

The need for updated evaluation approaches for e-health and m-health interventions - a dynamic concept for more efficient trials

Background

Clinical trials are notorious for falling behind schedule and over budget. In fact, nearly 90% of clinical trials fail to reach intended outcomes on time. Today, mobile health (m-health) technologies, e.g. apps for diabetes self-management, provide additional challenges by developing faster than clinical trials are able to evaluate them. Therefore, approaches to assess m-health self-management interventions, especially randomized controlled trials, must adapt.

Method

A review of traditional e-health and m-health assessment studies revealed that tested interventions were often outdated by the time trials ended, thus reducing their quality and potential impact. Major bottlenecks were identified and a holistic platform for electronically supporting study management was proposed. Specific technological functionalities were designed through collaboration between researchers, patients, medical experts, and improved through consultation with our hospital's research unit, the regional ethical board (REK) and Norwegian Data Protection Authority (Datatilsynet).

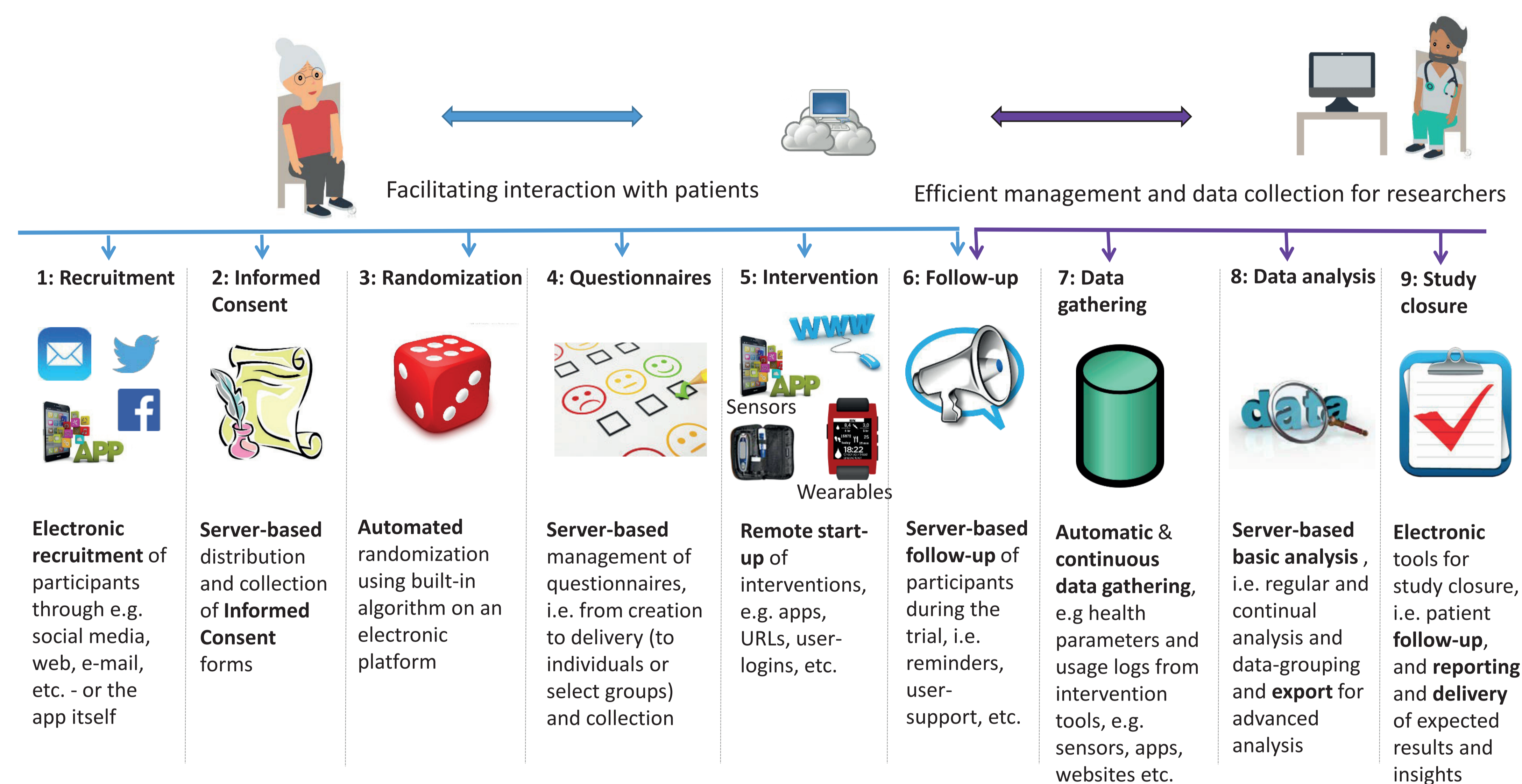


Figure 1. Visual representation of the elements in the proposed e-health and m-health research evaluation concept.

Results

An electronic study-management concept was developed. Modules with functionalities specific to major trial stages (Figure 1), several of which have been separately tested with success, facilitate a new holistic system for evaluation of e-health and m-health trials. The concept is acknowledged by Datatilsynet and REK (ref. 2013/1906/REK sør-øst B), and is currently under test as part of the “Tailoring Type 2 Diabetes Self-Management” project.

Conclusion

We expect this concept to enable researchers to more efficiently handle the administrative-, patient-, and data-related tasks of m-health and e-health interventions. By utilizing this concept in an ongoing clinical trial, we will demonstrate the potential of evaluating m-health technologies as disease and self-management treatment interventions.