Bench Science for Digital Behavioral Interventions: Making Every Study Count

Predrag "Pedja" Klasnja
University of Michigan

Despite the hype, when it comes to the design of digital behavioral interventions we still don't know what we are doing.

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ORIGINAL REPORTS | Health Services and Outcomes

Randomized Trial of Text Messaging to Reduce Early Discontinuation of Adjuvant Aromatase Inhibitor Therapy in Women With Early-Stage Breast Cancer: SWOG S1105

Dawn L. Hershman, MD, MS[1] ✉; Joseph M. Unger, PhD[2,3]; Grace Clarke Hillyer, EdD, MPH[1]; Anna Moseley, MS[2,3]; Kathryn B. Arnold, MS[2,3]; Shaker R. Dakhil, MD[4]; ...

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Original Investigation

Effect of Lifestyle-Focused Text Messaging on Risk Factor Modification in Patients With Coronary Heart Disease
A Randomized Clinical Trial

Clara K. Chow, MBBS, PhD; Julie Redfern, PhD; Graham S. Hillis, MBChB, PhD; Jay Thakkar, MBBS; Karla Santo, MBBS; Maree L. Hackett, PhD; Stephen Jan, PhD; Nicholas Graves, PhD; Laura de Keizer, BSc (Nutr); Tony Barry, BSc; Severine Bompoint, BSc (Stats); Sandrine Stepien, MBiostat; Robyn Whittaker, MPH; Anthony Rodgers, MBChB, PhD; Aravinda Thiagalingam, MBChB, PhD

IMPORTANCE Cardiovascular disease prevention, including lifestyle modification, is important but underutilized. Mobile health strategies could address this gap but lack evidence of therapeutic benefit.

OBJECTIVE To examine the effect of a lifestyle-focused semipersonalized support program delivered by mobile phone text message on cardiovascular risk factors.

DESIGN AND SETTING The Tobacco, Exercise and Diet Messages (TEXT ME) trial was a parallel-group, single-blind, randomized clinical trial that recruited 710 patients (mean age, 58 [SD, 9.2] years; 82% men; 53% current smokers) with proven coronary heart disease (prior myocardial infarction or proven angiographically) between September 2011 and November 2013 from a large tertiary hospital in Sydney, Australia.

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JAMA | Original Investigation

Effect of Wearable Technology Combined With a Lifestyle Intervention on Long-term Weight Loss
The IDEA Randomized Clinical Trial

John M. Jakicic, PhD; Kelliann K. Davis, PhD; Renee J. Rogers, PhD; Wendy C. King, PhD; Marsha D. Marcus, PhD; Diane Helsel, PhD, RD; Amy D. Rickman, PhD, RD, LDN; Abdus S. Wahed, PhD; Steven H. Belle, PhD

IMPORTANCE Effective long-term treatments are needed to address the obesity epidemic. Numerous wearable technologies specific to physical activity and diet are available, but it is unclear if these are effective at improving weight loss.

OBJECTIVE To test the hypothesis that, compared with a standard behavioral weight loss intervention (standard intervention), a technology-enhanced weight loss intervention (enhanced intervention) would result in greater weight loss.

We often put complex digital interventions into trials after a formative study, with only a superficial understanding of the nuances of their functioning.

Our Goals

- Design maximally effective digital interventions
- Learn as much as possible from each study, as efficiently as possible

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- Studies should advance science, not just be QA for intervention packages
- Evidence should inform the design of future interventions and our understanding of human behavior and intervention response

How Can We Get There?

- We should treat formative, small-N studies as bench science in the wild
  - Their goal should be to understand and optimize each aspect of the intervention in the context of its real use
- To do this, we should:
  - Focus on individual intervention components as analytical units
  - Assess effects on proximal outcomes
  - Study dynamics (and boundary conditions) of intervention response

Individual Intervention Components

Assessing effects of individual components helps directly answer the question "*How do we effectively design A [goal-setting, feedback, planning, etc.], delivered via modality B, for population C, in context D?*"

Why Focus on Individual Components?

- More direct assessment of mechanisms that underlie intervention functioning (as components should target distinct mechanisms)

- Granular understanding of conditions of effectiveness

- Efficient testing of different designs of a single component

- Building of an evidence base that readily informs future intervention development (easier uptake of study results)

How to Study Individual Intervention Components

- Randomize provision of components of interest, both across participants, and for "push" components, within a person
- Maximize efficiency by including randomizations that assess not just multiple components but also answer multiple questions
  - e.g., not only "does x work?" but "what form of x works?"
- Use efficient trial designs:
  - Factorial experiments
  - Micro-randomized trials
  - System ID experiments

Proximal Outcomes

Proximal outcome: Most immediate intended effect of an administration of a single "dose" of an intervention component.
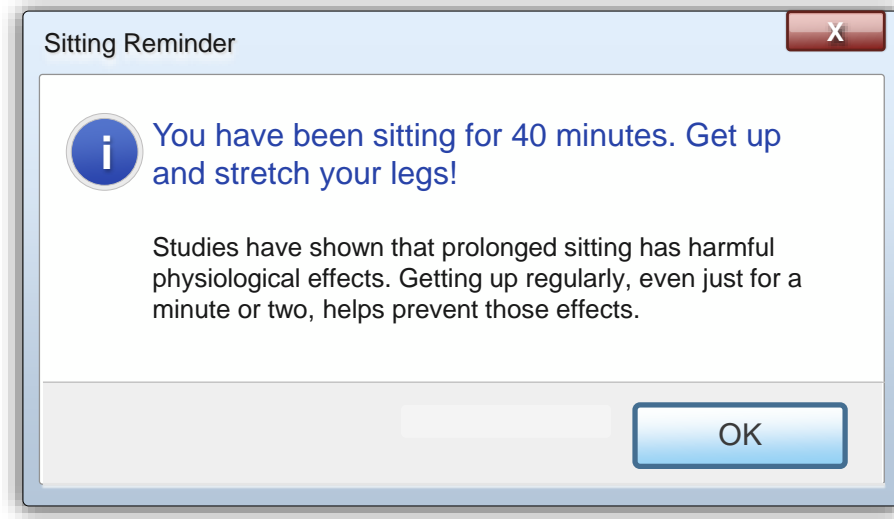
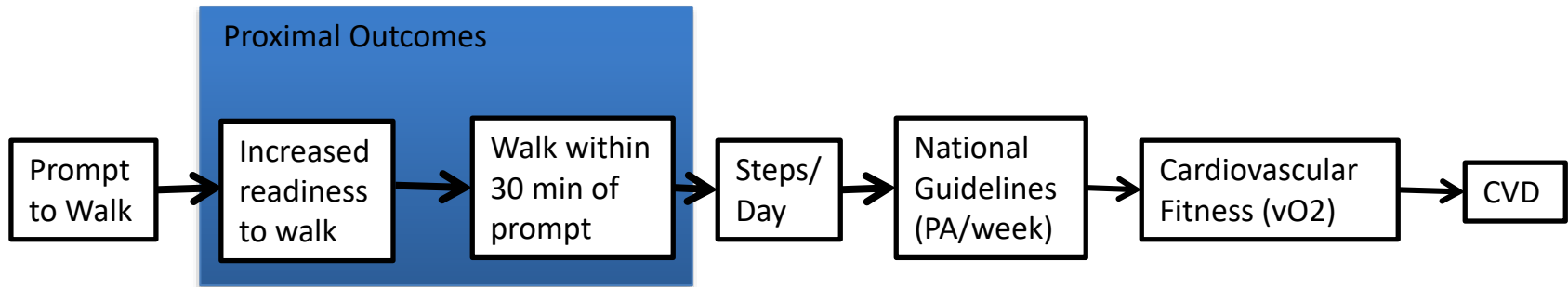Proximal outcome: whether the person got up after a reminder

Proximal outcomes are presumed mediators of desired distal health outcomes

- Micro versions of distal outcome
  - 15-min walk for walking 10,000 steps a day
- Part of causal pathway to distal outcome
  - Interactions with abstinence-supporting friends for remaining drug-free

Should be measurable after each administration of a dose of an intervention component

Proximal Outcomes in the Causal Pathway

Prompt to Walk → **Proximal Outcomes:** [Increased readiness to walk → Walk within 30 min of prompt] → Steps/Day → National Guidelines (PA/week) → Cardiovascular Fitness (vO2) → CVD

Hekler et al. 2016, TBM; Klasnja, et al. 2017, CHI; Nahum-Shani et al. 2015

Why Focus on Proximal Outcomes?

Assessment of proximal outcomes enables...

- Study of mechanisms underlying intervention functioning
  - Mechanistic outcomes (e.g., physiological, psychological)
  - Behavioral outcomes (e.g., PA or eating bouts) allow study of pattern formation
- Granular understanding of the dynamics of intervention response
- Examination of the impact of context and other time-varying factors (e.g., stress level, location, prior intervention exposure, etc.) on response to the intervention

Dynamics of intervention Response

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What We Should Try to Learn

- Does a component have any effect on its intended proximal outcomes?
- How does the effect of a component change over time?
  - What is the temporal form of the effect? Does it decay?
- How does the efficacy differ for different *forms* of a component?
  - Different designs, framings, etc.
- What contextual and individual state variables moderate the effect?
- How is the effect of a component moderated by other components and how does that change over time?
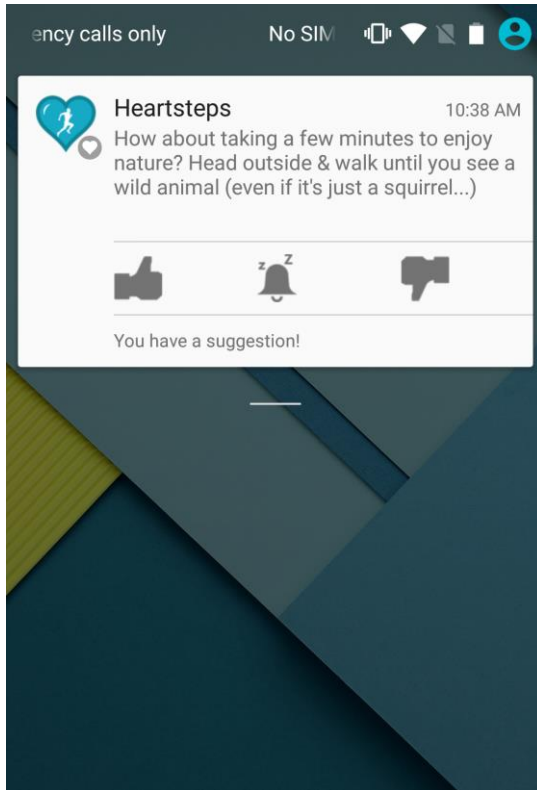- Who responds to the component?

A Couple of Examples

HeartSteps

Push Components

- Actionable, context-aware activity suggestions

- Planning of when, how, and where one will be active the next day (implementation intentions)

Suggestions

Tailored on:

- time of day
- weekday vs. weekend
- location
- weather

Two types of suggestions:

- to walk
- to interrupt sitting

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Planning

Two types of planning:

- Generate a new plan
- Select a plan from a list of previously made plans

How will you be active tomorrow?

Tomorrow, when I get to work in the morning, I will take a long route to the office to get some extra steps. ✓

Tomorrow, when I feel like a cup of coffee or tea, I'll go out to get it at a coffee shop or another building, so I can get a few steps. ✓

Every time I talk on the phone tomorrow, I will walk around to get some steps and stretch my legs. ✓

Tomorrow, when I come to work, I'll park or get off the bus a bit further to get a few extra minutes of walking. ✓

Next

How will you be active tomorrow?

Example :
Tomorrow, during lunch break, I will take a 10-minute walk close to the office before going back to work

what's your plan? **Submit**

Micro-Randomized Pilot Trial of HeartSteps

- Both components micro-randomized:
  - Suggestions randomized 5 times a day:
    - No-suggestion (40%), active suggestion (30%), sedentary suggestions (30%)
    - Proximal outcome: 30-minute step count post-randomization
  - Planning randomized every night:
    - No-planning (50%), create a new plan (25%), pick a plan (25%)
    - Proximal outcome: step count on the following day

Findings for Activity Suggestions

- Averaging over 6 weeks, 60 extra steps when a walking suggestion is delivered (24% increase over the average of 253 steps). No over-time effect for anti-sedentary suggestions

- Dynamics of walking and anti-sedentary suggestions are different
  - The effect of walking suggestions decreases with the time in study: Initially, delivering a walking suggestion vs. not adds 271 steps (107% incrase) but effect gets smaller over time, disappears after a month
  - The effect of anti-sedentary suggestions decreases with the total number of suggestions provided in the last 3 to 5 days, but does not decay with time in study

Findings for Planning

- Two types of planning do not work the same:
  - Open-ended planning adds ~ 900 steps per day vs. no planning.
  - No effect for picking a plan from a list (even though it is preferred by participants)
- Effect remains constant over 6 weeks and does not decay with time in study
- Planning only works on weekdays. No effect on weekends

BariFit

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Components

- Fitbit Charge 2 + Fitbit app
- Withings digital scale
- SMS interventions:
  - Adaptive daily step goal
  - Activity suggestions
  - Reminders to track food intake
  - Reminders for weekly weigh-ins
  - Bariatric diet tips

BariFit Optimization Pilot

- 4-month study with 51 bariatric patients from KPWA recruited post-op
- Pre-post changes in PA assessed by activPAL
- 2x2 factorial experiment to study adaptive goals
  - Variability: 60th percentile goal vs. variable daily goal (50%, 70%, 90%, 120%)
  - Rest days: yes vs. no (if yes, 1/7 probability of getting a rest day)
- Micro-randomized components
  - Activity suggestions: 5 times per day (~600 decision points) at .7 probability no-suggestion, .15 walking suggestion, .15 anti-sedentary suggestion
  - Reminders to track: 1 time per day (~120 decision points) at .5 probability

Feasibility Findings for Overall BariFit Package

- 96% of participants still tracking activity at week 16

- Baseline week to 16th week activPAL-measured steps increased by 1866 steps per day (p=.007), from 5312 to 7178 steps per day

- Sedentary time went down by 41 minutes per day (p=.07), and stepping time went up by 21 minutes per day (p=.02)

Findings for Adaptive Goals

- Average step count under variable percentile goal was 1141 steps per day higher than under 60th percentile goal (p=.096).

- Average step count with rest days 893 steps per day lower than without rest days, but not significant (p=.18).

Findings for Activity Suggestions

No effect

Summary

- Researchers should aim for evidence that maximizes knowledge accumulation and transfer

- This achievable through emphasis on individual components and proximal outcomes, and through use of efficient study designs

- Granular understanding of dynamics of functioning of individual components can advance both intervention development and basic behavioral science