

# Preparing and submitting a successful PCORI Proposal

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# Getting your patient-centered research funded

- Start your application early
  - At least six months before the deadline.
- Engage patients in (almost) all aspects of the application.
- Learn as much as possible about patient-centered research.
  - Talk to experienced investigators
  - Attend seminars
  - Present your research

# Summary of Patient Engagement

- -Specific Aims
- -Background and significance.
- -Intervention methods
- - Outcome measures.
- -Investigators
- -Advisory Panel
- DSMB member

# Specific Aim #1

- With input from PAD patients and healthcare providers for PAD patients, we will perform feasibility studies necessary to finalize our home-based exercise intervention.

# Specific Aim #2

- We will conduct a randomized controlled trial to determine whether our PAD patient-centered home-based exercise program improves walking ability, physical function, pain, and social functioning, compared to a usual care group.

# PAD Patients input:

## “Background and Significance”

Patient	Patient description of disability from PAD
Female, age 66	<ul style="list-style-type: none"> <li>• “I am a patient who suffers from PAD. I have had this condition for about five years and have found that it significantly limits my lifestyle. I used to feel that walking was a pleasant way to take a break. Now I see it as a chore I do only for the therapeutic value.”</li> <li>• “I live in Chicago, an amazingly beautiful city, and can remember a time when I walked for sheer enjoyment, window shopping, on the lake front, in fancy neighborhoods ogling the magnificent mansions. Now I’m embarrassed of all the time I spend watching TV”</li> <li>• “Because of my inability to walk long distances, I no longer take short getaways to quaint little towns to walk around the shops and attractions. To a moderate extent it is safe to say that I no longer look forward to the rest of my life.”</li> </ul>
Female, age 73	<ul style="list-style-type: none"> <li>• “I was diagnosed with PAD about ten years ago. My symptoms are burning leg pain increasing to cramping in the calves when climbing stairs or during prolonged standing. Leg pain causes me to stop, when walking farther than one city block.”</li> </ul>
Male, age 81	<ul style="list-style-type: none"> <li>• “For approximately eight years I have suffered from PAD. It has drastically altered my quality of life. My wife and I travel a great deal and we have had to make adjustments for my declining ability to walk distances. Even short trips to the store are a chore.”</li> </ul>

# Intervention Methods

- Pilot study of home-based exercise intervention.
- Feedback obtained by focus groups.
- Feedback by questionnaires

# Intervention Methods

## Patient Testimonials used to inform the intervention development

### *What are the main barriers to regular walking exercise?*

- “Exercise-related leg pain is a major barrier to walking exercise.”
- “Pain with walking is a big problem. I will think of any excuse not to walk. There is always a reason.”
- “I need something to motivate me.”
- “I need a “coach” that I am accountable to.”
- “I find it difficult to stick to a home-based exercise program, because I need some kind of skilled direction in the type of exercise I should do.”
- *Comment from a patient who indicated he did not know what exercise he should be doing for PAD: “...the best I had gotten for advice was physical therapy and the programs they had were not beneficial to my condition, and these therapies did not restore my ability to walk comfortably”*

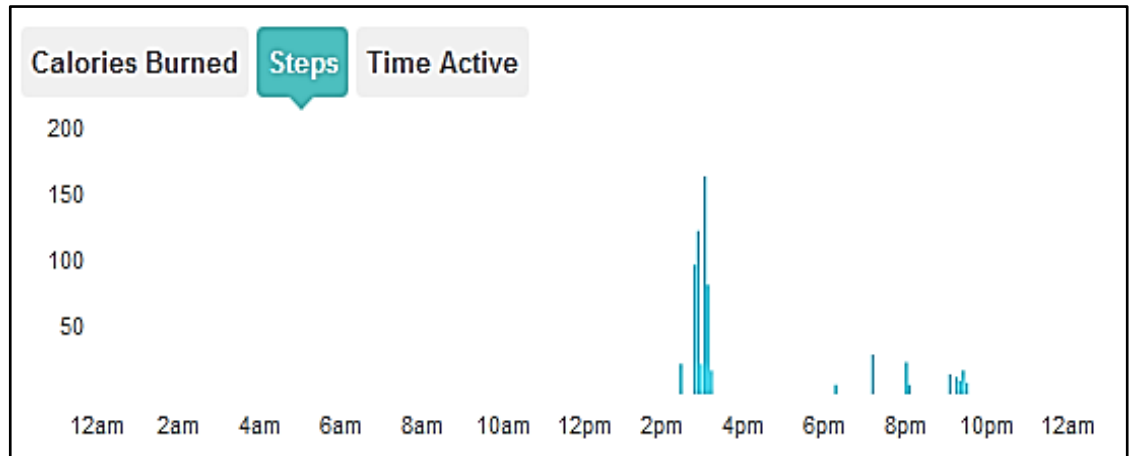


# Fitbit Activity Monitor

Figure 1a. Fitbit next to quarter



Figure 1b. Uploaded Fitbit data from PAD participant



*Figure 1 Legend.* Figure 1a shows the Fitbit adjacent to a quarter. Figure 1b shows uploaded data from a PAD participant in our pilot study. As shown in Figure 1b, the y axis shows number of steps and the x-axis shows time. As shown in Figure 1b, this PAD participant was extremely inactive when he was not exercising.

# Intervention Development: Feedback from Pilot Study Patient Testimonials

## Representative feedback from PAD patients regarding the pilot home-exercise study.

- “I loved monitoring with the Fitbit. It was easy to use. I could track my progress.”
- “The Fitbit made me realize how sedentary I am. Even walking to the bathroom in my apartment made a big “blip” on my Fitbit. So the Fitbit motivated me to walk more.”
- “If I saw that I was close to a threshold value, I walked further in order to break the threshold value.”
- “Four weeks was too short for using the Fitbit. I did not want to return it.”
- “The coach helped me stay on track.”

# Patient Engagement and Outcome Measures

- Six-minute walk – primary outcome
- Walking Impairment Questionnaire distance and speed scores
- Mobility Questionnaire (PROMIS)
- Global Health Questionnaire (PROMIS)
- Pain Questionnaire (PROMIS)
- Social Role Questionnaire (PROMIS)

# Results Of PROMIS Form Rankings From PAD Patients

<b>PAD patient ranking (1=best measures PAD-related physical limitations)</b>	<b>Name of Questionnaire</b>
1	Mobility (in the physical function PROMIS questionnaire) (56)
2	PROMIS Global Health (57)
3	Pain Interference (58)
4	Ability to participate in social roles and activities (59-60)

# Patient Members of Study Team

- Two patient investigators
- Advisory board members (1/2 of participants)
- DSMB member

# Patient Investigator Involvement

- Conference call participation.
- Review grant application and provide feedback.
- Review study materials (website) and provide feedback.

# Patient advisory board member involvement

- Participate in telephone conference calls and meetings.
- Provide feedback.
- Review study materials and provide feedback.

# DSMB patient member

- Training
- Voting member
- Mentorship



# Stakeholders/health care providers

- Focus groups with healthcare providers
  - General internists
  - Vascular surgeons
  - Vascular clinicians.
- Letters of support from major vascular societies.

# Developing the Intervention

## Healthcare Provider Messages

### *What are the barriers to treating PAD patients?*

- “Getting PAD patients to walk for exercise is difficult because walking is painful for PAD patients”.
- “Getting PAD patients to exercise regularly is like any health behavior change: Difficult to achieve.”
- “I would like to know exactly what characteristics of a walking exercise program are best. How many times should patients walk per week, for example, and how long should they walk per session.”
- “A hand out or written prescription that I could hand to the patient would be very helpful.”

# Summary of Contributions of PAD Patients and Healthcare Providers

	PAD Patients	Healthcare Providers for PAD Patients
<b>Proposal Development</b>	<ul style="list-style-type: none"> <li>• PAD patient focus groups;</li> <li>• Pilot studies of PAD patients;</li> <li>• We solicited feedback from PAD patients about the pilot study;</li> <li>• PAD patients selected study outcomes.</li> </ul>	<ul style="list-style-type: none"> <li>• Healthcare provider focus groups.</li> <li>• Reviewed and provided feedback of our intervention.</li> </ul>
<b>During the funding period.</b>	<ul style="list-style-type: none"> <li>• PAD patients are study investigators.</li> <li>• PAD patients are members of our Advisory Committee.</li> <li>• A PAD patient will serve on our DSMB</li> </ul>	<ul style="list-style-type: none"> <li>• Healthcare providers are members of our Advisory Committee.</li> <li>• Healthcare providers will serve as members of our DSMB.</li> </ul>
<b>After the study is complete.</b>	<ul style="list-style-type: none"> <li>• PAD patients will assist with disseminating results to healthcare providers and patients.</li> </ul>	<ul style="list-style-type: none"> <li>• Healthcare providers will assist with disseminating results.</li> </ul>

# Differences between NIH and PCORI

- Engage patients and stakeholders in all aspects of the proposal.
- PCORI has more/new components of the application.
- Focus on improving patient care and clinical practice.

# Conclusions/Summary

- Identify a key clinical question
- Involve patients and stakeholders in all aspects of the proposal.
- Involve patients and stakeholders in all aspects of the actual study.
- Emphasize your expertise as an investigator.