ABSTRACT

EFFECTIVENESS OF PROPRIOCEPTIVE NEUROMUSCULAR FACILITATION IN COMPARISON TO TRADITIONAL PROSTHETIC TRAINING ON UNILATERAL LOWER LIMB AMPUTEE GAIT: A META-ANALYSIS

Objective: The purpose of this meta-analysis is to assess the effectiveness of proprioceptive neuromuscular facilitation compared (PNF) to traditional prosthetic training (TPT) on spatial gait characteristics with regards to step length and step width in people with unilateral lower limb amputations ages 20 – 85 years old.

Data Sources: A literature search of electronic databases hosted by Henry Madden Library - CINHAL, PubMed, Science Direct, and EBSCO.

Study Selection: Three level 2 randomized control trials were appraised and determined to be appropriate for this meta-analysis.

Data Extraction: The articles that met the inclusion criteria were studied to evaluate the operational quality and met a PEDro score of at least a 5/10. Effect sizes were used to show the magnitude of the difference between experimental and control groups between studies.

Data Synthesis: Step length and step width showed a larger effect size in favor of PNF compared to subjects who underwent TPT. Step length data showed heterogeneity between studies, but step width data showed homogeneity between studies.

Conclusion: PNF is more effective than TPT in increasing step width and decreasing step width. PNF can be implemented in order to decrease step width, but the effectiveness of PNF increasing step length is equivocal.

Aaron Bae
May 2017
EFFECTIVENESS OF PROPRIOCEPTIVE NEUROMUSCULAR FACILITATION IN COMPARISON TO TRADITIONAL PROSTHETIC TRAINING ON UNILATERAL LOWER LIMB AMPUTEE GAIT:
A META-ANALYSIS

by
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A project
submitted in partial fulfillment of the requirements for the degree of Doctor of Physical Therapy in the Department of Physical Therapy College of Health and Human Services California State University, Fresno
May 2017
APPROVED

For the Department of Physical Therapy:

We, the undersigned, certify that the project of the following student meets the required standards of scholarship, format, and style of the university and the student’s graduate degree program for the awarding of the doctoral degree.

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BACKGROUND

Lower-Limb Amputation Prevalence and Problems

There are over 1 million individuals who live with a lower limb amputation in the United States.\(^1\) Approximately 68\% of lower limb amputations are transtibial (38\%) or transfemoral amputations (30\%).\(^2\) In 2010, the estimated number of individuals living with a major LLA in the United States was approximately 470,560.\(^1\) If the current rate of amputations does not change, the LLA population is anticipated to be over 592,000 by 2020.\(^1\) Etiologies which contribute to lower limb amputations include dysvascular disease, trauma, cancer, and congenital conditions. The most common cause of LLA is dysvascular disease.\(^1\) These individuals tend to be greater than 65 years old and account for approximately 81\% of cases.\(^1\) The second most common cause is trauma.\(^1\) This patient population tends to be under 65 years old and make up approximately 17\% of cases.\(^1\) LLA due to cancer and congenital disease together make about 2\% of LLA cases, and patients tend to be under the age of 65.\(^1\) Individuals with a lower limb amputation often favor their sound-side limb during daily activities such as walking.\(^3\) This leads to abnormal gait patterns when using their prosthetic.\(^4\)

Gait

In order to understand gait deviations as a result of LLA, it is important to be familiar with the gait cycle. The gait cycle is broken down into 2 periods, stance and swing. Each period is made of phases. The first 5 phases occur in the stance period, and the latter 3 phases occur in swing. Each phase has specific tasks during the gait cycle. The first 2 stance phases, initial contact and loading response occur during weight acceptance of the gait cycle. The functional demands of initial contact and loading response include shock absorption, initial limb stability, and
preservation of forward momentum. In the third and fourth phases, mid-stance and terminal stance, assist with single limb support. During this phase, one limb supports the entire body weight in the sagittal and coronal planes, as the body progresses forward. Stages 5 through 8 include pre-swing (the last phase of stance), initial swing, mid-swing, and terminal-swing. These phases are involved with the task of swing limb-advancement. In these phases, preparatory posturing is required to meet the demands of the advancing limb, advancement of the limb to complete the gait cycle, and preparation for the next gait cycle. Understanding each phase helps in identifying deviations and interventions to correct them.

**Amputee Gait Characteristics**

To properly assess LLA gait, spatial gait characteristics are utilized to show gait deviations in comparison to normal gait. In comparison, LLA gait shows asymmetry between the prosthetic and sound side limb. Studies have shown prosthetic limbs have increased step length, decreased stance time, decreased swing velocity, and decreased stride length when compared to sound limbs. Prosthetic legs also show decreased stance time and increased swing time. The resultant gait asymmetry is thought to be due to a lack of trust of the prosthesis during stance time on the prosthetic limb. Therefore, amputees transfer their weight to the sound leg as quickly as possible. Residual limb length has also been shown to influence gait symmetry. A longer residual limb allows additional control over the prosthesis during stance. The added stability distally prevents excessive movements in the hip and the trunk. A shorter residual limb has shown to increase movement in the pelvis and thorax. Gait compensations as a result of LLA occur due to absence of muscles which are normally used in gait. In addition to residual limb length, there are other factors which influence LLA
gait. This includes the presence of a pain free stump, optimally fitted socket, prosthetic alignment, the prosthetic type utilized by the amputee, and the overall health of the individual. Regardless of the reason for gait asymmetry, it must be addressed promptly as continued asymmetry between lower-limbs during lower limb amputee gait leads to unequal loading responses which can exacerbate musculoskeletal pathologies such as osteoarthritis, decreased bone mineral density, and muscle atrophy.\textsuperscript{11-16}

**Musculoskeletal Changes in Amputees**

Studies show physiological changes to the musculoskeletal system in lower limb amputees. These changes include osteoarthritis, decreased bone mineral density, and muscle atrophy. Osteoarthritis presents in both lower limbs suggesting overuse on the sound side limb and disuse on the amputated side.\textsuperscript{11-15} Individuals with a higher level LLA experience abnormal loading changes, which contributes to loss of bone mineral density on the amputated side.\textsuperscript{11,14} Reduction in bone mineral density has been observed on the amputated side in trabecular and cortical bone, and weight bearing locations such as the femoral neck and greater trochanter.\textsuperscript{11} Muscle atrophy is associated with high-level amputations as well, and over time there is a progressive decline in the strength of the quadriceps, hamstrings, and hip abductor musculature on the amputated limb.\textsuperscript{16-20} The result of these musculoskeletal changes leads to impairments in function, specifically those seen through gait deviations.\textsuperscript{17,21}

**Traditional Prosthetic Training**

The ultimate goal of LLA rehabilitation is community reintegration with minimal restrictions and activity modifications as needed.\textsuperscript{22} This is accomplished with a multifaceted rehabilitation program, which can be managed by physical
therapists to help patients with prosthetic management to increase functional use. An exercise which focuses on cardiovascular endurance, muscle extensibility, and strengthening is implemented to produce appropriate muscular forces for extended durations of walking. Pre-gait activities are also implemented before gait training in order to progress and improve gait strategies so individuals can proceed to functional activities. The combination of these exercise modalities during the prosthetic phase of LLA rehabilitation is traditional prosthetic training (TPT).

Each component of TPT is important for persons who undergo LLA. Cardiovascular endurance is important to develop because amputations at the transtibial and transfemoral levels consume increased caloric energy during gait. Flexibility of hip flexors and knee flexors are required to prevent muscle contractures from occurring and impeding gait. Strengthening of the gluteus muscles, quadriceps, hamstrings, and especially hip abductors is frequently used to further develop gait symmetry in order to improve stance time, weight bearing capability, and increase ambulatory capacity. Pre-gait activities, often done through activities such as weight shifting and proprioceptive exercise is considered to be fundamental to TPT in order to improve balance. There is strong evidence for a relation between balance and walking ability.

Gait training includes pre-gait activities where the gait cycle is broken down into individual phases for enhanced learning. The phases are gradually combined when the client is ready to accept a more challenging treatment intervention and progress to a more difficult, combined activity eventually leading to ambulation. After pre-gait activities have included all phases of gait and the person is able to walk with their prosthesis, the environment can be changed. Beginning from easy, smooth, and level surfaces, a higher challenging surface can be utilized. This is more functional because the task and environment is
manipulated in order to simulate an experience that a person may encounter in their daily activities. This is achieved through the use of obstacles, uneven terrain, and individual work tasks and is usually covered as part of the prosthetic rehabilitation program. Furthermore, advances in technology have allowed therapists to utilize virtual reality to enhance the gait training experience. Treadmill gait training while walking in a computer assisted virtual reality environment has shown similar find between individuals with transtibial amputees and unimpaired individuals.

To measure progress, gait parameters are a common primary outcome measures used to detect differences seen after implementing exercise activities. Gait is the preferred outcome measure as it is a component of functional mobility which is highly correlated with quality of life for individuals with or without a LLA. Evidence has shown TPT is an effective treatment method for LLA amputees. While there is supportive evidence recommending all components of prosthetic training, there is no conclusive evidence advocating a particular exercise modality or treatment component.

Effectiveness of PNF on Gait Training

An alternative treatment modality which has shown to be effective in improving gait parameters is Proprioceptive Neuromuscular Facilitation (PNF). PNF, originally created by neurophysiologist Herman Kabat is a method of modulating motoric output by influencing the input of the various sensory receptors of the body. PNF was originally used in the treatment of Multiple Sclerosis and Poliomyelitis. Since then, PNF has developed into treatment strategy primarily in neurologic conditions and conditions affecting gait.
The theory of PNF is centered on an adaptable human neuromuscular system which responds to, and moves in, diagonal patterns. These patterns are facilitated through various manual contacts to the extremities, pelvis, or scapula. Verbal and visual stimuli are also used for implementation. The combination of various manual contact patterns and facilitative techniques assists weaker muscles distal to the locus of contact.\textsuperscript{39}

PNF techniques have been demonstrated to improve on temporal-spatial gait characteristics.\textsuperscript{43} Trueblood et al. (1989) found following one session of PNF treatment, which utilized resisted pelvic PNF motion improvements in stance stability and limb advancement were observed in the involved lower extremity of hemiplegic patients.\textsuperscript{43} In addition, PNF techniques have shown improvements in balance during single leg stance. A study performed by Won and Park found contract-relax-antagonist-contract and antagonist-contract techniques had significantly improved overall stability, anterior-posterior stability, and medial-lateral stability.\textsuperscript{44} Despite the clinical acceptance of PNF as a method of treatment, the effects of PNF on people with LLA are limited in the available literature.

**Gaps in the Literature**

Although data exist advocating for TPT, there is no consensus as to which exercise intervention has the best outcomes on gait parameters.\textsuperscript{29} This makes finding an optimal rehabilitation program crucial, as anatomical and gait changes negatively impact people with LLA. There is an abundance of literature on the effects of PNF on gait parameters in patients with hemiplegia. However, there are very few studies looking at the effect of PNF on gait parameters in transfemoral and transtibial amputees. Given there are studies looking at the effect of TPT in amputees and the fact that PNF might also improve gait parameters, there is a need
of comparing the 2 approaches. This study aims to fill a gap in the literature since there is no meta-analysis or systematic review in the literature for LLA rehabilitation comparing PNF to TPT.

The purpose of this meta-analysis is to assess the effectiveness of PNF compared to TPT on spatial gait parameters with regards to step length and step width in individuals with unilateral lower limb transtibial or transfemoral amputation ages 20–85 years old. The null hypothesis is there will be no statistically significant difference between PNF and TPT on step length and step width. The alternative hypothesis is there will be a measureable, statistically significant improvement in step length and decrease in step width with the utilization of PNF as compared to those who underwent TPT.
METHODS

In order to provide a structured meta-analysis on the effects of PNF on the effects of gait in unilateral amputees, professional guidelines were used. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Explanation and Elaboration document was used to evaluate the studies. Along with the Explanation and Elaboration document, PRISMA 27-item checklist was also used to guide the writing process and assure that all pertinent sections were included in the meta-analysis.45

Search Criteria

A computerized search of the following databases CINHAL, PubMed, Science Direct, and EBSCO host through Fresno State Henry Madden Library was done between June 2016 and September 2016. The search strategy method can be seen in Figure 1. Articles were obtained after meeting the inclusion and exclusion criterion set by the reviewer. Keywords used in the search included: gait rehabilitation, proprioceptive neuromuscular facilitation, and amputee or amputation. Furthermore, a search of Google Scholar and reference searches were done to identify additional eligible publications that were not identified during the database searches. Articles reviewed were limited to peer-reviewed journals in the English language.

Inclusion and Exclusion Criteria

Studies included in this meta-analysis fulfilled the following criteria: a randomized controlled trial (RCT), pretest posttest study design, men and women between the ages of 20–85, subjects with either a unilateral transfemoral or transtibial amputation, at least one outcome measure assessing temporal-spatial
gait parameters at baseline and after treatment, and compare proprioceptive neuromuscular facilitation treatment or traditional prosthetic therapy. Studies were excluded if the subjects were bilateral amputees, reported no temporal-spatial gait characteristics, or if the subjects were unable to walk without an assistive aide.

**Outcome Measures**

Spatial gait parameters were recorded by measuring 6 footprints on a mat by an assessor. Obtaining spatial gait parameters by this method has been referred as a pencil-paper method.\(^{46}\) Step length is distance between 2 successive footprints of the opposite foot. Step width is the distance between the centers of 2 opposite heels. This method has a subject walk on a mat which can be covered with talcum powder or another medium which places footprints on a walkway.\(^ {46}\) The paper-pencil method has been proven to be a reliable and has shown to be valid when compared to contemporary methods of gait analysis.\(^ {46,47}\)

**Operational Definitions**

For clarity and uniformity purposes for this meta-analysis, the following definitions were cited. Subjects with LLA will either be a transtibial or transfemoral level amputee as all subjects in the studies were either one or the other. The definition of PNF is the use of hands on manual tactile and verbal cues incorporating techniques such as contract-relax, hold-relax rhythmic initiation, slow reversals, and approximation.\(^ {39}\) Traditional prosthetic training will include activities such as muscle strengthening, gait training, balance training, and functional training.\(^ {40-42}\) Spatial gait characteristics which will be examined for analysis will be step length and step width. Step length will be defined as the average distance between the 2 heels over 6 steps from sound heel to the
amputated heel, and amputated heel to the sound heel. Step width is the distance between the centers of 2 opposite heels.

**Data Collection**

One author reviewed titles, abstracts, and keywords of retrieved publications to assess their eligibility in this meta-analysis. An inclusion criterion was established after articles were retrieved. The full texts that fit the inclusion criteria were reviewed to assess the methodological quality and met a PEDro score of 5-6/10. OpenMeta(Analyst)© software was utilized to determine individual effect sizes of each study and a grand effect size for each outcome. Outcome measures utilized from each study included step length and step width for statistical analysis. Effect sizes were calculated by utilizing the means and standard deviations, which were acquired through independent contact of authors or extracted from the articles. Effect sizes were used to show the magnitude of the difference or relationship between interventions within a study or across multiple studies.

**Quality Appraisal**

The quality of the studies used in the meta-analysis was assessed by implementing the PEDro scale. The PEDro scale (see Appendix) was used to assess the quality appraisal of all studies included in this meta-analysis to show significance and any risk for bias. One point was awarded for each of the criterion clearly meeting preset guidelines and the 11 items were totaled to give a quality score. However, the first criterion was only used to assess external validity and is not added to the final score of the assessment, making the final score out of 10 points. This system helped the reviewer determine internal and external validity and any limitations that were present in each study (see Table 1).48
**Statistical Analysis**

Three randomized controlled trials each comparing PNF to TPT measuring step length and step width were analyzed. All data collected from each study was presented in the results section in tables, where overall target accuracy was obtained and further assessed individually. Each set of results was compared and analyzed to determine the effect sizes based on confidence intervals that were extrapolated from means and standard deviations for step length and step width of each selected study. Data were input into OpenMeta(Analyst)© software to determine individual effect sizes where quality of the data determined. Quality of data was determined by the grand effect size and homogeneity of data. The grand effect size was based on a 95% confidence interval from which the effectiveness of the interventions were determined favoring the intervention or control groups. Homogeneity of data was determined by a Q-statistic, degrees of freedom, and associated p-value which is generated by OpenMeta(Analyst)©. If a generated Q-statistic was greater than degrees of freedom, which was the number of studies minus 1, the data were determined to be heterogeneous. Likewise if the associated p value was less than 0.05 the data were determined to be heterogeneous. Data were determined to be homogeneous if the Q-statistic was less than degrees of freedom and if the associated p value was greater than 0.05. A random effects model was employed when data were determined to contain heterogeneous data, and a fixed effects model was employed when data were determined to contain homogeneous data. Effect sizes for this study were categorized by: small <0.2, medium 0.3-0.8, and large >0.8. A Q statistic was then calculated in order to determine the homogeneity or heterogeneity of the combined studies.
RESULTS

A computerized search of several academic databases identified 703 abstracts which were initially reviewed based on title and results. Keywords used in the search included: gait rehabilitation, proprioceptive neuromuscular facilitation, and amputee (1 from CINHAL, 38 from PubMed, 88 from Science Direct, 575 from Google Scholar, and 1 from a reference search). After an abstract review, 309 articles were screened and were deemed inappropriate due to titles, intervention, and duplicates. Eligibility criteria excluded 125 articles after determining inappropriate study design, outcome measures, and inability to fit the PICO. After an extensive search, 3 randomized control trials met the standards and were included for this meta-analysis. The studies that were deemed appropriate for this meta-analysis included research from Anjum et al., Sahay et al., and Yigiter et al. These studies were published between 2002 and 2016. Table 1 shows the process of inclusion and exclusion of all studies.

Once the studies were chosen, they were assessed using the PEDro scale for appraisal. PEDro scores assess the strength of each article by identifying the strengths and limitations of each study. The PEDro scores ranged from 5-6/10 for the selected articles. Common aspects of PEDro which were satisfied across studies were randomization and similarity of subjects at baseline. The PEDro scores are shown in Table 2.

Meta-Analysis: Study Characteristics

Articles in this meta-analysis were from the following authors, Anjum et al., Sahay et al., and Yigiter et al. All 3 studies met the PICO criteria and were included based on the population, study design, outcome measures, and availability of means and standard deviations. The most commonly unsatisfied
criteria included blinding of therapists and assessors. Each study obtained gait characteristics data analyzing the foot prints of 6 consecutive steps. Step length was measured as the distance between 2 successive foot-prints amputated to sound heel and sound heel to amputated heel. Step width was measured as the distance between the centers of 2 heels. Sahay did not report outcome measures on step width but rather stride width, but the definition used to determine stride width was identical to the step width definitions as determined by Anjum and Yigiter.\textsuperscript{40-42}

A functional outcome measure which was utilized by Sahay and Anjum, but not by Yigiter was the Locomotor Capabilities Index (LCI). The LCI is a subjective measurement composed of 14 questions which determine the lower-limb amputees’ ability to perform activities with prosthesis.\textsuperscript{49} Each item on the questionnaire is rated on a 4 point ordinal scale. A score of 0 indicates an inability to perform; 1 indicates they are able to perform with help from another person; 2 indicate the ability to perform under supervision; 3 indicate the ability to perform an activity independently. The total sum can range from 0 to 42, with higher scores reflecting increased independence. The LCI can be further analyzed as subscales which analyze basic and advanced functions on a 0 to 21 point scale.

Anjum et al. scored 6/10 on the PEDro scale. The purpose of the study was to determine the effects of PNF techniques compared to traditional prosthetic training, in improving ambulatory function in subjects with transtibial amputations. The unfulfilled PEDro criterion included blinding of the subjects, blinding of therapists, and blinding of assessors. Outcome measurements of knee extension, knee flexion, hip flexion, step length step width, cadence, and LCI were taken at baseline and at 4 weeks when the study ended. The frequency and duration of treatment during the 4 week study was undisclosed. At the end of the
study, the PNF group showed improvements in the LCI and gait parameters, but significant improvement was only found in the LCI.

Sahay et al. scored 6/10 on the PEDro scale. The purpose of this study was to compare the efficacy of PNF techniques with traditional prosthetic training in the enhancement of gait function in patients with transtibial amputations. The unfulfilled PEDro criterion included blinding of the subjects, blinding of therapists, and blinding of assessors. Outcome measures taken at baseline and after 10 days measured stride width, stride length, step length, and LCI. Exercises were implemented for 30 minutes daily for 10 treatment sessions. At the end of the study, the PNF group presented with improvements in all outcome measures with significance in stride width and LCI between groups posttest.

Yigiter et al. scored a 5/10 on the PEDro scale. The study compared the outcomes of PNF training and TPT on weight bearing and gait biomechanics. The unfulfilled PEDro criterion included blinding of the subjects, blinding of therapists, blinding of assessors, and reporting outcome measures from at least 85% of subjects. Outcome measures were taken at baseline and after 10 days which assessed weight bearing percentage on the amputated leg and temporal-spatial gait characteristics between lower limbs. This was the only study to examine outcomes between sound limb and amputated limb. Subjects were trained 30 minutes daily, for a total of 10 treatments. At the end of the study, the PNF group presented with statistically significant improvements in weight bearing percentage, stride length, step length in sound and amputated side, step width, self-selected comfortable gait, fast gait, and stride length.

Across the 3 studies used in the meta-analysis, all studies were randomized controlled trials examining the effects of PNF on unilateral transtibial or transfemoral amputees. All studies assessed average step length and step width
between lower limbs. The PEDro scores of the 3 studies ranged from 5-6/10. The common unfulfilled PEDro criterion included allocation of concealment, and blinding of subjects, therapists, and assessors. Two of the 3 studies had daily 30 minute treatments for 10 days while one study lasted for 4 weeks with an unknown frequency and duration of treatment sessions. All studies demonstrated improvement in step length and step width, but significance was only found in 2 of the 3 studies. Two of the 3 studies also examined showed a significant increase in function according to the Locomotor Capabilities Index (LCI).

**Meta-Analysis: Synthesis of Results**

A random effects model was used to analyze step length data, utilizing effect size, standard deviation, and confidence intervals based on a 95% confidence interval. The meta-analysis measuring step length, had an associated Q value of 2.177 and a p-value of 0.337 indicating the data from the studies measuring step length was heterogeneous. There is heterogeneity because the Q value is greater than the degrees of freedom (dof = 2), which is the number of studies minus 1. The combined effect size of 0.528 indicates PNF has a medium effect size when compared to TPT.

Results of the statistical analysis performed on step width across 3 groups of the studies demonstrated an associated Q value of 1.731 and a p-value of 0.421, indicating the data were homogenous. The combined effect size of the studies was -0.662, which indicates PNF has a medium effect size on decreasing step width when compared with TPT. Effect sizes, standard error of effect size, confidence intervals, and combined values for step length and step width, are displayed in Tables 3 and 4. The data are presented as forest plots in Figures 2 and 3.
According to the forest plot analyzing improvements in step length, the effect is positive. This indicates an improvement in overall step length when analyzing both legs in amputee gait with PNF compared to TPT. In addition, the forest plot analyzing step width has a negative effect size, which indicates a reduction in step width during amputee gait. According to the meta-analysis, the utilization of PNF training has a greater improvement in step length and step width during amputee gait when compared to TPT.
DISCUSSION

The purpose of this meta-analysis was to assess the effectiveness of PNF compared to TPT on spatial gait parameters for individuals with lower limb amputations. This meta-analysis attempted to bridge the gap in the literature regarding the effectiveness of PNF as an exercise modality for individuals with unilateral lower limb amputations. Systematic reviews have been performed on TPT and have shown increases in temporal-spatial gait parameters, but no consensus has been reached which determines the best intervention for restoring symmetrical gait patterns.\textsuperscript{29,33} This meta-analysis was the first attempt to compare TPT and PNF for individuals with LLA.

This meta-analysis demonstrated a medium effect size favoring PNF in comparison to TPT in increasing step length and decreasing step width. The null hypothesis was rejected based on the results of this meta-analysis as the grand effect sizes for both step length and step width favored PNF and the confidence intervals did not cross the 0 value line. Therefore, the alternative hypothesis was accepted because this study identified that individuals with LLA received more effective step characteristics by receiving PNF techniques compared to TPT. Temporal spatial gait parameters demonstrated a medium effect size of 0.528 and -0.662 for step length and step width respectively in favor of PNF when compared to those who underwent TPT.

Meta-Analysis on Step Length and Step Width

This meta-analysis demonstrated PNF alone had a greater effect than TPT. A medium effect size was found for both step length and step width was found supporting the alternative hypothesis that PNF increases step length and decrease in step width in individuals with a unilateral lower limb amputation ages 20 – 85
years old. However, heterogeneity was found between studies with step length results. Homogeneity was found between studies with step width results. So although both outcome measures resulted in favored PNF, there were heterogeneous findings. Due to the presence of heterogeneity, the evidence supporting the efficacy of PNF presents potential limitations to this meta-analysis that require further discussion.

**Strength of Results**

An external strength across studies was the use of a moderately large sample size (n=143) and similarities between the groups across all 3 studies. A greater sample size allows for application of PNF on LLA to the general population with a likelihood of observing similar results in a clinical setting.

Homogeneity in the studies was seen for step width. All baseline measurements for step width amongst all subjects were standardized at the beginning of each study. Similarity between groups across 3 studies indicates changes in step width can be attributed to the intervention provided to each study.

**Factors Contributing to Heterogeneity**

Three studies were determined to be eligible for this meta-analysis. All studies were randomized controlled trials. However, after article appraisal, there are potential factors which may have contributed to heterogeneity in the step length data. These include subject age, subject height, methods of collecting step length and step width data, and variable exclusion criterion.

The age range of the subjects was a concern for validity. The age range of the subjects in the study performed by Anjum et al. remains unknown for the experimental group. But after contacting one of the co-authors, the median age of control subjects was found to be 51.78 years old. In this control group, there were
7 subjects who were at least 65 years old. Also, the age range of the control group was from 20 to 85 years old. This age range is different when comparing mean subject age in the studies performed by Yigiter, which was 40.27 and 38.40 years old in the PNF and TPT group respectively. The mean age of the subjects in the study performed by Sahay was 28.16 and 28.18 years old for the PNF and TPT group respectively. This may have an effect on the outcomes as step length and step width are affected by the ability to balance by the amputee. Since balance begins to decline with age, results from this meta-analysis show both experimental and control groups to have a smaller combined effect size. On the other hand, as gait parameters are not expected to improve as much in an older person when compared to a younger person, the effect size was still in favor of the experimental intervention. Perhaps if the age ranges were to be more homogenous, a greater effect size would be seen.

Height and leg length differences were also a concern across studies on the validity and reliability of step length. Leg lengths of subjects in each study can influence the appearance of the effectiveness of the interventions. This is due to outcome measures measured by absolute values of step length. For an individual with greater height, leg length will presumably be longer than individuals who are shorter. Average heights of the subjects in the experimental groups in the studies performed by Sahay and Yigiter were on average 154.36 (±4.42) cm and 173 (±3.66) cm respectively. Therefore, improvements in step length in a taller individual will have greater absolute value than shorter subjects. These differences in value may have had an impact on the step length effect size. Future studies can correct for this by either examining subjects of similar heights or by measuring the angle of hip flexion during a step.
Another discrepancy for validity was the methodology in which outcome measures were obtained in order to represent improvements in spatial gait parameters. Two of the 3 studies used the same definition to determine step length and step width by taking the average of measures of subjects after they had taken 6 steps. These were averages of step length and step width taken by all 6 steps. Therefore, if all subjects increased step length through increased hip extension on their stance leg and increased hip flexion on their swing limb, the absolute values of step length gained may not be the best indicator of gait symmetry for these subjects. By taking overall averages of both legs, a claim of improved gait symmetry due to either experimental exposure is equivocal. However, Yigiter took step length measurements of sound limb and amputated limb. The study shows both groups increased sound step length which was significantly shorter than the amputated step length before intervention. In this regard, gait symmetry can be said to be improved in these subjects as the step length measurement data is available for both lower limbs. In future studies, it would be beneficial for researchers to take objective measurement methods by utilizing equipment such as a GaitRite, or obtain interrater and intrarater readings if equipment is unavailable. Also, measuring gait parameter changes of each lower limb is needed to show improved gait symmetry.

Another concern for validity in this meta-analysis is the variable exclusion criteria across studies. The study performed by Anjum et al. had subjects with comorbidities participate in his study, 61.9% of whom had diabetes mellitus. Subjects recruited by Sahay et al. had no comorbidities while subjects recruited by Yigiter did not make any exclusions based on presence of comorbidities. This may be because all subjects recruited by Yigiter were traumatic amputees. Although there are differences in the criterion between studies which make the
population of subjects heterogeneous when comparing factors such as presence of comorbidities, etiology, and age which was mentioned earlier, it is a good representation of individuals who live with a LLA. This study has individuals who are above the age of 65 with comorbidities, and individuals who are under the age of 65 who have no comorbidities. Each study also has subjects with different causes for amputation. Therefore, even though the inclusion criterion was different across studies, when combined, the population is representative of lower limb amputees as a whole. This is beneficial for application purposes. By including a diverse subject population based on comorbidities, age, and etiology of amputation, it can be said PNF has beneficial effects on temporal spatial gait parameters in individuals with LLA.

**Limitations of Meta-Analysis**

This study has several limitations. The studies included in this meta-analysis were the only studies that researched the effects of PNF on LLA gait for which there are limited studies. We also do not know the effects of function as a result of PNF training. Although Anjum et al. and Sahay et al. reported statistically significant improvements in function according to the LCI, this outcome measure was only performed in 2 studies. Although there were improvements in the step length and width, it would be beneficial to know if the effects of PNF are transferable into daily activities or recreational activities. Furthermore, long term follow-up on the subjects was not performed in the studies either. In order to determine the effectiveness of PNF, it is important to determine if there are any long term benefits to treatment. Also, a limited amount of outcome measures included in this study show a small portion of the improvements in spatial gait parameters. Future studies should include temporal-spatial gait parameters such as
gait velocity as studies have shown increasing self-selected walking speed in has shown an increase in gait symmetry.\textsuperscript{53} Including weight bearing percentage of the prosthetic limb would also be informative to determine gait changes. This meta-analysis should also be viewed with slight caution due to the limited number of studies included, and noted previous threats to external and internal validity.

**Effects of PNF on Amputee Gait**

The overall improvements seen in step length and step width may be due to the theory of PNF on gait training. Application of PNF techniques to pre-gait and gait training exhibited improved movement, balance, and appropriate facilitation of movement. In addition, the method in which these techniques are applied can address the unique gait adaptations that are seen in both transfemoral and transtibial gait.

In transtibial amputees, gait asymmetries occur because of missing plantarflexors and altered muscle firing patterns. Normally, plantarflexors provide the forward momentum during terminal stance.\textsuperscript{54} Since amputees do not have this musculature, forward momentum is generated by the hip extensors along with forward trunk flexion.\textsuperscript{6,21,55} EMG studies have shown prolonged co-contraction in the quadriceps and hamstrings at initial contact.\textsuperscript{6,21,54} This prolonged initial contact caused by decreased prosthetic and ankle mobility creates instability and results in increased activity of the hamstrings and quadriceps in order to stabilize.\textsuperscript{6,21,54} Therefore it is important to implement neuromuscular re-education during rehabilitation in order to prevent the early weight transfer to the sound limb in order to promote a more symmetrical gait pattern.

In transfemoral amputees, gait asymmetries occur as trunk muscles are utilized during gait along with compensations occurring on the sound side limb.\textsuperscript{8}
Gait in healthy individuals show a counter-rotation between thorax and pelvis during the swing phase of gait.\textsuperscript{8} But transfemoral amputees show a reduction in counter-rotation when taking a step.\textsuperscript{8} Also as the stump length decreases, there is increased muscle atrophy in the hips of the amputated limb and sound limb. This can result in excessive lateral bending to the ipsilateral side during the stance phase of the prosthetic limb. During the stance phase of the sound side, hip hiking of the contralateral hip occurs due to weakness in the ipsilateral hip abductors as a strategy to advance the swing limb.\textsuperscript{8,56} There is also increased muscle activation distally in both the tibialis anterior and plantarflexors as they are the primary generators of forward momentum. The increased activation in the distal muscles of the leg is attributed to the amount of power that needs to be generated in order to maintain forward momentum.\textsuperscript{57}

The favorable effects of PNF in individuals with LLA may be due to the PNF techniques that were able to address both the common and unique impairments of both transtibial and transfemoral amputees. Across all 3 intervention groups, approximation was applied to the amputated limb during the stance phase in order to enhance dynamic stability and postural control.\textsuperscript{40-42} Although this does not directly improve step length or step width, approximation is effective in promoting stabilization, weight bearing, and resisting component motions that are unnecessary or hindering to the movement goal.\textsuperscript{39} Evidence has also shown increased weight bearing through the prosthetic limb during stance phase allows for greater step length to occur as a result.\textsuperscript{50} A study performed by Nadolleck et al. found increased strength in the hip abductors were correlated with increased weight bearing on the amputated limb, and decreased center of pressure excursion in the medio-lateral direction.\textsuperscript{50} By applying approximation to the
pelvis, postural muscles such as the hip abductors have increased stability which can then assist with increasing step length and decreasing step width.\textsuperscript{39,50}

Another cause for the favorable outcome measures may be due to the individualized treatment received by the subjects from physical therapists. One-on-one time with a physical therapist has the advantage of receiving feedback on gait performance. When learning a new motor skill, feedback is a valuable asset. A study by Cirstea CM et al. found proper feedback can improve motor function, even in patients who have been incapacitated such as stroke.\textsuperscript{58} Also with an individualized treatment program, specific goals can be incorporated into each session which can be used in conjunction with feedback. Tzetis et al. demonstrated in order to learn a physical skill, it is important to have goal setting and feedback in order to improve performance.\textsuperscript{59}

Weight bearing percentage was an outcome measure that demonstrated improvement in the study by Yigit et al, however this was the only study to capture this variable. The study showed a significant improvement in weight bearing percentage in the amputated leg during gait. The participants in the PNF group increased weight bearing on their amputated limb by 16.59 ±8.87%. This is statistically significant compared to the TPT group which improved by 8.35±3.47%.

**Clinical Implications from Results**

Both intervention and control groups demonstrated improvement in step length and step width. However groups who were exposed to PNF improved more than those who received TPT. Increases in step length and decreases in step width are indicative of improved single leg balance.\textsuperscript{50} In order to maximize efficiency in the clinic, it would behoove the patient and therapist both if they implemented
both PNF and TPT into the plan of care. TPT could be done in the clinic initially and eventually transitioned into a home program. In this manner, the patient and physical therapist can continue to work on repeated pre-gait and gait activities using PNF. Furthermore, PNF does not require an entire hour of treatment time. The remainder of treatment time can still implement TPT or focus on functional activities which reflect prior level of function.

Potential Independence and Cost Efficiency

As stated in the background, the population of individuals who experience LLA continues to rise, it is important that an optimal exercise modality is identified to provide optimal outcomes. A physical therapy program during rehabilitation ensures patients are maximizing function with their new prosthesis to ameliorate the consequences of secondary physiological changes that occur with asymmetrical gait. PNF provides the patient with visual and tactile feedback in real-time which allows for corrected movements during activities such as gait. But there are disadvantages to this treatment. PNF seeks to eliminate dysfunctional movement patterns, by utilizing different facilitory procedures to enhance the desired voluntary responses. PNF requires the presence of a skilled physical therapist to perform the skilled intervention and can be time and labor intensive. This was seen in the studies used in this meta-analysis as each patient received hands-on manual PNF techniques. Another factor to consider is efficiency in the clinical setting. Successful implementation of PNF is based on motor learning principles where the patient is ultimately able to perform these acquired movements on their own without any external feedback. But in order to achieve this state, practice and repetition are required in addition to the presence of a physical therapist. Therefore, in order to be truly effective with long term
potentiation, there must be adequate patient-therapist interaction. While this may be the case in long term rehabilitation settings, this may not be the case for an outpatient setting. In many outpatient settings, patients are typically not seen every day throughout the week, so the benefits of applying PNF techniques may not be the most efficient method of rehabilitation. Conversely, TPT does not require hands-on care by a physical therapist and can be performed independently at home after being trained. Although TPT is not as effective as PNF on gait parameters, TPT has still been shown to be effective in improving function and independence.

Conclusion

This meta-analysis revealed PNF to have greater effect to TPT on step length and step width for people with LLA. However, the effects of TPT should not be discredited as ineffective for individuals with LLA. Due to anatomical changes after amputations, gait symmetry should be one of the goals for treatment. Although improvements in step length and step width were seen across studies and had a medium effect size when compared to TPT, there is still other gait parameters which need to analyzed. Components such as gait speed, cadence, and symmetry between legs need to be considered in order to assess if PNF is better than TPT. But according to the findings and limitations of this meta-analysis, it is important to consider both PNF and TPT in the treatment of gait asymmetries in individuals with LLA.

PNF is labor intensive, requiring manual skilled intervention by a PT and this may limit the practicality of application when a patient is seen during the outpatient setting. PNF as an exercise modality may be more effective during inpatient rehabilitation when frequency of therapy is more intensive and the ability to provide this service is optimal. TPT continues to demonstrate benefit and may
be ideal as part of home program training. Future studies are needed to address the unknown effects of PNF on other temporal-spatial gait parameters such as speed, symmetry between limbs, and carryover to function affecting quality of life.
REFERENCES
REFERENCES


TABLES
Table 1. PEDro Results of Individual Studies

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Sahay et al.</th>
<th>Yigiter et al.</th>
<th>Anjum et al.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Random allocation of subjects</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2. Allocation concealment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Similar groups at baseline</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>4. Subjects blinded</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Therapists administering treatment blinded</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Assessors blinded</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. One key outcome obtained from 85% of subjects initially allocated to groups</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>8. ‘Intention to treat’ used for analysis of one key outcome</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>9. Between-group statistics for one key outcome reported</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>10. Point measures and measures of variability for one key outcome</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Total Score</td>
<td>6</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>
Table 2. Study Characteristics for Meta-Analysis

<table>
<thead>
<tr>
<th>Study</th>
<th>Level of evidence</th>
<th>Sample size</th>
<th>Inclusion Criterion</th>
<th>Intervention</th>
<th>Outcome measures</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sahay et al 2014</td>
<td>Level 2, RCT</td>
<td>n=30; transtibial amputees</td>
<td>Lack of contracture, lack of limits in joint range of motion, absence of other limb segments, first time prosthetic user, minimum stump length 1/3 of the tibial length</td>
<td>PNF: Approximation, slow reversal, rhythmic stabilization, pelvic patterns TPT: weight bearing on prosthetic limb, weight shifting, balance exercises, and gait training</td>
<td>- Stride width - Step length - Stride length - LCI</td>
<td>10 days</td>
</tr>
<tr>
<td>Yigiter et al 2002</td>
<td>Level 2, RCT</td>
<td>n=50; transfemoral amputees</td>
<td>No muscular weakness related to amputation, no muscle shortening, no joint limitations, no problems weight bearing on amputated side</td>
<td>PNF: dynamic reversals, approximation, rhythmic initiation TPT: weight shifting, dynamic balancing activities, stool stepping, braiding, gait exercises, climbing/descending stairs</td>
<td>- Step width - Sound side step length - Amputated side step length - Stride length - Weight Bearing % - SSCG (steps/min) - FG (steps/min) - Velocity (cm/s) - SL/LEL</td>
<td>10 days</td>
</tr>
<tr>
<td>Anjum et al 2016</td>
<td>Level 2, RCT</td>
<td>n=63; all male; transtibial amputees</td>
<td>Unilateral transtibial amputee, lack of contracture, first time or old prosthetic user, and 1/3 of the tibial stump length</td>
<td>PNF: Manual contact, verbal command, vision, timing for emphasis, resistance, approximation, stretch, slow reversal, and rhythmic stabilization TPT: weight bearing, weight shifting, balance exercise, single limb loading, stepping, and strength training through sand bags</td>
<td>- Step width - Step length - MMT hip extensors - MMT knee extensors - MMT hip flexors - Cadence - LCI</td>
<td>4 weeks</td>
</tr>
</tbody>
</table>

SSCG = Cadence with self-selected comfortable gait

LCI = Locomotor Capabilities Index

SL/LEL = stride length/lower limb length
Table 3. Effect Size and Confidence Interval for Step Length

<table>
<thead>
<tr>
<th>Study</th>
<th>Effect Size</th>
<th>CI lower</th>
<th>CI upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sahay et al.</td>
<td>0.945</td>
<td>0.191</td>
<td>1.700</td>
</tr>
<tr>
<td>Yigiter et al.</td>
<td>0.591</td>
<td>0.025</td>
<td>1.157</td>
</tr>
<tr>
<td>Anjum et al.</td>
<td>0.280</td>
<td>-0.216</td>
<td>0.777</td>
</tr>
<tr>
<td>Total ES</td>
<td>0.528</td>
<td>0.169</td>
<td>0.887</td>
</tr>
</tbody>
</table>

Table 4. Effect Size and Confidence Interval for Step Width

<table>
<thead>
<tr>
<th>Study</th>
<th>Effect Size</th>
<th>CI lower</th>
<th>CI upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sahay et al.</td>
<td>-0.871</td>
<td>-1.620</td>
<td>-0.123</td>
</tr>
<tr>
<td>Yigiter et al.</td>
<td>-0.869</td>
<td>-1.449</td>
<td>-0.289</td>
</tr>
<tr>
<td>Anjum et al.</td>
<td>-0.415</td>
<td>-0.914</td>
<td>0.084</td>
</tr>
<tr>
<td>Total ES</td>
<td>-0.662</td>
<td>-0.999</td>
<td>-0.324</td>
</tr>
</tbody>
</table>
Figure 1. Study selection of all included and excluded trials.
Figure 2. Forest plot on the effects of PNF compared to TPT on step length between groups

Figure 3. Forest plot on the effects of PNF compared to TPT on step width between groups
APPENDIX: PEDro SCALE
**PEDro scale**

1. eligibility criteria were specified
   - no [ ] yes [ ] where:
2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated as order in which treatments were received)
   - no [ ] yes [ ] where:
3. allocation was concealed
   - no [ ] yes [ ] where:
4. the groups were similar at baseline regarding the most important prognostic indicators
   - no [ ] yes [ ] where:
5. there was blinding of all subjects
   - no [ ] yes [ ] where:
6. there was blinding of all therapists who administered the therapy
   - no [ ] yes [ ] where:
7. there was blinding of all assessors who measured at least one key outcome
   - no [ ] yes [ ] where:
8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups
   - no [ ] yes [ ] where:
9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”
   - no [ ] yes [ ] where:
10. the results of between-group statistical comparisons are reported for at least one key outcome
    - no [ ] yes [ ] where:
11. the study provides both point measures and measures of variability for at least one key outcome
    - no [ ] yes [ ] where:

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (Verhagen AP et al (1998). The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41). The list is based on “expert consensus” not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to “weight” scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (i.e. RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) is that relates to the external validity (or “generalisability” or “applicability” of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the “validity” of a study’s conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the “quality” of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Last amended June 21st, 1999
Notes on administration of the PEDro scale:

All criteria: Points are only awarded when a criterion is clearly satisfied. If, on a literal reading of the trial report, it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.

Criterion 1: This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.

Criterion 2: A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.

Criterion 3: Concealed allocation means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criterion, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was “off-site”.

Criterion 4: At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rate must be satisfied that the groups’ outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.

Criteria 4, 7-11: Key outcomes are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.

Criterion 5-7: Blinding means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be “blind” if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (e.g., visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.

Criterion 8: This criterion is only satisfied if the report explicitly states both the number of subjects initially allocated to groups and the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.

Criterion 9: An intention to treat analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.

Criterion 10: A between-group statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group x time interaction). The comparison may be in the form of hypothesis testing (which provides a “p” value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.

Criterion 11: A point measure is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. Measures of variability include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.
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