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Cohort profile: study design and baseline characteristics of an observational longitudinal weight loss cohort and biorepository of patients undergoing sleeve gastrectomy in the USA

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ABSTRACT

Purpose We developed a comprehensive sleeve gastrectomy (SG) weight loss study cohort and biorepository to uncover mechanisms, biomarkers and predictive factors of weight loss, weight maintenance and amelioration of obesity-related comorbidities. For this purpose, we collected psychosocial, anthropometric, clinical data and a variety of samples pre-surgery, intraoperatively and 1.5, 3, 12 and 24 months post-surgery. For longer-term assessment, the collection of psychosocial and anthropometric data was extended to 10 years. Here, we present in-depth characterisation of the cohort and detailed overview of study procedures as a foundation for future analyses.

Participants We consented 647 participants between June 2017 and March 2020 from two bariatric surgery clinics in New York City—one major urban hospital and one private hospital. Of 355 participants who provided baseline data, 300 underwent SG. Of these, 79% are females with an average age of 38 years, 68% are Hispanic, 20% are non-Hispanic Black and 11% are non-Hispanic White.

Findings to date We collected intraoperative adipose and stomach tissues from 282 patients and biosamples (blood, urine, saliva, stool) from 245 patients at 1.5 months, 238 at 3 month, 218 at 12 months and 180 at 24 months post-surgery. We are currently collecting anthropometric and psychosocial data annually until 10 years post-surgery. Data analysis is currently underway.

Future plans Our future research will explore the variability in weight loss outcomes observed in our cohort, particularly among Black and Hispanic patients in comparison to their White counterparts. We will identify social determinants of health, metabolic factors and other variables that may predict weight loss success, weight maintenance and remission of obesity-related comorbidities. Additionally, we plan to leverage our biorepository for collaborative research studies. We will complete long-term follow-up data by December 2031. We plan to apply for funding to expand biosample collection through year 10 to provide insights into the mechanisms of long-term weight maintenance.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Diverse patient cohort with substantial representation of Hispanic and Non-Hispanic Black individuals.
⇒ Long-term follow-up extending to 10 years post-surgery.
⇒ Extensive collection of biosamples and psychosocial data at multiple time points, coordinated with routine standard of care, maximized data quality and participant retention.
⇒ Observational design inherently limits the ability to establish causal relationships.
⇒ Includes participants from two hospitals in New York City only, which may limit the generalisability of findings.

INTRODUCTION

Obesity is considered a top public health concern of the 21st century, with a prevalence of 42.4%,[1] and is strongly associated with chronic diseases, including cardiovascular disease, diabetes, cancer, liver and kidney disease and chronic pain.[2] Treatment of chronic diseases accounted for 90% of the nation's healthcare spending in 2019.[3] Estimates of obesity and associated medical, psychosocial morbidity and mortality are growing in the USA, emphasising the need for more intensive efforts to treat this refractory problem.[4 5] The risk of obesity-associated

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comorbidities is related to the class of disease; described as *moderate* in class I (body mass index [BMI], 30–35 kg·m^{-2}), *severe* in class II (BMI 35–40 kg·m^{-2}) and *very severe* in class III (BMI ≥40 kg·m^{-2}).[6] At the *very severe* obesity level, the prevalence of co-morbidities (eg, diabetes, coronary heart disease) and mortality doubles compared with the general population.[7] Losing meaningful weight through diet and exercise is especially difficult for some individuals with severe obesity due to a combination of physiological, psychological and lifestyle factors that compound the challenges they face. These factors include slower metabolism, hormonal imbalances, emotional eating, genetic predisposition, physical limitations, lifestyle habits and societal barriers, which collectively create formidable obstacles to successful weight loss.

Currently, weight loss surgery is the most effective long-term treatment of obesity, resulting in significant long-term weight loss, improved quality of life and reductions in psychosocial conditions,[8 9] as well as amelioration of several obesity-associated comorbidities (eg, sleep apnoea, hypertension, insulin resistance), compared with non-surgical interventions.[10] Despite leading to an overall significant weight loss, a subset of patients that undergo bariatric surgery do not achieve successful weight loss and/or experience weight regain.[11] Weight regain can begin as early as 1 year post-surgery and may continue for several years.[8 12] A few have looked at predictors and mechanisms of inadequate weight loss and weight regain following bariatric surgery, both of which can significantly impact health outcomes. Further, while Black patients tend to lose less weight through bariatric surgery than White patients, the reasons for this disparity are unclear.[13] Studies that reported post-surgery weight loss in Hispanic patients are few and inconsistent, with some reporting equal weight loss compared with White patients and others reporting less weight loss in Hispanic patients compared with White patients.[14] Understanding the biological and psychosocial factors that contribute to successful surgical weight loss and postoperative weight maintenance is critical.[13 15 16]

Our overall objective is to create a New York University Langone Health (NYULH) Weight Loss Surgical Cohort and Biorepository to allow researchers to evaluate and explore novel mechanisms and predictors of weight loss and weight loss maintenance in patients who undergo bariatric surgery and to generate hypotheses for future studies. We chose to follow patients undergoing sleeve gastrectomy (SG) since this type of surgical intervention has emerged as the most popular weight loss surgery, accounting for 61.4% of weight loss surgeries performed in the USA in 2020.[17] We decided to collect clinical and questionnaire data as well as biosamples to study mechanisms and predictors of short- and long-term weight change and obesity-related disease progression following SG surgery in a mainly underrepresented patient cohort. Our secondary objective is to evaluate the impact of SG on several clinical, behavioural, metabolic and other long- and short-term outcomes. In addition, this study cohort and biorepository support an American Heart Association (AHA)-funded Centre (17SFRN33590133) to explore adipose tissue changes and inflammation, glucose metabolism and energy expenditure in a subset of participants; as well as an NIH K23 Career Development Award (K23AR080846), to explore the mechanisms of pain reduction or maintenance in chronic widespread pain after rapid weight loss.

COHORT DESCRIPTION

Study design and overview

This is a prospective longitudinal observational cohort study with biosample collection. This study protocol was approved in April 2017 by the NYU Langone Health's (NYULH) Institutional Review Board (IRB; (no. 16–01995) and, therefore, in accordance with the ethical standards of the Declaration of Helsinki. Written informed consent was obtained by trained research staff, in the participant's preferred language, from all individual participants before their inclusion in the study. A copy of the signed consent form was provided to the participants and a copy, along with a consent process note, was saved in the participant's study folder. While the original IRB approval was to follow patients for 2 years post-surgery, in 2021, we obtained NYULH IRB approval to follow participants for 10 years and are reconsenting participants for longer-term follow-up, where we will obtain remote weight measurements and questionnaire data.

We are conducting this study at NYULH Tisch Hospital and NYC Health+Hospital Bellevue Hospital, both located in New York City. Tisch Hospital is part of the NYULH hospital system, where most patients have private insurance, and Bellevue is a public hospital that is part of the Health and Hospitals Corporation in New York City. Most patients at Bellevue Hospital have public insurance and/or are uninsured. Each site conducts >1000 bariatric surgical procedures per year.

Recruitment to follow participants for 24 months started on 13 June 2017, and stopped on 12 March 2020, due to the COVID-19 pandemic lockdowns. We started reconsenting participants for a 10-year follow-up on 15 October 2021. We approached patients with planned SG surgery from two bariatric surgery clinics located at Tisch and Bellevue Hospitals before or after a standard-of-care clinic appointment to invite them to be part of the study and patients were given the option to participate in AHA Centre's grant's sub-study testing. Eligibility criteria were assessed by the research team with the final approval of the Principal Investigator, based on the inclusion and exclusion criteria. Participants were given an information sheet inviting them to participate in the main study and AHA Centre's grant's sub-study optional testing. This document included details of the study timeline, procedures and biosample collection. Table 1 lists the inclusion and exclusion criteria for the main study as well as for the AHA Centre grant's sub-study. Figure 1 details participant flows up to 2 years.

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Table 1 Participant eligibility criteria

Main study inclusion criteria	AHA centre grant's sub-study inclusion criteria
► 18–75 years of age ► Candidates for bariatric surgery and scheduled to undergo SG ► Able to communicate, read and write in English or Spanish ► Able to give voluntary, written informed consent	► Diagnosis of type 2 diabetes mellitus or an HbA1c ≥6.5% ► Patients without diabetes with an HbA1c <5.7% measured within the last 6 months, not on diabetic medication
Main study exclusion criteria	**AHA centre grant's sub-study exclusion criteria**
► Prior bariatric surgery ► Insulin-dependent diabetes ► Inability to discontinue the use of aspirin or non-steroidal anti-inflammatory medications for 72 hours before study testing	► HbA1c 5.7–6.4% ► History of autoimmune diseases ► History of myocardial infarction, coronary interventions/ angioplasty or stroke ► History of cancer within the past 3 years ► Use of immunosuppressive medication ► eGFR below 60 mL/min/1.73 m^2

AHA, American Heart Association; eGFR, estimated glomerular filtration rate; SG, sleeve gastrectomy.

Measurements, biosample collection and procedures

In-person measurements and biosamples were collected preoperatively and up to 24 months post-surgery. Research visits after 24 months post-surgery are currently taking place remotely, without biosample collection. Bellevue Hospital participant in-person study procedures were conducted at NYU Langone's Clinical and Translational Science Institute Clinical Research Centre (CTSI-CRC) located within Bellevue Hospital. Before the COVID-19 pandemic, Tisch Hospital participants' in-person study procedures were conducted at Tisch's bariatric surgery clinic. Post COVID-19 pandemic, Tisch participants' in-person research visits also took place at NYU Langone's CTSI-CRC. Participants' surgeries took

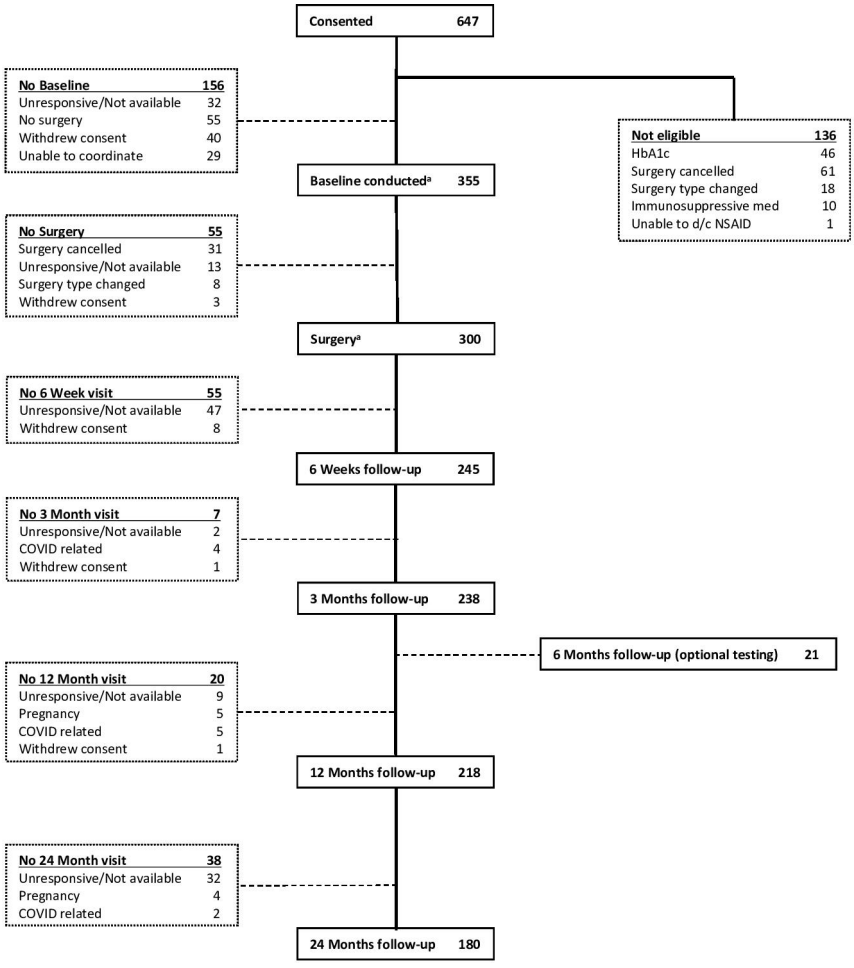


Figure 1 Flow diagram of participants.[a] 282 intraoperative samples were collected.

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Table 2 Study measurements

Measurement	Pre-surgery	Surgery	1.5M	3M	6M*	12M	24M	3-10Y
Anthropometric	X		X	X	X	X	X	X
Blood pressure	X		X	X	X	X	X	
Questionnaires	X			X	X	X	X	X
Blood, saliva, urine and stool	X		X	X	X	X	X	
Resting metabolic rate and continuous glucose monitoring*	X*		X*		X*	X*		
Fitbit*	X*		X*		X*			
Glucose tolerance test*	X*		X*		X*			
Adipose tissue collection		X	X*					
Stomach tissue		X						
Liver biopsy (wedge)*		X*						

*AHA Centre grant's sub-study testing. Saliva collection was suspended starting 16 March 2020

place at their respective hospitals. Measurements and biosamples were collected at in-person study visits at baseline (before the start of the pre-surgical liquid diet), intraoperatively and at 1.5, 3, 12 and 24 months post-surgery. In-person study visits were usually scheduled to coincide with clinical follow-up visits: AHA Centre grant's sub-study participants were invited to an additional 6 months post-surgery in-person study visit. All in-person research visits were paused on 16 March 2020 and re-started on 30 June 2020. During this pause period, research visits were conducted remotely without biosample collection. We have since completed all 24 months in-person visits. Long-term follow-up visits are currently taking place remotely with questionnaire and body composition data being collected for 10 years post-surgery.

We employed several strategies to maximise patient retention. These included having bilingual (English and Spanish) research staff, flexibility with rescheduling study visits when needed and scheduling study visits to coincide with clinical care. In addition, we scheduled visits using the patients' preferred mode of communication (ie, texting, email, phone) and provided frequent follow-ups and reminders. We provided post-card reminders for the 24-month study visit. Post COVID-19 pandemic, we started offering transportation to and from the clinical research site. We have less frequent interactions in our long-term follow-up timeline and plan to include yearly thank-you notes.

Table 2 outlines the study measurements and biosamples collected at each time point—described in more detail below. Biosamples were processed by and stored in the NYULH's Centre for Biospecimen Research and Development. After 24 months post-surgery, only body weight, body composition and questionnaires are collected yearly.

Anthropometric and blood pressure measurements

The height was measured at baseline to the nearest 1 cm using a stadiometer (CECA 213, Seca GmBH & Co. KG, Hamburg, Germany). For the first 24 months post-surgery, the body weight was measured in light clothing without shoes, to the nearest 0.1 lb using a Stow-A-Weigh scale (Scale-Tronix, Welch Allyn, Skaneateles, NY, USA). The waist circumference was measured twice using a Gulick tape (McKesson Medical-Surgical, Fairfield, NJ, USA) to the nearest 1 cm using a procedure adapted from the National Health and Nutrition Examination Survey (CDC, 2012). The body fat percentage and muscle mass weight were measured twice by bioelectrical impedance analysis (BIA; InBody 270, InBody, Inc. Cerritos, CA, USA or Bodycomp Scale Elite, Valhalla Scientific Inc, Poway, CA, USA). Systolic and diastolic blood pressures were measured twice on the left arm following a 5 min seated resting period using an automated blood pressure machine (Welch Allyn PROPAQcs, Welch Allyn, Inc., Skaneateles Falls, NY, USA). If the two values (either systolic or diastolic) differed by five points, blood pressure was remeasured, and previous values that did not meet this criterion were discarded. For follow-up visits after 24 months post-surgery, remote weight and body composition are measured twice using the Smart Body Fat Scale- Basic (Renpho, Los Angeles, CA, USA) shipped to each participant.

Questionnaires

Questionnaires are administered in the participants' preferred language (English or Spanish) either in person, using a tablet computer through NYULH's licensed version of Qualtrics, or remotely, through a secured link distributed through Qualtrics sent to the participant's email with their de-identification code embedded within. Qualtrics is an online research-based web server that is General Data Protection Regulation compliant with secure data encryption. No identifying information was collected in Qualtrics surveys. The questionnaires collect demographics, eating behaviours, substance abuse, physical activity, mental health, weight bias, experiences of discrimination, food security, quality of life, sleep, stress

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Table 3 Questionnaires administered before surgery and at 3 months, 12 months to 10 years post-surgery

Data collected	Questionnaire
Demographic	Standard self-report assesses ethnic background, age, gender, marital status, educational level, income level and country of origin
Eating behaviours	Eating Disorder Examination Questionnaire, Short Version (EDE-Q), The Yale Food Addiction Scale 2.0 (YFAS 2.0)
Physical activity	Godin Leisure-Time Exercice Questionnaire (GLTEQ)
Mental health	Patient Health Questionnaire-9 (PHQ-9)
Substance abuse	Alcohol, Smoking, Substance Involvement Screening Test (ASSIST)
Weight bias	Weight Bias Internalisation Scale (WBIS)
Experiences of discrimination	Experiences of Discrimination (EOD)
Food security	Food Security Questionnaire (FSQ)
Quality of life	Medical Outcomes Study Short Form Health Survey (SF-12)
Sleep	Pittsburg Sleep Quality Index (PSQ)
Stress	Perceived Stress Scale (PSS)
Pain	Brief Pain Inventory- Short Form (BPI)

and pain information using validated scales, as described in table 3.

Blood, saliva, urine and stool sample collection

Blood, saliva, urine and stool samples were collected after a 12-hour fasting period. Participants were asked to pause the use of aspirin for 72 hours before sample collection. Blood was drawn by a trained phlebotomist to measure HbA1c, glucose, insulin and lipid profile and for future experimental analyses. Blood for future experimental analyses was processed for plasma, serum and peripheral mononuclear cells (PBMCs). Saliva samples were collected via the 'Passive Drool Technique', where a straw was placed into the mouth allowing saliva to pool in the mouth followed by tilting the head forward and the saliva to passively travel through the straw into the storage tube (Miletic, Schiffman, Miletic & Sattely-Miller, 1996). Urine was collected in a sterile urine collection cup, and stool samples were self-collected at home using a DNAGenotek stool kit (Genotek: Omnigene-Gut OM-200). In addition to collecting stool in the DNAGenotek kit tube, participants were provided with two additional preservative-free tubes for stool collection. Stool samples were shipped by the participant to the study team with frozen ice packs using a pre-paid overnight mailer. All samples were stored at −80°C for future analyses.

Resting metabolic rate

Resting metabolic rate (RMR) was assessed via indirect calorimetry using a portable metabolic cart (Quark RMR, COSMED USA Inc., Chicago, IL, USA). Participants were instructed to fast for 12 hours and to avoid vigorous exercise for 48 hours before measurements. Participants were directed to lay supine for 10 min during which the metabolic cart was calibrated per the manufacturer's instructions. Oxygen and carbon dioxide production were measured for 20–25 min following a 5 min run-in period in thermoneutral conditions with participants in a relaxed but awake state. RMR was collected in participants enrolled in the AHA Centre Grant's sub-study at baseline, 1.5 months and 6 months post-surgery.

Glucose-tolerance test

In participants who enrolled in the AHA Centre grant's sub-study, glucose tolerance and insulin sensitivity were assessed through an oral-glucose-tolerance test (OGTT) at baseline, 1.5 months and 6 months post-surgery. Blood was collected after 12 hours of fasting for serum glucose and insulin measurements, which were performed at 30, 60, 90 and 120 min after consumption of a 75 g glucose solution. In addition, blood glucose dynamics were measured via continuous glucose monitoring (CGM) for 14 days using Abbott Freestyle Libre Pro, Abbott Park, IL, USA, at baseline, 1.5 months and 6 months post-surgery.

Continuous glucose monitoring

All participants were invited to participate in an optional test consisting of monitoring continuous glucose at baseline, 1.5 months and 12 months post-surgery. At the beginning of each 14-day monitoring period, a sensor was placed on the backside of the upper arm of the patient by trained study staff. The skin surface was prepared with Skin Tac (TORBOT Group, Inc., Cranston, RI, USA) to help prevent detachment of the CGM device. Participants were blinded to glucose tracing during data collection. After testing was complete, trained study personnel reviewed and shared the CGM data with participants interested in receiving that information. The CGM device was returned to the study team via a postage-paid sharps box.

Tissue collection

During surgery, visceral and subcutaneous adipose as well as a small portion of the stomach fundus were collected by the surgical team. In addition, an intraoperative wedge liver biopsy and 1.5 months post-surgery subcutaneous

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adipose tissue were collected from participants enrolled in the AHA Centre Grant's sub-study. The subcutaneous biopsy was obtained via a modified liposuction technique under sterile conditions and local anaesthesia.[18] Briefly, following local anaesthesia, an incision smaller than five millimetres was made in the left lower quadrant of the abdomen avoiding laparoscopy or other incision sites. A large bore modified liposuction cannula was inserted through the incision into the subcutaneous adipose tissue. The cannula was connected to a hand-suction device that aspirates a small amount of fat tissues (~200 mg). After the biopsy was performed, the incision was closed using adhesive strips, and a small dressing was applied to protect the incision site. Samples were stored at −80°C for future analysis.

Sample size

This study is exploratory and is designed to allow testing of multiple hypotheses. Given the large volume of data that will be used in our clinical prediction models, determining the sample size was not precise and was largely determined by the need to have various types of biosamples and data to explore the implications of rapid weight loss, metabolic changes and remission of comorbidities as a result of bariatric surgery. Including 200 participants with anthropometric and biosamples at 12 months post-surgery was agreed on by consensus of all the investigators involved in this study.

Patient and public involvement

The study design, recruitment, questionnaires selected and collection of biological samples were carried out without direct input from participants or the public. Results from future studies conducted within this cohort will be submitted for publication in peer-reviewed journals and presented at relevant conferences.

Characteristics of study participants and findings to date

This study involved a diverse sample of participants comprising 355 adults aged between 18 and 69 years (mean age=38 years, SD=12), with baseline BMI between 33 and 83 kg/m^2 (mean BMI=44 Kg/m^2, SD=7), 79% self-reported as female, with the majority of the participants self-identifying as Hispanic (table 4). Participants had various socioeconomic backgrounds and different income levels. Overall, 85% (300 in 355) of participants who provided baseline data had surgery within 6 months of our baseline visit. Of these, 73% were followed up at 12 months and 60% at 24 months post-surgery. Of note, the participants that did not have SG surgery differed in self-reported household income and self-reported employment status. The participants that did not undergo SG surgery reported greater income levels above $50 000 and lower income in the 'between $10 000 and $20 000 category' compared with those who had SG surgery. Regarding employment, the participants who did not have SG surgery reported more full-time work compared with those who underwent SG. The retention rate for patients who underwent surgery was 82% at 1.5 months, 79% at 3 months, 73% at 12 months and 60% at 24 months.

Strengths and limitations

SG has become the most common bariatric procedure performed in the USA and worldwide.[15] Slightly over a decade ago, SG represented just 5% of bariatric surgery procedures. By 2016, over half of new bariatric surgery procedures (54%) were SG.[17] However, the popularity of SG has preceded the availability of solid research on its long-term impact such as weight loss maintenance and comorbidity resolution. Of the few longer-term SG bariatric cohorts,[2 19–21] only a few collected biosamples and only up to 12 months post-surgery. In addition, that study was small (n=30) and took place in a mainly White population, which makes generalisability limited. Our population is unique since the majority of the cohort is from understudied Hispanic and Non-Hispanic Black race-ethnicity groups, which will allow us to investigate potential disparities in outcomes that have been observed in other studies. Our follow-up of patients is longer than most SG bariatric surgery cohorts, providing more information on long-term changes following SG. So far, we have collected several types of biosamples and psychosocial data at multiple timepoints and up to 24 months post-surgery. We will continue to collect anthropometric and psychosocial data for 10 years post-surgery. Our study is also unique as the data and biosamples collected are comprehensive and will allow for in-depth analysis of metabolic and psychosocial changes post SG and will generate rich datasets for future hypothesis-testing studies. We collected multiple biosamples and data at multiple timepoints within the first-year post-surgery, the period during which substantial and maximal weight loss is achieved, as well as at 24 months, at which time body weight has been reported to stabilise.[22] To capture weight maintenance and weight regain, we are collecting yearly body composition and psychosocial data remotely, which will help further understand weight maintenance (or/and regain) following bariatric surgery.

Given the observational nature of this study, there are inherent limitations. First, there is no comparison group such as a different weight loss surgery or a lifestyle intervention. However, the data generated from this study will allow us to design an intervention study to either improve weight loss during the active weight loss phase or to aid long-term weight maintenance. Given resource limitations, biosamples will only be collected up to 24 months post-surgery and only at fasted state. Given the importance of understanding hunger and satiety after bariatric surgery, future studies should consider including blood collection before and after a standardised meal. Nevertheless, the biosamples collected during the first 24 months post-surgery will generate in-depth insights into various mechanisms and outcomes following SG. Lastly, we have a 12-month follow-up rate of 73% and a 24-month follow-up rate of 60%. This retention rate is higher than that observed in clinical practice and similar to that seen

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Table 4 Baseline characteristics

Characteristic	Mean±SD	Range or %	Mean±SD	Range or %	Mean±SD	Range or %
	Baseline		**Yes SG**		**No SG**	
Subjects, n	355		300		55	
Sex, F/M, n	282/73		240/60		42/13	
Age, y	38±12	18–69	38±12	18–68	37±11	18–69
BMI (kg/m^2), n	44±7	33–83	44±7*	33–83	46±7*	33–81
Race ethnicity, n						
Hispanic	239	67%	205	68%	34	62%
Non-Hispanic black	74	21%	60	20%	14	25%
Non-Hispanic white	39	11%	32	11%	7	13%
Other	3	0.9%	3	1%	0	0%
Education, n						
Grad/prof school	33	9%	28	9%	5	9%
4 year college	74	21%	64	21%	10	18%
< 4 year college	102	29%	81	27%	21	38%
High school	82	23%	72	24%	10	18%
Some high school	63	18%	55	18%	8	15%
Missing	1	0.3%	0	0%	1	2%
Income, n						
<$10 000	84	24%	71	24%	13	24%
Between $10,000 & $20 000	80	22%	73	24%*	7	13%*
Between $20,000 & $30 000	53	15%	50	17%	3	5%
Between $30,000 & $40 000	24	7%	21	7%	3	5%
Between $40,000 & $50 000	36	10%	27	9%	9	16%
>$50 000	72	20%	56	19%*	16	29%*
Missing	6	2%	2	0%	4	7%
Marital status, n						
Married	111	31%	92	31%	19	35%
Single	180	51%	152	51%	28	51%
Divorced	12	3%	11	4%	1	2%
Separated	23	7%	22	7%	1	2%
Widowed	6	2%	6	2%	0	0%
Living common-law	22	6%	17	6%	5	9%
Missing	1	0.3%	0	0%	0	0%
Employment, n						
Working full time	99	28%	77	26%*	22	40%*
Working part time	41	11%	39	13%	2	4%*
Seeking work	20	6%	18	6%	2	4%
Going to school	33	9%	29	10%	4	7%
Caring for family	52	15%	45	15%	7	13%
Caring for family and seeking work	70	20%	66	22%*	4	7%*
Recovering from illness	25	7%	20	7%	5	9%
Missing	15	4%	6	2%	9	16%

Analyis of variance was used to test differences in baseline body mass index and age (*=p<0.05).X^2 test was used for categorical data. Fisher's exact test was used when expected counts were less than 5 (*=p<0.05).

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in other studies. A recent study in a private US bariatric centre that accepts public and private forms of insurance reported a 57% follow-up rate at 12 months and a 27% follow-up rate at 24 months.[17] Further, the fourth report of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) Global Registry Report, which encompasses 394 431 cases from 51 countries between 2012 and 2018, reported a 32.5% overall follow-up rate at 12 months worldwide.[23] Our relatively high retention rate indicates the commitment and engagement of the participants with the study protocol and the specific means by which the study team continues communications with the study participants over time, as detailed above. In addition, long-term follow-up data are collected remotely, which reduces participant burden. The data collected from this well-retained cohort provide a robust foundation for exploring the metabolic and psychosocial effects after metabolic and bariatric surgery.

FUTURE PLANS

The established cohort and collected data will be used to investigate predictors and mechanisms of weight loss and maintenance following SG, with a focus on understanding disparities among different demographic groups. We plan to secure additional funding to extend biosample collection through the 10-year follow-up period. Our biorepository will support collaborative research aimed at uncovering metabolic and psychosocial mechanisms underlying long-term outcomes. Additionally, we intend to enhance our understanding of the biological and behavioural factors contributing to successful surgical weight loss and long-term weight maintenance. We will also explore the impact of COVID-19 on both short-term and long-term outcomes of weight loss surgery, recognising the significant weight changes reported by individuals during the pandemic. These efforts will enhance our ability to provide tailored interventions and improve clinical practices for diverse patient populations.

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Contributors The study protocol and methods were designed by BE, MJ, CA, ES, AMS, MAS, SPH, CRF, MP, JOA, VI and SMV. The manuscript was drafted and revised by SMV, SC, ENM and MJ. AG, GV, SP, MR, CP, EA and SMV coordinated and conducted participant recruitment and study visits and conducted follow-up of samples and questionnaires. AG, GV and SMV contributed to database development, quality control and maintenance. HL assisted with data analysis and interpretation. All authors revised the manuscript. MJ is the guarantor of the study, accepts responsibility for the conduct of the study, had access to the data and controlled the decision to publish.

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Competing interests JOA is a consultant for Novo-Nordisk and clinical advisor for Intellihealth.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

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Ethics approval This study involves human participants and was approved by NYU Grossman School of Medicine's Institutional Review Board (No. 16-01995). Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available upon reasonable request. Researchers interested in accessing the data from this cohort study can request it by directly contacting the corresponding author at melanie.jay@nyulangone.org. De-identified data will be available to qualified researchers for approved analyses, and access will be granted following review and approval of a study proposal, data use agreement, and ethical approval. Restrictions may apply depending on the specific nature of the data requested to ensure participant privacy and compliance with institutional policies. We encourage collaboration on projects that align with the goals of our study, particularly those focused on metabolic and psychosocial outcomes following SG.

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REFERENCES

1 Hales CM, Carroll MD, Fryar CD, *et al*. Prevalence of Obesity and Severe Obesity Among Adults: United States, 2017-2018. *NCHS Data Brief* 2020;2020:1–8.
2 Tiwari A, Balasundaram P, Public Health Considerations Regarding Obesity. StatPearls.Treasure Island (FL) Ineligible companies. *Disclosure: Palanikumar balasundaram declares no relevant financial relationships with ineligible companies*. StatPearls Publishing LLC, 2023.
3 Martin AB, Hartman M, Lassman D, *et al*. National Health Care Spending In 2019: Steady Growth For The Fourth Consecutive Year. *Health Aff (Millwood)* 2021;40:14–24.

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4 Flegal KM, Carroll MD, Ogden CL, *et al*. Prevalence and trends in obesity among US adults, 1999-2008. *JAMA* 2010;303:235–41.
5 Ryan DH, Espeland MA, Foster GD, *et al*. Look AHEAD (Action for Health in Diabetes): design and methods for a clinical trial of weight loss for the prevention of cardiovascular disease in type 2 diabetes. *Cont Clin Trials* 2003;24:610–28.
6 Madlock-Brown CR, Reynolds RB, Bailey JE. Increases in multimorbidity with weight class in the United States. *Clin Obes* 2021;11:e12436.
7 Kral JG. Morbidity of severe obesity. *Surg Clin North Am* 2001;81:1039–61.
8 Dixon JB, Straznicky NE, Lambert EA, *et al*. Surgical approaches to the treatment of obesity. *Nat Rev Gastroenterol Hepatol* 2011;8:429–37.
9 Ricci C, Gaeta M, Rausa E, *et al*. Early impact of bariatric surgery on type II diabetes, hypertension, and hyperlipidemia: a systematic review, meta-analysis and meta-regression on 6,587 patients. *Obes Surg* 2014;24:522–8.
10 Sjöström L, Lindroos A-K, Peltonen M, *et al*. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. *N Engl J Med* 2004;351:2683–93.
11 Maciejewski ML, Arterburn DE, Van Scoyoc L, *et al*. Bariatric Surgery and Long-term Durability of Weight Loss. *JAMA Surg* 2016;151:1046–55.
12 El Ansari W, Elhag W. Weight Regain and Insufficient Weight Loss After Bariatric Surgery: Definitions, Prevalence, Mechanisms, Predictors, Prevention and Management Strategies, and Knowledge Gaps-a Scoping Review. *Obes Surg* 2021;31:1755–66.
13 Ivezaj V, Fu E, Lydecker JA, *et al*. Racial Comparisons of Postoperative Weight Loss and Eating-Disorder Psychopathology Among Patients Following Sleeve Gastrectomy Surgery. *Obesity (Silver Spring)* 2019;27:740–5.
14 Samaan JS, Abboud Y, Yuan L, *et al*. Racial disparities in bariatric surgery postoperative weight loss and patient satisfaction. *Am J Surg* 2022;223:969–74.
15 Angrisani L, Santonicola A, Iovino P, *et al*. Bariatric Surgery Survey 2018: similarities and Disparities Among the 5 IFSO Chapters. *Obes surg* 2021;31:1937–48.
16 Picot J, Jones J, Colquitt JL, *et al*. Weight loss surgery for mild to moderate obesity: a systematic review and economic evaluation. *Obes Surg* 2012;22:1496–506.
17 Clapp B, Ponce J, DeMaria E, *et al*. American Society for Metabolic and Bariatric Surgery 2020 estimateof metabolic and bariatric procedures performed in the United States. *Surg Obes Relat Dis* 2022;18:1134–40.
18 Alemán JO, Iyengar NM, Walker JM, *et al*. Effects of Rapid Weight Loss on Systemic and Adipose Tissue Inflammation and Metabolism in Obese Postmenopausal Women. *J Endocr Soc* 2017;1:625–37.
19 Jassil FC, Carnemolla A, Kingett H, *et al*. Protocol for a 1-year prospective, longitudinal cohort study of patients undergoing Roux-en-Y gastric bypass and sleeve gastrectomy: the BARI-LIFESTYLE observational study. *BMJ Open* 2018;8:e020659.
20 Twells LK, Gregory DM, Midodzi WK, *et al*. The Newfoundland and Labrador Bariatric Surgery Cohort Study: Rational and Study Protocol. *BMC Health Serv Res* 2016;16:618.
21 Neu C, Skitek K, Kissler H, *et al*. Body composition, mitochondrial oxygen metabolism and metabolome of patients with obesity before and after bariatric surgery (COMMITMENT): protocol for a monocentric prospective cohort study. *BMJ Open* 2022;12:e062592.
22 Grover BT, Morell MC, Kothari SN, *et al*. Defining Weight Loss After Bariatric Surgery: a Call for Standardization. *Obes Surg* 2019;29:3493–9.
23 Welbourn R, Hollyman M, Kinsman R, *et al*. Bariatric Surgery Worldwide: Baseline Demographic Description and One-Year Outcomes from the Fourth IFSO Global Registry Report 2018. *Obes Surg* 2019;29:782–95.

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