Efficacy of Self-hypnosis in Overweight and Obese Type 2 Diabetics: A Randomized Clinical Trial

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KEY POINTS

Question: Is self-hypnosis equivalent to Certified Diabetes Educator training for weight loss in obese Type 2 diabetics?

Findings: In this randomized trial Certified Diabetes Education (38 patients) and self-hypnosis (36 patients) are equivalent to each other, and superior to control (102 subjects) for weight loss. There is no significant effect on Hgb A1C.

Meaning: Self-hypnosis can be incorporated into the available options for treating weight loss in Type 2 diabetics.

SHORTENED TITLE

Randomized trial of Self-hypnosis for weight loss
SHORTENED ABSTRACT

**Objective:** Randomized trial comparing self-hypnosis, certified diabetes educator, and no special treatment (control) as respects weight loss and changes in A1c levels after one year in diabetics with BMI>25.

**Study:** Out of 189 consecutive patients, 13 were screen failures and 74 patients were randomized (38 CDE, 36 hypnosis)

**Results:** After 1 year CDE lost, on average, 3.7 pounds (95% CI 0.1, 7.2 pounds) more than did control patients. After 1 year self-hypnosis patients lost, on average, 5.2 pounds (95% CI 1.6, 8.8 pounds) more than did control patients. There was no reason to think certified dietician patients and self-hypnosis patients differed as respects weight loss after one year ($P = 0.68$).
FULL ABSTRACT

**Importance:** Obesity and diabetes are rampant epidemics in developed countries.

**Objective:** To compare treatment of obese diabetic patients by self-hypnosis, certified diabetes educator, and no special treatment (control) as respects weight loss and changes in A1c levels after one year.

**Setting:** Outpatient private practice.

**Participants:** Considered for study were diabetic patients with a body mass index above 25 kg/m² and a desire to lose weight. Out of 189 consecutive patients, 13 were screen failures and 74 patients were randomized. 115 subjects declined participation. Follow up data was available for 102 of the latter subjects (control group).

**Interventions:** The 74 patients who agreed to treatment were randomized to receive either certified diabetic educator treatment (38 patients) or self-hypnosis treatment (36 patients).

**Main Outcome and Measures:** Prespecified primary outcome measures were weight and A1c levels. Patients were also compared as respects initial weight, initial A1c levels, birth year, height, and gender.
Results: After 1 year certified dietician patients lost, on average, 3.7 pounds (95% CI 0.1, 7.2 pounds) more than did control patients. After 1 year self-hypnosis patients lost, on average, 5.2 pounds (95% CI 1.6, 8.8 pounds) more than did control patients. There was no reason to think certified dietician patients and self-hypnosis patients differed as respects weight loss after one year ($P = 0.68$). Differences among treatment groups as respects declines in A1c levels after one year, initial weight, initial A1c levels, birth year, height, and gender might have been due to chance ($P > 0.40$ for each analysis).

Conclusions and Relevance: Certified diabetic educator patients and self-hypnosis patients lost more weight than did control patients after 1 year; no difference was detected between certified diabetic educator and self-hypnosis patients. No differences among treatment groups were seen as respect changes in A1c levels after one year. Self-hypnosis should be considered a viable option for overweight, type 2 diabetic patients who seek to lose weight.

Trial Registration: Clinicaltrials.gov (registration #NCT02769585)

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BACKGROUND

Obesity has gained epidemic proportions in the United States\(^1\); more than 2 in 3 adults are overweight or obese\(^2\).

The overlap of type 2 diabetes mellitus (DM2) with obesity is significant\(^3\). Weight management through diet and exercise is the cornerstone for initial management of diabetes\(^4\). However, long term studies show very poor persistence, with only 8% of subjects maintaining glycemic targets after 9 years of follow up -- despite quarterly clinic visits\(^5\). Newer, more creative strategies for motivating patients and improving persistence may yield better long term results.

INTRODUCTION

There are numerous approaches for weight loss. Modalities include behavioral (certified diabetes education, personal trainers, etc.), diet programs, medications, surgeries and combinations of the aforementioned. Studies spanning half a century show similar recidivism
rates after successful weight loss ranging from 60-95%\(^6,7\). Contributing factors to failure might include a lack of persistence and frustration that goals are not being met in a desired timeframe.

Recidivism rates for other maladaptive behaviors/addictions are similarly wide ranging: narcotics (40-60\(^8\)), alcoholism (40-60\(^9\)), gambling (90\(^10\)), and smoking (up to 95\(^11\)). We hypothesized that a system that approached obesity similarly to an addiction, as opposed to simply a metabolic challenge, would yield positive long term results.

The standard approach for weight loss in diabetics involves individual or group sessions with a Certified Diabetes Educator (CDE)\(^12\). In addition to a dietary component, there is instruction on exercise, medication use and sick day management.

Self-hypnosis (SH)--simply defined--is a form of autosuggestion. SH is a technique that has been used successfully for controlling drug and alcohol addictions, with 87% abstinence at 7 weeks, and with better results in those who performed SH more often\(^13\). One such technique, the Harte System for Self-Hypnosis\(^14\) is a specially designed program that teaches subjects the proper skills necessary to carry out beneficial autosuggestion. This unique behavioral modification technique is used to help redirect subjects’ unwanted negative behavior(s) and substitute them with good or desirable alternatives.

Wide scale application of any treatment regimen for obesity or diabetes must consider the very high prevalence of these disorders as well as the limitations of healthcare resources, especially for preventative care and health maintenance. We endeavored to design a successful weight loss program that could be offered in almost any setting, including areas underserved medically,
be implemented with limited input from trained personnel (i.e., only a couple of training sessions), and could be scalable by involving group settings with minimal per participant cost.

We hypothesized that teaching subjects SH would be noninferior to traditional CDE instruction for initial weight loss, and would have a lower recidivism rate at one year.

METHODS

Participants:

This investigator-funded study protocol was approved by an external IRB. Between June and November 2013, all sequential overweight or obese Type 2 diabetics seen at a solo Endocrinologist's office were identified. Inclusion criteria included: DM2, BMI >25 kg/m² and a desire to lose weight. Exclusion criteria included: prior or planned bariatric surgery, current corticosteroid, psychiatric or weight loss medications, or current participation in any other weight loss program(s). Out of 189 subjects screened, thirteen (7%) screen failed based on exclusion criteria, and 74 (42%) agreed to participate in the study. Among the 102 otherwise eligible subjects who declined enrollment, the stated reasons were time constraints (n=18), not wanting to get involved in a clinical trial (n=17), not feeling healthy enough (n=6), and no stated reasons (n=61). These 102 subjects served as a control group for comparison to the two interventions (CDE and SH). They were not identified as being control subjects at the time of their routine office visits with the PI and were not given any specific weight loss instructions above and beyond standard of care for the practice.
Randomization:

The trial was a prospective, randomized, open label, unblinded comparison of two different behavioral approaches for weight loss. It was estimated that there would need to be approximately 17 subjects per cohort (4 cohorts, 68 total subjects) to detect a 5 lb difference, given a two-tailed test of differences in means that uses a $P = 0.05$ as a cutoff. Subjects were assigned on a first come basis into small groups of approximately ten, and were administered an Imagination/Persistence Quotient (IPQ™) test\textsuperscript{14}. Subjects listened to an audio recording where one is asked to imagine a series of described scenes, such as watching a film in a theater, or walking through a garden. Participants were subsequently administered a written questionnaire asking how vividly they could visualize the narrated scenes. The IPQ™ test stratifies individuals based on how well they employ their imaginative abilities. Thirty-one (42%) were low imaginative thinkers (score range = 0-42) and 43 (58%) were high imaginative thinkers (score range = 43-84). Once subjects were stratified to low or high based on their IPQ™ score, they randomly selected an envelope from a prepared stack with their next appointment date and time, at which point they were told to which group (CDE or SH) they were assigned. 38 were randomly assigned to CDE (17 low and 21 high), and 36 were assigned to SH (14 low and 22 high).

Interventions:

Two 1.5 - 2 hour group training sessions were scheduled for consecutive Sundays, 1 week apart. Based on the IPQ™ scores, there were four intervention groups: low CDE, high CDE, low SH, and high SH. The CDE and certified consulting hypnotist employed vivid imagery and visualization during the instruction of the high imaginative thinkers. Conversely, they used a
more task-oriented program for the low imaginative thinkers. Subjects were scheduled for a 1 month group follow up visit. The 3, 6, 9, and 12 month follow up visits were done as individual visits in the context of routine follow up with the PI (Endocrinologist).

Identical motivational emails were sent out to all study subjects--independent of cohort placement--once every 2 weeks to encourage performance of the skill sets that they were taught. Six subjects did not have email addresses; they were mailed a hard copy of the text on office letterhead.

Measures:

Baseline history included: HTN, dyslipidemia, hyperuricemia, current medications, weight loss history, diet history, duration of DM2, weight loss goal, max/min adult weight, age, gender, and self reported race/ethnicity. Height, weight and waist circumference were measured.

At all subsequent time points, weight, waist circumference, most recent fasting glucose, current medications with dosages, and a self reported assessment of compliance (“In the last week, for how many days did you follow the instructions offered at your initial teaching?”) were documented. A1c and postprandial glucose were obtained at 3, 6, 9 and 12 months. The IPQ™ was repeated in 70/72 subjects at the end of the study for a separate analysis of reliability; 2 study subjects refused retest.
Statistical analysis:

Control patients, certified diabetes educator patients, and self-hypnosis patients were compared as respects weight loss after one year, declines in A1c levels after one year, initial weight, initial A1c levels, birth year, height, and gender. ANOVA compared treatment group means, with Tukey multiple comparisons of means being used when differences among means were detected as being statistically significant. A $\chi^2$ test evaluated gender differences among treatment groups. Null hypotheses were rejected when $P < 0.05$. Linear regression models were compared with BIC.

RESULTS

Table 1 shows summary data by treatment group. Analyzed were 102 control patients, 38 certified dietician patients, and 36 self-hypnosis patients. ANOVA found the differences among treatment groups as respects weight loss after one year could not be explained by chance ($P = 0.001$); differences were also detected as being significant when percent weight loss was used in lieu of weight loss. ANOVA found that differences among treatment groups as respects initial weight, decrease in A1c after 1 year, initial A1c, birth year, and height might all have been due to chance ($P > 0.40$ for each analysis). A $\chi^2$ test failed to detect as significant differences among treatment groups as respects gender ($P = 0.46$).

Tukey multiple comparisons of means found that, after 1 year, certified dietician patients lost, on average, 3.7 pounds (95% CI 0.1, 7.2 pounds) more than did control patients and that self-hypnosis patients lost, on average, 5.2 pounds (95% CI 1.6, 8.8 pounds) more than did control patients, but that differences between certified dietician and self-hypnosis patients might have
been due to chance \((P = 0.68)\). The same results as respects detection of differences between means occurred when percent weight loss was used in lieu of weight loss.

A linear regression model of weight loss after 1 year upon treatment group had a BIC of 717; a model of weight loss after 1 year upon treatment group, initial weight, initial A1c level, birth year, height, and gender had a BIC of 729. Because the first model had the lower BIC, it was deemed the one with the greater explanatory power; there was no reason to include variables apart from treatment group as co-variates.

**DISCUSSION**

Both CDE and SH groups lost more weight than control patients. There is no clear consensus of the definition of clinically significant weight loss, but studies have demonstrated objective health benefits start accruing with as little as 5% loss in weight\(^1^5\). Ten (26%) of the CDE, 9 (25%) of the SH, and only 7 (7%) of the control subjects lost >5% of their initial weight at 12 months. The CDE group was specifically instructed on diet strategies, while the SH group focused on motivation and persistence with no formal diet instruction. Despite the differences in curriculum and approach, the results for weight loss and A1c reduction followed similar trends (Figure 1). At 6 months, CDE and SH subjects achieved A1c reductions of 0.45 and 0.41, respectively (Figure 2). The A1cs starting rising again by months 9 and 12. Whereas the weight loss also peaked at 6 months, there seemed to be a plateauing through 12 months in both CDE and SH groups.

Compliance as a Factor:
Dansinger\textsuperscript{16} compared four popular commercial diets (Atkins, Ornish, Weight Watchers and Zone) and found no differences between the diets (2.1 - 3.1 kg range weight loss), with compliance being the most important factor. Similarly, Sacks\textsuperscript{17} performed a randomized trial of four different diet compositions, and concluded that neither protein, fat nor carbohydrate composition was a factor in final weight loss.

Similar to our study, they also had group and individual follow up sessions. Weight loss seen in their study (3 - 4.5 kg) was higher than Dansinger’s and similar to ours. These data support the hypothesis that persistence, motivation, study effect and/or compliance may be the dominant factors. In our study, the SH group had no formal instruction on nutrient intake, and fared just as well as the CDE group.

Sacks noted that there was more weight loss with increased attendance at the group sessions and with adherence to diet. The present study also noted improved outcomes with higher compliance (Figure 3). Similarly, Sacks noted a reduction in weight loss (and adherence) starting at 6 months. In the present study, we also noted a corresponding reversal in the A1c drop starting at 6 months, and a corresponding plateauing of the weight loss curves.

Medications were adjusted as needed in all subjects to try to safely maintain an A1c of 7.0, as is the standard of care\textsuperscript{18}.

Role of Self Hypnosis:

These results support the effective nature of behavioral modification via SH as a tool to help Type 2 diabetics lose weight. Since every patient has individual strengths/weaknesses and different preferences for achieving successful weight loss, having SH as a complementary tool
to ‘traditional’ CDE training for weight loss can prove valuable. SH may be especially beneficial for certain subjects with high imagination potentials, strong motivation, and commitment to a behavioral modification regimen. Others may be more receptive to the approaches of traditional CDE.

Both CDE and SH subjects started plateauing with their weight loss, and showed reversal of the downward trend in A1c values starting at 6 months. Perhaps amending future study protocols to include additional reinforcement training sessions for study interventions at 6 months may prove beneficial. The control group was primarily focused on their A1c goals, perhaps explaining their continued improvement. Any improvement in A1c is particularly remarkable in this group since the vast majority were long standing patients of the practice, who would have been expected to have plateaued.

Imagination/Persistence Quotient (IPQ™):

Some patients had a low imaginary potential, and others a high one. Both CDE and SH instruction was geared towards the individual’s personal learning style. It is not known what value or significance this individualization had. However, the IPQ™ was a reliable measure. Most subjects -- 57 (79%) stayed within their group (high versus low imaginative) on the retest a year later. Fifteen (21%) crossed groups (10 went from high to low and 5 from low to high).

Cost:

In 2014, Weight Watchers cost $377 and Jenny Craig cost over $2,500 annually. Personal trainers and health coaches can charge $60 per hour, and many health plans do not cover
individual dietician counseling. One of the greatest potentials of our study is the demonstration that infrequent (i.e. 2) group sessions coupled with free emails and routine medical follow up was enough to show a significant effect for 6 months, and a lesser effect at 12 months. Even if group sessions were held every 3 months, it would still be a very cost effective modality for clinical practices.

Role of Motivational Email Reminders:

This study utilized motivational emails every two weeks to help the subjects stay focused and engaged. It is difficult to know exactly what value added the emails provided. The feedback by the subjects at the end of the study was mixed. Our study group was mostly elderly, and 8% did not even have an email address. Perhaps a younger population would be better suited for electronic interventions. For instance, Little et. al.\textsuperscript{20} randomized 818 subjects (average age of approximately 53) to 6 months of a web based learning system, followed by either 6 monthly nurse visits or face to face nurse support or remote nurse support. Despite having more ongoing professional contact hours than in our study, their results were fairly similar (3 - 4.5 kg weight loss) among the groups studied. In an even younger and presumably more tech savvy group of 35-55 year old Indian men, the prediabetics receiving 2 text messages a week for two years had a 36% lower incidence of developing diabetes\textsuperscript{21}. Future efforts for tackling global health problems like obesity and diabetes will most likely need to rely on group settings and/or technology in order to be cost effective.

Limitations:

The results of this trial can only be generalized to an adult, almost entirely caucasian population of overweight and obese Type 2 diabetics. One important take home point for behavioral
modifications is their high recidivism rate and that they rarely cure diabetes. In contrast, bariatric surgery\textsuperscript{22}, has shown long term (20 year) success in diabetes remission (83%), as well as reduction in MI (29%), stroke (34%) and even mortality (29%). Although lifestyle approaches can be a tiny fraction of the cost of surgery, especially utilizing group sessions as in this study, the lack of data showing remission of diabetes or other endpoint data, makes one pause and reflect whether we are being penny wise and pound foolish.

**CONCLUSIONS**

Certified diabetic educator and self hypnosis patients lost more weight than did control patients after 1 year; no difference was detected between CDE and SH subjects. No differences among treatment groups were seen as respect changes in A1c levels after one year.

**ACKNOWLEDGEMENTS**

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REFERENCES


http://thehartesystemforhypnosis.com/course.html


### FIGURES AND LEGENDS

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<td>1 (7)</td>
<td>4 (8)</td>
<td>6 (8)</td>
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<td><strong>Initial weight (lbs)</strong></td>
<td>199 (36)</td>
<td>207 (39)</td>
<td>199 (30)</td>
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<td><strong>Decrease in A1c after 1 year (g/dl)</strong></td>
<td>-0.2 (0.7)</td>
<td>-0.3 (0.7)</td>
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<table>
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Table 1: Summary Data by Group
Figure 1: Subgroup Analysis for Weight Loss
Figure 2: A1c Values vs. Time
Figure 3: Average Weight Loss vs. Compliance for CDE and SH