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TEChNology for OBesity Project: telecare in the rehabilitation of patients with obesity with type-2 diabetes

Submission date	Recruitment status	[ ] Prospectively registered
28/03/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/06/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/10/2017	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Gianluca Castelnuovo

Contact details
Clinical Psychology Lab
San Giuseppe Hospital
IRCCS Istituto Auxologico Italiano
Verbania
Italy
28824
-
gianluca.castelnuovo@auxologico.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
A hospital-based intensive treatment and the continuity of care at home using new information and communication technologies in the rehabilitation of obesity with type-2 diabetes: a randomised controlled trial

Acronym
TECNOB Project

Study objectives
The hospital-based intensive treatment and the continuity of care at home using new information and communication technologies (ICT), such as internet and UMTS-based mobile-phones ('health care everywhere'), can be a new useful care in the rehabilitation of obesity with type-2 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethics Committee of Istituto Auxologico Italiano approved the study protocol on the 1st April 2007

Study design
Randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Obesity with type-2 diabetes

Interventions
The TECNOB clinical protocol has a total duration of 13 months and consists of two stepped down phases: in-patient (1 month) and out-patient (the following 12 months). During the in-

patient phase, participants undergo an intensive four-week hospital-based and medically-managed program for weight reduction and rehabilitation. Along this period, participants live in a medical hospital-like environment located on a mountain highland and far away from towns and cities. Visits from parents are allowed only in the afternoon. All patients are placed on a hypocaloric nutritionally balanced diet tailored to the individual after consultation with a dietitian (energy intake around 80% of the basal energy expenditure estimated according to the Harris-Benedict equation and a macronutrient composition of 16% proteins, 25% fat and 59% carbohydrates). Furthermore, they receive nutritional counselling provided by a dietitian, receive psychological counselling provided by a clinical psychologist and have physical activity training provided by a physiotherapist.

The nutritional rehabilitation program aims to improve and promote change in eating habits and consists of both individual sessions (dietary assessment, evaluation of nutrient intake and adequacy, nutritional status, anthropometric, eating patterns, history of overweight, readiness to adopt change) and group sessions (45 minutes each twice a week) including: information on obesity and related health risks, setting of realistic goals for weight loss, healthy eating in general, general nutrition and core food groups, weight management and behaviour change strategies for preventing relapse).

Psychological counselling is provided once a week both individually and in group setting. Individual sessions, lasting 45 minutes each, are mainly based on a cognitive-behavioural approach and emphasise the techniques of self-monitoring, goal setting, time management, prompting and cueing, problem solving, cognitive restructuring, stress management and relapse prevention. Group sessions ("closed" groups of 5/6 persons), lasting 1 hour each, focus on issues such as motivation to change, assertiveness, self-esteem, self-efficacy and coping.

Physical activity takes place once a day except for week-end and consists of group programs (20 subjects) based on postural gymnastics, aerobic activity and walks in the open. Inpatients with specific orthopedic complications carry out individual activities planned by physiotherapists and articulated in programs of physical therapy, assisted passive and active mobilisation and isokinetic exercise.

In the last week, just before discharge from hospital, participants are instructed for the out-patient phase of the program. They receive a multisensory armband (SenseWear® Pro2 Armband), an electronic tool that enables automated monitoring of total energy expenditure (calories burned), active energy expenditure, physical activity duration and levels (METs) and sleep/wake states duration. Patients are instructed to wear this device on the back of the upper arm and to record data for 36 hours every two weeks in a free-living context. The Armband holds up to 12 days of continuous data which the outpatients are instructed to download into their personal computer and to transmit online to a web-site specifically designed for data storing. Outpatients are also told that they can view their progress using the InnerView® Software which analyses and organises data into graphs and reports. Participants are then instructed to use the TECNOB platform, an interactive web-site developed by TELBIOS S.P.A. (http://www.telbios.it). The TECNOB web-platform supports several functions and delivers many utilities, such as questionnaires, an animated food record diary, an agenda and a video conference virtual room. In the "questionnaires" section patients fill in the Outcome Questionnaire and submit data concerning weight and glycated haemoglobin. In the "food record diary" participants submit actual food intake day by day through the selection of food images from a comprehensive visual database provided by METEDA S.P.A. (http://www.meteda.it). The same procedure is also possible through a software called METADIETA (Meteda s.p.a.) previously installed on the outpatients' UMTS mobile phones before discharge. Through the mobile phone outpatients maintain the contact with the dietitian who regularly sends MMS and SMS with visual and text

content on the food choices (frequency and portions) outpatients have to adhere in order to follow a correct diet. By this way, outpatients can keep a food record diary allowing comparison between current eating and the recommended hypocaloric diet along the whole duration of the program. The "agenda" allows the patients to remember the video conference appointments with the clinicians and the days when to fill in the questionnaires. Moreover, the patients can use the "memo" space to note down any important event occurred to him/her in the previous week /month. Indeed, some research indicates that changes in behaviour (eating and exercise) often follow discrete moments which have been variably described as life events, life crises, teachable moments or epiphanies. Life events can lead to weight loss but also to weight gain and qualitative research shows that it is not the event per se that results in behaviour change but the ways in which this event is appraised and interpreted by the individual. The clinical psychologist has thus the opportunity to discuss with the outpatients about the significant events reported in the "memo" space during the video conference sessions and cognitively reconstruct appraisals in functional ways. Finally, outpatients are instructed to use the video conference tool.

Thanks to this medium, patients receive nutritional and cognitive-behavioural tele-counselling with the dietitian and the clinical psychologist who attended the patients inside the hospital. In particular, just after discharge, participants have 6 video conference contacts with both clinicians along 3 months. From the 3rd to the 6th month sessions are scheduled every 30 days and then even more spaced up to an interval of 60 days. During tele-sessions, clinicians (psychologist and dietitian) test the outpatients' progress, their mood, the maintenance of the "good alimentary and physical activity habits", the loss/increase of weight and ask about critical moments, especially those ones reported on the "memo" space. In particular, tele-sessions with the clinical psychologist aim to consolidate strategies and abilities acquired during the in-patient phase, to improve self-esteem and self-efficacy, to support motivation, to prevent relapse and to provide problem-solving and crisis counselling. On the other hand, dietitian assesses adherence and compliance to dietary therapy with a special focus on normal eating behaviour, sufficient fluid intake, hunger and fullness regulation, appropriate eating/etiquette (pace and timing of meals), slow rate of eating, and addresses critical points such as plateau in weight loss or lack of readiness to improve dietary habits.

In addition to video conference, outpatients can further contact clinicians by e-mail. Indeed, each patient is given the possibility to join his clinician beyond the established video conference contacts in case of urgency or emergency. According to the e-message's content, clinicians choose the most appropriate format for providing feedback among e-mail or telephone. In order to avoid excessive dependence and to contain costs, a maximum number of 1 not scheduled contact a week is established a priori.

Participants in the control group will receive the hospital-based treatment and will be asked to respond to the follow-up assessments. No contact will be maintained with them at home and no continuous care will be provided after discharge.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Weight in kilograms. Data will be collected at baseline, at discharge from the hospital (c.a. 1 month after) and after 3, 6 and 12 months from the end of the in-hospital treatment.

Secondary outcome measures
1. Energy expenditure
2. Glycated haemoglobin
3. Binge eating
4. Self-efficacy in eating and weight control
5. Body satisfaction
6. Healthy habit formation
7. Disordered eating-related behaviours and cognitions
8. Psychopathological symptoms
9. Weight-related quality of life

Data will be collected at baseline, at discharge from the hospital (c.a. 1 month after) and after 3, 6 and 12 months from the end of the in-hospital treatment.

Overall study start date
01/01/2008

Completion date
01/04/2010

Eligibility

Key inclusion criteria
Inpatients:
1. Aged between 18 and 65 years, either sex
2. Obesity according to the World Health Organization (WHO) criteria (body mass index [BMI] greater than or equal to 30)
3. Type 2 diabetes mellitus
4. Basic knowledge of informatics
5. Written and informed consent to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
154

Key exclusion criteria
1. Severe psychiatric disturbance diagnosed by Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) revised criteria
2. Concurrent medical condition not related to obesity

Date of first enrolment
01/01/2008

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
Italy

Study participating centre
Clinical Psychology Lab
Verbania
Italy
28824

Sponsor information

Organisation
Compagnia di San Paolo Private Foundation (Italy)

Sponsor details
C.so Vittorio Emanuele II, 75
Torino
Italy
10128
-
info@compagnia.torino.it

Sponsor type
Research organisation

Website
http://www.compagnia.torino.it/english/

ROR
https://ror.org/00d1b1c41

Funder(s)

Funder type
Research organisation

Funder Name
Compagnia di San Paolo Private Foundation (Italy)

Funder Name
TelBios S.p.A. (Italy) - technological partner

Funder Name
Meteda s.r.l. (Italy) - technological partner

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/04/2010		Yes	No
Interim results article	interim results	04/03/2011		Yes	No