TELEMEDICINE AS A NEW POSSIBILITY TO IMPROVE HEALTH CARE DELIVERY

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Part I: BASICS OF TELEMEDICINE

1. INTRODUCTION

Telemedicine is defined as the delivery of health-care and sharing of medical knowledge over a distance using telecommunication systems. The term telemedicine is usually associated with modern telecommunication systems: transmission of electronic medical records and images, remote monitoring of a patient's vital parameters, tele-conferencing and interactive tele-teaching.

2. MOBILE COMMUNICATION TECHNOLOGIES

The rapid technological progress in the last decade, with the deployment of high-speed, high-bandwidth telecommunication systems around the world and the development of devices capable of capturing and transmitting images or other data in digital form, has led to a surge of interest in telemedicine.

With the World Wide Web booming, the general public has gained easy access to a variety of information, some of which was initially intended for professionals only. This has brought with it security concerns. These issues can be avoided by maintaining the information in a private network, isolated from the public Internet, i.e. an intranet. Security is achieved at the cost of accessibility. The solution to this dilemma is the

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extranet, i.e. the use of Internet communication paradigm to allow secure access to private information to closed user groups over the public Internet. Typical extranet application scenarios involve employees of an organization (e.g. employees from a hospital) that need to access sensitive information or services, when physically far from organization premises. In telemedicine this might comprise communication between physicians or between a patient and his physician.

Also, personal mobility is playing an ever-increasing role in modern lifestyle. This applies to both professional and leisure activities. Enter the mobile extranet. In this concept, two principles are merged: the need for personal and/or terminal mobility and the need for access to information and services. Telemedicine is a field that stands to benefit greatly from the application of the mobile extranet.

3. PATIENT-FOCUSED HEALTH-CARE

Increasingly, patients are managed at home, in part because the cost of in-patient care is major concern in various countries. In many instances in the past, however, providing medical care at home just resulted in a shift of the costs rather than cost savings - complicated diseases require sophisticated treatment strategies with frequent home visits. Many people are seeing tele-homecare as a potential solution to the dilemma. Using low-cost equipment and regular telecommunication networks, the level of care of a patient at home can be improved through increasing the frequency of contacts at a much lower cost per contact as compared to physical visit.

Recently, attempts have been made to develop a new strategy for he telemedical monitoring of patients in the form of medical contact centres, offering their services to patients and doctors around the clock. These teleconsultation centres (MCC) act as interfaces between the patient, the treating physician (GP) and the medical competence centre (CoC e.g. teaching hospital) (figure 1). Communication between the patient, treating doctor and medical competence centre is established by different means using a mobile extranet as well as a conventional or mobile telephones. Clinical as well as technical feedback to patients and doctor-to-doctor dialogue is provided. Both patient and data triage are facilitated.

In this context we used the so called “Integrated mobile healthcare solution an management disease”-mode, which integrate diagnosis, therapy and nursing as showed in figure 2.

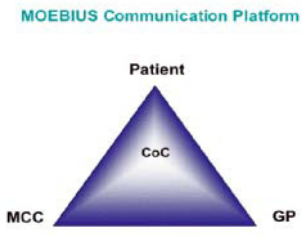

Figure 1. Organization of the communication

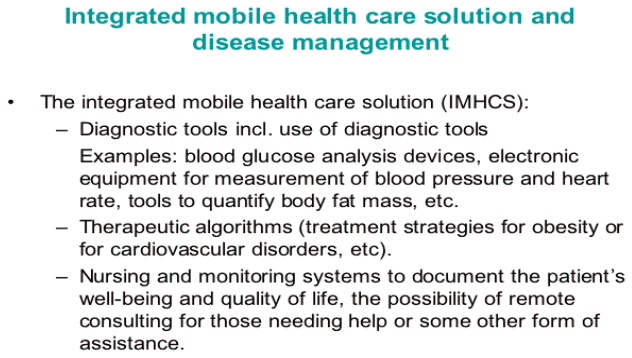

Figure 2. Integrated mobile health care solution

4. THE MOEBIUS PROJECT

With this background in mind, the information society technology project MOEBIUS (Mobile Extranet-Based Integrated User services) was planned. MOEBIUS aims to test the above-mentioned integrated mobile extranet concept: it entails a modern IT infrastructure along with an integrated communications tool for healthcare applications. The culmination of the MOEBIUS project is the realization of a clinical feasibility study using mobile technology in different aspects of patient-focused health-care.

Here we report on a specific clinical trial that was designed to gain experience in networked health-care delivery. The trial involved a group a young obese patients that participated in weight loss program.

The mobile extranet used in the trial was based on General Packed Radio Service (GPRS), as it was the most attractive mobile data transfer technology available. Due again to the modular infrastructure of the system, new solutions such as cellular IP and Universal Mobile Telecommunication Systems (UMTS) can be adopted as soon as they become available.

5. THE TECHNICAL SOLUTION OF MOEBIUS, INTRODUCTION AND DEFINITIONS

Clinical trials are one of the most important tools in the development process of a new drug. Legal offices and ethical reasons formed standard rules for development, well known as Good Clinical Practice (GCP). The last years introduced a new paradigm in information technology supporting clinical trials. While in former times case report forms (questionnaires) on paper have been used, today many trials use so called remote data

entry systems (RDE systems), that is questionnaires that can be answered using a standard PC or a laptop. Data is then submitted to the trial database via standard telephone/ISDN phone lines or via an internet connection or data is collected and transmitted to the trial database in a bulk once in a while.

5.1 Remote data entry (RDE) systems

There are many reasons why to use RDE systems in clinical trials. Just to mention a few, increased speed of information exchange, reduced errors, improved process control and enhanced accessibility are listed. In this paper we won't stress too much on the RDE system itself. But for understanding the rest of the paper, some important points have to be mentioned.

In general, RDE systems consist of a simple structure: on the backend a database serves as the main data storage. This database could be complex when serving different trials at the same time. When designing and implementing this part, the important rules given by GCP and legal offices (e.g. FDA, BfArm, IKS) must be followed for getting results of the trial officially accepted. On the client side there are three different categories of technologies being used. Starting with the most specific system, special software programs can be used for user interaction. These stand alone solutions are generally designed to run on one specific platform only. Today web based applications more and more are becoming accepted. In Web-RDE a standard WWW browser is used to present HTML forms that can be filled with trial data or the HTML page just serves as a host for an Java applet that directly connects to the trial database. This last solution is proved to work well in the e-banking field, too, and is supported by most major databases. Minor drawbacks are that there always has to be a special software or a browser for the patient to work with and that you need an online connection (which might be a problem when you travel around internationally). In many cases these systems perform well and offer an accepted platform for multicentre trials.

In some trials however, a better compliance and in consequence better data quality can be reached when using input devices that are always "near" the patient and help him to protocol things when they occur and not when he is possible to access a computer. One application area is the pain diary where the patient lists pain attacks and his treatment (drug, meditation,). Other areas of use are trials that deal with hay fever or allergic reactions. In this case the immediate event logging could lead to better data quality. One approach to better handle the patient interaction deals with using mobile devices as the input technology. Often used in daily live communications and in mobile commerce (mobile e-business), many persons are quite well familiar with this technology.

5.2 Mobile input devices

If talking about mobile devices many people just think of cellular phones that could be seen in daily live. Other could imagine no other solution than that one using a personal digital assistant (PDA), like the Palm Pilot. Indeed the use of cellular phones as point of interaction with the patient seems reasonable, but the same is true for the Palm solution.

As Wagner points out, you can cluster mobile devices into five categories: mobile phones, smart phones, Palmtop PDA, Handheld PDA and derivatives (Sub notebook, Mini-notebook, ...). There are some characteristics of the devices that have to be

recognized, when a mobile clinical trial is to be designed. These characteristics will be discussed in the two sections: hardware and software. The more important aspect seems to be that one of the hardware itself (screen size, weight of the system, ...), but as the software systems mature, software solutions will have bigger impact than hardware issues. We don't present a complete list of all aspects to be mentioned rather than point out some issues to show the diversity of aspects.

5.3 Hardware

To compare different devices categories have to be defined. Several approaches could be chosen, in clinical trials the compliance of the patient has a very important role and hence we look at categories that are directly related to the user interaction:

Size of display
Input of data
Access to the device
Life cycle without recharging the accumulator.

The size of the screen is important in all cases when data is output in a different way than by voice/sound. Because most voice processors don't work really well, manual output – and hence display size – plays an important role for the compliance of the user. When considering cellular phones, screens exceeding 100 x 70 pixels hardly can be found. This means the devices just can present 4 to 6 lines of black / white characters. Font modifications like centered, bold, italic or underlined mode vary from device to device. Things look a little bit better when you consider smart phones (like Ericsson R380s or the Nokia 9110 communicator). In the PDA family, the Palm (and related) devices have 160 x 160 pixel, the Compaq (Aero, IPaq) and Casio (Cassiopeia) systems offer even bigger screens (240x 320 pixel). These systems mostly use graphical character representation, so the screen size in number of characters vary. The next category (handheld like HP Jornada, Psion 5mx/ Revo etc.) nearly offers EGA resolution (640x480), so software that is based on a window based operating system can be used. The last group "derivatives" (SimPad, Compaq Aero, Getac CA35) generally offers at least 800x600 Pixels, meaning you have a "small PC screen" to present the questionnaires. In total screen size increases from cellular phones to the derivatives category. Another trial dependent aspect seems to be the abilities of the patients using the device. Especially in trials with elderly people, modern communication systems seem to present a major barrier to acceptance. These people aren't used to use a cellular phone, they may have problems with identifying the characters on the phone screen, may have problems using the multi function keyboard on the cell phone. Here special attention is needed to choose the right interface.

If you consider data input with the cellular phone, the user has to use the button set on the phone. PDA and handheld systems use a data pencil in combination with a touch screen whereas the derivatives also offer the keyboard. Here special patient groups have to be in mind, too, when the trial is to be designed.

These two dimensions show an increase of possibilities from cellular phone via PDA and handheld towards derivatives. Reciprocally the accessibility of the device decreases from the small cellular phones to the bigger derivatives: users of cellular phones and PDAs can access that device at nearly every time, being private life or in business. This is

not true for the other systems since the weight and the usage don't allow full mobility and immediate use.

So it has to be decided which system fits best to the needs in the trial.

5.4 The Software

In this paper we want to consider only two aspects of the underlying software: the operating system itself and the possibility to present WAP pages, since these probably will be the base for most trial systems, at least in near future.

There is hardly no impact of the used operating system (OS) for the design of the RDE system. In today's variety of devices only three different known OS are used: Windows CE (Microsoft), EPOC (Symbian consortium) and Palm OS. There is big effort to modify Linux to fit to these devices and it could be also one "player" in future. Since the cellular phone devices cannot use other programs than those built in by the manufacturer, there is only the possibility to use WAP pages for the RDE purpose.

Palm OS and WinCE based systems offer good support for programmers to implement own programs and run them on the device. The derivatives category is designed to work with software that is loaded to the device by the user.

One of the most important aspects of mobile systems is the ability to present WAP [WAP] pages. Since WAP offers the WWW front end to mobile systems, ordinary WWW based RDE systems can easily be extended to work with mobile devices. But because WAP or better said the Wireless Mark-up Language (WML) and WMLScript aren't really in a stable state [WML], the programs can only use limited possibilities of the devices. Many things, that work with the WWW (be it image maps, mixing of Mark-up and Scripts, ...), don't work with the WAP devices. So the program designer has to know the limited capabilities.

Part II: OBESITY TREATMENT BY TELEMEDICINE – THE MOEBIUS OBESITY TRIAL

1. OBESITY AS A HEALTH CARE PROBLEM

Obesity has become a major public health problem in most industrialized countries because of its high prevalence, causal relationship with serious medical diseases and economic impact. In the United States, it is estimated that 300'000 deaths a year are caused by obesity (1) – analogous, reliable figures are not available from Switzerland. Each year, enormous amounts of money is spent on weight loss efforts and the medical complication associated with obesity, but the long-term results of most weight management efforts have been disappointing. In the following sectors, the medical part of obesity is reviewed to provide the background information for the MOEBIUS obesity trial.

2. DEFINITION OF OBESITY

Obesity has increased at an alarming rate in recent years and is now a worldwide public health problem. In addition to suffering from poor health and increased risk of illness such as hypertension and hearth disease, obese people are often stigmatized socially.

Obesity is formally defined as a significant increase above ideal weight, ideal weight being defined as that which maximizes life expectancy. Actuarial tables indicate that life expectancy is reduced when body-mass index, an indicator of adiposity or fatness, is significantly increased above the ideal level. The most intriguing development is an alarming increase in adolescent obesity in recent years. Thus obesity is associated with a significant increase in morbidity and mortality and is a major public health problem. For reasons that are not known, obesity is associated with an increased risk of hypertension, heart disease, diabetes and cancer. Even modest weight loss ameliorates these associated conditions.

In addition to the prospect of diminished health, obese people are often stigmatized both socially and in the workplace. Although the premium on leanness has become especially prominent in late-twentieth-century Western societies, this view is dependent on the cultural context. In many cultures, obesity is considered to be a sign of affluence and prestige, particularly among those cultures where food is less available.

Excessive body fat content is associated with an increased risk for medical illnesses. The identification of patients at increased risk for adiposity-related medical complications is complex. Accurate assessment of body fat is difficult using sophisticated technologies. Data obtained from large-scale epidemiological studies that correlated body mass index (BMI) with clinical outcome have generated guidelines for identifying patients at risk for adiposity-related medical complications and premature mortality. BMI is accepted as the unit for definition of overweight (normal BMI rabge18.5-24.9 kg/m^2; overweight 25-29.9 kg/m^2 and obesity >30 kg/m^2; details in Table 1 (2)). The worldwide epidemic of obesity is signaled by the rise in the percentage of the population with a BMI of >30kg/m^2. BMI is calculated as weight (in kilograms) divided by height (in square meters). BMI correlates strongly with densitometry measurements of fat mass; the main limitation of BMI is that it does not distinguish fat mass from lean mass.

Obesity is not a single disorder but a heterogeneous group of conditions with multiple causes. Body weight is determined by an interaction between genetic, environmental and psychosocial factors acting through the physiological mediators of energy intake and expenditure.

Both genetic and environmental factors modify body weight. Acceptance that the current epidemic of obesity is largely environmental, because of a mismatch between man's ancient genes and his current environment, will help direct preventive and therapeutic strategies. BMI alone, however, is not a sufficient predictor of the detrimental effect of obesity. Central obesity (defined as waist circumference >102 cm in males, >88 cm in females) increases excess mortality and risk of diabetes, coronary heart disease and some forms of cancer. Weight gain after the age of 20 also predicts increased risk. Finally, a sedentary lifestyle by itself increases mortality rates from all causes (3).

BMI is a risk factor like blood pressure and cholesterol in that, as is increases, so does the risk for medical complications and adverse effects (4). Chronic exposure to any of these three factors produces disease – heart failure, stroke and renal failure for raised blood pressure; arteriosclerosis with coronary and cerebrovascular occlusion for

hypercholesterolaemia; and diabetes, gallstones, heart failure, and some forms of cancer for overweight (Table 2).

Effects of excess weight on morbidity and mortality have been known since the time of Hyppocrates, who said, "sudden death is more common in those who are naturally fat than in the lean". The epidemic of obesity is, however, recent. As a consequence, health-care expenditure has increased significantly. BMI has been associated with the annual number of hospital days, number and costs of outpatient visits, cost of outpatient pharmacy and laboratory costs in a large health-maintenance organization (5).

The most variable component of energy expenditure is physical activity. If overweight increases risk of mortality, intentional weight loss ought to reduce mortality and morbidity. As to this date, there is no definite studies documenting such an effect, but several studies document that intentional weight loss reduces risk factors other than obesity (6.7): it reduces blood pressure, improves lipid pattern, and reduces the risk of diabetes. These changes are linear and apparent with weight losses of 5-10%.

3. THERAPY

When prevention fails, medical treatment of obesity may become a necessity. Any strategic medicinal development must recognize that obesity is a chronic, stigmatized and costly disease that is increasing in prevalence.

Because obesity can rarely been cured, treatment strategies are effective only as long as they are used, and combined therapy may be more effective than monotherapy.

The cornerstone of obesity therapy is for the patient to eat fewer calories than are expended to consume indigenous fat stores as fuel. There are seven key principles for successful weight management (Table 3):

Obesity is a chronic illness which requires long-term treatment for long-term success;
Modest weight loss (5-10% of initial body weight) has considerable health benefits and improves insulin sensitivity, blood pressure, blood lipid levels and liver abnormalities;
Behavior modification is necessary for long-term lifestyle changes;
Diet education is needed to facilitate energy intake;
Physical activity is a critical component of weight management programs because it is associated with long-term success and may have beneficial cardiovascular and psychological effects;
Pharmacotherapy may support the weight to management efforts; and
Surgery is the most extreme, but effective approach for extremely obese patients who have been unable to maintain weight loss by dieting.

Diet advice should include encouraging patients to eat three meals a day, avoid snacking between meals, avoid energy-dense and high-fat foods, and increase the intake of fruits and vegetables. A diet with a deficit of 500-800 kcal/d is reasonable for the majority of patients (8). Dietary fat intake should be limited to >30% of total calories.

Behavior modification is needed to help patients change eating habits and increase physical activity and can be facilitated by appropriate physician-patient interaction. Physical activity is a key for long-term weight management success and improved health.

The amount of physical activity needed to prevent weight regain is not trivial and requires professional support. Physical activity should be increased slowly over time until the target goal is reached. Studies suggest that 80 minutes of moderate-intensity activity per day (example: brisk walking) or 35 minutes of vigorous activity (fast bicycling or aerobics) is needed for long-term weight maintenance after initial weight loss has been achieved (8).

Pharmacotherapy can support weight loss efforts. For a drug to have a significant impact on body weight, it must ultimately reduce energy intake, increase energy expenditure, or both. As 1958, the year in which thiazides were introduced, was a watershed in the treatment of hypertension, so 1998 may be a watershed for obesity (3). The effects of the weight-losing drug orlistat for the treatment of obesity might be analogous to the effect of thiazides on sodium excretion. As a potent inhibitor of pancreatic lipase, orlistat impairs fat digestion and absorption (9).

One complaint about treatments for obesity is that they "don't work" (10). A more realistic interpretation is that all treatments for obesity can produce weight loss, but overweight is not a curable disease. When treatment is stopped, weight is regained. A major difficulty in conducting long-term weight management programs is the high dropout rate (11). The completion rate of subjects in several behavioral-pharmacologic weight loss studies over 6 months to 2 years ranged from 30-63% (12-14). Keeping patients in a program promotes weight loss, lessens weight regain and improves obesity-related disease risk factors.

With this background in mind, the MOEBIUS weight control program was designed. The treatment included a controlled-energy diet. Energy intake was prescribed for each subject on the basis of estimated daily maintenance energy requirements. Dieticians at the site periodically provided instruction on dietary intake recording procedures as part of a behavior modification program. In addition, individuals were included in a physical activity program. The recommended changes in physical activity throughout the study were not assessed. The physical activity was, however, supported by regular sessions with a physiotherapist. Finally, patients were given orlistat (120 mg t.i.d.) to support the weight management program. orlistat was administered with the subjects three main meals and the controlled-energy diet. Drug intake was not assessed, as this was not an orlistat efficiency trial. Medication was given to the patients to support the weight control efforts.

4. METHODS

4.1. Subjects

Subjects were recruited, evaluated and monitored in the region of Schwyz. Entry criteria included age older than 18 years, BMI of >29 kg/m^2, subjects were excluded if they had a history or presence of substance abuse, excessive intake of alcohol, significant cardiac, renal, hepatic, gastrointestinal (GI), psychiatric or endocrine disorders, drug-treated diabetes mellitus type 2, or the concomitant use of medication that alter appetite or lipid levels.

4.2. Study Design

This was a feasibility study. The hypothesis that interactive communication technology is effective supportive measures for weight management that can be used by patients with obesity was evaluated in an open 4-month observational study.

There are are two distinct classes of telemedicine interactions – those that are pre-recorded (sometimes referred to as store-and-forward or asynchronous telemedicine) and those that occur in real-time (i.e. interactive or synchronous telemedicine). Pre-recorded telemedicine often depends on the use of e-mail or Internet access to online care. Real-time techniques often employ telephone consulting. In the present trial, both techniques were employed and integrated into the trial procedures.

Study procedures:

The initial screening visit included a medical history taking, physical examination, body weight evaluation, electrocardiogram, and clinical chemistry, hematology and urine-analysis laboratory tests. Fasting serum lipid levels were evaluated according to standard procedures. Fasting serum glucose and insulin levels were measured. The patients were then trained in self-assessment of the following parameters: blood pressure measurements and heart rate, blood glucose and cholesterol measurements, weight assessment. Body weight, physical parameters, blood glucose and serum lipid levels were evaluated every 2 weeks. In addition, patients were seen by one of the study physicians every 4 weeks. Each subject provided written informed content before entry into the trial. The study protocol was reviewed and approved by the local institutional review board.

4.3. Statistical Analysis

This was an open, observational study. Therefore no formal efficacy analysis was performed.

5. RESULTS

5.1. Enrollment

Seventeen patients were initially screened for this pilot trial. Two patients withdrew from the study after the initial teaching session as they considered the study procedures as too complicated. Therefore 15 subjects entered the treatment phase. During the treatment phase 2 patients dropped out of the study due to a lack of effectiveness, according to the opinion of the patients. All patients were white Caucasians. Demographic, anthropometrics, and baseline characteristics are given in Table 4.

5.2. Weight loss

Figure 2 shows the weight change for all 15 patients of the intention-to-treat population. During the treatment period, patients lost a mean 4.9 kg of body weight (-3.9 ± 0.8 kg in female subjects, - 7.7 ± 2.1 kg in males). The percentage of patients losing 5% of baseline weight (measured at visit 1) was also evaluated. This percentage

acknowledges that the reduction of bodyweight seen during this short treatment period is a substantial weight loss. 31% of patients experienced a 5% weight loss response. The majority of patients and investigators assessed the effectiveness of treatment as good to very good: 13 patients were willing to continue the programme outside the trial.

5.3. Cardiovascular Risk Factors

The results of the life style changing program are summarized in Table 5. Despite the short duration of treatment and the small number of patients, a significant reduction in blood pressure values was observed (Table 5). In contrast, patients with no weight loss exhibited no change in blood pressure values.

Total cholesterol values were significantly changed between visit 1 and end of study visit, but the decrease did not reach statistical significance. There were similar decreases in LDL-cholesterol values and a non-significant increase in triglyceride levels. The mean LDL/HDL ratio was relatively stable across the 4 months study period (Table 6).

5.4. Glucose and Insulin levels

Fasting plasma glucose and insulin concentrations obtained from measurement at baseline and at the end of the treatment period are given in Table 7. 3 patients exhibited abnormalities in glucose tolerance enabling the diagnosis of diabetes mellitus type 2. The weight loss program did not significantly change plasma glucose concentrations. Weight loss resulted in a decrease in plasma insulin concentration: 9/13 subjects exhibited lower insulin levels after treatment in comparison to pre-treatment plasma concentrations. In parallel, fasting glucose concentrations decreased from 6.1 ± 0.3mmol/l to 5.8 ± 0.2 mmol/l (NS), a 4 percent decrease. HbA1c concentrations were not affected by the treatment.

6. DISCUSSION

The key to successful telemedicine is not the technology but the delivery of care. The technology itself is simply a means to an end. The key issue concerning technology is that it does not operate in isolation, but as part of a system. Peripheral equipment - in the present study a device for measuring heart rate and blood pressure, a second device for measuring blood glucose and cholesterol concentrations - were connected to a hand-hold computer and a mobile telephone for online interactive communication.

This pilot study showed that patients enrolled into a comprehensive weight loosing programme which consists of a diet, an exercise programme, drug treatment (Xenical®) and an interactive communication system will loose weight. Despite the short duration of the trial, the results are consistent with those seen in previous studies lasting for longer periods. As even a moderate weight loss of approximately 5% provides unquestionable benefits for obese patients, the number of patients achieving such a weight loss reflects a possible advantage of our approach. The present study was primarily a feasibility study and not a comparative trial. Extrapolation of the data to larger populations and to other treatment strategies is therefore dangerous, as a possible bias of the results cannot be excluded by the design of the study. Nevertheless, the following statements are valid: 1.The programme provided a marked weight loss in the majority of patients; in addition,

there were beneficial changes in several risk factors. 2. Plasma total cholesterol and LDL-cholesterol concentrations fell during the treatment; more important a significant, clinically relevant reduction in systolic and diastolic blood pressure was documented. The results form a valid basis for an integrated mobile health care solution with three key elements: 1. Diagnosis, 2. Treatment, 3. Surveillance of treatment.

As in previous short-term studies (≤ 1 year), the treatment showed improvements in most risk factors after 4 months of treatment. Premature withdrawals were rare and less frequent than expected; although all participants in this study did constitute obese people within a randomly selected population, they were probably highly motivated to loose weight. Despite the selection they were representative of individuals who seek help for their obesity. The results of the present study support the treatment concept for long-term management of obese patients in conjunction with an appropriate diet, an exercise programme and, if necessary, specific drug treatment. The set-up used in the MOEBIUS trial showed that the majority of patients accepted the procedures. More important, the patients felt that the support they were given was extremely helpful. All patients (N=13) who lost weight were willing to continue the therapy outside the trial. The time frame of 4 months is considered too short for assessments of long-term results in a weight-loosing program. This time frame was dictated by the MOEBIUS framework, which did not allow for a longer follow-up period. With these limitations, the current pilot study can be classified as very encouraging. An appropriate controlled clinical study with prolonged fellow-up is warranted to support this statement. It is anticipated that a disease management program can be developed which would include the key elements of the present study resulting in an integrated mobile solution for the treatment of obesity.

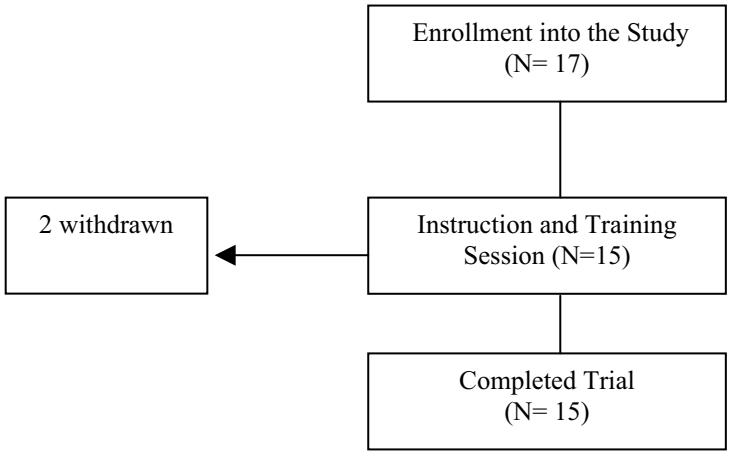

Figure 3. Flow and Disposition of Subjects Entered into the Study

Table 1. Body-weight associated disease risk

Obesity Class		BMI (kg/m²)	Risk
Underweight		>18.5	Increased
Normal		18.5 – 24.9	Normal
Overweight		25.0 – 29.9	Increased
Obesity	I	30.0 – 34.9	High
	II	35.0 – 39.0	Very High
Extreme Obesity	III	> 40	Extremely High

Table 2. Medical Complications associated with obesity

Gastrointestinal	Reflux disease, gallstones, Steatohepatitis, abdominal hernia, pancreatitis
Endocrine/metabolic	Diabetes, dyslipidemia, abnormal menses, infertility
Cardiovascular	Hypertension, coronary heart disease, stroke, deep venous thrombosis, pulmonary embolism
Pulmonary	Obstructive sleep apnoea, abnormal pulmonary function test results
Muscolosceletal	Osteoarthritis, gout, low back pain
Genito-urinary	Urinary stress incontinence
Cancer	Colon, prostate, breast, uterus, cervix, gallbladder
Postoperative events	Atelectasia, pneumonia, deep vein thrombosis, pulmonary embolism

Table 3. Seven principles of weight management (According to Klein (8))

1. Long-term weight loss therapy needed for long-term success
2. Even modest (5-10%) weight loss with considerable health benefits
3. Behavior modification
4. Nutrition education
5. Physical activity
6. Pharmacotherapy
7. Surgical therapy

Table 4. Characteristics of the study population at baseline (4 males, 11 females)

Age (years)	45.0 ± 2.4
Weight (kg)	95 ± 4
Height (cm)	172 ± 2
BMI (kg/m^2)	32 ± 1
Alcohol intake (g/ day)	3
Number of smokers	1

Table 5. Blood pressure measurements before during treatment. Data ± SEM

	Systolic Blood pressure (mm Hg)	Diastolic Blood pressure (mm Hg)
Baseline	130.0 ± 1.5	80.1 ± 0.8
1 month	124.1 ± 1.0	75.0 ± 0.7
2 month	125.7 ± 1.0	76.0 ± 0.7
3 month	122.4 ± 1.2	75.0 ± 1.0
End of treatment	119.8 ± 1.0	74.8 ± 1.1

Table 6. Fasting plasma lipid levels before and after treatment. Data ± SEM

	Baseline	At 4 month	% change
Cholesterol (mmol/l)	5.6 ± 0.2	5.0 ± 0.2	- 10.5 %
HDL (mmol/l)	1.43 ± 0.1	1.35 ± 0.1	- 6.5 %
LDL mmol/l)	3.19 ± 0.2	3.0 ± 0.2	- 5.7 %
Triglycerides (mmol/l)	1.46 ± 0.18	1.45 ± 0.15	- 6.6 %

Table 7. Fasting glucose levels (mmol/l), postprandial glucose levels (mmol/l), fasting insulin concentrations (□V/ml) and HbA1c values before and after treatment. Data are mean ± SEM.

	Baseline	At 4 month	% change
Fasting glucose	6.1 ±0.3	5.8 ± 0.2	- 3.9 %
Postprandial glucose	6.4 ± 0.3	5.9 ± 0.4	- 8.5 %
Insulin	32.2 ± 3.5	21.2 ± 1.4	- 26.0 %
HbA1c	5.6 ± 0.1	5.5 ± 0.1	- 2.1 %

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