

Experience from using a dynamic study management service for an mHealth diabetes type 2 RCT



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Background

Clinical trial performance is often delayed, which is especially critical when incorporating mobile health (mHealth). And while technical systems, such as web-platforms, are available to ease certain challenges of study management, these often provide support for, e.g., the recruitment and questionnaire phases only. In response, a dynamic study-management platform was developed to improve study efficiency and data-gathering capabilities.

The system is acknowledged by Datatilsynet and REK (ref. 2013/1906/REK sør-øst B), for use in the “Tailoring Type 2 Diabetes Self-Management” project, a cross-over RCT variant involving two groups assigned to use either a standard or tailored version of the Diabetes Diary self-management app [1]. The intervention spanned 6 months for each participant, and the RCT spanned 10 months (January–November 2017). Here we report experiences and main administrative findings from the trial.

Results

• Recruitment (11 weeks)

The study manager spent the following amount of time on each task per participant:

- Informed consent: delivery and collection (2-minutes)
- Randomization (1-minute)
- Delivery of the Initial questionnaire (1-minute)
- App administration (4-minutes)



• Administration (6 months)

- Mid-study questionnaire (1-minute)
 - Final questionnaire (1-minute)
 - Minutes spent logging into the system, checking participant status, sending questionnaire reminders, etc. approximately tripled these times
- Totaling 30-minutes per user**

• Data-gathering and analysis (ongoing)



Figure 1. Visual representation of the elements in the proposed eHealth and mHealth research evaluation platform. The functions were designed by using the following technologies and systems: LimeSurvey [3], Piwik [4], Django [5].

Method

The amount of time that the study manager spent using the platform [2], to complete each task per stage (see Figure 1) of the RCT, was approximated and summed up based on logs automatically gathered by the platform and manually by the study manager.

Conclusion

The most time consuming functionalities were the creation of the study elements: questionnaire, app-related materials, recruitment texts, administrative project documents and webpage, etc. We demonstrated the potential of efficiently managing a study involving mHealth technologies using the presented platform compared to paper or online alternatives that only offer support for certain study management tasks. Final results, as well as times that participants spent per study task, will be reported in coming venues and publications.

References

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