

APOLO-Bari: an internet program for supporting of bariatric surgery patients

Submission date 09/09/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/03/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Weight loss surgery, also called bariatric surgery, is a drastic measure used to help people who are dangerously overweight. There are a number of different types of bariatric surgery; however they all work by limiting the amount a person can eat or reducing the number of calories that are absorbed from food. Although these procedures can be very effective for losing weight in the short-term, many people put back on the weight they have lost in the long-term. There is a strong link between behaviour after surgery and the long-term outcomes, as people who fall back into old habits, such as overeating or an unhealthy diet, are unlikely to maintain their weight loss. Support groups to help people to stick to their weight loss plans after surgery have been suggested, however the feasibility of this has been questioned due to costs and limited human resources. One way of resolving these issues is by offering this support online. APOLO-Bari is an internet based programme which has been developed to help bariatric surgery patients to maintain their weight loss long-term. The aim of this study is to test the effectiveness of this programme in preventing weight regain after bariatric surgery.

Who can participate?

Adults with more than 30% post-operative weight loss.

What does the study involve?

Participants are randomly allocated into one of two groups. The first group (intervention group) receives full access to the APOLO-Bari programme. This includes a self-help manual, designed to educate people about behaviour, a weekly feedback monitoring system and interactive chat sessions with a trained psychologist. After 12 months access to the programme, participants will not be able to access it for a further 12 months (follow up period). The second group (control group) has no access to APOLO-Bari throughout the study, and participants are only able to access general information about obesity and bariatric surgery. Both groups complete questionnaires at the start of the study, every fourth month until the end of the intervention period, and then at 6 months and 12 months in the follow up period.

What are the possible benefits and risks of participating?

Benefits of participating include the free support from APOLO-Bari, which should help patients to lose more weight and not regain weight. There are no risks of participating in the study.

Where is the study run from?

1. Hospital de Braga (Portugal)
2. Hospital de São João (Portugal)

When is the study starting and how long is it expected to run for?

July 2011 to August 2014

Who is funding the study?

Foundation for Science and Technology (Portugal)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PTDC/MHC-PCL/4974/2012

Study information

Scientific Title

APOLO-Bari: an internet-based program for longitudinal support of bariatric surgery patients. A multicenter randomized controlled trial

Acronym

APOLO-Bari

Study objectives

The specific objectives of this project are:

1. To test short- and long-term efficacy of the program in preventing weight regain and promoting weight loss maintenance; promoting adjusted eating behaviors; decreasing psychological distress; enhancing individual self-concept and other psychological outcomes.
2. To test the utility, feasibility and satisfaction perceived with APOLO-Bari in terms of compliance to proposed tasks, log-in frequency and direct evaluation of satisfaction of participants. Participants with higher login frequencies and compliance to monthly assessments are expected to report better weight outcomes; higher levels of satisfaction with weight loss and surgical treatment; and lower levels on the self-reported measures, reflecting a better psychosocial functioning.
3. To study weight regain exploring the temporal courses of eating related features and predictors of weight regain. We expect to identify fluctuations in key-behaviors that precede weight regain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics Subcommittee for Life and Health Sciences, University of Minho, 21/04/2015, ref: SECVS 018/2015
2. Hospital de Braga ethics committee, 08/09/2015, ref: CESH044/2015

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet**Health condition(s) or problem(s) studied**

Obesity

Interventions

Those accepting entering the study will have a computer connected to the internet to their availability to accept the informed consent form online and register by creating a personal username and password. All participants respond an initial short socio-demographic and clinical questionnaire. To ensure the concealment of allocation, the system will then automatically randomize participants on a 1:1 basis, matching for age, gender and surgery type.

Intervention Group (IGroup): Receives full access to the the 3 components of APOLO-Bari program in their personal account. Intervention will last for 12 months and a 12 months period follows with no access possible to the program. During the intervention period the system will record data on login frequency, task submission and weekly monitoring from IGroup. The program includes three different components:

1. The self-help manual psycho-educational cognitive-behavioral based which includes information on different topics relevant for weight regain prevention, and tasks related to the different topic
2. The weekly feedback message system (FMS) with immediate feedback response which assesses risk behaviors, sending a feedback statement that relates to the information reported by the participant and his/hers historical reports, reinforcing and guiding when a problem is detected
3. Direct contact with a trained psychologist in the field through scheduled interactive chat sessions, where participants can pose personal questions.

Control Group (CGroup): Has only access to general information on obesity and bariatric surgery, and to the set of self-report measures at the different assessment times described below. CGroup participants will be informed about the assessment times and the possibility of accessing the full program after the study complete.

Both groups receive reminding messages in their email addresses every time a questionnaire /activity is available. Both groups will complete a similar set of questionnaires at baseline, every 4 month until the end of intervention, and at 6 and 12 month follow-up. Assessment includes anthropometric variables and psychological self-report measures.

Intervention Type

Behavioural

Primary outcome measure

1. Weight regain assessed at baseline, end of intervention and at follow up. Weight is measured in the presence of a research member with a TANITA scale.
2. Variant of weight loss estimations using percentage of total weight regain, percentage of excessive weight regain, percentage of total weight loss and percentage of excessive weight loss formulas.

Secondary outcome measures

1. Behavioral outcomes assessed weekly for one year during intervention as part of the monitoring feedback system of APOLO-Bari, using with a short self-report measure developed for this purpose: number of days with maladaptive eating behaviors (such as grazing, binge eating and overeating episodes), number of hours of sedentary and physical activities in the previous month
- 2, Psychological outcomes assessed with self-report measures at baseline (Tb), midterm (Tm4 and Tm8), end of treatment (Tf) and follow-up (Tfu6 and Tfu12) using the Eating disorder-15

questionnaire assessing eating disorder psychopathology, repetitive rating questionnaire to assess grazing, depression anxiety stress scale and negative urgency subscale to assess impulsivity.

Overall study start date

04/04/2015

Completion date

20/12/2019

Eligibility

Key inclusion criteria

1. Aged between 18 and 65 years old
2. Underwent bariatric surgery more than 12 months before recruitment
3. Patients with significant post-operative weight loss (% excessive weight loss > 30%).

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

180

Key exclusion criteria

1. Participants presenting significant weight regain (> than 15% of total weight loss) since nadir weight at the time of registration
2. No regular internet access
3. Inability to read and understand Portuguese instructions
4. Unwillingness to have/create and email account
5. Presence of active psychiatric disorder (e.g. bipolar disorder; psychotic disorder; suicidal ideation; eating disorders)
6. Intake of weight-affecting drugs
7. Concomitant weight loss treatment besides TAU
8. Pregnancy or lactation in female participants

Date of first enrolment

04/02/2016

Date of final enrolment

04/11/2019

Locations

Countries of recruitment

Portugal

Study participating centre

Hospital de Braga

Sete Fontes

São Victor

Braga

Portugal

4710-243

Study participating centre

Hospital de São João

Alameda Prof. Hernâni Monteiro

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Sponsor information

Organisation

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Sponsor type

Government

ROR

<https://ror.org/037wpkx04>

Funder(s)

Funder type

Government

Funder Name

Foundation for Science and Technology

Alternative Name(s)

Foundation for Science and Technology, Portuguese Science and Technology Foundation, Fundacao para a Ciencia e a Tecnologia, FCT

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Portugal

Results and Publications

Publication and dissemination plan

Participation in two annual scientific meetings will allow initial dissemination of the data. The first manuscript describing the study protocol is expected to be published in January 2016. A manuscript describing pilot data and characterizing the sample will be published in the end of December 2016. Midterm assessment will be analysed to describe trajectories of weight which are expected to be published in the beginning of 2017. Satisfaction and feasibility data will be published in 2019. End of treatment and follow/up data on efficacy will be published in 2020.

Intention to publish date

01/01/2016

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2016		Yes	No