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

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 09/09/2015 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 18/09/2015 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 02/03/2016 | Nutritional, Metabolic, Endocrine | [_] 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?
Dr Eva Conceicao
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### Protocol serial number
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: CESHB044/2015

## Study design
Randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Obsesity

## 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(s)
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.

### Key secondary outcome(s))
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.

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### 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
Porto

Portugal
4200-319

# Sponsor information

**Organisation**
University of Minho

**ROR**
https://ror.org/037wpkx04

# Funder(s)

**Funder type**
Government

**Funder Name**
Foundation for Science and Technology

**Alternative Name(s)**
Portuguese Science and Technology Foundation, Foundation for Science and Technology, Fundacao para a Ciencia e a Tecnologia, The Foundation for Science and Technology (FCT), FCT

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
Portugal

# Results and Publications

**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? |
|---|---|---|---|---|---|

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|---|---|---|---|---|
| Protocol article | protocol | 01/03/2016 | Yes | No |