

Evidence-Based Practice

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The Effects of Massage Therapy in Improving Outcomes for Youth with Cystic Fibrosis: An Evidence Review

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Cystic fibrosis (CF) is a genetic disorder found in approximately 30,000 children and adults in the United States. About 1 out of 3,500 babies are born with CF, and approximately 1,000 new cases are diagnosed each year (Cystic Fibrosis Foundation [CFF], 2005). CF is a life-threatening condition caused by a defective gene inherited from both parents. Life expectancy of individuals with CF has increased over the past several years and is now into the early 30s (CFF, 2005). Children with CF have very thick secretions that cause major organs to become damaged, typically resulting in severe lung disease, pancreatic insufficiency including diabetes, and reproductive problems (CFF, 2005; Mayo Foundation for Medical Education and Research, 2005; Orenstein, Winnie, & Altman, 2002).

As CF progresses, treatment intensifies and individuals often experience chest, head, back, limb, and abdominal pain (Ravilly, Robinson, Suresh, Wohl, & Berde, 1996). Pain may intensify as a result of musculoskeletal changes associated with postural shifting (intended to ease respiratory effort) and tissue irritation (from frequent coughing episodes). The musculature becomes dysfunctional over time as the individual develops compensatory breathing patterns, which includes overuse of accessory muscles. Pain restricts movement and may negatively affect the individual's ability to move secretions out of the respiratory tract; thereby contributing to recurring infections and disease progression.

Medical care that focuses on preventing and treating infection and improving nutrition may not adequately

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The Evidence-Based Practice section focuses on: the search for and critical appraisal of the "best evidence" to answer challenging clinical questions; single studies with strong clinical practice applications; or evidence-based strategies to improve practice so that the highest quality, up-to-date care can be provided to children and their families. To obtain author guidelines or submit manuscripts, please contact Bernadette Melnyk, PhD, RN, CPNP/NPP, FAAN, FNAP or Leigh Small, PhD, RN-CS, PNP; Section Editors; Arizona State University College of Nursing; PO Box 872602; Tempe, Arizona 85287-2602; 480-965-6431; Bernadette.Melnyk@asu.edu or Leigh.Small@asu.edu

address pain issues related to structural changes. Massage therapy (MT) is a treatment that may be beneficial to youth with CF. MT is described as hands on manipulation of the soft tissue of the body by a trained therapist with the intention to produce physiological effects (State Medical Board of Ohio, 2004). Selected benefits of MT include pain relief, relaxation, improved pulmonary function, decreased anxiety, improved mood, and sleep (Field, 1995, 1998; Ireland & Olson, 2000).

The purpose of this evidence review is to examine the research surrounding MT and CF to determine if there is adequate evidence to support the use of massage in youth with CF. The clinical question that guided this review was: In hospitalized youth, is MT effective in reducing pain and improving health outcomes?

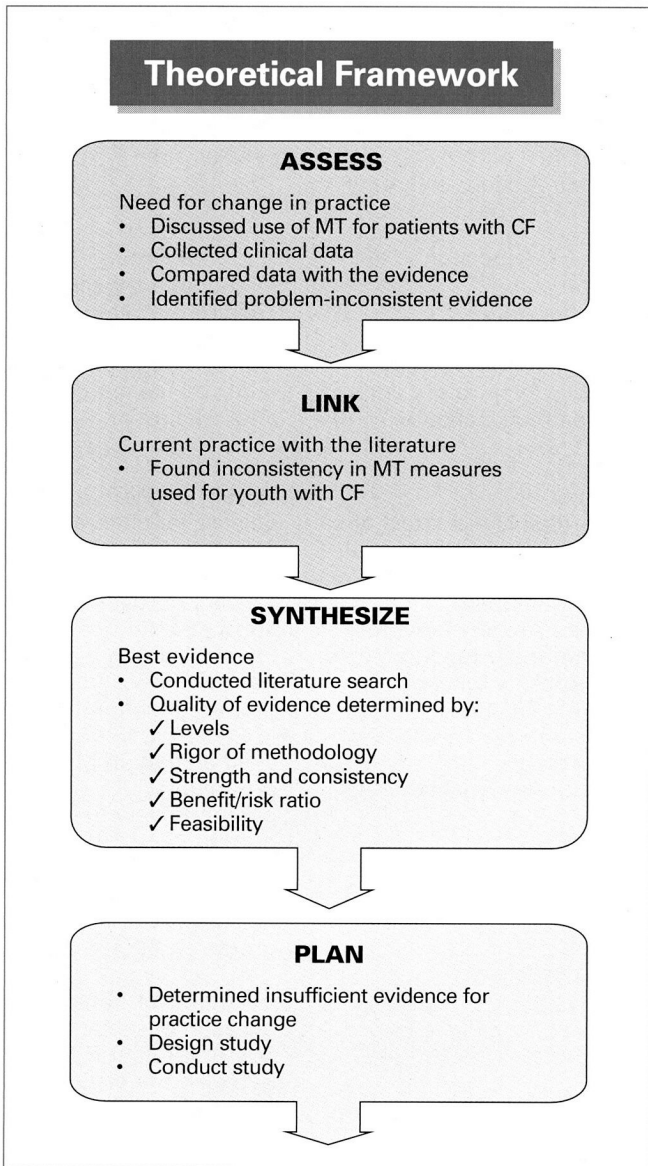
Theoretical Framework

The theoretical framework used for this evidence review was the Rosswurm and Larrabee Model (1999). This six-step model guides researchers and clinicians through assessing the need for change in practice to the integration of an evidence-based protocol. The process was modified to include four steps (see Figure 1). Step one, the assessment phase of the review, examined the need for change in clinical practice. Discussion ensued among the pulmonary team, clinical nurses, and massage therapist regarding the responses of hospitalized youth with CF who were currently receiving MT. These youth routinely reported that massage did promote comfort, enhance relaxation, and improve ease of movement. A licensed massage therapist (LMT) who also is a registered nurse (RN) was providing the massage services. Inconsistent and limited evidence from the literature regarding the benefits of MT in youth with CF was identified as a problem. In step two, the reviewers linked current clinical practice regarding MT to CF and other chronic lung conditions with the literature. There was inconsistency in findings on the effectiveness of MT; measures also were inconsistent. The third step, synthesizing best evidence, was conducted by examining the research data and determining the quality of evidence by grading the evidence; identifying the rigor of the methodology strength and consistency of the studies; and identifying the benefit/risk ratio and feasibility (see Tables 1 and 2). The fourth step, planning a change in practice, will occur after conducting a study on MT and CF. The last two steps of Rosswurm and Larrabee's Model, implementation and evaluation of a change in practice and integration and support for the change will be addressed after completion of the study.

The Search Strategy

An in depth literature search of studies completed over the past 20 years was conducted for evidence regarding the

Figure 1. Theoretical Framework for Change to Evidence-Based Practice



Note: Modified from Rosswurm, M., & Larrabee, J. (1999). A model for change to evidence-based practice. *Image: Journal of Nursing Scholarship, 31*(4), 318.

use of massage therapy for individuals with CF. Databases searched included the Cochrane Library, Ovid MEDLINE, CINAHL, EBSCO, PubMed, and Ohio Link. Key terms for the primary search included: "cystic fibrosis," "massage therapy," "asthma," and "chronic lung disease." An expanded search linked "cystic fibrosis" with "quality of life," "pain," "relaxation," "exercise," "complementary therapy," "physiotherapy," and "physical therapy." Related articles were excluded as they did not address MT and CF. Criteria for inclusion were studies written in English with clinical outcomes that focused on the use of MT for individuals with CF or other respiratory conditions. The literature review focused on children but was expanded to include adults due to limited findings. Out of 12 studies reviewed from the primary search, only four met the inclusion criteria. Three systemat-

ic reviews on MT were found and excluded because they did not employ a rigorous process for critiquing the quality of the research on the effect of MT in children or adolescents (Field, 1995, 1998; Ireland & Olson, 2000). Additionally, none of these previously mentioned reviews were true meta-analyses. One meta-analysis of MT research was identified; however, none of the participants had CF or a chronic lung disease. Therefore, it also was excluded (Moyer, Rounds, & Hannum, 2004).

Presentation of the Evidence

Factors that determined the quality of evidence for this review were the level and grade of the evidence (Melnik & Fineout-Overholt, 2005; Schiffer et al., 2001), rigor of the investigator's adherence to methodological principles (Jadad et al., 1996), benefit/risk ratio, and feasibility of the study (Rosswurm & Larrabee, 1999). The four studies that met the inclusion criteria were from Level II (Field et al., 1998; Hernandez-Reif et al., 1999; Witt & MacKinnon, 1986) or Level III evidence (Robertson, Gilmore, Frith, & Antic, 1984). Level II evidence was comprised of at least one well-designed randomized controlled trial (RCT) while Level III evidence was considered to be a quasi-experimental study or a well-designed trial without randomization (Melnik & Fineout-Overholt, 2005). A brief synopsis of the four intervention studies used in this review is presented below. Table 1 describes the methodology, instruments, and findings of the four studies.

Level II Evidence. Study #1. The most recent RCT measured the effects of massage given by parents to their children with CF (Hernandez-Reif et al., 1999). Twenty children (5-12 years) were randomly assigned to either a MT group or a reading control group. Depending on group assignment, children received either a 20-minute massage or 20 minutes a night of reading for 1 month by a parent. The investigators found that both children and parental anxiety was reduced, mood improved, and peak air flow readings increased in the MT group compared to the reading control group. The effect sizes of these outcomes were medium to large.

Study #2. Witt and MacKinnon (1986) used a RCT cross-over design to examine MT in adults with chronic lung disease. Twelve adult volunteers ($M = 64.1$ years) were randomly assigned to a treatment or control group. The treatment group received Trager Psychophysical Integration (TPI) massage by a physical therapist (PT) for 20 minutes, two times a week for 2 weeks. The control group continued their normal daily living and returned in 2 weeks for testing. After 2 weeks the control group became the treatment group and the first treatment group became the control group. Results indicated that both the first and second TPI treatment subjects showed a significant difference in respiratory rate (decreased), forced vital capacity (FVC) (increased), and chest expansion (increased) compared to the control subjects. Anecdotal reports support that the subjects felt better after the MT intervention.

Study #3. In another RCT, 32 asthmatic children (4 to 14 years) were randomly assigned to receive massage or relaxation by a parent (Field et al., 1998). Parents were instructed to administer the assigned therapy for 20 minutes prior to bedtime every night for 30 nights. Both groups (i.e., massage or relaxation) and age (i.e., 4-8 and 9-14 years) were factors in the analysis. These researchers found that children in the 4-8-year-old massage group showed an immediate reduction in anxiety. This age group also demonstrated significant improvement on activity ratings, vocalizations, and cortisol levels. Long-term effects reported for the younger group included an improved attitude toward asth-

Table 1. Summary of the Studies Reviewed

Investigators	Method/Design	Measurement	Findings
Hernandez-Reif et al. (1999)	Design: Experimental Sample: Convenience, <i>N</i> = 20, children with CF and their parents Intervention: Massage and positioning by parent Attention Control: Reading by parent Level of Evidence: 2	<i>Child</i> State Anxiety Inventory Profile of Mood States Peak air flow monitoring <i>Parent</i> State Anxiety Inventory	<i>MT Group</i> ↓ child and parent anxiety ↑ mood ↑ peak air flow
Witt & MacKinnon (1986)	Design: Cross-over Sample: Convenience (volunteer), <i>N</i> = 12, adults with chronic lung disease Intervention: TPI by PT Control: Daily routine Level of Evidence: 2	Chest expansion Heart rate Respiratory rate Blood pressure Forced vital capacity Forced expiratory volume Breathing difficulty (1-10)	<i>Treatment Group</i> ↑ forced vital capacity ↓ respiratory rate ↑ chest expansion Majority of subjects reported feeling better after treatment
Field et al. (1998)	Design: Experimental Sample: Convenience, <i>N</i> = 32, children with asthma Intervention: MT by parent Attention Control: Progressive muscle relaxation by parent Level of Evidence: 2	<i>Child</i> Cortisol levels affect anxiety, activity, and vocalization (videotaped) State Anxiety Inventory Pulmonary function tests (forced vital capacity, FEV, FEF, peak expiratory flow) <i>Parent</i> State Anxiety Inventory	<i>4-8-year-old MT Group</i> ↓ anxiety for children Improved activity and vocalizations ↓ salivary cortisol levels Improved attitudes toward asthma ↑ peak air flow and pulmonary function tests <i>9-14-year-old Group</i> ↓ child anxiety in MT group and ↓ parent anxiety in both groups Vocalizations, attitudes toward asthma, and FEF improved in MT group
Robertson et al. (1984)	Design: Quasi-Experimental Sample: Convenience, <i>N</i> = 10, moderately severe asthma Intervention: CTM by PT Attention Control: SSM by PT Level of Evidence: 3	FEV	No significant differences in baseline or post-treatment FEVs between the groups over 2 days Three patients found CTM mildly uncomfortable

ma and improved peak air flow and other pulmonary function measures (i.e., FVC, forced expiratory volume [FEV], forced expiratory flow [FEF], and peak expiratory flow rate).

The 9-14-year-old massage group also reported significantly lower anxiety immediately after massage than the relaxation group. Interestingly, parents in both groups reported significantly lower anxiety. Like their younger counterparts, the older group of children demonstrated greater improvement in their attitudes toward asthma, vocalizations, and FEF than the relaxation group.

Level III Evidence. *Study #4.* Robertson and colleagues (1984) conducted a quasi-experimental cross-over study in which 10 adults with moderately severe asthma were randomly ordered to receive either a connective tissue massage (CTM) or a simple surface massage (SSM). Massage in both groups was performed by a PT. The investigators reported that there were no significant differences in FEV

between the groups. Three patients (in the CTM group) reported mild discomfort with the CTM massage.

Critique of the Evidence

An instrument that assesses the quality of RCTs was developed from criteria identified by Jadad and colleagues (1996) to rate the evidence from each study. Based on 10 of their criteria and one additional criterion of pre-posttest measurement, each study was assessed and then a percentage was calculated (see Table 2). This method of analyzing a study was done to assure consistency and accuracy and limit the introduction of bias into the review process. The four studies received ratings on quality that ranged from 45% to 73%.

One of the strengths of all of the studies reviewed was the use of experimental and quasi-experimental designs. Also, all of the studies reported randomization. However, the

Table 2. Assessment of Quality of Randomized Clinical Trials

Criteria	Study #1	Study #2	Study #3	Study #4
Randomized	X	X	X	X
Blinded (single)	-	-	X	X
Description of withdrawals and dropouts	X	-	-	-
Outcome measures defined	X	-	X	-
Inclusion/exclusion criteria	-	-	-	-
Power calculations	X	-	X	-
Description of intervention	X	X	X	X
Control/comparison group	X	X	X	X
Adverse events described	-	-	-	X
Methods of statistical analysis described & appropriate	X	X	X	-
Pre-post test measures	X	X	X	X
Quality of study (%)	73%	45%	73%	55%

method used to generate the random assignment allocation was not described, despite the recommendation for improving the quality of reporting RCTs (Moher, Schulz, & Altman, 2001). A strength of study 3 was that randomization was based on confounding variables such as age, gender, duration, and severity of asthma. All of the studies reviewed used pre-post test measures.

A power analysis to determine sample size enhanced the robustness in studies 1 and 3. Both of these studies had medium to large effect sizes indicating that the sample size was adequate. Additionally, study one included the effect sizes of all outcome variables.

All four studies reported using a control or comparison group. However, studies 3 and 4 used muscle relaxation or surface massage as the comparison group. Relaxation and surface massage are both treatments that can dilute the effect of the massage intervention. Other criteria that strengthened the quality of these studies included: outcome measures were defined in studies 1 and 3; all four studies described the intervention; the methods of statistical analysis were well reported and appropriate in studies 1, 2, and 3; adverse events were described only in study 4, and studies 3 and 4 were single-blinded. Double-blinding for an intervention like massage is not possible.

According to the pre-determined review criteria described in Table 2, these studies had some major limitations. For example, two of the studies were un-blinded. Other issues of concern include unreported data for the following: withdrawals and dropouts, adherence to the protocol, inclusion/exclusion criteria, and adverse events. Several studies did not report a power analysis for sample size calculation a priority. A power analysis conducted before a study is initiated helps ensure the sample size is large enough to detect significance findings when they exist (Johnston, 2005).

Outcome variables for MT were inconsistent across the studies. Measures, as well as the time intervals in which measurements were made, varied in the studies reviewed. Studies 1 and 3 reported a significant decrease in child and parental state anxiety; however, the time points in which anxiety was measured varied greatly. The two studies cited previously also found a significant increase in peak air flow by day 30, but this was only significant in the younger age group in study 3. Lastly, findings from studies 2 and 3 indi-

cated an increase in FVC after a 2-week and a 30-day regimen. Study 4 did not find significant differences on FEV₁, which was the only outcome variable measured over a short duration of time (2 days). The lack of significance is most likely a result of the small sample size ($N = 10$) and the two massage interventions that were introduced.

Other confounding variables in the studies reviewed included adult samples, a variety of lung conditions and severity, and differences in interventions. Differences on these variables make comparisons across the studies difficult and uncertain. Therefore, findings from Level II and Level III evidence along with the assessment of the scientific rigor of each study, and inconsistency of the outcomes placed the strength and consistency of findings at a C ranking (Schiffert et al, 2001). According to the grade of evidence developed by Schiffert et al., a rating of A is the best evidence and a rating of D indicates little or no evidence.

Two additional factors that were used to determine the quality of the evidence were the benefit/risk ratio and feasibility. The benefits of change in practice were thought to be high and outweigh the low risk to children. Additionally, the authors determined feasibility by deciding that this intervention could be implemented in a large children's hospital. However, the authors believed that resources would need to be expanded (i.e., massage therapists). No cost information was provided in any of the studies reviewed.

These methodological limitations and inconsistencies on outcomes indicate a need for additional research that is rigorously controlled and accurately reported. Furthermore, well-designed and well-conducted RCTs with larger samples that employ effective and reproducible MT interventions are needed. The use of consistent interventions and outcome measures are needed to evaluate the effectiveness of MT across studies. Future research needs to determine the role of parents in MT and the child's perception when a parent is a partner in the treatment of CF, especially during adolescence. In addition, there is a need for future studies that assess whether early massage intervention can produce long-term positive outcomes. Finally, a cost analysis would provide useful information to health care organizations.

In conclusion, this review of MT yields preliminary support for the use of MT with youth who have CF. Providing MT to children and adolescents with CF has the potential to improve theirs and their families' quality of life. Additionally,

Glossary of Terms

Cross-over design: An experimental design in which the same subject receives both the treatment and the control in random order.

Meta-analysis: A rigorous process to analyze the results from multiple studies in order to answer a specific question and draw conclusions about the data gathered. This may be in the form of a summary statistic that represents the effect of the intervention across studies.

Quasi-experimental design: An experimental study that includes treatment and control/comparison groups, but the design lacks randomization.

Randomized controlled trial (RCT): An experimental design in which the subjects are randomly assigned to a treatment or control group.

Theoretical framework: Two or more concepts that are related and provide a structure on which to base a study or clinical practice.

offering an intervention that has both physiologic and psychological benefits supports nursing's holistic paradigm.

Clinical Implications

In pediatric health care, nurses and other direct care providers are in constant search of ways to improve comfort and quality of care. Nursing practice includes the use of touch to comfort and nurture the hospitalized child. In a pediatric hospital with holistic health services, such as MT, there is an opportunity to expand the use of massage techniques for hospitalized youth and incorporate massage interventions that promote comfort into nursing practice.

As children and adolescents with CF experience disease progression, they find it more difficult to breathe. Clinical research to date provides preliminary evidence supporting the use of MT for youth and adults with a variety of lung conditions. However, there exists a need for additional research to guide clinical practice related to the use of MT for hospitalized youth with CF.

Given more empirical support, massage interventions could become part of routine care for these patients. While the therapist may provide more complex tissue-specific massage, the nurse, given instruction and guidance, may apply comfort-focused massage techniques that are evidence based. The nurse could also expand physical assessment skills related to musculoskeletal changes and associated pain and determine when to refer the patient for MT. Thus, there would be a partnering between the massage therapist and clinical nurse in providing evidence-based care that promotes comfort and enhances quality of life for youth with CF.

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