THE EFFECTS OF DISTANT HEALING PERFORMED BY A SPIRITUAL HEALER ON TYPE 2 DIABETES: A RANDOMIZED CONTROLLED TRIAL

Kenjiro Tsubono

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The work reported in this thesis is original and carried out by me solely, except for the acknowledged direction and assistance gratefully received from colleagues and mentors.

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Kenjiro Tsubono

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ABSTRACT

Many people suffer from type 2 diabetes. No randomized controlled studies on distant healing for type 2 diabetes were found in the published literature. The objective of this study is to evaluate the effects of distant healing performed by a professional Japanese healer on type 2 diabetes subjects in North America. People suffering from type 2 diabetes were recruited in Springfield, Missouri and Boulder, Colorado through local radio advertising, newspaper advertising, and announcements at diabetes support group meetings. Subjects were randomly assigned to the treatment group (N=14) or the control group (N=13) using a double-blind procedure. All subjects met the healer at the initial session in which a 20-minute group meditation was performed. The healer went back to Japan after the session and started distant healing only to the treatment group for a four-month period by using the list of their names and photos. The outcome measures included the Hemoglobin A1c (HbA1c) levels, the Diabetes Symptom Checklist-Revised (DSC-R), the State-Trait Anxiety Inventory (STAI), and the Zung Self-Rating Depression Scale (SDS). Comparison of pre-treatment and post-treatment HbA1c levels and the STAI Y-2 scores ("trait" anxiety levels) showed a significant effect of distant healing (P=.029 and P=.047). The DSC-R, the STAI Y-1 ("state" anxiety levels), and the SDS scores showed improvement in the treatment group, but the difference between both groups was not statistically significant. Additional interesting findings are presented. Implications and future research recommendations are included.

Key Words: distant healing, remote healing, absence healing, intercessory prayer, diabetes, type 2 diabetes, Hemoglobin A1c (HbA1c), Diabetes Symptom Checklist Revised (DSC-R), the State-Trait Anxiety Inventory (STAI), the Zung Self-Rating Depression Scale (SDS), Japanese healer, Esoteric Buddhism, Shinto healing, randomized controlled trials (RCT), double blind trials.

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CHAPTER 1:
INTRODUCTION

Chapter 1 provides a background of the research problem at hand, explains the purpose of the study, articulates the two research questions, elaborates on the importance and scope of the study, provides a definition of terms the reader might find quaint, and ends with a brief treatise on the delimitations and limitations of the study.

Background of Problem

There are 20.8 million children and adults in the United States, or 7% of the population, who have diabetes.[1] Type 2 diabetes (formerly called non-insulin-dependent or adult-onset diabetes) results from the body's ineffective use of insulin. Type 2 diabetes comprises 90% of people with diabetes, and is largely the result of excess body weight and physical inactivity.[2] Healthy eating, physical activity, and blood glucose testing are the basic management tools for type 2 diabetes.[3] However the level of physical training recommended for type 2 diabetes patients is not feasible in many patients because of age, obesity, and other problems.[4] Therefore, the treatment compliance of diabetes patients is very poor.[5] Furthermore, diabetes imposes significant financial burden on individuals with the disease and on the entire nation. More than a decade ago the annual medical cost associated with diabetes in the US was already $98 billion.[6]

There is evidence that an increasing number of people in the US use one or more Complementary and Alternative Medical (CAM) remedies for the treatment of common medical conditions.[7] In the recent study of CAM in the US, 7% of persons surveyed reported having tried some form of "spiritual healing."[8] In the same study, 35% of

persons surveyed reported that they had used prayer to address their health-related problems. *Distant healing* has been defined as "a conscious, dedicated act of mentation attempting to benefit another person's physical or emotional well being at a distance."[9] One form of distant healing is intercessory prayer, in which a person prays for the healing of another person who is a great distant away, with or without that person's knowledge.[10] There are several studies which showed the positive effect of intercessory prayer.[11] As far as the Principal Investigator (PI) knows, only one clinical study which examined the effects of distant healing on type 2 diabetes has been published, but the final outcomes did not show a statistically significant improvement.[12]

The problem of the previous studies on distant healing is that the definition of healers was unclear. In personal knowledge of the PI, a substantial difference in the healing power between experienced healers and non-experienced healers seems to exist. The spiritual healer who performed distant healing in this study was a professional Japanese healer named Jiho Otsuki, who has had more than 20 years of experience in distant healing. He healed many patients with type 2 diabetes successfully in Japan.

Type 2 diabetes is much related to addiction to sugar or other unhealthy diet.[13] Many patients' also have psychological problems such as anxiety and depression.[14] These factors might also contribute to the poor compliance of diabetic patients with the treatment plan. To deal with both the physical and psychological problems of patients may be essential to treat this disease. Some studies that showed the effectiveness of distant healing on people's psychological conditions have been published.[15] Considering these things together, distant healing performed by the Japanese healer would be effective for various conditions of type 2 diabetes.

Purpose of the Study

The purpose of this study was to evaluate the effects of distant healing performed by the spiritual healer on type 2 diabetes. The outcome measures were the Hemoglobin A1c (HbA1c) levels, the Diabetes Symptom Checklist Revised (DSC-R) scores, the State-Trait Anxiety Inventory (STAI) scores, and the Zung Self-Rating Depression Scale (SDS) taken before and after the intervention.

Research Questions

The research questions this study sought to answers were as follows.

1) Does the distant healing performed by the Japanese healer lower the HbA1c levels?
2) Does the distant healing performed by a Japanese healer improve other related symptoms of type 2 diabetes including physical and psychological symptoms?

Importance of the Study

One of the goals of this research was to identify a non-invasive, effective treatment for type 2 diabetes. If the distant healing is proved effective for the conditions of people with type 2 diabetes, it would become an ideal adjunctive therapy (or primary therapy for some patients) for the treatment of type 2 diabetes, especially for those patients whose compliance with conventional treatments is low. Patients do not have to do anything to receive the healing treatment (the only thing the Researcher asked the participants to do was to focus on receiving healing energy for a few minutes a day).

The other goal of this research was to examine the reality of the non-local nature of mind. Some studies which examined the effects of distant healing have been published, but the reality of the non-local effects of mind is still controversial. A topic

which is often discussed in the study of distant healing is the so-called "placebo effect," which is synonymous with the power of suggestion.[16] To rule out the placebo effect, a double-blind procedure was used in this research in which the group assignment was concealed from both the experimenter and participants. If the significant difference is found in the final outcomes between the treatment group and the control group, it would provide an insightful indication to the field of the study on the non-local nature of consciousness.

Scope of the Study

The protocol of this study was approved by the Institutional Review Board (IRB) of Holos University Graduate Seminary on September 15, 2008 through an expedited review process. The study was conducted according to this approved protocol to ensure that it was safe and ethical for all the subjects.

The outcome measures in this study included the Hemoglobin A1c (HbA1c) levels, the Diabetes Symptom Checklist Revised (DSC-R), the State-Trait Anxiety Inventory (STAI), and the Zung Self-Rating Depression Scale (SDS). The HbA1c levels were measured with the A1CNow+® device (Metrica Inc.) which was designed for at-home monitoring of HbA1c. All of these tests were performed two times: before and after the intervention.

The intervention involved the initial session with the healer (in which a 20-minute group meditation was performed) and the following four-month distant healing performed by him. The population included men and women aged 18years or older with diagnosed type 2 diabetes. After collecting all data, statistical analysis of the data (specifically a mixed analysis of variance and a t-test) was performed to assess the results.

Definition of Terms

The following definitions of are derived from the *Merriam-Webster's Collegiate*®

Dictionary, Eleventh Edition unless indicated otherwise.

Absent Healing – *See* Distant Healing.

Animism – Attribution of conscious life to objects and phenomena of nature or to inanimate objects.

Boomerang Effect – The occult principle that a psychic attack which comes up against a stronger defense rebounds on the attacker. [17]

Bunrei – The phenomenon that a spirit splits itself and makes its exact copy.[18]

Complementary and Alternative Medical (CAM) Therapies – Therapies that are not generally offered within conventional medical care (such as acupuncture, homeopathy, spiritual healing, and many more).[19]

Consciousness – The quality or state of being aware of something within oneself or an external object.

Cosmic Consciousness – The concept that the universe has its self-consciousness which spans the entire cosmos.[20]

Diabetes – A variable disorder of carbohydrate metabolism caused by a combination of hereditary and environmental factors and usually characterized by inadequate secretion or utilization of insulin, by excessive urine production, by excessive amounts of sugar in the blood and urine, and by thirst, hunger, and loss of weight.[21]

Diabetes Symptom Checklist Revised (DSC-R) – A measure of both the occurrence and the perceived burden of physical and psychological symptoms related to type 2 diabetes and its possible complications.[22] It is a 34-item, self-report questionnaire in which each item is rated on a 4-point Likert scale.

Distant (absent) Healing – One modality of spiritual healing which is sent from any distance. This is done as mental focus, intent, meditation, or prayer.[23]

Electroencephalogram (EEG) – An electronic recording of voltages between points on the scalp, reflecting in a very rough way some of the electrical activity of the brain, especially at the surface of the cortex. Various wave frequencies have been correlated with different states of consciousness.[24]

Energy Healing – It is intended to affect energy fields that purportedly surround and

penetrate the human body. The existence of such fields has not yet been scientifically proven. Some forms of energy therapy manipulate biofields by applying pressure and/or manipulating the body by placing the hands in, or through, these fields.[25]

Energy Medicine – One of the CAM modalities which involves the use of energy fields. They are of two types: bio-field therapies (energy healing) and bio-electromagnetic-based therapies.[26]

Emptiness – The doctrine that all concepts and phenomena lack inherent existence.[27]

Esoteric Buddhism – One of several streams of practice within the Mahayana Buddhist tradition. It blends many doctrines, philosophies, deities, religious rituals, and meditation techniques from a wide variety of sources. Assimilation of Hindu, local deities, and rituals were especially marked in the Buddhism that became Esoteric Buddhism. Such diverse elements came together over time and, combining with Mahayana philosophical teachings, formed a comprehensive Buddhist system of doctrine and practice.[28]

Exorcism – An adjuration addressed to evil spirits to force them to abandon an object, place, or person; technically, a ceremony used in both Jewish and Christian traditions to expel demons from persons who have come under their power. The rites and practices of preliterate people to ward off or to expel evil spirits are also a form of exorcism, though they are sometimes considered witchcraft.

Exoteric Buddhism – The teachings of Buddhism which were all taught by the historic Buddha Sakyamuni. The teachings contain many illustrative stories.[29]

Four Noble Truths – One of the fundamental doctrines of Buddhism, said to have been set forth by the Buddha, the founder of the religion, in his first sermon, which he gave after his enlightenment. It is composed of the following four: the nature of suffering (*Dukka*), its origin (*Samudaya*), the cessation of suffering (*Nirodha*), and the way to lead the cessation of suffering (*Magga).*[30]

Four Tantras – The most fundamental textbook of Tibetan medicine.[31] It was systematized based on the teachings of Esoteric Buddhism.

Fructosamine Test – It reflects the average blood glucose level during the past two or three weeks.[32]

Genkyoku Qigong – One of qigong modalities which has more than 700 years of history. It has been known for its powerful healing effect. Usually, practitioners of qigong schools consider that there is only one fundamental component in the universe, which is qi. However, Genkyoku practitioners consider that the universe is composed of the three fundamental components instead of one: the original light (*genko*), the original sound (*genon*), and the original qi (*genki*).[33] It is believed that practitioners can develop their psychic ability effectively by controlling these three components.

Hemoglobin A1c (HbA1c) – A test that measures the amount of glycated hemoglobin in the blood.[34] Glycated hemoglobin is a substance in red blood cells that is formulated when hemoglobin is attached by blood sugar. This test is considered to provide the most reliable assessment of glucose management. It provides an index of a patient's average blood glucose level during the past 2-3 months.[35]

Hinduism – The dominant religion of India that emphasized dharma with its resulting ritual, social observances, and often mystical contemplation and ascetic practices.

Ikiryo – The spirit of living people which has left their body when they hold a strong grudge against others. [36]

Intention – A determination to act in a certain way.

Intercessory Prayer – Any form of requesting God to bring about a specific desired outcome.[37]

Kami – The name for the spirit-soul in Shinto traditions that is hidden, unseen, and has a sacred as well as awe-inspiring effect. This name is a rather recent one compared to other ancient ones.[38]

Kishin – The phenomenon that the spirit of *kami* comes down to shamans' body and starts demonstrating its power through them.[39]

Ko-Shinto – The most original type of Shinto which has inherited various spiritual practices of ancient times in its original form.[40]

Kukai – One of the best known and most beloved Buddhist saints in Japan, founder of the Shingon school of Buddhism that emphasizes spells, magic formulas, ceremonials, and masses for the dead. He contributed greatly to the development of Japanese art and literature and pioneered in public education.

Mahavairocana – The supreme Buddha, as regarded by many Mahayana Buddhists of East Asia and of Tibet, Nepal, and Java. Among the Shingon sect of Japan, it is the chief object of reverence and is regarded as the source of the entire universe. In Japanese, it is called Dainichi Nyorai ("Great Sun Buddha").

Mandala – A symbolic diagram used in the performance of sacred rites as an instrument of meditation in Hindu and Buddhist Tantrism. It is basically a representation of the universe, a consecrated area that serves as a receptacle for the gods and as a collection point of universal forces.

Mantra – A sacred utterance (syllable, word, or verse) that is considered to possess mystical or spiritual efficacy in Hinduism and Buddhism.

Mudra – A symbolic gesture of the hands and fingers used either in ceremonies and

dance or in sculpture in Buddhism and Hinduism. Mudras used in ceremony and dance tend to be numerous, complicated, and often esoteric.

Noble Eight Fold Paths – One of the fundamental concepts of Buddhism, which is said to have been taught by the Buddha Sakyamuni. It indicates the solutions to suffering and composed of the following practices: Right Views, Right Intent, Right Speech, Right Conduct, Right Livelihood, Right Effort, Right Mindfulness, and Right Concentration.[41]

Norito – Words, or prayer, addressed by worshipers to a deity in the Shinto religious practices of Japan.

Non-directed Prayer – Intercessory prayer in which the person praying wishes only that God's will be done in the life of the subject.[42]

Non-local Consciousness – The mind can reach across space and time to obtain and share information with other people, with the collective consciousness of groups of people or of all of mankind, and with transpersonal consciousness (spirits, spiritual luminaries, and God).[43]

Placebo – A treatment that has no intrinsic healing benefits but is perceived by the recipient to be a potent intervention and, therefore, influences the recipient to improve. This is a form of suggestion.[44]

Psychic Attack – The transference of negative energy between two persons through the use of telepathic skills.[45]

Qi, (Chi) or Ki – The ethereal psychophysical energies of which everything is composed. Early Daoist philosophers and alchemists regarded *qi* as a vital force inhering in the breath and bodily fluids and developed techniques to alter and control the movement of *qi* within the body. Their aim was to achieve physical longevity and spiritual power.

Qigong – An ancient Chinese healing art involving meditation, controlled breathing, and movement exercises.

Remote Healing – *See* Distant Healing.

Shingon Buddhism – Esoteric Buddhist sect that has had a considerable following in Japan since its introduction from China in the ninth century. Shingon may be considered as an attempt to reach the eternal wisdom of the Buddha that was not expressed in words and, thus, not in his public teaching. The sect believes that this wisdom may be developed and realized through special ritual means employing body, speech, and mind, such as the use of symbolical gestures (mudras), mystical syllables, and mental concentration (yoga).

Shinbutsu-shugo – Amalgamation of Buddhism with the indigenous religion Shinto in Japan. The precedents for this amalgamation were laid down almost as soon as Buddhism entered Japan in the mid-sixth century, and the process of blending Buddhism with

Shinto has dominated the religious life of the people up to the present.

Shinto – Based on the worship of spirits known as *kami*, it has no founder and no official scripture, though its mythology is collected in the *Kojiki* ("Records of Ancient Matters") and *Nihon shoki* ("Chronicles of Japan"), written in the eighth century.

Shugendo – A Japanese religious tradition combining folk beliefs with indigenous Shinto and Buddhism, to which have been added elements of Chinese religious Taoism. Its practitioner, the *yamabushi* (literally, "one who bows down in the mountains"), engages in spiritual and physical disciplines in order to attain magical power effective against evil spirits.

Spirit – A supernatural being or essence which includes a malevolent being that is bodiless but can become visible.

Spiritual Entity – *See* Spirit.

Sokushin-jobutsu – The concept that one becomes a Buddha with one's present physical body. The word "soku" means clinging to, adhering to, and becoming one with another object.[46]

Soul – The immaterial essence, animating principle, or actuating cause of an individual life.

Spiritual Healer – A person who performs spiritual healing.[47]

Spiritual Healing – Spiritual healing is a systematic, purposeful intervention by one or more persons aiming to help another living being (person, animal, or other living system) by means of focused intention, hand contact, or passes to improve their condition.[48]

State-Trait Anxiety Inventory (STAI) – The instrument which was developed in 1970 by Spielberger and his colleagues as a reliable self-report instrument for measuring anxiety and widely used all over the world.[49] It is a self-report instrument that measures levels of anxiety. It clearly differentiates between the temporary condition of "state anxiety" and the more general and long-standing quality of "trait anxiety."

Symbolic Techniques – Spiritual practices in Hinduism and Buddhism which include hand gestures (mudras), chanting (mantras) and the internal visualization of the Buddhas and other deities (mandalas).

Tanden – A point located about two inches below the navel, and it is considered as the source of spiritual strength.[50]

Theravada Buddhism – Major form of Buddhism prevalent in Sri Lanka (Ceylon), Myanmar (Burma), Thailand, Cambodia, and Laos. Theravada, like all other Buddhist schools, claims to adhere most closely to the original doctrines and practices taught by

the Buddha.

Type 1 Diabetes – Diabetes of a form that usually develops during childhood or adolescence and is characterized by a severe deficiency of insulin secretion resulting from atrophy of the islets of Langerhans and causing hyperglycemia and a marked tendency toward ketoacidosis.[51]

Type 2 Diabetes – Diabetes mellitus of a common form that develops especially in adults and most often in obese individuals and that is characterized by hyperglycemia resulting from impaired insulin utilization coupled with the body's inability to compensate with increased insulin production.[52]

Vajurasattva –The legendary figure of Esoteric Buddhism. He is believed to hide himself within an iron tower in southern India after having been initiated by Mahavairocana into the deepest mysteries of Buddhism.

Visualization – A meditation practice in which a practitioner visualizes mental images in the mind.

The Zung Self-Rating Depression Scale (SDS) – A self-administered test which is designed for assessing depression in patients whose primary diagnoses are that of a depressive disorder.[53]

Delimitations and Limitations

One of the limitations to the present study is that a convenience sample of volunteers was used. All subjects had a strong interest and belief in spiritual healing and a non-local nature of consciousness. Therefore, generalizability to other populations in different settings cannot be assumed. Another limitation is that statistical power analysis was not performed to estimate the necessary sample size. As far as the PI knows no controlled studies which used the HbA1c levels and the DSC-R as dependent variables to examine the effects of distant healing on type 2 diabetes had been published, so the impacts of the intervention on these variables could not be estimated before starting the study. Considering the small sample size of this study, lack of power analysis might have caused type II errors (false negatives).

The use of the HbA1c test as an outcome measure might have placed some limitation for the purpose to evaluate the effects of distant healing on diabetes. The HbA1c test provides an index of a patient's average blood glucose level during the past two to three months.[54] This test cannot evaluate the change of blood glucose levels for a short period of time. The length of the intervention in this research was a total of four months and the HbA1c levels were checked only two times: before and after the intervention. Considering the nature of HbA1c test, the length of four months might not have been long enough to detect the change of diabetic condition by using this test. The possible alternative test is the fructosamine test which reflects the average blood glucose levels during the past two or three weeks.[55] But at the time of starting this research, the fructosamine test designed for at-home monitoring was not available. Because of financial and other resources' limitations, a test kit which was designed for at-home use was needed, so the PI decided to use the HbA1c test as an outcome measure.

All subjects met the healer at the initial session and performed a 20-minute group meditation together then. It is possible that this factor might have affected the outcome in the way that reduced the difference in the final outcomes of both groups. The alternative way to address this problem is to conduct the study without the initial session. The PI conducted the pilot studies with the same healer by using the similar protocol and found that the initial session helped the subjects understand the purpose of the study and the healer's healing concept substantially. The subjects became highly motivated by meeting the healer, and the PI believed that the initial session might have contributed to the lowering of the attrition rate. With the findings of the pilot studies, the PI assumed that

to conduct the initial session would be better for the purpose to lower the attrition rate of the subjects.

This research was based on a single professional healer, so it is not clear whether the outcome was attributable to the specific healer or to the healing technique. The difference in the healing effects between experienced healers and novice ones also remains unclear. To answer these questions, it would be necessary to include more than one healer with different modalities and experiences, and compare the effects of their healing interventions.

Chapter 1 has presented a brief background of the research problem at hand, an explanation of the purpose of the study, an articulation of the two research questions, an elaboration on the importance and scope of the study, a definition of terms, and ended with a brief treatise on the delimitations and limitations of the study. Against that backdrop, Chapter 2 presents a review of the most pertinent published literature.

CHAPTER 2:
REVIEW OF LITERATURE

Chapter 2 reviews the most pertinent published literature on the research topic and closely related topics. It begins with a general overview of distant healing. It then reviews the literature on clinical studies of distant healing and on studies with physiological measurements and devices. The chapter follows those reviews with current major problems in conventional diabetes treatment, distant healing for diabetes, and the profile of the healer. Then the chapter delves into the teachings of Esoteric Buddhism and Shinto, and the etiology of Esoteric Buddhism and Shinto.

With that as background the chapter ends with a description of Jiho Otsuki's healing procedure, and the four outcome measures employed to evaluate those procedures.

An Overview of Distant Healing

For the entire history of the human race, people have believed that healing can take place at a distance. Distant healing is an ancient human activity still widely practiced throughout the world today. All major religions, including Buddhism, Judaism, Christianity, Islam, and Hinduism, endorse and encourage the use of distant healing among their adherents. *Distant healing* is an ancient human activity still widely practiced throughout the world today. Distant healing has been defined as "a conscious, dedicated act of mentation attempting to benefit another person's physical or emotional well being at a distance."[56] Targ categorized the distant healing interventions into the six modalities listed below.[57]

1) *Intercessory prayer*: Any form of requesting God to bring about a specific desired outcome.
2) *Non-directed prayer*: Intercessory prayer in which the person praying wishes only that God's will be done in the life of the subject.
3) *Energy healing*: This category describes attempts by a practitioner to send 'subtle' energy to the subject. Examples include Reiki and external Qigong.
4) *Shamanic healing*: Healers enter altered states of consciousness in which they interact with spirits whose aid may be enlisted in healing the patient.
5) *Non-contact therapeutic touch*: A technique developed by Dolores Krieger in which healers gets into a focused state and move their hands over the patients while holding an intention for the patient's healing.
6) *Spiritual healing*: Various forms of techniques including spiritist healing séances, meditation focused on visualizing the patient connected with God, a universal force.

The most common distant healing practices are offering prayers for those who are ill. Another form of distant healing is to use forms of meditation where the practitioner holds a compassionate intention to relieve others from their sufferings.[58] Intercessory prayer is the most typical kind of prayer, in which prayer is offered to supernatural beings such as God, an angel, or a spirit who has the power to grant a request. This type of prayer is practiced in almost all major religious traditions, and they claim that God can intervene to alter physical reality; it is God's action that brings about healing.

There are numerous perspectives on how distant healing works. Specific explanations of the mechanism of the healing are based largely on the worldview of the healer, but one of the common perspectives is the belief that a person's focused intention

can have a nonlocal effect. In other words, the healing intention of one person can affect another person in a positive way independent of distance.[59] Dossey discusses the non-local nature of consciousness by using the theory of non-Newtonian physics in *Healing Words*. According to him, close analogies exist between the non-local natures of small particles studied by quantum physics and "Thy will be done" approaches embodied in distant healing. He describes the similar natures of these two as follows.[60]

1. We cannot always "make it happen" by praying for specific outcomes in the same way that physicists cannot purposefully send messages to manipulate the non-local subatomic world.
2. Like non-local phenomena in the subatomic world can be detected only in retrospect, we usually know that non-local events have occurred between individuals only after they have taken place.
3. Aggressive activity does not favor the occurrence of non-local events both in the physics laboratory and in healing experience between people.

As described above, Dossey attempts to interpret the non-local nature of consciousness by analogy with the non-local behavior of small particles in the subatomic world. According to this rationale, a non-directed approach, so-called "Thy will be done" type of prayer is more effective than the prayer which is intended for specific purpose. To support this idea, he introduced the research conducted by the Spindrift organization (Salem, Oregon) which had suggested that non-directed techniques were more effective than the directed approach.[61] Considering the outcome of this research and Dossey's discussion on non-local phenomena, the model of non-local behavior of small particles seems applicable to the purpose to explain the non-local nature of consciousness. No

valid scientific evidence exists regarding the applicability of quantum physics to the study of consciousness even though this topic is widely discussed in the community of researchers and therapists on healing. Any definitive conclusion on how distant healing works has not yet been made. Its mechanism remains a mystery even though some studies suggest the consciousness has non-local effects.

Clinical Studies of Distant Healing

One of the popular studies on distant healing is for treatment of problems in a cardiac intensive care unit (CCU). Byrd explored effects of intercessory prayer by Christians on 192 patients hospitalized on a CCU in California and compared them with 201 in the control group.[62] The patients were randomized into the two groups: the treatment group and the control group. Prayer was offered only to the treatment group. The result showed that significantly fewer patients in the prayer group required intubation, ventilation, or antibiotics; had cardiopulmonary arrests; developed pneumonia; or required diuretics.[63] In a replicating study, Harris and his colleagues studied the effects of intercessory prayer in consecutively admitted patients on a CCU, and the treatment group showed significantly greater improvements compared to the control group.[64]

Not all studies support the positive effects of distant healing. The latest large clinical study on distant healing for cardiac patients did not show the positive effect of healing.[65] Herbert and his colleagues conducted a large clinical trial on distant healing for patients who had taken heart surgery. Patients at six hospitals in the US were randomly assigned to one of the three groups: 604 patients blind to the group assignment received intercessory prayer; 597 patients blind to the group assignment did not receive intercessory prayer; 601 patients who had known they would receive prayer received

intercessory prayer. The primary outcome was presence of any complication within 30 days of coronary artery bypass graft (CABG). The results showed no effect of prayer on complication-free recovery from CABG. In addition, the third group (who had known they would receive prayer) showed a higher incidence of complications. It is possible that some study design flaws (short observation period, inappropriate choice of condition and dependent variables) might have contributed to the lack of significant results, but these inconsistent results suggest that the efficacy of distant healing still remains controversial.

The study performed by Sicher and colleagues is one of the most-cited studies on distant healing.[66] They examined the effects of distant healing on AIDS at the California Pacific Medical Center's Complementary Medicine Research Institute. Forty volunteers with AIDS were solicited through local advertisements, and they were randomly assigned either to the treatment group or to the control group. In this study, distant healing was performed by 40 healers who had at least five years of experience. At six months following the initial assessment, the treatment group had significantly fewer AIDS-related illnesses and lower severity of illnesses. Their visits to doctors were less frequent, as were hospitalizations. CD4 counts were used as a physiological indicator, but it did not differ significantly between the two groups.

Some studies which examined the effects of distant healing on pain have been published. Lyvers and his colleagues studied the efficacy of psychic remote healing performed by a well-known Australian psychic on chronic pain, but the results did not show a statistically significant difference between the experimental and control groups. [67] They concluded that the effects of healing were attributable to the power of belief, or the

placebo effect. Abbot and colleagues examined the effects of distant healing performed by spiritual healers in the UK on chronic pain.[68] Subjects in the healing group reported significantly more "unusual experiences," but the change of primary outcome measures (such as the McGill Pain Questionnaire) and the visual analogue scale for pain was not significantly different between both groups.[69] Considering these findings, no definitive evidences exist which showed the significant effects of distant healing on chronic pain.

Matthews and his colleagues studied the efficacy of intercessory prayer on rheumatoid arthritis, but the results did not show the significant effects of prayer.[70] Austin conducted a systematic review of the available data on the efficacy of distant healing, and 13 of the 23 studies (57%) yielded statistically significant treatment effects.[71] This study has been quoted by many other scientists to explain the efficacy of distant healing. But, in another systematic review conducted in 2003, the result did not yield the supportive results regarding the efficacy of distant healing.[72]

In conclusion, some clinical studies which showed the positive effects of distant healing exist, but there are also some clinical trials including the latest large clinical studies with cardiac patients, chronic pain, and rheumatoid arthritis, which did not show the positive results. The latest systematic review of distant healing did not show the supportive results, either. Regarding the efficacy of distant healing, a definitive conclusion has not yet been yielded.

Studies with Physiological Measurements and Devices

William Braud and colleagues showed that mental intention can influence a remote person's autonomic nervous system, as measured by changes in electrodermal activity.[73] In this study, a total of seven persons acted as mental influencers, and ten

acted as the remote targets of influence. Influencers were instructed to either calm or activate a targeting persons' electrodermal activity, and less electrodermal activity in calm periods was found compared with activate periods.[74] In Braud's other study, a significant relationship was found between the calming or activating imagery of an influencer and the electrodermal activity of a target person who was isolated at a distance.[75] Regarding the distant intentionality study with electrodermal activity, heterogeneous replications in numerous laboratories have been conducted by independent investigators. The results showed a highly significant change of electrodermal activity during the distant intentionality periods, compared with control periods.[76]

Some studies which measured the electroencephalogram (EEG) of subjects during remote healing have been published.[77] Fahrion and colleagues reported the high frequency, high amplitude beta and gamma rhythms in the right frontal area and the low amplitude theta rhythms in the left occipital and central area in the subjects' EEG during remote healing session.[78] Bearden reported a drop in frontal beta power during healing.[79] Shealy and his colleagues measured the EEG of a total of 110 subjects during remote healing, and a great increase of brain wave activity (measured by power spectrum analysis) was found in the part of the brain to which the healers' energy was directed.[80] No definitive conclusions regarding the specific EEG pattern during remote healing have yet been made, but these studies suggest that the healing intention may affect the EEG of subjects from a distance.

In parapsychology, numerous experiments that have shown the non-local effects of consciousness have been conducted. The common experimental studies have been conducted using an electronic random number generator, which is a device designed to

generate a sequence of numbers randomly. Radin and his colleagues reviewed scientific literature on parapsychological studies using meta-analytic techniques and concluded that human intention can influence the results of a random number generator from a distance.[81]

Considering the aforementioned studies all together, human intention may have some non-local effects on the physiology of other people even though it is not clinically significant.

The Current Major Problems in Conventional Diabetes Treatment

Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that is needed to convert sugar, starches and other food into energy needed for daily life. The ineffective use of insulin causes the increase of glucose in the blood (instead of moving into the cells) which contributes to the development of type 2 diabetes. Other factors such as genetic predisposition appear to play a role,[82] but there still remains much mystery in the causes of type 2 diabetes.

The World Health Organization (WHO) estimates that more than 180 million people worldwide have diabetes; this number is likely to more than double by 2030.[83] The major problem in the diabetes care is that having type 2 diabetes increases our risk for many serious complications such as cardiovascular disease, retinopathy, neuropathy, and nephropathy [84] To lower the risk of these complications, the blood glucose level must be controlled strictly. Diet modification, physical exercise, and blood glucose testing are the basic management tools for type 2 diabetes. In addition, many people with type 2 diabetes require oral medication or insulin to control their blood glucose level.[85] However the level of physical training recommended for type 2 diabetes patients to lower

plasma glucose levels are not feasible in many patients because of age, obesity, cardiovascular disease, and other complications.[86] Many people with type 2 diabetes develop a condition called insulin resistance. [87] When insulin resistance is present, the body does not respond properly to the insulin. Consequently, the pancreas releases more insulin to keep up with the excess glucose, which creates a vicious cycle. Several kinds of medication address this insulin insensitivity, but patients must keep taking medications for a long time. It contributes to the increase of medical cost related to the treatment of type 2 diabetes. This disease imposes significant financial burden on patients and also the entire nation. The annual medical cost associated with diabetes in the US is $98 billion.[88]

Type 2 diabetes is much related to addiction to sugar, and exacerbation of the disease is triggered by patients' voluntary behavior such as overeating.[89] This addictive behavior also contributes to the patients' low compliance with strict diet modification programs. Most health care professionals would agree that patients with type 2 diabetes do not follow the instructions about diet and exercise regimen provided by doctors.[90] Doctors lecture the patients about the importance of following the treatment regimen and willpower to overcome the patients' addictive eating habit, but it ends up in vain.

If patients' addictive behavior is one of the primary issues in the treatment of diabetes, why wouldn't health care professionals deal with patients' addictive eating habit? According to *Dispelling Myths about Addiction*, only 1% of the typical medical school curriculum is devoted to patients' addictive behaviors.[91] It means that many doctors trained at a medical school do not know how to deal with the patient' addictive

behavior. It is true of the management of type 2 diabetes. Doctors do not know how to deal with this problem.

Diabetic patients' compliance with medication treatments is also poor. The results of studies with the total 2,920 subjects in the UK showed that the adequate adherence to oral medications (≥ 90%) was found in 31% of those prescribed sulphonylureas alone, and in 34% of those prescribed metformin alone. Moreover, significant linear trends of poorer adherence were found with each increase in the daily number of tablets taken ($P < .001$) and increase in co-medication ($P < .0001$).[92] Considering all things together, one of the biggest problems in conventional medical treatment of type 2 diabetes is that patients' low compliance with the treatment.

Mental stress may be related to type 2 diabetes and contribute to patients' addiction to unhealthy diet. Most patients have psychological problems that affect diabetes self-care. [93] These psychological problems must be addressed, but providers often reported they did not have enough resources to manage these problems.[94] The same study reported that many patients' psychological well-being is poor. Mental stress directly induces harmful chemical reaction in patients' body. For example, stress hormones directly affect blood glucose levels.[95] In addition, people under mental stress may not take good care of their health and plan good meals. Conventional treatments such as pharmaceutical treatments, strict diet modification do not address these patients' psychological issues, but focus only on biochemical aspects of the disease such as high blood glucose, insulin insensitivity, and body weight. Therefore conventional medical treatments for type 2 diabetes ignore the important aspects of the disease which needs to be addressed.

The Distant Healing for Diabetes

Our hypothesis was that distant healing intervention would lower the subjects' HbA1c levels and improve complications related to type 2 diabetes. Distant healing has several advantages compared with the conventional medical treatment. First, no conscious efforts such as physical exercise are required for patients; therefore it is feasible for patients with severe complications. Second, it does not cost for equipments, medication, and other materials. Third, distant healing might be effective for the mental stress of diabetic patients. As described previously, an addictive eating habit is one of the critical problems in people with type 2 diabetes.[96] To treat diabetes, patients' addictive behavior must be addressed. Mental stress contributes substantially to patients' addictive behavior and low self-management ability, so the intervention which addresses patients' mental problems is necessary. Several studies which suggested the positive effects of distant healing on anxiety, depression, and alcoholism have been published.[97] These studies suggest the possible effects of distant healing on the diabetic patients' psychological problems.

If the study hypothesis is correct, distant healing will not only be beneficial for patients' medical problem, but also contribute to the decrease of direct and indirect cost related to the treatment of diabetes; distant healing will become a cost-effective, non-invasive alternative or adjunctive therapy for conventional treatments.

The PI found one experimental study which studied the efficacy of distant healing on type 1 diabetes mellitus.[98] In this research, Wirth and his colleagues studied the effects of intercessory prayer on the insulin dose levels of type 1 diabetes patients. A reduction in the insulin dosage was found, but the difference between the treatment group

and the control group was not statistically significant.[99] As far as the PI knows, only one clinical study which examined the effects of distant healing on type 2 diabetes exists.[100] In this study, distant healing was performed by five "experienced and reliable healers."[101] Fourteen subjects received distant healing every day for four weeks. A short-term reduction of fluctosamine levels was found, which reflect the past few weeks of average blood glucose levels, but the final outcomes did not show a significant improvement. Some physical symptoms even deteriorated. For instance, sensitivity in the feet decreased, which was one of the symptoms of diabetes neuropathy. A significant increase of cholesterol levels was also found.

Garrow and his colleagues studied the prevalence of complementary and alternative medicine (CAM) use among adults with diabetes.[102] The result showed that prevalence of overall use of CAM did not differ significantly by diabetes status (47.6 versus 47.9%, P =.1) compared with people without diabetes.[103] However, persons with diabetes were more likely to use prayer than people without diabetes.[104]

Considering all things together, to conduct a clinical study on distant healing for type 2 diabetes would provide many valuable indications to the field of diabetes treatment.

The Profile of the Healer

The healer who performed distant healing in this research was Master Jiho Otsuki, who was an Esoteric Buddhist monk in Japan. He was 56 years old at the time of starting the research. He learned Esoteric Buddhism at the Daigo temple in Kyoto, Japan in his thirties. The Daigo temple is the headquarters of Japanese Esoteric Buddhism (Shingon Buddhism).[105] Esoteric Buddhism was established in the seventh century AD in India. It was transmitted to Japan in the ninth century by a Buddhist monk named Kukai who is

the founder of Shingon Buddhism. In contrast with Esoteric Buddhism, the historic Buddha Sakyamuni's original Buddhism is called "Exoteric Buddhism."[106] The difference between these two Buddhism is that Esoteric Buddhism had been developed by integrating various symbolic techniques of Hindu traditions. The core symbolic techniques include mudras (hand gestures), mantras (chanting), and visualization techniques.[107] It is believed that an Esoteric Buddhist practitioner can gain access to the cosmic principle of universe by practicing these symbolic techniques and finally become unified with the central deity called, Mahavairocana which is considered as the embodiment of the universe.[108] As a result of it, a practitioner is believed to acquire strong healing ability. The teaching of Esoteric Buddhism has been passed down to today in some Buddhist schools, but it has been kept in strictly secret from general public. The Daigo temple is one of those institutions which have inherited its traditions. The unique feature of the Daigo temple is that a practitioner of this temple must also study traditional Japanese spiritual practice called *shugendo*, the goal of which is to attain supernatural powers through the ascetic practice in a mountain.[109] By combining these two traditions, a practitioner is believed to develop spiritual ability effectively. After completing his practice at the Daigo temple, Otsuki went to China to study Genkyoku qigong. Genkyoku qigong is one of the healing modalities in China and has more than 700 years of history. It had been known for its powerful healing effects. Usually, practitioners of qigong schools consider that the universe has only one fundamental component called qi (ki in Japanese). However, Genkyoku practitioners consider that the universe is composed of the three fundamental components instead of one: the original light (*genko*), the original sound (*genon*), and the original qi (*genki*).[110] It is believed that

practitioners can develop their psychic ability effectively by controlling these three components. Through his study at China, Otsuki's healing ability was further developed and his understanding of healing practice became deepened. After his coming back to Japan, he studied the teaching of Shinto at the Kukugakuin University and obtained the certificate of Shinto priests.[111] Shinto is a Japanese native religion, the main focus of which is cultivating the faith in *kami*, which is a spirit of deity in nature. Shinto has its original concepts of healing and various techniques which have been developed since ancient times. Otsuki integrated mainly these three healing modalities into his practice and has practiced healing for many years in Japan. He has successfully healed many individuals with depression, diabetes, chronic pain, and other refractory diseases.

The Teachings of Esoteric Buddhism

Exoteric Buddhism, the focus of which is to reach enlightenment, was founded by Sakuyamuni Buddha in the sixth century BC in India. He is believed to have reached enlightenment under the Bodhi tree through extremely ascetic practices. Sakuyamuni himself did not write any documents, so his statements were recorded by his disciples after his death. One of the oldest documents in Buddhism is called The Pali Canon, which is the only completely-surviving early Buddhist canon.[112] The core teachings of Sakuyamuni's Buddhism could be summarized into the two fundamental principles: the Four Noble Truths and the Noble Eightfold Paths. The Four Noble Truths are composed of the following four: the nature of suffering (*Dukka*), its origin (*Samudaya*), the cessation of suffering (*Nirodha*), and the way to lead the cessation of suffering (*Magga).*[113] The Noble Eightfold Paths, which indicate the solutions to suffering, are composed of the following practices: Right Views, Right Intent, Right Speech, Right

Conduct, Right Livelihood, Right Effort, Right Mindfulness, and Right Concentration.[114] With these two principles, Sakyamuni educated his followers and encouraged them to reach enlightenment. He used many metaphors or examples to explain the path to enlightenment which was otherwise too profound for people to understand. His target population included not only religious professionals who intended to become a professional monk, but lay people who desired to apply the teachings of Buddhism to their daily life. Rather, Sakyamuni' focus was more inclined to teach the basic tenets for lay people instead of leading people to the complete enlightenment which he had attained through unimaginably severe spiritual practice.

In contrast, Esoteric Buddhism has a substantially different nature from that of Exoteric Buddhism. First, the founder of this Buddhism is not a real man like Sakyamuni. According to legends, the teachings of Esoteric Buddhism were directly given by a Buddhist deity called Mahavairocana which is considered as the embodiment of the universe. This episode is described in its primary scripture called the Mahavairocana Sutra in the form of the dialogues between this deity and Vajurasattva who is a legendary figure and considered the second patriarch of Esoteric Buddhism (Mahavairocana itself is considered as the first patriarch).[115] These dialogues take the form of questions and answers on how to reach enlightenment. The place where these dialogues took place was not in our three-dimensional world; it was the spiritual world of Mahavairocana which is believed to exist in the higher-dimensional world. Its teachings are profound; many technical terms are used in this scripture. It is difficult for lay people to understand its essence. The reason of its use of many technical terms is that this scripture is intended for professional Buddhist practitioners who dedicate their entire life to practice of

Buddhism at a temple. In this sense, this Buddhism has a totally different nature from that of Exoteric Buddhism, the primary target population of which is lay people.

Second, a clear difference exists in practice methods between these two Buddhism. In Exoteric Buddhism, Sakyamuni recommended people to practice meditation which is one of the main focuses of the Noble Eightfold Paths. But, he did not specify how to practice meditation or what kinds of meditation should be used in so detail. His passion might have been to spread the basic concepts of Buddhism into as many people as possible, so he might have kept his teachings as simple and easy as possible intentionally. As a result, Buddhism has spread widely mainly in Asia and became one of the major religions in the world. In contrast, Esoteric Buddhism does not intend to spread its teachings to so many people. Rather, its founders attempted to keep its teachings in secret and transmitted them only to limited number of people in their religious communities. Its primary purpose is to train professional practitioners who have a full command of Esoteric Buddhist techniques rather than spreading its teaching to many lay people. Therefore, they did not modify its teachings and practice methods into simple and easy ones in order to gain popularity. Instead, they have used various kinds of practice techniques without any limitations, whether they are complicating or not, to train masters of Esoteric Buddhism who have the qualifications to succeed to its teachings. For this purpose, the founders of Esoteric Buddhism adopted a large quantity of techniques from Hindu traditions and integrated them into their own spiritual practice. The core techniques which were invented through this fusion are called “symbolic practices,” which include mudras (hand gestures), mantras (chanting), and various visualization techniques.[116] The procedure of these symbolic techniques is complicating.

There are hundreds of kinds of symbolic techniques in Esoteric Buddhism, and a practitioner must memorize each technique one by one accurately. It takes many years of intensive training to master all of them.

Third, the process to achieve enlightenment is different between these two Buddhism. The goal of Esoteric Buddhism is to reach enlightenment, which is the same as that of Exoteric Buddhism. Sakyamuni encountered his enlightenment experience at the Indian city called Bodh Gaya according to the Pali cannon, in which he realized that all existence is subject to the law of impermanence. His discoveries are summarized into Buddhist scriptures later by his disciples, and as discussed previously, the Four Noble Truths and the Noble Eightfold Paths are the core teachings of his Buddhism. The final goal of his followers is to realize and understand what Sakuyamuni discovered in the moment of enlightenment, or the law of impermanence and the aforementioned two fundamental principles. Esoteric Buddhism has a different perspective regarding the process to attain enlightenment. The final goal of Esoteric Buddhism is to become unified with Mahavairocana, the embodiment of the universe.[117] To use New Age's words, its goal is to become one with the universe itself, so-called "the cosmic consciousness."[118] Sakuyamuni's core teachings such as the Four Noble Truths are not emphasized in Esoteric Buddhism. A practitioner focuses solely on the process to achieve the final goal, or the unification with Mahavairocana, by using the symbolic techniques. An Esoteric Buddhist practitioner considers that the unification with Mahavairocana is equivalent to the attainment of enlightenment. But the process to reach enlightenment and the explanation of its nature are different from those of Exoteric Buddhism.

Fourth, Esoteric Buddhism has various prayer healing techniques and considers them as crucial components in their practice. Prayer healing is offered for healing of the sick people, transforming misfortunes into blessings, or other materialistic and spiritual purposes. There are tens of kinds of prayer healing rituals, and they are offered depending on a client's need and situation. Most of them originate in Hindu traditions in the same way that the symbolic techniques were adapted from this most original spiritual tradition in India. In contrast, Sakyamuni did not emphasize the use of prayer healing for others even though he might have acknowledged its actual power. His focus was to eliminate sufferings solely by self-effort instead of relying on prayer healing offered by others people. One of the primary reasons of his avoidance of using any rituals including prayer healing might be attributable to his denial of Hinduism which had the discriminatory system called the caste.[119] The other reason was that he might have considered the use of any rituals as the obstruction to the attainment of enlightenment in the sense that it would create the attachment to the conduct of rituals.[120] Consequently, in Theravada Buddhism which inherited the original teachings of Sakyamuni, prayer rituals were never developed.

The Teachings of Shinto

Shinto, which is a native religion in Japan, is one of the core teachings of the healing practice of the healer, Otsuki. The origin of Shinto dates back to more than 10,000 years ago in prehistoric times. At that time, there was no Shinto shrine, the picture of which is often introduced in a picture book on Japan. Ancient Japanese people found many sacred places in nature such as deep in the mountain, a waterfall, a beautiful creek, and an old, big tree. They believed that various spirits existed in nature, what they

called *kami*, which translates as "god." But *kami* is not considered an absolute, almighty entity like God in the Judeo-Christian tradition. It is a more abstract concept which represents any supernatural force in nature. Shinto is an animistic religion which refers to a philosophical or spiritual idea that a soul or a spirit exists not only in people but also in other animals, plants, rocks, mountains, or other inanimate objects in nature.[121] Ancient Japanese people called these spirits as *kami* and worshipped them by conducting religious rituals.

Since ancient times, people have attempts to contact *kami* and acquire its spiritual power for their materialistic and spiritual benefits. The most original type of Shinto is called *ko-shinto* which has inherited various spiritual practices of ancient times in its original form.[122] In *ko-shinto*, the spirit, whether it is that of *kami* or other creatures, is considered to split itself on some occasions and make its exact copy. This phenomenon is called *bunrei* which translates as the splitting of spirit.[123] All human beings are considered the child spirit of *kami* formulated through the process of *bunrei*.[124] For some reasons such as conducting an immoral activity, the power of our spirit given by *kami* may become weaken. The primary purpose of *ko-shinto* is to get back its original power of our spirit by contacting *kami*. For this purpose, *ko-shinto* practitioners use various techniques such as meditation, breathing techniques, physical spiritual exercises, and chanting (called *norito* in Japanese). If practitioners successfully gain access to *kami*, the spirit of *kami* is believed to come down to their body and starts demonstrating its power through them. This phenomenon is called *kishin* which translates as "returning to *kami*."[125] Through these techniques, it is believed that practitioners can not only enhance their own vital energy, but also perform spiritual healing for others. In this way, the

healing power of *ko-shinto* practitioners is considered to come from *kami* in nature instead of their own spiritual power.

The Etiology of Esoteric Buddhism and Shinto

In Japan, Buddhism and Shinto are intermingled with each other, which have formulated the unique spiritual tradition called *shinbutsu-shugo*.[126] The teachings of these two spiritual traditions cannot be separated from each other, and it is hold true for their concepts of healing and etiology. The common ground between them is the concept of "a spirit." As described previously, in Shinto, everyone is believed to have its own spirit or soul. At the time of the physical death, the spirit is believed to leave the body for the world of the dead spirit. The physical body is considered to be a temporal house for the spirit in Shinto. According to its teaching, it is not only at the time of death when the spirit leaves the body.[127] For example, when people hold a strong grudge against others, a part of their spirit is considered to leave their body and appear before the target people in order to curse or harm them.[128] This free spirit of living people is called *ikiryo*. To use Western terminology, this phenomenon is called "psychic attack," which is defined as "the transference of negative energy between two persons through the use of telepathic skills."[129] Psychic attack is believed to take place when one person holds strong negative emotions such as jealousy, anger, or hatred against another person; this negative emotional energy causes both physical and psychological disorders in the target person.

In Esoteric Buddhism, it is also believed that the spirit of living people may cause a disease in others. Tibetan Buddhism, which is categorized as Esoteric Buddhism, has a systematic theory of etiology. With its etiology, the highly sophisticated system of medicine called Tibetan medicine has been developed. Its theory and treatment

techniques are summarized in the most fundamental medical textbook called the *Four Tantras*.[130] In this textbook, the case of psychic attack is clearly described; spirits of other living people leave their bodies for the target person and cause various dysfunctions.[131]

. Some studies which examined the harmful effects of human negative intention on living organism have been published.[132] Barry asked 10 people to try to inhibit mentally the growth of destructive fungus, Rhizoctonia solani, from a distance. [133] Growth of the fungus in the experimental group was significantly retarded compared with controls. It is unethical to attempt to test the effects of negative intention on human subjects, but the results of these studies with microorganisms suggest that our negative intentions might affect human subjects in a harmful way. Dossey reported a recent Gallop poll in life magazine in his presentation at Alternative Therapies Symposium and Exhibition, "The survey found that 5 percent of us actually pray for harm for other people and that's just the 1 in 20 who will admit it."[134] Considering these things together, it is possible that such unseen psychic battles between people might be more common in our daily life than expected and they might cause various diseases.

It is not only the target person who is affected by psychic attack. In Japanese spiritual traditions, the attacker himself is believed to be substantially damaged by his own negative emotional energy.[135] To use metaphysical words, this phenomenon is called "the boomerang effect" in the sense that the emotional energy of the attacker finally returns to him like a boomerang.[136] This phenomenon can be explained by using the concept of spirit. The spirit of the attacker, which has no place to go after damaging the target person, eventually returns to his place with its harmful energy. In this way, in

Shinto and Buddhist traditions, people's emotional energy is considered to travel between people in the form of a spirit, or *ikiryo*. The concept of a spirit is essential in the etiology of these two traditions.

The concept of a spirit is also directly related to their healing practice. As described previously, the final goal of Esoteric Buddhism is to become unified with Mahavairocana, or the embodiment of the universe. Mahavairocana is depicted as a personified form in mandalas which are the graphic symbols of the universe.[137] It is not only Mahavairocana that is portrayed in mandalas. Many other kinds Buddhist deities are depicted on them. These other deities do not exist independently, rather, they are considered as different manifestations of Mahavairocana. In the prayer rituals of Esoteric Buddhism, a practitioner prays to a different deity depending on purposes and clients' needs. The effect of prayer rituals is brought by the power of a deity, not by the power of a practitioner himself. In this respect, the healing concept of Esoteric Buddhism is similar to that of Shinto in which healing effect is considered to be brought by *kami*.

The Healing Procedure of the Healer, Jiho Otsuki

The PI has measured the EEG of the healer, Jiho Otsuki during his performing distant healing before. Normally, the intervention of this research, or the distant healing of the healer should be described in the section of methodology, but I would like to discuss it here by relating it to other researches on healing which used EEG as an outcome measure.

The distant healing of Otsuki is mainly based on the teachings of Esoteric Buddhism and Shinto. As described previously, practitioners of these two traditions ask *kami* or a Buddhist deity, which is so-called "spirit," to bring healing effects for clients.

In his healing session, he access and contacts "a spirit" at first. After getting access to "a spirit," he starts evaluating the energy field of a client by consulting "a spirit." An energy field (also called biofield) is a subtle form of energy that has yet to be measured by existing scientific devices.[138] In the assessment of a client's energy field, Otsuki mainly focuses on various kinds of negative energy attaching to the client's body. According to him, in many cases these negative energies come from other people in the form of psychic attack (*ikiryo* in Japanese) or the reflection of their own negative energies (the boomerang effect). As discussed above, these energies are considered to travel between people in the form of a mass of energy, or a spirit, instead of an energy which easily disperses. Otsuki can sense this mass of energy attaching to a client's energy field and body, and eliminate it all at once during the healing session. This procedure is also performed by asking for assistance from "a spirit." This procedure takes only a few minutes to be completed. In some spiritual traditions such as Christianity, they have the special ritual called 'exorcism.' According to the Oxford Dictionary, 'exorcism' is defined as "expulsion of an evil spirit by adjuration."[139] The healing session of Otsuki is similar to the ritual of exorcism in the sense that he attempts to cast out "the spirit of the living people" called *ikiryo* from the client's body. What he exorcises is not so-called "an evil spirit" which is a kind of supernatural being, but the spirit of living people.

Considering the nature of Otsuki' healing, which is similar to the traditional exorcism ritual, it is possible that various symptoms of a client which are caused by either psychic attack or the boomerang effect might disappear in a moment by his short-time healing session. What Otsuki does in his distant healing session is such a quick purification of a client's energy field. After the completion of this purification procedure,

the energy field of a client would become automatically balanced, which would induce the repair of damaged tissues and organs.

I described Targ's categorization of healing modalities in the section of "An Overview of Distant Healing." Considering the aforementioned nature of Otsuki's healing, his healing can be categorized as "intercessory prayer," in which asking God or other supernatural beings for bringing about a specific outcome. According to Targ's categorization, there are two different kinds of intercessory prayer: directed and non-directed prayer. Otsuki's healing session can be categorized as "directed intercessory prayer" in the sense that he purposefully assesses the energy field of a client and removes negative energies from it. His distant healing cannot be categorized as "energy healing" in Targ's classification of healing, which refers to the healer's attempts to send so-called "energy" to a client. Rather, Otsuki's healing focuses mainly on "eliminating" or "removing" negative energies from a client's body instead of "sending" energy. Therefore, its nature is different from that of many other energy healing modalities such as Qigong and Therapeutic Touch, the primary focus of which is sending healing energy to a client's body.

In conventional medical theory, the causes of any diseases can be roughly categorized into three factors: environmental, physical, and psychological. Environmental factors include the infections by a bacterium or a virus, the exposure to excessive heat, cold, moisture, and harmful chemical substances. Recently, the influence of electromagnetic contamination is becoming a hot topic. It is also categorized as an environmental factor. Physical factors include the imbalance of nutritional intake, lack of exercise, injuries caused by physical trauma, malpractice of surgeons, and genetic

predispositions. Psychological factors include various psychological stresses in life; PTSD (Posttraumatic Stress Disorder) is one of the major disorders related to psychological stresses. In the field of complementary and alternative medicine, the mind-body therapies such as relaxation, biofeedback, and hypnosis are gaining in popularity today.[140] These therapies focus mainly on psychological factors and aim to treat diseases by relieving psychological stress. Many common clinical conditions such as coronary artery disease and hypertension are considered to be linked to psychological factors, and considerable evidence exists regarding the efficacy of mind-body therapies on these diseases.[141] There is mounting evidence that suggests other spiritual practices are extremely influential in psychological stress.

It appears that all possible diseases can be explained by the combination of the above-mentioned three factors. But, in Esoteric Buddhism, there is another factor which cannot be categorized into any of them. They believe that so-called "spiritual factors" contribute to the formation of many diseases. According to the *Four Tantras*, which is the fundamental textbook of Tibetan medicine, these spiritual factors include the influence of various spiritual entities: evil spirits, the spirits of dead people, and living people, and *karma* in the past lives.[142] It describes that these spiritual factors cause various physical and psychological disorders, which belong to a different category from those caused by psychological factors. [143] According to this book, these "spiritual diseases" can be treated only by prayer rituals.[144] The founder of Japanese Esoteric Buddhism, Kukai mentioned the same thing, "Diseases caused by spiritual factors can be treated only by prayer healing."[145] No scientific evidence exists regarding the reality of these spiritual diseases, but the healer, Otsuki mainly focuses on these spiritual factors in

his healing session. According to today's medical theory, many diseases are considered "multifactorial," in other words, more than one factors contribute to the formation of diseases.[146] Depending on each disease and individual, the ratio of contribution of spiritual factors to the formation of diseases might be different. Accordingly, if someone's condition is caused largely by physical factors instead of spiritual factors, Otsuki's healing intervention might not be effective for his or her condition. This discussion is not the main focus of this research, so I will not discuss it further here. It would be an interesting subject for a future research project.

As mentioned previously, the PI has measured Otsuki's EEG during his remote healing session before. The EEG is a device to measure electrical activity along the scalp produced by the firing of neurons in the brain. The EEG records the brain's spontaneous electrical activity over a short period of time, usually 15 to 40 minutes. The EEG is typically described in terms of rhythmic activity which is divided into several kinds of bands by frequency. In the normal relaxed state with the eyes closed, the alpha activity (8-12 Hz) is seen predominantly in the posterior regions of the head, and the beta activity (12-30 Hz) is seen in other regions. The slower activities such as the theta and delta waves are seen only sporadically. His baseline EEG (no healing was performed) is

shown in Figure 1.

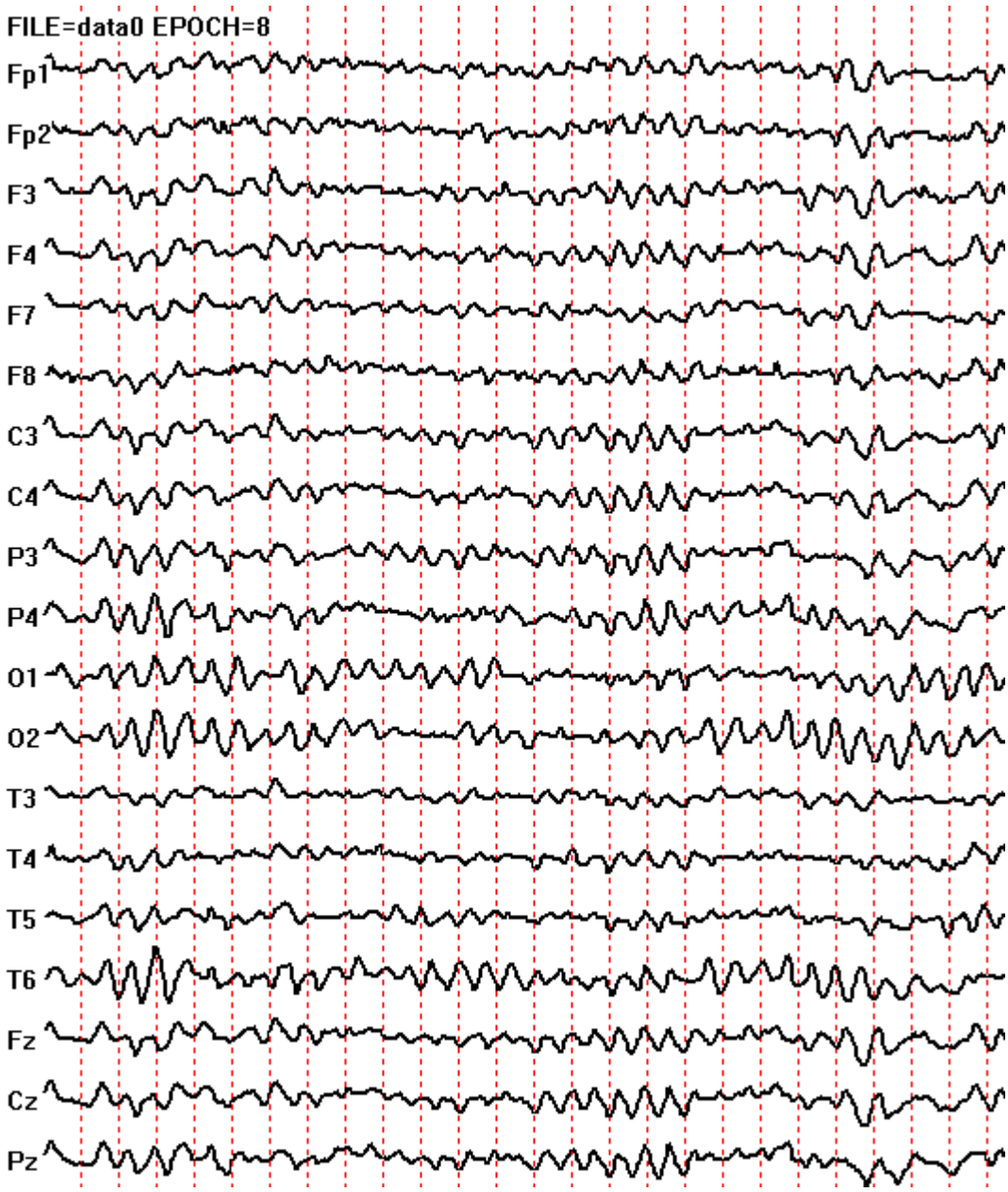


Figure 1. The EEG of the Healer, Otsuki (Baseline).

The slow alpha activity is seen dominantly in the occipital region, but sporadically it is also seen in the central and frontal regions rarely accompanied with theta waves. In this baseline EEG, no abnormal pattern was found. Figure 2 shows his EEG pattern during healing session.

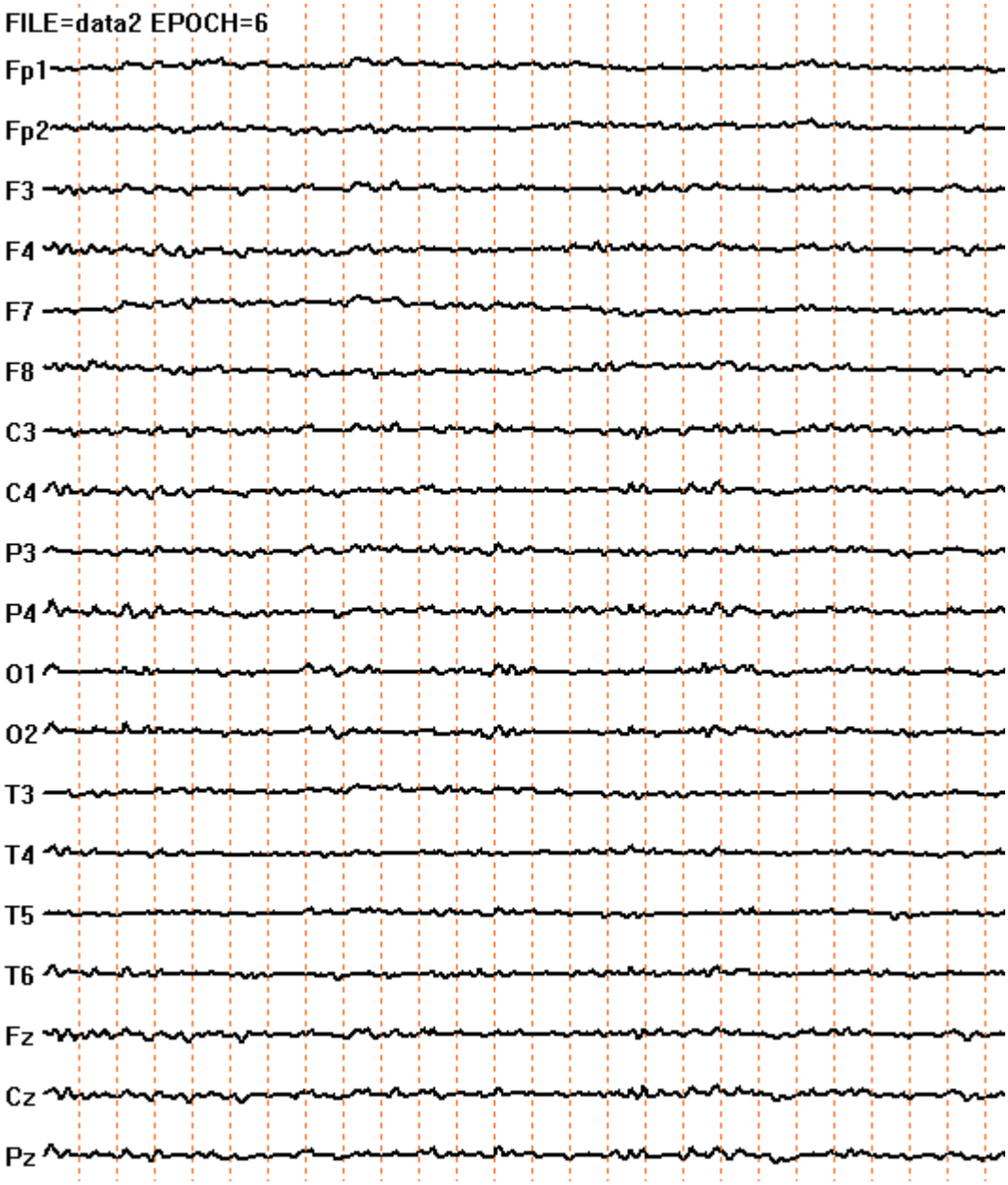


Figure 2. The EEG of the Healer, Otsuki (During Healing).

As soon as he started healing, his EEG pattern suddenly changed; all brain activity diminished significantly, and his EEG showed an almost flat pattern. The activity in alpha was significantly blocked, and the low-amplitude beta wave was rarely found. In this moment, Otsuki was contacting "a spirit" in order to perform healing. Medically, this extremely low-activity EEG pattern is seen in people

with pervasive brain damages or in the state of coma. His brain might have stopped its activity temporarily to contact "a spirit."

The PI found a few EEG studies that reported the similar EEG pattern to that of Otsuki. According to these studies, the EEG of highly experienced Qigong masters showed an almost flat EEG pattern.[147] Fujiki and his colleagues studied the EEG of the martial art master.[148] He was the master of *toate* which is a Japanese traditional martial art which aims to attack the opponent without touching him by using the power of qi. They found that the EEG of this master showed a significantly low activity. According to this master, during this moment, he was in the state of emptiness which means that no conscious thought existed in his mind, and transcended the boundary of himself and his opponent.[149] His mind became totally unified with that of his opponent; their consciousness became merged into one. Interestingly, as soon as his opponent thought about attacking him before moving into any action, his EEG suddenly changed; high-voltage brain waves appeared in all regions.[150] This finding suggests that the master's consciousness might have been merged with that of his opponent, so his EEG responded to the opponent's attack quickly before taking into action. Considering the findings of these studies, Otsuki's low-activity EEG might be the indication that his mind was a state of emptiness; he was merged with some other entity, or what he called "a spirit." These EEG patterns are different from that of concentrative Qigong state which is characterized by theta wave rhythm in the mid-frontal region. [151] It suggests that the healer, Otsuki does not concentrate on holding any particular image in his mind during the session. What is occurring in his brain during healing session remains unclear only with the

findings of the aforementioned EEG studies, but it would be an interesting subject to be explored in a future project.

Outcome Measures

The four outcome measures employed to evaluate the effects of the intervention are:

1. The Hemoglobin A1c (HbA1c) Levels (measured by the A1CNow+® device);
2. The Diabetes Symptom Checklist-Revised © (DSC-R);
3. The State Trait Anxiety Inventory (STAI); and
4. The Zung Self-Rating Depression Scale (SDS).

The Hemoglobin A1c (HbA1c) Levels (measured by the A1CNow+® device)

The Hemoglobin A1c (HbA1c) is a test that measures the amount of glycated hemoglobin in the blood.[152] Glycated hemoglobin is a substance in red blood cells that is formulated when hemoglobin is attached by blood sugar. The HbA1c measures provide the most reliable assessment of glucose management. [153] The HbA1c test provides an index of a patient's average blood glucose level during the past two to three months.[154] The Diabetes Control and Complications Trial established that maintaining HbA1c levels as close as possible to the normal range results in considerable reductions in long-term health complications. [155] In this research, subjects' HbA1c was measured by the A1CNow+® device (Metrica Inc.). This device was approved by the US Food and Drug Administration (FDA) for a home-use test (with no prescription) kit.[156] Therefore, this test can be performed either at clinician's office or at patients' home by themselves. It provides accurate HbA1c test results in five minutes. Its precision and accuracy were proved by several clinical studies.[157]

The Diabetes Symptom Checklist-Revised ©

The Diabetes Symptom Checklist-Revised © (DSC-R) is a measure of both the occurrence and the perceived burden of physical and psychological symptoms related to type 2 diabetes and its possible complications.[158] It is a 34-item, self-report questionnaire in which each item is rated on a 4-point Likert scale. It takes about 10 minutes to complete. Reliability and validity were studied by using 185 type 2 diabetic patients. According to the results of this research, the internal consistency was between 0.76 and 0.95 (with Cronbach alpha coefficients) and test-retest reliability was between 0.79 and 0.94 (with Pearson product-moment correlation coefficients).[159] The responsiveness, which refers to the ability to detect change over time, was estimated using sample size calculations and a minimal detectable mean change was 0.07-0.58 points in total score on the 10-point scale (with a group of 100 subjects). Significant differences in severity score were found among patients with different treatment mode and pathological conditions. These findings indicate that the internal consistency, the test-retest reliability, the responsiveness, and the construct validity of this checklist are satisfactory. The DSC-R is obtained from MAPI Research Trust. [160]

The State Trait Anxiety Inventory

The State-Trait Anxiety Inventory (STAI) is a self-report instrument for measuring the anxiety level and widely used all over the world. It clearly differentiates between the temporary condition of "state anxiety" and the more general and long-standing quality of "trait anxiety." The subject is asked to answer each statement on how they feel right now (state anxiety) and how they generally feel (trait anxiety) by using a four-point scale. The STAI was developed in 1970 by Spielberger and his colleagues.[161]

The Zung Self-Rating Depression Scale (SDS)

The Zung Self-Rating Depression Scale (SDS) is designed for assessing depression in patients whose primary diagnoses are depressive disorders. It is a self-administered test, and it indicates the patient's own response at the time when the scale is taken. The 20 items of the scale address each of the four commonly found characteristics of depression: the pervasive effect, the physiological equivalents, other disturbances, and psychomotor activities.[162] Its validity is widely accepted, and it has been used all over the world as an assessment tool of depression.[163]

Chapter 2 has reviewed the most pertinent published literature on the research topic and closely related topics. It began with a general overview of distant healing. It then reviewed the literature on clinical studies of distant healing and on studies with physiological measurements and devices. The chapter followed those reviews with current major problems in conventional diabetes treatment, distant healing for diabetes, and the profile of the healer. Then the chapter delved into the teachings of Esoteric Buddhism and Shinto, and the etiology of Esoteric Buddhism and Shinto.

With that as background the chapter ended with a description of Jiho Otsuki's healing procedure, and the four outcome measures employed to evaluate those procedures:

1. The Hemoglobin A1c (HbA1c) Levels (measured by the A1CNow+® device);
2. The Diabetes Symptom Checklist-Revised © (DSC-R);
3. The State Trait Anxiety Inventory (STAI); and
4. The Zung Self-Rating Depression Scale (SDS).

Chapter 3 now sets forth the research methods employed.

CHAPTER 3:
RESEARCH METHODS

Chapter 3 discusses the methodology and procedures used in this research. It captures the researcher's role throughout the study, the protocol, the selection of subjects (including the inclusion and exclusion criteria), and the data collection and analysis methods. The results of the pilot studies are also discussed.

The Study Protocol

The study protocol was constructed to implement the procedures for this research on type 2 diabetes. It detailed the precise procedures including the recruitment of subjects, the outcome measures, and the sequence of the interventions. The purpose of this reviewing was to insure that the study was carried out in accordance with established ethical and moral standards. The study protocol was submitted to the IRB of Holos University, and approved on September 15, 2008 through an expedited review process. The original protocol is included in APPENDIX C.

This study used a pretest-posttest control group design with repeated measure of the dependent variables such as the Hemoglobin A1c (HbA1c) levels, the Diabetes Symptom Checklist-Revised (DSC-R), the State-Trait Anxiety Inventory (STAI), and the Zung Self-Rating Depression Scale (SDS). The independent variables in this study included the one-time initial session and the following four-month distant healing session performed by the healer. The distant healing session was offered only to the experimental group.

Subjects were assigned randomly either to the experimental group or the control group by using a random number generator. Subjects and the PI were kept blind to the group assignment until the completion of the analysis of data.

The Research Intervention

The interventions of this study included the one-time initial session and the following four-month distant healing by the healer. At the initial session, a 20-minute group meditation was performed together after the meditation technique was explained to subjects. The simple meditation technique, which was based on Qigong, was introduced to subjects. During this meditation session, subjects were instructed to focus on their lower abdomen, which is called *tanden* (in Japanese); it is considered as the source of vital life energy. In case that subjects knew some kinds of meditation techniques, they were suggested to perform any forms of meditation techniques with which they were the most familiar. During the meditation session, the healer sent healing energy to each subject one by one at a distance without touching them. The purpose of this meditation session was to provide the subjects with the opportunity to experience the distant healing session of the healer with his presence. After completing the initial session with all subjects, the healer went back to Japan and started distant healing only to the subjects in the experimental group. The distant healing session was performed every day for four months. The healing session for each subject lasted for a few minutes, which was performed twice a day. The healer performed distant healing using the subjects' facial photographs and some information (their name and severity of disease). Whether subjects were assigned to the experimental group or not, all of them were asked to have the expectation to receive healing and visualize that they were receiving healing energy

from the healer in Japan by using the picture with a simple visual image of distant healing (which was provided by the PI) for a few minutes once a day. The PI explained to subjects that this visualization practice was not requirement to participate in the research, but entirely voluntary. The purpose of this practice was to become receptive to the healer's healing energy; it was explained to the subjects at the initial session.

The Researcher's Role

The Researcher's role in the beginning of the study was to establish the study protocol and recruit subjects. The initial screening was done by a telephone interview. Once eligible, the Researcher mailed all necessary documents including a consent form to eligible subjects. On a scheduled day, subjects visited the offices for the initial session. In the initial session, the Researcher gave them an in-person interview, in which the health history of subjects was obtained, and their HbA1c levels were checked by using the A1CNow+® device (Metrica Inc.). In the case that the subjects' HbA1c levels were lower than the minimum level described in the inclusion criteria, they were excluded from the study (see the inclusion and exclusion criteria in this chapter). The initial session was conducted in a group setting (between 3 and 10 people each time). After completing the initial interview with all subjects, the Researcher introduced the healer to them and explained again the entire study procedures. A 20-minute group meditation was performed there and the Researcher observed the session as a facilitator.

The Researcher conducted the intermittent phone calls every month and asked all subjects about any changes in their conditions. Especially, these telephone interviews focused on asking about their daily blood glucose levels, the change of medication doses if any, and the latest HbA1c data taken at their doctor's office if available. During the

study, the Researcher also filed reports regularly to the IRB and notified any untoward reactions reported by the subjects. The Researcher carried out all activities relevant to conducting this research.

After the four-month intervention period, the Researcher gave the second screening interview to all subjects on a scheduled day, which was performed in a one-on-one setting (It was done concurrently with the second session with the healer for the first and second group of subjects. For them, the interview was conducted in the beginning of the session). In the second screening interview, the Researcher asked them about any changes in their conditions, the medication doses, and again their HbA1c levels were measured by using the A1CNow+® device. All records pertinent to each subject were carefully filed and at all times confidentiality of records were strictly maintained.

Data Sources

The recruitment of volunteer subjects was accomplished in several different ways. First, the recruitment of subjects was conducted in two different areas: the South-West Missouri area and the Denver-Boulder, Colorado area. Subjects were sought through announcements on Dr. Norman Shealy's radio show and advertisements in local newspapers. Flyers were posted in various senior centers, coffee shops, and glossary stores through the posting service company. The announcement of the study was carried out at the diabetes support group meetings in the Boulder County. The specifications of the research as well as the requirements necessary to become a volunteer were clearly spelled out.

The Inclusion and Exclusion Criteria

Population: 18 Years and above, men and women

Inclusion Criteria:

・Subjects had to be clinically diagnosed as type 2 diabetes by a qualified physician (by self-report).

・The subject's HbA1c level is above 6.5% or FBS (Fasting Blood Sugar level) is above 120 mg/dl (self-report).

・Subjects show willingness to participate by signing a voluntary informed consent form.

・Subjects show ability and stated willingness to follow the directions of the Principal Investigator (PI) and the research staff.

・Subjects keep the same treatment regimen (including complementary and alternative therapies) during the study unless their physicians suggest doing so.

・Subjects do not take any other energy therapies by specific other healers during the study.

・If subjects are therapists of energy work, Reiki, spiritual counseling, massage, healing touch etc, they refrain from their practice temporarily during the study.

Exclusion Criteria:

・Subjects who are unable to comply with or attend the initial session and the post-intervention session

・Subject who were diagnosed as Type 1 diabetes

・Subject who cannot speak English

・Subjects who were diagnosed as psychotic disorder (self-reported)

・Subjects who have serious health condition(s) (unstable heart diseases, serious respiratory illnesses, terminal-ill patients etc) that the PI determines would make it difficult to complete the four-month study.

The reason of asking subjects to refrain from their energy work practice is that it possibly would affect the research outcome. This decision was made based on the findings of the preliminary studies. In the preliminary studies, some subjects, who were therapists (massage and Reiki) and continued their practice during the study, were not improved, or only slightly improved even after receiving healing. This idea is speculative and valid evidence does not exist. The possible explanation of this finding is that every time therapists saw their clients, they might have picked up some negative energy from their clients. These negative energies might have blocked their process of improving. For a similar reason, it would be required to ask subjects to refrain from taking any spiritual healing treatment by other specific healers during the study.

Data Collection

Subjects accepted in the study were also informed that they could be dropped from the study any time upon request without any penalty. Potential subjects were initially screened by telephone to determine their eligibility for the study. If they were deemed eligible, all necessary documents including the informed consent form, the medical history checklist, DSC-R, STAI, and SDS were sent to them by mail. Subjects were asked to check the inclusion and exclusion criteria described in the consent form again, and if they still met the criteria, they were scheduled for the initial session. The initial session was conducted at the sanctuary of Holos University (Fair Grove, MO) for

subjects from the South-West Missouri area, and the office of the Mindful Physiology Institute (Boulder, CO) for subjects from the Denver-Boulder area. The initial session was done in a group setting. At the initial session, subjects were given a short interview in which they were asked about their health history, and their HbA1c levels were checked by using the A1CNow+® device. The results were obtained in a five minute with this device. After making sure that they brought and filled out all necessary documents, the PI took their facial photographs one by one. Their facial photographs were used for the distant healing session by the healer. After completing a one-on-one interview with all subjects, the PI introduced the healer who came from Japan for this research to them. No conversation took place between the healer and subjects (no communication even through the translator). A 20-minute group meditation was performed together after explaining the meditation technique to them. The simple meditation technique, which was based on Qigong, was introduced to subjects, but they were instructed to perform any forms of meditation techniques with which they were the most familiar. During the meditation session, the healer sent healing energy to each of subjects one by one at a distance without touching them. The purpose of this meditation session was to make subjects experience the distant healing session of this healer with his presence. After completing the initial session with all subjects, the healer went back to Japan and started distant healing only to the subjects in the experimental group. The distant healing session was performed every day for four months.

In the beginning, the PI intended to recruit at least 60 subjects totally, but it turned out that only 29 subjects were recruited in the end (the subjects' demographics are shown in the section of "Research Findings"). The fist cycle of recruitment was conducted from

September, 2008 until November, 2008, and a total of 12 subjects were recruited. The initial session for these subjects was held in the middle of November, 2008. After completing the initial session with all these 12 subjects, they were randomly assigned either to the experimental group (N=6) or the control group (N=6). The PI made a notebook for each group in which the subjects' name and some information (age and the severity of disease) were described with their facial photographs. The PI passed these two notebooks to the healer; he took them with him to Japan. The healer randomly chose either one of these two notebooks and started distant healing session only to subjects listed in the notebook he picked up (as the experimental group). After the completion of four-month distant healing to the experimental group, the healer started distant healing to the other group (the control group) during the next four months. The second cycle of recruitment was conducted from November, 2008 until March, 2009. A total of 13 subjects were recruited, and the initial session for them was held in the end of March, 2009. The third cycle of recruitment was conducted from March, 2008 until June, 2009, and a total of 4 subjects were recruited. The initial session for the last group was held in the end of June, 2009. At the second and third time, the random assignment procedures of subjects and the following distant healing were performed in the same way as at the first time.

The PI conducted the intermittent phone calls every month and asked all subjects about any changes in their conditions. Especially, these telephone interviews focused on asking about their daily blood glucose levels, the change of medication doses if any, and the latest HbA1c data taken at their doctor's office if available.

After the four-month intervention period, the second session with the healer was held at the same place as the initial session (only for the subjects recruited in the first and second cycles). In the beginning of the session, the PI gave the second screening interview to all subjects in a one-on-one setting. In the interview, the PI asked them about any changes in their conditions, the medication doses during the intervention period, and again their HbA1c levels were measured by using the A1CNow+® device. After the interview with all subjects was completed, a 20-minute group meditation was performed together. After the meditation session, a short-time contact healing was performed by the healer to the subjects who were interested. For the subjects who were recruited in the final cycle (N=4), the second session following four-month distant healing was not held. Instead, the PI gave the second screening interview to them on a scheduled day, which was performed in a one-on-one setting. In the second screening interview, the information of their condition was obtained, and their HbA1c levels were measured in the same way as for the subjects who were recruited in the first and second cycle. The group assignment was kept blind to both the subjects and the experimenter throughout all the aforementioned procedures.

Data Analysis

As previously mentioned in this chapter, this study used an experimental design with a randomized convenience sample. The study design consisted of two groups of subjects. All subjects were randomly assigned either to the experimental group or to the control group. For each subject, the pre- and post- scores for the HbA1c levels, the DSC-R, the STAI, and the SDS were calculated and entered into an Excel spreadsheet. If any,

the change of their medication doses during the study period was also recorded in the spreadsheet.

It was expected that some subjects would change their medication doses during the study considering the length of the study period (four months). Especially, the increase of the medication doses would affect the final outcome substantially; the test scores would show the false improvement. To address this problem, the intention-to-treat analysis was used for the statistical analysis. The intention-to-treat analysis means that all subjects' data are included in the final analysis regardless of compliance with the study protocol and drop-outs status.[164] According to this analysis method, the subjects' latest data taken before the change of their medication doses or other unexpected changes were used for the final analysis. In case that no data other than the baseline values could be obtained, their baseline values were used as substitutes for the final results, which assumed no change with the healing intervention. This analysis method gives conservative results regarding the efficacy of the intervention, but it can keep the validity of randomization.[165]

The data was sent to the professional statistician to conduct the statistical analysis. The statistical test was conducted using the Statistical Package for the Social Sciences (SPSS) data analysis program by the statistician. The data was analyzed by using a mixed analysis of variance (ANOVA).

The subjects' baseline data were compared between both groups using a 2-tailed independent t-test. A matched pre-intervention and post-intervention comparison for each group was conducted by using a 2-tailed related t-test. The statistician was kept blind to the group assignment during his conducting the analysis.

Ethical Considerations

General safety was evaluated by monitoring the occurrence of any adverse effects experienced by the study subjects. The subjects were instructed to notify the PI as soon as possible adverse or unusual symptoms occurred. In the event of any unexpected adverse reaction related to the intervention, the PI was to notify the IRB chair within 24 hours and the full board within 72 hours. Any serious adverse reaction caused by the intervention was recorded in the complaint file and reported to the full IRB board. In this case, proper therapeutic measures and follow-up were done by the PI in accordance with their health care provider.

Pilot Study Results

The pilot study was conducted in August, 2007 at Holos University. All procedures were performed in accordance with the protocol accepted by Holos University Institutional Review Board. Because of the pilot nature of this study, a pre- and post-test single group design was used (no control group). In this study, a total of 13 subjects were recruited through the local radio and newspaper advertising in the South-West Missouri area. To be eligible for the study, subjects had to meet all of the following criteria: (a) being older than 18 years of age: (b) diagnosed as type 2 diabetes: (c) agreeing to participate in a study of prayer as a therapeutic intervention. Potential subjects were excluded for the following reasons: (a) being younger than 18 years of age: (b) diagnosed as type 1 diabetes. The primary outcome was the 10-day average of fasting blood sugar (FBS) levels. Subjects were asked to check the FBS levels every morning (subjects who received a sliding-scale insulin treatment were asked to record all blood glucose levels every time they checked before the insulin injection). The secondary outcome was the

Diabetes Symptom Checklist-Revised © (DSC-R). The DSC-R was filled out by subjects at their home three times before the intervention, two months after the study started, and at the completion of study. The healer was Jiho Otsuki who was the same healer as in the dissertation research. The initial session was held at Holos University in August, 2007. In this session, the subjects met the healer and received a few-minute contact healing (this procedure was optional). After that, a 20-minute group meditation was performed together.

The healer went back to Japan after the initial session and started the four-month distant healing. The distant healing was performed exactly in the same way as in the dissertation study. In this pilot study, the subjects were asked to practice daily 20-minute meditation during the study period. This meditation practice was recommended by the healer because according to him, meditation would enhance subjects' sensitivity to the healing energy. The subjects were also asked to keep the same treatment regimen (diet, exercise, etc) as much as possible during the study.

The statistical analysis used was a related t-test (one-tailed). The subjects' 10-day average blood glucose levels and DSC-R scores before and after the intervention were compared.

The Results of the Pilot Study

A total of 10 subjects completed the four-month study. We lost contact with one subject immediately after the initial session. One subject started taking new medication during the study, so we excluded her. The other subject got oral infection and started sliding-scale insulin treatment during the period of the study. Therefore, we excluded these three subjects from the final analysis. These 10 subjects were between the ages of

54 and 75 years (mean, 63.6 years), and included 7 males and 3 females. Their average duration of diabetes was 13 years with a range of 1.2-40 years. Three subjects had been treated with insulin, and four subjects had been treated with oral hypoglycemic drugs (see Table 1).

Subject	Age/Sex	BS[a](before)	BS(after)	DSC[b](before)	DSC(after)	Medication
1	71/male	190	160	2.2	1.0 ↓	Insulin
2	61/male	164	194	3.5	7.7	Oral drugs
3	73/female	133	122	2.0	1.0 ↓	N/A
4	64/male	139	104	8.2	2.9 ↓	Oral drugs
5	63/male	117	109	3.0	0.7 ↓	N/A
6	62/male	158	105	8.5	7.1 ↓	Insulin[c]
7	75/female	176	146	5.9	9.6	Insulin
8	54/male	347	128	10.8	6.0 ↓	Oral drugs
9	56/male	93	91	8.2	2.9 ↓	Oral drugs
10	57/female	224	217	0.8	6.2	N/A

[a] The average of ten-day fasting blood sugar levels(mg/dl). The average BS levels of the subjects that used sliding scale were calculated based on all measured BS data.

[b] Diabetes Symptom Checklist®.

[c] The combination of insulin and the other injectable hypoglycemic drug

Table 1. Changes of the Subjects' BS and DSC Scores

After four-month intervention, 8 out of 10 subjects' conditions were improved (see Table 1). Regarding the subject 1, the daily dose of long-acting insulin was reduced from 29 units (U) to 15 U. His hemoglobin A1c (HbA1c) levels had ranged between 8.0

and 9.0 % before the study, but it dropped to 6.5 % (taken at his doctor's office in January, 2008) after the four-month healing. The subject 3 had been recommended by her doctor to start oral hypoglycemic drug before the study started. Because of the improvement of her diabetic condition, she could stay medication-free. Her doctor told her that she did not need to take medication any more after the four-month healing. The subject 6 stopped taking pramlintide (a hypoglycemic drug, 60mg/ day) after the intervention because of the improvement of his diabetic condition. He had taken atorvastatin calcium 20mg/ day to control his cholesterol level before the study, but he stopped taking it after the healing intervention because of the improvement of his cholesterol levels. He had also suffered from neuropathic pain for many years, but his pain was substantially relieved after the intervention. The subject 7's daily dose of short-acting insulin was reduced 45.5U to 45.0U (she had taken only short-acting insulin). The subject 9's FBS was very high (347 mg/dl) in the beginning, but it dropped to 128 mg/dl after the study. He could reduce the daily dose of metformin (oral hypoglycemic drug) from 1000mg to 500mg. In the subject 5 and 9, their FBS had gone up greater than 120 mg/dl about once a week in the beginning of the study. But their FBS had showed below 120 mg/dl constantly after the completion of the study. Their DSC-R scores also indicated their improvement. The other subjects' daily dose of medication was not changed. All these 10 subjects claimed that they did not change particularly their diet and exercise regimen during the study. The average blood glucose levels of all the subjects dropped from 174 mg/dl to 137 mg/dl (Figure 3). The average DSC-R score of

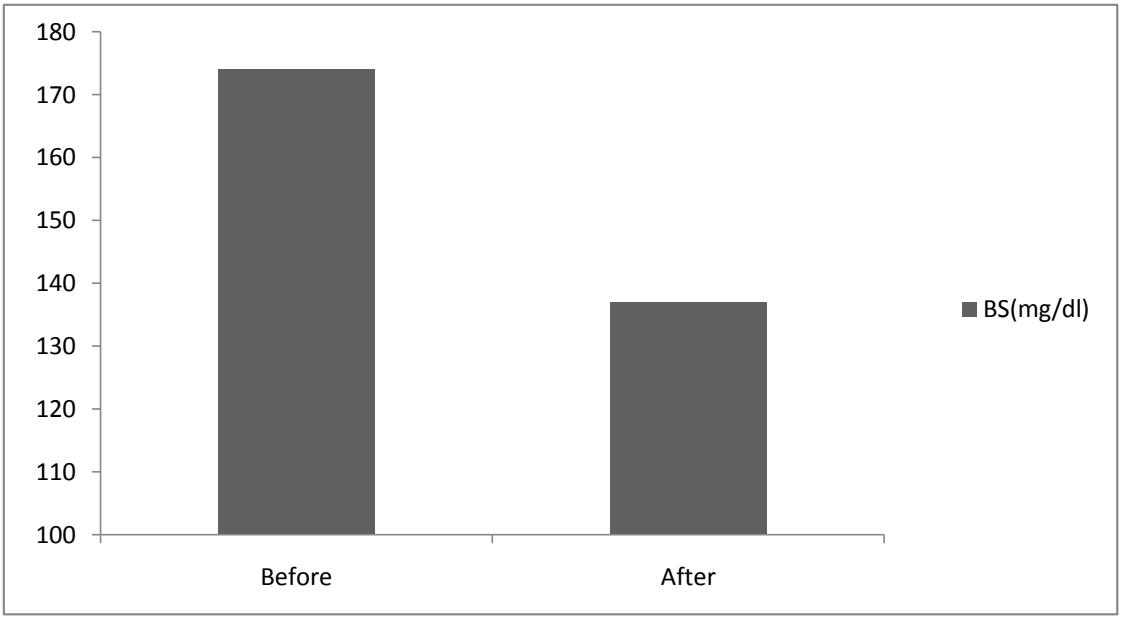


Figure 3. Changes of Average Blood Glucose Levels after Healing (N=10, p= .06).

all the subjects dropped from 5.3 to 4.3 (Figure 4). The changes of these two data were not statistically significant (p= .06 and p= .23).

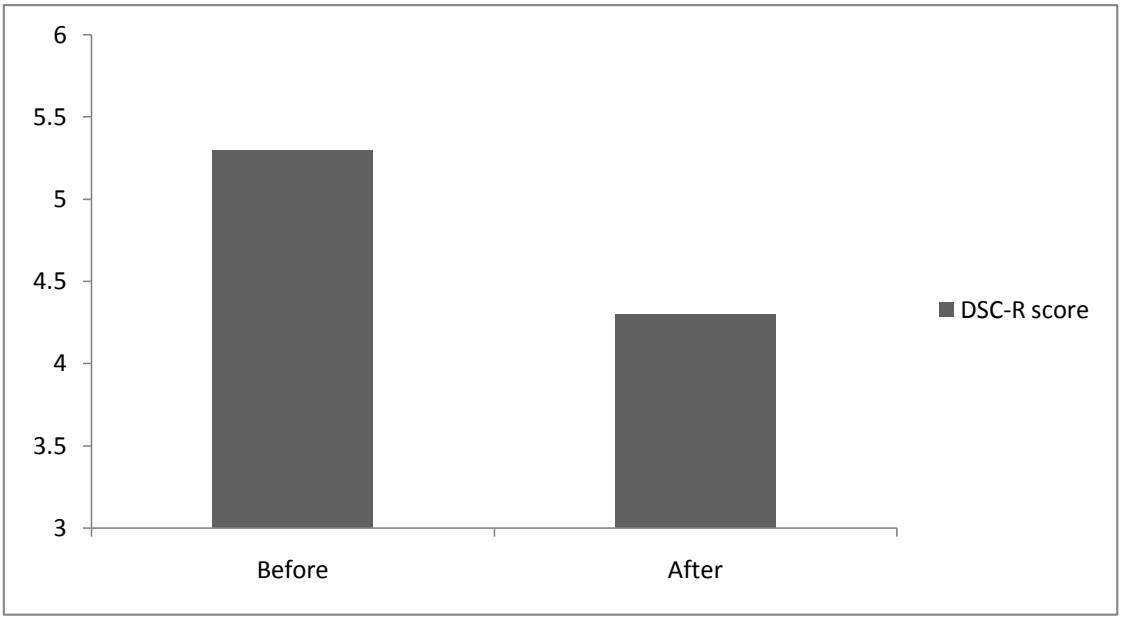


Figure 4. Changes of Average DSC-R Scores after Distant Healing (N=10, p= .23).

Chapter 3 discussed the methodology and procedures used in this research. It captured the researcher's role throughout the study, the protocol, the selection of subjects (including the inclusion and exclusion criteria), and the data collection and analysis methods. The results of the pilot studies were also discussed briefly. Chapter 4 presents the research findings.

CHAPTER 4:
RESEARCH FINDINGS

Chapter 4 presents the research findings, starting with a general statement of the Subjects' demographics and proceeding to a general statement of findings. Then the detailed results are presented for:

1. Hemoglobin A1c (HbA1c) levels;
2. Diabetes Symptom Checklist Revised® (DSC-R) Scores;
3. Zung Self-Rating Depression Scores (SDS);
4. State-Trait Anxiety Inventory (STAI) Y-1 Scores; and
5. State-Trait Anxiety Inventory (STAI) Y-2 Scores.

The chapter concludes with a brief presentation of anecdotal results.

The Subjects Demographics

The subjects for this research ranged in age from 38 to 82 (mean 60.45) years of age. Thirteen out of 29 subjects, or 44.8%, were male, and the other subjects (55.2%) were female. 19 out of 29 subjects (65.5%) were Caucasian, 5 subjects (17.2%) were Hispanic, 3 (10.3%) subjects were Asian, 1 (3.5%) subject was African American, and the remaining 1 (3.5%) subject was Native American. 15 out of 29 subjects were assigned to the experimental group (the healing group), and the other 14 subjects were assigned to the control group. The subjects' demographics are shown in Table 2. Regarding the age and the length of disease, no significant differences were found in the baseline data.

	The experimental group (N=15)	The control group (N=14)
Age	46-74 years (mean 61.2)	44-82 (mean 59.7)
Gender	6 males, 9 females	6 males, 9 females
Length of disease	0.2-39 years (mean 8.3)	0.5-27 years (mean 7.8)
Medication status	None: 2 Oral hypoglycemic drug: 10 Insulin: 3	None: 3 Oral hypoglycemic drug: 7 Insulin: 4

Table 2. Subjects' Demographics

The Statement of Findings

The PI carried out a quantitative research design for this study. The essential elements for this design included randomization of subjects and manipulation of one variable. The hypothesis of this research is that the distant healing intervention by the Japanese healer would lower the HbA1c levels of subjects with type 2 diabetes and improve other related symptoms. The null hypothesis is that the distant healing intervention by the Japanese healer would not lower the HbA1c levels of subjects with type 2 diabetes nor would it improve other related symptoms. In this study design, the dependent variables were the HbA1c levels (measured by the A1CNow+® device), the DSC-R scores, the STAI, and the SDS scores. These were selected as dependent variables because they were expected to be influenced by the independent variable. The independent variable for this research was the four-month distant healing session by the Japanese healer.

For the statistical analysis of the data, a mixed analysis of variance (ANOVA) was used to analyze group differences and interactions of group differences.[166] The F ratio was also calculated. The two-factor mixed design ANOVA involves one

independent factor and one repeated measures factor.[167] In this research, the PI conducted a combination of between-subjects (the comparison between the control and experimental group) and within-subjects' analysis (the comparison between a pre-test and post-test). The F ratio is the statistic which shows the systematic differences between treatment conditions by comparing the variance between conditions with the variance within conditions.[168] It was used to assess how much variability in the research was attributable to the intervention, or the systematic differences between the conditions. Regarding the determination of statistical significance, the alpha level was set $\alpha=0.05$, meaning that the study has 5 chances out of 100 of making a type 1 error, which rejects the null hypothesis when the null hypothesis is true.

As described in the Subjects Demographics, a total of 29 subjects (15 subjects for the experimental group and 14 for the treatment group) were recruited. In the experimental group, one subject dropped out from the study. The PI lost contact with him three months after the study had started. Until then, the PI had reached him every month on the phone and asked him about any changes of his conditions. Initially, his daily blood glucose (BS) levels were greater than 200 mg/dl and his HbA1c level was 9.9 %. At the second phone interview which was conducted two months after the study started, he reported that his daily BS dropped into around 160 mg/dl and indicated the improvement of his conditions. Even though his report indicated the improvement, only his baseline data was obtained because of his dropping out from the study before taking any further tests. Therefore, his baseline data were used as substitute for his post-test scores.

In the experimental group, two subjects dropped out from the study. The PI lost one subject immediately after the initial session (contact could not be made at the first phone interview which was conducted one month after the initial session). Regarding the other drop-out subject, the PI lost contact with her three months after the initial session. At the second phone interview conducted two months after the initial session, she reported that she did not have any change in her daily BS levels and conditions. Regarding these two subjects, only their baseline data were available, so the baseline data were used as substitute for the post-test scores.

In the experimental group, a total two subjects increased their medication doses. One of them increased her medication doses two months after the study had started. Until then, her report at the telephone interview did not show any indication that her diabetic conditions were becoming worse. The reason of her increasing the medication doses was that she just followed her primary doctor's suggestion. Regarding her HbA1c levels, only her baseline score was available, so it was used as a substitute for her post-test score. Before her changing the medication doses, the PI could obtain the results of the other tests (the DSC-R, the STAI, and the SDS), so they were used as substitute for the post-test results. One more subject in the experimental group increased the medication doses. It was two months after the study had started. The reason was that her daily blood glucose levels suddenly increased and she was recommended by her primary doctor to increase the medication doses. The PI could obtain all her new data just before her changing the medication doses, and it showed that her HbA1c went up from 7.7% to 8.7%. The results indicated that her diabetic conditions deteriorated during the study.

In contrast, a total of four subjects in the control group increased the medication doses. One of them increased his medication doses one month after the study had started. His HbA1c level was measured at his doctor's office just before this change, and it showed 7.9% (it was 7.4% at the pretest). His new scores of the other tests were not available, so this pre-test data were used as substitutes for his post-test data. The other three subjects increased their medication doses two months after the study started because their conditions deteriorated (it was indicated by their primary physicians). The new HbA1c data of one subject was obtained and it went up to 10% (from 9.4% at the pre-test). Her new data of the other tests were also obtained and they indicated that her diabetic conditions got worse.

Regarding the other two subjects, the new test scores were not available, so the pre-test scores were used as substitutes for the post-test scores. Table 3 shows the summary of subjects who dropped out or increased their medication doses during the study. All the subjects' raw data are shown in the APPENDIX A.

	The experimental group (N=15)	The control group (N=14)
Drop-out	1	2
Medication increase	2	4
Total	3	6

Table 3. Summary of Subjects who Dropped Out or Changed the Medication Doses

At first, the PI intended to evaluate the subjects' BMI (Body Mass Index) by asking them to check their body weight and height by themselves. The subjects were instructed to check these data newly before the beginning of the study, but many of them reported false data which had been taken much before the beginning of the study (several

months before the beginning of the study). The BMI was not the primary focus in this research, and many subjects were reluctant to check it by themselves, so the PI decided to give up evaluating it as part of the present research effort.

The Results of the Hemoglobin A1c (HbA1c) levels

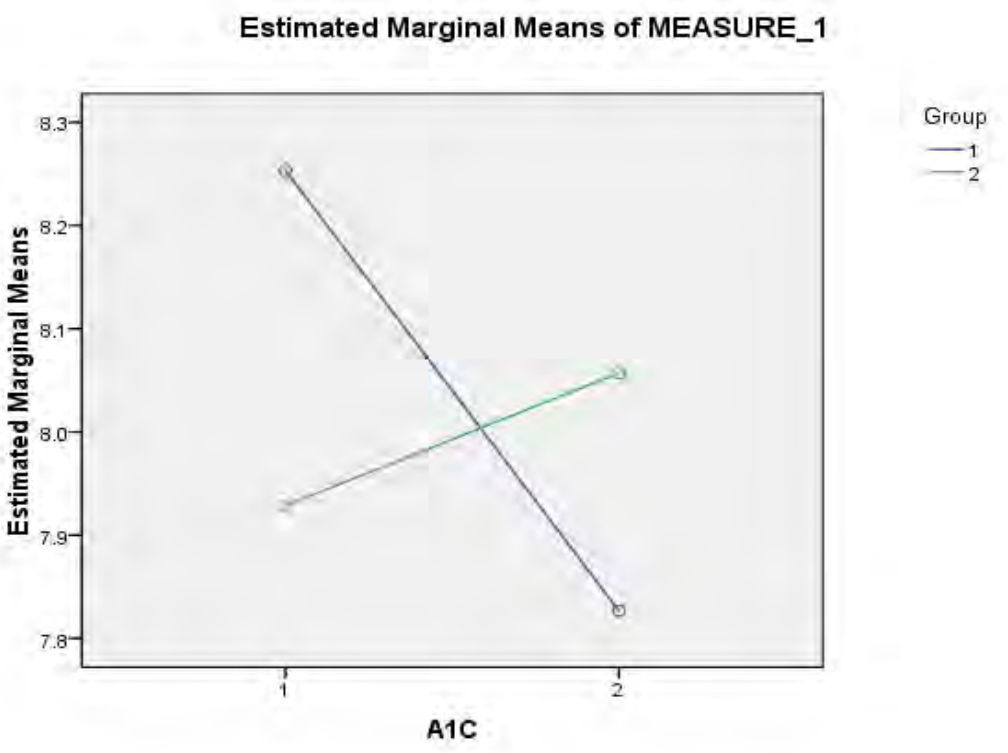
The average scores of the baseline HbA1c levels for each group were 8.25% (the experimental group) and 7.92% (the control group). The baseline HbA1c levels of the experimental group were higher than that of the control group, but there was no statistically significant difference between them (p=.64). The related t-test for the pre-test and post-test HbA1c levels showed significant improvement in the experimental group (p=.04), but not in the control group (p=.39). The interaction between groups and treatment conditions in the HbA1c scores calculated by the two-factor mixed ANOVA showed significant improvement of the HbA1c scores in the experimental group compared to the control group (F=5.316, p=.029). The results are shown in Table 4 and Figure 5.

Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
A1C	Sphericity Assumed	.322	1	.322	1.532	.226
	Greenhouse-Geisser	.322	1.000	.322	1.532	.226
	Huynh-Feldt	.322	1.000	.322	1.532	.226
	Lower-bound	.322	1.000	.322	1.532	.226
A1C * Group	Sphericity Assumed	1.116	1	1.116	5.316	.029
	Greenhouse-Geisser	1.116	1.000	1.116	5.316	.029
	Huynh-Feldt	1.116	1.000	1.116	5.316	.029
	Lower-bound	1.116	1.000	1.116	5.316	.029
Error(A1C)	Sphericity Assumed	5.669	27	.210		
	Greenhouse-Geisser	5.669	27.000	.210		
	Huynh-Feldt	5.669	27.000	.210		
	Lower-bound	5.669	27.000	.210		

Table 4. Final Results of the HbA1c Levels



Group 1= the experimental group (blue line)
Group 2= the control group (green line)

Figure 5. Changes of the HbA1c Levels

The Results of the Diabetes Symptom Checklist Revised (DSC-R) Scores

The average scores of the baseline DSC-R scores for each group were 1.79 (the experimental group) and 1.77 (the control group). The baseline DSC-R scores of the experimental group were slightly higher than that of the control group, but no statistically significant difference was found between them (p=.92). The related t-test for the pre-test and post-test DSC-R scores showed significant improvement in the experimental group (p=.02), but not in the control group (p=.77). The results showed that the DSC-R scores of the experimental group improved more

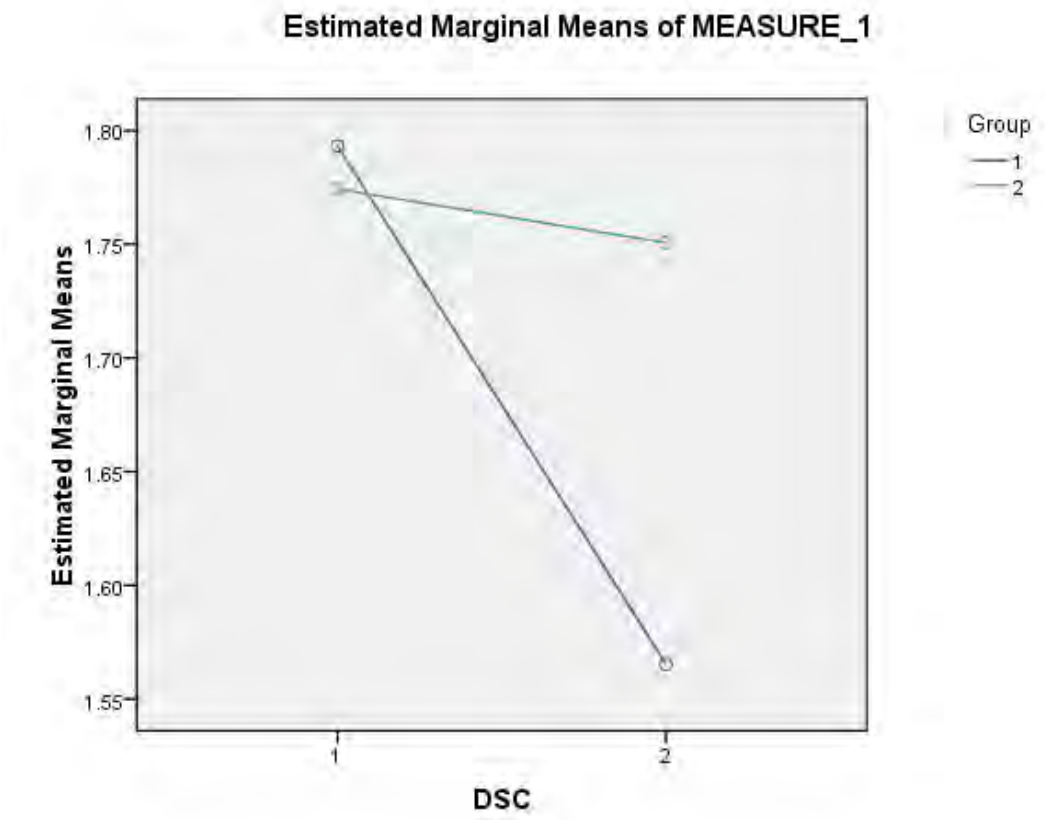
than those of the control group, but the interaction between groups and treatment conditions in the DSC-R scores calculated by the two-factor mixed ANOVA did not showed significant improvement in the experimental group compared to the control group (F=2.839, p=.104). The results are shown in Table 5 and Figure 6.

Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
DSC	Sphericity Assumed	.229	1	.229	4.300	.048
	Greenhouse-Geisser	.229	1.000	.229	4.300	.048
	Huynh-Feldt	.229	1.000	.229	4.300	.048
	Lower-bound	.229	1.000	.229	4.300	.048
DSC * Group	Sphericity Assumed	.151	1	.151	2.839	.104
	Greenhouse-Geisser	.151	1.000	.151	2.839	.104
	Huynh-Feldt	.151	1.000	.151	2.839	.104
	Lower-bound	.151	1.000	.151	2.839	.104
Error(DSC)	Sphericity Assumed	1.439	27	.053		
	Greenhouse-Geisser	1.439	27.000	.053		
	Huynh-Feldt	1.439	27.000	.053		
	Lower-bound	1.439	27.000	.053		

Table 5. Final Results of the DSC-R Scores



Group 1= the experimental group (blue line)
Group 2= the control group (green line)

Figure 6. Changes of the DSC-R Scores

The Results of the Zung Self-Rating Depression Scores (SDS)

The average scores of the baseline SDS for each group were 30.1 (the experimental group) and 32.0 (the control group). The baseline SDS of the control group were slightly higher than that of the experimental group, but no statistically significant difference was found between them (p=.64). The related t-test for the pre-test and post-test SDS did not show significant improvement in both groups (p=.27 for the experimental group; p=.45 for the control group). The results showed that the SDS of the experimental group lowered (improved) at the post-test, but those of the control group

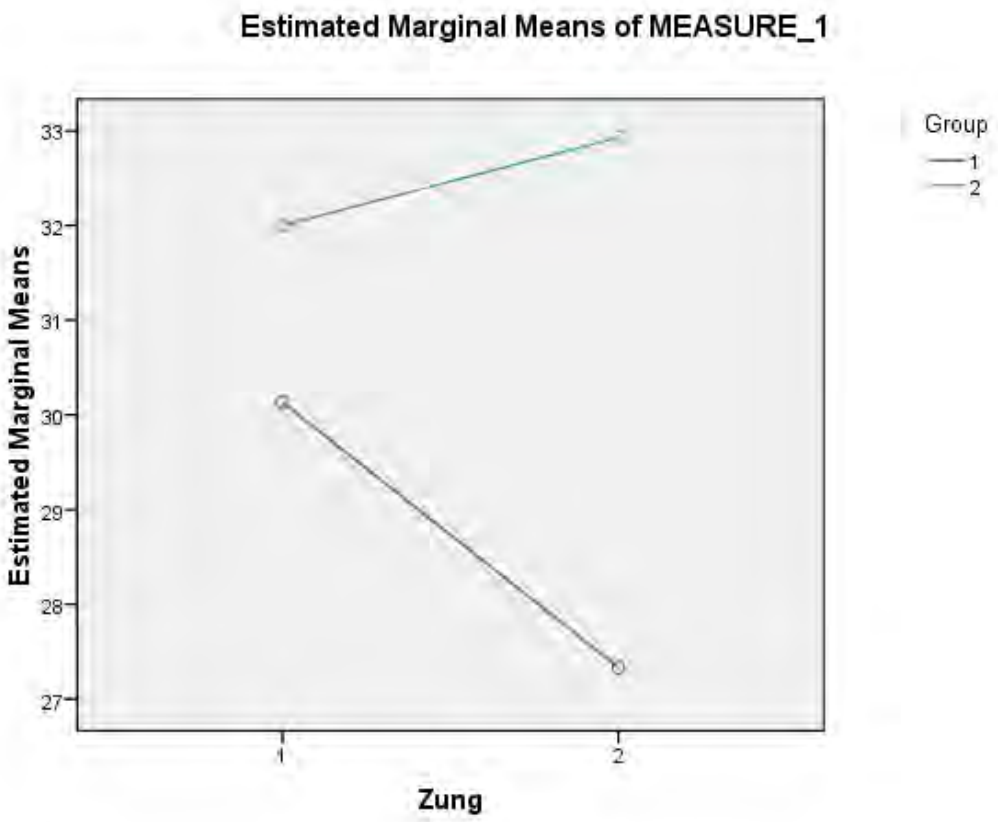
went up (got worse). The interaction between groups and treatment conditions in the SDS calculated by the two-factor mixed ANOVA did not showed significant improvement in the experimental group compared to the control group ($F=1.773$, $p=.194$). The results are shown in Table 6 and Figure 7.

Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Zung	Sphericity Assumed	12.681	1	12.681	.447	.510
	Greenhouse-Geisser	12.681	1.000	12.681	.447	.510
	Huynh-Feldt	12.681	1.000	12.681	.447	.510
	Lower-bound	12.681	1.000	12.681	.447	.510
Zung * Group	Sphericity Assumed	50.336	1	50.336	1.773	.194
	Greenhouse-Geisser	50.336	1.000	50.336	1.773	.194
	Huynh-Feldt	50.336	1.000	50.336	1.773	.194
	Lower-bound	50.336	1.000	50.336	1.773	.194
Error(Zung)	Sphericity Assumed	766.664	27	28.395		
	Greenhouse-Geisser	766.664	27.000	28.395		
	Huynh-Feldt	766.664	27.000	28.395		
	Lower-bound	766.664	27.000	28.395		

Table 6. Final Results of the SDS



Group 1= the experimental group (blue line)
Group 2= the control group (green line)

Figure 7. Changes of the SDS

The Results of the State-Trait Anxiety Inventory (STAI) Y-1 Scores

The STAI form Y-1 indicates so-called the "state" anxiety, or how subjects felt at the moment of conducting the test. The average scores of the baseline STAI Y-1 scores for each group were 34.2 (the experimental group) and 36.2 (the control group). The baseline STAI Y-1 scores of the control group were slightly higher than that of the experimental group, but no statistically significant difference was found between them (p=.64). The related t-test for the pre-test and post-test STAI Y-1 scores showed

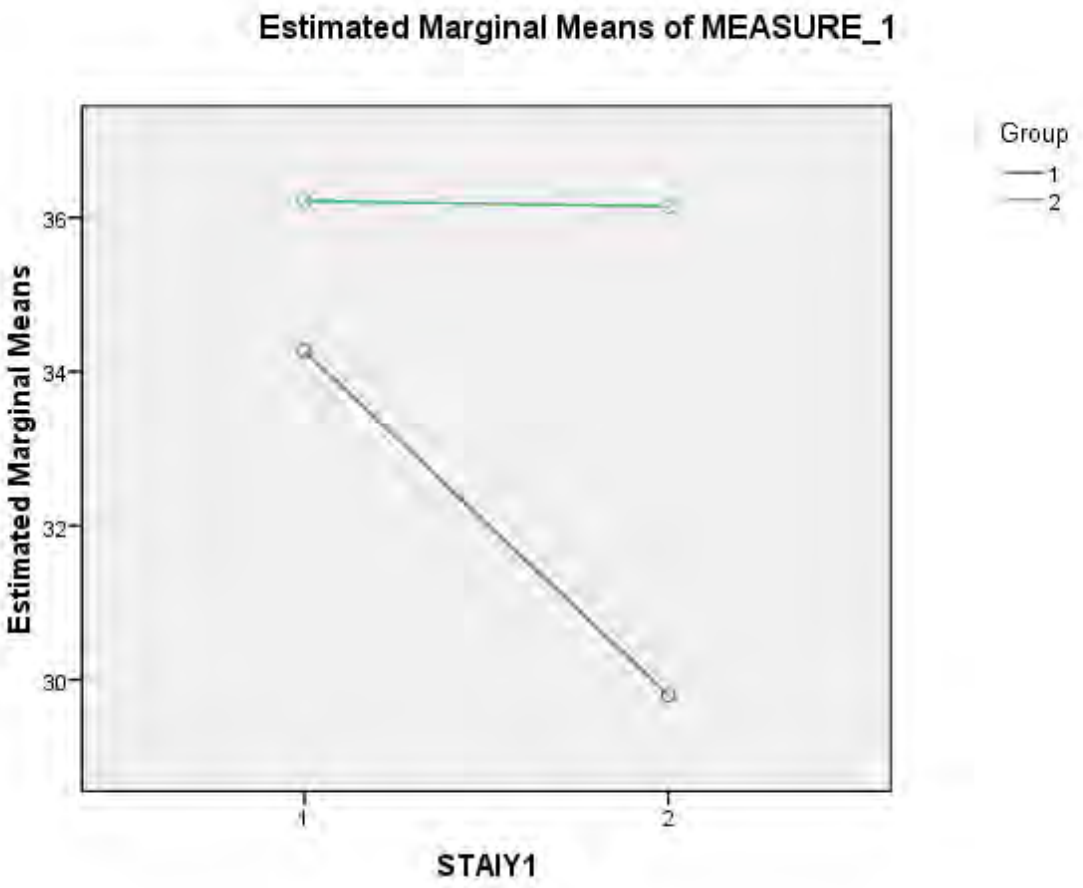
marginally significant improvement in the experimental group (p=.056), but did not show significant improvement in the control group (p=.95). The interaction between groups and treatment conditions in the calculated by the two-factor mixed ANOVA did not showed significant improvement in the experimental group compared to the control group (F=3.049, p=.092). The results are shown in Table 7 and Figure 8.

Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		F	Sig.
STAIY1	Sphericity Assumed	3.251	.083
	Greenhouse-Geisser	3.251	.083
	Huynh-Feldt	3.251	.083
	Lower-bound	3.251	.083
STAIY1 * Group	Sphericity Assumed	3.049	.092
	Greenhouse-Geisser	3.049	.092
	Huynh-Feldt	3.049	.092
	Lower-bound	3.049	.092

Table 7. Final Results of the STAI Y-1 Scores



Group 1= the experimental group (blue line)
Group 2= the control group (green line)

Figure 8. Changes of the STAI Y-1 Scores

The Results of the State-Trait Anxiety Inventory (STAI) Y-2 Scores

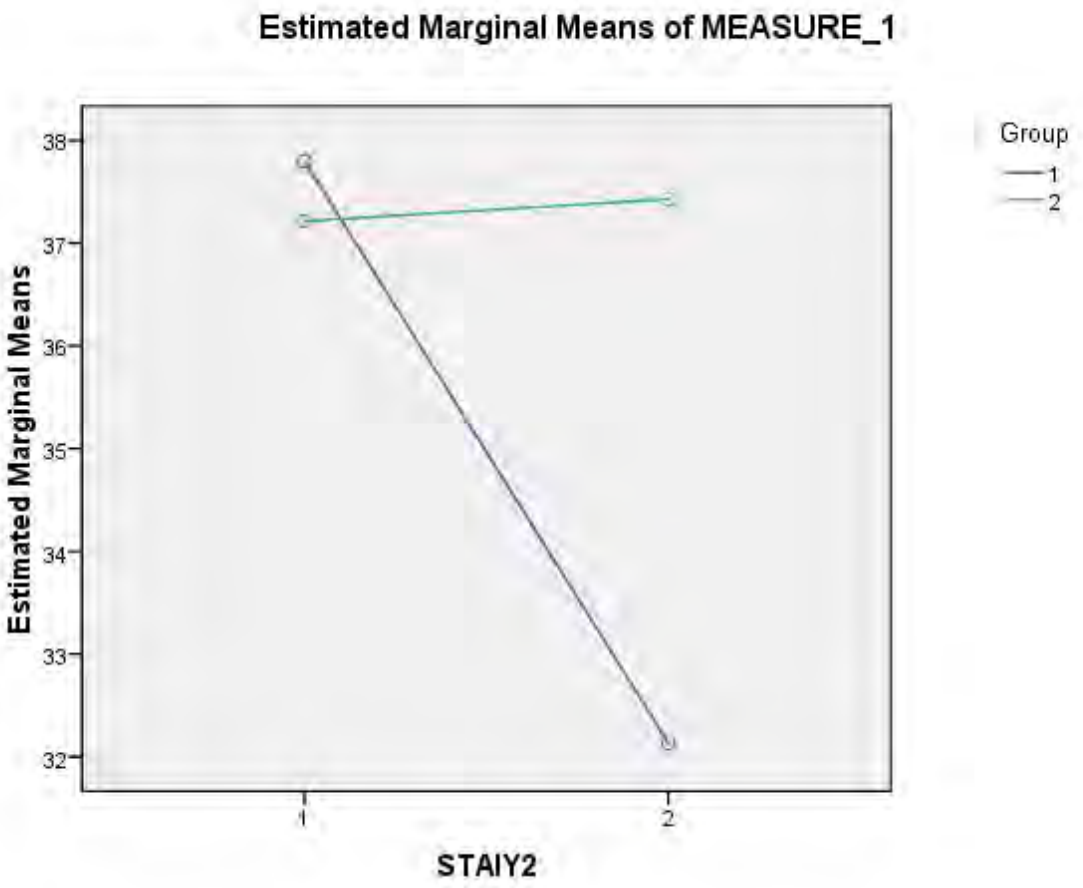
The STAI form Y-2 indicates so-called the "trait" anxiety, or how subjects generally felt. The average scores of the baseline STAI Y-2 scores for each group were 37.8 (the experimental group) and 37.2 (the control group). The baseline STAI Y-2 scores of the experimental group were slightly higher than that of the control group, but no statistically significant difference was found between them ($p=.89$). The related t-test for the pre-test and post-test STAI Y-2 scores showed significant improvement in the experimental group ($p=.04$), but did not show significant improvement in the control group ($p=.85$). The interaction between groups and treatment conditions in the calculated by the two-factor mixed ANOVA showed a significant improvement in the experimental group compared to the control group ($F=4.330$, $p=.047$). The results are shown in Table 8 and Figure 9.

Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		F	Sig.
STAIY2	Sphericity Assumed	3.722	.064
	Greenhouse-Geisser	3.722	.064
	Huynh-Feldt	3.722	.064
	Lower-bound	3.722	.064
STAIY2 * Group	Sphericity Assumed	4.330	.047
	Greenhouse-Geisser	4.330	.047
	Huynh-Feldt	4.330	.047
	Lower-bound	4.330	.047

Table 8. Final Results of the STAI Y-2 Scores



Group 1= the experimental group (blue line)
Group 2= the control group (green line)

Figure 9. Changes of the STAI Y-2 Scores

The Anecdotal Results

After the study was completed, the PI received spontaneous feedback from some subjects relevant to the effects they noticed during their receiving the distant healing. Also, the PI noticed some other findings which might be related to the effects of distant healing.

One subject in the experimental group suddenly started crying soon after finishing the 20-minute group meditation at the initial session. She began to shed many tears and did not stop for a while. Initially, she got confused at her sudden crying unexpectedly. According to her later report, she kept crying almost all day on the day of the initial session. Since then, she started having mystical experiences during her meditation practice almost every day. The following notes are some extracts from her meditation journal.

> *I could feel the healing energy and see yellow light with some pulsations. The light stayed yellow throughout. My body and mind became relaxed.*

> *I could feel and see this healing light going through every part of my body. Everywhere it touched it was healing and refreshing. There were tears. I felt very blessed.*

> *I saw lots of light and had lots of saliva. I just could not believe how much saliva!*

Every time she practiced meditation, she felt a warm healing energy. Also she recognized that the healing energy came from the healer. According to her, it was pulsating and shining like a golden, yellow light. She felt deeply blessed, and many tears were accompanied with this feeling. The PI did not ask her to practice meditation in

particular, but because of her experiencing a blessed, happy feeling during her meditation practice, she voluntarily continued practice for the entire study period. She also noticed that much saliva came out during meditation. In Eastern medicine, saliva is considered as the indicator of vital life energy. The production of much saliva indicates that her life energy was being restored. Her HbA1c slightly dropped from 9.1% to 8.1% and it still stayed greater than the normal range, but she felt much energized after the study completed. This study used a double blind procedure, so she did not know her group assignment. In spite of that, she felt the healing energy of the healer throughout the entire intervention period.

One subject in the experimental group had the vision of the healer during the study period. During his traveling to Mexico (his home country) during the study period, he suddenly saw the vision that the healer was sending healing energy to him. It occurred while he was taking a nap. It was only one time, but he recognized that he was in the experimental group even though he did not know his group assignment. His HbA1c dropped from 6.9% to 6.2%, and he clearly felt the improvement of his condition.

One more subject in the experimental group had an interesting experience. She had the vision of Japanese Shinto shrine buildings a few times during her meditation practice. At the second screening interview, she mentioned that these visions might be attributable to her receiving healing energy of the healer. She also reported that she became happier and more peaceful than before after the study completed.

The aforementioned three subjects felt healing energy from the healer during the study period in spite of their not having known their group assignment. No other subjects

in the experimental group felt healing energy of the healer clearly during the intervention period. Regarding people in the control group, no subjects had such experiences.

Two subjects in the experimental group got the acute symptoms such as nausea, vomiting, and diarrhea, which were diagnosed as virus infections by their primary physicians. These symptoms lasted only for a few days, and their condition completely recovered after this episode. In one of these subjects, his blood glucose went down during the study, and it suggests that his diabetic conditions improved (he dropped out from the study for unknown reason, so his new HbA1c data could not be obtained). Two subjects in the experimental group got a sty in their eye during the study. It occurred three months after the study had started. Anti-bacterial drugs were prescribed by their primary doctors, and their conditions had almost recovered at the end of the study. One subject in the experimental group got acute allergic symptoms (running nose and coughing) which had not occurred to her usually. Her primary doctors diagnosed that her symptoms were caused by allergic reaction to her pet (a cat). But, she had kept this cat for a long time before the study and never got such symptoms. Therefore, the true reason of her getting allergic symptoms unusually during the study remained unknown. Her symptoms completely disappeared by the end of study. These various acute symptoms were seen only in the subjects in the experimental group. No subjects in the control group got any unusual symptoms during the study.

Chapter 4 presented the research findings, starting with a general statement of the Subjects' demographics and proceeding to a general statement of findings. Then the detailed results were presented for:

1. Hemoglobin A1c (HbA1c) levels;

2. Diabetes Symptom Checklist Revised® (DSC-R) Scores;
3. Zung Self-Rating Depression Scores (SDS);
4. State-Trait Anxiety Inventory (STAI) Y-1 Scores; and
5. State-Trait Anxiety Inventory (STAI) Y-2 Scores.

The chapter concluded with a brief presentation of anecdotal results. Chapter 5 presents the study's conclusions in an overall discussion that includes suggestions for further studies.

CHAPTER 5:
CONCLUSIONS, DISCUSSION, AND SUGGESTIONS

Chapter 5 presents the study's conclusions in an overall discussion that includes a summary and conclusions. They are followed by a discussion of:

1. The subjects' demographics and their compliance with the Protocol;
2. The results of the HbA1c and the DSC-R;
3. The results of the SDS and the STAI; and
4. Anecdotal Findings.

The chapter and dissertation conclude with suggestions for Future Research.

Summary

In this study, the effects of distant healing on type 2 diabetes performed by a Japanese healer were measured by using the HbA1c levels (measured by the A1CNow+® device), the DSC-R scores, the STAI, and the SDS scores. All measurements were taken on subjects both in the experimental and control group (except for the drop-out subjects). The period of the distant healing intervention was four months. The results showed that the distant healing intervention had the health effects on people with type 2 diabetes. Among the dependent variables used in this study, significant improvements in the experimental group were found in the HbA1c levels and STAI Y-2 ("trait" anxiety). The other measurements showed the improvements in the experimental group, but the results were not statistically significant. In the following section, some of those findings are discussed.

Conclusions

The results showed that the experimental group significantly improved compared with the control group. The difference of HbA1c levels and the STAI Y-2 scores between both groups was statistically significant (p=.029 and p=.047 for each). The other measurements did not show statistically-significant improvements in the experimental group compared with the control group. The three subjects in the experimental group had experiences which might be related to their receiving healing energy during the study. These experiences included seeing the vision of the healer and Shinto shrines, and having a blessed feeling during meditation practice. Several subjects in the experimental group got acute symptoms such as a sty in the eyes, vomiting, diarrhea, and allergic symptoms during the study. These symptoms did not last for a long time, and the diabetic conditions of most of them improved in the end of the study. No subjects in the control group had either the aforementioned experiences or acute symptoms which were seen in the subjects in the experimental group. These results suggest that healing can take place even from a distance, and distant healing can be an effective treatment for type 2 diabetes.

Discussion

The Subjects Demographics and Their Compliance with the Protocol

In this research, a total of 29 subjects were recruited and they were randomly assigned either to the experimental group (N=15) or the control group (N=14). As described previously, any statistically significant difference was not found in the baseline data between both groups. During the study, one subject in the experimental group and two subjects in the control group dropped out from the study. In this research, the

intention-to-treat analysis was used to analyze the results in which all subjects' data including those of drop-out subjects were used for the final analysis. In case that the new data of these drop-out subjects were not available, their baseline data were used as substitutes for the post-test data. It means that their conditions were estimated to have no change during the study. Normally, the intention-to-treat analysis gives conservative results regarding the efficacy of the intervention, or it increases the risk of causing type 2 error (false negative). I would like to discuss the data of those drop-out subjects a little further here and examine whether using the intention-to-treat analysis in this research was reasonable or not. As described in the section of "the Statement Findings," two subjects in the experimental group and four subjects in the control group increased their medication doses during the study. The PI conducted the statistical analysis for their data based on the rationale of the intention-to-treat analysis (in case that their new data were not available, their baseline data were used as substitutes for the post-test data). I would also like to discuss their data here.

One subject in the experimental group dropped out for unknown reason three months after the study had started. The PI kept contact with him until then. According to the information obtained through the phone interviews, his fasting blood glucose levels were dropping down from 200 mg/dl (before the study) to 160 mg/dl. It suggests that his diabetic conditions were improving. His new HbA1c data were not available, so his baseline data were used as substitutes for the post-test data. It means that the PI estimated that his condition stayed the same even though his BS levels indicated his improvement. Considering these things together, regarding his case, using the intention-

to-treat analysis would contribute to yielding a conservative result regarding the efficacy of the intervention.

Two subjects in the control group dropped out during the study. The PI lost contact with one of them immediately after the study had started and had no way to estimate the change of her conditions during the study. Her baseline data were used as substitutes for her post-test data in the same way as the data of the other drop-out subjects. It means that her conditions were estimated to stay the same during the study. But there is no guarantee that her conditions did not change at all. Her conditions might have improved for some reason (for instance, the placebo effect) during the study. Therefore, regarding her case, it is impossible to estimate whether using the intention-to-treat analysis would have been reasonable or not.

Regarding the other drop-out subject, the PI lost contact with her three months after the study had started. According to the information obtained through the phone interview, her daily blood glucose levels did not change at all. She also indicated that she did not feel any change in her mental and physical conditions. Like the other drop-out subjects, her baseline data were used as substitutes for her post-test data. Considering the information of her blood glucose levels, it would be reasonable to use the intention-to-treat analysis and estimate that her conditions stayed the same during the study.

As described previously, two subjects in the experimental group increased their medication doses. One of them increased her medication doses two months after the study had started. The PI kept contact with her until then, and her report did not show any indication that her diabetic conditions were becoming worse (rather, her blood glucose levels slightly decreased). The reason of her changing of the medication doses

was due to her primary doctor's suggestion (the reason of her doctor's decision was unknown). Her new HbA1c data were not available, so her baseline data were used as substitutes for the post-test data. Regarding the other dependent variables (the DSC-R, the STAI, and the SDS), the PI could obtained the new data, so they were used as the post-test results. It is not certain, but considering her monthly reports on her diabetic condition, it is possible that her post-test results might have showed improvement (if she had not increased her medication doses during the study). Using her pre-test HbA1c data (6.7%) as a substitute for her post-test result might have contributed to yielding conservative result regarding the efficacy of the intervention.

The other subject in the experimental group increased her medication doses (insulin doses) two months after the study had started. Her daily blood glucose levels suddenly increased for several days, and her doctor suggested her increase the daily insulin doses. The PI had the chance to obtain her new results just before her changing the medication doses, and her HbA1c actually increased from 7.7% (at the pre-test) to 8.7%. She did not have any other changes on her physical and psychological conditions, but her data indicated that her diabetic conditions deteriorated. The reason of this aggravation was unknown. In her case, her latest data were used as substitutes for the post-test results.

A total of four subjects in the control group increased their medication doses. One of them increased his doses one month after the study had started. His HbA1c test was taken at his doctor's office at that time and it showed 7.9% (it was 7.4% at the pre-test). It suggests that his diabetes condition was becoming slightly worse during the initial one-month period. At the time of his increasing the medication doses, only one

month had passed since the beginning of the study, so it is possible that his diabetic conditions might have improved after the four-month study period if he had not increased the medication doses (he was in the control group, so he might have improved due to the placebo effects). Or considering the aggravation of his diabetic condition one month after the beginning of the study, it is also possible that his condition might have become even worse after the four-month study period. Regarding his case, there are both possibilities, and it is not certain whether using the intention-to-treat analysis for his results would have given a reasonable estimate on the efficacy of the intervention or not.

Regarding the other three subjects in the control group who increased the medication doses, their monthly reports actually indicated that their diabetic conditions were becoming worse. They increased the medication doses two months after the beginning of the study, and all of them were suggested by their primary doctors. One of them took the HbA1c test at her doctor's office before the change of medication doses, and it went up to 10% (from 9.4% at the pre-test). Her other tests (the DSC-R, the STAI, and the SDS) indicated that her conditions were getting worse. The PI used her new test scores (they were taken two months after the beginning of the study) as substitutes for the post-test results.

Regarding the other two subjects, the PI could not obtain the new test scores, so their pre-test scores were used as substitutes for the post-test scores based on the principle of the intention-to-treat analysis. It means that the PI estimated that their conditions stayed the same during the study period. Their reports obtained through the phone interview indicated that their conditions did not change at all (their daily blood glucose

levels stayed the same) or became worse. Therefore, it would be a reasonable estimation that their condition stayed the same during the study period.

The number of drop-out subjects was almost the same in both groups (one in the experimental group and two in the control group). It corresponded to about 10% of the total number of subjects. Considering the almost equal number of drop-out subjects in both groups and the above-discussed information of these subjects, it would be reasonable to say that their dropping out did not have much impact on the final outcome. Regarding the subjects who increased their medication doses, there were four subjects in the control group compared with two subjects in the experimental group. The number of those subjects in the control group was two more than that of the experimental group. It is not certain whether the difference of their number was attributable to the effects of the distant healing intervention, but the healing intervention might have contributed to the lower rate of the subjects who increased the medication doses in the experimental group. Considering the number of these subjects and their information obtained through the phone interviews, the PI had the impressions that there were more subjects in the control group whose conditions stayed the same or became worse during the study. These findings suggest that the distant healing intervention might have been effective for individuals with type 2 diabetes.

The Results of the HbA1c and the DSC-R

The results of the HbA1c showed the statistical improvement in the experimental group ($p=.029$). Regarding the baseline data, the average HbA1c score of the experimental group was higher than that of the control group (8.25 versus 7.92). The PI used the randomization procedure to distribute the subjects into two groups, and it

happened that the average HbA1c score of the experimental group was higher than that of the other group. The recruitments of subjects were conducted at the three different times, and the randomization procedure was performed each time. Every time, the PI used the stratified randomization procedure based on the baseline HbA1c levels and medication status.[169] In this procedure, two subjects who had the similar HbA1c levels initially were paired, and the randomization procedure was performed for each pair (one of them was assigned to the experimental group and the other one was assigned to the control group). The purpose of this stratified randomization is to distribute subjects equally in their baseline HbA1c levels. The reason that the difference of the initial HbA1c levels between both groups still existed even with this stratified procedure was that the randomization procedures were performed three different times instead of all at once. It happened that more subjects whose initial HbA1c levels had been relatively high were assigned to the experimental group than to the control group. The PI had no way to prevent this problem in these circumstances. Even though the average HbA1c scores was different between both groups, it was not statistically significant ($p=.64$). It is not certain that the difference of the initial data contributed to the final outcome favorably to the experimental group. But considering the fact that the difference was not statistically significant, its impact on the final outcome could be estimated to be small if any.

As shown in the previous chapter, the HbA1c levels of the experimental group decreased significantly compared with the control group. The results yielded with the related t-test showed the significant improvement of the experimental group. The HbA1c levels of the control group increased (it means their conditions got worse) rather than decreased. In eight out of 14 subjects in the control group, the HbA1c levels increased

(or were estimated to stay the same in the subjects who changed the medication doses). In contrast, the HbAlc levels increased in four (including the subjects who increased the medication doses) out of 15 subjects in the experimental group. Considering these findings all together, it would be reasonable to say that the distant healing intervention contributed to the decrease of the HbA1c levels in the experimental group.

Normally, the placebo effect is expected to affect the final outcome in various degrees in a controlled clinical trial. The placebo effect is attributable to the power of self-suggestion of subjects and in case that it works well, the conditions of subjects would improve even though they do not receive any treatment. The clinical trials in which this placebo effect is discussed most often are the trials of pharmaceutical drugs. Kirsch and Sapirstein conducted a meta-analysis of anti-depressant medication, and they found that only 25% of the response to medication may be a true drug effect and about 50% is due to the placebo effect.[170] The other study has shown that there is a high correlation (ranging from r=0.6 to r=0.8) between the placebo and pharmacological interventions in conventional medical treatments[171] It means that the true effect of specific pharmacological interventions is rather weak compared with that of the placebo effect.

In this research, the HbA1c levels of the control group increased; it means their conditions deteriorated during the study. The fact that four subject increased the medication doses in the control group supports this finding. These findings indicate that the placebo effect did not work well for the control group, which was contrary to our expectation. I would like to discuss the reason a little further.

At first, it might be related to the nature of the intervention. In this research, the intervention was the distant healing performed by a Japanese healer. Compared with the

pharmacological study, no tangible substances such as drugs were used in this research. In contrast, in the pharmacological study or other conventional medical study, subjects receive some kind of tangible treatments such as medications or the treatments with medical devices. The availability of these tangible substances to the study subjects might have contributed to the substantial placebo effect in the pharmacological study. This tendency is also seen in a clinical study on alternative complementary therapies. White and his colleagues studied the effects of acupuncture on smoking habit.[172] No difference in smoking cessation rates was found between acupuncture and most sham acupuncture treatment; it means that the placebo effects worked competitively with the actual acupuncture treatment. The latest clinical study on Reiki has shown that no difference in its effects on fibromyalgia between the treatment group and the control group was found (the intervention was performed by sham Reiki healers).[173] Reiki is one of energy healing modalities in which practitioners seek to transmit a so-called "universal energy" to a client. The reason of yielding the placebo effect in these treatments might be that subjects would feel 'treated' or 'cared' by therapists. In distant healing session, a therapist does not touch a client, and neither does he or she stay with a client in the same room during the healing session. A client does not have any way to feel 'treated' by a therapist unless a client makes frequent visit to a therapist for routine check-up interviews or other reasons. In this research, except the initial session and the post-intervention interview, the study subjects were not required to make additional visits (only the monthly short-time phone interviews were conducted). These factors might have contributed to the subjects' lack of feeling 'treated' by the healer.

The other reason might be attributable to the length of the study period. In this research, the intervention period was 4 months. It was determined by the healer because he thought that four-month intervention would be necessary for people with type 2 diabetes to exhibit clinically significant change. The PI agreed with his opinion regarding the length of intervention period because people with type 2 diabetes were expect to improve slowly based on the results of the pilot study. The problem was that in the previous pilot study, some subjects completely forgot the fact that they were participating in the research during the four-month period. One of the reasons might be that the PI did not conduct monthly phone interviews in the pilot study. This time, the short-time phone interviews were conducted every month (in the case that the PI could not reach them by calling, the other alternative ways such as mailing a letter or sending an email message were conducted), but it might have not given an enough incentive to generate the placebo effects in subjects. As described in the chapter of methodology, the PI provided the picture of visual image of distant healing for all subjects and recommended them to visualize their receiving distant healing every day by using this picture. But, almost all subjects in both groups did not continue this practice (even if some of them tried, but they stopped practicing it within a month). Therefore, this visualization practice might not have any meaningful impacts on the subjects' motivation for participating in the study.

These factors might have contributed to the lack of the placebo effect in the control group.

As described in the previous chapter, the HbA1c levels of one subject in the experimental group substantially increased during the study period (from 7.7%to 8.7%). Her daily blood glucose levels suddenly increased, and consequently, her medication

doses were increased. The reason of the deterioration of her diabetic conditions in spite of her receiving distant healing session is not clear, but it suggests that other factors than the healing intervention had a substantial impact on her conditions. Other than her case, the HbA1c levels increased or stayed the same (it means that their conditions did not improve) in the three subjects in the experimental group. The reason of these unexpected results is also not clear, but these findings suggest that the distant healing intervention might not be beneficial for all people with type 2 diabetes, and that other factors (psychological stress etc.) might have more significant impact on their diabetic conditions. Only from the findings of this research, the PI could not yield any definitive conclusion regarding these factors (almost all subjects in both groups indicated that their psychological stress must be related to their diabetic conditions). It would be an interesting subject for the future research.

Regarding the results of the Diabetes Symptom Checklist-Revised © (DSC-R) scores, no significant difference was found between both groups (p=.92). The DSC-R is a measure of both physical and psychological symptoms related to type 2 diabetes and its complications.[174] This result suggests that no significant difference in the improvement of their diabetes-related symptoms was found between both groups. But as shown in the research finding (see Figure 6), the scores of the experimental group decreased substantially, and the related t-test for the pre-test and post-test results showed that the improvement of the experimental group was significant (p=.02). The DSC-R scores of the control group slightly decreased, but it was not statistically significant (p=.77). These results of the DSC-R scores support the positive effects of the distant healing intervention.

Even though the results showed the improvement of the DSC-R scores in the experimental group and not in the control group, the other factor might have contributed to the difference between both groups. The new scores of a total of six subjects in the control group were not obtained (because three subjects increased the medication doses and two subjects dropped out) and their pre-test data were used as substitutes for the post-test scores. In contrast, only 1 subject's new DSC-R score was not obtained. It means that the new DSC-R scores of a large number of subjects were not available in the control group compared with the experimental group. There is a possibility that this factor might have contributed to the difference between both groups.

The Results of the SDS and the STAI

The results of the Zung Self-Rating Depression Scores (SDS) did not show statistically significant difference between both groups (p=.64). The related t-test for the pre-test and post-test SDS did not show statistically significant improvement in the experimental group, either (p=.27). As shown in Figure 7, the SDS of the experimental group decreased (it means their conditions improved) slightly, but that of the control group increased. The change of the scores was not large (2.7 for the experimental group and 0.92 for the control group) and it was not a clinically significant change at all. Therefore, no definitive conclusion regarding the effect of distant healing on depression (in people with type 2 diabetes) can be made only with this result. One of the reasons of the lack of any significant findings might be that the SDS of subjects had not been high from the beginning (the average SDS of the experimental group was 30.1 and that of the control group was 32). Normally, most people diagnosed as clinical depression score between 50 and 69.[175] Contrary to the expectation of the PI, the study subjects did not

have any clinically-significant depressive symptoms initially (except one subject in the control group). Therefore, the lack of any significant changes might be attributable to the ceiling effect, in other words, there was no room for the improvement.

Regarding the results of the State-Trait Anxiety Inventory (STAI) Y-1 (state anxiety), no statistically significant difference was found between both groups (p=.092). But, the related t-test for the pre-test and post-test STAI scores showed the marginally significant improvement in the experimental group (p=.056). The results of the STAI Y-2 (trait anxiety) showed the statistically significant improvement in the experimental group (p=.047), and the related t-test for the pre-test and post-test scores support this finding (p=.04). These results suggest that the distant healing intervention might have beneficial impact on the subject's anxiety level. In contrast, the STAI scores in the control group stayed almost the same (p=.95 for "state anxiety" score and p=.85 for "trait anxiety" score). One of the reasons was that the new data of the STAI scores were not obtained in a total of 7 subjects (including 2 drop-out subjects and 3 subjects who increased the medication doses) in the control group, and their baseline data were used as substitutes for their post-test results. Therefore, if their new data had been available, it is possible that the results of the control group would have shown some improvements due to the placebo effects or for other reasons. For this reason, it is difficult to yield any definitive conclusions regarding the efficacy of the distant healing on anxiety levels of individuals with type 2 diabetes only with this finding.

The Discussion of Anecdotal Findings

As described in the previous chapter, one subject in the experimental group had an interesting experience during the study. She suddenly started crying soon after the

group meditation session at the initial session. According to her, she kept crying almost all day long on that day. She did not have any idea on the reason why it had occurred. She did not experience any sad feeling while she was crying; rather her heart was filled with a blessed feeling. Her mystical experience continued during the entire study period. Every time she practiced meditation at her home, she felt a substantial blessed feeling. She had the vision that a golden, yellow light was pulsating and filled with the entire room. Interestingly, much saliva started coming out until it almost spilled from her mouth during meditation practice. As described, saliva is considered as the indicator of vital energy in Eastern medicine, so it suggests that her vital energy might have become enhanced. On some occasions, she saw the vision that the healing energy came from the healer. This research used the double-blind procedure, so she did not know her group assignment during the study. Therefore, it is not likely that her vision of the healer was created by her imagination. It would be reasonable to say that her visions and mystical experiences were attributable to the distant healing session itself. Strangely, her mystical experiences still continued even after the four-month intervention period. Almost every time she practiced meditation at home, she had the similar experiences to those obtained during the intervention period. The PI gave her detailed interviews a few times and found that her experiences slightly changed after the distant healing session had finished. She still kept experienced a blessed feeling, but it was not so intense compared with the time when she was receiving the distant healing. It suggests that the distant healing intervention might have triggered her mystical experiences and its effect might have continued even after the completion of the healing session. The reason of her starting

having these experiences is not clear, but the healing energy of the healer might have boosted up her sensitivity to energy.

One more subject in the experimental had the vision of the healer during the study. It was during his travel in Mexico when he got the vision that the healer was sending healing energy to him. It was only this one-time episode, but because of this experience, he became aware of his being receiving healing. Because of the double-blind setting, he did not know his group assignment, but he recognized that he was in the experimental group. Considering the fact that his prediction proved to be right, he might have perceived his receiving healing intuitively and that the healing intervention of the healer might have contributed to his getting the vision. One more subject in the experimental group had the vision which might be related to the distant healing intervention. She did not get the vision of the healer. What she saw during the meditation practice was the vision of a "beautiful" Japanese Shinto shrine. She had never visited Japan before, but she had seen the picture of the building of a Shinto shrine. She believed that her vision was related to the distant healing intervention. Actually, she described her experience during the study period, "I became happier and more peaceful than before." In spite of her feeling better, her HbA1c levels stayed almost the same (from 6.4% at the pre-test to 6.3% at the post-test) and she was still under medications. The improvement of the previously-mentioned subject, who had mystical experiences continuously during the entire study period, was not so dramatic (her HbA1c decreased from 9.1% to 8.1% and she was still under medication) even though she felt a substantial blessed feeling every time. Mental conditions were expected to be strongly correlated with diabetic conditions (the HbA1c levels of the subjects would decrease significantly if their mental conditions

improve), so the reason of the lack of significant improvements in these subjects remains unknown. One possible reason is that it might take more time to have significant improvement in the HbA1c levels considering the chronic nature of type 2 diabetes. If the distant healing intervention had continued more than four months, these subjects' diabetic conditions would have improved more. Only with the findings of this research, any definitive answer cannot be made on this question.

As described in the section of Research Findings, no subjects in the control group reported that they felt the healing energy of the healer or had the vision which might have been related to distant healing session. The lack of any of those aforementioned experiences in the control group also suggests that the healing energy might have induced these experiences in some subjects in the experimental group.

In the experimental group, several subjects got acute symptoms such as nausea, vomiting, a sty in the eye, and allergic symptoms. As described, most of these symptoms lasted only for a few days (a sty in the eye still stayed even after the completion of the study), and their condition completely recovered after this episode. Many of these subjects' diabetic conditions also improved, which was indicated by the decrease of HbA1c levels and BS levels. In contrast, no subjects in the control group got such acute symptoms. The PI had conducted another distant healing study with the same healer before, in which the effects of distant healing on chronic pain were studied.[176] In this previous study, several subjects in the experimental group exhibited acute symptoms such as high fever and temporal exacerbation of pain. These symptoms lasted only for several days and their chronic pain significantly improved after this episode. Again, no subjects in the control group exhibited these acute symptoms. Considering the fact that these

symptoms were found only in subjects in the experimental group, they might be related to the distant healing intervention. Their body might have responded to the healing energy of the healer, which manifested as various physical symptoms. The interesting finding was that their overall conditions significantly improved after these episodes. If these symptoms had been induced by receiving the healing energy, they would have been so-called "healing reactions." It is not certain whether these symptoms are healing reactions or not only with the findings of this research, but it would be an interesting subject for the future healing study.

Suggestions for Future Research

As described, a total of 29 subjects participated in this study. There were some drop-out subjects and those who did not follow the original protocol (they changed the medication doses). The intention-to-treat analysis was used as a statistical test of the data; it was assumed that the conditions of those subjects who did not follow the protocol stayed the same. The results showed the positive effects of the distant healing on type 2 diabetes, but it is not certain whether this assumption was reasonable or not considering a small sample size. The length of one distant healing session was only a few minutes, so it is not impossible for the healer alone to perform distant healing to larger number of people. Therefore, it would be necessary to conduct further study with a larger number of subjects to yield any definitive conclusion.

The distant healing intervention in this research was performed by a single healer. The results suggest the positive effects of healing, but it is not known whether the effects of healing were attributable to the healing treatment of this particular healer or the healing modalities (Esoteric Buddhism, Shinto and Qigong). To answer this question, it

would be necessary to conduct research with more than one healer and compare the effectiveness of each healer's healing intervention. In this case, a much larger number of subjects would be necessary to yield any definitive conclusion, but it would be an interesting, valuable research.

As discussed, several subjects had some interesting experiences and exhibited acute symptoms. All of them were in the experimental group, so it suggests that these experiences might be related to their receiving healing session. The findings suggest that the body might react to healing energy by exhibiting various acute symptoms or having visions related to healing. It would be also interesting to study these experiences further by conducting another research. If the similar episodes happen only to the subjects in the experimental group in the future controlled study, it would be reasonable to say that they are related to receiving healing energy.

The present dissertation is not the end of my research on distant healing. Nor is it the beginning of the end, but it is the end of the beginning.

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APPENDIX A
The Subjects' Raw Data

Subject (Number)	A1c[a] (pre)	A1c (post)	DSC[b] (pre)	DSC (post)	SDS[c] (pre)	SDS (post)	Y-1[d] (pre)	Y-1 (post)	Y-2[e] (pre)	Y-2 (post)
Healing										
1	11.9	11.5	1.42	1.42	33	33	44	44	51	51
2	9.1	8.1	1.8	1.77	24	27	32	32	39	37
3	7.6	6.9	1.52	1.62	14	27	28	20	27	23
4	6.9	6.2	1.46	1.07	34	25	51	23	56	25
5*	6.7	6.7	2.17	2.09	35	30	38	30	45	35
6	12.3	10.6	1.98	1.71	45	40	61	60	59	61
7*	7.7	8.7	2.25	1.47	27	34	34	34	39	37
8	7.5	6.3	1.71	1.27	34	14	34	24	38	24
9	7.7	7.8	1.37	1.37	26	22	23	24	26	27
10	6.6	6.6	1.4	1.65	15	27	22	25	21	22
11	6.2	6.5	1.29	1.41	27	17	31	22	29	21
12	6.4	6.3	1.55	1.38	36	29	24	24	31	34
13	6.9	6.1	1.7	1.55	31	36	24	30	31	31
14	10.6	9.2	2.9	2.25	42	36	42	31	54	33
15**	9.9	9.9	2.38	1.45	29	13	26	24	21	21
Control										
1	13	12.5	1.57	1.95	20	31	37	49	35	43
2*	9.4	10	1.29	1.55	20	27	29	20	30	21
3*	7.9	7.9	2.02	2.02	54	54	54	54	52	52
4	7.8	9.2	2.6	1.75	38	38	29	31	38	32
5	6.0	6.0	2.9	2.9	40	40	44	44	49	49
6	7.3	7.3	1.03	1.43	30	32	28	22	29	28
7*	8.8	8.8	1.55	1.55	20	20	32	32	34	34
8	8.2	8.5	2.15	2.15	54	54	59	59	57	57
9	7.5	6.5	1.34	1.24	28	30	20	22	23	28
10	7.4	7.7	1.38	1.09	25	25	38	26	29	35
11	6.8	7.0	1.49	1.36	16	17	28	28	27	27
12*	7.4	7.9	1.02	1.02	22	22	31	31	27	27
13**	6.9	6.9	2.6	2.6	41	41	43	43	53	53
14**	6.6	6.6	1.9	1.9	40	40	45	45	38	38

[a] Hemoglobin A1c (Normal Range: 6% or less)

[b] Diabetes Symptom Checklist- Revised (Minimum Score: 1, Maximum Score: 5)

[c] Zung Self-Rating Depression Scale (SDS) (Normal Range: 25-49)

[d] State Trait Anxiety Inventory Y-1 ("State" Anxiety) (Low Anxiety: 20-39, Moderate: 40-59, High: 60-80)

[e] State Trait Anxiety Inventory Y-2 ("Trait" Anxiety) (the same as the above)

* Subjects who increased the medication doses

** Drop-out subjects

APPENDIX B
Informed Consent Form

Faculty Supervisor: Bob Nunley Ph.D.

Holos University Graduate Seminary supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish to participate in the present study. You should be aware that even if you agree to participate, you are free to withdraw at any time without penalty.

The principal investigator, Kenjiro Tsubono, a psychiatrist in Japan, is interested in studying the effects of the distant healing on type 2 diabetes. Distant healing is a technique which tries to cure the disease of another person who is a great distant away by the focused intention of a healer. The mechanism of distant healing is still a mystery, but the non-local nature of the mind might contribute to the effectiveness of distant healing. The name of the healer is Mr. Jiho Otsuki, and he has many years of experience doing distant healing in Japan.

The inclusion and exclusion criteria are as follows.

Population: 18 Years and above, men and women

Inclusion Criteria:

- Participants had to be clinically diagnosed as type 2 diabetes by a physician (self-reported).
- The participant's HbA1c level must be above 6.5 % or FBS (Fasting Blood Sugar) must constantly show above 120 mg/dl (self-report).
- Participants must show willingness to participate by signing a voluntary informed consent form.
- Participants will show ability and stated willingness to follow the directions of the Principal Investigator (PI) and the research staff.
- Participants will keep the same treatment regimen (including complementary and alternative therapies) during the study unless their physicians suggest doing so.
- Participants will not take any other spiritual healing treatments by other specific healers during the study.
- If participants are therapists of energy work, such as Reiki, spiritual counseling, massage or healing touch, participants will abstain from their practice temporarily during the study.

Exclusion Criteria:

- Unable to comply with or attend the two-time session (the initial session, and the post-intervention session or interview)
- Type I diabetes

- Not English speaking
- Pregnant women
- Diagnosis of psychotic disorder (self-reported)
- Serious health condition(s) (unstable heart diseases, serious respiratory illnesses, terminal-ill patients etc) that the PI determines would make it difficult to complete the 4 month study

This study will use a double-blind randomized controlled design, so you may or may not be assigned to an experimental group. If you are assigned to an experimental group, your will receive his healing for the first four months. If you are assigned to a control group, you will not receive his healing for the first four months, but you can receive his healing for the second four months. You will not know which group you have been assigned until the completion of the study. The healer will send healing energy from Japan to you in the US every day. It will take about several minutes to complete one session of healing. During the session, you can just stay at home or go outside without doing anything special. You do not need to know the time when the healer will perform the healing. Whether you are assigned to an experimental group or not, you will be asked by the PI to expect to receive healing and visualize that you are receiving healing from Japan using a picture on which a visual image of distant healing (it will be provided by the PI at the session) is drawn once a day. The purpose of this visualization practice is to enhance your sensitivity to the healing energy.

In order to determine if his healing is effective on individuals with type 2 diabetes, you will be asked to fill in several different test forms. You will be asked to fill in these test forms at your home two times before the initial interview and after the completion of the intervention. The HbA1c (hemoglobin A1c) test will be performed two times at the initial screening interview and the second post-intervention interview using Metrika A1c Now + monitoring system by yourselves (Please bring your own lancet (a tiny needle for your daily BS check) to the screening interview). This test is approved by FDA for home use, so there is no serious risk with using them. You will be also asked to check you fasting blood glucose level every day during the study period. On the scheduled day, you will be asked to come to the initial session. In this session, the PI will introduce the healer to you and explain about the study procedure. After that, a 20-minute group meditation will be performed togher. At the session, the PI will take your facial photo by a digital camera. Your facial photo will be used by the healer in order to perform the distant healing. After the first four month period, you will be asked to come to the second screening interview. In this second interview, HbA1c test will be performed again to evaluate your diabetic condition. After the completion of the second screening interview, the healer will start distant healing to a control group.

Your participation is solicited although strictly voluntary. We assure you that your name will not be associated in any way with the research findings. The information will be identified only by a code number.

Employees of the Food and Drug Administration, the sponsoring institution and members of the Institutional Review Board can look at, and copy your medical records and any

information collected during this Study. Your identity will not be disclosed to anyone else, unless required by law.

There are some studies which show the effect of distant healing on physical and mental diseases. Therefore it is possible that your diabetic condition will be improved by distant healing. There are no side effects in distant healing as far as the PI knows.

Please sign your consent with full knowledge of the nature and purpose of the procedures, the benefits you may expect, and the risks which may be encountered. I appreciate your assistance. If you would like additional information concerning this study before or after it is completed, please feel free to contact me by phone, mail, or email. If you have concerns or questions about your rights as a research participant, you may contact the Holos University Graduate Seminary at (888) 272-6109, 5607 S. 222nd Road, Fair Grove, Missouri, 65648.

Sincerely,

Kenjiro Tsubono, Th.D. candidate

_____ _____

Signature of Person Agreeing to Participate Date

With my signature I acknowledge that I agree to take full personal responsibility for my participation in the protocol described above. I am 18 years of age and above. I have received a copy of this consent form to keep.

By signing this Consent Form, I am authorizing release of my medical records to the Food and Drug Administration, the Institutional Review Board and any third party required by law.

Print Your Name Here

_____

APPENDIX C
Experimental Protocol

Title of Research: The Effects of Distant Healing on Type 2 Diabetes Mellitus
Submitted by: Kenjiro Tsubono
Date Submitted to Exped. Review:
Date Approved: September 15, 2008
Assigned # of Protocol: #458

Background and Theoretical Framework:

Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that is needed to convert sugar, starches and other food into energy needed for daily life. "The cause of diabetes continues to be a mystery, although both genetics and environmental factors such as obesity and lack of exercise appear to play roles." There are 20.8 million children and adults in the United States, or 7% of the population, who have diabetes. While an estimated 14.6 million have been diagnosed with diabetes, unfortunately, 6.2 million people (or nearly one-third) are unaware that they have the disease. The World Health Organization (WHO) estimates that more than 180 million people worldwide have diabetes. This number is likely to more than double by 2030. Type 2 diabetes (formerly called non-insulin-dependent or adult-onset) results from the body's ineffective use of insulin. Type 2 diabetes comprises 90% of people with diabetes, and is largely the result of excess body weight and physical inactivity. Having type 2 diabetes increases the risk for many serious complications as heart disease (cardiovascular disease), blindness (retinopathy), nerve damage (neuropathy), and kidney damage (nephropathy). Healthy eating, physical activity, and blood glucose testing are the basic management tools for type 2 diabetes. In addition, many people with type 2 diabetes require oral medications, insulin, or both to control their blood glucose levels. However, the level of physical training recommended for type 2 diabetes patients to lower plasma glucose levels, decrease obesity and improve insulin sensitivity, or 50-70 % of maximum aerobic capacity lasting 30 minutes, three or five times a week are not feasible in many patients because of age, obesity, cardiovascular disease and other problems. Therefore, the treatment compliance of diabetes patients is very poor. Furthermore, diabetes imposes significant financial burden on individuals with the disease. The median annual direct medical costs for subjects with diet-controlled type 2 diabetes, BMI 30 kg/m^2, and no serious complications were $1,700 for white men and $2,100 for white women. A 10-kg/m^2 increase in BMI, treatment with oral medications, and complications such as kidney disease, cardiovascular disease, were each associated with 10–30% increases in cost. The annual medical cost associated with diabetes in the U.S. is 98 billion dollars, including direct and indirect medical costs and lost productivity.

There is evidence that an increasing number of individuals in the U.S. use one or more Complementary and Alternative Medical (CAM) remedies for the treatment of common medical conditions. A belief in the role of mental and spiritual factors in health

is an important predictor of CAM use. In a recent study of CAM in the United States, 7% of persons surveyed reported having tried some form of "spiritual healing." This was the fifth most frequently used treatment among all CAM therapies assessed. In the same study, 35% of persons surveyed reported that they had used prayer to address their health-related problems. *Distant healing* has been defined as "a conscious, dedicated act of mentation attempting to benefit another person's physical or emotional well being at a distance." One form of distant healing is intercessory prayer, in which a person prays for the healing of another person who is a great distant away, with or without that person's knowledge. There are several studies which showed the positive effect of intercessory prayer. The most notable of these studies is a randomized double-blind experiment which demonstrated that patients in a coronary-care unit who received the intercessory prayer had a significantly reduced requirement for antibiotics, diuretics, and ventilatory support compared to the control group. There is one experimental research which studied the efficacy of distant healing on diabetes mellitus. In this research, Daniel and his colleagues studied the effects of the combination of the therapeutic touch therapy (this therapy is a consciously directed process of energy exchange during which practitioners use their hands as a focus for facilitating healing) and intercessory prayer on the insulin dose levels of type 1 diabetes patients. The results showed that there was a reduction in the insulin dosage, but the difference between the treatment group and the control group was not significant. They concluded that some factors such as the utilization of insulin doses instead of objectively measured blood glucose values as the dependent variable, the short duration for treatment and control sessions, and the experimental instructions advising patients to adjust their caloric intake and expenditure prior to adjusting their insulin dose contributed to the non-significant results.

As far as the principal investigator (PI) knows, one clinical study which examined the effects of distant healing on type 2 diabetes exists. In this study, distant healing was performed by five "experienced and reliable healers." Fourteen subjects received distant healing every day for four weeks. There was a short-term reduction of fluctosamine level, but the final outcomes did not show a significant improvement. Some physical areas even deteriorated. For instance, sensitivity in the feet decreased, and there was a significant increase of cholesterol.

The problem of the previous studies on distant healing is that the definition of healers is unclear. For example, in Byrd's study, intercessors were defined as "active Christians and practiced daily devotional prayer." In personal knowledge of the PI, there seems a big difference in the healing power between experienced healers and inexperienced healers. The spiritual healer who will do distant healing in this study is a professional Japanese healer named Jiho Otsuki, and he has more than 20 years of experience in distant healing. He has treated patients with severe diseases such as malignant cancer, depression, alcohol abuse and auto-immune disorders. He also has treated patients with type 2 diabetes mellitus successfully. Type 2 diabetes mellitus is much related to addiction to sugar, and exacerbation of the disease is triggered by voluntary behavior such as overeating. Many patients also have psychological problems such as anxiety and depression, and their psychological well-being is very poor. That is why many diabetic patients cannot control their diet and exercise menu even though their

physicians repeatedly suggest them do so. So, it is essential to deal with patients' psychological problems in order to treat this disease. This Japanese healer has treated the patients with addiction and depression before. The PI has studied his healing power by using the electroencephalogram (EEG) before, and his healing energy remarkably changed the EEG of the subjects (all brain activity diminished significantly during the session); the subjects felt very relaxed during the session. The results suggest that his healing energy affected the nervous system of the subjects in a positive way and calmed them down. Considering the results of that study, it can be expected that his healing will be effective not only for patients' physical symptoms, but also for their mental symptoms. The PI has not studied the effects of his healing on addiction in a scientific setting, but the results of EEG study suggest that his healing might be effective for addiction which is one of mental disorders.

Therefore, the distant healing by this Japanese healer has many aspects that make it an excellent candidate for use to address these concerns.

Objective

To study the effects of distant healing performed by a Japanese healer on Type 2 diabetes.

Study Design:

This study uses a pretest-posttest control group design with repeated measure of the dependent variables such as hemoglobin A1c (HbA1c), fasting blood glucose level, the body mass index, and the Diabetes Symptom Checklist-Revised © (DSC-R) score. In this study, the PI will recruit a total of 80 participants with type 2 diabetes, and they will be assigned randomly either to an experimental group or to a control group.

Population: 18 Years and above, men and women (all races will be included)

Inclusion Criteria:

- Participants had to be clinically diagnosed as type 2 diabetes mellitus by a physician (self-report).
- The participant's HbA1c level must be above 6.5 % or FBS (Fasting Blood Sugar) must constantly show above 120 mg/dl (self-report).
- Participants must show willingness to participate by signing a voluntary informed consent form.
- Participants will show ability and stated willingness to follow the directions of the Principal Investigator (PI) and the research staff.
- Participants will keep the same treatment regimen (including complementary and alternative therapies) during the study unless their physicians suggest doing otherwise.
- Participants will not take any other energy healing treatments by other specific healers during the study.

- If participants are therapists of energy work, such as Reiki, spiritual counseling, massage, or healing touch, participants will abstain from their practice temporarily during the study.

Exclusion Criteria:

- Unable to comply with or attend the two-time session (the initial session and second session)
- Type I diabetes mellitus
- Not English speaking
- Pregnant women
- Diagnosis of psychotic disorder (self-reported)
- Serious health condition(s) (unstable heart diseases, serious respiratory illnesses, or terminal-ill patients) that the PI determines would make it difficult to complete the four month study

List Potential Risks/Safety:

The intervention in this study is the distant healing by the Japanese healer. Considering other studies on the nature of distant healing, there will be no greater risk than minimal risk in the intervention.

Discontinuation Criteria

- Participants may be dropped from the study at any time at their request or that of the PI of the project and reported to the IRB in the quarterly report.
- If participants terminate their participation in the study prematurely, the drop date and reason will be recorded in their Report Form and reported to the IRB.
- If adverse reactions occur during the study, the PI will determine whether a participant should be discontinued and report to the IRB in writing.

Safety Evaluation

Safety will be evaluated by monitoring the occurrence of any adverse effects. The participants will be instructed to notify the PI as soon as possible adverse or unusual symptoms occur.

There will be no serious adverse reaction, but in the event of any unexpected adverse reaction by the intervention, the PI must notify the supervising physician and the IRB chair within 24 hours and the full board within 72 hours. Any adverse reaction will be recorded in the complaint file and reported to the full IRB board. In case of adverse effects, proper therapeutic measures and follow-up will be done by the PI in accordance with there health care provider.

Tests to be used:

1) **Diabetes Symptom Checklist-Revised ©**

The Diabetes Symptom Checklist-Revised © (DSC-R) is a measure of both the occurrence and the perceived burden of physical and psychological symptoms related to type 2 diabetes and its possible complications. It is a 34-item, self-report questionnaire in which each item is rated on a 4-point Likert scale. It takes about 10 minutes to complete. The DSC-R is obtained from MAPI Research Trust.

2) Metrika A1cNow + monitor

Metrika A1cNow + monitor delivers fast, accurate A1C test results in just five minutes. Patients do not have to wait for lab results or schedule follow up visits. This test can be performed either at clinician's office or at patients' home by themselves. Hemoglobin A1c (HbA1c) measures provide the most reliable assessment of glucose management. The HbA1c test provides an index of a patient's average blood glucose level during the past 2-3 months. The Diabetes Control and Complications Trial established that maintaining A1c levels as close as possible to the normal range results in considerable reductions in long-term health complications.

3) Glucometer

The PI will choose participants' own glucometer to measure their daily fasting blood glucose level in the study. This devise is one of the most popular glucose meters in the world. This glucose monitoring system is intended to measure the glucose level in whole blood. This monitoring system is suitable for persons with diabetes to monitor their blood glucose at home by themselves because of its simplicity and accuracy. Nurses or professional people to test patients' blood glucose level in whole blood can also use this system at clinical sites. Based on the electrochemical biosensor technology and principle of capillary action, this monitoring system only needs a small amount of blood. Capillary action at the end of the test strip draws the blood into the action chamber and a blood glucose result is precisely displayed in five second. There are several studies that show the accuracy and reliability of home blood glucose monitoring system.

4) The State Trait Anxiety Inventory (STAI)

The State-Trait Anxiety Inventory Form Y (STAI) is the instrument for measuring anxiety in adults and widely used all over the world. The STAI clearly differentiates between the temporary condition of "state anxiety" and the more general and long-standing quality of "trait anxiety." The essential qualities evaluated by the STAI are feelings of apprehension, tension, nervousness, and worry.

5) The Zung Self-Rating Depression Scale (SDS)

The Zung SDS is designed for assessing depression in patients whose primary diagnoses are that of a depressive disorder. It is self-administered and indicates the patient's own response at the time the scale is taken. The 20 items of the scale address

each of the four most commonly found characteristics of depression: the pervasive effect, the physiological equivalents, other disturbances, and psychomotor activities. Its validity is widely accepted, and it has been used all over the world as an assessment tool of depression.

7) Body Mass Index (BMI)

The PI will ask participants to measure their body weight and height at their home (or other facilities) themselves. Body Mass Index (BMI) is a number calculated from a person's weight and height. BMI provides a reliable indicator of body fatness for most people and is used to screen for weight categories that may lead to health problems. The calculation is based on the following formulas:

Formula: weight (lb) / [height (in)]^2 x 703

Obesity and overweight is much related to type 2 diabetes. BMI is a good indicator of obesity. The height and weight of prospective participants will be measured, and BMI will be calculated based upon the above formulas in the study.

Consent Form for Participants:

The informed consent form is included at the end of this form as Appendix.

Participants Recruitment

Prospective participants will be recruited through the local radio and newspaper advertising, support group meetings (including online), the local churches, and other sources both in South-West Missouri area and Denver-Boulder, Colorado area.

Protocol Monitoring:

Pre-Inclusion Screening

The prospective participants who are interested in participating in the study will be asked to telephone the PI, who will ask them if they meet the inclusion criteria or not. If they do not meet the inclusion criteria, they will be excluded from the study.

Testing:

In this study, several different tests as described above will be performed two times before and after the intervention. The DSC-R, STAI, and SDS will be also performed two month after the study began (a total of three times). Participants will be asked to check their fasting blood glucose level every day by their own glucometer. After the pre-inclusion screening by phone, the test forms will be sent to the prospective participants by mail. All tests except HbA1c test will be done at their home by themselves. HbA1c test will be performed two times at the initial session and the second

post-intervention session using Metrika A1c Now monitoring system. This test was approved by FDA for home use and patients can perform it by themselves using their own finger stick (only monitor is reusable and some participants will share one monitor). At the initial session, participants will be given this monitoring system and perform this test by themselves. Participants will perform this test again at the second session in the same way (four month after the intervention).

Research Intervention:

The intervention of this study is the distant healing by a Japanese spiritual healer named Jiho Otsuki. In this study, he will do the distant healing by using the simple information of the prospective participants, which are their facial photos, names, addresses, and the severity of disease. The prospective participants will be asked to come to Holos University or a local community center (Boulder, CO) for the initial session on the scheduled day. The prospective participants will be assigned either to an experimental group or to a control group randomly. The matching procedure based upon the HbA1c level of the pretest and participants' medication status will be done by the PI. After the pair matching procedure is done, this information will be passed to the other staff that will randomize participants to either group by using a random number table (The PI will not be involved in this randomizing procedure). This procedure will be done blindly to the participants and the experimenter. The information of the group assignment will be passed to the healer in Japan and be kept secret until the study is completed. The healer will send healing energy only to the participants who will be assigned to an experimental group. It will take several minutes for him to complete one session. He will continue the distant healing for four months. During the session, at first, the healer will assess the energy field of the body from a distance. Second, he will remove the negative energies, which contribute to various physical and mental problems, from the body. Third, he will send the healing energy to participants. After completing four-months of healing intervention, again all participants will be asked to come to Holos University or a community center (Boulder, CO) for the second session. The healer will start the distant healing to the participants who will be assigned to a control group after the second session. Whether participants are assigned to an experimental group or not, all of them will be asked to expect to receive healing and visualize that they are receiving distant healing energy by using the picture with a simple visual image of distant healing (provided by the PI) for a few minutes once a day in order to become more receptive to the healer's healing energy.

Monitoring Personnel for Research:

Supervisor of this study: Bob Nunley, PhD

List Primary Researcher and any assistants:

Primary Researcher- Kenjiro Tsubono, M.D.

Assistant- Office assistants may be used to help assemble participant packages, but the PI will have responsibility for all packages sent.

Research Results:

Analysis

The analysis will be done by comparing between the above-mentioned dependent variables before the intervention and those after the intervention. The difference of the results of two groups will be assessed by the 2X2 mixed ANOVA. The PI will refer to a statistician to do the statistical analysis if necessary.

Confidentiality Statement

The following statement of confidentiality is included as part of the informed consent form:

"Your participation in this study and any forms generated will be held in strict confidence. We assure you that your name will not be associated in any way with the research findings. The information will be identified only by a code number. Results of the study may be reported in scientific presentations or publications, but you will not be identified."

Method of sharing results with research participants

Participants will be asked if they would like to receive a summary of the study results. Those who indicate that they would like to receive it will be mailed printed information including the purpose of the study, a brief background section, and the results of the study, with discussion. If enough interest is expressed, a presentation of the study results could be arranged

APPENDIX D
A1cNow™ for Home Use

The Company

Name: Metrika, Inc.
Address: 510 Oakmead Parkway, Sunnyvale, CA, 94085
Phone: (408) 524-2255
Fax: (408) 524-2252

Trade Name: A1cNow™ for Home Use
Common Name: percent hemoglobin A1c (percent glycosylated hemoglobin)

Device Description:
It is a four-channel reflectance photometer that includes microelectronics, optics, and chemistry strips. A whole blood sample is applied to the sample port, and the results are displayed in the device's crystal display in eight minutes. This device does not have any switches or buttons. It activates by itself upon addition of the blood sample.

This device uses both immunoassay and chemistry technology to measure the glycated hemoglobin (HbAlc) levels. This test provides quantitative measurement of the percent of HbAlc levels in capillary whole blood samples. Diabetes patients place their fingerstick blood into the monitoring device provided.

The test is approved by FDA for home use by people with diabetes to monitor glycemic control. This device was evaluated for nonclinical and clinical performance characteristics in studies. These studies demonstrated that the test is safe and effective for its intended use.

Reference Source:
U.S. Food and Drug Administration. "Metrika A1cNow® for Home Use - K02266," 2009. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm082921.htm (accessed November 29, 2009).

APPENDIX E
The Diabetes Symptom Checklist-Revised© (DSC-R)

Purpose: To measure both the occurrence and the perceived burden of physical and psychological symptoms related to type 2 diabetes and its possible complications

Population: Can be used for individuals with type 2 diabetes
Authors: Franck Snoek et al (The Netherlands)
Copyright: © EMGO Instituut 1998 Vrije Universiteit Amsterdam
Publisher: MAPI Research Trust (Lyon, France)
Description: The Diabetes Symptom Checklist-Revised © (DSC-R) consists of 34 questions about diabetes-related symptoms. It is divided into the following 8 dimensions.

1. Psychology (fatigue): 4 items
2. Psychology (cognitive): 4 items
3. Neurology (pain): 4 items
4. Neurology (sensory): 6 items
5. Cardiology: 4 items
6. Ophthalmology: 5 items
7. Hypoglycemia: 3 items
8. Hyperglycemia: 4 items

The possible answers include: 1=not at all, 2=a little, 3=moderately, 4=very and 5=extremely. The sum of the scores is calculated as a measure of severity. The minimum score is 8 (no symptoms at all) and the maximum is 40 (the most severe) (In this research, the result was further divided by eight, which is the number of dimension, and the total score ranged between 1 and 5).

Suggested Uses: Recommended for clinical and epidemiological studies to assess diabetes-specific symptom severity

Reference Source:
Grootenhuis, P.A., F.J. Snoek, R.J. Heine, and L.M. Bouter, "Development of a Type 2 Diabetes Symptom Checklist: A Measure of Symptom Severity," *Diabetic Medicine* 11(1994):253-61

MAPI Research Trust, "DSC-R (Diabetes Symptom Checklist-Revised)," 2009. http://www.mapi-trust.org/services/questionnairelicensing/cataloguequestionnaires/45-DSC-R (accessed November 29, 2009).

APPENDIX F
The Zung Self-Rating Depression Scale (SDS)

Purpose: To assess the level of depression for individuals with depressive disorder

Population: Can be used for individuals with depression
Authors: William W.K. Zung (Duke University)
Publisher: © Glaxo Wellcome Inc. 1997 (USA)
Description: The Zung Self-Rating Depression Scale (SDS) consists of 20 items related depressive symptoms which are roughly categorized into the four common characteristics of depression: the pervasive effect, the physiological equivalents, other disturbances, and psychomotor activities.

The possible answers include: 1=a little of the time, 2=some of the time, 3=good part of the time and 4=most of the time. The sum of the scores is calculated as a measure of severity of depression. Scores range from 20 to 80. Most people with depression score between 50 and 69.

Suggested Uses: Recommended for clinical and epidemiological studies to assess the severity of depression

Reference Source:
Carroll, Bernard J., John M. Fielding, and Timothy G. Blashki, "Depression Rating Scales: A Critical Review," *Archives of General Psychiatry* 28 (1973): 361-366.

Zung, W.W.K., "A Self-Rating Depression Scale," *Archives of General Psychiatry* 12 (1965): 63-70.

APPENDIX G
The State-Trait Anxiety Inventory (STAI)

Purpose: Designed to study levels of anxiety for both state (how you feel right now) and trait (how you generally feel) anxiety.

Population: Can be used for adults and teenagers (above the high-school age)
Authors: Charles D. Spielberger, Richard L. Gorusch, and Robert E. Lushene.
Publisher: Mind Garden, Inc.
Description:
The State-Trait Anxiety Inventory (STAI) is a self-report assessment device which includes measures of both state and trait anxiety. It consists of these two different tests and each having twenty questions.

The state questions refer to "how one is feeling right now," and the possible answer uses a 4-point scale including the following ones;
1=not at all, 2=somewhat, 3=moderately so and 4=very much so.

The trait questions refer to "how one is generally feeling," and also uses a 4-point scale including the following ones;
1=almost never, 2=sometimes, 3=often and 4=almost always.

Scoring: Scores are obtained by simply summing the scores of the twenty questions. The minimum score is 20 and the maximum one is 80.

Suggested Uses: Recommended for studying anxiety in research and clinical settings.

Reference Source:
Spielberger, Charles D., "State-Trait Anxiety Inventory for Adults," Mind Garden.
http://www.mindgarden.com/products/staisad.htm (accessed November 29, 2009)

APPENDIX H
The Initial Cover Letter

Dear Participant,

Thank you for your interest in this research project.
The initial session with the healer will be held at _____on _____at _____. Please let me know if you can come to the session as soon as possible you receive this letter. In the initial session, I will give a short interview and check your HbA1c level by using a simple test kit. Also, we will do a 20-minute group meditation together. The session will take about 90 minutes (depending on the number of participants).

If it is highly possible that you cannot complete four-month study (scheduled moving, big surgery etc), please refrain from participating in this project. It is because high dropout rate will skew the final outcome of a randomized controlled study.

In this package, you will find the following:

a) A consent form for participants
b) Medical history form
c) Participant intake form
d) The Diabetes Symptom Checklist Revised (DSC-Rⓒ)
e) The State-Trait Anxiety Inventory Form Y (STAI)
f) Zung self-rating depression scale

Please fill out the above documents and bring them to the initial session. HbA1c test will be done **using your own lancet (a tiny needle) for your daily blood sugar check, so please bring it with you to the session.**

If you have any questions, please feel free to call or email me. I will do my best to answer all of your questions.

Sincerely,

Kenjiro Tsubono
Th.D. candidate of Holos University Graduate Seminary

APPENDIX I
Participant Medical History Form

(Please fill out and turn in at the initial screening interview)

Name: _____ Date: _____

Body Weight: _____lb Height: _____ft (Date: _____)

The latest HbA1c: _____ (Date: _____) (if available)

1. When were you diagnosed as type II diabetes mellitus? _____

2. What do you think caused your diabetic condition? (Psychological stress, traumatic events, bad eating habit etc.) Please describe the situation or triggering events in detail if you have any ideas.

3. What kinds of treatment related to type 2 diabetes are you taking now?
   Diet and exercise therapy 1=yes, 2=no _____

   If yes, please explain in more detail. _____

   Hypoglycemic drug (oral or injection type) 1=yes, 2=no _____
   If yes, what kinds of medications are you taking?

Name of Drug	Dose (per day)	since when
_____	_____	_____
_____	_____	_____
_____	_____	_____

   Insulin injection 1=yes, 2=no _____
   If yes, what type of insulin do you use (both long and short acting types)?

Name of insulin	Dose (unit / day)	since when
_____	_____	_____
_____	_____	_____
_____	_____	_____

Are you taking some complementary or alternative therapy (supplements, herbs, acupuncture, Reiki and homeopathy etc)? 1=yes, 2=no _____

If yes, what kinds of therapies are you taking?

Name of Therapy	Frequency	since when
_____	_____	_____
_____	_____	_____
_____	_____	_____

4. Do you have any other diseases other than type 2 diabetes?
1=yes, 2=no _____

If yes, please explain in more detail below (since when, type of treatments etc).