan-Schindl et al., 2002, Sigurdardottir et al., 2009, Rahmani and Mohseni-Bandpei, 2011) or was not defined (Bø, 2015). In trials on cones or preventive pelvic floor muscle training post partum, strength contraction duration was not defined (Norton and Baker, 1990, Fischer and Baessler, 1996, Mørkved and Bø, 1997, Wilson and Herbison, 1998, Meyer et al., 2001). In observational studies on postpartum pelvic floor muscle strength, it ranged from 5 to 12 seconds (Cosner et al., 1991, Sigurdardottir et

al., 2011, Zizzi et al., 2017) or asked for “as strong and long as possible“ (Caroci et al., 2010, Friedman et al., 2012) or was not defined (Marshall et al., 2002, Baytur et al., 2007, Baracho et al., 2012, Hilde et al., 2013).

- To give muscles time for relaxation and to avoid fatigue, breaks are needed between contraction measurements (McKey and Dougherty, 1986, Hundley et al., 2005, Rahmani and Mohseni-Bandpei, 2011, Ratamess, 2012, Botelho et al., 2013). In different pelvic floor studies, these breaks were of different duration, e.g. 3, 10 or 30 seconds (Kerschan-Schindl et al., 2002, Hundley et al., 2005, Frawley et al., 2006, Gameiro et al., 2011, Friedman et al., 2012, Angelo et al., 2017, Zizzi et al., 2017). As there does not seem to be a mandatory standard, as participants only had to perform four contractions, and as it also seemed easiest in terms of assessment flow, the break duration between the contractions in this trial was specified as 10 seconds.

Measurement standard – English translation

Empty bladder:

- Participant has been informed by me, should arrive with empty bladder

Explanation about pelvic floor muscle contraction/measurement:

- Has been explained by me to participant at initial study meeting
- Check again before measurement whether participant has understood pelvic floor muscle contraction: “Squeeze the muscles around the vagina and lift them by closing the three openings for rectum, vagina and urethra and drawing them inwards (and a little bit forward)“
- Explain measurement

Positioning:

- Supine position, one or two pillows under the head
- Legs bent (knees 90° flexed, and 45° between thighs and examination table)
- Feet on examination table 30 cm apart

Checking of correct contraction:

- Instruction: “Squeeze the muscles and lift them inwards as strong as you can, continue breathing“
- Palpation: with 1 finger, until voluntary contraction clearly noticeable
- Correct contraction: Abdominal wall may contract slightly, no pelvic movement or contraction of thighs or gluteal muscles allowed

Positioning of probe:

- Condom: ask for latex allergy
- Some lubricant
- Do not touch probe (blue) any more, hold it at connecting tube
- Switch on device
- Adjust to 0 (shows minimal values)
- Insert: Middle (=sensitive) area of probe shall be 3,5 cm deep inserted at height of levator ani muscle = 1 cm of probe still outside of body

Measurement vaginal resting pressure:

- Read value after insertion = measurement
- Then inflate to 100 cm H_2O: with 20 ml syringe via the “T” in the connecting tube; before taking off syringe shortly draw back plunger, so that valve closes
- Adjust to 0 (do not press button too shortly, otherwise device does not clear earlier value)

Measurement muscle strength:

- Instruction: “Squeeze the muscles and lift them inwards as strongly as you can, continue breathing“ – always use same wording, same neutral voice/tone, no encouragement shouting
- Observe if contraction is performed correctly: as above, + inward movement of vulva and probe ventrally (+ maybe cranially)
- Read off (PEA) and note = first measurement
- Cave: device does not save maximal values below 5, one has to read them off the display

- 10 seconds break after contraction
- Adjust to 0
- Same instruction
- Observe if contraction is performed correctly
- Read off (PEA) and note = second measurement

- 10 seconds break after contraction
- Adjust to 0
- Same instruction
- Observe if contraction is performed correctly
- Read off (PEA) and note = third measurement
- 10 seconds break after contraction
- Adjust to 0

Measurement muscle endurance:

- Instruction: “Squeeze the muscles and lift them strongly inwards as long as you can, continue breathing – hold, hold, hold“ – neutral tone, no cheering
- Observe if contraction is performed correctly
- For a maximum of 10 seconds
- Read off (DUR) and note = measurement

Peritron accuracy, responsiveness and reliability

The Peritron device used was new and is therefore assumed to have measured accurately. The responsiveness (technical validity) of the Peritron is described by the manufacturer with the following values: operating range 0-300 cm H_2O, display resolution 0.1 cm H_2O, maximum error of < 0.7 cm H_2O full scale, sensitivity of response with inflation is reduced by 20% (LABORIE, 2012). The Peritron intrarater and interrater reliability is detailed in Table 16.

Table 16 Peritron reliability

Measure	Reliability
Vaginal resting pressure	• Intrarater reliability intraclass correlation coefficient[a] (*ICC*) 0.74 in bent-knee supine position (Frawley et al., 2006) • Interrater reliability correlation coefficient 0.78 in a dorsal lithotomy[b] position (Hundley et al., 2005)
Vaginal squeeze pressure (strength)	• Intrarater reliability *ICC* of 0.95 for bent-knee supine position by Frawley et al. (2006) and 0.88 by Rahmani and Mohseni-Bandpei (2011), in a butterfly position 0.97 (Kerschan-Schindl et al., 2002). Rahmani and Mohseni-Bandpei (2011) also demonstrated a good level of agreement[a]. • In a dorsal lithotomy position, interrater reliability correlation coefficient of 0.88 (Hundley et al., 2005)
Vaginal squeeze pressure (endurance)	• No reliability study could be identified which measured endurance as it was operationalised in the present trial. • Intrarater reliability *ICC* of 0.83 by Rahmani and Mohseni-Bandpei (2011) in a bent-knee supine position (measured as [seconds of(?)] 60% of maximum pressure maintained until fatigue or pressure down to 50% of these 60%), and for a butterfly position 0.96 (measured as mean pressure over 5 seconds) (Kerschan-Schindl et al., 2002) • In a dorsal lithotomy position, interrater reliability correlation coefficient of 0.55 (operationalised as maximum duration out of three maximal efforts and measured at each contraction together with maximum force) (Hundley et al., 2005)

[a]Correlation coefficients are to be differentiated from agreement–whereas correlation measures the strength of a relation between two data, agreement measures how much they agree in absolute terms which unlike correlation may not mislead (Bland and Altman, 2010).
[b]Supine body position with buttocks at the end of the table, hips and knees fully flexed, legs spread apart and supported by raised stirrups (Farlex, 2018d).

Appendix BB: Supplementary statistical information

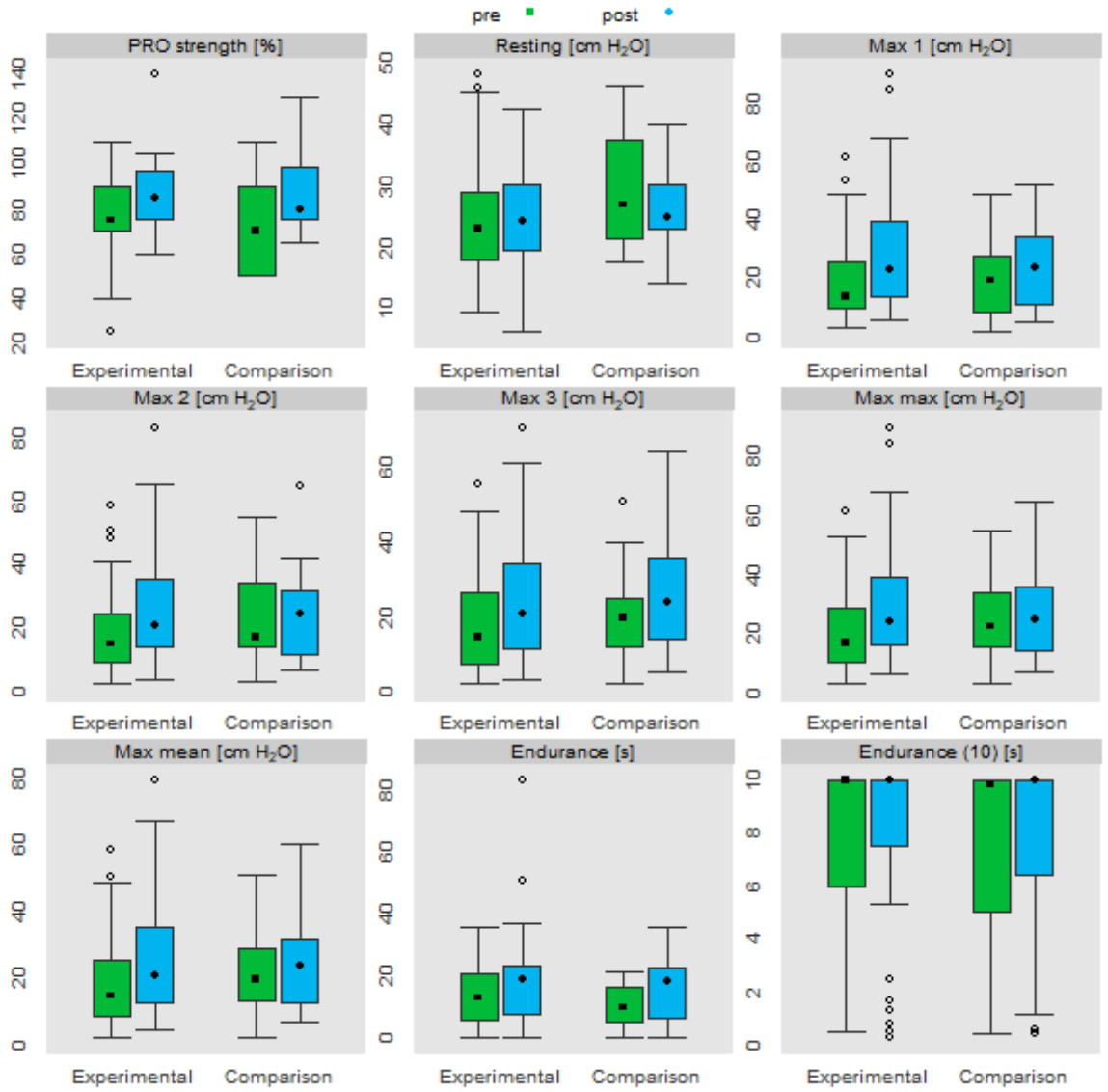
In the following, supplementary analysis information not appropriate for presentation in the main text is presented. This concerns missing data and the exploratory descriptive analysis.

Missing data

- For participant 11 (comparison group), the initial perineometry values for strength and endurance are missing. The likely reason for the strength values missing is that the Peritron does not save values ≤ 5 cm H_2O in its memory function and such values therefore have to be read directly from the display during measurement (LABORIE, 2012). Accordingly, endurance is only measured when strength raises above 5 cm H_2O. At the time of measurement, the respective assessor was newly introduced and not skilled yet in taking the measurements and did not recognise the displayed saved values of 0 as her/his error. This reasoning aligns with the low final values of the respective participant. The reason for the values missing thus is human error of the assessor, and the values are missing not at random as “the fact that they are missing is related to the [value of the] actual missing data” (Higgins et al., 2011b, p. 484).
- Participant 18 (experimental group) did not give a postintervention participant reported pelvic floor muscle strength value as she experienced repeated loss of the vaginal ball which rendered her insecure about her pelvic floor. Ball loss may have happened because of a weak pelvic floor (low value) and the value is therefore classified as missing not at random.
- Participant 40 (experimental group) withdrew from the trial and could not be followed up to collect her final outcome measures. Her values can be considered missing at random as they do not depend on the unobserved data but on adverse events as her reason for withdrawing (Higgins et al., 2011b, Joshi et al., 2013, The Analysis Factor, 2018).
- Five perineometry endurance values are missing because of measurement error or ambiguity. Four were preintervention values (three in the experimental and one in the comparison group), one was a postintervention value in the experimental group. The measurement errors are considered to be missing at random, as are the ambiguities which did not depend on the measured values.

Exploratory descriptive data analyses

Figure 1 Exploratory descriptive data analyses of continuous clinical outcome variables before and after the interventions



PRO strength = participant reported pelvic floor muscle strength; Resting = vaginal resting pressure; Max 1 = value of first squeeze pressure strength measurement; Max 2= value of second squeeze pressure strength measurement; Max 3 = value of third squeeze pressure strength measurement; Max max = maximum value of three squeeze pressure strength measurements; Max mean = mean of three squeeze pressure strength measurements; Endurance = endurance measurement; Endurance (10) = endurance measurement operationalised with 10 seconds as maximum value.

Appendix CC: Example questions to be asked in feasibility studies

All text is quoted directly from the authors.

Process questions

Thabane et al. (2010, p. 4):

- Recruitment rates
- Retention rates
- Refusal rates
- Failure/success rates
- (Non)compliance or adherence rates
- Eligibility criteria
  - Is it obvious who meets and who does not meet the eligibility requirements?
  - Are the eligibility criteria sufficient or too restrictive?
- Understanding of study questionnaires or data collection tools:
  - Do subjects provide no answer, multiple answers, qualified answers, or unanticipated answers to study questions?

Tickle-Degnen (2013, p. 173):

- What are the expected
  - Numbers of eligible members of the targeted population?
  - Recruitment rates?
  - Refusal rates for participation and for randomization?
  - Retention and follow-up rates as the participants move through the trial?
  - Adherence rates to study procedures, intervention attendance, and engagement?
- How feasible and suitable are
  - Eligibility criteria? Are criteria clear and sufficient or too inclusive or restrictive?
  - Data collection assessments? Do participants understand the questions and other data collection methods? Do they respond with missing or unusable data?
  - Amount of data collection? Do the participants have enough time and capacity to complete data collection procedures? Does the overall data collection plan involve a reasonable amount of time, or does it create a burden for the participants?

Management questions

Thabane et al. (2010, p. 4):

- What are the challenges that participating centres have with managing the study?
- What challenges do study personnel have?
- Is there enough room on the data collection form for all of the data you receive?
- Are there any problems entering data into the computer?
- Can data coming from different sources be matched?
- Were any important data values forgotten about?
- Do data show too much or too little variability?

Tickle-Degnen (2013, p. 174):
What are the challenges and strengths of

- The investigators' administrative capacity to manage the planned RCT?
- Research investigator and staff capacities, expertise, and availability for the planned research activities?
- Formats and structures of forms that document participant progress through the trial?
- Accurate data entry into the computer? Are data lost, forgotten, or entered incorrectly? How are data files organized, named, and dated? Who is in charge of tracking the latest data entry and the quality of entry?
- Matching of data to participants from different sources (e.g., participant screen data, consent and entry into the RCT, adherence, and responses on outcome measures)?
- Management of the ethics of the research? To what extent do staff comply with the approved human participants protocol? How effectively are adverse events during implementation identified, documented, and reported? What happens if a participant experiences a clinical emergency or if family abuse is identified during the trial?

Resources questions

Thabane et al. (2010, p. 4):

- Length of time to fill out all the study forms
- Determining capacity:
  - Will the study participants overload your phone lines or overflow your waiting room?
- Determining process time
  - How much time does it take to mail out a thousand surveys?
- Is the equipment readily available when and where it is needed?
- What happens when it breaks down or gets stolen?
- Can the software used for capturing data read and understand the data?
- Determining centre willingness and capacity
  - Do the centres do what they committed to doing?
  - Do investigators have the time to Perform the tasks they committed to doing?
  - Are there any capacity issues at each participating centre?

Tickle-Degnen (2013, p. 173):
Do we have the

- Physical capacity to handle the number of participants? What is the square footage as related to the stages and tasks of the procedures?
- Phone and communication technology capacity to stay in touch with and coordinate the participants? Is there Web and teleconferencing capability?
- Time to conduct each stage and aspect of the protocol? What are the time frames, and how do they coordinate with other responsibilities? How long does it take to connect with a participant or to send out mailings?
- Equipment in the correct place at the correct time? What equipment is needed, and is it available when needed?
- Ability to deal with broken, lost, or stolen equipment and materials? Are there backup plans for obtaining needed equipment and materials?

- Adequate software to capture and use data? What software is available for conducting the research?
- Institutional, departmental, and clinical centers' willingness, motivation, and capacity to carry through with project-related tasks and to support investigator time and effort? What administrative services are in place for research at this level?
- Documented evidence indicating that these centers abide by their commitments? What are the challenges in fulfilling research support commitments?
- Access to basic services, such as copying, libraries, institutional technology, data servers, and purchasing?

Clinical questions

Thabane et al. (2010, p. 4):

- Is it safe to use the study drug/intervention?
- What is the safe dose level?
- Do patients respond to the drug?
- What is the estimate of the treatment effect?
- What is the estimate of the variance of the treatment effect?

Tickle-Degnen (2013, pp. 174-175):

- What is the level of safety of the procedures in the intervention or interventions?
- What is the level of safety and burdensomeness of the frequency, intensity, and duration of the intervention? Can these and other elements be standardized in a protocol without loss of a client-centered, individualized focus?
- What are the reliability, validity, and trustworthiness of the assessments for the targeted population for this specific intervention? Do the assessments capture individual participants' needs and measure their responsiveness to these needs?
- What values constitute clinically meaningful differences on the primary outcome measures or assessment procedures?
- What is the expected degree of change (i.e., responsiveness) of the participants?
- What are the estimates of the intervention effect and the variance of that effect across the planned population?
- What are the expected subgroup effects (i.e., specificity effects or moderator variables)?

Appendix DD: Ethical approval confirmation

Ethical approval Medical University of Vienna

ethik kommission
Medizinische Universität Wien

Borschkegasse 8b/6
A-1090 Wien, Austria

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F +43 1 40 400 – 16900
ethik-kom@meduniwien.ac.at
ethikkommission.meduniwien.ac.at

Votum:

EK Nr: 1704/2014
Projekttitel: Machbarkeits-RCT zur Wirksamkeit von vibrierenden Beckenbodenkugeln zur Verbesserung der Beckenbodenmuskulatur nach der Geburt
Antragsteller/in: Frau M.A. Claudia Oblasser
Institution: City University London
Sponsor: City University London, School of Health Sciences

Teilnehmende Prüfzentren:

Ethik-Kommission	Prüfzentrum	Prüfärztin/arzt
Ethikkommission der Medizinischen Universität Wien	Univ.frauenklinik, Klin. Abt. für Geburtshilfe und feto-maternale Medizin, MUW	Herr Ao. Univ.-Prof. Dr. Engelbert Hanzal

Die Stellungnahme der Ethik-Kommission erfolgt aufgrund folgender eingereichter Unterlagen:

Dokument	Name	Version	Datum
Conflict of Interest	Conflict_Interest_Prüfarzt-signed	1	06.08.2014
Covering Letter	Cover letter	2	19.10.2014
	Cover letter	1	22.08.2014
Lebenslauf (CV)	CV Claudia Oblasser	1	13.08.2014
	CV Hanns Helmer	1	07.08.2014
	CV Engelbert Hanzal	1	09.07.2014
Sonstige	Rekrutierungsblatt	2	19.10.2014
	Provisional indemnity confirmation von City University London	1	06.08.2014
	CE-Zertifikat Laborie Peritron-Sonde	1	02.05.2014
	Produktbroschüre Intimina Laselle Beckenbodenkugeln	1	31.01.2013
	CE-Zertifikat Intimina Laselle Beckenbodenkugeln	1	21.11.2012
	Produktbroschüre Laborie Peritron Perineometer	1	09.02.2012
Patienteninformation	Patienteninformation	2	19.10.2014
	Patienteninformation	1	24.08.2014
Studienprotokoll (Prüfplan)	Research Protocol	2	19.10.2014

	Research Protocol	1	24.08.2014

Die Kommission fasst folgenden Beschluss (mit X markiert):

☒	Es besteht kein Einwand gegen die Durchführung der Studie.

Ergänzende Kommentare der Sitzung am 07.10.2014:

Zum Prüfplan:
Die Ethik-Kommission regt an, im Kapitel "Relevance of the topic and rationale for the research" die schlechte Compliance bei aktiven Beckenbodenübungen in der Postpartalperiode noch anzuführen.

Zur Patienteninformation:
Punkt 13: Eine Versicherung ist nicht notwendig, dieser Absatz ist zu streichen.
Punkt 17: Die Telefonnummer der Studiendurchführenden ist zu ergänzen.

Zur Versicherung: nicht erforderlich

Andere:
Das im Antrag erwähnte Rekrutierungsblatt ist vorzulegen.

Die Ethik-Kommission ersucht die Antragsteller, bei der Wiedervorlage von geänderten Unterlagen ein Exemplar mit hervorgehobenen Änderungen beizulegen.

Die Ethik-Kommission geht - rechtlich unverbindlich – davon aus, dass es sich um eine klinische Prüfung gemäß § 40 (5) MPG (keine Behördenmeldung erforderlich) handelt.

Ergänzende Kommentare:

Nachtrag vom 20. Oktober 2014:
Die Antragsteller legen am 19.10.2014 überarbeitete Unterlagen vor, die von der Ethik-Kommission akzeptiert werden.

Die Ethik-Kommision geht - rechtlich unverbindlich - davon aus, daß es sich um eine klinische Prüfung gemäß MPG handelt.

Die aktuelle Mitgliederliste der Ethik-Kommission ist unter der Adresse http://ethikkommission.meduniwien.ac.at/ethik-kommission/mitglieder/ abrufbar. Mitglieder der Ethik-Kommission, die für diesen Tagesordnungspunkt als befangen anzusehen waren und daher laut Geschäftsordnung an der Entscheidungsfindung/Abstimmung nicht teilgenommen haben: **keine**

ACHTUNG: Unter Berücksichtigung der "ICH-Guideline for Good Clinical Practice" gilt dieser Beschluss **ein Jahr ab Datum der Ausstellung**. Gegebenenfalls hat der Antragsteller eine Verlängerung der Gültigkeit rechtzeitig zu beantragen.

Dieses Votum ist für berechtigte Benutzer/innen in digitaler Form unter der Adresse https://ekmeduniwien.at/vote/5554/download/ abrufbar.

Signaturwert	bZwIyxQFIwAfZ9sEZAlCyAmyCK9GjVpGyxcSgQ6VeO7b9hHlWW3PDJz2gSyDqfnkRr+E5VtfFhLBOi07arxhfA==	
SIGNATURINFORMATIONEN	**Unterzeichner**	Dr. Jürgen Zezula
	Aussteller-Zertifikat	CN=a-sign-Premium-Sig-02,OU=a-sign-Premium-Sig-02,O=A-Trust Ges. f. Sicherheitssysteme im elektr. Datenverkehr GmbH,C=AT
	Serien-Nr.	851965
	Methode	urn:pdfsigfilter:bka.gv.at:binaer:v1.1.0
	Parameter	etsi-moc-1.1@cf3aca0
Prüfinformation	Informationen zur Prüfung der elektronischen Signatur und des Ausdrucks finden Sie unter: http://www.signaturpruefung.gv.at	
Datum/Zeit-UTC	2014-10-20T13:47:57Z	

Ethical approval City University London

CITY UNIVERSITY LONDON

Claudia Oblasser
School of Health Sciences
City University London
London
EC1V 0HB

6 January 2015

Dear Ms Oblasser

Reference: SREC 14-15 02 D 02 12 2014
Project Title: Feasibility trial on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth
Start Date: 6 January 2015
End Date: 31 October 2016
Approval Date: 6 January 2015

I am writing to you to confirm that the research proposal detailed above has been granted formal approval from the City University Senate Research Ethics Committee following Chair's action to approve the proposal.

Please note that you are required to report any adverse events within 5 days. You are also required to notify the Committee of any amendments made to this study. If there are significant alterations to the protocol you may need to reapply.

Should you have any further queries relating to this matter then please do not hesitate to contact me. On behalf of Senate Research Ethics Committee I do hope that the project meets with success and many thanks for your patience.

Kind regards

Anna Ramberg
Research Development Manager
Secretary to Senate Research Ethics Committee

Email: Anna.Ramberg.1@city.ac.uk
Tel: 020 7040 3040

Appendix EE: PPI information leaflet

CITY UNIVERSITY LONDON
EST 1894

School of Health Sciences

Claudia Oblasser MA, RM
PhD Student
Claudia.Oblasser.1@city.ac.uk

What am I here for?

I am here at this MSLC event to find 3-4 women to talk with me about your ideas on my planned study to make it as woman friendly as possible.

- **In a group or on our own (your choice)**
- **Once for about 1 hour**

What is the project about?

Women after childbirth often have pelvic floor problems (e.g. weak pelvic floor or urine leakage). Pelvic floor muscle training by squeezing the muscles around the vagina is a way to overcome these. This training can be done by vaginal balls (Kegel exercisers), however there is not enough scientific evidence about this method.

In my study, the participating women will be placed into a group using the balls or into a comparison group (receiving e.g. usual care). They will use the balls 15-30 minutes daily for about 6-12 weeks.

After this time, the strength of their pelvic floor muscles will be measured. This can be done by squeezing the vaginal muscles around a person´s finger or a small inserted balloon. Women will also be asked by a questionnaire for symptoms of urinary leakage and about their opinion on ball use.

The title of the study is:

Vibrating vaginal balls (Kegel exercisers) to improve pelvic floor muscle performance and urinary continence in women after childbirth

What I am NOT asking you for:

I am not asking you for any further commitment.

I am not asking you to participate in the study.

Appendix FF: Details for trial forms and their administration

Recruitment (process forms)

Forms. The original recruitment contact form was split into two different forms–one for active and one for passive recruitment–and underwent slight changes (new forms in Appendix L). The recruitment phone call eligibility checklist (Appendix I) proofed feasible as it was. The recruitment sheet for professionals and the participant name-number translation form were slightly changed (new forms as Appendices H and II). As midwives may have informed women in the early postpartum time, date of delivery was added to the midwives' list to not call potential participants too soon after birth.
Administration. Smooth.
Suggestions for full trial. Use optimised forms. Electronic form optional if desired by research team.

Participant information and consent form (process form)

Form (Appendix K)**.** No change was made during the trial.
Administration. As all potential participants had e-mail access, the participant information and consent form was exclusively sent via this route.
Suggestions for full trial. The instructions for ball use in the participant information and consent form need to have added that participants are not discouraged from doing their routinely recommended pelvic floor muscle exercises. Keep application option in electronic and paper form.

Information/consent/initial study meeting schedule (process form)

Form (Appendix J)**.** Slight changes were made on the schedule: insertion of participant's date of birth, baby's first name (for conversation purposes) and question on latex allergy; item order and wording slightly changed.
Administration. Smooth.
Suggestions for full trial. Use optimised schedule. Change to participant ID instead of name and date of birth. Question for allergies with respect to lubricant and ball cleaning soap should be inserted. Administration recommended in paper form as was.

Demographic and clinical baseline characteristics (data collection form)

Form (Appendix 19 in research protocol [Appendix N])**.** No change was made to the form during the trial.
Administration. All participants were able to present their maternity notes or answer the questions. However, in rare cases, the birth injury/injuries could not be identified properly–the most likely diagnosis from the participant's birth story was then recorded.
Suggestions for full trial. Delete BMI from form as calculated in SPSS, add variable "menstrual cycle returned". Electronic version, if desired by research team, would ease database entering.

Initial and final pelvic floor questionnaires (data collection forms)

Forms (Appendices 20a and b in research protocol [Appendix N])**.** The pelvic floor questionnaires did not undergo any change during the trial.
Administration. Completeness and correctness of answers after being handed back the questionnaires had to be checked.
Suggestions for full trial. Include a time indication ("within past 4 weeks" as on the ICIQ UI-SF) for all questions on the forms. Keep form administration as was, keep check for completeness and correctness of responses after being handed back the form. Consider providing electronic (online) forms but keep paper form as participants might not be able to handle electronic forms.

Perineometry (data collection form)

Form (Appendix S)**.** Amendments made to the online form during the trial were: insertion of greeting message, field for assessor name and date of measurement, participant date of birth, comments, tick box for measurement before or after, and decimal places. The tick boxes for the bus ticket as well as the "average strength value" field were deleted.
Administration. Smooth. Measurement indication as pre- or postintervention was not always correctly entered. Assessors did not have online access at the measurement site and had to note data on paper and enter them later.
Suggestions for full trial. Form ready for use, administration as was. Accurate completion by assessors may be enhanced with online form access being available at measurement site. Without online access, data need to be written down on paper (with names and values noted on two separate sheets) during the measurement and entered thereafter.

Perineometry measurement standard (process form)

Form (Appendix AA)**.** No change during trial.
Administration. Smooth.
Suggestions for full trial. Insert reminder to not reveal group allocation.

Adherence charts (data collection forms)

Forms (Appendices O and P)**.** The only change on the adherence charts deleted the weekday names from the heading lines with participants then having to fill in the weekdays according to their day of the week of intervention start.
Administration. A number of sheets was lost. Two participants reported to have noted their values in retrospect.
Suggestions for full trial. Forms ready for use; provide optional electronic version or application.

Adverse events calls (data collection form)

Form (Appendix T)**.** Added items: date of initial measurement, date of intervention start, calculated last day of 12 weeks, content and date of last call.

Administration. Some participants were difficult to reach via phone. Participants' e-mail addresses should therefore be included in administrative data so they can be contacted via e-mail. The standardisation of adverse events call was difficult to maintain
Suggestions for full trial. As not documented on any other form, group allocation should be noted on this form. Landscape layout would provide more space to document call content in respective fields. Administration as was. Keep meticulous ordering system of forthcoming calls. Electronic form optional if desired by research team.

Final study meeting schedule (process form)

Form (Appendix Y)**.** Newly designed during trial.
Administration. Smooth.
Suggestions for full trial. Use designed schedule. Administration recommended in paper form as was.

Initial/final interviews schedules (data collection forms)

Forms. Changes made on the long initial interview schedule (Appendix U) were: change of item position, slight wording changes; insertion of allocated group, of questions why participants could not show pelvic floor muscle exercises information and what they think of pelvic floor muscle exercises, of variable name. Changes made on the long final interview schedule (Appendix Q) were: layout, order of items, slight wording change, insertion of time and venue, of questions on whether ball group participants have performed pelvic floor muscle exercises, disadvantage(s) of intervention; for adverse events screening, changes made on the tool were to insert "bleeding" and "discharge" for probing. The schedules for the short interviews (Appendices V and R) were newly created as they had not been planned in the research protocol.
Administration. Collection of interview data went smoothly.
Suggestions for full trial. Probing for adverse events should be done in more detail with a list of potential adverse events and a yes/no and comments option to be completed for each item. Pelvic floor specific training activities performed in the intervention period and breastfeeding status/returned ovarian cyclicity as mediating/moderating variables must be asked at the final interview and should be added to the interview form. Administration as was, with electronic form option if desired by research team.

Online survey questionnaires (data collection forms)

Forms. A draft tool was submitted with the research protocol. The tool used was, as planned, fully developed during this feasibility trial, emerging out of the final long interviews, and is reproduced as Appendices W and X for each respective trial group.
Administration. Smooth.
Suggestions for full trial. Use newly developed forms and adapt to full RCT setting. Paper forms and stamped envelopes should be prepared for participants who do not use the Internet. Administration as was.

Appendix GG: Perineometry pressure strength variability data

Table 17 Perineometry strength variability data within six months post partum, from trials on pelvic floor muscle training/rehabilitation

Trial	Participants	Measurement device and timepoint	Values measured Mean (*SD*)	
			Intervention groups	**Comparison/control groups**
Dinc et al. (2009)	35/33 Parous women Any mode of delivery Mixed urinary (in)continent	Peritron 6-8 weeks post partum	46.8 (15.1) cm H_2O	30.9 (12.5) cm H_2O
Dougherty et al. (1989)	45 altogether, in three groups à 15 Parous women Vaginal delivery Pelvic floor symptoms not mentioned	Self-developed device (Dougherty et al., 1986) 12-23 weeks post partum	Exercise group: 34.2 (17.8) mm Hg (= 46.5 [24.2] cm H_2O) Exercise+device group: 37.1 (19.6) mm Hg (= 50.4 [26.6] cm H_2O)	24.6 (13.5) mm Hg (= 33.4 [18.4] cm H_2O)
Kim et al. (2012)	9/9 Parous women Normal vaginal delivery Urinary incontinent	Kontinence Clinical 14 weeks post partum	25.8 (10.7) mm Hg (= 35.05 [14.6] cm H_2O)	8.1 (2.6) mm Hg (= 11.3 [3.5] cm H_2O)
Mørkved et al. (2003)	143/146 Primiparous women	Camtech 3 months post partum	29.5 (95% CI [26.8, 32.2]) cm H_2O	25.6 (95% CI [23.2, 27.9]) cm H_2O

Trial	Participants	Measurement device and timepoint	Values measured Mean (*SD*)	
			Intervention groups	**Comparison/control groups**
	Any mode of delivery Mixed urinary (in)continent			
Nielsen et al. (1988)	32/26 Primiparous women Vaginal delivery Pelvic floor symptoms not mentioned	WISAP VaginoTonograph 8 weeks post partum	42.9 (20.5) mm Hg (= 58.3 [27.9] cm H_2O)	34.1 (26.4) mm Hg (= 46.4 [35.9] cm H_2O)
Reilly et al. (2002)	68/64 Primiparous women Any mode of delivery Mixed urinary (in)continent	Peritron 3 months post partum	11.5 (7.9) cm H_2O	10.5 (5.5) cm H_2O

Table 18 Perineometry strength variability data within six months post partum, from observational studies on pelvic floor muscle performance

Study	**Participants**	**Measurement device and timepoint**	**Values measured** Mean (*SD*)
Baracho et al. (2012)	32 primiparae with stress urinary incontinence after spontaneous birth 160 continent primiparae after spontaneous birth	Peritron 5-7 months post partum	19.3 (13.1) cm H_2O 30.4 (18.9) cm H_2O
Caroci et al. (2010)	73 primiparae after spontaneous birth Pelvic floor symptoms not mentioned	Perina 42-60 days post partum	13.7 (10.1) mm Hg (= 18.6 [13.7] cm H_2O)
Cosner et al. (1991)	22 women after (probably spontaneous) vaginal birth, parity 1-4 Pelvic floor symptoms not mentioned	Self-developed device (Dougherty et al., 1986) 6-13 weeks post partum	20.0 (11.6) mm Hg (= 27.2 [15.6] cm H_2O)
Hilde et al. (2013)	193 primparae after normal vaginal delivery 122 continent in pregnancy and postpartum 58 incontinent in pregnancy and postpartum	Camtech 6 weeks post partum	16.4 (12.3) cm H_2O 19.3 (14.8) cm H_2O 12.5 (9.4) cm H_2O
Peschers et al. (1997)	25 primparae after vaginal birth 20 multiparae after vaginal birth Pelvic floor symptoms not mentioned	Unclear, from Cardio-Design 6-10 weeks post partum	20.2 (10.6) cm H_2O 24.7 (14.7) cm H_2O
Zizzi et al. (2017)	128 women (=measurements in study) (mixed parity) Any mode of delivery (75.4% Caesarean section) Mixed (in)continent	Peritron Within first seven months post partum	33.1 (16.0) cm H_2O (numbers in abstract only)

Appendix HH: Risk of bias assessment for present feasibility RCT clinical outcomes according to the Cochrane Collaboration's tool for assessing risk of bias (Higgins et al., 2011a)

Domain	Support for judgement	Authors' judgement
Selection bias		
Random sequence generation	The randomisation sequence was produced via the online computer randomisation database for clinical trials Sealed envelope™.	Low risk
Allocation concealment	Blocked randomisation with randomly created blocks of different size made the allocation sequence unpredictable. Opaque sealed envelopes serially numbered with the participant identification numbers and containing the codes generated from the computer programme were prepared by a PhD colleague for CO. Each time a participant was to be randomised, the envelope with her participant number was opened by her or in her presence.	Low risk
Performance bias		
Blinding of participants and personnel	Participants cannot be blinded with these interventions. Of research personnel, CO as PI was not blinded, the perineometry assessors were blinded. No healthcare personnel was involved in the trial. Outcomes are likely to be influenced by lack of blinding.	High risk
Detection bias		
Blinding of outcome assessment Participant reported outcomes	Participants cannot be blinded with these interventions.	High risk

Domain	Support for judgement	Authors' judgement
External assessment	Perineometry was recorded by assessors, blinded to the group allocation. Blinding of assessors worked in all but two occasions.	Low risk
Attrition bias		
Incomplete outcome data	There was one participant exclusion after randomisation for ineligibility. This can be considered as not biasing the results as detected by blinded assessor. There was one withdrawal (of 54, 1.9%) in the experimental group with no postintervention outcome data (missing at random). There were no baseline outcome values for one participant in the comparison group for perineometry strength and endurance (missing not at random). There were five endurance values missing at random because of measurement error or ambiguity. Potential impact of missing data is assumed to be low.	Low risk
Reporting bias		
Selective reporting	Except for few incomplete outcome data, all outcomes of both groups and all cases were reported. A trial protocol and registration is available.	Low risk
Other bias		
Other sources of bias	No risk of other forms of bias identified.	Low risk

Appendix II: Participant name-number translation form

Date - included - closeout	Participant name, date of birth Address Tel, e-mail	Participant identification number	Contact form

Appendix JJ: Glossary

Accuracy	The degree to wich a measurement represents the true value (Hulley et al., 2013)
Bias	“[S]ystematic error, or deviation from the truth, in results or inferences”, “can lead to underestimation or overestimation of the true intervention effect” (Higgins and Altman, 2008, p. 188)
Concentric	Muscle contraction reducing muscle length (Farlex, 2018a)
Confounding variable (confounder)	Confounding variables are associated with the outcome and the exposure (intervention) but are not an effect of the exposure (Jager et al., 2008)
Construct validity	“[T]he degree to which a specific measuring device agrees with a theoretical construct” (Hulley et al., 2013, p. 39)
Content validity	“[E]xamines how well the measurement represents all aspects of the phenomena under study” (Hulley et al., 2013, p. 39)
Cystocele	Descent of the anterior vaginal wall (Haylen et al., 2010)
Detection bias	Systematic differences in how outcomes are assessed (The Cochrane Collaboration, 2018)
Eccentric	Muscle contracts while it is extended (Farlex, 2018b)
Face validity	“[D]escribes whether the measurement seems inherently reasonable” (Hulley et al., 2013, p. 39)
Hawthorne effect	Reactive effect to being studied (LoBiondo-Wood and Haber, 2013)
Hypertrophy	Increase in the size of muscle mass due to an increase in length and thickness of each muscle cell without an increase in the number of cells ('Muscular hypertrophy', 2007)
Interobserver variation	“[T]he amount observers vary from one another when reporting on the same material” ('Observer variation', 2008, http://medical-dictionary.thefreedictionary.com/observer+variation)
Isometric	Muscle contraction maintaining constant muscle length (Farlex, 2018c)
Mediating variable (mediator)	“[R]epresents the generative mechanism through which the focal independent variable is able to influence the dependent variable of interest” (Baron and Kenny, 1986, p. 1173)
Moderating variable (moderator)	“[V]ariable that affects the direction and/or strength of the relation between an indpendent or predictor variable and a dependent or criterion variable” (Baron and Kenny, 1986, p. 1174)

Performance bias	Systematic differences in exposure to other factors apart from the intervention of interets (The Cochrane Collaboration, 2018)
Perineometry	Vaginal manometric measurement of pelvic floor muscle pressure
Proprioception	Subconscious “internal sense of the relative position of the body’s musculoskeletal units with each other and the effort needed to move them” ('Proprioception', 2012, http://medical-dictionary.thefreedictionary.com/proprioception)
Rectocele	Descent of the posterior vaginal wall (Haylen et al., 2010)
Reflectory	“Designating or relating to an action or condition caused by an automatic response to a stimulus” (Oxford University Press, 2018, https://en.oxforddictionaries.com/definition/reflectory); also called reflexive (Farlex, 2018m)
Reflex	“[A]utomatic, involuntary response to a stimulus” ('Reflex', 2014, https://www.thefreedictionary.com/reflex)
Reflexive	See reflectory
Selection bias	“[S]ystematic difference in characteristics between those who are selected for study and those who are not” (The Cochrane Collaboration, 2018, http://community.chochrane.org/glossary#letter-S)
Social desirability bias	Tendency of research participants to give responses they believe are socially desirable instead of responses that reflect the truth to provide a better impression of themselves (Oppenheim, 2000)
Target population	Population to which results are planned to be generalisable (LoBiondo-Wood and Haber, 2013)
Vaginal atrophy (or atrophic vaginitis)	“[T]hinning, drying and inflammation of the vaginal walls” due to low oestrogen levels (Mayo Foundation for Medical Education and Research, 2018, www.mayoclinic.org/diseases-conditions/vaginal-atrophy/home/ovc-20200167)
Valsalva	“[A]ny forced expiratory effort against a closed airway, such as when an individual holds the breath and tightens the muscles in a concerted, strenuous effort to move a heavy object” ('Valsalva maneuver', 2009, http://medical-dictionary.thefreedictionary.com/Valsalva+manoever)

References

Angelo, P.H., Varella, L.R.D., de Oliveira, M.C.E., Matias, M.G.L., de Azevedo, M.A.R., de Almeida, L.M., de Azevedo, P.R.M., and Micussi, M.T. (2017) 'A manometry classification to assess pelvic floor muscle function in women', *PLoS ONE*, 12(10), p. e0187045. doi: 10.1371/journal.pone.0187045.

Baessler, K. and Kempkensteffen, C. (2009) 'Validierung eines umfassenden Beckenboden-Fragebogens für Klinik, Praxis und Forschung', *Gynäkologisch-geburtshilfliche Rundschau*, 49(4), pp. 299-307.

Baracho, S.M., Barbosa da Silva, L., Baracho, E., Lopes da Silva Filho, A., Sampaio, R.F., and Mello de Figueiredo, E. (2012) 'Pelvic floor muscle strength predicts stress urinary incontinence in primiparous women after vaginal delivery', *International Urogynecology Journal and Pelvic Floor Dysfunction*, 23(7), pp. 899-906.

Baron, R.M. and Kenny, D.A. (1986) 'The moderator–mediator variable distinction in social psychological research: conceptual, strategic, and statistical considerations', *Journal of Personality and Social Psychology*, 51(6), pp. 1173-1182.

Baytur, Y.B., Serter, S., Tarhan, S., Uyar, Y., Inceboz, U., and Pabuscu, Y. (2007) 'Pelvic floor function and anatomy after childbirth', *Journal of Reproductive Medicine*, 52(7), pp. 604-610.

Bland, J.M. and Altman, D.G. (2010) 'Statistical methods for assessing agreement between two methods of clinical measurement', *International Journal of Nursing Studies*, 47(8), pp. 931-936.

Bø, K. (2004) 'Pelvic floor muscle training is effective in treatment of female stress urinary incontinence, but how does it work?', *International Urogynecology Journal and Pelvic Floor Dysfunction*, 15(2), pp. 76-84.

Bø, K. (2015) 'Vaginal squeeze pressure measurement', in Bø, K., Berghmans, B., Mørkved, S. & Van Kampen, M. (eds.) *Evidence-based physical therapy for the pelvic floor: bridging science and clinical practice.* 2nd edn. Edinburgh: Churchill Livingstone, pp. 61-66.

Bø, K., Kvarstein, B., Hagen, R.R., and Larsen, S. (1990) 'Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: II. Validity of vaginal pressure measurements of pelvic floor muscle strength and the necessity of supplementary methods for control of correct contraction', *Neurourology and Urodynamics*, 9(5), pp. 479-487.

Bø, K., Larsen, S., Oseid, S., Kvarstein, B., Hagen, R., and Jørgensen, J. (1988) 'Knowledge about and ability to correct pelvic floor muscle exercises in women with urinary stress incontinence' [Abstract], *Neurourology and Urodynamcis*, 7(3), pp. 261-262.

Botelho, S., Pereira, L.C., Marques, J., Lanza, A.H., Amorim, C.F., Palma, P., and Riccetto, C. (2013) 'Is there correlation between electromyography and digital palpation as means of measuring pelvic floor muscle contractility in nulliparous, pregnant, and postpartum women?', *Neurourology and Urodynamics*, 32(5), pp. 420-423.

Buchheit, H. (1985) *Die vaginale Akupunktur: phylogenetische und embryogenetische Grundlagen; neurophysiologische und kulturhistorische Aspekte*. Heidelberg: Haug.

Bump, R.C., Hurt, W.G., Fantl, J.A., and Wyman, J.F. (1991) 'Assessment of Kegel pelvic muscle exercise performance after brief verbal instruction', *American Journal of Obstetrics & Gynecology*, 165(2), pp. 322-329.

Bundeskanzleramt Rechtsinformationssystem (1996) *Bundesgesetz betreffend Medizinprodukte (Medizinproduktegesetz - MPG)*. Available at:

https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003 (Accessed: 6 August 2018).

Caroci, A.d.S., Riesco, M.L.G., da Silva Sousa, W., Cotrim, A.C., Sena, E.M., Rocha, N.L., and Fontes, C.N.C. (2010) 'Analysis of pelvic floor musculature function during pregnancy and postpartum: a cohort study', *Journal of Clinical Nursing*, 19(17), pp. 2424-2433.

Chang, S.T. (1990) *Das Handbuch ganzheitlicher Selbstheilung: Handgriffe des medizinischen Tao-Systems*. Genf: Ariston.

Cheng, W.C. (1970) *Erotologie de la Chine*. Paris: Pauvert.

Chia, M. (1986) *Healing love through the Tao: cultivating female sexual energy*. Chiang Mai: Universal Tao Publications.

Chiarelli, P., Murphy, B., and Cockburn, J. (2003) 'Women's knowledge, practises, and intentions regarding correct pelvic floor exercises', *Neurourology and Urodynamics*, 22(3), pp. 246-249.

Cosner, K.R., Dougherty, M.C., and Bishop, K.R. (1991) 'Dynamic characteristics of the circumvaginal muscles during pregnancy and the postpartum', *Journal of Nurse-Midwifery*, 36(4), pp. 221-225.

Cremer, Y. (2018) *Pussy Yoga - mit dem Yoni-Ei: Kurzanleitung Beckenbodentraining mit Spass*. Available at: http://www.lovebase.com/produkt/pussy-yoga-mit-dem-yoni-ei-beckenbodentraining-mit-spass-2/ (Accessed: 26 June 2018).

Cremer, Y. (no date) *Yoni Yoga - mit dem Jade-Ei: Kurzanleitung Beckenbodentraining mit Spass.* [Leaflet obtained from author], 13 April 2017.

Dietz, H.P., Shek, K.L., Chantarasorn, V., and Langer, S.E.M. (2012) 'Do women notice the effect of childbirth-related pelvic floor trauma?', *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 52(3), pp. 277-281.

Dinc, A., Kizilkaya Beji, N., and Yalcin, O. (2009) 'Effect of pelvic floor muscle exercises in the treatment of urinary incontinence during pregnancy and the postpartum period', *International Urogynecology Journal and Pelvic Floor Dysfunction*, 20(10), pp. 1223-1231.

Dougherty, M.C., Abrams, R., and McKey, P.L. (1986) 'An instrument to assess the dynamic characteristics of the circumvaginal musculature', *Nursing Research*, 35(4), pp. 202-206.

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

Eldridge, S. and Kerry, S. (2012) *A practical guide to cluster randomised trials in health services research*. Chichester: Wiley.

Eltern Magazin Österreich (2015) 'Beckenbodenstudie in Wien', *Eltern*, (no. 6), p. 2.

Farlex, Inc. (2018a) *Concentric*. Available at: https://medical-dictionary.thefreedictionary.com/concentric (Accessed: 29 June 2018).

Farlex, Inc. (2018b) *Eccentric*. Available at: https://medical-dictionary.thefreedictionary.com/eccentric (Accessed: 29 June 2018).

Farlex, Inc. (2018c) *Isometric*. Available at: http://medical-dictionary.thefreedictionary.com/isometric (Accessed: 26 June 2018).

Farlex, Inc. (2018d) *Lithotomy position*. Available at: https://medical-dictionary.thefreedictionary.com/lithotomy+position (Accessed: 26 June 2018).

Fischer, W. and 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), pp. 208-214.

Fischer, W., Baessler, K., and Linde, A. (1996) 'Beckenbodenkonditionierung mit Vaginalgewichten – post partum und bei Harninkontinenz', *Zentralblatt für Gynäkologie*, 118(1), pp. 18-28.

Frawley, H.C., Galea, M.P., Phillips, B.A., Sherburn, M., and Bø, K. (2006) 'Reliability of pelvic floor muscle strength assessment using different test positions and tools', *Neurourology and Urodynamics*, 25(3), pp. 236-242.

Friedman, S., Blomquist, J.L., Nugent, J.M., McDermott, K.C., Munoz, A., and Handa, V.L. (2012) 'Pelvic muscle strength after childbirth', *Obstetrics & Gynecology*, 120(5), pp. 1021-1028.

Gameiro, M.O., Sousa, V.O., Gameiro, L.F., Muchailh, R.C., Padovani, C.R., and Amaro, J.L. (2011) 'Comparison of pelvic floor muscle strength evaluations in nulliparous and primiparous women: a prospective study', *Clinics*, 66(8), pp. 1389-1394.

Hahn, I., Milsom, I., Ohlsson, B.L., Ekelund, P., Uhlemann, C., and 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), pp. 269-274.

Haylen, B.T., de Ridder, D., Freeman, R.M., and Swift, S.E. (2010) 'An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction', *Neurourology and Urodynamics*, 29(1), pp. 4-20.

Higgins, J.P.T. and Altman, D.G. (2008) 'Chapter 8: Assessing risk of bias in included studies', in Higgins, J.P.T. & Green, S. (eds.) *Cochrane handbook for systematic reviews of interventions.* Chichester: Wiley-Blackwell, pp. 187-241.

Higgins, J.P.T., Altman, D.G., and Sterne, J.A.C. (2011a) 'Chapter 8: 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]*. No place: The Cochrane Collaboration. Available at: http://handbook-5-1.cochrane.org/ (Accessed: 29 July 2018).

Higgins, J.P.T., Deeks, J.J., and Altman, D.G. (2011b) 'Chapter 16: Special topics in statistics', in Higgins, J.P.T. & Green, S. (eds.) *Cochrane handbook for systematic reviews of interventions version 5.1.0 [updated March 2011]*. No place: The Cochrane Collaboration. Available at: http://handbook-5-1.cochrane.org/ (Accessed: 29 June 2018).

Hilde, G., Stær-Jensen, J., Engh, M.E., Brækken, I.H., and Bø, K. (2012) 'Continence and pelvic floor status in nulliparous women at midterm pregnancy', *International Urogynecology Journal*, 23(9), pp. 1257-1263.

Hilde, G., Staer-Jensen, J., Siafarikas, F., Engh, M.E., Braekken, I.H., and Bø, K. (2013) 'Impact of childbirth and mode of delivery on vaginal resting pressure and on pelvic floor muscle strength and endurance', *American Journal of Obstetrics & Gynecology*, 208(1), pp. 50.e1-50.e7. doi: 10.1016/j.ajog.2012.10.878.

Hooper, R. (no date) *Justifying sample size for a feasibility study*. Available at: http://www.rds-london.nihr.ac.uk/RDSLondon/media/RDSContent/files/PDFs/Justifying-Sample-Size-for-a-Feasibility-Study.pdf (Accessed: 29 June 2018).

Hulley, S.B., Cummings, S.R., Browner, W.S., Grady, D., and Newman, T.B. (2013) *Designing clinical research*. 4th edn. Philadelphia, PA: Lippincott Williams & Wilkins.

Hundley, A.F., Wu, J.M., and Visco, A.G. (2005) 'A comparison of perineometer to brink score for assessment of pelvic floor muscle strength', *American Journal of Obstetrics & Gynecology*, 192(5), pp. 1583-1591.

Jager, K., Zoccali, C., Macleod, A., and Dekker, F. (2008) 'Confounding: what it is and how to deal with it', *Kidney International*, 73(3), pp. 256-260.

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

Joshi, M., Royuela, A., and Zamora, J. (2013) 'Proper analysis in clinical trials: how to report and adjust for missing outcome data', *BJOG: An International Journal of Obstetrics & Gynaecology*, 120(8), pp. 915-919.

Jovanovic, B.D. and Zalenski, R.J. (1997) 'Safety evaluation and confidence intervals when the number of observed events is small or zero', *Annals of Emergency Medicine*, 30(3), pp. 301-306.

Kerschan-Schindl, K., Uher, E., Wiesinger, G., Kaider, A., Ebenbichler, G., Nicolakis, P., Kollmitzer, J., Preisinger, E., and Fialka-Moser, V. (2002) 'Reliability of pelvic floor muscle strength measurement in elderly incontinent women', *Neurourology and Urodynamics*, 21(1), pp. 42-47.

Kim, E.Y., Kim, S.Y., and 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), pp. 132-141.

LABORIE (2012) *Peritron owner's manual*. Canada: LABORIE.

Li, Y. (1965a) *The before midnight scholar*. London: Andre Deutsch.

Li, Y. (1965b) *Jou pu tuan: ein erotisch-moralischer Roman aus der Ming-Zeit (1633)*. Hamburg: Die Waage.

LoBiondo-Wood, G. and Haber, J. (2013) *Nursing research: methods and critical appraisal for evidence-based practice*. St. Louis, MO: Mosby.

Madill, S.J. and McLean, L. (2006) 'Relationship between abdominal and pelvic floor muscle activation and intravaginal pressure during pelvic floor muscle contractions in healthy continent women', *Neurourology and Urodynamics*, 25(7), pp. 722-730.

Marshall, K., Walsh, D., and Baxter, G. (2002) 'The effect of a first vaginal delivery on the integrity of the pelvic floor musculature', *Clinical Rehabilitation*, 16(7), pp. 795-799.

Mayo Foundation for Medical Education and Research (2018) *Vaginal atrophy*. Available at: http://www.mayoclinic.org/diseases-conditions/vaginal-atrophy/home/ovc-20200167 (Accessed: 26 June 2018).

McKey, P.L. and Dougherty, M.C. (1986) 'The circumvaginal musculature: correlation between pressure and physical assessment', *Nursing Research*, 35(5), pp. 307-309.

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

Mørkved, S. and Bø, K. (1997) 'The effect of postpartum pelvic floor muscle exercise in the prevention and treatment of urinary incontinence', *International Urogynecology Journal and Pelvic Floor Dysfunction*, 8(4), pp. 217-222.

Mørkved, S., Bø, K., Schei, B., and Salvesen, K.A. (2003) 'Pelvic floor muscle training during pregnancy to prevent urinary incontinence: a single-blind randomized controlled trial', *Obstetrics & Gynecology*, 101(2), pp. 313-319.

'Muscular hypertrophy' (2007), in *Saunders comprehensive veterinary dictionary*. 3rd edn. Available at: https://medical-dictionary.thefreedictionary.com/muscular+hypertrophy (Accessed: 29 June 2018).

Newman, D.K. and Laycock, J. (2008) 'Clinical evaluation of the pelvic floor muscles', in Baessler, K., Schüssler, B., Burgio, K.L., Moore, K.H., Norton, P.A. & Stanton, S.L. (eds.) *Pelvic floor re-education: principles and practice.* London: Springer, pp. 91-104.

Nielsen, C.A., Sigsgaard, I., Olsen, M., Tolstrup, M., Danneskiold-Samsoee, B., and Bock, J.E. (1988) 'Trainability of the pelvic floor. A prospective study during pregnancy and after delivery', *Acta Obstetricia et Gynecologica Scandinavica*, 67(5), pp. 437-440.

Norton, P. (2014) E-mail to Claudia Oblasser. 27 May.

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

'Observer variation' (2008), in *Mosby's dental dictionary*. 2nd edn. Available at: http://medical-dictionary.thefreedictionary.com/observer+variation (Accessed: 26 June 2018).

Oppenheim, A.N. (2000) *Questionnaire design, interviewing and attitude measurement*. 2nd edn. London: Pinter Publishers.

Oxford University Press (2018) *Reflectory*. Available at: https://en.oxforddictionaries.com/definition/reflectory (Accessed: 17 September 2018).

Peschers, U.M., Gingelmaier, A., Jundt, K., Leib, B., and Dimpfl, T. (2001) 'Evaluation of pelvic floor muscle strength using four different techniques', *International Urogynecology Journal and Pelvic Floor Dysfunction*, 12(1), pp. 27-30.

Peschers, U.M., Schaer, G.N., DeLancey, J.O., and Schuessler, B. (1997) 'Levator ani function before and after childbirth', *British Journal of Obstetrics and Gynaecology*, 104(9), pp. 1004-1008.

'Proprioception' (2012), in *Segen's medical dictionary*. Available at: http://medical-dictionary.thefreedictionary.com/proprioception (Accessed: 29 June 2018).

Rahmani, N. and Mohseni-Bandpei, M.A. (2011) 'Application of perineometer in the assessment of pelvic floor muscle strength and endurance: a reliability study', *Journal of Bodywork & Movement Therapies*, 15(2), pp. 209-214.

Ratamess, N.A. (2012) *ACSM's foundations of strength training and conditioning*. Philadelphia, PA: Wolters Kluwer Health/Lippincott Williams & Wilkins.

'Reflex' (2014), in *The American heritage® student science dictionary*. 2nd edn. Available at: https://www.thefreedictionary.com/reflex (Accessed: 18 September 2018).

Reilly, E.T.C., Freeman, R.M., Waterfield, M.R., Waterfield, A.E., Steggles, P., and Pedlar, F. (2002) 'Prevention of postpartum stress incontinence in primigravidae with increased bladder neck mobility: a randomised controlled trial of antenatal pelvic floor exercises', *BJOG: An International Journal of Obstetrics & Gynaecology*, 109(1), pp. 68-76.

Sheng, W.-s. (1963) *Erotologie de la Chine: Tradition chinoise de l'érotisme*. Paris: Pauvert.

Sheng, W.-s. (1966) *Die Erotik in China*. Basel: Desch.

Sigurdardottir, T., Steingrimsdottir, T., Arnason, A., and Bø, K. (2009) 'Test–retest intra-rater reliability of vaginal measurement of pelvic floor muscle strength using Myomed 932', *Acta Obstetricia et Gynecologica Scandinavica*, 88(8), pp. 939-943.

Sigurdardottir, T., Steingrimsdottir, T., Arnason, A., and Bø, K. (2011) 'Pelvic floor muscle function before and after first childbirth', *International Urogynecology Journal*, 22(12), pp. 1497-1503.

Talasz, H., Himmer-Perschak, G., Marth, E., Fischer-Colbrie, J., Hoefner, E., and Lechleitner, M. (2008) 'Evaluation of pelvic floor muscle function in a random group of adult women in Austria', *International Urogynecology Journal Pelvic Floor Dysfunction*, 19(1), pp. 131-135.

Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L.P., Robson, R., Thabane, M., Giangregorio, L., and Goldsmith, C.H. (2010) 'A tutorial on pilot studies: the what, why and how', *BMC Medical Research Methodology*, 10, p. 1. doi: 10.1186/1471-2288-10-1.

The Analysis Factor (2018) *How to diagnose the missing data mechanism*. Available at: https://www.theanalysisfactor.com/missing-data-mechanism/ (Accessed: 26 June 2018).

The Cochrane Collaboration (2018) *Glossary*. Available at: http://community.cochrane.org/glossary (Accessed: 11 August 2018).

Thibault-Gagnon, S., Yusuf, S., Langer, S., Wong, V., Sheck, K.L., Martin, A., and Dietz, H.P. (2014) 'Do women notice the impact of childbirth-related levator trauma on pelvic floor and sexual function? Results of an observational ultrasound study', *International Urogynecology Journal*, 25(10), pp. 1389-1398.

Tickle-Degnen, L. (2013) 'Nuts and bolts of conducting feasibility studies', *American Journal of Occupational Therapy*, 67(2), pp. 171-176.

'Valsalva maneuver' (2009), in *Mosby's medical dictionary*. 9th edn. Available at: http://medical-dictionary.thefreedictionary.com/Valsalva+maneuver (Accessed: 29 June 2018).

Wikipedia (2018) *Ben Wa balls*. Available at: https://en.wikipedia.org/wiki/Ben_Wa_balls (Accessed: 26 June 2018).

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

Zizzi, P.T., Trevisan, K.F., Leister, N., Cruz, C.d.S., and Riesco, M.L.G. (2017) 'Women's pelvic floor muscle strength and urinary and anal incontinence after childbirth: a cross-sectional study', *Revista da Escola de Enfermagem da USP*, 51, p. e03214. doi: 10.1590/s1980-220x2016209903214.