

Researching Complex Interventions and Holistic Biofield Therapies:

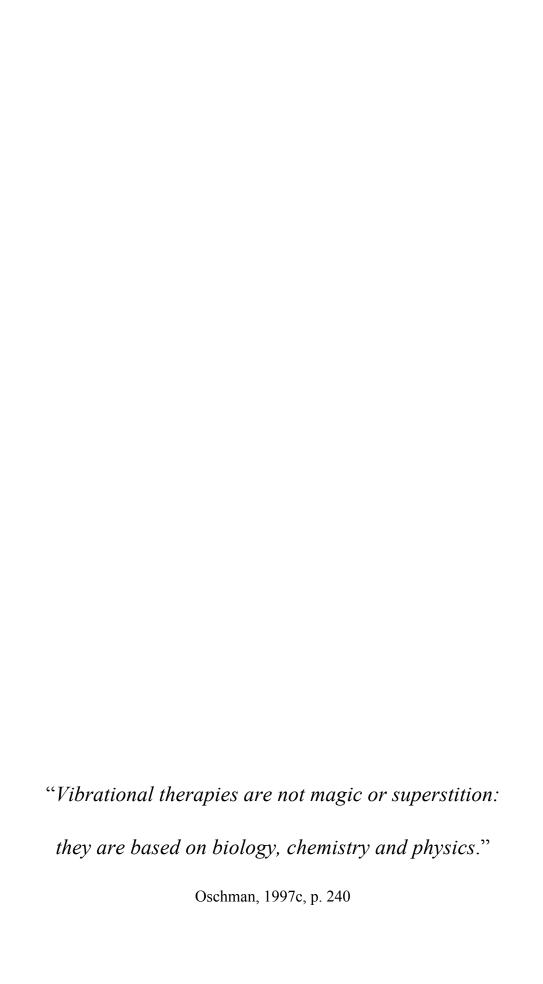
A Proposed Phenomenological Study of Reiki

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I. Introduction

PURPOSE OF THIS DISSERTATION

This dissertation represents the culmination of a Masters degree in Advancing Nursing Practice at Edinburgh University. It will explore the challenges of researching holistic biofield modalities, which are, by their nature, complex interventions. It will examine the holistic nursing paradigm, which is often used to validate the use of complementary therapies in nursing practice, as well as the Medical Research Council's 2000/ 2008 complex interventions research guidelines. It will critically appraise the available literature on biofield theories in general, and will then review the sparse and often methodologically flawed literature surrounding one specific biofield modality: Reiki. The dissertation will conclude by proposing a rigorous, scholarly, phenomenological study to begin filling essential knowledge gaps regarding the effects of Reiki.

INTRODUCTION OF THE TOPIC

The United States National Center for Complementary and Alternative Medicine (NCCAM) state that:

"Biofield therapies are intended to affect energy fields that purportedly surround and penetrate the human body.... Some forms of energy therapy manipulate biofields by applying pressure and/or manipulating the body by placing the hands in, or through, these fields. Examples include qi gong, Reiki, and Therapeutic Touch" (NCCAM, 2007).

Another way to look at this is that a 'field' is an area over which energy can exert force or have an influence (Movaffaghi & Farsi, 2009), therefore a 'biofield' would be an area of influence with a biological source or surrounding a biological entity.

In 2007, the United States National Institutes of Health (NIH) conducted a survey of American use of Complementary and Alternative Medicine (CAM), which showed that in the previous year, over 1.2 million adults and 161,000 children used biofield therapies as part of or in addition to their health care (NCCAM, 2009). Biofield therapies (a subcategory of energy therapies) are difficult to measure and there is much debate over how they should be researched. However, since the public is using biofield therapies as an adjunct or integrated part of their medical treatment, this paper contends that nurses have a responsibility to rigorously research these methods, in order to present patients and staff with the best possible evidence in the nursing roles of educator and patient advocate. One modality currently being studied with funding from the NCCAM is Reiki (NCCAM, 2009).

Reiki is a safe biofield healing modality that originated in Japan in the early 1900s (NCCAM, 2009). It is used for self-care and for care of others, in outpatient/ clinic settings (usually with a client lying fully clothed on a massage table), over a distance, and in acute healthcare environments. The treatments are performed by the practitioner placing his/her palms over the client (either touching lightly or a few inches above the body) and channeling healing energy from a universal source that flows through the practitioner and into the client, stimulating the body's ability to self-heal (NCCAM, 2009; Stein, 1995).

The philosophy of Reiki is based on the Eastern concept that all life is interconnected and that a vast, universal field of energy is the medium of connection between seemingly independent organisms, matter, and consciousness (Stein, 1995). When one considers the implication of this theory, questions naturally arise about the human ability to manipulate the energy field. If this vast store of energy can be accessed and manipulated, can it be used for healing?

While previously the domain of mystics and philosophers, there is current agreement in medical science that energy is present in the body and does have function, though that function is not always well understood (Oschman, 1997a; Oschman 1997b). Diagnostic testing is regularly conducted with technology that measures the body's electrical impulses and magnetic field (electrocardiograms [ECGs], electroencephalograms [EEGs], magnetic resonance imaging [MRI], etc.), and there is current medical research studying certain specific frequencies for their ability to stimulate tissue repair (Oschman, 1997a; Oschman 1997b).

Evidence regarding the electrical and magnetic nature of the body cannot be taken as proof of the validity of biofield theories such as Reiki. Nor can the knowledge of quantum physics, which tells us that all matter is composed of energy, and that at a subatomic level, the observer cannot be separated from the experiment (McTaggart, 2008). However, the combination of this knowledge provides a philosophical and scholarly base from which to theorise and research.

This dissertation will explore the philosophical and scientific basis for energy therapies as understood through the holistic nursing paradigm and quantum physics. It will critically evaluate the Medical Research Council (MRC) 2000 and 2008 frameworks for evaluating complex interventions, as well as critically appraising the current published literature (gathered via an extensive literature search) on the biofield therapy of Reiki. The dissertation will conclude with a qualitative research proposal developed out of an understanding of the complex interventions framework, holistic nursing philosophy, phenomenology, and the current evidence on Reiki.

The next section will explain how the evidence was compiled and the inclusion/ exclusion criteria of this dissertation's literature review.

METHOD

LITERATURE SEARCH

To find relevant research articles on biofield healing, a literature search was conducted using AMED (an alternative and complementary medicine database), CINAHL Plus, and Medline for articles written in or translated into English. A combination of category headings (all those related to energy/ biofield therapies) as well as keyword variations of "energy," "healing," "quantum," "physics," "nurs*," "complementary," "alternative," "Reiki," "biofield," and "therapies" were used to conduct database searches. The resulting articles were scanned by title and abstract and those that were deemed potentially relevant were marked for further review. Additionally, it appeared that certain journals were more germane to the topic and had a larger quantity of relevant articles, so the contents of every volume of the following journals were reviewed from January 1995 through June 2010: Complementary Therapies in Nursing & Midwifery (UK), Complementary Therapies in Clinical Practice (UK), and Journal of Holistic Nursing (US). When relevant articles were identified, their reference lists were scanned and additional relevant references from these sources were reviewed as well.

INCLUSION/EXCLUSION CRITERIA

While a large number of articles were found through the variety of searches, on the basis of the titles and abstracts 67 articles were considered potentially of value to this study. Articles relating to non-biofield areas of Complementary and Alternative Medicine (CAM) or those that did not specifically review biofield therapies or Reiki were excluded, as were articles that focused solely on other energy therapies such as therapeutic touch, healing touch, acupuncture, light and colour therapies, sound healing, meditation, tai chi, qigong, flower essences, prayer, massage, and reflexology. According to the literature search, each of the above was viewed as an energetic healing technique (along with other modalities not named here), but it was not possible to cover all of those therapies thoroughly within the remit of this dissertation.

Of the original 67 biofield healing articles found, 25 explanatory biofield references (including one book and one book chapter) and 17 Reiki references (including one book) were chosen for inclusion, to total 42 Reiki/ biofield/ energy references in this dissertation. The references

included were those that scientifically explained biofield therapies and the nature of the human energy body, and/or presented case studies or other research data. Some articles containing only anecdotes/ personal experiences or ones presented in a non-scholarly format were excluded since the data seemed unverifiable or non-generalisable. However, as Slater (2008) points out, energy healing is an area of CAM that is not well understood, so until we have a complete scientific understanding of the phenomenon, it is useful to include the experiences of those who are considered experts in the field to fill in the gaps of the scientific evidence we currently have. Therefore, if the references contained valuable information or insights (whether verifying or contesting information in other articles), they were included in a critical fashion, with the acknowledgement that the data was potentially less scholarly than the others.

In addition, fourteen articles, two books, and two book chapters were included as references that explored issues relating to researching complex interventions, phenomenology, and holistic nursing. While these references did not come from the original literature search, they were chosen for their scholarly review of key issues relating to the topics.

The next chapter will look at holistic nursing philosophy. Holistic nursing is a specialty that frequently uses CAM interventions and recognises the need for nursing research into these unconventional treatments. It was decided to explicitly state the philosophical background and underlying framework that interweaves nursing and CAM, as this can be a source of both bias and explanation. By stating and analysing the values of the holistic nursing paradigm, the author was reminded of potential sources of bias and was able to examine the data in a reflective, self-aware manner, providing greater rigour to the review and collection of data.

II. PHILOSOPHICAL BASIS: HOLISTIC NURSING

The American Nurses Association (ANA) officially recognized holistic nursing as a specialty in 2006, and it co-authored *Holistic Nursing: Scope and Standard of Practice* with the American Holistic Nurses Association (AHNA) in 2007 (Dossey & Keegan, 2008). They laid out five core values that define the specialty:

- Holistic Philosophy, Theories, and Ethics The holistic nurse respects and acknowledges the patient's beliefs and values, and with that awareness co-develops a plan of care with the patient (using nursing expertise and evidence-based practice) that engages the patient as an active partner in her/his healthcare. The holistic nursing philosophy also perceives all people as interconnected, with a responsibility to develop their own higher awareness, and care for the world around them. There is a focus on quality of life, personal dignity, empowerment, autonomy, and healing as an internal (rather than superimposed) process (Dossey & Keegan, 2008; Mariano, 2008).
- Holistic Caring Process The holistic nurse integrates holistic philosophy into the traditional nursing process, assessing the patient on all levels (physical, mental, emotional, spiritual, behavioural, cultural, transpersonal, and energetic). With relationship-centred care, the nurse-client partnership helps achieve the patient's goals. In accordance with legal regulations and standards, the holistic nurse's use of professional knowledge, current evidence, and intention ("intending for the wholeness, well-being, and highest good of the person with every encounter and intervention" [Mariano 2008, p. 55]), governs his/her integration of complementary and alternative modalities with standard care practices (Dossey & Keegan, 2008; Mariano, 2008).
- Holistic Communication, Therapeutic Environment, and Cultural Diversity The holistic nurse communicates authentically and compassionately, and he/she provides clients and staff with an environment of support, unconditional positive regard, and connectedness that helps them to find meaning in their experience. The holistic nurse goes beyond therapeutic communication techniques to achieve holistic communication with an understanding of symbolism and a willingness to address the human spirit while

being fully present for the client in difficult and joyful times. The holistic nurse has understanding of various cultural beliefs and values, but allows each patient to express her/his understanding of her/his own culture, and therefore delivers individualised, yet culturally competent care (Dossey & Keegan, 2008; Mariano, 2008).

- Holistic Education and Research Through formal academia and continuing education
 the holistic nurse is prepared to act as advocate and educator for patients, assisting them
 to navigate through the latest evidence in both allopathic and CAM treatments. The
 holistic nurse is responsible for his/her own professional growth and keeps abreast of
 and/or conducts research into various aspects of holistic nursing (Dossey & Keegan,
 2008; Mariano, 2008).
- Holistic Nurse Self-Care The holistic nurse recognises the importance of self-care when caring for others, and understands that she/he influences patients through personal and therapeutic presence, self-understanding, and personal development. The holistic nurse acts as a role model to others and strives toward a lifelong goal of reflection, introspection, and healing (Dossey & Keegan, 2008; Mariano, 2008).

The above holistic nursing values can be traced back to ideas of Socrates and Hippocrates, and are grounded in the work of nurse theorists such as Florence Nightingale, Jean Watson, Martha Rogers, Margaret Newman, Madeleine Leininger, Rosemarie Rizzo Parse, and Helen Erickson (Mariano, 2008). Holistic nursing practice is characterised by an understanding of healing as a process of becoming whole in body, mind, spirit, and in relation to self, others, and one's environment (Mariano, 2008). It emphasizes the subjective nature of one's experience of illness and/or health, the healing potential inherent within the nurse-patient relationship (including skills such as intentional presence, mindfulness, and therapeutic use of self), and integrating all of these aspects of care into healing interactions that honor and empower the patient's journey toward wholeness (Mariano, 2008).

Holistic Nursing frequently employs the use of CAM therapies that are intended to address the patient's whole being (body, mind, emotions, spirit). There is scholarly evidence for the efficacy of some CAM modalities, but not all, and what is available is not always of the highest quality

(Smith, 2008). For CAM to be accepted by the allopathic medical system, it needs to be researched rigorously and with strict standards that are understandable to the biomedical paradigm. It does no good to research and not publish the results, or to simply rely on experience and anecdotes (as is sometimes the case with CAM practitioners). Some might argue as long as they are safely achieving the desired results, the mechanism is unimportant, while others question the need for research on methods that are proven safe (Duerden, 2004a). Others contend that holistic modalities are mismatched philosophically with biomedical research and that studying CAM treatments in the same ways as medical interventions reduces the holistic nature and efficacy of CAM therapies. Wright and Sayre-Adams (1999) argue that:

"People come to the complementary therapies precisely because they are different than conventional approaches.... The reductionist biological model seems to be no place for the complementary therapies.... The linear biomedical model (add substance/treatment to body = predictable effect) is of questionable fit with approaches that assert concern for and work with the whole person. Pushing the complementary therapies ever deeper into the conventional health-care model reduces their potential and their impact" (p. 95).

No matter what one believes, the concept of evidence-based care demands diligent use of the best evidence, which requires research. If one accepts the premise that there is a duty to study the methods and modalities used in healthcare, then the next challenge is to determine how to research interventions that do not fit into a reductionist simple-intervention model. The Medical Research Council (MRC) addressed this question in 2000 and again in 2008, and developed a framework for researching complex interventions. Both of these frameworks will be critically examined with relation to biofield therapies and CAM in the next chapter.

III. RESEARCH BASIS: COMPLEX INTERVENTIONS GUIDELINES

DIFFICULTY OF RESEARCHING COMPLEX INTERVENTIONS

Randomised Controlled Trials (RCTs) are considered the gold standard of medical/ healthcare research (Smith, 2008). However, many researchers claim RCTs are not necessarily the best or most appropriate method for dealing with complex, behavioural, holistic, community or policy-based, and/or non-pharmaceutical interventions (Carter, 2003; Hawe, Shiell, & Riley, 2004; Mackenzie et al., 2010; Smith, 2008; Paterson & Dieppe, 2005; Stephenson & Imrie, 1998; Vickers, 1995a; Vickers, 1995b). According to Stephenson and Imrie (1998):

"In clinical medicine, the randomised controlled trial is considered the best way of measuring the efficacy of interventions because of its ability to minimise bias and avoid false conclusions.... it is considered ethical only when there is genuine uncertainty about which treatment to offer" (p. 611). "In terms of assessing healthcare interventions, pragmatic randomised controlled trials may... be more appropriate and manageable than explanatory ones, even if they do not identify the active ingredient" (p. 613).

The above authors paint a clear picture: RCTs are valuable and useful, but they do not always answer why interventions work, how they work, or if they will work when repeated in new contexts. RCTs are reductionistic (rather than holistic) approaches, designed to answer one question: does this intervention produce the desired results? (Polit & Beck, 2010; Vickers, 1995b; Zahourek, 2008). Questions regarding complex interventions, by their very nature, require answers that are more detailed than a simple yes or no. A standard RCT may not address all of the key issues that arise when dealing with complex interventions. Some potential challenges of RCTs of complex interventions (including Reiki and other biofield/ CAM therapies) are summarised below.

• Ethics: There may be ethical objections to withholding potentially beneficial treatments through the process of randomisation or having a control group that does not receive the treatment.

- Blinding/ Masking: Hiding who does and who does not receive the intervention from the clinician, patient, and evaluator may not be feasible. It could be impossible to disguise who is receiving the complex intervention, especially if the clinician and patient are directly involved in the treatment (such as in the case of behavioural interventions).
- Theory vs Practice: Study selection criteria, participant choice, and study environment may cause different results than real-world scenarios, which can raise questions about effectiveness of the intervention in practice (Carter, 2003; Stephenson & Imrie, 1998; Vickers, 1995b).

There are ways to lessen the effects of the first two problems listed above. A phased implementation of the intervention (delaying treatment of the control group) might address ethical objections by providing both a control and treatment for all participants (Craig et al., 2008; Polit & Beck, 2010; Stephenson & Imrie, 1998), though Mackenzie et al. (2010) point out that in many cases the control group may make anticipatory changes, thereby contaminating the control results. The second difficulty is more easily overcome: an inability to mask patients or providers during the implementation phase may be mitigated if the person assessing the outcomes is blinded to which patients are in the control and the treatment groups (Stephenson & Imrie, 1998).

It is more difficult however, to address the third concern. RCTs are intended to take place in an environment that isolates one variable from everything else, but doing that removes the complexity from the intervention, which may influence results. Hawe et al. (2004) and Paterson and Dieppe (2005) argue that isolating component parts of an intervention may fundamentally alter the intervention and provide false results, since it is the combination of all the factors in their total complexity (the additive effect) that are believed to produce the result. Paterson and Dieppe go on to explain that separating out component parts of a complex intervention and ignoring so-called incidental factors (i.e. patient expectations, credibility of the modality/ practitioner, a specific manner of communicating or diagnosing that is integral to the particular intervention/ modality) may produce false negative results, reducing the apparent efficacy of the intervention.

The above complications prompted a Medical Research Council (MRC) workshop to develop a framework for defining and researching complex interventions (Campbell, et al., 2000). Two reports were published in the British Medical Journal (BMJ), the first in 2000 and an updated version in 2008 (Craig et al., 2008). Though the planning was for medical research and not specifically intended for nursing research, these principles provide a scholarly structure to address the multifaceted nature of holistic nursing interventions. An overview of both sets of guidelines are explored in the next two sections, followed by a critical analysis examining their use in relation to CAM.

MRC 2000 "FRAMEWORK FOR DESIGN AND EVALUATION OF

COMPLEX INTERVENTIONS TO IMPROVE HEALTH"

Complex interventions, defined by Campbell et al. (2000), as "those that include several components" (p. 694) are difficult to research using linear methods such as randomised controlled trials (RCTs), since by their natures they have multiple variants that can affect the outcomes. RCTs are well suited for drug trials or other research that attempts to measure one variable; they provide a sequential, linear approach, and evaluate one intervention at a time. When evaluating complex interventions however, RCTs are unable to adjust to new information, and therefore provide an incomplete view of the intervention's effects (Campbell et al., 2000).

This led the Medical Research Council (MRC) to propose an iterative or circular design for evaluating complex interventions combined with qualitative research methods in the hopes that it would "lead to improved study design, execution, and generalisability of results" (p. 696). This design is divided into four phases: (1) defining intervention components, (2) designing the intervention/ study, (3) carrying out the main study (whilst addressing methodological issues), and (4) implementing the intervention effectively in the long term (follow-up). Additionally, it emphasizes the need for thorough preparatory and theoretical research into the topic to help researchers develop an implementation that effectively and specifically measures that which they wish to study (Campbell, et al., 2000).

MRC 2000: DEFINING COMPONENTS

In the first phase of the 2000 framework, qualitative research is heavily emphasized, so that the clinician can fully understand the phenomena being studied. These interventions may be affected by the therapeutic relationship or rapport of the clinician(s) and patient, the care environment/ timing, the individual patient's history/ beliefs, and other factors relating to the intervention itself. Qualitative research provides a unique insight into the experiences surrounding and related to the intervention, the relationships of the different components, and potential variations and complications. This allows the researchers to describe the interventions

in the most consistent and complete manner, which provides the foundation for the second phase: intervention and study design (Campbell et al., 2000).

MRC 2000: STUDY DESIGN

The second phase involves feasibility studies to determine the most effective and acceptable means of delivering the implementation along with the optimum study design. The MRC emphasizes the importance of consistent delivery of the intervention in the main study, so this is evaluated along with the initial responses of caregivers and patients. Campbell et al. (2000) recommend randomising participants in the feasibility studies so that effect size can be assessed and numbers calculated for the main study. The other key pieces to be defined during this exploratory phase are the control intervention (standard care, alternative intervention, placebo, or withholding treatment) and outcome measures (health-related, economic, practical, etc.). When the intervention and study are carefully designed and determined to be feasible, researchers can move on to phase three: carrying out the main study (Campbell et al., 2000).

MRC 2000: STUDY IMPLEMENTATION

The main study concerns itself with the above issues as well as the other methodological issues of the study itself, such as sample size, the process of randomisation, participant eligibility, and bias. RCTs (when done properly) are considered highly valid and reliable because of the strict protocols used to ensure correct measurement of the variable in question (Campbell et al., 2000). Complex interventions however, often cannot be blinded or masked and there is not usually a placebo to adequately replace the intervention (as there often is with drug trials). Campbell et al. state that one solution to the latter is for the control group to receive delayed treatment, but note that this does not give the same level of control as seen with an RCT, and do not address the issue of contamination that can happen with widely implemented interventions (Mackenzie et al., 2010). Randomisation can also be difficult with complex interventions, so inclusion/ exclusion criteria needs to take into account any potential bias (Campbell et al., 2000).

Additionally, environment of care is quite important during the study (complex interventions may be greatly affected by the treatment environment), so the study needs to take place in the normal environment in which the intervention would be provided to obtain accurate results.

Some researchers in fact, contend that context is one of the most important factors in implementing complex interventions both in study and in practice (Campbell et al., 2007; Hawe et al. 2004; Mackenzie, 2010). An example of this would be if one was to study the effect of massage on patient pain. The experience of patients who received massage in a spa where they had to pay out of pocket would not accurately duplicate the experience of patients who received massage as part of their care in an acute care hospital. There are too many different variables between the two scenarios that could not be accounted for if one was to attempt to generalise from the one scenario to the other.

MRC 2000: Long-term Follow-up

The fourth phase of this framework relates to monitoring the implementations once they are in place. Unless it is a longitudinal study, it is unlikely that the intervention trial would continue to follow up with participants for a lengthy time period, due to the financial burden this would cause (Campbell et al., 2000; Mackenzie, 2010). This said, it is important to have a follow-up process in place when implementing a new treatment or standard of care since some professionals might cut corners in practice (inadvertently or otherwise) that could potentially undermine the intervention (Mackenzie, 2010). If the processes studied are vastly different from the procedures put into practice, then obviously, the results in the real world may differ greatly from the original research.

MRC 2000: THE DEBATE

The original guidelines led to a great deal of continuing discussion about the best ways to research complex interventions. Paterson and Dieppe (2005) argued that RCTs and placebo-controlled studies were not appropriate for holistic modalities since the underlying assumptions were diametrically opposed. A placebo-controlled trial assumes one static diagnosis and one active ingredient. In contrast, many holistic modalities such as acupuncture diagnose patients in a more fluid manner, updating the diagnosis and treatment in each session, based on holistic communication and continuing patient assessments. The holistic communication and therapeutic relationship is essential and specific to acupuncture (though other holistic modalities may use similar techniques), since emotional, mental, and lifestyle factors are taken into account and

directly affect each treatment session. This is differentiated from the biomedical RCT model that discounts these factors; to do so with holistic modalities would undermine the entire modality (Paterson & Dieppe, 2005). In addition, Nelson (2006) found that a nurse's presence while delivering holistic care was potentially more beneficial than the treatment modality itself, which suggests that what placebo-controlled trials consider incidental may be an integral part of holistic therapies.

Complex interventions may also be considered complex or organisational systems. According to complex systems theory, separating a complex system into its component parts renders it less effective, since the combined effect of the parts is what makes the system what it is (Hawe et al. 2004). This is the same as divorcing a modality from its philosophical background, which could potentially render the trial itself useless or cause researchers to misconstrue the results (Paterson & Dieppe, 2005).

Another issue that is not addressed in the 2000 framework is standardisation. Traditional RCTs promote a standardised implementation that is not context-dependant. Hawe et al. (2004) however, propose a variation on the RCT and complex interventions framework wherein the goals and processes of the intervention are standardised, but the mechanisms of delivery are customised to the individual contexts or clients. Imagine a health promotion campaign with the goal of reducing smoking; if implementation was standardised, it might be decided to deliver an educational leaflet to specific high-risk communities. Suppose though, that one of those communities had a high population of smokers that were illiterate. A context-driven approach would allow that community to devise another means of educating their population (such as video or one-to-one with the subject's general practitioner); without it, researchers might conclude that the education programme itself was flawed, when the flaws were actually in the delivery system.

These issues and others led to a revision of the MRC framework in 2008. This is critically examined in the next section.

MRC 2008 "DEVELOPING AND EVALUATING COMPLEX INTERVENTIONS:

THE NEW MEDICAL RESEARCH COUNCIL GUIDANCE"

The Medical Research Council (MRC) made a major overhaul to the complex interventions framework and published their new guidelines in 2008. These expanded on the definition of a complex intervention, stating that an intervention's complexity was based on the number of interacting components, behaviours, groups, organisational levels, outcomes (and their variety), as well as the level of individual tailoring associated with delivery of the intervention (Craig et al., 2008).

Instead of a circular design consisting of phases, they drew up a new flowchart (Figure 1), which is less reminiscent of pharmaceutical trials and more indicative of the nature of complex interventions and the research that investigates their effects. There is flexibility in the new design that allows researchers to adapt to new information and modify the study in order to obtain the most accurate and practical results (Craig et al., 2008). The phases of the new framework are discussed below.

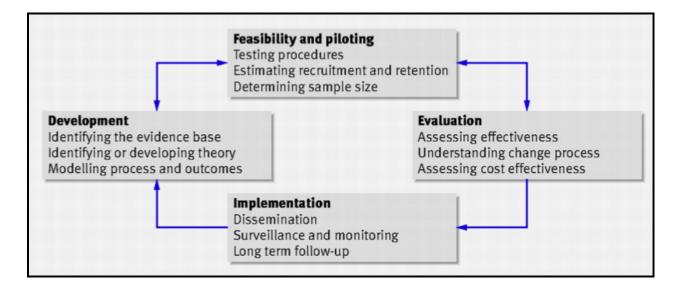


Figure 1 "Key elements of the development and evaluation process" (Craig et al., 2008)

MRC 2008: DEVELOPMENT

Research development is a particularly important piece of any study containing complex interventions (Craig et al., 2008). When researching a single intervention, such as whether or not a particular medicine produces a specified result, one does not necessarily need to develop the intervention itself in great depth; the intervention is either given or it is not (depending on the control method used in the study design). Complex interventions however, have multiple active parts, and therefore researchers need to be sure that all of the inherent uncertainties are studied, researched, and understood, so that they can be accounted for in the main study design. Implementation problems, small sample sizes, single outcome measures, and strict standardisation are all factors that could skew results, so it is recommended that researchers have a thorough theoretical and practical understanding when developing the intervention in order to minimise errors leading to false results (Craig et al., 2008).

When developing an intervention, there are two main questions researchers should ask: (1) will the intervention reliably produce results in real world scenarios? and (2) which components of the intervention produce which of the results (i.e. is it the face time with the clinician or the actual intervention that produces result X)? Researchers must have a clear understanding of the implications they are hoping to demonstrate (their hypotheses) in order to develop interventions and studies that will be useful in practice (Craig et al., 2008). This is where qualitative studies can be especially useful (Lewin et al., 2009).

MRC 2008: Feasibility and Piloting

Once the intervention is fully understood, both theoretically and practically, researchers can move on to pilot studies to determine the most feasible and acceptable processes and procedures to test their hypotheses. While Craig et al. (2008) recognise that best practice would involve a series of pilot studies investigating the many variations possible within a complex intervention, they concede that this is often not possible, due to financial, practical, and even political constraints. How much do these constraints, other methodological weaknesses, and researcher bias affect the validity and usefulness of the findings? Additionally, are the methods used the best possible ones for evaluating the intervention? These questions need to be answered when

designing any study, but especially for complex interventions since these contain so many additional variables. Pilot and feasibility studies examining key uncertainties are therefore of the utmost importance to fine-tuning both the intervention and the study. Even though these may not help predict the main study's outcomes, they will provide valuable insight into the process, which will eventually help produce more valuable results (Craig et al., 2008).

One way to decrease bias that the new guidelines highlight is randomisation. They state that whether randomisation is done on a traditional, individual, cluster, preference, or other basis it does help reduce bias and increase accuracy of results, so all attempts should be made to randomise participant assignments whenever possible. When randomisation is impractical or impossible, other measures should be taken to prevent bias and fairly interpret the results. In addition, if pilot and feasibility studies are randomised, they can help calculate the numbers needed to determine effect size in the main study (Craig et al., 2008).

MRC 2008: EVALUATION

While knowledge is certainly valuable for its own sake, the bodies funding health care research are often more interested in results that can be quantified and put into practice (as are practitioners concerned with evidence-based practice). A good study design will make evaluating the results more practical and useful; major methodological flaws can make even the most obvious and intuitive results questionable. While much of the evaluation planning needs to be done during the development period (primary/ secondary outcome measures, data analysis, etc.), the actual evaluation may bring up unanticipated issues. This is where the sound theoretical and practical background is so useful; it gives researchers ideas of what to expect so they can be prepared to deal with both expected and unexpected results (Craig et al., 2008).

MRC 2008: IMPLEMENTATION

Once research has been conducted and outcomes have been analysed, if the intervention is effective enough to be more broadly implemented, monitoring should be done to ensure that the intervention continues to be performed with to the same processes and procedures used in the study. Longitudinal studies may be conducted to monitor long-term effects as well as to discover any large-scale implementation challenges, secondary consequences, or unintended effects

(positive and/or negative). Long term follow-up may or may not be possible due to the financial burden of conducting such research, but can often offer valuable insights that will build upon the study findings and serve as a foundation for future research (Craig et al., 2008).

MRC 2008: The Continuing Debate

Although the 2008 guidelines addressed some of the issues raised by the 2000 framework, such as evaluating the processes/ delivery of the implementation and allowing adjustments for context, some researchers still do not think the 2008 guidelines are sufficient (Anderson, 2008; Mackenzie et al., 2010). In the new framework, RCTs are still deemed the best overall research method, but there is no mention of how to counteract the issue of systems that are fluid, constantly learning and adaptating (Mackenzie et al., 2010).

In his editorial, Anderson (2008) stresses that while the 2008 guidelines do not adequately address complex systems theory, modality-specific theoretical approaches, or economic evaluations, the continuing discussion raised by the 2000/2008 frameworks are likely to induce more research and debate that will benefit researchers and professionals in practice. He suggests that the lack of coverage of the above issues could be due to the lack of current evidence/examples of those theories and methods. It is hoped that the 2008 guidelines will continue the debate as these non-biomedical paradigms are better understood and scientifically utilised.

Though there are scholars and researchers on both sides of the debate, both praising and criticizing the MRC complex interventions framework, it is essential that the discussion continues. Every research method is likely to have benefits and flaws, and it is up to the individual researchers to identify a method that suits their aims and will appropriately and thoroughly answer the research questions. It is then up to the professionals to determine from the best evidence what will be most likely to help their patients. It seems that this is and has been the purpose of both the guidelines and the subsequent debates.

The next chapter will specifically examine the appropriateness of the MRC guidelines in relation to holistic nursing philosophy and CAM.

IV. COMMENTARY AND SYNTHESIS: HOLISTIC NURSING PHILOSOPHY AND COMPLEX INTERVENTIONS RESEARCH FRAMEWORK

The Medical Research Council frameworks require a great deal of theoretical work and piloting designs/ procedures, which could be perceived as difficult for smaller research studies or researchers with limited budgets. The approach was formulated by doctors for medical research, and could therefore be argued to be less applicable to nursing, since it is a separate (though related) profession. However, they do provide a good framework since many nursing interventions are complex (due to the nature of nursing practice) and therefore do not lend themselves to reductionist research designs intended to study only one variable. There is a balancing act between undertaking quality research and counteracting constraints such as time, funding, and other practicalities, but studies that attempt to follow the complex intervention guidelines seem more likely to advance nursing research and the nursing profession, by bringing more practical, scholarly knowledge into everyday practice.

The complex nature of holistic nursing philosophy and associated interventions have possibly been given less credence than they deserve. There is a dearth of scholarly research available, much of what has been published has poor methods and designs (Glasziou et al., 2008; Lee et al., 2008; Smith, 2008), and a great amount of the research that has been done well remains unpublished, as is the case with many masters or doctoral dissertations (Zahourek, 2008). Without proper instruction, adequate time, and/or funding for research, holistic nurses working clinically may be unable to produce the kinds of large-scale scholarly studies deemed most valuable by the profession (Nield-Anderson & Ameling, 2000). However, even small-scale studies (if well-designed, well-conducted, and adequately reported) can be used as a foundation for future research, and if holistic nurses are aware of the Medical Research Council framework, studies can be designed to fit into that structure (Glasziou et al., 2008).

For example, imagine that a nurse did not have the resources to do exploratory qualitative studies, pilot and feasibility development studies, an RCT, a longitudinal follow-up study, and a continuing implementation audit (it is hard to imagine, but please try). This nurse could (with an understanding of the complex interventions framework) design a rigorous foundational or pilot

study (depending on what she/he wanted to study) that could be part of a body of knowledge and serve as the basis for future, better-funded studies. Another option would be to look at studies that have already been published, determine the methodological flaws associated with the published studies, and design a study that would examine the phenomena while specifically counteracting the particular flaws of the published research. This would add to current knowledge by providing a fuller research base for future large-scale studies, as those future studies would have a greater variety of research to draw from with different strengths and weaknesses.

The complex interventions framework is useful to holistic nurses as well, in that it provides a legitimate, scholarly explanation for why extensive systematic literature reviews along with explanatory, feasibility, and pilot studies must be conducted prior to commencing a major study. If large or scarce resources are being funneled into research, it should be research of a high quality nature that will lead the most valuable and practical results. However, these reviews should be used carefully, and original research should be reviewed whenever possible, since both research articles and reviews do not always contain full and complete (i.e. replicable) descriptions of the interventions and study protocols (Glasziou et al., 2008).

Despite the fact that holistic nursing is relationship and philosophically based (in contrast to the biomedical model), there is still a professional duty to develop interventions and practices that are reliable and effective (Zahourek, 2008). While the reductionistic nature of RCTs does in some ways oppose the holistic nursing paradigm, it does not necessarily preclude the two from working together. If the researchers are studying one particular facet of a holistic intervention (i.e. to determine the active component or studying one specific variant of an intervention), an RCT may be appropriate (Zahourek, 2008) and the complex interventions framework could be utilised.

Whatever method a holistic nurse uses for research, the holistic nursing philosophy acts as a base. The American Holistic Nurses Association (AHNA) defines holism in two ways: unitary and integral. Unitary refers to the whole as being greater than the sum of the individual components, while integral refers to the relationship(s) between and integration of various elements into one complete whole (Zahourek, 2008). A unitary framework lends itself best to

qualitative research methods such as phenomenology (due to the concept that separating the parts gives one an incomplete view), while integral researchers often use more quantitative methods to study intervention components, and can make more use of RCTs and the complex intervention framework (Zahourek, 2008). Both types of research are necessary to gain a holistic view of complex, non-pharmaceutical, and complementary interventions, and the nurse's theoretical framework will help her/him determine which methods will yield the most promising data for specific questions (Zahourek, 2008).

With holistic nursing philosophy and the complex interventions guidelines as its foundation, this dissertation now moves into its next chapter: the nature of energy in the world, in the body, and in biofield healing. Following that, it will propose a research project and literature review which critically examines the current evidence base for Reiki healing.

V. THE NATURE OF ENERGY AND THE PHYSICAL BODY

ENERGY EXPLAINED

Classical Newtonian physics explained the world as a collection of separate entities existing in absolute time and space and following specific, explainable, unbreakable laws. Departing from classical physics, Einstein's theory of relativity stated that space and time were relative to one another, simply different aspects of a single entity referred to as space-time. While these scientific principles, along with the concepts of molecules, atoms, protons, neutrons, and electrons are commonly known, many of the twentieth-century advances in quantum physics remain unknown by the public at large, despite publication of numerous well-designed and highly reputable studies. Quantum physics takes science into the realm of the unknown, raising a myriad of questions about the very nature of existence and whose answers unsettle the foundations of common scientific ideas, which may be why these concepts remain mainly the domain of physicists and mystics (McTaggart, 2008).

It is because of this that a review of the evidence and studies underpinning quantum physics is presented herein. This is, of necessity, a simplified explanation, as it is not within the remit of this paper to provide a complete analysis of all the studies and information available relating to quantum physics. It is hoped that this moderate explanation will provide the reader with a basic understanding of relevant principles and findings in quantum physics relating to the nature of energy in order to better recognise the importance of energy with regard to healing.

Quantum physics tells us that all matter is composed of energy (Nemeth, 2008) that, when broken down into subatomic particles, acts as both a particle and a wave, and whose behaviour is inconsistent and influenced by the observer (Slater, 1995a; Slater 1995b). Heisenburg's uncertainty principle (developed in 1927) states that because of the participatory relationship between the observer and the observed, we can only observe one of the physical properties of subatomic particles at a time: either its energy or its lifetime. The implication of this is that quantum physicists believe that energy, which is defined as the ability to do work and/or the movement of electrons, is the basic underlying and connecting structure of the universe

(Movaffaghi & Farsi, 2009; Nield-Anderson & Ameling, 2000; Oschman 1996, Oschman, 1997a; Slater 1995a).

It is at this point that modern physics and ancient mystics come together, as well as where traditional Newtonian scientists turn away. Chaitow (1998) notes a common medical, academic, and professional tendency to dismiss biofield and energy theories as nonsensical and unbelievable despite what he considers to be 'overwhelming' evidence. On this same topic, Oschman remarks that:

"These critiques are out of date, as modern researchers have confirmed that living organisms are, indeed, comprised of dynamic energy systems involving the same sorts of field phenomena that physicists have been studying for a long time.... Vibrational therapies are not magic or superstition: they are based on biology, chemistry and physics" (1997c, p. 240).

Schwartz and Schloss (2006) refer to a time in history when the general consensus was that world was flat, as an example of the human tendency to dismiss that which one cannot visualise. They state that certain concepts (especially in advanced mathematics and physics) are inherently unimaginable and nonvisualisable, and therefore are dismissed despite evidence to the contrary. They remind their readers that:

"Just because something seems impossible and unbelievable does not necessarily make it unreal." (Schwartz & Schloss, 2006, p. 510).

While it would be foolish to surmise that current researchers understand or can explain all of the mysteries of the universe, the aim of scientific exploration is arguably to understand as much as we possibly can... and then to take it further. Quantum theory is one potential scientific explanation for what energy healers and biofield practitioners experience and speak of as universal life force energy, chi, and/or prana.

HUMAN ENERGETIC ANATOMY

Using research, her knowledge of physics, and expertise as a healer who works with biofield therapies, Slater (2008) compares the human energy body (auras, charkas, meridians) to electromagnetic fields, digital and analog computers, receivers, transmitters, transformers, and LCR circuits (inductance, capacitance, and resistance circuits used in televisions and radios). Other healers and spiritual/ philosophical traditions have described human energy anatomy in a myriad of ways, some scientific and some intuitive, however, it is not possible within the remit of this paper to explore them all in detail. Suffice it to say, these basic structures of human energy are commonly accepted within the paradigm of holistic nursing and while interpretations of meaning may differ, accepting and understanding their existence is the basic foundation of energy healing (Dossey, 2008).

According to Slater (2008), there are three main aspects of the human energy system: the aura, the meridians, and the chakras. The aura is similar to an electromagnetic field (such as one formed by a piece of iron wrapped in electric wire) and serves as a vast storage facility for all of a person's experiences, emotions, and memories. The circulatory system acts as the metallic iron core, while the meridians and other electrical impulses within the body carry energetic currents that interact with the iron in the blood to produce this field (Slater, 2008). It is important to keep in mind however, that current scientific measurement of these energetic concepts is hotly contested, so these descriptions are metaphorical accounts based on healers' experiences and teachings (Slater, 1995a).

Meridians are a complex system of weak, unidirectional electric currents in the body that are said to create a magnetic field (i.e. the aura) and energetically connect every cell in the body (Slater, 2008). Traditional Chinese Medicine (which includes acupuncture and acupressure) views the meridians in twelve main pairs which nourish the organs and cells of the body; each of the main body organs has a meridian going towards and away from it that carries data and energy to every cell in its path (Slater, 2008). It has been postulated that energy healers are able to modulate the frequencies of their meridians and use their frequencies to produce coherence and order in their clients' energy fields (Smith, 2003).

Now that the aura and meridians have been discussed, an explanation of the chakras is in order. Chakra is a Sanskrit word that translates as vortex or wheel of light and originally comes from the ayurvedic/yogic tradition, though many modern energy healing modalities (including Reiki) use the chakras as part of their teaching (Slater, 2008; Stein, 1995).

According to Slater (2008), the chakras act as filters, receivers, processors, and transmitters of information, akin to radio stations or television channels that receive specific frequencies, thereby broadcasting specific signals. Most of the chakra-based traditions state that that the human body contains seven main chakras (vortices of spiraling energy) located at specific points of the body and relating to internals organs, glands, and nervous system functions, as well as minor chakras in the joints, palms of hands, and soles of feet. Each chakra resonates to a specific frequency (often perceived as colour or sound vibrations) and acts as a receiver/ transmitter for information that progresses from concrete survival skills at the first chakra (located near the groin/ sacrum) to spirituality and wisdom at the seventh chakra (located at the crown of the head) (Slater, 2008).

Duerden (2004a) contends that there is a difference between the scientifically validated bioelectric field that surrounds living organisms (aura) and what some CAM practitioners (such as Slater, 2008) refer to as the vital life-force energy that permeates and surrounds living organisms (aura). Both are called auras, and Duerden believes that proof of the former is often given as proof of the latter. He states that healers' experiences of seeing auras can be explained by optical illusions, visual hallucinations, and the brain's normal processing of visual data, and that charismatic individuals can use physiologic processes to essentially dupe suggestive individuals. He concludes however, by stating that since visual systems can detect and process information unconsciously, the optical illusions that create perception of auras (as viewed in holistic therapies) could potentially give an understanding of a person's level of wellness or illness to people who are able to unconsciously understand the information. Therefore, while he is not disputing the existence of biofield healers' accounts of the aura, he is disputing the 'evidence' they use as validation.

Even with the myriad accounts of healers and healing traditions, it is still difficult to measure and validate the claims of healers with regard to the body's energetic systems and mechanisms

(Duerden, 2004a and 2004b). Scientists and professional on both sides of the issue are guilty of relying on anecdotal reports and personal beliefs that cannot be corroborated (similar to urban legends). Some professionals even question the need for research on safe complementary and alternative modalities that are perceived as beneficial by clients and their healers (citing from allopathic medicine the common prescribing of antibiotics for self-limiting viral infections) (Duerden, 2004a). This author, however believes that given the current climate of evidence-based medicine/ nursing and the public's expectation that healthcare providers will utilise the best and most proven care, the question of "should we research" is both outdated and naïve. Biofield therapies are being used in inpatient and outpatient healthcare settings, and the only way we can understand if and how they work is by conducting rigorous, scholarly research.

The next chapter of this dissertation is a synthesis and discussion of the material presented, which will be followed by a concise summary of the data presented.

VI. COMMENTARY AND SYNTHESIS: RESEARCHING COMPLEX INTERVENTIONS AND HOLISTIC BIOFIELD THERAPIES

So far, this dissertation has examined the Holistic Nursing philosophy, the Medical Research Council's 2000 and 2008 complex interventions research frameworks, and scientific studies and expert opinion relating to the nature of energy in the world, in the human body, and how it potentially relates to healing. It is conceivable that based on the above information some people might be inclined to move from scientific theories such as quantum physics to suppositions of whether and/or how biofield therapies work, while others will be inclined to dismiss these seemingly impossible or nonvisualisable theories, because they do not fit into the current mainstream paradigm.

Neither of these would be advisable however. Schwartz and Schloss (2006) remind those who are more comfortable with the mainstream paradigm of energy and matter that:

"Integrity in evidence-based science and medicine may require that scientists and nonscientists alike develop comfort and humility in accepting the human mind's restricted ability to envision and imagine certain nonvisualizable—yet fundamental and real—concepts and effects, as illustrated in contemporary physics and complementary and alternative medicine" (p. 509).

However, those who have adopted a nontraditional paradigm (be it based in quantum physics or mysticism) need to remain open-minded as well. If nontraditional holistic, complementary, and/or alternative modalities are to be taken seriously within the mainstream biomedical system, then they must be researched with rigour, and special care must be taken to remove as much bias as possible. While this may seem to be a bit of a double-standard (the nontraditional model having to prove itself more than the mainstream model), when one tradition (such as holistic biofield healing modalities) is attempting to gain acceptance into another, it is the responsibility of the nontraditional modality to speak in the language of the mainstream model. The current healthcare system does not *need* to accept complementary and alternative medicine; it is its own functioning system. The fact that consumers are using Reiki, other biofield modalities, and other forms of CAM, coupled with the fact that they are paying for it out of their own pockets however

(NCCAM, 2008), demonstrates that integration could be beneficial for both mainstream and CAM providers.

Therefore, the final chapter of this dissertation explores the literature specifically relating to Reiki and proposes a research project that this author believes will add to the current body of evidence and further the practice of holistic nursing and biofield therapies. The proposed research may not at first appear to be a nursing research project, as it is exploring the experience of healthy individuals. However, if research only examines people who are ill

This research project will add to the specific evidence regarding Reiki, and as discussed in Chapter V (The Nature of Energy), since the modality has been shown to be less important than the healing intent when biofield therapies are used, it will add to the general evidence on biofield therapies as well. The proposed research is well-suited to the holistic nursing paradigm as it is aligned with holistic nursing philosophy, specifically with its focus on self-care and on involving the patient as a partner in her/his healthcare. While this study will initially be carried out with healthy participants, once the process and key concepts are evaluated, the study can be repeated with different patient populations, and it is hypothesized that it will empower patients and give them a means of being involved in their own care.

The proposed study also fits into the complex interventions framework. The research on Reiki is scarce and does not progress in an orderly fashion as suggested in the complex interventions framework (see Reiki Literature Review in the next chapter). This study represents a starting point by going back to the basic concept in both the 2000 and 2008 guidelines and focuses on defining the intervention and describing its active components. Once these are better understood, then randomised controlled trials (RCTs) or other research methods can be better designed and developed to study a phenomena that is not currently well-understood.

This concludes the informational section of the dissertation (leaving only the proposed research) and explains why Reiki/ biofield research is needed. In the next chapter, the concise summary of this dissertation is the foundation and preparation for the final chapter: a phenomenological research proposal exploring the experience of self-Reiki treatments.

VII. SUMMARY

This dissertation explored the nature and philosophies behind holistic nursing, a nursing specialty that often integrates holistic, complementary, and alternative medical approaches into a compassionate care model when the nurse is a facilitator for patients' individual journeys toward wholeness. One of the complementary modalities holistic nurses may employ is a biofield modality called Reiki. Biofield modalities are based in Eastern traditions that have, as a component, the belief that all matter is composed of a conscious, purposeful, and universal life force energy, sometimes referred to as 'prana' or 'chi' (also spelled 'qi' or 'ki'). The findings of quantum physics state that all matter is composed of energy, and that the observer's very presence influences energy (quantum particles) on a subatomic level. This information is often used to support the belief in a universal energy and the other concepts associated with biofield modalities (including energetic structures such as the aura, meridians, and chakras), however the theories of quantum physics should not be considered to prove or disprove whether healing is possible through biofield modalities.

As holistic nursing and biofield interventions are by their nature complex, the Medical Research Council complex interventions 2000/ 2008 guidelines were critically reviewed and (despite ongoing criticisms and debate) found to be appropriate for biofield modalities. However, as will be demonstrated in the research proposal's Reiki literature review, the deficiency of adequate background research on the phenomenon of Reiki means that the intervention, processes, and procedures for use in nursing need to be developed. Since the research that is currently available is inconclusive regarding efficacy and often had results that were not specifically expected, it is clear that the majority of Reiki hypotheses, interventions, and trials were poorly designed due to a lack of understanding of the effects and actions of Reiki therapy.

The final section of this dissertation proposes a rigorously designed phenomenological study of Reiki. It aims to address the extreme lack of scholarly research on the subject and provide a solid foundation from which to base future studies.

VIII. PROPOSED RESEARCH PROJECT

BACKGROUND

Biofield healing therapies are those that claim to improve health and well-being by adjusting the bioelectromagnetic field (biofield) surrounding and within the human body. This model claims that illness is not only physical, but has a related component that is mental, emotional, or spiritual in nature. These illnesses are correlated with an imbalance or disturbance in the biofield, though there is no consensus as to whether the illness or energetic disturbance comes first (Dossey, 2008; Nemeth, 2008; Slater, 2008).

Many biofield healers and researchers contend that all healing is self-healing, and that the "healer" is simply a facilitator who provides a safe space and allows the healing to occur (Dossey, 2008; Lipinkski, 2006; Slater, 1995b; Slater, 2008; Stein 1995). The United States National Center for Complementary and Alternative Medicine (NCCAM) states that biofield therapies are being used as an adjunct to mainstream health care, and that Reiki is a modality that is often used for self-care as well as being used as a healing method for others (NCCAM 2008; NCCAM 2009).

AIMS

This study intends to examine the nature of Reiki as a self-care modality in people who report themselves to be healthy (not acutely or chronically ill). It will also strive to answer the following questions:

- 1. What is the experience like for self-reported 'healthy' people performing Reiki as a daily self-care modality?
- 2. How does Reiki as a daily self-care method differ from a daily meditation/ relaxation practice?
- 3. Are there any common themes between/among participants?

If the participants perceive the experience to be valuable, the study could then be repeated with patients who are ill. This would explore a different facet of the modality, generating more data on the experience of Reiki self-treatments, which could eventually lead to more controlled and randomised studies, moving further through the MRC complex interventions framework.

REIKI LITERATURE REVIEW

A literature search using AMED, CINAHL Plus, and Medline databases highlighted the lack of scholarly research relating to Reiki as a biofield therapy. (See Chapter I of this dissertation.) The articles retrieved show that Reiki is used in cases of cancer (Molassiotis et al., 2005; Owens et al., 2009), trauma (Kennedy, 2001; Slater 2004), stress/ anxiety, chronic pain, HIV/AIDS, treatment side effect reduction, and disease symptom management (NCCAM, 2009). The settings Reiki is used in varies, including hospice (Nelson, 2006), post-anesthesia care units (Scales, 2001), acute care wards, emergency departments, home care, and administrative settings (Lipinski, 2006). It is used in the United States (NCCAM, 2009) and Europe (Molassiotis et al., 2005), and is likely used in other countries as well, though the literature search did not identify any articles supporting this (the search was limited to articles in English). Unfortunately, many of the above-referenced articles simply states where Reiki was used or by which patient population, and did not show research on how it is used or its efficacy, a common problem in research reporting, according to Glasziou et al. (2008).

This lack of adequate reporting can be correlated with slow and/or inadequate research utilistion (Glasziou et al., 2008). If an intervention is not described in detail, it cannot be replicated in a manner that would be expected to generate the same results. Similarly, if the context in which the intervention is delivered is not made explicit, professionals cannot decide whether or not the research would be applicable in other settings. In cases of complex interventions such as Reiki and other biofield therapies, much more information needs to be provided if the results are to be utilised in practice (Glasziou et al., 2008).

Several authors did present case studies demonstrating the effectiveness of Reiki with individual patients. Two of these studies used multiple modalities (Slater 2004; Scales, 2001), one (Kennedy, 2001) was treating victims of violent war-related trauma, and the other (Nield-

Anderson & Ameling, 2000) was treating a dying friend, so while they were interesting cases, none of these provided information that was both specific to Reiki and generalisable to other settings.

Lee et al. (2008) conducted "the only systematic and critical appraisal of RCTs" (p. 947) which concluded that there was not enough evidence demonstrating efficacy of Reiki in practice, and that most of the trials were methodologically flawed (they included 9 out of 205 identified studies). The review was useful to this dissertation in that it had no language restriction, and was therefore able to review articles from Japan and Korea as well as those published in English. This author was unable to obtain all of the RCTs studied by Lee et al., however, some of the data that was available did not confirm the findings presented in the systematic review. The most glaring example of this is described below.

In their review, Lee et al. stated that there was no difference in the study results on painful diabetic peripheral neuropathy by Gillespie et al. (2007), while in the actual paper by Gillespie et al. (2007), the authors reported no difference between Reiki and mimic-Reiki (non-Reiki practicing actors who mimicked the actions and behaviours of the Reiki practitioners). There was however, a significant difference in pain reduction and functional ability between both the Reiki and mimic-Reiki groups and the usual care group. Gillespie et al. hypothesized that the pain reduction and increased walking distance was due to the continuing relationship with their providers experienced by the Reiki and mimic-Reiki groups, however this could possibly be related to the holistic care model and incidental factors in CAM therapies discussed by Paterson and Dieppe (2005). Unfortunately, the report by Gillespie et al. is a very short article without adequate descriptions of the intervention protocols, so the reader does not have enough information to decide whether or not this could be the case.

While this may not appear to be a major difference, given the complex nature and philosophical differences between reductionist and holistic models, there may be other factors that Lee et al. overlooked or dismissed in their review. There were quality of life improvements and pain reduction in many of the studies reviewed, but the results are still inconclusive. Since Reiki is not a simple intervention, to approach it as a one-size-fits-all review may be inadequate or even inappropriate. While Lee et al., adequately analyse the typical components of an RCT (sample,

effect size, blinding, control measures), they do not take into account the holistic nature of Reiki interventions or the differences between acute and chronic illnesses and their treatment. They do assert that the trials do not include adequate explanations of the interventions and that for the sake of repeatability, the expertise and protocols of the practitioner as well as the details of the intervention need to be more standardized. This debate has been discussed in Chapter III of this dissertation, but it is mentioned here because there is one study (published after Lee et al.'s review) that dealt with this issue quite nicely.

Bowden, Goddard, and Gruzelier (2010) conducted a well-designed RCT that showed Reiki had a preventative or moderating effect on illness when compared to the control group, but no effect on salivary cortisol levels or correlations between salivary cortisol and health/ mood changes. The groups were randomised and participants were blinded as to whether or not they received Reiki whilst participating in either self-hypnosis or guided relaxation. The process was standardised: each subject would sit in a chair and perform their self-hypnosis or guided visualisation with the Reiki Master (highest degree Reiki practitioner) seated behind the subject. The Reiki Master sent non-contact Reiki to the subjects in the Reiki group, and sat quietly behind those in the non-Reiki group; questionnaires administered to the subjects showed that they were successfully blinded to whether or not they received Reiki.

While the process was standardised in the above study, the Reiki Master used her judgement as a healer in choosing the individualised Reiki techniques during the treatments. This addresses the issue of standardisation whilst allowing the treatment to progress in a natural way, as it would in a non-experimental session. Additionally, while the results do point to a health benefit in Reiki treatment, Bowden et al. have shown that Reiki can be studied in a rigorous, scholarly RCT. The care taken with this study however, is the exception rather than the norm, and it is possible that since the study did not show the anticipated effects, that either the hypothesis or the outcome measures could have been improved before commencing the study. It is worth restating though, that this study was by far the most well-designed Reiki study (of any type, not simply RCTs) found during the course of this dissertation.

It is quite surprising, given the 1.2 million adults and 161,000 children who used Reiki in the US in 2006 (NCCAM, 2009), that the articles mentioned above are the only scholarly healthcare

research results this author could find on Reiki. This highlights a crucial need for more research, but with the majority of the current research being of poor quality and/or providing inconclusive data, it would appear that the way Reiki is being researched is inadequate. Moreover, if the current research is inadequate, maybe the best approach is to go back to the beginning and examine what Reiki is all about.

RESEARCH METHOD

While the Medical Research Council's complex interventions framework has both critics and supporters with regards to complementary and alternative interventions (see Chapters III-IV above), this author feels it is a useful framework to begin studying the efficacy and usefulness of Reiki. Due to the fact that much of the available literature is anecdotal or inconclusive, the author contends that it is necessary to 'go back to the drawing board,' and start with the first step of the guidelines: defining the components and understanding the theory, mechanisms, and the lived experience of the intervention. Without a clear understanding of the experience and effects produced by Reiki, it is difficult to know what questions to ask and which ones will just provide more inconclusive data. We must understand the phenomena in order to formulate appropriate research questions. It is for this reason that qualitative research (specifically, Husserlian phenomenology, as described by Priest, 2002) was chosen as the philosophical approach for this initial study.

Lewin et al. (2009) explored the use of qualitative research as a complement to RCTs, and concluded that qualitative studies can provide valuable information before, during, and after RCTs. Qualitative studies can help researchers develop interventions, hypotheses, and outcome measures for future RCTs as well as helping researchers understand the experiences and contexts relating to the intervention(s). During and after the RCTs, qualitative research can help explain findings, assess processes, and suggest improvements in future study design (including addressing issues such as attrition and refusal to participate). Despite the common concepts that well-designed and well-conducted RCTs produce the best evidence for practice, and that qualitative research can explain things RCTs cannot, Lewin et al. found the practice of linking RCTs with qualitative studies relatively uncommon. They suggest however, that it is a viable and useful practice requiring further development.

Phenomenology is one qualitative research method that could provide useful information for a future RCT of Reiki. Phenomenology is a descriptive method derived from Husserl's theory that all human knowledge in based on experience, with the word 'experience' broadened "to refer to anything of which a person may be conscious, such as a physical object, an abstract concept, or a mood state" (Priest, 2002, p.51). The goal of phenomenology is to understand the fullness of a phenomenon in its entirety. Priest (2002) describes this process as follows. First, the researcher must intentionally set aside his/her presuppositions, theories, and personal beliefs in order to view the phenomenon without bias. Next, the researcher reflects on the data, intuitively exploring it, investigating all possible implications, and removing inessential factors, to generate a common understanding of the experience. Finally, the researcher attempts describe the phenomenon in its purest state, the core essence of what separates that phenomenon from all others.

There are debates as to whether the essence of a phenomenon can be adequately described or generalised, since Husserl's original philosophy focused on individual experience. However, if the researcher is seeking to determine a common experience amongst a group of people, it can be a useful approach in disciplines such as nursing. Additionally, if the researcher takes care to examine, disclose, and suspend her/his own bias as well as that of the subjects (as much as possible), it should be possible to arrive at objective conclusions about the experiences in question (Priest, 2002). This suspension of one's natural beliefs and attitudes allows the researcher to be rigorous in examining data, which greatly increases the credibility, reliability, and validity of the study results (Priest, 2002).

PLAN, DESIGN, AND RATIONALE

Self-described healthy participants were chosen for this study because of the holistic nursing presumption that health is a natural state of balance (Dossey, 2008). This is beneficial as well, since it will not interfere with any longstanding medical treatment. However, upon completion of the study, the study processes and protocols will be assessed for effectiveness and if it is deemed appropriate, a second phase will be pursued with a sample of chronically ill patients, as they are the patient population most often cited as using complementary healthcare modalities (Nield-Anderson & Ameling, 2000). Thirty days was chosen as the intervention period since it

represents a sufficient amount of time to establish self-treatment as a habit and provide participants with a variety of experiences.

Self-treatments were chosen instead of treatments by a practitioner to eliminate the practitioner-client relationship as a potential confounding factor. An established daily meditation or relaxation practice eliminates relaxation as a confounding factor, since the subjects will be able to act as their own controls, determining whether the Reiki had a different effect from their previous practice. Additionally, the discipline required to practice some form of meditation/relaxation will be helpful in establishing a daily self-treatment routine. Finally, many of the healers in published studies used a variety of methods (such as in Scales, 2001 and Slater, 2004). If the subjects are new to biofield healing and establish a regular practice of self-treatments, this should give participants enough skill with Reiki to share their experiences in a reflective and purposeful manner while eliminating confusion over which method produced which results.

SAMPLE

Participants will be accepted based on the following criteria:

- 1. Willingness: Subjects must voluntarily agree to participate;
- 2. Health: Subjects must be currently free of acute or chronic illnesses and describe themselves as healthy;
- 3. Meditation: Subjects must have an established meditation or relaxation practice that lasts a minimum of 20-30 minutes per day, and is practiced five to seven times per week (daily practice is preferable);
- 4. New to Biofield Healing: Subjects must not be practitioners of Reiki or other biofield modalities.

The above elements were chosen as inclusion criteria because the goal is to understand the effects of Reiki self-treatments. The study will aim to recruit 6-10 people of varied age and gender. This should be a sufficient number of people to generate common themes and concepts, while being small enough to allow the researcher to gain an in-depth understanding of the experience of each subject.

While it is a possible study limitation that the common background of having a daily meditation practice will produce a sample that is different in personality than the mainstream public, the benefits of self-discipline (to keep up the daily practice) and experience in relaxation/ meditation (to rule out relaxation as a causative factor for any results) are worth it. Additionally, subjects who are new to the practice of biofield healing, will not have the complication of using multiple modalities. The combination of these factors is hypothesized to help the results of the Reiki self-treatments be clearly differentiated from relaxation or other modalities so that the results.

THE INTERVENTION

Once participants are screened and approved for participation (based on the above criteria and informed consent) they will be enrolled in a Reiki Level 1 class lasting 6-8 hours. Subjects will be instructed on the history, traditions, philosophy, and self-practice aspects of level 1 Reiki according to the tradition of the Reiki Master teaching the class (Reiki is passed on through an oral lineage as well as currently through published materials) (Stein, 1995).

During this class, participants will be further instructed on the protocols expected of them during the study as well as receiving written contact information for the researcher and materials reinforcing the study protocols and information. Participants will be shown how to perform self-treatments, which will include basic hand positions (as a starting point), and they will be able to practice and ask questions during the class so they are comfortable with the procedure.

Participants will be asked to perform Reiki self-treatments for a minimum of twenty minutes each day and to journal about their experiences immediately afterwards. Participants will continue this process daily for 30 days. Participants may choose to do this in lieu of or alongside their current meditation practice, but it is expected that the treatments will be done while participants are in a calm, relaxed state.

At the conclusion of the study, the participants will have the right to keep their journals private or to submit a copy of their journals to the researcher. If the subjects choose to submit their journals and comments are used in publication, identifying information will be altered to ensure anonymity. If the subjects choose not to submit their journals to the researcher (with the understanding that healing can be an intensely personal process), they will be asked to review

their journals prior to the follow-up interview, in order to give the researcher the clearest possible picture of their experience.

OUTCOME MEASURES

Since the study will be phenomenological in nature, the outcome measures will be flexible, designed to understand the lived experience of the participants and determine how the experience differed from their previous meditation practice and what effect (if any) they felt the self-Reiki treatments had in their lives. The follow-up interviews will be conducted in a comfortable, private setting and will be recorded and then transcribed by the researcher.

The participants will be asked the following questions (generated from reflecting upon the literature review) in a semi-structured interview:

- 1. How often did you do the Reiki self-treatments? (This is to determine if they followed study protocols. Follow-up questions will then be asked in order to evaluate the study process and design.)
- 2. What was your experience of performing Reiki as a (daily) self-care modality?
- 3. How does Reiki as a daily self-care method differ from your previous daily meditation/ relaxation practice?

Appropriate follow-up questions will be asked to explore emerging themes, experiences, and comments made by participants. The participants will also be given the option to add any comments or give feedback at the end of the interview.

After all of the interviews are conducted and the data is analysed, the participants will be invited to a focus group with the intention of exploring key concepts and themes that emerged in order to flesh out the understanding of the experience more fully. This will take place after the interviews so that the participants have the ability to share their experiences individually, without the opinions and statements of other participants potentially clouding or colouring the individual experiences. However, it is hoped that in the focus groups, the researcher will gain the fullest possible understanding of the subjects' experiences, while being able to share and verify (and if

necessary, have clarified) the understandings and outcomes discovered. The focus groups will be videotaped and transcribed as well.

DATA ANALYSIS & DISSEMINATION

Following Priests's (2002) phenomenological approach, the researcher will begin the process of exploration by extensively reviewing and reflecting upon the literature, examining personal beliefs, and writing up an initial written description of the phenomenon. This will help the researcher to identify personal presuppositions and bias that could interfere with rigorous examination of study findings. After conducting participant interviews, the researcher will transcribe and study the interview transcripts (and journals, where shared by the participants) one at a time. The researcher will highlight key phrases and themes in the first transcript, and will incorporate these (including verbatim quotes where appropriate) into the initial written description. This process will be followed for each of the subsequent interviews, with analysis of each transcript producing a revised, and more complete description of the phenomenon. The researcher will search for common themes and phrases in the data as well as variations and differences in participants' experience. Additionally, the principle of horizontalisation will be followed, which assigns all aspects the same significance initially, as another method to reduce evaluator bias (Priest, 2002).

When the written account is complete, this will be emailed or sent to participants for review. Next, focus groups will be held to explore, clarify, and verify the researcher's written description of the experience. These will inquire about the participants' experiences with the Reiki self-treatments as well as the study process and protocols. Participants will be invited to examine the study results and determine whether the written account accurately captures their experiences. Process evaluations will also be conducted by the researcher monthly or as needed throughout the course of the study, as well as upon study completion.

Regardless of the study results, the research will be documented and submitted for publication in appropriate healthcare journals such as *Complementary Therapies in Clinical Practice* (UK) and *Journal of Holistic Nursing* (US) in order to contribute to the current evidence regarding Reiki. The ultimate aim of this research is to provide information that will inform future rigorous

studies utilising the MRC's complex interventions framework. In this spirit, the treatment process, process evaluations, and other essential information will be described in detail so that the protocols may be replicated in future research and/or practice (Glasziou et al., 2008).

TIMETABLE

Months 1-3	Finalise study design; obtain ethical review board approval.		
Months 4-6	Recruit participants from local meditation centres.		
Month 7	Conduct Reiki level 1 class; attune subjects to Reiki energy.		
Months 7-8	Participants practice daily self-treatments for 30 days in conjunction with or in place of their established meditation/ relaxation practice.		
	Researcher again reviews/ reflects on literature and personal experience; generates initial written description to reveal bias and compare with findings.		
Month 8	Conduct individual interviews; begin transcribing data.		
Months 9-10	Analyse participant data; revise written description of phenomenon.		
Month 11	Run focus groups: verify data, share results, and follow-up with participants.		
Months 12-13	Write final description of phenomenon from interview/ focus group data; submit results to appropriate journals for publication.		

BUDGET

Personnel	Hourly Pay Rate	Expected Hours	Anticipated Cost
Registered Nurse (RN) Researcher	\$35/ hour	100 – Planning/ Recruiting 8 – Reiki I Class 30 – Interviews 200 – Transcribing/ Reviewing interview data 100 – Data analysis 6 – Focus group & preparation 20 – Final data analysis 40 – Writing article for publication Total: 504 hours	\$17,640.00
	\$17,640.00		

Other Anticipated Costs:	Obtaining Literature & Materials (i.e. recording device, software)	\$500	\$500
	Printing & Copying	\$350	\$350
		Total Expected Costs	\$18,490.00

ETHICAL IMPLICATIONS

Since the initial study will focus on people who are well, there will not be the same ethical concerns that there would be with sick patients, such as the study interfering with medical treatment. That said, as with any trial, participants may experience life or health changes during the course of the study causing them discomfort or illness. All participants will be advised in writing that Reiki self-treatment is not a substitute for medical or psychological treatment, and will be advised to seek out allopathic medical care or referred to appropriate practitioners/facilities if the need arises.

Participation in the study will be voluntary, and all participants will be notified in writing when they agree to participate that they are able to withdraw from the study at any time. Before agreeing to participate, each participant will have the study explained verbally and in writing, allowing them ability to ask questions and be fully informed when giving consent. Informed consent will be obtained in writing for all participants.

It could be argued that using a method whose efficacy is still undetermined could be a means of misleading or giving false hope to participants. However, the data reviewed above shows that the effects, efficacy, and mechanisms of action in Reiki are not well understood. Since Reiki has been determined to be safe (NCCAM, 2009) however, and this study is using healthy subjects, it can be intuited that this will not be giving false hope (as could be the case in terminal patients wishing for a 'miracle cure'). Patients will be instructed that the study is to describe the experience in a scholarly fashion and no claims will be made regarding potential healing effects.

Additionally, all attempts will be made to ensure confidentiality and anonymity of participants when study findings are published. Because of methods employed in the study, researchers will have direct contact with the subjects, and participants will meet other participants during the initial class and focus groups (on a first-name basis only). However, participants will not be

given information or access to other participants through the course of the study, including use of blind carbon copying (Bcc:) on any electronic communications sent out. During the focus groups, if findings are shared, any information revealed of a private nature during the interviews will be kept strictly anonymous so no participants feel singled out.

Ethical concerns specifically relating to holistic nursing (as discussed in Chapter II) include patient autonomy, concern for the patient's quality of life and personal dignity, empowerment, and the concept of healing as an internal rather than an external process (Mariano, 2008). Patient autonomy is reflected in the voluntary nature of the study. The concern for quality of life and patient dignity will be reflected in the researcher's interactions with the participants; the researcher will be consciously present, communicate holistically, and honour the participants' personal beliefs, values, and inherent dignity. Finally, the choice of Reiki self-treatments, as opposed to treatments by "a healer" empowers patients by acknowledging the holistic principle that all healing is self-healing (an internal process) and establishes the researcher as a willing and knowledgeable facilitator in the participants' journey toward wholeness.

Any other ethical concerns or questions that arise within the course of the study will be addressed immediately. All responses will follow guidelines established by law and the funding body's ethical review board.

CONCLUSION

This concludes the research proposal. As previously stated, it is hoped that this study will increase the rigorous, scholarly knowledge about Reiki available to researchers, and give future studies a firm foundation in the experience of Reiki as a biofield healing modality. In addition, it is hoped that this scholarly approach will inspire other holistic nurses and practitioners of complex interventions (including complementary and alternative therapies) to research both qualitatively and quantitatively, so that the complexities of these treatments can be explored. This way, a multitude of useful information can be gathered and more importantly, utilised.

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