Re-Engineering Precision Behavioral Therapeutics through N-of-1 Trials

International Behavioral Trials Network
May 24, 2018, Montreal, Canada
Karina Davidson, PhD & Ian Kronish, MD, MPH
Agenda

9:00 AM  Welcome and introductions

9:15 AM  How to decide if an N-of-1 trial design is right for you?

10:00 AM Breakout Session #1:  
   Discuss use cases for behavioral N-of-1 trials

10:30 AM Coffee break

10:45 AM How to design an N-of-1 trial protocol

11:30 AM The Science of Behavior Change (SOBC) Initiative

11:50 AM Wrap up discussion
Acknowledgements

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Disclosures

Ian Kronish
Funded by NHLBI, NCI, PCORI & the Irving Institute
No commercial conflicts of interest

Karina Davidson
Funded by NLM, NHLBI, NCI, PCORI & the Irving Institute
No commercial conflicts of interest
Introductions

Tell us who you are?

Where are you from?
(country, university, current institution)

How is N-of-1 relevant to your current or future work?

Also,
If you already have experience / expertise in N-of-1 design, we would love to hear about your work and draw on your examples during this meeting.
Conventional randomized trial

+0.5 SD
Net treatment benefit

Favors placebo  0  Favors treatment

Favors placebo   0   Favors treatment

+0.5 SD
Net treatment benefit
Heterogeneity of treatment effect

Positive Randomized Controlled Trial

- **Worse**
- **Neutral**
- **Harm**
- **Benefit**
- **Better**

Net Treatment Benefit:
- `+0.5`
- `+1`
- `0`
- `-0.5`
- `-1`
- **Worse**
**Conventional Personalized Medicine**

Use genetic or other information to identify subgroups of patients that are especially responsive to a treatment.
Limits of conventional personalized medicine

Genetic or other biomarkers not reliably available

Subgrouping, not truly individualizing treatments
RCT Design 1 for Depression

Depression Causes/Treatment targets

- Hypothyroidism
- Omega-3 fatty acid deficit
- Anemia
- Lack of Exercise
- Stress/social isolation
- "Essential"

Vitamin D deficiency

Intervene (just decrease depression)

Depression
RCT Design 2 for Depression

Depression Causes/Treatments targets

- Omega-3 fatty acid deficit
- Anemia
- Lack of Exercise
- Hypothyroidism
- Stress/social isolation
- "Essential"
- Vitamin D deficiency
- Vitamin D Intervention

Control Condition

Depression

Randomize

Z
RCT Design 3 (controlled)

Z = Difficult Behavior

- Z
- Z
- Z
- Z

D2 supplement
Placebo
Higher D2 supplement
RCT Design 4 (controlled)

$Z$ = Depression

- Iron or placebo supplement
- Stress or attention Management
- D2 or Placebo supplement
Does the risk factor/disease have treatments successful in ≥ 70% cases?

Yes → Establish prevalence of etiologies/risk markers

Yes → Treat all cases (Design 1)

Yes → Is one etiology/risk ≥ 70%?

Yes → Subgroup on that 1 factor and then treat (Design 2)

Yes → Is 1 etiology/risk ≥ 30%?

Yes → Can etiologies/risk be determined in individuals?

Yes → Try different treatments individually (Design 4)

Yes → Dose escalate on single etiologies (Design 3)

Yes → Treat all cases (Design 1)

No → If treatment fails (Design 2)

No → Design(1)

Design(1)

Design(2)
N-of-1 trials

Single patient, multiple crossover trials

Systematic collection of data on treatment effects

May include randomization, blinding, and placebo

Rigorous statistical analysis
N OF 1
RANDOMIZED TRIALS

Systematic reviews of randomized trials

Single randomized trial

Systematic review of observational studies

Single observational study

Physiological studies

Unsystematic clinical observations
Single case designs

Tate et al. Arch Scientific Psychol. 2016
Personalized Trials

N-of-1 trial designed to inform patient decision-making

Systematic collection of data on treatment effects

Data visualization

Shared decision-making
Benefits of Personalized Trials

Provide patients with real-time meaningful results

Awaken patients’ “inner scientist”

Results can be pooled to estimate population-level effects while relying on fewer subjects than conventional RCTs

Can be incorporated into a learning health system

1Zucker et al. J Clin Epidemiol 1997
Aggregating N-of-1 data

Can efficiently obtain generalizable knowledge in study populations

Methods
  Meta-analysis
  Bayesian

Meta-analysis of N-of-1 Trials

1. Systematic search for N-of-1 trials with individual patient data (hopefully, registries will exist in the future)

2. Evaluate risk of bias (i.e., adequate sequence generation, allocation concealment, blinding of participants and outcome assessors, completeness of outcome data, free of biased reporting)

3. Aggregate studies
   ① Assume all blocks are exchangeable, aggregate to calculate individual treatment effect
   ② Use random effects model
Meta-analysis
N-of-1 trials of methylphenidate vs. placebo

Meta-analysis

N-of-1 trials of methylphenidate vs. placebo

Registry N-of-1 Trials

When are personalized trials appropriate?

Nature of the Disorder

Nature of the Treatment

Outcome Assessment

Stakeholders

Kravitz et al. AHRQ Evidence Synthesis, 2014
Case Study:
Designing a Prototype of N-of-1 Trials for Depressive Symptoms in Cancer Survivors

K. Davidson and I. Kronish, Co-Project Leaders

NIH NATIONAL CANCER INSTITUTE
Nature of the disorder

Chronic stable

Slowly progressive

Frequently recurring
## Nature of disorder:
Depressive symptoms in cancer survivors

<table>
<thead>
<tr>
<th>Nature of the Disorder</th>
<th>☑️ Subset with chronic stable or slowly changing depressive symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature of the Treatment</td>
<td></td>
</tr>
<tr>
<td>Availability of Outcome Assessment</td>
<td></td>
</tr>
<tr>
<td>Willingness of Stakeholders</td>
<td></td>
</tr>
</tbody>
</table>
Nature of the treatments

Uncertainty about best treatment option

Heterogeneity of treatment effects

Fast onset

Fast washout
*statistical methods can potentially account for washout
Nature of treatments:
Antidepressants, psychotherapy, CAM

<table>
<thead>
<tr>
<th>Nature of the Disorder</th>
<th>✓ Subset with chronic stable symptoms</th>
</tr>
</thead>
</table>
| Nature of the Treatment | ✓ Uncertainty about best treatment in cancer survivors  
|                         | ✓ Significant individual differences in treatment effects  
|                         | +/- Some treatments have rapid onset (e.g., light therapy)  
|                         | +/- Not all treatments sufficiently rapid & safe “washout” |

Availability of Outcome Assessment

Willingness of Stakeholders
Availability of outcome assessments

Symptomatic conditions with valid, repeatable measures

Asymptomatic conditions with biomarkers
## Availability of outcome assessments:
Questionnaires, psychiatric interviews

<table>
<thead>
<tr>
<th></th>
<th>Nature of the Disorder</th>
<th>Nature of the Treatment</th>
<th>Availability of Outcome Assessment</th>
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<tbody>
<tr>
<td></td>
<td>✓ Subset with chronic stable symptoms</td>
<td>✓ Uncertainty about best treatment ✓ Significant individual differences in treatment effects +/- Some treatments have rapid onset +/- Not all treatments sufficiently rapid &amp; safe “washout”</td>
<td>✓ Valid, repeatable measures of depressive symptoms and treatment side-effects</td>
<td></td>
</tr>
</tbody>
</table>
Willingness of stakeholders

Patients, providers, and other stakeholders must be interested and engaged in such a trial.
## Willingness of Stakeholders:
Cancer survivors with depressive symptoms, clinicians

<table>
<thead>
<tr>
<th>Appropriate for N-of-1 trials if…</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature of the Disorder</td>
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<td>✓ Valid, repeatable measures of depressive symptoms and treatment side-effects</td>
</tr>
<tr>
<td>Willingness of Stakeholders</td>
<td>✓ Patients willing to use N-of-1 design to test CAM</td>
</tr>
</tbody>
</table>
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*Discuss use cases for behavioral N-of-1 trials*

10:30 AM Coffee break

10:45 AM How to design an N-of-1 trial protocol

11:30 AM The Science of Behavior Change (SOBC) Initiative

11:50 AM Wrap up discussion
Questions for Breakout #1

What are the best use cases for N-of-1 personalized trials?
## When are personalized trials appropriate?

<table>
<thead>
<tr>
<th>Nature of the Disorder</th>
<th>Nature of the Treatment</th>
<th>Outcome Assessment</th>
<th>Stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Chronic stable or</td>
<td>o Uncertainty about best treatment due to lack of evidence or large heterogeneity of treatment effects</td>
<td>o Validated, repeatable measures of treatment effects</td>
<td>o Patients, healthcare providers, health system willing to engage in N-of-1 trial effort</td>
</tr>
<tr>
<td>o Slowly progressive or</td>
<td>o Symptomatic conditions or asymptomatic conditions with biomarkers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Frequently recurring</td>
<td>o Rapid onset and washout</td>
<td></td>
<td></td>
</tr>
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</table>

Kravitz et al. AHRQ Evidence Synthesis, 2014
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11:15 AM Breakout Session #2: Design your own N-of-1 protocol

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11:50 AM Wrap up discussion
10:30AM Coffee break
Resume at 10:45AM
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Types of conditions in published behavioral N-of-1 trials

- cognition: 4 articles
- nausea/emesis: 4 articles
- depression: 4 articles
- well-being/mood: 6 articles
- ADHD: 8 articles
- sleep/fatigue: 13 articles
- pain: 15 articles

Shaffer et al. Ann Behav Med. 2017
Types of interventions in published behavioral N-of-1 trials

- Pharmacologic: 41 articles
- Behavioral: 4 articles
- Other: 9 articles

Shaffer et al. Ann Behav Med. 2017
Behavioral interventions in N-of-1 trials

Behavioral self-control v methylphenidate for ADHD

Behavior modification v methylphenidate for ADHD

Goal setting v self-monitoring for walking
A brief history of N-of-1 trials

1986
Guyatt et al. “Determining optimal therapy” NEJM

1990
Larson launches grant-funded N-of-1 service at UW
34 N-of-1 trials over 2 years
85% of physicians would refer again; 79% of patients found useful

1992
N-of-1 service folds after grant funding expires
Cost ~$500 per N-of-1 trial; ~17 staff hours/trial
“The question really is – how many patients are there that really want to know this? And how many doctors are there…to promote this to patients. There are an awful lot of people who just want you to tell them what to take, and they’ll do it.”
“Market research”

Engaging Stakeholders in Building Patient-centered, N-of-1 Randomized and Other Controlled Trial Methods
(K. Davidson, PI)

Focus Groups
54 patients with 2+ conditions
24 primary care providers

National Poll
500 patients with 2+ conditions

pcori®
Key questions

① What are the perceived benefits and barriers to N-of-1 trials?

② Which conditions, diseases, symptoms and/or treatments are amenable to N-of-1 trials?

③ What design decisions must be made to increase the acceptability and sustainability of N-of-1 trials?
## Perceived benefits

<table>
<thead>
<tr>
<th>Category</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical care</strong></td>
<td>Identifies best treatments for individual patients</td>
</tr>
<tr>
<td></td>
<td>Participation results in direct health benefit</td>
</tr>
<tr>
<td></td>
<td>Results are immediately known</td>
</tr>
<tr>
<td><strong>Clinician-patient relationship</strong></td>
<td>Facilitates communication</td>
</tr>
<tr>
<td></td>
<td>Validates patient feedback</td>
</tr>
<tr>
<td></td>
<td>Makes patients feel uniquely cared for</td>
</tr>
<tr>
<td><strong>Patient engagement in care</strong></td>
<td>Increases knowledge of own condition, treatment and treatment side-effects</td>
</tr>
<tr>
<td></td>
<td>Increases sense of autonomy</td>
</tr>
<tr>
<td><strong>Opportunity to participate in research</strong></td>
<td>Customized inclusion criteria</td>
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<td></td>
<td>Geographic availability</td>
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<tr>
<td></td>
<td>Promotes science to benefit self and community</td>
</tr>
</tbody>
</table>

“I kind of like that approach because I think it would empower me to really sense how the treatment is affecting my body. And I think that would be very beneficial, being responsible for my own health.”

-Patient D, 5.04.15
Perceived concerns of N-of-1 Trials

**Clinicians**
- Regulatory demands
- Loss of credibility
- Expectation of immediate feedback
- Lack of infrastructure for IRB, pharmacy, monitoring

**Time burden**
- Need for continuous monitoring
- Potential for negative health outcomes
- Disrupts clinical management
- Concern about being experimented on
- Results not generalizable to population
- Cost

**Patients**
- Fearful to change routines
- Easily overwhelmed by study protocol
- Preferred treatment may not be affordable

Perceived concerns of N-2 of 2 Trials
### Ideal conditions: focus groups

<table>
<thead>
<tr>
<th>Clinicians</th>
<th>Clinicians &amp; Patients</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Hypertension</td>
<td>• Chronic pain</td>
<td>• COPD</td>
</tr>
<tr>
<td>• Depression</td>
<td>• Diabetes</td>
<td>• IBS</td>
</tr>
<tr>
<td>• Seizures</td>
<td>• Arthritis</td>
<td>• Parkinson’s</td>
</tr>
<tr>
<td>• Dementia</td>
<td>• Medication side effects</td>
<td>• Shortness of Breath</td>
</tr>
<tr>
<td>• Acid reflux</td>
<td></td>
<td>• Cancer</td>
</tr>
<tr>
<td>• Allergies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Migraines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Oral contraceptives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Asthma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Hyperlipidemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Generic vs. trade name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Remedy for non-compliance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Treatment requires titrations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Medications with short half-life</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Good outcome measures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Safe to switch medications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Several treatment options</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• High stakes/hard to control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Expensive treatment options</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Ideal conditions: national poll

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain/Back Pain</td>
<td>57.6%</td>
</tr>
<tr>
<td>Hypertension (high blood pressure)</td>
<td>38.8%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>28.8%</td>
</tr>
<tr>
<td>Trouble sleeping/Insomnia</td>
<td>27.4%</td>
</tr>
<tr>
<td>Depression</td>
<td>23%</td>
</tr>
<tr>
<td>Hyperlipidemia (high cholesterol, high triglycerides)</td>
<td>19.4%</td>
</tr>
<tr>
<td>Asthma/Emphysema/Chronic</td>
<td>14.4%</td>
</tr>
<tr>
<td>Arthritis/Joint pain</td>
<td>14%</td>
</tr>
<tr>
<td>Bronchitis (breathing problems)</td>
<td>14.4%</td>
</tr>
<tr>
<td>Obesity</td>
<td>8.2%</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>5%</td>
</tr>
<tr>
<td>Headaches</td>
<td>3.6%</td>
</tr>
<tr>
<td>Allergies</td>
<td>3.4%</td>
</tr>
</tbody>
</table>
How to design an N-of-1 Trial

Determine whether N-of-1 methodology is applicable to the question

Select sequence: treatment period length and sequencing scheme (e.g., ABAB)

Invoke a suitable washout period

Decide whether or not to invoke blinding

Select suitable outcomes domains and measures

Analyze and present data
Other considerations

Ethical framework: clinical care vs. research vs. both

Financing

Information technology infrastructure

User engagement, training, and support
Which design feature(s) are most important?

Lifestyle Option
- Clinician chooses Treatment
- 12 week trial
- Blinding
- 3 data points per day
- Lifestyle option

Prescription Option
- Patient chooses Treatment
- 2 week trial
- No blinding
- 1 data point per day

Clinician conducts trial
- Prescription option
- 30 minutes per day
- $100 cost

Personalized trial service conducts trial
- Complementary Alternative Medicine Option
- 5 minutes per day
- No cost
Which design feature(s) are most important?

Lifestyle Option \(\rightarrow\) Prescription Option
Clinician chooses Treatment \(\rightarrow\) Patient chooses Treatment
12 week trial \(\rightarrow\) 2 week trial
Blinding \(\rightarrow\) No blinding
3 data points per day \(\rightarrow\) 1 data point per day
Clinician conducts trial \(\rightarrow\) Personalized trial service conducts trial
Lifestyle option \(\rightarrow\) Complementary Alternative Medicine Option
Prescription option \(\rightarrow\) Complementary Alternative Medicine Option
30 minutes per day \(\rightarrow\) 5 minutes per day
$100 cost \(\rightarrow\) No cost

Marginal Utility
Case Study

DJ is a 62 year-old male with fatigue and depressive symptoms after prostate cancer diagnosis.

He is concerned about side-effects from treatment and wants to be on the least amount of medication.

He wonders whether light therapy will be helpful for him.
Select sequence, washout period

randomize

3 Week → 6 Week → 9 Week → 12 Week

3 Week → 6 Week → 9 Week → 12 Week
Decide on blinding / masking
Select outcomes

How tired or fatigued are you feeling right now?

5

How sad or depressed are you feeling right now?

5
Analyze and present results

3 week

6 week

9 week

12 week

Fatigued

Depressed
Analyze and present results
Analyze and present results
Analytic approach

<table>
<thead>
<tr>
<th></th>
<th>Model 1: Regression</th>
<th>Model 2: Regression adjusted for linear time trend</th>
<th>Model 3: Regression adjusted for auto-correction</th>
<th>Model 4: Regression adjusted for auto-correction and linear time trends</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference in Mood VAS score: Red v Bright White (range: 0-10)</td>
<td>-1.53 p=0.004</td>
<td>-1.43 p=0.006</td>
<td>-1.50 p=0.02</td>
<td>-1.41 p=0.03</td>
</tr>
<tr>
<td>Linear trend</td>
<td>-</td>
<td>-0.48 p=0.04</td>
<td>-</td>
<td>-0.49 p=0.08</td>
</tr>
<tr>
<td>Auto-correction*</td>
<td>-</td>
<td>-</td>
<td>0.24</td>
<td>0.21</td>
</tr>
</tbody>
</table>
Analyze and present results
Other considerations

Ethical framework: clinical and research

Financing: via grants

IT Infrastructure: iPhone app

User engagement, training & support: conducted by study team
Personalized Trials is a different way to think about health care.

Not everybody responds to treatment the same way. Personalized Trials gives you the tools to find the treatment that's right for you.
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Bringing an Experimental Medicine Approach to Behavior Change Research:
The NIH Science Of Behavior Change Program
Behaviors are among the most important factors that determine whether people will live long, healthy lives.
Chronic diseases contribute to 7 out of 10 deaths in the U.S. Treatment of these diseases accounts for over 85% of U.S. health costs. Many of these chronic diseases are preventable.

Human behavior accounts for almost 40% of the risk associated with preventable premature deaths in the U.S.

Some interventions lead to changes in behavior for some people.
Even when an intervention works, scientists rarely know how or why it worked.
Just because an intervention worked for one person...
doesn’t mean it will work for another.
Scientists need to understand the how and why in order to develop interventions that work consistently.
If you've ever wondered why it's so hard to stick to that diet or exercise routine, researchers at Science Of Behavior Change are wondering that too.

A lot of work has been done in the field of behavioral medicine in order to help people make healthy choices, and some of that work has been successful. The problem is that even when these efforts are successful, we don't know why or how they worked. Understanding why successful behavior change occurs is the key to getting it to happen again.
A New Way Forward

Focus on mechanisms of change

Develop and apply a common and transparent scientific method

Optimize interventions to promote effectiveness by targeting mechanisms
The Method and the Measures
A Common Method
for understanding behavior change.
Experimental Medicine Approach

- Aims to **identify key mechanisms** underlying successful behavior change
- Offers **intermediate targets** on the causal path to behavior change
- Helps us understand **why** an intervention **worked** or **didn’t work**
Validating Measures with the Method
Developing a repository of validated measures

- Progress through steps of the method
- Open Science Framework (OSF) documentation
- 113 measures…and more to come!

Resource for the scientific community

www.scienceofbehaviorchange.org/measures
Access the Measures

- **10-Item Personality Inventory**
  - Self-Regulation, Stress Reactivity & Stress Resilience
  - Access Measure

- **Adaptive N-Back Task**
  - Self-Regulation
  - Access Measure

- **Affect Dysregulation Scale (Child-Reported)**
  - Self-Regulation, Stress Reactivity & Stress Resilience
  - Access Measure

The 10-Item Personality Inventory (TIP) is a brief assessment of the Big Five personality dimensions: (1) Extraversion, (2) Agreeableness, (3) Conscientiousness, (4) Emotional Stability, and (5) Openness to Experience. Items are rated on a scale from 1 (disagree strongly) to 7 (agree strongly). Examples include: “I see myself as extraverted, enthusiastic” (Extraversion) and “I see myself as dependable, self-disciplined.”

The Adaptive N-Back Task is a behavioral measure of working memory within the larger domain of executive function. It assesses the cognitive ability to store and control information on a short-term basis. In this computer task a sequential stream of visual stimuli (typically letters) are presented one at a time. Participants’ task is to identify whether a current stimulus (e.g., read more)

The Affect Dysregulation Scale (Child-Reported) is a six-item self-reported measure of adolescents' frequency of difficulties with affect regulation. Items were suggested by the Structured Interview for Disorders of Extreme Stress (SIDES) with modifications made to simplify the wording for an adolescent sample and to generalize items to reference all feelings rather than just anger. Participants are asked to report the read more.
### Access the Measures

**Kirby Delay-Discounting Task**  
**Self-Regulation**  
**TASK | 5 MIN**  

The Kirby Delay-Discounting Task (DDT) is a measure of temporal discounting, the tendency for people to prefer smaller, immediate monetary rewards over larger, delayed rewards. Participants complete a series of 27 questions that each require choosing between a smaller, immediate reward (e.g., $25 today) versus a larger, later reward (e.g., $35 in 25 days). The 27 items are divided into [read more](#).
Access the Measures

BIS/BAS Scale:

Each item of this questionnaire is a statement that a person may either agree with or disagree with. For each item, indicate how much you agree or disagree with what the item says. Choose only one response to each statement.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Very true for me</th>
<th>Somewhat true for me</th>
<th>Somewhat false for me</th>
<th>Very false for me</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A person’s family is the most important thing in life.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Even if something bad is about to happen to me, I rarely experience fear or nervousness.</td>
<td>☐</td>
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</tr>
<tr>
<td>3. I go out of my way to get things I want.</td>
<td>☐</td>
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</tr>
<tr>
<td>4. When I am doing well at something I love to keep at it.</td>
<td>☐</td>
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</tr>
<tr>
<td>5. I am always willing to try something new if I think it will be fun.</td>
<td>☐</td>
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</tr>
<tr>
<td>6. How I dress is important to me.</td>
<td>☐</td>
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<tr>
<td>7. When I get something I want, I feel excited and energized.</td>
<td>☐</td>
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<tr>
<td>8. Criticism or scolding hurts me quite a bit.</td>
<td>☐</td>
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</tr>
<tr>
<td>9. When I want something I usually go all-out to get it.</td>
<td>☐</td>
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<td>☐</td>
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</tr>
<tr>
<td>10. I will often do things for no other reason than that they might be fun.</td>
<td>☐</td>
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</tr>
</tbody>
</table>
Access the Measures

The experiment will launch in fullscreen mode when you click the button below.

Launch Experiment
SOBC/Experimental medicine approach

1. Hypothesize mechanisms first
2. Determine whether you can measure them
3. Determine whether you can influence them
4. Determine whether changing them can change behavior
5. Test an intervention optimized to change them, and thereby change behavior
Visit us at:
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Summary

N-of-1 trials can provide knowledge about the benefits and harms to the individual

May result in more precise regimen, higher satisfaction, better adherence, better health outcome

Pooling data provides opportunity for generalizable knowledge

N-of-1 observational studies can be used to identify personal predictors and triggers
Discussion & Wrap-Up
Thank you.

International Behavioral Trials Network
May 24, 2018, Montreal, Canada
Karina Davidson, PhD & Ian Kronish, MD, MPH