Orthopaedic Section of the APTA
Grant Program
Annual Progress Report Form

Date: March 18th, 2015

Name of Investigators: Steven Z. George PT, PhD
Name of Grant: OPT-IN
Award Period: ___Jan 2013__ to ___Jan 2016__ (Initial award date – date on contract as start date)
Current Year of Award completed (circle one): 2nd

Progress reports are due no later than 1 year plus 10 days after the initial award date. Failure to submit a timely progress report may result in the termination of your award.

1. Summary of accomplishments in the past year:

The second year of this study was highlighted by completion of analyses for the development phase, dissemination at scientific meetings, manuscript submission to peer-review journals, and completion of key beginning components of the validation phase. Details on Specific milestones that represent measurable goals to gauge our second year progress are presented below:

Milestones at 18 months
o 12-15 months (August 2014)
  ▪ Submit Western IRB for inclusion of additional clinics
    Western IRB was not pursued because of the anticipated difficulty of having physical therapists participating at each outside clinic responsible for consenting patients. In particular this would have triggered the need for additional IRB training for the participating clinicians and potential for individual IRB review at each clinic. Such a process would have greatly delayed recruitment. Therefore, an alternate IRB plan was developed through the University of Florida IRB and that approach is described in the next bullet.

  ▪ Renew University of Florida IRB approval
    The UF IRB was revised and approved to allow for on-line informed consent and data collection. This revision eliminated the need for Western IRB and provided maximum flexibility in adding participating clinics because participating patients are giving consent to a UF sponsored study directly, without involvement of the treating physical therapist. In this way the study is functioning much like a survey study and at a lower level of scrutiny for human subjects research.

  ▪ Update Manual of Procedures (MOP) to include finalized screening tools to be used in recruitment of the Validation Cohort
    This was completed and the updated screening tools are currently being used in the ongoing recruitment.

  ▪ Update database and data collection system to account for finalized screening tools
    This was initiated but not completed at this milestone, because screening tools were not finalized and
we could not update without screening tool fields known. It was decided at this milestone that data collection and storage would be done through Redcap.

- Initiate recruitment for Validation Cohort

Recruitment for the Validation Cohort did not begin at this milestone due to; 1) delay in getting the final analysis completed for the screening tools and 2) delay in navigating IRB issues that would allow for efficient recruitment.

- Submit findings from Development Patient Cohort for scientific meeting (Combined Sections or Orthopaedic Section meeting) and peer-review (target journal = J Orthop Sports Phys Ther)

Findings from the Development cohort were submitted for the Combined Sections meeting as abstracts, with 2 accepted as platforms and 1 accepted as poster. There were no submissions to peer-review journal at this milestone due to the aforementioned delay in completing analyses. However, the development of the Red Flags screening tool was submitted to JOSPT in November 2014, and is currently in revision.

- Quarterly OPT-IN investigator meeting

This was completed.

- 15-18 months
  - Recruitment for Validation Cohort (n = 100)

Recruitment for the Validation Cohort did not begin at this milestone due to; 1) delay in completing the data collection system which did not allow for training of additional clinical sites.

- Quarterly OPT-IN investigator meeting

This was completed. During this milestone there was an additional OPT-IN meeting held at Proaxis Therapy in Greenville, SC to introduce staff there to the on-line data collection system and provide a scientific update on red and yellow flag identification.

- Report to Orthopaedic Section Advisory Board for the CRN Grant

This report was completed and submitted (10/16/2014)

Milestones at 24 months (February 2015)
- 18-21 months
  - On-line refresher training for participating OPT-IN clinics

Refresher training for 7 new clinics has been completed for on-line data collection, see below for list and update on clinics and training/participation status.

Actively Recruiting
  1. University of Florida Health, Gainesville, Florida
  2. University of Southern California, Los Angeles, California
  3. Indiana State University, Terra Haute, Indiana

Training Completed
  1. Proaxis Therapy, Greenville, South Carolina
  2. Willow Grove Physical Therapy, Willow Grove, Pennsylvania
  3. University of Colorado, Boulder, Colorado

Pending Trainings (scheduled for February 2015)
  1. University of Illinois, Chicago, Chicago, Illinois
Recruitment for Validation Cohort (n = 200)

Recruitment for the Validation Cohort began in December 2014, but we do not have all n=200 recruited due to delay in completing the data collection system which did not allow for on-time training of clinical sites.

Quarterly OPT-IN investigator meeting

This was completed

- 21-24 months
  - Recruitment for Validation Cohort (n = 300)

Recruitment for validation cohort has continued but we do not have n = 300 recruited due to the delayed start. Total recruitment (n = 31) across 3 clinics to date. In addition to the clinics actively recruiting, we have 3 additional clinics that have completed their training and 3 clinics that will be trained in February. The clinics trained in February will be actively recruiting in March. The 9 clinics that are participating in recruitment have a strong history of collaboration and/or clinical data collection and will allow for rapid progress on previously identified recruitment goals. We anticipate the total recruitment time to be from 4-6 months once all 9 clinics are participating.

Quarterly OPT-IN investigator meeting

This was completed.

Report to Orthopaedic Section Advisory Board for the CRN Grant and meeting (if needed)

This will be completed during 2015 Combined Sections Meeting.

2. Recruitment Summary:

We are continuing with recruitment that was started in December via REDCap. Key indicators for the milestones are below:

Total enrollment: 31
Updated enrollment by site:

1. University of Florida Health, Gainesville, Florida (n=28)
2. University of Southern California, Los Angeles, California (n=1)
3. Indiana State University, Terra Haute, Indiana (n=2)

3. Attach a list of your publications published or accepted during the past year, or currently being written. Send reprints when available. List presentations made and abstracts accepted for presentation based on this work. Indicate with an asterisk (*) those publications supported by Orthopaedic Section funding.

**Publications**


**Presentations**

1. George, Wu, Bialosky, Zeppieri Jr, Lentz, Osborne, Rowe, Dai, Pei, Beneciuk. A red flag screening tool
for orthopaedic physical therapy settings: results from the Optimal Screening for Prediction of Referral and Outcome (OSPRO) cohort (abstracted JOSPT, 2015)

2. Beneciuk, Lentz, Wu, Bialosky, Zeppieri Jr, Osborne, Rowe, Dai, Pei, George. Development of a yellow flag screening tool for orthopaedic physical therapy settings: results from the Optimal Screening for Prediction of Referral and Outcome (OSPRO) cohort (abstracted JOSPT, 2015)


4. Provide a budget, using the original approved budget. Indicate total funds spent to date per major categories. If there was > 25% deviation (greater or less spent) of use of funds for any of the budget category, please BRIEFLY indicate the rationale. (See example below)

<table>
<thead>
<tr>
<th>EXPENSE CATEGORY</th>
<th>Budgeted Amount for Year 2</th>
<th>Actual Amount Spent in Year 2</th>
<th>Amount Remaining in Year 2 budget</th>
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<tr>
<td>Personnel</td>
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<tr>
<td>Consultation</td>
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<td>Subject Costs</td>
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<td>Travel</td>
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<tr>
<td>Other</td>
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<td>TOTAL</td>
<td>$100,000</td>
<td>$82,608.36</td>
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</table>

4. Objectives for the next year:

• Complete training for additional OPT-IN sites
• Complete recruitment of Development Cohort (n = 462; including test-retest portion)
• Quarterly OPT-IN investigator meeting
• Submit findings from Development Patient Cohort to peer-review journal
• Report to Orthopaedic Section Advisory Board and meeting

We continue to be on track with most of these timelines and milestones. Plans for dissemination in the next year are outlined above, including submissions for peer-review journals (n = 3) and scientific meeting (n = 2).

March 18th, 2015

Return to:
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