

Knee brace and accompanying app for rehabilitation post knee surgery: Funding Proposal

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1 Proposal Overview

The scope of this proposal aims to bridge the gap in communication in the management of knee pain and to enhance patient access to monitored physiotherapy through a wearable device and mobile application.

The market for such wearable devices is lucrative and growing rapidly. The orthopedic braces and supports market is expected to grow from \$4.1 billion to \$5.3 billion by 2028 globally and to grow by more than \$58 million in the UK alone. (cite these both) The reason for this rapid growth lies in the ever-increasing number of knee surgeries, particularly in the elderly population, as well as a growing awareness of the benefits of knee braces for injury prevention and rehabilitation. An additional factor is the growing uptake of sports and fitness activities, which increases the risk of knee injuries and can be a factor in the earlier onset of knee problems. In 2022, nearly 100,000 primary total knee replacement surgeries were performed in the UK, and this number has been predicted to increase by 85% by 2030, with one model even predicting over a million annual cases. Anterior cruciate ligament (ACL) and meniscal repair surgeries have also increased dramatically in the past two decades, with over 30,000 ACL reconstructions performed annually in the UK. Physiotherapy is vital for the management of knee pain, for post-operation recovery and for re-injury prevention, but is rarely well-monitored and often not followed correctly by patients.

The current system for the management of knee injuries and post-surgery rehabilitation is lacking in several key areas, in particular due to insufficient education, guidance and patient accountability. (cite NICE guidelines) These result in a shortfall of patients receiving first-line treatment (education and physical exercise) for common diagnoses such as osteoarthritis. In fact, less than 40% of patients with osteoarthritis receive such treatment. (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7990728/>) An evidence review of the management of osteoarthritis by NICE found that patients felt that insufficient information was provided, that direction on self-management techniques was vague and that a lack of monitoring reduced motivation to keep to the program. These issues are even more severe for vulnerable adults; The NICE review culminated in a recommendation to assess marginal groups, showing how little treatments for knee injuries cater even a little to vulnerable demographics. However, developing technology for small groups is not economically viable, and so the current system is unlikely to change without first targeting the masses. The scope of this proposal has therefore been developed to address these wider shortcomings in a way that is scalable and adaptable to vulnerable groups, such as children and adults with learning disabilities.

This proposal details a comfortable knee brace fitted with accelerometers and gyroscopes to monitor the range of motion (ROM) and velocity of movement of the knee joint during a set of exercises. The brace will be accompanied by a mobile application that will provide interactive education and real-time feedback to the user on their progress through a game interface. The app will be tailored by physicians to provide a prescribed series of exercises that the user can perform to aid in their recovery. The user's progress will be tracked over time, providing feedback to the user and their physiotherapist.

2 Economic Analysis

2.1 Market segmentation

The knee brace market can be segmented into medical and sport applications, as well as by type. The medical market is driven by the increasing prevalence of knee injuries and osteoarthritis, with the global knee brace market expected to reach \$1.9 billion by 2025. In the current market, high-quality knee braces can easily range from about £50-500. A study undertaken with the NHS used braces with an sensor comprised of accelerometers and gyroscopes at a cost of approximately £150 per patient and reduced the average number of post-TKR surgery physiotherapy visits by a third with positive outcomes.

The remote sensor saved the service £1,450 across the pilot

extra £100 to £200 per patient for the sensor Total physiotherapy visits reduced from 6 to an average of 4

2.2 Additional sources of support

Several grants exist in this area to provide support and fund research. The charity 'Versus Arthritis' has recently awarded almost £100,000 to a team at Leeds University developing an implantable sensor to monitor knee condition following total knee replacement, and almost £2 billion to a sport, exercise and OA centre. 'Power up to Play' is a charity that recently funded a study in Cambridge on warm ups to prevent knee injuries in athletes. Charities such as MenCap and the National Lottery Community Fund also provide grants for projects that improve the lives of people with disabilities. This could be instrumental in adapting commercially successful technology to cater to vulnerable groups that may not provide as large a return.

3 Device Design

3.1 Knee Brace

3.2 Sensor

A sensor comprising of gyroscopes and accelerometers, known as an Inertial Measurement Unit (IMU), is chosen to monitor the knee brace's orientation and motion over optical tracking or electromyography. This is because IMUs are small, lightweight and cost-effective, while having been shown to track joint angles and motion

Signal processing for an IMU involves refining data from the accelerometers and gyroscopes to determine orientation and motion. Filtering removes noise through algorithms like Kalman filters, calibration corrects sensor biases and alignment errors and sensor fusion integrates data from multiple sensors to smooth errors. This sort of signal processing optimizes IMU data for more precise orientation and motion tracking.

3.3

4 Policy Risk and Regulation

Policy Considerations:

- Ensure compliance with the General Data Protection Regulation (GDPR) regarding the collection, processing, and storage of personal data, including health-related information.
- Obtain explicit consent from users for data processing activities, providing clear information on how their data will be used and protected.
- Ensure that the knee brace meets the requirements of the UK Medical Devices Regulations (UK MDR) to be legally placed on the market.
- Verify conformity assessment procedures and obtain necessary certifications or approvals from a UK-approved notified body.

Risk Management:

- Implement robust encryption and data security measures to protect user information in compliance with GDPR requirements.
- Conduct regular security audits and risk assessments to identify and mitigate potential cybersecurity threats.
- Conduct clinical trials or studies involving UK-based participants to validate the efficacy and safety of the knee brace and mobile application within the UK healthcare context.
- Ensure that clinical evidence supports claims of effectiveness in aiding knee rehabilitation according to UK standards.

Regulatory Compliance:

- UKCA Marking:
 - Ensure that the knee brace and mobile application comply with UK Conformity Assessed (UKCA) marking requirements for medical devices.
 - Update labeling and documentation to reflect UKCA requirements, including information on conformity assessment and post-market surveillance.
 - NHS Guidelines:
 - Align the prescribed series of exercises provided by the mobile application with guidelines and recommendations from the National Health Service (NHS) for knee rehabilitation and physiotherapy.
 - Collaborate with healthcare professionals and physiotherapists to ensure the exercises prescribed by the app are in line with best practices endorsed by the NHS.

Market-specific Considerations:

- Localization:
 - Localize the mobile application interface and content to cater to UK users, including language, units of measurement, and culturally relevant imagery.

- Ensure that educational materials and instructions are tailored to the UK healthcare system and patient preferences.
- Reimbursement and Funding:
 - Explore opportunities for reimbursement through the NHS or private healthcare insurers for patients using the knee brace and mobile application as part of their rehabilitation regimen.
 - Provide documentation and evidence supporting the cost-effectiveness and clinical benefits of using the device for knee rehabilitation, facilitating reimbursement negotiations with healthcare payers.

5 Conclusion