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.

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

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	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 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 hour

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
Contact for Public Queries	Claudia Oblasser School of Health Sciences City University London 1 Myddelton Street London EC1R 1UW Tel: +(0) 20 7040 8337 E-mail: claudia.oblasser.1@city.ac.uk

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 balls are 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
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