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

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.

Trial registration. ClinicalTrials.gov: NCT02355327.

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

Keywords

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

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 (O'Reilly et al., 2009, Hägglund and Ahlström, 2007, Margalith et al., 2004).

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 three months postpartum, 33% of women are reported to experience urinary incontinence, with small changes over the first year post partum (Thom and Rortveit, 2010). Faecal and flatal incontinence were reported by 10% and up to 24% of women respectively at six weeks after delivery (Borello-France et al., 2006, Hall et al., 2003), and by 1% and 26% of women at nine 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. A number of studies found that the pelvic floor muscles of urinary continent women performed better than those of incontinent women (Hahn et al., 1996, Baracho et al., 2012, Mørkved et al., 2004, Hilde et al., 2013, Bø, 2003). Pelvic floor muscle weakness may also be a factor contributing to anal incontinence and pelvic organ prolapse (Sahlin and Berner, 2007, Mørkved, 2007, Koelbl et al., 2013, Bø and Frawley, 2007) .

Irrespective of pelvic floor symptoms, a reduced pelvic floor muscle performance after vaginal delivery was demonstrated in the short (Baytur et al., 2007, Marshall et al., 2002, Hilde et al., 2013, Sigurdardottir et al., 2011) 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 and 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 and 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 and 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) 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 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:

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

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

i. 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.
ii. 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 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 28g (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 within 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 within 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) 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., 1990b, Frawley et al., 2006, Bø et al., 1990a, Hundley et al., 2005). 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 one and two 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 within 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 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, acces 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^{TM} (from Laborie) does not have a CE mark. However, the Peritron^{TM} 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 the balls, 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, Williams and Lecouturier, no year, *Feasibility and Pilot Studies*, 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 and 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 – within 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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