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Iterative development and evaluation methods of mHealth behavior change interventions

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Social media and mobile devices are rapidly evolving environments for health interventions. There is growing recognition that traditional research processes cannot keep pace with this constantly shifting landscape. The changing technology landscape demands mHealth researchers use appropriate methods throughout the development cycle. Novel research methods allow researchers to capitalize on technological advances and more rapidly disseminate research findings. This manuscript reviews three iterative health behavior intervention development and research methodologies: Agile, Multiphase Optimization Strategy, and the mHealth Development and Evaluation Framework. This manuscript presents benefits and challenges of using such methodologies for mHealth interventions through selected case examples of these methods in practice.

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Introduction

Social media and mobile devices are rapidly evolving environments for health interventions. For example, Facebook launched in 2004 and counts over one-sixth of the world population as users (Facebook; URL: https://www.facebook.com/facebook/info). Nearly two-thirds of American adults are smartphone owners, though the iPhone was introduced in 2007 [1]. Over 100,000 mobile health ('mHealth') apps are now available on the marketplace, a doubling of the market from just two and half years prior [2,3]. These devices and applications present an unprecedented opportunity for broad, population-level health intervention research.

Traditional research processes struggle to keep pace with this constantly shifting landscape [4••,5•,6,7]. Researchers looking to deliver evidence-based technology-driven interventions may find this work challenging given the slow nature of the research process itself. It can take nearly six years to disseminate the results of a comparative effectiveness trial [8], and years longer when factoring in the time involved in grant conceptualization, writing, submission, and funding [4••]. A 2012 Institute of Medicine report summarized these challenges, stating that 'recognition is growing that the clinical trials enterprise in the United States faces substantial challenges impeding the efficient and effective conduct of clinical research to support the development of new medicines and evaluate existing therapies' [9]. Innovation in research design has been identified as one approach to speed the translation of research into practice [4••,10–16].

The changing technology landscape demands mHealth researchers use appropriate methods throughout the development cycle. Newer approaches to intervention design, such as the Multiphase Optimization Strategy (MOST) [17] and the mHealth Development and Evaluation Framework [18], enable flexibility to ensure the intervention proposed is relevant to participants once in the field. These approaches draw on methods from engineering and software development to more efficiently design, develop, optimize, deploy and evaluate behavioral interventions.

Novel research methods allow researchers to capitalize on technological advances and more rapidly disseminate research findings. This manuscript describes iterative research methods in several types of mHealth behavior change interventions. We also discuss the benefits and challenges of using such methodologies for mHealth interventions.

Description of iterative methods

Iterative research methods emerged out of engineering [19] and software development [20], which place a premium on cost efficiency, rapid learning, and product evolution. Historically, software development processes relied on a sequential model called 'waterfall' in which requirements for a project were gathered at the outset. Then, software developers designed, coded, tested, and delivered a finished product. This approach benefitted from straightforward planning and design and progress that were easy to measure given that the full scope of work was 'known' in advance. However, an inherent limitation of this approach is that the beginning of a project is the moment of greatest ignorance: it could be difficult, if not impossible, to fully scope out the requirements of the project at the very start. Another shortcoming of waterfall development is that problems in acceptance, usability, or effectiveness were often not identified until after the final product was finished.

Waterfall is increasingly being replaced by a philosophy called Agile. Agile allows for and encourages iterative, incremental and responsive-to-change development to produce rapid feedback loops for faster learning and product evolution [21,22]. This approach typically involves small, rapid-cycle studies focused on clearly specified outcomes related to uptake, feasibility, receptivity, acceptability, etc. These evaluation efforts often involve both qualitative and quantitative data collection to ensure the intervention is designed with the end user in mind. Metrics of interest in Agile development and evaluation efforts are often interim — rather than final — endpoints. Agile enables frequent and early opportunities to see how well the product is performing, and usually produces a viable version of the product more quickly.

One example of Agile in behavioral sciences is van Mierlo and colleagues' work developing a young adult smoking cessation intervention [23••]. van Mierlo's team implemented Agile for both the software *and* intervention development to maximize a fixed budget and timeline. The team iteratively tested the overall intervention concept and lightweight, 'minimum viable product' (MVP) versions of its core features, message content, functionality, and administrator interface over three short (<1 year) development phases. For example, integrated text-and-chat enabling direct communication with counselors via text message was not part of the original project plan. Feedback from Phase I users led the team to include this feature in an MVP version in Phase II, and incremental optimization made it a well-used feature by Phase III. Agile also provided a framework for their interdisciplinary team to work together (i.e., telephone quit specialists assessed need and functionality, designers and database architects crafted a usable front-end interface). The end result of these rapid-cycle evaluations was an intervention that was well-liked and heavily used by the target audience.

MOST [17,24] and the mHealth Development and Evaluation Framework [18] are two other iterative research approaches to intervention development that efficiently optimize specific intervention components [25]. Iterative methods used through throughout the intervention development period facilitate refinement and optimization. Used in 'Phase I,' they allow researchers to discover new features or flaws in the original design. These methods can yield feasibility and receptivity signals from the target audience, plus signals of efficacy before embarking on larger, longer, and more expensive trials that focus solely on comparative effectiveness. Researchers may also disseminate key lessons learned from early phases to more rapidly advance the knowledge-base in their field. To date, much of the research using these approaches has involved technology-based interventions; however, their relevance is not limited to mHealth implementations [26••,27]. Selected case examples of these approaches in practice are presented below.

Multiphase Optimization Strategy (MOST)

MOST [17,24] is a framework for preparing, optimizing, and evaluating behavioral interventions. In the preparation stage, researchers determine the theoretical or conceptual underpinnings of the intervention. These decisions drive the features to be included in an intervention, and how they will be measured. This phase also includes determining optimization criterion, such as engagement, cost-efficiency, or health impact. Once the general approach to the intervention is determined, the investigative team begins optimization work. This involves one or more pilot tests to refine intervention components until they meet or exceed the criterion, or are removed from the intervention. The evaluation phase consists of testing the optimized version of the intervention, typically in a comparative effectiveness trial. MOST can minimize the time and development work devoted to intervention features that may yield little or no effect. However, this approach may present challenges for some research teams: running sequential optimizations and recruiting participants for multiple fully powered small trials may be time and cost-prohibitive.

Case examples

Pellegrini and colleagues [28] used MOST to develop and optimize a weight loss intervention (Opt-IN) that yielded the best weight loss outcome for $500 or less. Their goal was to identify which of five treatment components contributed most meaningfully and cost-efficiently to weight loss over a six month period. This study employed a 16-cell fractional factorial design, which minimized recruitment requirements while maximizing scientific yield. Their work represents the first application of MOST to a weight loss intervention designed to be optimized for cost-effectiveness and scalability.

Cobb and colleagues [29] employed MOST in a study of the viral spread of a smoking cessation application through Facebook social networks. They built an evidence-based cessation application and conducted a fractional factorial randomized trial to evaluate which features contributed to viral spread. In Phase I, the team conducted a series of experiments to optimize each of the individual features hypothesized to drive diffusion.