

EFFECT OF ADVANCED PNEUMATIC COMPRESSION DEVICES IN THE TREATMENT OF LYMPHEDEMA: A SYSTEMATIC REVIEW AND META-ANALYSES

**D. Panchik, D. Klepper, K. Knecht, J. Pron, M. Schuller, V. Chinchilli, A. Cox,
J. Hornberger, S. Letnaunchyn**

Elizabethtown College, Department of Occupational Therapy, Elizabethtown, PA, USA (DP, DK, KK, JP, MS, AC, JH, SL); Department of Public Health Sciences, Penn State College of Medicine, Pennsylvania, USA (VC).

ABSTRACT

Lymphedema is a chronic, progressive impairment of the lymphatic system that can impact activities and quality of life. Research regarding conservative management of lymphedema primarily consists of complete decongestive therapy (CDT) and compression devices intended to promote lymphatic and venous return. Advanced pneumatic compression devices (APCDs) contain multiple programmable sleeves designed to mimic manual lymph drainage at home. This study aims to determine the effectiveness of APCDs in the treatment of lymphedema through the completion of a systematic review and meta-analysis. A systematic search of five databases was conducted, spanning the years 2010-2021. Only experimental designs of moderate or strong quality were chosen and final review set consists of twelve articles. APCDs are found to be effective for lymphedema treatment based on differences in pre- and post-intervention limb volumes and patient-reported outcomes. Two meta-analyses evaluated the impact of APCDs on both rates of cellulitis and manual therapy. Both analyses demonstrated significant decreases in rates after the APCD interventions. The data showed consistent reduction of limb volume and improved patient-reported outcomes,

indicating that APCDs are generally effective as a complementary intervention to CDT in the maintenance phase of lymphedema treatment.

Keywords: Lymphedema; Advanced pneumatic compression devices; Treatment, Systematic review; Meta-analysis

INTRODUCTION

Advanced pneumatic compression devices (APCDs) provide a new, technologically advanced way to help individuals manage their lymphedema symptoms in the home more effectively. This can reduce medical service needs, overall symptom burden, and pain while also improving overall quality of life. Living with lymphedema challenges participation in activities of daily living, instrumental activities of daily living, perceptions of self-image, and psychosocial and physical health due to decreased function in the affected body area (1).

Complete decongestive therapy (CDT) is the current gold standard in conservative lymphedema therapy (1,2). CDT has two major phases: the decongestive phase, which involves collaboration between a certified lymphedema therapist and the client to drain lymph fluid from the affected area, and the

maintenance phase, which is primarily client-driven and focuses on retaining progress (3). Manual lymph therapy is a method of decongesting the limb. Manual lymph drainage (MLD) is a gentle, hands-on treatment administered by a certified lymphedema therapist. Strokes must always be applied in a distal-to-proximal direction because lymph vessel valves allow only proximal flow (4). MLD drains lymph from the edematous area and increases lymphangiomotoricity in nearby healthy areas, pulling lymph from the affected area to the healthy areas (4).

When a patient transitions to the maintenance phase of CDT, they self-manage symptoms to maintain the progress achieved in the decongestive phase. The client engages in self-manual lymph drainage, wearing compression garments, and maintaining a clinician-approved exercise regimen (5). Self-management is essential for symptom reduction in the maintenance phase of CDT (2,6).

Advanced pneumatic compression devices (APCDs) are emerging as an individualized treatment to complement self-MLD in the maintenance phase (7). APCDs allow for treatment of the upper extremity, lower extremity, trunk, head and neck, and have been reported to reduce the risk of cellulitis. The programming can be adjusted to each client, and the devices demonstrate strong outcomes in edema reduction (8). APCDs are designed as in-home treatment devices and use light pressure throughout their chambers to mimic the effects of MLD (9). The Food and Drug Administration has cleared multiple brands of APCDs to be used for home treatment in lymphedema management (10,11). Treatment is customizable, with a selection of programs or compression sequences. Each garment contains chambers which deliver sequences of pressure in an overall distal to proximal pattern, mimicking the MLD process and stimulating lymphatic drainage (12). This systematic review and meta-analysis aimed to determine the effectiveness of APCDs in the at-home treatment of lymphedema. Prior to this inquiry, the most recent systematic review regarding intermittent pneumatic compression therapy was conducted in 2012 (13). A review

of the evidence gathered since 2012 is crucial to determine efficacy of APCDs.

MATERIALS AND METHODS

Search Strategy and Data Extraction

This systematic review of literature from 2010 to 2021 was conducted in several phases.

Phase 1: Database search

Step 1. Search terms using Medical Subject Headings (MeSH terms) were used to index PubMed articles and were refined by a health science librarian. The following search terms were identified: 'lymphedema' OR 'lymphoedema' AND 'advanced pneumatic compression devices' OR 'APCD' OR 'advanced pneumatic compression pumps' OR 'intermittent compression devices' OR 'advanced pumps' OR 'pneumatic compression pump' OR 'FlexiTouch' OR 'Tactile Medical' OR 'TactileMedical' OR 'Normatec' OR 'Airos' OR 'Huntleigh' AND 'treatment' OR 'interventions' OR 'physical therapy' OR 'occupational therapy' OR 'physiotherapy'.

Step 2. The following databases were searched using the previously mentioned search terms: MEDLINE, PubMed, CINAHL, Cochrane Central Register of Controlled Trials, and Academic Search Ultimate. The results were filtered to include only peer-reviewed, scholarly sources published in English between 2010-2021 and to exclude abstracts only and grey literature (n = 55).

Phase 2: Inclusion and Exclusion criteria

Step 1. Studies were included for this search of literature if the articles included empirical captures where: (1) participants have any stage of lymphedema, (2) participants received intervention for lymphedema, (3) therapy was provided by professionals and involved APCDs, (4) outcome measures were recorded within the studies, and (5) studies that stated that the pump or device used within the inquiry was an APCD.

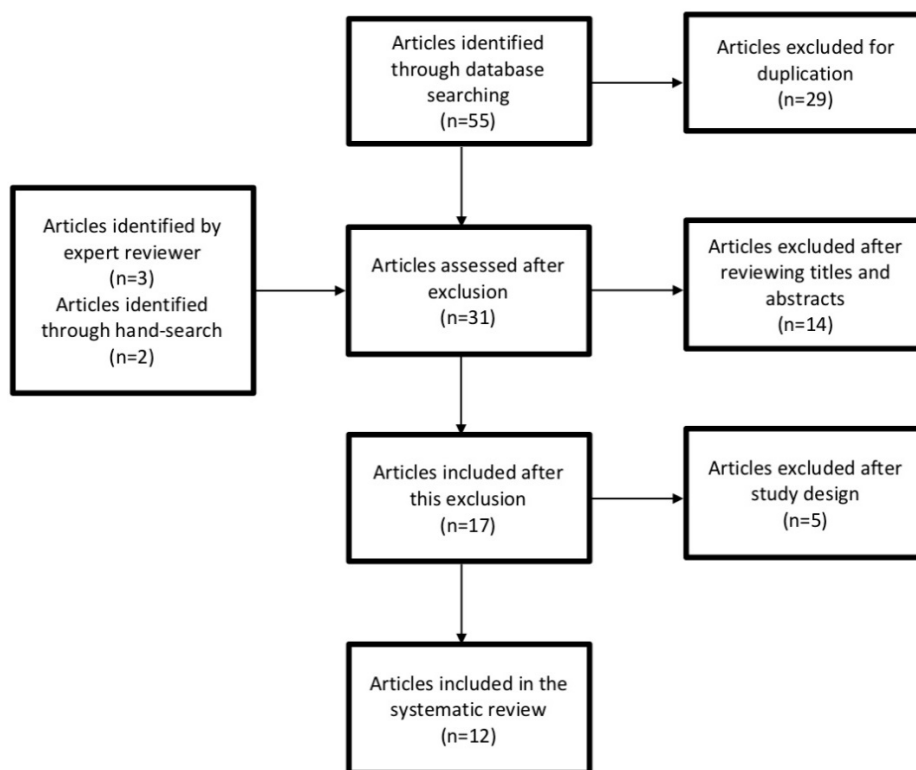


Fig. 1. PRISMA diagram for search strategies utilized and selection results for systematic review.

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Step 2. Studies outside the publication date range and duplicate articles ($n = 29$) were excluded, as well as inquiries not published in English. Remaining articles were analyzed for adherence to the following designs: experimental research, quasi-experimental research, cohort studies, single-subject experimental designs, and sequential clinical trials. Studies were excluded if they fell within the following

categories: case studies, systematic reviews, qualitative-only research, evaluation research, or descriptive research. An expert opinion process can be utilized to ensure the depth of a search and robustness of the literature selected (14). Therefore, a clinical expert assessed the range of studies and identified recently published articles ($n = 3$). Additional articles were identified through hand-search ($n = 2$).

Step 3. All titles and abstracts of articles ($n = 31$) were independently screened for relevance to the research question. Numerable studies were omitted ($n=14$) on the basis of titles and abstracts. The remaining articles ($n = 17$) were evaluated in full text to determine adherence to inclusion criteria. Articles that did not meet the exclusion criteria following this in-depth analysis ($n = 5$) were excluded. The final phase for evaluation of content and quality included the remaining articles ($n = 12$) (Figure 1).

TABLE 1
Articles Evaluated using EPHPP Rating

Articles	EPHPP Rating	Study Design
Adams et al., 2010	Moderate	Controlled clinical trial
Blumberg et al., 2016	Moderate	Cohort study
Fife et al., 2012	Strong	Randomized controlled trial
Gutierrez et al., 2019	Moderate	Controlled clinical trial
Gutierrez et al., 2020	Strong	Cohort study
Karaca-Mandic et al., 2015	Strong	Controlled clinical trial
Karaca-Mandic et al., 2017	Strong	Controlled clinical trial
Maldonado et al., 2020	Moderate	Observational clinical trial
Muluk et al., 2013	Moderate	Cohort study
Ridner et al., 2012	Moderate	Randomized controlled trial
Ridner et al., 2010	Moderate	Quasi-experimental cohort study
Ridner et al., 2020	Moderate	Randomized wait-list controlled trial

Phase 3: Analyzing included sources

The following data were extracted from the selected studies: study design, statistical components, and outcome measures. Next, the quality was rated using the Effective Public Health Practice Project (EPHPP) tool. This tool was created in 1999 by researchers from McMaster University in Canada to assist healthcare professionals with the analysis of quantitative literature (15). The tool is used for each individual article in a systematic review to evaluate the overall quality of the study based on specific categories.

Step 1. The EPHPP tool was used to evaluate study quality, rating each article as strong, moderate, or weak in six categories: selection bias, study design, confounders, blinding, data collection, and withdrawals and dropouts. The subcategory scores were combined to determine an overall rating for each article as strong, moderate, or weak. Quality assessments were conducted independently by each investigator prior to discussing ratings as a group in order to increase trustworthiness of extracted data.

Step 2. Articles rated as moderate ($n = 8$) or strong ($n = 4$) were included. A total of ($n = 12$) articles were yielded for final analysis

(Table 1). Critical appraisal of each included article was done independently to further extract data. Similarities and differences among critical appraisals were determined to organize results and solidify conclusions regarding the research question.

Phase 4: Statistical Analysis

Step 1. Meta-analyses were conducted to determine the impact of APCDs on rates of both cellulitis and manual therapy. Data were collected from studies that reported pre- and post-intervention rates of cellulitis or manual therapy.

Step 2. Of the 12 articles included in this study, 4 reported comparable measures of rates of cellulitis, and 2 reported comparable measures of rates of manual therapy. Statistics assessed inter-study variance and mean differences between pre- and post-intervention values.

RESULTS

An equal number of studies were controlled clinical trials ($n = 4$) and cohort studies ($n = 4$). A few studies ($n = 3$) were randomized controlled trials. The remaining study ($n = 1$)

TABLE 2
Summary of Body Area Investigated and Articles

Treatment Area	Head and Neck	Upper Extremity	Truncal	Lower Extremity	Other (Cellulitis)
Number of Articles	3	3	1	3	2
Articles Included	Gutierrez et al. (2019) Gutierrez et al. (2020) Ridner et al. (2020)	Adams et al. (2010) Fife et al. (2012) Ridner et al. (2012)	Ridner et al. (2010)	Blumberg et al. (2016) Maldonado et al. (2020) Muluk et al. (2013)	Karaca-Madic et al. (2015) Karaca-Madic et al. (2017)

was an observational clinical trial.

The number of participants in the included studies ranged from 9 to 1,731, with the majority ($n = 9$, 75%) having a sample size of at least 30. Outcomes were reported for lymphedema affecting different parts of the body (Table 2), including head and neck ($n = 3$), UE ($n = 3$), trunk ($n = 1$), and LE ($n = 3$). Other studies did not specify a certain area and instead focused on cellulitis ($n = 2$).

Positive Outcomes

Data, both patient-reported and quantitatively measured outcomes were extracted from 12 total studies (Table 3). Overall findings across the research showed that positive outcomes far outweighed any negative reports. All studies ($n = 12$) reported multiple positive outcomes, and only a quarter of the studies ($n = 3$) discussed negative outcomes (7,16,17). Out of a combined 3,280 participants, minimal adverse events ($n = 32$) were reported. Of these, few ($n = 3$) were identified as related to using the APCD.

APCDs improved participants' quality of life in several studies ($n = 5$) (7,18-21). Symptom management and symptom burden were improved in half of the studies ($n = 6$), including outcomes of improved body functioning, range of motion, and other measures of

increased comfort. A third of the studies ($n = 4$) reported decreased rates of cellulitis. Half of the studies ($n = 6$) showed decreased limb volumes in participants after APCD treatment. In a quarter of the studies ($n = 3$), participants' use of other medical services, such as inpatient hospital admissions, outpatient appointments, and manual therapies, decreased.

Negative Outcomes

Minimal negative outcomes were reported, with the majority of studies ($n = 9$) only containing positive results. Very few adverse events ($n = 3$) were likely directly related to APCD usage, and the others ($n = 6$) were not related to using the devices. In one study ($n = 1$), limb swelling was reported in 23 participants. Of those instances, only 4 participants had an increase in swelling above 10 percent.

Meta-Analyses

Two meta-analyses were run to evaluate the impact of APCDs on rates of cellulitis and manual therapy. Figures 2 and 3 display the forest plots generated from these analyses. In each graph, the null line, representing no significance, is not present. This demonstrates that both analyses represent significant decreases in rates after the APCD interventions.

TABLE 3
Reported Positive and Negative Outcomes for each Body Segment

Treatment Area	Positive Outcome	Negative Outcome
Head and Neck (n=3)	<ul style="list-style-type: none"> -Improved quality of life (n=2) -Improved symptom management/symptom burden (n=3) -Decreased rate of cellulitis (n=0) -Decreased limb volume (n=0) -Decreased use of other medical services (n=0) 	<ul style="list-style-type: none"> -Adverse events related to device use (n=0) -Adverse events not related to device use (n=1) -Limb volume increase (n=0) -Unspecified adverse events (n=0)
Upper Extremity (n=3)	<ul style="list-style-type: none"> -Improved quality of life (n=1) -Improved symptom management/symptom burden (n=1) -Decreased rate of cellulitis (n=0) -Decreased limb volume (n=2) -Decreased use of other medical services (n=0) 	<ul style="list-style-type: none"> -Adverse events related to device use (n=0) -Adverse events not related to device use (n=0) -Limb volume increase (n=1) -Unspecified adverse events (n=0)
Truncal (n=1)	<ul style="list-style-type: none"> -Improved quality of life (n=0) -Improved symptom management/symptom burden (n=1) -Decreased rate of cellulitis (n=0) -Decreased limb volume (n=1) -Decreased use of other medical services (n=0) 	<ul style="list-style-type: none"> -Adverse events related to device use (n=0) -Adverse events not related to device use (n=0) -Limb volume increase (n=0) -Unspecified adverse events (n=0)
Lower Extremity (n=3)	<ul style="list-style-type: none"> -Improved quality of life (n=2) -Improved symptom management/symptom burden (n=1) -Decreased rate of cellulitis (n=2) -Decreased limb volume (n=3) -Decreased use of other medical services (n=1) 	<ul style="list-style-type: none"> -Adverse events related to device use (n=1) -Adverse events not related to device use (n=0) -Limb volume increase (n=1) -Unspecified adverse events (n=0)
Other (Cellulitis) (n=2)	<ul style="list-style-type: none"> -Improved quality of life (n=0) -Improved symptom management/symptom burden (n=0) -Decreased rate of cellulitis (n=2) -Decreased limb volume (n=0) -Decreased use of other medical services (n=2) 	<ul style="list-style-type: none"> -Adverse events related to device use (n=0) -Adverse events not related to device use (n=0) -Limb volume increase (n=0) -Unspecified adverse events (n=0)

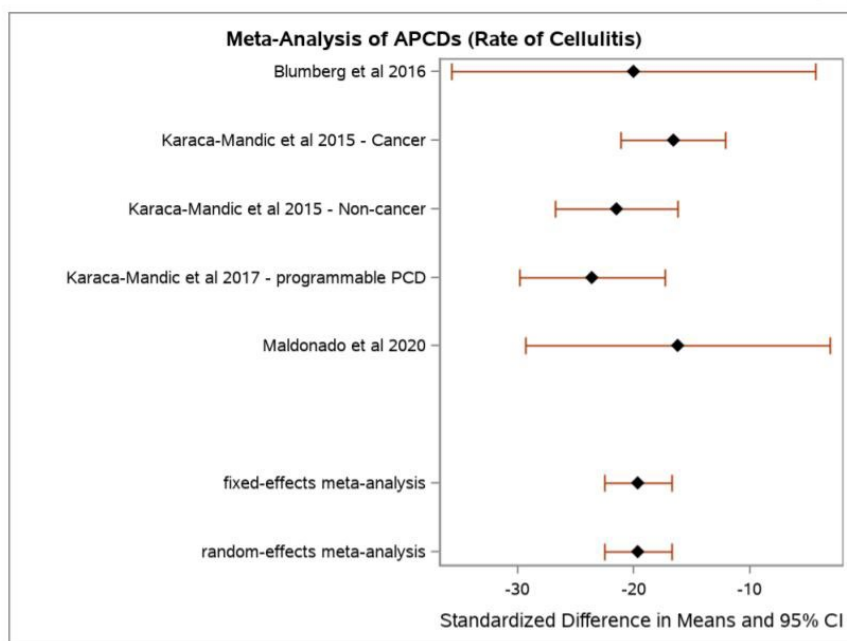


Fig. 2. Forest plot of meta-analysis of data focusing on change in rate of cellulitis. All data indicates significant reduction (null line not shown).

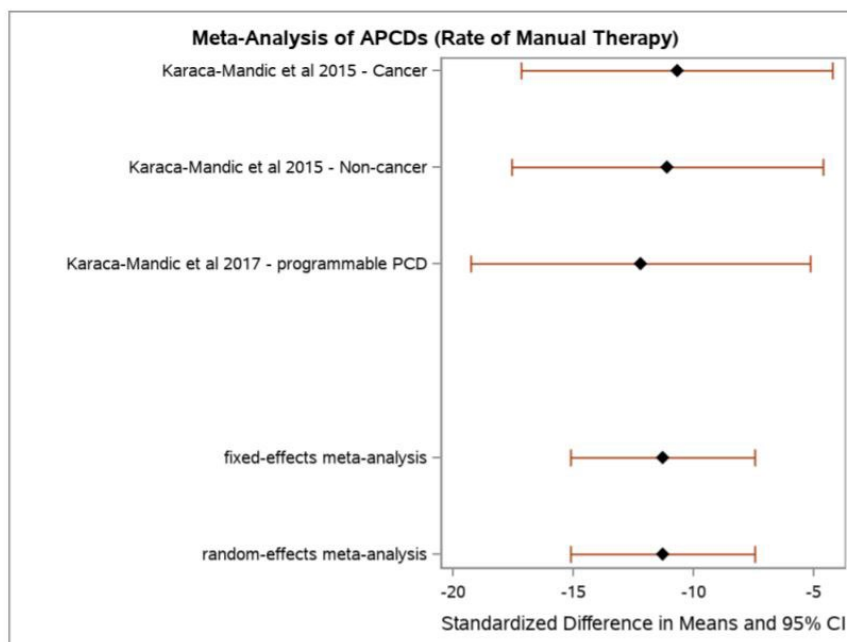


Fig. 3. Forest plot of meta-analysis of data focusing on use of APCD with MLD. All data indicates significant reduction (null line not shown).

The first analysis investigated the change in rates of cellulitis. Pre- and post-tests in four of the included studies determined effectiveness of APCD intervention. One study contained two intervention groups, resulting in two separate data sets (22). As displayed in the forest plot, the 95 percent confidence intervals are left of the null, showing significance in the decrease after APCD use. The Paule-Mandel test for inter-study variance on these values resulted in an omega squared value of 0.03, demonstrating minimal heterogeneity between the studies.

The frequency at which MLD is required was an outcome measure explicitly reported in two of the included studies ($n = 2$). The Paule-Mandel test was also completed for inter-study variance. This DerSimonean-Laird test of homogeneity resulted in an omega squared value of 0, showing no heterogeneity between these studies. In the forest plot, the 95 percent confidence intervals in both the random and fixed analyses fall to the left of the null, demonstrating the significance of the post-intervention values.

DISCUSSION

While the 12 selected articles varied in treatment duration, frequency, and affected area of the body, data across the literature showed consistent reduction of limb volume and improved patient-reported outcomes. Minimal adverse events were noted. These positive results indicate that APCDs are generally effective in the treatment of lymphedema. Patients may benefit financially from use of APCDs as coverage continues to increase under Medicare, Medicaid, and private insurances (8,23). Furthermore, clients utilized therapy services and other medical treatment routines less frequently, thereby reducing monetary demands.

Nearly all included studies reported high satisfaction with APCD usage due to decreased symptom burden and pain. Four studies directly observed a significant decrease in rates of cellulitis (20,22,24,25). These factors contribute to clients' overall quality of life, as they influence daily habits, routines, and meaning-

ful activities. Results of this systematic review emphasize the role APCDs have in a holistic approach to treatment by encompassing and improving the physical, emotional, and mental aspects of client health.

Strengths and Limitations

The exclusion of qualitative studies may have excluded data regarding the impact of APCDs on patients' quality of life. Two included studies were identified through hand search (24,26), and one included study was identified through a referral from an expert (17). This may indicate that the search terms or databases culled were incomplete.

Although limitations were present, this systematic review and meta-analysis had many strengths. A health sciences librarian was involved in assisting the researchers during the methodological process. Together, the researchers and librarian determined which databases to include in their search process and which MeSH terms would yield the most relevant results. Researchers also collaborated with an expert in APCDs who reviewed our included studies to identify any gaps in the articles found in the databases. These collaborations increased the robustness of the entire study (27). This review is further strengthened through the use of PRISMA to document inclusion and exclusion steps in the methodology of retrieving articles, ensuring both sensitivity and specificity (27). Furthermore, only robust experimental studies were included. Researchers analyzed the quality of all included studies through the use of the EPHPP to assure robustness of each included study. This tool ensures the validity of the literature findings, which proved appropriateness for inclusion within the review. This process displayed a high inter-rater reliability (27). Finally, the statistical analyses demonstrated very low heterogeneity, indicating similar results across studies, and further strengthening the evidence supporting APCD use. The strengths of this study demonstrate significant robustness that enhanced the findings of the review, despite the limitations above.

Clinical Implications

APCDs have been found to be effective for reducing limb volume, rates of cellulitis, and need for follow-up outpatient MLD treatment. This indicates that APCDs are beneficial for improving patient outcomes in the maintenance phase of CDT, and therapists may safely and confidently recommend APCDs for self-management of lymphedema symptoms at home.

Future Research

Future research may utilize a qualitative or mixed-methods design to explore impacts of APCD use on patients' quality of life and perceived symptom burden. Consistency of outcome measures across future studies would allow for further meta-analysis.

CONCLUSION

Findings support the hypothesis that APCDs are shown to be effective in the treatment of lymphedema and should be considered for use during the maintenance phase of complete decongestive therapy (CDT). Though CDT is the current best practice for lymphedema treatment, traditional CDT techniques are seen to be more effective when paired with complementary intervention programs such as an APCD. APCDs provide a new, technologically advanced way to help individuals effectively manage their lymphedema symptoms in the home. These devices offer benefits such as a decrease in medical costs, limb volume, symptom burden and pain, rates of cellulitis, and rates of manual lymph drainage. In decreasing these factors, individuals with lymphedema can increase their participation in meaningful, daily activities and inherently increase their overall quality of life.

CONFLICT OF INTEREST

All authors declare no competing financial interests exist.

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Daniel Panchik, DSc. OTR/L CLT (LANA)
Department of Occupational Therapy
Elizabethtown College, 1 Alpha Drive,
Elizabethtown, PA 17022
Phone: (717) 361-1366
E-mail: panchikd@etown.edu