Brief Interventions in Adult Roux-En-Y Gastric Bypass Patients with At-Risk Alcohol Use

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BRIEF INTERVENTIONS IN ADULT ROUX-EN-Y GASTRIC BYPASS PATIENTS WITH AT-RISK ALCOHOL USE

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ABSTRACT

Bariatric surgeries are the most effective treatment for severe obesity. However, despite the benefits, patients who undergo bariatric surgery, especially Roux-en-Y Gastric Bypass, are at a higher risk of developing alcohol use disorders compared to the general population. There is currently limited research that evaluates interventions to decrease unhealthy alcohol use in at-risk bariatric patients. This study aims to investigate whether an intervention strategy known as Brief Intervention can reduce alcohol consumption in Roux-en-Y patients who screen positive for at-risk alcohol use. We will randomize adult post-operative patients who screen positive to either receive brief interventions or usual care. Alcohol quantity and frequency will be analyzed through self-assessments over a one-year period. This study may be valuable in identifying an effective intervention to reduce unhealthy alcohol use and related complications in this patient population.
CHAPTER 1—INTRODUCTION

1.1 Background

As obesity has become a major public health crisis in recent years, bariatric surgery has concomitantly gained attention as an effective and relatively safe procedure for severe obesity cases. In the United States, the number of bariatric surgeries performed per year nearly doubled between 2011 and 2018. These procedures have shown significant long-term weight loss and a reduction in obesity-related comorbidities and overall mortality. Of the various types of procedures, Roux-en-Y gastric bypass (RYGB) surgery is the most common bariatric surgery performed worldwide and in the United States. This procedure creates a gastric pouch from the stomach and directly connects it to the distal end of the small intestine. This promotes accelerated transit and emptying of ingested content into the small intestine, leading to a malabsorptive state for the patient.

Although known to be highly effective, bariatric surgery is associated with several serious complications, including the gradual development of alcohol use disorder (AUD) in a notable percentage of patients. A recent systematic review evaluating 49,121 bariatric patients in 18 studies reported a four-fold increase in prevalence of alcohol use disorder after surgery. Most studies report that RYGB has the greatest association with AUD among weight loss procedures.

This association between RYGB and AUD is most likely attributed to changes in alcohol pharmacokinetics due to anatomical alterations made to the gastrointestinal tract. A notable source of alcohol dehydrogenase in the stomach is bypassed after the surgery, which in turn, leads to less alcohol being metabolized in the stomach.
Ingested alcohol is more readily and quickly “dumped” into the circulatory system, causing rapid elevations in blood alcohol concentrations (BAC) and more profound effects of intoxication.

Studies found that BAC increased at a faster rate, peaked two-fold higher, and increased subjective feelings of intoxication and reward in RYGB patients compared to their baseline before surgery and when compared to other pre-operative patients. \(^{12-14}\) Peak BAC level achieved in RYGB patients after consuming ~2 drinks was almost equivalent to ~4 drinks in the control group. \(^{12}\) Patients could potentially meet the national criteria for engaging in an episode of binge drinking (i.e., \(\geq 5\) drinks for men or \(\geq 4\) drinks for women), a known risk factor for AUD, simply from consuming 1-2 drinks based on their BAC levels. \(^{15}\) Although these studies were conducted in a laboratory setting, these findings illuminate a physiological and quantifiable change that may explain this phenomenon.

Another somewhat controversial theory is the idea of “transfer addiction” or “cross addiction”. This theory postulates that patients can gradually transfer an addiction from one substance to another after bariatric surgery. A qualitative study found that patients felt they began to depend on alcohol to “fill a void” once they were unable to consume as much food as before. \(^{16}\)

Several risk factors have been identified, such as prior history of AUD and male gender, that predispose post-bariatric surgery patients to develop AUD. \(^{6,17}\) However, no clear guidelines have been produced to best address this issue. Screening criteria and health evaluations, as well as post-operative support and management vary at different institutions. \(^{2}\) It is imperative to not only identify patients at risk of
developing AUD through screening, but also to intervene at an appropriate time point to prevent recurrent AUD or the development of new onset AUD.

Screening, Brief Intervention, and Referral to Treatment (SBIRT) is an evidence-based clinical practice that has shown promising results to reduce alcohol consumption amongst individuals with at-risk alcohol use behavior or patterns.\textsuperscript{18,19} Although it is applicable to any type of substance, SBIRT is best established as an intervention for alcohol use. Once patients are screened and evaluated on their alcohol use and drinking behavior, they are categorized into low, moderate, and high risk depending on their gender and age. Those with “moderate”, “at-risk”, or “hazardous” drinking, all interchangeable terms, are identified as consuming alcohol above recommended limits. Guidelines for alcohol use vary by country; U.S. recommendations are outlined in Section 1.5. These at-risk patients receive a clinician-guided brief intervention (BI) that focuses on assessing a patient’s readiness to change and establishing a plan for potential reduction or abstinence in drinking patterns.\textsuperscript{20} BIs are often reinforced by follow-up visits that integrate motivational interviewing and reassessment of shared goals. For patients who meet diagnostic criteria for AUD, prompt referral to addiction services is provided. A 2012 meta-analysis report by the U.S. Preventive Services Task Force revealed that patients who had a brief intervention by a trained clinician decreased alcohol consumption by about 3.6 drinks per week.\textsuperscript{21}

This study will evaluate whether brief interventions as compared to treatment as usual will decrease alcohol consumption and frequency at 6 months from baseline among patients with at-risk alcohol use status-post RYGB.
1.2 Statement of the Problem

Several guidelines recommend preoperative screening and education regarding alcohol use. Active AUD is considered a contraindication for surgery. Patients with AUD are recommended to be referred to addiction treatment services and demonstrate alcohol abstinence for 1-2 years to achieve clearance for surgery. Adherence to these guidelines vary depending on the institution.

Despite the measures taken to limit alcohol use before surgery, a subset of patients develop new-onset AUD or relapse several years after surgery. On average, patients reported concern about their alcohol use 1.6 years (SD 1.62) from time of surgery. Growing evidence shows that this risk continues to increase with time. Furthermore, a study showed that although 93.1% of patients (n=528) recalled receiving alcohol education prior to surgery, more than half continued to drink afterwards. Most patients did not feel that complete abstinence was feasible, and preferred a harm reduction approach. These studies suggest that simply recommending or stating the long term risks of alcohol use after surgery is insufficient in this patient population.

The gradual development of AUD is concerning due to a lack of screening, education, and treatment guidelines to address this risk in bariatric surgery patients. During the first year, patients are closely monitored for adverse effects. However, these visits become less frequent after the first year, which is when most patients show signs and symptoms of unhealthy alcohol use. It is crucial to routinely screen individuals during this period and implement active intervention strategies to progression to AUD and reduce alcohol use to recommended limits.
1.3 Goals and Objectives

The goal of this proposed study is to evaluate the efficacy of personalized BIs on decreasing alcohol consumption from baseline in adult RYGB patients identified as at-risk for developing AUD. The primary objective is to assess whether two BI sessions will significantly decrease the mean number of drinks per week compared to baseline at 6 months after initial intervention session. Our secondary objective is to assess whether the effects of these interventions will continue to influence the mean number of drinks per week at 12 months. We will also observe a mean change in AUDIT score at 12 months from baseline to examine whether these interventions confer clinical significance.

1.4 Hypothesis

We hypothesize that among adult patients with no prior AUD history who screen positive for at-risk alcohol use following RYGB surgery, those who receive clinician-guided BIs will have a significantly decreased average drinking quantity and frequency by 6 months from baseline compared to those who receive standard of care.

1.5 Definitions

- National Institute on Alcohol Abuse and Alcoholism (NIAAA) definition of “standard” drink in the United States: one “standard” drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer (5% alcohol), 5 ounces of wine (12% alcohol), 1.5 ounces of distilled spirits (40% alcohol). 27
- Current NIAAA drinking recommendations in the United States: Men 21-65 years old consume no more than 4 drinks (56g) on any day or 14 drinks/week (196g/week). All women and men older than 65 years consume no more than 3 drinks (42g) on any day and 7 drinks/week (98g/week). 27
• At-risk/risky/hazardous alcohol use: Consumption above recommended levels or consumption that increases risk for health consequences. The amount of use is not above the threshold to meet the diagnostic criteria for AUD. However, these patients can potentially go on to develop AUD.\textsuperscript{18}

• Alcohol Use Disorder (AUD): A person with a problematic pattern of alcohol use with clinically significant impairment or distress, meeting at least 2 of the criteria listed in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) within a 12-month period.\textsuperscript{28}

• Brief intervention (BI): 10-15 minute personalized counseling sessions to increase the screened individual’s awareness of alcohol use and increase motivation to make changes to reduce unhealthy alcohol use. Clinicians utilize motivational interviewing techniques that employ the transtheoretical model of health behavior change to promote reductions in alcohol use.\textsuperscript{18}

1.6 References


CHAPTER 2—REVIEW OF THE LITERATURE

2.1 Introduction

A comprehensive literature review was conducted between June 2022 and May 2023 using online databases such as Cochrane, Pubmed, Ovid, and Scopus. Literature searches were performed using different combinations of key terms, such as: “alcohol use”, “alcohol use disorder”, “drinks”, “SBIRT”, “brief interventions”, “bariatric surgery”, “weight loss surgery”, “screening guidelines”, “Roux-en-Y”, “RYGB”, “alcohol-related complications”, “alcohol overconsumption”. Search results were sorted and prioritized based on title, abstract review, and date of publication. Additional references were found using reference lists of systematic reviews and meta analyses. Literature included in the comprehensive review are written in English.

2.2 Review of Empirical Studies

2.2.1 Prevalence of Alcohol Use in Bariatric Surgery Populations

Several studies conducted in the United States and internationally collectively point to a statistically significant association between bariatric surgery and increased alcohol consumption. Regardless of the differences in study designs, methods, analysis, timeline, and sample size, there is strong empirical evidence that demonstrates an increased risk of AUD following bariatric surgery. One study found that 53.9% of patients consumed alcohol regularly one year after surgery, and this rate increased to 63.2% at 2 years. ¹ This steady increase in regular alcohol consumption is observed in conjunction with an increase in patients who develop AUD symptoms. These changes in alcohol use patterns typically appear several years after surgery and continue to increase temporally. Among the different types of bariatric surgery, RYGB surgery is associated with the highest risk for developing AUD. ²
The most recent systematic review\(^3\) in 2021 included 18 original English and Spanish papers (n=49,121) to investigate the prevalence of AUD in preoperative vs. postoperative periods and differences in types of surgery. Data extraction was limited to a range of 2-6 years after surgery. Results showed high variability in odds ratio [between 0.24; 95% CI:0.09-0.68 and 19.98; 95% CI:1.15-345.88] most likely due to a diverse range of methodologies in studies. An increased prevalence in AUD after surgery was noted in 9 of the 11 studies that investigated different types of bariatric surgeries, including RYGB. Prevalence of AUD was 1.58 ± 10.7% before surgery, 4.58 ± 5.3% after surgery, and 1.11 ± 0.25% in control subjects without surgery. Eight of 10 studies exclusively analyzing RYGB patients noted an increased risk with an OR of 1.40 [95% CI: 1.06-1.85]. The weighted mean difference of the OR for RYGB compared to other bariatric surgeries was 1.83 [95% CI: 1.51-2.21]. The meta-analysis from this review found a pooled OR of 1.852 and a statistically significant increase in AUD three or more years after surgery, especially after RYGB. Overall, this systematic review strengthened findings from prior systematic reviews by including newly published trials. A limitation of this review is the exclusion of recent papers that expressed prevalence as hazard ratios and review of several papers that did not include control groups in their studies.

Several rigorous prospective and longitudinal studies with large sample sizes investigated alcohol use before and after bariatric surgery. The Longitudinal Assessment of Bariatric Surgery (LABS-2) study, which is one of the most frequently referenced, was a prospective observational cohort study conducted at 10 hospitals across the United States from 2006 to 2015.\(^4\) Adult RYGB or laparoscopic adjustable gastric banding (LAGB) patients (n=2,003) self-reported AUD symptoms, illicit drug use, and any substance use disorder treatment before and after surgery annually for up
to seven years. This study revealed several important findings on the prevalence of regular alcohol consumption and AUD over time, incidence rates, and risk factors.

Over 7 years, the prevalence of regular alcohol consumption doubled in both RYGB and LAGB patient populations. AUD in RYGB patients increased from 6.6% at baseline [95% CI, 5.3-7.9] to 16.4% after surgery [95% CI, 14.1-18.7, p<0.001]. On the other hand, AUD in LAGB patients remained at around 6-8% during the study period. This contrast between surgeries is also reflected in the incidence rates. In the fifth year of the study period, the cumulative incidence of AUD was 20.8% [95% CI, 18.5-23.3] for RYGB and 11.3% [95% CI, 8.5-14.9] for LAGB patients. Overall, RYGB was found to be strongly associated with double the risk of incident AUD [AHR 2.08; 95% CI, 1.51-2.85] after controlling for potential confounders. This study’s large and diverse sample size along with its longitudinal design strengthens these findings and increases generalizability.

A nationwide prospective cohort study in Denmark identified all citizens who underwent bariatric surgery between 2005 and 2013. Of the entire census, 13,430 adult bariatric surgery patients (95% RYGB) were referenced with 21,021 control non-surgery patients and followed for a median time of 6.9 years. Results indicated a significantly higher risk of AUD in the bariatric surgery population compared to the control group at <1 year, 1-5 years, and >5 years. Similarly, the study found that the risk increased over time, with the highest hazard ratio occurring more than 5 years after surgery [HR 12.1, 95% CI: 7.79-18.7]. Results from these large-scale papers cumulatively show that the risk of onset of alcohol-related problems begins around 1-2 years after surgery, and continue to increase as a function of time. This study along with the LABS-2 study corroborated this increased risk with a large sample size and longitudinal design. Some limitations should be noted, such as the lack of a
control group and grouping of incident cases, which makes it difficult to distinguish de novo and recurrent AUD.

Another long-term prospective project called the Swedish Obese Subjects (SOS) study followed 2,010 surgical adult patients (68% vertical banding gastroplasty, 19% banding, 13% RYGB) and 2,037 control subjects for 8-22 years. These groups were matched based on 18 variables related to demographics, comorbidities, and substance use behaviors. Patients underwent physical examinations and completed health and lifestyle questionnaires at matching, baseline, and at ten time points over a 20 year period. At baseline, mean alcohol consumption, self-reported alcohol problems, and prevalence of medium risk alcohol consumption did not differ between groups. Follow-up results showed that the proportion of individuals with at least WHO medium risk alcohol intake was always highest among gastric bypass surgery patients [unadjusted HR 2.63; p<0.001, adjusted HR 2.69; p<0.001]. The gastric bypass group had the highest adjusted hazard ratio for AUD diagnosis during any hospital admission during the study period [4.97; p<0.001]. Overall, this study revealed that gastric bypass and vertical banding gastroplasty patients had an elevated risk of alcohol abuse diagnosis and at least medium risk of alcohol use when compared to control subjects. No increased risk was observed in gastric banding patients. Consistent with other studies, this study notes that in the first year, there is a decrease in alcohol consumption but continues to climb 2 years from time of surgery. The study concludes that although there is an increased risk, 93.1% of the surgery patients reported low risk alcohol use, and therefore the benefits of bariatric surgery outweigh the potential risks. The limited exclusion criteria and use of a nationwide cohort may make these results more generalizable to other populations. Patients were also followed for over two decades, which allowed for close monitoring of long-term
effects. Limitations included some baseline differences between groups, exclusion of outpatient clinic data leading to potential underestimation of incidence, and the use of self-reported data.

While most studies focus on prevalence of AUD, a recent cross-sectional paper shed light on the prevalence of at-risk alcohol use in this population. Patients up to 4 years post-RYGB or sleeve gastrectomy surgery were surveyed on their alcohol use. Before surgery, only 2.5% (n=14) screened positive for at-risk alcohol use. After surgery, 57.5% of participants reported alcohol consumption and 72.5% within the past month. Among those who were regularly drinking, 16.1% fit the NIAAA criteria for at-risk alcohol use. Hazardous drinking rates were highest in patients 3-4 years post-surgery (33.3%, p <0.01) with no significant differences between surgery types. Much like the findings on prevalence of AUD, at-risk alcohol use seems to develop in a similar trend. The prevalence of regular and at-risk alcohol consumption increases after surgery and over time. One in three patients who were 3-4 years from surgery had hazardous drinking habits in contrast to a 6% prevalence rate found in the general population.

2.2.2. Incidence of New Onset Alcohol Use Disorder

Patients with no discernable risk factors, such as a prior history of AUD or other substance use disorder (SUD), have also been found to develop de novo AUD after bariatric surgery. One study found that 93.6% of patients met criteria for at-risk drinking despite having no history of hazardous alcohol use prior to surgery. Several studies that focused more broadly on SUD with included measures on alcohol use have investigated new onset cases.

A retrospective study conducted at Brighton Hospital’s drug and alcohol rehabilitation center evaluated bariatric surgery patients from a sample of patients
receiving substance use treatment. Among the 56 patients included in the study, 34 developed an SUD after bariatric surgery. Data collection relied on semi-structured interviews and electronic medical records. Patients participated in a 30-60 minute interview about their pre-surgical screening process and the timeline of regular alcohol use, tobacco smoking, and illicit substance use (i.e. cocaine, heroin, opioids). Results showed that 2.8% (n=129) of admitted patients had a history of bariatric surgery (90.6% RYGB). 68.8% of these patients were diagnosed with AUD and were significantly more likely to have AUD than those without this surgical history \( \chi^2 = 7.41, 1, n=45658, p <0.01 \). New onset SUD cases on average appeared at a later age than those with prior SUD history \( \bar{X}=32.72, SD =13.23 \) vs. \( \bar{X}= 41.35, SD =9.94, t(49) = -1.72, p <0.05 \) and took about 1.6 years (SD 1.62) after surgery for patients to note concerns about their substance use patterns. There were no significant differences in the average number of drinks per drinking day between prior history or new onset patients. Interestingly, this study shows that patients who had a prior SUD history were not using substances for an average 9.18 years (SD 8.37) before their procedure. As with some retrospective study designs, there is risk of recall bias. Some other limitations are the smaller sample size and generalizability, given the sample consisted of admitted patients seeking substance use treatment. These findings may not apply to those who exhibit at-risk or hazardous drinking and are not reaching the threshold for treatment referrals. Regardless, this study corroborates evidence from other studies.

Another retrospective study based in the U.S. queried deidentified patient data from The Diamond Network of the TriNetX Research Platform to assess new onset cases of SUD amongst bariatric surgery patients up to two years post-operatively. It also compared this rate to incident SUD rates in a general population cohort and
another cohort of obese patients without surgical intervention. Current Procedural Terminology (CPT) codes for RYGB, sleeve gastrectomy, gastric banding were included in the search along with ICD-10 codes for alcohol, opioid, nicotine, cannabis, and “other”. 6.55% (n=2,523) of surgery patients were identified to have newly developed SUD. Nicotine dependence had the highest frequency amongst the different substances (3.66%, n=1411). Interestingly, when considering the different surgeries and substances, this study states that bariatric patients had a decreased risk of newly diagnosed SUD compared to the general control population [OR 0.89; 95% CI, 0.86-0.93] and obese population [OR 0.65; 95% CI, 0.62-0.67]. However, when evaluating different surgery types, this study agrees with prior studies that show RYGB patients have an increased risk of incident AUD when compared to the general population [OR 1.36; 95% CI, 1.16-1.59]. The positive association in this study developed at an earlier timeline than other studies that state AUD symptoms start roughly after 2 years. While this study corroborates that RYGB patients have an increased risk of newly developing AUD, there may be risk of sample bias and misclassification error with the database. Another notable limitation is that the subjects were not matched for confounding variables, which could skew the true association.

Another U.S. study compared incidence rates of hazardous drinking in sleeve gastrectomy (SG) patients versus RYGB patients over a 2 year period along with risk factors associated with each.Researchers utilized prospective, patient-reported data from the Michigan Bariatric Surgery Collaborative (MBSC) registry that includes 95% of Michigan state patients who had bariatric surgery. Baseline AUDIT-C scores were collected for 4,718 SG patients and 1,006 RYGB patients and reassessed at 1 year and 2 years postoperatively (24.1% follow up rate). The prevalence of AUD
symptoms in RYGB patients increased from 7.6% to 11.9% by the end of the study (p=0.02). At the 1-year time point, there was an insignificant and minimal increase (0.54%) in patients with new onset AUD. At 2 years, the proportion of those with new onset AUD substantially increased to 7.2%. This pattern was similar in the SG population. Overall, this study showed that new onset AUD may develop similarly in RYGB and SG surgery populations.

While most studies underscore the increased risk of AUD after weight loss surgery, a few studies report contradictory findings. The Assessment of Bariatric Surgery (ABS) Study found that more than half of patients who originally had high risk alcohol use before surgery no longer reported high risk drinking behavior after bariatric surgery. This study is limited in generalizability as patients were recruited from a single geographic location and one third of patients were subsequently lost to follow up. Another study found that more than one year after RYGB surgery, overall alcohol use significantly decreased by 9.1% in patients who had baseline consumption. However, there are notable weaknesses to this study, such as a low attrition rate of 38%, small sample size, lack of a standardized and validated alcohol screening test, and an ambiguous range of the post-operative period (simply defined as more than 365 days). These limitations warrant more longitudinal studies with diverse and larger sample sizes to support these findings.

2.2.3 Alcohol Screening and Brief Interventions for Adult Patients

Screening, Brief Intervention, and Referral to Treatment (SBIRT) is a systematic public health approach that identifies and delivers early interventions or referral to treatment to individuals with an increased risk of SUD. Those diagnosed SUD are offered brief treatment and/or referred to substance use treatment programs. Those with at-risk substance use are provided brief interventions, which involve brief
advice incorporating motivational interviewing approaches. The SBIRT model actualized in the 1980-1990s to address growing concerns of substance and alcohol use in the U.S and worldwide. At the time, there was a lack of preventative measures set in place and only individuals with severe symptoms were treated. This unified effort from various organizations such as World Health Organization led to the development of several validated screening tools for alcohol and drug use. Although it was originally designed for use in primary care, SBIRT is now widely utilized in a variety of healthcare settings, such as emergency care departments.

The most comprehensive and well-vetted systematic review on SBI and alcohol use in adults and adolescents was conducted by the U.S. Preventive Services Task Force (USPSTF) in 2018. This report included 113 studies (n=314,466) in its analysis of the benefits and harms of SBI to “reduce unhealthy alcohol use in nondependent alcohol users in primary care-relevant settings or in other general populations judged to be comparable to primary care populations.” The review included RCTs and non-RCTs with comparison groups, adolescent, or adult populations, use of validated screening tools (AUDIT, AUDIT-C, SASQ, etc.), and reported alcohol use as an outcome with a minimum of 6 months for follow up. Sixty-eight trials (n=36,528) were specifically chosen for evaluating the efficacy of brief interventions in participants with at-risk alcohol use, 29 of which addressed the general adult population (n=16,944). Although brief intervention duration and frequency varied between studies, most involved 1-2 sessions with a median of 30 minutes per session with personalized normative feedback, drinking diaries, and action plans. Across all populations, brief interventions were associated with an average decrease of 1.6 drinks per week from baseline [WMD -1.6; 95% CI, -2.2-1.6]. The general adult population studies found a weighted mean reduction in 2.51
drinks per week [WMD -2.51; 95% CI, -3.81-1.21]. The mean number of drinks per week in treatment groups decreased from 26.0 to 19.1 drinks at follow-up versus 25.6 drinks at baseline to 21.6 drinks in control groups. Furthermore, brief interventions led to a 14% absolute increase of participants meeting criteria for at-risk drinking to reduce alcohol use within recommended limits [NNT 7.2; 95% CI, 6.2-11.5]. While the effect of these brief interventions was sustained for 6 to 12 months in most studies, there is variable data on whether BI has long lasting impact. Four trials showed treatment benefits sustained for 2\textsuperscript{17-19} to 3 years\textsuperscript{20}, while other studies contradicted these findings with no significant differences between treatment and control groups at 2 to 4 years.

Although this systematic review corroborates the effect of brief interventions, there is heterogeneity of effect size for this primary outcome between the 2018 USPSTF report that included newer studies [WMD -0.77; 95% CI, -1.24 to -0.30] and the previously published 2013 USPSTF report [WMD -2.83; 95% CI, -3.89 to -1.76]. This discrepancy is most likely explained by older studies having smaller sample sizes and including participants with heavier alcohol use patterns. The effect size, however, was not affected by intervention design, study quality, loss to follow up, or variations in baseline characteristics.

Project Trial for Early Alcohol Treatment (TrEAT) was the first large scale RCT in the U.S. that examined brief interventions for reducing alcohol overconsumption. This study screened 17,695 adult patients (ages 18 to 65) in 17 primary care clinics in 10 Wisconsin counties.\textsuperscript{17} “Problem drinking” was defined as more than 14 drinks/week in men and more than 11 drinks/week in women. 382 participants were randomized into the control group and 392 subjects in the treatment
group, with no statistically significant differences between groups at baseline regarding covariates such as age, smoking status, socioeconomic status. Those allocated to the treatment group were delivered two 15-minute counseling interventions scheduled one month apart. Each patient also received follow up phone calls two weeks after each in-person session. These interventions utilized a workbook with feedback and patient education, worksheet, drinking diary cards. Of the various outcomes collected at 6 months, this study found that among the 93% of participants who completed follow up, the mean number of drinks in the past 7 days were reduced from 19.1 to 11.5 in the experimental group vs. 18.9 drinks to 15.0 drinks in the control group ($t=4.10, p<0.001$). This decrease was also sustained at 12 months. By the end of the follow-up period at 1 year, a 40% reduction was noted in the treatment group compared to the 18% reduction in alcohol consumption for the control group. This study has several strengths, such as a large and diverse sample size from rural and urban settings utilizing community-based providers. One point to note is that the recommended NIAAA drinking limits today remains at 14 drinks/week for men but decreased to 7 drinks/week for women. This difference in the drinking recommendation may have under-screened women with at-risk drinking patterns.

SBI is feasible and effective in catering to subpopulations with a known increased risk of alcohol consumption similar to the bariatric surgery population. One example is the Sexual Health and Excessive Alcohol (SHEAR) study published in London that recruited adult patients from a sexual health clinic. Researchers screened 802 eligible patients using the Modified-Single Alcohol Screening Question (M-SASQ), which has the same recommended drinking limits as our proposed study. 402 patients allocated to the intervention group received 30 minutes of individual counseling using the FRAMES approach, while 400 patients received a general health
information leaflet. At the 6-month follow-up, those who were randomized to receive BI drank an average 2.3 units (18.4g) of alcohol less per week [AMD -2.33; 95% CI, -4.69 to 0.03]. This reduction may not be clinically significant when converted to number of standard drinks. This may in part be due to a 26% loss to follow-up and a single session of BI. Regardless, this trial demonstrates that one session of patient-centered counseling can positively impact alcohol consumption.

2.3 Review of Studies to Identify Possible Confounding Variables

Post-bariatric surgery alcohol use and overconsumption is most likely multifactorial. The most referenced risk factors were baseline alcohol use or AUD history, RYGB surgery, male gender, and younger age. These confounding variables are important to identify to effectively randomize patients in our study and subsequently strengthen internal validity.

Baseline alcohol consumption and AUD are strong risk factors for AUD development after bariatric surgery. Even with occasional alcohol use, simply consuming alcohol prior to surgery conferred a 3-fold risk of AUD [AHR 2.95; 95% CI, 2.17-4.03] and an even higher 13-fold risk with regular alcohol use [AHR 12.68; 95% CI, 8.34-19.26]. Of the entire sample, 8.3% of the total participants exhibited hazardous drinking and had higher baseline alcohol consumption frequency (OR 7.53, p<0.001) and quantity (OR 1.42, p=0.001). People who consumed alcohol after surgery had consumed alcohol more frequently (OR 2.43, p>0.001) and in larger quantities (OR 1.69, p<0.001) before surgery. A rural study evaluating 899 RYGB patients before and after surgery through self-administered surveys showed that as preoperative alcohol quantity rose, the odds of consuming any alcohol after surgery increased 6.4 fold [OR 6.36; 95% CI, 3.09-
Another study\textsuperscript{23} observed a similar 6.37 fold increase in postoperative AUD for patients who reported baseline regular alcohol consumption of 2 or more drinks per week. These findings highlight the importance of tracking average number of drinks per week as an outcome measure.

Those with preoperative AUD were more likely to relapse into postoperative alcohol use or AUD.\textsuperscript{25} Suzuki et al.\textsuperscript{2} enrolled and interviewed 51 patients who had undergone RYGB or LAGB surgery at least in the past two years. 10\% of the participants, notably all RYGB surgery patients, developed active AUD 2-5 years after surgery; 83.3\% of these individuals had a lifetime history of AUD. Findings also showed that even if patients with prior AUD were not actively drinking at the time of surgery, this risk factor alone conferred a higher risk of alcohol use afterwards. A study by King and colleagues\textsuperscript{23} found that 62.3\% of the bariatric surgery patients who had preoperative AUD continued to have recurrent AUD within the first two years after their procedure. A retrospective cohort study that tracked a quantitative alcohol biomarker in 410 bariatric patients also found that prior AUD history conferred an increased risk of alcohol overconsumption [OR 3.57; 95\% CI, 1.10-11.54, p=0.034]. This evidence supports that patients with any pre-surgical alcohol use or AUD should be closely monitored after the procedure.

Among the different types of bariatric surgery, RYGB has been found to be the most strongly associated with the development of AUD. Most studies evaluating this association compared RYGB surgery with adjustable gastric banding, a type of restrictive surgery, and sleeve gastrectomy. A retrospective cohort study with 11,115 post-bariatric surgery patients (RYGB, vertical banded gastroplasty, gastric banding) from nationwide bariatric surgery hospitals in Sweden focused on the relative risk of
inpatient care for alcohol problems. Researchers used the Swedish Patient Register to collect the number of hospitalizations associated with diagnoses such as AUD. Before surgery, there was no difference in inpatient treatment for alcohol use between patients who underwent RYGB or restrictive surgeries [incidence rate ratio 1.1; 95% CI, 0.8-1.4]. After surgery, those who underwent RYGB had double the risk of hospitalization for alcohol use when compared to those who had restrictive surgeries [HR 2.3; 95% CI, 1.7-3.2]. The higher risk of alcohol-related hospitalizations associated with RYGB may be explained by this procedure having the greatest physical and metabolic alterations. Conversely, gastric banding is purely anatomical, minimally invasive, and completely reversible, and thus has minimal effect on the body’s metabolism. While some studies have demonstrated an increased risk of AUD with sleeve gastrectomy, this risk is often less significant than that associated with RYGB.

Despite 70-80% of bariatric surgery patients being female, strong evidence shows that male gender is a significant risk factor for post-surgical AUD. Being male confers almost double the risk of AUD. This risk factor is not specific just to this population. Globally and in the U.S., men consume alcohol more frequently and almost three times as much per year than women. Younger preoperative age is cited commonly as a risk factor in the same studies. A study by Siikaluoma et al. contradicts this by concluding that older age is a risk factor, although this association is minimal [OR 1.06; 95% CI, 1.03-1.09].

2.4 Review of Relevant Methodology

We referenced different study designs and methodology from prior studies when designing this current study. We chose to adopt methods that showed high
quality of evidence and minimal bias. Our priority was to design a rigorous and replicable study that was also feasible in terms of resources and time.

2.4.1 Alcohol Use Disorders Identification Test (AUDIT) as Screening Tool

A validated screening tool is essential for recruiting a representative sample population from our population of interest. Our study will use the most widely utilized Alcohol Use Disorders Identification Test (AUDIT) as our screening tool of choice. This test is a 10-item questionnaire created by the World Health Organization that gauges alcohol consumption, alcohol-related problems and symptoms of dependence. The original purpose of AUDIT aligns with the goal of our study in that it focuses on identifying and targeting those with hazardous alcohol consumption who do not have physical dependence to alcohol. A systematic review analyzed 45 studies that studied the accuracy of different screening instruments, including AUDIT. When the cutoff score was set to an AUDIT score of 8 or higher in the general adult population, the sensitivity ranged from 0.38 to 0.73 [95% CI, 0.33-0.84] but reported a high specificity of 0.89 to 0.97 [95% CI, 0.84-0.98]. Overall, the AUDIT along with the AUDIT-C, which is a condensed three-item version of the AUDIT, and SASQ were deemed to have the best evidence for use.

2.4.2. Brief Interventions (BI) Description

One of the most important elements of this study is the description and characterization of the “Brief Intervention” (BI). Current literature varies considerably in the type of BI, duration of each session, frequency of sessions, and provider delivering the intervention. Our study will implement two 10-15 minute BI sessions integrating motivational interviewing strategies that are mainly delivered by advanced practice providers (APPs) and physicians not specializing in addiction treatment.
Alcohol BIs are patient-centered collaborative efforts that aim to increase awareness, motivate patients to change consumption patterns, and/or adopt a different mindset regarding unhealthy alcohol use. They primarily focus on a particular behavior or attitude towards a subject, such as alcohol use, and recommend a specific change. Regardless of the length of intervention and number of sessions, a systematic and consistent approach to each session is important. In 1993, six key elements of a BI were identified and named the FRAMES approach: feedback, responsibility, advice, menu of strategies, empathy, and self-efficacy. After the patient is screened and identified as having unhealthy alcohol use, they are provided feedback about their personal risk level. Responsibility for change is verbally reinforced to the patient, along with the provider’s advice to change. The provider offers a “menu” of options or strategies to supplement the change. The provider and patient will deliberate together and set a realistic goal for behavior change. Providers are reminded to be empathetic when counseling and to encourage the patient to practice self-efficacy and optimistic empowerment. At follow-up BI sessions, the patient’s progress is monitored and goals are revisited if needed. We adopted the FRAMES approach in our study because it is SAMHSA-endorsed and used in a majority of studies.

BIs are distinguished from “extended interventions”. BIs are typically delivered over one to four sessions that are generally 5-15 minutes long, and no more than two hours total. Extended interventions are anything beyond these criteria. A systematic review found that extended interventions did not have greater impact than BIs [MD 2g/week; 95% CI, -42 to 45]. However, evidence for this was low considering this was data collected from only three studies. An RCT randomized 301 adult patients into three groups: brief advice (BA), motivational enhancement
(ME) or standard care (SC). ³⁴ The BA intervention was one 10-15 minute session that is similar in structure to the BI in our study. The ME intervention was one longer (30-45 minute) session with two shorter (15-20 minute) reinforcement sessions, which fits into the category of an extended intervention. The SC group received limited feedback on their screening assessment but did not receive an intervention. Results showed that all groups reduced alcohol use at 6 months and 12 months post-assessment. Since there is no definitive evidence that longer counseling sessions are warranted and more effective, our study will utilize brief interventions. These interventions are more cost-effective and feasible in terms of total time needed for patients and providers.

2.4.3 Alcohol Timeline Followback Interview (TLFB)

Self-reported assessments of alcohol consumption are easy to implement and cost effective. One way to address the concern of reliability and validity with self-reports is the use of cognitive processing methods. Timeline Followback (TLFB) is an evidence-based approach for assessing and collecting retrospective information on daily drinking or recent alcohol use. ³⁴ During the interview, researchers ask respondents to recall their drinking on a daily basis over a period of time while looking at a calendar. This memory aid, along with others such as a standard drink-conversion card, is used to improve cognitive processing and aid in information recall. ³⁵ Reliability coefficients on test-retest reliability studies with different populations displaying a spectrum of alcohol use was consistently above 0.85, which underscores a good level of consistency. ³⁶ In our proposed study, research personnel not involved in the brief interventions will collect information on alcohol use at baseline, 6 months, and 12 months using the TLFB method. We will set the timeline to alcohol use in the previous 90 days as studies have shown that this window is sufficiently representative.
of annual pre-treatment and posttreatment drinking for individuals with at-risk alcohol use. Furthermore, a shorter versus longer recall timeframe decreases participant attrition and requires a shorter time (10 minutes) needed for interview.

2.5 Conclusion

Evidence shows that bariatric surgery populations are at risk of developing AUD after surgery, especially for those who undergo RYGB. This risk is heightened in patients who are male, younger, and have a prior history of AUD or baseline alcohol consumption. Studies reveal that brief counseling interventions are effective in reducing average number of drinks consumed per week in different populations and settings. These BIs vary in some aspects, but overall aim to motivate and guide patients to make behavioral changes using the FRAMES structure. These interventions can potentially lower healthcare costs and significantly decrease the number of alcohol-related problems in this patient population.

2.6 References


29. Center for Substance Abuse T. SAMHSA/CSAT Treatment Improvement Protocols. *Brief Interventions and Brief Therapies for Substance Abuse*. Substance Abuse and Mental Health Services Administration (US); 1999.


CHAPTER 3—STUDY METHODS

3.1 Study Design

This experimental study will be a two-arm, parallel group RCT that investigates the effects of BIs on status-post RYGB patients who screen positive for at-risk alcohol use. The study will be conducted over a two-year period that includes time needed for site and clinician training, patient evaluation and recruitment, interventions, and follow up assessments. Clinicians, including physicians, physician associates, and advanced practice registered nurses, will participate in training workshops provided by SAMHSA funded SBIRT training programs. Training sessions for all clinicians will include standardized presentations and scripted workbooks (Appendix D). Providers will practice patient-centered scenarios with the FRAMES motivational interviewing guide (Appendix E). They will also be instructed on important patient information to deliver, such as changes in alcohol metabolism after surgery and criteria for hazardous drinking.

Patients who have had RYGB surgery in the past year at time of recruitment will be given a generalized health screening survey at their usual visit. This survey will include AUDIT questions along with questions about nutrition, exercise, and substance use (Appendix A). Those who screen positive for at-risk alcohol use (AUDIT score of 8-15) and meet inclusion criteria (see Section 3.2) will be invited to participate in the study. Participants will then be enrolled with written consent (Appendix G). Baseline characteristics, such as age, comorbidities, alcohol quantity and frequency in the past 90 days, will be assessed and collected by research staff independent of clinical care. This information will be recorded in an encrypted database that is shared between all participating sites. A data analyst will then
randomize patients to the intervention or control arm using block randomization software.

Subjects assigned to the control or “standard of care” group will receive results from the screening survey and a general health booklet. They are not provided with any specific counseling or feedback. Patients will be advised to continue with their regularly scheduled post-op visits and told to speak with their providers if any general health concerns arise. Participants assigned to the intervention group will be given screening survey results, the general health booklet, and receive two clinician-guided brief intervention sessions. The first intervention session will take place between 2-4 weeks from enrollment in the study. The second intervention session will be scheduled between 3-4 months from study enrollment. These two intervention sessions are scheduled in conjunction with their regularly scheduled visits to improve adherence. All patients will be contacted by independent research personnel about their alcohol use in the prior 90 days at the 6 month and 12 month time points using the TLFB method. Research personnel will be blinded to patient assignment.

3.2 Study Population and Sampling

This trial is interested in a subset of post-bariatric surgery patients who undergo Roux-en-Y. It will be conducted at academic bariatric surgery centers in urban settings across all five regions of the United States (Northeast, Southeast, Southwest, Midwest, West). We anticipate affiliations with two centers in each region. Each center will be evaluated to ensure quality of care and follow-up rates before the start of the study. Any adult RYGB patient who has had surgery in the past year will be asked to complete the AUDIT and general health questionnaire as a component of routine care. Those who screen positive for at-risk alcohol use will then be informed of the study and actively recruited. After obtaining written consent, the
patient’s information and baseline characteristics will be entered into the database and randomized.

Inclusion criteria will be English speaking adult patients (18-64 year old) who have undergone RYGB within the past year and have not had a prior history of AUD. Pre-surgical regular alcohol consumption within recommended limits or at-risk alcohol use status that resolved on its own are acceptable for inclusion. AUDIT score at time of screening must be between 8-15 points. This study excludes patients who have low risk (less than 8) and those with alcohol dependence (greater than 15 points). We will continue to recruit until we reach our target sample size (see Section 3.6.6) with consideration for attrition rates.

3.3 Subject Protection and Confidentiality

Before initiating this trial, we will submit an application and obtain approval for our protocol for research on human subjects from the Institutional Review Board (IRB) at Yale University. Yale Human Research Protection Program (HRPP) resources were referenced when constructing the informed consent form and protocol. Our informed consent form includes an explanation of the purpose of the study, patient participation expectations, risks and benefits, measures to protect confidentiality, and the right to withdraw from the study at any point. Research investigators will be present and available at time of consent and throughout the study to answer questions or concerns. We anticipate minimal risk with enrollment in the trial. All patient protected health information (PHI) will be secured in the electronic health record system. Only providers directly responsible for the patient’s care and brief interventions will be allowed access to medical records. Each patient will have a generated unique patient identifier (UPI) that will be utilized during the
randomization process to protect confidentiality. Investigators will use these identifiers to contact patients during follow up and data collection.

3.4 Recruitment

Participants will be recruited during routine post-operative visits. Most bariatric surgery patients are closely followed with multiple visits (usually 4-6) during their first year to monitor labs, diet, weight changes. Failure to follow up care after surgery has been linked with more postoperative complications and surgery related morbidity. It is a standard of care to highly encourage all patients to continue with their visits. The first visit is normally scheduled 2-3 weeks after surgery, followed by another visit a few weeks after to transition into a more solid diet. Patients are then usually scheduled for a visit every 3 months until the first year mark. At this time point, these patients are scheduled for follow ups annually for an indefinite period. Given the frequency of visits during this timeline, we anticipate that aligning the BIs with these already necessary visits will increase patient participation and adherence. A larger pool of patients can also be eligible for recruitment during this time frame. We anticipate that recruiting participants and providing brief interventions during this critical period of transition will have a lasting positive effect on lifestyle habits, especially alcohol use.

3.5 Study Variables and Measures

The independent variable in this study will be the structured BIs. These 10-15 minute in-person intervention sessions will be interactive and personally tailored to the patient’s needs. During these sessions, clinicians utilize motivational interviewing techniques that employ the transtheoretical model of health behavior change. These interventions are structured according to the FRAMES approach that is outlined in
Chapter 2. The first intervention may include setting goals depending on the patient’s readiness to change. During the second intervention session, the patient and provider can revisit these goals together.

The primary dependent variable is a continuous variable (number of drinks per week at 6 months from baseline). The secondary outcome will be evaluation of number of drinks per week at the conclusion of the study at 12 months. Another secondary outcome will measure a change in AUDIT score from baseline at 12 months. Average number of drinks per week will be calculated with the TLFB information extracted during follow-up interviews at 6 months and 12 months. During the 12 month follow up session, the investigator will also ask additional AUDIT questions and measure a new AUDIT score (Appendix F). The control variable will be standard of care. Patients in the control group will complete a screening test at the initial visit and receive their results. However, they will not receive additional counseling. They will be interviewed at 6 month and 12 month time points with the same questions as the treatment group.

3.6 Methodology Considerations

3.6.1 Blinding of Intervention

This study will aim to partially blind patients, providers and investigators given the difficulty of triple-blinding RCTs that study behavioral interventions. Patients are not informed of the study prior to taking the health survey. They will be told that the questionnaire is to evaluate general health and lifestyle patterns to minimize reporting bias in alcohol use. Alcohol use will also be assessed by the researchers prior to assignment of intervention. Patients will be informed of the study details after eligibility screening.
Clinicians and staff involved in patient management will be blinded to the patient’s assignment status. Each clinician will only be informed of the patients that they are specifically assigned to deliver brief interventions. Providers will be unaware of patients allocated to the control group. Clinic staff members will also be blinded to the patient’s assignment as the brief interventions will occur during routine visits. These measures will minimize any potential impact on the patient’s post-operative care.

3.6.2 Blinding of Outcome

Most importantly, this trial will ensure blinded assessment of patient outcomes. Research investigators are not directly involved in patient care and interventions. Assignment status will be concealed to those interviewing the patients on their alcohol use. Patients will be instructed at the beginning of the interview not to reveal their assignment status. Researchers will also rotate through the list of patients at 6 months and 12 months to ensure that they do not interview the same patient twice. This will help avoid interviewer bias, similar to Project TrEAT. 5

3.6.3 Assignment of Intervention

Baseline patient information and demographics from all participating sites are entered into a single pooled database. A randomization software, such as RRApp 6 or the Random Allocation Software 7, will use a stratified randomization technique to allocate patients from each center into a 1:1 parallel intervention or control arm while accounting for covariates such as gender.

3.6.4 Adherence

Patients assigned to the treatment arm are encouraged to participate in both brief interventions and follow up interview sessions. Patients in the control group are
encouraged to continue attending post-operative visits and interview sessions. All patients will be compensated for their time with a $15 Amazon gift card at both 6 months and 12 months. Patients will be reminded of upcoming visits with texts and phone calls from the clinic. If patients are unable to attend a session due to personal or health-related issues, these visits may be rescheduled to fit within the timeframe. Treatment patients who do not receive two total brief interventions will be excluded from the study. Attrition rates at both follow-up interview sessions will be noted.

3.6.5 Data Collection

This study will mainly rely on self-reported assessments for outcome measurements. Patients will fill out the general health questionnaire privately in the clinic waiting room. AUDIT questions and survey results will be recorded subsequently to assess eligibility. The patient’s electronic medical health record will also be reviewed to ensure the patient has no prior ICD codes or diagnosis of AUD. Those who fall within the 8-15 point range will be informed of the study and recruited for enrollment. Additional baseline characteristics will be collected through the interview or electronic health records.

Primary and secondary outcome measures will also be self-reported assessments collected through phone or video interviews. As detailed before, TLFB techniques will assist patients in recalling alcohol use.

3.6.6 Sample Size Calculation

Our sample size calculation is based on Project TrEAT\(^5\) because of its similarity in study design and primary outcome measure. The trial was a two-arm, parallel group RCT conducted in the United States that found that at 6 month follow up, participants who received a brief intervention consumed an average of 11.57 +/- 10.94 drinks in the
past week whereas participants with usual care drank an average of 14.98 +/- 11.12 drinks in the past week. Using a calculated Cohen’s $d$ of 0.309, a 2-sided significance level of 0.05 ($\alpha$), powered at 80%, our study will need a sample size of 332 participants. This would mean 166 participants would be in the intervention group and 166 participants would be in the control group. In anticipation of 7% loss to follow up, we will obtain a sample size of 356. 178 participants will be in the intervention group and 178 participants will be in the control group.

3.7 Analysis
A Chi-square test will be used to analyze categorical variables while a t-test will be used to analyze continuous variables at baseline between intervention and control groups. This study will use an intention-to-treat analysis for all participants. A student t-test will be used to compare the mean number of drinks per week between intervention and control group at each time point. A paired t-test will be used to compare AUDIT scores between baseline and at conclusion of the study at 12 months. A repeated measures ANOVA will be used to analyze the change in number of drinks from baseline to 6 months and 12 months within the groups. A linear regression model will be utilized to analyze whether the independent variable (brief interventions) has a significant effect on mean drinks per week (dependent variable) after adjusting for covariates.

3.8 Timeline and Resources
We will submit our IRB application in June 2023 and await approval. Once our protocol is approved, we will begin site trainings delivered by two members of the investigate team with expertise in delivering SBIRT based on SAMHSA recommendations. We anticipate 1-2 training sessions will be needed for all clinicians
at each site over the span of a month. We will actively recruit patients from August 2023 to June 2024. If we can consent more patients beyond our estimated sample size, we will continue to add patients until June 2024 to increase power. We will collect baseline information at the patient’s initial visit, and schedule two brief interventions thereafter, one for 3-4 weeks from the initial visit and another at 3-4 months from consent date. Patients will be contacted and interviewed for outcome measures at 6 months and 12 months from enrollment in the study.

We will need one study coordinator and three research investigators, including a site principal investigator, present at each site. The study coordinator at each site will manage logistics with scheduling and report site data at meetings between all study coordinators and principal investigators. Research investigators will interview patients who are actively recruited and input patient information into the shared database. We will need two data analysts who may work remotely to randomize patients and conduct statistical analyses. Our study will also require at least 10 off-site research investigators to conduct follow up interviews. All research investigators are trained to in the TLFB technique and given standardized questions to ask each patient. The principal investigators will oversee all activities and coordinate accordingly.

Our trial will need adequate funding to cover the costs at each of the sites, research staff, and patient compensation.

3.9 References


CHAPTER 4—CONCLUSION

4.1 Advantages and Disadvantages

This proposed study has several strengths. It is a novel study that will utilize an evidence-based approach aimed at decreasing at-risk alcohol use in a higher risk population. Currently, there are no published trials that have examined the effect of brief interventions among patients who have received RYGB. This study will implement multiple strategies in the study design, recruitment, randomization process and data collection to strengthen internal and external validity. It is designed as an RCT with parallel group design and a stratified randomization technique to ensure groups are relatively similar at baseline. Patients will be recruited from multiple sites in a diverse geographical range. Providers will undergo stringent SBIRT training from members of an investigative team with SBIRT expertise that will further ensure quality and standardized brief interventions. Study coordinators and investigators facilitating data collection will be blinded to the patient’s assignment. Furthermore, we do not anticipate a significant loss to follow-up since interventions will coincide with a patient’s usual timeline of postoperative care.

Several limitations should be noted in this study proposal. This study relies heavily on self-reported information on alcohol use, which is oftentimes prone to social desirability bias. ¹ Patients may be more subconsciously motivated to underreport or deny their alcohol use in fear of repercussions to their care. However, we plan to use TLFB to collect outcomes data which has been established to be a reliable method for collecting self-reported data. ² Patients will also be reminded throughout the study that enrollment and participation in this study will not affect their relationship with Yale University and their respective bariatric center. A research investigator who is not involved directly in patient care will be collecting detailed
alcohol use that will be protected information from providers. This study also proposes a relatively short follow-up timeline of 12 months. Most studies indicate that symptoms and signs of at-risk alcohol use begin to emerge around the two-year postoperative timepoint and continue to increase temporally. Our study will recruit patients who have had RYGB surgery in the past year and will approach this two-year postsurgical timepoint by the end of the study. We chose this inclusion characteristic for several reasons. Patients are more closely and frequently monitored during the year after surgery, which provides an ideal opportunity for interventions that we hope will prevent escalation of at-risk use to alcohol use disorder. Another important limitation is the generalizability of this study. We are targeting patients with a specific surgical procedure from a subpopulation in urban and academic medical settings. As mentioned above, we aim to minimize this concern by recruiting a pool of diverse and representative adult patients across the United States.

4.2 Clinical and/or Public Health Significance

The findings from this study are anticipated to have several important public health and clinical implications. This study supports the use of a preventative, public health approach to decrease at-risk alcohol use with a low healthcare burden in terms of cost and resources. SBI has the potential to subsequently decrease alcohol-related inpatient admissions, health complications, and mortality cases in this population of RYGB patients. Prior research stresses the importance of incorporating an interprofessional team with physicians, advanced practice providers, and front desk staff in maximizing patient impact. Adequate training of physician associates, advanced practice registered nurses and other APPs in SBI can distribute this clinical responsibility and ultimately lead to improved patient outcomes.
4.3 References


4.4 Appendices

Appendix A: Excerpts from Generalized Health Screening Survey

General Health

1. In general, would you say your health is:
   __Excellent __Very Good __Good __Fair __Poor
2. How would you rate your quality of life?
   __Excellent __Very Good __Good __Fair __Poor
3. I feel restricted because of my weight.
   __No ___Yes
   If yes, in which setting(s) do you feel restricted?: __at work __at home
   __privately __other

Exercise

1. In the past week, on how many days have you done a total of 30 minutes or more of physical activity, which was enough to raise your breathing rate? (This may include sport, exercise, and brisk walking or cycling for recreation or to get to and from places, but should not include housework or physical activity that may be part of your job.) ___ day(s)

Nutrition

1. Over the past 7 days, how many times did you eat fast food? ____ day(s)
2. Over the past 7 days, how many servings of fruits or vegetables did you eat each day?
   __3 or more servings __2 servings __1 serving __none
3. Over the past 7 days, how many sodas and sugar sweetened drinks (regular, not diet) did you drink each day?
   __3 or more drinks __2 drinks __1 drink __none

Medications

1. Do you take any medications regularly? (Not including vitamins or supplements) __Yes __No
2. If yes, how often do you have trouble taking medicines the way you have been told to take them?
   __I always take them as prescribed __Sometimes I take them as prescribed
   __I seldom take them as prescribed

Substance Use

1. Have you used an illegal drug or used a prescription medication for nonmedical reasons in the past six months? __No __Yes
   If yes, how many times? ___
2. In the last 30 days, have you smoked cigarettes or used a smokeless tobacco product? __No __Yes
Appendix B: AUDIT Screening Tool (Self-Report Version) provided by National Institute on Drug Abuse

### The Alcohol Use Disorders Identification Test: Self-Report Version

**PATIENT:** Because alcohol use can affect your health and can interfere with certain medications and treatments, it is important that we ask some questions about your use of alcohol. Your answers will remain confidential so please be honest. Place an X in one box that best describes your answer to each question.

<table>
<thead>
<tr>
<th>Questions</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How often do you have a drink containing alcohol?</td>
<td>Never</td>
<td>Monthly or less</td>
<td>2-4 times a month</td>
<td>2-3 times a week</td>
<td>4 or more times a week</td>
</tr>
<tr>
<td>2. How many drinks containing alcohol do you have on a typical day when you are drinking?</td>
<td>1 or 2</td>
<td>3 or 4</td>
<td>5 or 6</td>
<td>7 to 9</td>
<td>10 or more</td>
</tr>
<tr>
<td>3. How often do you have 4 or more drinks on one occasion?</td>
<td>Never</td>
<td>Less than monthly</td>
<td>Monthly</td>
<td>Weekly</td>
<td>Daily or almost daily</td>
</tr>
<tr>
<td>4. How often during the last year have you found that you were not able to stop drinking once you had started?</td>
<td>Never</td>
<td>Less than monthly</td>
<td>Monthly</td>
<td>Weekly</td>
<td>Daily or almost daily</td>
</tr>
<tr>
<td>5. How often during the last year have you failed to do what was normally expected of you because of drinking?</td>
<td>Never</td>
<td>Less than monthly</td>
<td>Monthly</td>
<td>Weekly</td>
<td>Daily or almost daily</td>
</tr>
<tr>
<td>6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?</td>
<td>Never</td>
<td>Monthly or less</td>
<td>Monthly</td>
<td>Weekly</td>
<td>Daily or almost daily</td>
</tr>
<tr>
<td>7. How often during the last year have you had a feeling of guilt or remorse after drinking?</td>
<td>Never</td>
<td>Less than monthly</td>
<td>Monthly</td>
<td>Weekly</td>
<td>Daily or almost daily</td>
</tr>
<tr>
<td>8. How often during the last year have you been unable to remember what happened the night before because of your drinking?</td>
<td>Never</td>
<td>Less than monthly</td>
<td>Monthly</td>
<td>Weekly</td>
<td>Daily or almost daily</td>
</tr>
<tr>
<td>9. Have you or someone else been injured because of your drinking?</td>
<td>No</td>
<td>Yes, but not in the last year</td>
<td>Yes, during the last year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?</td>
<td>No</td>
<td>Yes, but not in the last year</td>
<td>Yes, during the last year</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total**
# Appendix C: Standard Drink Equivalents Chart

<table>
<thead>
<tr>
<th>STANDARD DRINK</th>
<th>APPROXIMATE NUMBER OF STANDARD DRINKS IN:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BEER or COOLER</strong></td>
<td></td>
</tr>
<tr>
<td>12 oz.</td>
<td>12 oz. = 1</td>
</tr>
<tr>
<td></td>
<td>16 oz. = 1.3</td>
</tr>
<tr>
<td></td>
<td>22 oz. = 2</td>
</tr>
<tr>
<td></td>
<td>40 oz. = 3.3</td>
</tr>
<tr>
<td>~5% alcohol</td>
<td></td>
</tr>
<tr>
<td><strong>MALT LIQUEUR</strong></td>
<td></td>
</tr>
<tr>
<td>8-9 oz.</td>
<td>12 oz. = 1.5</td>
</tr>
<tr>
<td></td>
<td>16 oz. = 2</td>
</tr>
<tr>
<td></td>
<td>22 oz. = 2.5</td>
</tr>
<tr>
<td></td>
<td>40 oz. = 4.5</td>
</tr>
<tr>
<td>~7% alcohol</td>
<td></td>
</tr>
<tr>
<td><strong>TABLE WINE</strong></td>
<td></td>
</tr>
<tr>
<td>5 oz.</td>
<td>a 750 mL (25 oz.) bottle = 5</td>
</tr>
<tr>
<td>~12% alcohol</td>
<td></td>
</tr>
<tr>
<td><strong>80-proof SPIRITS (hard liquor)</strong></td>
<td></td>
</tr>
<tr>
<td>1.5 oz.</td>
<td>a mixed drink = 1 or more*</td>
</tr>
<tr>
<td></td>
<td>a pint (16 oz.) = 11</td>
</tr>
<tr>
<td></td>
<td>a fifth (25 oz.) = 17</td>
</tr>
<tr>
<td></td>
<td>1.75 L (59 oz.) = 39</td>
</tr>
<tr>
<td>~40% alcohol</td>
<td></td>
</tr>
</tbody>
</table>

*Note: Depending on factors such as the type of spirits and the recipe, one mixed drink can contain from one to three or more standard drinks.

Sample pre-course questionnaire

1. Which service do you work? ..........................................................................................................................  

2. What is your job title/position? ...................................................................................................................  

3. How long have you been in this post? ..........................................................................................................  

4. Previous training in alcohol issues (please circle all that apply):  

   This is the first time I have attended a training course in alcohol issues  
   I received training in alcohol issues during my professional training/qualification  
   I have completed a formal training course (> 1 day in duration) or have a qualification related to  
   alcohol/drugs/addiction  
   I have received training in relation to changing health behaviour  
   I have received training in alcohol and brief interventions  

If you circled any of B–E at Q4 above, please give details of the course/s attended.  

..................................................................................................................................................................  

..................................................................................................................................................................  

5. How important do you think it is for health professionals to be able to address patients’ drinking  
   behaviour (please circle one option)  

   Very important ...................................................... 1  
   Quite important .................................................. 2  
   Neither important nor not important .................... 3  
   Not very important ............................................. 4  
   Not at all important ............................................ 5  

6. Knowledge of alcohol-related issues  

   Please indicate how knowledgeable you feel about the following by assigning a score from 1–4 according to  
   the following scale:  

   1 = I do not know much about this  
   2 = I understand a little about this  
   3 = I understand this well  
   4 = I understand this very well
7. Dealing with alcohol-related situations

Please indicate how you feel in managing the situations below by assigning a score from 1–4 according to the following scale.

1 = I would not be confident about managing this situation and would not know what to do/say.
2 = I think I could manage this situation but would be a little unsure of what to do/say.
3 = I think I would manage this situation well and I would have a good idea of what to do/say.
4 = I am sure I would manage this situation well – I feel confident about what to do/say and I know who to refer to and where to get appropriate support or advice.

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>The health effects of alcohol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard drinks of alcohol and the alcohol content of common drinks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brief interventions as a means of preventing/reducing alcohol problems</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motivational interviewing techniques</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The AUDIT screening test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Services for referral of people affected by alcohol problems/dependency</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explain what alcohol is and the impact it has on individuals and wider society</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In terms of standard drinks, explain the alcohol content of common drinks and risks to health from different levels of consumption</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raise the issue of alcohol in an appropriate way</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Encourage patients to take personal responsibility for their drinking/behaviour</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use the AUDIT screening test to explore current alcohol use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Be able to give structured feedback to patients on the results of screening using the elicit – provide – elicit technique</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Be able to use open questions to elicit change talk from patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Be able to use reflections to elicit change talk from patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Be able to support patients to plan behaviour change and build their confidence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Be able to deliver alcohol SBIs in routine practice</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Thank you for taking the time to fill in this questionnaire
Sample post-course questionnaire

1. Knowledge of alcohol-related issues

Please indicate how knowledgeable you feel about the following by assigning a score from 1–4 according to the following scale:

1 = I do not know much about this
2 = I understand a little about this
3 = I understand this well
4 = I understand this very well

<table>
<thead>
<tr>
<th>Topic</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Dealing with alcohol-related situations

Please indicate how you feel in managing the situations below by assigning a score from 1–4 according to the following scale.

1 = I would not be confident about managing this situation and would not know what to do/say.
2 = I think I could manage this situation but would be a little unsure of what to do/say.
3 = I think I would manage this situation well and I would have a good idea of what to do/say.
4 = I am sure I would manage this situation well – I feel confident about what to do/say and I know who to refer to and where to get appropriate support or advice
3. On a scale of 1–5 how useful did you find this training course?

1 = Very useful  2 = Useful  3 = Okay  4 = Not very useful  5 = Not useful

Reasons for your choice (please indicate the most and least useful aspects of the course):

________________________________________________________________________________________

________________________________________________________________________________________

4. Any other comments?

________________________________________________________________________________________

________________________________________________________________________________________

Thank you for taking the time to fill in this questionnaire
## Appendix E: Sample Script for FRAMES Approach

### Chapter 2

**Figure 2-5**

<table>
<thead>
<tr>
<th>Component</th>
<th>Script in the emergency department, primary care office, or other setting where consultations will be performed</th>
<th>Script in the substance abuse treatment unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introducing the Issue</td>
<td>“I’m from the substance abuse disorder unit. Your doctor asked me to stop by to tell you about what we do on that unit. Would you be willing to talk to me briefly about it? Whatever we talk about will remain confidential.” Or, “This must be tough for you. Would it be OK with you if we take a few minutes to talk about your drinking?”</td>
<td>“Would it be OK with you if we discuss some of the difficulties you’ve had in getting homework done for the group meetings and how we can work together to help you take advantage of the treatment process?”</td>
</tr>
</tbody>
</table>
| Screening, Evaluating, and Assessing | “In reviewing the information you’re given me, using a scale of ‘not ready,’ ‘unsure,’ and ‘ready,’ how prepared do you feel you are to stop drinking?”  
Client says “unsure.”  
“One of the factors that might tie together your accident and your problems with your wife is your drinking.”  
“I think it would be worth talking more to some of the people at the substance abuse disorder unit so that your problems don’t get worse,” or, “I think a 2-week trial when you don’t drink alcohol at all would be helpful in determining whether or not drinking makes things worse and if stopping use works for you. What do you think?” | “Given what you see as the additional stress in your family and your desire to make the treatment work for you this time, on a scale of 1 to 10, how ready do you feel to find a way to put time into your homework?”  
Client says, “6.”  
“I am pleased that you are willing to consider trying this, even though it won’t be easy. Let’s come up with some strategies that we can write down to help you accomplish this goal.” |
| Providing Feedback               | “I’d like to get some confidential information about your drinking to give me a better idea of your drinking style. Can you tell me how many days a week you drink? How many drinks a day?” | “I’d like to talk about what was going on when you decided not to do the homework assignment. Can you tell me a little about what you were thinking or feeling at the time? Why do you think it was difficult to get your homework done?” |
Appendix F: AUDIT Screening (Interview Version) for Follow-Up Sessions provided by National Institute on Drug Abuse

The Alcohol Use Disorders Identification Test: Interview Version

Read questions as written. Record answers carefully. Begin the AUDIT by saying "Now I am going to ask you some questions about your use of alcoholic beverages during this past year." Explain what is meant by "alcoholic beverages" by using local examples of beer, wine, vodka, etc. Code answers in terms of "standard drinks". Place the correct answer number in the box at the right.

1. How often do you have a drink containing alcohol?
   (0) Never [Skip to Qs 9-10]
   (1) Monthly or less
   (2) 2 to 4 times a month
   (3) 2 to 3 times a week
   (4) 4 or more times a week

2. How many drinks containing alcohol do you have on a typical day when you are drinking?
   (0) 1 or 2
   (1) 3 or 4
   (2) 5 or 6
   (3) 7, 8, or 9
   (4) 10 or more

3. How often do you have six or more drinks on one occasion?
   (0) Never
   (1) Less than monthly
   (2) Monthly
   (3) Weekly
   (4) Daily or almost daily
   Skip to Questions 9 and 10 if Total Score for Questions 2 and 3 = 0

4. How often during the last year have you found that you were not able to stop drinking once you had started?
   (0) Never
   (1) Less than monthly
   (2) Monthly
   (3) Weekly
   (4) Daily or almost daily

5. How often during the last year have you failed to do what was normally expected from you because of drinking?
   (0) Never
   (1) Less than monthly
   (2) Monthly
   (3) Weekly
   (4) Daily or almost daily

6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?
   (0) Never
   (1) Less than monthly
   (2) Monthly
   (3) Weekly
   (4) Daily or almost daily

7. How often during the last year have you had a "feeling of guilt or remorse after drinking?"
   (0) Never
   (1) Less than monthly
   (2) Monthly
   (3) Weekly
   (4) Daily or almost daily

8. How often during the last year have you been unable to remember what happened the night before because you had been drinking?
   (0) Never
   (1) Less than monthly
   (2) Monthly
   (3) Weekly
   (4) Daily or almost daily

9. Have you or someone else been injured as a result of your drinking?
   (0) No
   (1) Yes, but not in the last year
   (2) Yes, during the last year

10. Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down?
    (0) No
    (1) Yes, but not in the last year
    (2) Yes, during the last year

Record total of specific items here

If total is greater than recommended cut-off, consult User's Manual.

50
Appendix G: Participant Consent Form

CONSENT FOR PARTICIPATION IN A RESEARCH STUDY
YALE UNIVERSITY SCHOOL OF MEDICINE

**Study Title:** Brief Counseling Interventions in Adult Roux-en-Y Gastric Bypass Patients with At-Risk Alcohol Use

**Principal Investigator (the person who is responsible for this research):** Ruth Seok, PA-S and Dr. Kenneth Morford, MD, FASAM

**Why is this study being offered to me?**
We are asking you to take part in a research study because you We are looking for a sample size of **356 participants** to be part of this research study.

**What is the study about?**
The purpose of this study is to investigate whether an intervention strategy known as Brief Interventions (BI) can reduce alcohol consumption in Roux-en-Y patients who screen positive for at-risk alcohol use on the Alcohol Use Disorder Identification Test (AUDIT).

**What are you asking me to do and how long will it take?**
If you agree to take part, your participation in this study will involve two personalized 10-15 minute brief counseling interventions that are added to your regular post-operative visits. The first intervention will occur 2-4 weeks after enrollment. The second intervention will be scheduled for 3-4 months from enrollment date. We will contact you at 6 months and 12 months from study onset to ask follow up questions. We think that the brief interventions and follow up sessions will take maximum 15 minutes of your time at each session.

**Are there any risks from participating in this research?**
If you decide to take part in this study, you may experience minimal risks such as distress over the nature of the questions, informational risks, possible risk of loss of confidentiality. We do not expect any physical risks from taking part in this study.

**How can the study possibly benefit me or others?**
You may benefit from taking part in this study. We hope that our results will add to the knowledge about whether brief alcohol interventions can help participants decrease alcohol use to recommended limits.

**Are there any costs to participation?**
You will not have to pay for taking part in this study. The only costs may include transportation and your time coming to the study visits. If these are an issue for you, we can potentially accommodate telehealth sessions.
**Will I be paid for participation?**
You will be compensated for taking part in this study. You will receive a $15 Amazon gift card for your time after each follow-up session at 6 months and 12 months.

**How will you keep my data safe and private?**
All of your responses will be held in confidence. Only the researchers involved in this study and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program, the Yale University Institutional Review Boards, and others) will have access to any information that could identify you that you provide. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if we learn that you are hurting a child or an older person.

**What if I want to refuse or end participation before the study is over?**
Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with Yale University and your bariatric center.

**Who should I contact if I have questions?**
Please feel free to ask about anything you don't understand. If you have questions later or if you have a research-related problem, you can email the Principal Investigator at kenneth.morford@yale.edu.

**Documentation of Informed Consent**
Your signature below indicates that you read and understand this consent form and the information presented and that you agree to be in this study.

We will give you a copy of this consent form.

<table>
<thead>
<tr>
<th>Participant Printed Name</th>
<th>Participant Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person Obtaining Consent</td>
<td>Person Obtaining Consent</td>
<td>Date</td>
</tr>
<tr>
<td>Printed Name</td>
<td>Signature</td>
<td></td>
</tr>
</tbody>
</table>
BIBLIOGRAPHY


doi:10.1007/s10880-020-09751-3


55. O’Connor EA, Perdue LA, Senger CA, et al. Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: Updated


82. White AM. Gender Differences in the Epidemiology of Alcohol Use and Related Harms in the United States. Alcohol Res. 2020;40(2):01. doi:10.35946/arcr.v40.2.01


