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REPORTING NUMBER NEEDED TO TREAT IN CLINICAL TRIALS PUBLISHED IN PHYSICAL THERAPY SPECIFIC LITERATURE 1989 – 2018

by

SUSAN ANN TALLEY

DISSERTATION

Submitted to the Graduate School

of Wayne State University,

Detroit, Michigan

In partial fulfillment of the requirements

For the degree of

DOCTOR OF PHILOSOPHY

2019
MAJOR: EDUCATION EVALUATION AND
RESEARCH
Approved by:

	Advisor	Date
_		

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DEDICATION

I dedicate this dissertation to my husband, Joe, and our children,

Jason (my favorite son) and Katy (my favorite daughter). Your unending love,

support and belief in me made what seemed to be an impossible goal, doable. It's great

having you as my personal cheerleading team.

I also dedicate this dissertation to my physical therapist students,
former students and colleagues. Translating evidence into practice is no easy task but
striving to do so can only improve the quality of life of our patients/clients

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Thank you, Dr. Donald Marcotte, one of my first EER instructors. On the first day he asked us to write down why we were taking that course and I wrote "for fun." Dr. Marcotte's masterful teaching and passion, indeed made it fun and propelled me forward.

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INTRODUCTION

Clinical Decision Making in Physical Therapy

Physical therapists are required to make many clinical decisions about the best plan of care or intervention to use when providing physical therapy to patients or clients. Evidence-based practice is the foundation for making decisions that reflect best practices in the care of patients with impairments and activity limitations. D. L. Sackett, Rosenberg, Gray, Haynes, and Richardson (1996) defined evidence-based practice as "integrating individual clinical expertise with the best available external clinical evidence from systematic research" (p. 71). Clinically based research informs the decision to choose an intervention with the intent of improving a patient/client's ability to perform activities and to participate, as desired, in life activities and roles.

Null Hypothesis Statistical Testing as the Basis for Clinical Decisions

The effectiveness of physical therapy interventions is commonly evaluated by comparing means of two or more groups, ideally through randomized control trials. At the least complex level, in a comparative study the mean of a treatment group is compared with a control group or means of two treatment groups could be compared. By controlling confounding variables, the only difference expected between groups is the intervention. This permits judgements to be made about the efficacy of the treatment relative to the specific measured outcomes.

Thompson (1996) opined effect sizes are interpretable when the null hypothesis is retained. However, Sawilowsky and Yoon (2002) and Sawilowsky (2003) noted it is futile to discuss effectiveness of a given treatment if the null-hypothesis is found to be non-

significant (see also Sawilowsky (2007); Sawilowsky, Sawilowsky, & Grissom, 2011). Similarly, (Cohen, 1988) indicated:

Whatever the manner of representation of a phenomenon ... the null hypothesis always means the effect size is zero... [but] when the null hypothesis is false, it is false to some specific degree, i.e., the effect size (ES) is some specific nonzero in the population (p. 10).

It is difficult for a clinician to translate the results of group comparison studies to the clinical decision-making process required to select an intervention for an individual patient/client. The problem is how to determine which intervention will be the most effective for a patient/client. In too many instances individuals attempt to interpret the results inappropriately, such as estimating the value of a treatment based on the magnitude of the p value or on the difference between raw scores (Sawilowsky, 2007; Sawilowsky, 2009; Sawilowsky et al., 2011) For example, a calculated *p* value that is very small might be inappropriately interpreted as meaning that the effect of the treatment is very strong when there is little clinical difference. Similarly, the mean raw score difference is simplistic in nature and is not robust as the finite break-down point is 1/n.

Magnitude of Differences or Associations as the Basis for Clinical Decisions

Alternative methods for evaluating the relative effectiveness of potential interventions include calculating effect size utilizing one of over 40 effect size measures such as Cohen's *d*. However, the underlying assumptions such as normality, homogeneity of variance, outliers and heteroscedasticity is problematic (Knapp & Sawilowsky, 2001; Sawilowsky (2018); Sawilowsky & Blair, 1992; Vacha-Haase & Thompson, 2004). The number needed to treat (NNT) is an alternative effect size method to interpret the effectiveness of an intervention compared to other interventions when measuring dichotomous outcome variables. NNT reflects the effect size of the treatment

and indicates the number of patients who would need to be treated to ensure one successful outcome (Portney & Watkins, 2009).

NNT was first introduced by Laupacis, Sackett, & Roberts in 1988. Although multiple articles on NNT were published in the medical literature during the 1990's (Cook & Sackett, 1995; McQuay & Moore, 1997; D. L. Sackett et al., 1996), the first article about NNT in the physical therapy literature did not occur until 2000 in the journal *Physical Therapy*, the flagship journal of the American Physical Therapy Association (Dalton & Keating). Only one article utilizing NNT was found in *Physical Therapy* by (Dalton & Keating, 2000) searching Medline back to 1991. Subsequent articles encouraging the use of NNT in physical therapy intervention studies were published in 2004 (Weeks & Noteboom), 2006 (Hilton, Reid, & Paratz) and, most recently, 2016 (Hancock & Kent, 2016). Although using and reporting NNT to assist in interpreting the clinical importance of the results of an intervention study will help translate research into clinical practice, no studies were found that have examined the use of NNT in the physical therapy literature during the three decades since it was introduced in 1988. The effectiveness of publishing "encouraging articles" to increase use of NNT is unknown.

Purpose of the Study

The purpose of the study is to examine the methods of reporting research results of intervention studies in the physical therapy literature. Specifically, the purpose of this study is to explore the reporting of null hypothesis statistical tests, effect size and number needed to treat in physical therapy intervention studies over time in the physical therapy literature. Bibliometric studies to identify core journals in physical therapy, primarily through citation analyses and content analyses, have been conducted to describe content

at a single point in time and longitudinally. There are no bibliometric analyses that explored trends in reporting results to inform treatment selection in evidence-based physical therapist practice.

Assumptions

It is assumed investigators intended to publish results of intervention studies in a manner which facilitates the use of the results to inform clinical decision making in physical therapist practice including the use of statistical methods. Consequently, it is assumed that investigators are aware of NNT, or at least have had increasing awareness over the past 3 decades, so that reporting (or not reporting) NNT is an active choice. It is further assumed that investigators were free to choose statistical methods for publication in the physical therapist literature without publication bias. Finally, it is assumed that interpretation and categorization of bibliometric variables are accurate and appropriate as the variables are clearly defined.

Limitations

A limitation is the sampling strategy. Articles will be limited to intervention studies published in select journals of the physical therapy professional association in the United States, the American Physical Therapy Association (*Journal of Neurologic Physical Therapy*, *Journal of Orthopedic and Sports Physical Therapy*, *Physical Therapy*) limiting generalizability of the findings. A different sampling strategy may result in different results. Bibliometric content analysis is a historical descriptive study of published physical therapy literature. It is beyond the scope of this study to assess the quality of the research methodology for each article. The results reflect the published physical therapy literature in the sample which is not the same as the broader state of current physical therapy

research. It is possible that articles may have been submitted for review, accepted for publication and/or published in different years due to the lag time for publication which may influence the outcomes.

Operational Definitions

Alpha: nominal value determined a priori to indicate the acceptable maximum probability of a Type I Error (Portney & Watkins, 2009).

Bracketed Interval: commonly referred to as a confidence interval. The determination of a range of values for an outcome, for which the value of a population parameter is located between the upper and lower limits at a given probability.

Clinical trial: "A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes" (National Institutes of Health, 2014).

Effect size: "A statistical expression of the magnitude of the difference between two treatments or the magnitude of a relationship between two variables, based on proportional relationship of the difference to the variance" (Portney & Watkins, 2009, p. 867); "the magnitude of a treatment (or naturally occurring) effect when the null hypothesis is false" (Sawilowsky, p. 1).

Number Needed to Treat (NNT): "The number of patients that need to be treated to prevent one adverse outcome or achieve one successful outcome" (Portney & Watkins, 2009, p. 872).

p value: calculated value in inferential statistics to evaluate a null hypothesis; the probability of the available (or even less likely) data, given that the null hypothesis is true.

Statistical non-significance: when the calculated p value is greater than the predetermined nominal alpha the null hypothesis is not rejected, indicating no statistically significant effect.

Statistical significance: when the calculated p value is less than or equal to the predetermined nominal alpha the hull hypothesis is rejected, indicating a statistically significant effect. "The term indicating that the results of an analysis are unlikely to be the result of chance at a specified probability level" (Portney & Watkins, 2009, p. 877).

Type I error (α): the probability of rejecting a null hypothesis when the null hypothesis is true.

Type II error (β): the probability of failing to reject a null hypothesis when the null hypothesis is false.

Table 1

NHST Decision Making and Type I and Type II Error

		Truth		
		H₀ is True	H₀ is False	
DECISION	Reject H ₀	Type I Error α	Correct	
DE(Fail to Reject H₀	Correct	Type II Error β	

Note. Adapted from Portney, L.G. & Watkins, M.P. (2009). Statistical inference. In L.G. Portney & M.P. Watkins (Eds). Foundations of clinical research: Applications to practice (2nd ed., p. 418). Upper Saddle River, ND: Pearson Education, Inc.

CHAPTER 2 REVIEW OF LITERATURE

Limitations of Null Hypothesis Statistical Testing

Null hypothesis significance testing (NHST) is a statistical approach frequently used in quantitative research in the social, behavioral and health sciences to help answer a research hypothesis. NHST is one of several approaches to interpret the outcome of a clinical trial investigating the comparative effectiveness of an intervention, compared to a control or another intervention. However, there is longstanding controversy about the appropriate use and interpretation of NHST. Thompson (1998) identified five "methodological errors" that occur commonly in educational research including "the incorrect interpretation of statistical significance and the related failure to report effect sizes present in all quantitative analyses" (Thompson, 1998, p. 6). Thompson further stated "...even today some researchers still do not understand what their statistical significance tests do and do not do" (Thompson, 1998, p. 39). Campo and Lichtman (2008) wrote a position paper published in *Physical Therapy* on the limitations of NHST in interpreting physical therapy research, identifying issues and suggesting alternative measures to consider. Cohen (1994) was widely credited with having written the seminal article at the base of the NHST controversy, which at the time had already spanned four decades, and suggested NHST be replaced with other methods, such as examining the data graphically as in Exploratory Data Analysis (Cox, 2017; John W Tukey, 1977) and the reporting of effect sizes by using bracketed (confidence) intervals. Others defended use of NHST when used appropriately (Compton & Sawilowsky, 2003; Cortina & Landis, 2011; Hagen, 1997; Knapp & Sawilowsky, 2001). However, Cohen (1994) advised "don't look for a magical alternative to NHST, some other objective mechanical ritual to replace it. It doesn't exist"

(p.1001). The NHST discussion continues for more than 60 years without real change in the arguments and counterarguments. A review of several of these arguments are particularly relevant to utilizing outcomes from clinical trials to inform clinical decision making in physical therapist practice.

A common assertion fueling the question regarding the utility of NHST is the null is always false (Cohen, 1994; Hays, 1981; Meehl, 1978; Thompson, 1993; Thompson, 1996; Tukey, 1991), and therefore there is no justification for NHST. Thompson (1993) stated "Virtually all null hypotheses will be rejected at some sample size" (p.362). Gross (2015) echoed this argument 20 years later, stating that NHST:

...compels us to engage in sort of Kabuki theater, going through the motions of what Rozeboom (1960) has called our "tribal ritual" of rejecting H₀, when we know that with a large enough sample, a point null hypothesis will almost surely be rejected. (p.777)

However, Knapp and Sawilowsky (2001) stated there are clearly circumstances in which the null hypothesis is indeed true, for example when testing a null hypothesis for an experiment where there is a dichotomous outcome. They further stated that a Monte Carlo simulation with two groups randomly selected with replacement from a given population with a Gaussian, or normal, distribution would result in the null hypothesis being rejected 5% of the time as predicted because the nominal alpha was set to .05. Sawilowsky and Blair (1992) demonstrated this in a Monte Carlo simulation testing the robustness of the *t* test for Type I errors using authentic social or behavioral data sets. They stated "thus, under the truth of the null hypothesis, the notion that there must be some large sample size that will reject a true null hypothesis, aside from committing a Type I error, is false" (Sawilowsky & Blair, 1992, p. 72). Knapp and Sawilowsky (2001) stated clinically trivial effects may become statistically significant if the sample size is sufficiently large.

Another alleged concern raised against NHST is that it does not lead to the cumulation of scientific knowledge or discoveries (Cohen, 1994; Thompson, 1996). Cohen (1994) stated NHST "has not only failed to support the advance of psychology as a science, but has seriously impeded it" (p. 997). It may be that the problem lies in depending on a NHST in isolation to make decisions about the clinical relevance and importance of an observed difference necessitating the need for additional analysis such as confidence intervals, effect size or number needed to treat, as well as interpretation by subject matter experts (Campo & Lichtman, 2008; Cortina & Dunlap, 1997; Cortina & Landis, 2011; Gross, 2015; Knapp & Sawilowsky, 2001). However, NHST contributes to the body of scientific knowledge, particularly with purposeful replication of experiments (Frick, 1996; Gross, 2015; Hagen, 1997; Robinson & Levin, 1997). Knapp and Sawilowsky (2001) advised statistical testing must be understood as separate, in the sense being just a tool, from scientific discovery.

Misinterpretation of the results of NHST, specifically the p value, is widespread (for example see Campo & Lichtman, 2008; Cohen, 1994; Falk & Greenbaum, 1995; Gross, 2015; Haller & Krauss, 2002; Hubbard & Lindsay, 2008; Nickerson, 2000; Sawilowsky, 2011). Ninety percent of participants in a study at six German universities (students and faculty/scientists) held at least one misconception of the meaning and interpretation of p values (Haller & Krauss, 2002). Examples of common misconceptions include (a) treating the p value as the probability that the null hypothesis is true (or false), (b) the complement of the p value (1 – p) is the probability that the study could be replicated with the same outcome, (c) statistical significance implies the results are also clinically important, (d) interpreting the magnitude of the p value as a measure of the magnitude of the treatment

effect, and (e) a *p* value equal to or less than a nominal alpha of .05 provides conclusive evidence against the null hypothesis or in support of the alternative hypothesis, among others. Although there is agreement that misinterpretation occurs, there is not agreement on the appropriate response to those misinterpretations ranging from abandoning NHST (Cohen, 1994, 1995) to asserting that NHST is a necessary first step to interpreting research results (Knapp & Sawilowsky, 2001). Falk and Greenbaum (1995, p. 93) stated "To be fair, the fact that people misinterpret significance tests is not the tests' fault and is no reason to discard them altogether. Misconceptions may, after all, be clarified and the right meaning restored" (p. 93). Gross (2015) stated misinterpretations of the *p* value are "merely the most recognizable trappings of an overall framework that overemphasizes minor details. It is not so much their inclusion in analyses that is objectionable as much as their outsized role" (p. 777).

Effect Size

An effect size is an estimate of the magnitude and direction of a relationship (mean differences or associations) (Campo, Eckardt, Findley, Cardinale, & Shiyko, 2017; Sawilowsky). It was recommended that effect size be used in addition to NHST to interpret and make decisions about the clinical relevance and importance of an observed difference in addition to including interpretation of results by subject matter experts (Campo & Lichtman, 2008; Cortina & Dunlap, 1997; Cortina & Landis, 2011; Gross, 2015; Knapp & Sawilowsky, 2001; Sawilowsky). Campo et al. (2017) stated that "Effect sizes offer an important way to move beyond the limitations of significance testing, because they offer estimates of the magnitude of treatment effects, between-group differences, and associations between variables" (p. 67). Effect sizes may be easier for most people,

including physical therapists, to understand than NHST, thereby helping the clinician decide if statistically significant results are also clinically important outcomes (Campo et al., 2017; Tracey, 2000; Vacha-Haase & Thompson, 2004). Sink and Stroh (2006) stated "if researchers fail to report [effect sizes], and only include the research findings' derived significance levels, key information is missing that assists in understanding the practical value of the results" (p. 402). Although it was advocated that effect size be reported regardless of the result of NHST (Carver, 1978, 1993; Rosnow & Rosenthal, 1989; Thompson, 1996, 1998; Vacha-Haase & Thompson, 2004; Wilkinson, 1999), it is illogical to compute an effect size when the null hypothesis is not rejected. "Trivials are effect sizes associated with statistically non-significant results" and are problematic (Sawilowsky & Yoon, 2002, p. 143). Sawilowsky et al. (2011) stated:

Under the truth of the null hypothesis observed results are not statistically different from zero, and thus the magnitude of the observed result is meaningless. Hence, effect sizes are only meaningfully reported in conjunction with a statistically significant hypothesis test. (p. 1413)

Sawilowsky and Yoon (2002) demonstrated the lack of meaning of effect sizes generated when the hull hypothesis was true through a Monte Carlo simulation which generated effect sizes (|d| = .34) even though the effect size was modeled as zero ($n_1 = n_2 = 0$), Gaussian Distribution, Nominal $\alpha = 0.05$, (Sawilowsky, 2003). When interpreting the outcomes of a study physical therapists should heed the admonition by Robinson and Levin (1997) to "First convince us that a finding is not due to chance, and only then, assess how impressive it is" (p. 23).

More than 40 indices of effect magnitude have been developed (Kirk, 1996; Vacha-Haase & Thompson, 2004) which may give differing results depending on the measure used (Knapp & Sawilowsky, 2001). Effect size measures have been grouped to facilitate understanding although the number of groupings has varied from two to four (Campo et al., 2017; Ferguson, 2009; Kline, 2013; Sawilowsky; Sink & Stroh, 2006; Vacha-Haase & Thompson, 2004). Two groups of effect size measures are identified consistently: (a) group mean differences/ standardized mean differences and (b) strength of association indices. However, effect size methodology is relatively young. Consequently, effect size must be interpreted with caution. Violations of assumptions (normality, homogeneity of variance, heteroscedasticity and outliers) can distort the derivation of effect size (Knapp & Sawilowsky, 2001).

There are multiple resources that explored the calculation of effect size in depth (for example, see Campo et al., 2017; Ferguson, 2009; Sink & Stroh, 2006; Vacha-Haase & Thompson, 2004). Commonly used effect size measures to assess mean differences include Cohen's d (Cohen, 1988), Hedge's g (Λ) (Hedges, 1982), Glass' Δ (Campo et al., 2017; Sawilowsky, 2018). Other approaches to measure effect size include the point serial rpb, r², partial η^2 , η^2 , odds ratio, and number needed to treat (Campo et al., 2017; Sawilowsky et al., 2011). Each effect size measure has strengths and weakness in both the denominator and numerator, which in actuality are generally shared mathematically, i.e. one can be translated from one to another (Sawilowsky et al., 2011). For example, Glass' Δ uses the standard deviation of the control group for the denominator instead of the pooled standard deviation, with the intent to compensate for differences in variability between the control and intervention groups. Campo et al. (2017) advocated that physical therapist education curricula include a wide variety of approaches to measuring effect size including those for mean difference, proportions, ANOVA and regression and correlation.

Cohen (1988) created guidelines, or rules of thumb to help interpret the meaning of Cohen's *d*, recognizing that these are guidelines that require the context to be considered when attempting to discern the practical or clinical importance of an effect size (Table 2)

Table 2

Effect Size "Rules of Thumb"

Magnitude	Description	Source
0.01	Very Small	Sawilowsky (2009)
0.2	Small	Cohen (1988)
0.5	Medium	Cohen (1988)
0.8	Large	Cohen (1988)
1.2	Very Large	Sawilowsky (2009)
2.0	Huge	Sawilowsky (2009)

Osborne (2008) reflected on those guidelines and later stated "It is unclear whether these [ES = .20, .50 or .80] accurately reflect effect sizes observed in our (or any other) field...I have yet to find published reports of average effect sizes reported in various fields" (p. 154).

The development of an encyclopedia of effect sizes in psychology and education was proposed (but not funded) by Sawilowsky (2009, p. 9) with widespread support from leaders in the field. This resource would have been useful for sample size estimation and power analysis. Sawilowsky (2009) recognized the thresholds suggested by Cohen (1988) were useful, but they could not reflect the range of effect sizes that observed in the social sciences. In lieu of the encyclopedia, Sawilowsky (2009) developed new rules of thumb for effect size to expand those suggested by Cohen (Table 2). A limitation of these rules

of thumb is they do not translate beyond Cohen's *d*. Sink and Stroh (2006, pp. 404-405) published a table of effect size magnitudes for multiple effect size measures to two decimal places, although only for small, medium and large effects based on the work of Green and Salkind (2004). Similarly, Sawilowsky (personal communications, 2017) transformed effect size magnitudes for a variety of effect size measures across the expanded rules of thumb to four decimal places (Table 3).

Table 3

Transformation of Effect Size Magnitudes for Multiple Effect Size Measures

Description	d	r	η^2	f	OR	NNT
Very Small	0.01	0.005	0	0.005	1.0183	177.2364
Small	0.2	0.0995	0.0099	0.1	1.4373	8.8919
Medium	0.5	0.2425	0.0588	0.25	2.4766	3.6189
Large	8.0	0.3714	0.1379	0.4	4.2675	2.3343
Very Large	1.2	0.5145	0.2647	0.6	8.8159	1.656
Huge	2.0	0.7071	0.5	1	37.6224	1.1867

Note. d = Cohen's d; r = Pearson r, η^2 = eta squared; f = ANOVA f ratio; OR = odds ratio; NNT = number needed to treat. Adapted from personal communications by Sawilowsky, 2017.

Number Needed to Treat

One method of measuring effect size that may be particularly useful when translating the results of intervention research to clinical practice is the Number Needed to Treat (NNT) (Cook & Sackett, 1995; Dalton & Keating, 2000). Pinson and Gray (2003) defined NNT as "the number of patients who would need to be treated with a specified intervention in order to obtain one additional positive outcome that would not have occurred had the patient not received the comparison treatment" (p. 146) in a given period

of time (Weeks & Noteboom, 2004). A positive outcome is interpreted as either the prevention of an adverse effect or the occurrence of a desirable effect (Herbert, 2000; Hilton et al., 2006; Laupacis, Sackett, & Roberts, 1988; Weeks & Noteboom, 2004). Laupacis et al. introduced NNT as a measure of effect size in 1988 and stated that it "expresses efficacy in a manner that incorporates both the baseline risk without therapy and the risk reduction with therapy" (p. 1730). Cook and Sackett (1995) add that "it is more meaningful to use the measure 'number needed to treat'...it has the advantage that it conveys both statistical and clinical significance" (p.452). Although NNT was initially used for studies of drug therapy, surgical procedures, immunization, diagnosis and risk factors (Laupacis et al., 1988) it is appropriate for intervention studies in other disciplines including physical therapy.

NNT is a measure of effect size for dichotomous (binary) outcome variables (Dalton & Keating, 2000; Herbert, 2000). It is the reciprocal of absolute risk reduction which is the difference in risk between the experimental and comparison groups (Cook & Sackett, 1995; Dalton & Keating, 2000; Laupacis et al., 1988; McQuay & Moore, 1997; Portney & Watkins, 2009):

$$NNT = \frac{1}{\frac{Pi}{Ti} - \frac{Pc}{Tc}}$$

NNT = number needed to treat

Pi = number of positive outcomes in the intervention group

Ti = total number of participants in the intervention group

Pc = number of positive outcomes in the comparison group

 T_C = total number of participants in the comparison group

The NNT always refers to outcomes relative to a comparison group (McQuay & Moore, 1997). The magnitude of NNT is impacted by both the effectiveness of the intervention and the baseline risk in the comparison group (Hancock & Kent, 2016;

Laupacis et al., 1988). If the control/comparison group has better outcomes than the experimental group, the NNT will be negative and the intervention may be interpreted as potentially ineffective or harmful. NNT is typically rounded to the nearest whole number (Weeks & Noteboom, 2004). A NNT of 1 indicates that one patient would need to be treated to experience a positive outcome. Hence, the closer the NNT is to 1 the more likely a patient will benefit from the intervention compared to the alternate (control or comparison) intervention (McQuay & Moore, 1997; Portney & Watkins, 2009). Sawilowsky transformed effect size magnitudes for a variety of effect size measures, including NNT, based on effect size rules of thumb (Table 3) (Cohen, 1988; Sawilowsky, 2009). McQuay and Moore (1997) stated that an NNT = 2-3 would indicate an intervention that was effective although Weeks and Noteboom (2004) stated an NNT = 2-5 would indicate an effective intervention. Pinson and Gray (2003) found that psychiatric therapies had reported NNTs between 3 and 6 which is comparable to those reported for other medical therapies (D. Sackett, Straus, & Richardson, 2000). In a study of 9 high quality (PEDro score > 6) randomized control trials selected from the *Physiotherapy Evidence* Database (PEDro) to demonstrate NNT, six studies had a reported NNT between 2 and 6, two had a reported NNT of 7-8 and one study had a reported NNT = 34 (Hilton et al., 2006). Sawilowsky stated that an NNT = 2 indicates a large to very large effect size and an NNT = 5-7 could be interpreted as a small to medium effect size. A large NNT does not necessarily rule out the use of an intervention particularly if the positive outcome is the prevention of a serious undesirable outcome such as death or permanent disability (Weeks & Noteboom, 2004).

It is not clear how often NNT is calculated and reported in the literature to help translate the results of intervention studies for clinical decision making, particularly in the physical therapy literature. Cook and Sackett (1995) reported that NNT was "becoming widely used as a tool for the rapeutic decision making and bedside teaching" (p. 453). Weeks and Noteboom (2004) stated that NNT was gaining attention as a method of reporting the results of clinical trials with dichotomous outcome measures. However, multiple authors reported that NNT is not widely used (Dalton & Keating, 2000) or is underused (Hilton et al., 2006; Nuovo, Melnikow, & Chang, 2002; Pinson & Gray, 2003). The CONsolidated Standards of Reporting Trials (CONSORT) 2010 guidelines state "For both binary and survival time data, expressing the results also as the number needed to treat for benefit or harm can be helpful" (Moher et al., 2010, Section 17a). This CONSORT recommendation for improving the reporting of the results of randomized controlled trials, including reporting effect size, were first made in 1996 (Begg et al.). Nevertheless, Nuovo et al. (2002) reported that only 8 of 359 (2.2%) eligible papers in five major biomedical journals (Annals of Internal Medicine, British Medical Journal, Journal of the American Medical Association, the New England Journal of Medicine, Lancet) published in four discrete years at 3-year intervals (1989, 1992, 1995, 1998) reported the NNT. The first year, 1989, was selected because it was one year following the introduction of NNT by Laupacis et al. (1988). Nuovo et al. (2002) stated that guidelines, such as CONSORT, may not be sufficient motivation to increase the reporting of NNT and that "additional measures to ensure compliance with reporting standards may be needed" (p. 2814). In contrast, Naing, Aung, and Mak (2012) found that 7 of 8 (87.5%) systematic reviews accessed through PUBMED on a single date in 2012 included NNT in the results, perhaps

an indication of increasing reporting of NNT in recent years as there is a 14-year difference between the end of the Nuovo et al. (2002) study and the Naing et al. (2012) study.

Over the past 18 years five articles have been published in the physical therapy specific literature encouraging the utilization of NNT when reporting outcomes of clinical trials. In 2000, *Physical Therapy (PTJ)*, the journal of the American Physical Therapy Association, published the first article which introduced and advocated for inclusion of NNT in the reporting of physical therapist intervention studies (Dalton & Keating). The authors stated that "NNT provides results in a way that is directly transferrable to the clinical setting" (Dalton & Keating, 2000, p. 1216). The purpose of the paper, although not explicitly stated, was to introduce the potential usefulness of NNT to report and interpret outcomes of clinical trials to readers of *PTJ*. Dalton and Keating (2000) conducted a MEDLINE search dating back to 1991 using the search terms "number needed to treat" OR "NNT" and identified 121 citations which reported NNT. Of those, only three involved physical therapist outcomes and only one of those three was published in a physical therapist specific journal (*PTJ*) in 1994 (Moreland & Thomson), six years after Laupacis et al. (1988) first introduced NNT.

Although the journal *Archives of Physical Medicine and Rehabilitation (Arch PM&R)* is not a physical therapy specific journal, it is considered a core physical therapy journal (Wakiji, 1997). In 2004 *Arch PM&R* published a special communication to describe the NNT statistic and how it can be used for the selection of clinical interventions (Weeks & Noteboom). The authors stated that "there is a growing application of the NNT in the rehabilitation literature, both in single studies and meta-analysis of multiple studies"

(Weeks & Noteboom, 2004, p. 1730) and cited a physical therapist intervention study for acute low back pain as an example (Fritz, Delitto, & Erhard, 2003). The next article published on the use of NNT specific to physical therapy was published in 2006 in Physiotherapy, the journal of the physiotherapy professional association in the United Kingdom (Hilton et al., 2006). The purpose of this study was to demonstrate how "the NNT can help clinicians to converse with patients to convey details about the likelihood of benefit with treatment and/or likelihood of risk, in order that a decision may be made with respect to therapy" (Hilton et al., 2006, p. 240) with the aim to "provide practical examples to demonstrate the utility of this statistic in the interpretation of findings in the physiotherapy literature" (Hilton et al., 2006, p. 241). As discussed earlier, Campo and Lichtman (2008) published an article on uses and limitations of NHST and recommended that physical therapist students and educators consider using other measures including NNT. Finally, in 2016 Hancock & Kent published a paper in the *Journal of Physiotherapy* (journal of the Australian Physiotherapy Association) with the intent to "describe the correct interpretation of commonly used methods of reporting dichotomous outcomes" (p.172) which included risks, odds, absolute and relative risk reduction and NNT. Despite the interest in the utilization of NNT in physical therapy research as evidenced by the aforementioned articles, there is a paucity of research on the frequency of reporting of NNT in the physical therapy literature nor is there research on trends of reporting NNT over time.

Bibliometric Analysis of Physical Therapy Literature

The definition of bibliometric analysis in not easily conveyed as there is no consistent, satisfactory definition. Pritchard (1969) referred to "bibliometrics", defined as "...the application of mathematics and statistical methods to books and other media of concern" (p.348). A more specific definition was offered by de Glas (1986) "generally speaking bibliometrics could be defined as the search for systematic patterns in comprehensive bodies of literature" (p. 40). Pritchard and Wittig (1981) expanded the definition: bibliometrics "includes all studies which use or discuss statistical analysis of data relating to printed communication, e.g. citation studies, abstracts journals studies, publication counts, some circulation studies...and studies of individual elements within papers" (p.3). There are numerous other histories of the field of bibliometrics available (see, for example Broadus, 1987a, 1987b; Hertzel, 1987; Hood & Wilson, 2001). In short, bibliometrics is a scientific method to explore the content and meaning of scientific literature. Bibliometric analysis has increased in prevalence in the literature of many fields (Borgman, 1989). Bibliometric citation analysis has been used to identify core journals or map the literature of a given field. Bibliometric citation analysis can also be used to quantify productivity of individuals or groups of investigators. It has been used to quantify characteristics or describe trends over time in scientific literature (Smith & Rivett, 2009).

The first bibliometric analysis specific to the physical therapy literature was a citation analysis of contributors to the journals *Physical Therapy* and *Physiotherapy Canada* over a two-year period published in *Physical Therapy* (*Dean & Davies, 1986*). Since 1986, more than 19 bibliometric analyses of the physical therapy literature were published: five citation analyses focused on identifying core physical therapy journals

(Bohannon, 1999; Bohannon & Gibson, 1986; Bohannon & Tiberio, 1989; Fell, Burnham, Buchanan, Horchen, & Scherr, 2011; Wakiji, 1997), two analyses of core journals used the Physiotherapy Evidence Database (PEDro) as the source (Costa et al., 2010; C. Maher, Moseley, Sherrington, & Herbert, 2001), two content analyses focused on physical therapy clinical trials (Babu, Veluswamy, Rao, & Maiya, 2014; Hoderlein, Moseley, & Elkins, 2017), three content analyses focused on statistical methods used in physical therapy literature to inform physical therapist education curriculum (Bandy, 2003; Roush et al., 2015; Tilson, Marshall, Tam, & Fetters, 2016), one analysis utilized inclusion in Medline as an indicator of quality (Roberts, 1992), five bibliometric content analyses explored characteristics and trends over time (Coronado, Riddle, Wurtzel, & George, 2011; Miller, McKibbon, & Haynes, 2003; Paci, Cigna, Baccini, & Rinaldi, 2009; Simon, Coronado, Wurtzel, Riddle, & George, 2014; Wiles, Matricciani, Williams, & Olds, 2012), and one content analysis focused specifically on neurologic physical therapy (Fell et al., 2015). Three bibliometric analyses related to physical therapist practice were more broadly focused on rehabilitation (Bohannon & Roberts, 1991; Franchignoni & Munoz Lasa, 2011; Tesio, Gamba, Capelli, & Franchignoni, 1995), and one explored the research productivity of physical and occupational therapy faculty in Canada (MacDermid, Fung, & Law, 2015).

Bibliometric citation analysis was used to map physical therapy literature with the purpose of identifying core journals. Bohannon and Gibson (1986) stated "citation analyses, which assess the frequency with which specific journals are cited in the scientific periodical literature, were performed to assist librarians, authors, practitioners, and others in identifying important journals for acquisition, publication, and reference" (p.

540). Costa et al. (2010) used a different approach to identify core physical therapy journals. The *Physiotherapy Evidence Database* (*PEDro*) was used to identify the journals which published the most randomized control trials (RCTs). The key components of these studies can be found in Table 4.

TABLE 4
Bibliometric Analyses of Physical Therapy Literature: Core Journals

Authors	Source	Time	Sampling	no.	PT Specific
Bohannon and	PTJ^a	4 years	All citations	67	PTJ ^a
Gibson (1986)			Articles		Physio
		1980-84	Editorials		Physio Can
			Commentary		
Bohannon and	Austr Physio	1 year	All citations	64	PTJ ^a
Tiberio (1989)	PTJ ^a		Articles		Physio
	Physio	1987	Editorials		Physio Can
	Physio Can		Commentary		Austr Physio
	Physio Pract				Physio Pract
Wakiji (1997)	Arch PM&R	3 years	All citations	14	PTJ ^a
	PTJ ^a		Articles		
		1991-93	Commentary		
			Letter		
			Lecture		
			Study Guide		

TABLE 4 continued

Bibliometric Analyses of Physical Therapy Literature: Core Journals

Authors	Source	Time	Sampling	no.	PT Specific
Bohannon	Austr Physio	1 year	All citations	47	PTJ ^a
(1999)	PTJ ^a		Articles		Physio
	PT Sci	1997-98	Commentary		Physio Can
	Physio		Letter		Austr Physio
	Physio Can				JOSPT ^a
	Physio Res Int				
C. Maher et al.	Physio Theory PEDro	June 2, 2000	Journals that	75	Austr Physio
(2001)		2000	published 5+		Physio Pract
			RCTs		PTJ^a
					Physio
					Physio Can
Costa et al.	PEDro	Sept. 7, 2009	Journals that	22	PTJ ^a
(2010)		2009	published 80+		Physio
			RCTs		JOSPT ^a
Fell et al. (2011)	Austr Physio	3 years	All Articles	16	PTJ ^a
	PTJ^a				Physio
	Physio	2005-07			Physio Can
	Physio Can				Austr Physio

Note: Arch PM&R = Archives of Physical Medicine & Rehabilitation; Austr Physio = Journal of Physiotherapy; JOSPT = Journal of Orthopedic and Sports Physical Therapy; PEDro = Physiotherapy Evidence Database; Physio = Physiotherapy; Physio Can =

Physiotherapy Canada; Physio Pract = Physiotherapy Practice; Physio Res Int = Physiotherapy Research International; Physio Theory = Physiotherapy Theory and Practice; PTJ = Physical Therapy; PT Sci = Journal of Physical Therapy Science; no. = number of core journals identified

aJournal of the American Physical Therapy Association

Each of the bibliometric citation analyses used source journals from which to map to the most frequently cited journals, ranging from a single journal to seven journals specific to physical therapist practice. Only one journal, *Physical Therapy*, was included as a source journal in all the studies. Bohannon and Gibson (1986) stated "Although analyses can be conducted using a large number of source journals, 'a good approximation' can be determined by starting with a journal or set of journals relevant to a particular field" (p. 540). The citation analyses studies varied in the time span for which citations were collected, including one year (Bohannon, 1999; Bohannon & Tiberio, 1989), three years (Fell et al., 2011; Wakiji, 1997), and four years (Bohannon & Gibson, 1986). Costa et al. (2010) and C. Maher et al. (2001) accessed the PEDro database on a single day to identify all indexed RCTs.

There is an inverse relationship between number of source journals and the time frame, likely a practical solution to manage the amount of data generated. Journals were ranked according to frequency of citation from the source journals. Core journals were identified as some portion of all the journals cited. Bradford's Law of Scattering directs that for a given field "there are a few very productive periodicals, a larger number of more moderate producers, and a still larger number of constantly diminishing productivity" (Bradford, Egan, and Shera (1953) as cited in Nash-Stewart, Kruesi, and Del Mar (2012, p. 135).

Practically applied, the top one-third of the most frequently cited journals are considered the core journals for the field. Wakiji (1997) applied Bradford's law directly using it to identify 14 core journals in physical therapy. Despite the variations in sources, time frames and methods, the lists of core journals in physical therapy, while varied, have many journals in common. Physical Therapy was consistently identified as the top ranked core journal specific to physical therapy. *Physiotherapy* was identified as a core journal in five studies (Bohannon, 1999; Bohannon & Gibson, 1986; Bohannon & Tiberio, 1989; Costa et al., 2010; Fell et al., 2011), *Physiotherapy Canada* in four studies (Bohannon, 1999; Bohannon & Gibson, 1986; Bohannon & Tiberio, 1989; Fell et al., 2011) and Australian Journal of Physiotherapy was included in three studies (Bohannon, 1999; Bohannon & Tiberio, 1989; Fell et al., 2011). Physiotherapy and Physiotherapy Canada were identified as core journals in only one study where they were not a source journal (Bohannon & Gibson, 1986). The Journal of Orthopedics and Sports Physical Therapy was identified as a core journal in two studies (Bohannon & Leveau, 1986; Costa et al., 2010) but was not a source journal for any of the citation analyses. Costa et al. (2010) found that Physical Therapy had about twice as many RCTs indexed in PEDro (161) as Physiotherapy (84) and the Journal of Orthopedic and Sports Physical Therapy (78).

Several physical therapy specific content analyses have been published utilizing a variety of sampling strategies, varying on time period and article selection method (Table 5). Coronado et al. (2011) reported an "increased emphasis on publishing articles consistent with evidence-based practice and clinically based research" (p. 642) and the findings were similar to other reviews such as C. G. Maher, Moseley, Sherrington, Elkins, and Herbert (2008) and Moseley, Herbert, Sherrington, and Maher (2002). Wiles et al.

(2012) reported the results were similar to other health professions (Gore, Nordberg, Palmer, & Piorun, 2009; Potter, 2010; Shadgan, Roig, HajGhanbari, & Reid, 2010). Common trends included an increasing total number of articles published (Coronado et al., 2011; Paci et al., 2009; Simon et al., 2014; Wiles et al., 2012), an increasing number of research articles with a concomitant decrease in the number of topical reviews (Coronado et al., 2011; Simon et al., 2014; Wiles et al., 2012), an increased use of symptomatic or patient populations as participants (Coronado et al., 2011; Simon et al., 2014), and an increased number of authors including more with international affiliations (Wiles et al., 2012).

TABLE 5

Bibliometric Content Analyses of Physical Therapy Literature

Authors	Journal(s)	Time	Sampling	no. Articles
Miller et al.	Austr Physio	6 months	6 consecutive	179
(2003)	PTJ ^a		issues	
	Physio Physio Can	Jan – June 2001	All article types	

TABLE 5 continued

Bibliometric Content Analyses of Physical Therapy Literature

Authors	Journal(s)	Time	Sampling	no. Articles
Paci et al.	Austr Physio	5 years	All issues	1,627
(2009)	Geriatric PT ^a		Research articles	
	Neuro PTª	2003-07	Review articles	
	JOSPT ^a			
	Ped PT ^a			
	PTJ ^a			
	Physio			
	Physio Res Int			
	Physio Theory			
Coronado et al.	PTJ ^a	30 years	All issues	2,519
(2011)		1980-2009	Research report	
			Topical review	
			Case report	
Wiles et al.	PTJ ^a	65 years	4 issues every	337
(2012)		1945-2016	5 th year at	
			3-month intervals	
			within the year	
			All article types	

TABLE 5 continued

Bibliometric Content Analyses of Physical Therapy Literature

Authors	Journal(s)	Time	Sampling	no. Articles
Simon et al.	JMMT	20 years	All issues	375
(2014)		1993-2012	Research report	
			Topical review	
			Case report	
Hoderlein et al.	PEDro	2 years	10% of RCTs	2001: n = 70
(2017)		2001 and	randomly	11 – 70
		2015	selected in 2001	2015:
			and in 2015	n = 151

Note: Austr Physio = Journal of Physiotherapy Australia; Geriatric PT = Geriatric Physical Therapy; JMMT = Journal of Manual and Manipulative Therapy; JOSPT = Journal of Orthopedic and Sports Physical Therapy; Neuro PT = Journal of Neurologic Physical Therapy; PEDro = Physiotherapy Evidence Database; Ped PT = Journal of Pediatric Physical Therapy; Physio = Physiotherapy; Physio Can = Physiotherapy Canada; Physio Res Int = Physiotherapy Research International; Physio Theory = Physiotherapy Theory and Practice; PTJ = Physical Therapy.

^aJournal of the American Physical Therapy Association

Coronado et al. (2011) found no change in the number of random control trials in *Physical Therapy* during the period 1980 – 2009, although others found an increase in RCTs in physical therapy literature. The percentage of RCT's varied from 10% in 2009 (Coronado et al., 2011) to 24.3% in 2010 in *Physical Therapy* (Wiles et al., 2012). Paci et al. (2009) reported 12.6% RCTs in 2007 across nine physical therapy specific journals. Less than 10% of articles were RCTs in the *Journal of Manual & Manipulative Therapy* (Simon et al., 2014). Differences, particularly between 2009 and 2010 in *Physical*

Therapy, may be due to varying sampling strategies or classification methods. The Journal of Manual & Manipulative Therapy had the lowest number of RCTs (less than 10%) and is the newest and most narrowly focused journal. Using the PEDro database to identify clinical trials, the number of clinical trials doubled comparing 2001 to 2015 (Hoderlein et al., 2017). Although the number of RCT's is increasing, the proportion of RCTs of all research articles remains small. Systematic reviews, although also trending upward, represent an even smaller proportion of articles ranging from less than 5% (Coronado et al., 2011) to 8.1% (Wiles et al., 2012).

The level of evidence is increasing in physical therapy specific journals but there is a paucity of evidence on the quality of the research studies. Miller et al. (2003) used the Hedges Project criteria to assess research articles for high quality evidence suitable for application to patient/client care in four physical therapy specific journals. Only 19 of 179 articles met the standard for sufficient rigor. All the assessed intervention studies in *Physical Therapy* (n = 7) met the Hedges Project standards compared to only 36% - 80% in the other three physical therapy related journals included in the study. None of the bibliometric content analyses examined trends in how outcomes were reported for application to patient/client clinical decision making, specifically the reporting of null hypothesis statistical testing, effect size and number needed to treat.

In the past 15 years, three physical therapy specific bibliometric analyses focused on the use of statistics in the physical therapy literature (Bandy, 2003; Roush et al., 2015; Tilson et al., 2016). The earliest study (Bandy, 2003) utilized content analysis to identify the type and frequency of statistical techniques used by articles identified as Research Reports in a single journal, *Physical Therapy*, during a two-year span of publication (2000-

2002; 90 articles). The intent was to inform educators about which commonly used statistical techniques should be included in the physical therapist research curriculum. The 10 most frequently occurring statistical techniques accounted for 82.4% of all statistical techniques used during the 2-year period. Five of the top 10 statistical techniques identified utilized NHST. However, EST and NNT were mentioned as included amongst the 307 statistical techniques identified in the study.

Similarly, Roush et al. (2015) used content analysis to identify commonly used statistical techniques in articles during a two-year period (2009-2010; 5,546 articles) in the 16 journals identified as core physical therapy or physiotherapy journals by Fell et al. (2011). Articles included in the analysis included those identified as research reports, scientific articles, original contributions, clinical investigations or brief reports. Journals that were considered of interest, but not specific to, physical therapists such as the British Medical Journal, and the Clinical Journal of Pain were included in this study as they were among the most frequently cited journals as mapped from four physical therapy or physiotherapy specific journals (*Physical Therapy*, *Physiotherapy*, *Physiotherapy*, *Physiotherapy*, *Canada*, and *Australian Journal of Physiotherapy*).

However, only 6.0% of the articles reviewed were from physical therapy or physiotherapy specific journals. Despite the increased number and breadth of journals used in this study, the results were very similar to Bandy (2003). The top 10 statistical methods or categories of statistical methods (e.g. descriptive statistics were considered a category of statistical methods) accounted for 82.56% of the statistical methods used. (Bandy, 2003) included confidence intervals with descriptive statistics while Roush et al. (2015) listed them separately, ranking second in frequency (9.29%). Effect size was the

15th most frequently occurring statistical method (1.04%). NNT was not included in the top 25 statistical methods and may have been among the 534 statistical methods not reported but could not have occurred more frequently than 0.06%.

The third bibliometric analysis related to the use of statistical methods in the physical therapy literature expanded the definition of statistical methods. Tilson et al. (2016) stated that focusing specifically on statistical techniques did not address the level of understanding that physical therapists require to understand, interpret and apply the results of a research study. Consequently, Tilson et al. (2016) asks the question "What are the most common statistical terms and research concepts physical therapists are likely to encounter in the physical therapy literature that need to be included in professional education curricula?" (p.119). The method for identifying statistical terms is not clear, initially beginning with 532 terms which were collapsed into 321 representative terms.

Examples of statistical terms unique to this study compared to the previous two statistical bibliometric studies included statistical significance, *p*-value, significance level, minimal detectable change, minimally clinically important difference and degrees of freedom among many others. The sample included all research, case series and case report articles published in the 14 peer-reviewed journals associated with the American Physical Therapy Association during a 12-month period (2011-2012; 391 articles). Confidence intervals and effect size were included in a category labeled "Clinically Meaningful Statistics" and were referred to in 34.8% and 11.5% of the articles included in this study respectively. However, Cohen's *d* was listed in a separate category (3.6%) even

though it is an effect size. NNT was reported in supplemental materials (Additional File 1 – Statistical Terms) as having been reported in four articles (1.0%)

Common to these three studies is the limitation that using a statistical technique in a study does not necessarily make it the appropriate statistic. These studies report frequencies of occurrence which cannot be interpreted to mean that they are also the most important. Recommendations for modifications to physical therapist education research curriculum need to be interpreted in light of these limitations. Interestingly, all three bibliometric analyses found little to no use of effect size or number needed to treat in the articles reviewed. The low frequency of occurrence may reflect the breadth of research designs included in the sample as effect size and number needed to treat are primarily limited to intervention studies.

CHAPTER 3 METHODS

Design

This study is a bibliometric content analysis of clinical trial/intervention studies published in physical therapy specific literature.

Human Subjects

No human subjects were involved in this bibliometric analysis of published research.

Sample

Journal Selection.

Three journals of the American Physical Therapy Association (APTA) were used as the source journals for articles included in this bibliometric study: (a) *Physical Therapy*, the (b) *Journal of Orthopaedic and Sports Physical Therapy* and the (c) *Journal of Neurologic Physical Therapy*). *Physical Therapy* has been consistently included as a source journal or target journal for citation analysis or content analysis of the physical therapy literature (see Tables 4, 5). It is a well-established international journal with the largest circulation of all physical therapy specific journals. Editorial policy is consistent across APTA journals. The *Journal of Orthopaedic and Sports Physical Therapy (JOSPT)* and the *Journal of Neurologic Physical Therapy* represent the two largest areas of physical therapist practice (Human Resources Research Organization, 2017). Prior to 2003, the *Journal of Neurologic Physical Therapy* was known as *Neurology Report*, but for the purposes of this project it was labeled as its current name for the entire final dataset.

Article Selection.

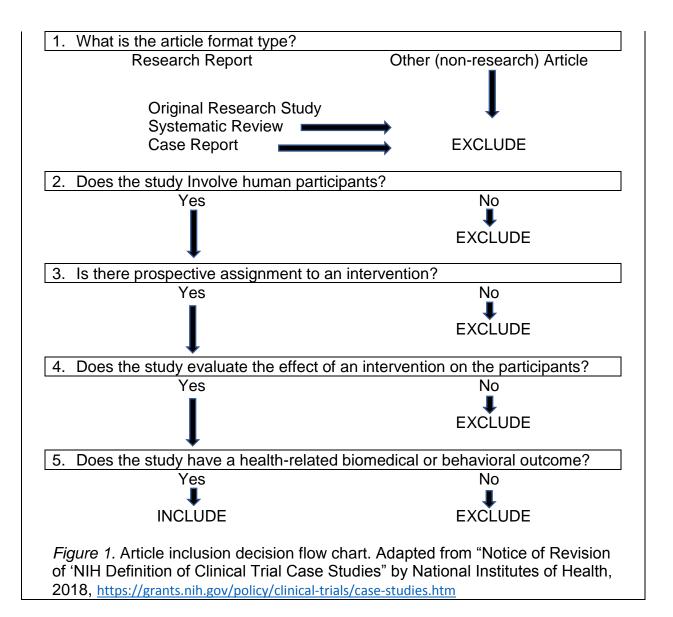
All research reports that are clinical trials as defined by the NIH and published in *Physical Therapy*, the *Journal of Orthopaedic and Sports Physical Therapy* or the *Journal of Neurologic Physical Therapy* between July 1989 and July 2018 qualified for potential inclusion in the final dataset sample. NIH defines a clinical trial as "A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes" (National Institutes of Health, 2014). NIH clarified the definition in 2018 by adding that researchers:

apply the following four questions to determine whether NIH would consider the research study to be a clinical trial:

- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect being evaluated a health-related biomedical or behavioral outcome?

If the answer to all four questions is "yes" then the clinical study would be considered a clinical trial according to the NIH definition. (National Institutes of Health, 2018)

See Figure 1 for the decision flow chart for including an article in the study.



Most articles that qualified as clinical trials under the NIH definition also qualified for inclusion in this study. However, because the purpose of this study is to investigate effect size, specifically NNT, within clinical trials, certain trials that intrinsically preclude calculation of NNT, such as case studies or other trials where n = 1, were excluded from this study. In addition, secondary analyses, e.g. systematic reviews, were not included to avoid the potential for clinical trials to be included multiple times. Abstracts and article briefs from clinical trials were excluded as these were typically reporting on articles published previously in other journals.

Bibliometric Variables

Bibliometric variables were divided into three categories: (a) characteristics related to the publication (Appendix A), (b) characteristics related to author and institution (Appendices B) and (c) characteristics related to the study design and data analysis (Appendix C). Information from each article was coded based on the variables and entered into a database spreadsheet. In cases where more than one outcome variable was reported in an article only one was recorded. If one of the outcome variables was a dichotomous outcome variable and NNT was reported it was chosen to be coded. If there was not a dichotomous outcome variable the first outcome variable reported was chosen to be coded.

Data Analysis

An a priori sample size analysis was conducted to determine the minimum required sample size for the study. A chi-squared goodness of fit test was calculated estimating a small to medium effect size (r = 0.3), df = 4 and a nominal alpha (α) = 0.05. A minimum sample size of 133 qualified clinical trial journal articles were required to achieve a statistical power of at least 0.80. The critical chi-squared value for this study size was calculated to be $\chi^2 = 9.49$.

Descriptive statistics (count, percent, cumulative percent) were calculated for variables describing the sample in total and over time. Variables relevant to characterizing the reporting of research design and outcomes were analyzed using descriptive statistics annually and for 5-year time intervals beginning with 1993 and ending with 2017 (1993–1997; 1998–2002; 2003–2007; 2008–2012; 2013–2017) in total and individually for each journal. Specifically, variables described over time included (a) number of articles that

were a clinical trial as defined by the NIH, (b) number of articles in which an effect size was reported, (c) number of articles in which a dichotomous outcome variable was reported, and (d) the number of articles in which NNT was reported. Additionally, contingency tables displaying the expected and observed distribution of reporting type (NHST, effect size and NNT) over 5-year periods and separated by journal are presented along with the chi-squared distribution tests. These tests were performed to determine if the incidence of each reporting type increases or decreases over time, and if the distribution of reporting type is statistically significantly different among the three journals.

Descriptive statistic tables, contingency tables and accompanying chi-squared distribution tests were calculated and organized in JASP version 0.9.1.0 (JASP Team, 2018). Pearson correlation was calculated using SPSSv24. All primary figures were created in R version 3.5.1 'feather spray' (R Core Team, 2018) with the package Kendall installed and using the graphical package 'ggplot2' (Wickham, 2016). A priori and post-hoc power analyses were conducted using G*Power 3.1.9.2 (Faul, Erdfelder, Lang, & Buchner, 2007).

CHAPTER 4 RESULTS

Journals

Three journals of the American Physical Therapy Association, the *Journal of Neurologic Physical Therapy*, the *Journal of Orthopaedic and Sports Physical Therapy* and *Physical Therapy*, were used as source journals for this study. Characteristics of these journals can be found in Table 6. They are published in the USA, are highly ranked among rehabilitation journals, include authors from international institutions, and have Impact Factors that increased during the span of this study, which is 1989 – 2018 (Clarivate & Institute for Scientific, 1997).

TABLE 6
Source Journals

	JNPT	JOSPT	PTJ
Inception	1976	1979	1931
Issues per Year	4	12	12
Publisher	Lippincott,	APTA,	Oxford
	USA	USA	University
			Press, USA
No. Contributing Countries (2017)	21	34	50
No. Contributing Organizations (2017)	50	50	50
Rank in Rehab Journals (2017)	5/65	9/65	13/65
	Q1	Q1	Q1
Rank in Orthopedic Journals (2017)	NA	12/77	23/77
		Q1	Q2

TABLE 6 continued
Source Journals

	JNPT	JOSPT	PTJ
Rank in Clinical Neurology Journals	51/187	NA	NA
(2017)	Q1		
1-year Impact Factor (1997)	NA	0.576	0.833
1-year Impact Factor (2017)	3.633	2.090	2.587
5-year Impact Factor (2017)	3.743	4.061	3.343
Medline Indexed	since 2005	Yes	Yes

Note. JNPT = Journal of Neurologic Physical Therapy; JOSPT = Journal of Orthopedic and Sports Physical Therapy; PTJ = Physical Therapy; Rehab = rehabilitation; Q1 = ranked in 1st quartile. Adapted from Clarivate and Institute for Scientific (1997).

Articles

Descriptive statistics.

A total of 448 articles met the inclusion criteria for this study across the three physical therapy specific journals, the *Journal of Neurologic Physical Therapy*, the *Journal of Orthopaedic and Sports Physical Therapy* and *Physical Therapy*. The distribution frequency table for the included articles from the three journals can be found in Table 7. The most clinical trials which met the inclusion criteria were published by the *Journal of Orthopaedic and Sports Physical Therapy* followed by *Physical Therapy*. The *Journal of Neurologic Physical Therapy* published only 11% of the articles meeting the inclusion criteria.

Table 7
Frequencies of Included Articles by Journal

Journal Name	Frequency	Parcant	Valid	Cumulative	
Journal Name	rrequericy	ercent	Percent	Percent	
Journal of Neurologic Physical	50	11.2	11.2	11.2	
Therapy					
Journal of Orthopaedic & Sports	215	48.0	48.0	59.2	
Physical Therapy					
Physical Therapy	183	40.8	40.8	100.0	
Missing	0	0.0			
Total	448	100.0			

Post-hoc power analysis was conducted on the final acquired sample size for this dataset. The a priori minimum sample size for a chi-squared goodness-of-fit test estimating a small to medium effect size r = 0.3, a nominal alpha (α) = 0.05, and 4 degrees of freedom was calculated to be 133 qualified journal articles to achieve a statistical power of at least 0.80; the final sample size of 448 articles meeting the inclusion criteria resulted in a statistical power of 0.99.

Frequency tables displaying total number of articles reporting NHST, effect size (EST) and NNT measurements for each journal are summarized in Tables 8-10. Total percentage of qualified articles that reported NHST, effect size and NNT separated by journal is presented in Table 11 and graphically in Figure 2. Annual number of articles in which NHST, EST and NNT are reported, separated by journal, is shown in Figure 3. Total

number of qualified articles, separated by journal are displayed annually in Figure 4, and over 5-year periods in Figure 5.

Table 8

Frequencies of Articles in which NHST is Reported by Journal

Levine al Maria	NUICT	T. F		Valid	Cumulative
Journal Name	ICHN	Frequency Per	cent	Percent	Percent
Journal of Neurologic Physica Therapy	al R	47	94.0	94.0	94.0
	NR	3	6.0	6.0	100.0
	Missing	0	0.0		
	Total	50 1	0.00		
Journal of Orthopaedic & Sports Physical Therapy	R	209	97.2	97.2	97.2
	NR	6	2.8	2.8	100.0
	Missing	0	0.0		
	Total	215 1	0.00		
Physical Therapy	R	171	93.4	93.4	93.4
	NR	12	6.6	6.6	100.0
	Missing	0	0.0		
	Total	183 1	0.00		

Note. NHST = Null Hypothesis Statistical Test; R = Reported; NR = Not Reported.

Table 9
Frequencies of Articles in which EST is Reported by Journal

Lavora et Maria	БОТ	-OT Francisco-Danasari		Valid	Cumulative
Journal Name	EST Frequency Percent		Percent	Percent	
Journal of Neurologic Physica Therapy	R	13	26.0	26.0	26.0
	NR	37	74.0	74.0	100.0
	Missing	0	0.0		
	Total	50	100.0		
Journal of Orthopaedic & Sports Physical Therapy	R	32	14.9	14.9	14.9
	NR	183	85.1	85.1	100.0
	Missing	0	0.0		
	Total	215	100.0		
Physical Therapy	R	32	17.5	17.5	17.5
	NR	151	82.5	82.5	100.0
	Missing	0	0.0		
	Total	183	100.0		

Note: EST = Effect Size Test; R = Reported; NR = Not Reported.

Table 10

Frequencies of Articles in which NNT is Reported by Journal

Lavernal Marca	AINIT			Valid	Cumulative
Journal Name	NNT	Frequency Pe	ercent	Percent	Percent
Journal of Neurologic Physical Therapy	R	0	0.0	0.0	0.0
	NR	50	100.0	100.0	100.0
	Missing	0	0.0		
	Total	50	100.0		
Journal of Orthopaedic & Sports Physical Therapy	R	3	1.4	1.4	1.4
	NR	212	98.6	98.6	100.0
	Missing	0	0.0		
	Total	215	100.0		
Physical Therapy	R	5	2.7	2.7	2.7
	NR	178	97.3	97.3	100.0
	Missing	0	0.0		
	Total	183	100.0		

Note. NNT = Number Needed to Treat; R = Reported; NR = Not Reported.

Table 11

Total Percentage of Reporting Type by Journal

Туре	Journal Name	Percentage
NHST	Journal of Neurologic Physical Therapy	94.00
	Journal of Orthopaedic & Sports Physical	
	Therapy	97.21
	Physical Therapy	93.44
EST	Journal of Neurologic Physical Therapy	26.00
	Journal of Orthopaedic & Sports Physical	
	Therapy	14.88
	Physical Therapy	17.49
NNT	Journal of Neurologic Physical Therapy	0.00
	Journal of Orthopaedic & Sports Physical	
	Therapy	1.40
	Physical Therapy	2.73

Note. NHST = Null Hypothesis Statistical Test; EST = Effect Size Test; NNT = Number Needed to Treat.

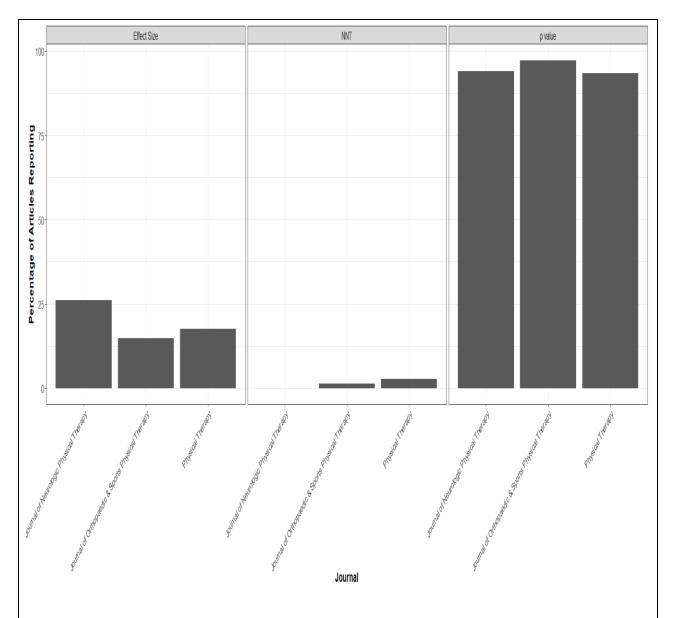
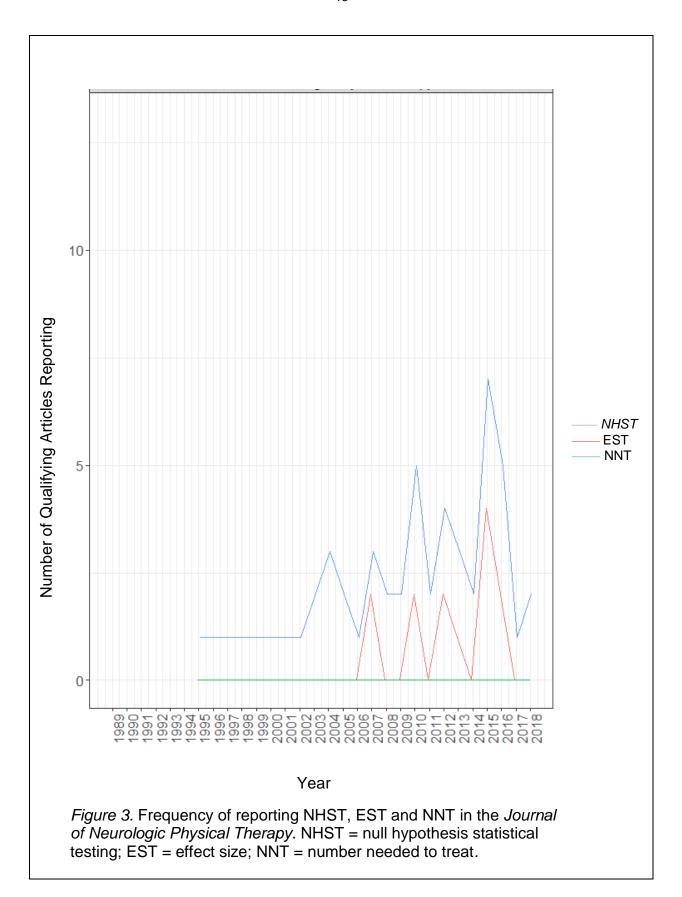
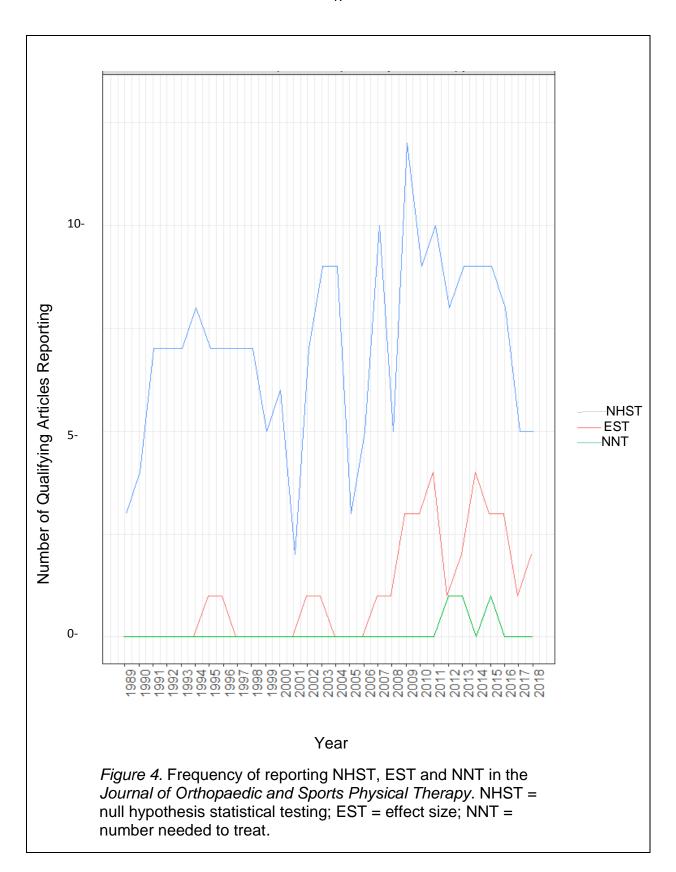
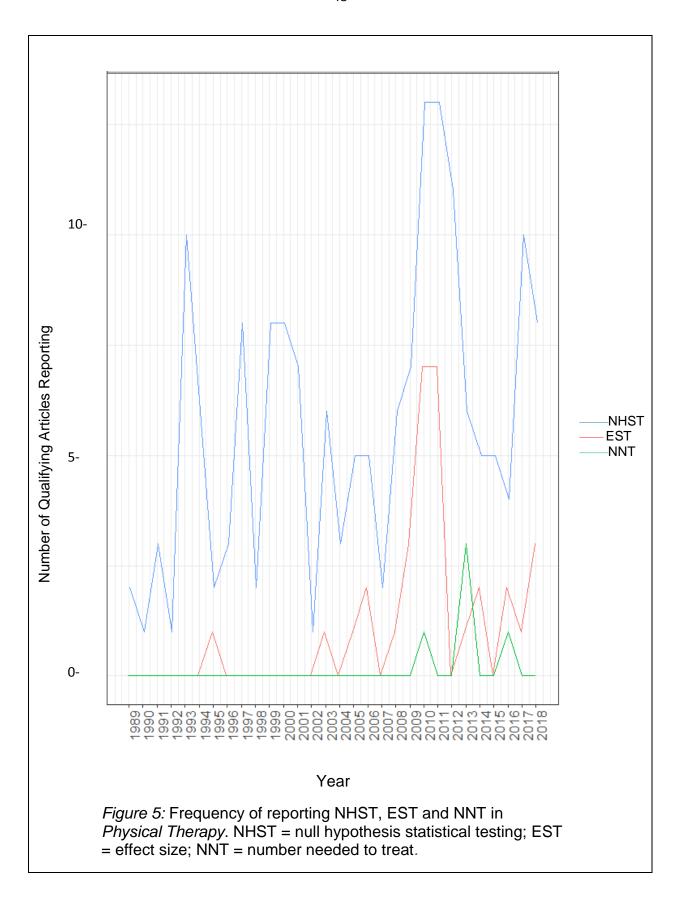


Figure 2. Total percentage of reporting type by journal. NNT = number needed to treat; p value = report from a null hypothesis statistical test.







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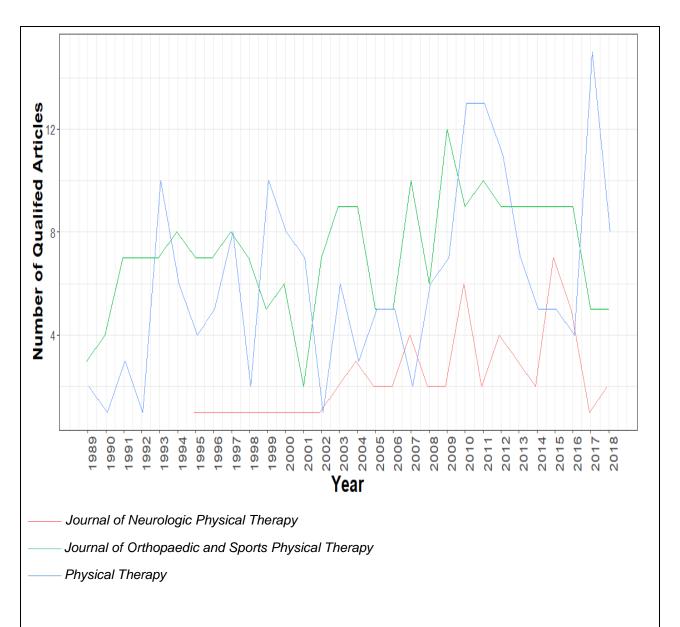
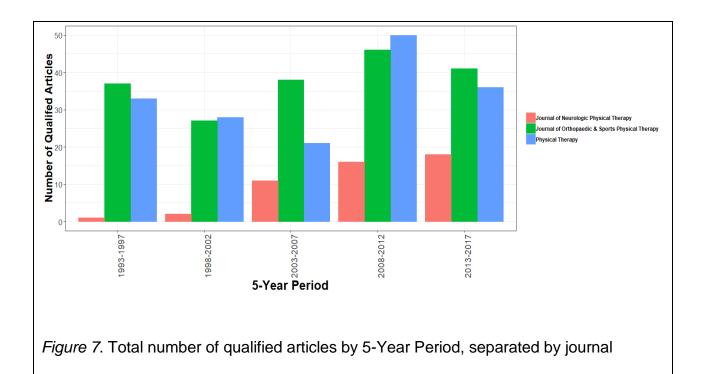


Figure 6. Total number of qualified articles published by year, separated by journal.



Statistical analysis.

Contingency tables displaying the expected and observed distribution of reporting type (NHST, EST and NNT) over 5-year periods are presented along with their chi-squared distribution tests and likelihood ratios in Tables 12-14. Contingency tables displaying the expected and observed distribution of reporting separated by journal are presented along with their chi-squared distribution tests and likelihood ratios in Tables 15-17.

Table 12
5-Year Contingency Table and Chi-Squared for Report of NHST

				NHS	Т	
5-Yr Period			_	R	NR	Total
1993-1997	Count			66.00	5.00	71.00
1993-1997	Expected co	unt		67.32	3.68	71.00
1000 0000	Count			55.00	2.00	57.00
1998-2002	Expected co	unt		54.04	2.96	57.00
0000 0007	Count			66.00	4.00	70.00
2003-2007	Expected co	unt		66.37	3.63	70.00
0000 0040	Count			109.00	3.00	112.00
2008-2012	Expected co	unt		106.19	5.81	112.00
0040 0047	Count			88.00	7.00	95.00
2013-2017	Expected co	unt		90.07	4.93	95.00
Tatal	Count			384.00	21.00	405.00
Total	Expected co	unt		384.00	21.00	405.00
Chi-Squared T	ests					
	Value	df	ı	p		
$\overline{X^2}$	3.216	4	0.522			
Likelihood ratio	3.399	4	0.493			
N	405					

Note. NHST = Null Hypothesis Statistical Test; R = Reported; NR = Not Reported.

Table 13
5-Year Contingency Table and Chi-Squared for Report of EST

		EST			
5-Yr Period		_	R	NR	Total
1993-1997	Count		3.00	68.00	71.00
1995-1997	Expected count		12.62	58.38	71.00
1998-2002	Count		1.00	56.00	57.00
1990-2002	Expected count		10.13	46.87	57.00
2003-2007	Count		8.00	62.00	70.00
2003-2007	Expected count		12.44	57.56	70.00
2008-2012	Count		34.00	78.00	112.00
2006-2012	Expected count		19.91	92.09	112.00
2013-2017	Count		26.00	69.00	95.00
2013-2017	Expected count		16.89	78.11	95.00
Total	Count		72.00	333.00	405.00
Total	Expected count		72.00	333.00	405.00
Chi-Squared T	ests				
	Value df	р			
X ²	38.97 4	< .001			
Likelihood ratio	45.39 4	< .001			
N	405				

Note: EST = Effect Size Test; R = Reported; NR = Not Reported

Table 14
5-Year Contingency Table and Chi-Squared for Report of NNT

				N		
5-Yr Period			=	R	NR	Total
1993-1997	Count			0.00	71.00	71.00
1990-1997	Expected co	ount		1.40	69.60	71.00
1000 0000	Count			0.00	57.00	57.00
1998-2002	Expected co	ount		1.13	55.87	57.00
0000 0007	Count			0.00	70.00	70.00
2003-2007	Expected co	ount		1.38	68.62	70.00
0000 0040	Count			2.00	110.00	112.00
2008-2012	Expected co	spected count		2.21	109.79	112.00
0040 0047	Count			6.00	89.00	95.00
2013-2017	Expected co	ount		1.88	93.12	95.00
Takal	Count			8.00	397.00	405.00
Total	Expected co	ount		8.00	397.00	405.00
Chi-Squared T	ests					
	Value	df	р			
X ²	13.25	4	0.010			
Likelihood ratio	13.81	4	0.008			
N	405					

Note: NNT = Number Needed to Treat; R = Reported; NR = Not Reported.

Table 15
Contingency Table and Chi-Squared for Report of NHST by Journal

				NHST				
Jou	R	NR	Total					
lournal of Nouvalogia Physical Thoras			Count	47.00	3.00	50.00		
Journal of Neurolog	Journal of Neurologic Physical Therapy Expected count			47.66	2.34	50.00		
Journal of Orthopaedic & Sports Physical			Count	209.00	6.00	215.00		
Therapy			Expected count	204.92	10.08	215.00		
Physical Therapy			Count	171.00	12.00	183.00		
			Expected count	174.42	8.58	183.00		
			Count	427.00	21.00	448.00		
Total			Expected count	427.00	21.00	448.00		
Chi-Squared Tests								
	Value df	p						
X²	3.356 2	0.187						
Likelihood ratio	3.472 2	0.176						
N	448							

Note: NHST = Null Hypothesis Statistical Test; R = Reported; NR = Not Reported.

Table 16

Contingency Table and Chi-Squared for Report of EST by Journal

					EST				
Journal Name					R	NR	Total		
Journal of Neurologic Physical Therapy			Count	13.00	37.00	50.00			
Journal of Neurolo	yic Filysica	ттетар	Эу	Expected count	8.59	41.41	50.00		
Journal of Orthopaedic & Sports Physical				Count	32.00	183.00	215.00		
Therapy				Expected count	36.95	178.05	215.00		
Physical Therapy			Count	32.00 151.00 183.					
			Expected count	31.45	151.55	183.00			
				Count	77.00	371.00	448.00		
Total				Expected count	77.00	371.00	448.00		
Chi-Squared Tests									
	Value d	f	p						
X ²	3.541 2		0.170						
Likelihood ratio	3.279 2		0.194						
N	448								

Note: EST = Effect Size Test; R = Reported; NR = Not Reported.

Table 17

Contingency Table and Chi-Squared for Report of NNT by Journal

				NNT					
Journal Name					NR	Total			
Journal of Neurologic Physical Therapy				0.00	50.00	50.00			
Physical III	erapy		Expected count	0.89	49.11	50.00			
Journal of Orthopaedic & Sports Physical					212.00	215.00			
			Expected count	3.84	211.16	215.00			
			Count	5.00	178.00	183.00			
Physical Therapy				3.27	179.73	183.00			
			Count	8.00	440.00	448.00			
			Expected count	8.00	440.00	448.00			
Chi-Squared Tests									
Value (df	р							
2.031	2	0.362							
2.809	2	0.245							
448									
	Value 2.031 2.809	Physical Therapy 2 & Sports Physical Value df 2.031 2 2.809 2	Physical Therapy 2 & Sports Physical Value df p 2.031 2 0.362 2.809 2 0.245	Count Expected count C & Sports Physical Count Expected count Ount Expected count Ount Expected count Ount Expected count Ount Ount Expected count Ount Ount Expected count Ount Ou	Count 0.00	Count 0.00 50.00 Expected count 0.89 49.11 C & Sports Physical Count 3.00 212.00 Expected count 3.84 211.16 Count 5.00 178.00 Expected count 3.27 179.73 Count 8.00 440.00 Expected count 8.00 440.00 Value of p 2.031 2 0.362 2.809 2 0.245			

Note: NNT = Number Needed to Treat; R = Reported; NR = Not Reported.

As indicated in Tables 12-14, although there is a statistically even distribution of NHST being reported in qualified articles over every 5-year period (p = 0.522, Table 12), the distribution of EST and NNT are uneven (p < 0.001, Table 13, p = 0.010, Table 14 respectively). Specifically, although NHST was evenly reported over every 5-year period, EST was under-represented from 1993-2007 and over-represented from 2008 onward

(Table 13). Similarly, NNT was under-represented from 1993-2012, but over-represented in the 2013-2017 period (Table 14). This indicated rather than a consistent distribution of reporting EST and NNT from 1993-2017, they become statistically more prevalent in the literature.

As indicated in Tables 15-17, this phenomenon was not dependent on journal type. There was no statistically significant difference in reporting frequency among journals for NHST (p = 0.187, Table 15), EST (p = 0.170, Table 16) or NNT (p = 0.332, Table 17). This occurred despite *The Journal of Neurologic Physical Therapy* not having a single qualified article report NNT from 1989-2017. It may have been due to the frequency of *Physical Therapy* and *The Journal of Orthopaedic and Sports Physical Therapy* with low incidences of reporting NNT as well (2.7% & 1.4% respectively, Table 10).

Articles in which NNT was reported

The authors of only eight (1.79%) of the 448 articles meeting the inclusion criteria for this study reported NNT for at least one outcome variable. Citations for these articles are found in Appendix C. The patient/client population for all eight studies was orthopedics. Intervention was provided for neck pain in three (37.5%) of the eight studies (Cleland et al., 2010; Dunning et al., 2012; Masaracchio, Cleland, Hellman, & Hagins, 2013) and were multi-center studies conducted exclusively in the United States. The *Global Rating of Change* (GROC) (Jaeschke, Singer, & Guyatt, 1989) was used as an outcome measure in each of these studies and was used to determine the NNT. Dunning et al. (2012) also reported NNT using the *Neck Disability Index* (MacDermid et al., 2009). One author was common to these three studies (Cleland). These three studies were published over the course of four years, 2010 – 2012. The Cleland et al. (2010) study was

published in *Physical Therapy* and the authors were the first to report NNT in any of the three source physical therapy specific journals in this study.

Intervention was provided for chronic low back pain in three (37.5%) of the eight studies (Garcia et al., 2013; Miyamoto, Leonardo Oliveira Pena, Galvanin, & Cristina Maria Nunes, 2013; Siemonsma et al., 2013). These were conducted exclusively outside of the United States, two in Brazil (Garcia et al., 2013; Miyamoto et al., 2013) and the third in the Netherlands and United Kingdom (Siemonsma et al., 2013). One author (Costa) was common to the two studies conducted in Brazil. All three studies were published in 2013 in *Physical Therapy* and each used different outcome measures to determine the NNT. The remaining two studies were the most recently published of the eight articles (Abbott et al., 2015; Christiansen et al., 2016). Published in the Journal of Orthopaedic and Sports Physical Therapy and Physical Therapy, intervention was provided for knee and shoulder diagnoses respectively. Christiansen et al. (2015) was conducted internationally (Denmark, Germany, United Kingdom) and Abbott et al. (2015) was conducted both in the United States and New Zealand. The outcome measures used to determine the NNT in these studies were unique to these studies. The computed NNT(s) reported in the eight studies can be found in Table 18.

Table 18
Outcome Measures Reported using NNT

Article	System	Outcome Measure	NNT	NNT 95% CI
	Diagnosis			
Christiansen et al. (2016)	Orthopedics	OSS	5.0	[2.6, 48.6]
	Subacromial Impingement Syndrome post- surgery			
Abbott et al. (2015)@	Orthopedics	WOMAC	2.8*	[1.7, 50.5] *
	Knee Osteoarthritis		2.7*	[1.7, 3.4] **
Garcia et al. (2013)	Orthopedics	RMDQ	4	NR
	Chronic LBP			
Siemonsma et al. (2013)	Orthopedics	PSC	4	NR
	Chronic LBP			
Miyamoto et al. (2013)	Orthopedics	GPE	4	[2.0, 32.0]
	Chronic LBP			
Masaracchio et al. (2013)	Orthopedics	GROC	2	[1.0, 3.0]
	Mechanical Neck Pain			
Dunning et al. (2012)	Orthopedics	GROC	1.8	[1.4, 2.6]
	Mechanical Neck Pain	NDI	2.3	[1.7, 3.5]
Cleland et al. (2010)	Orthopedics	GROC	15^	[-4.6, 18.9]
	Neck Pain		6^^	[-1.9, 34.8]
	lad to Treat. OCC Outsid Sh		4^^^	[2.1, 7.5]

Note: NNT = Number Needed to Treat; OSS = Oxford Shoulder Score; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index; RMDQ = Roland-Morris Disability Questionnaire; NR = Not

reported; PSC = Patient-Specific Complaints Questionnaire; GPE = Global Perceived Effect Scale; GROC = Global Rating of Change; NDI = Neck Disability Index.

@ four groups *group 2; **group 3; ^ at 1 week; ^^ at 4 weeks; ^^^ at 6 months.

CHAPTER 5 DISCUSSION

The purpose of this study was to examine the methods of reporting research results of intervention studies in the physical therapy literature. The reporting was considered regarding the number needed to treat (NNT) relative to null hypothesis statistical tests (NHST) and effect size (EST) in physical therapy clinical trials over time published in physical therapy specific journals. The methods used to report the results of a clinical trial impact the ability of physical therapists to translate the results into clinical importance and practice.

Summary of Findings

The frequency of reporting the result of NHST, EST and NNT was examined in 448 clinical trials published in three physical therapy specific journals (*Journal of Neurologic Physical Therapy*, *Journal of Orthopaedic Physical Therapy* and *Physical Therapy*) between 1989 and 2018. More than 90% of clinical trials included a report of the result of NHST, ranging from 93.4% (*Physical Therapy*) to 97.2% (*Journal of Orthopaedic and Sports Physical Therapy*). The reporting of EST in the clinical trials was much less frequent than for NHST, ranging from 14.9% (*Journal of Orthopaedic Physical Therapy*) to 26.0% (*Journal of Neurologic Physical Therapy*). The reporting of NNT in clinical trials was non-existent in the sample prior to 2010. NNT was reported in eight clinical trial articles 2010 – 2018. None of these were published in the *Journal of Neurologic Physical Therapy*.

To determine if there was a change in reporting frequency of NHST, EST and/or NNT over time, the articles were combined into 5-year time span groups, enabling analysis of expected and actual counts of reporting for each 5-year period. There was no statistically significant difference in reporting of NHST for the full sample, nor for any of the individual journals. EST was reported more often than expected beginning with the

2008-2012 5-year period and remained high in 2013-2017 5-year period. NNT was reported more frequently than expected only during the last 5-year period in this study, 2013- 2017. In summary, NHST has remained the most frequently and consistently reported statistic in the clinical trials included in this study. An increase in reporting of EST did not occur until the fourth of the five 5-year periods, followed by an increase in reporting of NNT, albeit a small percent of all the included clinical trials (1.7%), in the most recent 5-year period, 2013-2017.

Translation of research into practice takes many years. Although a common lag time cited is 17 years (Morris, Wooding, & Grant, 2011), there were multiple influencing factors such as the adoption of new statistical methods. There were several events occurring from the time NNT was first introduced to when NNT was reported in the source journals. In Figure 6, the left side of the time line represents published articles where the use of NNT were introduced or encouraged since the introduction of NNT (Laupacis et al.) in 1988. Note the 12-year lag until the first article aimed at physical therapy was published in *Physical Therapy* in 2000 (Dalton & Keating). Three additional articles in physical therapy supporting the use of NNT in clinical trials (Campo & Lichtman, 2008; Hilton et al., 2006; Weeks & Noteboom, 2004) were published before the first article in which NNT was reported was published in Physical Therapy in 2010, 22 years after the introduction of NNT. The eight articles in which NNT was reported in the source journals are marked on the right side of the time line as are the points where EST and NNT reporting exceeded expectations.

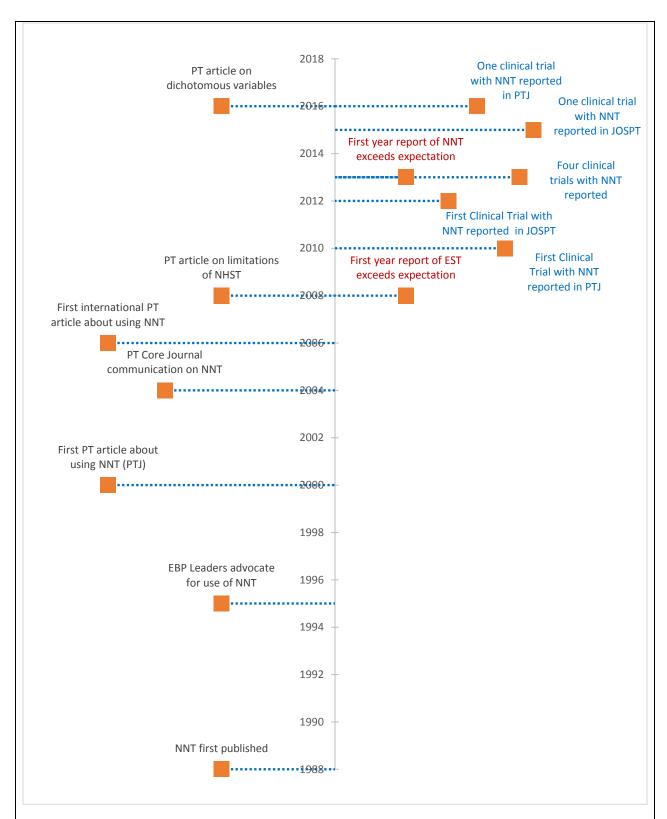


Figure 7: Number Needed to Treat (NNT) Timeline. PTJ = Physical Therapy; JOSPT = Journal of Orthopaedic and Sports Physical Therapy; EST = Effect Size.

Interpretation of Findings

The reporting of NNT in articles published in physical therapy specific journals increased. However, the number of articles is a very small proportion (n = 8, 1.79%) of the 448 clinical trials published since the introduction of NNT and all were published only in the past 9 years. The correlation between the number of NNT per year during the nineyear period from 2010 to 2018 with the number of clinical trials reported was not statistically significant, r = 0.18, p = 0.964. The Mann-Kendall test for linear trend was conducted on the total number of NNT and clinical trials. Although there was a statistically significant increase in linear trend (tau = 0.684, p = 0.016) of the number of clinical trials reported during these nine years, there was no similar increasing trend in the number of NNT (tau = 0.272, p = 0.354). Although the number of articles in which NNT was reported increased during the most recent 5- year period included in this study there is no evidence of a positive linear trend during the past nine years. The number of clinical trials published in the source journals did increase but there was no concomitant increase in NNT. This may indicate that there was only a short-lived time period of increased NNT which may be attributed to two authors (Cleland, Costa) who were authors of five of the eight articles in which NNT was reported.

Interestingly, EST reporting increased above expectations during the 5-year period immediately preceding the 5-year period in which NNT increased above expectations. Editorial boards for many journals, including the source journals in this study, have increasingly required the reporting of effect size. NNT is one of over 40 types of effect size measures. Increased use of EST may have influenced an increased awareness of

the many effect size measures, including NNT. However, it was beyond the scope of this study to identify any causal relationships.

It was not clear, across multiple disciplines, how often NNT was calculated and reported in the literature. It was stated that awareness and use of NNT has been increasing (Cook & Sackett, 1995; Weeks & Noteboom, 2004). Conversely, others have reported that NNT is not widely used or is underused (Hilton et al., 2006; Nuovo et al., 2002; Pinson & Gray, 2003). The results of this study provided the first evidence that the use of NNT is increasing in the physical therapy specific literature, but it does not represent a positive linear trend 2010 - 2018

Contextual Considerations

The computation of NNT requires that the outcome variable be dichotomous. Outcome measures reported in physical therapy clinical trials reflect all levels of measurement, continuous, ordinal and nominal, including dichotomous variables. Dichotomous outcome variables may occur naturally or may be derived from continuous or ordinal measurement scales. Many outcome measures used in physical therapist practice are naturally continuous (e.g. time, distance, repetitions, degrees of movement) or ordinal (manual muscle tests, 11-point pain scales, fear of falling ratings) levels of measurement. Consequently, conversion into a dichotomous variable would be required in order compute NNT.

Some physical therapy outcome measures which use continuous/ordinal scales have an identified cut score. The cut score is used to define a positive or negative outcome. For example, *Timed Up and Go (TUG)* is a timed test that involves rising from a chair, walking 3 meters, turning around, walking back to the chair and sitting down

(Shumway-Cook, Brauer, & Woollacott, 2000). The cut score for fall risk in community dwelling older adults is 13.5s. Although typically recorded as time to complete, a dichotomous variable, at risk for falls, could be derived using scores above 13.5s representing at risk for falls and other scores representing no increased risk for falls. Cut scores can be similarly derived for many physical therapy outcome measures.

The Global Rating of Change (GROC) is a self-report outcome measure of perceived change in a health condition over time and was used in three of the eight articles in this study in which NNT was reported. Dunning et al. (2012) stated that

we dichotomized patients as having experienced as having a successful outcome using...greater than or equal to +4 on the GRC (Cleland, Glynn, et al., 2007). It has been reported that scores of +4 are indicative of moderate changes in patient status and have been previously used as a measure of success in clinical research (Cleland, Childs, Fritz, Whitman, & Eberhart, 2007; Whitman et al., 2009). (p. 10)

Unfortunately, in a different study Cleland et al. (2010) used +5 (also indicative of moderate change) on the GROC to define a successful outcome (Jaeschke et al., 1989). Using a different cut score to dichotomize an outcome variable invalidates the ability to compare NNT across studies. Another method that has been used to identify a cut point to dichotomize a continuous or ordinal level outcome measure is to use the Minimal Clinically Important Difference (MCID) sometimes referred to as the Minimal Clinically Important Change (MCIC). For example, the MCIC was determined to be a score of 6 for the Oxford Shoulder Score (Christiansen et al., 2015; van Kampen et al., 2013). Christiansen et al. (2016) used this MCIC to define the cut score to define a successful outcome. Although this intuitively makes sense, Siemonsma et al. (2013), after using clinically relevant change to define a successful outcome, stated:

The best method to define and determine a clinically relevant change, however, is under debate. (Frost, Lamb, & Stewart-Brown, 2008) Fundamental statistical

issues currently cloud the precise estimation of clinically relevant changes in general. (Terwee et al., 2010) Therefore, some caution in the interpretation of our results is warranted. (p. 444)

Implications of Findings

The findings of this study may advance research methodology by increasing awareness and understanding of the usefulness of NNY in translating research findings into clinical practice. Although the frequency of authors reporting NNT in clinical trials published in physical therapy specific journals has increased recently it is not known if physical therapist practitioners have the knowledge of how to use the NNT when making clinical decisions when developing a plan of care, specifically when selecting an intervention for a specific patient/client. As previously referenced, Dalton and Keating (2000, p. 1216) stated "NNT provides results in a way that is directly transferable to the clinical setting" which reinforces its role in clinical decision making as well as helping patients/clients make better informed consent decisions.

Limitations

There are several limitations of this study which should be considered. The first relate to sample selection which was limited to three physical therapy specific source journals (*Journal of Neurologic Physical Therapy*, *Journal of Orthopaedic Physical Therapy* and *Physical Therapy*). These journals of the American Physical Therapy Association were selected because they are highly regarded, large circulation and readily available core physical therapy journals. Orthopedics and neurology are primary practice areas in physical therapy. However, there are other physical therapy specific journals both in the United States and internationally that could have been source journals. Similarly, physical therapy clinical trials may have been identified by using the

Physiotherapy Evidence Database (PEDro)(The PEDro Partnership, 2019). The PEDro database includes a wide variety of physical therapy core journals, many of which are not physical therapy specific. Authors of physical therapy clinical trials may choose to submit to journals that are not specific to physical therapy for many reasons. Varying the sampling strategy may have resulted in different outcomes and limits the generalizability of the results.

Although the post hoc power for this study was 0.99, the total number of articles in which NNT was reported very small and limited to the orthopedic physical therapy patient/client population. The small number of articles in which NNT is reported limits any broader interpretation of the data such as identifying factors that may increase the likelihood of NNT being reported in a study. The frequency of articles published with NNT reported did not become statistically greater than expected until the 5th of the five 5-year periods considered.

The increased reporting of NNT does not imply appropriate nor accurate use. Methods for calculating bracketed intervals for NNT have been suggested or recommended by some authors (Cook & Sackett, 1995; Laupacis et al., 1988; Weeks & Noteboom, 2004). However, the use of bracketed intervals in NNT is not well supported and there is not agreement on how to, or if it is meaningful, to do so (Hancock & Kent, 2016; Julious, 2005). Despite this, 6 of the 8 (75%) studies included 95%CI for the computed NNT (Table 18). Cleland et al. (2010) reported NNT even though the results of the NHST at one-week post intervention were non-significant. As stated previously, Sawilowsky and Yoon (2002) and Sawilowsky (2003) noted it is futile to discuss

effectiveness of a given treatment if the null-hypothesis is found to be non-significant (see also Sawilowsky (2007); Sawilowsky et al., 2011).

Future Research

There are many directions for future research related to the use of NNT in physical therapy clinical trials. Future studies should incorporate different sampling strategies, expanding to other physical therapy specific journals nationally or internationally or to other core physical therapy journals accessed through a database such as PEDro. Future research should explore the knowledge/utilization of various methods of reporting effect size of various stakeholders including student physical therapists, physical therapist educators in both entry-level and post-professional programs, physical therapist researchers and physical therapist practitioners to barriers to the implementation of NNT in clinical trials. It is important to utilize one or more common outcome measure(s) for specific or similar diagnoses such as the GROC which was used in each of the 3 clinical trials for neck pain. Future research should focus on developing a consistent set of outcome measures, exploring valid and reliable methods of dichotomizing continuous or ordinal outcome variables.

There were no articles in the sample which used NNT to identify the risk for adverse effects in physical therapist interventions, only for what would be considered positive outcomes. Newman and Allison (2007) wrote an editorial in *Journal of Orthopaedic and Sports Physical Therapy* encouraging researchers to investigate risk using measures including absolute risk reduction, relative risk reduction, NNT and number needed to harm. Although physical therapy interventions tend to be conservative, understanding risk is essential for risk management.

Conclusion

In the 30 years since NNT was introduced by Laupacis et al. (1988) it has only recently been included in the results of clinical trials published in two of the three source journals (Journal of Orthopaedic Physical Therapy and Physical Therapy) in this study. This study is the first to report increased reporting of NNT in the physical therapy specific literature but there is no evidence of a positive trend during the past nine years. Stakeholders, including physical therapist students, educators, researchers and practitioners would be well served to improve their understanding of how to include NNT in clinical trial research designs, for making clinical decisions about the physical therapist plan of care including the selection of interventions and to explain intervention selection and effectiveness at the level of patient/client numbers to referring healthcare practitioners and patients. It is recommended that this process include the development of an agreed upon set dichotomous outcome variables used consistently across studies of similar health conditions that would result in easier translation of research results into physical therapist clinical practice. Additionally, NNT cannot be interpreted in isolation. Generalizability and importance of the results of this study need to be considered by the physical therapist as the subject matter expert.

APPENDIX A

Bibliometric Variables: Article Publication Information

Variable Name	Variable	Values
(Level)	variable	values
Article_No	Article Number	N/A
(Nominal)		
Article_Yr	Year Published	N/A
(Nominal)		
Article_Vol	Volume Number	N/A
(Nominal)	Published	
Article_Iss	Issue Published	N/A
(Nominal)		
Article_Mo	Month Published	N/A
(Nominal)		
Article_Cit	Number of times article	N/A
(Scale)	cited	

APPENDIX B

Bibliometric Variables: Author and Institution Information

Variable Name	Variable	Values
(Level)		
1stAuthor_L_N	1st Author Last Name	N/A
(Nominal)		
1 st Author F_N	1 st Author First Name	N/A
(Nominal)		
1 st _Author_Inst	Name of home institution	N/A
(Nominal)	of the first author	
1 st _Author_Country	Country of 1st author's	N/A
(Nominal)	home institution	
1 st _Author_Inst_Type	Type of institution of 1st	1. Education
(Nominal)	author	2. Research
		3. Health Provider

Variable Name	Variable	Values
(Level)		
1 st _Author_Rank	Academic Rank of 1st	Assist Prof TT
(Nominal)	Author	2. Assist Prof non-TT
		3. Assist Prof research
		4. Assoc Prof tenured
		5. Assoc Prof non-TT
		6. Assoc Prof research
		7. Prof tenured
		8. Prof non-TT
		9. Prof research
		10. Lecturer/Instructor
		11. Post-doc
		12. Other
		13. Not applicable
1 st _Author_PT	Is first author a physical	1. Yes
(Nominal)	therapist?	2. No

Variable Name	Variable	Values
(Level)		
1 st _Author_Prof	What is the first author's	Physical Therapist
(Nominal)	profession?	2. Medical Doctor
		3. Doctor of Osteopathy
		4. Biologic Sciences
		5. Behavioral/Social Sciences
		6. Other
Corr Author_L_N	Corresponding Author (if	N/A
(Nominal)	different from 1st author)	
	Last Name	
Corr Author F_N	Corresponding author (if	N/A
(Nominal)	different from 1st author)	
	First Name	
Corr Author_Inst	Corresponding author (if	N/A
(Nominal)	different from 1st author)	
	Name of home institution	
Corr_Author_Country	Corresponding author (if	N/A
(Nominal)	different from 1st author)	
	country of home	
	institution	

Variable Name	Variable	Va	alues
(Level)			
Corr_Author_Inst_Type	Corresponding author (if	1.	Education (e.g. university,
(Nominal)	different from 1st author)		college)
	type of institution	2.	Research
		3.	Health Provider (e.g.
			hospital, clinic)
Corr_Author_Inst_Carn	Corresponding author (if	1.	R1 Doctoral University -
(Nominal)	different from 1st author)		highest
	Carnegie classification if	2.	R2 Doctoral University -
	education institution		higher
		3.	R3 Doctoral University -
			moderate
		4.	M1 Master's College larger
		5.	M2 Master's College
			medium
		6.	M3 Master's College
			smaller
		7.	Special Focus
		8.	Not Applicable

Variable Name	Variable	Values
(Level)		
Corr_Author_Dept	Corresponding author (if	N/A
(Nominal)	different from 1st author)	
	home unit (department,	
	program)	
Corr _Author_College	Corresponding author (if	N/A
(Nominal)	different from 1st author)	
	name of unit that the	
	dept is housed in (e.g.	
	college, school).	

Variable Name	Variable	Values
(Level)		
Corr_Author_Rank	Corresponding author (if	Assist Prof TT
(Nominal)	different from 1st author)	2. Assist Prof non-TT
	academic rank	3. Assist Prof research
		4. Assoc Prof tenured
		5. Assoc Prof non-TT
		6. Assoc Prof research
		7. Prof tenured
		8. Prof non-TT
		9. Prof research
		10. Lecturer/Instructor
		11. Post-doc
		12. Other
		13. Not applicable
Corr_Author_PT	Is corresponding author	1. Yes
(Nominal)	(if different from 1st	2. No
	author) a physical	
	therapist?	

Variable Name	Variable	Values
(Level)		
Corr_Author_Prof	Corresponding author (if	Physical Therapist
(Nominal)	different from 1st author)	2. Medical Doctor
	profession?	3. Doctor of Osteopathy
		4. Biologic Sciences
		5. Behavioral/Social Sciences
		6. Other
N_Authors	Number of authors	N/A
(Scale)		
N_Inst	Number of unique	N/A
(Scale)	institutions represented	
	by authors	
N_Dept	Number of unique	
(Scale)	departments represented	
	by authors	
N_Countries	Number of unique	N/A
(Scale)	countries represented by	
	institutions	

Variable Name	Variable	Values
(Level)		
N_Educ_Inst	Number of unique	N/A
(Scale)	educational institutions	
	represented	
N_Res_Inst	Number of unique	N/A
(Scale)	research institutions	
	represented	
N_Health_Inst	Number of unique health	N/A
(Scale)	institutions represented	

APPENDIX C

Bibliometric Variables: Research Design and Data Analysis

Variable Name	Variable	Values
(Level)		
Research Design	Is there randomized	1. Randomized
	assignment to groups	2. Non-Randomized
N_Grps	Number of Groups	N/A
(Scale)		
Sample_Size	Number of participants	N/A
(Scale)		
Control_Group	Is there a control group?	1. Yes
(Nominal)		2. No
Control_Size	Number participants in	N/A
(Scale)	control group	
TxGrp_Size	Number participants in	N/A
(Scale)	treatment group 1	
TxGrp2_Size	Number participants in	N/A
(scale)	treatment group 2	
TxGrp2_Size	Number participants in	N/A
(Scale)	treatment group 2	
TxGrp3_Size	Number participants in	N/A
(Scale)	treatment group 3	

Variable Name	Variable	Values
(Level)		
Pt_Pop	What is the patient	1. Cardiovascular
(Nominal)	condition category	2. Lymphatic
		3. Oncology
		4. Orthopedics
		5. Neurology
		6. Pulmonary
		7. Sports
		8. Women's health/pelvic
		floor
		9. Other
Sample Age Cent Tend	How is central tendency	1. Mean
Measure	measured?	2. Median
(Nominal)		3. Mode
Sample Age Cent Tend	Reported central	N/A
(Scale/Ordinal)	tendency of sample age	
Sample Age Dispersion	How is dispersion of the	1. SD
Measure	sample age reported	2. Range
(Nominal)		

Variable Name	Variable	Values
(Level)		
Sample Age dispersion	Reported dispersion of	N/A
(Scale/Ordinal)	sample age	
NHST	Is a NHST reported?	1. Yes
(Nominal)		2. No
NHST_Type	What category of NHST	1. Independent t test
(Nominal)	was reported	2. Paired t test – equal
		variance
		3. F Test
Alpha	What is the reported	N/A
(Scale)	nominal alpha?	
Stat_Sig	Was the result reported	1. Yes
(Nominal)	as statistically	2. No
	significant?	
EST	Is an effect size	1. Yes
(Nominal)	reported?	2. No

Variable Name	Variable	Values
(Level)		
EST_Type	What type of EST was	Absolute mean difference
(Nominal)	computed?	2. Cohen's d
		3. Hedge's g
		4. Glass's Δ
		5. Cohen's f
		6. Eta
		7. Partial Eta
		8. Omega
		9. Partial Omega
		10. Other
EST_Mag	Magnitude of the effect	N/A
(Scale)	size reported?	
EST_CI	Is a confidence interval	1. Yes
(Nominal)	reported for the ES?	2. No
EST_CI_Level	What is the confidence	N/A
(Scale)	level for the ES CI?	
NNT	Is number needed to	1. Yes
(Nominal)	treat reported?	2. No

Variable Name	Variable	Values
(Level)		
NNT_Mag	Magnitude of the number	N/A
(Scale)	needed to treat	
NNT_CI	Is a confidence interval	1. Yes
(Nominal)	reported for NNT?	2. No
NNT_CI_Level	What is the confidence	N/A
(Scale)	level for the NNT CI?	
Dichot	Is there a dichotomous	1. Yes
(Nominal)	outcome variable?	2. No

APPENDIX D

Eight Articles in which NNT was Reported

- Abbott, J. H., Chapple, C. M., Fitzgerald, G. K., Fritz, J. M., Childs, J. D., Harcombe, H., & Stout, K. (2015). The incremental effects of manual therapy or booster sessions in addition to exercise therapy for knee osteoarthritis: A randomized clinical trial. Journal of Orthopaedic and Sports Physical Therapy, 45(12), 975-983. doi:10.2519/jospt.2015.6015
- Christiansen, D. H., Frost, P., Falla, D., Haahr, J. P., Frich, L. H., Andrea, L. C., & Svendsen, S. W. (2016). Effectiveness of standardized physical therapy exercises for patients with difficulty returning to usual activities after decompression surgery for subacromial impingement syndrome: Randomized controlled trial. *Physical therapy*, *96*(6), 787-796. doi:10.2522/ptj.20150652
- Cleland, J. A., Mintken, P. E., Carpenter, K., Fritz, J. M., Glynn, P., Whitman, J., & Childs, J. D. (2010). Examination of a Clinical Prediction Rule to Identify Patients With Neck Pain Likely to Benefit From Thoracic Spine Thrust Manipulation and a General Cervical Range of Motion Exercise: Multi-Center Randomized Clinical Trial. *Physical therapy*, 90(9), 1239-1250. doi:10.2522/ptj.20100123
- Dunning, J. R., Cleland, J. A., Waldrop, M. A., Arnot, C., Young, I., Turner, M., & Sigurdsson, G. (2012). Upper cervical and upper thoracic thrust manipulation versus nonthrust mobilization in patients with mechanical neck pain: A multicenter randomized clinical trial. *Journal of Orthopaedic and Sports Physical Therapy*, 42(1), 5-18. doi:10.2519/jospt.2012.3894

- Garcia, A. N., Lucíola da Cunha Menezes, C., Tatiane Mota da, S., Francine Lopes Barreto, G., Cyrillo, F. N., Costa, R. A., & Leonardo Oliveira Pena, C. (2013). Effectiveness of Back School Versus McKenzie Exercises in Patients With Chronic Nonspecific Low Back Pain: A Randomized Controlled Trial. *Physical therapy*, 93(6), 729-747. doi:10.2522/ptj.20120414
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ABSTRACT

REPORTING NUMBER NEEDED TO TREAT IN CLINICAL TRIALS PUBLISHED IN PHYSICAL THERAPY SPECIFIC LITERATURE 1989-2018

by

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Evidence-based practice requires physical therapists to make clinical decisions about the best intervention to use when providing services to patients/clients. Although null hypothesis significance testing (NHST) is frequently used to interpret the outcome of a clinical trial investigating the comparative effectiveness of an intervention, statistical significance does not directly translate into clinical importance. Number needed to treat (NNT) is a measure of effect size (ES) that may be particularly useful when translating the results from clinical trials to PT clinical practice. The purpose of this study was to conduct a bibliometric content analysis of the methods of reporting research results of clinical trials published in the physical therapy specific literature, specifically NHST, ES and NNT.

The frequency of reporting the result of NHST, EST and NNT was examined in 448 clinical trials published in three physical therapy specific journals (Journal of Neurologic Physical Therapy, Journal of Orthopaedic Physical Therapy and Physical Therapy) between 1989 and 2018. More than 90% of clinical trials included a report of the result of NHST but less than 30% reported effect size. NNT was reported in only eight (1.79%)

articles. The number of articles in which NNT was reported during 2013-2018 was statistically greater than the previous four 5-year periods. However, there was no positive linear trend of the frequency of NNT during the last nine years, 2010 – 2018. This is the first study in which evidence is presented indicating increased reporting of NNT in the physical therapy specific literature however there is no evidence of a positive trend during the past nine years. Physical therapist students, educators, researchers and practitioners would be well served to improve their understanding of how to include NNT in clinical trial research designs to improve decisions about the clinical importance of an intervention.

AUTOBIOGRAPHICAL STATEMENT

Susan Ann Talley was born in Highland Park, MI and grew up in Detroit in the house her father lived in from the time he was 10 years old, blocks from the house where her mother grew up. She attended the Detroit Public Schools, graduating from Pershing High School in 1972. Her father was a Detroit police officer for 31 years after serving in the Navy and having earned a GED. Her mother, who also graduated from Pershing High School (does this make Sue a DPS legacy student?), was an office worker. Growing up in the late 60's and early 70's was a riot (literally in 1967) and she leaned toward humanism, the anti-war movement, the Beatles and folk music.

In 10th grade Sue decided that she wanted to become a pediatric physical therapist (PT). Although no one in her family had graduated from college she was determined to earn her BS in PT. Wayne State was her only option and she earned her PT degree in 1976. PT school was the most intense educational experience in her life (until her PhD Qualifying exams!) and she swore she would never go to school again, ever! One year later she started taking French courses and then decided she may as well work on a degree. In 1982 she earned a MA degree in Human Development and Relationships with a focus on infants and toddlers from Wayne State University.

Her first professional position was as a pediatric physical therapist at the MSCCA, working with children with cerebral palsy and with sensory processing disorders for three years. She was asked to become a TA in her master's program and thus began her affinity for academia. At the age of 25 she joined the PT faculty at Wayne State, teaching human development, neurologic and pediatric physical therapy and... research. Fortunately for the students, a mentor was hired to teach the research course that first year, mentored her the following year, and then she was on her own. Recognizing her woeful preparation to teach research, she pursued professional development courses, leading to her first exposure to Education Evaluation and Research. At the time faculty were not allowed to earn degrees at Wayne State so she took a smattering of courses. Along the way she earned a Doctor of PT degree from Creighton University in 2005. A few years later she realized that she had taken nearly enough courses to earn her PhD in EER and officially enrolled in the doctoral program.

After 34 years as a member of the PT faculty at Wayne State, including 10 years as the academic director, she retired – but only for a blink of an eye. The next day she started as Associate Director for Professional Education for the PT department at the University of Michigan-Flint in 2014. Along the way she practiced as a PT with a variety of patients, including adults and children with neurological conditions, cardiac rehabilitation, and palliative care.

Dr. Talley has co-authored eight peer-reviewed articles largely focusing on physical performance in community dwelling older adults, most recently looking at the contribution of genomics. She has also authored four chapters on a variety of physical and occupational therapy topics. Throughout her career she has been very active in the Michigan Physical Therapy Association, including serving as President for four years. She was awarded the Marjorie L Stamm Outstanding Service award and the Jane Murdock Legislative Advocacy award by her colleagues.

She has been married to Joe Olesnavage for 30+ years. Her children, Jason and Katy, live in Chicago, IL and Hermosa Beach, CA. respectively. She has hiked on the Appalachian Trail, canoed in the Boundary Waters and performed folkdance on Moscow TV. Life is good!!!