

## In Brief

Massage is among the fastest growing complementary therapies used in the United States. This article systematically reviews the available evidence on potential benefits and adverse effects of massage for people with diabetes. Massage at injection sites may increase insulin absorption. In addition, uncontrolled studies suggest that massage may have a positive effect on blood glucose levels and symptoms of diabetic neuropathy. However, randomized, placebo-controlled studies are needed to confirm any short- and long-term benefits of massage as a complementary treatment for diabetes and to further define an optimal massage treatment.

# Is Massage Useful in the Management of Diabetes? A Systematic Review

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Massage has been recommended for diabetes for nearly 100 years.<sup>1</sup> However, the usefulness of massage for people with diabetes remains unclear as evidenced by a recent exchange on an Internet diabetes message board. One writer posts the message, "Does anyone know if massage can help diabetes?" The only reply is another inquiry: "Hi! If you find out any information on massage therapy, please let me know. I just want to help my 16-year-old daughter, who has been diagnosed with diabetes. How do you think massage can help? Even type 2 diabetics, do you think?"<sup>2</sup>

If these writers were to surf the World Wide Web in search of answers to their questions, they would likely be left confused and frustrated. Internet information on this topic is fraught with unsubstantiated claims. One site actually suggests that diabetes can be prevented through self-massage.<sup>3</sup> Another reports on an individual who allegedly had the bottoms of his feet massaged, eliminated large amounts of sugar in his urine during the second week of treatment, and then recovered from his disease.<sup>4</sup> How, then, do consumers decide, or clinicians advise, about the usefulness of massage to people with diabetes?

This article aims to clarify what is and is not known about the usefulness of massage for people with diabetes by summarizing a systematic review of the scientific literature using Cochrane

review methodology,<sup>5</sup> a method specifically designed to maximize comprehensiveness and minimize bias. Through this method, all relevant studies that meet prespecified inclusion criteria are included in the review regardless of their results.

Using this method, we will address four frequently asked questions:

1. Can massage improve insulin absorption, for example, by increasing serum insulin in type 1 diabetes or increasing tissue insulin sensitivity in type 2 diabetes?
2. Can massage help normalize blood glucose levels?
3. Can massage provide relief of symptoms associated with diabetic neuropathy?
4. What are the known adverse effects, contraindications, or precautions related to massage for people with diabetes?

## MESSAGE OVERVIEW

### Trends in Use and Attitudes Toward Massage in the United States

Utilization of massage is rising, making the examination of this issue quite timely. From 1990 to 1997, the proportion of U.S. consumers using massage jumped from 7 to 11% of the population, the most statistically significant increase of any complementary medicine (CM) modality.<sup>6</sup>

Despite stereotypical images of people receiving massage as a way of

pampering themselves, nearly three-fourths of those who seek massage do so for a specific health complaint for which they have already consulted a physician.<sup>7</sup> Among rehabilitation outpatients, massage ranks as one of the most common CM therapies sought.<sup>8</sup> Among general practice patients, 32% report using massage, and this proportion exceeds that of individuals reporting the use of herbs, megavitamins, or meditation.<sup>9</sup>

Not only is massage use increasing, but survey evidence indicates that utilization will continue to rise as health plans provide reimbursement. A recent health insurance survey found that respondents were not only willing to pay more for their insurance if CM therapies were covered but also ranked massage as the number one CM therapy they would be most likely to use if it were covered by their health plan.<sup>10</sup> Third-party payers, however, cite lack of efficacy data as the primary reason for their reluctance to reimburse CM.<sup>11</sup>

Massage is among the CM therapies with the highest physician referral rate,<sup>12</sup> and family practice physicians rate bodywork as the CM therapy most likely to be beneficial and least likely to be harmful.<sup>13</sup> Given the growing popularity of massage, it is not surprising that magazines for people with diabetes have begun to offer information about the therapeutic effects of massage.<sup>14</sup>

### Types of Massage/Bodywork

Swedish massage is the most widely practiced type of massage in the United States. Developed in 1914 by Per Henrik Ling, this method is considered one of the first scientific approaches to massage, aiming specifically to affect the circulatory, lymphatic, and nervous systems. Long, gliding strokes (referred to as friction) are used to enhance blood and lymph flow; kneading (called petrissage) is used to relax muscle tension; and tapping, cupping, and hacking movements (called tapotement) are used to stimulate nerves.<sup>15</sup>

There are other popular forms of bodywork in the United States. Trager uses a gentle, rhythmic, rocking motion to help the body relax.<sup>16</sup> Rolfing uses intense deep-tissue manipulation to restructure fascia.<sup>17</sup> Craniosacral therapy aims at gently influencing the rhythm and flow of the cerebrospinal fluid.<sup>18</sup> Neuromuscular therapy manipulates the deep soft tissues to improve

circulation, release nerve entrapment, and deactivate trigger points.<sup>19</sup> Manual lymphatic drainage lightly redirects subcutaneous lymphatic stasis or blockages into functional lymphatic channels.<sup>20</sup>

### Swedish Massage Procedure

Swedish massage is the manipulation of the soft tissues of the whole body to bring about generalized improvements in health. Generally, sessions range from 30 to 90 min. The procedure usually begins with a medical history. Then, the massage therapist leaves the room while the person receiving the massage disrobes and lies under a sheet or flannel blanket on a massage table.

The massage usually begins with the patient lying supine. The therapist administers massage first to the arms, neck, and head and then progresses to the torso, feet, and legs. The patient then lies prone, and the legs, hips, and back are massaged. Massage lotion or oil may be applied to minimize friction on the skin.

Trained massage therapists work in spas, health clubs, private practices, chiropractic offices, physical therapy practices, and hospitals.

### Physiological Effects of Massage

Several studies have documented the relaxing effects of massage. Massage has been demonstrated to reduce muscle tension in both subjective self-reports<sup>21</sup> and objective electromyographic testing.<sup>22</sup>

Relaxation from massage has been demonstrated to be greater than that brought about from rest alone.<sup>23</sup> Massage can reduce heart rate and blood pressure, two features of the relaxation response.<sup>24</sup>

Additionally, massage has been shown to decrease anxiety in a variety of patient populations, including people with diabetes.<sup>25-27</sup> These stress-reducing benefits of massage have raised the possibility that massage may be of benefit to people with diabetes by inducing the relaxation response, thereby controlling the counter-regulatory stress hormones and permitting the body to use insulin more effectively.

## LITERATURE SEARCH

### Methods

A Medline search was conducted for the years 1966 to 2001. Search terms included "massage," "touch," "chiro-

practic," "Trager," "Rolfing," "craniosacral therapy," "neuromuscular therapy," "acupressure," "Shiatsu," and "manual lymphatic drainage." These search results were combined with a search of the terms "diabetes," "blood glucose," "diabetic neuropathy," "hyperglycemia," and "insulin."

Searches were also made of EMBASE (Excerpta Medica Database), PsychInfo, MANTIS (Manual Therapies Information Systems), CAMPAIN (Complementary and Alternative Medicine and Pain), CCTR (Cochrane Controlled Trials Registry), Cochrane Collaboration Complementary Medicine Field Trials Registry, the Bodywork Knowledge Base,<sup>28</sup> and the Touch Research Institute Database.<sup>29</sup>

Trials reported in any language were included if the study:

1. involved the administration of massage either manually or mechanically to patients with diabetes, and
2. measured at least one relevant primary diabetes outcome (i.e., insulin absorption, blood glucose, HbA<sub>1c</sub>, or symptoms related to diabetic neuropathy) or a potentially relevant secondary diabetes outcome (i.e., induction of relaxation response, anxiety level, quality of life, sense of well-being, depression, cortisol level, blood pressure, or heart rate).

### Results

Results of the literature search identified one study<sup>30</sup> pertaining to the first of our four frequently asked questions, three publications of two studies<sup>25-27</sup> and one unpublished study pertaining to our second question, one study<sup>31</sup> pertaining to our third question, and one report<sup>32</sup> pertaining to our fourth question.

Studies were found pertaining to Swedish massage and acupressure. No studies were identified pertaining to the other brand names of bodywork or chiropractic therapy. Therefore, these were omitted from further analysis.

### Question #1: Can Massage Improve Insulin Absorption?

Our searches identified one study<sup>30</sup> on insulin absorption in type 1 diabetes. No studies were found examining whether massage can increase insulin sensitivity in the peripheral tissues resulting in increased glucose clearance in type 2 diabetes.

Dillon<sup>30</sup> observed that eight lean,

well-controlled patients with type 1 diabetes, using their usual dosages of regular and intermediate-acting insulins, who massaged their insulin injection sites with an electric vibrator for 3 min at 15 min post-injection, experienced higher insulin levels and lower serum glucose levels by 15 min after the start of massage and 29 min post-injection. At this interval, changes were not statistically significant. Serum glucose levels, however, fell 8.3% lower ( $P < 0.05$ ) 30 min after massage and 44 min post-injection compared to the control day when participants did not massage their injection sites, and this was significant. At 45 min post-massage, the difference in glucose levels was even more striking (76 mg/dl  $\pm$  6%) when compared to the control day (89 mg/dl  $\pm$  4%).

The same report<sup>30</sup> revealed 2-year follow-up data on these eight patients, as well as on 18 others who had been massaging their injection sites for 3 min at each meal in order to achieve a beneficial postprandial rise in insulin levels. After 3–6 months of massage, the mean HbA<sub>1c</sub> for the 26 patients fell from 10.56  $\pm$  1.73 to 8.55  $\pm$  1.69%. (Normal HbA<sub>1c</sub> was <8.2% according to the laboratory assay used.) After 12–18 months of injection-site massage, 8 patients had normal HbA<sub>1c</sub> levels, and the remaining 18 patients had mean HbA<sub>1c</sub> levels of 8.41  $\pm$  1.58%, a significant improvement from baseline ( $P < 0.001$ ). Dillon proposed that injection-site massage can improve conventional insulin therapy by increasing the bioavailability of insulin in the postprandial state.

### **Question #2: Can Massage Help Normalize Blood Glucose Levels?**

Three published results<sup>25–27</sup> of two trials and one unpublished preliminary study have examined the effects of massage on normalizing blood glucose.

Fields and colleagues, describing a single-group, pre/post-test design in two publications of the same study population,<sup>25,26</sup> reported that after 1 month of parents administering nightly full-body massage to their children with diabetes ( $n = 14$ ), the children's glucose levels decreased from an average of 158 to 118 mg/dl. Exactly when and how often blood glucose levels were measured was not stated.

The authors also reported that both parents' and children's anxiety and depression levels decreased imme-

diately after massage. However, the methodology for measuring these levels was not reported.

Vest<sup>27</sup> trained clinical staff to administer 15-min sessions of breathing instruction, light touch, and acupressure to diabetic patients for 6 consecutive weeks using a one-group, pre/post-test design ( $n = 12$ ). Outcomes were blood glucose, persistence of physical symptoms, and perception of well-being. Patients experienced a reduction in blood glucose, anxiety, headaches, depression, work stress, and anger. Self-reports also indicated the patients were sleeping better and had improved relations with their families. No  $P$  values were cited. When and how often blood glucose was measured, the length of follow-up time, definitions of clinically significant blood glucose changes, and proportions achieving the various changes were not reported.

Preliminary data were available from one small randomized trial comparing people with type 2 diabetes receiving 45-min, full-body massage three times a week for 12 weeks ( $n = 6$ ) to similar patients on a waiting list for massage ( $n = 2$ ). (M.C., unpublished observations). Researchers found that of the six patients receiving massage, HbA<sub>1c</sub> decreased in three patients from a baseline of 7.9, 8.3, and 9.8% to 7.3, 8.1, and 8.6%, respectively. In the other three patients receiving massage, HbA<sub>1c</sub> increased from a baseline of 7.4, 8.2, and 8.0% to 7.9, 10.0, and 8.5%, respectively. These patients, whose glycemic control deteriorated while receiving massage, were obese, injecting insulin, or both. None of the group whose glycemic control improved with massage had either of these characteristics. In the waiting list control group, HbA<sub>1c</sub> level also declined from 7.3 and 8.6% to 6.9 and 8.4%, respectively.

### **Question #3: Can Massage Provide Relief for Symptoms Associated With Diabetic Neuropathy?**

Our searches identified one trial<sup>31</sup> assessing the effects of massage on the symptoms of diabetic neuropathy. This single-group, pre/post-test design assessed 25 patients with symmetrical diabetic neuropathy of the lower extremities and complaints of burning, tingling, pain, itching, restless legs, paresthesias, and often loss of reflexes. The duration of disease was 6–17 years, and the duration of neu-

ropathic symptoms averaged 14 months.

All patients were treated with syncardial massage, a mechanical leg massage technique in which a cuff inflates at the moment an electrocardiogram pulse wave passes beneath it. The cuff releases when the  $R$  wave of the electrocardiogram signals. It is believed that the pressure provided by the cuff aids the arterial elasticity in providing a fuller contraction so that the flow of blood through the limb is increased.

In this study, the cuff was initially placed around patients' thigh and then around their leg for the last half of the treatment. Syncardial massage was administered every 2 days with the total number of treatments ranging from 20 to 30 in those who appeared to benefit. Therapy was discontinued after the tenth treatment for those who experienced no benefit.

Subjective outcomes were defined as no effect, improved (decrease of patients' symptoms to the extent that they considered the treatment worthwhile and wanted to continue it after the first 10 treatments), or good (complete disappearance of symptoms or symptoms becoming so slight that patients considered themselves to need no further treatment). At the 1-month follow-up, results showed good response in 14 cases (56%), improvement in 8 cases (32%), and no effect in 3 cases (12%).

### **Question #4: What Are the Known Adverse Effects, Contraindications, or Precautions Related to Massage for People With Diabetes?**

A potential adverse effect of massage for diabetes appears to be the risk of inducing hypoglycemia in insulin-using patients. This risk is extrapolated from massage studies using healthy volunteers.<sup>33,34</sup> None of the studies of massage and diabetes reports adverse effects. However, it is not clear from the reports whether adverse effects did not occur or whether they did occur but were just not measured or not reported.

In the study of massage for diabetic neuropathy,<sup>32</sup> Kurashova specifically cites contraindications and precautions for people with diabetes. In the beginning, it is recommended only to use continuous effleurage (a light, long stroke around the contours of the body, during which the massage therapist does not press down into the tissues but rather glides always in the

direction of the heart). Massage should begin with 5–7 min on the back, then proceed to the thigh, and then to the calf. Approximately 20–30 min can be spent effleuraging the posterior side of the body and 10–15 min effleuraging the front of the legs and the arms.

For patients suffering from peripheral nerve damage, gentle friction of the lower extremities can be added only after a sufficient amount of effleurage has been completed. This may require 7–10 treatments of effleurage before introducing friction.

Because vascular dysfunction may render the tissues of a person with diabetes fragile, friction should be done lightly to avoid vascular damage or bruising. In swollen areas, friction should be avoided because the direct pressure into the tissues that is characteristic of friction may further close the dysfunctioning vessels. Pressure should be sufficiently light so that the massage creates no pain.

## DISCUSSION

We have examined the literature pertaining to massage as it relates to diabetes, particularly to insulin absorption/sensitivity, blood glucose levels, diabetic neuropathy, and contraindications. However, important questions remain unanswered.

Although studies indicate that massage may influence insulin uptake at the injection site and decrease blood glucose levels, it should not be assumed that this is always a desirable effect. Rather, the circumstances in which this would be a desirable, even salubrious, effect versus an undesirable effect need further elucidation. For example, if massage induces a relaxation response, thereby controlling counter-regulatory stress hormones and allowing the body to use insulin more effectively, this would be a desirable effect. However, if massage concomitantly induces a precipitous drop in blood glucose into the hypoglycemic rather than the normoglycemic range in patients using hypoglycemic medications, this would be an undesirable effect. Likewise, if massage over time assists in normalizing glycemic control, as suggested by Fields and colleagues,<sup>26</sup> that is a desirable effect. However, if drops in blood glucose from massage make it more difficult to normalize glycemic control and titrate medications, that would be an undesirable effect.

Given the possibility that injection-

site massage can increase serum insulin as well as decrease blood glucose, more understanding is needed about the appropriate timing of pre-massage insulin injection as well as about the differences in the potential risks and benefits to people with type 1 versus type 2 diabetes. From this knowledge, ways to maximize benefit and minimize risk can be ascertained.

Although the existing studies suggest that massage can help normalize blood glucose, important questions need to be addressed before this can be accepted as true. For example, most trials do not report the proportion of patients who actually responded in a clinically significant way. Although a clinically meaningful drop in blood glucose was defined as 15% in one study,<sup>25,26</sup> there is no mention of the proportion of subjects who achieved this clinically meaningful change. Instead, it is noted only that the post-treatment blood glucose group average more than achieved a 15% reduction over the baseline average. This is problematic because group averages are notoriously vulnerable to large changes in just a few patients and can lead to falsely optimistic conclusions about an intervention based on one or two very good responders.

Reporting standard errors with group means makes means more interpretable. However, these statistics were not provided. Medians and quartiles, on the other hand, are largely invulnerable to skewed data, and, similar to reporting proportions improved/not improved, can provide a more complete profile of how the study populations responded overall.

A further limitation exists in the selection of study designs. Most of the identified studies used single-group, pre/post-test designs, which do not control sufficiently for confounders. For example, in one study,<sup>26</sup> dietary and insulin compliance increased during the same 1-month experimental massage treatment period, but this was not offered as a possible explanation for decreases in blood glucose. Remissions related to the natural history of a disease or symptom as well as placebo effects can also be major confounders. For example, in one drug intervention study of diabetic neuropathy,<sup>35</sup> 15% of the placebo group reported having no pain by the end of the study, and 33% in the placebo group had at least a moderate improvement on the Patient Global

Impression of Change scale. Clearly, for a symptom such as pain from diabetic neuropathy, which can have both placebo effects and natural fluctuations in severity, a control group is necessary before any inference of treatment effectiveness can be made.

## How Can the Existing Studies Guide Clinical Practice?

Based on the available literature, there is little to suggest that massage may be harmful or contraindicated for people with diabetes. However, common sense can prevent potential problems. Clinicians wanting to refer people with diabetes for massage should keep three things in mind.

First, clinicians should provide guidance to insulin- or sulfonylurea-treated patients. Specifically, these patients should monitor their blood glucose levels carefully before and after massage to watch for decreases. If pre-massage blood glucose levels are low or normal (<120 mg/dl), patients may wish to eat something before their massage. A blood glucose taken immediately after massage can guide patients about whether the amount they ate was appropriate. If pre-massage blood glucose levels are high enough to use supplemental insulin, patients may wish to use a less-than-usual amount of insulin before massage.

For these insulin- or sulfonylurea-treated patients, monitoring blood glucose three to four times a day (fasting, before lunch, before dinner, and before bedtime) can provide insight into how massage may affect blood glucose and aid in determining whether medication changes are needed. As with exercise guidelines, patients should be instructed not to schedule massage during the peak of insulin activity. For intermediate-acting insulins (lente or NPH) injected at breakfast, this would be approximately 8 h later, in mid-afternoon. For rapid-acting insulins (lispro or aspart) or short-acting insulin (regular), this would be anywhere from 1 to 3 h after injection.

Second, clinicians may wish to suggest a practitioner who is trained in Swedish massage, given that most of the identified massage research has utilized this massage technique.

Third, because some states require no credentialing of massage therapists, a massage therapist holding a national certification from the National Certification Board of

Therapeutic Massage and Bodywork or the American Massage Therapy Association would be preferred.

Massage therapists can exercise caution by ascertaining during the initial phone conversation whether a person has diabetes and, if insulin is used, when and where it is generally injected. Massage therapists should book treatments when insulin is not at its peak activity.

### How Can the Existing Studies Guide Future Research?

Insulin injection-site massage compared to no massage in people with type 1 diabetes appears to increase blood levels of insulin and decrease blood glucose.<sup>30</sup> A next step would be to examine whether massage can be used in type 1 diabetes to reduce and stabilize blood glucose. Another research issue would be to examine whether massage can augment tissue insulin sensitivity similar to exercise<sup>36</sup> in people with type 2 diabetes so that endogenous insulin can be used more efficiently.

Before a large randomized trial is conducted, potential mechanisms of action should be explored, and an optimal massage protocol should be established. This can be accomplished through a series of small pilot studies. Efficacy, by definition, is the assessment of an optimal treatment under ideal conditions, and an optimal massage treatment protocol for diabetes needs to be systematically and scientifically developed.

Specific characteristics of the massage protocol that would need to be examined in pilot studies would include the relative contribution of 1) body surface area, 2) depth of massage, 3) rate of massage, 4) duration of treatment, and 5) frequency of massage administration on outcomes of insulin sensitivity (measured by insulin clamp analysis), blood glucose levels (measured three to four times per day and also measured by fructosamine for a 2-week average glucose measure), and the relaxation response (measured by heart rate, blood pressure, self-report, and salivary cortisol).

Depression and sense of well-being should also be measured. People with diabetes experience a fourfold elevation in the risk of depression over the general population, although the reasons are not well understood.<sup>37</sup> The massage studies measuring depression<sup>25-27</sup> noted that depression improved. The unpublished study

(M.C., unpublished observations) showed improvements in sense of well-being. If these findings are replicable in controlled trials, this would be an important contribution of massage to diabetic patients independent of blood glucose effects.

Pilot studies may also allow observation of potential drug-massage interactions. For example, massage may have a harmful interaction with insulin and sulfonylureas, which can cause hypoglycemia, whereas massage may interact in a therapeutically positive way with insulin-sensitizing drugs.

In pilot studies, one could also look at duration of response and whether there are any preliminary trends suggesting that massage can assist in normalizing glucose levels. One could also investigate whether there is a glucose level above which massage would be detrimental. For example, patients with diabetes are typically encouraged not to exercise when blood glucose levels are >250 mg/dl for fear of causing these levels to rise even higher. This is because the gluconeogenic effect of catecholamines appears to predominate when patients are hyperglycemic—a time when ambient insulin levels are low. This would not be anticipated to occur in patients receiving massage therapy because counterregulatory hormones would not be expected to increase; however, this remains an unexamined possibility.

Following are potential research questions related to specific characteristics of massage. These would need to be studied while holding all of the other characteristics constant.

**Surface area.** A major question exists about whether a full-body massage that covers a maximal surface area should be the optimal treatment or whether massage of the large muscle groups would be sufficient or even preferred.<sup>38</sup> This could be tested by comparing two randomly assigned groups: one that receives a full-body massage and the other that receives massage of just the large muscle groups for the same time period.

**Depth of massage.** If massage pressure is partly responsible for increased absorption at injection sites, then it may also be true that pressure plays some role in increasing insulin sensitivity of the tissues. If that is so, then deeper treatments, such as those provided in neuromuscular therapy,<sup>19</sup> might be more effective than the

milder pressure of a Swedish massage for those without progressive disease. This could be tested by using the same massage techniques (i.e., friction, effleurage, and petrissage) and altering only the pressure.

**Rate of massage.** It has been suggested that decreases in blood glucose may, in part, be modulated by interstitial exchange.<sup>34</sup> If that is so, then a quick hand motion might maximize interstitial exchange. On the other hand, if decreases in blood glucose occur primarily through the relaxation response, one would opt for slow stroke techniques that induce that response.<sup>24</sup>

**Duration of treatment.** Given the same type of massage, is 60 min of massage superior to 30 min? If it is found that there is no additional benefit to be gained in the 60-min group, then this has implications for devising an optimal, yet cost-effective dose. If there is an additional benefit, then a 30-min treatment in efficacy trials might be considered a suboptimal dose.

**Frequency of treatment.** Massage can be administered on a weekly or even daily basis. What is an optimal therapeutic frequency? Kurashova<sup>32</sup> suggests that twice-weekly massage can be beneficial for people with diabetes. This remains to be examined.

**Duration of benefit, possible cumulative effects, and therapeutic versus maintenance dosing.** There is little in the literature to suggest how long a treatment effect may last. Although it may not be practical to keep patients hooked up to an insulin clamp to determine duration of benefit, monitoring blood glucose several times a day would provide some insight. Additionally measuring fructosamine would provide a 2-week average of potential benefits on blood glucose. If benefit is noted, then one could examine whether treatment effects last longer with more treatments (cumulative effects), a trend one would wish to see if massage truly assists with normalizing blood glucose. If there is some evidence of a cumulative effect, then one could explore whether a less-frequent maintenance dose can sustain benefits in responders.

**Selection of population.** The justification for the selection of a study population should be well considered. Because the potential risks and benefits may vary according to whether a patient has type 1 or type 2 diabetes and whether a patient uses hypo-

glycemic medications, a homogeneous study population is suggested. For example, a study sample of people with relatively well-controlled type 2 diabetes could help determine whether increased insulin sensitivity results from massage and whether this can translate into changes in insulin or hypoglycemic medication doses.

Regardless of the population sample, the selection of a homogeneous population is preferred because investigators should not assume that the same type of massage may be equally efficacious for all groups. Different exercise regimens are needed for different groups of people with diabetes,<sup>36</sup> and this point should be well taken in massage research. A pilot population that is too heterogeneous may fail to identify benefit in a specific subgroup.

Once an optimal treatment protocol has been established, that protocol can be used in a larger, randomized controlled trial. In the selection of an optimal treatment, one should also have determined a least- or less-optimal treatment protocol as a control group.

A randomized, controlled trial could involve three arms: the optimal treatment, the least-optimal treatment, and a delayed treatment or waiting-list control. The waiting-list control would provide insight on natural fluctuations in the outcome measures in this population but would not measure placebo effects. The least-optimal massage group could control for placebo effects.

Because even a least-optimal massage treatment may elicit some non-specific physiological effects that are beyond the placebo effect, it is imperative to be sure in advance that the least-optimal massage treatment protocol will not physiologically approximate the optimal massage treatment. Administering two physiologically similar massage treatments would greatly narrow between-group differences causing huge increases in sample size requirements or, if ample sample size is not anticipated in advance, leading to a type II (false-negative) error.

Any randomized trial should provide treatment for at least 3 months. This would permit changes to become evident in the HbA<sub>1c</sub>. Trials measuring HbA<sub>1c</sub> should also have a 2-month lead-in period during which values are measured but no interven-

tion is given in order to obtain valid baseline measures.

Changes in HbA<sub>1c</sub> may demonstrate whether massage may, in fact, be able to alter disease outcome. The sample size for a large, randomized controlled trial, therefore, should be calculated based on a clinically important change in HbA<sub>1c</sub>. A 1% decrease in HbA<sub>1c</sub> reflects a 30 mg/dl decrease in blood glucose.

Further research is also needed regarding the uses of massage for diabetic neuropathy. To date, no trials assessing manually applied massage have been reported. The positive results of the mechanical syncardial massage trial offer a proof of principle that massage may be beneficial in diabetic neuropathy, but clearly more needs to be done to understand the potential benefit, possible mechanisms of action, and contraindications of manually applied massage. By assessing outcomes used in other diabetic neuropathy trials,<sup>35</sup> one can explore whether massage can be beneficial in neuropathy as well as explore which massage techniques (effleurage versus petrissage versus friction) are of optimal benefit.

## SUMMARY

Massage at an insulin injection site can significantly increase serum insulin action, thereby decreasing blood glucose levels in people with type 1 diabetes. We do not know whether massage can improve insulin sensitivity and therefore be a useful adjunct to the management of diabetes for those with type 2 diabetes.

Uncontrolled studies suggest that massage may help normalize blood glucose and symptoms of diabetic neuropathy. Randomized, placebo-controlled studies are needed to further clarify what an optimal massage treatment might be and to elucidate any short- and long-term benefits of massage as a complementary treatment for diabetes.

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