Design and Aims of Study to Measure Long-term Efficacy of Interactive Online Dietician Weight Loss Advice in General Practice

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***Abstract*—Obesity is an increasing drain on the resources of general practitioners, who have few effective options for treatment other than surgery and (often prohibitively expensive) personal dietician advice. A study has been designed to investigate the effects of internet-based dietary advice compared with a placebo non-interactive web-support to conventional practice during 24 months. Using data from a previous pilot project for the power calculation, by recruiting 300 patients we will obtain sufficient power to reliably detect a long-term weight loss of 2.5 kg, or, if this figure is higher, to obtain more detailed information about criteria distinguishing patients more or less likely to benefit from this type of Internet based weight loss program.**

Keywords-obesity; Internet community; treatment; preventive medicine

I. INTRODUCTION

Obesity is a growing problem and up to 30% of Europeans are obese, with body mass index (BMI) > or = 30 kg/m^2 [1]. Obesity increases the risk of type 2 diabetes, cardiovascular disease, joint-, and musculoskeletal diseases and cancer. Furthermore the fertility decreases and the risk of spontaneous abortion increases. According to the Framingham study, obesity shortens life with 3 to 8 years for a 40-year-old person [2]. The general recommendations for a weight reduction consist of a change in life style. Form and content of communication are important for the modification of life style factors [3].

Treatment results are modest, except from surgery, but surgery is only recommended to people with BMI > 35 kg/m^2 with complications, or BMI> 40 kg/m^2 without complications [1]. This treatment is expensive, which limits the number of operations that can be performed. In addition, many early and long-term complications with surgery that can reduce the quality of life are reported [4], and there is still uncertainty about the long-term results.

Cochrane reviews show only a very modest effect of conventional advice in general practice compared to placebo [5], while several randomized trials have shown a greater weight loss by adding online dietician advice [6][7][8].

Recent studies suggest that an Internet community with experts is the most effective nonsurgical way to lose weight [6][9]. Online contacts can be an economically attractive contact form for optimizing guidance on diet and exercise and in keeping the patients motivated [10][11][12][13].

There is evidence from some long-term studies that support the choice of such treatment form [5][14], however it is not sufficient to provide a definitive recommendation.

Eighty-six % of the population in Denmark has Internet access at home [15]. This makes it possible to reach most of

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the patients via online intervention. The Internet also provides the benefit of self-monitoring, which has been used successfully in other approaches of Internet based weight loss interventions [7].

Conventional dietician advice is costly and access to professional dieticians is limited. Therefore, it is important to ensure that resources are being used in the best way possible. In Denmark it is possible to employ dieticians in general practice and health care centers. Many practices are however experiencing difficulty organizing the activities in a way that makes it economically feasible to offer diet treatment to patients within the rates provided by the Danish National Health Service. In a previous uncontrolled prospective pilot project [13], using an Internet based interactive weight loss program in a clinical practice setting, we found a sustained average weight loss of 7 kg (95% CI: 4.6-9.3 kg) during 20 months among obese patients with average initial BMI of 36.4.

The present paper describes the rationale and elements of an evidence-based protocol for investigating the long-term efficacy of this Internet based weight loss program, in the context of the capabilities and resources available in typical publicly funded Danish GP practices.

II. OBJECTIVE

The objective is to examine how Internet consultations, with dieticians and personal trainers, as well as an Internet community, in combination with dietician consultations using an existing commercial weight loss program "Slankedoktor" [16] (designed for healthy overweight users) for obese patients in a general practice setting, affects body weight during 24 months compared to the usual treatment of obesity in general practice, supported by a placebo website without interactive online communications.

III. STUDY DESIGN

The study is designed as a randomized controlled single-blind trial.

A. Before randomization

- Patients from 10 medical centers are consecutively offered study inclusion.
- Inclusion criteria are BMI $\geq$ 27 kg/m^2 or BMI $\geq$ 25 kg/m^2 plus at least one risk factor (infertility caused by obesity, hypertension, hyper-cholesterolemia or diabetes).
- Patients are continuously invited until there is a total number of 150 patients randomized to the intervention group and control group respectively.
- Patients who receive oral information concerning the study and who agree to participate are scheduled for an appointment with a nurse. By receiving the first information at the doctor, full confidentiality is secured and the patient will be able to bring a companion.
- The appointment with the nurse must be scheduled within 14 days after the oral information, thus the patient has 14 days to reflect on the decision.
- The nurse obtains the approved informed consent and proceeds with weighing and measuring the patient (Figure 1) moreover the patient is instructed to use a web link to a standard questionnaire from the webpage "Praksisdiætisterne" and thereby supplying basic personal information such as age and gender as well as approval of study conditions (Figure 1). These are necessary requirements in order to participate in the trial.
- Patients are randomized immediately after the questionnaire is filled out. The computer will perform the randomization.
- Based on this scenario drop outs can be recorded, as well as certain characteristics for the patients who choose to drop out.

B. Randomization

- Patients are invited to a consultation where the first physical examination by a nurse takes place (0 months). Afterwards patients are randomized to the intervention and control group respectively (Figure 1). Patients, who are randomized to the intervention group, are instructed on how to fill in information on the website before the initial consultation with the dietician.
- Each medical centre receives two randomization lists, one for females and one for males. Patients are assigned to treatment groups according to the next available item on the list, The relatively low number of patients per centre, the likely gender imbalance and the competitive recruitment may result in some centers recruiting very few patients within a gender. Due to this, the randomization list sequences will be sequential with a base number of two with 20% random offset (for each two consecutive patients, the first one is randomly assigned to one treatment group, the subsequent patient is then assigned to the other group, and an additional patient is inserted at random before 20% of these pairs), hereby minimizing the risk of unbalanced allocation of treatments within a gender at each of the medical centers. If all patients of one gender from one centre who complete the study are in the same treatment group (e.g. if there is only one patient), then the data from these patients will not be used in the overall analysis.

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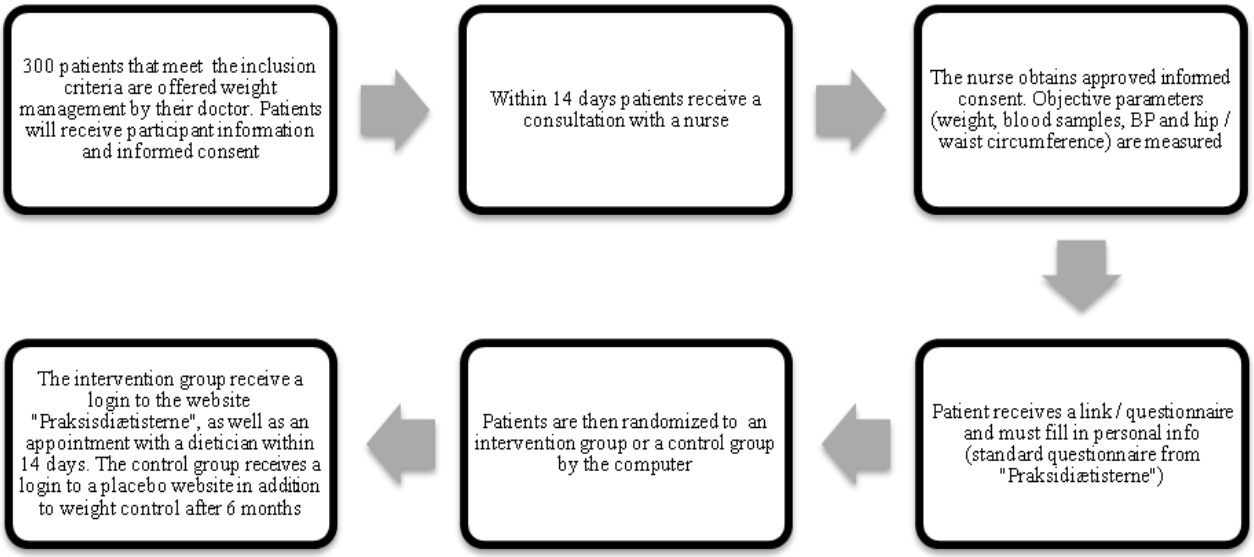

Figure 1. Flow chart of inclusion and randomization. BP = blood pressure.

- Intention to treat method in data handling is used.

D. Control group

- The control group participants receive placebo treatment by getting a login to a website that looks like "Praksisdiætisterne". It will contain dietary advice (e.g. the National Food Administration's (Fødevarestyrelsen) "all about diet") and exercise
- advice, but with neither dietician consultations nor community membership (Figure 2).
- They will receive usual care according to the medical centre they are assigned to and attend weight control sessions where the objective parameters are measured (Figure 2).

C. Intervention Group

- The intervention group receives a login to the website "Praksisdiætisterne" as well as a consultation with a dietician within 14 days (Figure 1).

Figure 2. Treatment of the control group.

- At "Praksisdiætisterne" the patients will have to fill in a daily diet record as well as their doubts and questions to the dietician, who will have access to all patient profiles. Patients will be able to keep up with their weight loss progress by using the website. They will have access to a community where they are able to chat with other participants and share weight loss experiences as well as give advice and support to each other.
- Patients receive subsequent consultations with the dietician by appointment (Figure 3).
- The dieticians provide therapy individually according to their patients' needs and based on information supplied via the website "Praksisdiætisterne", which will use the same technology and procedures for communicating with the patients as the publicly available slimming program 'Slankedoktor' [16] and described in more detail by Brandt et al. [13]. The dietician will generate a personalised daily caloric reduction plan of approximately 1600-4800 KJ based on the patients' diet record. The dietary advice should be as standardized as possible, by following the same simple dietary guidelines that are given at "Slankedoktor" [16].
- Patients are measured and weighed at the start, after 6, 12, 18 and 24 months and blood pressure is measured and blood samples taken at start, 12 and 24 months (Figure 4).
- Patients are reminded by SMS in order to maximize attendance.

E. Standardization of measurement methods

- The measurements must be standardized to avoid

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bias in internal validity (e.g., hip / waist circumference guidelines and standardization of blood pressure measurements), using detailed Standard Operating Procedures (SOPs) agreed among all centers before the start of the study.

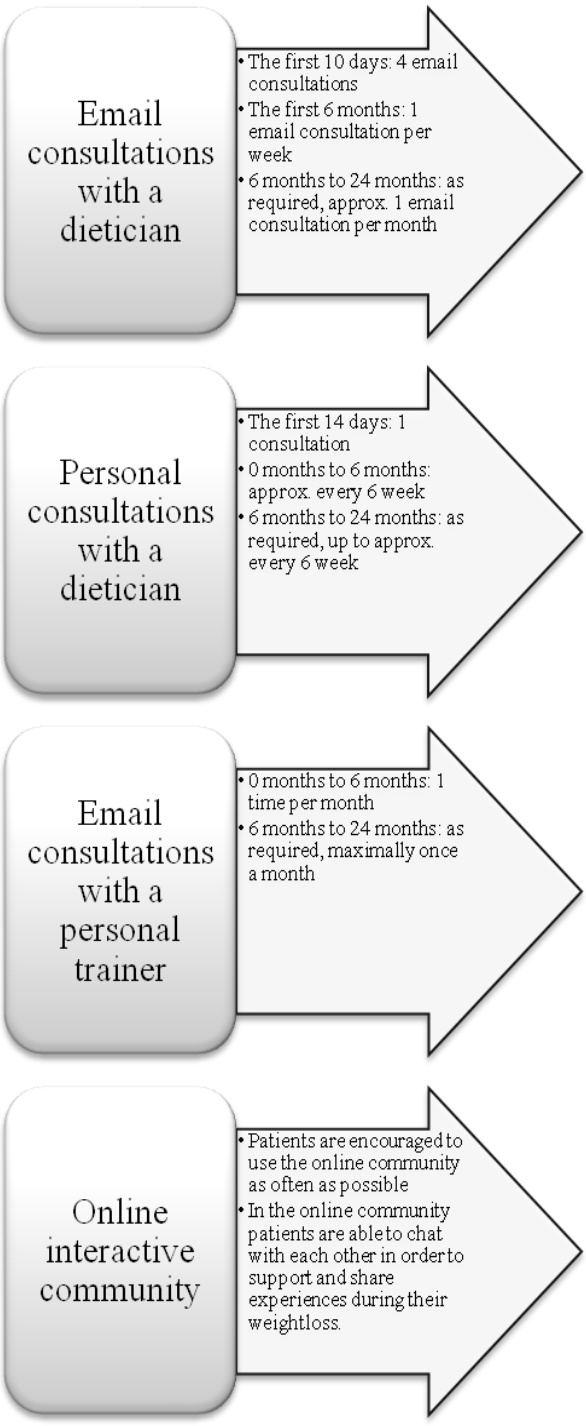

Figure 3. Consultation schedules in the intervention group.

F. Collecting data

- Data will be continuously added to a database, making it easy to extract relevant information.
  The dietician will be using a standardized questionnaire in order to collect data.
- This data includes: weight, waist/hip circumference, blood pressure, number of logins to "Praksisdiætisterne" and number of comments added to the online community.
- In the case of exclusion before the end of the trial, for example by moving or pregnancy, the patient will be encouraged to complete a final questionnaire and objective parameters (Figure 4) in order to provide surrogate endpoint data. The medical centers will be responsible for this.

G. Inclusion Criteria

- BMI $\geq$ 27 kg/m^2.
- BMI $\geq$ 25 kg/m^2 plus a risk factor in the form of:
  - Hypercholesterolemia
  - Hypertension (systolic $\geq$ 140mmHg, diastolic $\geq$ 90mmHg) or patients receiving treatment for hypertension
  - Infertile women (where infertility is considered to be caused by obesity)
  - Type 2 diabetes
- Age at least 18 years.
- Obtained informed consent for use of data in an anonymous form.
- Communication with the patient via cell phone is required.

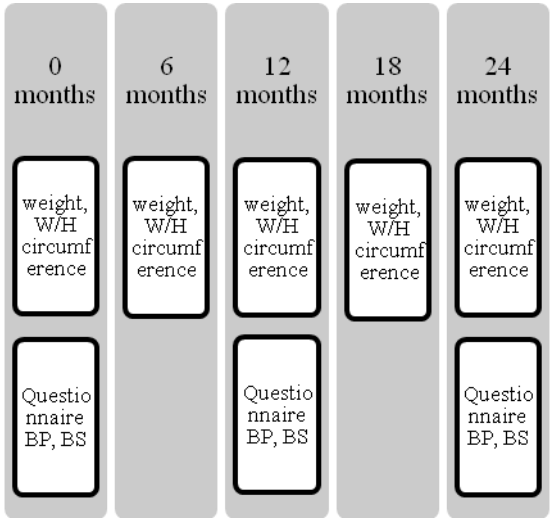

Figure 3. Measurement of objective parameters W= waist, H= hip, BP= blood pressure, BS= blood sample.

H. Exclusion Criteria

- Patients without daily access to the internet.
- Patients who fail to complete the initial questionnaire online.
- Patients who are incapable of using the Danish language, based on writing and reading skills.
- Patients who cannot be expected to use a computer or cell phone for any kind of physical or psychological reason.
- Patients who do not wish to participate.
- Pregnancy at the time of enrolment.
- Weight loss > 3 kg within the last 2 months

I. Study Program

Medical history is obtained by questionnaire at study inclusion, 12 and 24 months:

- Name, age, occupation, marital status.
- Cell phone number, email address.
- Number of family members, number of pregnancies.
- History of obesity (always, since youth, max and min weight in adult life).
- Instances of weight loss events> 10 kg during adult life, for example pregnancies.
- Current illnesses.
- Education history.
- Current medication, smoking, use of dietary supplements, use of alternative medicine.
- Working hours (full time, part-time, overtime), hobbies, habits of exercise (type, times per week), transportation (bike, train / bus, car, walking).
- Food intake (morning, afternoon, evening and snacks), cooking (own, purchase, fast food), use of canteen.

The objective parameters continuously recorded by the user at "Praksisdiætisterne":

- Height
- Weight
- Hip measurement
- Waist measurement

Objective measurements obtained by a dietician, nurse or doctor (Figure 3):

- Weight
- Permanent lipid status
- HbA1C
- BP
- Hip and waist circumference

IV STATISTICS

The primary objective of this study is measurement of changes in body weight and waist circumference. Weight loss in the intervention group and control group will be compared and analyzed using an unpaired t-test. A weight loss of 5-7 kg in the study group and 2-3 kg in the control group is expected after 6 months of treatment. After 2 years we expect the control group to return to the starting weight, while the study group is expected to maintain a weight loss of 3-5 kg. Power calculation based on standard deviations observed in a previous pilot project [13], shows that to detect a difference in weight loss of 2.5kg with a power of 90% requires 142 patients per group. 150 patients will be randomized to each group to allow for dropouts. If the difference is greater than 2.5 kg, the planned total of 300 patients will make it possible to examine interactions between treatment and gender, age and obesity level. Due to this, the randomization will be stratified by gender, while age and obesity level will be analysed as continuous variables.

V. ETHICS

The intervention is not considered to cause any side effects or discomfort. Obesity can cause illness and death. Therefore it is essential to find a validated method for weight reduction with a long-term follow-up. Patient data is handled and stored on the servers of "E-Doktor" and "Praksisdiætisterne". This approach is approved by the Danish Data Inspectorate (Datatilsynet).

VI. CONCLUSION AND FUTURE WORK

The study with the described protocol will provide definitive data on the efficacy of the use of a commercially available interactive Internet based weight loss program in the context of the GP practices in the Danish health care service, with a power to detect a long-term weight loss difference of 2.5kg. If the program turns out to be successful (more effective and/or cheaper than existing options), the collected data will further allow the generation of hypotheses on how the program can be further improved to increase efficacy and/or extend to other patient groups with high frequency of internet access such as younger teenagers.

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