Agile Science Techniques for Digital Health

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agenda

• vocabulary
• challenges
• from agile development to agile science
• discuss use case
digital health
software development
Fixed design and development of digital health interventions in a mandatory-phase environment is fundamentally incompatible with the technology used.
RESEARCH ARTICLE

Behavioral and technological interventions targeting glycemic control in a racially/ethnically diverse population: a randomized controlled trial

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Abstract

Background: Diabetes self-care by patients has been shown to assist in the reduction of disease severity and associated medical costs. We compared the effectiveness of two different diabetes self-care interventions on glycemic control in a racially/ethnically diverse population. We also explored whether reductions in glycated hemoglobin (HbA1c) will be more marked in minority persons.

Methods: We conducted an open-label randomized controlled trial of 376 patients with type 2 diabetes aged ≥18 years and whose last measured HbA1c was ≥7.5% (≥58 mmol/mol). Participants were randomized to: 1) a Chronic Disease Self-Management Program (CDMSP; n = 101); 2) a diabetes self-care software on a personal digital assistant (PDA; n = 81); 3) a combination of interventions (CDMSP + PDA; n = 93); or 4) usual care control (n = 95). Enrollment occurred January 2009-June 2011 at seven regional clinics of a university-affiliated multi-specialty group practice. The primary outcome was change in HbA1c from randomization to 12 months. Data were analyzed using a multilevel statistical model.

Results: Average baseline HbA1c in the CDMSP, PDA, CDMSP + PDA, and control arms were 9.4%, 9.3%, 9.2%, and 9.3%, respectively. HbA1c reductions at 12 months for the groups averaged 1.1%, 0.7%, 1.1%, and 0.7%, respectively and did not differ significantly from baseline based on the model (P = .771). Besides the participants in the PDA group reporting eating more high-fat foods compared to their counterparts (P < .001), no other significant differences were observed in participants’ diabetes self-care activities. Exploratory sub-analysis did not reveal any marked reductions in HbA1c for minority persons but rather modest reductions for all racial/ethnic groups.

Conclusions: Although behavioral and technological interventions can result in some modest improvements in glycemic control, these interventions did not fare significantly better than usual care in achieving glycemic control. More research is needed to understand how these interventions can be most effective in clinical practice. The reduction in HbA1c levels found in our control group that received usual care also suggests that good routine care in an integrated healthcare system can lead to better glycemic control.

Trial registration: ClinicalTrials.gov Identifier: NCT01221090.

Keywords: Chronic disease, Glycemic control, HbA1c, Self-management, Type 2 diabetes
• trials take approximately 5.5 years from the initiation of enrollment to publication

• follow-up periods for relevant outcomes can extend this time period to a decade

• during this period, scientific and technological advances will occur that may make the eventual findings less relevant or even obsolete
agile development
• highest priority is to satisfy the customer through early and continuous delivery of valuable software

• welcome changing requirements, empowers business to adapt at its own pace

• deliver working solutions frequently, solicit continuous feedback

• business and developers work together throughout the project, promoting collaboration

• build projects around motivated individuals

• convey information with face-to-face conversation, focused and efficient stand-ups

• maintain a constant pace indefinitely

• continuous attention to technical excellence, good design enhances agility

• pursue simplicity, maximizing the amount of work not done

• the best architectures, requirements, and designs emerge from self-organizing teams, focused on continuous improvement
agile science
<an adaptation of agile values>

- **relevance and social value** over pure academic pursuit
- **outputs as non-technical insights, tools, and solutions** over outputs as publications
- **iterative experimentation** over long time-scale, pre-planned research
- **openness and sharing** over knowledge as property
- **interdisciplinary teamwork and community engagement** over isolated expertise
enable the formation of managing, *transdisciplinary* teams
- monitor regulatory affairs and collaborate with IRBs to *accelerate* approvals
- convene *stakeholders* early to assist with trial design and sustain through execution
- establish *citizen-scientist* panels; leverage networking technologies
- replace traditional pilots with light-weight, *iterative* N-of-1 / optimization designs
- emphasize importance of *small, actionable* lessons
- *reevaluate* the relevance and potential for positive impact
- consider *alternatives* to the two-arm randomized controlled trial
- use data standards and common elements to *facilitate sharing*
- report *proximal outcomes* while follow-up data collection continues
- *share* methods, techniques, code, and other output
- encourage *online and open access* peer-reviewed publishing
use case: FXSDA
“Decision aids differ from usual health education materials because decision aids make explicit the decision being considered, and provide detailed, specific, and personalized focus on options and outcomes for the purpose of preparing people for decision making.”

– Cochrane Review (2014)
Goals of the Decision Support Tool and Benefits

**Two Primary Goals:**
1. Assess **capacity** to make decisions about clinical trial participation
2. Promote more **informed** decisions about clinical trial participation

**Potential Secondary Benefits**

- Enhance (remote) enrollment and/or retention in clinical trials
- Increase **scientific knowledge** base and quality of clinical trial data
- Enhance dissemination of information
- **Reduce** caregiver burden in decision making
- Foster good will and greater trust with participants
Background on FXS

FXS is an X-linked condition which results in wide variability of severity, but most often is associated with cognitive impairment, behavioral co-morbidities (e.g., attention problems, autism symptoms), and some medical problems (e.g., seizures).

Over the past 10 years, the number of clinical trials aimed at treating symptoms of FXS or the core mechanisms of the condition has increased steadily.
How Decisional Capacity is Being Assessed

Characterize and explain individual differences in decisional capacity

Assessing 200 individuals with FXS using a battery of validated measures
- Neurocognitive direct assessment
- Parent/guardian report

End Result

First comprehensive description of decisional capacity of individuals with FXS

Identify factors associated with variability in decisional capacity

Determine the validity of ratings

Develop evidence-based guidelines for categorizing decisional capacity of individuals with FXS
What is Decisional Capacity and How Do We Assess It?

Ask questions about these 4 areas and score them:

- Understanding
- Appreciation
- Reasoning
- Expressing a Choice
FXSDA contains 6 “vignettes”

After I tell you about this study, I will ask if you want to help with it. It’s your choice. So please, listen carefully.
What Makes This Unique?

Tablet-based, interactive

Theory-driven

IRB required elements

Plain language, low literacy

Interactive sorting exercise (shown here)

Iterative user-centered design and testing process
## How Do We Know if it Works?

### RCT Design-

<table>
<thead>
<tr>
<th>Component</th>
<th>Both Conditions</th>
<th>Control only</th>
<th>Experimental only</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Delivery of Information</strong></td>
<td>Paper</td>
<td>+ Verbal</td>
<td>+ Visual, and audio</td>
</tr>
<tr>
<td><strong>Language</strong></td>
<td>Complex (paper)</td>
<td>+ Simplified highlights (verbal)</td>
<td>+ Simplified (tablet-based application)</td>
</tr>
<tr>
<td><strong>Exposure to Information</strong></td>
<td>Prior to visit, paper consent form sent</td>
<td>During visit, simplified overview highlights provided up to 2 times</td>
<td>During visit, simplified tablet-based tool content repeated up to 3 times</td>
</tr>
<tr>
<td><strong>Assessing Understanding Questions</strong></td>
<td>Same wording of questions</td>
<td>Asked at end</td>
<td>Asked after each vignette/disclosure section</td>
</tr>
<tr>
<td></td>
<td>Multiple choice options with one correct answer</td>
<td>Paper and pencil data collection</td>
<td>Electronic data collected within the app</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Asked up to 2 times</td>
<td>Asked up to 2 times</td>
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Techniques

• Team formation and management
• Feature-driven design
• Stakeholder engagement
• Communications and collaboration
Team formation and management

• Lean
• Empowered
• Team of teams
Feature-driven development

is an iterative and incremental software development process.

It is one of a number of lightweight or Agile methods for developing software.

FDD blends a number of industry-recognized best practices into a cohesive whole.

These practices are all driven from a client-valued functionality (feature) perspective.

Its main purpose is to deliver tangible, working software repeatedly in a timely manner.

Stakeholder engagement

• Multiple stakeholders involved
  • Project team
  • Advisors
  • Program officer
  • Family members
  • Individuals with FXS

• Iterative engagement cycles
  • Tracked with FDD
  • Worked across three groups
    • Internal
    • External
    • Participants
  • Time = fidelity
  • Fidelity = complexity
Communications & collaboration

• Consider institutional barriers
• Frankenflow
• Leverage platforms for collaboration
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