Reiki to Reduce Pain During Hemodialysis: A Systematic Review and Feasibility Study

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Savannah Zins

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Cynthia R. Gross, PhD, Advisor

Mary Catherine Hooke, PhD, APRN, PCNS, CPON, Advisor

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Abstract

Background: Pain is one of the most prevalent symptoms among individuals receiving hemodialysis. Management is often suboptimal and effective interventions are needed. Reiki, a natural system of healing using universal life-force energy to heal, relax, and restore the whole person, is a promising, non-pharmacologic approach to pain management. A systematic review, conducted as a part of this dissertation research, found few studies of non-pharmacological, complementary therapy use for individuals receiving hemodialysis, and confirmed that Reiki's impact is unknown in this population. Thus, the purpose of this study was to examine the feasibility and efficacy of Reiki for pain management among individuals receiving hemodialysis. The validity of computer adaptive technology (CAT) instruments compared with established symptom scales was also explored.

Method: A one group, repeated-measures pilot study was conducted with a convenience sample of 15 individuals over four weeks. Pain, fatigue, and depression were measured using established symptom scales and CAT instruments. Reiki was administered for 20-minutes, twice per week during hemodialysis.

Results: Recruitment goals fell short whereas target completion and adherence rates for Reiki were met. The study was feasible for participants and no adverse events from Reiki occurred. Participant feedback revealed positive experiences with Reiki and web-based measures. Hemodialysis staff feedback reported no impact on workflow and improvement observed in patients. Significant, moderate to very strong correlations with established symptom scales support the construct validity of the CAT instruments. There

were significant improvements in pain, fatigue, and depression over the course of the Reiki sessions.

Conclusion: Findings support Reiki as a promising, acceptable, low risk complementary intervention and support conducting future larger-scale randomized clinical trials with longer follow-up periods to evaluate the effects of Reiki for individuals undergoing hemodialysis.

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Chapter 1: Introduction

At the end of 2013, it was estimated that over 661,000 individuals in the U. S. were receiving treatment for end-stage renal disease (United States Renal Data System, 2015). Approximately 64% of those with end-stage renal disease were receiving hemodialysis treatment. In a recent review of 52 studies that included almost 7000 individuals receiving hemodialysis, researchers found that 82% of hemodialysis patients reported acute pain and up to 92% experienced chronic pain (Brkovic, Burilovic, & Puljak, 2016). They found many individuals receiving hemodialysis suffered from severe pain and that pain occurred in a variety of locations and arose from disparate causes, including headache, generalized or musculoskeletal pain, and pain related to fistula access.

End-stage renal disease can significantly impair quality of life, and evidence suggests that even patients who are at early stages of chronic kidney disease have decreased quality of life compared to the general population (Soni, Weisbord, & Unruh, 2010). Thus, even in its early stages, chronic kidney disease reduces life satisfaction and impedes physical and mental functioning. Research to identify promising complementary therapy approaches for symptom management among adults receiving hemodialysis is beginning to emerge. Usage reported by these studies ranged from 26-61% (Arjuna Rao et al., 2016; Birdee, Phillips, & Brown, 2013; Nowack et al., 2009). Mind-body approaches are the most often utilized. Several small studies have shown efficacy in improving symptom management and quality of life among this population. Although research suggests that these patients turn to complementary therapies for symptom control and coping with the chronic nature of kidney disease, the evidence concerning

complementary therapy use among individuals receiving hemodialysis continues to be insufficient and more research should be conducted to assess impact and safety of complementary therapies for this population.

Reiki Overview

Reiki is a noninvasive, energy-based complementary therapy believed to support the innate healing abilities of the body (National Center for Complementary and Integrative Health (NCCIH), 2017). NCCIH (2016) defines a complementary therapy as "a non-mainstream practice used together with conventional medicine." This will be the operational definition for this dissertation.

Believed to have originated in Tibet or India more than 2,000 years ago, Reiki was rediscovered in the early 20th century and named through the work of Dr. Mikao Usui, a lifelong practitioner of Tendai Buddhism, in Japan (Miles, 2006; Miles & True, 2003). During a spiritual pilgrimage seeking knowledge of healing practices, Dr. Usui experienced what he called Reiki energy. He proceeded to bring Reiki back to his family and opened a small clinic to teach classes and provide Reiki sessions (Rand, 2005). Mrs. Hawayo Takata is recognized as a Grand Master Teacher and for disseminating Reiki to the western parts of the world. Reiki has never been a religion, but is part of a larger spiritual practice, similar to other mind and body complementary therapies (Miles, 2008). Although no single accepted mechanism of action explains the process and effects of Reiki, the presence of biofield energy has led to several proposed explanations including bioelectromagnetism, homeodynamics, and quantum physics (Miles & True, 2003, Oschman, 2000).

Two Japanese words meaning “spirit” and “life-force energy” comprise the word Reiki (Hulse, Stuart-Shor, & Russo, 2010). The practice of Reiki is primarily passive, embodying the Asian philosophy of non-action, in that the practitioner does not produce energy, rather acts as a conduit for energy flow (Vitale, 2007). Energy flows through the Reiki practitioner to allow the spirit, mind, and body to heal by helping stimulate the body’s self-healing abilities. During Reiki, there is no attempt to manipulate an individual’s energy or condition. Hands-on Reiki sessions are offered through light touch on a fully clothed recipient seated in a chair or reclining on a treatment table. A quiet setting conducive to relaxation is desirable, but not necessary. A session can be as short or as long as needed with treatments lasting anywhere between 20 to 90 minutes (Meland, 2009; Olson, Hanson, & Michaud, 2003; Vitale, 2007). Although Reiki has early origins, it is adaptable and suitable to use in current clinical practice settings. Symptom improvement, relaxation, and improved well-being are among the benefits credited to Reiki.

Reiki practitioners act as a conduit to guide energy to recipients in order to aid innate healing and assist with self-healing (NCCIH, 2017). The ability to facilitate healing derives from knowledge and practices that are passed from master practitioner to student. Reiki is practiced at the level I, II, and master level, with each level having a defined scope of practice. At the core of the education, which is cognitive, experiential, and unique to this practice, are a series of initiations called attunements. These are believed to connect the student to the core knowledge that permeates creation and maintains life, regardless of the Reiki student’s health, mental state, or intention (Meland, 2009; Vitale, 2007). Level I practitioners can treat themselves and others using light, non-

manipulative touch to precipitate the flow of healing energy. Level II practitioners are taught the use of specific symbols to access Reiki mentally for distance healing (Richeson et al., 2010). The flow of Reiki is believed to increase as the practitioner becomes inwardly more still, a skill acquired through extended practice into mastery. Although a practitioner's ability to be a conduit for the energy may fluctuate, there is ultimately no wrong technique (Assefi, Bogart, Goldberg, & Buchwald, 2008; Meland, 2009; Richeson et al., 2010).

Reiki holds that lack of harmony or imbalance of energy results in pain or illness (Ring, 2009). Research has produced positive, as well as equivocal, results concerning the benefits of Reiki in the treatment of pain and other symptoms among a wide variety of patient populations. Reiki has been shown to reduce pain (Birocco et al, 2012; Fazzino, Griffin, McNulty, & Fitzpatrick, 2010; Vitale & O'Conner, 2006), fatigue (Tsang, Carlson, & Olson, 2007), and depression (Bowden, Goddard, & Gruzelier, 2011; Thrane & Cohen, 2014), improve relaxation and quality of life (Marcus, Blazek-O'Neill, Kopar, 2013; Wardell & Engebretson, 2001), and reduce anxiety and stress (Birocco et al., 2012; Hulse et al., 2010; Tsang et al., 2007) in surgical, oncology, and procedural populations. Various physiological changes have also been associated with Reiki, including blood chemistry and vital sign changes (Friedman, Burg, Miles, Lee, & Lampert, 2010; Wardell & Engebretson, 2001). Individual experiences associated with Reiki vary, however common feelings and themes have emerged. A qualitative study found that during a Reiki session, participants felt secure, soothed, calm, clear, grounded, and relaxed (Ring, 2009). Furthermore, Vitale (2009) conducted a phenomenological study of the lived experience of nurses using Reiki for self-care and found that nurses

used Reiki during their workday in order to feel calmer, centered, and connected with others to improve care for patients. Many studies have been criticized for small sample sizes and design flaws. Literature reviews support positive effects on the symptom experience and no reports of harm or side effects, however, there are still major gaps and additional research applying rigorous methodologies needs to be undertaken to verify effectiveness and generalizability (Baldwin et al., 2010; Jain & Mills, 2010; Thrane & Cohen, 2013).

Purpose

The purpose of this dissertation research was to assess, via systematic review, complementary therapies used for pain reduction among individuals receiving hemodialysis and evaluate the feasibility and potential benefits associated with a four-week Reiki session intervention for individuals receiving hemodialysis. Secondary purposes were to assess Patient Reported Outcomes Measurement Information System (PROMIS) computer adaptive technology (CAT) instruments for construct validity by comparing them with established symptom scales, as well as to compare results obtained with brief and longer form scales. The aims and hypotheses for this dissertation research are provided below.

Specific Aims

Aim 1. Examine the feasibility of Reiki for adults undergoing hemodialysis by evaluating: (a) study enrollment rate for eligible adults; and (b) rate of completion for intervention sessions (eight sessions, two times a week over 4-weeks).

Benchmark 1a: Fifty percent of eligible adults will enroll in the Reiki study.

Benchmark 1b: Enrolled participants will complete at least 75% of the Reiki sessions (average completion of six or more of the eight sessions).

Aim 2. Examine the feasibility and acceptability of using web-based data collection tools to measure symptoms in adults undergoing hemodialysis who have pain by evaluating (a) rate of completion for study measurements performed two times a week over four weeks and (b) self-report of acceptability. **Benchmark 2a:** Enrolled participants will complete 75% of the web-based measurements.

Benchmark 2b: Enrolled participants will rate the web-based measurements as acceptable to very acceptable on a 5-question survey.

Aim 3. Examine acceptability of on-site Reiki sessions for patients from the perspective of staff at a hemodialysis center.

Hypothesis 3: Staff will report minimal interference with workflow on a 5-question survey.

Aim 4. Validate the PROMIS computerized adaptive test (CAT) measures of Pain Interference, Fatigue, and Depression as compared to established measures in the hemodialysis patient population.

Hypotheses 4a: Baseline PROMIS CAT Pain Interference scores will significantly, strongly, and positively correlate ($r>0.70$) with baseline scores for: the subscales of the Brief Pain Inventory and Brief Pain Inventory short-form.

Hypothesis 4b: Baseline PROMIS CAT Fatigue scores will significantly, strongly, negatively correlate ($|r|>0.70$) with baseline scores for the FACIT Fatigue Scale.

Hypothesis 4c: Baseline PROMIS CAT Depression scores significantly, strongly, positively correlate (r>0.70) with baseline scores for the Beck Depression Inventory II and Beck Depression Inventory fast screen.

Hypotheses 4d: Changes from baseline to post-intervention in the PROMIS CAT Pain Interference instrument will significantly, strongly, positively correlate (r>0.70) with the baseline to post-intervention change scores for the subscales of the Brief Pain Inventory, and Brief Pain Inventory short-form.

Hypothesis 4e: Changes from baseline to post-intervention in the PROMIS CAT Fatigue instrument will significantly, strongly and positively correlate (r>0.70) with the baseline to post-intervention change scores for the FACIT Fatigue Scale.

Hypothesis 4f: Changes from baseline to post-intervention in the PROMIS CAT Depression instrument will significantly, strongly and positively correlate (r>0.70) with the baseline to post-intervention change scores for the Beck Depression Inventory II and Beck Depression Inventory fast screen.

Hypotheses 4g: Effect sizes using the PROMIS CAT instruments will be of comparable magnitude as the effect sizes for the established measures for pain, fatigue, and depression.

Exploratory Aim 5. Examine the trends over time in pain, fatigue, and depression among patients undergoing hemodialysis receiving Reiki.

Hypothesis 5a: There will be significant decreases in mean pain scores as measured by the PROMIS CAT Pain Interference instrument, Brief Pain Inventory, and Brief Pain Inventory short-form between baseline and the end of the intervention period.

Hypothesis 5b: There will be mean decreases in fatigue as measured by the PROMIS CAT Fatigue instrument and the FACIT Fatigue Scale between baseline and the end of the intervention period.

Hypothesis 5c: There will be mean decreases in depression as measured by the PROMIS CAT Depression instrument, Beck Depression Inventory II, and Beck Depression Inventory fast screen between baseline and the end of the intervention period.

Significance

This pilot study was the beginning of a program of research that may lead to Reiki becoming an adjunct therapy for improved symptom management in individuals receiving hemodialysis. The trajectory of patients receiving hemodialysis who experience pain is often one of increased acuity, prolonged hospitalizations, increased costs, and poor quality of life. Currently, there is no published research using Reiki in the hemodialysis population. If feasibility is supported by this study, future research can determine if Reiki could be a practical and low-cost intervention to incorporate during already scheduled hemodialysis appointments to reduce the burden of extra appointments on patients and the resources of hemodialysis units. It is non-invasive, unlike other forms of energy medicine such as acupuncture, and can also be safely used in conjunction with other forms of medications and treatments.

A recent review of clinical evidence suggests complementary approaches are an appropriate option for providers' pain management strategies (Nahin, Boineau, Khalsa, Stussman, & Weber, 2016). As nonpharmacological therapies are preferred for chronic pain, a major challenge to incorporating these therapies into practice is that insurers do not adequately cover or reimburse for such therapies currently. Nonpharmacological,

complementary therapies are important approaches in the management of not only chronic pain, but other symptoms as well. Patients should have options available that are reimbursed as lack of insurance coverage often hinders access for patients and limits provider options for providing treatment. Thus, the need for high quality research to clearly examine the effectiveness of such interventions would be beneficial to encourage payment by insurers and improve widespread accessibility. The Academic Collaborative for Integrative Health provided recommendations to not only research whole systems healing, but also to focus on cost effectiveness in order to provide further access of non-pharmacological therapies (Menard et al., 2015)

According to Florence Nightingale, nature can cure, but nursing needs to lay the foundation and provide the environment for the patient (Scovil, 1927). Thus, as nurses, we must advance our knowledge to shift outside traditional western practices so we can recognize the value of complementary therapies, such as Reiki. This work is congruent with NCCIH's (2016) strategic plan by identifying an innovative and promising intervention in the area of symptom management in the clinical setting. This dissertation research provides evidence of feasibility and a foundation for future studies to determine effectiveness of Reiki during hemodialysis for pain management.

Organization of the Dissertation

This dissertation is organized in chapters. Chapter 2 is presented in manuscript form and presents evidence of the need for more research into complementary therapies to be used among individuals receiving hemodialysis. Chapter 3 is also presented in manuscript form and presents the results of implementing Reiki sessions in a hemodialysis clinic. Chapter 3 results include evaluating feasibility (aims 1-3), validation

of PROMIS CAT instruments (aim 4), and examining symptom changes over time (aim 5). Chapter 4 provides a summary to discuss dissertation findings, limitations, and research implications. References for Chapters 1 and 4 are found in the dissertation bibliography. References for Chapters 2 and 3 are found following each manuscript and in the dissertation bibliography.

Chapter 2: Manuscript One

This chapter is a systematic review on complementary therapy use for pain among individuals receiving hemodialysis. This chapter is written in manuscript form for a journal following their manuscript requirements. It has been submitted for publication.

Summary

Pain is significant problem for individuals undergoing hemodialysis and can lead to decreased quality of life when ineffectively managed. As pain is often reported as burdensome, nurses must learn effective, nonpharmacological adjuncts to help care for symptomatic patients. The purpose of this review was to identify nonpharmacologic complementary therapies and evaluate their effectiveness in minimizing pain among individuals undergoing hemodialysis. Multiple complementary interventions were identified and several were found to significantly reduce pain, although evidence is qualified by limitations in study methods. It is concluded that complementary therapies have the potential to reduce pain among individuals undergoing hemodialysis, however more research is needed.

Pain is a significant problem in more than 50% of individuals undergoing hemodialysis (HD), with many of these individuals describing ineffective pain management (Claxton, Blackhall, Weisbord, & Holley, 2010; Davison, 2003; Williams & Manias, 2009). Physical and psychological strain from pain can continue for months to years after beginning HD, impacting quality of life and ability to perform activities of daily living (Davison & Jhangri, 2005). In 2012, the United States had more than 660,000 individuals being treated for end-stage renal disease, with 468,000 receiving hemodialysis (U.S. Renal Data System, 2015). As current methods of pain management are insufficient for this large patient population, it is fundamental that this burden is addressed.

Individuals receiving HD are among the most symptomatic of any chronic disease group (Davison et al., 2007; Kimmel, Emont, Newmann, Danko, & Moss, 2003; Weisbord et al., 2005). Inadequate symptom management in this population is a unique challenge due to the relationship between medication distribution and clearance of bi-products with renal dysfunction, as well as polypharmacy in the elderly (Bailie, Mason, Bragg-Gresham, Gillespie, & Young, 2004; Davison, 2003). Opioids and other classes of medications are associated with undesirable side effects yet up to one-third of renal disease patients use opioids to reduce pain (Davison, 2003). The etiology of pain during HD is often multifactorial, and can be acutely HD related or chronic. Pain can occur in the context of concurrent symptoms and comorbidities such as fatigue and depression or diabetes and vascular disease (Davison, 2003; Leinau, Murphy, Bradley, & Fried, 2009; Weisbord et al., 2005). Capturing the type of pain and the pain itself has shifted from a linear assessment of bodily pain, to using multidimensional instruments to conduct a

comprehensive assessment of attributes contributing to total pain perception. For example, an analog scale is useful for assessing a global perception of pain, whereas the Brief Pain Inventory and McGill Pain Questionnaire are more comprehensive, addressing intensity, duration and interference with activity.

Many HD patients are willing or are already using some form of complementary therapy (Akyol, Yildirim, Toker, & Yavuz, 2011; Birdee, Phillips, & Brown, 2013). There is a growing interest in complementary therapy among nephrology patients and few studies have evaluated the strengths and weaknesses of implementation, as well as effectiveness, of complementary therapies in dialysis clinics and among the population (Nowack & Birck, 2012). Complementary therapies offer additional treatment options to improve the pain experience and quality of life for individuals receiving HD. The aim of this systematic review is to evaluate the evidence for the effectiveness of nonpharmacologic, complementary therapies in reducing pain among individuals undergoing HD.

Methods

Databases and Search Terms

A systematic search was conducted in three databases, including using the ancestry approach to find additional studies. To locate intervention studies on the topic, the following databases were searched: OVID Medline, Embase, and CINAHL. Subject headings included “hemodialysis” OR “renal dialysis,” AND “complementary therapies*.” The subject heading “pain” was not used in order to identify papers that may have included pain as a secondary outcome. The search resulted in a total of 811 citations. After removing duplicates, 686 papers were reviewed by title and abstract.

Inclusion Criteria

Studies retained for review included results of non-pharmacologic and non-herbal intervention research, included patients receiving hemodialysis, used a randomized control trial (RCT) or quasi-experimental design, had pain as a primary or secondary outcome, and were published in English. If studies used multi-symptom instruments, pain subscale results had to be included. These studies were reviewed for quality by examining design, interventions, pain measures, and strengths and limitations. After reviewing titles and abstracts to exclude articles using herbal therapies, animals, case reports, and those not in English, 148 remained. After applying all inclusion criteria on the remaining full-text articles, eight articles were identified as relevant and included in this review (see Figure 1).

Results

The eight studies chosen for review were published between 2007-2014. There was one article published in each 2007, 2008, 2010, 2013, and four in 2014. The studies included seven randomized controlled trials (RCTs) and one quasi-experimental design. All the studies reviewed had two-group designs. Bagheri-Nesami, Espahbodi, Nikkhah, Shorofi, and Charati (2014) used a placebo control group, and Yurtkuran, Alp, Yurtkuran, and Dilek (2007) assigned active range of motion exercises to both groups, while the remaining studies had usual care controls. Four groups of researchers (Alhani, Shad, Anoosheh, & Hajizadeh, 2010; Bagheri-Nesami et al., 2014; Heidari Gorji, Abbaskhani Davanloo, & Heidarigorji, 2014; Pothoulaki et al., 2008) measured pain pre- and post-intervention, whereas researchers conducting the remaining four studies measured pain at baseline and again at the end of the study period. The investigators (Rambod, Sharif, Pourali-Mohammadi, Pasyar, & Rafii, 2014) who used a numeric rating

pain scale did not explain whether participants were asked to recall pain over a period of time or were to report pain in the moment. Most studies did not measure comorbidities (n=7) or concurrent symptoms (n=4).

All eight studies were conducted in Mediterranean countries (n = 4) or Iran (n= 4). Characteristics of the eight studies are shown in Table 1. The sample sizes of the eight studies ranged from 37 to 114 participants. Gender and age were reported by all research teams. The mean age ranged from 38 to 68 years in the seven studies of adults; one study included a group of adolescents with a mean age of 14. Most participants were male, with percentages of males ranging from 37.5% to 70%; two studies (Burrai, Micheluzzi, Zito, Pietro, & Sisti, 2014; Ozdemir, Ovayolu, Ovayolu, 2013) had more females. Two groups of investigators did not report education data (Pothoulaki et al., 2008; Yurtkuran et al., 2007). Only Burrai et al. (2014) reported religion. Four research teams reported mean duration of hemodialysis, ranging from one to five years for participants (Alhani et al., 2010; Ozdemir et al., 2013; Rambod et al., 2014; Yurtkuran et al., 2007).

The eight studies reviewed included the following as pain interventions: Hatha yoga, distraction, reflexology, aromatherapy, Benson's relaxation method, and music. Only Alhani et al. (2010) mentioned being guided by a theory about pain; none included a theory relating the intervention to pain. Yoga was the only group intervention. The remaining interventions were all provided on an individual level. In two studies, the interventionist was a researcher (Ozdemir et al., 2013; Pothoulaki et al., 2008), one intervention was delivered by a certified yoga teacher (Yurtkuran et al., 2007), and another was delivered by a holistic nurse (Burrai et al., 2014). Interventionist education

was described in two studies (Ozdemir et al., 2013; Yurtkuran et al., 2007). The interventionist was not described in four articles.

Two trials were conducted in HD units and were designed to reduce venipuncture pain. Alhani et al. (2010) investigated the effect of programmed distraction on pain caused by venipuncture in adolescents and reported significant differences between groups and within the intervention group. The intervention was investigated over 12 HD sessions and pain intensity was measured using the Wong-Baker FACES pain scale. This study lacked power calculations, random assignment, blinding, and investigators did not report any drop-outs. Bagheri-Nesami et al. (2014) aimed to determine the effects of lavender aromatherapy on pain caused by venipuncture in adults and reported significant differences between mean pain severity score between groups after three interventions. The intervention was investigated over three consecutive HD sessions and pain intensity was measured using a visual analog scale (VAS). These researchers reported power calculations, appropriately described attrition, accounted for pain medications given to participants, and used a placebo aromatherapy group as the control. In both studies, the researchers were unable to assign one individual to perform all venipunctures.

Two trials designed to investigate the effects of music on pain were conducted during HD. Pothoulaki et al. (2008) aimed to determine the effects of preferred music listening, via compact discs, on anxiety and pain perception and reported no significant difference between groups in pain intensity but a significant increase in pain intensity in the control group, as well as a significant, positive correlation between pain intensity and state anxiety scores indicating a relationship between symptom experiences. The intervention was investigated over one HD session and pain intensity was measured using

a VAS and the McGill Pain Questionnaire. No power calculation was reported for this study. Burrai et al. (2014) aimed to determine the effects of live saxophone music on various physiological parameters and on pain, mood and itching levels, and reported a significant baseline to post-intervention difference in pain within the music group and between the two groups. The intervention was investigated one time per week over four weeks and took place in a HD unit. Acute pain intensity was measured using a VAS and a power calculation was provided. Both studies lacked blinding, did not have any reported drop-outs, and measured pain related to HD.

Two trials designed to evaluate the effect of Benson's relaxation technique were conducted in the HD unit and continued at home. Rambod et al. (2014) studied the effects of Benson's relaxation technique on relieving pain and improving quality of life, and reported a significant difference in mean pain scores between groups. The intervention was conducted over eight weeks and pain intensity was measured by a numeric pain scale at baseline and again at the end of eight weeks. The numeric pain scale had a test-retest reliability of r= 0.94. Intervention adherence measures were reported. The relaxation technique was performed a mean of 11.34(SD=2.55) times per week out of 14 possible times, and for a mean duration of 34.5 minutes (SD=5.32) out of 40 minutes per day. The researchers did not measure anxiety or stress to assess if participants could relax during the intervention. Heidari Gorji et al. (2014) aimed to determine the impact of Benson's relaxation method on stress, anxiety, and pain perception and reported a significant difference in pain between groups. These investigators also found significant correlations between pain and stress, as well as between pain and anxiety. The intervention was investigated over four weeks and pain severity was measured by the McGill Pain

Questionnaire short form, with an internal consistency of .84, pre- and post-intervention. The study lacked detail about intervention adherence. Both groups of investigators provided power calculations, appropriately described attrition, had partial blinding of data collectors and interventionists, provided pain measure psychometric results, and measured chronic pain.

The remaining two trials were designed to reduce pain using Hatha yoga or foot reflexology for individuals receiving HD. Yurtkuran et al. (2007) investigated the effects of a yoga based exercise program on pain, fatigue, sleep disturbance, and biochemical markers and reported significant improvements in pain intensity between groups and a 37% reduction in pain intensity in the intervention group. The intervention was delivered twice per week over three months and pain intensity was measured using a VAS at baseline and upon completion of the study. The study report lacked detail about the timing of yoga sessions in relation to HD sessions and adherence (e.g., average number of yoga sessions attended), and lacked a power calculation. The physician examining patients was partially blinded with respect to group assignment, and attrition was appropriately described. Ozdemir et al. (2013) aimed to determine the effect of foot reflexology on fatigue, pain, and cramps and reported a significant difference in pain within and between groups. They also found that participants with lower Kt/V and albumin had significantly more pain and that women experienced more pain and fatigue. The intervention was delivered after three HD sessions and pain severity was measured using a VAS at baseline and upon study completion. The researchers mentioned a power calculation without adequate detail, and did not report any drop-outs. The study lacked blinding. Both studies lacked detail about recall duration and type of pain measured.

Discussion

The aim of this review was to evaluate the evidence from controlled trials on the effectiveness of complementary therapies as a treatment for pain in individuals undergoing HD. Evidence of the effectiveness of complementary therapies for pain in HD patients was found, but study limitations qualify the findings. Most of the studies used only one pain measure and did not report concurrent symptoms or comorbidities. Only one study was conducted by a nurse investigator or had a nurse as the interventionist (Burrai et al., 2014). This discussion will highlight the methodology, pain measures, as well as the strengths and limitations of the studies reviewed.

Sample sizes were small or relatively modest; only 1 included over 100 participants. No large imbalances or significant differences in baseline characteristics between intervention and control groups were found, supporting internal validity. Pothoulaki et al. (2008) are the only investigators lacking a detailed power calculation and reporting a nonsignificant difference in pain between groups.

Of the seven studies with significant outcomes, all reported some form of recurring contact with intervention group participants, possibly indicating that individual attention and social support are important in promoting treatment effects. Protocol integrity of the intervention and clinical effectiveness of the HD sessions were not described in any of the study reports, and thus treatment fidelity cannot be confirmed.

Both groups of investigators reporting interventions specifically for venipuncture were unable to control for venipuncturist technique as there were no uniform staff to perform the procedure. This confounding variable could impact reports of pain if

participants had a previous relationship, good or bad, with a venipuncturist, or if different venipuncturists used different techniques, yet both studies had significant findings.

More detail about the individual treatment protocols and consistent reporting of adherence ("dose") received by participants would enhance validity and reproducibility. One reviewed study provided individualized reflexology based on pain reported, but did not adequately describe different protocols for each participant at each reflexology session (Ozdemir et al., 2013). Given the holistic and individualized nature of many complementary therapies, a thorough protocol needs to be developed and followed to provide a standard or manual for study replication by others to establish effectiveness for individualized treatments.

In seven reviewed studies, the intervention was performed on HD days. Both interventions before venipuncture supported favorable outcomes, however timing patterns over the other reviewed studies did not appear to predict favorable outcomes. Delivering interventions in coordination with HD sessions can increase intervention consistency and adherence for the HD population. Accounting for nursing workflow and resource management is important when attempting to implement interventions during scheduled HD appointments to reduce burden on staff, maintain clinical flow, and decrease cost of delays, as well as reduce participant burden, and possibly increase intervention compliance. One study was conducted after the HD sessions (Ozdemir et al., 2013), which could have an impact on nursing workflow and cost as it could cause schedule and transportation delays for patients.

Only one group of researchers reported using a theory, specifically in regard to pain (Alhani et al., 2010). A theoretical approach could improve the intervention and

study design to enhance the quality of findings. Given the complex nature of symptoms, standard treatments for individuals receiving HD could benefit from a theoretical framework based on the complementary therapy being studied (Lewith, Walach, & Jonas, 2012). As many complementary therapies, such as mind-body therapies, are based on interconnectedness and individuality, the challenge for researchers is to connect the philosophical values of complementary therapies with the rigorous standards of research design and implementation. Using a theoretical framework can help researchers navigate the challenges of constructing uniform experimental conditions while remaining true to the holistic basis of many complementary therapies.

There are different types of pain reported by individuals receiving HD, including hemodialysis-related pain and chronic pain. Assessing not only the pain itself, but the type can help investigators to tailor interventions appropriately. Several research reports included in this review lacked detail concerning the type of pain that was being measured as well as the recall period that the participants were self-reporting on. The type of pain to be treated could impact the choice of intervention as well as its effectiveness, and guide selection of the appropriate pain measurement tool.

Fatigue, intradialytic hypotension, cramps, dizziness, as well as headache, pruritus, and backache are common during HD sessions (Caplin, Kumar, & Davenport, 2011; Garmondi et al., 2013). In addition to these treatment-related pains, chronic pain from co-morbidities, including musculoskeletal pain, neuropathies, and peripheral vascular pain are common for individuals undergoing HD (Davison, 2003; Murtagh, Addington-Hall, & Higginson, 2007). Because pain is multidimensional and often chronic among individuals undergoing HD, it can continue beyond HD sessions. Other

physical and psychological symptoms are also known to be multifactorial and of high burden (Patel, 2013). The presence of disease burden, comorbidities, and concurrent symptoms may impact the perception of pain, as well as the effectiveness of the selected interventions. The findings from this review are inconsistent regarding this topic. Rambod et al. (2014) did not measure stress or anxiety to determine if participants relaxed after Benson's relaxation technique, which could impact pain reports of participants and overall study findings. Pothoulaki et al. (2008) measured pain intensity and anxiety and found a positive, significant correlation ($p<.01$), whereas Ozdemir et al. (2013) found no relationship between the mean pain and fatigue scores or other physiological factors. None of the investigators reported comorbidities, and most did not measure or compare concurrent symptoms. As chronic pain may contribute to symptoms of anxiety and physiological imbalances, such symptoms may also lower pain thresholds. Davison (2003) found that 83% of HD patients had experienced moderate or severe pain in the previous 24 hours. She also found that distressing symptoms such as depression often co-exist in this population (Davison & Jhangri, 2005). This emphasizes chronic pain as a fundamental concern among individuals receiving HD, and is often associated with psychosocial distress and burden (Davison, 2007). Assessing and addressing psychosocial burdens, as well as comorbidities, may decrease the impact of pain among the HD population, thus improving overall quality of life (Patel, 2013).

Four different pain measures were used, with the VAS used most often. Variety in timing of pain measures make it difficult to directly compare results across the studies reviewed. The lack of consistency in timing could reflect the lack of using a theoretical framework to guide intervention selection, or inadequate consideration of the physiologic

impacts of HD. For example, in many studies pain has been measured pre- and post-intervention, whereas in others it has been measured at baseline and at the end of the study. Because pain is associated with psychosocial factors, the assessment of pain has progressed from a single measurement of physical pain to a comprehensive measurement of attributes contributing to the perception of pain (Breivik et. al, 2008). To assess all these components, comprehensive pain measures that capture the multidimensional nature of pain should be used. Such instruments have been suggested for the HD population, including the Brief Pain Inventory, McGill Pain Questionnaire, Pain Management Index, and Edmonton Symptom Assessment System, but none are consistently used (Upadhyay, Cameron, Murphy, & Battistella, 2014). In the reviewed studies, investigators measured pain using the McGill Pain Questionnaire (n=2) and the VAS (n=5). Only one study used both the McGill Pain Questionnaire and a VAS to capture global pain (Pothoulaki et al., 2008). Using a multidimensional method of measuring pain in addition to a VAS can be more effective for examining the clinical importance of pain and emotional functioning as a research outcome (Dworkin et al., 2008). Quality of life is important for the HD population. Thus, the perception of symptom burden could provide a more complete picture of how the patient is feeling, than pain experienced or measured alone.

Current methods of symptom management may contribute to under-treatment of symptoms or over-sedation and other unfavorable side effects. Complementary therapies often focus on minimizing how bothersome symptoms are, and improving physical and emotional well-being, rather than curing. Several groups of researchers have reported a wide range of complementary therapy usage prevalence among individuals undergoing

HD (Akyol, Yildirim, Toker, & Yavuz, 2011; Birdee, Phillips, & Brown, 2013). In a study of 89 individuals receiving HD 61% of individuals reported using complementary therapies at some point in their lifetime. Mind-body interventions were the most popular and the highest rates of use were among individuals 50 to 64 years old and women (Birdee, Phillips, & Brown, 2013). In another study, 25% of 206 individuals receiving HD reported the use of one or more complementary therapies. The highest rates of use were among women and among individuals 51 to 70 years old. Mind-body interventions were the most popular, and were used by 46% of participants (Akyol et al., 2011). Given that Ozdemir at al. (2013) found that women experienced more pain, fatigue, and more intense cramping than men and Heidari Gorji et al. (2014) found age and pain are correlated, it is plausible that women and older adults could be more symptomatic, and thus willing to try complementary therapies.

Indications for Future Research

The prominent finding of this systematic review was that several complementary therapies show promise as adjunct therapies for pain reduction in HD. Although most of the studies reviewed were RCTs, the diversity of complementary therapies, lack of replication, and methodological shortcomings limit generalizability of findings. Because none of the studies reviewed were longitudinal, there was no information concerning the durability of pain reductions, which is particularly important for chronic pain. Also, relationships among co-morbidities and symptoms were largely unexamined. Moreover, there are many other complementary therapies with potential to reduce pain symptoms which have not been tested in the HD population. Individuals receiving HD need more therapeutic options for pain, and these patients have been found to be interested in

complementary therapies, yet research to unlock the potential of complementary therapies to reduce pain and improve HD patient outcomes has received scant attention. Future research in which replication with fully powered RCT studies using multidimensional pain measures may better determine the value and generalizability of interventions for this population, as well as safety and efficacy. Using a theory base to help guide methodological design for complementary therapies could lead to more significant and generalizable findings for pain control.

Implications for Practice

The findings of this review support the potential of complementary therapies as an adjunct for pain management among individuals receiving HD. Some therapies may be less feasible due to lack of experienced interventionists or the potential time and cost involved. However, promising results emerging from Mediterranean countries and Iran could provide evidence for Western settings to accept these therapies and increase accessibility. There is a need to implement effective therapies to reduce pain and incorporating them into already scheduled HD sessions may prove to be beneficial to patients and the multidisciplinary team. Opportunities exist for nurses to adopt approaches and make complementary therapies more convenient and acceptable to patients.

Conclusion

In conclusion, there could be a role for complementary therapies to contribute to improving pain management among individuals undergoing HD. Although promising results have been found, the overall evidence is not sufficiently robust to recommend specific interventions as safe and effective for pain management among individuals

receiving HD. An important role of nurses is to find ways to alleviate the symptoms of HD. Complementary therapies show potential for reducing pain, but they require an acceptance within the traditional Western healthcare model, as well as expertise to ensure accuracy and safety of intervention modality. More RCTs to explore options for reducing pain that are acceptable to patients receiving HD are needed. With a high level of interest in complementary therapies, further research is needed in the U.S. and Canada to further advance our knowledge of the benefits of integrative therapies in the HD population.

Figure 1. PRISMA flow diagram of identification and selection of articles (Moher, Liberati, Tetzlaff, & Altman, 2009).

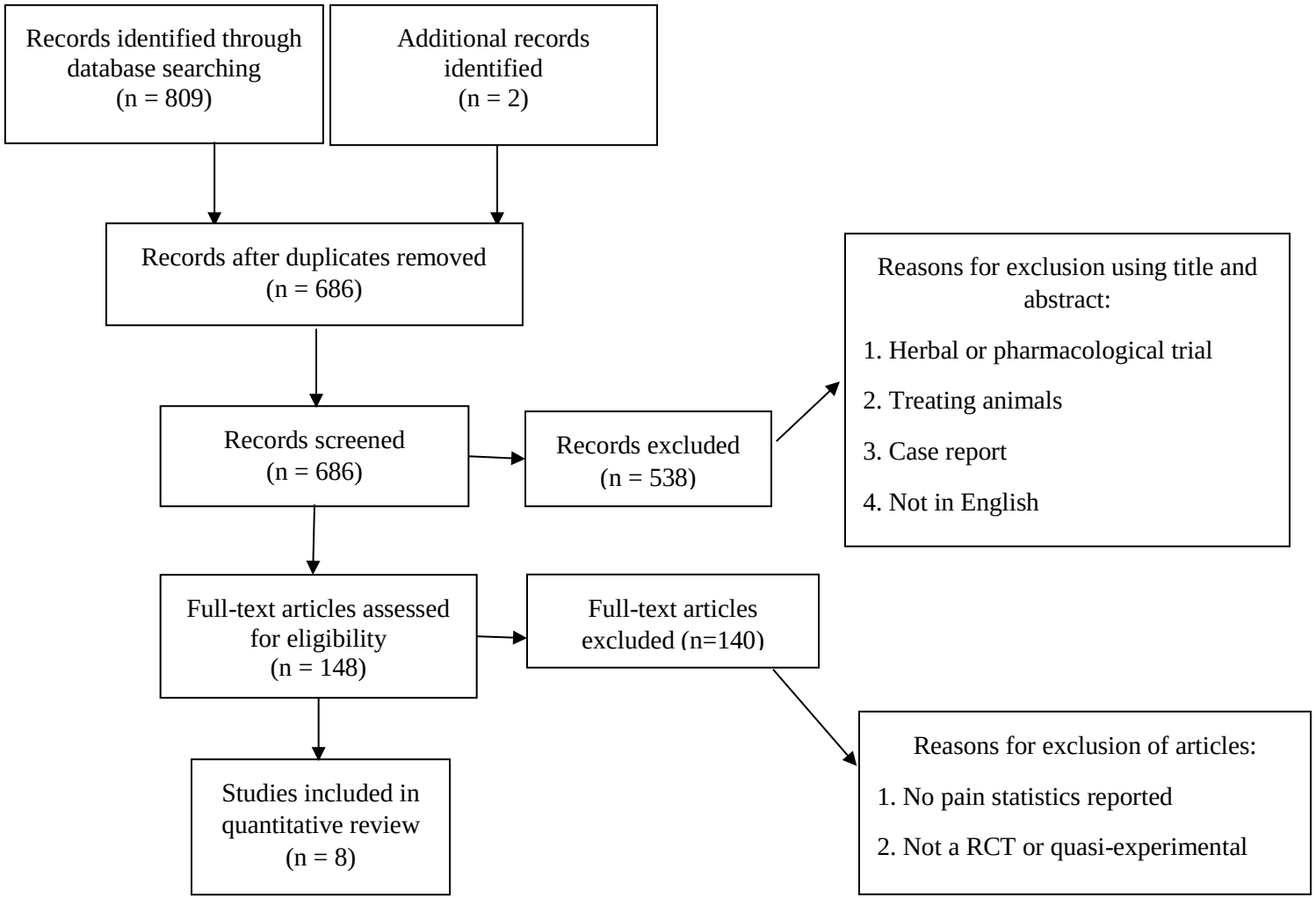

Table 1.

Reviewed Studies of Complementary Therapies for the Treatment of Pain

Reference & Country	**Purpose**	**Design**	**Sample/ Setting**	**Intervention**	**Pain Measures**	**Pain Outcomes**	**+ Strengths & - Limitations**
Yurtkuran et al. (2007) Country: Turkey	Evaluate the effects of a yoga based exercise program on pain, fatigue, sleep disturbance, and biochemical markers in HD patients.	Randomized controlled trial	N=37: Intervention (n=19), control (n=18) Convenience sampling Gender: Males (n=16), Females (n=21) Mean age: intervention 38(SD=14.2), control 41(SD=9.97) No significant group differences	Modified Hatha yoga: 30 minutes per day, twice a week for 3 months. Gradually increased over time from 15 minutes to goal of 30 minutes. Active ROM exercises at home daily for ten minutes for both groups. Interventionalist: Certified yoga teacher	VAS	Significant improvements in pain intensity between groups (p<0.05). 37% change in pain intensity in intervention group.	- Classes at HD center, but lacked detail if participants completed yoga before or after HD sessions. - No report of comorbidities or HD duration. - No power analysis. - No theory.
Pothoulaki et al. (2008)	Evaluate the effects of preferred music	Randomized controlled trial	N=60: Intervention (n=30), control (n=30) Convenience	Experimental group listened to preferred music provided during HD via	VAS McGill Pain	No significant difference between groups in	- A third of participants did not have any pain at baseline.

Country: Greece	listening on anxiety and pain perception among patient undergoing HD.	sampling Gender: Males (n=42), Females (n= 18) Mean age: 52.9 No significant group differences	CD player Control group had standard care Interventionist: Researcher	Questionnaire	pain intensity. No significant within-group differences in pain intensity scores for intervention group. Significant increase in pain intensity post intervention for control group (p<.001). Positive, significant correlation between pain intensity and state anxiety	- Sample included both inpatient and outpatient HD patients. - No inclusion criteria, report of comorbidities, or HD duration. - No power analysis. - No theory.

						scores (p<0.01).	
Alhani, Shad, Anoosheh, & Hajizadeb (2010) Country: Iran	Evaluate the effect of programmed distraction on pain caused by venipuncture among adolescents on HD.	Quasi-experimental design	N= 42: Intervention (n=21; one HD center), control (n=21; 2 HD centers) Convenience sampling Gender: Males (n= 25), Females (n= 17) Mean age: 13.86(SD=3.19) intervention, 14.81(SD=3.51) control No significant group differences	Content: Two pictures for adolescents to identify differences during venipuncture over 12 HD sessions. Different pictures each HD session. Control group had standard care Interventionist: Unidentified	Wong-Baker FACES Pain Rating Scale	Significant difference within intervention group and between groups. No change in pain after five sessions, but significant decrease in pain at sixth HD session.	- Three individuals did venipunctures. -No report of comorbidities - No power analysis. - Theory provided for pain, not intervention.
Ozdemir, Ovayolu, & Ovayolu (2013) Country: Turkey	Evaluate the effect of foot reflexology on fatigue, pain and cramps in HD patients.	Randomized controlled trial	N=80: Intervention (N=40), control (N=40) Convenience sampling Gender: Males (n= 30), Females	Reflexology for 1 week across three HD sessions; each session lasting 30 minutes after HD session 15 minutes per	VAS	Significant difference in pain was found within and between groups (p<0.05).	-No report of comorbidities - No power analysis. - No theory.

			(n= 50) Mean age: 43.1(SD=15.8) intervention, 54(SD=12.8) control No significant group differences	foot: Seven minutes of reflexology, five minutes before and three minutes after of relaxation technique. Control group had standard care Interventionist: Certified reflexologist		In both groups, women experienced more fatigue, pain and cramp more intensively compared with men (p<0.05). Patients with lower hematocrit, albumin, and Kt/V levels experienced more pain.	
Bagheri-Nesami et al. (2014) Country: Iran	Evaluate the effects of lavender aromatherapy on pain following needle insertion	Randomized controlled trial	N=92: Intervention (n=46), placebo (n=46), with 4 drop outs Convenience sampling Gender: Males (n= 52), Females	Intervention group inhaled lavender essence with concentration of 10% for 5 min during 3 consecutive HD sessions.	VAS	No significant differences between mean pain severity score between the two groups, but	- Unable to assign consistent nursing staff for all needle insertions. - No report of comorbidities

into a fistula.	(n= 40) Mean age: 60.95(SD=1.93) intervention, 58.06(SD=1.83) control No significant group differences	Control group inhaled aromatherapy free of lavender essence. Lavender and placebo both diluted with sweet almond oil. Interventionist: Unidentified	significant difference between groups in mean pain severity after three interventions (p=0.009). Significant differences within intervention group of mean pain severity before and after three interventions (p= 0.0001). Patients receiving three placebo therapies experienced less pain than they did before the	- No theory + Provided power analysis

						interventio n (p= 0.0001).	
Burrai et al. (2014) Country: Italy	Evaluate the effects of live saxophone music on various physiologic al parameters and on pain, mood and itching levels in patients undergoing hemodialys is	Randomized controlled trial	N= 114: Intervention (n=57), control (n=57) Convenience sampling Gender: Males (n= 49), Females (n= 65) Mean age: 68.2(SD=11.7) No significant group differences	Intervention group received 30 minutes of individualized selection of live saxophone music weekly for four weeks. Control group had standard care Interventionist: Holistic nurse	VAS	A significant difference in pain was found within the music group and between the two groups (p < 0.05)	- Lacked detail if saxophone music was played before, during, or after HD sessions. - No report of comorbidities - No theory + Provided power analysis.
Heidari Gorji, Abbaskhan i Davanloo, & Heidarigorj i (2014) Country: Iran	Evaluate the impact of Benson's relaxation method on stress, anxiety, and pain perception of HD patients.	Randomized controlled trial	N= 80: Intervention (n=40), control (n=40). Convenience sampling Gender: Males (n= 44), Females (n= 36) Mean age:	Intervention group watched video to learn Benson relaxation method, as well as caregiver, in the HD center. Technique performed twice a day for 15 minutes for four	McGill Pain Questionn aire short form	A significant difference in pain was found between groups (p < 0.001). A correlation between	- Lacked detail if video was played before, during, or after HD sessions. - Excluded anyone with a comorbidity except diabetes and

			48(SD=12.53) No significant group differences	weeks. Control group had standard care Interventionist: Unidentified		pain and stress (r = 0.563), anxiety and pain (r = 0.489), and age and pain (r = 0.268) was found (p<0.000)	hypertension. - No theory + Provided reliability and validity for measures. + Provided power analysis.
Rambod et al. (2014) Country: Iran	Evaluate the effects of Benson's relaxation technique in relieving pain and improving quality of life in HD patients.	Randomized controlled trial	N=86: Intervention (n=41), control (n=40), with 5 drops outs Convenience sampling Gender: Males (n= 53), Females (n= 33) Mean age: 49.07(SD=13.31) intervention, 50.72(SD=11.68) control No significant group differences	Intervention group listened to audiotape of technique twice a day for 20 minutes each time for 8 weeks. Control group had standard care. Interventionist: Unidentified	Pain numeric rating scale	A significant difference in mean pain scores between groups (p=0.01). Mean score of pain intensity had significantly decreased within intervention group.	- Participants with physical limitations were excluded from the study. - Anxiety and stress not measured. - No report of comorbidities - No theory + Provided reliability and validity for measures.

+ Provided power analysis.

Chapter 3: Manuscript Two

This chapter presents the design and results of a feasibility study using Reiki to reduce pain among individuals receiving hemodialysis. This chapter is written in manuscript form for a journal following their manuscript requirements. It has yet to be submitted for publication.

Summary

Purpose: Pain is a significant problem for individuals undergoing hemodialysis. Renal disease, co-morbidities, concurrent symptoms, and dialysis procedures pose barriers to adequate pain management. The purpose of this study was to evaluate feasibility, examine construct validity of PROMIS computerized adaptive testing (CAT) instruments, and explore pain benefits of Reiki sessions conducted during hemodialysis.

Design: A one group, repeated-measures design was used.

Methods: Fifteen participants received Reiki for 20 minutes, twice a week for four weeks. Pain, fatigue, and depression were evaluated using established symptom scales and PROMIS CAT instruments.

Findings: Participants reported general relaxation feelings with Reiki and acceptability of using a touch-screen device to respond to web-based measures. Although staff were initially reluctant to engage patients for Reiki, they reported Reiki did not interfere with workflow and thought Reiki could be integrated into the practice setting. Significant, strong correlations with established symptom scales support construct validity of PROMIS CAT instruments. There was a significant decrease in mean symptom scores after four weeks of Reiki. Effect size values suggest a range of practical significance.

Conclusions: Findings suggest Reiki provides symptom relief for individuals receiving hemodialysis, and randomized clinical trials to establish Reiki's pain benefits in this population are warranted.

Hemodialysis is an essential treatment for end-stage renal disease (ESRD), with over 468,000 individuals receiving hemodialysis in the United States (U.S. Renal Data System, 2016). Pain is a significant problem in more than half of individuals undergoing hemodialysis, and is not being adequately controlled, with many people describing ineffective pain management (Claxton, Blackhall, Weisbord, & Holley, 2010; Davison, 2003; Williams & Manias, 2009). Davison and Jhangri (2005) established a relationship between depressive symptoms and chronic pain, finding that 55% (n=205) of individuals receiving hemodialysis reported pain interfered with their mood. In subsequent research, they found that individuals receiving hemodialysis (n=591) reported pain (72%), fatigue (92%), decreased well-being (91%), and depression (65%). They also reported that pain, fatigue, and decreased well-being accounted for almost 39% of physical health composite scores on the Kidney Dialysis Quality of Life Short Form (Davison & Jhangri, 2010). The etiology of this pain may be from numerous causes; it can be the result of concurrent comorbidities such as diabetes and vascular disease, or venipunctures and muscle cramping during the hemodialysis treatment itself (Davison, 2003; Williams & Manias, 2009). Although inadequate symptom management is not unique to nephrology, managing pain in the hemodialysis population poses unique challenges due to medication bi-products and renal clearance (Bailie, Mason, Bragg-Gresham, Gillespie, & Young, 2004; Davison, 2003).

Reiki is a non-invasive, natural system of healing that uses universal life-force energy to heal, relax, and restore the whole person (Meland, 2009; Richeson, Spross, Lutz, & Peng, 2010). Reiki emerged in the early 20th century in Japan and is a holistic modality that supports overall healing and well-being by moving and releasing blocks of

energy in the body that are contributing to illness or symptoms and promotes mental and emotional balance (Potter, 2007; Richeson et al., 2010; Vitale, 2007). Reiki has been studied as an adjunct therapy for pain, depression, anxiety, sleep, and quality of life with mixed results among procedural, surgical, and oncology populations (Baldwin, Vitale, Brownell, Kryak, & Rand, 2017; Birocco et al., 2012; Potter, 2007).

Literature Review

Conducting a recent review, Zins, Gross, and Hooke (under review) found that only a few groups of researchers (n=8) have evaluated complementary therapies for pain reduction among individuals undergoing hemodialysis and none reported Reiki sessions. Reiki is ideal for individuals during hemodialysis because Reiki is a holistic, passive therapy requiring low cognitive load and no movement, thus promoting much needed relaxation during fluid shifts and prolonged periods of immobility during hemodialysis treatments. Exploring the role of complementary therapies for symptoms such as pain, fatigue, and depression that can co-vary in chronic illness is crucial because pharmacologic therapies for these symptoms can lead to polypharmacy, drug to drug interactions and other side effects. Moreover, individuals receiving hemodialysis are becoming increasingly interested in using or are already using complementary and alternative treatments, such as mind-body techniques (Akyol, Yildirim, Toker, & Yavuz, 2011; Birdee, Phillips, & Brown, 2013).

Recent studies have supported the health benefits of Reiki, including improving pain and anxiety (Baldwin et al., 2017; Birocco et al., 2012), fatigue (Tsang, Carlson, & Olson, 2007), depression and mood (Bowden, Goddard, & Gruzelier, 2011), and decreasing symptoms of clinician burnout (Rosada, Rubik, Mainguy, Plummer, & Mehl-

Madrona, 2015). Results of these studies should be cautiously interpreted due to the limited number of randomized controlled trials, lack of sham and control groups, small sample sizes, population characteristics, and variations in protocol frequency and duration.

Patient-reported outcomes measures are crucial for evaluating whether therapies and treatments are improving patient health. The Patient-Reported Outcomes Measurement Information System (PROMIS) was funded by the National Institutes of Health and offers a collection of precise and efficient tools to measure individual functioning and health-related quality of life across a wide variety of healthy and chronic illness populations (Cella et al., 2010). Some of these tools include item banks and computerized adapted testing (CAT) instruments. An item bank is a collection of statements or questions to evaluate the frequency or severity of a symptom or functional problem. A CAT instrument is one way to administer an item bank. A CAT instrument begins with a single item, and then depending on the response, presents additional items until responses are sufficient to accurately assess the individual's symptom level. A unique characteristic of all PROMIS item banks is that results are reported on a T-score metric (a mean of 50 and SD of 10) that is standardized to mean levels of each outcome measured in the healthy U.S. general population (Rothrock et al., 2010). PROMIS item banks and CATs provide reliable and precise measures of patient-reported symptoms and mental and physical function comparable to established self-report scales (i.e., "legacy measures"). Furthermore, PROMIS CAT instruments using the PROMIS item banks are expected to produce a more precise measurement of symptom experience using fewer items than a comparable established symptom scale or a paper and pencil PROMIS short

form, therefore reducing participant burden (Cella, Gershon, Lai, & Choi, 2007). PROMIS item banks for pain, fatigue, and depression have been validated for use in several chronic disease populations, including back pain, cancer, heart failure, chronic obstructive pulmonary disease, and rheumatoid arthritis (Amtmann et al., 2010; Cook et al., 2015; Pilkonis et al., 2011).

Reiki's role in holistic symptom management among individuals receiving hemodialysis has not been evaluated. The primary purpose of this one group, repeated-measures pilot study was to evaluate the feasibility of a four-week Reiki intervention for individuals receiving hemodialysis and examine the construct validity of PROMIS CAT instruments by comparing CAT instrument results to results from legacy measures for pain, fatigue, and depression. In addition, potential benefits associated with Reiki were explored.

Conceptual Framework

Rogers' (1970) science of unitary human beings guided this study. Based in Eastern philosophy that all living things are supported by universal life force energy, Rogers' framework is distinctive to nursing and conceptualizes the individual as an energy field continuously interacting within his or her environment. Well-being requires a balanced, continuous energy flow throughout the mind, body, and environment. Disruptions, blockages, or deficits in energy can result in physical and mental health deterioration (Ring, 2009). By strengthening the individual energy field and balancing both the individual and environmental fields, Reiki can promote well-being and aid in improving symptom management.

Methods

Design and Sample

For this feasibility study, a within-subjects, single group, pre- and post-intervention design with repeated measures was used. The setting was an outpatient hemodialysis clinic affiliated with a major-medical center in the Upper Midwest. A convenience sample was used. Patients were invited to take part in the study if they met the following inclusion criteria: aged 18 years or older, English speaking, currently undergoing hemodialysis at least three times per week, receiving hemodialysis for greater than six months, and cognitively intact as evidenced by a score of 26 or greater on the Montreal Cognitive Assessment Tool (Nasreddine et al., 2005). Patients were excluded if they could not read or understand English. In addition to individuals undergoing hemodialysis participating, hemodialysis staff were also asked to participate in a workflow impact survey at study completion.

Ethical Considerations

This study was approved by the Institutional Review Boards of the University of Minnesota and Mayo Clinic. Hemodialysis staff gave the study brochure to patients and asked patients if they would be interested and willing to speak with the research team. Interested patients met with the researcher to learn more about the study, were evaluated for eligibility, and were invited to participate in the study during their regularly scheduled hemodialysis sessions. All participants signed consent documents.

Reiki Session Protocol

Hemodialysis sessions typically occur three times per week on a Monday, Wednesday, Friday or Tuesday, Thursday, Saturday schedule. The Reiki sessions were

administered during the second and third hemodialysis sessions of the week, as toxic bi-products have more time to accumulate in the blood stream before the first treatment of the week and this may negatively affect participants' symptom experience. The intervention occurred approximately one hour after hemodialysis began to ensure adequate blood pressure for hemodialysis treatment and provide time for participants to adjust to fluid shifts.

The intervention protocol consisted of a series of hand placements allowing energy flow while hands were held for four minutes at each of five positions over the participant's clothes. This treatment time is similar to Reiki protocols used by Catlin and Taylor-Ford (2011) and Miles (2003). Participants were in a seated or reclined position in a recliner during hemodialysis. The treatment began with three head positions (top, sides, and forehead and back of skull) and continued to two upper body positions (neck and shoulders). To ensure treatment fidelity, a level II Reiki practitioner (SZ, the study investigator) performed all Reiki sessions. Participants were asked to state if they felt uncomfortable with touch at any time so the practitioner would know to move her hands away. Protocol treatment frequency and time for Reiki healing were 20 minutes, two times per week for four weeks during hemodialysis sessions. As protocols vary among the published studies as to timing, duration, and frequency of intervention, this protocol was created specifically for the outpatient hemodialysis population. Reiki requires no specific setting and can be adapted to any clinical setting. Treatment fidelity was maintained and assessed by maintaining a timekeeping log to remain consistent with Reiki timing during hemodialysis sessions, and by supervision of research assistants during data collection.

Measures

Participants completed a series of self-report symptom instruments using an online, touch screen device connected to the PROMIS Assessment Center (www.assessmentcenter.net). The Assessment Center is an online research organization that manages and administers the PROMIS CAT instruments and other study-specific instruments. Instruments were completed pre- and post- each Reiki session, as described in Table 1. All legacy measures and PROMIS CAT instruments were collected once per week, pre-Reiki because of recall periods. All VAS measures were collected four times per week, pre- and post-Reiki. The legacy measures were chosen because they have been validated and widely used for symptom assessment in the hemodialysis population. The briefer PROMIS CAT instruments were included to evaluate their construct validity relative to these established self-report scales. Because they were developed using item response theory and administered via CAT, which selects different items for each participant, the reliability of the PROMIS CAT instruments cannot be assessed using Cronbach's alphas.

Legacy Measures. The Brief Pain Inventory (BPI) is a measure of pain interference that assesses the severity of pain and the impact of pain on daily functions over the last seven days. The BPI includes four pain intensity items and seven pain interference items. The BPI has internal consistency across cultural backgrounds and disease populations, including the hemodialysis population (Davison, 2003; Davison & Jhangri, 2005; Golan, Haggiag, Os, & Bernheim, 2009). Cronbach alpha reliability for the BPI ranges from 0.77 to 0.93. In this sample, the Cronbach alpha at baseline was 0.92, which is excellent.

The Functional Assessment of Chronic Illness Therapy-Fatigue Scale (FACIT-F) is a 13-item questionnaire that assesses self-reported fatigue and the impact upon daily activities and function over the past seven days. The FACIT-F has been validated for use in chronic illness and has an internal consistency reliability > 0.91 (Butt et al, 2013). In this sample, the Cronbach alpha was 0.73 at baseline; values of 0.70 or higher are adequate for group comparisons.

The Beck Depression Inventory II (BDI II) is a 21-item tool to assess the intensity of depression over the past two weeks. The BDI II has been used in studies of dialysis patients (Griva, Davenport, Harrison, & Newman, 2010; Kimmel et al., 2000). The BDI II has an internal consistency reliability of 0.92 (Beck, Brown, & Steer, 1996). In this sample, the Cronbach alpha at baseline was 0.75.

Short Forms and Visual Analog Scales. The BPI short form (BPI-SF) includes seven items measuring pain interference and two items measuring pain intensity in the last 24-hours. Cronbach alpha reliability ranges from 0.77 to 0.93. In this sample, the Cronbach alpha at baseline was 0.80.

The BDI fast screen (BDI-FS) extracts seven symptoms from the BDI II. A strong correlation (Pearson $r = 0.85$, $p < 0.0001$) and specificity of 91.8% (95% CI: 84.5%, 96.4%) exists between the BDI-FS and BDI II in patients undergoing hemodialysis (Neitzer, Sun, Doss, Moran, & Schiller, 2012). In this sample, the Cronbach alpha for the BDI-FS was 0.74 at baseline.

Eleven-point visual analog scales (VAS) were used to measure participants' pain, fatigue, and depression immediately pre- and post-intervention. Participants were asked

to rate the amount of pain, depression, or fatigue they were experiencing ranging from 0 (none) to 10 (as bad as you can imagine).

PROMIS. All PROMIS item banks use five-level response options to reflect frequency or intensity. The PROMIS CAT instruments are programmed to administer enough items from the symptom specific item banks to achieve a standard error <0.30 (corresponding to reliability >0.90). The first item is always in the middle range of the symptom concept to roughly estimate the individual's health status. The following items refine this estimate until the estimated level of the symptom reaches the benchmark for reliability (Forrest et al., 2012). The PROMIS instruments have a seven-day recall period. All PROMIS instruments were administered via CAT once per week during this study.

The PROMIS Pain Interference (PI) instrument was developed to measure participants' severity of pain and interference with activities of daily living (ADLs). Choi et al. (2012) used the BPI Interference subsection for evaluation of the PROMIS PI instrument. They reported a Cronbach's alpha internal consistency for the 40-item PROMIS PI item bank of 0.987. The PROMIS Fatigue instrument was designed to evaluate a range of subjective symptoms that likely decreases an individual's ability to perform daily activities. Fatigue is separated into the experience of fatigue and the impact of fatigue on ADLs. Choi et al. (2012) utilized the FACIT-F for evaluation of the PROMIS Fatigue instrument. They reported a Cronbach's alpha internal consistency for the 95-item PROMIS Fatigue instrument of 0.994. The PROMIS Depression instrument was developed to assess subjective negative mood, self-views, social cognition, and decreased positive affect and engagement. Choi et al. (2012) utilized The Center for Epidemiologic Studies Depression Scale for evaluation of the 28-item PROMIS

Depression instrument and reported a Cronbach's alpha internal consistency for the PROMIS Depression instrument of 0.980.

Participant Acceptability and Staff Perceptions of Workflow. Investigator-developed, web-based surveys composed of five questions each were used to assess participant acceptability of web-based data collection tools, and perceived workflow interference for hemodialysis staff, including nurses and technicians. The participant survey was completed on the last day of the intervention and included items related to using a touch-screen device and completing measures electronically, as well as one open-ended item to allow for overall comments. The staff survey was emailed to staff caring for patients receiving Reiki at the completion of the study. This questionnaire contained four items related to impact of Reiki on workflow and integration of Reiki into their practice, as well as one open-ended item to allow for comments about the study.

Analysis

Quantitative data were analyzed using IBM SPSS Statistics version 22 (IBM Corp, Armonk, NY, USA). Descriptive statistics were calculated and distributions were examined for all variables. Demographic data were described using proportions or means, ranges, and standard deviations. Cronbach's alphas were calculated for each legacy measure at baseline and reliabilities of 0.70 or above were considered satisfactory for group data (Nunnally & Bernstein, 1994). Feasibility was assessed by calculating the accrual rate as the percentage of patients providing informed consent over the number invited to participate. Reasons for not participating in the study were recorded. Compliance rates with Reiki were summarized by the number of treatments that were delivered divided by the number of treatments expected by protocol. Baseline scores are

defined as Study Week 1, Reiki Session 1 pre-intervention. Study completion scores are defined as Study Week 4, Reiki Session 7 pre-intervention for all measures except the VAS, which were analyzed Study Week 4, Reiki Session 8, post-intervention. Correlations were used to explore relationships between the PROMIS CAT instruments and the BPI, BPI-SF, FACIT-F, BDI II, BDI-FS, and VAS. Strength of the association for absolute values of *r* was measured as very weak (0-0.19), weak (0.2-0.39), moderate (0.40-0.59), strong (0.6-0.79), and very strong (0.8-1) (Wechsler, 1997). Pre- and post-intervention data were compared using paired t-tests. Comparisons included same day, pre- to post- VAS changes, as well as baseline to study completion changes. Effect sizes were calculated using Cohen's *d* statistic. Magnitudes of the effect sizes were classified as small (0.2-0.49), medium (0.5-0.79), or large ($\geq$ 0.8) (Cohen, 1992). A p-value < 0.05 was considered statistically significant. *P*-values between 0.05 and 0.10 were considered slight differences. There was not adjustment for multiple comparisons.

Results

Participants

Demographics of the participants are summarized in Table 2. Participants' ages ranged from 30-85 years (Mean=59.33, SD=14.75) and a majority were male, married, and Caucasian. Diabetes was the most common comorbidity and being on hemodialysis two to four years was typical.

Feasibility

There were 89 patients at the hemodialysis center during the recruitment window, of these 63 spoke English and were given the study brochures by hemodialysis staff. Seventeen of the 63 patients (27%) expressed interest in participating, and 15 of the 17

interested patients (88%) completed the consenting process after being screened for eligibility, and enrolled in the study. “Not interested” was the reason provided for not participating in the study; no one was eliminated based on exclusion criteria. Reiki session compliance rates were high, as 93% of participants completed all eight sessions. One participant missed one Reiki session. The rate of completion of web-based measurements was also high, with 1,194 out of 1,200 (99%) measurements completed.

Participant Acceptability. At study completion, the participants were asked questions regarding their perception of the acceptability of using a touch-screen device to complete web-based assessments. Overall, participants found the touch screen device easy to use (73%), required little skill (93%), they enjoyed using the device (80%), and preferred the device over paper and pencil measures (93%). When asked to provide comments about their study experience, participants described feelings of relaxation and described Reiki as pleasant. The following quote is an exemplar: “The Reiki was wonderful. I always feel so relaxed.” Participants also described Reiki as helping to relieve pain. For example, one participant stated: “This was amazing. I felt so relaxed and I really feel like my pain has gone down.”

Staff Perceptions of Workflow. The staff workflow questionnaire was sent to 14 individuals and answered by 11 (76%) hemodialysis staff. They reported that Reiki did not impact clinical flow (91%), and dialysis monitoring was completed as usual (91%). Although most thought Reiki could be integrated into their practice setting (73%), only a minority reported being personally interested in offering Reiki (27%). Comments provided by hemodialysis staff described observations of patients. The following quotes

are examples: “I saw the patients really enjoyed and looked forward to the sessions” and “patients seem to enjoy the Reiki stating it helped with their pain.”

Construct Validity

Correlational analyses were used to evaluate the construct validity of the PROMIS CAT instruments relative to legacy measures at baseline (see Table 3). For pain, very strong, positive correlations were found between both the BPI and BPI-SF with the PROMIS CAT PI instrument ($p<.01$). For fatigue, a very strong, negative correlation between the FACIT-F and the PROMIS CAT Fatigue instrument was found ($p<.01$). An inverse relationship exists because the FACIT-F is scored such that higher scores equal better quality of life and less symptom burden, while the other measures are scored such that higher scores equal worsening symptoms. For depression, the BDI-FS was positively, strongly correlated with the PROMIS CAT Depression instrument ($p<.01$), whereas the BDI II correlation with the PROMIS CAT Depression instrument was moderate.

To examine discriminant validity, correlations were calculated between baseline scores of instruments measuring different symptoms. The PROMIS CAT PI instrument was more strongly related to the BPI and BPI SF than to any fatigue or depression measure. The PROMIS CAT Fatigue instrument was more strongly correlated with the FACIT-F than to any other measure. The PROMIS CAT Depression instrument was more strongly correlated to the BDI-FS than any other measure. Cross-symptom correlations showed that pain and fatigue, and fatigue and depression, appeared to be more strongly related than pain and depression.

To assess the responsiveness to change of the PROMIS CAT instruments relative to the legacy measures, correlations of change scores from baseline to study completion between legacy measures and PROMIS CAT instruments were calculated (See Table 4). Strengths of correlations between these change scores were lower than the correlations between baseline scores. A positive, moderate correlation was found between the changes on the PROMIS CAT PI instrument and the BPI and BPI-SF changes ($p<.05$). A negative, strong correlation was found between the PROMIS CAT Fatigue instrument changes and the FACIT-F changes ($p<.01$). Positive, very weak to weak correlations were found between the PROMIS CAT Depression instrument changes and the BDI II and BDI-FS changes.

Relationships between long and short legacy measures, and between VAS and other instruments for each symptom at baseline were also examined. As expected, a positive, very strong correlation was found between the BPI and BPI-SF ($p<.01$), and a positive, strong correlation was found between the BDI II and BDI-FS ($p<.01$). VAS correlations with legacy and PROMIS CAT instruments at baseline varied in strength by symptom domain. The correlations between the pain VAS and the BPI, BPI-SF, and PROMIS CAT PI instrument were only weak to moderate, whereas correlations between the fatigue VAS and the FACIT-F and PROMIS CAT Fatigue were moderate to strong, and correlations between the depression VAS and the BDI II, BDI-FS, and the PROMIS CAT Depression were very weak to moderate.

Symptom Outcomes

Mean scores from baseline and study completion for each measure with effect sizes are presented in Table 5. There was a significant decrease in pain scores on all

measures: the BPI and BPI-SF Interference and Severity items, PROMIS CAT PI instrument, and pain VAS (p <.01, all). Fatigue scores also improved on all measures: FACIT-F (p<.01), PROMIS CAT Fatigue instrument (p<.05), and fatigue VAS (p<.01). Improvement in depression scores as measured by the BDI II, BDI-FS, and depression VAS were significant (p <.01), however there was a little change in scores on the PROMIS CAT Depression instrument. The effect sizes of the pain and fatigue VASs were large from baseline to study completion (d=0.80 and 0.87 respectively), the BPI-SF Interference and Intensity items and two of the BPI Intensity items were medium (d=0.53-0.66), whereas the effect sizes for the remaining measures were small (d=0.24-0.48).

The Reiki session-by-session effects on pain, fatigue, and depression measured by VAS are depicted in Figures 1a, b, and c respectively. The mean pre-VAS scores from Week 1 to Week 4 decreased and reductions were statistically significant, indicating symptom improvement. Visual analog scores decreased from baseline to study completion. Pain VAS scores decreased from to 4.73 to 0.87 (p <.01), fatigue VAS scores decreased from 5.27 to 0.87 (p <.01), and depression VAS scores decreased from 1.60 to 0.73 (p <.01). Average pain ratings were reduced by 3.86 points, and can be considered clinically significant (Farrar, Young, LaMoreaux, Werth, & Poole, 2001).

Discussion

To our knowledge, this is the first study of the role of Reiki for individuals receiving hemodialysis. Findings demonstrate that it is feasible to provide Reiki in the outpatient hemodialysis setting without disrupting patient care. Compliance rates for Reiki and completion rates of questionnaires were excellent, reinforcing that individuals

undergoing hemodialysis adhere to treatments they perceive as simple and effective (Kammerer, Garry, Hartigan, Carter, & Erlich, 2007).

Overall, participants liked using the touch-screen device and completing measures online. This online method offers researchers and clinicians more flexibility in methods of data collection, immediate scoring for comparison to the general population, and across multiple health conditions. Although an internet connection is required, the PROMIS CAT instruments minimize participant burden while preserving reliability as fewer questions are asked, less time is often required, and there is less risk of missing data.

The original target sample size for this study was 20 participants. Recruiting the full 20 participants in the 2-month period allocated for accrual was not possible, but our experience provides valuable data for planning recruiting strategies and estimating recruitment rates for future studies. In our study one in four patients was willing to speak with our research team. This low participant accrual rate is in contrast to surveys suggesting that many individuals with kidney disease seek out complementary therapies (Osman, Hassanein, Leil, & NasrAllah, 2015), and that complementary treatments are becoming more readily accepted among the hemodialysis population (Birdee, Phillips, & Brown, 2013). Upon reflection, it is likely that our recruiting efforts did not fully tap into this trend due to reliance of hemodialysis staff to approach patients. Hemodialysis bedside staff were initially skeptical of Reiki and the potential impact on participants, which could have discouraged patient participation. The support of staff is pivotal to successful recruitment and participation, especially for holistic, complementary interventions. Increasing collaboration and investment with nursing staff, describing

potential benefits and low risk of side effects more in-depth, and discussing impact of cost and patient choice in therapies may help improve recruitment (Ferraresi et al., 2013). However, upon study completion, staff verbalized they were pleased that Reiki did not impact workflow and believe it would be beneficial in the hemodialysis setting. This suggests that preceding a full study with targeted efforts to engage staff support will be important for achieving recruitment goals in future trials.

One of the aims of this study was to examine the construct validity of the PROMIS CAT instruments in participants receiving hemodialysis as these measures were designed to be appropriate for a wide range of chronic illnesses. Overall, PROMIS CAT instrument scores were significantly and strongly to very strongly correlated with the symptom-specific legacy measures at baseline for pain and fatigue. Correlations between the PROMIS CAT Depression instrument and the BDI-FS were also strong and significant, but correlations with the BDI II were only moderate. Concurrent validity with legacy measures was strong for pain and fatigue, and reasonably good for depression. The PROMIS CAT instruments were adequately, but slightly less responsive than their corresponding legacy measures. These findings suggest that the legacy measures may be preferable to the PROMIS CAT instruments as a primary clinical trial outcome, but these responsiveness results will need to be confirmed in larger studies.

Discriminant and longitudinal validity findings also support the construct validity of the PROMIS instruments. The PROMIS CAT instruments are designed for the multidimensional measurement of symptom severity or experience, thus they not only capture the intended symptom experience, but can also indirectly capture another symptom experience as is consistent with our results, supporting discriminant validity.

Correlations between measures and symptoms over time remained similar, but weaker and less significant than at baseline, as should have been expected as change scores have more sources of variability than a one-time score. Although the sample size for this study was small, the results are favorable, particularly for pain and fatigue, that the PROMIS CAT instruments may serve as a replacement for standard, longer measures, particularly as secondary outcomes in clinical trials.

Additionally, the findings also show the pain and fatigue VAS to be relatively sound outcome measures with a large degree of responsiveness and validity properties, as compared to the depression VAS for patients receiving hemodialysis. The VAS is helpful clinically when determining severity or intensity of symptoms, but lacks the multidimensional capability of legacy and PROMIS CAT instruments for assessing symptom experience and impact on quality of life. It is possible that participants were ranking their level of sadness (or any single aspect of depression) on the depression VAS, whereas the multidimensional measures were able to examine the many aspects of depression in addition to the experience of sadness to determine overall severity and interference.

Participants had significant decreases in pain, fatigue, and depression consistent with Reiki research in other populations. Previous research has shown that Reiki has been linked to reduced pain in surgical and oncology populations (Birocco et al, 2012; Sagkal Midilli & Ciray Gunduzoglu, 2016; Vitale & O'Connor, 2006). Reiki has also been found to reduce fatigue and depression as well as increase relaxation and improve well-being, aspects that are important in contributing to overall quality of life (Richeson et al., 2010; Tsang, Carlson, & Olson, 2007). With effect sizes ranging from 0.46-0.80 on pain

interference and significant decreases in pain, results provide a foundation for future efficacy studies of Reiki in decreasing pain levels among this population. Furthermore, scores on fatigue and depression also decreased over the course of eight Reiki sessions, suggesting the impact of Reiki might be cumulative.

Scores on PROMIS CAT instruments in this sample were close to one standard deviation worse than the general U.S. population for pain, and about half a standard deviation worse for fatigue. The depression domain was less than half of a standard deviation worse than the general U.S. population. At baseline, participants reported mild to moderate pain and fatigue and very mild depression, levels lower than those described in the literature (Davison & Jhangri, 2005; Kimmel & Peterson, 2005). Selection bias and small sample size could account for these results, as those with the highest burdens may have been the least willing to engage with researchers, and encouragement to try Reiki was probably minimal, given the staff attitudes at study onset.

Limitations

Limitations of the current study include the small sample size and relatively short intervention period. As the primary outcome was feasibility, a convenience sample was selected, although the sample size for this study (N=15) was below the desired level. Sampling may have led to under- or over-representation of certain features within our sample, such as symptom experience. Score variability from the current study could be helpful for determining sample size in a larger clinical trial over a longer intervention period. We calculated effect sizes for pain, fatigue, and depression, which suggest small to large-sized effects of Reiki overall. Future larger, longitudinal studies will help

identify minimum clinically important differences, and responsiveness to change in the hemodialysis population.

Another limitation was lack of active control condition and no randomization. In this study we were not able to isolate effects due to Reiki from the effects attributable to receiving attention from the Reiki practitioner. Future studies would benefit from comparison conditions that control for this factor. Research on Reiki in individuals receiving hemodialysis should also expand into differentiating differences between sham Reiki vs Reiki. There was also no control for the presence of the nurse in the current study, a factor that could improve patient outcomes.

Lastly, there was potential that uncontrollable variables could have possibly affected participant scores on their questionnaires. Patients with pre-existing depression, psychiatric disorders, chronic pain, or specific comorbidities were not excluded. We did not track medication use or titration for any of the symptoms. Since participants had been on dialysis for years, it is unclear what other factors might have led to improvements in pain from the beginning to the end of the study.

Significance

This study provided valuable information on untapped potential to improve symptom management for individuals receiving hemodialysis. This pilot study established a preliminary framework and foundation for further rigorous holistic research. The current study expands the opportunities for conducting Reiki research by demonstrating the feasibility and acceptability of the delivery of Reiki in an outpatient hemodialysis setting and examining Reiki's impact on patient-reported outcomes. Promising evidence was found that brief, web-based data collection tools can be used to

assess symptom outcomes during hemodialysis. Additional research is necessary to determine the overall efficacy of Reiki on symptoms among individuals receiving hemodialysis compared to a randomized control group. As this current study was a pilot project, future studies could address the limitations of this study and focus on Reiki and symptom experience in a larger population and in patients with specific types of renal disease or comorbidities.

The premise that a relaxing, passive, and non-invasive intervention such as Reiki is feasible and possibly efficacious for disease and treatment-related symptom burden confronts the current healthcare system weaknesses that treatments often rely heavily on pharmaceuticals. Individuals with ESRD are among the most symptomatic of any chronic disease group (; Davison, 2007; Weisbord et al., 2005), and drug side effects and drug-drug interactions are particular problems for those with compromised kidney function. Reiki is inexpensive, has no known side effects or interactions with medications, and can be incorporated during already scheduled hemodialysis appointments to reduce burden of extra appointments on patients and the resources of dialysis units. This study illustrates that Reiki has potential effectiveness to reduce symptoms. Reiki may play a role in the multidimensional management of individuals undergoing hemodialysis and promotes the complementary therapy goal of safe, non-pharmacological interventions as adjuncts to medical treatments.

Conclusion

Our study demonstrated that Reiki has no side effects and is appreciated by patients, although staff reluctance remains a barrier to implementing complementary therapies. Reiki seems to be a promising, holistic adjunct for pain relief. Advancing

research on nonpharmacological, complementary approaches of symptom relief is valuable to individuals receiving hemodialysis, as well as their friends and families. Additionally, Reiki could be of significant financial impact to insurers, patients, and providers as incorporating cost-effective approaches that can be performed by nurses and other healthcare professionals is desired. Hemodialysis affects many aspects of everyday life and overall well-being. Investigation and consideration of new approaches will provide individuals receiving hemodialysis with added resources to help alleviate their symptoms and improve satisfaction with care.

Table 1

Summary of Instruments and Timing of Data Collection

	Week 1		Week 2		Week 3		Week 4	
	Reiki Session		Reiki Session		Reiki Session		Reiki Session	
Measure	1[a]	2	3	4	5	6	7[b]	8[c]
Visual Analog Scale-Pain	Y	Y	Y	Y	Y	Y	Y	Y
Brief Pain Inventory	X		X		X		X	
Brief Pain Inventory-SF	X		X		X		X	
PROMIS Pain Interference	X		X		X		X	
Visual Analog Scale-Fatigue	Y	Y	Y	Y	Y	Y	Y	Y
FACIT-Fatigue	X		X		X		X	
PROMIS Fatigue	X		X		X		X	
Visual Analog Scale-Depression	Y	Y	Y	Y	Y	Y	Y	Y
Beck Depression Inventory II	X		X		X		X	
Beck Depression Inventory II-FS	X		X		X		X	
PROMIS Depression	X		X		X		X	

Note. The VAS measures were collected pre- and post each Reiki session. All other measures were collected pre-Reiki session once per week, first session of the week, sessions 1,3,5, and 7. X= measured only pre-Reiki, Y= measured pre- and post-Reiki.
[a]Baseline scores are defined as Study Week 1, Reiki Session 1, pre-intervention. [b]Study completion scores are defined as Study Week 4, Reiki Session 7, pre-intervention for all measures except the VAS. [c]Study completion scores for VAS are defined as Study Week 4, Reiki Session 8, post-intervention.

Table 2

Baseline Characteristics of the Sample (N=15)

	n	%
Gender		
Male	11	73.3
Female	4	26.7
Racial/ethnic background		
Non-Hispanic White	10	66.7
Black	1	6.7
Hispanic	3	20.0
Other	1	6.7
Religion		
Islamic	1	6.7
Protestant	7	46.7
Roman Catholic	5	33.3
Other	2	13.3
Marital Status		
Single, never married	3	20.0
Married/committed relationship	9	60.0
Divorced	2	13.3
Widowed	1	6.7
Education		
Some High School	1	6.7
High School	1	6.7
Some college or vocational	8	53.3
Bachelor's Degree	5	33.3
Employment		
Employed	3	20.0
Retired	7	46.7
Disabled	4	26.7
Other	1	6.7
Comorbidity		
Hypertension	8	53.3
Coronary artery disease	6	40.0
Heart failure	2	13.3
Polycystic kidney disease	2	13.3
Peripheral vascular disease	1	6.7
COPD	2	13.3
Diabetes	11	73.3
Obstructive sleep apnea	4	26.7
Anxiety disorder	1	6.7
Depression	3	20.0
Malignancy	1	6.7

Other	6	40.0
Time on hemodialysis		
6 months	1	6.7
1 year	4	26.7
2-4 years	7	46.7
4-6 years	1	6.7
Greater than 6 years	2	13.3

Table 3

Baseline Correlations among Measures of the Same Symptom Concept and Cronbach Alphas for Legacy Measures (N=15)

	BPI	BPI-SF	Pain VAS	PROMIS PI	FACIT-F	Fatigue VAS	PROMIS Fatigue	BDI II	BDI-FS	Depression VAS
BPI	**.92**									
BPI-SF	.957**	**.80**								
Pain VAS	.391	.466	**NA**							
PROMIS PI	.899**	.892**	.495	**NA**						
FACIT-F	-.757**	-.814**	-.302	-.620*	**.73**					
Fatigue VAS	.357	.528*	.789**	.396	-.597*	**NA**				
PROMIS Fatigue	.623*	.727**	.339	.460	-.893**	.716**	**NA**			
BDI II	.226	.397	.486	.387	-.507	.799**	.612*	**.75**		
BDI-FS	-.232	-.078	.193	-.024	-.233	.505	.293	.782**	**.74**	
Depression VAS	-.073	.014	.292	.001	-.014	.395	.171	.575*	.392	**NA**
PROMIS Depression	-.208	-.101	.241	.018	-.010	.372	-.040	.498	.713**	.173

Note. Values given in bold are Cronbach alphas for each legacy measure. PROMIS CAT Fatigue instrument is scored such that lower scores equal improvement.

*Correlation is significant at the 0.05 level (2-tailed). **Correlation is significant at the 0.01 level (2-tailed).

Table 4

Mean Change Score Correlations among Measures of the Same Symptom Concept (N=15)

	BPI	BPI-SF	Pain VAS	PROMIS PI	FACIT-F	Fatigue VAS	PROMIS Fatigue	BDI II	BDI-FS	Depression VAS
BPI										
BPI-SF	.800**									
Pain VAS	.125	-.021								
PROMIS PI	.551*	.518*	.056							
FACIT-F	-.525*	-.507	-.177	-.570*						
Fatigue VAS	.228	.225	.287	.074	-.328					
PROMIS Fatigue	.455	.550*	.004	.478	-.711**	.467				
BDI II	.135	.302	.177	.343	-.597*	.622*	.635*			
BDI-FS	-.206	-.115	.309	.028	-.145	.313	.169	.573*		
Depression VAS	-.333	-.452	-.198	-.209	.191	-.424	-.051	-.038	-.137	
PROMIS Depression	-.329	-.107	-.257	-.263	.109	.049	-.262	.001	.278	-.467

Note. PROMIS CAT Fatigue instrument is scored such that lower scores equal improvement.
*Correlation is significant at the 0.05 level (2-tailed). **Correlation is significant at the 0.01 level (2-tailed).

Table 5

Baseline versus Study Completion Changes in Pain, Fatigue, and Depression

	Baseline[1]		Study completion[2]			95% CI	Effect Size (*d*/Pooled SD)
Measure	Mean	SD	Mean	SD	Paired *t*-test		
BPI Interference	27.73	14.57	14.60	8.32	5.102, $p<.01$	[-18.66, -7.61]	0.48
BPI Intensity							
Worst pain	7.47	1.92	4.53	1.85	-8.191, $p<.01$	[-3.70, -2.17]	0.61
Average pain	4.33	1.68	2.67	1.35	-5.801, $p<.01$	[-2.28, -1.05]	0.48
Least pain	1.73	1.16	0.27	0.46	-5.047, $p<.01$	[-2.09, -0.84]	0.64
BPI-SF Interference	27.20	14.64	12.73	7.50	-4.920, $p<.01$	[-20.77, -8.16]	0.53
BPI-SF Intensity							
Worst pain	6.73	2.15	3.40	1.64	-6.070, $p<.01$	[-4.51, -2.16]	0.66
Average pain	4.20	1.47	2.40	1.24	-5.077, $p<.01$	[-2.56, -1.04]	0.55
Least pain	1.87	1.19	0.47	0.52	-4.583, $p<.01$	[-2.06, -0.75]	0.60
Pain VAS	4.73	1.83	0.87	0.83	-8.110, $p<.01$	[-4.89, -2.84]	0.80
PROMIS PI	59.66	4.76	54.64	4.88	-4.404, $p<.01$	[-7.46, -2.58]	0.46
FACIT-F	30.40	7.04	35.47	5.42	5.551, $p<.01$	[3.11, 7.02]	0.37
Fatigue VAS	5.27	1.39	0.87	1.06	-11.720, $p<.01$	[-5.21, -3.60]	0.87
PROMIS Fatigue	55.96	4.94	53.92	3.04	-2.322, $p<.05$	[-3.92, -0.16]	0.24

BDI II	14.00	5.54	10.53	3.91	-5.626, p<.01	[-4.79, -2.15]	0.34
BDI-FS	3.93	2.37	2.93	1.53	-3.090, p<.01	[-1.69, -0.31]	0.24
Depression VAS	1.60	1.12	0.73	0.88	-4.026, p<.01	[-1.33, -0.41]	0.40
PROMIS Depression	51.10	5.42	48.22	6.05	-1.947, p=.072	[-6.05, 0.29]	0.24

Note: FACIT-F is scored such that higher scores equal better QOL and less symptom burden.
[1]Baseline scores are defined as Study Week 1, Reiki Session 1, pre-intervention [2]Study Completion scores are defined as Study Week 4, Reiki Session 7, pre-intervention for all measures except the VAS, which are defined as Study Week 4, Reiki Session 8, post-intervention.

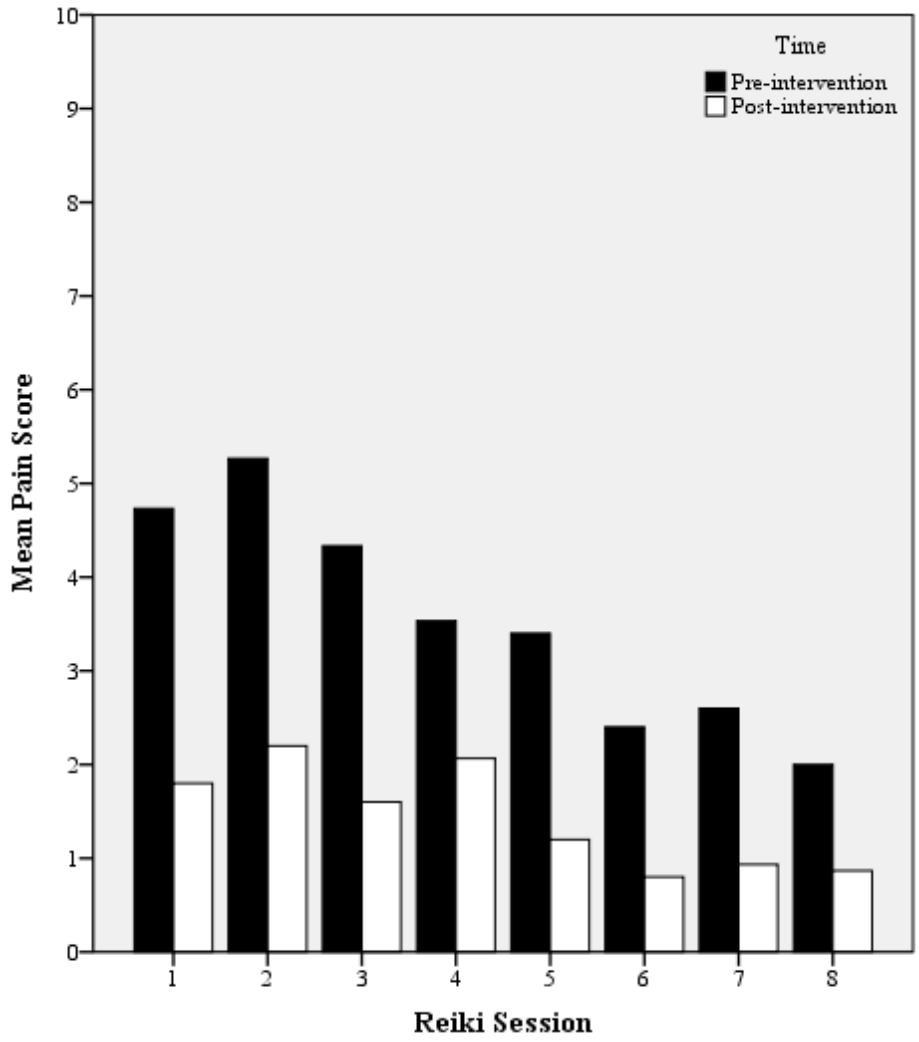

Figure 1a. Mean Pre- and Post-Reiki session: Daily trends for Pain VAS Scores

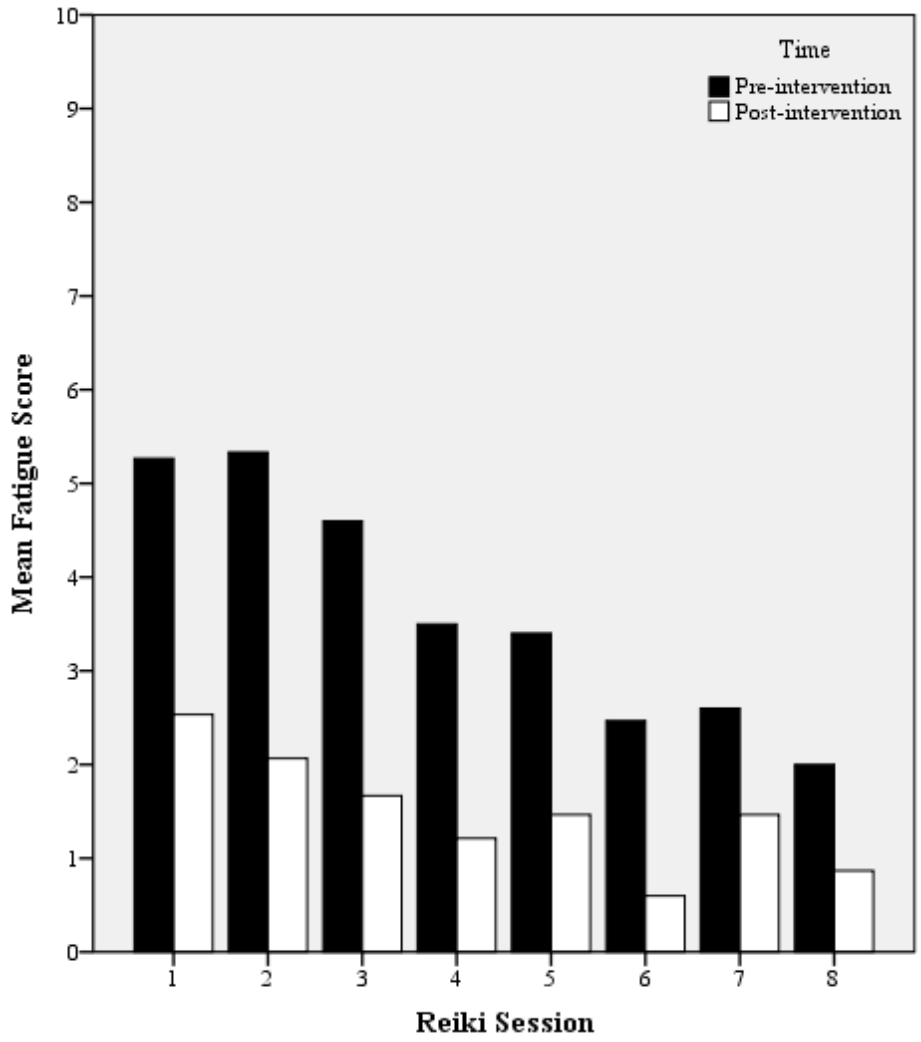

Figure 1b. Mean Pre- and Post-Reiki session: Daily trends for Fatigue VAS Scores

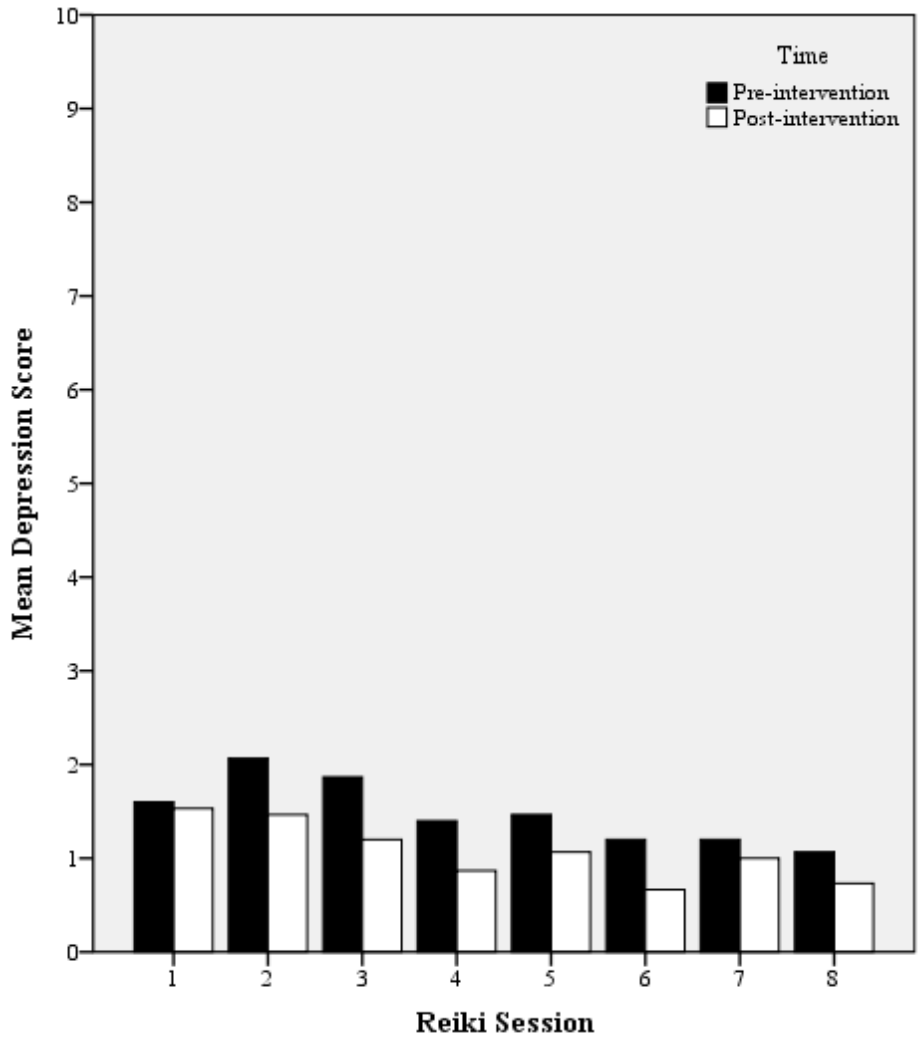

Figure 1c. Mean Pre- and Post-Reiki session: Daily trends for Depression VAS Scores

Chapter 4: Discussion

For this dissertation research I examined published reports of complementary therapy use for pain among individuals receiving hemodialysis, and evaluated the feasibility of implementing Reiki during hemodialysis, the construct validity of PROMIS CAT instruments, and the potential impacts of Reiki on pain, fatigue, and depression among individuals receiving hemodialysis. As individuals with end-stage renal disease are among the most symptomatic of any chronic disease group, it is imperative to provide practical and effective interventions to improve their quality of life (Weisbord et al., 2005; Davison, 2007). To the best of my knowledge, this dissertation reports the first evaluation of Reiki in individuals undergoing hemodialysis. These research findings provide guidance for future research and implications for hemodialysis clinical practice.

Nonpharmacologic, complementary therapy use for pain among individuals receiving hemodialysis was evaluated with a systematic literature review (Zins, Gross, & Hooke, under review). Multiple complementary therapy approaches were identified and several studies reported significant reductions in pain, although varying methodologies and lack of use of multidimensional pain measures limit generalizability of results. All eight reviewed studies were conducted in Mediterranean countries or Iran and pain reduction interventions included Hatha yoga, programmed distraction, reflexology, aromatherapy, Benson's relaxation method, or music. Results from the systematic literature review highlighted how few complementary therapy studies were conducted in Western healthcare settings for individuals receiving hemodialysis. Although there are many complementary therapy modalities with the potential to reduce pain, including mind and body therapies such as meditation, movement therapies such as Tai Chi, and

energy therapies such as Reiki, many have not been tested in this clinical population. Although some therapies many not be widely available or cost effective due to lack of experienced interventionists, potential time and cost involved, or safety, the studies reviewed demonstrated that a variety of therapies are accessible and acceptable to this vulnerable population within the countries studied. This systematic literature review supported the need to examine the feasibility of implementing Reiki among individuals receiving hemodialysis in the United States.

Feasibility of Reiki, construct validity of PROMIS CAT instruments, and potential symptoms impacts of Reiki were evaluated in a pilot study. Participant recruitment proved much more challenging than anticipated. The primary investigator discussed a recruitment timeline with the nephrologists from the hemodialysis clinic and decided that one month seemed feasible to recruit 20 participants as the clinic serves a stable cohort of patients and there is minimal influx of new patients. All 15 participants were recruited in the first two weeks, and after that, recruitment stalled and no other participants were identified from the population at the clinic even after extending the timeline to two months.

Overall, participants reported they enjoyed the Reiki sessions and were not bothered by multiple questionnaires completed via a touch screen device over the course of the study, as evidenced by high Reiki compliance, measure completion, and acceptance rates. Many hemodialysis staff were reluctant and lacked enthusiasm at study onset, as evidenced by lack of desire to ask questions and learn more about Reiki. However, after hearing comments from the participants and reportedly seeing improvement in their patients, the hemodialysis staff were satisfied that Reiki did not

impact their workflow and thought it could be used to improve pain and promote holistic care in their setting.

PROMIS CAT instruments can be completed quickly, have formats and time frames that are consistent across symptom domains, use concise language, are uniform with current guidelines for word usage, and have validated versions available in multiple languages that have been used in many chronic illness populations. Correlational analyses were conducted to assess the construct validity of the PROMIS CAT instruments compared to the legacy measures. Strong correlations were found between each PROMIS CAT and at least one of the established legacy instruments in every domain, supporting construct validity. The PROMIS CAT PI instrument was strongly correlated with both the pain legacy measures at baseline and changes in the PROMIS CAT PI were moderately correlated with changes over time in these legacy measures. The PROMIS CAT Fatigue instrument was strongly correlated with the fatigue legacy measure at baseline and changes in the PROMIS CAT Fatigue continued to be strongly correlated with changes over time in the legacy measure. The PROMIS CAT Depression instrument was strongly correlated with the short form legacy measure, but only moderately correlated with the long form legacy measure at baseline. Changes in the PROMIS CAT Depression were very weak to weakly correlated with changes over time in both legacy measures. Considering the need for quick, but accurate, assessments of pain and other symptoms in both research and clinical practice, the PROMIS CAT instruments are likely to play an important role in reducing response burden and optimizing measurement methods for assessing symptoms. Whereas these findings provide evidence of construct validity for the PROMIS CATs in the hemodialysis population, the responsiveness of

PROMIS CATs appeared to be somewhat less for these instruments than for the legacy measures. Therefore, larger trials to determine if the PROMIS CAT instruments would be suitable replacements for longer legacy measures as the primary pain outcome in randomized clinical trials and for tracking individual patient outcomes in the hemodialysis clinical setting are needed.

To explore whether potentially clinically meaningful changes in pain, fatigue, and depression symptoms were possible, changes in scores over time were tested for significance using 95% confidence intervals and paired t-tests. There were statistically significant decreases in pain, fatigue, and depression. Fatigue and depression confidence intervals (CIs) for most measures included symptom reductions which exceed one half standard deviation, a commonly used benchmark for clinically meaningful change (for example, 95% CIs for PROMIS CAT Fatigue and Depression instruments were [-3.92, -0.16] and [-1.33, -0.41], respectively). The pain CIs did include symptom reductions, but not to the same benchmark. These findings suggest larger scale Reiki trials are warranted to establish clinical efficacy and effectiveness. Moreover, there was also anecdotal evidence that participants benefitted from the Reiki protocol as evidenced by their written comments and statements of verbal appreciation to study staff. Although the sample size was too small to establish efficacy, evidence from this dissertation study provides support for a larger randomized clinical trial to measure efficacy of Reiki among this population.

Limitations

This dissertation study had several limitations affecting generalizability, but findings are suggestive of areas for future study and impacts likely to have clinical importance. Limitations included convenience sampling, small sample size, lack of long-

term follow-up, and single group design lacking a randomized control group to eliminate bias from extraneous variables, maturation, testing, and regression. In this pilot study, a convenience sample was drawn from a single local hemodialysis clinic. The study population and findings do not represent all individuals receiving hemodialysis, as individuals that did not speak English were excluded due to lack of availability of measures in languages other than English and lack of bilingual study staff. This study included a largely homogenous sample, mostly Caucasian and male. This study did include African American and Hispanic individuals in small numbers, consistent with the hemodialysis clinic population at the site, but proportionately much less than their presence in the hemodialysis population as a whole (USRDS, 2015). African American individuals are estimated to have a 3.5-fold higher incidence of end-stage renal disease than non-Hispanic white individuals, whereas Hispanic individuals are estimated to have a 1.5-fold higher incidence (USRDS, 2015). More than 35% of all individuals receiving hemodialysis in the United States are African American (National Kidney Foundation, 2016). Future research should assess if findings are similar or different in a larger, more diverse population of individuals receiving hemodialysis using probability sampling.

The main objective of this study was to assess feasibility; thus, sample size was not based on a power analysis. The small sample size can decrease the external validity of findings (limit generalizability to the larger hemodialysis population) and limit the power to identify Reiki effects when there are some to be identified (increase the likelihood of a Type II error). For example, the impact on depression found in this study was not statistically significant on all measures, but it is possible that statistically significant and clinically meaningful symptom reductions will be found if studied in a larger sample with

a higher level of depression symptoms at baseline. The small sample size also reduces precision of estimates, so confidence intervals can be wide indicating a relatively large margin of error. A basis for Reiki effectiveness cannot be reliably established in a small, unpowered sample. Effect sizes that can be detected are limited to large or very large impacts, and Type II error rates are higher than optimal. Therefore, the benefits of Reiki on pain found in this feasibility study must be interpreted as indications of possible effectiveness. Protocol adherence and patient acceptance support the feasibility of a future trial. Importantly, it would be premature to discard Reiki based on non-significant findings in a small pilot study, since estimates of impact in small samples can be unreliable (Leon, Davis, & Kraemer, 2011). The potential for meaningful improvement in symptoms with Reiki sessions is important among individuals receiving hemodialysis. The clinically meaningful difference is defined as being able to detect the smallest difference in symptom domain score which patients perceive as beneficial without side effects, cost burden, and a substantial change in the patient's management (Jaeschke, Singer, & Guyatt, 1989). Attempting to identify a difference below the clinically meaningful difference is not meaningful, even if it is statistically significant. This pilot study was not powered to detect differences, but the differences detected may be compared to benchmarks of clinically meaningful change. Future research with a sample size powered to detect clinically meaningful differences in pain is warranted.

Disease activity, pharmaceutical therapy changes, and natural fluctuations in symptoms could conceivably impact pain levels and should be considered in a future randomized, controlled efficacy study, powered to detect significant differences after adjustment for differences in these variables. Inferences about efficacy or identification

of long-term associations between Reiki and pain cannot be made with high confidence based on the current research. However, the present study does suggest significant short-term improvements in symptoms, supporting design and assessment of a future, full-scale confirmatory trial with long-term follow-up.

The lack of a randomized controlled trial design to remove bias is also a limitation. Incorporating multiple hemodialysis centers; randomizing participants; adding control, Reiki, and sham Reiki groups; and blinding or concealment of the intervention from hemodialysis staff, study staff, and patients would reduce biases. Systematic baseline differences between groups are eliminated when randomization is conducted and concealed, and generalizability is enhanced when participants are drawn from multiple hemodialysis centers. The study's internal validity would be increased by including a sham Reiki control group. This would eliminate the bias from patients' expectancies of benefit. Moreover, without including an active control or sham Reiki group, conclusions regarding the degree to which Reiki had effects above and beyond other aspects of the treatment, such as presence of a provider, are limited. The current pilot study suggests that improvements seen are evidence of the impact of Reiki, however future research using both longitudinal and experimental methods can provide stronger evidence of Reiki's effectiveness on pain in the hemodialysis population.

Implications for Research

There are important complementary therapy research implications for individuals receiving hemodialysis. The most important next step for research is conducting an adequately powered, randomized controlled trial, ideally including both control and sham Reiki groups to evaluate the efficacy of Reiki for pain in a sample drawn from a dialysis

center with a more diverse patient population. Adding a sham Reiki group will help account for human touch and interaction that is also present during Reiki sessions. In this feasibility study, a single Reiki dose was standardized and based on previous Reiki studies done in other populations. Future studies could examine extending or shortening the duration of Reiki sessions or times per week and measuring impact on pain, or tailoring Reiki doses to fit the needs of each individual.

This study supports the construct validity of the PROMIS CAT instruments. Further evidence in larger samples would be useful to confirm these findings. If PROMIS CAT instruments are found to be valid and reliable, they could be used in clinical settings to quickly understand an individual's symptom experience and manage the symptoms more effectively, as well as to measure outcomes in research settings to reduce burden on participants.

Researchers should also consider exploring mixed methods to capture more about individual experiences with Reiki. Although written comments were recorded, they were not evaluated with a standardized approach, which would increase methodological rigor (Horsburgh, 2003). A qualitative component could be implemented to elicit information about the overall hemodialysis symptom experience, Reiki impact on the symptom experience, and general feedback from the participants. For example, when determining Reiki dose, asking participants whether the intervention duration was adequate to experience changes in symptoms. This information could also help inform tailored Reiki sessions in the clinical setting.

An additional interventional approach for future research would be to teach Reiki to participants or family members to provide to themselves and measuring self-efficacy

and efficacy of Reiki self-treatment. Self-treatment using Reiki has been shown to promote relaxation and reduce physical and emotional distress among nurses (Gallob, 2003). Participants could perform Reiki on themselves whenever they required, while effects and frequency are measured. This could be a way to improve participants' perception of their ability to manage their symptoms (improved self-efficacy), thus reducing reliance on external providers (increased autonomy) and burden of waiting for treatments.

Implications for Clinical Practice

This dissertation study provides evidence that in a technology driven healthcare environment thriving on pharmaceutical advancement, complementary therapies and holistic care should not be overlooked. Although the implications for clinical practice include additional education, nursing presence is a standard of care such that nurses are present during hemodialysis treatments and well-positioned to provide a needed intervention for symptom management. Furthermore, hemodialysis technicians could also be taught so that they would be able to provide complementary therapies to their patients.

As the number of individuals with end-stage kidney disease increases, a new paradigm that positions an individual's perception of illness and symptom burden within a perspective of self-efficacy and resilience is needed in nephrology nursing. Major goals of treatment for individuals receiving hemodialysis are to help reduce perceptions of pain and its interference in activities of daily living, and improve mood and adjustment to living with a chronic illness (Davison & Jhangri, 2010). Every individual receiving hemodialysis has varying needs based on illness severity and disability. Thus, incorporating a multidimensional, individualized, symptom management approach for

this population based on these needs instead of a generalized approach is preferred. Complementary therapies, such as Reiki, can be tailored to fit these needs.

An important role of healthcare professionals is to find ways to alleviate the symptoms and symptom burden. Unfamiliarity or inexperience with complementary therapies, unfounded safety concerns, queries about effectiveness, or negative opinions about an unfamiliar therapy are some reasons healthcare providers and nurses often are not involved in discussions with patients about complementary therapies as adjuncts to primary treatments. Increased communication about complementary therapies, including Reiki, as a potential treatment for pain between providers, nurses, and patients is needed. Incorporating research findings and information about the use of complementary therapies into healthcare providers' educational curriculums will help providers gain familiarity with treatment options and implications. This will lead to increased awareness, acceptability, and more accurate information about such therapy options being relayed to individuals undergoing hemodialysis (Pearson & Chesney, 2007). Improved competence would be helpful for healthcare professionals to create an open dialogue with patients to encourage sharing of complementary therapy usage with providers and for providers to advise patients as to efficacy and safety (Nowack & Birck, 2012).

Cost can be considered a deterrent to use of complementary therapy use as it is not routinely covered by insurance in the United States and often too expensive for patients to seek regular treatments. Patients often report that the price of complementary treatments is a reason for discontinuing use (Pearson & Chesney, 2007). If health insurance covered complementary therapies, then a higher prevalence of use could possibly occur among individuals receiving hemodialysis. To increase insurance

coverage in the future, well designed randomized controlled trials are absolutely necessary to prove efficacy and cost-effectiveness among individuals receiving hemodialysis. A cost analysis should be considered after efficacy is determined to provide evidence for supporting the recommendation of some complementary therapies as adjuncts for symptom management. This would have significance to policy makers, providers, and patients to improve access and quality of life.

Conclusion

This dissertation study is innovative and provides a valuable foundation for future research with individuals receiving hemodialysis. I explored the premise that Reiki, a relaxing and passive energy modality, is feasible and possibly efficacious for disease and treatment-related symptom burden during regularly scheduled hemodialysis appointments. A current healthcare system weakness is that symptom management treatments often rely heavily on pharmaceuticals. The findings of this study indicate that Reiki may be a useful complementary therapy for patients receiving hemodialysis. Future studies are needed to address the limitations of this dissertation study and establish an evidence base to support expansion of the use of Reiki in the hemodialysis population. A paucity of data related to complementary therapies, and more specifically Reiki, for pain among individuals receiving hemodialysis exists. Nurses are compassionate and caring professionals particularly suited to becoming Reiki practitioners because they often have insight into their patients' needs and desire the best outcomes for care. During a time when cost containment and improvement is of high importance in healthcare, Reiki is a modality that is non-invasive, easily learned, and can provide a non-pharmacological, interventional adjunct option for pain improvement of these individuals.

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Appendix A

University of Minnesota IRB Letter of Approval

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

D528 Mayo Memorial Building
420 Delaware Street S.E.
MMC 820
Minneapolis, MN 55455

Office: 612-626-5654
Fax: 612-626-6061
E-mail: irb@umn.edu or ibc@umn.edu
Website: http://research.umn.edu/subjects/

March 8, 2016

Savannah M Zins
300 University Square
111 S Broadway
Rochester, MN 55904

RE: "Reiki for Symptom Management during Hemodialysis: A Feasibility Study"
IRB Code Number: **1512P81262**

Dear Ms. Zins:

The Institutional Review Board (IRB) received your response to its stipulations. Since this information satisfies the federal criteria for approval at 45CFR46.111 and the requirements set by the IRB, final approval for the project is noted in our files. Upon receipt of this letter, you may begin your research.

IRB approval of this study includes the consent form received March 7, 2016 and recruitment materials received December 8, 2015.

The IRB would like to stress that subjects who go through the consent process are considered enrolled participants and are counted toward the total number of subjects, even if they have no further participation in the study. Please keep this in mind when calculating the number of subjects you request. This study is currently approved for 30 subjects. If you desire an increase in the number of approved subjects, you will need to make a formal request to the IRB.

On January 20, 2016 the IRB approved the referenced study through January 18, 2017 inclusive.

The Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003). Research projects are subject to continuing review and renewal. You will receive a report form two months before the expiration date. If you would like us to send certification of approval to a funding agency, please tell us the name and address of your contact person at the agency.

As Principal Investigator of this project, you are required by federal regulations to inform the IRB of any proposed changes in your research that will affect human subjects. Changes should not be initiated until written IRB approval is received. Unanticipated problems or serious unexpected adverse events should be reported to the IRB as they occur. Notify the IRB when you intend to close this study by submitting the Study Inactivation Request Form.

The IRB wishes you success with this research. If you have questions, please call the IRB office at 612-626-5654.

Sincerely,

Clinton Dietrich, MA

Research Compliance Supervisor

CD/bw

CC: Cynthia Gross

Appendix B

Mayo Clinic IRB Letter of Approval

Principal Investigator Notification:

From: Mayo Clinic IRB
To: Savannah Zins
CC: Savannah Zins
There are no items to display

Re: **IRB Application #:** 16-002854
Title: Reiki for Symptom Management during Hemodialysis: A Feasibility Study

IRBe Protocol Version: 0.01
IRBe Version Date: 5/25/2016 1:16 AM

IRB Approval Date: 6/20/2016
IRB Expiration Date: 6/19/2017

The above referenced application is approved by expedited review procedures (45 CFR 46.110, items 4, 5, 7). This approval is valid for a period of 1 year. The Reviewer conducted a risk-benefit analysis, and determined the study constitutes minimal risk research. The Reviewer determined that this research satisfies the requirements of 45 CFR 46.111. The study brochure and surveys were reviewed and approved as written.

The written consent form was reviewed and approved as written for the patient subjects.

The Reviewer noted that oral consent is appropriate for this study. The e-mail script was reviewed and approved with revisions. As protected health information is not being requested from subjects, HIPAA authorization is not required in accordance with 45 CFR 160.103. The Reviewer approved waiver of the requirement for the Investigator to obtain a signed consent form in accordance with 45 CFR 46.117 as justified by the Investigator.

The Investigator is reminded to contact Legal Contract Administration regarding a Data Use Agreement because this study involves sending a limited data set to an external party.

AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY.

1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc.
2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes.
3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO).
4) Compliance with Mayo Clinic Institutional Policies.

Mayo Clinic Institutional Reviewer

Appendix C

Touch Screen Satisfaction Survey

You recently participated in a Reiki treatment. In an effort to evaluate feasibility of this intervention in the outpatient hemodialysis setting, we are asking you a few questions. This brief survey should take 1 minute or less to complete. Thank you in advance for your assistance.

1. I found the touch screen device easy to use.

Disagree Somewhat disagree Somewhat agree Strongly agree

2. Using the touch screen device required a lot of skill.

Disagree Somewhat disagree Somewhat agree Strongly agree

3. When gathering information from you, would you prefer using a touch screen device (as used in this study) or paper and pencil?

Touch screen device Paper and pencil

4. Overall, I liked using the touch screen device to report my symptoms.

Disagree Somewhat disagree Somewhat agree Strongly agree

5. Please leave any comments.

Appendix D

Nursing Workflow Satisfaction Survey

Your hemodialysis patient recently participated in a Reiki treatment. In an effort to evaluate feasibility of this intervention in the outpatient hemodialysis setting, we are asking you a few questions. This brief survey should take 1 minute or less to complete. Thank you in advance for your assistance.

1. Did your patient's participation in the Reiki treatment disrupt the "clinical flow" in your department?

No disruption A little disruption Somewhat of a disruption Great disruption

2. Were you able to complete all your regular assessments and tasks as usual for your patient receiving Reiki?

No disruption A little disruption Somewhat of a disruption Great disruption

3. Do you feel like this is an intervention that could be integrated into your practice setting?

Yes Maybe No

4. Would you personally be interested in Reiki training and offering Reiki to your patients?

Yes Maybe No

5. Please leave any comments.

Appendix E

PROMIS CAT Pain Intensity Instrument Sample Questions

Sample Questions:

How often did pain make you feel depressed?

How often did pain prevent you from sitting for more than 30 minutes?

How often was it hard to plan social activities because you didn't know if you would be in pain?

How often did pain restrict your social life to your home?

How often was your pain so severe you could think of nothing else?

Sample Responses:

- Never
- Rarely
- Sometimes
- Often
- Always

Appendix F

PROMIS CAT Fatigue Instrument Sample Questions

Sample Questions:

How often did you have to push yourself to get things done because of your fatigue?

How often did your fatigue make it difficult to organize your thoughts when doing things at home?

How often did your fatigue make you feel less alert?

How often did you think about your fatigue?

How often were you too tired to watch television?

Sample Responses:

- Never
- Rarely
- Sometimes
- Often
- Always

Appendix G

PROMIS CAT Depression Instrument Sample Questions

Sample Questions:

I felt hopeless.

I felt ignored by people.

I felt that I had nothing to look forward to.

I withdrew from other people.

I found that things in my life were overwhelming.

Sample Responses:

- Never
- Rarely
- Sometimes
- Often
- Always

Appendix H

Recruitment Brochure

Reiki for Symptom Management during Hemodialysis: A Nursing Research Study

You are invited to participate in a research study for people with pain who are receiving hemodialysis.

This study will use a Reiki healing intervention and assess the impact on pain, depression, and fatigue. Eligible participants will receive Reiki treatments.

A research study conducted at

funded by the University of Minnesota

Study #

BACKGROUND INFORMATION

Reiki is a non-invasive, relaxation technique that involves the practitioner lightly placing her hands on the head, neck, and shoulders. This is a 4-week intervention that will happen during your regularly scheduled hemodialysis sessions, twice per week.

WHO CAN PARTICIPATE?

- ✓ Patients undergoing hemodialysis for at least 6 months and 3 days per week
- ✓ Age 18 or older
- ✓ Able to speak and read English
- ✓ Willing to complete the study questionnaires
- ✓ Must be receiving standard medical care.

If you are interested in participating, you will meet with a study staff member to learn more about the study, complete the informed consent process, and complete study questionnaires about your symptoms and well-being.

Participants will complete study questionnaires at the beginning of the study and before and after each Reiki treatment. All participants will receive Reiki for 20 minutes after hemodialysis has begun, twice per week.

CONTACT INFORMATION

All inquiries for information regarding the study are welcome. Please call or email with your questions.

Savannah Zins, RN
PhD Candidate
Study Investigator
University of Minnesota