

ASX ANNOUNCEMENT

Analytica Presents PeriCoach Real-World Data on Eight-Week Challenge and the Effect of Clinician Engagement

2 October 2019. Analytica Ltd (ASX:ALT) Analytica would like to update our shareholders on a recent presentation of PeriCoach data to the American Urogynecologic Society / International Urogynaecological Association (AUGS/IUGA 2019) meeting in Nashville, Tennessee on Saturday 28 September.

After thorough statistical analysis of PeriCoach de-identified data by an independent 3rd party biostatistician, two very insightful retrospective studies resulted. The first looked at comparison of PeriCoachV3 real-world data with PeriCoachV2 Randomised Clinical Trial (RCT) data, and the result had PeriCoachV3 been used in the trial. The results showed that use of the V3 would have seen predictably more significant improvements in outcome measures for the same RCT, under the *modest assumption* of 10% impact improvement. This study was on display as an e-Poster throughout the meeting (attached).

Mrs Chelsea Cornelius, Analytica's Operations and Product Development Manager delivered the second study results as a presentation (attached) describing a paper co-authored with Analytica Chairman Dr Michael Monsour and biostatistician Mo Noursalehi. The presentation highlighted the impact of the 8-Week Challenge (8WC – introduced with PeriCoach V3) on pelvic floor strength and leakage on users that were compliant with the program vs non-compliant. A secondary endpoint looked at clinician impact on those outcomes.

Results showed that compliance with the 8WC resulted in statistically significant improvement in strength as well as highly significant reduction in leakage episodes and volume for 8WC-compliant users. Whilst non-compliant users also saw improvement, this was just 10% compared to 70% or higher for 45% of compliant users for strength outcomes.

Being connected to a clinician through the PeriCoach online web Portals demonstrated further improvement in outcomes.

The data shows that use of PeriCoach + following the 8WC results in meaningful and significant improvement in continence symptoms.

It also highlights the value of clinician engagement which significantly influences user adherence to the treatment programme, further improving outcomes.

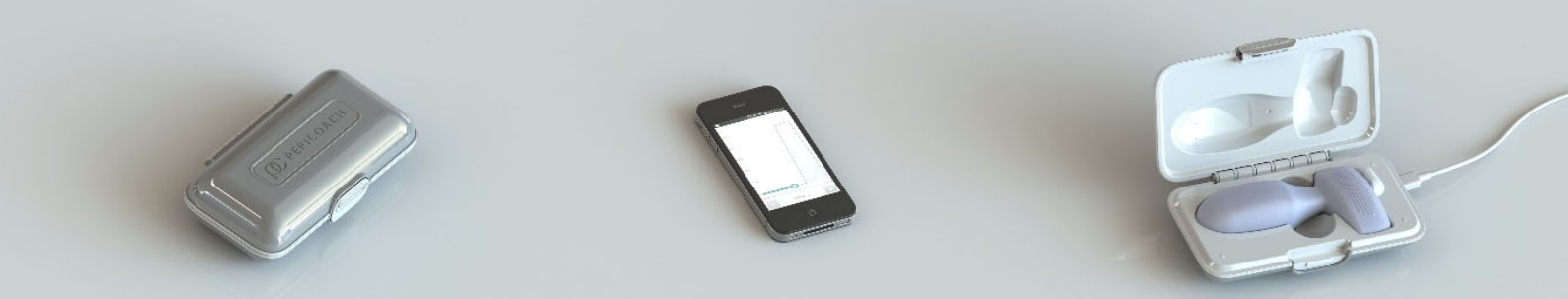
This data was well-received by those attending the presentation and the conference generally and demonstrates the data insights able to be provided by the PeriCoach database, as well as the significant effectiveness of its use.

For more information, please contact: investorrelations@analyticamedical.com

For more information about the PeriCoach System, visit: www.PeriCoach.com

For more information about Analytica, visit www.AnalyticaMedical.com





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About Analytica Limited

Analytica's lead product is the PeriCoach® System – an e-health treatment system for women who suffer Stress Urinary Incontinence. This affects 1 in 3 women worldwide and is mostly caused by trauma to the pelvic floor muscles as a result of pregnancy, childbirth and menopause.

PeriCoach comprises a device, web portal and smartphone app. The device evaluates activity in pelvic floor muscles. This information is transmitted to a smartphone app and can be loaded to a cloud database where physicians can monitor patient progress via web portal. This novel system enables physicians to remotely determine if a woman is performing her pelvic floor exercises and if these are improving her condition. Strengthening of the pelvic floor muscles can also potentially improve sexual sensation or satisfaction and orgasm potential in some women.

PeriCoach has regulatory clearance for urinary incontinence in Australia and has CE mark and USFDA 510(k) clearance.

PeriCoach also has clearance in Australia, and CE Marking in Europe for the treatment of pelvic organ prolapse, a condition that affects up to 1 in 5 women during their lifetime.

Authors: Chelsea Cornelius BME(Hons)/BA & MBiomedEng; Michael Monsour MBBS (Hons) and Mojtaba Noursalehi, PH.D

Objective

Technology available today has led to the development of vital eHealth tools that enhance treatments and outcomes. PeriCoach is one such pelvic floor muscle therapy (PFMT) eHealth system, designed to provide consistent, accurate biofeedback and additional motivation to the user, as well as reliable data collection for ongoing progress analysis.

Two investigations using the PeriCoach were conducted to determine and compare outcome measures: a randomized controlled trial (RCT) and an all-comer, real-world data study (RWD).

Methods

Study 1: RCT comparing clinician supported PFMT with PeriCoach V2 to clinician support PFMT over 20 weeks.

Study 2: Real-World Data retrospective study of PeriCoach V3 users using de-identified data.

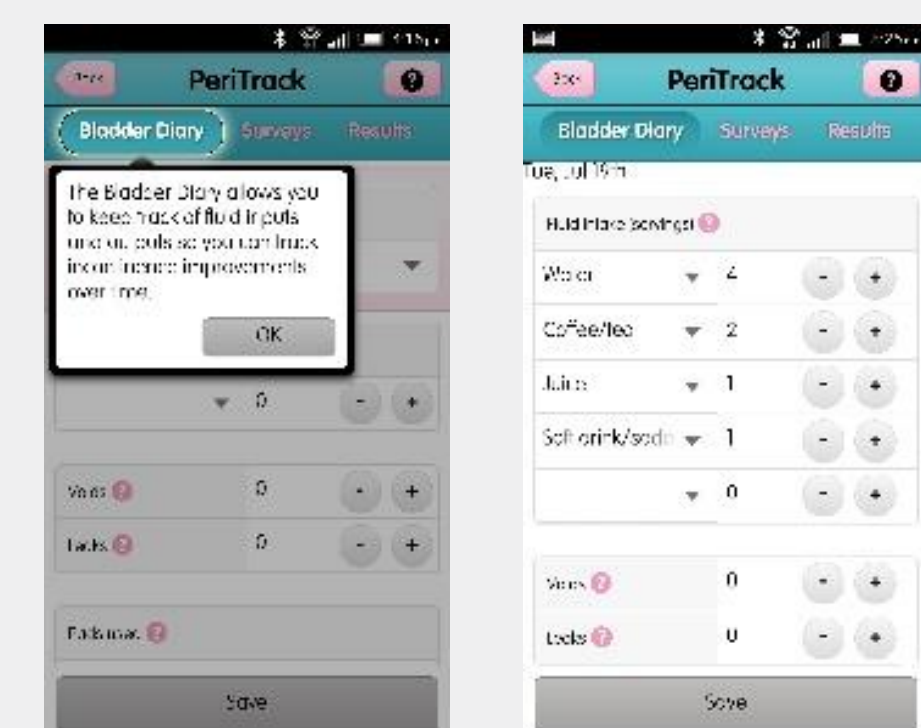
Analysis of key efficacy endpoints for both studies, including quality of life scores, sexual function scores, PFM strength as well as number and volume of urine leakage episodes.

In both studies, women used PeriCoach, an eHealth perineometry system consisting of a vaginal probe, Smartphone app, web portal and database, as well as support from pelvic health clinicians for some users.

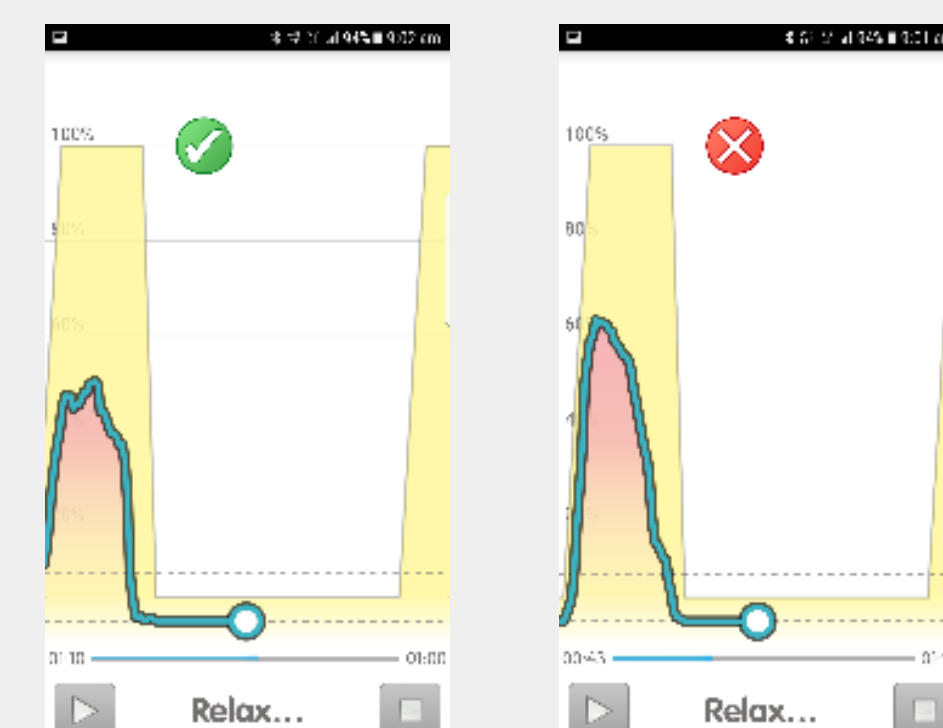
- The PeriCoach app provides a bladder diary and survey function for users to record key symptom data.
- Pelvic floor muscle (PFM) strength is measured via force sensors in the probe.

Rigorous statistical analyses were performed on both studies separately, and then compared to reassess the outcome of the RCT had V3 been used instead.

PeriCoach V3, released in mid-2017, introduced enhanced sensor readings through inclusion of a gyroscope/accelerometer which allowed for real-time technique guidance for the user, using movement and force data. Additionally a structured 8-week program along with enhanced user interface was integrated to further drive user engagement and motivation.



Figures 1. The PeriCoach app Bladder Diary



Figures 2. Technique feedback during exercise

Results

For both studies, outcomes for which statistical significance could be performed, considerable improvement were demonstrated.

- The RCT Q-IQOL and PSQUIR scores revealed significance over control group ($p=.0154$, $p=0.0061$), pad weight did not meet significance yet trend in favor of interventional system.
- The RCT Q-IQOL scores revealed a significant improvement in PFMT+PeriCoach over PFMT group (mean change at week 4 to week 20: 11.50 to 18.67 vs. 5.73 to 10.85, $p=0.0154$, Table XX).
- Change in sexual satisfaction was measured only at baseline and at week 20, demonstrating improvement in PFMT+PeriCoach v2, and deterioration in PFMT group (Mean Change: 1.71 vs. -2.46, $p=0.0061$, Table YY).
- Both RCT and RWD studies demonstrated improvement in strength with PeriCoach use (**RCT** $p=0.0985$, **RWD** $p<0.0001$).
- For the RWD study, at 3 weeks and beyond there was a reduction of leakage volume ($p=0.0410$) and episodes ($p=0.0671$).

When comparing the strength results across both studies, RCT participants who performed PFMT with the V2 device would have shown statistically significant improvement under the *modest assumption* of 10% impact improvement had the V3 been used in the study (mean change from baseline at Week 4 to 20: 3.7 to 4.3 in PFMT+PeriCoachV2 vs. 3.0 to 3.6 in PFMT group; $p=0.0014$), where V3 demonstrated between 20% to 30% improvement over V2 for different endpoints.

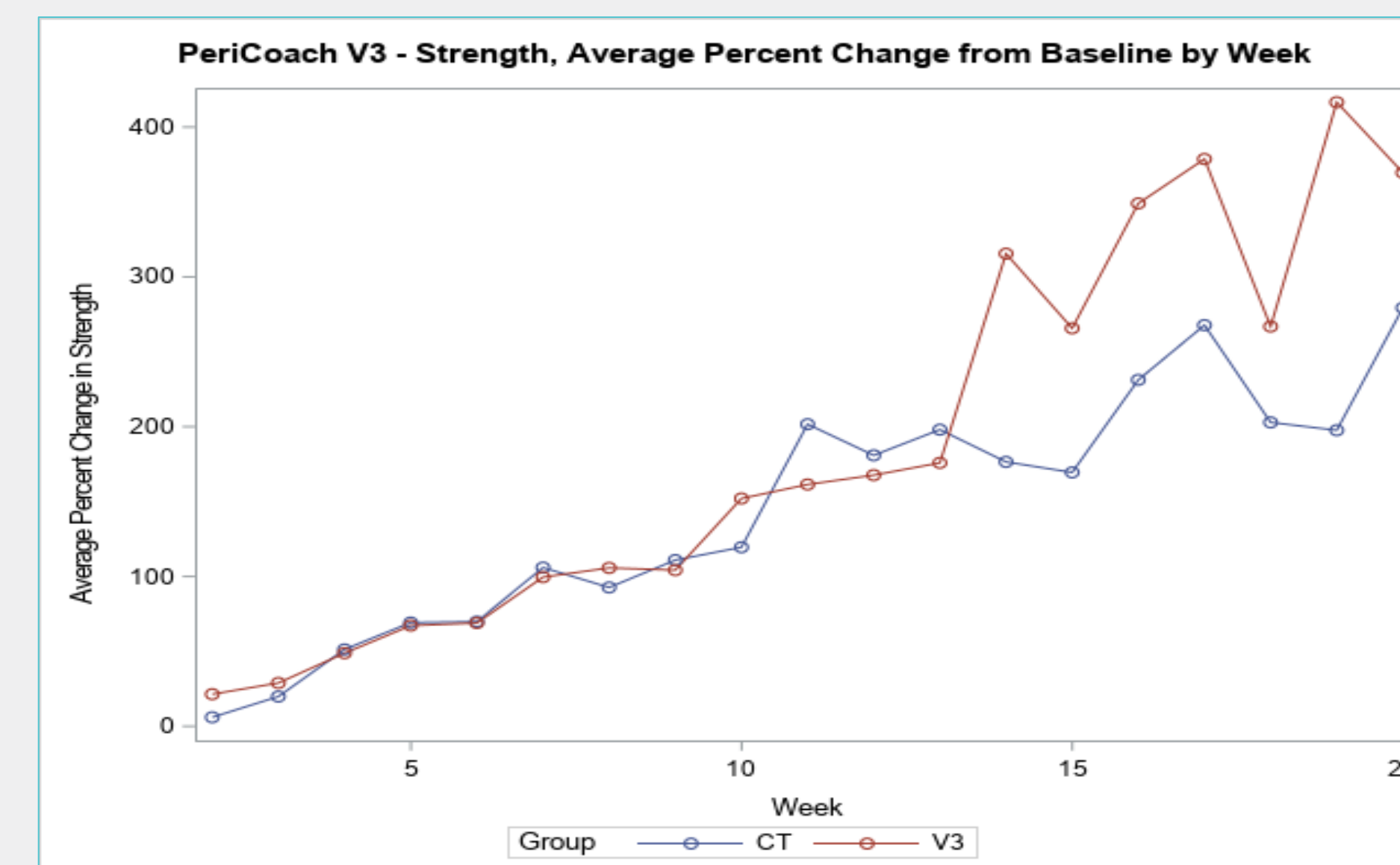


Figure 3. Strength percent change from baseline for both groups

Conclusion

- The RCT results demonstrated that use of the PeriCoach eHealth biofeedback system for guided PFMT supports compliance, improved strength and positive outcome measures.
- The PeriCoach V3 – with the inclusion of real-time technique feedback and structured, comprehensive 8-week program - would see predictably more significant improvements in outcome measures for the same RCT based on analysis of de-identified RWD.
- eHealth systems enable the automated collection of data without interventional bias, whilst using platforms that are easily accessible and familiar to the patient.

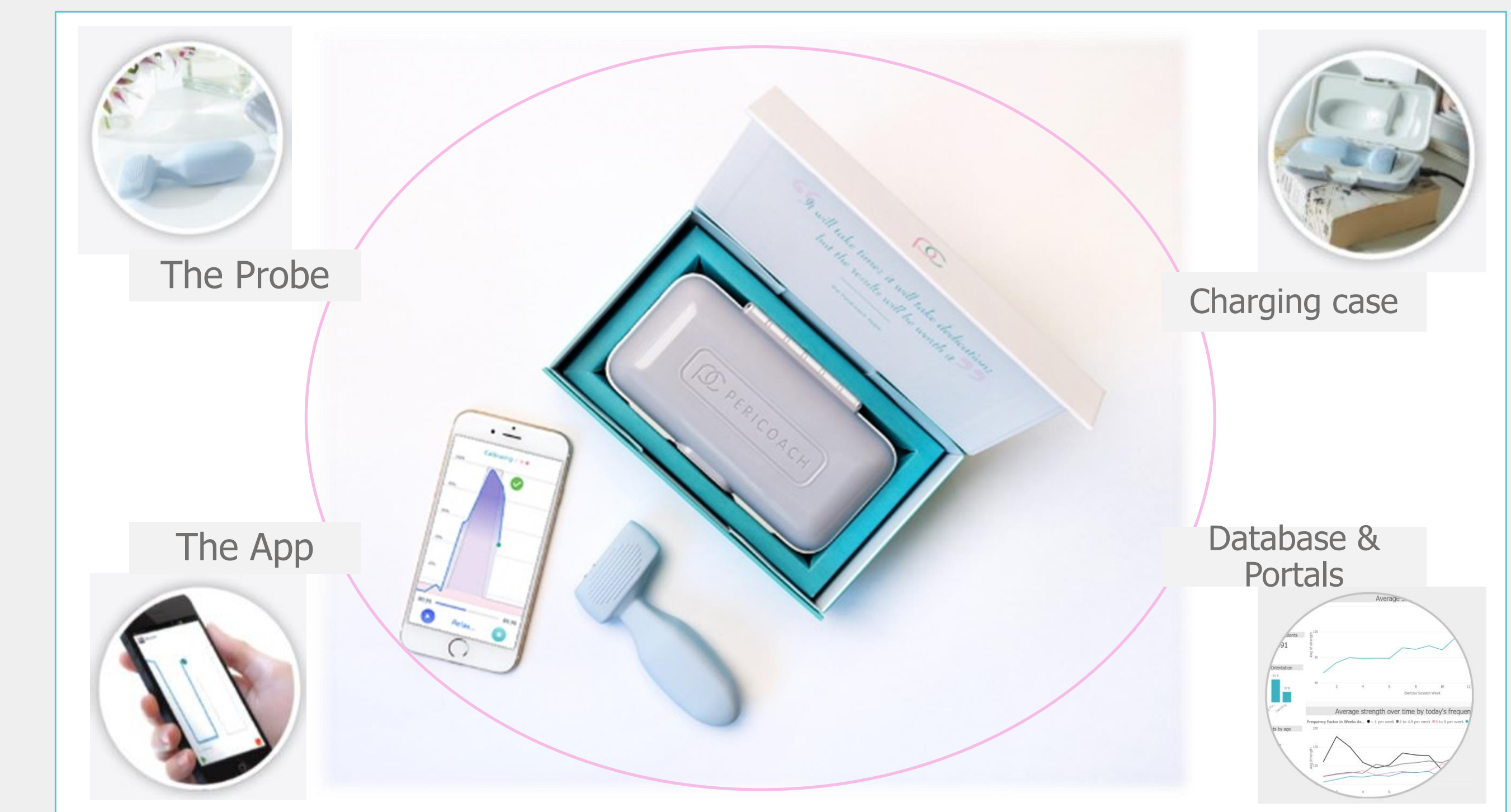


Figure 4. Elements of the PeriCoach System

Source of funding: Internal

Conflict of Interest: The author is an employee of Analytica Ltd.



Chelsea Cornelius

**PeriCoach® 8-Week Structured
Programming Real-World Data and
Impact of Clinical Engagement**

C. Cornelius; M. Monsour; M. Noursalehi

Disclosures

Product Development Manager for Analytica Ltd

Introduction

The PeriCoach is a home biofeedback system designed to overcome the many barriers to Pelvic Floor Muscle Exercise (PFME) through:

- ❑ Real-time muscle contraction feedback
- ❑ Real-time technique guidance
- ❑ Clinically designed exercise programs
- ❑ Performance checks & tools to track progress
- ❑ Encouragement messages & reminders
- ❑ Structured comprehensive exercise and lifestyle program – 8 Week Challenge
- ❑ Data uploaded to PeriCloud for remote clinician access



8 Week Challenge – Structured Programming

Activity	Requirement (minimum)
Bladder Diary entries	3 every 7 days
QoL Surveys	1 survey at onset, 4 & 8 weeks
Milestone Measurements	1 session every 2 weeks
Exercise Sessions	5 sessions every 7 days

Structured programming “8 Week Challenge” released with the latest version (V3):

- Allows Analytica to ‘standardise’ use enabling better outcome analysis
 - Gain greater insights into compliance, strength development, clinician influence and symptom changes.
- Provides the patient with a timeline expectation and guidelines to follow to achieve the best outcomes
 - Developed from existing PeriCoach best outcomes data

*All users enrolled by default

Study

A retrospective study using de-identified data collected by the PeriCoach*

Hypothesis

1. PeriCoach use + 8 Week Challenge will improve compliance and motivation → increase PF strength + reduce leakage events & volume
2. Clinician connection through the PeriCoach system will further improve outcomes

Inclusion criteria

1. PeriCoach V3 users
All V3 users enrolled in 8WC by default during registration.

Method

- PF muscle strength is measured via force sensors in the PeriCoach probe.
- Users record their leakage events and volumes in the Bladder Diary section of the Smartphone app.
- This data can be optionally shared with a treating clinician through a PeriCoach web portal available to clinicians.

Primary objective was to assess change in strength and leakage episodes & volume using de-identified data; comparing outcomes for 8WC compliant and non-compliant users.

Secondary findings looked at the influence of clinician connection on these outcomes.

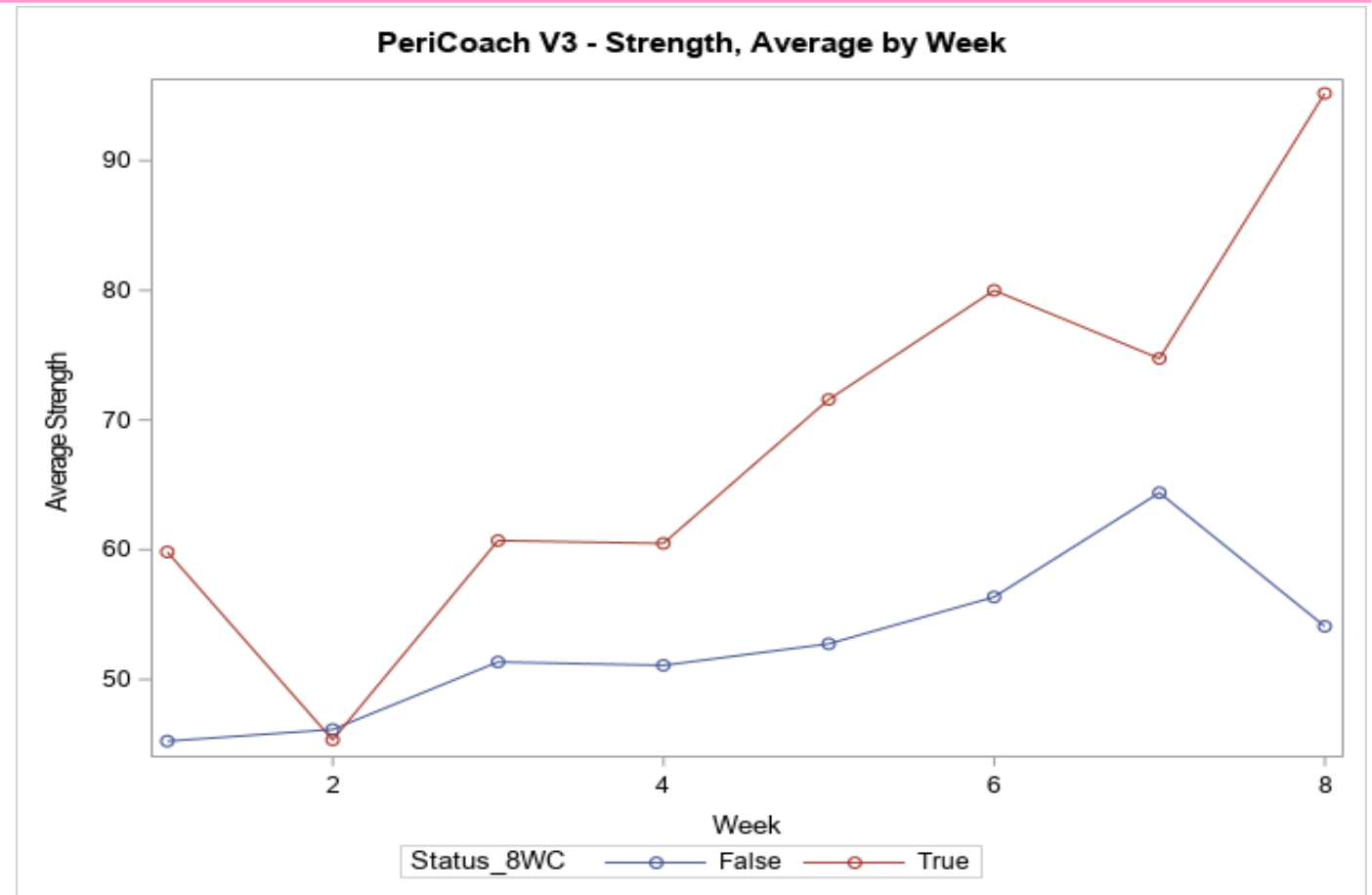
- Users that completed at least 75% of the 8WC requirements were determined compliant. Analysis was percentage change from baseline.

*Users of the PeriCoach system have agreed to de-identified data being used for research.

Results

- 265 users met the inclusion criteria
- 38 were compliant
 - Of those, 30 were connected to a clinician (79%)

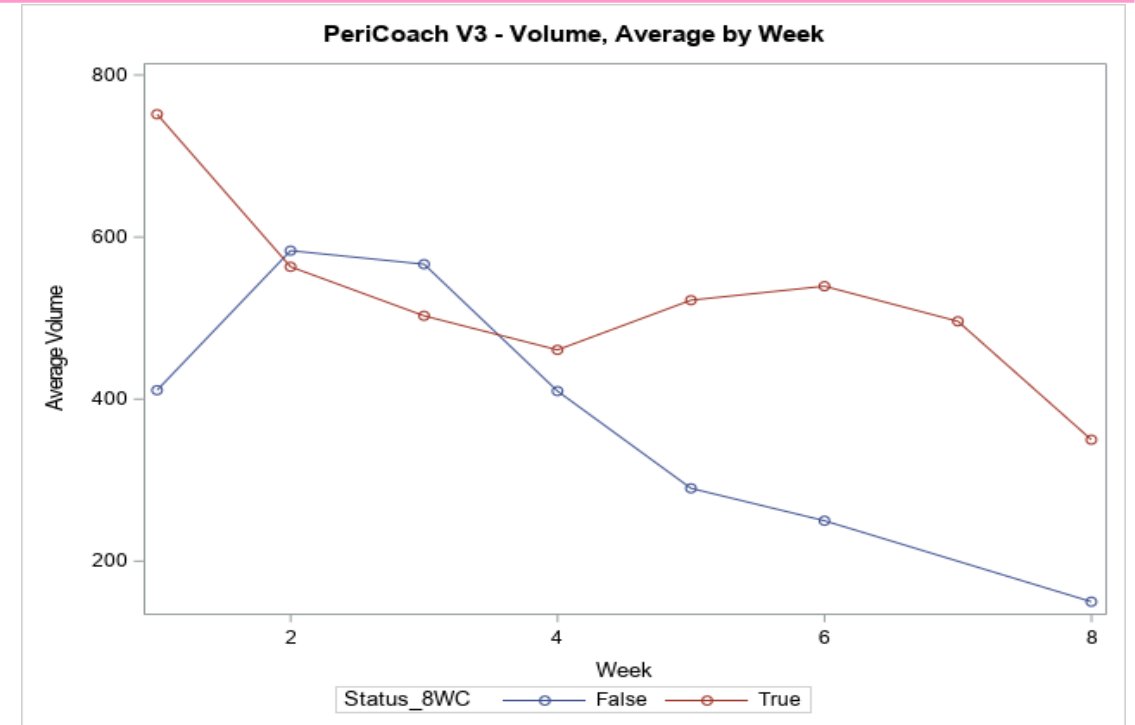
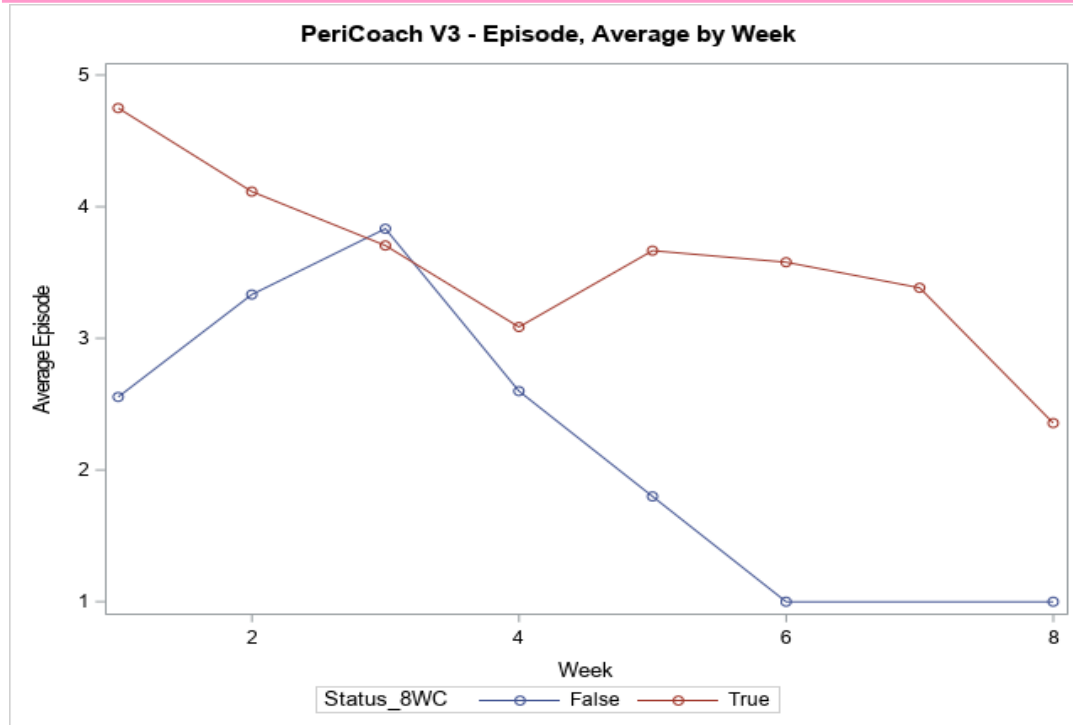
- ❑ Strength improved significantly by week 5 ($p=.0090$).
- ❑ Strength improved by 70% or higher for 45% of the 8WC-compliant users vs. only 10% strength improvement for non-compliant.
- ❑ Clinician connection significantly influenced improvement in strength by Week 8 ($p=0.0047$).



% change from baseline for compliant users → highly significant for duration of program ($p=0.0001$)

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Results



- ❑ V3 users reported a highly significant reduction in leakage **episodes** ($p=0.0219$) by week 4 and **volume** ($p=0.0401$) by week 3 and beyond.
 - On average, **$\geq 50\%$ improvement is seen in nearly a third of users.**
- ❑ At the conclusion of the 8WC more than 75% of compliant users have **at least 80% reduction in leakage volume and episodes**
 - Highly meaningful and significant improvement in continence symptoms.

Conclusion

- Use of the PeriCoach + 8 Week Challenge demonstrates **meaningful improvements** in key continence measures within 3 weeks of use.
- A structured 8-week program **improves compliance**
→ results in improved outcomes
- Clinician engagement holds **significant influence** on PeriCoach user adherence to structured programming, further improving outcomes.



Meaningful
reduction in
leakage events



100% increase
from baseline Pelvic
Floor Strength in
8 weeks



Significant
improvement in
leak volume in 8
weeks



Clinician
engagement
benefits patient
outcomes

Questions?