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Clinical Psychology and Medicine for the Treatment of Obesity in Out-patient Settings: the TECNOB Project

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1. Introduction

In 2005, about 1.6 billion adults (above 15 years of age) were estimated to be overweight, whereas about 400 million people were obese. Obesity is a condition with such an increasing prevalence that it can be defined as a global epidemic. In 2015, approximately 2.3 billion adults will be overweight and more than 700 million will be obese (WHO, 2006). Obesity increases the risk of many health complications such as cardiovascular diseases, some types of cancer, osteoarthritis, hypertension, dyslipidemia, and hypercholesterolemia, and is associated with early death (Flegal, Graubard, Williamson, & Gail, 2005; Whitlock, et al., 2009). Obesity is a strong risk factor for the development of type 2 diabetes (Klein, et al., 2004a, 2004b). Indeed, as BMI (Body Mass Index) increases, the risk of developing type 2 diabetes increases in a "dose-dependent" manner (Colditz, et al., 1990; Must, et al., 1999). The prevalence of type 2 diabetes is 3–7 times higher in obese than in normal-weight adults, and those with a BMI >35 are 20 times more likely to develop type 2 diabetes than those with a BMI between 18.5 and 24.9 (Field, et al., 2001; Mokdad, et al., 2003).

Obesity-related medical complications weigh heavily on public health care costs and developing effective interventions for substantially reduce weight, maintain weight loss and prevent or manage associated diseases like type 2 diabetes in cost-effective manner is a priority.

Stand-alone and combined treatment options (dietetic, nutritional, physical, behavioral, cognitive-behavioral, pharmacological, surgical) are available, but clinical practice and research have shown significant difficulties with regard to availability, costs, treatment adherence and long-term efficacy (Weinstein, 2006). These procedures imply high costs both for the obese individuals and the public health system, overall within an enduring care setting. Indeed, the main challenge in the treatment of obesity is to maintain weight loss in the long term (Hill, Thompson, & Wyatt, 2005). Most overweight and obese individuals regain about one third of the weight lost with treatment within 1 year, sometimes even before the end of the intervention, and they are typically back to baseline in 3 to 5 years (Jeffery, et al., 2000; Katan, 2009; Wing, Tate, Gorin, Raynor, & Fava, 2006). Similarly, few

patients with diabetes go on taking their prescribed medication entirely as intended (Dale, Caramlau, Docherty, Sturt, & Hearnshaw, 2007; Donnan, MacDonald, & Morris, 2002).

Continuous and cost-effective approaches that can reach a large number of obese individuals are thus needed. A new promising method for granting continuity of care to wide populations of patients at low costs is telemedicine and its more specific branches called "e-therapy", "telecare" and "e-health": information and communication technologies (ICT) used in order to exchange information useful for the diagnosis, treatment, rehabilitation and prevention of diseases (Eysenbach, 2001; Pagliari, et al., 2005). Telecare can be carried out with tools such as web-sites, e-mail, chat lines, videoconference, telephone and mobile phones (Castelnuovo, Gaggioli, Mantovani, & Riva, 2003). As already indicated in several studies (Cline & Wong, 1999; Goulis, et al., 2004; Jeffery, et al., 2003; Maglaveras, et al., 2002; Rice, 2005) and in various reviews (Neve, Morgan, Jones, & Collins, 2009; Saperstein, Atkinson, & Gold, 2007; Weinstein, 2006), behavioral treatments delivered through the internet (web-site and e-mail) may be valid alternatives to reduce expensive and time-consuming clinical visits.

2. Clinical telepsychology and telemedicine for obesity

Nowadays Clinical Psychology has found a lot of different applications in traditional clinical settings (public and private hospitals, clinics, services, laboratories, etc.) and innovative clinical settings (remote outpatients' clinics, tele-health and e-health based settings). Medicine alone could be "a soul without psychology" (TIME magazine, Dec. 24, 1956) and so "in these times there is no medical area without a corresponding field in Clinical Psychology: psycho-cardiology, psych-oncology, psycho-geriatrics are only three examples of this significative spread of psychology into the clinical settings, traditionally limited to a bio-medical source" (p.1, Castelnuovo, 2010).

The Internet offers a novel delivery tool in clinical psychology for weight loss and weight loss maintenance interventions, with the potential to offer long-term intervention at a low cost, in comparison to traditional face-to-face treatments.

A recent systematic review has underlined the evidence on the effectiveness of internet-based interventions for weight loss and maintenance enhanced by professional feedback (Manzoni, Pagnini, Corti, Molinari, & Castelnuovo, 2011). Moreover, although Internet programs with counseling from a human therapist may make treatment more effective than automated e-counseling, developing technologies make virtual counselors possible.

Unfortunately studies that have been conducted up to date on this issue are very heterogeneous and furthermore no study has compared an internet based program with a "real" control group (Manzoni, et al., 2011).

About the cost of treatment delivery, only 2 studies of the 26 reviewed assessed cost-effectiveness of an internet-based intervention. Telemedicine applications for obesity would take into account the saving of additional costs through elimination of travel costs and travel time (Manzoni, et al., 2011; Rojas & Gagnon, 2008).

Up to now Internet and Telemedicine have offered a novel tool for weight loss and weight loss maintenance interventions with the potential to improve long-term intervention at low cost, in comparison to traditional face-to-face treatments (Ekeland, Bowes, & Flottorp, 2010; Khaylis, Yiaslas, Bergstrom, & Gore-Felton, 2010).

Khaylis and colleagues identified five components that are considered crucial in facilitating weight loss in technology-based interventions (Khaylis, et al., 2010):

1. SELF-MONITORING: the process in which individuals regulate and keep track of their own behaviors and changes.
2. COUNSELOR FEEDBACK AND COMMUNICATION: the feedback from a professional therapist regarding goals, progress, and results.
3. SOCIAL SUPPORT: the group treatment modality that could be the preferred setting in behavioral weight-loss interventions.
4. STRUCTURED PROGRAM: the structured technology-based weight-loss interventions programs including principles of behavior therapy and change.
5. INDIVIDUALLY TAILORED PROGRAM: the interventions that have to be individually tailored to each participant characteristic

3. An application of telemedicine with clinical psychology in the treatment of obesity in out-patient settings: the TECNOB project

In order to determine which features of telemedicine and internet-based interventions are critical in a cost-effective approach, TECNOB project has been developed.

TECNOB (TEChNology for OBesity) Project is a comprehensive two-phase stepped down program enhanced by telemedicine for the medium-term treatment of obese people seeking intervention for weight loss (Castelnuovo, et al., 2011; Castelnuovo, et al., 2010). Its core features are the hospital-based intensive treatment (1-month), that consists of diet therapy, physical training and psychological counseling, and the continuity of care at home using new information and communication technologies (ICT) such as internet and mobile phones. The effectiveness of the TECNOB program compared with usual care (hospital-based treatment only) will be evaluated in a randomized controlled trial (RCT) with a 12-month follow-up. The primary outcome is weight in kilograms. Secondary outcome measures are energy expenditure measured using an electronic armband, glycated hemoglobin, binge eating, self-efficacy in eating and weight control, body satisfaction, healthy habit formation, disordered eating-related behaviors and cognitions, psychopathological symptoms and weight-related quality of life (Castelnuovo, et al., 2011; Castelnuovo, et al., 2010).

During the in-patient phase, participants attend an intensive four-week hospital-based and medically-managed program for weight reduction and rehabilitation. 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 counseling provided by a dietitian, brief psychological counseling provided by a clinical psychologist and have physical activity training provided by a physiotherapist. 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 behavior change strategies for preventing relapse) (Castelnuovo, et al., 2011; Castelnuovo, et al., 2010).

Psychological counseling is provided once a week both individually and in group setting. Individual sessions, lasting 45 minutes each, are mainly based on the cognitive-behavioral approach described by Cooper and Fairburn and emphasize the techniques of self-

monitoring, goal setting, time management, prompting and cueing, problem solving, cognitive restructuring, stress management and relapse prevention. Group sessions (small groups of 5/6 persons), lasting 1 hour each, focus on issues such as motivation to change, assertiveness, self-esteem, self-efficacy and coping. Developing a sense of autonomy and competence are the primary purposes of the in-hospital interventions. Patients are afforded the skills and tools for change and are supported in assigning positive values to healthy behaviors and also in aligning them with personal values and lifestyle patterns (Castelnuovo, et al., 2011; Castelnuovo, et al., 2010).

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

In the last week of hospitalization, just before discharge from the hospital, participants allocated to the TECNOB program are instructed for the out-patient phase. Firstly, they receive a multisensory armband (SenseWear® Pro3 Armband), an electronic tool that enables automated monitoring of total energy expenditure (calories burned), active energy expenditure, physical activity duration and levels (METs). 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 review their progress using the SenseWear® 6.1 Software which analyzes and organizes data into graphs and reports. Secondly, participants are instructed to use the TECNOB web-platform, an interactive web-site developed by TELBIOS S.P.A. (<http://www.telbios.it>) (see Figure 1 and 2).

The TECNOB web-platform supports several functions and delivers many utilities, such as questionnaires, an animated food record diary, an agenda and a videoconference virtual room. In the “questionnaires” section, patients submit data concerning weight and glycated hemoglobin. 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’ mobile phones before discharge. Through the mobile phones outpatients maintain the contact with the dietitian who regularly sends them SMS containing syntax codes that METADIETA, the software previously installed into the outpatients’ mobile phones, uses in order to visually display the food choices (frequency and portions) outpatients have to adhere according to dietary prescriptions (see Figure 3 and 4).

By this way, outpatients can keep a food record diary allowing comparisons between current eating and the recommended hypocaloric diet along the whole duration of the program. The “agenda” allows the patients to remember the videoconference 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. The clinical psychologist has thus the opportunity to discuss with the outpatients about the significant events reported in the “memo” space during the videoconference sessions and cognitively reconstruct dysfunctional appraisals in functional ways. Finally, outpatients are instructed to use the videoconference tool (see Figure 5).

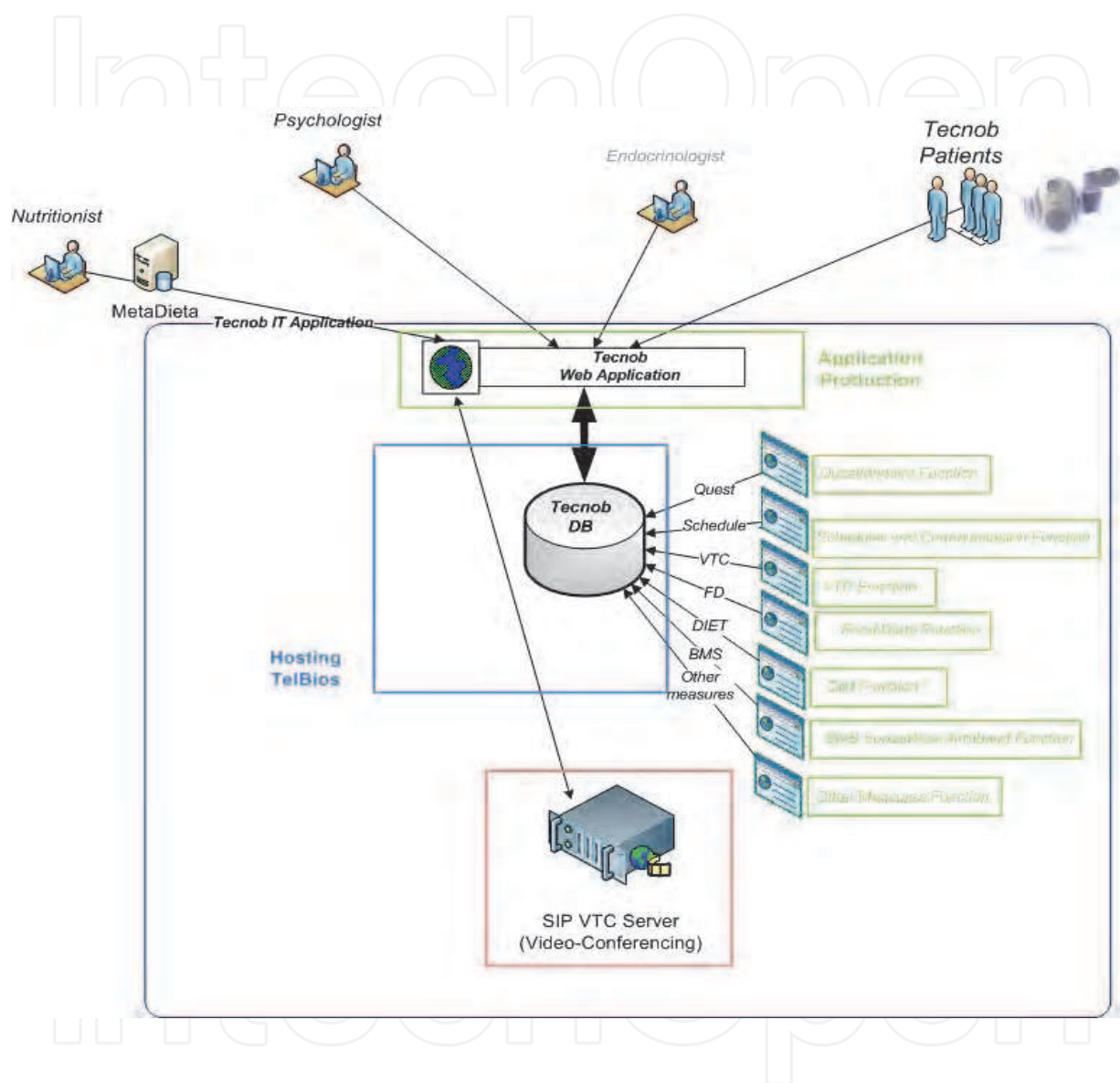


Fig. 1. The TECNOB Telemedicine Platform (developed by TELBIOS <http://www.telbios.it>)



Fig. 2. A screenshot of the TECNOB web-platform with the ARMBAND application (devoloped by TELBIOS <http://www.telbios.it>)



Fig. 3. A screenshot of the METADIETA application for mobile phones (developed by METEDA <http://www.meteda.it>)

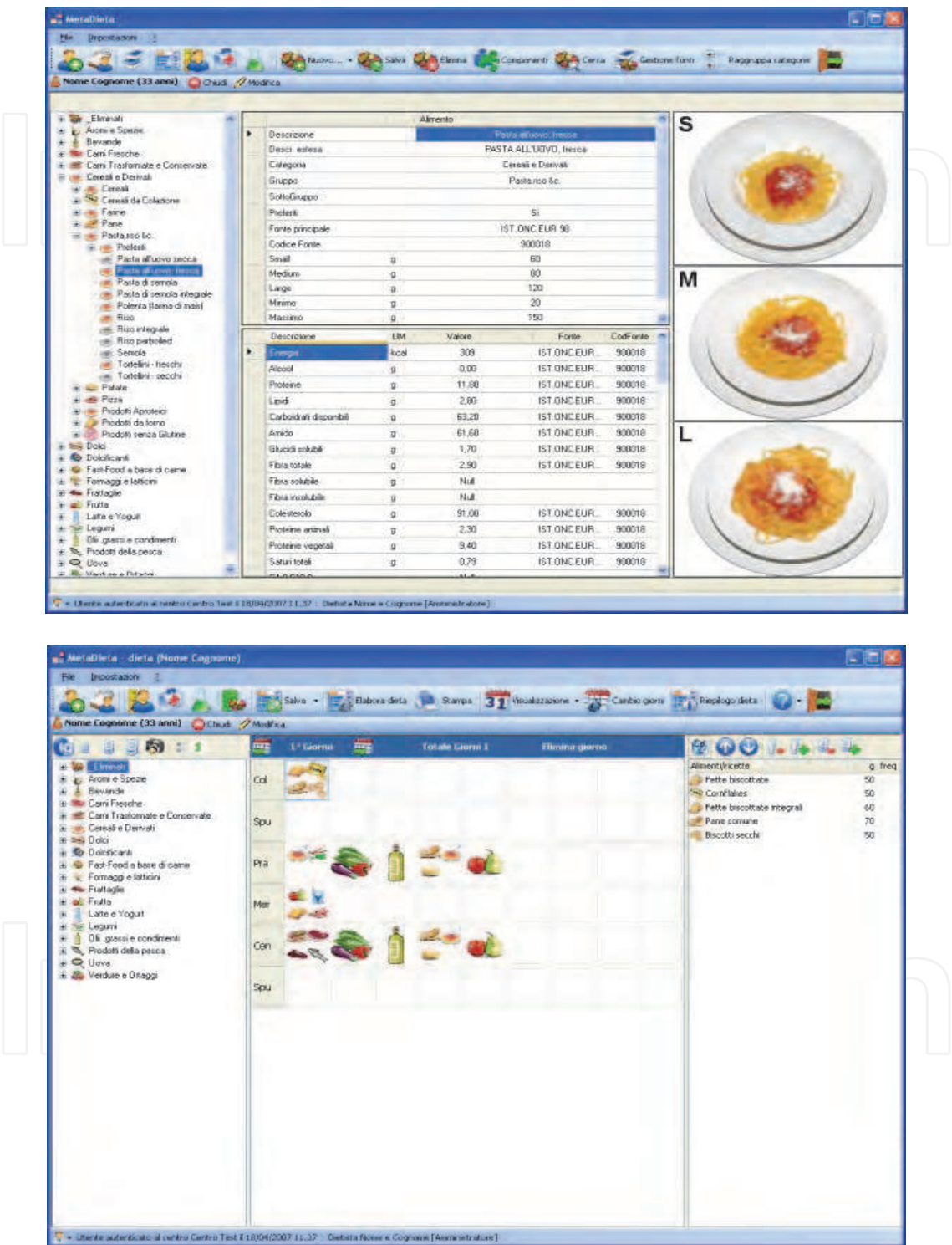


Fig. 4. Two screenshots of the METADIETA application to manage the diet (devoloped by METEDA <http://www.meteda.it>)

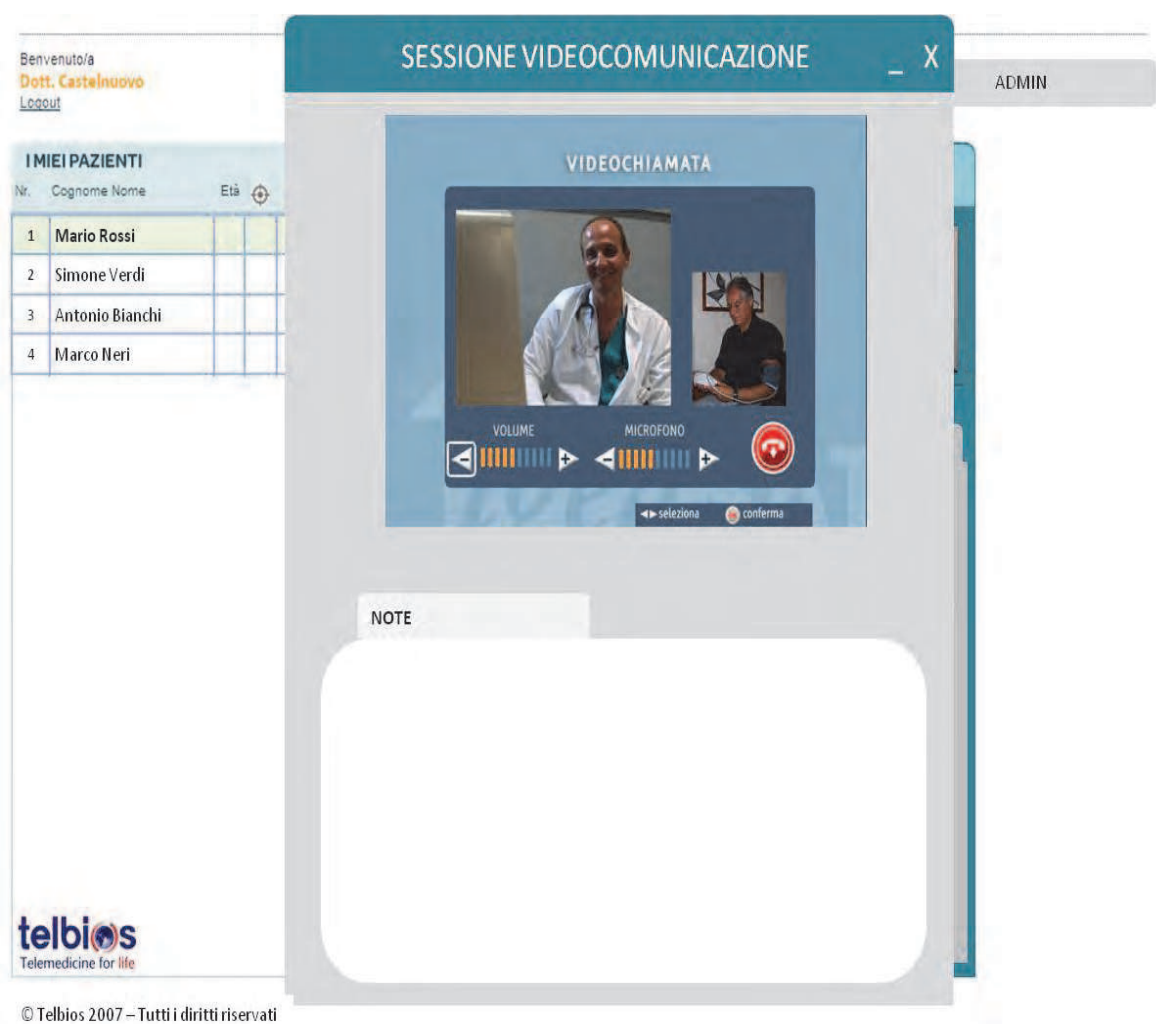


Fig. 5. A screenshot of the TECNOB web-platform with the VIDEOCONFERENCE application (developed by TELBIOS <http://www.telbios.it>)

Thanks to this medium, they receive nutritional and cognitive-behavioral tele-counseling with the dietitian and the clinical psychologist who attended the patients inside the hospital. In particular, just after discharge, participants have 6 videoconference 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" web-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 counseling. On the other hand, dietitian assesses adherence and compliance to dietary therapy with a special focus on normal eating behavior, 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 (Castelnuovo, et al., 2011; Castelnuovo, et al., 2010).

In addition to videoconference, outpatients can further contact clinicians by e-mail. Indeed, each patient is given the possibility to join his clinician beyond the established videoconference contacts in case of urgency or emergency. According to the e-message's content, clinicians choose the most appropriate format for delivering 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. Great relevance is given to the clinicians-patient relationship as an important medium and vehicle of change. After discharge, out-patients begin to experience the autonomy and competence to change they develop during the in-patient phase and inevitably face resistances and barriers. Thanks to videoconferences, outpatients are supported by the clinicians who attended them during the in-hospital phase in exploring resistances and barriers they experience and in finding functional pathways to cope. Furthermore, out-patients are helped to experience mastery in terms of the health behavior change that needs to be engaged (Castelnuovo, et al., 2011; Castelnuovo, et al., 2010).

Some preliminary results are now available. As indicated in a recent paper (Castelnuovo, et al., 2011), at present 72 obese patients with type 2 diabetes have been recruited and randomly allocated to the TECNOB program (n=37) or to a control condition (n=39). However, only 34 participants have completed at least the 3-month follow-up and have been included in this ad interim analysis. 21 out of them have reached also the 6-month follow-up and 13 have achieved the end of the program.

The first ad interim analysis of the data from the TECNOB study has not revealed any significant difference between the TECNOB program and a control condition in weight change at 3, 6 and 12 months. Within-group analysis showed significant reductions of initial weight at all time-points but not at 12-month follow-up (Castelnuovo, et al., 2011). The median percentage of initial weight loss for the whole sample was -5,1 kg (-6,6 to -3,7) at discharge from the hospital. Completers analysis of data collected at 6 and 12 months showed that participants regained back part of the weight loss and the difference between weight at baseline and at 12-month follow-up was no more statistically significant. Notably, sample sizes at 6 and 12 months are small (n=21 and n=12 respectively) due to the ongoing status of the study and these results may be unreliable (Castelnuovo, et al., 2011).

These ad interim findings did not support the effectiveness of the TECNOB protocol over a control condition. Notably, this kind of data analysis (ad interim analysis) is underpowered and results we obtained may be unreliable, in particular at 6 and 12 months. However, we gained a significant insight into an important component of the study design, i.e. the hospital-based program. The effect that such uncontrolled factor has on weight loss was very high and probably overwhelmed the effect of the TECNOB intervention. Hence, much statistical power is necessary to enhance the chance to detect the effect of the TECNOB program: the hospital-based program has a very high effect in the first months after discharge but such effect may reduce in the long term. A 12-month follow-up is probably sufficient to detect the TECNOB effect over and above the weakened effect of the hospital-base program (Castelnuovo, et al., 2011). Study is still on-going and complete results will be published in the next years.

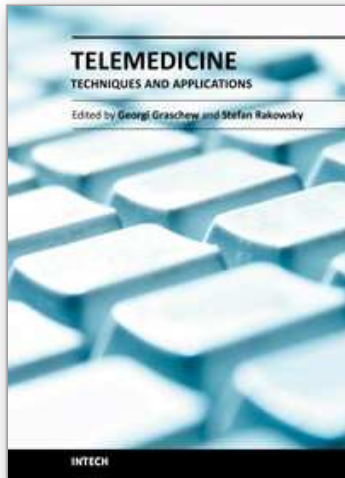
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Telemedicine is a rapidly evolving field as new technologies are implemented for example for the development of wireless sensors, quality data transmission. Using the Internet applications such as counseling, clinical consultation support and home care monitoring and management are more and more realized, which improves access to high level medical care in underserved areas. The 23 chapters of this book present manifold examples of telemedicine treating both theoretical and practical foundations and application scenarios.

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