Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	At-home monitoring systems for movement symptoms in Parkinson's disease
Topic exploration report number:	TER221

Introduction and aims

Health Technology Wales researchers searched for evidence on the use of at-home monitoring of movement symptoms in Parkinson's disease supported by the Parkinson's KinetiGraph system, or similar technologies. This is an update to a previous topic exploration report on this technology, produced in October 2018 (TER028).

Summary of evidence

Validation

The clinical evidence summary submitted by the manufacturer describes a series of validation studies for their technology (Global Kinetics Corporation, 2020). Details on study methodology and results are limited but the Parkinson's KinetiGraph system is reported to have validity across a range of movement symptoms (e.g. bradykinesia, dyskinesia, immobility, tremor). A systematic review of wearable devices for management of Parkinson's disease was also found and demonstrated validation of devices with similar aims as the Parkinson's KinetiGraph system (Rovini et al. 2019). Additional primary studies on validation of other technologies have also been published since the most recent review (e.g. Gatsios et al. 2020).

Effectiveness and Cost-Effectiveness

The manufacturer highlighted a series of single arm and non-randomised controlled evaluations that examine the effectiveness of the Parkinson's KinetiGraph in influencing management of Parkinson's disease (Global Kinetics Corporation Clinical Evidence Summary, 2020). It was reported that the technology can assist clinicians in identifying uncontrolled motor symptoms and influences treatment decisions compared to clinical judgement without the Parkinson's KinetiGraph (Farzanehfar et al. 2018; Joshi et al. 2019, Nahab et al. 2019).

There appears to be limited evidence that the Parkinson's KinetiGraph or similar technologies, improves clinical outcomes or quality of life. One small randomised controlled study on an earlier iteration of this type of technology was identified (Cubo et al. 2016). The study was

reported as a trial-based economic evaluation and included patient outcomes and quality of life measures. The study found that technology-based at-home monitoring was more expensive than usual treatment but results on benefits were mixed, with outcomes on a functional measure favouring at-home monitoring but no difference shown on a generic quality of life measure. A further non-randomised controlled trial conducted in Australia using the Parkinson's Kinetigraph was highlighted by the manufacturer (Woodrow et al. 2020). This study reported null results when analysing improvements from first to last visit across the intervention and control arms for their primary outcome and had important methodological limitations. This included an imbalance between groups at baseline that was not addressed in analyses.

The most recent systematic review of similar technologies also noted that there is a lack of evidence on effectiveness on clinical outcomes (Rovini et al. 2019).

Ongoing Studies

The topic proposal from the manufacturer highlighted two studies that are currently underway in the United Kingdom. One is described as an audit and aims to explore how the Parkinson's KinetiGraph system can support decisions around treatment pathways and referrals to allied health professionals. The other study is described as a study aimed at developing new home based care pathways. The proposal also states that further studies are underway in the US, France, and Germany.

In addition, two ongoing randomised controlled trials that aimed to evaluate other systems for monitoring Parkinson's disease symptoms were identified (NCT02937324; NCT04176302) and reported that improvement of symptoms and quality of life are included outcomes. Both ongoing trials are past their reported study completion dates but no publications were available at the time of search.

Evidence Standards

The Parkinson's KinetiGraph system is a digital health technology and is likely to sit within Tier 3b technologies according to the [Evidence Standards Framework for Digital Health Technologies](). Technologies within this classification include tools used for treatment and diagnosis, as well as those influencing clinical management through active monitoring. For technologies of this classification, the best practice evidence standard is a high quality randomised controlled study in a relevant health setting to demonstrate effectiveness of the technology. The minimum standard is a high quality intervention study (experimental or quasi-experimental) showing improvements in relevant outcomes.

Areas of uncertainty

Some identified studies were limited by small sample sizes and a more comprehensive review would be needed to assess the quality of studies that used quasi-experimental methods. Other studies identified in the search are randomised and an assessment of their quality would be needed.

It is unclear how the technology would fit into pathways of care in Wales and there are limited studies in the UK setting. The duration and frequency of continuous monitoring that would be required is also unclear. The technology may require additional time from specialists to assess reports and may generate a need for additional contacts for medication management. These may be beneficial and provide cost-savings but there is limited evidence on this to date.

There is also uncertainty around the comparator for the technology. The manufacturer's clinical evidence summary states that other methods of monitoring (i.e. patient/carer diaries) are subjective and may be unreliable but their evaluations appear to rely on uncontrolled trials and it is unclear whether the technology would prove effective when compared to these monitoring approaches. There appear to be other alternatives to the technology based on smartphone monitoring, although the validity of these is unclear and they may not have CE marking for clinical use.

Conclusions

The Parkinson's KinetiGraph system and similar technologies appear to be well validated in monitoring motor symptoms in Parkinson's disease. However, there is a lack of evidence for the effectiveness of these technologies to improve patient outcomes and quality of life and on their economic value. Several ongoing studies were found and their results may provide additional information on these issues once published.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland	We did not identify any relevant guidance from this source.
Health Technology Assessment Group	We did not identify any relevant guidance from this source.
Health Information and Quality Authority	We did not identify any relevant guidance from this source.
EUnetHTA	We did not identify any relevant information or guidance from this source.
International HTA Database	We did not identify any relevant guidance from this source.
UK guidelines and guidance	
SIGN	We did not identify any relevant guidance from this source.
NICE	We did not identify any relevant guidance from this source.
Secondary literature and economic evaluations	
Cochrane library	We did not identify any relevant reviews from this source.
Medline	Rovini et al. (2019). Automated Systems Based on Wearable Sensors for the Management of Parkinson's Disease at Home: A Systematic Review. *Telemedicine Journal and e-Health, 25,* 167-183. https://doi.org/10.1089/tmj.2018.0035
Primary studies	
Cochrane library	Cubo et al. (2016). Prospective study on cost-effectiveness of home-based motor assessment in Parkinson's disease. *Journal of Telemedicine and Telecare, 23,* 328-338. https://doi.org/10.1177/1357633x16638971 Gatsios et al. (2020) Feasibility and Utility of mHealth for the Remote Monitoring of Parkinson Disease: randomized Controlled Trial. *JMIR mHealth and uHealth, 8,* e16414. https://doi.org/10.2196/16414
Medline	
Ongoing primary or secondary research	
PROSPERO database.	We did not identify any ongoing reviews from this source.
Clinicaltrials.gov	The CloudUPDRS Smartphone Software in Parkinson's Study. (CUSSP) - NCT02937324 Monitoring of Mobility of Parkinson's Patients for Therapeutic Purposes - Clinical Trial (MoMoPa-EC) - NCT04176302
Other	
Evidence provided by topic proposer	Farzanehfar et al. (2018). Objective measurement in routine care of people with Parkinson's disease improves outcomes. *npj Parkinsons Disease*, 3, 10. https://www.nature.com/articles/s41531-018-0046-4 Global Kinetics Corporation Clinical Evidence Summary (2020), unpublished Joshi et al. (2019). PKG Movement Recording System Use Shows Promise in Routine Clinical Care of Patients With Parkinson's Disease. Frontiers in Neurology, 10, 1027. https://doi.org/10.3389/fneur.2019.01027

	Nahab et al. (2019). Evaluation of Clinical Utility of the Personal KinetiGraph in the Management of Parkinson's Disease. Advances in Parkinson's Disease, 8, 42-61. https://doi.org/10.4236/apd.2019.83005
	Woodrow et al. (2020). A blinded, controlled trial of objective measurement in Parkinson's disease. NPJ Parkinson's Disease, 6, 35. https://doi.org/10.1038/s41531-020-00136-9

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Concepts used:	Parkinson's disease; monitoring; assessment; motor symptoms; movement