Web-based insulin titration: Improving diabetes care in the Netherlands. A pilot study of the PANDIT® system.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON34035

Source
ToetsingOnline

Brief title
Web-based insulin titration: A pilot study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: decision support, diabetes, insulin titration, self-management

Outcome measures

Primary outcome

*Dosing advices given by the DN (phase 1)

*Dosing advices generated by the PANDIT system (phase 1)

*Dosing advices generated by the PANDIT system that are declined by the DN (phase 2)

*Episodes of hypoglycaemia

Secondary outcome

*Usability evaluation

*The amount of patients visiting the PANDIT® system at least every week

*The number of unscheduled contact moments with the DN because of medical questions

*The number of unscheduled contact moments with the DN because of technical questions

*Self monitored blood glucose values

*Used daily insulin doses

*Laboratory fasting plasma glucose

*HbA1c

*Adverse events

*Serious adverse events

Study description

Background summary

Diabetes mellitus is a disease characterized by an absolute or relative deficit of insulin, a hormone necessary for the uptake of glucose into the cells. As a consequence, the blood glucose levels of patients with diabetes are high, leading not only to acute complaints such as thirst and fatigue, but also to serious long term complications such as blindness, kidney failure and cardiovascular disease. The occurrence of these long term complications can be significantly reduced by adequate treatment, aiming for a reduction of blood glucose levels to non diabetic values by diet, oral anti-diabetic treatment or insulin therapy.
The effect of this treatment is evaluated by the widely accepted marker HbA1c (glycosylated haemoglobin), which reflects the average blood glucose level over a period of six to eight weeks. Current guidelines recommend an HbA1c goal of 7% or lower, which has been shown to result in a significant reduction of diabetes related morbidity and mortality. This, however, has proven to be an elusive goal, the average HbA1c level in the Netherlands being 7.6% for type 2 diabetes patients and 7.8% in type 1 diabetes patients.
A new strategy to achieve the appropriate HbA1c value in these patients is urgently needed, as none of the novel pharmacotherapeutic options can be expected to deliver such a result. Insulin therapy is still the most potent agent in the therapeutic arsenal, being cost-effective and without an upper dose limit. However, treating patients with insulin requires active dose titration, increasing or decreasing the insulin dose according to blood glucose response, diet, physical activity and the occurrence of possible side effects such as hypoglycaemia (low blood glucose). The average 3-4 clinical visits per year fail to provide sufficient titration opportunities and may cause the treating physician or nurse to be cautious with dose increments, thus not reaching the treatment*s full potential and HbA1c levels below 7%.
Therefore, we propose to develop an online, computerized titration algorithm to guide patients in self-titration, the PANDIT system (Patient Assisting Net-based Diabetes Insulin Titration). The use of an online, insulin titration algorithm will not only allow for intensive treatment of patients with diabetes but also shifts the focus of their treatment to self-management.
The Diabetes Research Group and Clinical Informatics Division of the Academic Medical Center will develop the program that gives advice on insulin doses. An algorithm for adjusting insuline doses that has already been proven to be effective will be used. Patients are given a unique account and password to the website. The Pandit be developed for patients with diabetes mellitus type 2, using once daily insulin injections.

Study objective

The main purpose of this pilot study is to evaluate the safety of the PANDIT

system by testing the system in a group of patients, under strict supervision of a diabetes nurse. The main objective is to check whether PANDIT provides correct insulin dosing advices. Furthermore, after the safety checks, patients will be asked whether the system is user-friendly, easy to use and if they have suggestions for improvement. Based on the evaluations of these 20 patients we will improve the PANDIT system.

Study design

This will a pilot study divided in two phases of respectively 4 and 8 weeks. In total 20 patients will participate in this study, divided in two study phases, resulting in 10 patients for each study phase.

During the first phase of the pilot 10 patients will make use of the PANDIT system at their home for 4 weeks. Every dosing advice will be given by both a diabetes nurse (DN) and the PANDIT system. Only the dosing advice given by the DN will be displayed to the patient. When all patients have finished the first phase, both advices will be compared and all discrepancies bewteen the DN and the PANDIT system will be evaluated by a panel.

During the second phase of the pilot, another 10 patients will use the PANDIT system at their home for 8 weeks.
During the 8 weeks they will receive the dosing advice directly from the PANDIT system. This is checked by the DN on a daily basis. The DN will intervene only if necessary (foreseeing any danger). An explanation will be given when rejecting the PANDIT advice. Similarly, when all patients have finished this second phase, all rejected advices will be evaluated by a panel.

Intervention

The patient has to measure his/her fasting glucose value with the glucose meter on a daily basis. After three days patients have to enter their fasting plasma glucose values in the PANDIT system, confirm if they have used the previously advised insulin dose and whether they experienced symptoms of a hypoglycaemia. In addition the patient has to indicate whether they have started using corticosteroids. Entering the information can also be done each day, but the insulin dosing advice will always be provided after three days if an adequate number of fasting glucose values has been collected.
After receiving the insulin dosing advice on the third day (if enough values have been entered) the patient has to use the newly recommended dose on the following three days.
The patient will be reminded by sms or e-mail if three days have passed and no fasting glucose value has been entered yet.

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Study burden and risks

Participation mainly requires daily blood glucose measurements and daily use of a computer program on the Internet. PANDIT® titration will be performed at home with a fixed interval of three days.
A site visit will be performed at the beginning and at the end of the study. In total two venapunctures and a usability evaluation will be performed by the patient.
Affirmation of the safety of patients using a web-based insulin titration system will indicate that an improvement in HbA1c can be possibly achieved through this system. This knowledge can justify the performance of a randomized controlled trial in which the clinical efficacy of the algorithm will be testes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Male or female between 18 and 80 years
* Type 2 diabetes mellitus
* Using once daily basal Insulin therapy or requiring once daily basal insulin
* Fasting glucose * 7 mmol / l on 3 consecutive measurements, no restriction on HbA1c
* BMI <45 kg/m2
* Familiarity with and access to the internet and a mobile phone
* Ability to read and understand the Dutch language
* Ability and willingness to adhere to the protocol, including daily performance of self monitored plasma glucose profiles according to the protocol
* Confirmed Written consent
* Recent (<1 year) documentation of retinopathy status

Exclusion criteria

*Type 1 diabetes
*Non compliance with regard to daily measurement of FPG
*Recurrent severe hypoglycaemia or hypoglycaemic unawareness
*Active proliferative diabetic retinopathy
*Any clinically significant disease or disorder, except for conditions associated with type 2 diabetes, which could interfere with the results of the trial
*Mental condition rendering the patient unable to understand the nature, scope and possible consequences of the study
*History of alcohol abuse
*Night shift workers

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	19-07-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL33819.018.10