Effects of telemedicine in the treatment of patients with type 2 diabetes – a study protocol

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ABSTRACT

INTRODUCTION: Despite rehabilitation programmes offered to all patients with newly diagnosed type 2 diabetes in Denmark, a number of patients either never accomplish good diabetes regulation or the regulation deteriorates with time. Therefore, new approaches are needed. The aim of the present study is to examine whether telemedicine conferences with a nurse can contribute to achieving good diabetes control among patients with poorly regulated type 2 diabetes.

MATERIAL AND METHODS: A total of 165 patients with type 2 diabetes who have formerly undergone a rehabilitation programme are randomized to either telemedicine intervention or usual care. The intervention lasts for 32 weeks and consists of monthly videoconferences with a nurse from a health-care centre as an add-on to usual care. Blood sugar, blood pressure and weight are regularly self-monitored and measurements are automatically transferred to a database. Glycaemic control (HbA_{1c} level) is examined at baseline, 16 weeks, 32 weeks and 58 weeks (six months post intervention). Blood pressure, weight, waist/hip ratio, quality of life, physical activity, lipids, creatinine and haemoglobin are examined at baseline and after 32 weeks.

CONCLUSION: The study will examine whether telemedicine technology can contribute to achieving good diabetes regulation.

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Type 2 diabetes (T2DM) is a growing health-care problem due to the growing amount of patients and the complications of diabetes. Non-pharmacological treatment consists of lifestyle counselling and education regarding diabetes, and it is considered fundamental in the treatment of patients with T2DM. It is internationally recognized that non-pharmacological intervention should be offered to all patients with newly diagnosed T2DM [1]. In Denmark, a National programme for T2DM has been developed in order to secure minimum standards for control and treatment [2]. The counselling programme in the Capital Region of Denmark can be either group-based or individual. These two programmes have previously been analysed in a randomised controlled trial which compared rehabilitation in a community health-care centre and an outpatient diabetes clinic. Both types of rehabilitation resulted in a decrease in HbA_{1c} level, weight and blood pressure compared to baseline [3]. There was no significant difference between the two types of rehabilitation.

All patients with T2DM who are referred to the diabetes clinic at Bispebjerg Hospital are offered four months of rehabilitation consisting of lifestyle intervention, education, medical treatment and screening for complications; for details, please see [3].

Diabetes is associated with an increase in cardiovascular and all-cause mortality [4]. However, multi-factorial intervention reduces the occurrence of complications and mortality [5].

Education and lifestyle intervention also reduce HbA_{1c} level and cardiovascular risk factors [6-8], but the effect often declines towards baseline levels after cessation of the intervention [6, 8]. Good self-care and compliance seems essential for maintaining good diabetes control and reducing diabetes complications [9], and it is one of the great challenges in the treatment of T2DM. New methods to achieve good self-care are needed. Furthermore, the methods must be applicable to daily clinical practice.

Patients with a low socioeconomic position have a higher prevalence of diabetes, poorer diabetes regulation, higher occurrence of diabetes complications and a higher mortality than those with a high socioeconomic position [10-12]. Thus, methods allowing us to reach this group of patients are of great importance.

Telemedicine represents an alternative way of controlling chronic diseases and has been tested in various designs. Five years of telemedicine, consisting among other things of video-conferencing, clinical data entry and review, web-based educational materials and monitored chat groups reduced HbA_{1c} level in patients with diabetes [13]. Follow-up showed a more pronounced reduction in HbA_{1c} level in a group with poor glycaemic control and low socioeconomic position [14]. In another study, home telemonitoring was compared with monthly telephone calls showing advances towards the telemonitoring group in reducing the HbA_{1c} level in patients with T2DM [15].

PROTOCOL ARTICLE

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Nurse initiating video conference.

MATERIAL AND METHODS

Study objective

The aim of the study is to investigate whether telemedicine can contribute to achieving and maintaining good diabetes control among a group of patients with T2DM who remain poorly regulated despite former rehabilitation and to describe these patients' vulnerability and socioeconomic resources. In this study, telemedicine consists of monthly video conferences with a nurse, preceded by self-monitored regular measurements of blood sugar, weight and blood pressure. The measurements are automatically uploaded via a tablet computer to a database, and the results are visible to both patient and health-care professional. The tablet computer also features an electronic diary where participants can enter events of relevance to their diabetes.

The aim of the study is also to investigate whether the intervention changes the number of hospital admissions, visits at the emergency intake or the amount of contacts to the GPs, and to investigate whether any effects observed during intervention persist beyond the intervention period.

The study examines new cooperation practices between partners in the primary and secondary sector – specifically, between the Health and Care Administration of the City of Copenhagen and Bispebjerg Hospital.

The involved nurses from the health-care centre have considerable experience in educating patients with diabetes, for example through rehabilitation programmes. They are, however, not diabetes nurses, so in order to secure their skills, all nurses have attended an educational programme prior to the project. The educational programme is followed up by regular sessions where relevant issues and problems are discussed.
A diabetes nurse and an endocrinologist conduct the educational programme as well as the follow-ups.

Hypotheses

Telemedicine intervention, as described above:

1) Reduces HbA_{1c} level and bodyweight and induces more physical activity
2) Results in an improved quality of life
3) Can reduce the amount of no-shows at diabetes controls as well as the number of hospital admissions and emergency room visits.

Endpoints

Primary endpoint: HbA_{1c} level

Secondary endpoints: bodyweight, blood pressure, lipids, physical activity and quality of life.

Number of diabetes controls (at diabetes unit or GP), emergency room visits, admissions to hospital during and the intervention and six-month follow-up will be recorded.

Inclusion criteria

Patients must have completed a rehabilitation programme (individual or group-based) at least six months prior to inclusion.

- Age 30-75 years
- HbA_{1c} concentration > 7.5% (59 mmol/mol)
- Body mass index (BMI) > 25 kg/m^2
- Ability to speak Danish.

Exclusion criteria

Serious disease with an expected lifespan < 6 months
Need for an interpreter.

Method

Residents of Copenhagen who meet the inclusion criteria are identified among patients who have formerly participated in a rehabilitation programme at a health-care centre or diabetes clinic and are informed about the project. Those willing to participate are screened after written informed consent has been obtained. Provided they still fulfil the inclusion criteria, baseline tests are planned and questionnaires handed out.

After sampling of baseline tests, randomisation is performed by drawing a sealed envelope.

Baseline data

- Anthropometrical measurements: weight, height, BMI, waist/hip-ratio, blood pressure
- Biochemical measurements: levels of HbA_{1c}, creatinine, haemoglobin, fasting blood sugar, and lipids; urine-albumin/creatinine ratio; extra blood sample for bio-bank
- Lifestyle factors: smoking and drinking habits
- Pharmacological treatment
- Diabetes duration
- Age at diabetes onset
- Complications of diabetes: ischaemic heart disease,

apoplexy, ischaemia of the lower limbs, amputations, peripheral neuropathy, erectile dysfunction, diabetic kidney- or eye disease
- Socio-economic factors: education, marital status, ethnicity, number of children, contact with relatives, financial challenges
- Questionnaires: Short Form (SF)-36 for assessment of quality of life, a Danish version of the validated "recent physical activity questionnaire" (RPAQ) [16] for assessment of physical activity and "Hvordan har du det?" ("How are you doing?") for assessment of other diseases, food and alcohol consumption and smoking habits (a questionnaire developed by the Capital Region of Denmark for a national self-reported health profile investigation).

Intervention group

Telemedicine treatment is an add-on to usual care (at the diabetes clinic or GP).

Patients are equipped with a tablet computer. The tablet computer can automatically upload data from a manometer ("Contec 08C"), a blood glucose monitor ("USB Contour") and a scale, either via a USB jack (blood pressure and glucose) or bluetooth (scale).

Blood pressure and weight are measured once a week (the blood pressure should be measured three times after a minimum five-minute resting period). Blood pressure is measured with an automatic manometer. Blood glucose is measured (at least) twice a day (before breakfast and dinner) for patients on insulin. For patients who are *not* on insulin, blood glucose is measured once weekly, also before breakfast and dinner.

Measurements are automatically transferred via the tablet to a database and are visible to both the patient and to health-care professionals at the health-care centre.

Once a day the patient uses the tablet computer to indicate whether he or she has taken the prescribed medication the past day.

Once a month, the patient has a video conference with a nurse from a health-care centre. Here, the patient and nurse together study the past month's data concerning blood glucose, blood pressure and weight. These levels, as well as the patient's lifestyle in regards to physical activity, dietary and smoking habits and compliance with medication during the past month are discussed. Special attention is drawn to patients with ischaemic heart disease who should not be too tightly regulated in order to avoid hypoglycaemia [17]. The conversation between the nurse and patient is based on the principles of health education aiming to enhance the patient's self-efficacy in order help the patient gain control over his or her life with diabetes.

When needed, nurses at the health-care centre can seek medical advice from either nurses or specialists at the Department of Endocrinology, Bispebjerg Hospital. A note is made when assistance is sought.

In case of acute need of intervention, the staff at the health-care centre can contact the doctor responsible of the patient's treatment (GP or endocrinologist). Furthermore, the patient is free to contact his or her GP/endocrinologist throughout the trial period.

The video conference is documented in a note visible to both patient and nurse.

A variation of ± one week is accepted, i.e. the interval between teleconferences can vary from three to five weeks.

In order to complete, 25% absence is accepted (i.e. six of the eight teleconferences must be held).

Control group

Patients randomided to the control group follow ordinary controls and are recommended to do the same measurements as patients in the intervention group and to record their results in a diabetes diary. The diabetes diary should be brought at all diabetes controls. If necessary, patients can contact their regular doctor (GP or endocrinologist) or the investigator who will be of assistance in contacting the relevant doctor.

Intervention period and post-intervention tests

The intervention lasts for 32 weeks.

In both groups, HbA_{1c} level is measured after 16, 32 and 58 weeks (six months after the intervention period has ended).

Furthermore, the following measurements are repeated at the hospital at 32 weeks (by the end of the intervention period):

- Weight, BMI, waist/hip-ratio, blood pressure
- Levels of HbA_{1c}, creatinine, haemoglobin and fasting blood sugar and fasting lipids
- Questionnaires: SF-36 and the Danish version of the RPAQ (in order to detect changes in quality of life and exercise)
- Changes in pharmacological treatment.

Visits at GP, hospital, referrals to specialists/hospitals, admissions to hospital, emergency room visits, etc., are registered during the 32-week intervention period and during the six-month follow-up period.

Technical platform and evaluation

The technical platform is developed specifically for the project and is customized continually in order to overcome any obstacles. Since newer technologies are expensive and sometimes not user friendly for the average consumer – who are most likely overrepresented

amongst vulnerable patients with diabetes – we have included extensive evaluation of the technical aspects of the project and calculations of cost-effectiveness are intended.

Risks, side effects or disadvantages

There are no immediate risks associated with the project. Blood tests can cause discomfort, but since the tests are taken under sterile conditions, the risk of infection is minimal. The patients might find the frequent telemedicine contacts a disadvantage; the frequent contacts, however, are one of the purposes of the study.

Ethics

The study will be conducted according to the Helsinki Declaration.

The Research Ethics Committee, Capital Region of Denmark, has approved the study (H-2-2011-158) as has the Danish Data Protection Agency (2011-41-6999).

Statistics

Power calculation

The study is designed to detect a difference of 0.5 percentage points in HbA_{1c} level. A test strength of 90%, risk of type 2 error 10% and a level of significance of 0.05 were chosen. Standard deviation 0.9. 2N = 137.

Due to an expected 20% dropout, 2N is increased to 165.

Plan for statistical analyses

Baseline data for the control and the intervention group will be compared using an unpaired T-test for continuous variables and the χ^2-test for categorical data.

Differences in HbA_{1c} level, blood pressure, BMI, waist/hip ratio, etc., over time between the two groups will be investigated using mixed models.

DISCUSSION

As previously described, a great challenge in the treatment of T2DM is achieving and maintaining lifestyle changes, good self-care and compliance with control and medication [6, 8]. Rehabilitation programmes have been successful in achieving a small but relevant change; however, the effect tends to wear off over time [6, 8].

Since good diabetes control reduces the risk of complications to diabetes, efforts should be made to obtain good control. A special group of interest is the vulnerable patients with poor compliance since they have an increased risk of complications [12].

Telemedicine could be a way of reaching these people. The intention of the study is to clarify if telemedicine combined with the use of an empowerment-based education programme and feedback on continuous measurements can contribute to achieving and maintaining lifestyle changes, compliance and good diabetes regulation and whether it can be of special benefit in a group of vulnerable patients.

It is expected that the patients who participate in the study will achieve a better understanding of diabetes and improve their glycaemic regulation and thereby reduce their risk of complications in the long term.

In case of positive results, telemedicine could be implemented in daily clinical practice.

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LITERATURE

1. Nathan DM, Buse JB, Davidson MB et al. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. Diabetes Care 2009;32:193-203.
2. Drivsholm TB, Snorgaard O. Organization of treatment and control of type 2 diabetic patients. Ugeskr Læger 2012;174:2159-62.
3. Vadstrup ES, Frolich A, Perrild H et al. Effect of a group-based rehabilitation programme on glycaemic control and cardiovascular risk factors in type 2 diabetes patients: the Copenhagen Type 2 Diabetes Rehabilitation Project. Patient Educ Couns 2011;84:185-90.
4. Lotufo PA, Gaziano JM, Chae CU et al. Diabetes and all-cause and coronary heart disease mortality among US male physicians. Arch Intern Med 2001;161:242-7.
5. Gaede P, Lund-Andersen H, Parving HH et al. Effect of a multifactorial intervention on mortality in type 2 diabetes. N Engl J Med 2008;358:580-91.
6. Goudswaard AN, Stolk RP, Zuithoff NP et al. Long-term effects of self-management education for patients with type 2 diabetes taking maximal oral hypoglycaemic therapy: a randomized trial in primary care. Diabet Med 2004;21:491-6.
7. Mitra A, Dewanjee D, Dey B. Mechanistic studies of lifestyle interventions in type 2 diabetes. World J Diabetes 2012;3:201-7.
8. Norris SL, Lau J, Smith SJ et al. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. Diabetes Care 2002;25:1159-71.
9. Ho PM, Rumsfeld JS, Masoudi FA et al. Effect of medication nonadherence on hospitalization and mortality among patients with diabetes mellitus. Arch Intern Med 2006;166:1836-41.
10. Espelt A, Borrell C, Roskam AJ et al. Socioeconomic inequalities in diabetes mellitus across Europe at the beginning of the 21st century. Diabetologia 2008;51:1971-9.
11. Evans JMM, Newton RW, Ruta DA et al. Socio-economic status, obesity and prevalence of type 1 and type 2 diabetes mellitus. Diabetic Med 2000;17:478-80.
12. Walker JJ, Livingstone SJ, Colhoun HM et al. Effect of socioeconomic status on mortality among people with type 2 diabetes: a study from the Scottish Diabetes Research Network Epidemiology Group. Diabetes Care 2011;34:1127-32.
13. Shea S, Weinstock RS, Teresi JA et al. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus: 5 year results of the IDEATel study. J Am Med Inform Assoc 2009;16:446-56.
14. Weinstock RS, Teresi JA, Goland R et al. Glycemic control and health disparities in older ethnically diverse underserved adults with diabetes: five-year results from the Informatics for Diabetes Education and Telemedicine (IDEATel) study. Diabetes Care 2011;34:274-9.
15. Stone RA, Rao RH, Sevick MA et al. Active care management supported by home telemonitoring in veterans with type 2 diabetes: the DiaTel randomized controlled trial. Diabetes Care 2010;33:478-84.
16. Besson H, Brage S, Jakes RW et al. Estimating physical activity energy expenditure, sedentary time, and physical activity intensity by self-report in adults. Am J Clin Nutr 2010;91:106-14.

17. Action to Control Cardiovascular Risk in Diabetes Study Group, Gerstein HC, Miller ME et al. Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med 2008;358:2545-59.