Multicenter, Randomized, Crossover Study Comparing Digital Health Intervention with Fitbit Tracking versus Usual Care with Patient Self-Report for Claudication Exercise Adherence and Patient-Reported Outcomes

(Vascular Outcomes Improvement through Patient Communication and Engagement)

Matthew A. Corriere, Timothy E. Craven, Gabriela Velazquez-Ramirez, Donna Keith, Linda Batrow, Lisa Huntzinger, Justin B. Hurie, Matthew S. Edwards
Background and rationale

• Structured walking exercise programs with activity tracking are an alternative to supervised exercise therapy for claudication
  – Comparisons with usual care have been limited
  – Feasibility, effectiveness and efficacy are unknown

• Goals
  – Compare structured exercise with Fitbit tracking vs. usual care for patients with claudication
  – Establish feasibility versus usual care
  – Obtain variance estimates to design larger randomized study
    • Walking data
    • Patient-reported outcomes
Methods

- We conducted a multicenter, randomized crossover study. We conducted a randomized crossover study.

Interventions:

- Usual care (walking advice with paper logsheet)

  vs.

- Fitbit tracking integrated within PAD digital health platform
### Project Voice II - Daily Walking Log

**Name:** ____________________________________________  
**Study ID:** P V 2 ___ ___ ___ ___  
**Date Control Phase Start:** ___/___/20___

For each day NOT marked through on the calendar below please indicate whether you walked *for exercise* until you had pain in your leg muscles.

<table>
<thead>
<tr>
<th></th>
<th>Sunday</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
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<tbody>
<tr>
<td>Week 1</td>
<td>Yes</td>
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<td>Yes</td>
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<td>Yes</td>
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Intervention:
Digital Health Platform: Dashboard

Hello LisaPVoice

Health Tools

Home
Complete Questionnaire
Learn About Vascular Disease
Track Exercise
Health Communities
Peripheral Artery Disease
Diabetes - Type 2
Connect a Health Device
Logout

Weekly Exercise

45 min out of 210
5 days left to hit your goal
Update your exercise > Last updated Feb 22

Walking and PAD

Learn why walking helps PAD

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Interval-based view of walking activity

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Activity</th>
<th>Duration</th>
<th>Calories</th>
<th>Distance</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/22/16</td>
<td>8:31 am</td>
<td>Walking</td>
<td>45 minutes</td>
<td>244 calories</td>
<td>2.0 miles</td>
<td>4432 steps</td>
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<td>2/19/16</td>
<td>11:41 am</td>
<td>Walking</td>
<td>83 minutes</td>
<td>365 calories</td>
<td>3.2 miles</td>
<td>7754 steps</td>
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<td>2/18/16</td>
<td>6:13 pm</td>
<td>Walking</td>
<td>6 minutes</td>
<td>41 calories</td>
<td>0.3 miles</td>
<td>614 steps</td>
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<td>2/17/16</td>
<td>4:40 pm</td>
<td>Walking</td>
<td>4 minutes</td>
<td>41 calories</td>
<td>0.3 miles</td>
<td>484 steps</td>
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<tr>
<td>2/10/16</td>
<td>8:54 am</td>
<td>Walking</td>
<td>33 minutes</td>
<td>269 calories</td>
<td>2.0 miles</td>
<td>3928 steps</td>
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<tr>
<td></td>
<td>1:04 pm</td>
<td>Walking</td>
<td>8 minutes</td>
<td>36 calories</td>
<td>0.3 miles</td>
<td>780 steps</td>
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<tr>
<td></td>
<td>4:24 pm</td>
<td>Walking</td>
<td>12 minutes</td>
<td>48 calories</td>
<td>0.4 miles</td>
<td>1048 steps</td>
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<tr>
<td></td>
<td>4:37 pm</td>
<td>Walking</td>
<td>9 minutes</td>
<td>42 calories</td>
<td>0.4 miles</td>
<td>898 steps</td>
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</table>
Total Steps and Distance
Peripheral Artery Disease Community

This patient support community is for discussions relating to Peripheral Artery Disease (PAD)

1 - 20 (of 33) questions

PAD, Stents and travel

My dad had a procedure yesterday (dye in the arteries) to determine the degree to which his arteries are blocked. We now know that he is getting almost no blood flow to his legs. He has an appointment with the cardiologist in 4 days to...

Violamom | Last answer Jan 10, 2016

I think i have PAD but i am very confused
Diabetes - Type 2 Community

A community of people with Type 2 Diabetes to guide and support your health journey. Ask a question, join a conversation, share experiences: nutrition, wellness, symptoms, and treatments.

1 - 20 (of 4885) questions

how to calculate the exact amount of insulin per day

Im diabetes 2 since 3 years a go, I used pills at the begining and 2 years ago my doc changed my treatment to insulin. Some days I wake up and my BS is high as today, was 225. I'm using an app for counting carbs, yesterday I ate 220gs or ...

LorenaMF26 | Last comment Feb 21, 2016

I dont know what type of diabetic I am.

Got here diagnosed, it was 2 diabetes, but sm & insulin 70/50 mix.
Inclusion and Exclusion Criteria

**Inclusion Criteria:**
- Clinical diagnosis of symptomatic PAD with claudication
- Ankle-brachial index (ABI) < 0.9 or non-compressible leg arteries
- Walking exercise therapy recommended as treatment for PAD by the healthcare provider
- Willing to be randomized to VOICE platform or control group
- Able to access the internet.

**Exclusion Criteria:**
- Walking exercise therapy not recommended due to contraindication or any other reason
- Wheelchair dependence or inability to walk unassisted
- Foot ulcers, wounds, or gangrene, history of major extremity amputation
- Lack of objective physiologic data validating PAD diagnosis
- Claudication symptoms due to diagnoses other than PAD (i.e., popliteal entrapment syndrome)
- age <21, inability to speak or read English, severe mental illness, inability to give informed consent.
Primary and Secondary Outcomes

• Primary Outcome: Walking adherence
  – % of days each phase with ≥ 3 walking exercise intervals
    • Self-reported during control phase
    • Identified based on interval 2 minutes or longer during digital health phase

• Secondary Outcomes:
  – Patient-Reported Outcomes Measures
    • VascuQol-6
    • Walking Impairment Questionnaire (WIQ)
    • PROMIS Physical Function Short Form 4a
    • PROMIS Pain Interference Short Form 6a
    • PROMIS Sleep Disturbance Short Form 4a
    • Patient Activation Measure (PAM) 10©

  – Tracked data
    • Fitbit-derived walking and sleep
Design

Study design for patient participants

[Diagram showing the study design with steps and data collection points]

Informed Consent & Enrollment

Baseline data collection
- Clinical & Demographic data
- WIQ
- PAM-10
- VascuQol-6
- PROMIS (Pain, sleep physical function)

Randomization

Usual care phase (4 weeks) → VOICE phase (5 weeks)

End Phase 1
- WIQ
- PAM-10
- VascuQol-6
- PROMIS

VOICE phase (5 weeks) → Usual care phase (4 weeks)

End Phase 2
- WIQ
- PAM-10
- VascuQol-6
- PROMIS

Usual care (Patient keeps Fitbit) (63 weeks/6 months enrollment)

Completion Survey
- WIQ
- PAM-10
- VascuQol-6
- PROMIS

https://clinicaltrials.gov/ct2/show/NCT03554564
<table>
<thead>
<tr>
<th>Data Element</th>
<th>Collection and Storage</th>
<th>Mechanism</th>
<th>Frequency</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Enrollment</td>
</tr>
<tr>
<td>Informed consent</td>
<td>Local site</td>
<td>Local, in person</td>
<td>✓</td>
</tr>
<tr>
<td>Demographic and clinical data</td>
<td>Local site</td>
<td>Local EMR abstraction</td>
<td>✓</td>
</tr>
<tr>
<td>QOL survey instrument</td>
<td>Local site + VOICE portal</td>
<td>Survey*</td>
<td>✓</td>
</tr>
<tr>
<td>Walking activity*</td>
<td>VOICE portal</td>
<td>FitBit Flex 2</td>
<td>✓</td>
</tr>
<tr>
<td>Walking activity log</td>
<td>VOICE portal</td>
<td>Manual entry</td>
<td>✓</td>
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<tr>
<td>Pain Interference</td>
<td>Local site + VOICE portal</td>
<td>Survey*</td>
<td>✓</td>
</tr>
<tr>
<td>Short Form 6a (PROMIS)</td>
<td>Local site + VOICE portal</td>
<td>Survey*</td>
<td>✓</td>
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<tr>
<td>Sleep Disturbance</td>
<td>Local site + VOICE portal</td>
<td>Survey*</td>
<td>✓</td>
</tr>
<tr>
<td>Short Form 4a (PROMIS)</td>
<td>Local site + VOICE portal</td>
<td>Survey*</td>
<td>✓</td>
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<tr>
<td>Physical Function</td>
<td>Local site + VOICE portal</td>
<td>Survey*</td>
<td>✓</td>
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<tr>
<td>Short Form 4a (PROMIS)</td>
<td>Local site + VOICE portal</td>
<td>Survey*</td>
<td>✓</td>
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<td>Patient Activation Measure</td>
<td>Local Site</td>
<td>Survey*</td>
<td>✓</td>
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<tr>
<td>Provider Post-Survey</td>
<td>Local Site</td>
<td>Survey*</td>
<td>✓</td>
</tr>
<tr>
<td>Participant Post-Survey</td>
<td>Local Site</td>
<td>Survey*</td>
<td>✓</td>
</tr>
</tbody>
</table>

*Patient surveys will be administered using the VOICE platform during the VOICE phase of the study, and using paper forms either in person, by email, or by postal mail during the usual care phase and at 6 months post-enrollment. Provider surveys will be administered by email after completion of the crossover phase (i.e., after all patient participants have completed the VOICE phase).
Statistical Analysis

• Primary outcome: T-tests

• Secondary outcomes:
  – Descriptive statistics for tracked walking parameters
  – Mixed linear models for PRO scores
CONSORT recruitment and Retention Diagram

Enrollment

Assessed for eligibility (n=6139)

Excluded (n=6111)
  - Not meeting inclusion criteria (n=5850)
  - Declined to participate (n=70)
  - Other reasons (n=191)

Randomized (n=28)

Allocation

Allocated to Usual Care followed by Digital Health Intervention (n=14)
  - Completed allocated intervention (n=10)
  - Did not complete allocated intervention (n=4 withdrew)

Allocated to Digital Health Intervention followed by Usual Care (n=14)
  - Completed allocated intervention (n=12)
  - Did not complete allocated intervention (n=1 withdrew, n=1 lost to follow-up)

Follow-Up

Lost to follow-up (n=0)
Discontinued intervention (n=4 withdrew)

Lost to follow-up (n=1 lost, could not contact)
Discontinued intervention (n=1 withdrew)

Analysis

Analysed Walking Data (n=10)
  Excluded from analysis (n=3 did not have Fitbit data, n=1 did not have Fitbit or Control Log data)
  Analysed Questionnaire Data (N=14)

Analysed Walking Data (n=12)
  Excluded from analysis (n=2 did not have Control Log data)
  Analysed Questionnaire Data (N=14)
<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± SD or Count(%)</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>65.9 ± 8.8</td>
</tr>
<tr>
<td>Female</td>
<td>9 (32%)</td>
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<tr>
<td>African American</td>
<td>2 (7%)</td>
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<tr>
<td>Baseline ABI</td>
<td>0.6 ± 0.2</td>
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</table>
Primary Outcome: Walking Exercise Compliance

- 68 ± 32% during control phase (walking advice)
- 72 ± 28% during the digital health phase with Fitbit
- P=0.64
<table>
<thead>
<tr>
<th>Patient-Reported Outcomes</th>
<th>Walking Advice with Self-Report (Mean±SEM)</th>
<th>Digital Health with Fitbit Tracking (Mean±SEM)</th>
<th>Between-phase Difference (P)</th>
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</thead>
<tbody>
<tr>
<td>PROMIS Physical Function SF 6b</td>
<td>39.1±1.5</td>
<td>39.0±1.4</td>
<td>0.83</td>
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<tr>
<td>PROMIS Pain Interference SF</td>
<td>61.5±1.3</td>
<td>60.4±1.4</td>
<td>0.34</td>
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<tr>
<td>VascuQuol-6</td>
<td>13.4±0.9*</td>
<td>13.7±0.8*</td>
<td>0.47</td>
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<tr>
<td>Walking Impairment Questionnaire (WIQ)</td>
<td>28.7±4.6</td>
<td>36.9±4.5*</td>
<td>&lt;0.01</td>
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<tr>
<td>Distance Subscale (WIQ)</td>
<td>32.8±5.6*</td>
<td>37.3±6.9*</td>
<td>0.45</td>
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<td>Speed Subscale (WIQ)</td>
<td>26.6±4.3</td>
<td>32.8±4.5*</td>
<td>0.03</td>
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<tr>
<td>Stairs Subscale (WIQ)</td>
<td>26.9±5.2</td>
<td>38.0±5.7*</td>
<td>&lt;0.01</td>
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*P<0.05 versus baseline score at enrollment
### Secondary outcome: tracked walking (28 days)

<table>
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<tr>
<th>Variable</th>
<th>Mean</th>
<th>Std Dev</th>
<th>Minimum</th>
<th>Maximum</th>
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</thead>
<tbody>
<tr>
<td>Total distance (miles)</td>
<td>20.78</td>
<td>19.29</td>
<td>1.11</td>
<td>75.56</td>
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<tr>
<td>Total steps</td>
<td>78430.04</td>
<td>74333.65</td>
<td>3988.00</td>
<td>274934.00</td>
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<td>Total hours of walking</td>
<td>26.32</td>
<td>25.01</td>
<td>1.47</td>
<td>93.62</td>
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<tr>
<td>Cadence (steps/minute)</td>
<td>46.46</td>
<td>8.29</td>
<td>35.70</td>
<td>64.24</td>
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Discussion

• Study designed as pilot study
  – Lack of observed difference in primary outcome ≠ no difference

• Interesting differences identified for secondary PRO outcomes
  – PROMIS: No difference from baseline or between interventions
  – VascuQol-6: Improved relative to baseline with both interventions, but no difference between interventions
  – WIQ: Compared to usual care, the digital health intervention was associated with significantly greater increases in
    • Higher overall WIQ score (P<0.01),
    • Higher WIQ Speed subscale score (P=0.03)
    • Higher WIQ Stairs subscale score (P<0.01)
    • No difference in WIQ distance subscale score (P=0.45).
Potential limitations

• Dropout rates were significant
  – Analysis approach adapted for PRO to account for dropout

• Tracked walking activity based on assumptions
  – Not all intervals > 2 minutes necessarily intentional exercise sessions
  – Cannot tell which intervals were halted due to leg pain
  – Nonetheless, potentially tracked walking during ADLs

• Self-report biases during control phase
  – Recall
  – Possible for participants to inflate reported exercise
  – Don’t know that logbook filled out daily versus in one sitting
Summary and Conclusions

• Digital health with Fitbit tracking is feasible for patients with PAD and claudication symptoms

• Similar walking exercise compliance observed for Fitbit tracking versus self-report
  – Suggests feasibility of structured exercise as alternative to supervised exercise therapy

• Structured exercise with activity tracking generates objective, quantifiable metrics

• WIQ have sensitivity advantages over other PRO for walking exercise interventions
  – Especially speed and stairs subscales
Unanswered questions and future research

- Advantages of smartphone versus wearable tracker
  - Dropout and data capture rates
- Relative impacts of tracker versus digital health content
- Total walking activity versus during deliberate exercise
  - How do we separate the “noise”?
  - How do we identify symptom onset?
  - Does it even matter?*
- Sleep data as an outcome
- What characteristics identify ideal versus non-ideal user?
- How should physicians interpret results and council patients?
  - Transition from self-reported distance and time to other metrics

Acknowledgements:

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