

SELF-REPORTED CHANGES IN PELVIC FLOOR TRAINING FREQUENCY AND INCONTINENCE SYMPTOMS WITH THE INTRAVAGINAL ELVIE DEVICE

Hypothesis / aims of study

Elvie is a commercially available intravaginal pelvic floor exercise device (see Figure 1). It contains a force-sensitive resistor and accelerometer, to simultaneously measure users pelvic floor contraction and motion. The device connects to a smartphone via Bluetooth and an associated application provides users with biofeedback and guidance on pelvic floor muscle training (PFMT) exercises. Users can set notifications to encourage PFMT frequency. The device has potential as an adjunct or alternative to supervised PFMT.

We conducted a web survey of current users of the device in the United States (US) and United Kingdom (UK) aiming to better understand the demographics of users of PFMT devices, gauge user attitudes towards the Elvie, and determine if users perform PFMT more often with Elvie. We further investigated the odds of self-reported improvement in stress urinary incontinence (SUI) symptoms from the use of Elvie, dependent on duration and frequency of use.



Figure 1: the Elvie device

Study design, materials and methods

The questionnaire was sent to US- and UK-based user email addresses, attached to Elvie accounts from which user consent had been given to receive communications from the company. We incentivised user participation through the opportunity to enter a prize draw for a 150GBP/200USD retail voucher on questionnaire completion. Prior to taking the questionnaire, users were informed on how their data would be used and that their responses would remain anonymous. It was not compulsory to answer any questions relevant to symptoms to complete the survey and no identifying data were collected.

Items asked included demographics (age, parity, age of youngest child, if currently pregnant), motivations (frequency of PFMT before and after using Elvie device, main motivation to purchase) and invited general feedback. Users who answered "Improve bladder control" or "Prevent bladder problems in the future" to the question regarding main motivation to purchase were invited to answer questions from the ICIQ-UI short form questionnaire on urinary incontinence symptoms and experience, and a Global Perception of Improvement (GPI)[1] question on improvement of condition with Elvie. All respondents were invited to answer the Net Promoter Score (NPS) question on satisfaction: 'How likely is it that you would recommend Elvie to a friend or colleague?' (responses '0' (not at all likely) through '10' (extremely likely)).

Frequency of performance of pelvic floor exercise was assessed by two questions: "How frequently did you do pelvic floor exercise before using Elvie?" and "How frequently do you do pelvic floor exercise now that you have an Elvie?", both of which had options: "Never", "Rarely", "At least once a month", "At least once a week", "At least three times a week", and "At least once a day". Statistical significance of the difference in resulting proportions was assessed via a chi-square contingency test.

Respondents who filled out the ICIQ-UI questionnaire were assessed for symptoms of SUI via the frequency and amount of leakage, and the conditions under which urine leaked. For these respondents, duration of use was segmented into intervals ([0, 2) months, [2, 4) months, and [4, 6) months), and frequency into bins ("Rarely" or "At least once a month", "At least once a week", and "At least three times a week" or "At least once a day") to improve sample sizes. Multiple logistic regression was used to determine relationships between these variables and the odds of respondents reporting improvement in the GPI question.

Results

Data analysed are from the first 417 users to complete the survey. The median age of survey respondents was 39 years (interquartile range 33-49 years). 33.5% of respondents were nulliparous, 25.0% were primiparous, and 41.5% multiparous. Median parity was 1 (interquartile range 0-2). Of the respondents who had children, 46% had not given birth for at least 10 years. 9.5% had had a child within the previous 6 months. 6.5% of respondents answered that they were currently pregnant.

All 417 participants answered the questions regarding how frequently they performed PFMT. Prior to purchasing Elvie, the modal answer was "Rarely" and 25.9% of respondents reported exercising at least once per week. After purchasing Elvie, the modal response was "At least three times a week" and 77.0% of participants reported exercising more than once per week. The proportions of responses were found to be significantly different ($p < 0.001$) between the two questions. The modal pairwise difference in the rank of responses was found to be +1 rank. The modal combination of answers was "Rarely" before receiving Elvie and "At least three times a week" after receiving Elvie (14.6%), followed by "Rarely" before receiving Elvie and "At least once a week" after receiving Elvie (11.8%).

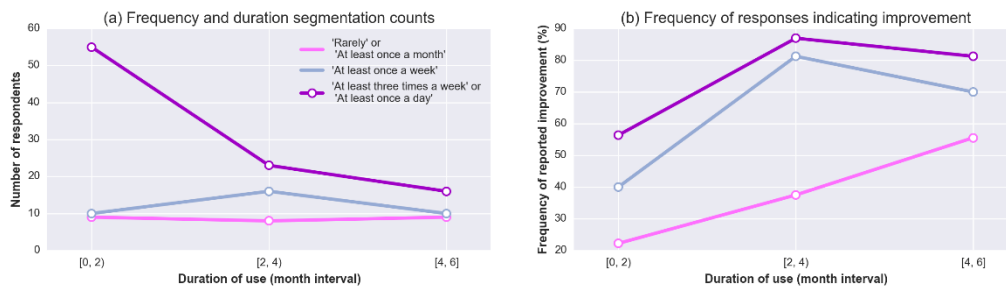


Figure 2: (a) Counts of binned duration and frequency segmentations, and (b) frequency of any reported improvement.

Results of the number of respondents and proportions of reported improvement in SUI symptoms are shown in Figure 2 after segmentation by time duration and frequency of use. After filtering, 156 respondents remained. Among these, the percentage of respondents who reported an improvement in symptoms (gauged by selecting either “A little better” or “Very much better”) was 62.8%, while the proportion who answered “Very much better” was 10.3%. Multiple logistic regression revealed a statistically significant relationship between odds of improvement and duration of use ($p=0.001$), with an odds ratio of 2.24 per duration segment (95% CI: 1.4-3.7). A statistically significant relationship was found between odds of improvement and frequency of use ($p=0.002$), with an odds ratio of 2.17 (95% CI: 1.34-3.51) per frequency segment. Across all respondents, 67.8% of respondents indicated a high degree of satisfaction with the device (NPS score of 8 or more).

Interpretation of results

Respondents report more frequent performance of PFMT after purchasing an Elvie compared to prior to purchase, suggesting that Elvie motivates users to exercise more frequently. However, this result is based on self-reported data and is likely to be subject to bias. Statistically significant relationships in the odds of improvement were found with both duration and frequency of use, indicating that Elvie users are more likely to see improvements given more time or an increase in frequency.

Concluding message

Using questionnaire results from 417 users of a commercially available PFMT device, we assessed the impact of the device on frequency of PFMT and its benefits. Our findings resonate with literature on the effectiveness of biofeedback as an adjunct to PFMT[2]. Future work is needed on the impact of baseline incontinence severity on improvement rate, and to compare training with an Elvie with conventional supervised PFMT.

References

1. Burgio, K. L., Goode, P. S., Richter, H. E., Locher, J. L., & Roth, D. L. (2006). Global ratings of patient satisfaction and perceptions of improvement with treatment for urinary incontinence: Validation of three global patient ratings. *Neurourology and Urodynamics*, 25(5), 411–417.
2. Imamura M., Abrams P., Bain C., et al. (2010). Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence. *Health Technology Assessment*, 14(40):1–188.

Disclosures

Funding: Jack Coggins and Hannah Rose Thomson are employed by Chiaro Technology Ltd., the manufacturer of Elvie. **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** Data were routinely collected for product development purposes. **Helsinki:** Yes **Informed Consent:** Yes