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Electronic clinical study management system

with artificial intelligence-based data processing capabilities

the PhD thesis submitted by **Ing. Miroslav Mužný**

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Opponent´s review

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Current technology offers ever more sophisticated sensors, wearable devices and other gadgets that promise to mediate reliable information about selected characteristics of a person who wears them. Often, they target not only values of the vital signs but they offer possibilities to provide information about number of other characteristics which might be useful for monitoring physical activity or patients at risk. It seems so tempting to combine these tools with a mobile communication device to design a dedicated monitoring system that could warn the endangered patient whenever his/her data readings do not correspond the intended values and provide a suggestion for an appropriate intervention based on an advice of the participating researcher. Development of such a system represents a very complex process and the resulting system needs extensive testing in everyday use that starts with the considered sensors (they have to be tested because most often they do not have medical certification) and goes on until the full designed concept including provision of interventions has to prove its value in a reliable clinical trial. This demanding process requires lot of time and energy of the participating expert team because it is necessary to cover all the phases necessary for ensuring the clinical study for testing a medical product from recruitment and randomization of the patients, over communication with the users during the designed interventions, data collection and management up to evaluation of the final outcomes of the trial.

The considered topic – its timeliness/topicality

The thesis is dedicated to design and testing of a SW system *Hubro* for complex management of clinical studies that efficiently supports all their upper mentioned phases and provides the patient e.g. with an easy to use solution for self-reported data collection. Thanks to modular design *Hubro* can be further customized according the needs of the considered application, the connected technical equipment and its requirements for necessary data (post)processing. Pluggable modules with implemented AI algorithms can be applied e.g. for finding patterns in the collected data or to improve/simplify communication with the patient. These features make the designed SW system unique and ready to be used for various purposes.

Hubro is a SW tool many researchers have been waiting for – it comes just in time because its features make it ready to cope with the demand for collecting big sets of real-life longitudinal data that are necessary e.g. for design of reliable decision support algorithms using machine learning.

Methods and procedures applied and originality of the presented results

State of art methods are applied in *Hubro* design as well as during testing its functionality in two patient studies. One of the studies tested an original product Smartwatch/Smartphone Application for Diabetes Self-Management, which proved to be very well accepted by the participants of the study who appreciated e.g. the possibility to use the application even offline (not having it connected to the phone) for some limited time.
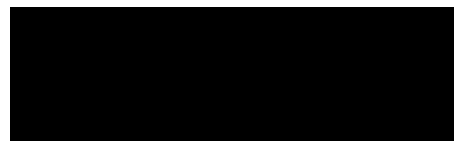
Presetation and style of the thesis

Both upper mentioned studies have been prepared with exceptional care. Special attention has been devoted to selection of the wrist-worn wearable equipment for measurement of physical activity. Results of this study have been described in two journal papers that succeeded to attract lot of attention – the paper from the year 2018 has already 69 citations and that from the year 2020 has 7 citations. This certainly confirms that the considered problem is highly relevant.

Conclusions

The thesis presents original results that can significantly contribute to advance of the state of art in the relevant domain. I confirm that the submitted thesis proves capacity of its author to conduct independent creative research and that Ing. Mužný deserves to be awarded by the title "Ph.D." to be used after his surname.

Praha, 14.2. 2021   Olga Štěpánková