



Application of “Startup” Methodologies to the Design and Implementation of a Pragmatic Randomized Controlled Trial



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MeYou Health is a Healthways company

Disclosures



Both authors are full-time employees of MeYou Health,
the company that owns the intervention product and funded the trial.

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Background



Recognized problems in evaluation of eHealth

- Poor *intervention* adoption and/or adherence/engagement
- Difficulty in achieving reasonable *evaluation* follow-up rates
- Lack of evidence demonstrating impact
- Progression to RCTs is difficult for multiple reasons, leading to reliance on uncontrolled observations

Evaluation can be difficult

- Evaluation requires interdisciplinary collaborations between software developers and health researchers
- Ever advancing technology requires short timeframes
- Funding is scarce and often requires 5-year cycles to maximize

[Pagliari, 2007]

Our model: Adoption of engineering approaches

- Rapid (2-week cycles) and iterative product development
- Continuous evaluation throughout the intervention life cycle to inform design
- Software project management strategies to work quickly and nimbly

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Intervention: Daily Challenge



Daily Challenge

- Freely accessible web, text, mobile intervention for well-being
- > 250,000 members since launch (9/2010)
- Members receive a daily email/text suggesting a small health action

Participants

- report completing the action (“challenge”)
- optionally share with other members how they did it
- may recruit family members and friends
- may connect with other DC members
- can cheer each other on via smiles, comments, pacts
- collect virtual rewards



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Objectives



1. Determine effectiveness of intervention early in its lifecycle (waypoint not endpoint).
2. Feedback effectiveness data to development team quickly to enable product design changes *while still applicable*.
3. Produce generalizable results on overall approach.
4. Inform marketplace and support potential sales of intervention.

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Pragmatic Effectiveness RCT



Use of industry techniques and of in-house product development team to minimize trial implementation cost, time, attrition

- Large-scale: n=1,503
- Fast: rigorous RCT completed in < 6 months
- Funding: minimal required amount, internal.

Trial Characteristics

- 2 arms: treatment & control
- Primary outcome: well-being
- Follow-up: 30 and 90 days
- Emphasis on generalizability, minimal exclusion criteria
- Streamlined data collection to minimize attrition (enrollment duration: <15min)
(eliminated redundancy, limited number/length questionnaires)
- Registration with Clinicaltrials.gov (NCT01586949)
- Approved by Independent IRB Inc (Protocol DC-EFF-2012)

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Implementation



Recruitment, enrollment, data collection conducted online

- Real-time recruitment, eligibility check, enrollment, intervention participation
- No in-person visits or phone screenings
- Automated randomization

Trial-specific tools as extensions of intervention interface

- Employed existing visual designs
- Eliminated redundant data collection (study + intervention)
- Enhanced visual appeal and user experience

Research staff time minimized

- Multi-level participant communication and fallback follow-ups
- Automated incentive distribution
- Collaboration with academic statistician and behavioral scientist with online trials experience.

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Recruitment



320 million US-based adults targeted

23 million individuals reached

129,777 visited the intervention website

Daily CHALLENGE

Focus on Well-Being Today
challenge.meyouhealth.com



Online tips to improve well-being and live a happier, healthier life. Sign up today!

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Enrollment



Improved well-being. Delivered daily.

We send you a challenge every day. You do it and mark it as Done. Share with friends and family. Simple!

Easy sign up
One click using Facebook.

We'll send you challenges
Something small you can do to help your health and well-being.

Share
Complete the challenge and share with friends!

Yes, Sign Me Up
Sign up with Facebook FOR FREE.

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Enrollment



Daily CHALLENGE by me you

Check out what we're doing



Want to take part in a study that may improve well-being?

MeYou Health is working on a study to learn how Daily Challenge can help people's well-being. It happens online, and everything is confidential. There is no cost.

If you are eligible and agree to join, you get:

- useful, easy-to-read health information emailed right to your inbox
- up to \$60 in Amazon.com Gift Cards*
- knowledge about your personal well-being

No, Thanks [I WANT TO LEARN MORE](#)

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Enrollment



Daily CHALLENGE by me you

Here's everything you need to know about the study

Welcome! Thanks for checking out our study.

You are being asked to participate in a research study. MeYou Health is funding and running a research study called "A randomized controlled trial of the effectiveness of the web-based well-being intervention Daily Challenge." Your study investigators are employees or paid advisors of MeYou Health. If you have concerns about this employment or income, you can ask the investigators for more information.

The purpose of the study is to evaluate the Daily Challenge program on people's well-being compared to the Weekly Well-being program. You must be 18 years or older (19 years of age or older if you reside in Alabama or Nebraska) and already registered in the Daily Challenge program. Approximately 2,010 people will be enrolled in the research study. There is no cost to take part in the study.

I have read and understood the information provided

[I AGREE TO PARTICIPATE](#)

We'll check your eligibility next.

No, thanks
We'll take you straight to Daily Challenge

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Enrollment



Please Enter a valid ZIP code.

CHALLENGE **STUDY**

Demographic Questions

Gender Male Female

Age

ZIP Code I'm outside the U.S.

Ethnicity Hispanic or Latino
 Not Hispanic or Latino

Race American Indian or Alaska Native
 Asian
 Black or African American
 Native Hawaiian or Other Pacific Islander
 White

NEXT

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Daily CHALLENGE

Well-being Tracker: Emotional Health

In general, how strong are your social ties with your family and/or friends?

Very strong About average Weaker than average Don't know

SAVE AND CONTINUE

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Daily CHALLENGE by me you

Last step. You're almost there!

Please help us verify your cell phone number

We will ask you to take the same questionnaire again in 1 month. If we see that you aren't able to take it online, we will call and give you the chance to take it by phone.

How would you like to verify your cell phone number?

Text message Automated call

123-456-7890

SEND VERIFICATION CODE

Enter your 10-digit cell phone number above and keep your phone handy. You will receive a text message with a 4-digit verification code. Your standard text messaging rates apply.

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Daily CHALLENGE by me you

Welcome

Success! You're now in the study.

Daily Challenge will be delivered to your inbox every day during the study. You'll get the chance to make small health changes, connect with the Daily Challenge community, and more!

In the next 48 hours, we will send an email to berry.lynden@me.com that explains how to redeem your \$20 Amazon.com Gift Card.* If you don't receive this email in the next 48 hours, please email us at study@meyouhealth.com.

GO TO DAILY CHALLENGE

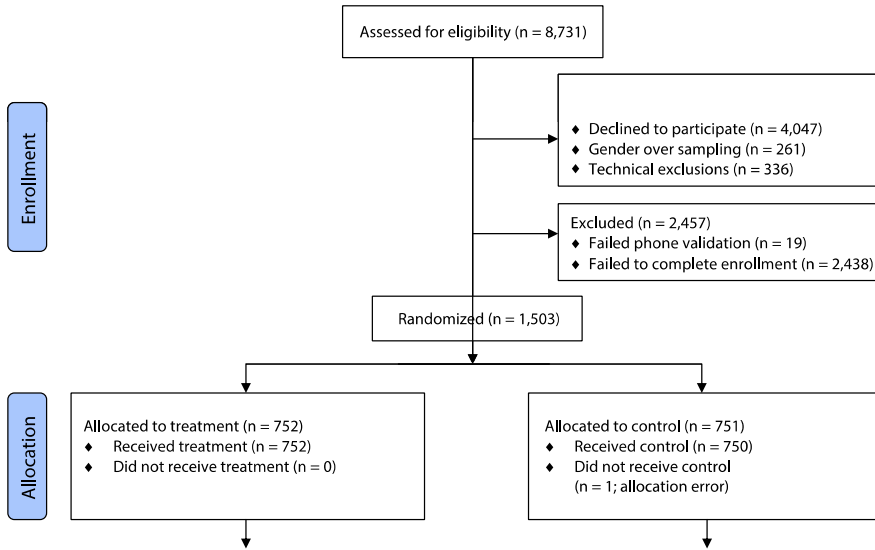
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Enrollment



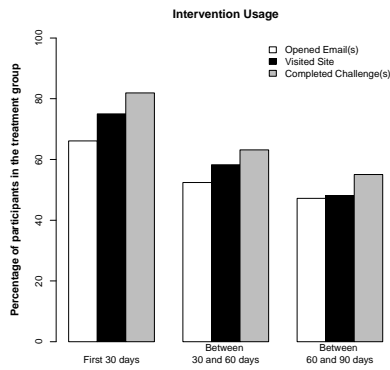
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Program Participation



Participants (n=1,503)	
Gender	30.1% men
Age	42.5 yrs (1Q = 30.0. 3Q = 54.0)
Zip	
Income	\$56,561
Education Level	29.7% college grads +
Ethnicity	90.8% non-Latino
Race	87.7% White

- 74.6% opened an email (51% control group)
- 85.0% visited the site
- 92.0% completed a challenge



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Follow-up



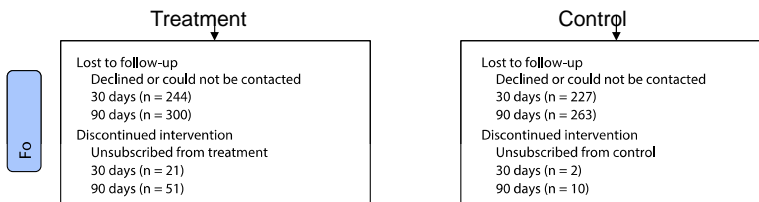
Multi-channel follow-up strategy



	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Email	✓	✓	✓	✓			✓
SMS	✓	✓	✓	✓			
On-site Prompts	✓	✓	✓	✓	✓	✓	✓
Facebook PM					✓		
Phone call					✓	✓	✓

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Follow-up



- Participants reached**
- 74.9 % (n=1,126) at least once
 - 56.3% (n=846) at both follow-ups

- Methods**
- 91.1% of participants followed up online at least once
 - 8.9% of participants were reassessed exclusively by phone

- Timing of reassessments**
- ~ 90% within first 4 days of participants' resampling windows

- Compensation**
- \$42 on average

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Conclusions



- Early effectiveness trials are feasible for eHealth interventions
- The use of integrated study enrollment process appears to minimize funnel attrition
- Multimodal contact strategies enhance follow-up (email, SMS, Facebook, phone)

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Discussion



Optimization of timeliness and cost-efficiency

- Use medium of intervention (i.e., online)
- Leverage of existing interfaces
- Rapid recruitment at large scale
- 89% of follow-ups conducted online
- Staff time mainly restricted to incentives and fallback follow-up contacts

An effective follow-up strategy

- Participants were reached through channels they commonly use
- Online rates only improved marginally by the addition of phone calls (106/1503 participants at 30 days; 107/1503 participants at 90 days)
- Phone validation had minimal impact on enrollment while providing a reliable contact means for follow-up
- Email addresses provided through Facebook were occasionally invalid

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Limitations

- Restricted set of demographic and psychometric data
- No long-term follow-up beyond 90 days
- Behavioral outcomes limited to those present in the IWBA

Data-driven product development

- Rigorous trials conducted efficiently and in a timely manner
- Empirical evidence immediately incorporated into intervention design
- Development should include ongoing empirical input to inform product iterations
- This development and evaluation model requires close collaboration between software developers and health researchers a

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Thank You!



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