SUMMARY
Self-monitoring is fully integrated into our daily lives. With the advent of new technological developments, possibilities for self-monitoring at home, beyond the scope of our senses, have taken a flight. Even though at present evidence for a beneficial effect of self-monitoring for all its users is insufficient. Self-monitoring of blood glucose levels provides type 2 diabetes patients with real-time information on their blood glucose levels and consequently, offers them a possibility to get their blood glucose levels within the desired range. These actions are believed to be beneficial for reaching and maintaining glycaemic control. Evidence whether self-monitoring of glucose in type 2 diabetes patients not treated with insulin is of value for glycaemic control is conflicting. Furthermore, information on the impact of self-monitoring on diabetes-specific well-being and self-efficacy is limited. The aim of this thesis was twofold: Firstly to assess whether self-monitoring has positive effects on glycaemic control and emotional well being both on the short and long term in non-insulin treated diabetes patients. And secondly, to explore the mechanisms through which self-monitoring benefits non-insulin treated diabetes patients.

Systematic review

In order to explore the evidence base of effects of self-monitoring of blood glucose in non-insulin treated type 2 diabetes patients we performed a systematic review and meta-analysis (CHAPTER 2). Multiple electronic bibliographic and ongoing trial databases were searched for randomised controlled trials investigating effects of self-monitoring of blood glucose on glycaemic control, quality of life, well-being and patient satisfaction compared with usual care, self-monitoring of urine glucose or both. Results from the meta-analysis showed that when diabetes duration is over one year, the overall glycaemic result of SMBG is small up to six months after initiation (-0.3% in HbA1c) and subsides after 12 months (-0.1% in HbA1c). Further, a best-evidence synthesis found no evidence for a SMBG induced effect on patient satisfaction, general well-being or health related quality of life. We concluded that more research is needed to explore the psychological impact of SMBG and its impact on diabetes-specific quality of life and well-being.
Design of a randomised controlled trial

**Chapter 3** describes the background, methods and outcomes of the **IN CONTROL**-trial: a 3-armed randomised controlled trial designed to assess the effects of self-monitoring of glucose levels in patients with type 2 diabetes who are not using insulin compared to control. The intervention consisted of a training in SMBG or SMUG and a flowchart with instructions when to perform self-monitoring, how to interpret the outcomes and which actions to take. Follow-up was at 4 and 12 months. The trial was implemented into three regional diabetes care systems in The Netherlands and was underpinned by Leventhal's Common Sense Model (CSM). This model suggests that 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 in his self-care management. In time, this would result in positive changes in quality of life, well-being and glycaemic control. The primary outcomes were changes in diabetes-specific emotional distress and self-efficacy. Secondary outcomes included changes in glycaemic control (HbA1c).

**Effectiveness of self-monitoring of glucose in blood or urine**

The effectiveness of self-monitoring of glucose in blood or urine is described in **Chapters 4 & 5**. One hundred eighty-one patients were randomized in the **IN CONTROL** trial. This number of included participants was sufficient to provide adequate statistical power to detect clinical relevant differences in distress and HbA1c. Compliance with the minimal requested self-monitoring frequency was moderate and marginally changed over time. The results on glycaemic control are presented in **Chapter 4**. We showed that performing SMBG or SMUG was not more effective on regulating HbA1c than control, after 4 and 12 months. We concluded that there is no evidence for a short or long term glycaemic effect of self-monitoring of glucose levels in blood or urine with pre-set instructions compared to usual care.

**Chapter 5** presents results of self-monitoring of glucose levels on diabetes-specific emotional distress and self-efficacy. No statistically significant mean adjusted differences were seen between SMBG and control.
(2.6 pts. 95% CI -0.1 to 5.2) and between SMUG and control (0.8 pts. 95% CI -2.1 to 3.7) for changes in levels of distress. Similar, no mean adjusted differences were found between SMBG and control (0.5 pts. 95% CI -2.7 to 3.6) and SMUG and control (-1.4 pts. 95% CI -5.0 to 2.1) for changes in self-efficacy. We concluded that the IN CONTROL-trial demonstrated that self-monitoring of glucose in blood or urine had no impact on diabetes-specific distress.

Illness perceptions

In CHAPTER 6 we explored the theory underlying the effects of self-monitoring of glucose levels observed in the IN CONTROL-trial. For this, changes in illness beliefs and also perceived severity of diabetes were analyzed, 2 and 4 months after baseline to provide additional insights and explanations.

The results indicated that there were no statistically significant differences in changes in illness beliefs and perceived severity of diabetes between the SMBG, SMUG and control group scores at two and four months after baseline. Furthermore, these results suggest that feedback from self-monitoring might not be sufficient to allow adaptation of illness beliefs.

Our conclusion is that self-monitoring of glucose levels in blood or urine did not change patients’ illness beliefs and perceived severity of diabetes in this population of moderately controlled non-insulin treated type 2 diabetes patients.

Hypoglycaemia associated illness beliefs and health status

Experiencing moderate to severe hypoglycaemia can cause distress and may lead to changes in the way patients manage and think about their diabetes. These changes may in turn influence subsequent self-care behaviour and adherence to medical regimen. Self-monitoring of blood glucose might be a useful tool in identifying episodes of low-blood glucose and in confirming subjective feelings of hypoglycaemia. CHAPTER 7 describes the results of a one-year prospective cohort analysis exploring associations between experience of hypoglycaemia and changes in diabetes beliefs and health status in patients with non-insulin treated type 2 diabetes, using a blood glucose meter.
This study was conducted with data from the Diabetes Glycaemic Education Monitoring (DiGEM) trial (Oxford, United Kingdom). The DiGEM-trial was also a randomised controlled trial assessing effects of self-monitoring in non-insulin treated type 2 diabetes patients. Our findings indicate that beliefs about personal control statistically significant increased in patients experiencing grade 1 hypoglycaemia, compared to patients not experiencing hypoglycaemia (1.14 pts; 95% CI 0.14 to 2.14). Further, no significant differences in changes in health status were found between groups. This study does not provide support for a long-term adverse impact on beliefs about diabetes or health status from the experience of mild symptomatic hypoglycaemia, in well-controlled, non-insulin treated patients with type 2 diabetes using SMBG.

**General Discussion**

**Chapter 8** provides the general discussion of this thesis. The main findings of included studies were summarised and methodological aspects in relation to the included studies were addressed. Furthermore, possible explanations for the findings were discussed and recent developments were highlighted. Finally, suggestions for future research and implications for clinical practice were discussed.

**Concluding**

In light of our results and previous research we conclude that there is no evidence that self-monitoring of glucose in blood or urine in moderately controlled, non-insulin treated type 2 diabetes patients helps them to constructively target emotional and biochemical outcomes of their illness. Hence, we currently advise non-insulin treated patients with type 2 diabetes not to self-monitor glucose levels.