

KegelSmart™ clinical trial

Conducted by Dr. Debra Wickman MD FACOG and Banner
University Medicine Institute: Phoenix Arizona



The most thorough clinical trial in the world
conducted for a pelvic floor biofeedback device:

49

women

12

weeks

100%

improved pelvic floor*

* Measured with a clinical perineometer



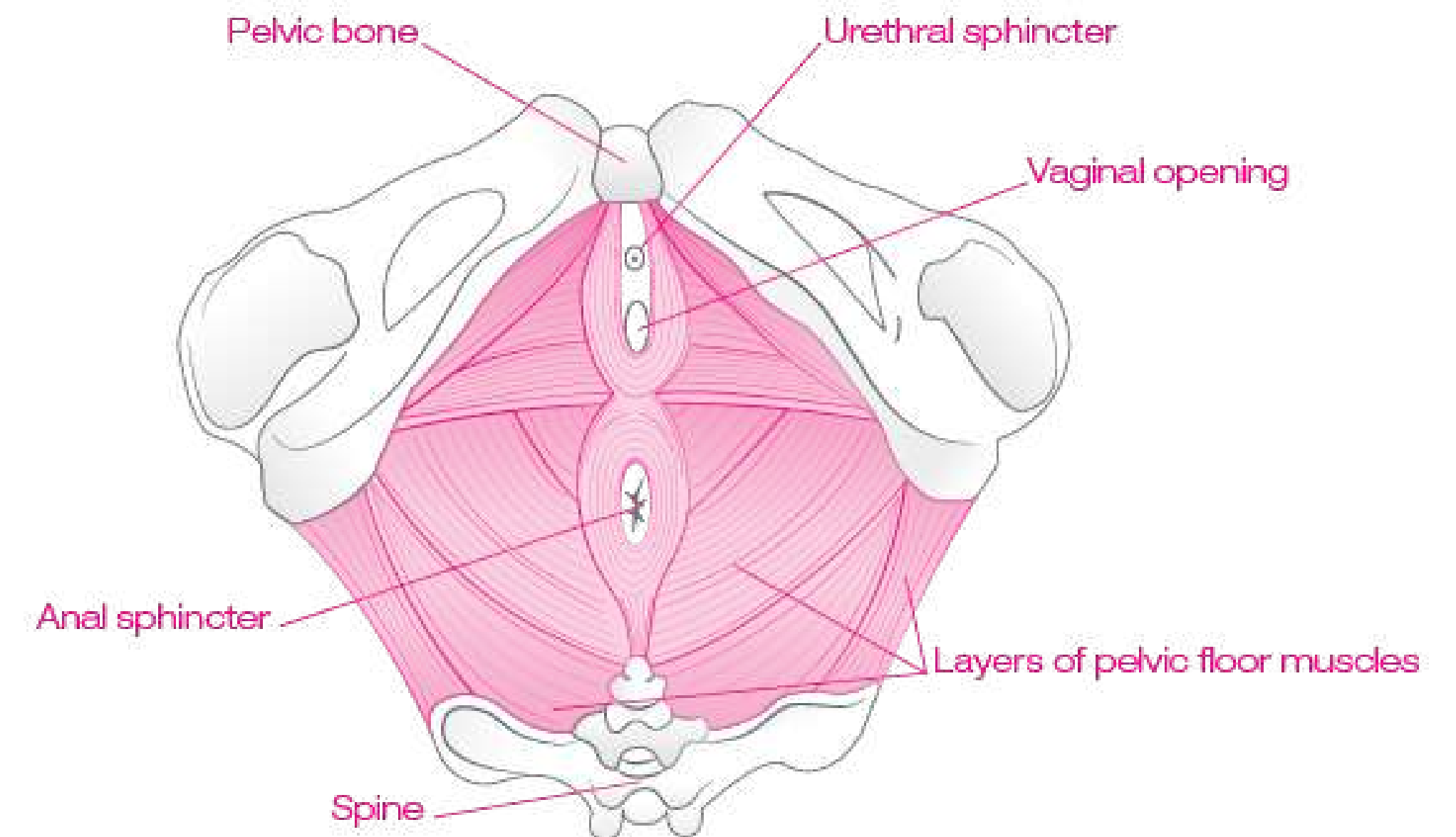
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What is the pelvic floor?

The pelvic floor muscles support internal organs; control bladder and bowel function and directly affect the pleasure and comfort experienced during intimacy.

The facts

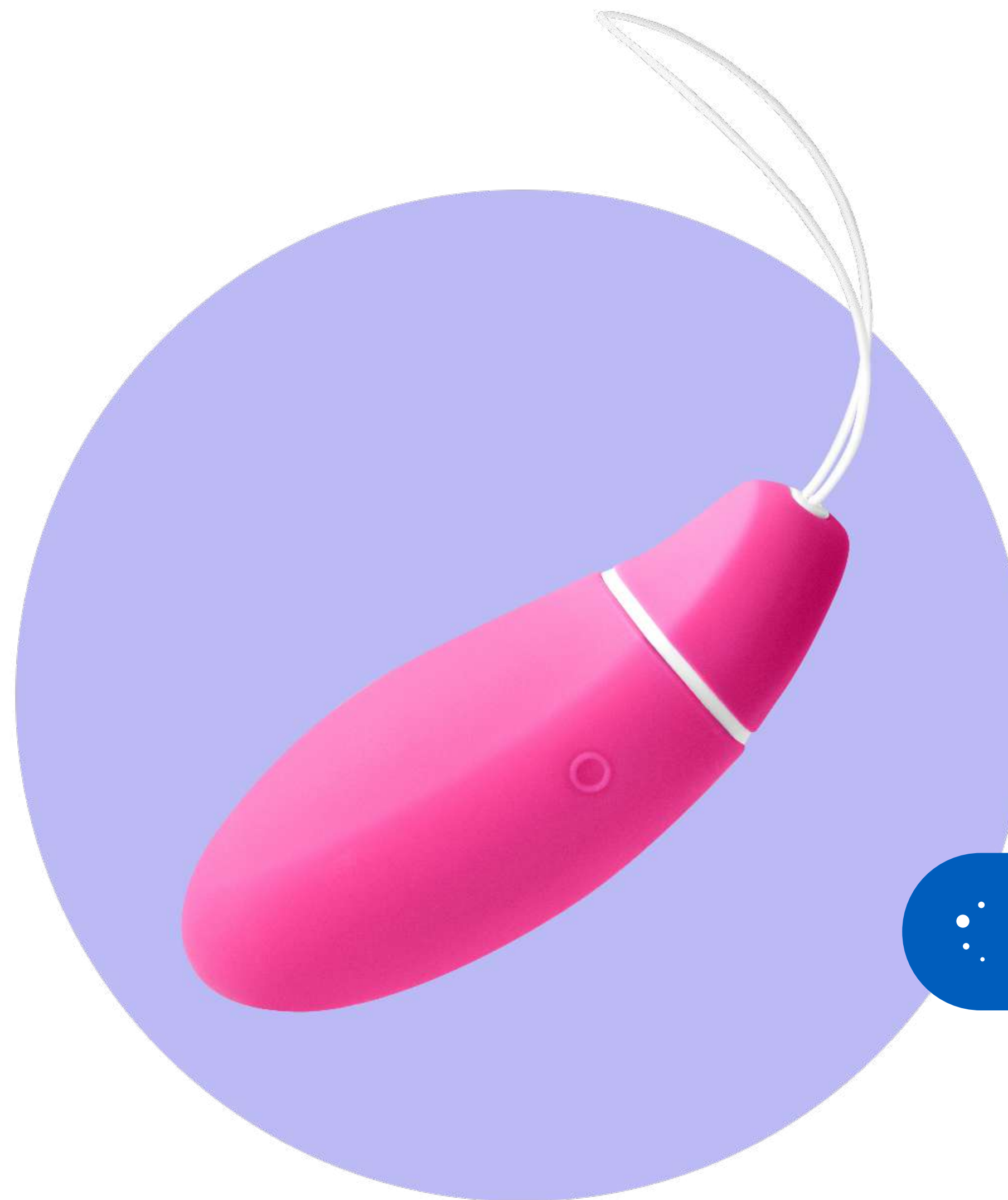
- ✓ 1/3 of women worldwide are affected by pelvic floor disorders that can severely affect their quality of life
- ✓ 50% of women experience urinary incontinence during pregnancy
- ✓ Pregnancy, childbirth and hormonal changes during menopause can all contribute to pelvic floor weakness.



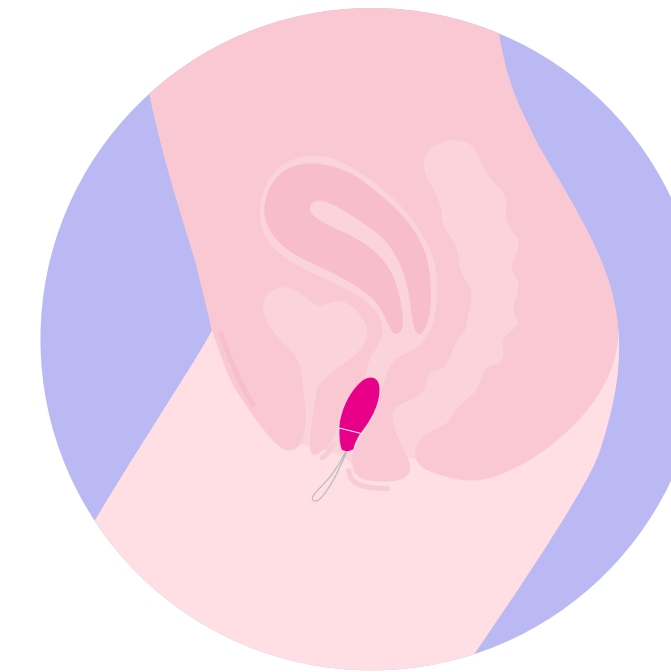
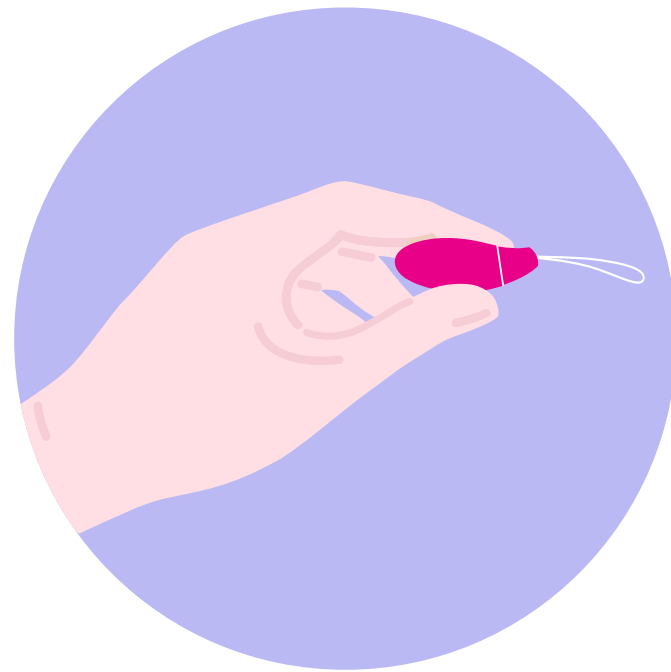
Expert pelvic floor training in less than 5 minutes a day

KegelSmart™ is the only smart pelvic coach in the world that can register:

- ✓ strength
- ✓ contraction length
- ✓ reaction time



• **Patented**
• technology



Registers pelvic strength

Patented touch-sensor technology registers pelvic floor strength every time users exercise. It rates contraction strength on 5 levels, from very weak to very strong, allowing users to track their progress.

Automatically sets exercise level

Device automatically measures the strength, endurance and reaction speed of each Kegel contraction and then adjusts the exercise level (up or down) accordingly based on the previous session.

Vibration-guided program

Device coaches users through each contraction with gentle vibrations. It automatically determines the duration and rhythm of the exercises to ensure the routine is right for you, every time.

Check your level at each session

Every time you turn on KegelSmart™ a flashing LED light will indicate your current level - from one flash for level 1 to five flashes for level 5. This feature gives users immediate feedback, allowing them to track progress and stay motivated.

Pelvic floor disorders are not an inevitable part of aging and can be prevented and improved with exercise.

The INTIMINA KegelSmart™ Clinical Trial was conducted by Banner University Medicine Institute: Phoenix Arizona under the guidance of Dr. Debra Wickman MD FACOG from November 2015 to July 2017. The results of the 12 week trial were collected through clinical pelvic examinations performed in a medical facility by a medical practitioner and through self-assessment questionnaires.

Trial objective

To test the effectiveness of KegelSmart™ on women who are experiencing symptoms of pelvic floor weakness, namely urinary incontinence, vaginal laxity and sexual sensation problems, to assess the changes in pelvic floor muscle strength over a period of 12 weeks.

Key outcomes measured and tracked:

- ✓ Increase in pelvic floor strength (measured in cm H₂O)
- ✓ Subjective reporting of urinary incontinence episodes
- ✓ Subjectively improved vaginal tightness
- ✓ Subjective sexual response.

- ✓ Each participant completed a pelvic floor exam using a clinical perineometer at the start and finish of the study. A perineometer is an instrument that measures the strength of voluntary contractions in the pelvic floor muscles. The pelvic floor examinations were performed at Banner University Medicine under the supervision of Dr. Debra Wickman.
- ✓ Each participant was required to use the KegelSmart™ device once per day for the duration of the pre-programmed exercise routine (3.5 to 5 minutes) for 12 weeks.*
- ✓ Participants were required to fill out a questionnaire before completing the trial and after finishing the trial. Participants also answered weekly questionnaires about their experience using the KegelSmart™ device and noted any improvements in their symptoms.



* only 31% of participants consistently exercised more than 4 times per week

The **49 participants** who successfully completed the KegelSmart™ Clinical Trial met the following criteria:

- ✓ Female
- ✓ Between ages of 20 and 69
- ✓ Experienced urinary incontinence and/or vaginal laxity and/or decreased sexual sensation for a period of 6 weeks or more.

* Dr. Debra Wickman and the participants of this clinical trial voluntarily completed this study without any compensation.



The results

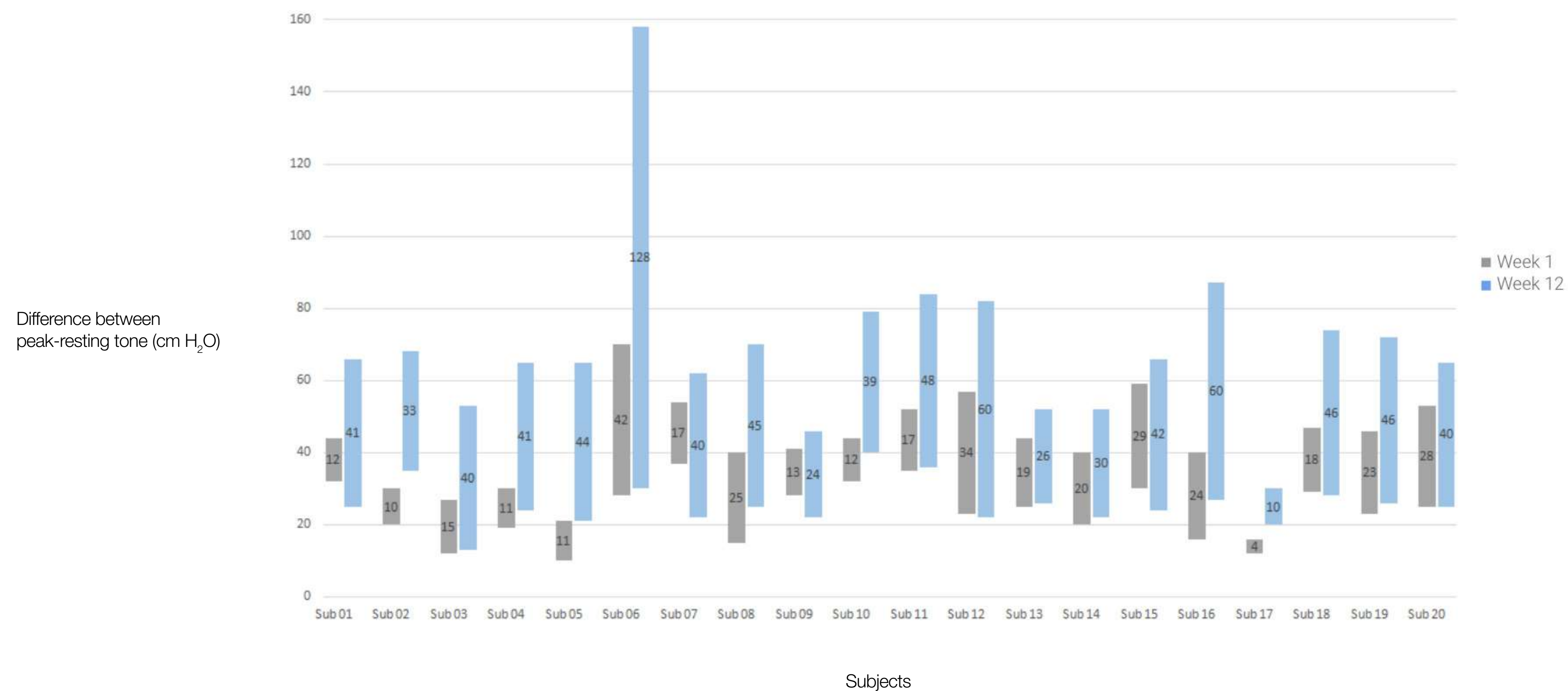
**Following the successful completion of the 12 week study,
the participants reported the following results.**

Improved pelvic floor strength



* After 12 weeks, measured with a clinical perineometer

Pelvic floor strength measured over course of the study

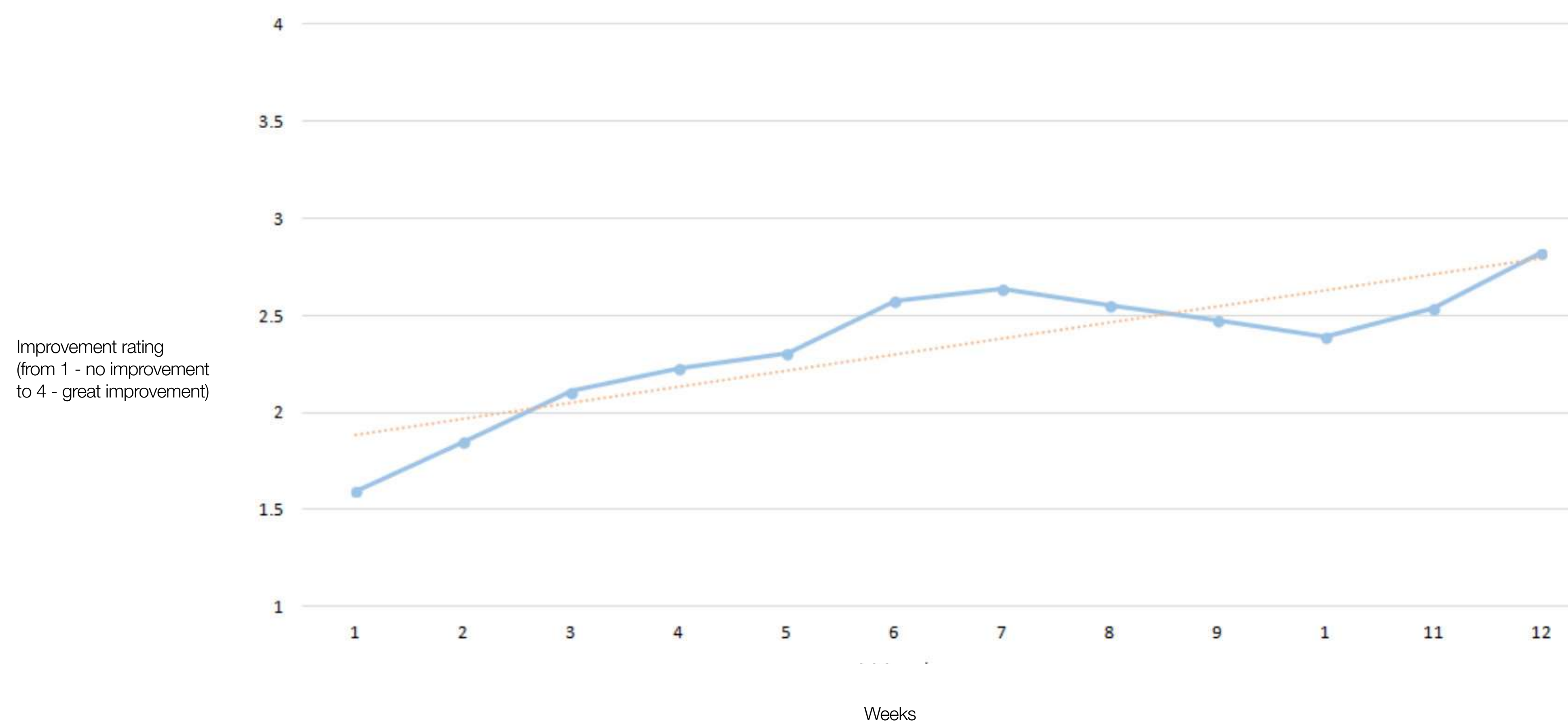


90%

reported improved
bladder control

* Women aged 23 - 50

Bladder control improvement rating reported over course of the study





“KegelSmart™ is easy to use and I have had a significant reduction in episodes of leakage since using it. Leaks are rare now!”

-Participant, Age 49-

The percentage of women describing their leaks as frequent decreased by

75%

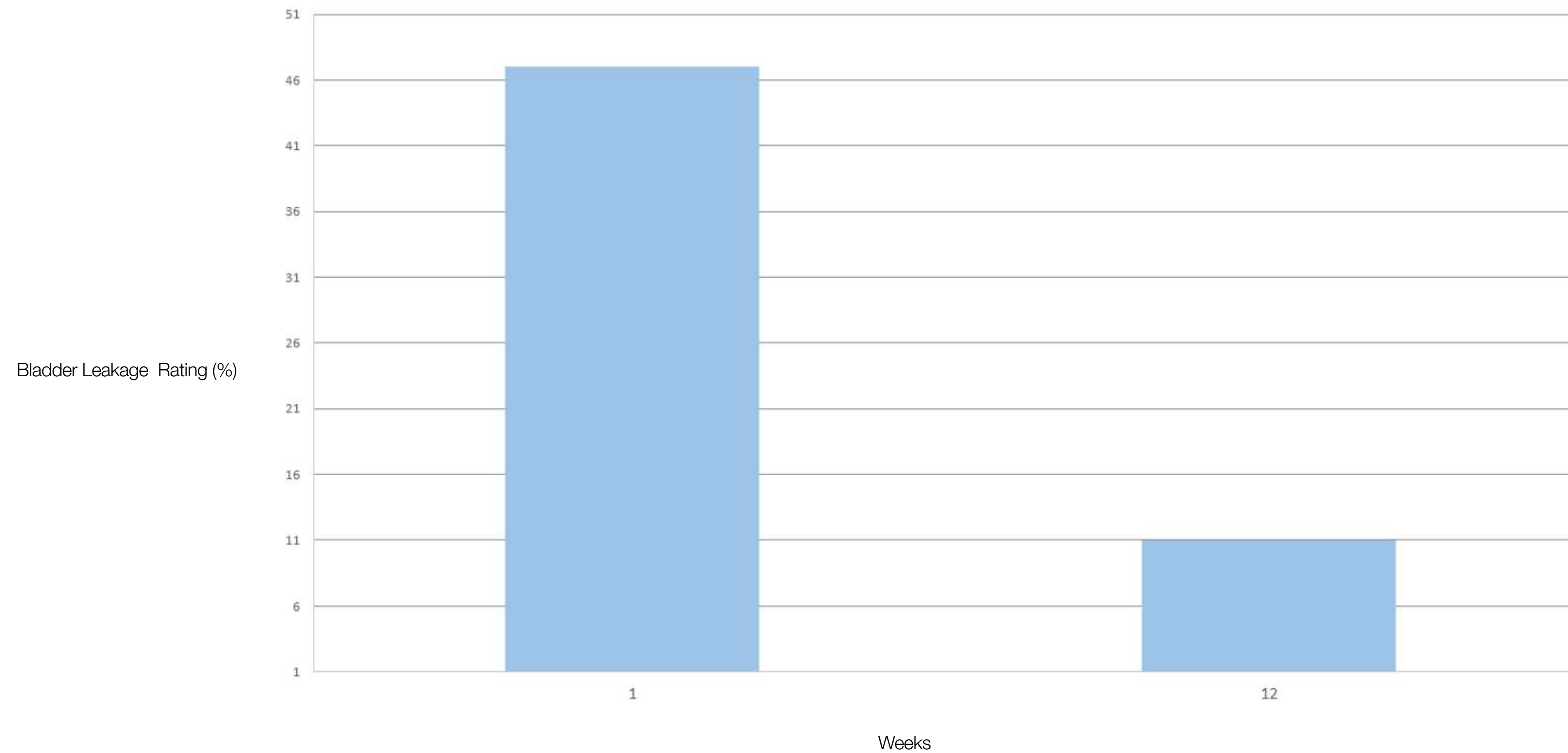
at the end of the study.*

* Women aged 23 - 50

* Leaks due to physical activity/sneezing/coughing/laughing

* At the beginning of the study 47% of women described their leaks as ‘frequent’. This decreased to only 11% by the end of the study.

Decrease in leaks reported over course of the study



Improved tightness and tone

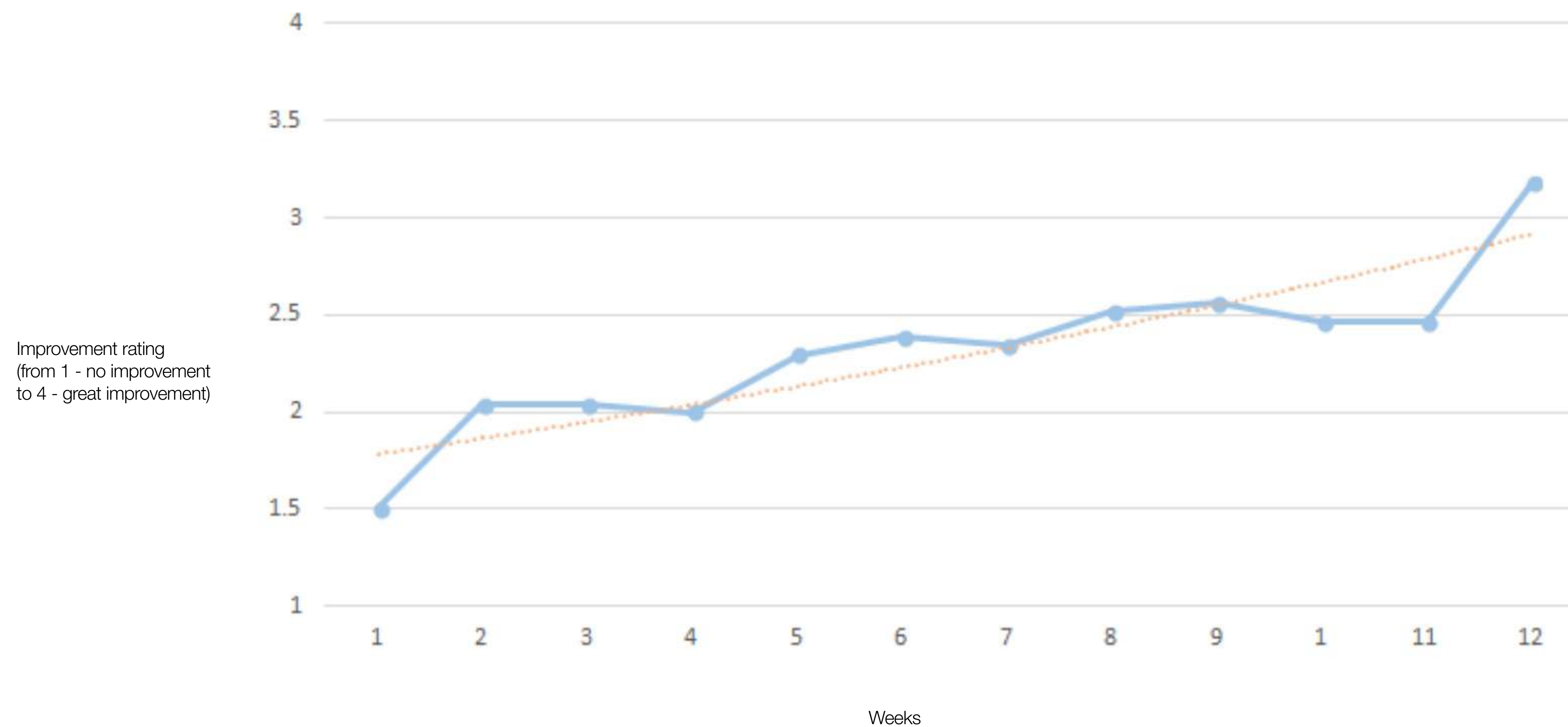


94%

reported improved vaginal
tightness and tone

* Women aged 23 - 50

Vaginal tightness and tone improvement rating reported over course of the study



92%

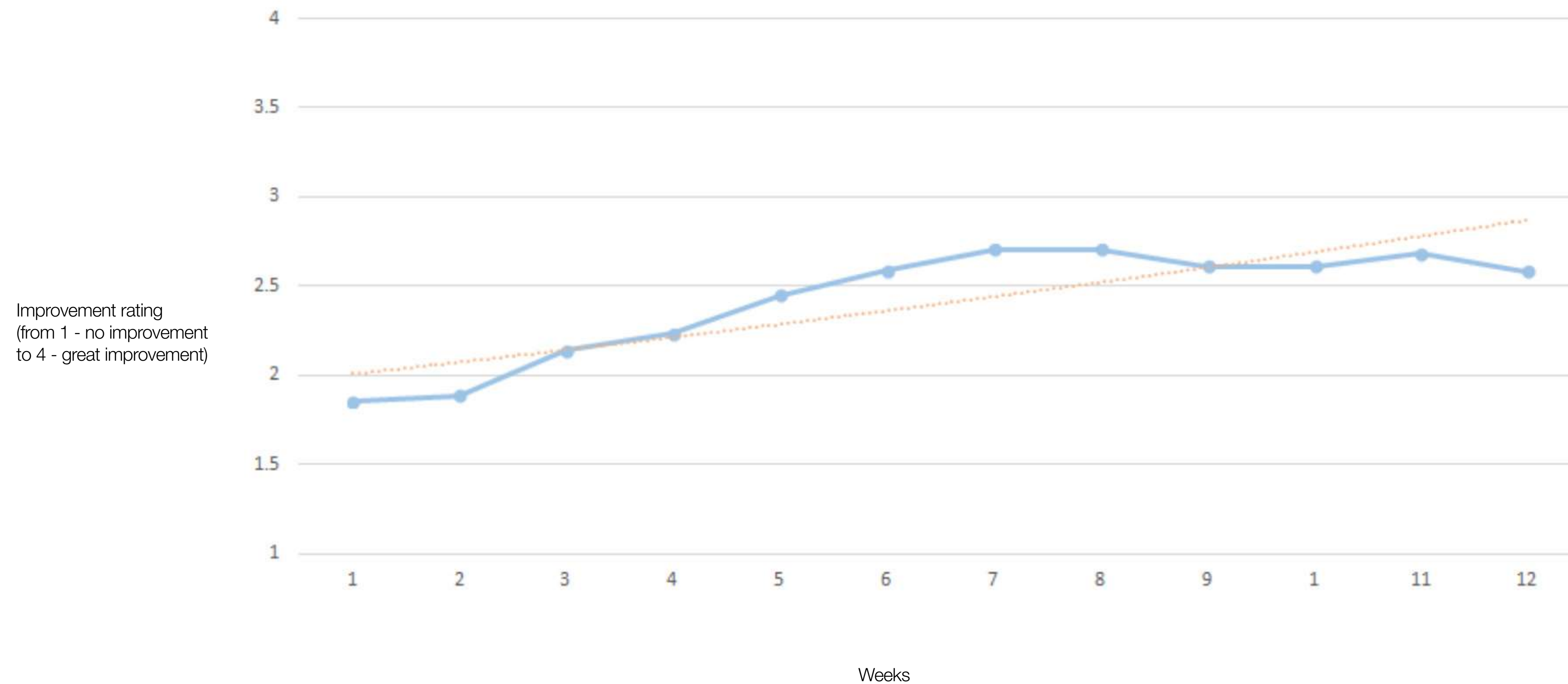
reported improved
sexual sensations

**“KegelSmart™ has
dramatically changed my
sex life for the better.”**

-Participant, Age 50-

* Women aged 23 - 50

Sexual sensations improvement rating reported over course of the study





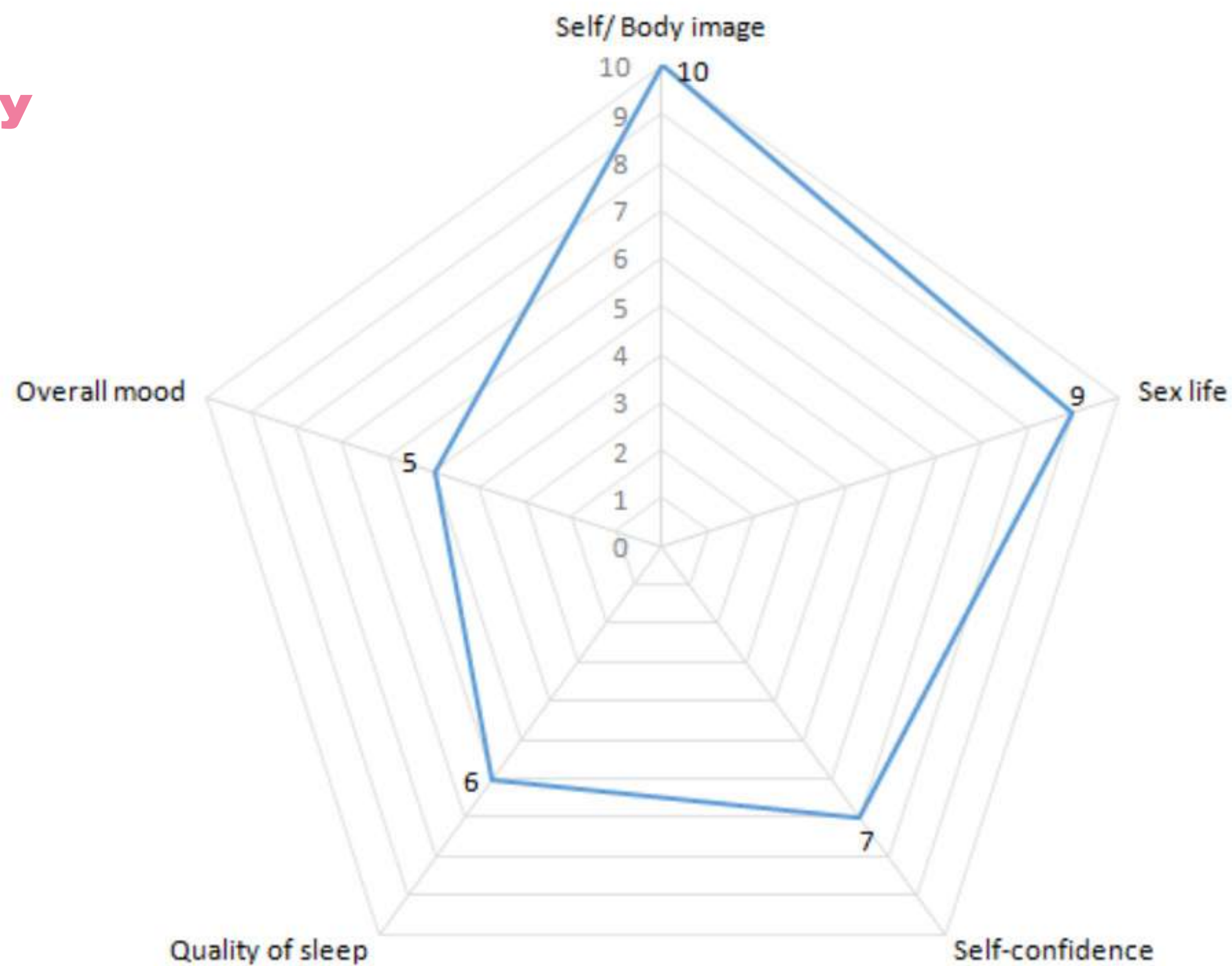
“After using KegelSmart™ I have seen a big improvement in my quality of life. I’ve had no leakage when sneezing or coughing and very little for jumping and lifting activities during exercise.”

-Participant, Age 39-

83%

reported improved quality of life

Quality of life areas of improvement reported over course of the study



92%

would recommend
KegelSmart™

85%

found exercising with
KegelSmart™ to be easy



“I no longer worry about bladder leakage, in fact I don't even think about it anymore. I will continue to make KegelSmart part of my daily routine, it's the only exercise I don't dread doing!”

-Participant, Age 57-

“It radically improved my orgasms!”

-Participant, Age 56-

“I am so thrilled I have more control of my urine leakage, especially during physical activity. KegelSmart™ has made my quality of life greatly improve.”

-Participant, Age 60-

“I have reduced the amount of leakage and frequency of leakage thanks to KegelSmart™!”

-Participant, Age 60-

About dr. Wickman

Dr. Debra Wickman is an obstetrician-gynecologist in Phoenix, Arizona. She received her medical degree from University of Washington School of Medicine and has been in practice for more than 20 years.

About Banner University Medicine

Researchers at Banner Health are committed to conduct high-quality clinical trials and other research projects that are medically and scientifically important, and have a strong potential to benefit patients. They conduct ground-breaking studies through their Banner Research division and the Banner University Medicine division.

