

## Complementary Healing Therapy For Patients With Type I Diabetes Mellitus

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**Abstract** — The effect of Noncontact Therapeutic Touch (NCTT) therapy and Intercessory Prayer (IP) on patient determined insulin dosage was examined in an exploratory pilot study which utilized a randomized, double-blind, within subject, crossover design. Sixteen type I diabetes mellitus patients were examined and treated daily by NCTT and IP healers for a duration of two weeks. Each patient underwent two separate sessions—one in the treatment condition and one in the control condition—with the patients crossing over to the opposite condition for the second session. The results indicated that while 11 of the 16 patients (69%) in the treatment group showed a reduction in insulin dose levels as compared to the control group, the difference in insulin dosage did not reach significance. It is suggested that various methodological considerations may have been important contributing factors in the nonsignificant results obtained including: (1) the utilization of insulin dose instead of objectively measured laboratory blood glucose values as the dependent variable, (2) the four foot distance and mirrored glass barrier between healer and patient, (3) the short duration for treatment and control sessions, (4) the experimental instructions advising patients to adjust their caloric intake and expenditure prior to adjusting their insulin dose, and (5) the use of healthy longterm IDDM patients with a stable insulin dose who did not exhibit any diabetic sequelae.

### Introduction

Diabetes has been recorded in the annals of medical history since ancient Egyptian times when the papyrus of Ebers dated at 1550 BC recommended dietary remedies for those passing abundant urine. Early Sanskrit and Roman literature also included references to 'honeyed urine' and a 'mysterious affection' where thirst was unquenchable and death inevitable (Bloom and Ireland, 1980). Although many researchers have theorized about the cause of the illness, diabetes remains a mysterious and debilitating disease with an unknown etiology (Trucco and Dorman, 1989).

Diabetes mellitus is defined as a chronic disorder which is characterized by an elevated level of glucose in the blood due primarily to inadequate secretion or utilization of insulin (Bloom and Ireland, 1980). In nearly every early textbook or treatise on diabetes, diet was stated to be the cornerstone of treatment (Nuttall, 1983). The discovery of insulin by Dr. Frederick Banting and Charles

Best in 1921, however, completely revolutionized the treatment of diabetes and was hailed as one of the greatest medical triumphs of the twentieth century.

Since the time of Banting and Best, therapy for diabetes mellitus, especially type I (insulin-dependent) diabetes, has changed rapidly. The most important new developments are the synthesis of nonimmunogenic insulin and the introduction of portable blood glucose meters (PBGGM). The recent advent of PBGM has allowed diabetes mellitus patients to accurately monitor their own blood glucose levels on a daily basis and has been called the single most significant advancement in diabetes management since the discovery of insulin (Watts and Keffer, 1989). Current research strongly supports the concept that the debilitating sequelae often associated with diabetes mellitus—such as vascular disease, retinopathy, nephropathy, and neuropathy—can be curtailed by careful daily metabolic control of blood glucose levels (Brownlee and Cahill, 1979; Cahill et al., 1976; Camarin-Davilos et al., 1983; Jackson et al., 1982a; Jackson et al., 1982b; Raskin et al., 1983; Tchobroutsky, 1978).

In the past, blood glucose levels were determined by an occasional urine test or laboratory analysis of blood plasma conducted once every few weeks or months (Guthrie et al., 1986). Physicians have long recognized that such periodic testing offered only a crude estimate of glycemic control due to the fact that blood glucose concentrations change rapidly in diabetic patients (Bruckel et al., 1990). Recent studies performed on PBGM under closely controlled conditions in diabetic units have demonstrated that reflectance meters give reliable quantitative estimates of venous glucose concentrations (Clements et al., 1981; Reeves et al., 1981; Shapiro et al., 1981; Steinbeck et al., 1981; Worth et al., 1981). Although measurements of blood glucose concentrations using PBGM are not as scientifically precise as those performed on state-of-the-art, clinical laboratory analyzers, they are nevertheless easy to perform and sufficiently accurate to allow the patient to make daily adjustments in their insulin dose. While the literature is replete with evaluations of PBGM (Clarke et al., 1987; Hunt and Alojado, 1989; North et al., 1987), the Accu-Chek model is considered one of the most accurate and convenient to use (Aziz and Hsiang, 1983; Brooks et al., 1986). The Accu-Chek III reflectance meter was therefore utilized in the current study as a reliable means by which patients could monitor their daily blood glucose concentrations and thereby adjust their daily insulin dosage accordingly.

The purpose of this exploratory pilot study was to examine the combined effect of Therapeutic Touch therapy and Intercessory Prayer on the insulin dose levels of IDDM patients. The theoretical premise evaluated was whether the implementation of these complementary healing therapies would result in an alteration in patient administered insulin dosage. The Therapeutic Touch method utilized in this study is based on the ancient healing practice of laying on of hands and was originally conceptualized by Dr. Dolores Krieger as an adjunct to traditional medical care (Heidt, 1991; Krieger, 1990; Krieger et al., 1979). Therapeutic Touch is based on a theory of energy transfer wherein the practitioner is said to direct healing energy through their hands to the patient

for the purpose of helping or healing (Krieger, 1979). Prior research has indicated that Therapeutic Touch is effective in increasing the regeneration rate of salamander forelimbs (Wirth et al., 1992), accelerating human dermal wound repair (Wirth, 1990; Wirth et al., 1993a), reducing pain (Keller, 1983; Keller and Bzdek, 1986), anxiety (Heidt, 1981; Quinn, 1982, 1984), and decreasing overall muscle tension as evaluated by multi-site surface electromyographic analysis (Wirth and Cram, 1993). Intercessory Prayer, on the other hand, is not based on a theory of energy interaction between healer and subject but, rather, is a traditional religious healing practice which is a fundamental component of virtually all societies and religions of the world (Byrd, 1988; Spivak, 1917; Wirth, 1993). In the west, prayer healing formally began with the ordained rites and rituals of early Christianity (Dossey, 1993; Frost, 1949). Modern medical literature, however, contains only a few scientific studies on the therapeutic efficacy of prayer (Byrd, 1988; Collipp, 1969; Joyce and Weldon, 1965). The most notable of these studies is a randomized double-blind experiment which demonstrated that patients in a coronary care unit who received the benefit of Intercessory Prayer had a significantly reduced requirement for antibiotics, diuretics, and ventilatory support as compared to the control group (Byrd, 1988; Wirth, 1993).

Complementary healing has become increasingly popular in the United States and Europe and is normally performed in one of two ways: (1) by the laying on of hands, and (2) by healing at a distance in which healing occurs through thought or energy projection (Attevelt, 1988; Beutler et al., 1988; Eisenberg et al., 1993; Fulder and Munro, 1985; Reilly, 1983; Wirth et al., 1993b). Therapeutic Touch therapy generally utilizes the laying on of hands approach, though often without physical contact—i.e., Noncontact Therapeutic Touch (NCTT)—whereas Intercessory Prayer is routinely performed at a distance from the patient. Prior research on complementary healing methods has demonstrated that up to 85% of patients who visit complementary healers claim to experience an improvement in their condition (Attevelt, 1988; Wirth, 1987, 1994). To our knowledge, however, no experimental data are available on whether complementary healing approaches such as Therapeutic Touch or Intercessory Prayer result in a measurable improvement for diabetes mellitus patients. Therefore, the following double-blind, within subject, crossover study was conducted in order to investigate the influence of Therapeutic Touch therapy and Intercessory Prayer in combination on the insulin dosage of type I diabetes mellitus patients.

### **Patients and Methods**

Initially, 38 IDDM patients responded to advertisements placed at several local hospitals requesting subjects with type I diabetes mellitus to participate in a research study. The patients were screened and 22 were excluded from the study for the following reasons: pregnancy (1 patient), a prior history of arterial hypertension (3), recurrent hypoglycemia (4), retinopathy (3), nephropathy

TABLE 1  
Demographic Data

<i>Patient/sex</i>	<i>Age</i>	<i>Duration of Diabetes</i>	<i>Dose of Insulin Prestudy (U/Day)</i>
1/F	25	15	47
2/F	26	10	50
3/F	29	7	26
4/F	32	7	41
5/F	34	16	32
6/M	36	11	44
7/F	40	10	46
8/M	28	8	40
9/F	38	26	38
10/F	46	14	46
11/F	44	14	38
12/M	39	18	41
13/F	40	7	27
14/F	41	23	42
15/F	43	16	34
16/M	48	11	66

(3), neuropathy (2), alcoholism (1), or other serious medical problems (2). In addition, 3 patients who were regularly using acetaminophen, ascorbic acid, or salicylic acid were excluded from the study due to the fact that these substances depress blood glucose values using the glucose oxidase measurement method employed by the Accu-Check III reflectance meter (Boehringer Mannheim Diagnostics, Indianapolis, IN).

There were therefore 16 type I diabetes mellitus patients who were eligible for inclusion in the study. The patients were normotensive, nonketotic, and in good health with an age range of 25-48 years (mean, 37 years). Written informed consent was obtained from each participant. The participants included 12 females and 4 males whose average duration of diabetes was  $13.3 \pm 1.41$  years with a range of 7-26 years (Table 1). All patients included in the study were long-term diabetics utilizing a multiple-dose insulin regimen and were allowed to remain on their regular diet. Their diet had been previously chosen by the patient and a dietitian as being nutritionally adequate. A patient-selected dietary regimen with assistance from a dietician is considered to be the best approach to dietary regulation for IDDM patients (Nuttall, 1983; Jovanovic et al., 1984).

The goal of diabetes mellitus therapy is to afford the patient "tight control" of insulin dosage and blood glucose values within a delineated normoglycemic range (Skyler et al., 1981). The ability of the patient to maintain normoglycemia and a stable insulin dosage is greatly enhanced by the use of PBGM. Eight Accu-Chek III reflectance meters were utilized in this study and the reliability of each instrument was evaluated using a standard test solution provided by the manufacturer. All patients had prior experience with PBGM and

were instructed in the use of the Accu-Chek III and the Autolet fingerstick technique (Ames Division, Miles Laboratory, Elkhart, Indiana). Patients were also instructed in the use of the algorithms and tables attached to their meters which listed the ideal and acceptable values of blood glucose at various times of the day (Skyler et al., 1981).

As part of the standard experimental regimen, patients were asked to record capillary blood glucose data, insulin dose and type, significant changes in food intake or activity, and any other event or thoughts which they felt were noteworthy in a logbook. Patients were told that the PBGM contained a memory chip which would record each blood glucose value obtained. This protocol was followed due to the fact that prior research has indicated that subjects obtained a higher degree of accuracy and reliability in reference to logbook recordings when they were aware of the memory chip capabilities of the meter (Mazze et al., 1985).

The current study incorporated a double-blind, within subject, crossover design which included two randomly assigned blocks of 8 patients each with the patients acting as their own controls for each block. The 8 patients were randomly assigned to treatment and control conditions with trials lasting seven weeks per block. The trials included: (1) two weeks to become accustomed to the PBGM; (2) a two week session; (3) a one week period which was not included in the statistical analyses; and (4) a second two week session with patients crossing over to the opposite condition-i.e., those subjects who were in the treatment group during the first session became control group subjects in the second session, and those subjects who were in the control group during the first session became treatment group subjects for the second session.

During each two week session, the subjects visited the laboratory on a daily basis and were escorted by an independent experimenter who was unaware of group assignment to a room containing a recliner chair and a tape machine with headphones. The subjects and independent experimenter were informed that the study was designed to measure the effects of relaxation on blood glucose values. Once the subject was comfortably seated with the headphones in place, a tape of instrumental music of twenty minutes duration was begun.

The recliner was situated approximately four feet from a specially modified door equipped with a one-way mirror measuring 2 feet x 3 feet. During the treatment condition, the healer was in the adjoining room and had a clear view of the patient through the one-way mirror. The treatment regimen consisted of fifteen minutes per day for each subject with the Therapeutic Touch practitioner being present in the adjoining room during the even days (i.e., day # 2, 4, 6, etc.), and the Prayer Healer present in the room during the odd days (i.e., day # 1, 3, 5, etc.). The Therapeutic Touch healer utilized in this study was a trained practitioner with over three years of healing experience. The prayer healer was a participating Christian who had been a Church member for eight years and an active healer for six years. The healers were told that the patients had diabetes mellitus and were asked to perform a generalized healing for their condition. The healers were present in the adjoining room only when a treatment group

TABLE 2  
Mean Insulin Values (U/Day)  $\pm$  Sem

<i>Patient Number</i>	<i>Treatment</i>	<i>Control</i>
1	46.14 $\pm$ .77	46.86 $\pm$ .63
2	48.00 $\pm$ .52	48.93 $\pm$ .54
3	26.46 $\pm$ .73	27.15 $\pm$ .63
4	41.54 $\pm$ .69	42.23 $\pm$ .46
5	33.07 $\pm$ .46	32.57 $\pm$ .54
6	45.36 $\pm$ .63	45.21 $\pm$ .63
7	43.00 $\pm$ .62	44.86 $\pm$ .63
8	40.29 $\pm$ .62	40.86 $\pm$ .85
9	37.71 $\pm$ .51	38.00 $\pm$ .46
10	45.83 $\pm$ .73	45.36 $\pm$ .55
11	36.79 $\pm$ .47	37.00 $\pm$ .55
12	42.71 $\pm$ .60	41.57 $\pm$ .99
13	27.29 $\pm$ .46	26.93 $\pm$ .47
14	40.86 $\pm$ .72	41.43 $\pm$ .51
15	33.57 $\pm$ .61	34.64 $\pm$ .37
16	65.29 $\pm$ .59	66.31 $\pm$ .65

Figures given as mean  $\pm$  SEM

subject was in the recliner. The room remained empty during the control condition.

The subjects were monitored on a bi-weekly basis by a physician. During the bi-weekly evaluations, the data from the patients' logbooks were recorded by the independent experimenter and the PBGM were checked for accuracy. Patients were instructed to use the PBGM a minimum of four times per day during the experiment (three preprandial, and once at bedtime) and were encouraged to adjust their caloric intake and expenditure in response to blood glucose values before adjusting their insulin dose (Schiffrin and Belmonte, 1982; Skyler, 1982)

### Statistical Analysis

Results are expressed as mean values  $\pm$  SEM with a 95% confidence interval (Table 2). All patients completed the 7 week trial period and the data were initially analyzed using an analysis of variance (ANOVA) which took into consideration the effect of the following six factors on the treatment outcome: patient, block, sequence, day, treatment, and period. Paired comparisons for each individual subject were then analyzed utilizing a dependent means T-test with Bonferroni correction to account for Type 1 error.

### Results

The bi-weekly clinical evaluations showed no intercurrent illness and no significant change in diet or exercise throughout the observation period. All patients completed the 7 week trial period with 3 patients missing 2 days each,

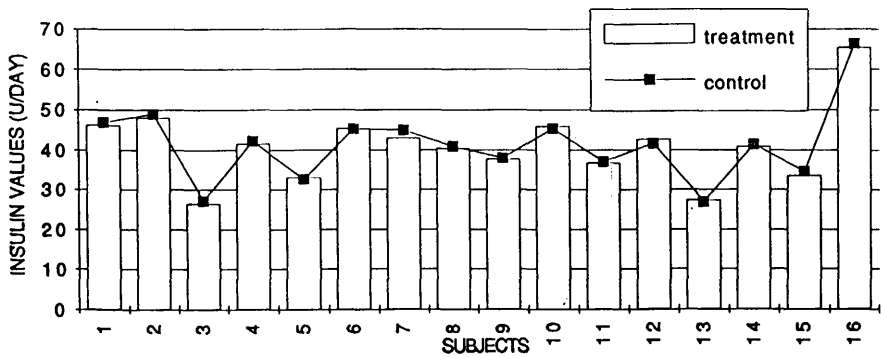


Fig. 1 Mean Insulin Values for All Subjects

and 1 patient missing 1 day during the two week runs. The data for all 16 subjects were therefore included in the statistical analyses. The results showed that there was a reduction in the insulin dosage for 11 of the 16 subjects (69%) (Table 2). Although there was a reduction for the treated group versus the control group for a majority of the patients, the difference was not significant ( $F=2.35$ ;  $df=1$ ;  $p>.12$ ) (Figure 1).

### Discussion

This study examined the combined effect of Noncontact Therapeutic Touch therapy and Intercessory Prayer healing on patient administered insulin dosage for type I diabetes mellitus patients using a double-blind, within subject, crossover design. While the results were not significant, the majority of patients (11 of 16) did demonstrate a reduction in insulin dose levels. It should be noted, however, that these reductions were not clinically significant (i.e., less than two units) and were within the range of error normally demonstrated by IDDM patients who measure and administer their own insulin.

In analyzing the data and methodological protocol of the study, it was determined that several factors may have contributed to the nonsignificant results including: (1) utilization of insulin dose instead of objectively measured laboratory blood glucose values as the dependent variable, (2) the four foot distance and mirrored glass barrier between healer and patient, (3) the short duration of the sessions—two weeks for treated and control conditions with a one week transition interval between sessions, (4) the experimental instructions advising patients to adjust their caloric intake and expenditure prior to adjusting their insulin dose, and (5) the use of healthy longterm IDDM patients with a stable insulin dose who did not exhibit any diabetic sequelae.

Insulin dosage levels were specifically utilized in this study as the dependent variable in lieu of blood glucose values as recorded by PBGM because patient determined glucose readings are generally considered to be scientifically imprecise and therefore unacceptable for statistical analysis in an experi-

mental study. While the utilization of PBGM requires the patient to visit the laboratory less frequently and therefore adds a desirable methodological element, the fact that glucose concentrations change rapidly over a short period of time coupled with the fact that PBGM measurements may be biased by recording or timing errors and are not as accurate as laboratory determined objective measurements, indicated that insulin dose levels were the more accurate and statistically reliable measurement.

Although previous research has demonstrated that Noncontact Therapeutic Touch therapy is effective through a glass barrier at a distance of over one foot (Wirth et al., 1993a), the incorporation of a one-way mirror and four foot distance between healers and subjects may have created an experimental environment that adversely affected the healers. Traditionally, distance is considered to be an insignificant factor in Prayer healing, whereas Therapeutic Touch practitioners generally work within the patient's presence. The methodological protocol utilized, in conjunction with the experimental inexperience of the healers (neither had participated in a previous experimental study), may have therefore contributed to the ineffectiveness of the intervention.

The experimental advice given the patients in regards to adjusting their caloric intake and expenditure prior to adjusting their insulin dosage was incorporated into the study because significant changes in insulin dosage following unsuccessful attempts to maintain glycemic control by diet and exercise would indicate a substantive physiological treatment effect thereby strengthening the results obtained. A similar rationale was utilized in the selection of longterm diabetes mellitus patients as subjects in that longterm type I diabetes patients are known to maintain relatively stable insulin dosage regimens. The use of these patients, however, may have resulted in a reduced frequency of insulin dosage alterations as compared to patients exhibiting various diabetic sequelae.

The experiment incorporated the use of a logbook which included a section where the patients were free to record events, emotions, or thoughts which they felt were noteworthy. This section was included due to the fact that prior research has indicated that psychological factors may be important in the consideration of the onset and course of diabetes (Conn and Fajans, 1961; Dupuis et al., 1980; Grant et al., 1974; Hauser and Pollets, 1979; Holmes and Masuda, 1974; Kimball, 1971; Seigler et al., 1982; Slawson et al., 1963; Stein and Charles, 1971; Stein and Charles, 1975; Tietz and Vidmar, 1972). Although the results of these studies did not conclusively establish psychological disturbances as etiological factors for diabetes mellitus, they did suggest that such intrapsychic conflicts can significantly upset glycemic control after the onset of the disease. The logbook recordings were therefore examined and revealed an interesting phenomenological trend. In general, during the treatment condition for both blocks the subjects reported feeling a greater degree of calm and peace and less depression than during the control condition. Although the logbook observations were not standardized and therefore were not statistically analyzed, the patients' reports appear to support previous research which sug-



gested that complementary healing may have a positive psychological effect on patients (Attevelt, 1988; Heidt, 1981; Quinn, 1982, 1984; Wirth, 1987, 1994).

In summary, the results of this study were inconclusive in determining the therapeutic efficacy of complementary healing therapy on insulin dosage. Several factors were postulated as important considerations for the nonsignificance obtained including the distance or duration of the sessions, the subject population and instructions given, and the use of insulin dose instead of objectively measured laboratory blood glucose values as the dependent variable. It should be noted that had statistical significance been obtained in this study, the generalizability of the results would have been limited due to the inherent confound presented by the subjective nature of the dependent variable. The preferred dependent variable in diabetes research has traditionally been laboratory assessed blood glucose values. Due to the limited resources available for this pilot study, however, incorporation of this type of analysis was precluded. This was a recognized inherent limitation of the experimental protocol and must be accounted for in future research studies. In this respect, additional research would benefit by including quantitative laboratory assessments of plasma glucose and insulin values, hemoglobin A1C determinations, maintenance of the same diet and exercise regimen for the patient during control and treatment periods, controlled medication intake, and the incorporation of measurements for glycosuria, ketoacidosis, retinopathy and other diabetic sequelae.

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## **Response to Wirth *et al.***

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Before I comment on this paper I should state my credentials for doing so. I am a psychiatrist, not an expert on diabetes mellitus, at least from the perspective of an investigator. It happens, however, that my first wife suffered from diabetes mellitus from her youth until her death. She had every known complication of the disease to which she eventually succumbed. I became intensely involved in her care, especially during her final years, which occurred just as the discovery was being made that rigid control of blood glucose could significantly retard the development of the various complications that particularly affect the eyes, kidneys, and nervous system. I may add that the discoverer of this important correlation was Richard Bernstein, who had been a diabetic since his childhood. Richard Bernstein subsequently trained in medicine. Through a mutual friend we became acquainted. I was a firsthand observer of Dr. Bernstein's efforts, struggle I should say, to convince skeptical physicians about the importance of close control of blood glucose in diabetes mellitus. I am, therefore, deeply imbued with an awareness of the importance of accurate measurements of blood glucose in any serious investigation of the treatment of diabetes mellitus.

Wirth and Mitchell are also aware of the importance of reliable measures of blood glucose. Unfortunately, they give no data about blood glucose. They state that the patients were advised to adjust their insulin dosages on the basis of the results obtained from portable blood glucose monitors (PBGm) which they acknowledge are unreliable instruments. Their disclaimers have not overcome my concerns in this matter. Wirth and Mitchell report the results in terms of insulin dosages, not insulin requirements. It is absolutely essential to measure blood glucose reliably in any study of the treatment of diabetes mellitus for which the authors expect to receive attention from physicians for their proposed treatment.

The results obtained by Wirth and Mitchell leave open the interpretation that the intended healing effects influenced the behavior of the patients, not the disease process. This could happen if the patients had somehow become aware, perhaps through telepathy, of the activities of the healers.

The overall design of the investigation is excellent. I am not in the least bothered by the meagerness of the differences noted between the treatment and control groups. An investigation may lack statistical significance and still have scientific significance.

I hope Wirth and Mitchell will continue to regard their paper, as they say they do, as a pilot study only. In a further endeavor, however, they should associate themselves with a physician expert in diabetes mellitus. This may be difficult, but not impossible. Wirth and Mitchell were able to arrange for a physician to monitor their patients every two weeks. With some further effort they should be able to enlist the collaboration of a specialist in diabetes mellitus. As they themselves acknowledge, a further study should also be longer than the one here reported. I commend the authors for their initiative in undertaking the investigation and hope they will now go on to do a better one, the results of which would certainly be of great interest and might be important.