mActive: A Blinded, Randomized mHealth Trial Supporting Digital Tracking and Smart Texting for Promotion of Physical Activity

Seth S. Martin, MD MHS

on behalf of the mActive investigators
Disclosures

Investigators report no financial disclosures

Fitbug provided devices in-kind
How are we doing today?

You should exercise more.

How's the exercise going?

6 months
Digital revolution

The Creative Destruction of Medicine
How the Digital Revolution Will Create Better Health Care

Eric Topol, M.D.
Hypothesis

A fully-automated, fully-mobile, and physician-designed tracking-texting intervention to provide individual encouragement and foster feedback loops increases physical activity.
**Week 1**

- **Blind Run-In**
  - N = 48

**Phase I**

Weeks 2-3

- **Unblind**
  - N = 32

**Phase II**

Weeks 4-5

- **Smart Texts**
  - N = 16
- **No Texts**
  - N = 16
- **Blind**
  - N = 16
Eligibility

Inclusions
- Patient at Ciccarone Center
- 18-69 years of age
- User of a compatible smartphone

Exclusions
- Already using an activity tracker
- Regular leisure-time activity by IPAQ
- Prohibited from normal activity
Interventions

Phase I: Unblinding
- continuous access to activity data via smartphone
Phase 2: Smart Texts

- smartphone-delivered coaching
- theory-based, physician-written
- leverage therapeutic relationship
- 3 times/day
  - customized to patient schedule
- booster and positive reinforcement messages
  - individual encouragement, foster feedback loops
- fully-automated using real-time activity data and 16 personal factors with a 10,000 steps/day goal
Outcome measures

• **Primary**
  – Change in accelerometer-measured daily steps

• **Secondary**
  – Change in accelerometer-measured daily activity time
  – Change in accelerometer-measured daily aerobic activity time
    • walking continuously for $\geq 10$ minutes without breaking for more than a minute
## Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>All (n=48)</th>
<th>Blind (n=16)</th>
<th>No Texts (n=16)</th>
<th>Texts (n=16)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, yrs, mean ± SD</strong></td>
<td>58 ± 8</td>
<td>60 ± 7</td>
<td>58 ± 8</td>
<td>55 ± 8</td>
<td>0.22</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.00</td>
</tr>
<tr>
<td>Men</td>
<td>26 (54%)</td>
<td>9 (56%)</td>
<td>9 (56%)</td>
<td>8 (50%)</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>22 (46%)</td>
<td>7 (44%)</td>
<td>7 (44%)</td>
<td>8 (50%)</td>
<td></td>
</tr>
<tr>
<td><strong>White race</strong></td>
<td>38 (79%)</td>
<td>14 (88%)</td>
<td>12 (75%)</td>
<td>12 (75%)</td>
<td>0.60</td>
</tr>
<tr>
<td><strong>Dog owner</strong></td>
<td>21 (44%)</td>
<td>7 (44%)</td>
<td>9 (56%)</td>
<td>5 (31%)</td>
<td>0.36</td>
</tr>
<tr>
<td><strong>Married</strong></td>
<td>35 (73%)</td>
<td>13 (81%)</td>
<td>13 (81%)</td>
<td>9 (56%)</td>
<td>0.19</td>
</tr>
<tr>
<td><strong>Employed</strong></td>
<td>42 (88%)</td>
<td>13 (81%)</td>
<td>13 (81%)</td>
<td>15 (94%)</td>
<td>0.67</td>
</tr>
</tbody>
</table>
### Baseline characteristics (cont.)

<table>
<thead>
<tr>
<th></th>
<th>All (n=48)</th>
<th>Blind (n=16)</th>
<th>No Texts (n=16)</th>
<th>Texts (n=16)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CHD</strong></td>
<td>14 (29%)</td>
<td>7 (44%)</td>
<td>5 (31%)</td>
<td>2 (13%)</td>
<td>0.15</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td>11 (23%)</td>
<td>4 (25%)</td>
<td>5 (31%)</td>
<td>2 (13%)</td>
<td>0.44</td>
</tr>
<tr>
<td><strong>Smoker</strong></td>
<td>1 (2%)</td>
<td>0 (0%)</td>
<td>1 (6%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>24 (50%)</td>
<td>11 (69%)</td>
<td>8 (50%)</td>
<td>5 (31%)</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>Dyslipidemia</strong></td>
<td>39 (81%)</td>
<td>13 (81%)</td>
<td>14 (88%)</td>
<td>12 (75%)</td>
<td>0.90</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td>31 ± 6</td>
<td>33 ± 7</td>
<td>30 ± 5</td>
<td>30 ± 7</td>
<td>0.28</td>
</tr>
<tr>
<td>≥30</td>
<td>26 (54%)</td>
<td>10 (63%)</td>
<td>7 (44%)</td>
<td>9 (56%)</td>
<td></td>
</tr>
</tbody>
</table>
## Baseline activity (blind run-in)

<table>
<thead>
<tr>
<th>Steps, count/day</th>
<th>Activity Time, min/day</th>
<th>Aerobic Time, min/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>9670 ± 4350</td>
<td>93 ± 45</td>
<td>13 ± 18</td>
</tr>
</tbody>
</table>

97% capture of daily activity data throughout trial
**Phase I**

<table>
<thead>
<tr>
<th></th>
<th>Unblind (n=32) Mean ± SD</th>
<th>Blind (n=16) Mean ± SD</th>
<th>Unblind – Blind Mean Difference (95% CI), p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steps, count/day</td>
<td>408 ± 2701</td>
<td>-616 ± 2385</td>
<td>1024 (-580 to 2628), p=0.21</td>
</tr>
<tr>
<td>Activity Time, min/day</td>
<td>2 ± 27</td>
<td>-6 ± 26</td>
<td>8 (-9 to 25), p=0.33</td>
</tr>
<tr>
<td>Aerobic Time, min/day</td>
<td>-3 ± 12</td>
<td>-11 ± 14</td>
<td>8 (0 to 16), p=0.05</td>
</tr>
<tr>
<td></td>
<td>Texts (n=16)</td>
<td>No Texts (n=16)</td>
<td>Blind (n=16)</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------------</td>
<td>-----------------</td>
<td>--------------</td>
</tr>
<tr>
<td><strong>Steps, count/day</strong></td>
<td>2334 ± 1714</td>
<td>-200 ± 1653</td>
<td>-1042 ± 2202</td>
</tr>
<tr>
<td><strong>Activity Time, min/day</strong></td>
<td>21 ± 20</td>
<td>0 ± 17</td>
<td>-8 ± 23</td>
</tr>
<tr>
<td><strong>Aerobic Time, min/day</strong></td>
<td>13 ± 11</td>
<td>-1 ± 8</td>
<td>-3 ± 10</td>
</tr>
</tbody>
</table>
10K step goal attainment

- **Baseline**
  - Blind (n=48): 48%

- **Phase I**
  - Unblind (n=32): 41%
  - **Phase II**
    - Texts (n=16): 81%
    - No Texts (n=16): 44%
    - Blind (n=16): 50%
Conclusions

• In adult patients who are smartphone users, a novel mHealth strategy coupling activity tracking with smart texts resulted in a large near-term increase in physical activity.

• Initial step forward in an area of rapidly growing interest in critical need of clinical trial evidence.
Wearable Devices as Facilitators, Not Drivers, of Health Behavior Change

Patel MS, Asch DA, Volpp KG
JAMA 2015;313:459-60
Next steps

• Long-term mAActive follow-up

• Build additional text content

• Larger, longer-term trials
Thank you

PI: Mike Blaha

Coordinator: David Feldman

Hopkins co-investigators:
• Roger Blumenthal
• Steve Jones
• Elizabeth Ratchford
• Chiadi Ndumele
• Becky McKibben
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• Paul Landau
• Lolita Cintron

• Ralph Passarella
• Henry Li