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[1] **Type**: Use one of the following codes (in consistence with the Description of the Action):
- R: Document, report (excluding the periodic and final reports)
- DEM: Demonstrator, pilot, prototype, plan designs
- DEC: Websites, patents filing, press & media actions, videos, etc.

[2] **Dissemination level**: Use one of the following codes (in consistence with the Description of the Action)
- PU: Public, fully open, e.g. web
- SEN: Sensitive, limited under conditions of the Grant Agreement

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Summary

Digital Health technologies can be used to monitor the course of a disease and fatigue in a new dimension of granularity and detail. Work package 6 team has adapted a platform for miGut-Health to investigate the connection between fatigue and IBD. Recruitment and data collection is in progress. The technology stack works as expected. First results are promising for a connection of fitness tracker data and disease activity. An issue of allergic reaction to the wristband of the fitness tracker needs to be resolved.

1 Introduction

Modern mobile technology increasingly used for medical purposes allows assessing daily life behavior, quality of life and disease activity in a new dimension of precision. The data captured by the integration of fitness trackers and a PRO App will provide new detailed datapoint and new biomarkers to understand the trajectories of fatigue in connection with IBD. We believe the new biomarkers and models can be used for detailed fatigue assessment and disease management. The existing infrastructure for wearable data capturing at the UKSH was adopted for miGut-Health and the first participants have been enrolled.

2 Description of Activities

UKSH adapted the wearable infrastructure for usage in miGut-Health. The backend to collect wearable data is adapted and deployed. The studyportal developed by UKSH was modified to meet the needs of the subproject WP2 with partner UKE. The study protocol, ethics application and study procedure were developed together with the UKE team. Meetings and training sessions on setting up and handing out the wearables were conducted jointly with UKE. Participants are regularly recruited. Data collection and storage are working as expected and an ETL pipeline is stablished. Technical support was provided regularly for the setup of the wearables and enrolment of the study participants. At the time of writing this report, 17 participants were included at the UKE. Additionally recruiting at the Comprehensive Centers for Inflammation Medicine (CCIM) is started.

Analyses of the collected data and data collected in the GUIDE-IBD project hast started and shows first results.

The integrated technology stack was tested and reviewed for validation.

3 Results & Discussion

From the technology point of view all tasks are done and the used technology stack shows a that is can run stable and is easy to adapt for other study settings.

We could catch up with recruitment at the UKE to reach the goal of 30 participants. Unfortunately, we have a dropout rate of 30% with the reason of “allergic reaction” to the wristband of the fitness tracker. This high rate was not expected. In ongoing projects at the UKSH we had rates of 1 - 3% of participants with “allergic reaction”. This results in insufficient data from the UKE for analysis.

Data from UKSH was analyzed and showed first signals that Steps, Heart Rate and Stress measured with the fitness tracker are connected to disease activity.

4 Conclusion

Data collection and monitoring is established as expected. Recruitment is catching up and will increase at the UKE and UKSH. We have no final signals of biomarkers we can use for fatigue assessment and disease management, but with more data coming in we expect that our findings will show that there is a connection between the data from the fitness tracker and fatigue/disease activity.

The unexpected allergic reactions are a severe problem. We approached Garmin with the situation, and they assured that there was no exchange in materials for the wristband, compared to ongoing projects. We shall investigate what is the cause as fast as possible.