CHAPTER 1

GENERAL INTRODUCTION
Though not always conscious, self-monitoring is part of every day life. The last look in the mirror before going to work, tasting a dish while cooking, or our weekly climb on the weighing scale are all examples of self-monitoring. The monitoring results are used to adjust the outcome to a pre-set image. For the outcomes of the examples above they are looking decent, creating the right taste, and weight maintenance, respectively.

From early 1900, improving technological developments enable us to monitor processes beyond the scope of our senses, such as blood pressure and glucose levels. The main reasons for monitoring these processes are twofold: firstly to gain information on the progression of illnesses, such as cardiovascular disease or diabetes, and secondly to be able to target the progression with corresponding treatment. Because monitoring tools such as blood pressure monitors and blood glucose monitors are now readily available and cheap, monitoring outside the clinic has increased. Blood pressure monitoring is practised by approximately 10% of the general population \(^1\) and glucose monitoring is practiced by more than 50% in type 2 diabetes patients, even though at present, there is insufficient evidence that self-monitoring at home is of use for all its users.

**Self-monitoring: How does it work?**

The theoretical principle of self-monitoring is best described by Leventhal’s Common Sense Model of Self-Regulation (CSM) \(^2;^3\). The CSM describes how patients come to understand their illness by monitoring their efforts and outcomes in managing illness related tasks. This information is then used to develop coping strategies to manage their illness.

The model identifies three phases: representation, coping and appraisal (Figure 1). In the first phase the model proposes that a patient construct cognitive and emotional representations of his illness and health-threatening conditions based on his understanding of the illness and with the sources of information that is available to him (e.g. cultural information, social communication, doctor information). In the second phase the illness representations influence the coping process, during which the patient adopts coping strategies, to manage both the illness and emotional well-being.
The adopted coping strategies will influence outcomes such as social functioning and emotional distress. In the final phase (appraisal), the patient evaluates his coping strategy and decides whether to continue or to try another strategy. In summary, this theory views the patient as an ‘active problem-solver’ and emphasizes the role of both cognitive and emotional processes in influencing illness perceptions and coping strategies, including self-management behaviours. In reference to self-monitoring, it is believed that feedback from self-monitoring dynamically allows adaptation of illness perceptions, specifically, to the extent to which patients believe their illness is amenable to personal control or to control by treatment, leading to decrease in illness specific emotional distress and an increase in self-efficacy.

**Figure 1.** The common sense model of self-regulation (adapted from Hagger & Orbell, 2003:144)
CHAPTER 1

Self-monitoring in diabetes care

To assess the effectiveness of treatment on glycaemic control (and to prevent the emergence of acute and chronic complications in patients with type 2 diabetes), it is recommended to test fasting glucose levels approximately every 3 months and Hemoglobin A1c (HbA1c) every year. However, since fasting glucose values is a poor reflection of the variation in glucose values during the day, and HbA1c values reflect average blood glucose levels over a period of approximately 2 months, the daily variation in blood-glucose levels is often assessed with self-monitoring methods. It is suggested that feedback from self-monitoring helps in maintaining average blood glucose levels within a desired range. An often-heard explanation for the value of self-monitoring of blood glucose is that it provides more accurate and precise estimates of the true underlying blood glucose level than measuring the blood glucose level at some time points during the year at the doctor’s office. In addition, performing multiple measurements a day provides information about variability and allows adjustment of lifestyle behaviour and/or adjustment of medication in patients who are using insulin. Both, patients and health professionals, claim that self-monitoring can make patients more aware of their glucose level. According to the CSM it is believed that this increased awareness might influence a patient’s perception of illness and subsequent health behaviours, and possibly adherence to medication. Other thoughts suggest that self-monitoring may lead patients to discuss their glucose levels with their care providers, which may encourage appropriate changes in treatment strategies and prescription of medication.

Self-monitoring of glucose: How do we monitor glucose levels?

The most widely used self-monitoring methods in diabetes care are tools monitoring the presence of glucose in blood or urine. Where historically glucose was universally monitored in urine, the introduction of blood glucose monitoring in the 1960s replaced the frequent use of urine monitoring in most resource-rich settings.

Self-monitoring of blood glucose (SMBG) is based on measuring the percentage of glucose in a small blood sample (<1µml). This blood sample is
obtained by pricking the skin with a lancet, which is subsequently placed on a test strip. The blood glucose meter calculates the blood glucose level from the test strip and presents it on a continuous scale.

Self-monitoring of urine glucose (SMUG) is based on the excretion of glucose in urine when reabsorption of filtered glucose in the kidneys has reached its maximum value while blood glucose is rising. The appearance of glucose in urine is reflected in the concept of a renal threshold for glucose excretion, which is propagated, with the threshold specified at 10 mmol$^{-1}$ $9$. According to this concept, no glucose should be detectable in urine at sub-threshold blood glucose levels.

Even though feedback from SMUG is dichotomous and has a cut-off point in the outer regions of hyperglycaemia, SMUG may still be a valuable, non-invasive and inexpensive tool in areas where SMBG is not accessible, affordable, or desired $^{10}$.

**Self-monitoring of glucose: How can it be effective?**

As mentioned before, the principles of self-monitoring of glucose in blood or urine are grounded in the CSM $^{2;3;11}$, which explains that the process of monitoring, getting feedback from self-monitoring, (re)acting and evaluating may lead to enhanced beliefs of control and self-efficacy, and may encourage active participation of the patient’s in its self-care management. The decision to self-monitor can be a followed advice from a caregiver, yet does not have to be fully supported by the patient. However, self-monitoring is most effective when the decision to monitor is consciously made and the full process of self-monitoring is under complete volitional control $^{12}$. Therefore, it is required that patients know how and when to perform self-monitoring, understand when readings are above (or below) target values and can connect deviating readings with prior behaviour (e.g. eating, exercise, and under- or overuse of medication). Subsequently, patients should have several actions stand-by, known to properly influence glucose levels, yet expectations as to the response outcomes should be appropriate. Finally, it is important that patients are able to rely more on objective indications rather than subjective feelings to evaluate the efficacy of the actions taken. With these steps patients should be able to create simple action plans that will allow for easy integration into ongoing life patterns.
CHAPTER 1

Self-monitoring of glucose: What do we (already) know?

It is generally accepted that self-monitoring of blood glucose is beneficial in improving or maintaining glycaemic control for patients with type 1 diabetes\textsuperscript{13} and in patients with type 2 diabetes\textsuperscript{14;15} who are requiring insulin. These patients can use the self-monitoring information to refine and adjust insulin dosages, which can result in improved glycaemic control. For self-monitoring of glucose in patients with type 2 diabetes not using insulin, there is conflicting evidence to its value in glycaemic control\textsuperscript{5;12;16-24}. Still, the prevalence of patients with non-insulin requiring type 2 diabetes who perform self-monitoring, with associated increasing costs, is growing. Earlier studies investigating effects of self-monitoring in non-insulin treated patients revealed none to moderate effects in HbA1c over a short-term period, of which the clinical relevance can be questioned\textsuperscript{22}. Furthermore, because psychological effects of self-monitoring were mainly secondary outcomes if measured at all, information on the impact of self-monitoring on diabetes-specific well-being and self-efficacy is limited.

The utility of self-monitoring in the management of glycaemic control has been taken up in several clinical guidelines and position statements\textsuperscript{5;16}. Because of a lack in scientific consensus most guidelines base their recommendation for self-monitoring in non-insulin dependent type 2 diabetes patients on expert consensus or clinical experience\textsuperscript{25;26}. For the future fine-tuning of self-monitoring it is important to not only assess whether self-monitoring has positive effects on glycaemic control and emotional well-being both on the short and long term, but also to explore the mechanisms through which self monitoring benefits diabetes patients who are not using insulin.

Objectives and outline of this thesis

The principle aim of this thesis is to investigate effects of self-monitoring of glucose in patients with non-insulin treated type 2 diabetes.

In Chapter 2 we report on the results of a broad literature search in MEDLINE, EMBASE, PsycINFO and the Cochrane Library. Aim of the systematic Review was to assess the effects of self-monitoring of blood glucose on glycaemic control,
quality of life, well-being and patient satisfaction in patients with non-insulin treated type 2 diabetes compared to usual care.

**CHAPTER 3** describes the design of the IN CONTROL-trial. This is a 3-armed randomized clinical trial designed to assess the effects of self-monitoring of blood glucose (SMBG) and self-monitoring of urine glucose (SMUG) regarding diabetes-specific emotional distress and self-efficacy in patients with non-insulin treated type 2 diabetes, compared to control.

The effects on glycaemic control and the effects on diabetes related distress and self-efficacy of SMBG and SMUG assessed in the IN CONTROL-trial are shown in **CHAPTER 4** and **CHAPTER 5**, respectively. Thereafter, in **CHAPTER 6**, we explained the results of the IN CONTROL-trial by evaluating the processes presumably underlying the (in) effectiveness of self-monitoring of glucose and underpinned by Leventhal’s Common Sense Model of Self-Regulation.

**CHAPTER 7** reports on the associations between experience of hypoglycaemia and changes in beliefs about diabetes, self-reported well-being, health status and health behaviours in a prospective cohort of SMBG using patients with non-insulin treated type 2 diabetes.

Finally, in **CHAPTER 8** the general discussion displays an overview of the main findings and results of this thesis and puts them in a broader perspective. To conclude, suggestions for future research and implications for clinical practice are provided.


CHAPTER 1

References


