

PeriCoach® Structured Programming and Effect of Clinical Engagement

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INTRODUCTION

Pelvic floor muscle exercises (PFME) are recommended as first line treatment for UI and mild to moderate POP. As many as 50% of women do not perform PFME properly nor consistently enough to be effective. The PeriCoach system comprises a vaginal probe, Smartphone app, web portals and database. It includes an optional 8-week structured program, technique guidance, exercise notifications and ability for users to share data with their clinician.

AIM

The PeriCoach system captures the exercise history and performance in a data repository, which allows for analysis of the deidentified real-world data. This feature coupled with the PeriCoach v3, lead to the introduction of the PeriCoach "8 Week Challenge" structured programming to drive compliance, accountability and visibility to real-world user interaction with the system.

METHOD

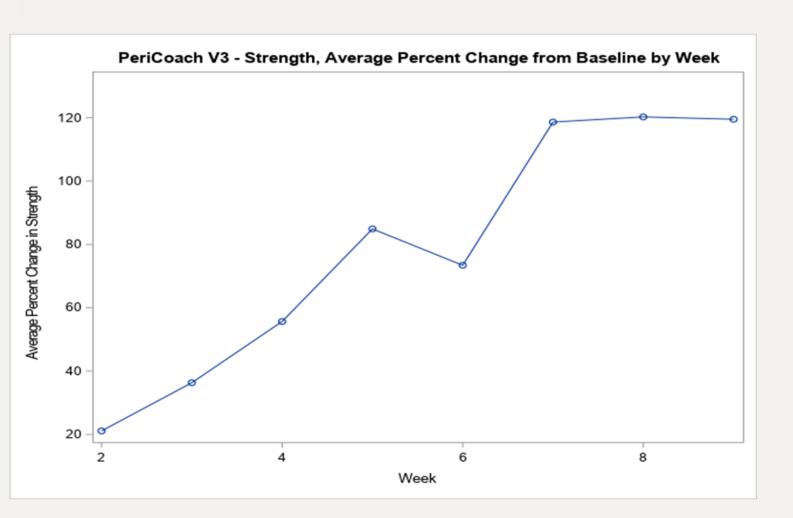
All-comers, prospective study of PeriCoach version 3 (v3) users that participated in the 8 Week Challenge. All users were default enrolled into the PeriCoach 8-week program.

- The program provides the user with app notification and progress reports to meet the requirements of: 5 days of exercise and 3 days of bladder diary entries per week, milestone measure testing every 2 weeks and quality of life survey completion at onset, 4 and 8 weeks.
- The primary objective was to assess change in strength as measured by the PeriCoach and leakage episodes and volume as recorded in the app based on program compliance.
- Secondary findings were the influence of connection with clinician on the strength, episodes and volume outcomes.
- The users that completed at least 75% of the 4 requirements were determined compliant.
- Analysis was percentage change from baseline.

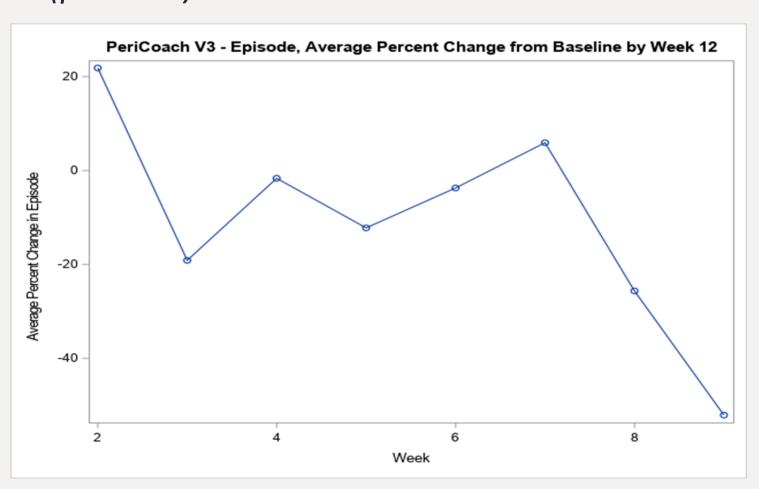
RESULTS

To date, de-identified data has been gathered and analysed for 242 PeriCoach v3 users that participated in the 8 –week program and 38 were compliant. Of those 30 (79%) are connected to a clinician. PeriCoach real-world data continues to be collected.

The overall strength comparison between compliant and non-complaint users was highly significant (p<0.0001).



Ave. percent change from baseline of strength improved significantly by week 5 (p=.0090).

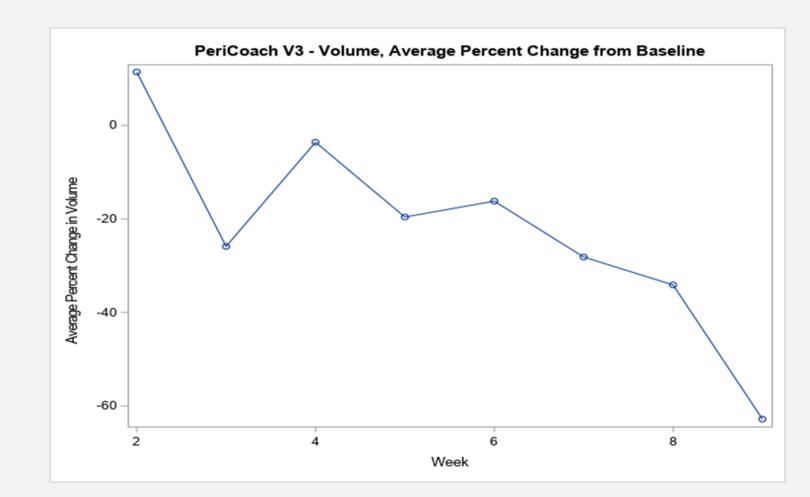


Improvement by week 3 and beyond (p=0.0671) in reported leakage episodes.

Strength improved by 70% or higher for 45% of the users who completed 8-week program vs. only 10% for those who didn't comply with the program (p=0.0047).

Clinician connection significantly influenced improvement in Strength by Week 8 (p=0.0047).

By week 8, 75% of the users demonstrated 80% or more reduction in leakage and episodes.



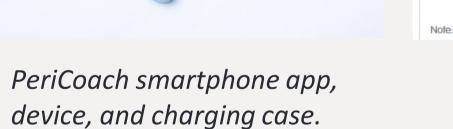
By week 3, significant reduction in reported leakage volume (p=0.0410).

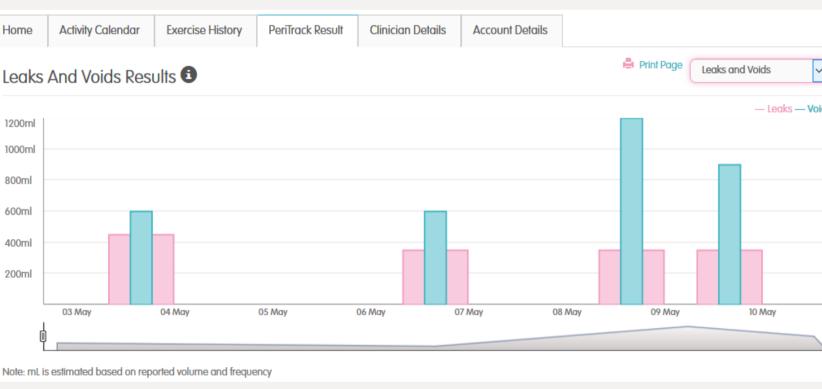
CONCLUSIONS

The real-world evidence gathered by PeriCoach v3 together with the 8-week program proves marked improvements in key continence measures within 3 weeks of use. Clinician engagement holds significant influence on PeriCoach user adherence to structured programming, as well as improved strength outcomes.

Please direct any queries to Product Management: USANZ2019@analyticamedical.com







Example user portal results for reported Leaks and Voids

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