



**Universidade do Estado do Rio de Janeiro**

Centro Biomédico

Faculdade de Ciências Médicas

Eline Coan Romagna

**Nível de atividade física, tempo sedentário e ganho ponderal em pacientes submetidos à cirurgia bariátrica sem acompanhamento em serviços especializados de saúde: um estudo transversal**

Rio de Janeiro

2020

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Dissertação apresentada, como requisito parcial para obtenção do título de Mestre, ao Programa de Pós-Graduação em Fisiopatologia Clínica e Experimental, da Universidade do Estado do Rio de Janeiro.

Orientador: Prof. Dr. Luiz Guilherme Kraemer de Aguiar

Coorientadora: Prof.<sup>a</sup> Dra. Karynne Grutter Lisboa Lopes dos Santos

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2020

CATALOGAÇÃO NA FONTE  
UERJ/REDE SIRIUS/CBA

R756 Romagna, Eline Coan.  
Nível de atividade física, tempo sedentário e ganho ponderal em pacientes submetidos à cirurgia bariátrica sem acompanhamento em serviços especializados de saúde: um estudo transversal / Eline Coan Romagna – 2020.  
82 f.

Orientador: Luiz Guilherme Kraemer de Aguiar.

Coorientadora: Karynne Grutter Lisboa Lopes dos Santos.

Dissertação (mestrado) – Universidade do Estado do Rio de Janeiro, Faculdade de Ciências Médicas. Programa de Pós-graduação em Fisiopatologia e Clínica e Experimental.

1. Obesidade – Fisiopatologia - Teses. 2. Comportamento sedentário – Teses. 3. Exercícios físicos – Teses. 4. Ganho de peso – Teses. 5. Cirurgia bariátrica – Teses. I. Aguiar, Luiz Guilherme Kraemer de. II. Santos, Karynne Grutter Lisboa Lopes dos. III. Universidade do Estado do Rio de Janeiro. Faculdade de Ciências Médicas. IV. Título.

CDU 616-056.52:616-092

Bibliotecária: Kalina Silva CRB7/4377

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Assinatura

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Data

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2020

## **AGRADECIMENTOS**

Agradeço aos pacientes voluntários desta pesquisa, que se comprometeram e entenderam a importância da sua participação para o estudo do tema.

Agradeço enormemente a Dra. Karynne Grutter Lisboa Lopes dos Santos, que além de minha coorientadora, se tornou amiga, exemplo de pesquisadora, dedicada, e com um amor enorme pela ciência e pela arte de ensinar. Sem seu apoio e ensinamentos durante todo o mestrado não teria chegado aqui.

Agradeço ao meu orientador, Dr. Luiz Guilherme Kraemmer de Aguiar, pela imensa sabedoria, seriedade e competência no seu trabalho de orientador, professor e médico. Exemplo de pesquisador com muito amor pelo conhecimento de qualidade e ético.

Agradeço aos residentes de endocrinologia da Policlínica Piquet Carneiro pela convivência tão amigável e feliz nos dias de ambulatório e discussão de artigos.

Agradeço à enfermeira Kelly, às técnicas de enfermagem, às secretárias, ao nutricionista Nelson e à psicóloga Hilma, que juntos acolheram tão bem os pacientes da pesquisa.

Agradeço também ao meu noivo Diogo pelo super incentivo para realização do mestrado e pela ajuda acadêmica, além do companheirismo durante todo o processo.

Agradeço aos meus pais por sempre me incentivarem a buscar meus sonhos, mesmo que distante de casa, a estudar e ser alguém melhor.

## RESUMO

ROMAGNA, Eline Coan. *Nível de atividade física, tempo sedentário e reganho ponderal em pacientes submetidos à cirurgia bariátrica sem acompanhamento em serviços especializados de saúde: um estudo transversal*. 2020. 82 f. Dissertação (Mestrado em Fisiopatologia Clínica e Experimental) – Faculdade de Ciências Médicas, Universidade do Estado do Rio de Janeiro, Rio de Janeiro, 2020.

Evidências se acumulam mostrando a relação entre baixos níveis de atividade física (AF) e aumento do tempo em comportamento sedentário com piores desfechos em saúde. Comparamos os níveis de AF e tempo sedentário (TS) em pacientes pós-bariátricos sem acompanhamento multiprofissional de saúde prévio, com baixo *vs.* alto reganho ponderal. Adicionalmente, investigamos a concordância entre as medidas autorrelatadas *vs.* objetivas da AF de intensidade moderada a vigorosa (AFMV) e TS. As medidas de AF foram realizadas através da versão curta do Questionário Internacional de Atividade Física (IPAQ) e do acelerômetro ActiGraph GT3X+. Uma coorte prospectiva de 90 pacientes após *bypass* gástrico em Y de Roux (RYGB; n=76) ou gastrectomia vertical (SG; n=14), com idade de  $42 \pm 8$  anos, índice de massa corporal (IMC) de  $32,9 \pm 6,6$  kg/m<sup>2</sup>, foi alocada em dois grupos de acordo com o tempo desde a cirurgia < ou  $\geq 5$  anos (G5- ou G5+) e classificados em baixa ou alta taxa de reganho ponderal (TRP <20% ou  $\geq 20\%$ , respectivamente). Os pacientes também foram estratificados de acordo com o nível de AF <ou  $\geq 5000$  passos/dia (G1 ou G2, respectivamente). PA e TS foram semelhantes entre os grupos em G5- ( $P \geq 0,13$ ). Tempo de AFMV ( $P=0,04$ ), número de passos/dia ( $P=0,005$ ), percentual dos pacientes moderadamente ativos ( $P=0,007$ ) e de pacientes com 30–60 min/dia de AFMV ( $P=0,02$ ) foram maiores no grupo com taxa de reganho  $\geq 20\%$ , enquanto aqueles com <30 min/dia de AFMV ( $P=0,004$ ) estavam no grupo com taxa de reganho  $\geq 20\%$  *vs.* <20 / G5+. AFMV e TS autorreferidos *vs.* medidas objetivas estiveram correlacionadas ( $r=0,49$ ;  $P < 0,001$ ). No entanto, não houve concordância entre essas medidas ( $P > 0,05$ ). Baixo nível de PA e maior TS ocorreram mais em TRP  $\geq 20\%$ , especialmente com o tempo de cirurgia  $\geq 5$  anos. Não houve concordância entre as medidas do IPAQ e do acelerômetro, mas foi observada uma alta correlação linear.

Palavras-chave: Obesidade. Cirurgia bariátrica. Comportamento sedentário. Atividade física.

Recuperação de peso.

## ABSTRACT

ROMAGNA, Eline Coan. *Physical activity level, sedentary time and weight regain after bariatric surgery in patients without medical follow-up: a cross sectional study*. 2020. 82 f. Dissertação (Mestrado em Fisiopatologia Clínica e Experimental) – Faculdade de Ciências Médicas, Universidade do Estado do Rio de Janeiro, Rio de Janeiro, 2020.

The relationship between low levels of physical activity (PA) and increase of time of sedentary behavior with poorer health outcomes has been suggested. We compared physical activity (PA) levels and sedentary time (ST) between post-bariatric patients without medical follow-up at their first appointment, with low *vs.* high weight regain. Moreover, correlations between self-reported *vs.* objective measures in moderate-to-vigorous PA (MVPA) and ST were tested. A prospective cohort of 90 patients after *Roux-en-Y* gastric bypass (RYGB; n=76) or Sleeve gastrectomy (SG; n=14), aged 42±8 years, body mass index (BMI) 32.9±6.6 kg/m<sup>2</sup>, was allocated into two groups according to time since surgery < or ≥5 years (G5- or G5+), and assigned into low or high rate of weight regain (RWR<20% or ≥20%, respectively). They were also stratified according to PA level < or ≥5000 steps/day (G1 or G2, respectively). PA and ST were measured by International PA Questionnaire (IPAQ) and ActiGraph GT3X+ accelerometer. PA and ST were similar between groups/G5- ( $P \geq 0.13$ ). MVPA time ( $P=0.04$ ), number of steps/day ( $P=0.005$ ), % of patients somewhat active ( $P=0.007$ ), and patients with 30–60 min/day of MVPA ( $P=0.02$ ) were higher in RWR≥20%, while those with <30 min/d of MVPA ( $P=0.004$ ) were in the RWR≥20% *vs.* <20/G5+. MVPA and ST self-reported *vs.* objective measures were correlated ( $P < 0.001$ ). Nevertheless, there was no concordance between these measures ( $P > 0.05$ ). Low level of PA and longer ST occurred more in RWR≥20%, especially with time since surgery ≥5 years. There was no concordance between IPAQ and accelerometer measures, but a high linear correlation was noted.

Keywords: Obesity. Bariatric surgery. Sedentary behavior. Physical activity. Weight regain.

## LISTA DE ABREVIATURAS E SIGLAS

AACE	<i>American Association of Clinical Endocrinologists</i>
ABESO	Associação Brasileira para o Estudo da Obesidade e da Síndrome Metabólica
AF	Atividade física
AFMV	Atividade física moderada a vigorosa
ASMBS	<i>American Society for Metabolic and Bariatric Surgery</i>
CC	Circunferência da cintura
CQ	Circunferência do quadril
DP	Desvio padrão
GV	Gastrectomia vertical
IMC	Índice de massa corporal
IPAQ	Questionário Internacional de Atividade Física
OMS	Organização Mundial da Saúde
PA	Pressão arterial
PAD	Pressão arterial diastólica
PAS	Pressão arterial sistólica
PEP	Perda do excesso de peso
PPC	Policlínica Piquet Carneiro
RCQ	Relação cintura-quadril
RYGB	<i>Bypass Gástrico em Y de Roux</i>
SBCBM	Sociedade Brasileira de Cirurgia Bariátrica e Metabólica
TOS	<i>The Obesity Society</i>
TRP	Taxa de ganho ponderal
TS	Tempo Sedentário
UERJ	Universidade do Estado do Rio de Janeiro
VIGITEL	Vigilância de Fatores de Risco e Proteção para Doenças Crônicas por Inquérito Telefônico



## LISTA DE SÍMBOLOS

%	Porcentagem
$\geq$	Maior ou igual
kg/m <sup>2</sup>	Quilograma por metro ao quadrado
$\pm$	Mais ou menos
=	Igual
+	Adição
x	Multiplicação
<	Menor que
Hz	Hertz
$\leq$	Menor ou igual
>	Maior que

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## INTRODUÇÃO

A Organização Mundial de Saúde (OMS) aponta a obesidade como um dos maiores problemas de saúde pública no mundo. Em 2016, 39% dos adultos com idade 18 anos ou mais estavam com sobrepeso [índice de massa corporal (IMC)  $\geq 25$  kg/m<sup>2</sup>] e 13% tinham obesidade (IMC  $\geq 30$  kg/m<sup>2</sup>). Assim, mais de 1,9 bilhão de adultos apresentavam excesso de peso e, destes, mais de 650 milhões estavam no grupo considerado portadores de obesidade. No Brasil, segundo o Programa de Vigilância de Fatores de Risco e Proteção para Doenças Crônicas por Inquérito Telefônico (VIGITEL), a obesidade aumentou de 11,8% em 2006 para 18,9% em 2016 e 20,3% em 2019, mais da metade da população está com o IMC acima do recomendado pela OMS, isto é, um IMC de 18,6–24,9 kg/m<sup>2</sup>, contribuindo para o aumento das comorbidades cardiovasculares e metabólicas.

O tratamento da obesidade é um desafio para os profissionais da saúde, pois se trata de uma doença crônica multifatorial, de fisiopatologia complexa e com altos índices de recidiva ao longo da vida do paciente. As Diretrizes Brasileiras de Obesidade da Associação Brasileira para o Estudo da Obesidade e da Síndrome Metabólica (ABESO) orientam tratamento farmacológico e mudanças do estilo de vida, com dieta alimentar e prática regular de atividade física (AF). Quando a obesidade é refratária ao tratamento clínico há, no mínimo, dois anos indica-se a cirurgia bariátrica para pacientes com obesidade grau 2 (IMC  $\geq 35$  kg/m<sup>2</sup>) com comorbidades de difícil manejo clínico e naqueles com obesidade grau 3 (IMC  $\geq 40$  kg/m<sup>2</sup>) (1).

A cirurgia bariátrica é uma intervenção eficaz para o tratamento da obesidade, resultando em perda de peso substancial e sustentada, remissão de comorbidades metabólicas e cardiovasculares e redução nas taxas de mortalidade (2, 3). Embora os benefícios da cirurgia sejam reconhecidos, o manejo da obesidade não se limita ao procedimento cirúrgico. Observa-se que um subconjunto de pacientes submetidos à bariátrica (ou também conhecidos como “pós-bariátricos”) exhibe recuperação de peso a longo prazo e falha na perda de peso (4). A falha do procedimento cirúrgico, as alterações hormonais e metabólicas, os distúrbios de saúde mental, a não adesão nutricional e a inatividade física foram associadas à etiologia dessas condições (5), indicando a importância do apoio de uma equipe médica multidisciplinar para acompanhamento regular a longo prazo.

A adoção de um estilo de vida mais saudável, como a implementação das rotinas de AF, é um dos principais requisitos de qualquer programa de manutenção e perda de peso a

longo prazo (6, 7), sendo recomendado pelas diretrizes da *American Association of Clinical Endocrinologists* (AAACE), da *American Society for Metabolic and Bariatric Surgery* (ASMBS) e da *The Obesity Society* (TOS) no tratamento de pós-bariátricos (8). Além disso, os vários benefícios à saúde, como aumento da aptidão cardiorrespiratória, melhora do perfil metabólico, redução dos fatores de risco cardiovascular e minimização da perda de massa muscular e óssea, reforçam o potencial clínico da AF no tratamento desses pacientes (9-13). Por outro lado, os efeitos deletérios do comportamento sedentário foram associados ao risco de mortalidade por todas as causas e doenças cardiovasculares (14, 15), indicando que a modificação do perfil sedentário para o fisicamente ativo é necessária para promover efeitos protetores à saúde.

Dado o potencial efeito clínico da AF em pacientes pós-bariátricos, pouco se sabe se eles se exercitam o suficiente para obter benefícios à saúde (16). As medidas objetivas e autorreferidas para quantificação do nível de AF e tempo sedentário (TS) sugerem concordância limitada e destacando-se a importância de mais estudos comparativos em pós-bariátricos (17-19). Jacobi et al. (17) e Bond et al. (18) mostraram, através de medidas de autorrelato, que os pacientes se tornassem mais ativos fisicamente após a cirurgia. No entanto, medidas objetivas indicaram que esses pacientes não alteram seus níveis de AF (17, 18). Ao comparar medidas da AF de intensidade moderada a vigorosa (AFMV) de questionários vs. acelerômetros em pacientes antes e após o *bypass* gástrico em Y de Roux (RYGB) e banda gástrica ajustável por laparoscopia, Bond et al. (18) observaram aumento (cerca de cinco vezes) no tempo gasto na APMV pelos questionários em comparação com nenhuma mudança pelo acelerômetro, de antes para após a cirurgia bariátrica. Berglind et al. (19) também observaram que os aumentos da AF autorreferida do pré para o pós-RYGB não foram confirmados pelo acelerômetro.

Além disso, o papel do exercício físico para melhorar a perda de peso após cirurgia bariátrica não foi bem elucidado (16). A quantificação do nível de AF e o comportamento sedentário podem contribuir para entender a influência na perda de peso a longo prazo (2, 20) e, portanto, como uma terapia complementar à cirurgia. Cabe ressaltar que para um bom resultado da cirurgia bariátrica os pacientes devem manter acompanhamento médico e multiprofissional após o procedimento. Evidências mostram que pacientes que frequentam as consultas de acompanhamento, chamado *follow-up*, apresentam perda do excesso de peso (PEP) maior e taxa de ganho ponderal (TRP) menor do que aqueles que perderam o seguimento (21, 22). Considerando o exposto, investigamos a TRP em pacientes pós-bariátricos sem acompanhamento médico, comparando o nível de AF e o TS dessa população,

com baixo e alto ganho ponderal. Além disso, comparamos as medidas de AFMV e do TS pelo questionário IPAQ *vs.* aquelas aferidas através do acelerômetro.

## **1 OBJETIVOS**

### **1.1 Geral**

Investigar a taxa de ganho ponderal, o nível de atividade física e o tempo sedentário em pacientes pós-bariátricos sem acompanhamento em serviços especializados de saúde.

### **1.2 Específicos:**

- a) comparar os níveis de atividade física e tempo sedentário entre pacientes pós- bariátricos com baixo e alto ganho ponderal;
- b) comparar as medidas autorreferidas *vs.* objetivas da atividade física de intensidade moderada a vigorosa e o tempo sedentário em pacientes pós-bariátricos.

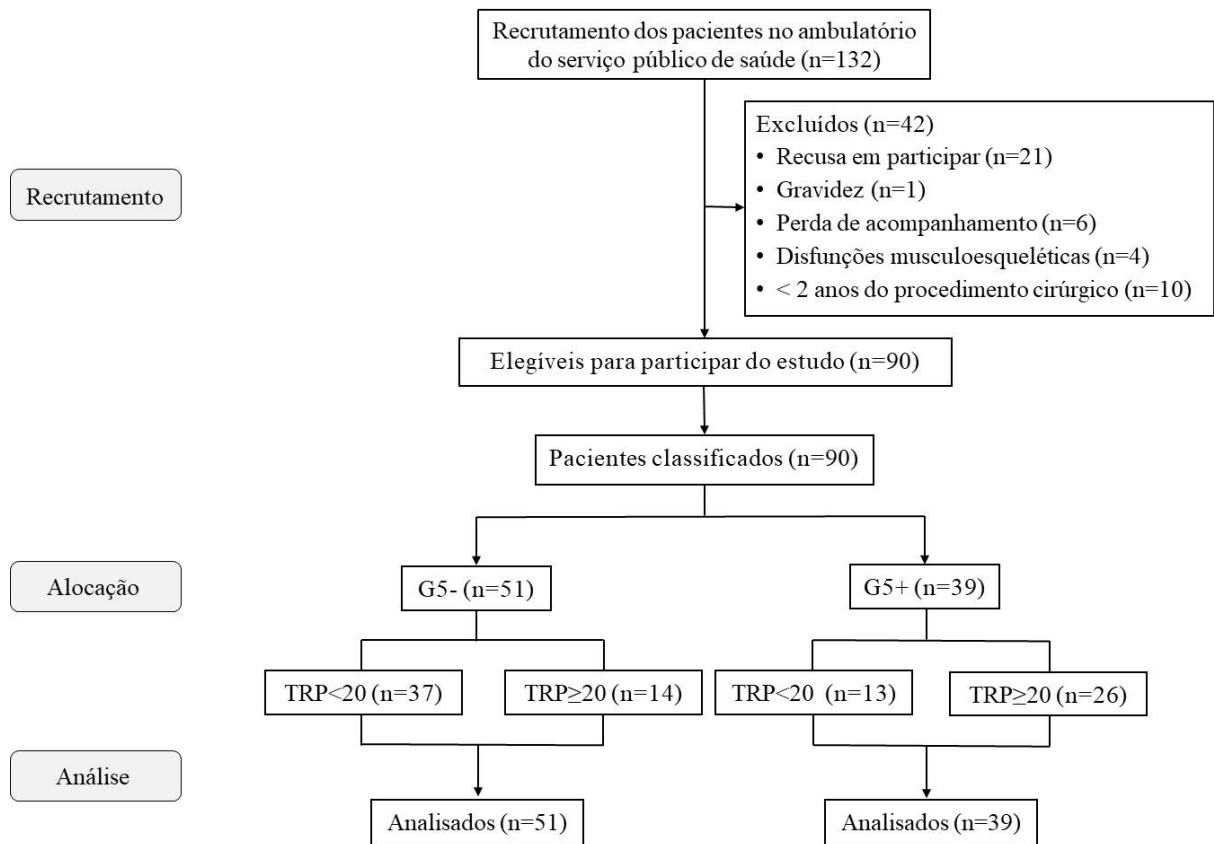
## 2 MATERIAL E MÉTODOS

### 2.1 Amostra

Noventa pacientes submetidos à cirurgia de *bypass* gástrico em Y de Roux (RYGB; n=77) ou gastrectomia vertical (Sleeve; n=13) (82 mulheres e 12 homens), com idade entre  $42\pm 8$  anos,  $IMC=32,9\pm 6,6$  kg/m<sup>2</sup>,  $PEP=89.3\pm 18.8\%$ ,  $TRP=18.7$  [9,7-33.3]% e tempo de cirurgia de  $6,2\pm 4,0$  anos participaram do estudo. Esses pacientes estavam sem acompanhamento por meio de consultas médicas ambulatoriais, orientações nutricionais e exames laboratoriais, pelos sistemas de saúde público e privado. Todos os voluntários foram recrutados na consulta de primeira vez em uma unidade de atendimento ambulatorial endocrinológico público, especializada em cirurgia bariátrica e obesidade.

Participantes com dificuldades de locomoção ou outras limitações clínicas que caracterizam mudanças na semana habitual, tempo de cirurgia bariátrica menor que dois anos e gravidez foram excluídos do estudo. Assim, do total dos 132 indivíduos recrutados inicialmente, quatro apresentaram comprometimentos osteomioarticulares, dez tinham menos de dois anos de procedimento cirúrgico, uma estava grávida, 21 tiveram perda de seguimento, seis tiveram perda de seguimento e 90 usaram o acelerômetro e responderam o questionário de AF. A Figura 1 exibe o diagrama de recrutamento, alocação e análise dos pacientes do estudo.

Figura 1 - Diagrama de recrutamento, alocação e análise dos participantes do estudo



Legenda: G5- – Tempo de cirurgia <5 anos; G5 + – Tempo de cirurgia ≥5 anos; Taxa de reganho ponderal (TRP)<20 –Taxa de reganho ponderal <20%; TRP≥20 –≥20%.

Fonte: A autora, 2020.

## 2.2 Tipo de estudo

O presente estudo caracterizou-se como um coorte transversal prospectivo realizado no Ambulatório de Obesidade e Medicina Bariátrica da Policlínica Piquet Carneiro (PPC) da Universidade do Estado do Rio de Janeiro (UERJ).



### 2.3 Ética da pesquisa

Este estudo foi aprovado pelo Comitê de Ética do Hospital Universitário Pedro Ernesto (CAAE: 07662918.1.0000.5259) e registrado no ClinicalTrials.gov (número de identificação NCT04193384). Todos os procedimentos envolvendo os participantes foram realizados de acordo com os princípios descritos na Declaração de Helsinki.

### 2.4 Grupos do estudo

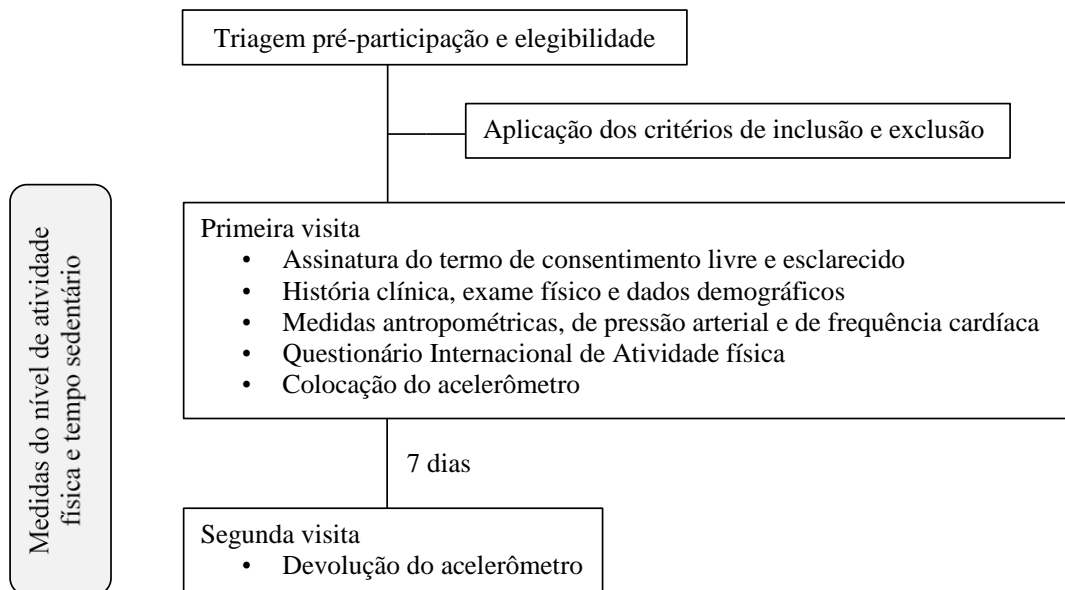
Os pacientes foram alocados em grupos de acordo com o tempo decorrido da cirurgia em menor ou maior ou igual a cinco anos (G5- ou G5+, respectivamente) e classificados de acordo com a TRP em baixa ou alta, quando menor que ou maior ou igual a 20% (TRP <20 ou TRP ≥ 20, respectivamente). Estratificação adicional foi feita com base no nível de AF regular (G1: <5000 passos/dia; G2: ≥ 5000 passos/dia).

### 2.5 Desenho experimental

Os participantes foram submetidos a uma triagem pré-participação antes de serem elegíveis para o estudo. O protocolo de pesquisa foi explicado e o consentimento informado por escrito foi obtido de todos os voluntários. Na primeira consulta, foram realizados histórico clínico, exame físico, medidas demográficas, antropométricas e de pressão arterial (PA). Após as medições, os participantes responderam ao questionário Internacional de Atividade Física (IPAQ) e foram convidados a usar o acelerômetro.

Na segunda visita, os pacientes retornaram para entregar o acelerômetro. Os pacientes foram recrutados e avaliados de novembro de 2018 a dezembro de 2019. A Figura 2 mostra o fluxograma do desenho experimental.

Figura 2 - Desenho experimental



Fonte: A autora, 2020.

## 2.6 Antropometria e pressão arterial

A estatura e a massa corporal foram medidas por meio de estadiômetro e balança eletrônica calibrada (Welmy<sup>TM</sup> W300A, São Paulo, SP, Brazil ). O IMC foi calculado como a razão entre a massa corporal e a estatura ao quadrado ( $\text{kg}/\text{m}^2$ ). A circunferência do pescoço foi medida ao longo da margem inferior da proeminência laríngea e ao longo do eixo do pescoço. A circunferência da cintura (CC) foi medida no umbigo após a expiração e o quadril (CQ) na maior circunferência em torno da região glútea. A relação cintura-quadril (RCQ) foi calculada. Todas as medidas foram realizadas pelo mesmo avaliador treinado.

O peso pré e pós-operatório (o peso pós-operatório foi considerado o menor peso atingido após a cirurgia bariátrica) foram obtidos por autorrelato por duas vezes (em ocasiões distintas, sendo a primeira vez nessa consulta e a segunda vez, por consulta telefônica) em todos os pacientes. O IMC pré-operatório e mínimo no pós-operatório foram calculados. A PEP e a TRP foram obtidas pelas equações:

PEP =  $(\text{peso pré-cirurgia} - \text{peso mínimo} \times 100 / (\text{peso pré-cirurgia} - \text{peso ideal; com refer\u00eancia ao IMC de } 25 \text{ kg/m}^2))$ , expressa em percentual. (1)

TRP =  $[(\text{peso atual} - \text{peso m\u00ednimo ap\u00f3s a cirurgia}) \times 100 / (\text{peso pr\u00e9-cirurgia} - \text{peso m\u00ednimo ap\u00f3s a cirurgia})]$ , expressa em percentual. (2)

A PA foi medida duas vezes, com o paciente sentado e em p\u00e9 por dispositivo oscilom\u00e9trico semiautomatizado (G-Tech<sup>TM</sup> BSP11, Hangzhou, Zhejiang, China) de acordo com a recomenda\u00e7\u00e3o padr\u00e3o (23).

## 2.7 Medida da atividade f\u00edsica objetiva

O monitor de atividade triaxial ActiGraph GT3X + (Actigraph, Pensacola, FL, EUA) foi utilizado para avaliar os n\u00edveis de AF e o TS. Os pacientes foram instr\u00fados a usar o aceler\u00f4metro no quadril (lado dominante) atrav\u00e9s de um cinto el\u00e1stico espec\u00edfico por sete dias consecutivos de uma semana habitual e remov\u00ea-lo apenas durante o sono e o banho. Os pacientes foram orientados a n\u00e3o alterar intencionalmente seus h\u00e1bitos de atividade f\u00edsica ou rotina di\u00e1ria ao longo do estudo. Foram realizadas liga\u00e7\u00f5es telef\u00f4nicas di\u00e1rias para garantir o uso adequado dos equipamentos. Os dados foram coletados em uma frequ\u00eancia de 30Hz e analisados em epochs de 60 segundos usando o software ActiLife vers\u00e3o 6.8.2 (Actigraph, Pensacola, FL, EUA). Foram considerados dados v\u00e1lidos o uso do aceler\u00f4metro por no m\u00ednimo quatro dias, sendo um dia de fim de semana, com registro de pelo menos 10 horas de uso. Para avaliar os minutos gastos em AF por dia, calculamos a contagem de atividades por minuto e o n\u00famero de minutos gastos em diferentes n\u00edveis de atividade e tempo em estado sedent\u00e1rio.

Tempo sedent\u00e1rio e de atividades de intensidades leves, moderadas e vigorosas foram definidas na faixa de *counts*/minutos de 1–99, 100–2019, 2020–5998 e acima de 5999, respectivamente (24). Os valores de *counts* s\u00e3o traduzidos para minutos de atividade f\u00edsica. A contagem de passos por minuto foi registrada continuamente por 1440 min/dia para produzir um registro di\u00e1rio e, foram somadas e divididas pelo n\u00famero de dias em que o aceler\u00f4metro foi usado para derivar passos m\u00e9dios por dia. Utilizamos pontos de corte determinados por n\u00famero de passos/dia, como segue: a) <5000 (sedent\u00e1rio); b) 5000–7499 (pouco ativo); c)

7500–9999 (moderadamente ativo); d) 10000–12499 (ativo) e e)  $\geq 12500$  (altamente ativo) (25, 26).

## 2.8 Medida da atividade física autorreferida

A versão curta do IPAQ foi aplicada como um instrumento para monitorar a AF autorreferida, nos últimos sete dias, em uma semana habitual (27). Foram obtidas a frequência e a duração (em min/sem) de caminhada, de atividades de intensidades moderadas e vigorosas, bem como o tempo gasto sentado, globalmente em todos os contextos da vida cotidiana.

## 2.9 Análise estatística

A normalidade dos dados foi confirmada pelo teste de Shapiro Wilk e os resultados foram expressos como média $\pm$ desvio padrão (DP). As diferenças entre os grupos foram testadas por meio dos testes t não pareado ou do qui-quadrado. Correlações de Pearson testaram as associações entre AFMV e TS medidos pelo IPAQ vs. acelerômetro, bem como as informações obtidas por autorrelato em dois momentos cirúrgicos (peso pré-operatório e peso mínimo pós-operatório) e em duas ocasiões diferentes. O coeficiente de correlação interclasse foi usado para verificar a concordância entre as medidas do IPAQ vs. acelerômetro.

Foram criadas novas variáveis categóricas binárias para indicar: a) tempo desde a cirurgia  $\geq$  ou  $< 5$  anos; b) tempo desde a cirurgia  $\geq$  ou  $< 10$  anos; c) TRP  $\geq$  ou  $< 20\%$ ; d) se o paciente é sedentário; e) se o paciente é fisicamente ativo. As variáveis categóricas binárias da atividade do paciente foram derivadas de dados obtidos por meio do acelerômetro. Dessa forma, o conjunto de dados enriquecido foi processado por meio do algoritmo de eliminação de características *backward*, apoiado por um classificador Bayesiano ingênuo para indicar as variáveis mais relevantes para a classificação de um paciente de acordo com o ganho de peso. Vale ressaltar que a variável de recuperação de peso (TRP  $\geq 20\%$ ) não é utilizada entre as variáveis de classificação, mas é a classe alvo do classificador Bayesiano. Para atingir 95% de precisão na classificação, o algoritmo para eliminação de recurso reverso determinou que as

seguintes variáveis foram as mais importantes: tipo de cirurgia, peso ideal, CQ, PA sistólica (PAS), AFMV medido pelo IPAQ, equivalentes metabólicos/dia, AF leve, TS, “ativo” (10000-12499 passos/dia) medido pelo acelerômetro e tempo de cirurgia  $\geq 5$  anos. Assim, adotamos o ponto de corte de 5 anos de cirurgia. Ao dividir o conjunto de dados em dois grupos,  $<$  ou  $\geq 5$  anos desde a cirurgia (G5- ou G5 +), é possível observar que a variável TRP apresenta um comportamento diferente entre os grupos ( $P < 0,001$ ), considerando um teste t para independente grupos, ambos assumindo variância igual ou variância diferente entre os grupos. Todos os cálculos foram realizados pelo software estatístico NCSS<sup>TM</sup> (Kaysville, UT, EUA) e pelo KNIME 4.1.0 (KNIME AG, Zurique, Suíça) e a significância estatística foi fixada em  $P \leq 0,05$ .

### 3 RESULTADOS

#### 3.1 Physical activity level, sedentary time and weight regain after bariatric surgery in patients without medical follow-up: a cross-sectional study (artigo submetido)

(1ª submissão – Obesity Surgery Journal – IF: 3,412)

**Full title:** Physical activity level, sedentary time and weight regain after bariatric surgery in patients without medical follow-up: a cross-sectional study

**Short title:** Physical activity and obesity

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**Word count:** Main document – words; Abstract – words; Tables – 3; Figures – 1

## **Abstract**

**Background:** We compared physical activity (PA) levels and sedentary time (ST) between post-bariatric patients without medical follow-up at their first appointment. Moreover, we investigated the correlations between self-reported and objective measures in moderate-to-vigorous PA (MVPA) and ST.

**Methods:** A prospective cohort of 90 patients after *Roux-en-Y* gastric bypass (RYGB; n=76) or Sleeve gastrectomy (SG; n=14), aged  $42\pm 8$  years, BMI  $32.9\pm 6.6$  kg/m<sup>2</sup>, was allocated into two groups according to time since surgery < or  $\geq 5$  years (G5- or G5+), and assigned into low or high rate of weight regain (RWR < 20% or  $\geq 20\%$ , respectively). They were also stratified according to PA level < or  $\geq 5000$  steps/day (G1 or G2, respectively). PA and ST were measured by International PA Questionnaire (IPAQ) and ActiGraph GT3X+ accelerometer.

**Results:** PA and ST were similar between groups/G5- ( $P\geq 0.13$ ). MVPA time ( $P=0.04$ ), number of steps/day ( $P=0.005$ ), % of patients somewhat active ( $P=0.007$ ), and with 30–60 min/day of MVPA ( $P=0.02$ ) were higher in RWR  $\geq 20\%$ , while those with <30 min/d of MVPA ( $P=0.004$ ) were in the RWR  $\geq 20\%$  vs. <20/G5+. MVPA and ST self-reported vs. objective measures were correlated ( $P<0.001$ ). Nevertheless, there was no concordance between these measures ( $P>0.05$ ).

**Conclusions:** Low level of PA and longer ST occurred more in RWR  $\geq 20\%$ , especially with time since surgery  $\geq 5$  years. There was no concordance between IPAQ and accelerometer measures, but a high linear correlation was noted.

**Keywords:** bariatric surgery, sedentary behavior, physical activity and weight regain.

## **Introduction**

Bariatric surgery is effective treatment for obesity. It induces substantial and sustained weight loss, remission of metabolic and cardiovascular comorbidities related to obesity, improvement in the quality of life, and reduction in mortality rates [1,2]. Although with all these benefits, the management of post-bariatric patients is not limited to the surgical procedure. A minority of post-bariatric patients may exhibit failure of weight loss, and unfortunately, long-term weight regain is a cause of concern [3]. Multiple interrelated factors are possibly associated with post-surgery weight regain, like procedure failure, hormonal and metabolic alterations, mental disorders, nutritional non-adherence, and physical inactivity [4]. For better health outcomes, long-term results on post-bariatric patients indicate the importance of support from multidisciplinary interventions in a regular follow-up.

Current position statements recommend the adoption of a healthier lifestyle with the implementation of physical activity (PA) routines, being one of the requirements of any long-term program for weight loss or maintenance [5,6], including for post-bariatric patients [7]. Benefits are not limited to weight loss or maintenance, but also include increased cardiorespiratory fitness, improved metabolic profile, and reduced cardiovascular risk, while the loss of muscle and bone masses are minimized. These benefits reinforce PA's clinical impact as a non-pharmacological strategy to treat post-bariatric patients [8–12]. Recently, the deleterious effects of the sedentary behavior were associated with a higher risk for all-cause and cardiovascular mortality [13,14]. Therefore, it is of utmost importance to warn the population and implement more significant efforts to combat the physical inactivity, especially those clinical groups followed on the healthcare system.

Although the clinical potential of physical exercise for post-bariatric patients is recognized, little is known if post-bariatric patients exercise enough to get health benefits [15]. Besides, it is unknown the influence of exercise to prevent weight regain following



surgery [15]. In this context, habitual PA quantification may contribute to our understanding of how PA may influence weight loss and regain [16,17]. Moreover, how PA should be prescribed as a post-surgery complementary therapy. However, trials comparing objective *vs.* self-reported measures produced limited concordance [18,19]. Bond *et al.* observed increased time spent in moderate-to-vigorous PA (MVPA) reported by questionnaires compared to no significant change in accelerometer-measured MVPA in post-surgery [19]. Berglind *et al.* also observed substantial increases in self-reported PA post-surgery, which were not confirmed by accelerometer-measured PA [18]. Additional studies are needed to confirm the possible overstimulation of self-reported measures in post-bariatric patients.

Post-bariatric weight regains frequently occur, and when limited to 20%, it is even considered expected, especially after the weight stability [20]. There is a lack of studies in post-bariatric patients on different levels of PA, sedentary behavior, weight regain, and other surgical outcomes. Additionally, a comparison between self-reported *vs.* objective measures of PA is still a matter of contradiction. We aimed to study post-bariatric patients without any clinical follow-up in regard to low and high regain, PA level, and sedentary time (ST). Additionally, correlations between self-reported *vs.* objective PA in MVPA and ST measures have been tested. We hypothesized that non-adherence to recommendations of MVPA and the increased sedentary behavior would contribute to weight regain.

## **Methods**

### **Participants**

We enrolled 132 post-bariatric volunteers who were without any clinical follow-up. Ninety patients [76 were subjected to *Roux-en-Y* gastric bypass (RYGB) and 14 to sleeve gastrectomy (SG)] participated in the study. Of these, 80 females/10 males, aged  $42 \pm 8$  years, with a BMI of  $32.9 \pm 6.6$  kg/m<sup>2</sup>, an excess of weight loss (EWL) of  $89.3 \pm 18.8\%$ , a rate of weight regain (RWR) of  $18.7$  [9.7–33.3]% and mean time since surgery of  $6.2 \pm 4.0$  years.

Patients were allocated into groups according to the time since surgery  $<$  or  $\geq$  five years (G5- or G5+) and assigned into low or high RWR  $<$  or  $\geq 20\%$  (RWR $<20$  or RWR $\geq 20$ ), respectively. Additional stratification was made based on regular PA level (G1:  $<$  5000 steps/day; G2:  $\geq$  5000 steps/day).

All volunteers were recruited in the outpatient care at University Clinic during their first appointment. Participants with musculoskeletal impairments, or other limitations that prevent wearing an accelerometer,  $<2$  years of surgical procedure and pregnancy were excluded. All excluded patients were followed to routine treatment at the unit. Figure 1 presents the flowchart of the enrollment, allocation, and follow-up of participants.

Insert (Figure 1)

### **Experimental design and ethics**

The prospective cohort study was settled in a public health care unit that received patients submitted to a bariatric procedure at the supplementary health system who were without medical follow-up. The recruitment period occurred from November 2018 to December 2019. The participants were subjected to a pre-participation screening before being eligible for the study. Type of surgery was related by all participants and posteriorly confirmed by digestive endoscopy. The research protocol was explained, and all volunteers gave us a signed informed consent. In the first visit, clinical history, physical examination, demographic, anthropometric, and blood pressure (BP) measurements were assessed. Furthermore, participants answered the short-version of the International Physical Activity Questionnaire (IPAQ) and were invited to wear the accelerometer, which was delivered seven days after.

All procedures involving the participants were performed according to the principles outlined in the Declaration of Helsinki, and the protocol was approved by the local Ethics

Committee (CAAE: 07662918.1.0000.5259) and registered in ClinicalTrials.gov (NCT04193384).

### **Anthropometry and blood pressure assessments**

Body mass and height were measured using a calibrated electronic scale and stadiometer (Welmy™ W300A, São Paulo, SP, Brazil). Waist circumference was measured at the umbilicus level after expiration, and hip at the widest circumference around of the gluteal region. BMI and waist-to-hip ratio were calculated. Neck circumference was measured along the inferior margin of the laryngeal prominence and perpendicular to the neck's long axis. All measures were performed twice by the same trained evaluator.

Preoperative weight and minimum postoperative weight were self-reported by all patients, and BMI according to these self-reported weights was calculated. We have also called all these patients six months after the first visit and re-asked about their preoperative weight and minimum postoperative weight. EWL and RWR were obtained by percentage as follows: a)  $EWL = (\text{preoperative weight} - \text{minimum postoperative weight}) / (\text{preoperative weight} - \text{ideal weight for BMI of } 25 \text{ kg/m}^2) \times 100\%$  and b)  $RWR = (\text{current weight} - \text{minimum weight postoperative}) / (\text{preoperative weight} - \text{minimum weight postoperative}) \times 100\%$ .

BP was measured twice in a sitting position by a semiautomated oscillometric device (G-Tech™ BSP11, Hangzhou, Zhejiang, China) according to standard recommendations [21].

### **Self-reported and objective physical activity and sedentary time**

Short-version of IPAQ was applied as an instrument for monitoring of self-reported PA and ST in the past seven days considering an usual week, as described elsewhere [22]. IPAQ's data on frequency and duration of participation in PA were recorded as min/week of walking, moderate, and vigorous activities and spent time sitting.

PA and ST levels were also objectively measured using a triaxial accelerometer (ActiGraph GT3X+, Actigraph<sup>TM</sup>, Pensacola, FL, USA). Patients were instructed to wear the device at the end of the first medical appointment. The site to use it was on their hip with an elasticized fabric belt for seven consecutive days and removing it only during sleeping and bathing. They were oriented not to intentionally change their PA habits or daily routine throughout the target week. Data were analyzed in 60s epochs using the ActiLife<sup>TM</sup> software version 6.8.2 (Actigraph, Pensacola, FL, USA). Sixty or more consecutive minutes of zero counts defined a non-wear period, excluding the recordings from the analysis. Inclusion criteria for valid data were: more than 10h of valid data recorded/day, and data of, at least, four days, including at least one weekend day. Sedentary, light, moderate, and vigorous-intensity activities were expressed in counts/min and ranged from 1–99, 100–2019, 2020–5998, and >5999, respectively [23]. Steps/min were recorded continuously during 1440 min/day to produce a daily record, which was summed and divided by the number of wearing days to derive the average steps/day.

Validated cut-off points [24,25] were used to classify the PA level based on steps/day, as follows: a) <5000, “sedentary”; b) 5000-7499, “low active”; c) 7500-9999, “somewhat active”; d) 10000-12499, “active”; and e)  $\geq 12500$ , “highly active”.

### **Statistical analysis**

Data normality was confirmed by the Shapiro Wilk test and results were expressed as mean $\pm$ standard deviation (SD). Between-group differences were tested through unpaired t-test or Chi-square test. Pearson correlations determined the associations between MVPA and ST by IPAQ *vs.* accelerometer, and informations obtained by self-report (pre and minimum post-surgery weight). The Interclass Correlation Coefficient was used to verify the concordance between IPAQ *vs.* accelerometer measurements.

We create new binary categorical variables to indicate: i) time since surgery  $>$  or  $<5$  years, ii) time since surgery  $>$  or  $<10$  years, iii) RWR  $>$  or  $<20\%$ , iv) whether the patient is sedentary, and v) whether the patient is physically active. The binary categorical variables of the patient's activity were derived from data obtained through the accelerometer. In this way, the enriched dataset was processed through the backward feature elimination algorithm, supported by a naive Bayesian classifier, to indicate the most relevant variables for the classification of a patient according to weight regain. It is noteworthy that the weight regain variable (RWR $>20\%$ ) is not used among the classification variables, but it is the target class of the Bayesian classifier. To achieve 95% accuracy in classification, the algorithm for backward feature elimination determines that the following variables are the most important: type of surgery, ideal weight, hip circumference, systolic BP (SBP), MVPA measured by IPAQ, metabolic equivalent/day, light PA, ST, “active” (10000–12499 steps/day) measured by the accelerometer, and time since surgery  $\geq 5$  years. Thus, we adopted the cutoff of 5 years since surgery. When splitting the dataset into two groups,  $<$  or  $\geq 5$  years since surgery (G5- or G5+), it is possible to observe that the RWR variable presents a different behavior between groups ( $P < 0.001$ ), considering a *t*-test for independent groups, both assuming equal variance or different variance between groups. All calculations were performed by NCSS<sup>TM</sup> statistical software (Kaysville, UT, USA) and by KNIME 4.1.0 (KNIME AG, Zurich, Switzerland) and statistical significance was set at  $P \leq 0.05$ .

## Results

Demographic characteristics, clinical history and bariatric surgery data are displayed in Table 1. Significant differences in weight, BMI, hip circumference, RWR and time after surgery were detected between RWR $<20$  and RWR $\geq 20$  ( $P \leq 0.05$ , for both groups). Heart rate ( $P=0.02$ ) was significantly higher in RWR $\geq 20$  than RWR $<20$  (G5-), but it did not differ in G5+ ( $P=0.21$ ). Female, height, neck and waist circumference, and diastolic (DBP) were

higher in  $RWR \geq 20$  compared to  $RWR < 20$  in G5+ ( $P \leq 0.05$ , for all variables). No differences were found for age, waist-to-hip ratio, SBP, clinical history and other bariatric surgery data in both groups. Highly significant correlations were detected between self-report data on first vs. second reports for preoperative and minimum postoperative weight, respectively ( $r=0.97$  and  $r=0.91$ ,  $P < 0.0001$ ).

Insert (table 1)

### **Physical activity levels and sedentary time**

Data of PA levels and ST are depicted in Table 2. There was no difference between groups in G5- for PA levels and ST ( $P \geq 0.13$ ). On the counterpoint, in G5+ we noticed many differences between groups according to weight regain. MVPA time, number of steps/day, percentages of patients somewhat active and with 30–60 min/day of MVPA were significantly lower in  $RWR \geq 20$  vs.  $RWR < 20$  in G5+, and with  $< 30$  min/day of MVPA was higher in  $RWR \geq 20$  ( $P=0.004$ , for all comparisons).

Significant correlations were detected in the pooled sample between MVPA self-reported vs. MVPA objective measure ( $r=0.49$ ;  $P < 0.001$ ) and between ST self-reported vs. ST objective ( $r=0.32$ ,  $P < 0.001$ ). The Interclass Correlation Coefficient (ICC) analysis verifies the agreement between the classification of activities between objective measures from the accelerometer and the self-reported measures. It was deployed the Two-Way Mixed-Effects model. For all reported activities, it was not possible to verify the agreement between the two assessments, as the ICC value reported for each activity was much less than 0.5, considering a 95% confidence interval. However, a low ICC may reflect the low degree of agreement in the evaluations and may be related to the lack of variability between the samples, the small number of samples, and the small number of raters. It is worth noting that the highest concordance level is in moderate activities,  $ICC = 0.344$  ( $P < 0.01$ ). The result reveals that there is a more significant concordance between the accelerometer measurements and the self-

reported moderate activity than reports of other activity levels. It is also noteworthy that there is no concordance when evaluating the sedentary time, with an ICC value less than 0.25 for a 95% confidence interval. The self-reported time sitting is, on average, 37.8% of the measured time, with values varying 2% for a 95% confidence interval.

Insert (table 2)

### **Data of study subjects by physical activity level**

Table 3 exhibits results of demographic characteristics, clinical history and bariatric surgery data of study subjects by PA level. Those with <5000 steps/day (G1) exhibited higher weight, BMI, waist and hip circumferences, systolic (SBP) than G2 ( $P \leq 0.03$ , for all variables), while the height was lower in G1 vs. G2 ( $P = 0.004$ ). No differences across groups were found for the prevalence of clinical history ( $P \geq 0.09$ ). Minimum postoperative weight, RWR and surgery time were higher in G1 vs. G2 ( $P \leq 0.02$ , for all variables).

Insert (table 3)

### **Discussion**

The present study compared post-bariatric patients without any medical follow-up in regard to low and high weight regain, PA level, and ST. In addition, concordance between self-reported vs. objective PA in MVPA and ST measures were tested. Although patients came from different surgeons, we confirmed it by gastro endoscopy. Besides, we can assure they were effective [26] in promoting weight loss since EWL post-surgery was substantial and did not differ between groups. Therefore, we can exclude surgical failure in those with weight regain [4].

The clinical history did not differ between studied groups, reflecting the efficacy of bariatric surgery in the treatment of obesity [1,2]. As expected, in general, patients with  $RWR \geq 20$  exhibited higher weight, BMI, neck, waist and hip circumferences, DBP, and heart rate than  $RWR < 20$ , demonstrating a poor cardiometabolic profile [27–30], which is a

clinically relevant issue. However, bariatric surgery is still considered the most effective treatment for obesity with well-established benefits, including improvement of cardiometabolic profile and control of comorbidities [1,2]. Lifestyle modifications after surgery are recommended to maintain the achieved weight loss, optimizing the obtained results [31]. The statement is also consistent with our results, in which the majority of our patients are physically inactive [32,33], spending long hours sedentary [39,40].

Differences in level PA and ST were only noticed in those >5 years since surgery with lower time of MVPA and steps/day in  $RWR \geq 20$  (table 2). The results suggest that the surgically induced weight loss implies no changes in the PA routine and, thus, after surgery, patients did not increase their PA levels to meet current recommendations of 30 min per day of MVPA [19,34–36]. In addition, the increases in body weight observed in  $RWR \geq 20/G5+$  may have contributed to decreased mobility for activities of daily living [37].

Recently, pieces of evidence indicate that sedentary behaviors, like spent time watching TV and reductions in energy expenditure in occupational activities, are risk factors for cardiometabolic disease and mortality [14,38]. Besides, they are associated with weight gain and several health-related outcomes negative [39,40], which are consistent with our results. On the other hand, the replacement of time sitting with light-intensity walking improved insulin sensitivity and reduced 24-h glucose levels in patients with metabolic disease [41]. It was prospectively demonstrated reduction by 11% and 24% of mortality risk from all-cause and cardiovascular, respectively when 30 min/day of ST is replaced with 30 min/day of light-intensity PA [42]. These data reinforce the importance of reducing ST and highlight the potential clinical application of light-intensity PA in individuals with limitations for MVPA, such as those with obesity.

Considering steps/day, we observed that 41% of our patients are physically inactive [24,25]. Both groups ( $>$  or  $\leq$  5000 steps/day) showed similar preoperative weight, BMI, and



EWL, but those less active exhibited higher minimum postoperative weight and RWR than those with more than >5000 steps/day (table 3). Additionally, the worst metabolic and cardiovascular profile was observed in those less active. We could speculate that a sedentary lifestyle already existed in G1 since surgery, contributing to poorer outcomes [43].

Active lifestyle should be incorporated into routine clinical care [44,45]. Post-bariatric patients should be encouraged to increase levels of MVPA and to lower sedentary behaviors, with resultant improvements in body composition and surgical outcomes [46,47]. Although, improvements in health outcomes may be reached by modest weight loss (5–10%) [48], the physical exercise promotes numerous benefits that occur regardless of body weight loss, as in disease parameters, cardiovascular and metabolic risk profile, cardiorespiratory and muscle fitness, and quality of life [32,33,47], indicating the therapeutic effect of physical exercise on several health markers.

Current guidelines recommend  $\geq 150$  min/week of MVPA for improving or maintaining physical fitness and health [32,33,47]. Higher volume physical exercise can promote weight loss and prevent weight gain in post-bariatric patients [5,49,50], but it may be difficult to meet long-term adherence [12]. Physical exercise counseling strategies can help post-bariatric patients to increase the PA level in the daily routine [46], and must be considered in clinical care for obesity management.

Finally, although there is no concordance between self-reported and accelerometer-measured PA, we showed that there is a linear correlation between them, which is in contradiction with other trials that observed an overestimation in self-reported MVPA compared to objective measures post-surgery but tested yet in the first year post-surgery [18,19]. In this way, we conclude that the self-reported measurements are reliable indicators to qualify PA performance, but they are not reliable to quantify them, since these measurements translate the patients' perception about the level of PA, while the accelerometer

measurements are objective quantifiers. Following our data, when evaluating patients with longer post-operative time (48 months post-RYGB), a significant correlation between questionnaire and accelerometer measures was noted [51].

The perceptions of improvement in physical function, health-related quality of life, and emotional and mental well for the PA by weight loss post-surgery may be associated with the subjective perception of increased MVPA reported by IPAQ observed in studies [37,52–54]. The results support whether the reliable use of questionnaires as a practical and inexpensive alternative in clinical practice to quantify PA and ST levels in post-bariatric patients.

### **Limitations**

The present study has limitations. The cross-sectional design of the study limits our discussion, not allowing causal relationships. Different medical staff and experiences with bariatric procedures imply varied surgical technical factors and should be considered among patients, although they all reached adequate EWL. We could not address whether RWR occurred due to other predictive factors [3] and whether the RWR would decrease by adherence to recommendations of MVPA. Finally, the investigation of other etiological factors that influence weight regain following bariatric surgery, as endocrine and metabolic alterations, mental health issues, and nutritional non-adherence, would allow a better understanding of the pathophysiology of obesity in sampled data.

### **Conclusions**

In conclusion, in the first appointment of post-bariatric patients without medical follow-up the MVPA measured was lower than the current recommendations to control body weight and improve health outcomes, and a longer time spending in sedentary behavior was observed. Additionally, the IPAQ was useful and reliable for qualifying PA and ST in these patients. In routine clinical practice post-bariatric patients should be encouraged to regularly

perform physical activities to improve the surgical outcomes, and to obtain health benefits, especially after 5-years from surgery. Further research is warranted to confirm the present results and to investigate the role of PA and ST in the etiology of weight regain post-surgery.

### **Funding**

Coordination for the Improvement of Higher Education Personnel (CAPES), Brazilian Council for Technological and Scientific Development (CNPq) and Carlos Chagas Filho Foundation for the Research Support in the State of Rio de Janeiro (FAPERJ) supported this work.

### **Conflict of interest statement**

The authors declare no conflict of interest.

### **Author contributions statement**

The original study design was made by LGK-A. The project administration and supervision were performed by LGK-A. ECR and KGL recruited the patients and collected the data. ECR, KGL, DMF, PF, and LGK analyzed the data, interpreted the results, and drafted and revised the manuscript. All authors approved the final version of the manuscript.

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## FIGURE

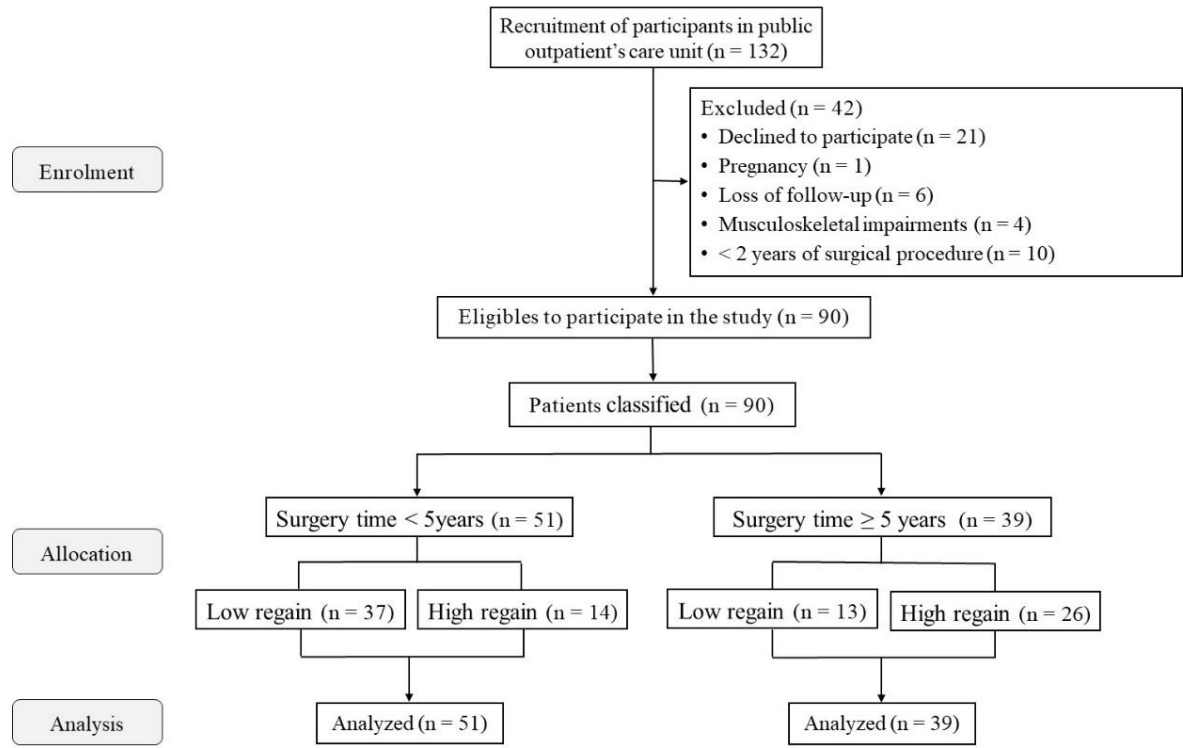


Figure 1. Flow diagram of participants enrolment, allocation, follow-up and data analysis.

G5- – Time since surgery < five years; G5+ – Time since surgery  $\geq$  five years; RWR<20 – Rate of weight regain <20%; RWR $\geq$ 20 – Rate of weight regain  $\geq$ 20%

## TABLES

Table 1. Demographic characteristics, clinical history and bariatric surgery data of study subjects

Variable	PS (n=90)	G5- (n=51)		P value	G5+ (n=39)		P value
		RWR<20 (n=37)	RWR≥20 (n=14)		RWR<20 (n=13)	RWR≥20 (n=26)	
Demographic characteristics							
Age (yrs)	42±8	41±8	38±8	0.13	46±7	43±9	0.19
Female (n, %)	80 (88.9)	34 (91.9)	12 (85.7)	0.50	8 (61.5)*	26 (100)	< 0.001
Weight (kg)	84.0 [71.7–100.5]	78.3±14.0*	88.7±18.8	0.02	78.9±12.8*	106.9±25.4	< 0.001
Height (cm)	163.0±0.1	162±0.1	165±0.1	0.11	161±0.1*	166±0.1	0.04
BMI (kg/m <sup>2</sup> )	32.9±6.6	29.8±4.1*	32.7±6.4	0.03	30.6±5.0*	38.5±7.0	< 0.001
Neck circumference (cm)	35.9±3.6	35.0±2.8	35.8±3.2	0.18	34.3±2.2*	37.9±4.6	0.005
Waist circumference (cm)	96.2±14.4	91.1±12.2	94.0±12.1	0.22	92.4±11.5*	106.4±28.8	0.05
Hip circumference (cm)	117.3±14.1	109.0 [104.5–114.0]*	116.7±12.2	0.04	113.4±10.5*	129.7±14.6	< 0.001
Waist-to-hip ratio	0.81 [0.75–0.89]	0.82±0.09	0.81±0.08	0.51	0.82±0.06	0.83±0.21	0.40
Systolic blood pressure (mmHg)	124.8±15.5	124.8±15.6	120.6±14.6	0.19	120.5±15.4	129.0±15.9	0.06
Diastolic blood pressure (mmHg)	79.4±11.7	79.0±12.4	79.0±10.5	0.49	74.9±12.0*	82.4±10.7	0.03
Heart rate (bpm)	77±12	74±11*	81±10	0.02	82±14	78±11	0.21
Clinical history – n (%)							
Diabetes Mellitus	4 (4.4)	1 (2.7)	1 (7.1)	0.46	0 (0)	2 (7.7)	0.30
Hypertension	13 (14.4)	3 (8.1)	0 (0)	0.27	3 (23.1)	7 (26.9)	0.79
Dyslipidemia	3 (3.3)	1 (2.7)	1 (7.1)	0.46	0 (0)	1 (3.8)	0.47
Smoker	11 (12.2)	3 (8.1)	1 (7.1)	0.90	3 (23.1)	4 (15.4)	0.55
Bariatric surgery data							
Preoperative weight (kg)	125.5 [111.5–140.0]	119.0 [108.0–139.0]	122.6±20.9	0.43	126.7±16.0	133.5 [120.0–150.5]	0.13
Preoperative BMI (kg/m <sup>2</sup> )	46.7 [43.4–52.1]	46.1 [43.1–51.0]	45.1±5.9	0.08	49.3±6.8	47.8 [44.2–54.3]	0.47
Minimum postoperative weight (kg)	75.3±15.4	74.3±13.7	73.5±13.9	0.42	71.6±12.6	79.5±19.4	0.09
Minimum postoperative BMI (kg/m <sup>2</sup> )	28.1±4.5	28.3±4.2	27.1±4.8	0.19	27.8±4.7	28.5±5.0	0.33
EWL (%)	89.3±18.8	87.2±17.0	93.8±22.8	0.13	92.6±19.4	88.1±19.0	0.25
RWR (%)	18.7 [9.7–33.3]	8.6±6.6*	31.7±12.8	< 0.001	12.8±6.0*	45.5±20.1	< 0.001
RYGB (n, %)	76 (84.4)	29 (78.4)	13 (92.9)	0.22	11 (84.6)	23 (88.5)	0.73
Time since surgery (years)	6.2 ± 4.0	3.2±0.9*	3.9±0.7	0.008	8.4±3.1*	10.5±3.7	0.05
Surgery in public health unit (n, %)	16 (17.8)	7 (18.9)	4 (28.6)	0.45	1 (7.7)	4 (15.4)	0.50

PS – Pooled sample; G5- – Time since surgery < five years; G5+ – Time since surgery ≥ five years; RWR – Rate of weight regain; RWR<20 – Rate of weight regain <20%; RWR≥20 – Rate of weight regain ≥20%; BMI – Body mass index; EWL – Excess weight loss; RYGB – Roux-en-Y gastric bypass; \*P value, unpaired Student *t*-test or chi-square test; results expressed as mean±SD, median [percentiles 25–75] and n (%).

Table 2. Results of physical activity levels and sedentary time of the study subjects

Variable	PS (n=90)	G5- (n=51)		P value	G5+ (n=39)		P value
		RWR<20 (n=37)	RWR≥20 (n=14)		RWR<20 (n=13)	RWR≥20 (n=26)	
PA levels and sedentary time							
Sedentary (min/day)	1139.5±89.3	1139.4±93.5	1117.3±91.5	0.22	1123.6±70.1	1159.4±91.0	0.11
Ligh PA (min/day)	270.2±77.3	267.0±79.4	295.1±85.0	0.13	269.0±47.9	261.8±83.0	0.38
MVPA (min/day)	25.0±18.5	29.9±19.9	27.6±16.8	0.45	29.4±18.6*	18.8±16.3	0.04
Steps (n/day)	6072±2498	6336±2646	6844±2620	0.27	6822±2575*	4907±1801	0.005
PA levels by step per day							
Sedentary	37 (41.1)	12 (32.4)	3 (23.1)	0.52	5 (35.7)	17 (65.4)	0.07
Low active	30 (33.3)	14 (37.8)	5 (38.5)	0.96	3 (21.4)	8 (30.8)	0.52
Somewhat active	16 (17.8)	6 (16.2)	4 (30.8)	0.26	5 (35.7)*	1 (3.8)	0.007
Active	6 (6.7)	4 (10.8)	1 (7.7)	0.74	1 (7.1)	0 (0)	0.16
Highly active	1 (1.1)	1 (2.7)	0 (0)	0.55	0 (0)	0 (0)	–
Step-determined MVPA cut points							
< 30 min/day	64 (71.1)	26 (70.3)	9 (64.3)	0.68	6 (46.2)*	23 (88.5)	0.004
30–60 min/day	23 (25.6)	10 (27.0)	6 (46.2)	0.20	5 (35.7)*	2 (7.7)	0.02
> 60 min/day	3 (3.3)	1 (2.7)	1 (7.7)	0.43	0 (0)	1 (3.8)	0.45

Table 2. Results of physical activity levels and sedentary time of the study subjects

PS – Pooled sample; G5- – Time since surgery < five years; G5+ – Time since surgery ≥ five years; RWR – Rate of weight regain; RWR<20 – Rate of weight regain <20%; RWR≥20 – Rate of weight regain ≥20%; PA – Physical activity; MVPA – Moderate-to-vigorous physical activity; \*P value, unpaired Student *t*-test or chi-square test; results expressed as mean±SD and n (%).

Table 3. Demographic characteristics, clinical history and bariatric surgery data of study subjects by physical activity level

Variable	G1 (n=37)	G2 (n=53)	P value
<b>Demographic characteristics</b>			
Age (yrs)	42±8	42±8	0.49
Female (n, %)	32 (86.5)	48 (90.6)	0.54
Weight (kg)	97.4±25.1*	80.3 [69.0–90.6]	0.001
Height (cm)	161±0.1*	166±0.1	0.004
BMI (kg/m <sup>2</sup> )	35.1±7.5*	31.3±5.5	0.003
Neck circumference (cm)	36.8±4.1	35 [33–37.5]	0.90
Waist circumference (cm)	100.8±25.7*	93.0±12.7	0.03
Hip circumference (cm)	123.2±15.6*	113.3±11.5	0.004
Waist-to-hip ratio	0.82±0.07	0.82±0.18	0.45
Systolic blood pressure (mmHg)	128.4±17.4*	122.2±13.7	0.03
Diastolic blood pressure (mmHg)	81.2±11.1	78.1±12.0	0.10
Heart rate (bpm)	78±12	76±12	0.23
<b>Clinical history – n (%)</b>			
Diabetes Mellitus	2 (5.4)	2 (3.8)	0.71
Hypertension	7 (18.9)	6 (11.3)	0.31
Dyslipidemia	1 (2.7)	2 (3.8)	0.78
Smoker	2 (5.4)	9 (17.0)	0.09
<b>Bariatric surgery data</b>			
Preoperative weight (kg)	126.0 [113.5–146.5]	123.8 [110.0–137.0]	0.07
Preoperative BMI (kg/m <sup>2</sup> )	45.2[42.6–54.1]	48.3±6.9	0.67
Minimum postoperative weight (kg)	80.0±17.2*	72.0±13.2	0.007
Minimum postoperative BMI (kg/m <sup>2</sup> )	28.9±5.3	27.5±3.8	0.07
EWL (%)	86.3±21.1	91.2±16.9	0.11
RWR (%)	29.7±23.0*	16.0 [6.5–25.8]	0.009
RYGB (n, %)	32 (86.5)	44 (83.0)	0.65
Time after surgery (years)	7.2±4.5*	5.4±3.5	0.02
Surgery in public health unit (n, %)	6 (16.2)	10 (18.9)	0.74

G1– <5000 steps/day; G2 – ≥5000 steps/day; BMI – Body mass index; EWL – Excess weight loss; RWR – Rate of weight regain; RYGB – Roux-en-Y gastric bypass; \*P value, unpaired Student t-test or chi-square test; results expressed as mean±SD, median [percentiles 25–75] and n (%).

## 4 DISCUSSÃO

A cirurgia bariátrica é um dos tratamentos mais efetivos para a obesidade, proporcionando redução de comorbidades e aumento de sobrevida (1-3, 28, 29). Segundo a Sociedade Brasileira de Cirurgia Bariátrica e Metabólica (SBCBM), entre 2011 e 2018, houve um crescimento do número de cirurgias bariátricas no país de 84,73%. Nesse período, foram realizados cerca de 424 mil procedimentos. No entanto, o tratamento cirúrgico da obesidade demanda cuidados que vão além do procedimento *per se* (8, 30). Muitos pacientes, como os desta amostra, no entanto, perdem o acompanhamento multidisciplinar após a cirurgia, e uma das principais preocupações é o reganho ponderal e retorno das comorbidades nos anos seguintes.

Sabe-se que atividade física regular é importante para a prevenção do reganho ponderal (4, 31). Evidências recentes mostraram que indicadores de comportamentos sedentários, como longo tempo assistindo TV e redução do gasto energético em atividades ocupacionais, por exemplo, foram associados ao aumento de fatores de risco para doenças cardiometabólicas e maiores taxas de mortalidade (15, 32). Além disso, estão associados ao ganho de peso e a vários desfechos negativos à saúde (33, 34). Por outro lado, a substituição do tempo sentado por caminhada leve, melhorou a sensibilidade à insulina e reduziu os níveis de glicose de 24 horas em pacientes com doença metabólica (35). Foram demonstradas reduções de 11% e 24% do risco de mortalidade por todas as causas e por doença cardiovascular, respectivamente, quando 30 min/dia de TS é substituído por 30 min/dia de AF de intensidade leve (36).

O presente estudo contou com uma amostra de pacientes pós-bariátricos que apresentavam-se sem acompanhamento clínico por médico, nutricionista ou psicólogo após a cirurgia bariátrica, em consulta de primeira vez no serviço. A grande maioria dos pacientes, 82,2%, possuía plano de saúde e realizou cirurgia bariátrica com equipes e em hospitais da saúde suplementar, ficando sem acompanhamento algum após perda deste plano. Estes pacientes encontravam-se com diferentes taxas de reganho ponderal e níveis de AF.

Embora os pacientes tenham realizado a cirurgia em diferentes centros, estas foram confirmadas por endoscopia digestiva alta e também se pode assegurar que foram eficazes na promoção da perda de peso (37), uma vez que a PEP pós-cirurgia foi maior que 50% e não diferiu entre os grupos. Portanto, podemos excluir a falha cirúrgica naqueles com reganho ponderal (5).

Dos 90 pacientes estudados, 76 tinham sido submetidos ao RYGB e 14 a SG. Estes dados estão de acordo com os números brasileiros de cirurgia bariátrica, onde a RYGB é a técnica mais realizada no Brasil, correspondendo a 75% dos procedimentos (38). Os pacientes apresentaram IMC de  $32.9 \pm 6.6$  kg/m<sup>2</sup>, PEP de  $89,3 \pm 18,8\%$ , TRP de  $18,7 [9,7-33,3]\%$  e tempo de cirurgia de  $6,2 \pm 4,0$  anos.

A história clínica não diferiu entre os grupos estudados, refletindo a eficácia da cirurgia bariátrica no tratamento da obesidade (3, 29). Como esperado, de uma forma geral, os pacientes com TRP  $\geq 20$  exibiram maior peso, IMC, circunferências do pescoço, cintura e quadril, PA diastólica (PAD) e frequência cardíaca do que aqueles com TRP  $< 20$ , demonstrando um pior perfil cardiometabólico (39-42). Tal fato é de relevância clínica, uma vez que além de terem tido maior ganho ponderal, tinham maior risco cardiometabólico e, mais importante, encontravam-se sem qualquer acompanhamento. Voorwinde *et al.* avaliaram a recuperação de peso a longo prazo após cirurgia bariátrica e suas associações com resultados clínicos. O ganho ponderal após 5 anos de cirurgia bariátrica foi associado à deterioração na qualidade de vida relacionada à saúde física (43).

Apesar da possibilidade de ganho ponderal ao longo dos anos, a cirurgia bariátrica ainda é considerada o tratamento mais eficaz para a obesidade com benefícios bem estabelecidos, incluindo melhora do perfil cardiometabólico e controle das comorbidades (3, 29). Modificações no estilo de vida após a cirurgia são recomendadas para manutenção da perda de peso alcançada, otimizando os resultados obtidos (30). A afirmação também é consistente com nossos resultados, nos quais a maioria de nossos pacientes são fisicamente inativos (44, 45), passando longas horas sedentários (33, 34).

Diferenças nos níveis de AF e TS só foram notadas nos pacientes com mais de 5 anos de cirurgia, com menor tempo de AFMV e passos/dia no grupo com TRP  $\geq 20$ . Os resultados sugerem que a perda de peso induzida cirurgicamente não resultou em mudanças na rotina de AF. Após a cirurgia bariátrica, os pacientes não aumentaram seus níveis de AF para atender às recomendações atuais de 30 min/dia de AFMV (18, 46-48). Além disso, podemos inferir que os aumentos no peso corporal observados nos pacientes do grupo TRP  $\geq 20$ /G5+ podem ter contribuído para a diminuição da mobilidade para as atividades da vida diária (49).

Observamos baixas taxas de adesão a AF independente do tempo pós-operatório, consistente com estudos anteriores (20, 50). Nosso estudo evidenciou uma média de 6072 passos/dia, muito abaixo dos mais de 10000 passos/dia recomendados pelas diretrizes mundiais para uma vida saudável e fisicamente ativa (25). Este nível de atividade física,



considerado pouco ativo, está de acordo com outros estudos em populações de pós-bariátricos (51).

Considerando a contagem de passos/dia, observamos que 41% dos nossos pacientes são fisicamente inativos (25, 26). Ambos os grupos ( $>$  ou  $\geq 5000$  passos/dia) apresentaram peso pré-operatório, IMC e PEP semelhantes, mas aqueles menos ativos exibiram peso mínimo pós-operatório e TRP maiores do que aqueles com mais de  $\geq 5000$  passos/dia. Além disso, um pior perfil metabólico e cardiovascular foi observado nos menos ativos. Poderíamos especular que já existia no G1 (aqueles com menos de 5000 passos/dia) um estilo de vida sedentário desde a cirurgia, contribuindo para piores resultados em marcadores de saúde (52).

Observamos, também, que não houve diferença entre os grupos de alto e baixo reganho com menos de 5 anos de cirurgia (G5-) para os níveis de AF e TS ( $P \geq 0,13$ ), diferindo de estudos anteriormente publicados sobre AF, perda de peso e reganho ponderal pós cirurgia bariátrica (53, 54). Amundsen *et al.* demonstraram que pacientes com 4 anos de pós-operatório, com reganho ponderal significativo e perda de peso subótima eram menos ativos fisicamente (54). Assim como este estudo, Freire *et al.* também observou que as TRP aumentam significativamente ao longo dos anos após a cirurgia bariátrica, especialmente após 5 anos (55). Além do fator tempo, no G5+, o tempo gasto em AFMV, o número de passos/dia e o percentual de pacientes em 30 a 60 min/dia de AF foram significativamente mais baixos no  $TRP \geq 20$  em comparação com  $TRP < 20$ .

O estilo de vida ativo deve ser incorporado aos cuidados clínicos de rotina (56, 57). Os pacientes pós-bariátricos devem ser encorajados a aumentar os níveis de AFMV e diminuir os comportamentos sedentários, para obtenção de melhorias na composição corporal e nos resultados cirúrgicos (31, 58). Embora, importantes resultados de saúde possam ser alcançadas pela perda ponderal modesta (5–10%) (59), o exercício físico promove inúmeros benefícios independentemente da perda ponderal, como nos parâmetros da doença, perfil de risco cardiovascular e metabólico, aptidão cardiorrespiratória e muscular e nos indicadores de qualidade de vida (31, 44, 45). Tudo isso, ratifica o efeito terapêutico do exercício físico sobre diversos marcadores de saúde.

As diretrizes atuais recomendam  $\geq 150$  min/sem de AFMV para melhorar ou manter os componentes da aptidão física e a saúde (31, 44, 45). Alto volume de exercício físico pode promover perda de peso e prevenir o reganho ponderal em pacientes pós-bariátricos (31, 60, 61). No entanto, pode ser difícil para o paciente manter a adesão da atividade a longo prazo (12). Estratégias de aconselhamento de exercícios físicos podem ajudar os pacientes pós-

bariátricos a aumentar o nível de AF na rotina diária (58) e devem ser consideradas no tratamento clínico para o controle da obesidade .

Finalmente, embora não haja concordância entre AF autorrelatada vs. medida por acelerômetro, mostramos que há uma correlação linear entre elas, o que está em contradição com outros estudos que observaram uma superestimação na AF autorrelatada em comparação com medidas objetivas obtidas após a cirurgia, verificado ainda no primeiro ano após o procedimento (18, 19). Desta forma, concluímos que as medições autorreferidas são indicativos confiáveis para qualificar o desempenho de PA, mas não são confiáveis para quantificá-los, uma vez que essas medidas traduzem a percepção dos pacientes sobre o nível de AF, enquanto as medições do acelerômetro são quantificadores objetivos. Assim como em nossos dados, ao avaliar pacientes com maior tempo pós-operatório (48 meses pós-RYGB), uma correlação significativa entre o questionário e o acelerômetro foi observada (62).

As percepções de melhora na função física, da qualidade de vida relacionada à saúde e do bem-estar emocional e mental para a AF devido a perda de peso após a cirurgia bariátrica (49, 63, 64) podem estar associadas à percepção subjetiva de aumento de AFMV relatada pelo IPAQ. Os resultados apoiam o uso confiável de questionários como alternativa prática e econômica para ser utilizada no âmbito clínico para qualificar os níveis de AF em pacientes pós-bariátricos. Medidas que quantificam a AF junto ao paciente podem ser úteis para traçar estratégias de manejo mais adequadas para promover a redução do TS.

O presente estudo evidenciou que a cirurgia bariátrica realizada previamente à inclusão dos pacientes no atendimento ambulatorial de nossa unidade foi efetiva, apresentando ótima PEP em todos os pacientes da amostra (PEP média=89,3%). Além disso, apesar de autorreferido, o peso mínimo após a cirurgia, que serviu de base para o nosso cálculo da PEP, foi perguntado aos pacientes por duas vezes, em duas ocasiões diferentes e apresentou uma alta correlação ( $r=0,91$ ;  $P<0,01$ ). O IPAQ foi útil e confiável para quantificação da AF e do TS comparando com os resultados do acelerômetro. O nível de AF da população estudada foi muito inferior às recomendações atuais para obtenção de desfechos positivos em saúde.

Na prática clínica de rotina, os pacientes pós-bariátricos devem ser incentivados a realizar AF regularmente para manter os resultados cirúrgicos e obter benefícios para a saúde, especialmente após 5 anos decorridos da cirurgia. Os achados deste estudo tornam evidentes a complexidade do mecanismo de reganho ponderal em pós-bariátricos e o entendimento ainda incompleto deste tema na literatura corrente. Além disso, nossos resultados ressaltam a importância de acolher pacientes pós-bariátricos no sistema de saúde. Maior promoção da AF

no acompanhamento destes pacientes e mais estudos sobre o tema devem ser realizados para implementar estratégias de prevenção e manejo do ganho ponderal, a favor de um estilo de vida ativo e redução do comportamento sedentário, e conseqüentemente, a favor de uma melhor saúde cardiometabólica.

## CONCLUSÃO

Os pacientes submetidos a cirurgia bariátrica que estavam sem acompanhamento médico recrutados em consulta de primeira vez apresentaram diferentes taxas de ganho ponderal, baixos níveis de atividade física e maior tempo em comportamento sedentário. O questionário pode ser uma ferramenta prática e econômica a ser utilizada no âmbito clínico para qualificar a atividade física e o tempo sedentário de pacientes pós-bariátricos.

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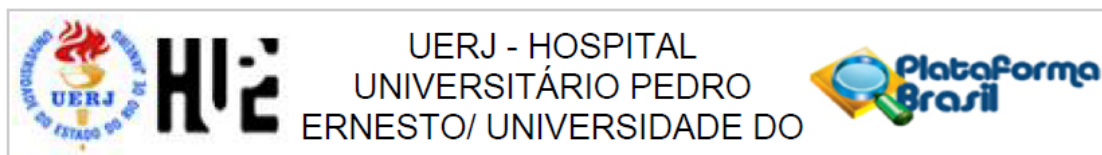
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## ANEXO A – Aprovação do Comitê de Ética em Pesquisa



### PARECER CONSUBSTANCIADO DO CEP

#### DADOS DO PROJETO DE PESQUISA

**Título da Pesquisa:** ANÁLISE DA TAXA DE REGANHO PONDERAL E FATORES PREDITIVOS PARA O REGANHO DE PESO EM PACIENTES SUBMETIDOS À CIRURGIA BARIÁTRICA

**Pesquisador:** Luiz Guilherme Kraemer de Aguiar

**Área Temática:**

**Versão:** 1

**CAAE:** 07662918.1.0000.5259

**Instituição Proponente:** Hospital Universitário Pedro Ernesto/UERJ

**Patrocinador Principal:** Financiamento Próprio

#### DADOS DO PARECER

**Número do Parecer:** 3.222.918

#### Apresentação do Projeto:

Transcrição editada do conteúdo do registro do protocolo e dos arquivos anexados à Plataforma Brasil. Introdução: A cirurgia bariátrica é recomendada para o tratamento da obesidade, resultando em maior perda ponderal e melhora das comorbidades cardiovasculares e metabólicas. No entanto, o reganho de peso é observado em uma parcela dos pacientes após a cirurgia, levando a desfechos adversos à saúde. Objetivos: Identificar a taxa de reganho ponderal (TxR) e os fatores preditivos do reganho de peso em pacientes submetidos à cirurgia bariátrica sem acompanhamento regular em serviços especializados de saúde. Métodos: Serão recrutados pacientes pós-bariátricos sem acompanhamento por profissional de saúde. Os pacientes serão divididos, inicialmente, em dois grupos pelo tempo pós-procedimento cirúrgico, como segue: Grupo 1 (G1) – pacientes que realizaram cirurgia bariátrica há 1 ano e Grupo 1> (G1>) – pacientes que realizaram cirurgia bariátrica há > 1 ano. Na Policlínica Piquet Carneiro (PPC) estes pacientes realizarão consulta médica de primeira vez, que constará de anamnese e exame físico, com aquisição de dados demográficos, socioeconômicos, uso de medicamentos e história clínica. A TxR será calculada por  $TxR = (\text{peso atual} - \text{peso mínimo relatado}) \times 100 / (\text{peso pré-operatório relatado} - \text{peso mínimo relatado})$  e as

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Continuação do Parecer: 3.222.918

informações sobre as variáveis preditivas para ganho de peso serão obtidas através do Alcohol Use Disorders Identification Test (AUDIT), Beck Depression Inventory (BDI), International Physical Activity Questionnaire (IPAQ), acelerômetro ActiGraph GT3X+, 36-Item Short-Form Health Survey (SF-36), Eating Disorder Examination Questionnaire (EDE -Q) e Repetitive Eating Questionnaire [Rep(eat)-Q]. O período de inclusão desses pacientes de primeira vez neste estudo será de um ano. Palavras-chave: Obesidade, cirurgia bariátrica, ganho ponderal, fatores preditivos.

**Objetivo da Pesquisa:**

Transcrição editada do conteúdo do registro do protocolo e dos arquivos anexados à Plataforma Brasil. Identificar a taxa de ganho ponderal e os fatores preditivos do ganho de peso em pacientes submetidos à cirurgia bariátrica sem acompanhamento regular por profissionais de saúde.

**Avaliação dos Riscos e Benefícios:**

Prezado pesquisador: Caracteriza-se como risco direto para os participantes da pesquisa a possibilidade de desconforto ou constrangimento no momento do preenchimento dos questionários. Os pesquisadores devem se comprometer a minimizar os riscos ou desconfortos que possam vir a ser causados.

**Comentários e Considerações sobre a Pesquisa:**

Transcrição editada do conteúdo do registro do protocolo e dos arquivos anexados à Plataforma Brasil. Os pacientes que realizaram cirurgia bariátrica e estão sem acompanhamento por equipe especializada serão atendidos para consulta médica de primeira vez no Ambulatório de Obesidade e Medicina Bariátrica e serão convidados a participar do estudo, sendo informados quanto ao propósito, procedimentos, e benefícios da pesquisa para possível assinatura do Termo de Consentimento Livre e Esclarecido (TCLE). Nessa consulta, os pacientes serão atendidos em uma pré-consulta com enfermagem para coleta de dados antropométricos e de pressão arterial e, posteriormente, por um médico endocrinologista. Estes pacientes serão submetidos à anamnese e exame físico, obtendo-se dados demográficos, socioeconômicos, uso de medicamentos e história clínica. A técnica cirúrgica realizada, tempo de realização e possíveis

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Continuação do Parecer: 3.222.918

complicações da mesma serão anotadas. Além disso, o peso relatado pré-cirúrgico e o peso mínimo pós-cirúrgico também serão coletados em duas ocasiões (no momento da pré-consulta e ainda na consulta com médico endocrinologista). As informações sobre as variáveis preditivas para ganho de peso serão obtidas através do Alcohol Use Disorders Identification Test (AUDIT), Beck Depression Inventory (BDI), International Physical Activity Questionnaire (IPAQ), acelerômetro ActiGraph GT3X+, 36-Item Short-Form Health Survey (SF-36), Eating Disorder Examination Questionnaire (EDE-Q) e Repetitive Eating Questionnaire [Rep(eat)-Q]. Os pacientes colocarão o acelerômetro, que deverá ser utilizado durante uma semana de atividade habitual (sete dias) e ser entregue, em dia e horário marcados, no BIOVASC. Neste dia, os pacientes serão novamente inquiridos sobre peso pré-cirúrgico e peso mínimo pós-cirúrgico. A pesquisa está bem estruturada e o referencial teórico e metodológico estão explicitados, demonstrando aprofundamento e conhecimento necessários para sua realização. As referências estão adequadas e a pesquisa é exequível.

**Considerações sobre os Termos de apresentação obrigatória:**

Os documentos de apresentação obrigatória foram enviados a este Comitê, estando dentro das boas práticas e apresentando todos dados necessários para apreciação ética e tendo sido avaliadas as informações contidas na Plataforma Brasil e as mesmas se encontram dentro das normas vigentes e sem riscos iminentes aos participantes envolvidos de pesquisa.

**Recomendações:**

Alterar e acrescentar:

Contado do Comitê de Ética em Pesquisa - Caso seja necessário você pode entrar em contato com o Comitê de Ética em Pesquisa do HUPE para esclarecimentos ou informações quanto a validade da pesquisa: Av. 28 de setembro, 77 térreo Vila Isabel – CEP 20551-030 - Tel: 21-2868.8253 – Email: cep-hupe@uerj.br.

**Conclusões ou Pendências e Lista de Inadequações:**

O projeto pode ser realizado da forma como está apresentado. Diante do exposto e à luz da Resolução CNS nº466/2012, o projeto pode ser enquadrado na categoria – APROVADO.

**Considerações Finais a critério do CEP:**

Tendo em vista a legislação vigente, o CEP recomenda ao Pesquisador: Comunicar toda e qualquer alteração do projeto e no termo de consentimento livre e esclarecido, para análise das mudanças;

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Informar imediatamente qualquer evento adverso ocorrido durante o desenvolvimento da pesquisa; O Comitê de Ética solicita a V. S<sup>a</sup>., que encaminhe relatórios parciais de andamento a cada 06 (seis) Meses da pesquisa e ao término, encaminhe a esta comissão um sumário dos resultados do projeto; Os dados individuais de todas as etapas da pesquisa devem ser mantidos em local seguro por 5 anos para possível auditoria dos órgãos competentes.

**Este parecer foi elaborado baseado nos documentos abaixo relacionados:**

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1251035.pdf	18/01/2019 16:08:15		Aceite
Outros	CEP.pdf	18/01/2019 16:05:27	Luiz Guilherme Kraemer de Aguiar	Aceite
Folha de Rosto	FOLHA_DE_ROSTO.pdf	12/11/2018 19:40:29	Luiz Guilherme Kraemer de Aguiar	Aceite
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	12/11/2018 19:33:28	Luiz Guilherme Kraemer de Aguiar	Aceite
Projeto Detalhado / Brochura Investigador	PROJETO_DETALHADO.pdf	12/11/2018 19:33:07	Luiz Guilherme Kraemer de Aguiar	Aceite

**Situação do Parecer:**

Aprovado

**Necessita Apreciação da CONEP:**

Não

RIO DE JANEIRO, 26 de Março de 2019

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**Assinado por:**  
**DENIZAR VIANNA ARAÚJO**  
(Coordenador(a))

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## ANEXO B - Comprovação de submissão do estudo original

## Obesity Surgery

### Physical activity level, sedentary time and weight regain after bariatric surgery in patients without medical follow-up: a cross-sectional study

--Manuscript Draft--

<b>Manuscript Number:</b>	OBSU-D-20-01101
<b>Full Title:</b>	Physical activity level, sedentary time and weight regain after bariatric surgery in patients without medical follow-up: a cross-sectional study
<b>Article Type:</b>	Original Contribution
<b>Keywords:</b>	bariatric surgery, sedentary behavior, physical activity and weight regain.
<b>Corresponding Author:</b>	Luiz Guilherme Kraemer-Aguiar Universidade do Estado do Rio de Janeiro - Campus Vila Isabel Rio de Janeiro, BRAZIL
<b>Corresponding Author Secondary Information:</b>	
<b>Corresponding Author's Institution:</b>	Universidade do Estado do Rio de Janeiro - Campus Vila Isabel
<b>Corresponding Author's Secondary Institution:</b>	
<b>First Author:</b>	Eline Coan Romagna, Post-Graduate student
<b>First Author Secondary Information:</b>	
<b>Order of Authors:</b>	Eline Coan Romagna, Post-Graduate student Karynne Grutter Lopes, PhD Diogo Menezes Ferrazani Mattos, PhD Paulo Farinatti, PhD Luiz Guilherme Kraemer-Aguiar, PhD
<b>Order of Authors Secondary Information:</b>	
<b>Funding Information:</b>	
<b>Abstract:</b>	<p>Background: We compared physical activity (PA) levels and sedentary time (ST) between post-bariatric patients without medical follow-up at their first appointment. Moreover, we investigated the correlations between self-reported and objective measures in moderate-to-vigorous PA (MVPA) and ST.</p> <p>Methods: A prospective cohort of 90 patients after Roux-en-Y gastric bypass (RYGB; n=76) or Sleeve gastrectomy (SG; n=14), aged 42±8 years, BMI 32.9±6.6 kg/m<sup>2</sup>, was allocated into two groups according to time since surgery &lt;or ≥5 years (G5- or G5+), and assigned into low or high rate of weight regain (RWR &lt;20% or ≥20%, respectively). They were also stratified according to PA level &lt;or ≥5000 steps/day (G1 or G2, respectively). PA and ST were measured by International PA Questionnaire (IPAQ) and ActiGraph GT3X+ accelerometer.</p> <p>Results: PA and ST were similar between groups/G5- (P≥0.13). MVPA time (P=0.04), number of steps/day (P=0.005), % of patients somewhat active (P=0.007), and with 30–60 min/day of MVPA (P=0.02) were higher in RWR≥20%, while those with &lt;30 min/d of MVPA (P=0.004) were in the RWR≥20% vs. &lt;20/G5+. MVPA and ST self-reported vs. objective measures were correlated (P&lt;0.001). Nevertheless, there was no concordance between these measures (P&gt;0.05).</p> <p>Conclusions: Low level of PA and longer ST occurred more in RWR≥20%, especially with time since surgery ≥5 years. There was no concordance between IPAQ and accelerometer measures, but a high linear correlation was noted.</p>

## ANEXO C - Estudo correlato desenvolvido em paralelo com o estudo original

**Title:** Do changes in appetite, taste, smell, and also food aversion influence weight loss and regain in post-bariatric patients?

**Short title:** Sensory changes and bariatric surgery

**Authors:** Karynne Grutter Lopes<sup>1</sup>, Gabriel Pires dos Santos<sup>2</sup>, Eline Coan Romagna<sup>1</sup>, Diogo Menezes Ferrazani Mattos<sup>3</sup>, Tassia Gomide Braga<sup>1</sup>, Carolina Bastos Cunha<sup>1</sup>, Priscila Alves Maranhão<sup>4</sup>, Luiz Guilherme Kraemer de Aguiar<sup>1,5\*</sup>

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**Word count:** Main document – 2732 words; Abstract – 272 words; Tables – 3; Figures – 1



**Abstract**

We investigated if changes in appetite, taste, smell, and food aversion occurred in patients following two types of bariatric surgery without medical follow-up. Additionally, we compared those with and without these changes concerning the excess weight loss (EWL), rate of weight regain (RWR), and time since surgery. A prospective cohort included 146 post-bariatric patients in the study (126 post-*Roux-en-Y* [RYGB] and 20 post-sleeve gastrectomy [SG]), aged  $42 \pm 8$  yrs, body mass index of  $32.6 \pm 6.3 \text{ kg/m}^2$ , EWL of  $87.5 \pm 20.2\%$ , RWR of  $15.4 [3.9-30.9]\%$  and the time since surgery of  $5.0 \pm 4.0$  yrs. They all answered a questionnaire about sensory and food perceptions at their first appointment in our unit. Sensory and food aversion perceptions, taste changes to a specific food, and loss level of taste and smell were similar between RYGB and SG ( $P \geq 0.10$ ). Changes in appetite (76%), taste (48.6%), and an increased sensation for sweet taste (60.2%) frequently occurred in our sample. No difference was observed between patients with or without changes in appetite, taste, smell, and food aversion perceptions concerning EWL ( $P \geq 0.06$ ). RWR was lower in post-RYGB with changes in taste and smell ( $P = 0.05$ ), while in those post-SG any difference was detected ( $P \geq 0.11$ ). Sensory changes were noted in those with shorter time since surgery for both procedures ( $P \leq 0.05$ ), but following the type of surgery, they were similar. Sensory and food perceptions are usual post-bariatric procedures but did not differ between them. All patients had significant weight loss, with a lower weight regain in post-RYGB with changes in taste and smell. Patients with a shorter time since surgery showed more frequently the occurrence of changes in appetite, taste, and smell in post-RYGB.

**Keywords:** Appetite, taste, smell, food aversion, obesity, bariatric surgery.

## 1. Introduction

Bariatric surgery is an effective treatment for the treatment of obesity with efficacy in sustained weight loss. Additionally, surgically treated patients improve or prevent obesity-related comorbidities and also reduce their mortality rates (Reges et al., 2018; Sjöström, Lissner, Wedel, & Sjöström, 1999).

Several mechanisms contribute to weight loss after surgery, including reduction of caloric intake through restriction of the amount of food, malabsorption of nutrients, and changes of gastric and intestinal peptides (Dimitriadis, Randeve, & Miras, 2017; Sweeney TE, 2014). Probably changes in appetite, taste, and smell perceptions underlying by the gut-brain axis (Behary & Miras, 2015) appear to contribute to food changes, affecting caloric consumption and subsequent weight loss after surgery (Ahmed, Penney, Darzi, & Purkayastha, 2018; Graham, Murty, & Bowrey, 2014).

Rapid and substantial weight loss may occur with an average 61% within the first two years after the procedure (Buchwald et al., 2004) compared to traditional non-surgical methods, like diet, physical exercise, and pharmacotherapy (Lars Sjöström M. et al, 2004). Although bariatric surgery shows a significant result on BMI, some patients regain weight (Lauti, Kularatna, Hill, & MacCormick, 2016; Magro et al., 2008). Magro *et al.* reported a rate of weight regain varying from 46 to 63% between 2 and 4 years post-surgery, respectively (Magro et al., 2008), while others showed 75% within six years post-surgery (Lauti et al., 2016). Multiple etiologic factors were associated with weight regain after surgery, such as surgical failure, metabolic and hormonal imbalance, mental disorders, nutritional non-adherence, and physical inactivity. However, many are still unclear (Karmali et al., 2013).

Some possible changes in appetite, taste, and smell perception should also be investigated as a predictor for higher rates of weight regain (RWR) following surgery (Karmali et al., 2013; Zhang et al., 2020). Changes in taste perception might have an essential role in food preferences and eating

behaviors (Behary & Miras, 2015; Bryant, Malik, Whitford-Bartle, & Waters, 2020). However, some points are still unclear. May be possible sensory changes occur regardless of the type of bariatric procedure (Altun et al., 2016; Welbourn et al., 2019), or perhaps is sustained for several years after surgery (Altun et al., 2016), and may also be influenced by the weight changes (Karmali et al., 2013).

Optimize long-term weight loss and minimize weight regain in patients following bariatric surgery is a challenge to health professionals (Welbourn et al., 2019). We hypothesize that sensory and dietary changes may be more frequently presented after surgery in those with lower rates of weight regain and that these changes vary according to the bariatric procedure and the time of surgery. Therefore, the present study compared the differences in appetite, taste, smell, and food aversion in a cohort of patients undergoing *Roux-en-Y* gastric bypass (RYGB) vs. Sleeve Gastrectomy (SG). Additionally, we compared the excess weight loss (EWL), RWR, and time since surgery in patients with sensory and food changes vs. counterparts without changes.

## **2. Methods**

### **2.1 Subjects**

We enrolled 269 volunteers previously subjected to a bariatric procedure in private and public health care units, and 146 patients (126 post-RYGB and 20 post-SG) participated in the study. Of these, 130 females/16 males, aging  $42\pm 8$  years, body mass index (BMI) of  $32.6\pm 6.3$  kg/m<sup>2</sup>, EWL of  $87.5\pm 20.2\%$ , RWR of  $15.4$  [3.9–30.9]%, with time since surgery of  $5.0\pm 4.0$  years. Recruitment was performed at the Obesity Unit for outpatient care at University Clinic during their first appointment. Exclusion criteria were: a) use any medication or gastrointestinal disease that might affect appetite, taste, and smell; b) information incomplete on anthropometric and surgery (procedure data and pre

and postoperative weight); c) unanswered questionnaires and d) questionnaires not adequately fulfilled.

Out of 269 individuals enrolled, 151 patients answered the questionnaire. A total of 146 (96.7%) patients fulfilled the questionnaires with care and were included in the final analysis. They were allocated into two groups, according to the bariatric procedure (RYGB or SG). In each group (RYGB and SG), the patients were reallocated into appetite, taste, smell, and food aversion subgroups according to the presence or absence of them. Figure 1 presents the flow chart of the enrollment, allocation, and follow up of participants.

----Insert figure 1 here----

## **2.2 Data assessment and ethical approval**

Participants were subjected to a pre-participation screening before being included in the study. In this visit, the research protocol was explained, and the written informed consent was obtained from all volunteers. Afterward, a clinical history, physical examination, demographic, anthropometric, heart rate, and blood pressure measurements, and questionnaire application were performed. All patients confirmed the surgery procedure by digestive endoscopy.

The study was approved by the local Ethics Committee (CAAE: 07662918.1.0000.5259) and registered in ClinicalTrials.gov (NCT04193384). All procedures involving the participants were performed according to the principles outlined in the Declaration of Helsinki.

## **2.3 Anthropometry, blood pressure, and questionnaire application**

Body mass and height were measured by a calibrated electronic scale and stadiometer (Welmy™ W300A, São Paulo, SP, Brazil). Waist circumference was measured at the umbilicus after expiration, and hip at the widest circumference around the gluteal region. BMI and waist-to-hip ratio were calculated. Neck circumference was measured along the inferior margin of the laryngeal prominence and perpendicular to the long axis of the neck. All measures were performed twice by the same trained nurse. Preoperative weight and minimum postoperative weight were self-reported by all patients in the first visit, and after three months, and BMI was calculated.

EWL and RWR were calculated, as follows: a)  $EWL = (\text{preoperative weight} - \text{minimum postoperative weight}) / (\text{preoperative weight} - \text{ideal weight for BMI of } 25 \text{ kg/m}^2) \times 100\%$  and b)  $RWR = (\text{current weight} - \text{minimum weight postoperative}) / (\text{preoperative weight} - \text{minimum weight postoperative}) \times 100\%$ . Both were expressed as percentages. BP was measured in a sitting position by a semiautomated oscillometric device (G-Tech™ BSP11, Hangzhou, Zhejiang, China) according to standard recommendations (Pickering et al., 2005). After measurements, the participants received the questionnaire and were followed to a room to answer it while waiting for a clinical appointment. This questionnaire was adapted from a previously used and validated one by Tichansky *et al.* (Tichansky, Boughter, & Madan, 2006), which was modified by Graham *et al.* (Graham et al., 2014). It has 33 questions about postoperative sensory changes.

#### 2.4 Statistical analysis

The Shapiro-Wilk test tested data normality. Chi-square tests were used for categorical data and presented as percentages of the total. Between-group differences were determined by unpaired Student *t*-test or Mann-Whitney *U*-test, as appropriate, and the results were expressed respectively as, mean  $\pm$  standard deviation (SD) or median [percentiles 25–75]. All calculations were performed using

the NCSS™ statistical software (LLC, Kaysville, Utah, USA), and statistical significance was set at  $P < 0.05$ .

### 3. Results

Table 1 presents the demographic characteristics, clinical and surgery data of the patients enrolled. The groups were similar concerning all variables ( $P \geq 0.09$  for all comparisons), except for age ( $42 \pm 8$  vs.  $39 \pm 8$  years;  $P = 0.05$ ), preoperative weight ( $126.0$  [113.7–140.0] vs.  $119.0 \pm 18.9$  kg;  $P = 0.03$ ), preoperative BMI ( $46.5$  [43.5–52.4] vs.  $44.2 \pm 5.0$  kg/m<sup>2</sup>;  $P = 0.005$ ) and time since surgery ( $5.3 \pm 4.1$  vs.  $3.2 \pm 1.8$  years;  $P = 0.01$ ) which were higher in RYGB compared to SG, respectively.

----Insert table 1 here----

#### 3.1 Sensory and food perceptions

Data for sensory and food perceptions following RYGB and SG are depicted in Table 2. No differences between groups were found for sensory and food changes, taste changes to a specific food, or loss level of taste and smell ( $P \geq 0.10$ , for all comparisons). Even without any differences between groups, a higher percentage of patients reported changes in appetite (RYGB=75.4 and SG=80%), or in taste (RYGB=46 and SG=65%), and also an increased sensation for sweet taste (RYGB=57.4 and SG=76.5%)

----Insert table 2 here----

#### 3.2 Excess weight loss, rate of weight regain, and surgery time

Table 3 exhibits results of EWL, RWR, and time since surgery of patients with and without changes in sensory and food perceptions. No difference was observed between patients with or without changes in appetite, taste, smell, and food aversion perceptions and EWL in the pooled sample (PS), RYGB, or SG ( $P \geq 0.06$ , for all comparisons). In the PS, there was a significant difference between the change in smell and lower RWR ( $P=0.02$ ) and between changes in appetite ( $P=0.03$ ), taste ( $P=0.004$ ), and smell ( $P<0.001$ ) and less time since surgery. Concerning RYGB, as well as for PS, the RWR was lower in patients with changes in taste ( $P=0.05$ ) and smell ( $P=0.05$ ). The time since surgery was also shorter in patients with taste and smell changes ( $P<0.001$ , for both), and also in those with changes in appetite ( $P=0.05$ ) in the RYGB. On the counterpart, in the SG, no difference was detected between sensory and food variables and RWR ( $P \geq 0.11$ , for all comparisons). As for time analyses, time since surgery was shorter in patients with changes in smell ( $P=0.03$ ).

----Insert table 3 here----

#### 4. Discussion

The present study compared the changes in appetite, taste, smell, and food aversion perceptions in patients undergoing RYGB vs. SG. Additionally, we compared the EWL, RWR, and time since surgery in patients with sensory and food changes vs. counterparts without them. As expected, our findings showed higher percentages of changes in appetite, taste, smell, and food aversion, taste changes to the specific food (sweet, salty, and sour), and a loss level of taste and smell in our sample. These data concur with prior research that noted that the sensory and food perceptions changes are common in patients after RYGB and SG (Graham et al., 2014; Tichansky et al., 2006; Zerrweck et al., 2016).

However, we noted that none of the sensory and food changes differed between the surgical procedures. On the other hand, we can speculate that testing a non-surgical group could result in significant differences between surgical procedures vs. sham operation, since some variables showed high positivity, especially in appetite, taste, and sweet taste (reported by 76, 48.6 and 60.2% of patients, respectively). Maybe, adding a sham group would possibly show many differences between them.

Previous studies showed that the bariatric procedures promote effects in adipose tissue, gastrointestinal tract, and central nervous system, that seem to explain the sensory and food changes and, consequently, possible influences in weight loss (Behary & Miras, 2015; Dimitriadis et al., 2017; Karamanakos, Vagenas, Kalfarentzos, & Alexandrides, 2008; Mulla CM, Middelbeek RJW, 2018). Bariatric surgery leads to critical changes in gastrointestinal peptides, like glucose-dependent insulinotropic polypeptide (GIP), glucagon-like peptide-1 (GLP-1), peptide YY (PYY), ghrelin, and cholecystokinin (CCK). All of them interact with the nervous system and integrate signals of hunger and satiety, regulating energy balance.

Besides, some gut hormones, like GLP-1, CCK, PYY, and ghrelin may also act in gustative receptors of tongue and or olfactory neurons, modulating taste, smell, and food preferences (Behary & Miras, 2015; Dimitriadis et al., 2017; Karamanakos et al., 2008; Mulla CM, Middelbeek RJW, 2018). Therefore, it is possible to infer that bariatric surgery, especially those with critical influences in gut peptides, would cause sensory and food changes. The resultant altered feeding behavior and modified caloric intake would favor a negative energy balance, and consequently, loss of weight or even lower rates of weight regain.

When we compared the EWL, RWR, and the time since surgery in patients with and without sensory and food changes, we noted that the observed results in the PS reflect the RYBG data. SG results do not seem to influence them. All of the recruited patients had effective surgery since the EWL was excellent (Guraya & Strate, 2019). However, our results did not show significant



differences between patients with and without sensory and food changes concerning EWL in both surgical procedures. Previous studies that report the influence of changes in appetite, taste, and smell in weight loss in the post-bariatric patient were performed during the first year post-surgery (Holinski, Menenakos, Haber, Olze, & Ordemann, 2015; Karamanakos et al., 2008; Pepino MY, Bradley D, Eagon JC, 2013; Zerrweck et al., 2016). The authors speculate that these changes may have a higher impact during the first year than afterward. We originally tested many patients after the first year post-surgery.

Concerning the influence of food changes in EWL, our study noted a percentage relatively low of post-bariatric patients with food aversion compared with observed by Graham *et al.* (73% of 103 patients with a median of 19 months post-RYGB) (Graham et al., 2014). Besides, as this variable was associated with more significant weight loss in patients with ten months post-surgery (Zerrweck et al., 2016), it is feasible to wonder that temporal changes were responsible for our findings. Other potential mechanisms by which bariatric surgery lead to loss of weight should be considered (Buchwald et al., 2004; Dimitriadis et al., 2017; Sjöström et al., 1999; Sweeney TE, 2014) and may explain the effective EWL observed in our study, independently whether the patients have sensory and food changes or not.

Indeed we observed that the patients with changes in appetite, taste, and smell in post-RYGB and smell post-SG presented the time since surgery shorter than those without changes. Although the surgery is known to promote sensory alterations in the short term (Ahmed et al., 2018; Altun et al., 2016), long-term effects still need to be better elucidated. Based on our findings, we can speculate that sensory changes gradually decrease over time, due to the physiological adaptation of the gut-brain axis (Sinclair, Brennan, & le Roux, 2018).

On the other hand, we were also interested in investigating sensory and dietary changes as in weight regain after surgery. We observed that those subjected to RYGB with changes in taste and smell presented lower RWR compared to those without them. This result may be related to eating

behavior changes, suggesting that the smell and the taste of foods seem to have influenced their preferences and choices and possibly interfered with the number of calories ingested, and consequently, lesser weight regain. Changes in dietary habits, with a healthier and a more balanced diet, was observed in patients after RYGB (Ernst, Thurnheer, Wilms, & Schultes, 2009), which may have contributed to lower RWR observed in this group.

Sensory and food changes could be considered potential mechanisms for weight loss or regain to post-bariatric patients. Our data points to this as a possible influence, and long-term clinical follow-up may corroborate it. The investigation of other mechanisms involved in the pathophysiology of obesity and weight changes, regardless of the effects of bariatric surgery *per se*, that can be considered as confounding factors is mandatory (Karmali et al., 2013; Mulla CM, Middelbeek RJW, 2018). On the design of our study, it could be speculated that there is a relationship between taste and smell changes and weight regain.

The major limitation of this study regards the cross-sectional design, damping causal relationships, and also not allowing us to follow how the sensory and food changes occurred over time since surgery. Since our recruited patients were those without follow-up attended in a first medical appointment, several bariatric procedures, and their minimal specificities in technical operations in respect to surgeon's techniques were involved. Independently, an adequate mean EWL was successfully achieved.

In conclusion, post-bariatric patients exhibited similar changes in appetite, taste, smell, and food aversion. Additionally, they also showed taste changes to the specific food (sweet, salty, and sour), and loss level of taste and smell independently of the type of surgery. Sensory and food perceptions did not differentiate the EWL following RYGB and SG. Of note, the RWR was lower in patients post-RYGB with a change in taste and smell, while any sensory variables were associated with the RWR in that post-SG. Appetite, taste, and smell changes were present in patients with a shorter time since surgery, regardless of the type of surgery. Longitudinal studies are needed to

elucidate better if the sensory and food changes are predictive factors to long-term weight maintenance and regain in post-bariatric patients.

## **5. Funding**

Coordination for the Improvement of Higher Education Personnel (CAPES), Brazilian Council for Technological and Scientific Development (CNPq), and Carlos Chagas Filho Foundation for the Research Support in the State of Rio de Janeiro (FAPERJ) supported this work by scholarships for some authors.

## **7. Author contributions**

Conception and design of the study: GPS and LGK-A; administration and supervision of the study: KGL and LGK-A; patient recruitment and data collection: KGL, GPS, ECR, DMFM, TGB, CBC; analysis or interpretation of data: KGL, DMFM, LGK-A, and draft the manuscript: KGS and GPS; revising the work: KGL and LGK-A. KGL and GPS had the same participation in drafting the present work. All authors read and approved the final manuscript.

## **8. Conflict of interest statement**

The authors declare no conflict of interest.

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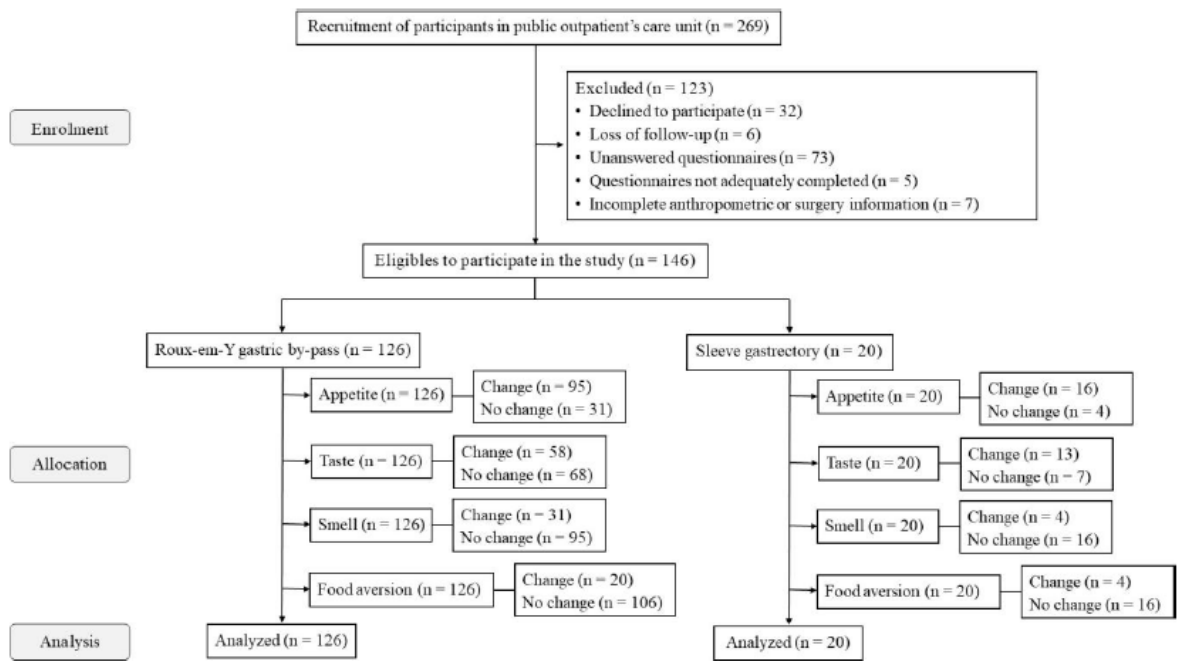
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## FIGURE CAPTIONS

**Figure 1.** Flow diagram of participants enrolment, allocation, follow-up and data analysis.





**Table 1.** Demographic characteristics, clinical history and surgery data of the study groups

Variable	PS (n=146)	RYGB (n=126)	SG (n=20)	P value
<b>Demographic characteristics</b>				
Age (years)	42±8	42±8*	39±8	0.05
Female (n, %)	130 (89)	110 (87.3)	20 (100)	0.09
Weight (kg)	88.0±21	84.9 [71.9–100.2]	86.1±19.3	0.29
Height (cm)	164.0±0.1	163.0±0.1	164.0±0.1	0.49
BMI (kg/m <sup>2</sup> )	32.6±6.3	32.7±6.3	32.0±6.7	0.40
Neck circumference (cm)	35.9±3.6	35.8±3.6	36.9±3.5	0.11
Waist circumference (cm)	97.4±17.5	95.5 [86.2–108.0]	97.5 [90.0–104.0]	0.61
Hip circumference (cm)	115.0 [107.0–124.5]	116.0 [106.0–125.0]	115.2±11.7	0.24
Systolic blood pressure (mmHg)	124.5±16.1	125.2±16.0	120.7±16.6	0.87
Diastolic blood pressure (mmHg)	78.4±11.6	78.5±11.6	77.1±11.4	0.31
Heart rate (bpm)	77±12	77±12	75±8	0.29
<b>Clinical history – n (%)</b>				
Diabetes Mellitus	11 (7.5)	8 (6.3)	3 (15)	0.17
Hypertension	28 (19.2)	26 (20.6)	2 (10)	0.26
Dyslipidemia	8 (5.5)	7 (5.6)	1 (5)	0.92
<b>Bariatric surgery data</b>				
Preoperative weight (kg)	126.0 [112.0–140.0]	126.0 [113.7–140.0]*	119.0±18.9	0.03
Preoperative BMI (kg/m <sup>2</sup> )	46.3 [43.2–51.6]	46.5 [43.5–52.4]*	44.2±5.0	0.005
Minimum postoperative weight (kg)	76.5±15.4	76.8±15.9	75.3±12.0	0.35
Minimum postoperative BMI (kg/m <sup>2</sup> )	28.4±4.7	28.5±4.7	28.2±4.6	0.38
EWL (%)	87.5±20.2	87.8±19.2	85.4±25.9	0.31
RWR (%)	15.4 [3.9–30.9]	14.9 [3.9–29.7]	23.5±21.5	0.27
Time since surgery (years)	5.0 ± 4.0	5.3± 4.1*	3.2± 1.8	0.01

PS – Pooled sample; RYGB – Roux-en-Y gastric bypass; SG – Sleeve gastrectomy; BMI – Body mass index; RWR – Rate of weight regain; EWL – Excess weight loss; \*P value, unpaired Student t-test or chi-square test; results expressed as mean ± standard deviation (SD), median [percentiles 25–75] and %.

**Table 2.** Sensory and food perceptions following Roux-en-Y gastric bypass and sleeve gastrectomy

Variable	PS (n=146)	RYGB (n=126)	SG (n=20)	P value
<b>Sensory and food changes – n (%)</b>				
Change in appetite	111 (76)	95 (75.4)	16 (80)	0.65
Change in taste	71 (48.6)	58 (46)	13 (65)	0.11
Change in smell	35 (24)	31 (24.6)	4 (20)	0.65
Food aversion	24 (16.4)	20 (15.9)	4 (20)	0.64
<b>Taste changes to specific food – n (%)</b>				
Sweet taste increased	71 (60.2)	58 (57.4)	13 (76.5)	0.13
Sweet taste decreased	19 (16.2)	18 (18)	1 (5.9)	0.21
Salty taste increased	35 (30.2)	27 (27.3)	8 (47.1)	0.10
Salty taste decreased	21 (17.9)	18 (18)	3 (17.6)	0.97
Sour taste increased	27 (23.3)	21 (21)	6 (37.5)	0.15
Sour taste decreased	8 (7)	8 (8.1)	0 (0)	0.24
<b>Loss level of taste and smell</b>				
Sweet taste	2.1±2.1	2.1±2.2	1.7±1.3	0.23
Salty taste	2.4±2.3	2.3±2.2	3.1±2.3	0.12
Sour taste	1.6±1.7	1.6±1.7	1.7±1.6	0.42
Smell	1.3±1.2	1.4±1.3	1.4±1.1	0.43

PS – Pooled sample; RYGB – Roux-en-Y gastric bypass; SG – Sleeve gastrectomy; \*P value, unpaired Student t-test or chi-square test; results expressed as mean ± standard deviation (SD) and %.

**Table 3.** Excess weight loss, rate of weight regain, and time since surgery in post-bariatric patients with and without changes in sensory and food perceptions.

Variable	Appetite		P value	Taste		P value	Smell		P value	Food aversion		P value
	Change	No change		Change	No change		Change	No change		Change	No change	
PS	n=111	n=35		n=71	n=75		n=35	n=111		n=24	n=122	
EWL (%)	87.2±21.2	88.4±16.6	0.38	86.6±22.4	88.3±17.9	0.30	88.6±22.8	87.1±19.3	0.35	90.3±23.5	86.9±19.4	0.22
RWR (%)	14.0 [3.9–30.5]	18.3 [5.6–32.3]	0.19	13.2 [0.1–29]	16.5 [6.7–33.2]	0.08	12.3 [0–24.0]*	17.0 [6.1–33.9]	0.02	23.4±22.1	15.4 [3.8–29.2]	0.28
Surgery time (years)	4.7±3.7*	6.1±4.4	0.03	3.1 [1.7–4.8]*	6.0±4.2	0.004	2.8 [1.1–3.9]*	5.5±4.1	< 0.001	4.7±3.7	5.1±4.0	0.35
RYGB	n=95	n=31		n=58	n=68		n=31	n=95		n=20	n=106	
EWL (%)	87.5±20.8	88.8±13.5	0.36	87.2±21.0	88.3±17.6	0.37	88.3±20.3	87.7±18.9	0.44	93.9±22.7	86.7±18.3	0.06
RWR (%)	13.9 [3.9–29.0]	18.3 [2.1–32.3]	0.24	12.7 [0.1–25.8]*	16.7 [6.3–32.9]	0.05	12.3 [0–24.0]*	16.5 [5.8–33.5]	0.05	25.3±22.8	14.7 [2.3–27.8]	0.14
Surgery time (years)	5.0±3.9*	6.3±4.6	0.05	4.3±3.6*	6.2±4.4	0.004	2.8 [1.2–4.3]*	5.9±4.3	< 0.001	5.1±3.9	5.3±4.2	0.42
SG	n=16	n=4		n=13	n=7		n=4	n=16		n=4	n=16	
EWL (%)	85.6±24.2	84.6±36.0	0.47	84.0±28.6	87.9±21.7	0.38	91.4±42.1	83.9±21.9	0.31	72.5±21.6	88.6±26.4	0.13
RWR (%)	21.9±20.6	29.6±27.4	0.27	23.3±21.4	23.7±23.5	0.48	11.5±14.4	26.4±22.3	0.11	13.9±17.7	25.9±22.2	0.16
Surgery time (years)	2.9±1.8	4.1±1.1	0.12	2.8±1.7	3.9±1.7	0.08	1.8±1.6*	3.5±1.6	0.03	2.7±2.6	3.3±1.6	0.28

PS – Pooled sample; RYGB – Roux-en-Y gastric bypass; SG – Sleeve gastrectomy; EWL – Excess weight loss; RWR – Rate of weight regain; \*P value, denote comparisons between change and no change; results expressed as mean ± standard deviation (SD), median [percentiles 25–75]

## ANEXO D - Comprovante de submissão do estudo correlato

## Appetite

## Do changes in appetite, taste, smell, and also food aversion influence weight loss and regain in post-bariatric patients?

--Manuscript Draft--

Manuscript Number:	
Article Type:	Full Length Article
Section/Category:	Health Sciences
Keywords:	Appetite; taste; smell; food aversion; obesity; bariatric surgery
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Abstract:	<p>We investigated if changes in appetite, taste, smell, and food aversion occurred in patients following two types of bariatric surgery without medical follow-up. Additionally, we compared those with and without these changes concerning the excess weight loss (EWL), rate of weight regain (RWR), and time since surgery. A prospective cohort included 146 post-bariatric patients in the study (126 post-Roux-en-Y [RYGB] and 20 post-sleeve gastrectomy [SG]), aged 42±8yrs, body mass index of 32.6±6.3kg/m<sup>2</sup>, EWL of 87.5±20.2%, RWR of 15.4 [3.9–30.9]% and the time since surgery of 5.0±4.0 yrs. They all answered a questionnaire about sensory and food perceptions at their first appointment in our unit. Sensory and food aversion perceptions, taste changes to a specific food, and loss level of taste and smell were similar between RYGB and SG (P≥0.10). Changes in appetite (76%), taste (48.6%), and an increased sensation for sweet taste (60.2%) frequently occurred in our sample. No difference was observed between patients with or without changes in appetite, taste, smell, and food aversion perceptions concerning EWL (P≥0.06). RWR was lower in post-RYGB with changes in taste and smell (P=0.05), while in those post-SG any difference was detected (P≥0.11). Sensory changes were noted in those with shorter time since surgery for both procedures (P≤0.05), but following the type of surgery, they were similar. Sensory and food perceptions are usual post-bariatric procedures but did not differ between them. All patients had significant weight loss, with a lower weight regain in post-RYGB with changes in taste and smell. Patients with a shorter time since surgery showed more frequently the occurrence of changes in appetite, taste, and smell in post-RYGB.</p>
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