Data Published in Sensors Supports the Use of Global Kinetics' Personal KinetiGraph® for Objective Assessment of Parkinson's Disease Patients Who May Benefit From Device-Assisted Therapies

Novel screening tool provides first objective assessment for managing referral for device-assisted therapy (DAT), including deep brain stimulation (DBS) and infusion therapies, and has potential to improve management of Parkinson's Disease

PORTSMOUTH, N.H. and LONDON and MELBOURNE, Australia, June 04, 2019 (GLOBE NEWSWIRE) -- Global Kinetics Corporation Ltd. today announced the publication of a study demonstrating that the use of data from its wearable FDA-cleared watch, the Personal KinetiGraph® (PKG®), can provide an objective approach to identifying Parkinson's Disease (PD) patients who may be candidates for device-assisted therapies (DAT) such as deep brain stimulation (DBS). Study results were published in a special issue of the journal *Sensors* titled "Wearable, Smart, Pervasive, and Unconventional Sensing for Health Monitoring: Solutions from Today and for Tomorrow" (https://www.mdpi.com/1424-8220/19/10/2241/pdf).

"Although there is broad consensus with respect to the criteria for selecting PD patients who will benefit from DBS, these symptoms may be difficult for physicians to identify when relying on patient self-report or in-clinic exam findings that may not reflect the spectrum of the individual's symptoms and result in treatment delays," said Fatta Nahab M.D., Associate Professor of Neurosciences at the University of California San Diego. "The study shows that PKG data can be used to develop a program that can help to guide clinicians in the timely identification of patients who should be referred for advanced therapies based on their likelihood to benefit. This is especially important given that there is a window of optimum benefit for advanced therapies and late referral can lead to sub-optimal outcomes or to patients missing the opportunity for benefit."

Parkinson's disease patients typically respond well to medical therapy in the early years of their disease, but the duration and symptomatic benefit derived from these medications begins to diminish over time for the majority of patients. This results in reduced efficacy in treating their symptoms, referred to as "off" periods. Long-term use of medications can also lead to disabling "fluctuations" that take the patient from "off" periods to developing involuntary movements referred to as dyskinesias multiple times a day. As adjusting oral therapies become less effective, advanced therapies such as DBS can provide an improvement in symptoms for many PD patients. Despite the potential benefits of DBS, as many as 67% of patients referred may not be suitable candidates for the procedure[1,2] and only approximately 1% of PD patients receive DBS[3] despite estimates that as many as 20% of patients may be eligible for it.[4]

The study results describe the development and validation of a research tool to help identify patients who may benefit from DAT. The study looked at 172 PD patients who underwent assessment for DAT suitability and were classified according to the presence or absence of troublesome "off" periods or dyskinesia that could not be adequately addressed by adjustments in oral medications.

Three criteria were used to identify patients suitable for advanced therapies: the presence of excessive "off" periods, the inability to manage these "off" periods with oral medication alone and the absence of contraindications for DAT. Four clinicians evaluated the data from 172 patients and sorted them based on meeting both of the first two criteria; patients who met both were classified as criteria positive (CP) and those who did not were classified as criteria negative (CN). Just under two-thirds of patients meeting both criteria proceeded to DAT.

Key study findings include:

- PKG data demonstrated high sensitivity and specificity for classifying PD patients for DAT eligibility based on the recommendations of specialist clinicians.
- The PKG-based DAT score correctly predicted a patient's eligibility for DBS in 87% of cases who had already been preselected for surgery.

- A low DAT score indicated that referral was not recommended, while a high DAT score in patients who could not undergo further medication adjustments suggested that referral to DAT was appropriate.
- The reduction in DAT scores following an advanced therapy suggests that there is a predictable change in the score if the intervention is successful.

John Schellhorn, CEO of Global Kinetics Corporation, said, “The lack of objective measurements for PD symptoms has been a barrier to optimizing care and outcomes for PD patients across the continuum of disease. This new study shows that PKG data has significant potential to enable new assessment methods that support the accurate and timely identification of patients who may benefit from advanced therapies. Objective, reproducible assessment methods that allow for data-driven clinical decision-making in the treatment of PD can help benefit patients, physicians and overall healthcare costs.”

References

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About Global Kinetics Corporation Ltd.

Global Kinetics Corporation Ltd. is committed to improving the lives of those with Parkinson’s disease with advanced medical technologies. The company was formed in 2007 to commercialize its lead product, the Personal KinetiGraph (PKG). The PKG enables the precise monitoring, quantification, and reporting of movement symptoms in Parkinson’s. To date, Global Kinetics has supported clinical decisions for doctors who have treated more than 42,000 patients with Parkinson’s disease, generating more than 6,000,000 hours of clinical data from our FDA-cleared, CE-marked PKG wearable device. Global Kinetics, a privately held company, is headquartered in Melbourne, Australia with offices in London, UK, Minneapolis, MN, and Portsmouth, NH, USA.

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