Are Non-Nutritive Sweetened Beverages Comparable to Water in Weight Loss Trials?


Study Overview

Objective. To compare the efficacy of non-nutritive sweetened beverages (NNS) or water for weight loss during a 12-week behavioral weight loss treatment program.

Study design. 2-arm equivalence randomized clinical trial.

Setting and participants. Participants were recruited at the University of Colorado and Temple University. A total of 506 participants were screened and 308 were enrolled in the study. Inclusion criteria included being weight stable within 10 pounds in the 6 months prior to the trial, engaging in fewer than 300 min of physical activity per week and consuming at least 3 NNS beverages per week. Exclusion criteria included pregnancy, diabetes, cardiovascular disease, uncontrolled hypertension, and the use of medications affecting metabolism or weight. Participants also had physician approval stating they were in good health and could handle the nutrition and exercise requirements of the trial. Participants were randomly assigned to a NNS or water treatment arm using a computer-generated randomization that equally distributed men and women between the 2 groups. Participants had to be willing to discontinue consumption of NNS beverages for the duration of the 1-year study if they were randomized to the water-only group.

Intervention. The study was designed to include a 12-week weight loss phase followed by a 9-month maintenance phase. All participants received a cognitive-behavioral weight loss intervention called The Colorado Weigh. The program involved weekly hour-long group meetings led by registered dieticians or clinical psychologists. Groups were split by research arm and participants were taught about different weight loss strategies including self-monitoring, portion sizes, and physical activity. Participants were weighed at each meeting. The group curriculum was the same for both arms of the study except in the type of beverage they were encouraged to consume.

Participants were given individual energy targets based on their estimated resting metabolic rate (RMR), determined by using a Tanita Model TBF-300A bioelectrical impedance device that assesses body composition. Group leaders adjusted these targets as needed for participants in order to achieve a goal weight loss of 1 to 2 pounds per week. Physical activity targets were set to increase each participant’s typical physical activity by 10 minutes a week with a final target of 60 minutes a day, 6 days a week. Participants filled out daily exercise logs. Additionally, physical activity was assessed by the use of a Body Media armband that participants wore weeks 1 and 12.

Participants in the NNS group were asked to consume at least 24 fluid ounces of NNS beverage per day.
Their water consumption was not limited. A beverage was considered NNS if it had less than 5 kcal per 8-ounce serving, was pre-mixed, and contained non-nutritive sweeteners. Participants in the water-only group were asked to drink at least 24 ounces of water a day and not drink any NNS beverages. They were allowed to eat foods that contained NNS but could not intentionally add NNS to beverages such as coffee. Participants in both groups were asked to record their beverage intake daily. Participants were given manufacturers’ coupons for bottled water or NNS beverages.

Main outcome measures. The primary outcomes were weight loss at 12 weeks (weight loss period) and at 1 year (weight loss maintenance). All assessments were conducted at baseline and after 12 weeks. This was designed as an equivalence trial, and the authors’ hypothesis was that there would be no clinically meaningful difference in weight change between the 2 groups. The authors pre-specified that the bounds of equivalence would be 1.7 kg. Waist circumference was recorded in addition to height and weight. Participant’s blood pressure was also recorded and blood samples were collected to measure lipids and glucose. Urine samples were collected to measure urine osmolality. Participants completed questionnaires at baseline and 12 weeks to assess changes in perceived hunger.

Results. A total of 308 patients were randomized following baseline assessment but 5 did not begin treatment. 279 of the remaining 303 participants completed the full 12-week weight loss phase of the study. The dropout rate in the water group was 10% compared to 5.8% in the NNS group, but this was not statistically significant. 80% of participants were female, 68% were white, and 27% African American. There were no significant differences at baseline in age, gender, race/ethnicity or other measures between the water-only and NNS groups. There was no significant difference in adherence to the beverage requirements between the 2 groups (96.6% in the NNS group and 95.7% in the water-only group), and similarly group attendance did not differ between the 2 groups (90.8% for NNS and 89.7% for water-only).

The mean weight loss difference between the water and NNS groups was –1.85 kg (90% confidence interval [CI], –1.12 to –2.58 kg). Because the lower confidence limit of –2.58 kg was outside the equivalence limit set in the hypothesis, the 2 treatments were not considered equivalent and paired comparisons were carried out. Analysis done using an intention-to-treat scheme indicated that the weight loss in the NNS group (5.95 kg ± 3.94 kg) was significantly higher than the weight loss in the water-only group (4.09 ± 3.74 kg, P < 0.001). 43.0% of participants in the water-only group lost > 5% of their body weight and 64.3% of participants in the NNS group lost > 5% of their body weight (P < 0.001).

After 12 weeks of treatment there was no significant difference between the 2 groups in changes in waist circumference, blood pressure, HDL, triglycerides, or urine osmolality. Reductions in total cholesterol and LDL were significantly greater in the NNS group than the water group. There were no significant changes in physical activity between the 2 groups as measured by the exercise logs or the Body Media armbands. There was a statistically significant difference in hunger between the 2 groups (P = 0.013): participants in the water group reported increased hunger, while participants in the NNS group reported a slight decrease in hunger.

Conclusion. Participants who drank at least 3 servings of NNS beverages a day at baseline lost more weight during a behavioral weight loss program when they continued to drink NNS beverages than participants who were asked to cut NNS beverages and drink only water. The study was designed as an equivalence trial but paired comparisons showed a significant difference in weight loss between the 2 groups.

Commentary

Obesity is a major public health concern in the United States and drinking sugar-sweetened beverages has been indicated as a significant contributing factor. Consumption of sugar-sweetened beverages increased considerably from 1994 to 2004 [1]. Fortunately, there is strong evidence that decreasing the consumption of sugar sweetened beverages can lead to weight loss [2]. Most studies look at the effect of replacing sugar-sweetened beverages with water [3] and, in fact, increased consumption of water has been shown to aid weight loss [4]. The relationship between diet drinks and obesity, however, has been a source of controversy. Since NNS beverages contain little to no calories they are a logical replacement for sugar-sweetened beverages, but observational studies have shown a positive correlation between diet drinks and obesity [5,6] as well as type 2 diabetes [7]. Additionally, a recent study by Suez et al [8] found that consumption of artificial sweeteners
affects the gut microbiota and increases glucose intolerance. However this correlation may not be causal; NNS beverage consumption may be higher in overweight individuals. A study by Tate et al [9,10] looked at replacing sugar-sweetened beverages with water or artificially sweetened beverages and found no significant difference in weight loss between the 2 groups. However, the Tate et al study used beverage replacement as the primary intervention. This experiment by Peters et al is unique because it tested the hypothesis that NNS is equivalent to water alone when combined with a structured weight loss program. Their results reject the equivalence hypothesis and suggest that NNS beverages facilitate weight loss for patients already consuming them.

Strengths of this study included the use of a randomized, equivalence design. The study also examined secondary outcomes (eg, waist circumference, lipids, and urine osmolality) that helped reinforce that participants consuming NNS were able to lose weight without compromising their health. Further, they measured hunger and found that participants in the NNS beverage group had decreased hunger while those in the water group had increased hunger, which points to a potential mechanism for their findings.

However, the potential for bias in this study is concerning. One major weakness is that all the participants were initially regular drinkers of NNS beverages. The authors never explain why consuming 3 NNS beverages per week was an inclusion criteria. Participants in the water group had to change their behavior to abstain from NNS beverages and this may have impacted results. More concerning, this study was fully funded by the American Beverage Association, who has an obvious interest in promoting NNS beverage consumption. Finally, the authors mention that 5 participants dropped out after randomization but before the start of treatment and were excluded from the study after baseline assessment. The authors do not provide information about group allocation or if the participants knew which group they were assigned to, calling into question the integrity of the intention-to-treat design.

Applications for Clinical Practice
For patients who already drink NNS beverages and are motivated to lose weight, these results support continued use. However, it is unclear how NNS beverages impact weight loss efforts for patients who do not currently drink them. Further, since other studies have shown potential harm of NNS beverages [6–8], more studies are needed to better elucidate their health effects.

—Susan Creighton and Melanie Jay, MD, MS

References
2. Hu FB. Resolved—there is sufficient scientific evidence that decreasing sugar-sweetened beverage consumption will reduce the prevalence of obesity and obesity-related diseases. Obesity Rev 2013;14;606–19.
Optimizing the Primary Care Management of Chronic Pain Through Telecare


Study Overview

Objective. To evaluate the effectiveness of a collaborative telecare intervention on chronic pain management.

Design. Randomized clinical trial.

Settings and participants. Participants were recruited over a 2-year period from 5 primary care clinics within a single Veterans Affairs medical center. Patients aged 18 to 65 years were eligible if they had chronic (≥3 months) musculoskeletal pain of at least moderate intensity (Brief Pain Inventory [BPI] score ≥5). Patients were excluded if they had a pending disability claim or a diagnosis of bipolar disorder, schizophrenia, moderately severe cognitive impairment, active suicidal ideation, current illicit drug use or a terminal illness or received primary care outside of the VA. Participants were randomized to either the telephone-delivered collaborative care management intervention group or usual care. Usual care was defined as continuing to receive care from their primary care provider for management of chronic, musculoskeletal pain.

Intervention. The telecare intervention comprised automated symptom monitoring (ASM) and optimized analgesic management through an algorithm-guided stepped care approach delivered by a nurse case manager. ASM was delivered either by an interactive voice-recorded telephone call (51%) or by internet (49%), set according to patient preference. Intervention calls occurred at 1 and 3 months. Additional contact with participants from the intervention group was generated in response to ASM trend reports.

Main outcome measures. The primary outcome was the BPI total score. The BPI scale ranges from 0 to 10, with higher scores indicating worsening pain. A 1-point change is considered clinically important. Secondary pain outcomes included BPI interference and severity, global pain improvement, treatment satisfaction, and use of opioids and other analgesics. Patients were interviewed at 1, 3, 6, and 12 months.

Main results. A total of 250 participants were enrolled, 124 assigned to the intervention group and 126 assigned to usual care. The mean (SD) baseline BPI scores were 5.31 (1.81) for the intervention group and 5.12 (1.80) for usual care. Compared with usual care, the intervention group had a 1.02-point lower BPI score at 12 months (95% confidence interval [CI], −1.58 to −0.47) (P < 0.001). Patients in the intervention group were nearly twice as likely to report at least a 30% improvement in their pain score by 12 months (51.7% vs. 27.1%; relative risk [RR], 1.9 [95% CI, 1.4 to 2.7]), with a number needed to treat of 4.1 (95% CI, 3.0 to 6.4) for a 30% improvement. Patients in the intervention group were more likely to rate as good to excellent the medication prescribed for their pain (73.9% vs 50.9%; RR, 1.5 [95% CI, 1.2 to 1.8]). Patients in the usual care group were more likely to experience worsening of pain by 6 months compared with the intervention group. A greater number of analgesics was prescribed to patients in the intervention group; however, opioid use between groups did not differ at baseline or at any point during the trial period. For the secondary outcomes, the intervention group reported greater improvement in depression compared with the usual care group, and this difference was statistically significant (P < 0.001). They also reported fewer days of disability (P = 0.34).

Conclusion. Telecare collaborative management was more effective in improving chronic pain outcomes than usual care. This was accomplished through the optimization of non-opioid analgesic therapy facilitated by a stepped care algorithm and automated symptom monitoring.

Commentary

Chronic pain affects up to 116 million American adults and is recognized as an emerging public health problem that costs the United States a half trillion dollars annu-
ally, with disability and hospitalization as the largest burdens [1]. The physical and psychological complexities of chronic pain require comprehensive individualized care from interdisciplinary teams who will facilitate prevention, treatment, and routine assessment in chronic pain sufferers [2]. However, enhancing pain management in primary care requires overcoming the high costs and considerable time needed to continually support patients in pain. Telecare represents an improved means by which doctors and nurses can provide primary care services to patients in need of comprehensive pain management. However, the effectiveness of interventions delivered to patients suffering from chronic pain, via telecare, is largely unknown.

This study had several strengths, including a distinct and well-defined intervention, population, comparator, and outcome. The inclusion criteria were broad enough to account for various age-groups, and therefore various pain experiences, yet excluded patients with characteristics likely to confound pain outcomes, such as severe mental health disorders. Participants were randomized in blinded fashion to 1 of 2 clearly defined groups. The stepped algorithm used in the study, SCOPE [3], is a validated and reliable method for assessing chronic pain outcomes. The statistical analyses were appropriate and included analyses of variance to detect between-group differences for continuous variables. The rate of follow-up was excellent, with 95% of participants providing measurable outcome assessments at 12 months. The scientific background and rationale for this study were explicit and relevant to current advances in medicine.

The study is not without limitations, however. It is unclear whether the 2 trial groups were treated equally. Data received through ASM from the intervention group prompted physicians to adjust a patient’s medication regimen, essentially providing caregivers updates on a patient’s status. This occurred in addition to the 4 monthly interviews that both groups received per protocol. The study did not elucidate exactly what care was provided to the usual care group and, therefore, does not allow for the disaggregation of the relative effects of optimizing analgesics and continuous provider monitoring. It is difficult to distinguish if additional care or the intervention was more effective in managing pain than usual care. Another limitation, noted by the authors, is the study’s use of a single VA medical center. Demographics reveal a skewed population, 83% male and 77% white, limiting the trial’s generalizability. Most clinical outcomes were considered, though cost-effectiveness of the intervention was not analyzed. As the VA is a cost-sensitive environment, it is important that interventions assessed are not more costly than usual care. Further cost analysis beyond health resource utilization reported in the study would provide a nuanced assessment of telecare’s feasibility as a replacement for usual primary care. Statistically, the study shows significant improvements in chronic pain in those who received the intervention via telecare, therefore, cost analysis is indeed warranted.

**Applications for Clinical Practice**

This study illuminates the need for a more intensive pain management program that allows for continuous monitoring. Though the intervention was successfully delivered via telecare, further research is needed to assess whether other programs would be as effective when delivered through telecare, and more importantly, to investigate what characteristics of interventions make telecare successful. Telecare has the potential to improve outcomes, reduce costs, and reduce strains on understaffed facilities, though it is still unknown which conditions would gain from this innovation. This study shows that chronic disease, a predominately self-managed condition, would benefit from a more accessible management program [4]. This, however, may not be the case for other health issues, which require continual testing and equipment usage, such as infectious diseases. Further studies should focus on populations that command a patient-centered intervention delivered using a potentially low-cost tool, like the telephone or internet. Finally, a significant cost driver with chronic pain is disability, and though change in disability days was not statistically significant in this trial, patients in the intervention group self-reported a decrease in disability days, where as patients in the usual care group self-reported an increase. A clinical improvement in pain management has the potential to shave millions of dollars from the U.S. economy, this hypothesis deserves further investigation.

—Sara Tierce-Hazard, BA, and Tina Sadarangani, MSN, ANP-BC, GNP-BC

**References**


2. McGeary DD, McGeary CA, Gatchel RJ. A comprehensive review of telehealth for pain management: where we are and
Telehealth as an Alternative to Traditional, In-Person Diabetes Self-Management Support


Study Overview

Objective. To investigate the feasibility and effectiveness of administering diabetes self-management support (DSMS) via telephone or secure messaging.

Design. Prospective, longitudinal quasi-experimental study.

Setting and participants. Participants (n = 150) who had previously completed diabetes self-management education (DSME) received follow-up DSMS in 1 of 3 self-selected ways: a one-time in-person visit, 3 brief visits by telephone, or via secure messaging via the electronic health record. The (usual care) in-person group (n = 47) received 1 follow-up appointment at the patient’s request with a certified diabetes educator (CDE) within 3 to 6 months of DSME completion. The telephone group (n = 44) was given follow-up phone appointments with a CDE, each lasting approximately 20 minutes, at 3, 6, and 9 months post-DSME. The secure message group (n = 59) received follow-up messages via the patient portal from a CDE at 3, 6, and 9 months post-DSME. At each interval, patients received 3 messages, an initial one followed by 2 structured replies. Motivational interviewing techniques were used in all 3 groups to identify barriers to achieving behavior goals and solutions.

Main outcome measures. Behavior goal measures, feasibility measures, and physiologic measures at 9 months’ post DSME. Behavior goal achievement was measured using a survey that asked patients to rate their achievement regarding the following AADE7 goals: healthy eating, being active, self-monitoring, taking medications, problem solving, reducing risks, and healthy coping. Goals are rated on a scale from 0 to 10, with a rating ≥7 considered successful completion. Feasibility to integrate this technology into a DSME platform was assessed by comparing the number of attempts to contact patients with the number of contacts achieved; also calculated was intervention completion, mean time spent with the CDE, and total cost of each visit. Physiologic measures included HbA1c and LDL levels collected through medical record review.

Results. There were no statistically significant differences between groups with respect to any of the primary outcomes. Behavioral goals were achieved by 59% of the in-person group, 73% of the telephone group, and 77% of the secure message group. Mean goal achievement for all 3 groups combined improved from 6.2 ± 2.4 to 7.2 ± 1.8 (P < 0.05). Overall, 70.3% ± 0.46% achieved behavioral goals, with no difference among groups. In terms of feasibility, at 3 months the contact success rate was 39%, 46%, and 29% in the in-person, telephone, and secure message groups, respectively. At 6 months, the contact success rate was 47% in the phone group versus 32% in the secure message group. At 9 months, the contact success rate was 35% in the phone group versus 21% in the secure message group. Sixty-two participants (41%) completed the intervention per protocol: 51% of in-person patients, 47% of phone patients, and 28% of secure message patients (P < 0.02). Visits lasted and cost, on average, 60 minutes and $50.00, 45.3 minutes and $37.75, and 17.8 minutes (P < 0.05) and $14.83 for the in-person, telephone, and secure message groups, respectively. There was no difference in HbA1c among groups. Overall, HbA1c decreased by −0.88% ± 1.63 (P < 0.05) from baseline to 9 months. Change in LDL was not significant, and neither were there statistical differences among groups.
Conclusion. Diabetes follow-up care delivered via telephone and secure messaging is feasible. Using either of these methods results in similar outcomes compared with the traditional in-person visit, while requiring less staff time.

Commentary
Diabetes mellitus is a growing epidemic in the United States, affecting nearly 10% of American adults [1]. The disease is associated with multiple, potentially fatal complications, including heart disease, stroke, kidney failure, and limb amputation [1]. Studies show that ongoing diabetes self-management education (DSME) can result in lifestyle and behavioral changes that improve glycemic control, ultimately reducing the risk of complications [2,3]. However, traditional follow-up care and education for patients with diabetes requires considerable time on the part of patients and providers, and is both costly and resource-intensive [4]. The use of telehealth to educate and monitor patients with diabetes is a growing phenomenon. Theoretically, telehealth enables providers to reach greater subsets of the population who may not otherwise be able to consult with a doctor or nurse regularly. However, little is known about the overall effectiveness of telehealth compared with regular office visits with respect to diabetes and patient outcomes.

This study investigated the feasibility of using telephone and secure message methods to deliver ongoing DSMS after the completion of an existing DSME program. The results suggest that there is no difference in behavioral goal achievement, feasibility, and clinical outcomes among usual care and intervention groups. This study had a number of strengths, including a strong scientific background in support of research that examines telehealth options for diabetes management. The inclusion criteria were straightforward and appropriate for the targeted patient population: all participants were over 18 and had previously completed the DSME class; all participants in the phone group were required to have a working telephone line, while the secure message group participants were required to have internet access. However, there were some methodologic weaknesses, most of which were pointed out by the authors. These included (1) lack of randomization, (2) a high attrition rate, and (3) nonspecific outcome measures. In addition, participants were able to self-enroll into a category of their choice. The lack of randomization enabled selection bias and prohibits the authors from inferring a causal effect between DSMS and improved health outcomes. Attrition rates were also problematic in this study. Not only did 59% of enrolled participants fail to complete the intervention, but the overall contact success rates declined over time. Finally, the outcome measure for feasibility is poorly defined because the authors never provide a numerical measure limitation. External validity is limited by a largely Caucasian sample that is predominately female. Due to the weaknesses inherent in the study’s methodology, the findings should be interpreted with some degree of caution.

Applications for Clinical Practice
Given the potential for long-term complications from diabetes, the rising cost of health care services, and the overall shortage of medical and nursing personnel, alternative methods of patient follow-up are needed in the management of diabetes. Telehealth has the potential to reach a significant portion of the population that is receiving little or no care in rural and underserved areas in a convenient and less costly way than traditional care. Investigating which alternatives to usual care are effective for which patient groups will pave the way for resource optimization and cost-effectiveness. Providing DSME follow-up through telehealth methodologies may be an effective alternative to in-person visits. Additional research is needed to support the outcomes of this study and to determine the duration of DSMS that is needed to ensure sufficient diabetes self-management.

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References