Remote Assessment of Disease and Relapse in Central Nervous System Disorders

Reporting

Project Information

RADAR-CNS

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Periodic Reporting for period 6 - RADAR-CNS (Remote Assessment of Disease and Relapse in Central Nervous System Disorders)

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Summary of the context and overall objectives of the project

RADAR-CNS has developed and tested a transformative platform of remote monitoring of disease state in three CNS diseases: epilepsy, multiple sclerosis (MS) and depression. The development of remote measurement technologies (RMT) is an innovation which could be used to predict and avert negative clinical outcomes by providing real time information on the patient's current clinical state and providing predictive information indicative of a future deterioration. RMT is a disruptive innovation which requires careful evaluation, with an eye kept on implementation in real world settings. CNS disorders are an excellent test bed for such evaluation because they are chronic diseases whose course is dynamic with multiple relapses that could be measured remotely and passively via unobtrusive on-body biosensors and smartphones.

Our specific objectives are:
1. Building a generic RMT platform for smartphone and wearable devices to generate passive and active measurement data using experience sampling methodology
2. Devising clinical observational studies to follow patients, stratified by known prognostic indicators, to test the acceptability and determine the added value of RMT
3. Engaging stakeholders at the outset to maximise real world use of RMT and to produce relevant questions to inform clinical study design

Work performed from the beginning of the project to the end of the period covered by the report and main results achieved so far

The translational cluster (WP2, 9, 10) has concluded research determining the acceptability and potential barriers for RMT in people with MS, epilepsy and MDD. A systematic review summarising previous findings on barriers and facilitators to RMT across a breadth of health conditions has been published. Focus groups in the three disorders and three countries (UK, Italy and Spain) have been completed and analysed by WP2, with results now published. Detailed care pathway mapping and surveys have been completed by WP9 identifying the likely points at which RMT will have greatest clinical utility. WP10 has mapped out the current regulatory climate for the application of RMT in healthcare. We have presented our programme at the European Medicines Agency (EMA) and at a seminar at the Foundation of National Institutes of Health where members of the US Food and Drug Administration and EMA were present.
The technical work packages (WP7, 8) have delivered RADAR-base, a platform for the storage and analysis of data from RMT, and developing an analytic framework for future studies. The platform has been successfully deployed first in an in-hospital study of WP4 (epilepsy, study 1). Since November 2017 it has been deployed in the first ambulatory community study of depression and subsequently in MS and most recently epilepsy. All clinical studies have now completed recruitment including a total of 623 patients in our depression study, 537 in MS and 243 in epilepsy. RADAR-CNS has accumulated more patient years exposure of sensor data than virtually any similar study internationally.

The main purpose of our clinical studies was firstly to demonstrate the acceptability of these technologies in real world settings, including recruitment, retention, data completion and patient experience. We have published extensively on this topic demonstrating that with the infrastructure we

provided within RADAR-CNS consortium it is possible to gain far more complete and long-term data than previous research would have suggested was possible. The greatest challenge we identified is in data completeness as there are multiple steps required to ensure data completeness, including (a) that the smartphone/wearable is working (charged, functioning properly), (b) that participants are interacting with the technology appropriately (e.g. wearing the wearable, completing questionnaires etc) (c) that there are no technical issues beyond the control of the study team (e.g. changes to operating systems of permissions allowed by Android for data extraction from smartphones). These challenges are integral to conducting distributed studies, and therefore it is necessary to develop frameworks for the adequate description of incomplete data and to ensure that data missingness does not lead to systematic biases. We have explored these issues, for example showing the depression status does not strongly predict data incompleteness.
The second purpose of the clinical studies was to determine whether signals from smartphones or wearables could be used to gain an better indication of disease status. Here we have shown through multiple publications in WP4 that wearables can provide adequate and acceptable indications of seizure activity. In WP5 upcoming publications will demonstrate that the signals from wearables are able to detect “silent progression” in multiple sclerosis – i.e. gradual worsening in functioning which is of such insidious onset that patients and clinicians are unable to detect changes easily. This has major implications for clinical practice, offering the potential for us to intervene earlier in those who require it. In depression we have demonstrated that numerous data streams including GPS, Bluetooth handshakes and sleep, are associated with depressive symptomatology.
Finally, we have preliminary evidence that clinical state (e.g. depressive relapse) can be predicted by data signals collected from smartphones. Using the participant’s own data when they are in a state of health, we were able to train models to relapse. Because they are individualised, these models take account of the wide inter-individual variation in parameters such as GPS and Bluetooth handshake data, detecting departures from the individuals’ normal daily patterns, which appear to predate relapse. Such signals from smartphones could be used in a highly economical manner to trigger actions by the healthcare provider (e.g. further assessments, preventive lifestyle advice) which would meet our goal of moving healthcare from a model of “diagnose and treat” to one of “predict and prevent”. These models will be validated and refined over the next 3 months with submissions to leading journals in the latter half of 2022.

Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the project so far)

A major outcome of RADAR-CNS is the open source software infrastructure RADAR-base created for collecting mHealth datasets from devices, phones and apps, consisting of:
• A github organisation to host code repository: http://github.com/RADAR-base
• A website hosted by KCL: https://radar-base.org/
• A confluence-based wiki for the documentation of the software: https://radar-base.org/index.php/documentation/
• Docker hub containers defining the backend components

By offering an end-to-end platform capable of data capture, management, modelling and visualization, we will be able to test the acceptability and clinical utility of multimodal RMT. By supporting cheap and widely available devices and where possible passive monitoring, our platform will be scalable to large populations of patients. It also offers the potential for adding new devices, new target outcomes and new diseases. With early engagement from stakeholders our system will anticipate translational and implementational barriers. The clinical management of depression, epilepsy and MS would be readily translated by this technology, with real-time monitoring and an interactive style of communication between patient and clinician. A point of strength of the RADAR-CNS project therefore refers to its potential to translate research findings into both clinical applications and technological opportunities.

Logo

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