Access to a Behavioral Weight Loss Website With or Without Group Sessions Increased Weight Loss in Statewide Campaign


Study Overview

Objective. To determine the efficacy and cost-effectiveness of adding an evidence-based internet behavioral weight loss intervention alone or combined with optional group sessions to ShapeUp Rhode Island 2011 (SURI), a 3-month statewide wellness campaign.

Design. 3-arm randomized clinical trial.

Setting and participants. Study participants were recruited from the Rhode Island community via employers, media, and mass mailings at the time of SURI 2011 registration. Of the 3806 participants that joined the weight loss division, 1139 were willing to be contacted for research, and the first 431 were screened for study eligibility. Exclusion criteria were minimal: age < 18 years or > 70 years, body mass index (BMI) < 25 kg/m², pregnant, nursing, or plans to become pregnant, a serious medical condition (eg, cancer), unreliable internet access, non-English speaking, current or previous participation in our weight loss studies, and planned relocation. Those who reported a medical condition that could interfere with safe participation (eg, diabetes) obtained doctor’s consent to participate. Of those screened, 230 met inclusion criteria, completed orientation procedures, and were randomized using a 1:2:2 randomization scheme to the standard SURI program (S; n = 46); SURI plus internet behavioral weight loss intervention (SI; n = 90); or SURI plus internet behavioral weight loss intervention plus optional group sessions (SIG; n = 94). To avoid contamination, individuals on the same SURI team (see below) were randomized to the same intervention.

Intervention. Participants in the standard SURI program did not receive any behavioral weight loss treatment. SURI is a self-sustaining, annual community campaign designed to help Rhode Islanders lose weight and increase their physical activity through an online, team-based competition. Participants join in teams, enter the weight loss or physical activity division or both, and compete with other teams. Throughout the 3-month program, participants have access to a reporting SURI website where they submit their weekly weight and activity data and view their personal and team progress. They also receive paper logs to record weight and activity, a pedometer, access to newsletters and community workshops, and recognition for meeting goals.

Participants in the SI arm received the 3-month SURI program plus a 3-month internet behavioral weight loss intervention. Before SURI began, SI participants attended a 1-hour group meeting during which
they received their weight loss goal (lose 1 to 2 pounds per week), calorie and fat gram goal (starting weight < 250 lbs: 1200–1500 kcal/day, 40–50 g of fat; starting weight ≥ 250 lbs: 1500–1800 kcal/day, 50–60 g of fat), and activity goal (gradually increase to 200 minutes of aerobic activity per week). During this session, participants were also taught self-monitoring skills and oriented to an internet behavioral weight loss intervention website developed by the authors. The intervention website included 12 weekly, 10- to 15-minute multimedia lessons based on the Diabetes Prevention Program and a self-monitoring platform where participants tracked their daily weight, calorie, and activity information. Participants received weekly automated feedback on their progress. The intervention website also included information on meal plans, prepackaged meals, and meal replacements.

Participants in the SIG arm received everything in SI and were additionally given the option to attend weekly group meetings at Miriam Hospital’s Weight Control and Diabetes Research Center during the 3 months. The 12 weekly, optional group sessions were led by masters-level staff with extensive training in behavioral weight loss. Sessions involved private weigh-ins and covered topics that supplemented the internet intervention (eg, recipe modification, portion control).

**Main outcomes measures.** The main outcome was weight loss at the end of the 3-month program. Participants completed measures (ie, weight, BMI) in person at baseline and 3 months (post-treatment), and at 6- and 12-month follow-up visits. Adherence measures included reported weight and physical activity on the SURI website (S, SI, and SIG), log ins, viewed lessons, and self-monitoring entries on the intervention website (SI, SIG), and number of groups meetings attended (SIG). To measure weight loss behaviors, the authors used the Weight Control Practices questionnaire to assess engagement in core weight loss strategies targeted in treatment, and the Paffenbarger questionnaire to assess weekly kcal expended in moderate to vigorous activity. The authors also assessed costs from the payer (labor, rent, intervention materials), participant (SURI registration fee, transportation, time spent on intervention), and societal perspective (sum of payer and participant costs) in order to calculate the cost per kg of weight lost in each study arm.

**Results.** Participants were predominantly female, non-Hispanic white, and had a mean BMI of 34.4 kg/m² (SE = 0.05). Groups differed only on education (P = 0.02), and attendance at post-treatment and 6- and 12-month follow-up were high (93%, 91%, and 86% respectively). The authors found that weight loss did not differ by educational attainment (Ps > 0.57).

Overall, there was a significant group-by-time interaction for weight loss (P < 0.001). Percentage weight loss at 3 months differed among the 3 groups—S: 1.1% ± 0.9%; SI: 4.2% ± 0.6%; SIG: 6.1% ± 0.6% (Ps ≤ 0.04). There was also an overall group effect for percentage of individuals achieving 5% weight loss (P < 0.001). SI and SIG had higher percentages of participants who achieved a 5% weight loss than the control (SI: 42%; SIG: 54%; S: 7%; P < 0.001) but did not differ from one another (P = 0.01). Initial weight losses and percentage of participants who achieved a 5% weight loss were largely maintained through the no-treatment follow-up phase at 6-months, but the 3 groups no longer differed from one another at 12 months (S: 1.2% [SE = 0.9]; SI: 2.2% [SE = 0.6]; SIG: 3.3% [SE = 0.6]; Ps > 0.05).

All groups reported significant increases in physical activity over time (P < 0.001). More reporting of weight and physical activity data on the SURI website was associated with greater percentage weight loss (r = 0.25; P < 0.001). Number of log ins and lessons viewed on the intervention website were positively associated with percentage weight loss (r = 0.45; P ≤ 0.001; and r = 0.34; P ≤ 0.001 respectively). Greater attendance to group sessions was associated with better weight outcomes (r = 0.61; P ≤ 0.001). Younger age was associated with poorer adherence, including less reporting on the SURI website, viewing of lessons, and logging in to the weight loss website.

There was a significant group-by-time effect interaction for the use of behavioral weight loss strategies (P < 0.001), and increased use of these strategies was associated with greater percentage weight loss in all 3 groups post-treatment. At 12 months, however, there were no differences between groups in the use of these strategies (Ps ≤ 0.07).

Cost per kg of weight loss was similar for S ($39) and SI ($35), but both were lower than SIG ($114).

**Conclusion.** Both intervention arms (SI and SIG) achieved more weight loss at 6 months than SURI alone. Although mean weight loss was greatest with optional group sessions (SIG), the addition of the behavioral intervention website alone (SI) was the most cost-effe-
fective method to enhance weight loss. Thus, adding a novel internet behavioral weight loss intervention to a statewide community health initiative may be a cost-effective approach to improving obesity treatment outcomes.

Commentary

Weight loss treatment is recommended for adults with a BMI of > 30 kg/m², as well as those with BMI < 25 kg/m² with weight-related comorbidities [1]. Intensive behavioral treatment should be the first line of intervention for overweight and obese individuals and can lead to 8% to 10% weight loss [2], particularly in initial months of treatment [3]. However, behavioral treatment is inherently challenging and time-consuming, and readily available to only a fraction of the intended population. Although weight losses achieved from intensive lifestyle interventions such as the Diabetes Prevention Program (DPP) [4] may be higher, innovative community weight loss programs that use a variety of weight loss strategies can provide opportunities to a wider population of overweight and obese individuals and at a lower cost [3].

This study built upon the authors’ previous work [5], which showed that SURI participants with behavioral weight loss strategies via email significantly improved 3-month weight losses. In this current study, they compared SURI alone to SURI with additional access to an internet behavioral weight loss website with or without optional group sessions. Since significant weight loss was not maintained at 12 months, this suggests that perhaps access to the behavioral weight loss website should have continued for longer and/or included a maintenance phase after the 3-month intervention. Weight loss often reaches its peak around 6 months, and weight regain occurs without effective maintenance therapy [6].

General strengths of the study included the use of a randomized, intention-to-treat design, dissemination of evidence-based weight loss strategies, objective outcomes measurement, adherence metrics, and strong retention of participants with clear accounting of all enrolled patients from recruitment through analysis. This study demonstrated significant weight loss in an intervention with minimal/optional health professional interaction. This intervention also placed responsibility on participants to self-monitor their diet and physical activity, participate in online lessons, and attend optional group sessions. The success of this community-based intervention suggests feasibility and scalability within a real-world setting. The authors also conducted cost-effectiveness analyses demonstrating that the SI program was more cost-effective than SIG.

However, there are weaknesses as well. In setting the sample size for each arm of this study, no justification was described for choosing a 1:2:2 randomization scheme. In randomized control trials, the allocation of participants into the different study arms is often balanced to equal numbers which maximizes statistical power [7]. However, the use of unequal randomization ratios among study arms can be beneficial and even necessary for various reasons including cost, availability of the intervention, overcoming intervention/treatment learning curves, and if a higher drop-out rate is anticipated. Providing a justification for unbalanced sample sizes would be helpful to future researchers looking to replicate the study. Additionally, participants were mostly non-Hispanic white and female, thus limiting generalizability. While representative of the broader Rhode Island population, findings based on this population this may not be applicable to vulnerable (ie, low literacy, resource-poor) or underrepresented populations (ie, minorities) [8].

Applications for Clinical Practice

An internet-based behavioral weight loss intervention, when added to a community weight management initiative, is cost-effective and can lead to short-term weight loss. Given that clinicians often lack time, training, and resources to adequately address obesity in the office [9,10], encouraging patients to enroll in similar programs may be an effective strategy to address such barriers. The study also highlights the need for maintenance interventions to help keep weight off. Findings should be replicated in more diverse communities.

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References

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**Epidural Steroid Injections for Spinal Stenosis Back Pain Simply Don’t Work**


**Study Overview**

**Objective.** To determine the effectiveness of epidural injections of glucocorticoids plus anesthetic compared with injections of anesthetic alone in patients with lumbar spinal stenosis.

**Design.** The LESS (Lumbar Epidural Steroid Injection for Spinal Stenosis) trial—a double-blind, multisite, randomized controlled trial.

**Setting and participants.** The study was conducted at 16 sites in the United States and enrolled 400 patients between April 2011 and June 2013. Patients at least 50 years of age with spinal stenosis as evidenced by magnetic resonance imaging (MRI) or computed tomography (CT) were invited to participate. Additional eligibility criteria included an average pain rating of more than 4 on a scale of 0 to 10 (0 being the lowest score) for back, buttock, or leg pain. Patients were excluded if they did not have stenosis of the central canal, had spondylolisthesis requiring surgery, or had received epidural glucocorticoid injections within the previous 6 months. Patients were randomly assigned to receive a standard epidural injection of glucocorticoids plus lidocaine or lidocaine alone. At the 3-week follow-up they could choose to receive a repeat injection. At the 6-week assessment they were allowed to cross over to the other treatment group. Patients were blinded throughout the study. The treating physicians were also blinded through the use of 2 opaque pre-filled syringes provided by the study staff—one marked “inject” and one marked “discard.”

**Main outcome measures.** The 2 outcomes, measured at 6 weeks, were the Roland-Morris Disability Questionnaire (RMDQ) score (range, 0 to 24, with higher scores indicating greater physical disability) and the patient’s rating of average buttock, hip, or leg pain in the previous week (scale of 0 to 10 with 0 indicating no pain and 10 indicating “pain as bad as you can imagine”).

Eight secondary patient-oriented outcomes were also measured: (1) at least minimal clinically meaningful improvement (≥30%), (2) substantial clinically meaningful improvement (≥50%), (3) average back pain in the previous week, and scores on the (4) Brief Pain Inventory (BPI) interference scale, (5) 8-question Patient Health Questionnaire (PHQ-8), (6) Generalized Anxiety Disorder 7 scale (GAD-7), (7) EQ-5D (a health status measure) and (8) Swiss Spinal Stenosis Questionnaire (SSSQ).

**Main results.** The 2 groups were similar with respect to baseline characteristics, except that the duration of pain was shorter in the lidocaine-alone group. At 6 weeks, both groups had improved RMDQ scores (glucocorticoid −4.2 points vs. no glucocorticoid −3.1 points, respectively). However, the difference in RMDQ score between the 2 groups was not statistically significant (−1.0 points [95% CI, −2.1 to 0.1]; P = 0.07). In addition, there was no differ-
ence in treatment effect at 6 weeks as measured by patient’s reported leg pain (−0.2 points [95% CI, −0.8 to 0.4]; P = 0.48). Furthermore, there were no significant differences in the secondary outcomes of clinically meaningful improvement, BPI, SSSQ symptoms and physical function, EQ-5D, and GAD-7 scales at 6 weeks. Among the secondary outcomes, only symptoms of depression and patient satisfaction showed a statistically significant improvement in the glucocorticoid plus lidocaine group. Of note, though not statistically significant, there were more adverse events in the glucocorticoid plus lidocaine group compared to the lidocaine alone group (21.5% vs. 15.5%, respectively). Finally, the glucocorticoid plus lidocaine group also had a significantly higher proportion of patients with cortisol serum suppression compared to the lidocaine alone group.

Conclusion. The authors concluded that there was no difference in pain-related functional disability (as measured by the RMDQ score) and pain intensity between patients receiving fluoroscopically guided epidural injections with glucocorticoids plus lidocaine compared with lidocaine alone for lumbar spinal stenosis. The injection of glucocorticoid should be avoided due to its potentially systemic effects, including suppression of the hypothalamic-pituitary axis and reduction in bone mineral density, which may increase the risk of fracture.

Commentary
Lumbar spinal stenosis is one of the most common causes of spine-related back and leg pain; it disproportionately affects older adults due to degenerative changes resulting in narrowing of the spinal canal and nerve-root. Epidural glucocorticoid injections containing a glucocorticoid and an anesthetic are commonly used to relieve symptoms of lumbar stenosis. While this treatment approach is controversial, more than 2.2 million lumbar epidural glucocorticoid injections are performed in the Medicare population each year [1,2]. Previous uncontrolled studies suggest that epidural glucocorticoid injections provide short-term pain relief for some patients with spinal stenosis [3]. While complications from the procedure are rare, a multistate outbreak of fungal meningitis due to contaminated glucocorticoid injections affected at least 751 patients with 64 deaths in 2012 [4].

The purpose of the current study by Friedly et al was to determine whether adding a glucocorticoid to an anesthetic in epidural spinal injections is superior to anesthetic alone for symptom relief and functional improvement in patients with lumbar spinal stenosis. In contrast to previous studies, the authors defined short-term results as 3 weeks after injection, and long-term results as 6 weeks after injection. Despite the shorter follow-up period, results were similar to previous studies, in that adding glucocorticoid to anesthetic in epidural spinal injection reduced pain and improved patient’s functionality short-term, but improvements were not sustained long-term. Based on these results, the authors concluded that there is no benefit in adding glucocorticoid epidural injections for back pain arising from lumbar spinal stenosis.

One major limitation of this study is the lack of a placebo arm. Because of the lack of a placebo arm, it cannot be ascertained whether epidural injection with lidocaine alone conferred a benefit. However, this study provides robust evidence that epidural steroid injections are not beneficial for treatment of back and leg pain associated with lumbar spinal stenosis.

Applications for Clinical Practice
Epidural steroid injection is long accepted in medical communities as a safe and effective treatment for lumbar spinal stenosis symptoms. In light of the potential dangers of epidural steroid injections, including meningitis, coupled with the increasing cost of the procedure, other potential side effects, and demonstrated ineffectiveness of the treatment, providers should stop recommending epidural steroid injections for lumbar spinal stenosis.

—Ka Ming Gordon Ngai, MD, MPH

References