The effectiveness, appropriateness and meaningfulness of self-monitoring blood glucose (SMBG) in type 2 diabetes: a mixed methods systematic review

July 2009

This review was commissioned by the Australian Diabetes Educators Association and funded through the National Diabetes Services Scheme (NDSS). The NDSS is an initiative of the Australian Government administered by Diabetes Australia
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Executive Summary

Objectives

The objective of the review was to examine the effectiveness, appropriateness and meaningfulness of self-monitoring of blood glucose (SMBG). Specifically, the review sought to address the question:

‘What is the current best evidence of the effectiveness, appropriateness and meaningfulness of SMBG in people with type 2 diabetes who are not treated with insulin?’

Inclusion criteria

The effectiveness component of the review considered systematic reviews and randomised controlled trials (RCTs) while the appropriateness and meaningfulness part of the review considered interpretive studies. All studies and papers that involved adults (aged 16 years or over) with type 2 diabetes who were not treated with insulin were included. Studies involving participants who used SMBG or educators who provided SMBG education were also included.

Search strategy

The search strategy aimed to find both published and unpublished studies and papers written in the English language. For the systematic reviews and qualitative evidence, studies published between 2002 and 2008 were targeted. An additional search to identify primary studies was also conducted to find any RCTs published between the years 1986 to 2008. This search sought to establish to what degree the systematic reviews had captured the relevant primary research.

Results

Seven systematic reviews were identified, 39 RCTs and 351 qualitative papers were also identified through the search strategies. Screening by title and abstract against the inclusion criteria resulted in the acceptance of 4 systematic reviews published between 2005-2007; 10 RCTs published between 1989 - 2008, and 10 qualitative studies published between 2003 - 2007.

Effectiveness

For the effectiveness of SMBG, meta analysis found SMBG was no more effective than other forms of monitoring of control. A meta analysis at 6 months using strict criteria was not statistically significant, and was also confounded by statistical heterogeneity. The statistical benefit at 6 and 12 months in a
follow up exploratory meta analysis was also confounded by clinical heterogeneity among the included studies.

The evidence also suggests people using SMBG will identify more otherwise “silent” episodes of hypoglycaemia, have improved total serum cholesterol and may be more aware of how lifestyle, diet and exercise choices can impact on their glycaemic control. Glycaemic control is associated with frequency of SMBG, people who use higher numbers of monitoring strips having better glycaemic control than other people on SMBG using less monitoring strips

**Appropriateness**

One available study examined the perspective of the care provider/educators to articulate insights into the value system and culture behind the education and practice of SMBG. The results of the meta-synthesis derived from the subjective accounts of participants were clearly consistent with the major findings from the accounts of the care providers/educators, which suggests the existence of values and assumptions shared by people with type 2 diabetes and educators in the use of SMBG.

Several informative and valuable findings were identified in relation to the appropriate practice and education of SMBG. There is a shared belief that the use of SMBG should be encouraged for the purpose of facilitating effective diabetes self-management. SMBG is considered to be a superior method of self-monitoring of glycaemic control to that of urinalysis. The autonomous decision-making and active involvement of people were considered to be important in the use of SMBG, as were the provision of tailored educational/supportive intervention to meet the needs of the individual.

**Meaningfulness**

SMBG was understood and experienced as an effective means to facilitate an empowering process that raises positive and active attitudes toward self-management. Negative experiences in the use of SMBG were often caused by insufficient knowledge and skills, and unconstructive coping strategies concerning diabetes management. The belief of each person concerning the use of SMBG, such as stigma and the purpose and the needs of SMBG, should be assessed if the commencement of SMBG is recommended. In confronting SMBG, people are required to prioritise their life needs (such as financial cost in the use of SMBG) or individual-physical circumstances (such as poor eyesight). Individualised assessment of such factors is recommended.

**Conclusions**

The findings from this review do not identify beneficial effects of SMBG in people with type 2 diabetes up to six months from commencement of SMBG interventions.
However, qualitative findings indicate that the use of SMBG may be encouraged as a part of diabetes self-management in people with type 2 diabetes provided adequate supervision and assessment is provided. In particular, SMBG is associated with greater individual engagement with ones’ own glycaemic control and lifestyle related needs.

Implementation of SMBG should be also considered within the context that qualitative findings revealed the overall preference for SMBG over urine testing. Determining which people might benefit most from SMBG in light of this evidence should include a detailed assessment leading to targeted interventions in order to meet each individual’s various life needs such as the status of personal finance and insurance, and physical/mental status in order to make beneficial use of SMBG. Individualised educational interventions are considered important in order to enhance the knowledge and skills required for the appropriate use of SMBG in the self-management of diabetes. It should be understood that SMBG itself is not a goal, but the learning process to actualise self-management of diabetes with the use of SMBG is important.

Investigating the effectiveness of SMBG in daily life settings presented challenges to researchers and this may be the reason for the lack of high-quality RCTs on the effectiveness of SMBG. Further high quality quantitative research is needed to determine the clinical effectiveness of SMBG in achieving glycaemic control in recommended target range. It is particular important that further research focuses on ensuring homogeneity of sample characteristics and interventions. Further investigation is also required to determine the potential variables that may affect the outcome in the use of SMBG to achieve glycaemic control, such as age, and recency of diagnosis.

This systematic review has lead to the development of a comprehensive list of recommendations for practice. These recommendations include:

- The use of SMBG may be encouraged as a part of diabetes self-management in non-insulin treated type 2 diabetes people with adequate supervision and assessment. (Grade A)

- SMBG will lead to the increased detection of episodes of hypoglycaemia, health professionals should make people aware of the benefits of increased detection. (Grade B)

- It is recommended that clinicians be aware that qualitative research findings revealed the individuals’ overall preference for SMBG. (Grade B)

- The autonomous decision making of individuals should be supported and facilitated in the use of SMBG. (Grade B)

- Individualised educational interventions are essential in order to enhance the knowledge and skills required for the appropriate use of SMBG in the self-management of diabetes. (Grade B)
- It should be understood that SMBG itself is not a goal, but the learning process to actualise self-management of diabetes including the use of SMBG. (Grade B)

- Multifactorial assessment and interventions are necessary in order to meet each persons’ various life needs such as the status of personal finance and insurance, and physical/mental status in order to make beneficial use of SMBG. (Grade B)

- In the absence of conclusive evidence, the frequency of SMBG should be decided depending on individual circumstance and clinical judgment. (Grade B)

- Education concerning the management and prevention of hypoglycaemia as well as dietary, activity and lifestyle modifications to optimise glycaemic control is recommended. (Grade B)

- For individuals with a recent diagnosis, the introduction of SMBG should be supported with strategies to evaluate and enhance the individuals psychosocial status. (Grade B)

**Keywords**

Self-monitoring blood glucose, self-monitoring, type 2 diabetes, glycaemic control, blood glucose, hypoglycaemic, experience, education.
Introduction

The purpose of this systematic review was to identify evidence for the effectiveness, appropriateness and meaningfulness of SMBG in individuals with type 2 diabetes. This mixed methods review brought together qualitative and quantitative data, although for clarity, the results section has been presented as two discrete sections. The effectiveness component of this review was conducted according to the norms of the quantitative paradigm, including studies such as systematic reviews of RCTs and primary RCTs that had not been previously identified in such systematic reviews. The review of the appropriateness and meaningfulness of SMBG was conducted according to the norms of the interpretive paradigm, including existing interpretive studies. The design and conduct of this review was in accordance with the methods established by The Joanna Briggs Institute (JBI). The JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI) was used to assist with the review.

Background

Self-monitoring of blood glucose (SMBG) has been increasingly used for the management of diabetes and has been promoted as an integral part of diabetes self-management. [1, 2] Educational and supportive programs with the use of SMBG based on principles of self-management have been advocated by clinicians and educators alike. [1, 3, 4]

Clinical use of SMBG is accepted practice for people with type 1 diabetes [5] and people with type 2 diabetes who are treated with insulin.[4, 6] SMBG has become an important component of diabetes self-management programs. SMBG can provide insulin treated people with guidance on adjusting insulin dosage according to their individual needs, which can directly improve glycaemic control.[7, 8] However, in the case of people with type 2 diabetes not using insulin, the evidence is conflicting.[9, 10]

The first question the present review sought to address was the effectiveness* of SMBG on glycaemic control, self-care, diabetes-related complications and quality of life (QOL). To answer this question, the review examined systematic reviews and randomised controlled trials.

The second addressed appropriateness* of SMBG and the third question concerned meaningfulness* of SMBG.

To answer questions two and three, the review examined interpretive studies that reported on the subjective accounts of diabetes educators and people in the use of, and education concerning SMBG, in order to gain a deeper understanding of the phenomena around the use of SMBG among people with non-insulin treated diabetes.
*In the context of this review, the following definitions were applied:[11, 12]*

**Effectiveness:** the extent to which an intervention, when used appropriately, achieves the intended effect. Clinical effectiveness is about the relationship between an intervention and clinical or health outcomes.

**Appropriateness:** the extent to which an intervention or activity fits with or is apt in a situation. Clinical appropriateness is about how an activity or intervention relates to the context in which care is given.

**Meaningfulness:** how intervention or activity is experienced by the people with diabetes or health professionals. Meaningfulness related to the personal experience, opinions, values, thoughts, beliefs and interpretations of people with diabetes.

**SMBG:** Self Monitoring Blood Glucose, also known as SBGM – self blood glucose monitoring, or CBGM – client blood glucose monitoring, or HBGM – home blood glucose monitoring. In this report, only the term SMBG has been used.

**Objectives**

The objective of the review was to establish the appropriateness, meaningfulness and effectiveness of self-monitoring blood glucose (SMBG).

- The specific objective in examining effectiveness was to analyze the evidence across existing systematic reviews on the clinical effectiveness of SMBG,

- The specific objective in reviewing the appropriateness of SMBG was to identify cultural perceptions embedded in being a diabetes educator and examine the underlying assumptions and expectations related to teaching people SMBG,

- The specific objective in reviewing evidence of meaningfulness was to identify the experiences of both diabetes educators, and individuals with type 2 diabetes in relation to SMBG to uncover the meanings they attribute to the experience of education for SMBG.

Specifically, the review addressed the question:

*What is the current best evidence of the effectiveness, appropriateness and meaningfulness of SMBG in people with type 2 diabetes who are not treated with insulin?*
Review Methods

Inclusion criteria

A-priori inclusion criteria were used to assess whether papers were relevant to the review topic. Papers that met the inclusion criteria were considered to be applicable to the review topic and retrieved for further assessment of quality. The inclusion criteria for this review were as follows.

Types of studies/papers

To establish the effectiveness of SMBG, the review included systematic reviews of the effectiveness of SMBG. Additionally, as a method of testing the completeness of systematic reviews, any randomised controlled trials (RCTs) undertaken to investigate effectiveness of SMBG that had been published during the dates of included systematic reviews were sought and considered for inclusion. To avoid duplication of effect (ie RCTs which were already reported in systematic reviews, and identified in the RCT specific search), only RCTs that were subsequently identified as not being included in the identified reviews were reported.

To establish the appropriateness and meaningfulness of SMBG, the review included qualitative evidence on the meaning and experience of participants who received SMBG or delivered education programs on SMBG. Therefore, research designs such as phenomenology, grounded theory and ethnography were considered. All studies were categorised according to the JBI Levels of Evidence (Appendix I).

Types of participants

To establish the effectiveness and meaningfulness of SMBG, the participants of interest were adults (aged 16 years or over) who had non-insulin treated type 2 diabetes. No restrictions were placed on gender or co-morbidities.

To establish the appropriateness and meaningfulness from the educators’ perspectives, the participants were educators who had been involved in teaching/training people regarding SMBG.

Types of intervention(s)

The intervention of interest was SMBG and all forms of educational interventions of SMBG by educators. These interventions were compared to standard practice (usual diabetes care) without SMBG.
Type of outcomes

This review considered studies that include the following outcome measures:

Effectiveness

- Blood glucose control as measured by routine BGL testing and, validation by HbA1c,
- Effectiveness outcomes, including diabetes self efficacy, self care knowledge scores and reduction of acute diabetes complications,
- Individual related outcomes including QOL and satisfaction.

Meaningfulness and appropriateness

- Individual perceptions diabetes educators associate with the provision of SMBG education to people with diabetes,
- The perceptions of individuals who have attended or are attending education provided by diabetes educators on SMBG,
- The phenomenon of being a person who has experienced education for SMBG and is practicing SMBG (including their interpretation of SMBG results).

Search Strategy

The search strategy aimed to find both published and unpublished studies and papers written in the English language. For the systematic reviews and qualitative study reports, papers published between 2002 and 2008 were targeted. A three-step search strategy was used. The first step was a limited search of MEDLINE and CINAHL followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the articles to collate key words related to the topic. The second step was a search using all identified keywords and index terms specific to each database across all included databases from 1998 to February 2008. Thirdly, the reference lists of all identified reports and articles were searched for additional studies. An additional search was also conducted to find any RCTs published between the years 1986 to 2008, which had not been identified in published systematic reviews. The earliest published RCT identified in the included reviews was 1989, going back to 1986 allowed for capture of studies that may have been published during the conduct of early reviews.

The databases searched included:

MEDLINE
CINAHL
Cochrane Library
EMBASE
Current Contents
PsycINFO

The search for unpublished studies included:
Digital Dissertations (Proquest)

For a complete list of search terms, see Appendix II

Assessment of Methodological Quality

Identified papers that met the inclusion criteria were grouped into one of the following categories: systematic reviews, experimental studies and qualitative studies. The papers were then assessed by two independent reviewers for methodological quality before inclusion in the review using JBI SUMARI. (Appendix III) Any disagreements that arose between the reviewers were resolved through discussion and if necessary with a third reviewer.

Data Collection

Following assessment of methodological quality, papers were grouped according to study methodology.

The quantitative data were extracted using the standardized forms from JBI-Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix IV), while qualitative data were extracted using the standardized forms from JBI Qualitative Assessment and Review Instrument (JBI-QARI.) (Appendix V).

Data Synthesis

Quantitative data analysis

The findings from the included systematic reviews were analysed in narrative format. The Cochrane statistical package Review Manager (RevMan) Version 5 was used for the statistical analysis of the included RCTs. All results were double entered to confirm reliability of data extraction. Clinical heterogeneity was assessed by considering the populations, interventions and outcomes between the studies. The I² was used in the assessment of statistical heterogeneity and if this indicated a high level of heterogeneity among the included studies in the meta-analysis, a random effects model was also
performed. In meta-analysis, both fixed effects model and random effect models were used for combining study data if the trials were judged to be sufficiently similar.

For continuous data, the mean and standard deviation values were used to derive weighted mean differences and their 95% CI. The outcomes captured from the included papers were all based on continuous data, hence methods for combining dichotomous data were not required. Where synthesis was inappropriate (including a high degree of heterogeneity between study populations, interventions and outcome measures) the analysis was presented in a narrative summary format.

**Qualitative data synthesis**

Qualitative research findings were pooled using the Qualitative Assessment and Review Instrument (JBI-QARI). The process of meta-synthesis embodied in this program involved the aggregation or synthesis of findings/conclusions made in relation to the intervention, activity or phenomenon that is the subject of the review. The aim of the process was to generate a set of statements that represent aggregation through assembling the findings or conclusions rated according to their credibility, and categorising these findings/conclusions on the basis of similarity in meaning. These categories were then subjected to a meta-synthesis in order to produce a single comprehensive set of synthesized findings that are used as a basis for evidence-based practice.[12]

In qualitative and textual evidence, findings or conclusions are not study “results”, rather they are the spoken words, themes or metaphors of persons who conducted the research based on their analysis of the experiences of the people they were conducting the research with.[12]

**Results**

**Description of studies**

For the search of systematic reviews, approximately 1,300 studies were identified. Following removal of duplicates, the majority were excluded based on assessment of the title and abstract of the citation against the inclusion criteria. A total of 7 systematic reviews were retrieved, critically appraised and 4 subsequently met the inclusion criteria.

Forty-one primary studies (17 RCTs and 24 non-experimental studies) were identified out of the 4 included systematic reviews (Appendix VI). Of the 17 RCTs, 7 had included type 1 participants and/or insulin treated participants and therefore did not meet the inclusion criteria of the present review. Of the remaining 10 RCTs, one study was a duplicate of another article published in the following year.[13] One study was only available in abstract form and full text could not be obtained.[14] Therefore, from the included systematic reviews, 8 RCTs that examined the effectiveness of SMBG in people with type 2 diabetes, were included in this review.
An additional RCT specific search was conducted as directed by the Review Reference Group as a method of validating the comprehensiveness of the identified systematic review papers search strategies. From this additional database search between 1986 (three years before the oldest RCT in the included systematic reviews was published) to April 2008, a total of 31 new studies were identified and considered for inclusion. Full texts were obtained and critically appraised. Two new RCTs met the inclusion criteria and 29 studies were excluded (Appendix VII). In total, 10 RCTs (8 from systematic reviews and 2 from the new database search) involving 2115 participants were included in the final analysis (Appendix VIII).

From the search for qualitative studies, 351 papers were identified for possible inclusion. Based on the title and abstract, 42 papers that were relevant to the review topic were retrieved for evaluation of methodological quality. Thirty-two papers were excluded due to incongruity with the review objectives and/or outcomes (Appendix IX) and 10 papers were included. (Appendix X)

The design of the included studies is as follows:
Figure 1: Effectiveness Search strategy: Numbers of papers identified, retrieved, included and excluded.

- 1300 papers
- 7 SRs
- 4 SR included
- 17 RCTs in SRs for re-analysis
- 8 included
- 31 RCTs retrieved
- 2 included
- 10 RCTs in re-analysis

Included quantitative systematic reviews (4):
- Jansen, 2006
- McGeoch, 2007
- Sarol, 2005
- Welschen, 2005

Included RCTs (10):
- Allen, 1990
- Davidson, 2005
- Estey, 1996
- Farmer, 2007
- Fontbonne, 1989
- Guerci, 2003
- Muchmore, 1994
- O’kane, 2008
- Rutten, 1990
- Schwedes, 2002

Figure 2: Appropriateness and Meaningfulness Search Strategy: Numbers of papers identified, retrieved, included and excluded.

- 351 papers
- 42 retrieved
- 10 included

Included qualitative papers (10):
- Abbott et al, 2004
- Benavides-Vaello et al, 2004
- Burke et al, 2006
- Davis et al, 2007
- Holmstrom et al, 2005
- Jeanfreau, 2005
- Lawton et al, 2004
- Peel et al, 2007
- Peel et al, 2004
Effectiveness of SMBG in diabetes management

The results regarding the clinical effectiveness of SMBG in people with type 2 diabetes are presented in two sections: findings of systematic reviews and a further analysis of 10 randomised controlled trials. The analysis of trials was performed as a verification of the meta analysis within the systematic reviews, and added a further two studies that had been published since the most recent review was published.

Results from systematic reviews

All four identified systematic reviews investigated the relative efficacy of SMBG versus other types of care such as urine monitoring and usual care without SMBG.[15-18] Only 3 reviews included studies of participants with type 2 diabetes who were not treated with insulin.[16-18] The review by Jansen included 5 studies that involved both insulin treated and non-insulin treated participants.[15] Sub group analysis was undertaken to separate insulin treated from non-insulin treated participants in this review. Results are presented under the primary outcomes of interest.

Glycaemic control

Systematic reviews of people with type 2 diabetes not-treated with insulin

Three of the 4 systematic reviews that met the inclusion criteria and are reported in this section. McGeoch[16] Welschen[18] and Sarol[17] reviewed RCTs of participants with type 2 diabetes who were not treated with insulin. Sarol conducted a meta-analysis that demonstrated a significantly positive effect of a diabetic management strategy including the use of SMBG in reduction of HbA1c values.[17] Results from the other two reviews also support the effectiveness of SMBG in glycaemic control in the people with Type 2 diabetes.[19,18].

McGeoch et al, 2007 [16]

McGeoch conducted a systematic review of 3 RCTs to examine existing clinically relevant evidence related to the use of SGBM in people with type 2 diabetes who were not receiving insulin treatment.[16] The author did not conduct meta-analysis due to different populations and interventions. The review included 3 RCTs with a total of 1000 participants.[19-21], the larger 2 studies indicated a statistically significant reduction in HbA1c levels with SMBG.[20, 21] Although it should be noted that even the smaller study reported a trend favoring SMBG.[19] The review concluded that SMBG was likely to be beneficial for people with type 2 diabetes who have poor glycaemic control and are not using insulin and as an educational tool due to the ability to read results of SMBG tests and observe the impact of diet and lifestyle on blood glucose levels.[16]
The monitoring process varied across studies, but included education given in different amounts, advice on monitoring practice, nutritional counseling and diet diaries, active modification of behavior based on SMBG results and management algorithms.

Table 1: studies interventions and results for HbA1c as reported in the included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Intervention</th>
<th>Final HbA1c</th>
<th>Average HbA1c change</th>
</tr>
</thead>
</table>
| Schwedes, 2002   | type 2 diabetes, diet or oral medications. Outcome measured at 6 months    | Intervention Group (n=113): Training, SMBGX6 per day for 2 days/wk, diet and wellbeing diary  
Control Group (n=110): Routine training on diet and lifestyle, 4 weekly review  | Intervention Group: 7.47±1.27  
Control Group: 7.81±1.52  
p=0.0086 | Intervention Group:  -1.0±1.27  
Control Group:  -0.54±1.14 |
| Guerci, 2003     | type 2 diabetes, diet or oral medications, poor glycaemic control. Outcome measured at 6 months | Intervention Group (n=345): GP training to do ≥6 readings per week  
Control Group (n=344): No self-monitoring training or instruction  | Intervention Group: 8.1±1.6  
Control Group: 8.4±1.4  
p=0.012 | Intervention Group:  -0.9±2.1  
Control Group:  -0.5±1.9 |
| Davidson, 2005   | type 2 diabetes, diet or oral medications, from low socioeconomic and educational backgrounds. Outcome measured at 6 months | Intervention Group (n=43): Nutrition advice plus self-monitoring plus diary  
Control Group (n=45): Nutritional advice  | Intervention Group: 7.7±1.6  
Control Group: 7.8±1.5  
p=0.58 | Intervention Group:  -0.8±1.6  
Control Group:  -0.6±2.1 |

Table 1 shows average changes in HbA1c, with Schwedes and Guerci obtaining statistically significant results favouring self-monitoring with mean reductions of around 1% in HbA1c, however, the control group results were only marginally lower.
Welschen, 2005 [18]

Welschen et al, reviewed 6 RCTs to examine the effects of SMBG in HbA1c control among participants with type 2 diabetes not treated with insulin.[18] The review used narrative summary as the participant characteristics, interventions and outcomes were considered too divergent to combine in meta analysis.

Of the six included RCTs, four reported improvement across study groups, with a slight trend to better HbA1c values in SMBG groups than in conventional/usual care without SMBG groups.[18, 19, 22, 23] While 2 studies reported statistically significant improvement in HbA1c value.[20, 21] (It should be noted that the data tables for these reviews include studies that are common across other reviews cited in this report).

Table II: studies, interventions and results for HbA1c as reported in included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Intervention</th>
<th>Final HbA1c</th>
<th>Average HbA1c change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schwedes, 2002 [21]</td>
<td>type 2 diabetes, diet or oral medications. Outcome measured at 6 months</td>
<td>Intervention Group (n=113): Training, SMBGX6 per day for 2 days/wk, diet and wellbeing diary Control Group (n=110): Routine training on diet and lifestyle, 4 weekly review</td>
<td>Intervention Group: 7.47±1.27 Control Group: 7.81±1.52 p=0.0086</td>
<td>Intervention Group: -1.0±1.27 Control Group: -0.54±1.14</td>
</tr>
<tr>
<td>Guerci, 2003 [20]</td>
<td>type 2 diabetes, diet or oral medications, poor glycaemic control. Outcome measured at 6 months</td>
<td>Intervention Group (n=345): GP training to do ≥6 readings per week Control Group (n=344): No self-monitoring training or instruction</td>
<td>Intervention Group: 8.1±1.6 Control Group: 8.4±1.4 p=0.012</td>
<td>Intervention Group: -0.9±2.1 Control Group: -0.5±1.9</td>
</tr>
<tr>
<td>Davidson, 2005 [19]</td>
<td>type 2 diabetes, diet or oral medications, from low socioeconomic and educational backgrounds. Outcome measured at 6 months</td>
<td>Intervention Group (n=43): Nutritional advice plus self-monitoring plus diary. Control Group (n=45): Nutritional advice</td>
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</tr>
<tr>
<td>Study</td>
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<td>Final HbA1c</td>
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<tr>
<td>---------------</td>
<td>--------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
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<td>---------------------</td>
</tr>
<tr>
<td>Allen 1990, [24]</td>
<td>type 2 diabetes, diet or oral medication. Outcome measured at 6 months</td>
<td>Intervention Group (n=27): Self-monitoring blood glucose, diet advice, food and fibre booklet, individual instruction Control Group (n=27): Self urine glucose monitoring, diet advice, food and fibre booklet, individual instruction</td>
<td>Intervention Group: 10.4±2.9 Control Group: 9.7±2.6 p&gt;0.95</td>
<td>Intervention Group: 2.0±3.4% Control Group: 2.0±3.4% p&lt;0.01</td>
</tr>
<tr>
<td>Fontbonne 1989 [22]</td>
<td>type 2 diabetes, diet or oral medication. Outcome measured at 6 months</td>
<td>Intervention A Group (n=68): GP monitoring, personal dietary advice, 2 monthly review Intervention B Group (n=72): Self Urine monitoring, personal dietary advice, 2 monthly review Intervention C Group (n=68): SMBG, personal dietary advice, 2 monthly review</td>
<td>Intervention A Group: HbA1c 7.7 % Intervention B Group: HbA1c 8.5 % Intervention C Group: HbA1c 7.8 % P≥0.5</td>
<td>Intervention A Group: HbA1c-0.5%±1.5 Intervention B Group: HbA1c-0.1%±2.2 Intervention C Group: HbA1c -0.4%±3.1</td>
</tr>
<tr>
<td>Muchmore, 1994 [23]</td>
<td>type 2 diabetes, overweight. Outcome measured at 12 months</td>
<td>Intervention Group (n=12): Group and individual teaching on carbohydrate counting and SMBG Control Group (n=11): Same time allocation but general information only</td>
<td>Intervention Group: HbA1c 8.8%±1.7 Control Group: HbA1c 9.6%±2.09 P≥0.05</td>
<td>Intervention Group: HbA1c -1.5% Control Group: HbA1c -0.9%</td>
</tr>
</tbody>
</table>

Table II shows end of study and average changes in HbA1c. Schwedes and Geurci found in favour of SMBG, while the results were non-significant for Davidson, Allen, Fontbonne and Muchmore. The timeframes for outcome measurement varied between 6-12 months.

This was a focused review, with tight inclusion criteria and a particular focus on study methodology. The results and discussion focus more on methodological quality and potential limitations than they do on the actual results. Tightly defined inclusion criteria limited the number of papers included, although the outcomes reported are congruent with other reviews and primary evidence. Fontbonne[22],
Muchmore[23], Allen[24] and Davidson[19] all reported an improvement in HbA1c for all trial participants regardless of group allocation. However, Schwedes[21] and Guerci[20] found a statistically significant improvement favouring self-monitoring blood glucose.

Sarol, 2005 [17]

Sarol conducted a systematic review to determine if therapeutic management programs with SMBG result in greater HbA1c reduction in people with type 2 diabetes compared to programs without SMBG.[17] Heterogeneity among included studies was not statistically significant (p=0.19).

Table III: studies, interventions and results for HbA1c as reported in included studies

<table>
<thead>
<tr>
<th>Study</th>
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<th>Intervention</th>
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</table>
| Schwedes, 2002  | type 2 diabetes, diet or oral medications. Outcome measured at 6 months     | Intervention Group (n=113): Training, SMBGX6 per day for 2 days/wk, diet and wellbeing diary  
Control Group (n=110): Routine training on diet and lifestyle, 4 weekly review | Intervention Group: 7.47±1.27  
Control Group: 7.81±1.52  
p=0.0086 | Intervention Group: 7.47±1.27  
Control Group: 7.81±1.52  
p=0.0086 | Intervention Group: -1.0±1.27  
Control Group: -0.54±1.14 |
| Guerci, 2003    | type 2 diabetes, diet or oral medications, poor glycaemic control. Outcome measured at 6 months | Intervention Group (n=345): GP training to do ≥6 readings per week  
Control Group (n=344): No self-monitoring training or instruction | Intervention Group: 8.1±1.6  
Control Group: 6.4±1.4  
p=0.012 | Intervention Group: -0.9±2.1  
Control Group: -0.5±1.9 | |
| Davidson, 2005  | type 2 diabetes, diet or oral medications, from low socioeconomic and educational backgrounds. Outcome measured at 6 months | Intervention Group (n=43): Nutrition advice plus self-monitoring plus diary.  
Control Group (n=43): Nutritional advice | Intervention Group: 7.7±1.6  
Control Group: 7.8±1.5  
p=0.58 | Intervention Group: -0.8±1.6  
Control Group: -0.6±2.1 | |
<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Intervention</th>
<th>Final HbA1c</th>
<th>Average HbA1c change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fontbonne, 1989 [22]</td>
<td>type 2 diabetes, diet or oral medication. Outcome measured at 6 months.</td>
<td>Intervention A Group (68): GP monitoring, personal dietary advice, 2 monthly review  Intervention B Group (72): Self Urine monitoring, personal dietary advice, 2 monthly review  Intervention C Group (n=68): SMBG, personal dietary advice, 2 monthly review</td>
<td>Intervention A Group: HbA1c 7.7%  Intervention B Group: HbA1c 8.5%  Intervention C Group: HbA1c 7.8% p≥0.05</td>
<td>Intervention A Group: HbA1c-0.5%±1.5  Intervention B Group: HbA1c-0.1%±2.2  Intervention C Group: HbA1c -0.4%±3.1</td>
</tr>
<tr>
<td>**Kwon, 2004 [25]</td>
<td>type 2 diabetes, diet or oral medication. Outcome measured at 12 weeks.</td>
<td>Intervention Group (n=40): Internet information support system  Control Group (n=41): Usual outpatient care</td>
<td>Intervention Group: 7.49±1.54  Control Group: 6.97±0.89 p≤0.05</td>
<td>WMD (95%CI) -0.84 (-1.35-0.33)</td>
</tr>
<tr>
<td>**Jaber, 1996 [26]</td>
<td>type 2 diabetes, diet or oral medication. Outcome measured at 4 months.</td>
<td>Intervention Group (n=17): Instruction on diabetes and diet, medication counseling, exercise, SMBG  Control Group (n=22): Usual care</td>
<td>Intervention Group: 9.23±2.08  Control Group: 9.72±2.58 p≤0.05</td>
<td>WMD (95%CI) -1.55 (-0.78-0.31)</td>
</tr>
<tr>
<td>**Estey, 1990 [27]</td>
<td>type 2 diabetes, diet or oral medication. Outcome measured at 4 months.</td>
<td>Intervention Group (n=28): SMBG, 3 day education program, follow-up  Control Group (n=25): 3 day education program, no follow-up</td>
<td>Intervention Group: 6.3±1.1  Control Group: 6.1±1.4 p≥0.05</td>
<td>WMD (95%CI) -0.40 (-0.85-0.05)</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Intervention</td>
<td>Final HbA1c</td>
<td>Average HbA1c change</td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>----------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>*Muchmore, 1994 [23]</td>
<td>type 2 diabetes, overweight.</td>
<td>Intervention Group (n=12): Group and individual teaching on carbohydrate counting and SMBG Control Group (n=11): Same time allocation but general information only</td>
<td>Intervention Group: HbA1c 8.8%±1.7 Control Group: HbA1c 9.6%±2.09 P≥0.05</td>
<td>Intervention Group: HbA1c -1.5% Control Group: HbA1c -0.9%</td>
</tr>
</tbody>
</table>

* HbA1c percentage and percentage change  
** WMD with 95% CI

Table III again shows the variability in outcomes achieved in different studies, albeit with more diverse timeframes for outcome measurement than table I and table II. Some studies reported in the review by Sarol were screened and excluded from this review report due to methodological issues. Interestingly, the smaller studies tended toward non-significant findings while Schwedes and Guerci, the two larger studies found in favour of SMBG.

Result of the meta-analysis of 8 RCTs demonstrated a multi-faceted management strategy that included SMBG showed a mean additional HbA1c reduction of 0.39% (95%CI: -0.54%, -0.23%) under fixed effects model and 0.42% (95%CI: -0.63%, -0.21%) under random effects model.

**Systematic review of RCTs on people with type 2 diabetes including both non-insulin treated and insulin treated participants**

One systematic review examined the effect of SMBG in the diabetes management of people with type 2 diabetes who were either treated with insulin or not treated with insulin.[15] The review incorporated two separate analyses, therefore, only the meta analysis that did not include insulin treated people was included in this report.

**Jansen, 2006 [15]**

Jansen evaluated the relative effectiveness of interventions with SMBG and self-monitoring urine glucose, versus interventions without self-monitoring in terms of HbA1c reductions in type 2 diabetes. Thirteen randomised controlled trials with a total of 2080 participants were included. Five RCTs included both insulin-treated and non-insulin-treated participants with type 2 diabetes. However, two separate meta-analyses (Bayesian random effect model) of all included 13 RCTs and a meta-analysis of 8 RCTs with non-insulin treated type 2 diabetes participants were performed (only the non insulin group meta analysis is reported here).
The meta-analysis by Jansen indicated 2 findings in the clinical effectiveness of SMBG in glycaemic control. Firstly, interventions with SMBG were more effective than interventions without self-monitoring in reducing HbA1c value. [Pr=98%: 0.42% reduction] Secondly, interventions with SMBG that include regular feedback were more likely to be effective than interventions with SMBG that did not include feedback [Pr=99%; CI=1.49; -0.13]. Additionally, interventions with SMBG were more likely to be effective than interventions with urine monitoring [Pr=80%; 0.28% reduction]; urine monitoring had similar results to interventions without self-monitoring. This meta analysis indicates that among this group of people, SMBG was an independent variable associated with a reduction in HbA1c.

**Results from newly identified randomised controlled trials**

The search strategy also identified primary research that had been published since the systematic reviews. There were two RCTs that had been published since the reviews and met the inclusion criteria. These are reported below.

Farmer, 2007 [28]

Farmer conducted a three-armed trial of 453 participants to examine the efficacy of SMBG in glycaemic control and efficacy of additional education of interpretation of results and behavioural modifications.[28] The results did not support the effectiveness of SMBG in the glycaemic control either with or without educational supports.

The control group received standard care that consisted of goal setting and review without SMBG unless their doctor suggested, while two intervention groups received either standard care plus SMBG without specific education on interpretation of the readings, or standard care plus SMBG with additional training on interpretation and application of the results to enhance motivation and maintain adherence to a healthy lifestyle. The follow up period was 12 months. The study did not find significant differences in HbA1c values at the end of the study period (p=0.12). Mean difference in changes of HbA1c from baseline to 12 months were as follows: between control and SMBG without educational supports: -0.14% (CI 95% -0.35 to 0.07%) and between control & SMBG with education: -0.17% (-0.37 to 0.03%). No statistically significant differences were found in changes of HbA1c between the groups (p=0.38).[28]

Additionally, a significant difference was found in changes in total cholesterol level favouring the SMBG group without education: -0.06mmol/L (-0.26 to 0.14), and the SMBG group with education: -0.23mmol/L (-0.43 to –0.04). Hypoglycaemic episodes were identified more often in the SMBG group than the control group: control group: 14 episodes/152, SMBG group without education: 33/150, SMBG group with education: 43/151. The higher frequency of identification of episodes of hypoglycaemia (BGL<4mmol/L) is not surprising given the control group only monitored blood glucose levels on the
specific advice of their GP while the interventions groups used routine self-monitoring and were hence more likely to identify hypoglycaemic events.

O’Kane, 2008 [29]

O’Kane conducted a RCT of 180 participants with newly diagnosed type 2 diabetes to examine the effect of SMBG on glycaemic control and psychological status. The study compared a control group with no monitoring and an intervention group that received an additional educational program on SMBG testing. Follow up was scheduled every 3 months until 12 months. The study found no significant difference between groups in HbA1c values. Concerning psychological status, a significant association was found between SMBG and higher scores on a depression subscale.

At the end point (month 12), HbA1c values were 6.9% (±1.2) in the control group and 6.9% (±0.8) in the SMBG group: p=0.69; (95% CI −0.25% to 0.38%). Mean HbA1c value in the SMBG group changed from 8.8% (±2.1) to 6.9% (±0.8) while the control group changed from 8.6% (±2.3) to 6.9% (±1.2). There was no statistically significant difference between the groups at any time point. In regards to non-significant difference between the groups in the mean changes of HbA1c values, the authors noted, the rigorous use of a treatment algorithm applied equally to all participants across both groups during the study period may have over-shadowed the observable subtle benefit of SMBG.[29]

In the well-being questionnaire of the psychological indices, SMBG was associated with a 6% higher score on the depression subscale (p=0.01). The authors concluded that the result could be due to psychological reaction to the new diagnosis of diabetes and related life changes. The participants in this study were still very early stage of the coping/adjusting process while other included studies had participants with long established diabetes. The authors concluded that the newly enforced discipline of regular SMBG in uncertain and unfamiliar life circumstances appeared to have impacted on the psychological status of newly diagnosed people in the study.[29]

**Meta analyses of primary RCTs of the effects of SMBG on HbA1c**

While there were already systematic reviews including meta-analyses available on the effectiveness of SMBG in diabetes management in people with type 2 diabetes in the last 5 years, there was justification for conducting another meta-analysis as two new RCTs had been identified, and the review by Welschen in particular had focused more on exploring methodology through meta analysis and had used restrictive criteria.[18]

The following meta analysis was based on clinical homogeneity using strict entry criteria, therefore, only four studies with outcome of HbA1c measured at six months were included. In this analysis, the outcome measurement is mean difference from baseline to final measurement point, hence the figures per study vary from the previous inclusive analysis. In spite of the stricter entry criteria, both fixed and
random effect models demonstrated statistical heterogeneity, therefore the findings from this analysis should be considered carefully. The studies that compared control groups without SMBG (n=414) and intervention groups with SMBG (n=393) were entered for meta-analysis. All interventions were conducted over 6 months and follow-up data were collected 6 months after the commencement of the interventions.

Figure 3: Meta-analysis 1: Fixed Effect Model

Both fixed effect model and random effect model were utilised to investigate the degree of heterogeneity between the studies. A high degree of statistical heterogeneity was observed (I²=83%). Fontbonne is a statistical outlier in both analyses, and is given a very high weighting in the fixed effect model, removing the Fontbonne study from the analysis results in an analysis that is statistically significantly in favour of SMBG, and is homogenous. However, removal of studies to identify sources of heterogeneity is a test for, rather than a solution to, the problem of heterogeneity. The weighting in the random effect model is more balanced between studies of comparable sizes and this model is probably the more reliable presentation of the data.

Statistical heterogeneity arises when there is variability in the intervention effects in the included studies (either or both of clinical or methodological diversity). Fixed-effect meta-analysis is based on the assumption that observed differences between studies are due solely to chance rather than bias (i.e. there is no statistical heterogeneity). Where there is statistical heterogeneity (as with this analysis) a random effects model is applied as it involves an assumption that the effects being estimated in the different studies are not identical.

The result of the fixed effect model indicated modest-negative effect of SMBG in the changes of HbA1c value at 6 months while the result of the random effect model found a modest positive effect (neither result being statistically significant). Possible causes of the inconsistency of these results includes: poor
methodological quality and limited number of included studies; and very stable effect of SMBG in the control of HbA1c in a 6 months period. The difference between fixed and random effects model outcomes in terms of statistical significance is explained by the underlying assumption that fixed effects models of meta analysis calculate based on the assumption of a single effect size where as the random effects model allows for greater error in effect size by assuming that it varies (in a normal distribution) between studies.

**Exploratory meta analysis**

The following meta analysis includes only non insulin treated people with diabetes controlled by diet and/or oral medication, but explicitly excluded people on insulin. It is a deliberately broad analysis, with open inclusion criteria covering the scope of care across 1346 participants at 6 months, and 634 participants at 12 months. Despite the inclusive approach, statistical heterogeneity was not evident for 6 or 12 month data.

Not all primary studies reported outcome data in the same way, with some reporting the mean difference and standard error of the mean rather than the mean and standard deviation; therefore regression analysis was undertaken to standardise results and enable comparison.

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>Weight</th>
<th>Mean Difference IV, Fixed, 95% CI</th>
<th>Mean Difference IV, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.2 6 month data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allen 1990</td>
<td>10.4</td>
<td>2.9</td>
<td>27</td>
<td>9.7</td>
<td>2.6</td>
<td>27</td>
<td>1.1%</td>
<td>0.70 [-0.77, 2.17]</td>
<td></td>
</tr>
<tr>
<td>Davidson 2005</td>
<td>7.7</td>
<td>1.6</td>
<td>43</td>
<td>7.8</td>
<td>1.5</td>
<td>45</td>
<td>5.4%</td>
<td>-0.10 [-0.75, 0.55]</td>
<td></td>
</tr>
<tr>
<td>Fontbonne 1989</td>
<td>7.84</td>
<td>2.17</td>
<td>54</td>
<td>7.7</td>
<td>1.54</td>
<td>54</td>
<td>4.5%</td>
<td>0.14 [-0.57, 0.85]</td>
<td></td>
</tr>
<tr>
<td>Cuenc 2003</td>
<td>8.1</td>
<td>1.6</td>
<td>345</td>
<td>8.4</td>
<td>1.4</td>
<td>344</td>
<td>45.3%</td>
<td>-0.30 [-0.52, -0.08]</td>
<td></td>
</tr>
<tr>
<td>Okane 2008</td>
<td>7.0</td>
<td>0.9</td>
<td>96</td>
<td>7.1</td>
<td>1.1</td>
<td>88</td>
<td>26.8%</td>
<td>0.00 [-0.29, 0.29]</td>
<td></td>
</tr>
<tr>
<td>Schведес 2002</td>
<td>7.47</td>
<td>1.27</td>
<td>113</td>
<td>7.81</td>
<td>1.52</td>
<td>110</td>
<td>16.9%</td>
<td>-0.34 [-0.71, 0.03]</td>
<td></td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>678</td>
<td></td>
<td></td>
<td>668</td>
<td></td>
<td>100.0%</td>
<td></td>
<td>-0.18 [-0.34, -0.03]</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Chisq = 5.50, df = 5 (P = 0.36); I² = 9%
Test for overall effect: Z = 2.40 (P = 0.02)

<table>
<thead>
<tr>
<th>1.1.3 12 month data</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>Weight</th>
<th>Mean Difference IV, Fixed, 95% CI</th>
<th>Mean Difference IV, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farmer 2008</td>
<td>7.36</td>
<td>1.05</td>
<td>150</td>
<td>7.49</td>
<td>1.2</td>
<td>150</td>
<td>48.7%</td>
<td>-0.13 [-0.39, 0.13]</td>
<td></td>
</tr>
<tr>
<td>Muchmore 1994</td>
<td>8.75</td>
<td>1.66</td>
<td>12</td>
<td>9.6</td>
<td>2.09</td>
<td>11</td>
<td>1.2%</td>
<td>-0.85 [-2.40, 0.70]</td>
<td></td>
</tr>
<tr>
<td>Okane 2008</td>
<td>6.9</td>
<td>0.8</td>
<td>96</td>
<td>6.9</td>
<td>1.2</td>
<td>88</td>
<td>35.4%</td>
<td>0.00 [-0.30, 0.30]</td>
<td></td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>313</td>
<td></td>
<td></td>
<td>321</td>
<td></td>
<td>100.0%</td>
<td></td>
<td>-0.10 [-0.28, 0.08]</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Chisq = 1.56, df = 3 (P = 0.67); I² = 0%
Test for overall effect: Z = 1.13 (P = 0.26)

Test for subroubo differences: Chisq = 0.48, df = 1 (P = 0.49); I² = 0%

![Figure 5: Fixed Effects meta-analysis of effects of interventions including SMBG on HbA1c.](image-url)
The study by Estey was not included in this exploratory analysis (figure 5 and 6) as it was testing a different intervention to SMBG.[27] The pooled results of the total scores were significant and favouring the intervention at 6 months. The result of both models indicated a beneficial effect of SMBG in the changes of HbA1c value at 6 months, however this effect does not continue at 12 months.

The above meta analysis is exploratory in nature and clinical heterogeneity was likely between studies, although statistical heterogeneity was not evident. These results should be considered carefully before application to practice or policy.

Changes in HbA1c over other timeframes

Of the included RCTs, 3 reported mean changes in HbA1c values other than at 6 months, including 3 months[27], 11 months[21] and 12 months[29]. None of these studies demonstrated that SMBG inclusive methods of care was effective for any of these timeframes.

Frequency of SMBG and changes in HbA1c

Fontbonne (n=164) reported that there was a significant association between the number of SMBG strips used and the decrease in HbA1c (P<0.02) in the SMBG group.[22] Participants in the SMBG group whose HbA1c decreased over 1% used significantly more blood strips than participants who had less reduction in HbA1c in the same SMBG group.[22]

Farmer (n=453) reported that mean frequency of SMBG use was significantly higher in the SMBG group with educational intervention compared with the SMBG group without educational intervention (p=0.022).[28] However, association between the frequency of the SMBG use and glycaemic control
was not reported and overall no significant difference in changes in HbA1c was found between the groups.

*Episodes of hypoglycaemia*

Two studies reported episodes of hypoglycaemia during the study periods. Findings support the modest/moderate association between the frequency of hypoglycaemic episodes and the use of SMBG.[20, 28] In Farmer’s study, an episode of hypoglycaemia was found in 9.2% of participants in the non-SMBG group, 22.0% in the less intensive SMBG group and 28.4% in the intensive SMBG group, further to this, the study found significant episodes of hypoglycaemia were highest in the SMBG group and lowest in the control group, although the authors did not discuss whether this was a feature of frequency or accuracy of monitoring.[28] Guerci also reported 2 times higher hypoglycaemic episodes in the SMBG group (10.4%) compared with 5.2% of participants in the non-SMBG group, although there were no serious episodes, with all identified episodes being classified as asymptomatic.[20] Without monitoring, the author suggests it is possible these episodes would have been missed.[20]

*Psychological outcomes*

Three studies indicated ambivalent results regarding the impact of SMBG on the QOL or satisfaction rate of non-insulin treated participants with type 2 diabetes. O’Kane examined the impact of SMBG on the psychological status of 180 newly diagnosed participants.[29] It was reported that SMBG was associated with a 6% higher scores on the depression sub-scale of the Patient Well-Being Questionnaire at the 12 months point (p=0.01) compared with a control group without SMBG. No statistically significant between group differences were found in the sub-scale of anxiety, or positive well-being, or energy.

In contrast, Schwedes reported a positive effect of SMBG in the scores of depression and well-being.[21] The Patient Well-Being Questionnaire was used to assess the psychological well-being of 223 participants with type 2 diabetes in the control group without SMBG and the SMBG group with structured counseling. In both groups, treatment satisfaction improved to a similar extent while well-being scores improved in the SMBG group (p=0.9). Statistically significant improvements were found in the SMBG group in the depression score (p=0.032) and lack of well-being (p=0.02).

Muchmore (n=23) used The Quality-of-Life Inventory to compare the effect of SMBG in participants QOL.[23] Differences in the scores between the control group without SMBG and the SMBG group were assessed. Identical results were found between the control group and the SMBG group in satisfaction, impact, worry-social/vocational and worry-diabetes related categories. In both groups, the satisfaction score improved between 0 to 24 weeks (p<0.05). There were no change to scores on the impact, worry-social/vocational and worry-diabetes over time (p>0.3).
The total duration of diabetes among the included individuals appeared to have a large impact on the results from 3 studies. O’Kane[29] studied individuals with newly diagnosed type 2 diabetes, while 2 studies included individuals with relatively established diabetes around 5-6 years after the initial diagnosis.[21, 23] Muchmore had a very small population size (n=23), which limits the validity of the study and interpretation of the results need to be carefully considered.[23]

**Summary of effectiveness data**

In terms of impact on HbA1c, the primary outcome measure used across studies to indicate glycaemic control, individuals using SMBG were no more likely to have improved control at 6 months than those who did not use SMBG in a meta analysis of 4 studies.

In the exploratory analysis, there was an effect at 6 months that did not continue by 12 months. However, this analysis used very open criteria and was very likely to be confounded by clinical heterogeneity.

Some studies found an association between the frequency of SMBG monitoring and HbA1c, with evidence suggesting increased monitoring is associated with a decrease in HbA1c (P<0.02). While Farmer found an association between adherence to SMBG and educational interventions, SMBG was also associated with a higher level of detection of episodes of hypoglycaemia compared with either no monitoring, or alternate forms of monitoring.[28]

There is no clear evidence regarding the impact of SMBG on sense of well-being, energy, anxiety or depression with some studies finding an effect for particular sub scales, while other studies found no effect, or the opposite effects. Further studies are needed to determine the significance of psychological outcomes from the individual’s perspective. Further detail on the trials included in this report is located in Appendix XIII.

**Appropriateness and meaningfulness of SMBG**

Following the literature search and critical appraisal, 10 interpretive studies were included in the final review. From the database search to the data collection of the qualitative part of the present review, particular attention to the following 2 issues was required.

Firstly, maximum effort was paid to maintain consistency with the review objectives which specifically focused on the use of SMBG in the management of diabetes. It was evident that many qualitative studies had taken a broad perspective to examine the phenomenon of diabetes self-management while only a few studies narrowly examined SMBG and related issues. Judging the extent to which SMBG had been examined was often impossible unless a careful examination of the full text was conducted.

The scope for retrieving full texts was expanded in order to include a number of studies that may have addressed SMBG in a broad exploration of diabetes self-management. From the studies of diabetes...
self-management with a minor focus on SMBG, only the parts explicitly addressing SMBG were included in this review in order to comply with the review objectives of examining the phenomenon of SMBG.

Secondly, maximum effort was made not to distort the findings from primary studies in the process of meta-synthesis. Quantitative examination measures variables such as HbA1c and BGL ranges in order to find statistical explanations for the impact of SMBG on glycaemic control/management. In contrast, interpretative understanding is concerned with the wholeness of subjective experience, including values and cultures embedded in the historical moment of the practice shared by people.

In a practical sense, it was often impossible and inappropriate to make a clear distinction between studies on the meaningfulness of the SMBG practice (what is the experience like to use SMBG) and the appropriateness of the SMBG practice (whether the practice of SMBG is appropriate to the specific context at the time or not). Interpretive representation of the meaningfulness and appropriateness of SMBG was often expressed in inter-related and inseparable forms. Therefore, the relevant data from included studies were pooled together in the JBI-QARI to make a broad synthesis and each review objective, appropriateness and meaningfulness of SMBG, is elaborated and discussed in the following section.

The list of excluded studies is presented in Appendix IX. The summary of 10 included studies is presented in Appendix X.

**Meta-synthesis**

The following meta-synthesis is based on a thematic analysis of the included papers related to the meaningfulness and appropriateness of the use of SMBG. The synthesized findings were identified by a process of iterative reading and recording of statements (narratives and conclusions) from the papers. These were then aggregated based on similarity of meaning or intent, into a smaller number of categories. The categories were then similarly reduced to a small number of synthesised findings in the tradition of thematic analysis emanating from the interpretive research paradigm. The quotations and extracts that informed the synthesis are in Appendix XII.
Synthesised finding 1

Experience of the use of SMBG is an empowering process that can foster positive and active attitudes toward diabetes and self-management in everyday life.

<table>
<thead>
<tr>
<th>Category</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMBG facilitates peoples' understanding of their own life with diabetes.</td>
<td>SMBG helps patients to accept the diagnosis of diabetes.</td>
</tr>
<tr>
<td>SMBG is a useful and convenient tool to assess ones' glycaemic control.</td>
<td>SMBG provides people with an objective/clear status of their glycaemic control.</td>
</tr>
<tr>
<td>SMBG provides reassurance concerning successful self-management of diabetes.</td>
<td>A low reading is perceived as an indication of successful disease management.</td>
</tr>
<tr>
<td>SMBG provides peace of mind.</td>
<td>People can modify their diet depending on the readings.</td>
</tr>
<tr>
<td>SMBG raises positive consciousness towards self-management.</td>
<td>People search for a rational cause for every reading such as food intake prior to the reading.</td>
</tr>
<tr>
<td></td>
<td>Self-management of diabetes can become a part of normal life and normal self-image.</td>
</tr>
</tbody>
</table>

A total of 8 findings were grouped into 3 categories and derived into a synthesis related to a positive learning process toward diabetes self-management with the use of SMBG.

In the first category: **SMBG facilitates people's understanding of their own life with diabetes**, peoples' perception toward SMBG are described as a convenient indicator of their current life with diabetes, which helps peoples to understand and to accept diabetes.

The second category: **SMBG provides people with reassurance concerning successful self-management of diabetes**, is related to the feeling of reassurance towards their appropriate diabetes management which peoples can receive through the use of SMBG.
The third category: SMBG raises positive consciousness towards self-management illuminates the individual’s transition to the stage of taking initiative/control of own diabetes management in everyday life with the use of SMBG.

These 3 categories were synthesised into the first synthesis, “Experience of the use of SMBG is an empowering process that can foster positive and active attitudes toward diabetes and self-management in everyday life”. SMBG is not perceived as a mere tool but it is experienced as a powerful vehicle to facilitate the process of transcendence to a successful/active diabetes self-management.

**Synthesised finding 2**

People using SMBG weight glycaemic control against perceived life needs.

<table>
<thead>
<tr>
<th>Category</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belief impacts on adherence</td>
<td>Questioning the need for regular and frequent use of SMBG.</td>
</tr>
<tr>
<td></td>
<td>Negative meanings attached to SMBG</td>
</tr>
<tr>
<td></td>
<td>Being sceptical about the accuracy of SMBG</td>
</tr>
<tr>
<td></td>
<td>Personal preference to use urine testing to SMBG.</td>
</tr>
<tr>
<td>Ineffective adjusting/coping strategies</td>
<td>Knowledge and skills deficiency</td>
</tr>
<tr>
<td></td>
<td>Feelings of self-blame, disappointment, anger and other negative emotional reactions to high readings. (U)</td>
</tr>
<tr>
<td>Prioritisation of life needs</td>
<td>Lack of understanding of the value and purpose of SMBG and diabetes self-management.</td>
</tr>
<tr>
<td></td>
<td>Physical barriers</td>
</tr>
<tr>
<td></td>
<td>Financial strain</td>
</tr>
</tbody>
</table>
A total of 9 findings were grouped into 3 categories and derived into a synthesis related to several negative or challenging attributes of the use of SMBG.

The first category: **Belief impacts on adherence** is related to negative personal beliefs or conceptions that influence the patients’ adherence to SMBG. Despite advice/suggestion from health care professionals, some people were not convinced of the necessity of SMBG in their glycaemic control. For instance, SMBG was often understood as a therapeutic tool for people who required insulin treatment; therefore, non-insulin treated type 2 diabetes individuals were not *bad enough* to start SMBG. Inconsistency between the HbA1c values and everyday readings could raise questions about the accuracy of the blood glucose meter and the need for use of SMBG itself. Some people did prefer to continue using urine monitoring despite its possibly inconvenient features.

The second category: **Ineffective adjusting/coping strategies** is related to various negative or unconstructive involvements with the use of SMBG. Insufficient knowledge and skills in the actual practice of SMBG and related behavioural modifications were found to hinder the beneficial outcome of SMBG. Positive attributes of SMBG as a central mean of diabetes self-management were not blindly shared and understood by everyone. Many individuals perceived high readings as proof of failure in the required behavioural/dietary modification and blamed themselves without constructive solutions.

The third category: **Prioritisation of life needs**, is related to peoples experiences and individual life circumstances which arise with the use of SMBG. Physical barriers such as poor eyesight were reported to make the use of blood glucose meters very difficult. Depending on the health insurance system in each country, SMBG could be financially too demanding for everyday use for some patients.

These 3 categories were synthesized into the first synthesis, “**People using SMBG weight glycaemic control against perceived life needs**”. In contrast with the first synthesis which described the positive and empowering attributes of the use of SMBG, it is represented as a challenge or some sort of burden that people do not/cannot accept without difficulties and questions. This synthesis illuminates the need for appropriate educational and other support strategies while respecting the individuals’ own belief and autonomous decision making.

**Summary of meaningfulness and appropriateness**

A total of 8 findings were grouped into 3 categories and derived into a synthesis related to a positive learning process toward diabetes self-management with the use of SMBG. While in the second synthesized finding, 9 primary findings were grouped into 3 categories and derived into a synthesis related to several negative or challenging attributes of the use of SMBG.

In relation to “a positive learning process toward diabetes self-management”, the evidence suggests attitude toward and perception of SMBG is indicative of ones attitude toward and potential acceptance
of having diabetes. SMBG was seen by participants as promoting their sense of confidence and certainty to the otherwise “invisible” nature of glycaemic control and enabled people with diabetes using SMBG to take greater control of their lives, becoming active participants and managers of their everyday life.

The second synthesized finding established that participants may feel using SMBG is related to perceived severity of diabetes, and that potential disparities between HbA1c and regular SMBG testing was difficult to conceptualise. This highlighted the felt need for greater levels of knowledge, and coping strategies for life changes to manage higher readings without feeling a sense of failure. Participants views and beliefs were impacted by practical experiences, in particular the support and education they perceived they had received helped transform their perspective from one of “success” or “failure” to one of empowerment and informed decision making.

Discussion

Effectiveness

Four existing systematic reviews and 10 primary studies were included in the final quantitative analysis (systematic reviews were appraised and presented as narrative summary). Two of the reviews combined types of participants, i.e.: those not on insulin, and those using insulin, hence the data from those two reviews were reported separately. Of the 10 trials included in this review, 8 had been identified in existing reviews, and 2 were new, having been published after the most recent review.

The meta analysis of people with poor glycaemic control in this review found no statistically significant benefit for SMBG at 6 months. This suggests no additional clinical benefit for people with type 2 diabetes not using insulin who have not been able to obtain good glycaemic control. Further to this, the studies included in this meta analysis were statistically heterogeneous. In an attempt to explore the research further, an open, exploratory analysis for HbA1c at 6 and 12 months was conducted.

The exploratory meta analysis did not control for clinical heterogeneity, the primary criterion for inclusion being that the intervention group be the only group to use SMBG. The meta analysis shows that strategies for glycaemic control inclusive of SMBG are effective. However, while these meta analysis were not statistically confounded, clinical heterogeneity was highly likely given only the intervention was used to guide inclusion – potential variations in populations were ignored.

The initial meta-analysis of 4 RCTs was much tighter in design, accepting only studies where clinical heterogeneity was not evident in the inclusion criteria and methods. Interestingly, this meta analysis was confounded by statistical heterogeneity, with the studies clearly showing disparate weightings and measures of effect that were not at all consistent. Therefore, no clear conclusions can be drawn from
these meta analyses other than that the studies included complex interventions where a specific effect attributable to SMBG was not able to be established.

The newly identified RCTs [28, 29] from additional database searches found a range of interesting trends in relation to SMBG for glycaemic control. Farmer conducted a three-armed trial of 453 patients in order to examine the efficacy of SMBG in glycaemic control and efficacy of additional education of interpretation of results and behavioural modifications.[28] Outcomes in terms of HbA1c were similar across groups, with SMBG inclusive glycaemic control interventions providing as effective a level of control as non-SMBG interventions. However, SMBG appeared to be associated with several additional benefits that the non SMBG group did not experience. Participants in the SMBG group experienced a statistically significant beneficial change in total serum cholesterol levels compared with the study arm that did not use SMBG but was otherwise treated the same. SMBG itself is unlikely to be the casual factor in this difference, but it may be that people who are actively monitoring their glycaemic control may also be more likely to make healthy, proactive choices in other areas of their lives, such as dietary control. The second benefit was that significantly more hypoglycaemic episodes were identified in the SMBG trial arms compared with the non-SMBG arm. While no serious episodes of hypoglycaemia occurred in any trial included in this review, the evidence does clearly suggest that increased monitoring is associated with more accurate and reliable rates of detection of changes in glycaemic control.[28]

Participants in the Farmer study had a higher mean age - the highest among the included studies: 66.3 in the control group, 65.2 in the less intensive SMBG group, and 65.9 in the intensive SMBG group; this requires further investigation to determine whether age is an independent variable in terms of glycaemic control and adherence to interventions that include SMBG.[28]

The second newly identified RCT compared a control group without SMBG and an experimental group with SMBG of 180 newly diagnosed participants with type 2 diabetes, who were not treated with insulin. The study found both groups glycaemic control improved, with no net negative impact from the use of SMBG in the intervention group. As the authors [29] noted, the treatment algorithm was applied in a rigorous manner during the study period, which may have produced a Hawthorne effect that negated measurable benefit of SMBG.

The participants in this study were newly diagnosed and in the early stages of adjustment and developing coping strategies. Interestingly, participants in the SMBG group study had higher scores on a depression subscale. At the end point, HbA1c value indicated 6.9% (±1.2) in the control group and 6.9% (±0.8) in the SMBG group: p=0.69; (95% CI −0.25% to 0.38%). Mean HbA1c value in the SMBG group changed from 8.8% (±2.1) to 6.9 (±0.8) while the control group changed from 8.6% (±2.3) to 6.9 (±1.2). The authors suggest these findings could be that individuals’ readiness to accept the newly found diagnosis and daily discipline of regular SMBG and related life modification.[29] The findings suggest careful assessment and consideration of peoples’ degree of acceptance and readiness.
concerning their own diagnosis and related regular behavioural modification in daily life. When assisting newly diagnosed individuals to commence SMBG, health care professionals should be aware of their psychological needs, facilitate access to appropriate services and encourage such people in their adjustment to life with type 2 diabetes.

Overall, the body of evidence of effectiveness related to SMBG is accumulating, with growing numbers of trials available. Such trials are necessarily complex in design, and the multi interventional nature of management required for type 2 diabetes is a challenge for reviewers seeking to pool evidence of effects related to the impact of SMBG on clinical outcomes. Current evidence suggests the use of SMBG is no more effective than not using SMBG other than the benefit of increased individual surveillance leading to higher detection rates of episodes of hypoglycaemia.

**Summary of findings – effectiveness**

The central finding of the present review of the effectiveness of SMBG in glycaemic control in people with type 2 diabetes is:

- There is no clear evidence that SMBG improves glycaemic control in people with type 2 diabetes not on insulin compared with not using SMBG. (Level I)

** Appropriateness and Meaningfulness**

Included interpretive studies explored a range of issues related to the appropriateness and meaningfulness of SMBG. These studies provided synthesised evidence related to the appropriateness of certain cultural and experiential perspectives associated with SMBG and the meaningfulness of SMBG.

The experience of self monitoring of blood glucose among people with type 2 diabetes was found to be heavily influenced by the individuals sense of self, their life view of diabetes as being either an illness, somewhat separate from themselves (eg: associating not requiring insulin with not having “severe diabetes”). Individuals’ attitudes and responses to SMBG results were found to differ depending on their life view, and this was influenced by knowledge and exposure to specific education such as reading or interpreting results from SMBG.

Where individuals’ had received education and training in SMBG, they were more likely to perceive test results as informative and enabling, leading to active participation in their glycaemic control. Where the participants’ felt SMBG highlighted “poor” results, this could be seen as a personal failure in the absence of positive self-views, and/or inadequate education and training. This evidence highlights the value of delivering education and training that provides not only the technical and process based information required to monitor glycaemic control, but also the less technical self actualization
knowledge that needs to be individually realized in order for people with type 2 diabetes to progress beyond seeing SMBG results as either indicative of personal success or failure.

**Appropriateness of SMBG from educators’ perspectives**

In relation to the appropriateness of the use of SMBG from the perspectives of educators, one interpretive study reported the values and culture shared by community nurses[35] in relation to recommending SMBG to people with type 2 diabetes in the community. Moreover, from the meta-synthesis of included interpretive studies, both from the perspectives of care providers and patients, further valuable evidence were aggregated which provides rich information concerning culture and values embedded in the use of SMBG.

In addition, several studies which examined appropriateness in the quantifiable aspects of SMBG practice were identified but they were not included in order to comply with the review objectives.

Of 10 included interpretive studies, one study [35] examined the reasons why community nurses recommended the use of SMBG to their patients in UK settings. Several themes emerged from the analysis which illuminated the beliefs that formed the specific culture embedded in their everyday practice. The community nurses held the following general ideas associated with their shared values in relation to SMBG: SMBG is a superior means of diabetes self control compared with urine testing and the use of SMBG should be encouraged. Respecting the patients’ autonomous decision and the choice of equipment regarding SMBG was also commonly considered important. The individuals’ passive attitudes in both decision making in the use of SMBG and lifestyle modifications including diet or exercise were perceived as barriers against the beneficial use of SMBG in successful diabetes self-management. Individual life circumstances such as poor eyesight also emerged as factors to consider in terms of provision of appropriate support for the patients with diverse health and lifestyle needs.

The following figures demonstrate how such values and beliefs shared by community nurses are inter-related with each category of the meta-syntheses that were largely derived from the perspectives of participating individuals. It was evident that the experiences and perceptions of people have strongly affected how community nurses make sense of their role and develop certain views regarding the support and education of these people, and *vice versa*. 
Figure 7 illustrates positive perspectives concerning the use of SMBG which is shared by community nurses and the empowering features of SMBG are reported largely from the perspectives of people with type 2 diabetes. The community nurses’ belief that SMBG is better than urine testing. This belief is associated with the category of ‘SMBG facilitates people’s understanding’. SMBG was often preferred over the urine monitoring method by people with type 2 diabetes because of its ability to provide objective glycaemic status in a practical and convenient way. The use of SMBG was also reported to be useful in the self-assurance of their own diabetes, which helped people accept the diagnosis and take responsibility for diabetes self-management. From these positive effects concerning the use of SMBG, community nurses appeared to have developed the view that the use of SMBG should be recommended and encouraged.

As SMBG is continuously used, SMBG helps people to foster positive attitudes and consciousness towards the importance and value of diabetes self-management. This notion runs parallel with the educators’ belief that peoples’ autonomous decision making in the process of learning diabetes self-management should be encouraged and respected. The popular discourse around the self-
management of diabetes which emphasises the individual taking responsibility/control over their own lifestyle and health is evident in the community nurses’ account. The positive experiences of the individuals in learning to manage SMBG, clearly justifies the appropriateness of encouraging the use of SMBG in diabetes self-management, in which individuals are expected to play the leading role.

**Figure 8: Relationship between the educators’ belief and meta-synthesis 2**

Figure 8 presents the perceptions and beliefs shared by community nurses in relation to various challenging experiences/outcomes and their direct relation with the categories from the meta-synthesis 2 which captured the confronting issues mainly experienced by patients in the use of SMBG. These findings capture the belief shared by educators that SMBG cannot be fully used by all people depending on individual circumstances while the related categories derived from the lived experiences support this notion.

The educators held the view that people do not often have an active role in decision-making. The passive attitudes of not taking initiative in the use of SMBG reported by community nurses’ are consistent with the category derived from the account of people with type 2 diabetes. Despite a general
consensus that the use of SMBG should be encouraged as a central means of diabetes self-management, as discussed in the previous section, some people were found to hold conflicting values and attitudes in relation to the use of SMBG in general; to the need of SMBG for their own diabetes, and to the value of SMBG including the concept of self-management itself.

The educators’ belief that most people do not take an active role in responding to the readings in terms of modifying diet and exercise corresponds with another category; ‘poor control’ indicates learning needs and behavioural changes’. While the importance of respecting autonomous decision making by individuals in their self-management has been emphasized by health care professionals, a clear dilemma is also evident in that not all people can use SMBG as an effective guide for daily behavioural modifications, such as diet and exercise. Lack of knowledge and skills, unconstructive psychological reaction to high readings, such as self-blame and avoidance, not understanding the value and the need of SMBG in diabetes self-management, all hinder the appropriate use of SMBG.

The educators’ account, there were individual limitations concerning the appropriate use of SMBG related to the individual life circumstances that influence the persons’ decision making and experience in the use of SMBG. Physical problems such as poor eyesight, physical discomfort of fingers from regular blood checks and problems of financial capacity for long-term use of SMBG, were identified as conflicting life circumstances that some people are forced to prioritise, according to their individual needs and SMBG.

**Summary of findings - appropriateness**

Findings from one interpretive study that reported the educators’ perceptions towards SMBG and related findings from the meta-synthesis, largely concerning the experiences of people with type 2 diabetes. The levels of evidence for the following findings are described in appendix I. The following conclusions reflect shared values related to appropriateness:

- There is a shared value between providers of diabetes education and people with type 2 diabetes that SMBG is a superior method of self-monitoring. (Level III)

- There is a shared value that SMBG can be recommended for people with type 2 diabetes whether treated with insulin or without insulin. (Level III)

- There is a shared assumption that individual autonomy should be respected and encouraged in the decision making process. (Level III)

- There is a shared value that SMBG should be used for the purpose of facilitating effective diabetes self-management. (Level III)
- The findings suggest that some individuals remain passive or refuse to take an active role in the use of SMBG due to their conflicting beliefs concerning the needs and the use of SMBG, or lack of knowledge and skills. (Level III)

- The findings suggest that some people can not adjust their lifestyles such as diet and exercise, in response to high readings, due to insufficient knowledge and skills and the use of inadequate coping strategies. (Level III)

- The findings suggest that introduction of SMBG for all people is not appropriate and may need individualised consideration depending on various life circumstances such as financial strain, physical discomfort associated with SMBG or physical problems such as poor eyesight. (Level III)

Meaningfulness

Two meta-syntheses of 10 included interpretive studies clearly indicate the meaning that both people with type 2 diabetes and educators attribute to the experience of education and the use of SMBG.

The first synthesis, SMBG facilitates peoples’ understanding of their own diabetes, is related to a positive learning process concerning diabetes self-management with the use of SMBG. In the first category: SMBG facilitates peoples’ understanding of their own diabetes, states that people perceive SMBG as a convenient indicator of up-to-date glycaemic control, which helps them to comprehend and to accept their own diagnosis. The second category: SMBG provides people with reassurance concerning successful self-management of diabetes captures the feeling of reassurance towards their successful diabetes management that people can receive through the use of SMBG. The third category: SMBG raises positive consciousness towards self-management addresses the individuals' transcendental experience in the stage of taking initiative/control of own diabetes. It is evident that SMBG is not perceived as a mere tool but it is experienced as a powerful vehicle to facilitate the learning process in the successful/active diabetes self-management in which SMBG and related behavioural modification become a normal part of everyday life and self-image.

In contrast, the second synthesis, Individuals using SMBG weigh glycaemic control against perceived life needs, captures the negative/challenging experiences in the use of SMBG. While the first synthesis described the positive and empowering attributes of SMBG, the second synthesis represents the experience of SMBG as a challenge or some sort of burden that some people do not/cannot accept without difficulties and questions. The synthesis illuminates the particular issues and need for appropriate educational and other supportive strategies while respecting and encouraging the individuals' own beliefs; autonomous decision-making is important. The first category: Belief impacts on adherence is related to negative personal beliefs or conceptions that influence adherence to SMBG. The second category: Ineffective adjusting/coping strategies is related to various negative or
unconstructive involvements with the use of SMBG. The third category: *Prioritisation of life needs*, is related to experiences with individual life circumstances which arise with the use of SMBG. Since some of these issues have been already discussed in relation to the appropriateness of SMBG in the previous part, the key findings in this section will have particular focus on the experience of the individual in the use of SMBG in a broad scope.

**Summary of findings – meaningfulness**

These qualitative findings are derived from critical and interpretive literature, which is ranked differently in terms of levels of evidence to the quantitative findings listed above, see Appendix I for further detail. From two meta-syntheses from 10 interpretive studies that reported the experiences of both people with type 2 diabetes and educators of SMBG, the following conclusions relating to meaningfulness were derived:

- Qualitative meta-synthesis concluded that SMBG can be used as an effective means to facilitate an empowering process that raises positive and active attitudes to self-management. (Level I)
- People using SMBG balance glycaemic control against perceived life needs. (Level I)
- Despite absence of evidence to support the superiority of SMBG in glycaemic control, qualitative findings support the role of individual preference for methods of monitoring glycaemic control. (Level III)
- SMBG facilitates peoples’ understanding of their own glycaemic control by providing objective glycaemic status in a convenient and practical manner. (Level III)
- SMBG provides individuals with reassurance concerning successful self-management of diabetes which provides peace of mind and a sense of achievement. (Level III)
- SMBG raises positive consciousness towards self-management as individuals start questioning their recent diabetes-related behaviours such as diet and exercise and ongoing readings from SMBG. (Level III)

**Conclusions**

**Effectiveness**

The findings from this review suggest no clinically significant beneficial effects of SMBG as measured by HbA1c in people with non-insulin treated type 2 diabetes. However, current evidence suggests people with type 2 diabetes can benefit directly from SMBG in terms of greater awareness of their level
of glycaemic control, and general health. The studies included in this review also found better general health knowledge may also lead to improvements in serum cholesterol, ability to identify how dietary, exercise and lifestyle choices impact glycaemic control, and episodes of hypoglycaemia. Further research evaluating the impact of age as a potential independent variable in acceptance and adherence to SMBG should be considered.

Appropriateness

One study was available that examined the perspective of care provider/educators to articulate insights into the value system and culture behind the education and practice of SMBG. The results of the meta-synthesis that largely derived from the subjective accounts of individuals were clearly consistent with the major findings from the accounts of the care providers/educators, which suggests the existence of values and assumptions shared by people with type 2 diabetes and educators in the use of SMBG.

Several informative and valuable findings were identified in relation to the appropriate practice and education of SMBG. There is a shared belief that the use of SMBG should be encouraged for the purpose of facilitating effective diabetes self-management. SMBG is largely considered to be a superior method of self-monitoring of diabetes than the historic method of urine monitoring. The autonomous decision making and active involvement of people were considered to be important in the use of SMBG, and the provision of individually tailored educational/supportive intervention to meet the unique needs of individuals is advanced.

Meaningfulness

SMBG can be used as an effective means to facilitate an empowering process that raises positive and active attitudes toward self-management. Negative experiences in the use of SMBG were often caused by insufficient knowledge and skills, and unconstructive coping strategies concerning diabetes management. The belief of each individual concerning the use of SMBG, such as stigma and misunderstanding of the purpose and the needs of SMBG, should be assessed if the commencement of SMBG is recommended. In confronting SMBG, people are required to prioritise their life needs such as financial cost in the use of SMBG, or individual-physical circumstances such as poor eyesight. Individualised assessment of such factors is recommended.

Implications for Practice

From the overall results of the review, a number of recommendations are made for practice. Grades of recommendations have been assigned (see Appendix X).

- The use of SMBG may be encouraged as a part of diabetes self-management in non-insulin treated type 2 diabetes people with adequate supervision and assessment. (Grade A)
- SMBG will lead to the increased detection of episodes of hypoglycaemia. Health professionals should make people aware of the benefits of increased detection. (Grade B)

- It is recommended that health professionals need to be aware that qualitative research findings revealed the individuals’ overall preference for SMBG. (Grade B)

- The autonomous decision making of individuals should be supported and facilitated in the use of SMBG. (Grade B)

- Individualised educational interventions are essential in order to enhance the knowledge and skills required for the appropriate use of SMBG in the self-management of diabetes. (Grade B)

- It should be understood that SMBG itself is not a goal, but the learning process to actualise self-management of diabetes including the use of SMBG. (Grade B)

- Multifactorial assessment and interventions are necessary in order to meet each persons’ various life needs such as the status of personal finance and insurance, and physical/mental status in order to make beneficial use of SMBG. (Grade B)

- In the absence of conclusive evidence, the frequency of SMBG should be determined by individual circumstance and clinical judgment. (Grade B)

- Education should include the management and prevention of hypoglycaemia as well as dietary, activity and lifestyle modifications to optimise glycaemic control. (Grade B)

- For individuals with a recent diagnosis, the introduction of SMBG should be supported with strategies to evaluate and enhance the individuals psychosocial status. (Grade B)

**Implication for Research**

Investigating the effectiveness of SMBG in daily life settings presented challenges to researchers and this may be the reason for the lack of high-quality RCTs on the effectiveness of SMBG. Further high quality quantitative research is needed to determine the clinical effectiveness of SMBG in the control of diabetes. Further investigation is required to determine the potential variables that may affect the outcome of glycaemic control in the use of SMBG, including: demographic background, health status, treatments and other possible variables that may affect the outcome. The relationship between the frequency of SMBG and timing of SMBG also requires further investigation, with a methodologically sound approach. Timing, quality and volume of educational programs and educational interventions, frequency and nature of support by health care providers, should also be investigated. The impact of recency of diagnosis prior to commencement of SMBG, the impact of age, and the role of SMBG in relation to secondary outcomes such as total serum cholesterol also warrant further investigation.
In the interpretive investigations of appropriateness and meaningfulness of SMBG, most identified papers have examined the perspectives of people with type 2 diabetes. This may be due to an unchallenged shared discourse around the use of SMBG among educators and care providers. Further study is needed to facilitate understanding of the values and cultures associated with the SMBG for the provision of appropriate educational supports. Furthermore, most studies specifically examining the phenomena around the use of SMBG were largely targeted at the Caucasian population in Anglo and European countries. Some studies examined Latino, African and non-Caucasian groups but the scope of such papers tended to be very broad, encompassing whole experiences related to diabetes self-management. Further investigation is required to understand the subjective accounts of such non-Caucasian groups to gain insights to understand their values and experiences associated with the use of SMBG, in order to facilitate the beneficial use of SMBG as a central part of diabetes self-management.

**Acknowledgements**

This study was commissioned by the Australian Diabetes Educators Association. The review team would like to express sincere thanks to the chair and the reference group members for their guidance and suggestions.
References


## Appendix I: JBI Levels of Evidence

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>Feasibility, Appropriateness, Meaningfulness</th>
<th>Effectiveness</th>
<th>Economic Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Metasynthesis of research with unequivocal synthesised findings</td>
<td>Meta-analysis (with homogeneity) of experimental studies (eg RCT with concealed randomisation)</td>
<td>SR (with homogeneity) of Level 1 economic studies</td>
</tr>
<tr>
<td>II</td>
<td>Metasynthesis of research with credible synthesised findings</td>
<td>One or more RCT, retrospective cohort studies or untreated control groups in RCTs. Retrospective cohort study or follow-up of untreated control patients in an RCT</td>
<td>SR (with homogeneity) of Level 2 economic studies</td>
</tr>
</tbody>
</table>
| III               | a. Metasynthesis of text/opinion with credible synthesised findings  
   b. One or more single research studies of high quality | Case-series (and poor quality prognostic cohort studies) | Analysis without accurate cost measurement but including a sensitivity analysis incorporating clinically sensible variations in important variables |
| IV                | Expert opinion | Expert opinion, or physiology bench research, or consensus | Expert opinion, or based on economic theory |
Appendix II: Comprehensive Search Terms

Limiters: 1998-2008; English language; adult >16

MEDLINE (OVID)

Database: Ovid MEDLINE(R) <1996 to February Week 2 2008>

Search Strategy:

1. exp Diabetes Mellitus, Type 1/ or type 1 diabetes.mp. (23818)
2. type I diabetes.mp. (1685)
3. insulin pump.mp. or exp Insulin Infusion Systems/ (876)
4. insulin pump therapy.mp. (143)
5. insulin dependent diabetes.mp. (7500)
6. exp Blood Glucose/ or continuous subcutaneous insulin infusion.mp. or exp Diabetic Ketoacidosis/ (36905)
7. exp adolescent/ or exp adult/ (1932465)
8. exp Patient Education as Topic/ or diabetes education.mp. (30381)
9. diabetes educators.mp. (179)
10. 1 or 2 or 5 (28466)
11. 3 or 4 or 6 (37263)
12. 8 or 9 (30431)
13. 10 and 11 (5348)
14. 12 and 13 (199)
15. 7 and 14 (118)
16. limit 15 to (english language and humans and yr="1998 - 2008") (89)
17. from 16 keep 1-89 (89)
18. from 16 keep 1-89 (89)
19. from 16 keep 1-89 (89)
20 from 16 keep 1-89 (89)
21 from 20 keep 1-89 (89)

CINAHL (EBSCOHOST)

--------------------------------------------------------------------------

S1 (type 1 diabetes) or (MH "Diabetes Mellitus, Insulin-Dependent")
S2 insulin dependent diabetes
S3 type I diabetes
S4 S3 or S2 or S1
S5 (adult) or (MH "Adult")
S6 S5 and S4
S7 (education) or (MH "Education") or (MH "Outcomes of Education") or (MH "Adult Education")
S8 (diabetes education) or (MH "Diabetes Education") or (MH "Diabetes Educators")
S9 training or blood glucose monitoring
S10 diabetes training
S11 S10 or S9 or S8 or S7
S12 (insulin pump therapy) or (MH "Insulin Infusion Systems")
S13 (continuous subcutaneous insulin infusion) or (MH "Insulin Infusion Systems")
S14 S13 or S12

Cochrane DSR, ACP Journal Club, DARE, CCTR, CMR, HTA, and NHSEED

Database: All EBM Reviews - Cochrane DSR, ACP Journal Club, DARE, CCTR, CMR, HTA, and NHSEED

Search Strategy:

--------------------------------------------------------------------------

1 type 1 diabetes.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] (975)
2 type I diabetes.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] (251)
3 insulin dependent diabetes.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] (2199)
4 diabetes mellitus.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] (11324)
5 insulin pump therapy.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] (32)
6 education.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] (16610)
7 1 or 2 or 3 or 4 (11465)
8 5 and 7 (28)
9 limit 8 to english language [Limit not valid in: CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained] (27)
10 limit 9 to humans [Limit not valid in: CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained] (26)
11 limit 10 to yr="1998 - 2008" [Limit not valid in: DARE; records were retained] (18)
12 from 11 keep 1-18 (18)

EMBASE
Database: EMBASE <1980 to 2008 Week 07>
Search Strategy:

1 exp Insulin Dependent Diabetes Mellitus/ or type 1 diabetes.mp. (36812)
2 type I diabetes.mp. (3597)
3 insulin pump.mp. or exp Insulin Pump/ (1324)
4 exp Insulin Treatment/ or insulin pump therapy.mp. (8892)
5 Adult/ (2041241)
6 Adolescent/ (410551)
7 education.mp. or exp EDUCATION/ (292416)
8 diabetes education.mp. or exp Health Education/ or exp Diabetes Education/ or exp Patient Education/ or exp Education/ (260386)
9 diabetes educators.mp. or exp Diabetes Educator/ (104)
10 self management.mp. or exp Self Care or blood glucose monitoring/ (14671)
11 exp EXPERIENCE/ or exp PERSONAL EXPERIENCE/ or experience.mp. (224029)
12 1 or 2 (37684)
13 exp Subcutaneous Drug Administration/ or continuous subcutaneous insulin infusion.mp. (72498)
14 3 or 4 or 13 (80772)
15 5 or 6 (2206908)
16 7 or 8 or 9 (292440)
17 10 or 11 (237788)
18 12 and 14 (4631)
19 15 and 16 and 17 and 18 (27)
20 limit 19 to (human and english language and yr="1998 - 2008") (17)
21 from 20 keep 1-17 (17)
22 from 20 keep 1-17 (17)

Current Contents
-------------------------------------------------------------------------------------------------------------------------
1. insulin pump
2. continuous subcutaneous insulin infusion
3. 1 OR 2
4. educat*
5. 3 AND 4

PsycINFO
Database: PsycINFO <1985 to February Week 2 2008>
Search Strategy:
-------------------------------------------------------------------------------------------------------------------------
1 diabetes/ or exp diabetes mellitus/ (4914)
2 type 1 diabetes.mp. (392)
3 type I diabetes.mp. (189)
4 insulin dependent diabetes.mp. (785)
Basic search strategy: 1998-2008 'insulin pump therapy'
Appendix III: JBI-SUMARI Package Validity Checklists

JBI Critical Appraisal Checklist for Systematic Reviews

<table>
<thead>
<tr>
<th>Reviewer ___________________</th>
<th>Date ________</th>
<th>Author ___________________</th>
<th>Year ________</th>
<th>Record Number ______</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Is the review question clearly and explicitly stated?  ❏  ❏  ❏

2. Was the search strategy appropriate?  ❏  ❏  ❏

3. Were the sources of studies adequate?  ❏  ❏  ❏

4. Were the inclusion criteria appropriate for the review question?  ❏  ❏  ❏

5. Were the criteria for appraising studies appropriate?  ❏  ❏  ❏

6. Was critical appraisal conducted by two or more reviewers independently?  ❏  ❏  ❏

7. Were there methods used to minimise error in data extraction?  ❏  ❏  ❏

8. Were the methods used to combine studies appropriate?  ❏  ❏  ❏

9. Were the recommendations supported by the reported data?  ❏  ❏  ❏

10. Were the specific directives for new research appropriate?  ❏  ❏  ❏

Overall appraisal:  Include ❏ Exclude ❏ Seek further info. ❏

Comments (Including reasons for exclusion)
JBI Critical Appraisal Checklist for Experimental Studies

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the assignment to treatment groups truly random?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Were participants blinded to treatment allocation?</td>
<td></td>
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<tr>
<td>3. Was allocation to treatment groups concealed from the allocator?</td>
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<tr>
<td>4. Were the outcomes of people who withdrew described and included in the analysis?</td>
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<tr>
<td>5. Were those assessing outcomes blind to the treatment allocation?</td>
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<tr>
<td>6. Were the control and treatment groups comparable at entry?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>7. Were groups treated identically other than for the named interventions?</td>
<td></td>
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</tr>
<tr>
<td>8. Were outcomes measured in the same way for all groups?</td>
<td></td>
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<tr>
<td>9. Were outcomes measured in a reliable way?</td>
<td></td>
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<tr>
<td>10. Was appropriate statistical analysis used?</td>
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</tbody>
</table>

Overall appraisal: Include [ ] Exclude [ ] Seek further info. [ ]

Comments (Including reasons for exclusion)
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is there congruity between the stated philosophical</td>
<td></td>
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</tr>
<tr>
<td>perspective and the research methodology?</td>
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<tr>
<td>2. Is there congruity between the research methodology</td>
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<tr>
<td>and the research question or objectives?</td>
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<tr>
<td>3. Is there congruity between the research methodology and</td>
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<tr>
<td>the methods used to collect data?</td>
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<tr>
<td>4. Is there congruity between the research methodology and</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>the representation and analysis of data?</td>
<td></td>
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<tr>
<td>5. Is there congruity between the research methodology and</td>
<td></td>
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<tr>
<td>the interpretation of results?</td>
<td></td>
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<tr>
<td>6. Is there a statement locating the researcher culturally or</td>
<td></td>
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<tr>
<td>theoretically?</td>
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<tr>
<td>7. Is the influence of the researcher on the research, and vice-</td>
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<tr>
<td>versa, addressed?</td>
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<tr>
<td>8. Are participants, and their voices, adequately represented?</td>
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<tr>
<td>9. Is the research ethical according to current criteria or, for</td>
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<tr>
<td>recent studies, and is there evidence of ethical approval by an</td>
<td></td>
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<tr>
<td>appropriate body?</td>
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<tr>
<td>10. Do the conclusions drawn in the research report flow from</td>
<td></td>
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<td></td>
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<tr>
<td>the analysis, or interpretation, of the data?</td>
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</tbody>
</table>

Overall appraisal: Include☐ Exclude☐ Seek further info.☐

Comments (Including reasons for exclusion)
Appendix IV: JBI-Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) Data Extraction Forms

JBI Data Extraction Form for Systematic Review of Experimental/Observational Studies

<table>
<thead>
<tr>
<th>Reviewer</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Year</td>
</tr>
<tr>
<td>Journal</td>
<td>Record Number</td>
</tr>
</tbody>
</table>

Included studies

- RCT
- Quasi-RCT
- Longitudinal
- Retrospective
- Observational
- Other

Participants

- Setting
- Population

Interventions

- Intervention 1
- Intervention 2
- Intervention 3

Clinical outcome measures

<table>
<thead>
<tr>
<th>Outcome Description</th>
<th>Scale/measure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
## Meta-analysis results
### Dichotomous data

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention ( ) number / total number</th>
<th>Intervention ( ) number / total number</th>
<th>Statistic Combined measure (CI)</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

### Continuous data

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention ( ) number / total number</th>
<th>Intervention ( ) number / total number</th>
<th>Statistic Combined measure (CI)</th>
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### Summary of Narrative Results

____________________________________________________________________

____________________________________________________________________

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### Authors Conclusions

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____________________________________________________________________

### Comments

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____________________________________________________________________

____________________________________________________________________
JBI Data Extraction Form for Experimental and Observational Studies

<table>
<thead>
<tr>
<th>Reviewer:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author:</td>
<td>Publication year:</td>
</tr>
<tr>
<td>Journal:</td>
<td>Record number:</td>
</tr>
</tbody>
</table>

**Study Method:**

- ( ) RCT
- ( ) Quasi-RCT
- ( ) Longitudinal
- ( ) Retrospective
- ( ) Observational
- ( ) Other ______________

**Participants:**

<table>
<thead>
<tr>
<th>Setting:</th>
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</thead>
<tbody>
<tr>
<td>Population:</td>
</tr>
<tr>
<td>Sample size:</td>
</tr>
<tr>
<td>Intervention 1:</td>
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</tbody>
</table>

**Types of Interventions:**

<table>
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<tr>
<th>Intervention 1:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention 2:</td>
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<tr>
<td>Intervention 3:</td>
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</table>

**Clinical Outcome Measures:**

<table>
<thead>
<tr>
<th>Outcome Description</th>
<th>Scale / Measure</th>
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</table>
### Study Results:

#### Dichotomous Data:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention ( ) number / total number</th>
<th>Intervention ( ) number / total number</th>
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#### Continuous Data:

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<thead>
<tr>
<th>Outcome</th>
<th>Intervention ( ) number / total</th>
<th>Intervention ( ) number / total</th>
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</tbody>
</table>

#### Authors’ conclusions:

__________________________________________________________________________

__________________________________________________________________________

#### Comments:

__________________________________________________________________________

__________________________________________________________________________
Appendix V: JBI QARI Data Extraction Form for Interpretive & Critical Research

Reviewer ___________________________ Date ________________
Author ___________________________ Year __________
Journal ___________________________ Record Number ________

Study Description

Methodology

________________________________________________

________________________________________________

________________________________________________

Intervention

________________________________________________

________________________________________________

Setting

________________________________________________

Geographical

________________________________________________

Cultural

________________________________________________

Participants

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Data analysis

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Authors Conclusions

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

Comments

__________________________________________________________________________

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__________________________________________________________________________

<table>
<thead>
<tr>
<th>Findings</th>
<th>Illustration from Publication (page number)</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Unequivocal</td>
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</tbody>
</table>
## Appendix VI: Included Systematic Reviews

<table>
<thead>
<tr>
<th>Author</th>
<th>Objectives</th>
<th>Included studies</th>
<th>Included studies</th>
<th>Analysis</th>
<th>Findings</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jansen 2006</td>
<td>To evaluate the relative effectiveness of interventions with SMBG and self-monitoring urine glucose, versus interventions without self-monitoring in terms of HbA1c reductions in type 2 diabetes</td>
<td>RCTs type 2 diabetes including insulin treated participants</td>
<td>Allen et al. (1990) Fontbonne et al. (1989) Miles, et al. (1997) Brown et al. (2002) Davidson, et al. (2005) Guerci et al. (2003) Jaber et al., (1996) Muchmore et al., (1994) Rutten et al., (1990) Schwedes et al., (2002) Wing et al., (1986) Estey et al., (1990) Kwon et al., (2004)</td>
<td>n= 54 208 150 252 89 689 39 23 149 223 50 53 101</td>
<td>Meta-analysis (Bayesian random effect model) 1) Analysis with all type 2 diabetes mellitus patients 2) Analysis with only non-insulin treated type 2 diabetes patients 3) Adjustment of baseline glycaemic level 4) Adjustment for study quality</td>
<td>Including insulin treated patients  • Interventions with SMBG showed a reduction in HbA1c of 0.40% (95% CrI: 0.07 to 0.70%) in comparison to interventions without self-monitoring.  • Regular feedback reduced HbA1c more than two times.  • Urine monitoring and interventions without monitoring showed similar results (0.02% reduction in HbA1c: 95%CrI-0.62 to 0.70%).  • There is 88% probability that SMBG is more effective than urine testing (relative reduction in HbA1c is 0.38%, 95% CrI-0.3 to 1.00%).  Relative efficacy among non-insulin treated patients  • Interventions with urine monitoring had comparable results to interventions without self-monitoring.  • Interventions with SMBG are more effective than interventions without self-monitoring [88% probability: 0.42% reduction]  • Interventions with SMBG are more likely to be effective than interventions with urine monitoring. [80%probability: 0.28% reduction]  • Interventions with SMBG + feedback are more likely to be effective than interventions without feedback [99%CrI-1.49; -0.13].</td>
</tr>
<tr>
<td>Author</td>
<td>Objectives</td>
<td>Included studies</td>
<td>Analysis</td>
<td>Findings</td>
<td>Conclusion</td>
<td>Author</td>
</tr>
<tr>
<td>-------------</td>
<td>-----------------------------------------------------------------------------</td>
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</tbody>
</table>
| McGeoch 2007| 1) To examine all of the clinically relevant evidence regarding the use of SMBG in patients with type 2 diabetes not using insulin.  
2) To identify how to use SMBG to the greatest effect. | RCTs                                                                                                  | n=       | Narrative summary due to the clinical heterogeneity                                               | • In 3 RCTs, the two larger studies (Schwedes, Guerci) had statistically significant reduction in HbA1c levels with SMBG.  
• In observation studies, smaller studies had lower initial HbA1c and showed no association between SMBG and laboratory or clinical improvement.  
• Larger studies tended to have higher initial HbA1c and did show an association between SMBG and laboratory or clinical improvement.  
• Overall, improvement in glycaemic control with SMBG tended to be seen in studies with initial HbA1c above 8%. |            |
<table>
<thead>
<tr>
<th>Author</th>
<th>Objectives</th>
<th>Included studies</th>
<th>Analysis</th>
<th>Findings</th>
<th>Conclusion</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sarol 2005</td>
<td>To determine if therapeutic management programs with SMBG result in greater HbA1c reduction in non-insulin-requiring type 2 diabetes patients compared to programs without SMBG.</td>
<td>RCTs (type 2 diabetes with/without insulin treatment)</td>
<td>8 RCTs</td>
<td></td>
<td>Anti-diabetic therapies that included SMBG as part of a multi-component management strategy produced a mean additional HbA1c reduction of • -0.39% (95%CI: -0.54%, -0.23%) (fixed effects model) • -0.42% (95%CI: -0.63%, -0.21%) (random effects model) • Without 3 studies with C rate (poor quality), summary effect estimate was −0.31% (95% CI: -0.49%, -0.14%). • Heterogeneity among studies was not statistically significant. (chi-square test).</td>
<td>Multi-component diabetes management programs with SMBG result in better glycaemic control among non-insulin-using type 2 diabetes patients.</td>
</tr>
<tr>
<td>Welschen 2005</td>
<td>To assess the effects of SMBG in patients with type 2 diabetes not using insulin.</td>
<td>RCTs (type 2 diabetes non-insulin treated)</td>
<td>6 RCTs</td>
<td></td>
<td>SMBG might be effective in improving glycaemic control in patients with type 2 diabetes who are not using insulin. (Previous reviews (Faas 1997 Holmes 2002 Coster 2000) reported there was insufficient evidence).</td>
<td></td>
</tr>
</tbody>
</table>

- RCTs: Randomized Controlled Trials
- Estey et al, (1990)
- Jaber et al, (1996)
Appendix VII: Excluded Studies - Effectiveness

3 Systematic Reviews


Reason for Exclusion: Literature review only, no description of methodology.


Reason for Exclusion: Did not meeting methodological criteria; one reviewer, limited search

McAndrew, L,Schneider, SH,Burns, E,Leventhal, H. Does patient blood glucose monitoring improve diabetes control? A systematic review of the literature.[comment]. Diabetes Educator,33, 6, 991-1011; discussion 1012-3

Reason for Exclusion: Did not distinguish between people on insulin and those not receiving insulin in the analysis

9 RCTs From Systematic Reviews


Reason for Exclusion: Insulin users were included in the study, could not be extracted.


Reason for Exclusion: Only abstract was published.


Reason for Exclusion: No medication limits were identified.


Reason for Exclusion: Data from insulin users were included.

**Reason for Exclusion:** No medication limits were identified.


**Reason for Exclusion:** No medication limits were identified.


**Reason for Exclusion:** Type 1 and insulin treated patients were included.


**Reason for Exclusion:** We could not identify this paper.


**Reason for Exclusion:** Insulin users are included.

**29 RCTs from New Search**


**Reason for Exclusion:** Insulin users are included.


**Reason for Exclusion:** Protocol awaiting completion.


**Reason for Exclusion:** The study compared glucose measurement between fingertip and forearm using the blood glucose (BG) monitoring system.

**Reason for Exclusion:** Quasi-experimental study. No medication limits were identified.


**Reason for Exclusion:** No a RCT.


**Reason for Exclusion:** SMBG is not a main intervention.


**Reason for Exclusion:** Both intervention and control groups used SMBG.


**Reason for Exclusion:** SMBG was not used in intervention or control groups.


**Reason for Exclusion:** SMBG is not a main intervention. Insulin users were included.


**Reason for Exclusion:** SMBG was not used in intervention or control groups.


**Reason for Exclusion:** SMBG is not the main intervention.


**Reason for Exclusion:** No medication limits were identified.

Reason for Exclusion: Insulin users are included.


Reason for Exclusion: SMBG is not the main intervention.


Reason for Exclusion: SMBG is not included.


Reason for Exclusion: SMBG is not included.


Reason for Exclusion: Insulin users are included.


Reason for Exclusion: Not an RCT.


Reason for Exclusion: We could not identify and retrieve this paper.


Reason for Exclusion: SMBG is not a main intervention.


Reason for Exclusion: SMBG is no a main intervention.

**Reason for Exclusion:** SMBG is not included.


**Reason for Exclusion:** SMBG is not included.


**Reason for Exclusion:** SMBG is not a main intervention.


**Reason for Exclusion:** Focus of study was on cost effectiveness of SMBG.


**Reason for Exclusion:** SMBG is not included. Insulin users are included.


**Reason for Exclusion:** Insulin users are included.


**Reason for Exclusion:** Not an RCT.


**Reason for Exclusion:** SMBG is not a main intervention.
### Appendix VIII: Included RCTs

<table>
<thead>
<tr>
<th>Author</th>
<th>Methods</th>
<th>Population</th>
<th>Interventions</th>
<th>Outcome measures</th>
<th>Main Results (HbA₁c, FBG)</th>
<th>Other findings</th>
<th>SRs using article</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allen 1990</td>
<td>Randomised Control Trial (RCT)</td>
<td>Country: USA</td>
<td>Control: Urine monitoring (n=27)</td>
<td>1. HbA₁c at 3mths and 6mths by affinity chromatography</td>
<td>1. HbA₁c at 6mths: SMBG : 10.4% (P&lt;.001) Urine Baseline: 9.7% (P&lt;.001)</td>
<td>Medication changes 1. Started insulin SMBG: 1 patient Urine testing: 2 patients 2. Started oral medication: SMBG: 2 patients Urine monitoring: 4 patients 3. Changed dosage of oral medication or switched to a new medication SMBG: 9 Urine testing: 14 4. SMBG was 8-12 times more expensive than urine testing. 5. Younger and better educated participants improved more. 6. Baseline HbA₁c, weight, FGB, use of oral medications, duration of diabetes and race did not have association with improving glucose control. 7. Control group used standardised urine monitoring.</td>
<td>Jansen McAndrew Welschen</td>
</tr>
<tr>
<td></td>
<td>Randomised in groups of 10 by computer generated table Duration: 6 mths Allocation concealment: - neither patient or study physician blinded to the interventions</td>
<td>n=54 male=100% Drop out 7/61 No ITT (Intention-to-treat analysis) Inclusion Criteria: - type 2 diabetes non-insulin dependent patients - fasting glucose &gt;8.8 mmol/L and &lt;22 mmol/L - no history ketoacidosis - diet controlled or diet controlled + hypoglycaemic agent - no active infection or serious concurrent infection - no physical/mental handicap determined by cognitive-capacity screening examination &amp; physical-abilities questionnaire</td>
<td>Intervention: SMBG (n=27) 36 blood glucose determinations/mth, before meal every other day</td>
<td>2. Fasting plasma glucose, (FPG) monthly by glucose oxidase method. 3. Total cholesterol, high density lipoprotein cholesterol, Measured by spectrophotometer with Beckman Dri-Stat reagents. 4. Weight, monthly, patients fully clothed.</td>
<td>2. No significant difference in HbA₁c was found between two groups. (P&gt;0.95) 3. Within each group, HbA₁c significantly improved. 4. No significant difference in FPG (P&gt;0.86), Glycosylated haemoglobin (P&gt;0.95) or weight (p&gt;0.19) was found between the two groups 5. Within each group, FPG improved significantly.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Country: USA</td>
<td>Both received diet + counselling and monthly visits with treatment team, which used treatment algorithm (including medication changes) in response to monitoring results.</td>
<td>Follow up: Monthly follow up for 6mths</td>
<td>3. Within each group, HbA₁c significantly improved. 4. No significant difference in FBG (P&gt;0.86), Glycosylated haemoglobin (P&gt;0.95) or weight (p&gt;0.19) was found between the two groups 5. Within each group, FPG improved significantly.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Exclusion Criteria: - SMBG devices used before - serum creatinine &gt;177 mmol/L</td>
<td>Mean age (yrs): SMBG: 58.2 ± 9.7 Urine testing: 57.9 ± 10.7 Diabetes duration (yrs): SMBG: 6.8± 6.5 Urine testing: 9.0 ± 10.3 Baseline HbA₁c (%): SMBG: 12.4±3.3 Urine testing: 11.7±3.0</td>
<td>5. Younger and better educated participants improved more.</td>
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<td>Control: Urine monitoring (n=27) 36 urine glucose determinations/mth, before meal every other day</td>
<td>Control: Urine monitoring (n=27) 36 urine glucose determinations/mth, before meal every other day</td>
<td>1. HbA₁c at 3mths and 6mths by affinity chromatography</td>
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<td>Intervention: SMBG (n=27) 36 blood glucose determinations/mth, before meal every other day</td>
<td>Intervention: SMBG (n=27) 36 blood glucose determinations/mth, before meal every other day</td>
<td>2. Fasting plasma glucose, (FPG) monthly by glucose oxidase method. 3. Total cholesterol, high density lipoprotein cholesterol, Measured by spectrophotometer with Beckman Dri-Stat reagents. 4. Weight, monthly, patients fully clothed.</td>
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<td>Follow up: Monthly follow up for 6mths</td>
<td>Follow up: Monthly follow up for 6mths</td>
<td>3. Within each group, HbA₁c significantly improved. 4. No significant difference in FBG (P&gt;0.86), Glycosylated haemoglobin (P&gt;0.95) or weight (p&gt;0.19) was found between the two groups 5. Within each group, FPG improved significantly.</td>
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<tr>
<td>Davidson 2005</td>
<td>Randomised Control Trial</td>
<td>Country: USA n=88 Drop out 1/89 ITT</td>
<td>Control: (n=45) dietary counselling 5 times; at randomisation and 2,4,8 and 12 weeks later, Intervention: (n=43) SMBG before and between 1 and 2 hrs post meals 6 days per week + dietary counselling 5 times; at randomisation and 2,4,8 and 12 weeks later, Both groups had nurse follow-up with detailed algorithms to make therapeutic decisions based on laboratory determined FPG &amp; HbA1c with oral drugs sulfonylurea, metformin and glitazone</td>
<td>Follow up: 6mths follow up</td>
<td>1. HbA1c (Every 2mths for 6mths) 2. Medication changes</td>
<td>1. Medication levels at the end of the study had similar outcomes in both groups. 2. Glucose monitoring is expensive but no definitive costs calculated 3. Overall there was no evidence that SMBG for these patients gave them a better glycaemic outcome.</td>
<td>Jansen McAndrew McGeoch Welschen</td>
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</tbody>
</table>

**Inclusion Criteria:**
- Patients not on insulin
- Type 2 diabetes with oral medication (sulfonylurea, metformin, glitazone)

**Mean age: (yrs)**
- Control: 49.8±11.2
- SMBG: 50.9±11.0

**Diabetes duration: (yrs)**
- Control: 5.5±4.7
- SMBG: 5.8±5/8

**Baseline HbA1c**
- Control: 8.4%±2.1
- SMBG: 8.5±2.2

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</table>
| Estey 1996 | Randomised Control Trial  
-methode unclear and allocation concealment unclear, no blinding) | Country: Canada  
n=53  
Drop out: 7/60 No-ITT | Control: 3 days diabetes education program  
Intervention: 3 days diabetes education program  
-SMBG 4 follow up calls for review of learned skills and for encouragement over 10 wk period  
-keeping a diary of all their SMBG values  
4mths follow up | 1. Changes in pre- to post-study HbA1c values.  
2. Weight.  
3. Frequency of SMBG practice | 1. Frequency of SMBG practice was significantly higher for the intervention group (P< .0001).  
2. No significant differences were found in post-study HbA1c or weight changes in the two groups. | 1. No information on treatment adjustments  
2. Providing an intense follow-up intervention appeared to improve SMBG practices compared with an intervention that focused primarily on providing only information.  
3. Telephone calls can be an effective means of reinforcing behaviour  
4. Factors influencing noncompliance were job, lack of family support, knowledge deficiencies, and financial concerns.  
5. Educational effect diminishes quickly subsequent to educational programs.  
6. Less-frequent, but long-term reinforcement is probably required to sustain behaviours rather than intense intervention | Jansen Sarol |

Country: Canada  
n=53  
Drop out: 7/60 No-ITT  

**Inclusion Criteria:**  
- type 2 diabetes not on insulin  
- referred by physician for diabetes education  
- diabetes controlled by either diet, and exercise, or diet, exercise, and oral hypoglycaemic agents.  
- completion of 3-day education at the Diabetes Centre  
- willingness to practice SMBG  
- accessibility by phone  

**Exclusion Criteria:**  
- none specified  

**Mean age: (yrs)**  
Control: 54.2±13.3  
Intervention: 56.2±11.1  

Male/Female  
Control: 54/46  
Intervention: 39/61  

Baseline HbA1c  
Control: 6.1±1.4  
Intervention: 6.3±1.1
**Author** | **Methods** | **Population** | **Interventions** | **Outcome measures** | **Main Results (HbA1c, FBG)** | **Other findings** | **SRs using article**  
--- | --- | --- | --- | --- | --- | --- | ---  
Farmer 2007 | Randomised Control Trial - randomised by computer generation + partial independent minimisation procedure to adjust randomisation probabilities between groups. | Country: U.K. n=453 | Control: (n=152) Standard care with goal setting and review 3 mthly HbA1c. | 1. Primary outcome: HbA1c at 12mths measured using Variant II Hemoglobin Testing System (Bio-Rad Laboratories, Hercules, CA) 2. Secondary outcome: BP, weight, total cholesterol, ratio of total cholesterol to high density lipoprotein cholesterol, body mass index at 12mths 3. Hypoglycaemia, frequency of SMBG | 1. No significant improvement in glycaemic control was found after 12mths in patients with non-insulin treated diabetes 2. Using SMBG when compared to those not self-monitoring, HbA1c at 12 mths No significant differences in HbA1c value between the 3 groups were found (p= .12). 2. Mean difference in change in HbA1c from baseline to 12mths Between Control & Less SMBG: -0.14% (CI 95% -0.35 to 0.07%) Control & Intensive SMBG: -0.17% (-0.37 to 0.03%) 4. No differences in HbA1c changes between groups (p=0.38%) 5. Significant difference in the change in total cholesterol level: Control vs. less intensive SMBG: -0.08mmol/L (-0.26 to 0.14) Control vs. intensive SMBG: -0.23mmol/L (-0.43 to −0.04) 6. Hypoglycaemia: Control: 14. Less SMBG: 33. Intensive SMBG: 43 (χ²=18.3, P<0.001) 6. Less SMBG group was more likely to persist with SMBG than the intensive SMBG group. (67% vs 52%) | 1. There was no difference between groups in the proportions of patients prescribed an increase in hypoglycaemic drugs between baseline and 12mths 2. There were no significant differences between subgroups of patients on the impact of SMBG 3. On glycaemic control (as defined by duration of diabetes, therapy, diabetic complications or health status) 4. There were no differences in glycaemic control between the more, or less monitored SMBG groups. 5. Patients with reasonably controlled diabetes do not need active encouragement to use a meter. | New  
| | Drop out: 57/510 ITT | Inclusion Criteria: - type 2 diabetes - non-insulin treated - invited and referred by their own practitioner - ≥25yrs at diagnosis - managed with diet or oral hypoglycaemic agents alone - HbA1c ≥6.2% on assessment visit - independent in daily living activities | Intensive SMBG: Standard care + SMBG with advice for patients to contact their doctor for interpretation of results (if it is too high (>15mmol/L) or too low (<4 mmol/L). 3 SMBG daily readings on 2 days during the week (one after fasting, the other two before meals or two hours after meals). No specific instruction on how to interpret the readings. Diaries were kept by patient of SMBG readings |  |  |  |  
| | | Exclusion Criteria: - use of blood glucose monitor ≥2 times/wk over last three mths - serious illness - limited life expectancy making glycaemic control inappropriate - inability to follow trial procedures | Mean age: (yrs) Control: 66.3 ±10.2 Less intensive SMBG: 65.2 ±10.6 Intensive SMBG: 65.9 ±9.9 Male (%): Control: 55.9 Less SMBG: 58.7 Intensive SMBG: 57.6 Duration of diabetes: (yrs) Control: 3 (2-6) Less SMBG: 3 (2-7) Intensive SMBG: 3 (2-6) Baseline HbA1c: Control: 7.49 ±1.09 Less intensive SMBG: 7.41 ±1.02 Intensive SMBG: 7.53 ±1.12 | 12mths follow up |  |  |  

**Australian Diabetes Educators Association**

**Self-monitoring blood glucose (SMBG) in type 2 diabetes**

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<tbody>
<tr>
<td>Fontbonne</td>
<td>Randomised Control Trial</td>
<td>Country: France</td>
<td>Control:</td>
<td></td>
<td>1. HbA1c</td>
<td>1. HbA1c based treatment adjustment by physicians 2. In group C, significant association was found between the number of SMBG strips and the decrease in HbA1c. 3. Some patients motivated by SMBG may benefit from its use. 4. Methods used to reduce poor compliance may not always yield better metabolic control. 5. Comprehensive programs are yet to be designed and validated, where SMBG is to find a place of choice in routine management of type 2 diabetes without insulin treatment.</td>
</tr>
<tr>
<td>1989</td>
<td>Randomised procedure stratified by clinic</td>
<td>n=164</td>
<td>Group A- (n=54)</td>
<td></td>
<td>1. HbA1c or weight over 6mths was not significantly different between the three groups (P&lt; .02) Mean ± SEM; Group A: -0.5 ±0.2% Group B: -0.1 ± 0.3% Group C: -0.4 ± 0.3%</td>
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<tr>
<td></td>
<td>Randomised procedure stratified by clinic</td>
<td>Drop out 44/208</td>
<td>HbA1c readings taken bimonthly and monitored by physician but no self-</td>
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<td></td>
<td></td>
<td>No-ITT</td>
<td>monitoring</td>
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<td>Inclusion Criteria:</td>
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<td></td>
<td></td>
<td>- type 2 diabetes non-insulin treated</td>
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<td>-managed with diet and/or oral hypoglycaemic agents alone.</td>
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<td>-poorly controlled with FPG &gt;8.8mmol/L or postprandial blood glucose &gt;11mmol/L, 3 times within preceding yr.</td>
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<td>-presence of occasional glucosuria (renal glucose threshold &lt;11mmol/L) to justify randomisation to self urinary glucose monitoring group.</td>
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<td>-duration of diabetes- at least 3 yrs.</td>
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<td>-a contact with the diabetic clinic 6mths previously and had attended 2 outpatient appointments since first contact.</td>
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<td>Exclusion Criteria:</td>
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<td>-no rapidly progressing diabetic complications, and no severe illness.</td>
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<tr>
<td>Mean age:</td>
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<td>Group A: 56.3±9.1</td>
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<td>yrs</td>
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<td>Group B: 54.9±10.2</td>
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<td>Group C: 54.5±10.7</td>
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<td>Male/Female:</td>
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<td>Group A: 40/28</td>
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<td>Group B: 52/20</td>
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<td>Group C: 36/32</td>
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<td></td>
<td>Baseline HbA1c</td>
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<td>Group A: 8.2±0.3</td>
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<td>Group B: 8.6±0.3</td>
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<td>Group C: 8.2±0.3</td>
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<td>Diabetes duration (yrs)</td>
<td>Group A: 12.7±0.8</td>
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<td>Group B: 13.3±6.8</td>
<td>Group B: 13.3±6.8</td>
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<td></td>
<td>Group C: 12.2±6.6</td>
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<tr>
<td>Guerci 2003</td>
<td>Randomised control trial</td>
<td>Country: France n=689 303/988 Drop out No-ITT</td>
<td>Inclusion Criteria: -Poorly controlled type 2 diabetes &gt; 1yr non-insulin treated for ≤7 consecutive days -oral antidiabetics -40 to 75yrs - HbA1c level ≥7.5 and ≤11% -no previous SMBG - able to perform own SMBG</td>
<td>Control: (n=344) conventional care -12 wkly laboratory measured HbA1c Intervention: (n=345) conventional care + SMBG with initial training by G.P. -6 SMBG readings per week (on 3 different days) - including 6wkly follow-up over 6mths including 5 visits -trained to monitor their blood glucose which could give them feedback to change their lifestyle accordingly (diet &amp; physical activity).</td>
<td>HbA1c (baseline, 3, 6mths) weight, Systolic BP Diastolic BP at baseline, 3, 6mths At 3 mths each general practitioner (G.P.) could modify treatments of diabetic patients according to HbA1c Number of hypoglycaemia episode</td>
<td>1. Final HbA1c: SMBG: 8.1±1.6 Control: 8.4±1.4 (p=.012) The statistically significant difference between the two groups (P&lt;.005) Mean change: SMBG: −0.88±1.54 Control: −0.60±1.54 There was a significant difference between the two groups. 2. There was no statistically difference in fasting blood glucose levels at endpoint between the two groups. 3. No difference was found in mean change of weight, drugs prescribed, diet or physical activity between the two groups. 4. Overall SMBG was associated with a slight but significant improvement of metabolic control. The benefit was greater in patients with higher initial HbA1c levels, lower BMI and lower duration of T2 diabetes.</td>
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<td>Open label randomised prospective trial</td>
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<td>1. (Treatment modification unknown) 2. Hypoglycaemic episodes Control: 25 (5.2%) SMBG: 53 (10.4%) 3. Age and educational level approached statistical significance, concluding that educated patients might benefit from a program of intensive SMBG with 36 blood glucose determinations per month.</td>
<td>2. Hypoglycaemic episodes Control: 25 (5.2%) SMBG: 53 (10.4%) 3. Age and educational level approached statistical significance, concluding that educated patients might benefit from a program of intensive SMBG with 36 blood glucose determinations per month.</td>
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<tr>
<td>Muchmore 1994</td>
<td>Randomised control trial Prospective RCT</td>
<td>Country: USA n=23 Drop out 6/29 No-ITT</td>
<td>Inclusion Criteria: Overweight BMI 27.5-44 kg/m² -40-75 yrs -type 2 diabetes, diet and/or oral medication &gt;1yr duration -non-insulin treated -HbA1c at entry 9.5%-13.5% (normal=5.1%-7.7%) -compliance with protocol</td>
<td>Control: (n=11) -conventional care -teaching individually and at group level on general principles of diabetes nutrition. Intervention: (n=12) -conventional care -SMBG,6x per day (pre &amp; 2h postprandially) for 4 wks then pre and postprandially for a single meal per day for 16 wks. SMBG beyond 20weeks was at own expense and choice. -dietary CHO counting teaching individually and at group level. -results of SMBG and calorie counting was charted on a daily worksheet. -Teaching focused on postprandial increment in blood glucose of 2.2 to 3.9mMol/L.</td>
<td>1. HbA1c progressively declined in SMBG group (P&lt;0.05) and no improvement in control group. 2. HbA1c at week 44 SMBG: 8.75%±0.63: 1.54% (1.46) reduction (P&lt;0.05) Control: 9.6%±0.63: 0.84% (1.87) reduction (P&gt;0.3) No significant differences between groups at study end.</td>
<td>1. Duration of diabetes, initial HbA1c, and number of SMBG were not related to HbA1c. 2. QOL results were identical in both groups.</td>
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<tr>
<td>Jansen McAndrew Sarol Welschen</td>
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<td>Exclusion Criteria: -SMBG use within last 3mths -serious underlying medical or psychiatric illness, drug abuse, or alcoholism. -received previous dietary carbohydrate counselling. Mean age: (yrs) SMBG: 57.3 ± 2.3 Control: 60.1 ± 2.2 Male/Female: SMBG: 4/8 Control: 5/6 Diabetes duration: (yrs) SMBG 5.7 ± 1.4 Control 5.2 ± 1.4 Baseline HbA1c SMBG: 10.29 ± 0.33 Control 10.45 ± 0.44</td>
<td>Control and Intervention: -Both groups received care under their primary physician who coordinated any decision on medication adjustment. -1st 8wks run-in period formed in groups of 7-8 members and met for 90min wly for formal proprietary behavioural weight management program (L.E.A.R.N.) + 1hr counselling by diabetes nurse educator + individual session with dietician. -follow-up one-on-one sessions with the dietician (30min) at wks 1 and 3 and the nurse educator at wks 1, 3, and 24. -both groups were recommended a meal composition of 50% of calories from carbohydrates, 30% from fat, and 20% from protein. Total calories were individualized for a weight loss of 0.5-1kg per week. 44 wks follow up</td>
<td>1. HbA1c (-8, 0, 16, 28 and 44 weeks) 2. Weight measured at every encounter Diabetes Quality of Life (QOL) Inventory (0, 24, 44 weeks)</td>
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| O'Kane 2008 | Randomised control trial | Randomised by randomly generated allocation code in consecutively numbered sealed envelopes. | Country: Northern Ireland (U.K.)
- n=180
- Drop out:
  - 4/184
  - No-ITT | Both groups received an identical structured core education program. | 1. differences in HbA1c, psychological indices, use of oral hypoglycaemic drugs, body mass index and glycaemia rates. | 1. No significant differences were found between groups in the use of oral hypoglycaemic medicines and hypoglycaemia. | New |
| | | Inclusion Criteria | - type 2 diabetes
- newly diagnosed
- <70yrs | **Control:** (n=88)
- no monitoring (no monitoring during the study period) | 2. SMBG was associated with a 6% higher score (i.e. more depressed) on the depression subscale of the wellbeing questionnaire (p=0.01). Therefore SMBG can be associated with reduced wellbeing. | | |
| | | Exclusion Criteria | - secondary diabetes
- insulin treatment
- previous self-monitoring of diabetes
- major illness within previous six months, chronic liver disease, and alcohol misuse. | **Intervention:** (n=96)
- additional educational program on SMBG
  - SMBG (4 times fasting and 4 posprandial SMBG per week)
  - education given as to responses needed for high or low readings (dietary and exercise)
  - Every 3mths follow up for 1 year | | | |
| | | Mean age: (yrs) | **Control:** 60.9 (±11.5)
- SMBG: 57.7 (±11.04)
| Male/Female: | | **Control:** 55/41
- SMBG: 56/32 | **Control & Intervention:**
- both underwent identical education programs involving nurse practitioners, dieticians, podiatrists, and medical staff.
- all reviewed by doctor, diabetes nurse practitioner, and dietician at 3mthly intervals for 1yr. All glycaemic indices were reviewed.
- identical treatment algorithms for dietary and pharmacological glycaemic management based on HbA1c targets. | 2. At each 3mthly visit patients completed a questionnaire survey incorporating diabetes treatment satisfaction, a diabetes attitude scale and well-being questions (depression, anxiety, energy, positive wellbeing, and general wellbeing) | | |
| | | Baseline HbA1c | **Control:** 8.6 (±2.3)
- SMBG: 8.8 (±2.1) | | | | |
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<th>Author</th>
<th>Methods</th>
<th>Population</th>
<th>Interventions</th>
<th>Outcome measures</th>
<th>Main Results (HbA1c, FBG)</th>
<th>Other findings</th>
<th>SRs using article</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rutten 1990</td>
<td>Randomised control trial Multi G.P. Centre, randomised controlled design Patients chosen from G.P. centres randomised by care levels (not high or low care)</td>
<td>Country: Netherlands n=139 Drop out 10/149 No-ITT</td>
<td>Inclusion Criteria: - type 2 diabetes &gt;6mths - under G.P. care -40-75yrs Exclusion Criteria: - insulin therapy - treatment for diseases other than obesity or hypertension Mean age SMBG: 62.6±9.9 Control: 63.7±8.1 Male/Female SMBG: 34/66% Control: 36/64% Duration of diabetes: (yrs) SMBG: 10.0±7.8 Control 6.6±4.0 Baseline HbA1c SMBG: 9.7±2.1 Control: 8.9±1.9</td>
<td>Control: (n=36) G.P. consultation 4/year. No SMBG instruction. Intervention: (n=34) - 2-5 education session on SMBG - patients contacted diabetes nurses monthly to report SMBG readings. If high, made appointment with G.P. - All patients also met with G.P. after 6mths. - medication algorithms were followed by G.P.s 12mths follow up</td>
<td>1. HbA1c 2. weight 3. Number of SMBG strips</td>
<td>1. Final HbA1c SMBG: decreased by 0.4% Control: increased by 0.5% (P&lt;0.005) 2. SMBG: HbA1c decreased in two patients with an initial HbA1c &lt;8 (14%). Control: HbA1c unchanged or increased in all patients. 3. SMBG: HbA1c decreased in 80% of the patients with an initial value of &gt;10. Control: HbA1c decreased in 53% of the patients with an initial value of &gt;10.</td>
<td>Jansen McAndrew</td>
</tr>
</tbody>
</table>

**Conclusion:** The study by Rutten et al. (1990) demonstrated that self-monitoring blood glucose (SMBG) in combination with education and support from diabetes nurses was effective in improving glycemic control, as measured by HbA1c, in patients with type 2 diabetes. The intervention group showed a significant decrease in HbA1c compared to the control group, who showed an increase. Significant improvements were also noted in other outcome measures such as weight and number of SMBG strips, although the changes did not reach statistical significance in all cases. The improvement was more pronounced in patients with initial HbA1c levels above 10, and the effect was maintained over the 12-month follow-up period.

**Implications:** This study highlights the importance of patient education and support in achieving better glycemic control. SMBG can be a useful tool in managing type 2 diabetes, and its integration into routine care can lead to positive outcomes. However, further research is needed to confirm the sustainability of these effects and to explore potential barriers and facilitators to SMBG implementation in clinical settings.
<table>
<thead>
<tr>
<th>Author</th>
<th>Methods</th>
<th>Population</th>
<th>Interventions</th>
<th>Outcome measures</th>
<th>Main Results (HbA1c, FBG)</th>
<th>Other findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schwedes 2002</td>
<td>Randomised control trial</td>
<td>Country: Germany &amp; Austria n=223 Drop out 27/250 No-ITT</td>
<td>Control: (n=110)</td>
<td>HbA1c</td>
<td>1. Final HbA1c: SMBG: 7.47±1.27. Control 7.81±1.52 (p=0.0086)</td>
<td>1. Body weight, total cholesterol and microalbumin improved in the SMBG group but no significant difference between the two groups. 2. All items of the Patient Well-being Questionnaire improved in SMBG group with statistically significant improvement in depression (p=.032) and lack of well-being (p=.02)</td>
</tr>
<tr>
<td></td>
<td>Multicentre, prospective, randomised controlled design (21 centres)</td>
<td>Inclusion Criteria: - type 2 diabetes &gt;3mths -BMI&gt;25kg/m² - HbA1c between 7.5 &amp; 10% -managed with diet and/or oral hypoglycaemic agents alone. -45-70yrs -participation in diabetes education within previous 2yrs</td>
<td>Intervention: (n=113) -structured counselling focused on self-perception, reflection and regulation, eating diary - SMBG 6x per day on 2 days per week. -recordings of blood glucose data, eating habits and state of wellbeing entered in diary. - blood glucose meter testing continued during follow-up period. 6mths trial with 6mths follow up</td>
<td>Lipid and microalbumin Well-being and treatment satisfaction, by the Patient Well-being Questionnaire and the Diabetes Treatment Satisfaction Questionnaire.</td>
<td>2. Average change SMBG –1.0 ± 1.08. Control –0.54±1.41</td>
<td>3. There was a statistically significant difference between the groups. 4. SMBG group had better treatment satisfaction.</td>
</tr>
<tr>
<td></td>
<td>Randomised within blocks of 8 for treatment</td>
<td>Exclusion Criteria: -incapable of maintaining an eating diary or documenting state of wellbeing. -sensomotor disturbances -used regular SMBG during 6mths prior to study -participated in previous clinical study within 30days before study. -women who were pregnant, lactating or without safe contraceptive method. -treatment with other anti-diabetic agents such as insulin, non-selective b-blockers, glucocorticoids, amphetamines, or anabolic agents. -diet reduction during course of study (&lt;1,000 Kcal/day) -serum creatinine&gt; 3mg/dl-serum transaminases&gt;50 units/l -serious underlying medical or psychiatric disorders or drug or alcohol abuse. -use of acarbose</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Mean age: (yrs) SMBG: 58.7 ± 7.6 Control: 60.5 ± 6.6 Male/Female SMBG: 47.8/52.2% Control: 48.2/51.8% Diabetes duration: (mths) SMBG: 65.5 ± 57.2 Control: 62.6 ± 47.3 Baseline HbA1c SMBG: 8.47±0.86 Control: 8.35±0.75</td>
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</table>
Appendix IX: Excluded Qualitative Studies (appropriateness and meaningfulness)

   **Reason for Exclusion:** This is not a research article.

   **Reason for Exclusion:** This is not a research article.

   **Reason for Exclusion:** This study examined the experiences of pregnant women with type 1 diabetes.

   **Reason for Exclusion:** The study investigated the research priorities of people with diabetes from an inner city community. SBGM related experience was not specifically addressed.

   **Reason for Exclusion:** This study examined the experiences and responses to type 2 diabetes among Chinese immigrant families. SBGM related experience was not specifically addressed.

   **Reason for Exclusion:** This study examined the experiences of patients with type 2 diabetes in general. SBGM related experience was not specifically addressed.

   **Reason for Exclusion:** This study described a Hmong cultural model of type 2 diabetes. SBGM related experience was not specifically addressed.

**Reason for Exclusion:** This is not a qualitative study.


**Reason for Exclusion:** The study did not specifically address SBGM.


**Reason for Exclusion:** This study did not specifically address SBGM.


**Reason for Exclusion:** This is not a qualitative study.


**Reason for Exclusion:** This is a systematic review of quantitative studies.


**Reason for Exclusion:** This study explored how Cherokee Indians cope with a diagnosis of Type 2 Diabetes. SBGM related experience was not specifically addressed.


**Reason for Exclusion:** This study reported on Hispanic migrant farm workers and their perceptions of living with diabetes in general. SBGM related experience was not specifically addressed.


**Reason for Exclusion:** This study explored beliefs about health and illness in females with diabetes mellitus (DM) in Sweden. SBGM related experience was not specifically addressed.
   **Reason for Exclusion:** This is not a research article.

   **Reason for Exclusion:** This study examined inner city American Indians' perceptions of diabetes in general. SMBG related experience was not specifically addressed.

   **Reason for Exclusion:** This study examined British Pakistani and British Indian patients' perceptions and experiences of taking oral hypoglycaemic agents. SMBG related experience was not addressed.

   **Reason for Exclusion:** This study examined the experiences of African-American men living with type-2 diabetes in general. SMBG related experience was not specifically addressed.

   **Reason for Exclusion:** This is not a research article.

   **Reason for Exclusion:** This study examined the experiences of low-income Appalachians living with type 2 diabetes. SMBG related experience was not specifically addressed.

   **Reason for Exclusion:** This is a systematic review of quantitative studies.

   **Reason for Exclusion:** This study examined the experience and attitude towards control of diabetes among Kashmiri men with diabetes in the UK. SMBG related experience was not specifically addressed.
   Reason for Exclusion: This study examined the experiences of African American patients with diabetes. SBGM related experience was not specifically addressed.

   Reason for Exclusion: This study examined the experience of living with, and growing old with, diabetes for Nigerians and for African Americans. SBGM related experience was not specifically addressed.

   Reason for Exclusion: This study examined the early experiences of women learning intensive self-management of type 2 diabetes. SBGM related to experience was not specifically addressed.

   Reason for Exclusion: This study examined the patients' experience with a diabetes support programme based on an interactive electronic medical record. SBGM related experience was not specifically addressed.

   Reason for Exclusion: This study examined the experiences of women with type 2 diabetes. SBGM related experience was not specifically addressed.

   Reason for Exclusion: This is not a research article.

   Reason for Exclusion: This is not a research article.
   **Reason for Exclusion:** This study evaluated an educational intervention for patients from Northern Plains American Indian reservations. SBGM related experience was not specifically addressed.

   **Reason for Exclusion:** This study examined the adherence of type 2 diabetes patients to their therapeutic regimens. SBGM related experience was not specifically addressed.
### Appendix X: Included Qualitative Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Purpose</th>
<th>Participants</th>
<th>Methods</th>
<th>Analysis</th>
<th>Findings and conclusion</th>
</tr>
</thead>
</table>
| Abbott et al. 2004 | To explore the reasons why nurses working in the community recommend SMBG to their patients. | 7 community nurses caring primarily for housebound patients                                    | Semi-structured qualitative interviews by primary care nurses acting as researchers          | Thematic analysis (4 researchers worked together)                                                         | • The participants believed that SMBG was superior to urine testing.  
• The participants had a general assumption that SMBG should be encouraged.  
• There was no indication that patients had an active role in decision-making.  
• There were patient limitations to the appropriate use of SMBG such as poor eyesight.  
• Most patients do not take active role in responding to the readings such as modification of diet or exercise.  
• The participants felt that it was important to respect the patients’ choice (SMBG or urine testing, type of glucose meters, SMBG or no-SMBG) |
| Benavides-Vaello et al. 2004 | To illustrate the successful use of focus groups in evaluating diabetes education intervention for Mexican Americans in a south Texas border community. | 40 individuals type 2 Mostly female Mexican Americans in a south Texas border community.      | 6 focus group sessions in 2 counties (Starr County and Hidalgo County) by the trained moderator, assistant moderator and an expert in focus group administration (the moderator and transcriber were native Spanish speaker) | Content analysis method                                                                                   | **Starr County**  
• The participants were confident with their abilities to manage their diabetes and take control of their health.  
• Other emerged themes were: maintenance, barriers, familial support, self-awareness and folk remedies.  
**Hidalgo County (lack of formal diabetes education in the area)**  
• The participants’ knowledge and skills in self-management was limited.  
• Other themes were: confusion, fear, distrust of healthcare providers, reliance on folk remedies, varying motivation, persistence of hunger, barriers to diabetes management, and the overriding theme of lack of self-confidence in managing diabetes.  
• Results support the importance of diabetes educational intervention to facilitate self-management. |
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<tr>
<th>Study</th>
<th>Purpose</th>
<th>Participants</th>
<th>Methods</th>
<th>Analysis</th>
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<tbody>
<tr>
<td>Burke et al, 2006</td>
<td>To examine the patients’ perspectives for medical interviews in order to determine how physicians could improve the health care outcomes of patients with diabetes.</td>
<td>8 participants with diabetes who were recruited from urban-suburban family practice clinic in a large city in northwest Ohio, Ohio, US</td>
<td>2 focus group interviews (4 participants each)</td>
<td>Grounded theory</td>
<td>Six themes emerged: 1. The participants experienced many complications and comorbidities which affected their practice of self-care. 2. Time is seen as a valued resource that is inexorably consumed by having diabetes. 3. Achieving control in glycaemic or metabolic status and self-control was a major concern. 4. The need for reliable information to manage their illness was emphasised. 5. The participants most often expressed how their family supported or hindered their dietary management. 6. Physician behaviours largely influenced the patients’ satisfaction with their medical appointments.</td>
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</table>
| Davis et al, 2007      | To describe ways in which community health workers (CHW) are used in various clinic and community settings to support diabetes self-management. | 1859 CHWs from a US national program to improve the QOL of people with diabetes.  
*Qualitative part:* 47 Hispanic adults with type 2 diabetes who had received service by CHW.  
Missouri, US | Quantitative and qualitative mixed method  
*Quantitative part:* descriptive method using the data from CHW’s worker logs semi-structured interviews | descriptive statistics and thematic analysis | 1. Providing assistance and teaching or practicing skill to patients were the most common objectives of individual visit. 2. Providing encouragement/motivation to the patients was the most reported service CHW offered. 3. The participants (patients) largely shared the view that CHWs were helpful in demonstrating how to incorporate diabetes self-management into their daily lives. 4. Openness to individual problem was widely appreciated. |
<p>| Hill-Briggs, et al, 2003 | To explore and compare diabetes-related problem solving in urban African Americans in good and poor glycaemic control. | 15 participants with diabetes (7 in poor control, 8 in good control) | 2 focus groups (a good control group and a poor control group) | 1) Focus group data analysis method by Kruger 2) Coding using QSR NUDIST Vivo 3) Review by expert panel | 1. Similar type of primary problems with diabetes self-management were found in both groups. 2. A good control group expressed a positive orientation toward diabetes self-management and problem solving, a rational problem-solving process, and a positive transfer of past experience. 3. A poor control group expressed a negative orientation, careless and avoidant problem-solving processes, and negative transfer of past learning to new situations. |</p>
<table>
<thead>
<tr>
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<th>Methods</th>
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<tbody>
<tr>
<td>Holmstrom et al, 2005</td>
<td>To describe the misunderstandings that Swedish patients with type 2 diabetes have about their illness and treatment.</td>
<td>18 participants with type 2 diabetes Sweden</td>
<td>1. 18 authentic encounters between a patient with diabetes and physician, or a diabetes nurse were video-taped. 2. Patients’ reflection</td>
<td>Phenomenology (thematic analysis)</td>
<td>Misunderstanding of diabetes and treatment were common. Five themes were emerged: 1. type 2 diabetes was understood as not real diabetes in contrast to type 1- a real diabetes. 2. The fear of complications of diabetes was constantly threatening the participants. 3. SMBG and medication was perceived as a routine, not a learning tool. 4. Misunderstanding in diet was commonly identified. 5. Understanding of the benefit of physical exercise was superficial.</td>
</tr>
<tr>
<td>Jeanfreau 2005</td>
<td>To describe the basic social psychological processes experienced during 11 adults’ transitions toward self-management of Type 2 diabetes.</td>
<td>11 participants with Type 2 diabetes Louisiana, US</td>
<td>Grounded theory</td>
<td>Grounded theory (constant comparison, cross-case analysis, use of time, metaphor, narrative analysis)</td>
<td>1. The diagnosis of type 2 diabetes strongly impacts the person’s life. 2. People with type 2 diabetes undergo multiple transitions that must be processed and resolved through the establishment of a sense of renewal and the disengagement from perceived losses. 3. Development of the Diabetic self occurs. 4. People with diabetes can benefit from having contact with other people with the same diagnosis. 5. Adherence ambivalence, mixed feelings regarding the extent to which they should alter their life-style.</td>
</tr>
<tr>
<td>Lawton et al, 2004</td>
<td>To explore the respective merits of urine testing and SMBG from the perspectives of newly diagnosed patients with Type 2 diabetes.</td>
<td>40 participants with Type 2 diabetes no-insulin treated Scotland</td>
<td>Grounded theory (In-depth interviews)</td>
<td>Grounded theory (constant comparison, concurrent data collection and analysis)</td>
<td>1. Participants largely expressed negative views of urine testing when it was compared with SMBG. 2. It was largely assumed that SMBG meter were given to those with people with more serious diabetes. 3. Participants expressed that SMBG was easier to use. 4. For SMBG users, low reading was understood as indicating successful self-management. 5. For some urine testing users, low reading was misunderstood as cure of diabetes or misdiagnosis by their physicians.</td>
</tr>
<tr>
<td>Study</td>
<td>Purpose</td>
<td>Participants</td>
<td>Methods</td>
<td>Analysis</td>
<td>Findings and conclusion</td>
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| Peel et al, 2007| To explore views of patients with Type 2 diabetes about SMBG. | 18 participants with Type 2 diabetesScotland     | In-depth interviews          | Thematic analysis               | 1. The relationship with GP, diabetes nurses, and diabetologists had strong impact on the participants’ self-monitoring.  
2. Interpreting readings was problematic for some participants.  
3. Health care professionals’ lack of interest in SMBG readings was a cause of discontinuity of SMBG in some cases.                                                                                                         |
| Peel et al, 2004| To explore the pros and cons of glucose monitoring from the patients’ perspectives. | 40 participants with Type 2 diabetesScotland     | Qualitative repeat-interview study | Thematic analysis (Grounded theory) | 1. SMBG heightened participants’ awareness of the impact of lifestyle.  
2. SMBG amplified a sense of success or failure about self-management.  
3. High readings often resulted in anxiety and self-blame.  
4. Counter-intuitive readings could have negative affect on participants’ self-management.                                                                                                                                 |

Appendix XI: JBI Grades of Recommendation

In 2007 these grades of recommendation were adopted for evidence of Feasibility, Appropriateness, Meaningfulness and Effectiveness (FAME).

<table>
<thead>
<tr>
<th>Grade of Recommendation</th>
<th>Description</th>
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<tbody>
<tr>
<td>A</td>
<td>Strong support that merits application</td>
</tr>
<tr>
<td>B</td>
<td>Moderate support that warrants consideration of application</td>
</tr>
<tr>
<td>C</td>
<td>Not supported</td>
</tr>
</tbody>
</table>
Appendix XII: Quotations and Extracts Informing the Meta-Synthesis

Synthesized finding 1

**Experience of the use of SMBG is an empowering process that can foster positive and active attitudes toward disease and self-management in everyday life.**

The key findings of included studies in the meta-synthesis and illustrations to support those findings were:

**Category 1. SMBG facilitates peoples' understanding of their own life with diabetes.**

**Finding 1. SMBG helps people to accept the diagnosis of diabetes.** (C)

It had obviously crept up from when I started taking readings. But it got to a point where I felt, y'know, it was high both in the morning and in the evening. So that's when I took it up with the doctor. (p.495) [32]

**Finding 2. SMBG is both a useful and convenient tool to check ones' glycaemic control.**

SMBG is really nice and quick. (p.1047) [33]

(With urine testing) you've got to go to a toilet, and if you go to a toilet, it's usually too small or too whatever you know what I mean. The little meter (blood sugar meter), you just take it out and that's you, there's no problem. (p.1047) [33]

**Finding 3. SMBG provides people with an objective/clear status of their glycaemic control**

....."Well, I would rather have that so's I know exactly what's going on." And I do find it reassuring that when you do your check you can see right away what's registering and that. (p.496) [32]

**Category 2. SMBG provides people with reassurance concerning successful self-management of diabetes**

**Finding 1. A low reading is perceived as an indication of successful disease management.**

(I am)....quite pleased I think if I get a low reading "cos I'm obviously doing something right." (p.185) [34]
I'm obviously doing something right. (p.1047) [33]

**Finding 2. SMBG provides peace of mind.**

It's just sort of comforting to know that it's not going high and it's at the level where it won't cause any complications that's the biggest thing I think...I find it reassuring. (p.185) [32]

**Category 3. SMBG raises positive consciousness towards self-management.**

**Finding 1. People can modify their diet depending on the readings.**

I guess the first thing relevant to diabetes is I do my blood sugar before breakfast. Then I eat breakfast and I eat more or less a standard breakfast....And then, unless something awful happens, the next event is lunch.........And then I eat a sensible lunch...evening comes and I again measure my blood sugar and eat sensible (healthy) supper. (p.131) [35]

**Finding 2. People search for a rational cause for every reading such as food intake prior to the reading.**

Some mornings it would be great, other mornings it would be awful. Sometimes at lunch times it was (sigh) you'd think, "What have I had? Oh I had a digestive biscuit, maybe that was it." But they say you can eat digestive biscuits, you know. So you bla-try to think, "What on earth's caused it?......You think, "well, I've not done that so it shouldnae be high," y'know. And then if you have eaten something and you are high you though, "Well hell bloody mend you, you shouldnae have eaten that. (p.496) [32]

**Finding 3. Self-management of diabetes can become a part of normal life and normal self-image.**

I check my blood sugar. I take seriously the need to count carbohydrates-I don't always do it, but I know it needs to be done...I don't think of diabetes as something separate that I have to deal with; it is simply the way life is... (p.131) [35]
Synthesised finding 2

**People using SMBG weight glycaemic control against perceived life needs.**

**Category 1. Belief impacts on adherence.**

**Finding 1. Questioning the need for regular and frequent use of SMBG.**

I stopped about a year ago because I was getting to the stage I was getting the same sort of levels every day...it wasn't sort of fluctuating up and down. (p.496) [32]

**Finding 2. Negative meanings attached to SMBG**

(Blood glucose meters were given to people who were) a higher level of diabetic. (p.1047) [33]

(My diabetes is) not serious enough (to use SMBG). (p.1047) [33]

**Finding 3. Being sceptical about the accuracy of SMBG**

Yes, stopped totally because, whereas I thought I was doing quite well, and when he (diabetologist) said to me I wasn't, I thought, "Well, that's pointless using that machine." Maybe lulling myself into a false sense of security. (p. 495) [32]

Yes, then I thought, "Well, I've no medical knowledge so." But sometimes I did think, "That's a bit unfair, I've been really good. (p.496) [32]

**Finding 4. Personal preference to use urine testing rather than SMBG**

There are a few people that I have been to who have urine sticks. But that is very much their own business, and I don't get involved. (p.10) [36]

**Category 2. Poor control indicates learning needs and behavioural changes.**

**Finding 1. Knowledge and skills deficiency**

(I struggle to)....work that darned thing, that machine. ( p.185) [34]

One client was documenting 'error' every time meter said error...no one had explained this meant error with machine/strip. Sometimes people stick rigidly to what they think has been said to them, but that isn't what was meant. The patient is at fault in misunderstanding information. (p.9) [36]
I didn't know how to check my blood sugar, and they (Community Health Workers) showed me. Also how to calibrate the machine. (p.214) [37]

**Finding 2. Feelings of self-blame, disappointment, anger and other negative emotional reactions to high readings**

It's telling me I'm being bad maybe or not keeping-not being strict enough-and I think, "Oh, I ain't using you today," or whatever. I think that's why I don't use it. (p.496) [32]

(I was)....letting it (SMBG) rule me. (p.186) [34]

If I feel I don't want to do it (SMBG), I just don't do it.... (p.1024) [38]

**Finding 3. Lack of understanding the value and purpose of SMBG and diabetes self-management**

I do not know the value of that...I cannot say anything about it really. What I could use it for I do not know. I do what they tell me to. (p.150) [39]

I did gather the impression that they didn't really bother too much with the day to day results....they certainly didn't sort of, ask, for these. In fact, when I did-if I told them about it they were inclined to say, "Oh it varies very much depending on whether you've had a cup of tea or biscuit or whatever," At least, I got that impression, and it seemed to me that it---maybe wasn't worth keeping an eye on all of this." (p.494) [32]

Four checks in the week, I do. But I write it down, and that's as far as it goes. (p.495) [32]

**Category 3. Prioritisation of life needs.**

**Finding 1. Physical barriers**

They got me a glucometer....but I had so much trouble...ya gotta get the blood right down on one particular spot. And I couldn't see it good enough, and I'd always get blood all over everything. And I'd get four or five of those strips in there and still wouldn't get an answer. (p.107) [40]

I have only five fingers and they're all sort of pricked useless." (p.186) [34]

**Finding 3. Financial strain**

I check myself every now and then because the strips are expensive. (p.248) [40]

I have the bill (for lancets) to pay as soon as my cheque arrives. (p.248) [40]
Appendix XIII: Additional Detail on Trials Included in this Report

Description of interventions from the existing trials

The trials included in the meta analysis included a range of interventions, were based on populations with elevated HbA1c values and used a variety of comparator methods of monitoring. While the meta analysis did not show statistical heterogeneity, there is often a lack of detail in systematic review reports on the specific interventions that are included. These have been extracted from the included studies and are reported below and focus on describing the types of interventions that included SMBG in the experimental or interventional arm of the study. Where available, details on the control intervention and nature of follow up have also been provided, however, it should be noted that reporting of such data, particularly control group data is not always sufficiently described as to enable detailed write up.

Farmer, 2007 [28]

The objective of this three arm, open trial was to investigate the impact of self-monitoring of blood glucose among non insulin treated participants with type 2 diabetes, the primary outcome was HbA1c, measured at 12 months.[28]

Standard usual care consisted of measurement of HbA1c by a health professional every 3 months. Participants in this group used a diary to record their self-care goals and strategies and were asked to not use blood glucose monitoring unless specifically advised by their General Practitioner. This group had their HbA1c level taken two weeks prior to their scheduled GP review, and were given feedback on their glycaemic control.

The second arm used a blood glucose meter and was advised to contact their GP for interpretation of the results. These participants also used goal setting and review methods from their first assessment. Additionally, they conducted three daily blood glucose recordings on two days each week for the duration of the study. These were both pre and post-prandial. Their goal setting included targets of 4-6mmol/L pre-prandial and 6-8mmol/L post-prandial. Readings outside the range of 4-15mmol/L were a trigger for contacting their GP. Follow up for participants in this arm and the third arm included review of blood glucose results and feedback on their level of control.

The participants in the third arm received training on the conduct and interpretation of blood glucose monitoring results, and application to self managed changes in diet, physical activity, and medication adherence. This more intensive group used goal setting as a means of increasing motivation to maintain adherence with diet, physical activity, and medication regimens. Additionally, this group was encouraged to experiment with monitoring outside prescribed times and frequencies to learn how exercise and dietary...
patterns could influence their glycaemic control. Further to this information, the authors have published a separate description of the interventions offered.[30]

**Allen, 1990 [24]**

The objective of this dual arm, randomised trial was to compare the efficacy and cost of self-monitoring against routine urine testing for participants with type 2 diabetes not being treated with insulin over a period of 6 months.[24] All participants in the trial were given education and advice on diet titrated to their ideal body weight and activity level, with a focus on increased fibre intake. The urine-monitoring group were expected to conduct up to 36 episodes of monitoring per month. The test instruction was for single-voided urine samples prior to each meal every second day, with the aim of achieving negative urine checks.

The self-monitoring blood glucose group were also required to conduct 36 checks per month, undertake monitoring as prescribed, prior to each meal every second day and aim to achieve a BGL of <7.7mmol/L fasting or <8.8mmol/L prior to lunch or dinner. Follow up across both groups was by the individuals General Practitioner, and adherence was tested by observation of BGL checking technique and ability to identify appropriate actions based on the responses via regular monthly visits.[24]

**O’Kane, 2008 [29]**

This prospective trial sought to establish the effectiveness of self-monitoring compared with no monitoring over a 12 month timeframe.[29] Participants in the self-monitoring group were required to conduct four fasting and four postprandial tests per week and were advised (by who is not clear) on how to manage their diet, and exercise based on whether the results were high or low. Adherence was measured by verification of SMBG readings from the monitor at clinic visits. Participants in the control group (no monitoring) were not required to perform any monitoring for the duration of the study.

Both groups received the same structured education program conducted by diabetes nurse practitioners, dietitians, podiatrists and medical staff. The multi disciplinary team reviewed both groups at three monthly intervals. The only difference in treatment algorithm between groups was that the monitoring group also received ongoing advice and support in the interpretation and management of their regular monitoring results.[29]

**Rutten, 1990 [31]**

This trial explored the effectiveness of protocol based blood glucose self-monitoring within the context of general practice over a 12-month time frame.[31]
The unit of randomisation was general practice clinics rather than individual people with type 2 diabetes, those in experimental settings were given a protocol that emphasised home monitoring at self selected times of the day, and to provide monthly feedback to the clinic on their fasting blood glucose. They were also given a program that emphasised weight reduction and management of oral hypoglycaemic agents. Participants were advised to only contact their GP if blood glucose was inadequately balanced. The educational preparation for this study arm was repeated between 2-5 times.

The control group continued with their usual care pattern and consulted their regular GP or specialist at least four times per year and more frequently as required.

Guerci, 2003 [20]

This 6 month trial examined changes in glycaemic control when using self-monitoring blood glucose compared with usual care.[20] The experimental group received specific training and were required to perform six tests per week, this training was conducted by the GP at the time of study enrolment. Participants were followed up every 6 weeks throughout the 24 week study. Visits were used by the participant’s GP to titrate management to keep HbA1c within a specified range and to discuss glycaemic control, weight loss and exercise.

Schwedes, 2002 [21]

This prospective multi centre study compared use of SMBG at meal times with usual care that did not include self-monitoring.[21] The experimental group were required to measure their capillary blood glucose prior to and one hour after main meals 2 days per week, to maintain a diary of glycaemic control and dietary habits. Participants in the experimental group were reviewed every 4 weeks and given counseling to evaluate their self perception, self reflection and self regulation. Blood glucose monitoring technique was also checked by the practice nurse at these visits.

The control group received non standardised counseling with an emphasis on diet and lifestyle choices. It was not clear whether the control group were required to keep a diary of any sort.[21]

Fontbonne, 1989 [22]

This three armed trial examined changes in metabolic control over six months across three endocrine clinics in France.[22] In Group A, participants were assigned to General Practitioner assessment of HbA1c every second month, with written feedback to the participant from their GP; in Group B, participants undertook self-urine glucose measurement twice every second day, on first morning void, and on the first void following the evening meal and an additional test on first void following Sunday
lunch, and in Group C participants undertook self blood glucose monitoring twice every second day, once fasting and two hours after the evening meal, with an additional test two hours after Sunday lunch.

On randomisation, baseline data including HbA1c was collected for each participant, additionally personal dietary recommendations were given, but no specific behavioural strategies were offered. On follow up (each two months for the duration of the trial), weight and HbA1c was again measured, and number of reactive strips used since previous visit was recorded. Dietary adjustments were also discussed between participant and GP on an individual basis, these conversations were limited to the scope of data collected during the trial to avoid contamination.[22]

Davidson, 2005 [19]

This 6 month trial sought to establish the effects of self-monitoring blood glucose on HbA1c levels, with an emphasis on post prandial measurements of capillary glucose levels by participants in the experimental arm of the trial.[19] Participants in both groups met with a dietitian 5 times throughout the study to discuss nutritional goals and receive education and counseling related to dietary based glycaemic control. A nurse (blinded to allocation) also provided regular review and used a treatment algorithm to guide therapeutic decisions. Participants in the monitoring group were requested (and adherence was checked) to monitor their blood glucose levels prior to meals, and between 1-2 hours after meals 6 days per week, with equal spread across the 3 main meals. The study did not include any further details on either the experimental or control group interventions.[19]

Muchmore, 1994 [23]

This small trial sought to establish whether the combination of carbohydrate counting and SMBG would benefit overweight people.[23] Both groups received the same intervention for the first 8 weeks, consisting of a ninety minute, facilitated weekly meeting to undertake a formal weight loss program and individual counseling by a diabetes nurse educator and a nutritionist. Following week 8, the intervention groups also received group and individual education on carbohydrate counting, while the control groups were allocated the same amount of time to general counseling related to nutritional management. The intervention groups were also taught SMBG technique by the diabetes nurse educator and were required to demonstrate competency prior to commencing testing 6 times daily for 4 weeks. After this 4 week period, the frequency of testing was reduced pre and post prandial once per day for 16 weeks, followed by individually determined testing frequencies up to 44 weeks. The control group received the same amount of time with health professionals, at each follow up point, but did not receive information on carbohydrate counting, although the guidance they were offered was based on current national guidelines at the time of publication.