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Quality of Life in Telemedicine-Based Interventions for Type-2 Diabetes Patients: The TECNOB Project

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Additional information is available at the end of the chapter

1. Introduction

Worldwide, diabetes has become an overwhelming problem due to the increase of over-weightness and obesity. As estimated by WHO in 2011 [1], 346 million people globally suffer from diabetes and there is an approximate 3,4 million mortality rate from the consequences of DMT. WHO predicts that diabetes related deaths will double by 2030. Throughout the course of time, diabetes damages the heart, blood vessels, eyes, kidneys, and nerves. Indeed, 50% of people with diabetes die due to cardiovascular disease (primarily heart disease and stroke). Reduced blood flow and neuropathic pain can increases the chances of complications such as ulcers and even limb amputations. Diabetic retinopathy represents a significant cause of blindness, as a consequence of damage to blood vessels in the retina. 2% of diabetics become blind after 15 years. Diabetes can result in neuropathy, whose common symptoms are tingling, pain, numbness, or weakness both in feet and hands. Diabetes is the seventh leading cause of death in the US [2]. These complications are very important determinants of quality of life. Low QoL may, in turn, affect metabolic control by reducing regimen adherence. Treatment of diabetes involves lowering blood glucose and the levels of other known risk factors that could damage blood vessels. Lifestyle measures, such as the control of body weight, physical activity, a healthy diet and avoidance of tobacco use, have been shown to be effective in preventing the onset of type 2 diabetes.

In addition, estimated global healthcare expenditures to treat and prevent diabetes and its complications total at least $376 billion in 2010. By 2030, this number is projected to exceed some USD490 billion. Expressed in International Dollars (ID), which correct for differences in purchasing power, estimated global expenditures on diabetes was ID418 billion in 2010, and it will be at least ID561 billion in 2030. An estimated average of USD703 (ID878) per person

will be spent on diabetes in 2010 globally [3]. Besides excess healthcare expenditure, diabetes also imposes large economic burdens in the form of lost productivity and foregone economic growth. The American Diabetes Association estimated that the US economy lost USD58 billion, equivalent to about half of the direct healthcare expenditure on diabetes in 2007, as a result of lost earnings due to lost work days, restricted activity days, lower productivity at work, mortality and permanent disability caused by diabetes [4]. The largest economic burden, therefore, is the monetary value associated with disability and loss of life as a result of the disease itself and its related complications. This economic burden, however, can be reduced by implementing many inexpensive, easy-to-use interventions, most of which are cost-effective or cost-saving. Advancement in treatment for diabetes have resulted in reduced lengths of hospital stay and, in some cases, the avoidance of hospital visits, so the demand for home care services has increased [5]. Health-care providers can deliver home care services by visiting the patient at home or by using information and communication technology, also known as telehealth or telemedicine.

2. Quality of life in diabetic population

In the past two decades, research has increasingly highlighted quality of life (QoL) as an important health outcome in diabetes, if not the 'ultimate goal' of treatment [6, 7]. In recent years, there has been a burgeoning interest in quality of life issues, and especially in health-related quality of life, fueled by several factors, including a growing body of evidence concerning the potent effect of psychosocial factors on physical health outcomes, and dramatic changes in the organization and delivery of health care. People with diabetes often feel challenged by their disease and its day-to-day management demands. And these demands are substantial. Patients must deal with their diabetes all day, every day, making countless decisions in an often futile effort to approximate the non-diabetic metabolic state. Diabetes therapy, such as taking insulin, can substantially affect quality of life either positively, by reducing symptoms of high blood sugar, for instance, or negatively, by increasing symptoms of low blood sugar, for example. The psychosocial toll of living with diabetes is often a heavy one, and this toll can often, in turn, affect self-care behaviour and, ultimately, long-term glycaemic control, the risk of developing long-term complications, and quality of life. Psycho-logical adjustment to chronic disease embraces emotional, cognitive and behavioural dimen-sions. Several adaptation tasks need to be accomplished, such as negative and positive affective self-regulation, daily functioning contingent to treatment needs and the reformulation of beliefs and expectancies about health and disease, self and others, life and death. It is a complex dynamic process for someone with a chronic disease [8-10]. The daily psychological stress of living with a chronic disease in a world with professional and interpersonal challenges and specific diabetes-related psychological distress, associated with repetitive intrusive treatment regimens or disabling chronic complications are two correlated sources of stress in people with DMT2 [11-13]. There is good evidence that psychosocial issues are critical to good diabetes care [14, 15]. Psychosocial factors often determine self-management behaviours, and psycho-social variables (such as depression) are often stronger predictors of medical outcomes such

as hospitalization and mortality than are physiologic and metabolic measures (such as the presence of complications, BMI and HbA1c)[16]. Greater attention is now being devoted to evaluating the quality of health care and the economic value associated with new interventions. Managed care organizations have stimulated a growing effort to determine whether the costs associated with new or existing therapies and educational interventions are justified within fairly short time frames, often less than 3 years. Quality of life is a multidimensional construct comprising the individual's subjective perception of physical, emotional and social well-being, including both a cognitive component (e.g. satisfaction) and an emotional component (e.g. happiness)[17]. In addition to overall or global quality of life there are many specific sub-domains (e.g. health, job, family, friends, community, etc.). Some research on the impact of health on quality of life has examined the impact of domain-specific satisfaction on global life satisfaction. There has been substantial research on the effect of objective health status on overall life satisfaction or on a global measure of health-related quality of life. Yet, while the objective dimension of health status (as assessed by physicians' reports of symptoms or the presence of complications, for instance) is important, the patient's subjective perceptions of health translate the objective facts of his or her health status into an actual quality of life experience. This view is generally endorsed by researchers in this field [18-20] who point out that since expectations regarding health and the ability to cope with limitations and disability can greatly affect a person's perception of health and satisfaction with life, two people with the same objective health status may have a very different quality of life [21]. There is also general consensus that various domains of functioning and well-being can each contribute independently to global quality of life, thus making multidimensional measurement of quality of life necessary [19]. Simply asking one question, such as 'please rate your overall health-related quality of life on a scale from 0 to 100', may provide a useful global assessment, but it does not identify the underlying dimensions which contribute to the overall or health-specific quality of life [21]. Thus, almost all quality of life research involving people with diabetes employs multidimensional assessment of quality of life and typically assesses several dimensions, including physical, psychological, and social functioning and well-being.

Two broad approaches to health-related quality of life measurement have emerged – generic and disease-specific. The generic approach involves the use of measures applicable across health and illness groups. The most widely used generic measure of quality of life in studies of people with diabetes is the Medical Outcomes Study (MOS) Short-Form General Health Survey [22], in its several forms (SF-36, SF-20, SF-12). The MOS instrument includes physical, social and role functioning scales to capture behavioural dysfunction caused by health problems. Measures of mental health, perceptions of overall health, and pain intensity reflect more subjective components of health and general well-being. The authors of this measure claim that these six health concepts are comprehensive in terms of those aspects of health considered most important to patients [23]. These instruments have been translated into many languages, and used in these forms in studies which include people with diabetes. The Rand Quality of Well-Being Self-Administered (QWB-SA) survey [24] is similar to the SF-36 in its aim to comprehensively assess health-related well-being or quality of life. It contains scales designed to measure acute and chronic emotional and physical symptoms, mobility, and physical activity. Other instruments used at least occasionally to assess general health status in people with diabetes include the

Sickness Impact Profile [25] and the Nottingham Health Profile [26]. Generic measures like the SF-36 are most useful for comparing quality of life in people with different diseases and the quality of life in people who have no diseases with the quality of life in people who have a disease. Some generic measures, such as the Quality of Well-Being Scale [24], generate a single utility index of overall quality of life. This index usually ranges from 0 to 100 and these values can be used to adjust for years of life by degree of health experience to yield a measure of 'quality-adjusted life years'. Such a measure can be used to assess cost-effectiveness and cost benefits across various interventions and illnesses. Many generic measures of emotional status have been employed in studies which include people with diabetes. These include the Well-Being Questionnaire [27], the Profile of Mood States [28], the Symptom Checklist (SCL-90R) [29], the Mini-Mental Status Exam [30]. Depression in people with diabetes has been studied using the following scales: the Beck Depression Inventory [31] and the Zung Self-Rating Depression Scale [32]. Anxiety in people with diabetes has been studied using the following scales: the Beck Anxiety Inventory [33], and the Zung Self-Rating Anxiety Scale [34]. Both depression and anxiety in people with diabetes have been studied using the Hospital Anxiety and Depression Scale [35]. Illness-specific quality of life measures can focus on the specific problems posed by an individual illness. For example, even a well-designed generic quality of life scale will not address certain aspects of life with diabetes such as hypoglycaemia, insulin injections, self-monitoring of blood glucose (SMBG), and dietary restrictions, which may be critical to an individual's health-related quality of life. Generic measures may not be specific enough to detect effects in some areas of functioning among some people with diabetes. For example, generic measures of mental health may not identify fear of complications as an important contributing factor. More and more, researchers have added disease-specific assessments to generic ones, to increase the ability of their measures to identify the factors most relevant to the health-related quality of life of people with a specific disease. Some [18] have even advocated a 3-level approach for clinical trials, incorporating generic and disease-specific measures and, finally, situation-specific questions that apply to the specific condition (neuropathy, for example) or intervention being investigated.

As shown in literature, individuals with DMT2 are known to have lower health-related quality of life (HRQOL) and more depressive symptomatology than those without diabetes [36-39]. The comorbidity of depression in patients with type 2 diabetes mellitus has been observed in several studies [40, 41]. Anderson [41] summarized 20 cross-sectional reports and found that the odds of depression in the diabetic group was twice that of the nondiabetic comparison group. In a population-based study of adults with and without DMT2, investigators found EQ-5D index scores and visual analogue scores were significantly lower for respondents with DMT2 and those with 3–5 risk factors for DMT2 than for those with 0–2 risk factors [42]. In a longitudinal analysis of EQ-5D data collected in 2004 and 2009 among SHIELD (Study to Help Improve Early Evaluation and management of risk factors Leading to Diabetes) respondents with DMT2, found their health status declined significantly, indicating that burden of disease has a long-term detrimental impact on the QoL of individuals living with DMT2 [43]. The high prevalence of depressive symptoms among people with diabetes can be explained by two scenarios: that depression may occur as a consequence of having diabetes or a risk factor for the onset of DMT2. The first prospective study where this association was suggested emerged from the work of Eaton and collaborators in 1996 [44]. Afterwards, several prospective studies

provided further solid evidence of this fact, even when controlling for usual T2DM risk factors, such as BMI, sedentary lifestyle or family diabetes [45-49]. Two meta-analyses based on 9 [50] and 13 [48]) prospective studies, reported an increase of 37% risk of depressed adults or a global risk increase of 1.6 (CI 95% 1.37–1.88) which led to T2DM later on. In recent study by Pan [51], conduced on a total of more than 55'000 US women with a 10 years' follow-up, was shown that depression and diabetes are closely related to each other, and this reciprocal association depends on the severity or span of these conditions

Depressive symptoms and diabetes-specific distress correlate with each other, although only specific distress displays more links with behavioural markers, such as self-management. treatment adherence, exercise and glycaemic control [52-55]. Psychological adjustment to type 2 diabetes explains 48% of the variance in diabetes-specific distress [56]. Nevertheless, diabetes distress remains the most prevalent long-lasting factor associated with hyperglycaemia in DMT2 [53]. Predictors of diabetes stress are related to chronic complications, negative life events, chronic stress in daily life, setbacks in diet and exercise management and previous history of depression. Also, depressive symptoms emerge mostly when more intrusive kinds of treatment begin, such as insulin use [51, 57] or if some complications in late diabetes arise [58, 59]. Furthermore, it has been shown that diabetic patients with severe depressive symptoms adhere less well to diet and medication regimes than patients with less severe or no depressive symptoms [60-63]. In particular, depressed mood in diabetic patients might lead to pessimism regarding perceived benefits and lowered self-efficacy, and could result in poor self-care and compliance [64]. The diabetes patient who has low adherence to their diabetes management, lipid, or blood pressure medication as a result of depression is placed at greater risk for both micro- and macrovascular comorbid events and retinopathy [65, 66]. Finally, the course of depression is also more chronic and severe in people with diabetes [67].

3. Telemedicine

One of the most promising methods for the management of chronic illness and, in particular, diabetes and its consequences is represented by the use of Information and Communication Technology (ITC) tools [68]. Telemedicine includes timely transmission and remote interpretation of patient data for follow-up and preventative interventions. The main purpose of this approach is to facilitate a productive interaction between the patient and the health care provider in order to achieve improved treatment results and lower treatment costs. The five components of a sound telemedicine system include:

1. a process for accurate data collection in digital format,

2. an electronic medical record for data incorporation and remote transmission,

3. a set of protocols for distant data analysis,

4. a variety of communication tools to permit effective dialogue between patients and health care providers, and

5. a system for automatically flagging and providing feedback for outlier data [69].

Telemedicine interventions can be communicated from handheld hardware devices to a remote Web server. Hardware for transmission may include

1. cell phones [70],

2. handheld personal digital assistant devices or diaries [71], and

3. portable/laptop computers or desk computers [72].

Data may be transmitted in the form of

1. voice messages over the phone,

2. text messages (short message services) over wireless networks to Web interfaces,

3. email messages over the internet, or

4. live streaming audio or video over the internet.

Data are then incorporated into the patient's electronic medical record, analyzed, flagged if necessary, and responded to by way of automatic or personalized treatment recommendations, which are transmitted into the patient's computer, cell phone, or other handheld device.

Telemedicine is an automated support tool for patients with diabetes to facilitate better decisions by patients and health care providers. Although some of the most widely implemented applications of telemedicine have been designed to support recording and interpretation of serial blood glucose measurements by patients with diabetes, systems have been developed to organize a broadest variety of uploaded objective and subjective data of interest to managing diabetes [73], including patient-collected physiological data, such as

1. blood glucose levels, continuous glucose levels, and blood pressure;

2. laboratory data, such as haemoglobin A1c (A1C) or lipid levels;

3. behavioural information, such as dietary intake and exercise patterns;

4. medication dosages, allergies, and other history;

5. subjective symptoms of hypoglycaemia or other complaints;

6. pertinent event data, such as emergency room visits, hospitalizations, scheduled ophthalmology visits, vaccines, and missed clinic appointments; and

7. images of retinal photos, wounds, or other structures. The pattern of information can be analyzed with decision support software.

A physician can contact the patient either on a scheduled regular response basis if the situation is safe or on an automatic immediate as-needed basis in the event of a high-risk dangerous event [74]. Images of retinal examinations [75] or foot wounds [76] can be transmitted from a general practitioner's office to a specialist consultant at a remote central location.

Telemedicine programs can impact various aspects of patient care, including informational, clinical, behavioural, structural, and economic [77, 78]. The informational impact is a better

quality of information than handwritten records, which may be incomplete or inadvertently forgotten at home on appointment days. The clinical impact is a more frequent communication of information and instructions, which can lead to improved outcomes with lower A1C levels or fewer adverse sequelae. The behavioural impact is more frequent therapy adjustments and reminders, leading to greater patient education and empowerment. The structural impact is usually time-saving for patients who might need to come in to the physician's office for fewer visits; however, the physician workload of reviewing messages and updated data on a regular basis may actually increase.

In a recent review and meta-analysis [79], carried out to determine the effects of telemedicine and teleconsultation regarding clinical, behavioural, and care coordination outcomes of diabetes care compared to usual care, twenty-six studies related to home telehealth for diabetes are included. Results show that, overall, home telehealth interventions were found to be effective in improving glycaemic control (HbA1c) for diabetic persons. Patients in telemedicine group are encouraged to self-monitor blood glucose levels as a part of their disease management programme. The home telehealth interventions help to reduce the number of patients who are hospitalized, number of hospitalizations and bed days of care. However, nonuniform outcomes on the effects of DMT control on quality of life are shown. In fact, in literature, QoL in diabetes is measured by a broad range of validated instruments (the World Health Organization Quality of Life-Bref, World Health Organization–Diabetes Treatment Satisfaction Questionnaire, SF-12, SF-36, Diabetes Quality of Life, Depression Scale CES-D, Problem Areas in Diabetes Scale, Visual Analog Scale, Zung Self-Rating Depression Scale, Depression Short-CARE, Diabetes Distress Scale and Health-Related Quality of Life). Despite these reported methodological issues, telemedicine interventions in DMT control show an increase in contact between health care provider and patient, health care perceived as more supportive according to patients, more effective communication, increased metabolic data transmission, availability and completeness of data among health carers, and improved communication both with health carers and peers [80].

A telemedicine program can be judged as successful if it meets four criteria by being (1) sound, (2) effective, (3) cost-effective, and (4) practical [69]. A sound telemedicine technology facilitates accurate collection of data, accurate input of data, verification of data accuracy, and a process to correct incorrect data. A sound technology will include time stamping of input data to avoid back filling, forward filling, or other data manipulation. An effective technology allows for the determination of process outcome measures, clinical outcome measures, and patient satisfaction. First, the effectiveness of automated telemedicine systems can be measured to assess the adoption of process outcomes, such as timely foot screenings, retinal evaluations, vaccine administrations, and measurement of laboratory tests. These tests include A1C, glucose, lipids for all patients with diabetes, and other laboratory analyses for selected diabetes patients, including serum creatinine levels in users of metformin, liver tests in users of statins, serum potassium in hypertensive patients on selected blood pressure medications, and serum fructosamine in some patients with hemoglobinopathies. Second, the effectiveness of telemedicine programs can be assessed on the basis of improvements in objective clinical outcomes, such as A1C levels, number of hypoglycaemic events, glycaemic variability

according to a predefined formula, or emergency room visits for diabetes-related events. Finally, patient satisfaction can also be used to measure the effectiveness of a telemedicine program. User experience can be quantified by using surveys to measure patient satisfaction, classifying patient feedback in response to provider instructions, and determining the amount of system use by patients [81]. A cost-effective telemedicine technology, compared to usual care, will provide benefits for a cost that is either less expensive than current care ('cost-saving intervention') or a cost-per-benefit ratio, which is within a range that society is already willing to pay for other widely used services. This amount is typically in the range of a cost of up to $50,000 per each quality adjusted life year gained [82]. At last, a practical telemedicine program will overcome technical and structural problems that have hindered the adoption of many new medical programs. Such problems have included (a) a lack of connectivity between stand-alone diabetes telemedicine systems and hospital electronic medical record systems, (b) inadequate decision support software, and (c) inadequate data encryption and security systems to fully ensure patient privacy. Based on these four criteria for a successful telemedicine program, telemedicine has been demonstrated to be substantial, possibly effective, and somewhat practical, but has not been demonstrated to be cost-effective. Research on telemedicine programs that has been published has typically described short-term projects of up to 12 months. Although most studies of telemedicine programs for type 2 diabetes mellitus have demonstrated improved A1C outcomes [83], such programs in type 1 diabetes have not consistently demonstrated improved A1C levels [84]. One on the largest telemedicine studies conducted was the Informatics for Diabetes Education and Telemedicine project [85]. This study compared the outcomes of a combined Web and streaming video telemedicine system against base therapy without a telemedicine system in 1665 Medicare patients. Telemedicine subjects experienced an improvement in glycaemia control, blood pressure levels, and total and low-density lipoprotein cholesterol levels at 1 year of follow-up. The long-term costs and benefits of telemedicine programs are unknown [84]. Cost-effectiveness data are very sparse, however, because there has been very little work in the way of realistic economic modeling or empiric data analysis in the field of diabetes telemedicine [86]. Patients and providers will need to demonstrate continued ongoing compliance and favourable medical and economic results before these programs will be funded on a widespread basis for long-term care. Telemedicine systems are hindered by technical and structural problems that are being corrected gradually and will likely be solved in the near future.

4. Technology for obesity 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 (TECh-Nology for OBesity) Project is a comprehensive two-phase stepped down program enhanced by telemedicine for the medium-term treatment of obese and diabetic people seeking intervention for weight loss [87, 88]. Its core features are the hospital-based intensive treatment (1-month), that consists of diet therapy, physical training and psychological counselling, and the continuity of care at home using new information and communication technologies (ICT) such

as internet and mobile cell 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 haemoglobin, binge eating, self-efficacy in eating and weight control, body satisfaction, healthy habit formation, disordered eating-related behaviours and cognitions, psychopathological symptoms and weight-related quality of life (The Self-Report Habit Index – SRHI[89], Weight Efficacy Life Style Questionnaire – WELSQ [90], Body Uneasiness Test – BUT [91], Binge Eating Scale – BES [92, 93], Eating Disorder Inventory EDI-2 [94], Symptom Check List - SCL-90 [95], Impact of Weight on Quality of Life-Lite - IWQOL-Lite [96], The Outcome Questionnaire - OQ 45.2 [97]). According to the Consensus Statement on the Worldwide Standardization of the Haemoglobin A1C Measurement [98], the haemoglobin A1C (A1C) assay has become the gold-standard in measurement of chronic glycaemia for over two decades. Anchored in the knowledge that elevated A1C values increase the likelihood of the micro-vascular complications of diabetes (and perhaps macro-vascular complications as well), the assay has become the cornerstone for the assessment of diabetes care. In this study, we adopt the measurement method (concentration of only one molecular species of glycated A1C) and results reporting (mmol/mol and derived NGSP %) developed by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)

In this paper only weight and disordered eating-related behaviours and cognitions (EDI- 2) data were analyzed and reported. Weight was assessed with the participant in lightweight clothing with shoes removed on a balance beam scale. The EDI-2 is a widely used, standardized, self-report measure of psychological symptoms commonly associated with anorexia nervosa, bulimia nervosa and other eating disorders. The EDI-2 does not yield a specific diagnosis of eating disorder. It is aimed at the measurement of psychological traits or symptom clusters presumed to have relevance to understanding and treatment of eating disorders. The EDI-2 consists of 11 subscales derived from 91 items. Three of the subscales were designed to assess attitudes and behaviours concerning eating, weight and shape (Drive for Thinness, Bulimia, Body Dissatisfaction) and the remaining eight ones tapped more general constructs or psychological traits clinically relevant to eating disorders (Ineffectiveness, Perfection, Interpersonal Distrust, Interoceptive Awareness, Maturity Fears, Asceticism, Impulse Regulation and Social Insecurity) [94, 99].

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 dietician (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 receivegeneral well-being. The authors of this measure nutritional counselling provided by a dietician, brief psychological counselling provided by a clinical psychologist and physical activity training provided by a physiotherapist. Nutritional rehabilitation program's aim 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 being 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 the cognitive-behavioural approach described by Cooper and Fairburn [100] 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 behaviours and also in aligning them with personal values and lifestyle patterns. Physical activity takes place once a day except for weekends and consists of group programs (20 individuals) based on postural gymnastics, aerobic activity and walks in the open. Patients with specific orthopaedic 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 outpatient phase. Firstly, they receive a multisensory armband (SenseWear® Pro3 Armband) [101], 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 Sense-Wear® 6.1 Software which analyzes and organizes data into graphs and reports. Secondly, participants are instructed to use the TECNOB webplatform, 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 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, used in order to visually display the food choices (frequency and portions) outpatients have to adhere according to dietary prescriptions. In 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. Thanks to this medium, they receive nutritional and cognitive-behavioural telecounselling 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 telesessions, 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, telesessions 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, a dietician 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 videoconferences, 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 priority. Great relevance is given to the clinicians-patient relationship as an important medium and vehicle of change. After discharge, outpatients 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, outpatients are helped to experience mastery in terms of the health behaviour change that needs to be engaged.

5. Conclusion

Some preliminary results are now available. As indicated in a recent paper [87], 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. 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.

Differences in eating-related behaviours and cognitions (EDI-2) were also examined. At baseline, the control group showed higher scores in many EDI-2 scales, i.e. Drive for Thinness, Ineffectiveness, Interoceptive awareness, Impulse regulation and Social Insecurity, compared with the TECNOB group. Notably, these groups included selected participants (those patients that have come through at least the 3-month follow-up) and such statistically significant differences were not found when the original groups were compared. Control group showed higher scores also in Interpersonal distrust at 12 months. However, this result has to be seen with caution because of the few patients (n=12) who have achieved the end of the program at present.

Remarkably, 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. 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 obtained may not be reliable, 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. Study and information collection is an on-going process and complete results, in particular about glycated haemoglobin and QoL indices, will be published in the next years.

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