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### 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

<table>
<thead>
<tr>
<th>Variable(s)</th>
<th>Timepoint</th>
<th>Method of collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility variables (see criteria in table 2)</td>
<td>Throughout study and at the end of trial data collection</td>
<td>Calculation</td>
</tr>
<tr>
<td>Staff, time, and budget necessary</td>
<td>Throughout study</td>
<td>Noting down in a list, calculation</td>
</tr>
<tr>
<td>Baseline variables</td>
<td>Before the intervention</td>
<td>Structured interview</td>
</tr>
<tr>
<td>Participant reported pelvic floor outcome measures</td>
<td>Before and after the intervention</td>
<td>Structured questionnaire to be completed by participant</td>
</tr>
<tr>
<td>Technically assessed pelvic floor muscle performance</td>
<td>Before and after the intervention</td>
<td>Physiological measurement by perineometry</td>
</tr>
<tr>
<td>Women’s perspectives and experiences</td>
<td>Before and after the intervention OR after the intervention</td>
<td>Structured interview OR structured anonymous questionnaire</td>
</tr>
<tr>
<td>Concordance</td>
<td>Throughout study</td>
<td>Training diary</td>
</tr>
<tr>
<td>Adverse events/harm</td>
<td>Throughout study</td>
<td>Phone interviews, question in final interview/survey, self-reporting by participants</td>
</tr>
</tbody>
</table>
Table 4: Schedule of enrolment, interventions, and assessments

<table>
<thead>
<tr>
<th>Study period</th>
<th>Enrolment</th>
<th>Allocation</th>
<th>Post-allocation</th>
<th>Close-out</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-t3</td>
<td>-t2</td>
<td>-t1 not before six weeks after birth</td>
<td>0 = -t1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7-10 days after -t3</td>
<td></td>
<td>t1 = -t1/0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>t2 within 2 weeks of t1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>t3-t7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>t8 within 2 weeks after ending the intervention</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>t9 within 2 weeks after ending the intervention</td>
</tr>
</tbody>
</table>

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

Perineometry

b

Interviews OR questionnaire

a

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
| Primary Registry and Trial Identifying Number | www.clinicaltrials.gov  
                             NCT02355327 |
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Date of Registration in Primary Registry</td>
<td>January 2015</td>
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</tbody>
</table>
| 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) |
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<table>
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<tr>
<th>Contact for Scientific Queries</th>
<th>As above</th>
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<tbody>
<tr>
<td><strong>Public Title</strong></td>
<td>Feasibility study on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth [translated from German]</td>
</tr>
<tr>
<td><strong>Scientific Title</strong></td>
<td>Feasibility trial on the effectiveness of vibrating vaginal balls to improve pelvic floor muscle performance in women after childbirth</td>
</tr>
<tr>
<td><strong>Country of Recruitment</strong></td>
<td>Austria</td>
</tr>
<tr>
<td><strong>Health Condition or Problem Studied</strong></td>
<td>Pelvic floor health after childbirth</td>
</tr>
</tbody>
</table>
| **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 care.
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.

<table>
<thead>
<tr>
<th>Key Inclusion and Exclusion Criteria</th>
<th>See table 1</th>
</tr>
</thead>
</table>
| Study Type and Design | Study type: interventional  
Allocation: randomised  
Intervention Model: parallel assignment  
Masking: single blind (outcome assessor)  
Purpose: feasibility trial |
<p>| 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) |</p>
<table>
<thead>
<tr>
<th>Feasibility as measured by pre intervention pelvic floor muscle measurement attendance rate (Timepoint: within 4 weeks of ending data collection)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility as measured by start of intervention rate (Timepoint: within 4 weeks of ending data collection)</td>
</tr>
<tr>
<td>Feasibility as measured by concordance rate (Timepoint: within 4 weeks of ending data collection)</td>
</tr>
<tr>
<td>Feasibility as measured by retention rate (Timepoint: within 4 weeks of ending data collection)</td>
</tr>
<tr>
<td>Feasibility as measured by post intervention data collection attendance rate (Timepoint: within 4 weeks of ending data collection)</td>
</tr>
<tr>
<td>Feasibility as measured by staff necessary (Timepoint: within 4 weeks of ending data collection)</td>
</tr>
<tr>
<td>Feasibility as measured by time necessary (Timepoint: within 4 weeks of ending data collection)</td>
</tr>
<tr>
<td>Feasibility as measured by budget necessary (Timepoint: within 4 weeks of ending data collection)</td>
</tr>
</tbody>
</table>
| 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 |