

ASX ANNOUNCEMENT

Publication of Randomised Controlled Clinical Trial Findings Demonstrating PeriCoach® Parity to Physical Therapy Intervention for Stress Urinary Incontinence

PeriCoach showed non-inferiority for treating Stress Urinary Incontinence to traditional supervised pelvic floor physical therapy by pelvic floor physiotherapist.

20 November 2020 Analytica Ltd (ASX: ALT) announces publication of an independent clinical trial from The University of New Mexico in the prestigious Journal of Female Pelvic Medicine & Reconstructive Surgery, the official journal of the American Urogynecologic Society, demonstrating PeriCoach non-inferiority to in-clinic pelvic floor physical therapy.

The randomised single-centre study, led by principal investigator Dr. Lauren de Winter (formerly Barnes), was designed to assess if home biofeedback is non-inferior to standard of care supervised pelvic floor physical therapy (PFPT) for the treatment of stress urinary incontinence (SUI) in women who desire non-surgical therapy. The 48-participant study compared the use of a PeriCoach personal biofeedback device with PFPT.

PFPT has proven to be an effective tool for reducing SUI symptoms and improving quality of life. However, women living in remote areas, or who cannot afford, do not wish to access, or have otherwise limited access to PFPT may need alternative treatment options to gain the same benefits of monitored pelvic floor rehabilitation. The goal of the study was also to support the implementation of personal biofeedback devices to overcome issues with patient distance and ability to maintain clinician monitoring. The PeriCoach feature set of technique guidance technology, the unique ability to measure muscle strength directly, comprehensive measurement and data analytics, and clinical connectivity features were able to meet these challenges.

The primary outcome measurement was met, with the biofeedback group using PeriCoach demonstrating non-inferiority to PFPT based on quality of life score as measured by the International Consultation on Incontinence Questionnaire short form (ICIQ-SF). For the primary outcome of change in ICIQ-SF scores (where lower scores indicate less urinary incontinence), the home biofeedback group using PeriCoach was found to be non-inferior to PFPT [-4.73 (-3.21 to -6.25) vs -3.95 (-2.21 to -5.70), $p=0.009$].

Dr Michael Monsour, Chairman of Analytica said "This work by Dr de Winter confirms my own clinical experience in regional Queensland and the real-world data we've collected from thousands of women. Whilst the gold standard is in-person consultations, for those women who are too remote, can't afford multiple visits, or are just too time poor, the PeriCoach offers treatment that's now proven to be on-par with specialised clinician treatment in most instances."

"Doctors and physiotherapists can teach a woman to do their pelvic floor exercises in clinic, but most women forget the technique when they return home. And what about the women we never see? A weak pelvic floor can lead to surgery in later years and PeriCoach can help avoid that need. This is a massive, hidden



public health concern and this study shows that it could be addressed effectively without overburdening health systems.”

“Analytica set out with the ambitious aim of developing a system that could provide treatment similar to the standard of specialised pelvic floor physiotherapy and this published study confirms that we have achieved that goal.”

Reference:

Barnes, Kara Lauren MD^{}; Cichowski, Sara MD, FACOG, FPMRS^{*}; Komesu, Yuko M. MD, FACOG, FPMRS^{*}; Jeppson, Peter C. MD, FACOG, FASC, FPMRS^{*}; McGuire, Brenna MD^{*}; Ninivaggio, Cara S. MD, FPMRS^{*}; Dunivan, Gena C. MD, FACOG, FPMRS^{*} Home Biofeedback Versus Physical Therapy for Stress Urinary Incontinence, Female Pelvic Medicine & Reconstructive Surgery: November 16, 2020 - Volume Publish Ahead of Print - Issue - doi: 10.1097/SPV.0000000000000993*

Disclosure:

No extramural funding: Analytica Ltd extended a 25% discount for devices for this study as is usual for clinical multi-unit orders, but did not have access to the data and did not participate in the study design, data analysis, interpretation of results, or manuscript creation.

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 in Australia and has CE mark and USFDA 510(k) clearance.

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

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