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Investigating and Designing the Appearance of a Device for Facilitating Pelvic Floor Exercises: A Case Study on Design Sensitivity for Women's Healthcare

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Abstract

Pelvic floor disorder (PFD) refers to a weakened or damaged muscle structure affecting the self-esteem, confidence and social participation of affected women. With appropriate training, the weakened muscles can be strengthened, but for a long-term improvement the women need to be actively engaged in the process. While there exists a range of devices that can intra-vaginally measure pelvic floor activation and help women do their exercises, it is unclear how the appearance of the devices may affect women's willingness to use them. We believe that a further understanding around the appearance of these devices may help women feel more comfortable using them, therefore helping them care for their health. We carried out interviews and online questionnaires with women (n:70) who use the devices and clinicians (n:4). We report on identified areas where the appearance of devices is important for women. We present the iterative design process and evaluation of a system aimed at facilitating self-directed pelvic floor management based on this research. We suggest that discrepancies in the responses from participants call for personalisation of the device to meet individual user expectations and increase the design sensitivity when designing for smart devices that help women care for their health.

Keywords: pelvic floor disorder, PFD, iterative design, design system, health, engagement, pelvic floor muscle training, PFMT, appearance, design and emotion, semantics of form

1. Introduction

Pelvic floor disorders (PFDs) can affect up to 44% [1] of all women and symptoms like urinary incontinence (UI) can have a significant effect on self-esteem, confidence and social

participation [2]. Pelvic floor muscle training (PFMT) is the first-line conservative management programme for women experiencing PFD.

The condition is a significant healthcare concern for the affected women and has a variety of causes such as childbirth and ageing. A recent study showed that even women who do not show any symptoms do not always know how to contract the muscles correctly [3]. Reports suggest that 70% of women are unable to perform correct voluntary PFM contractions and 97% of them showed low PFM strength [3]. PFMT can increase strength and endurance, particularly when coupled with behavioural training [4–6].

There are some devices in the market that help women carry out their PFMT. The devices detect the pressure applied by the pelvic floor muscles through an intra-vaginal physical device with pressure sensors that communicate via Bluetooth to a mobile app [7]. Existing devices include the LOOP [8], the SKEA [9], the KGoal [10], the PeriCoach [11], Elvie [12] and the Kegel smart [13]. While the use of these devices has been reported as helpful, their uptake has been slow and there seem to be barriers to their adoption [7]. Currently, there is no literature that reports on how the appearance of the devices may help women feel more comfortable in using them or help them understand its use, particularly in this area where education about its correct use is essential.

There are models that can be used to increase the patient's engagement to therapies. The IMS model recommends three steps: (1) information about the condition and how to adhere, (2) motivation to participate in the training and (3) a strategy to overcome practical treatment barriers to treatment adherence and incorporate the training into a daily routine [14]. We used this model to assess women's experience with PFMT and how they perceive the appearance of devices.

2. Methods

We analysed online commentary from PFD forums, carried out semi-structured interviews (45 min) and questionnaires (A, 20 min) with health professionals (three pelvic floor physiotherapists and one urogynecologist) and women with self-reported PFD (n:70; New Zealand = 24, USA = 22, UK = 13, Australia = 5, Canada = 4, Taiwan = 1, France = 1), ages 20–69 (median 35). A total of 54 women had children. We asked clinicians to describe the process for prescribing and monitoring PFMT and the main issues they have found for women using PFD devices. We asked women to describe their overall experience of using PFD devices, including how and how often they use them and any issues they have found with them.

We defined a set of design criteria through a thematic analysis of all the data and we used an iterative research-through-design process [15] to arrive to a testable physical device and mobile app. We asked women to watch a 5-min presentation that explained our design concept through video and to answer a second online survey (B, 15 min).

3. Results

We coded the findings from the literature review, online forums, semi-structured interviews and questionnaires with health professionals and women with self-reported PFD using NVivo (Figure 1). Below we present a deductive thematic analysis based on the IMS model and the responses from participants.

3.1. Information barriers

3.1.1. Female anatomy

A lack of information about female anatomy can be a significant barrier in the process of women carrying out PFMT or using devices. Women often do not understand their own anatomy, are unable to locate genital openings correctly, and may feel unreceptive to looking and touching their own genitals.

For many ladies that area of their body is still quite sort of shameful and unknown and so I take the view that for a lot of women they have not learnt anything about their body anatomically since year 7 science when it was embarrassing to say the words penis and vagina at school. (Clinician 04)

I show them what their anatomy is like cause a lot of women have never looked at themselves. They don't know where the muscles are – so I point out the hip bone the pelvic bone and the

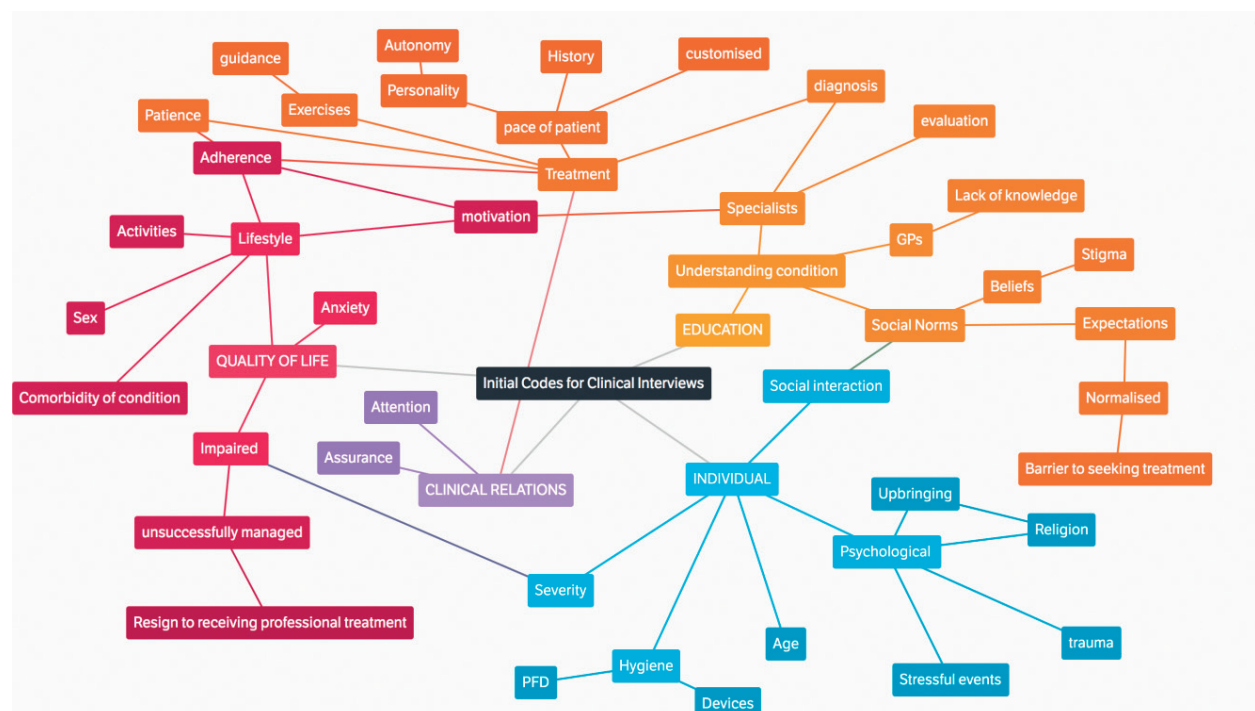


Figure 1. Initial codes from analysis of interviews with health professionals and women with PFD.

tailbone, I show them that the pelvic floor sits down here and wraps around inside and that it's not just some muscles sitting down there. Then I've got fairly basic pictures. Unless they have a medical background then I'd show them a more anatomical one. (Clinician 02)

3.1.2. Appearance: clinical or like a sex toy?

Even though some clinicians use medical equipment that they rent out to women, one mentioned that sometimes sex toys get already used to relax the pelvic floor: "I buy the devices and then people borrow them off of me – I will give them out." (Clinician 01); "there are some people who actually use vibrators to relax the pelvic floor." (Clinician 02). The women favoured discreteness in form along with ease and simplicity of use. Comments given about the performance of the devices included, "good enough to lessen physical symptoms" and in turn reduce psychological distress. Some disliked their devices being too "clinical" in appearance. However, some women expressed that they did not want their device to appear too much like a sex toy because if features were too strongly associated with it, this would create a sense of psychological awkwardness for the user: "Don't like that it's so clinical, something more shapely [sic] without crossing into sex toy territory would perhaps make it less of an awkward experience." (Participant 04).

3.1.3. Muscle awareness and metaphors

Being able to contract the right muscles is determined by a muscle awareness that the women need to establish [4]. This muscle awareness can be difficult to develop due to the 'hidden location' of the muscles and lack of intrinsic feedback. Clinicians often use metaphors to teach women how to locate and move those muscles: "Going up in the lift... Puddle of water – sucking it in..." (Clinician 01).

3.2. Motivation barriers

3.2.1. Stigma and emotional responses

Clinicians pointed out that women can feel uncomfortable using an internal device. Reasons are the location where the device needs to be placed as well as the associated stigma with PFD conditions such as UI and faecal incontinence. Some women say: "Oh I don't like to poke those things inside of me in case I get an infection" (Clinician 01).

It was mentioned that women tend to be hesitant to talk about the condition and that once they have developed a feeling of trust they start opening up and talk about their symptoms:

And their GPs had sort of brushed them off. 'Oh, you know, it's just you. You just have to put up with it' you know, they trivialised it to them whereas, it's not trivial." (Clinician 03). Also, "It's just developing trust as well, people trusting you enough to say whatever the problem is, and I think when I realised there were so many people with those issues". (Clinician 01)

As expected, more negative feelings than positive tend to be associated with the experience of having a PFD. Words such as "embarrassed" and "frustrated" were commonly used. Negative

feelings contribute to the development of stigma as well as perpetuating these feelings when a condition has a stigma attached to it. Some women were worried their children might play with the device if they found it.

3.2.2. Ease of use

Respondents mentioned how some existing devices are difficult to learn to use:

The instructions are not clear. I have used this thing only once. A diagram would be helpful to show the correct way to insert the probe. Does it matter if the metal part is against the pelvic floor or to the wall of the vagina? (Participant 04)

3.3. Design process

3.3.1. Design criteria

We defined set of design criteria for the form of the device and the app based on the different IMS themes. The form of the device should:

- a. clearly indicate how it should be inserted and how it needs to be positioned, this may be done through familiar/related objects (tampons, sanitary pads, etc.) (information)
- b. avoid the threatening appearance of some current devices (motivation)
- c. express a high level of performance and professionalism that gives women reassurance (information, motivation)
- d. avoid perpetuating the stigma of doing PFMT (information and motivation).
- e. investigate the responses of looking medical or like a sex toy (motivation)

The app should:

- f. teach women about their anatomy (information)
- g. relate to metaphors women or clinicians use to carry out their exercises to facilitate muscle awareness (information)
- h. present steps for carrying out exercises that use engagement principles from games and psychology (motivation)
- i. present the exercises in an order and form that allows women to learn the right way of doing exercise and increase intensity (strategy)
- j. develop a sense of trust through facilitating communication with clinician (motivation).

3.3.2. Design experiments

We developed different prototypes in an iterative process to address the criteria above (Figures 2–10).



Figure 2. Early form iterations that investigate criteria (a): forms to insert and position the device (bottom sides) and to hold it (top parts). For instance, the first form on the left has an elongated loop at the bottom that is slightly open, and closes when inserted and when applying pressure to it. The second and fourth shapes from the right intend to indicate that the bottom part is insertable by having shapes at the top that would be very difficult to insert.



Figure 3. Form iterations based on the shape of a tampon to indicate how to insert the device through the form of a familiar object (criteria (a)).

3.3.3. Testable design

The app and device we tested through online survey B is part of a system (**Figure 11**). The physical device has two parts. The slim top part is insertable and contains the array of sensors that had been developed by our engineering collaborators (**Figure 12**). This part has two states: a slim and minimally intimidating form for the insertion and an expanded form to secure the device once inserted that activates through bending the device into place (**Figure 8**). The wider part contains the electronic components. The app teaches women about their anatomy and



Figure 4. Colour variations based on devices that are currently available.



Figure 5. Experiments with an outer part that can be placed between the body and underwear to secure a stable position once the device is inserted.

creates an individualised programme based on the initial calibration of the device, which works as an assessment of the condition too.

3.4. Assessment of the testable design

Our initial findings suggested that the appearance of a device does not only involve a sense of aesthetics, but it should also communicate important issues for women that included: how



Figure 6. Iterations of regular and irregular patterns that guide the user during the insertion through tactile feedback offered by the form of the device and its texture. The textures also intend to mimic jewellery to minimise stigma (criteria (b) and (d)).

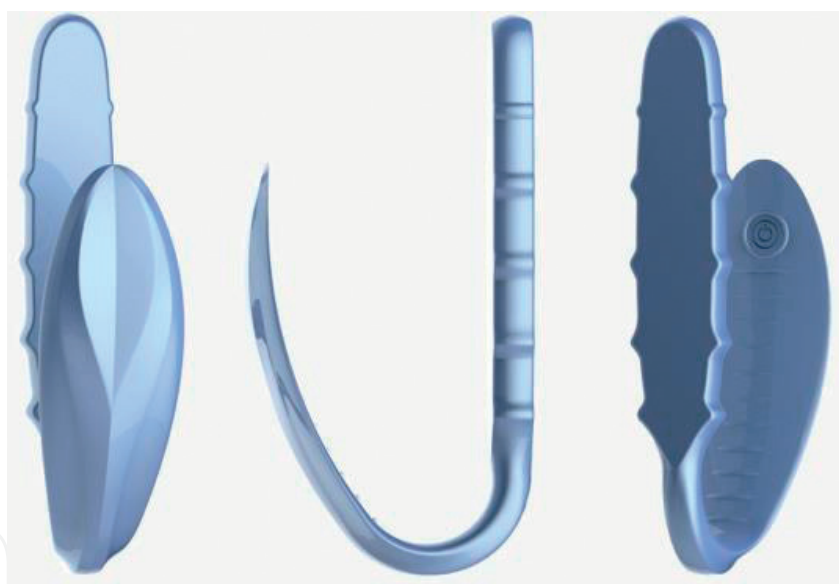


Figure 7. Once the device is placed at the right position it needs to be stable during the training. One of our iterations investigated how small wings appear once the top is bent to stabilise the device.

intuitive it is to use, how professionally it will treat women and their condition, how the sensors work and where they should be placed.

Positive feedback included the quantifiable results (“quantifiable results would be incredibly helpful”, participant 4), ease of use, and the immediate assessment and feedback that the system offers during training. Some participants requested a colourful appearance while others found the paler colour more appealing. Participants understood the value of

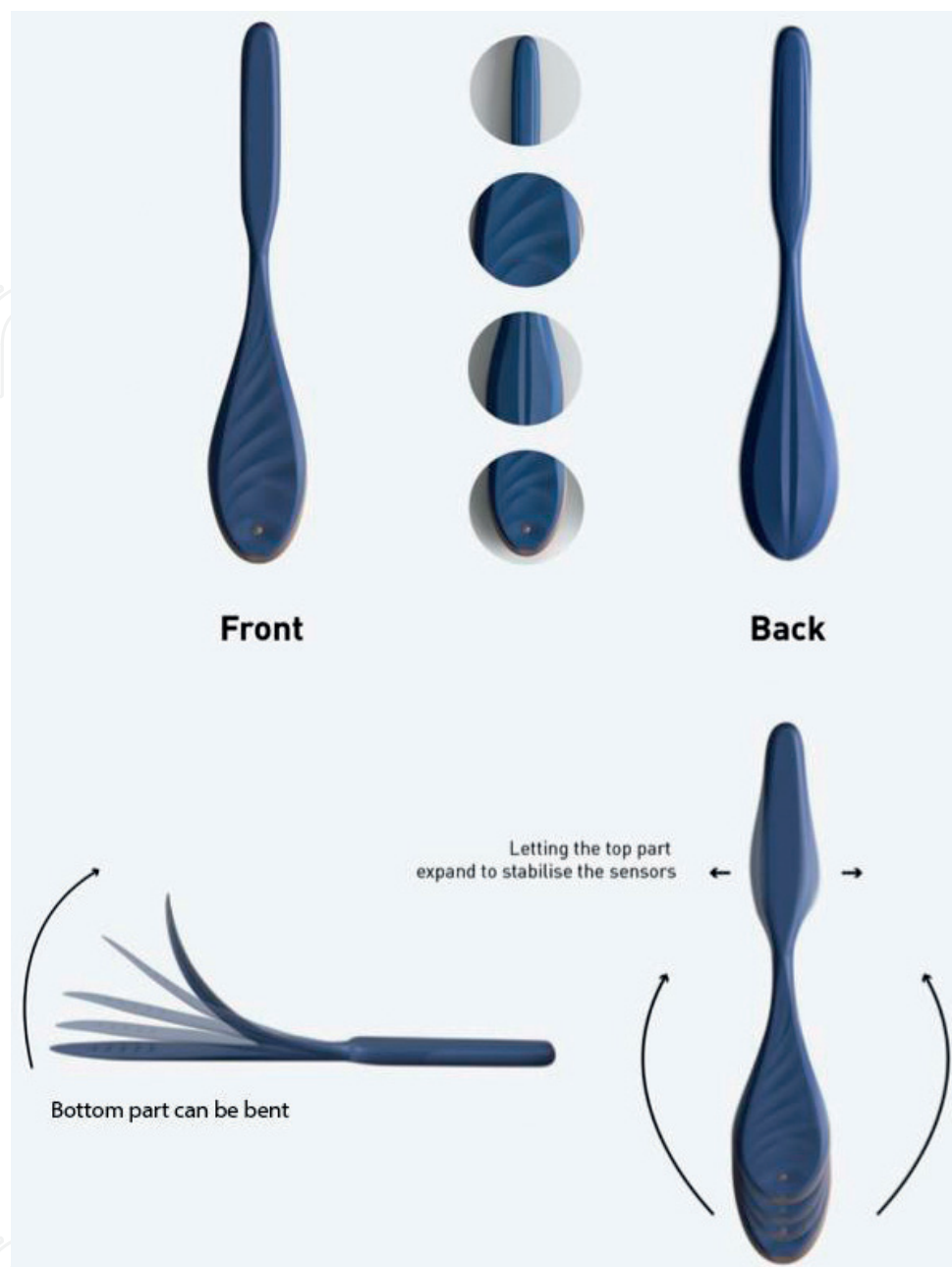


Figure 8. Bending of the bottom part to stabilise the sensors (by becoming wider) while looking as little threatening as possible (small and thin) when it needs to be inserted (criteria (b)).

including sensors: “[I like] that it shows how strong the muscles are and if you're using the wrong ones” (participant 6). Other participants liked its discreetness: “I like that it is discrete and quite private, with the training times set to suit the user” (participant 1). A participant was worried about whether the device would sit on her clitoris.

3.5. Final design

We used the feedback to define a final iteration of the design (**Figure 13**).

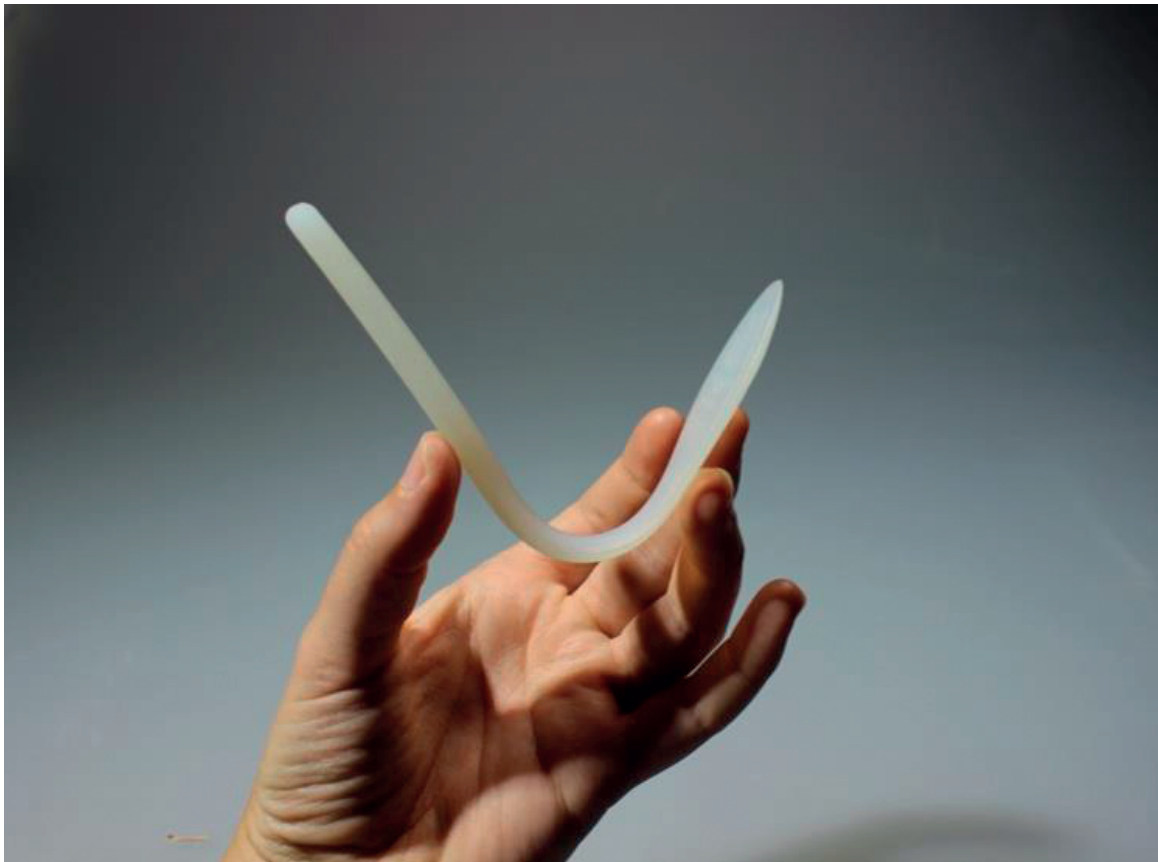


Figure 9. 3D printed prototype to test bending.



Figure 10. Tests with different materialities looking for a high performance and professional feeling (criteria (c)).

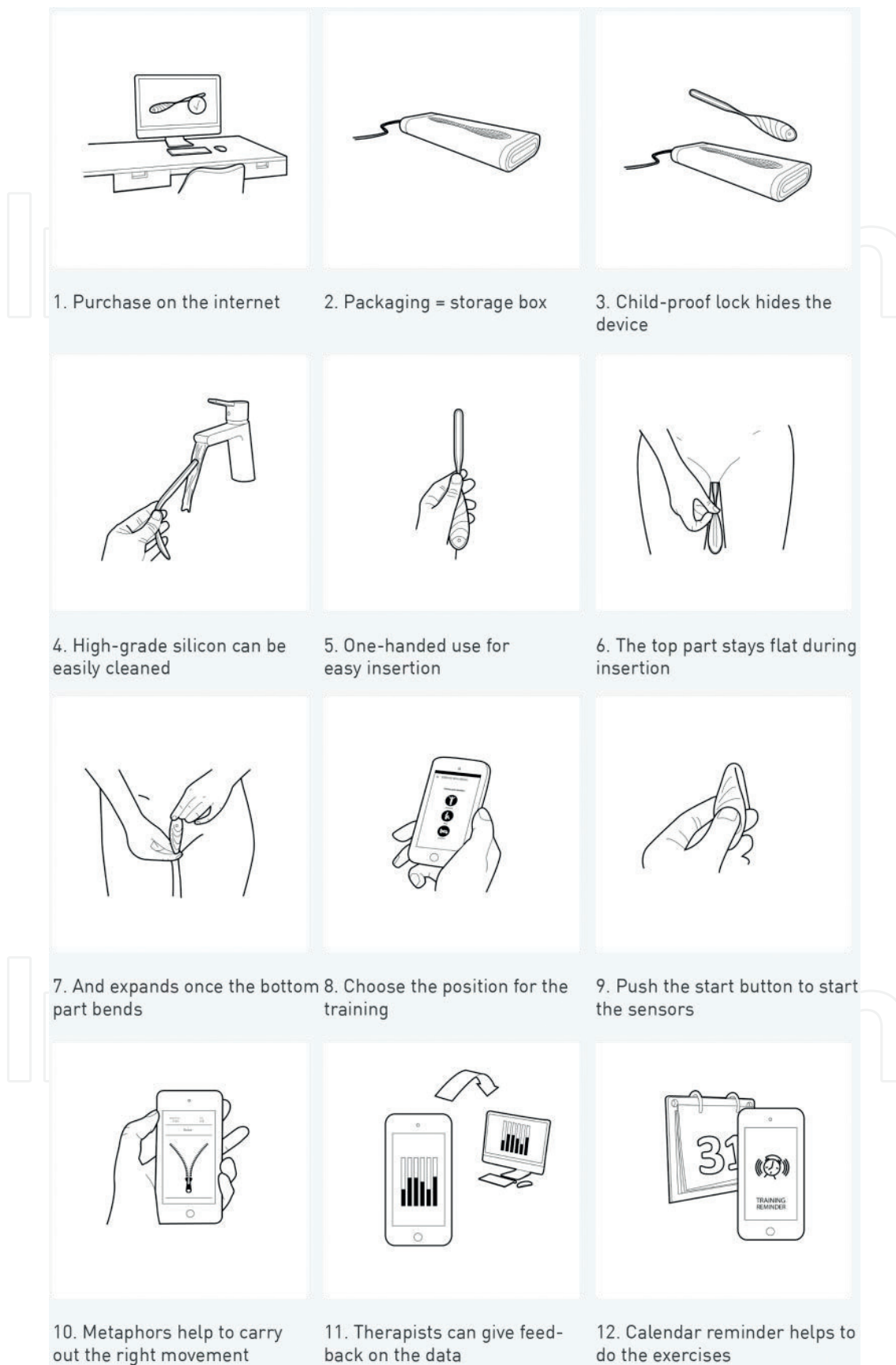


Figure 11. User scenario.



Figure 12. The physical device we tested with participants.



Figure 13. A render of the final design based on feedback from users.

4. Discussion

Women who experience PFD are a diverse user group. Depending on the severity of the disorder they can have different symptoms, be from different age groups, experience a significant degree of shame and stigma, and the dimensions of the human vagina can differ significantly. All of these questions the assumption that one device fits all [16].

Women reported different expectations on how such an intimate device should look. User feedback indicates a discrepancy of expectations concerning the visual aesthetic of such an intimate device. There were some women assessing our design who wanted it to look like a medical device while other would prefer it to be more playful and even resemble and be used as a sex toy. We suggest that further research is necessary to investigate the motivations behind these preferences and how designs may address it. Further studies could investigate from a design perspective where form-wise lies the tipping point between clinical device and sex toy; build functional prototypes and test them with women in order to assess the usability and interaction with the device over long-term use.

5. Conclusion

This paper reports on what factors should influence the physical appearance of an intra-vaginal device to help women carry out pelvic floor exercises. A review of the literature, interviews and questionnaires with clinicians and women with PFD helped us develop a set of criteria that we used to design a device and app for PFMT. User feedback indicates that there are different expectations about the aesthetics of such an intimate device. This discrepancy in expectations and the fact that the range of disorders and users can differ rather significantly suggest that individualising the device might be an appropriate strategy to address the demands of this diverse user group.

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