AWARD NUMBER: W81XWH-17-1-0478

TITLE: Effectiveness of a Peer Visitation Program to Improve Patient Activation and Functional Outcomes and Quality of Life During Amputation Rehabilitation

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8. PERFORMING ORGANIZATION REPORT

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
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14. ABSTRACT

INTRODUCTION

The emotional adjustment to amputation can be a challenging aspect of reintegration. Peer visitation allows the patient going through rehabilitation and reintegration to speak directly with another amputee who has shared that similar experience. A wide variety of organizations are offering patient education and peer visitation programs. The outcome for individuals attending these programs is improvement in quality of life, patient empowerment, self-efficacy, and self-management. The mission of the Amputee Coalition (AC) has the only formally recognized Peer Visitation Program (PVP). However, it has not been tested for effectiveness. There are no known clinical trials regarding PVPs for people living with limb loss. Therefore, the purpose of this study is to demonstrate that a PVP will improve functional outcomes during amputation rehabilitation.

METHOD

Subjects: 18 Females, 28 Males (n=46), 57.4y mean age; 36 below knee and 10 above knee amputations. Aetiologies were 24 Diabetes, 12 PVD, 5 infection, 3 Trauma, 2 Blood clots. *Sites:* 2 separate rehabilitation sites provided the Subjects for this clinical trial. *Intervention:* The AC PVP *Outcome Measures*: The SF-36 quality of life survey, the PHQ-9 Depression survey and the Patient Activation Measure (PAM). *Procedures*: Subjects were randomized into 2 Groups. The AC PVP was administered to Group A immediately (Day 1) and to Group B 15 days after being consented in the rehab center. The data collections were administered upon informed consent (baseline), at 15 days and then again at 30 days. WCG IRB, Army's HRPO and Local IRB oversaw the study. *Data Analysis*: paired ttests were used for data comparisons. The primary endpoint was at the end of Group A's PVP (15 days) compared to Group B's non-exposure to PVP. The secondary endpoint was at 30 days once Group B had completed the PVP, Significance was set at $p \leq 0.05$.

RESULTS

At 15 days when Group A had completed their PVP and Group B had not yet started their PVP, depression scored significantly better using the PHQ-9 for Group A compared to Group B (7.0, 5.0) p=0.007. Once Group B was exposed to the PVP from 15 days to 30 days, depression improved significantly for Group B at 30 days (7.0) p=0.001. Regarding Patient activation, at 15 Days Group A experienced a significant improvement using the PAM score compared to Group B (71.7, 64.1) p=0.034; PAM level improved for Group A significantly compared to Group B (3.2, 2.8) p= 0.039. While Group B experienced non-exposure to the PVP, PAM score degraded significantly from baseline compared to 15 days (73.5, 64.1) p=0.02; in the same period and comparison for Group B, PAM level degraded significantly from baseline to 15 days (3.4, 2.8) p=0.01. Once Group B was then exposed to the PVP (15-30 days), PAM score improved significantly from 15 days compared to 30 days (64.1, 75.5) p=0.001, while PAM level improved significantly from 15 days compared to 30 days (2.8, 3.6) p=0.001. At 15 days, Quality of life measures were significantly improved for Group A in the SF-36 health scales: Role limitation-emotional health (Group A: 36.8, Group B: 19), Pain (Group A: 57.8, Group B: 46.1), and General health (Group A: 57, Group B: 48) $p \geq 0.05$; while Group B improved significantly in the Social functioning scale (Group A: 57.8, Group B: 73) p=0.004. At 30 days Group A significantly improved on health scales: Physical function (Group A: 18, Group B: 7.9), and Pain (Group A: 63.1, Group B: 45) $p \geq 0.001$; while Group B improved significantly in the Role limitations - Physical health (Group A: 15, Group B: 44), Emotional well-being (Group A: 64.2, Group B: 76), and Social functioning (Group A: 61.1, Group B: 75) $p \geq 0.002$.

DISCUSSION

The Peer Visitation Program (PVP) significantly improved depression for Group A compared to Group B who did not receive the PVP for 15 days. When Group B did then receive the PVP, their depression scores improved significantly due to the exposure to the PVP. Immediate exposure to PVP could help mitigate depression and possibly prevent escalation. Patient activation improved when Subjects were exposed to the PVP, while degrading in the non-exposure Subjects. Patient activation can be a significant step in a patient's journey to help themselves and mitigate depression and loss of quality of life. Quality of Life scores did improve at 15 days for the Group exposed to the PVP at 15 days in some health scales, however this outcome was more nuanced and a clear improvement of PVP exposure did not emerge. While not all study endpoints showed a significant difference, the trends were towards improvement with PVP. A larger study needs to be conducted.

CONCLUSION

The Amputee Coalition's Peer Visitation Program improved depression and patient activation for people rehabilitating from amputation in this randomized clinical trial.

15. SUBJECT TERMS	NONE LISTED				
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Table of Contents

1. Introduction

The increased epidemiology of chronic conditions due to an aging population has mandated enhanced organizational and economic efforts of the health care system (Barello et al., 2012; Graffigna et al., 2015). With an aging population, it is estimated that the number of amputees will sharply increase by 2050 (Ziegler-Graham et al., 2008). Considering the reduction of resources health care systems and organizations face in the current climate of health care change, new strategies must be developed and implemented to improve health outcomes while reducing costs (Barello et al., 2012; Graffigna et al., 2015). In the fields of medicine and public health management, navigation and peer visitation programs consider patients as are their own important resources, who should be actively involved in the health care organization and throughout the process of care delivery and rehabilitation (Barello et al., 2012; Clancy, 2011; Crawford et al., 2002; Graffigna et al., 2015). The importance of promoting a more active role of patients in the management of their own health care is recognized by health care experts, managers, and policy makers (Barello et al., 2012; Graffigna et al., 2015). There is reported agreement that programs which aim to educate patients and create more direct responsibility for a patient's health care management can improve functional outcomes while considering broad economic, organizational, and psychological implications (Barello et al., 2012; Graffigna et al., 2015) Programs that engage patients in their own health care are reported as an important strategy to improve adherence, outcomes, satisfaction toward the health care provider, and reduction of health care costs (Barello et al., 2012; Graffigna et al., 2015). There is increasing national and international interest in patient education programs (Barello et al., 2012; Graffigna et al., 2015).

The emotional adjustment to amputation can be a challenging aspect of reintegration. Peer visitation allows the patient going through rehabilitation and reintegration to speak directly with another amputee who has shared that similar experience, enabling the patient to relate feelings and concerns about the loss of a limb. There is increasing national interest in this type of patient-centric education. A wide variety of organizations, including hospitals and community-based facilities, are offering patient education and peer visitation programs. The outcome for individuals attending these programs is improvement in quality of life, patient empowerment, self-efficacy, and self-management. Peer support and navigation was introduced as an intervention to reduce patient barriers to reintegration and achieve optimal healthcare outcomes. The mission of the Amputee Coalition (AC) is to reach and empower people affected by limb loss. The AC has the only formal recognized Peer Visitation Program (PVP). The US Department of Veterans Affairs (VA) has partnered with the AC to establish peer support programs as part of the Amputee System of Care. The AC trains and certifies current people living with limb lost to become certified peer visitors. The AC has trained and certified Veterans with amputations across the country to be peer supporters for fellow veterans with amputations. While the AC PVP program is the only nationally recognized PVP program for amputees, it has not been tested for effectiveness. There are no known clinical trials regarding PVPs. Therefore, the purpose of this study is to demonstrate that a Peer Visitation Program (PVP) may improve functional outcomes in Service Member, Veteran, and civilian lower extremity amputees during amputation rehabilitation.

The primary objective of this randomized clinical trial is to determine if a peer visitation program is effective in improving patient activation and quality of life during amputation rehabilitation.

2. Keywords

Amputation; patient activation; patient engagement; quality of life; rehabilitation.

3. Accomplishments

What were the major goals of the project?

- **Major Task 1: Complete all human subject protection protocols, clinical trial registry, and coordinate study sites for clinical trial.** This Task was designed to be completed within 8 months of the start date. The actual completion of this task was 02/2020. This Task was fully completed.
- **Major Task 2: Randomized Clinical Trial, begin enrollment-complete enrollment.** This Task was designed to be started 9 months from the start date and completed 30 months from the start date. The actual start of this task was 3/8/2021, the completion of this task was 08/01/2023. This Task was fully completed.
- **Major Task 3: Complete enrollment, all testing, finalize study and data analysis.** This Task was designed to be started 27 months from the start date and completed 36 months from the start date. The actual completion of the enrollment, testing, and finalizing the study was 08/01/2023. The completion of all data analysis task was 10/30/2023. These Tasks was fully completed.

What was accomplished under these goals?

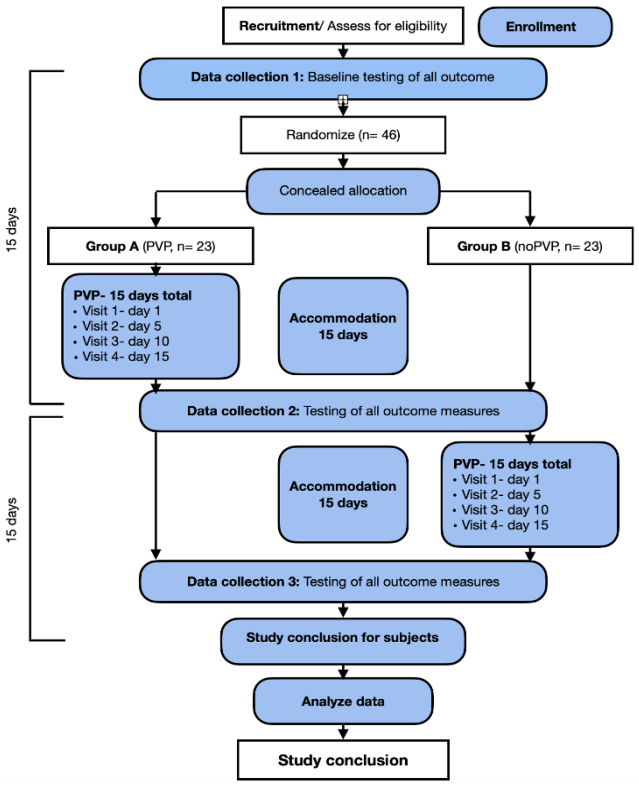
1) Major activities/ Tasks for the entire study are defined above in more detail. For this reporting period the major goal and activity was to finish data collection, close the study, and analyze all data.

2) Specific objectives were to complete the study with all Subjects completing consent, enrollment and data collection.

3) Significant results- key outcomes, major findings, developments, and conclusions (both positive and negative)

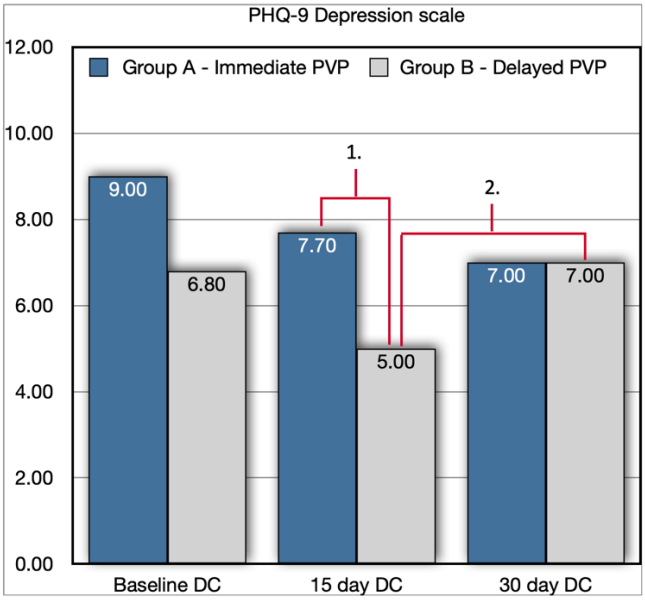
METHODOLGY

Subjects: 18 Females, 28 Males (n=46), 57.4y mean age; 36 below knee and 10 above knee amputations. Etiologies were 24 Diabetes, 12 PVD, 5 infection, 3 Trauma, 2 Blood clots. *Sites: 1*6 Subjects came from the AHC rehabilitation site, 24 Subject came from the MOSS rehabilitation site, and 6 Subjects were seen at Home. *Intervention:* The AC PVP *Outcome Measures*: The SF-36 quality of life survey (RAND 36-Item Health Survey 1.0), the PHQ-9 Depression survey and the Patient Activation Measure (PAM) were chosen for their psychometric properties and an emphasis on clinical translation of Patient Reported Outcome Measures. *Procedures*: Subjects were randomized by the investigators. The AC PVP was administered to Group A immediately (Day 1) and to Group B 15 days after being consented in the rehab center. The data collections were administered upon informed consent (baseline), at 15 days and then again at 30 days. This protocol allowed both groups the opportunity to experience the PVP, but at different times in the rehab course. It allowed a true intervention to no intervention (SoC) comparison, while addressing equipoise. Two rehab sites were chosen, in Philadelphia, PA (MOSS) and Washington DC (AHC). WCG IRB, Army's HRPO and Local IRB oversaw the study. *Data Analysis*: paired ttests were used for data comparisons. The primary endpoint was at the end of Group A's PVP (15 days) compared to Group B's non-exposure to PVP. The secondary endpoint was at 30 days once Group B had completed the PVP, which allowed an a priori aim of comparing a timing effect of PVP completion. Significance was set at $p \leq 0.05$, intention to treat analysis principle was used for missing data.

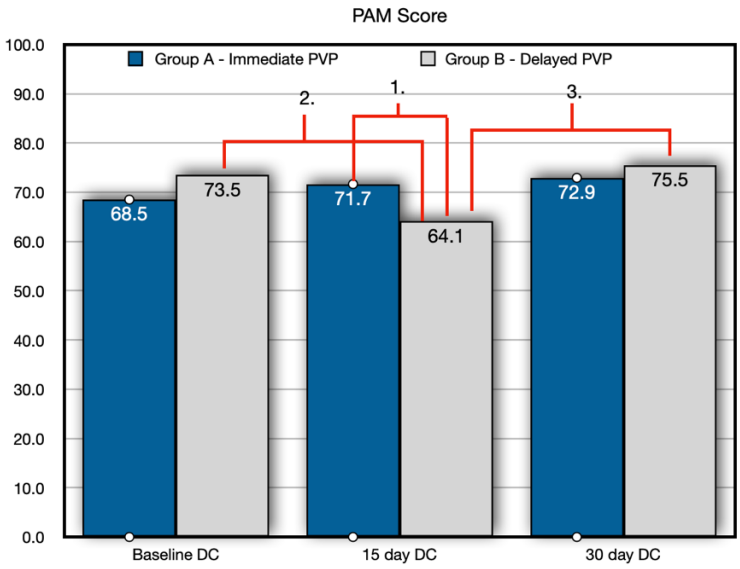


RESULTS

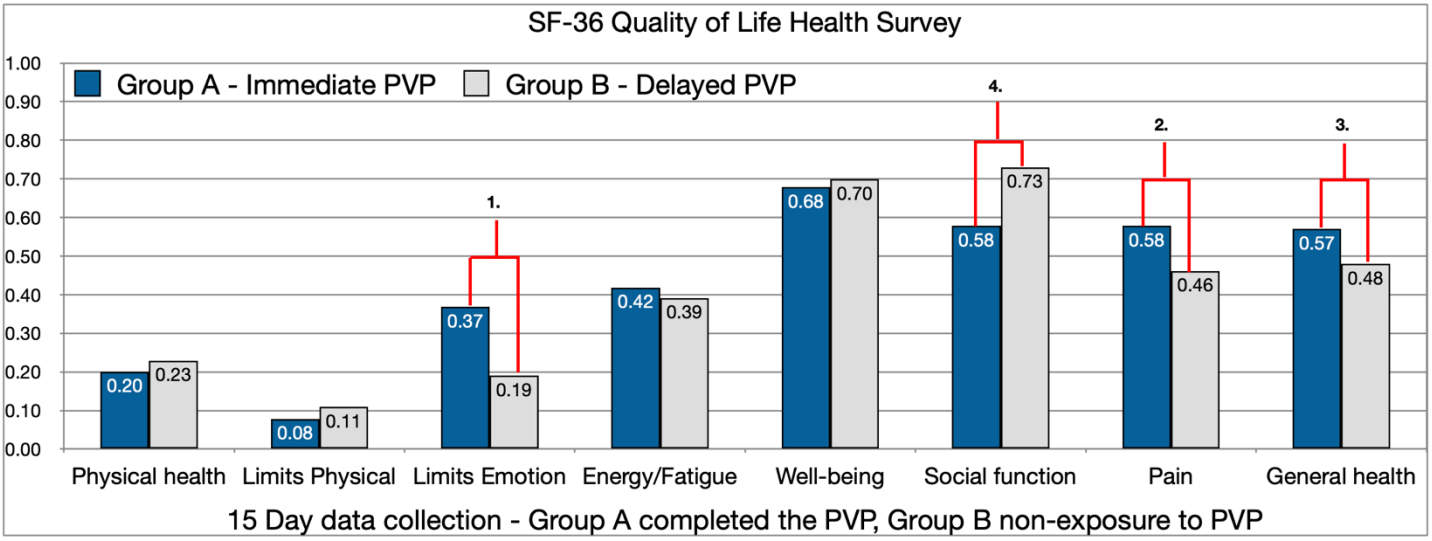
At 15 days when Group A had completed their PVP and Group B had not yet started their PVP, depression scored significantly better using the PHQ-9 for Group A (7.7 ± 4.36, 2-20) compared to Group B (5.0 ± 5.67, 1-11) p=0.007. Once Group B was exposed to the PVP from 15 days to 30 days, depression improved significantly for Group B at 30 days (7.0 ± 2.26, 1-13) p=0.001. Regarding Patient activation, at 15 Days Group A experienced a significant improvement using the PAM score (71.7 ± 12.7, 46-100) compared to Group B (64.1 ± 9.5, 43.7-90.7) p=0.034; PAM level improved for Group A significantly (3.2 ± 0.7, 1-4) compared to Group B (2.8 ± 0.6, 1-4) p= 0.039. While Group B experienced non-exposure to the PVP, PAM score degraded significantly from baseline (73.5 ± 16.3, 51-100) compared to 15 days (64.1 ± 9.5, 43.7-90.7) p=0.02; in the same period and comparison for Group B, PAM level degraded significantly from baseline (3.4 ± 0.7, 2-4) to 15 days (2.8 ± 0.6, 1-4) p=0.01. Once Group B was then exposed to the PVP (15-30 days), PAM score improved significantly from 15 days (64.1 ± 9.5, 43.7-90.7) compared to 30 days (75.5 ± 5.2, 58.1-90.7) p=0.001, while PAM level improved significantly from 15 days (2.8 ± 0.6, 1-4) compared to 30 days (3.6 ± 0.2, 3-4) p=0.001. At 15 days Quality of life measures using the SF-36 were significantly improved for Group A in the health scales: Role limitations due to emotional health (Group A: 36.8, Group B: 19), Pain (Group A: 57.8, Group B: 46.1), and General health (Group A: 57, Group B: 48) p≥0.05; while Group B improved significantly in the Social functioning scale (Group A: 57.8, Group B: 73) p=0.004. At 30 days Group A significantly improved on health scales: Physical function (Group A: 18, Group B: 7.9), and Pain (Group A: 63.1, Group B: 45) p≥0.001; while Group B improved significantly in the Role limitations due to Physical health (Group A: 15, Group B: 44), Emotional well-being (Group A: 64.2, Group B: 76), and Social functioning (Group A: 61.1, Group B: 75) p≥0.002. All other outcome measure comparisons trended in favor of the administration of the PVP, however failed to meet statistical significance.



Statistically significant comparisons were, 1. The primary endpoint (15 day data collection) Group A compared to Group B: Group A's exposure to the PVP resulted in significantly less depression than Group B's non-exposure to the PVP.
2. Once Group B was exposed to the PVP and then tested after completion, their depression improved significantly.



Statistically significant outcomes were, 1. The primary endpoint (15 days); Group A's exposure to the PVP resulted in significantly improved patient activation. 2. Group B's non-exposure period showed a significant decline in patient activation, 3. Then, when exposed to the PVP, Group B's patient activation significantly improved.



2nd Data collection (DC); 15 days after base line DC. Group A completed PVP, Group B has not started PVP. Statistically significant improvements for Group A in the health scales, were 1. Role limitations due to emotional health (Group A: 36.8, Group B: 19), 2. Pain (Group A: 57.8, Group B: 46.1), and 3. General health (Group A: 57, Group B: 48) $p \geq 0.05$; while Group B improved significantly in the 4. Social functioning scale (Group A: 57.8, Group B: 73) $p=0.004$.

DISCUSSION

The Peer Visitation Program (PVP) significantly improved depression for Group A compared to Group B who did not receive the PVP for 15 days. When Group B did then receive the PVP, their depression scores improved significantly due to the exposure to the PVP. Depression is common when a person undergoes a major medical change that drastically alters their life. Mitigating depression with exposure to peers who can share real-life experiences is a valuable health improvement. Some Subjects in this clinical trial experienced significant levels of depression. Immediate exposure to PVP could help mitigate depression and possibly prevent escalation. Patient activation improved when Subjects were exposed to the PVP, while degrading in the non-exposure Subjects. Patient activation, education, and empowerment has become emphasized in healthcare and as a directive of HHS. Patient activation can be a significant step in a patient's journey to help themselves and mitigate depression and loss of quality of life. If a patient's activation level improves it has been shown to reduce overall healthcare costs as much as 15%. Quality of Life scores did improve at 15 days for the Group exposed to the PVP at 15 days in some health scales, however this outcome was more nuanced and a clear improvement of PVP exposure did not emerge. While not all study endpoints showed a significant difference, the trends were towards improvement with PVP. A larger study needs to be conducted.

4) Other achievements. From the outset, the PI considered this to be a preliminary data trial to test the efficacy of the Peer Visitation Program. While there were many challenges, the PI and study team have learned valuable lessons of what elements would require modification in methodologies and study protocols to conduct a larger prospective clinical trial. The data analyzed in this project is and significant and convincing to garner a larger clinical trial with stratified analysis. Different PVP protocols could also be compared, studying the timing of the PVP and different PVP protocol settings. In short, the PI and study team consider this project a success and plan on a manuscript submission as well as a larger clinical trial grant submission in 2024.

- All Goals were met, however there were many unforeseen delays which were remedied with 3 no cost extensions, allowing the team to complete all enrollment and stated goals.

What opportunities for training and professional development has the project provided?

- Regarding training, there is nothing to report.
- Regarding professional development, The PI and study team increased their knowledge of how to manage a randomized clinical trial where intervention is a program, rather than a device or therapy which has been the primary focus of the PI and study team in the past. The PI has had the opportunity to present preliminary data at 2 national conferences and 1 poster presentation at another national conference.

How were the results disseminated to communities of interest?

- As the trial was recently closed and the data analysis has recently been completed, the PI has not had the opportunity to submit an abstract with the final data analysis. However, future dissemination is planned for 2024 to include a manuscript submission, the 2024 Military Health System Research Symposium (MHSRS), The Amputee Coalition national conference and American Orthotic and Prosthetic Association's national meeting. This dissemination plan will ensure a diverse audience can be exposed to this positive data to improve amputation rehabilitation.

What do you plan to do during the next reporting period to accomplish the goals?

Nothing to report, this is the final report.

4. Impact

Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

- The main impact of this project is the provision of valuable preliminary data suitable to support a larger clinical trial. If successful, and Peer Visitation proves to be efficacious in a larger clinical trial, Peer Visitation Programs could become the standard of care with the prospective clinical trial providing evidence based clinical practice guidelines.

What was the impact on other disciplines?

- Two specific lessons learned from this clinical trial included, 1. The prospective clinical trial will include the addition of a designated study site coordinator, such as a social worker to help mitigate attrition of the data collections, and 2. The PVP was modified for this project because the PI discovered in the original research for this grant submission that the most successful peer visitation programs include at least 4 encounters with the Subject. This clinical trial protocol included 4 encounters and proved efficacious. The Amputee Coalition is now carefully considering modifying their active PVP program to be more comprehensive, as it is currently only 1 encounter.

What was the impact on technology transfer?

- Nothing to Report.

What was the impact on society beyond science and technology?

- The nature of the Peer Visitation Program is to impact people rehabilitating through limb loss amputation. Successful PVPs will improve the knowledge, attitudes, patient activation skills, and ultimately the abilities of the person going through the program by helping them rehabilitate and reintegrate into society and resume their normal activities of daily living. Improving patient activation has been proven to improve health economy; this PVP improved patient activation for a cohort that has high health economic impact, which could be mitigated.

5. Changes/Problems

The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change

- The PI made a change in approach, on the demand of one of the sites. The change required the inclusion of anyone with an amputation for up to 30 days, whereas the original protocol was 15-day inclusion criteria. The PI submitted all changes to WIRB, the local site IRB and to HRPO, with HRPO approving this change 02/24/2020.

Actual or anticipated problems or delays and actions or plans to resolve them.

- WIRB was first approved on 4/12/2018. However, one of the rehab sites demanded protocol changes related to the recruitment time fame after amputation (above). Further the site was very slow to respond and delayed communications. HRPO then requested restructuring of a more detailed protocol and many clarifications on 5/2019. This was completed after significant coordination between the 2 named rehabilitation facilities that served as the recruitment sites. HRPO then reviewed for nearly 6 months and did not approve the protocol until 2/24/2020. 3 weeks after the HRPO approval, Covid forced a temporary shutdown of the study for 1 year. The PI and study team resolved these major delays by filing 3 no cost extensions over the course of the study. The study persevered through the delays and fully completed all Subject enrollment. While there was attrition and missing data, the PI and statistical team resolved tis by using intention to treat analysis.

Changes that had a significant impact on expenditures

- Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents.

- Nothing to report.

6. Products

- **Publications, conference papers, and presentations**
    - **Journal publications.** Nothing to Report
    - **Books or other non-periodical, one-time publications.** Nothing to Report
    - **Other publications, conference papers, and presentations.**
        - Effectiveness of the Amputee coalition peer visitation program: randomized clinical trial, American Academy of Orthotists & Prosthetists, *49th Academy Annual Meeting & Scientific Symposium*, March 1-4, 2023, Conference presentation
        - Effectiveness of the Amputee coalition peer visitation program: randomized clinical trial, 2022 American Orthotic & Prosthetic Association National Assembly, Poster presentation

- **Website(s) or other Internet site(s)**
  Nothing to report.
- **Technologies or techniques**
  Nothing to report.
- **Inventions, patent applications, and/or licenses**
  Nothing to report.
- **Other Products**
  Nothing to report.

7. Participants & Other Collaborating Organizations

- What individuals have worked on the project?

Name:	Rebecca Miro
Project Role:	Consultant, Research coordinator
Researcher Identifier (e.g. ORCID ID):	0000-0003-1198-6787
Nearest person month worked:	1.2
Contribution to Project:	Led initial administrative and regulatory study matters immediately follow award notification. Reviewed award terms & conditions; set up electronic files; prepared IRB application; drafted subcontracts, templated all upcoming reports.

- Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period? Nothing to Report
- What other organizations were involved as partners?
    - Organization: Amputee Coalition
        - Location: 601 Pennsylvania Avenue NW, Suite 420, South Building, Washington, DC 20004

        - Partner's contribution to the project:
            - Collaboration – worked with PI on recruitment, and study site coordination, Peer visitation assignment, and all Subject and Peer Visitor payments.
    - Organization: Jefferson Moss – Magee Rehabilitation
        - Location: Elkins Park, 60 Township Line Road, Elkins Park, PA 19027
        - Partner's contribution to the project:
            - Facilities – One of the clinical sites where new amputees were recruited, screened, consented and enrolled into the study.
    - Organization: Adventist Rehabilitation Hospital
        - Location: 9909 Medical Center Dr, Rockville, MD 20850
        - Partner's contribution to the project:
            - Facilities – One of the clinical sites where new amputees were recruited, screened, consented and enrolled into the study.

8. Special Reporting Requirements

Updated QUAD CHART:

Effectiveness of a peer visitation program to improve patient activation and functional and quality of life during amputation rehabilitation. W81XWH-16-OPORP-PORA

PI: Jason T. Kahle, MSMS, CPO, FAAOP **Org:** Prosthetic Design and Research (Tampa, FL) **Award Amount: $494,912.94**

Study Specific Aims/ Hypothesis:

A prospective randomized clinical study of a peer visitation program (PVP) for people with living with limb loss will:

- identify specific time points in the course of patient treatment where a PVP is the most effective.
- compare effectiveness of different treatments regarding the use of PVP.
- demonstrate PVP decreases the incidence of secondary consequences in Service members, Veterans and civilians during amputee rehabilitation.
- demonstrate PVP will improve patient activation and quality of life in Service members, Veterans and civilians during amputee rehabilitation.

Approach

This was be a 2-year, randomized, parallel pre-post intervention (PVP), multi-site clinical study of 46 (n=46) people living with limb loss. This randomized clinical trial will use the Amputee Coalition's nationally recognized PVP, currently used by the Veterans Health administration, to compare pre- and post- peer visitation program education using patient activation and quality of life outcome measures to determine the level of difference and effectiveness of the PVP. Ultimately, effectiveness of a peer visitation program could improve patient activation and quality of life in Service members, Veterans and civilians during amputation rehabilitation and improve reintegration.

Diabetes Patients	% change for a 1 point change in PAM score	10 point gain impact 54 (L2) to 64 (L3)
Hospitalization	1.7% decline	17% decrease likelihood of hospitalization
Good A1c control (HgA1c<8%)	1.8% gain	18% greater likelihood of good glycemic control
A1c testing LDL-c testing	3.4% gain	34% improvement in testing

Source: Is Patient Activation Assoicated with Future Health Outcomes and Healthcare Utilization Among Patient with Diabetes? Journal of Amulatory Care Managment, Oct/Dec 2009.

Figures. A PAM score is predictive of utilization and outcomes. In this case for diabetes a 10 point gain resulted in decreased hospitalization. and improved glycemic control and testing. A PVP could result in improved PAM scores, and decreased healthcare cost.

Timeline and Cost

Activities	CY	17/18	19	20	21	22	23	24
Completed all regulatory approvals - IRB/site/HRPO changes 2/2020								
Covid halts all amputation surgery and recruitment until 3/2021								
Recruitment, data collection of all Subjects, n=46								
Dissemination of preliminary data, all data analysis, submit manuscript								
Estimated Budget		$ 91K	26K	48K	78K	251K		

Updated: 1/12/2024

Goals/Milestones

CY17 - 2020 Goals Funding finalization and study kick-off

- Completed all necessary intake forms and methods
- Completed IRBs, Site protocols, HRPO approval

CY20-21 Delay

- Paused study for 1 year while amputation is considered "elective" and recruitment is halted by study sites.

CY21-23 Goal

- Recruitment completed
- Data collection completed
- Preliminary data analyzed and disseminated

Comments/Challenges/Issues/Concerns

- Sites, IRBs, HRPO, Covid caused unexpected delays
- PI and Co-I addressed these challenges by submitting NCEs and persevering through the challenges and delays.

Budget Expenditure to Date

Projected Expenditure: $494,912.94

9. Appendices

Reminder: Pages shall be consecutively numbered throughout the report.

Study questionnaires

Depression survey - PHQ-9

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

Patient Activation Measure (PAM)

Patient Activation Measure

Instructions: Below are some statements that people sometimes make when they talk about their health. Please indicate how much you disagree or agree with each statement as it applies to you personally by checking your answer. Your answers should be what is true for you and not just what you think others expect of you. If the statement does not apply to you, check "N/A."

	Disagree strongly	Disagree	Agree	Agree strongly	N/A
1. When all is said and done, I am the person who is responsible for managing my health.					
2. Taking an active role in my own health care is the most important factor in determining my health and ability to function.					
3. I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health.					
4. I know what each of my prescribed medications does.					
5. I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself.					
6. I am confident I can tell a doctor concerns I have even when he or she does not ask.					
7. I am confident that I can follow through on medical treatments I need to do at home.					
8. I understand the nature and causes of my health problems.					
9. I know the different medical treatment options available for my health condition.					
10. I have been able to maintain the lifestyle changes for my health that I have made.					
11. I know how to prevent further problems with my health.					
12. I am confident I can figure out solutions when new situations or problems arise with my health.					
13. I am confident I can maintain lifestyle changes, like diet and exercise, even during times of stress.					

13 items with a 5-point Likert response scale. The raw scores are summed and transformed to 0-100 metric (0 = lowest activation level, 100 = highest).

Activation Level 1 (PAM Score < 47) Patients tend to be overwhelmed and unprepared to play an active role in their own health.

Activation Level 2 (PAM Score 47.1 – 55.1) Level 2: Patients lack knowledge and confidence for self-management.

Activation Level 3 (PAM Score 55.2 – 67) ,Level 3: Patients are beginning to take action, but lack confidence and skill to support behaviors.

Activation Level 4 (PAM Score >67) People have adopted many of the behaviors to support their health, but may not be able to maintain them in the face of life stressors.

RAND HEALTH

36-Item Short Form Survey Instrument (SF-36)

RAND 36-Item Health Survey 1.0 Questionnaire Items

Choose one option for each questionnaire item.

1. In general, would you say your health is:

- 1 - Excellent
- 2 - Very good
- 3 - Good
- 4 - Fair
- 5 - Poor

2. **Compared to one year ago**, how would you rate your health in general **now**?

- 1 - Much better now than one year ago
- 2 - Somewhat better now than one year ago
- 3 - About the same
- 4 - Somewhat worse now than one year ago
- 5 - Much worse now than one year ago

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing **several** flights of stairs	1	2	3
7. Climbing **one** flight of stairs	1	2	3
8. Bending, kneeling, or stooping	1	2	3
9. Walking **more than a mile**	1	2	3
10. Walking **several blocks**	1	2	3
11. Walking **one block**	1	2	3
12. Bathing or dressing yourself	1	2	3

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	Yes	No
13. Cut down the **amount of time** you spent on work or other activities	○ 1	○ 2
14. **Accomplished less** than you would like	○ 1	○ 2
15. Were limited in the **kind** of work or other activities	○ 1	○ 2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	○ 1	○ 2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	No
17. Cut down the **amount of time** you spent on work or other activities	○ 1	○ 2
18. **Accomplished less** than you would like	○ 1	○ 2
19. Didn't do work or other activities as **carefully** as usual	○ 1	○ 2

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- ○ 1 - Not at all
- ○ 2 - Slightly
- ○ 3 - Moderately
- ○ 4 - Quite a bit
- ○ 5 - Extremely

21. How much **bodily** pain have you had during the **past 4 weeks**?

- ○ 1 - None
- ○ 2 - Very mild
- ○ 3 - Mild
- ○ 4 - Moderate
- ○ 5 - Severe
- ○ 6 - Very severe

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

- ○ 1 - Not at all
- ○ 2 - A little bit
- ○ 3 - Moderately
- ○ 4 - Quite a bit
- ○ 5 - Extremely

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks**, how much of the time has **your physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time

How TRUE or FALSE is **each** of the following statements for you.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5