# Web-based insulin titration: Improving diabetes care in the Netherlands. An efficacy study.

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The main objective of the present study is to determine whether an intensive internet based titration system is effective in improving glycemic control in patient with diabetes mellitus type 2 using a basal insulin, compared to standard care.

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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-OMON39501

**Source**
ToetsingOnline

**Brief title**
Web-based insulin titration. An efficacy 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

•To measure the mean changes in HbA1c from baseline to end point in the PANDIT group as compared to the control group. A difference of 0.5% after 26 weeks of follow-up in the PANDIT group as compared to the control group will be considered effective. HbA1c will be measured at baseline, after 13 weeks and after 26 weeks of treatment.

### Secondary outcome

•To evaluate the effect of PANDIT on the patient*s quality of life compared to standard care, as measured by the SF-36 quality of life questionnaire and the Diabetes Treatment Satisfaction Questionnaire (DTSQ) at baseline, after 13 weeks and after 26 weeks of treatment

•To measure the total contact time with the PANDIT system and study staff in the PANDIT group as compared to the contact time with the study staff in the control group

•To measure the proportion of subjects who reach the target of HbA1c < 7.0% in the PANDIT group as compared to the control group after 26 weeks of treatment

•To measure the mean changes in fasting plasma glucose (FPG, central laboratory) in the PANDIT group as compared to the control group. FPG will be

measured at baseline, after 13 weeks and after 26 weeks of treatment.

•To compare the overall incidence and rate of hypoglycaemia (mild hypoglycaemia, probable hypoglycaemia, severe hypoglycaemia and relative hypoglycaemia) in the PANDIT group as compared to the control group after 26 weeks of treatment

•To explore the frequency of the usage of PANDIT among patients and assess important factors for patient compliance to internet-based self-care interventions

## 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 objective of the present study is to determine whether an intensive internet based titration system is effective in improving glycemic control in patient with diabetes mellitus type 2 using a basal insulin, compared to standard care.

## Study design

This will be an open multi-center randomized controlled trial. Patients will be randomized to receive either 26 weeks of standard care (control group) or care via an intensive internet based titration system (PANDIT, intervention group).

## Intervention

The intervention group needs to access the PANDIT site once every three days, to enter their fasting glucose values from the last three days, their insulin dosages and whether they experienced hypoglycemia. Based on those data the PANDIT system will immediately provide an insulin dosing advice for the patient. The control group will receive usual care.

## 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 intervals of 3-7 days. Participants will be asked to fill in several questionnaires, and to visit their caregiver at the beginning, halfway and at the end of the study. During visits, a venapuncture will be performed.

The most important benefit for the patient is a possible improvement in glycemic control through this system. Furthermore, PANDIT supports and reminds the patient to measure and document their fasting glucose values. This will raise more awareness among patients and thereby motivates the patient to actively participate in the management of their disease. In addition, receiving insulin dosing advice from and through an online application (telemedicine functionalities also enable direct contact with the caregiver) spares them the need to travel to the clinic.

# 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 (diagnosed clinically) for >= 6 months

•HbA1c >7.5%
•Once daily basal insulin therapy usage of <= 1 year or having an indication for basal insulin therapy
•Fasting glucose values >= 7 mmol/L on three consecutive measurements
•BMI < 40 kg/m2
•Ability to read and understand the Dutch language
•Familiarity with the Internet and use of a mobile phone
•Ability and willingness to adhere to the protocol including daily performance of self monitored plasma glucose (SMPG) profiles according to the protocol
•Ability and willingness to use a web-based insulin self-titration system
•Confirmed written consent

### Exclusion criteria

•Type 1 diabetes
•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 in the Investigator*s opinion 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

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Treatment

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 30-01-2013 |
| Enrollment: | 160 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 02-08-2012 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 21-01-2013 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 19-08-2013 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 28-08-2013 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 04-09-2013 |
| Application type: | Amendment |
| 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 | NL40248.018.12 |