IDEA-FAST

Identifying Digital Endpoints to Assess FAtigue, Sleep and acTivities in daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases.

Grant Agreement No. 853981

WP2 – Clinical Knowledge and Insight

D2.1: First study subject approvals package of the Feasibility Study (FS)

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Table of Contents

1 Abstract 3
2 Introduction 3
3 Final version of the study protocol 3
4 Registration number of feasibility study 3
5 Ethics approval 4
6 Conclusions 4
Appendix A – IDEA-FAST Feasibility Study Protocol 5
Appendix B – Ethics approval for UKSH 6

1 Abstract

The first study subject approvals package includes the final version of the feasibility study (FS) protocol, the registration number of the feasibility study as well as a short report on the ethical approval status at all four sites. Ethical approval was obtained at one of the four sites so far. As a result, the first subject was included in the IDEA-FAST FS as planned in July 2020 (Month 9).

The FS aims to identify candidate digital parameters of fatigue and sleep disturbances to be further tested in the subsequent, larger clinical validation study (CVS). Four European centres (Universitätsklinikum Schleswig-Holstein, Campus Kiel (UKSH), Newcastle upon Tyne Hospitals NHS Foundation Trust/Newcastle University (UNEW), Erasmus University Medical Centre (EMC), and George-Huntington-Institut GmbH (GHI)) will investigate this research question in four parallel studies in different disease populations which include Parkinson's disease (PD), Huntington's Disease (HD) inflammatory bowel disease (IBD), primary Sjögren's syndrome (PSS), rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE) as well as healthy volunteers (HV). Participants will be asked to report sleep disturbances and fatigue by means of questionnaires and a digital diary during a study period of 28-36 days. During the study period, they will also use various digital devices/technologies for four periods of five days each (devices worn consecutively, maximum of three devices simultaneously in addition to a smartphone). Measures collected through novel digital tools will be compared with traditional measures: i) clinical outcomes (e.g., surveys) and ii) patient-reported outcomes (questionnaires and diaries). Digital measures which best correlate with the patient-reported measures of sleep disturbances and fatigue as well as the clinical outcome measures will be considered for further investigations in the CVS. The FS will also assess usability, acceptability, tolerability and compliance aspects concerning the different digital technologies as well as social functioning measures.

2 Introduction

The first study subject approvals package can be delivered as expected. A first template for the FS study protocol was developed and internally reviewed by all WP2 partners in February 2020 (Month 5). In the following months, open questions were resolved before the four sites adapted the final template to reflect the individual participant population and to fulfil local as well as national requirements. Based on this study protocol, the FS was registered at the German Clinical Trial Registry. The adapted study protocols have been submitted to three of the local ethics committees. The last site (GHI Münster) will submit its study protocol to the local ethics committee in August (Month 10).

The FS protocol is a confidential document. Therefore, there are two versions of this current deliverable report – a confidential version which includes the full FS protocol and a public version with the FS protocol removed.

3 Final version of the study protocol

The Feasibility Study protocol is shown in Appendix A but, for confidentiality reasons, it is not included in the public version of this deliverable.

4 Registration number of feasibility study

The study is registered in the German Clinical Trial Registry (DRKS, https://www.drks.de/) under the number DRKS00021693.

5 Ethics approval

The final version of the study protocol has been adapted and submitted to the local ethics committees (EC). The work of the local ECs and the clinical sites has been somewhat impacted by Covid-19, leading to delays at several sites. The Kiel site (UKSH) has been cleared to start recruitment (see Appendix B), all other sites are in the process of obtaining ethical approval. UKSH has successfully included the first participant in July 2020.

Site	**Status**
UKSH (Kiel Germany)	Approved by the ethics committee of the Medical Faculty of Kiel University (D 491/20).
UNEW (Newcastle, UK)	Submitted, study will be discussed at local EC meeting on 3 August 2020 (London Riverside ethic committee, REC reference: 20/PR/0185, IRAS project ID: 282329).
EMC (Rotterdam, The Netherlands)	Submitted, EC requires discussion with other local studies using digital technologies and translation of all patient-facing material, revision currently in progress.
GHI (Muenster, Germany)	Submission delayed, planned in August 2020 (Month 10).

6 Conclusions

In conclusion, the study protocol for the feasibility study has been successfully designed and adapted by the four participating sites. The feasibility study has been registered at the German Clinical Trial Registry (DRKS00021693) and approved by the ethics committee of the Medical Faculty of Kiel University (D 491/20). The first participant was included as expected in Kiel in July 2020. The next step will be to obtain ethical approval for the other three sites and start recruitment at these sites as soon as the Covid-19 situation allows.

Appendix A – IDEA-FAST Feasibility Study Protocol

For confidentiality reasons, the Feasibility Study protocol is not included in the public version of this deliverable.

Appendix B – Ethics approval for UKSH

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Datum: **04.Juni 2020**

AZ.:	**D 491/20** (bitte stets angeben)
Studienplan:	**Eine Beobachtungsstudie zur Beurteilung von Schlaf und Fatigue mit digitaler Technologie im häuslichen Umfeld, im Rahmen des IDEA-FAST Projekts** Anschreiben v. 16.04.2020 mit Basisformular; Prüfplan V 1.0 vom 09.Apr2020, Teilnehmerinformation und Datenschutzerklärung V 1.0 vom 08.Apr2020, Informationsblatt zu den digitalen Geräten und Apps in der IDEA-Fast Studie; Information zur Studie und zum Datenschutz für Kontaktperson V 1.0 vom 08.Apr2020; Einwilligungserklärung
Studienleiter:	**Prof. Dr. Walter Maetzler, UKSH, Campus Kiel**
Finanzierung:	**Horizon 2020**
Antrag vom:	**07. Mai 2020**

Sehr geehrter Herr Kollege Maetzler,

wir bestätigen den Eingang des obengenannten Antrages zur Beratung gemäß § 15 Berufsordnung (BO) der Ärztekammer Schleswig-Holstein. Nach Durchsicht der Unterlagen durch die Geschäftsstelle und durch mich als Vorsitzenden der Ethik-Kommission bestehen gegen die Durchführung der Studie keine berufsethischen und berufsrechtlichen Bedenken.

Die im Folgenden aufgefuhrten Hinweise mussen beachtet werden:
1.Datenschutzrechtliche Aspekte von Forschungsvorhaben werden durch die Ethik-Kommission grundsatzlich nur kursorisch geprüft. Diese Bewertung ersetzt nicht die Konsultation des zuständigen Datenschutzbeauftragten.
2.Es wird darauf hingewiesen, dass künftige Änderungen der Studie der Ethik-Kommission anzuzeigen sind und gegebenenfalls eine erneute Beratung erforderlich machen.
3. Die ethische und rechtliche Verantwortung fur die Durchführung dieser Studie verbleibt beim Studienleiter.
4. Gemäß Deklaration von Helsinki **muss** der Ethik-Kommission nach Studienende ein Abschlussbericht vorgelegt werden, der eine Zusammenfassung der Ergebnisse und Schlussfolgerungen der Studie enthält.

Wir wünschen Ihnen für die Durchführung der Studie viel Erfolg.

Mit freundlichen kollegialen Grüßen

Prof. Dr. med. H. M. Mehdorn
Vorsitzender der Ethik-Kommission

Dr. med. Christine Glinicke
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