APPENDIX A. DATA COLLECTION FORMS

VA-EPC Self-Monitoring of Blood Glucose
Article Screener

Article ID **Reviewers:** **Assigned on:**

Citation:

First Author:_____

Complete Q7 & Q8 on ALL forms

1. Is the study a test of efficacy or effectiveness of SMBG alone or as part of a multi-component intervention?

(Check all that apply)
Alone……..… □
Multi-component….……..…. □
No……..□ **(STOP)**

2. Study design

(Circle one)
RCT/CCT…….…..…1
Review article: systematic or M-A....2
Observational Study (cohort, case control, etc)……3 **(STOP)**
Review article: Not systematic……..4 **(STOP)**
Review article: letter, editorial, other syst review…….. 5 **(STOP)**
Other……..6 **(STOP)**

2a. Is this a crossover study?

(Circle one)
Yes……1
No…….0

3. Is A1c reported as an outcome?

(Circle one)
Yes……1
No…….0

4. Is hypoglycemia reported as an outcome?

(Circle one)
Yes……1
No…….0

5. Is the frequency of SMBG testing reported?

(Circle one)
Yes……1
No…….0

6. If RCT/CCT or observational study, what is the duration of the follow up?

(Circle one)
< 12 weeks/not an RCT/CCT or observational study……0 **(STOP)**
12 weeks or greater ……1

If >=12 wks, write in the duration

___ ___ ___	___ ___
Duration	**Units**

Units
01. Days 04. Years
02. Weeks 05. NR
03. Months

7. If this article meets no other criterion, should it be saved for background?

(Circle one)
Yes……1
No…….0

8. Are any of the subjects identified as Veterans?

(Circle one)
Yes……1
No…….0

Notes

VA Self-Monitoring of Blood Glucose Project-Detailed Review Form

Article ID: Reviewer:

First Author:
(Last Name Only)

Study Number: ___of____Description:_____
(Enter '1of 1' if only one) (if more than one **study)**

FINAL 12-14-06

1. Do you think that this article might include the same data as another study?

(CIRCLE ONE)
Yes.....1
No.....2

If YES enter IDs:

ID(s) : _____

2. Design: (CIRCLE ONE)
RCT.....1
CCT 2
Other design..... .....3 (STOP)

3. Is the study described as randomized? (CIRCLE ONE)
Yes.....1
No 2

4. If the study was randomized, was method of randomization appropriate? (CIRCLE ONE)
Yes.....1
No.....2
Method not described.....8
Not applicable (not randomized) 9

5. Is the study described (with respect to SMBG)as: (CIRCLE ONE)
Double blind.....1
Single blind, patient..... 2
Single blind, outcome assessment 3
Single blind, not described 4
Open.....5
Blinding not described.....8
Not applicable 9

6. If reported, was the method of double blinding appropriate? (CIRCLE ONE)
Yes.....1
No.....2
Double blinding method not described 8
Not applicable 9

7. If study was randomized, did the method of randomization provide for concealment of allocation? (CIRCLE ONE)
Yes.....1
No 2
Concealment not described.....8
Not applicable (not randomized) 9

8. Are withdrawals (W) and dropouts (D) described? (CIRCLE ONE)
Yes, reason described for **all** W and D.....1
Yes, reason described for **some** W and D.....2
Not described.....8
Not applicable 9

9. Is the study a cross-over study design? (CIRCLE ONE)
Yes.....1
No 2

10. Sample size: (Enter 999 for not reported)

Enrolled: _____ _____ _____

Followed-up/analyzed: _____ _____ _____

11. What were the characteristics of the patient population?

A. Demographics:

% women = _____ _____

(CHECK ALL THAT APPLY)

Caucasian ..... ❑
African Ancestry ..... ❑
Hispanic..... ❑
Other (Specify: _____) ..... ❑
Demographics not reported..... ❑

12. What was reported for the following questions regarding subjects' ages? (Enter number 999 for not reported)

Mean Age..... _____
Median Age..... _____
Age Range....._____ to _____

13. Was BMI reported?

(CIRCLE ONE)

Yes.....1
No.....2

If yes, please enter the following: (Enter number 999 for not reported)

Mean BMI..... _____
Median BMI..... _____
BMI Range....._____ to _____

14. Was weight reported?

(CIRCLE ONE)

Yes.....1
No.....2

If yes, please enter the following:

	Weight	Units
Mean weight.....	_____	_____
Median weight	_____	_____
Weight Range..._____ to	_____	_____

Units
1. kilograms
2. pounds
3. NA
4. ND
999. NR

15. Was duration of diabetes reported?

(CIRCLE ONE)

Yes.....1
No.....0

If yes, please enter the following:

	Time	Units
Mean time.....	_____	_____
Median time.....	_____	_____
Time Range..._____ to	_____	_____

Units
1. Hour 5. Year
2. Day 8. ND
3. Week 9. NA
4. Month 999.NR

16. Which of the following co-morbidities were reported on:

(CHECK ALL THAT APPLY)

Myocardial infarction..... ❑
Congestive Heart Failure ..... ❑
Peripheral vascular disease ..... ❑
Cerobrovascular disease..... ❑
Dementia..... ❑
Chronic pulmonary disease..... ❑
Rheumatologic disease..... ❑
Peptic ulcer disease..... ❑
Mild liver disease..... ❑
Hemiplegia or paraplegia ..... ❑
Renal disease ..... ❑
Malignancy, leukemia, lymphoma ..... ❑
Moderate-severe liver disease..... ❑
AIDS ..... ❑

VA Self-Monitoring of Blood Glucose Project-Detailed Review Form

Enter sample size and intervention/exposure data for each arm beginning with CONTROL/USUAL CARE for arm 1, then in order of first mention. For observational studies answer only columns denoted with asterisks (*):

Arm/ Group	Sample size *	Components * (check all that apply)	Total # of Visits	Frequency of SMBG	Number of Days per week	Duration of * treatment	Units *	Co-therapies(s)
1	P PY CNTRL _____ N ENTERING CASES _____ N COMPLETING	SMBG.....❑ Exercise.....❑ Dietician.....❑ Other.....❑ Pt Control.....❑ Not applicable..❑ Not Reported..❑ Diabetes counseling/Education.....❑	_____	**Control**	_____	_____	_____	_____ _____ _____
2	P PY CNTRL _____ N ENTERING CASES _____ N COMPLETING	SMBG.....❑ Exercise.....❑ Dietician.....❑ Other.....❑ Pt Control.....❑ Not applicable..❑ Not Reported..❑ Diabetes counseling/Education.....❑	_____	GD.....❑ BID.....❑ TID.....❑ QID.....❑ PP.....❑ Other...❑ Before/After meals...❑ NR.....❑	_____	_____	_____	_____ _____ _____
3	P PY CNTRL _____ N ENTERING CASES _____ N COMPLETING	SMBG.....❑ Exercise.....❑ Dietician.....❑ Other.....❑ Pt Control.....❑ Not applicable..❑ Not Reported..❑ Diabetes counseling/Education.....❑	_____	GD.....❑ BID.....❑ TID.....❑ QID.....❑ PP.....❑ Other...❑ Before/After meals...❑ NR.....❑	_____	_____	_____	_____ _____ _____
4	P PY CNTRL _____ N ENTERING CASES _____ N COMPLETING	SMBG.....❑ Exercise.....❑ Dietician.....❑ Other.....❑ Pt Control.....❑ Not applicable..❑ Not Reported..❑ Diabetes counseling/Education.....❑	_____	GD.....❑ BID.....❑ TID.....❑ QID.....❑ PP.....❑ Other...❑ Before/After meals...❑ NR.....❑	_____	_____	_____	_____ _____ _____
	Enter a number for N entering and N completing or enter 9999 if not reported. If observational study, circle appropriate unit of measurement: P Persons PY People years CNTRL Control CASES Cases		Enter # of visits or contact s		Enter a number 997. Variable 998. ND 999. NA	Enter a number 997. Variable 998. ND 999. NA	Enter a number 1.Hour 2.Day 3.Week 4.Month 5.Year 8.ND, 9. NA	

Outcomes

17. Please check the type of outcomes measured. For case control enter the outcome that defines the study:

(CHECK ALL THAT APPLY)

HbA1c ..... ❑
Fasting glucose ..... ❑

Fructose ..... ❑
BMI/Weight loss ..... ❑

Fast v. meal glucose ..... ❑
Health related quality of life ..... ❑

Evaluation

18. When, relative to the start of the intervention, were outcomes reported?

(Enter the number/code in the appropriate box)

	Control		Intervention	
	Number	Units	Number	Units
1st follow-up				
2nd follow-up				
3rd follow-up				
4th follow-up				
5th follow-up				
6th follow-up				
Additional follow-ups				

Units

1. Hour	5. Year
2. Day	8. ND
3. Week	9. NA
4. Month	999. NR

Adverse Events

19. Were any of the following adverse events mentioned?

(Check all that apply)

Hypoglycemia ..... ❑
Other adverse events ..... ❑
No Adverse events ..... ❑

Not described ..... ❑
Not applicable ..... ❑

20. Is there a reference that needs to be checked?

(Circle one)

Yes 1
No 2
If YES, which one(s) :

_____

(Enter reference # and/or author or 9999 if don't know.)

SMBG Project- Randomized Controlled Trials Quality Measurement

Article ID:_____ Reviewer:

First Author:
_____

PILOT 03/14/07

1. Treatment Allocation

a. Was a method of randomization performed?

Yes ..... ❑
No..... ❑
Don't know ..... ❑

b. Was the treatment allocation concealed?

Yes ..... ❑
No..... ❑
Don't know ..... ❑

2. Were the groups similar at baseline regarding the most important prognostic indicators?

Yes ..... ❑
No..... ❑
Don't know ..... ❑

3. Were the eligibility criteria specified?

Yes ..... ❑
No..... ❑
Don't know ..... ❑

4. Was the outcome assessor blinded?

Yes ..... ❑
No..... ❑
Don't know ..... ❑

5. Was the care provider blinded?

Yes ..... ❑
No..... ❑
Don't know ..... ❑

6. Was the patient blinded?

Yes ..... ❑
No..... ❑
Don't know ..... ❑

7. Were point estimates and measures of variability presented for the primary outcome measures?

Yes ..... ❑
No..... ❑
Don't know ..... ❑

8. Did the analysis include an intention-to-treat analysis?

Yes ..... ❑
No..... ❑
Don't know ..... ❑

APPENDIX B. PEER REVIEW COMMENTS TABLE

Peer Review Comments Table 1.

Reviewer	Section	Comment	Change
Pogach	Background	The investigators frame the background in terms of targets and measures. I would suggest that the background by Guerci in the ASIA study frames the question better: "Theoretically, SMBG can improve compliance with recommendations on diet and exercise and medication regimens. The American Diabetes Association has recommended that the optimal frequency of SMBG for patients with type 2 diabetes should be adequate to facilitate reaching glucose goals. This hypothesis is based on the fact that lifestyle changes are facilitated by SMBG. Under these conditions, we should expect an improvement of glycemic control SMBG increases patient management costs, and because of the high prevalence of type 2 diabetes, efforts to establish the efficacy of SMBG in type 2 diabetes mellitus are of greater relevance."	This suggested change was made, however, reference to targets was kept in this revision as the key questions from VA concern targets and not general improvements in glycemic control.
Pogach	Background	If the investigators want to include a discussion of targets, their reliance on ADA Clinical Practice Recommendations is incomplete, and needs to take into account other guidelines and be more complete in describing the ADA recommendations. The authors frame the ADA recommendations to bias the reviewer towards tight control for most. "The Association (ADA) recommends an A1c goal of <7% for "patients in general" but adds that, "for the individual patient," intensive therapy to achieve an A1c as close to normal (<6%) without hypoglycemia is the goal, although the latter recommendation is based on weaker or incomplete evidence.4 ". To be evidence explicit and transparent, the investigators need to note (to be evidence explicit) that multiple guidelines, including the ADA, American Geriatric Society, and VHA-DOD discuss the need for less stringent targets based upon life expectancy (AGS and VA) or age (ADA >65 years of age), comorbid conditions, and side effects (including hypoglycemia). The ADA "in general" thus refers to individuals who are younger without contraindications. Moreover, the NHLBI study permits an A1c between 7.0-7.9%(expected mean 7.5%) in the control group.	We deemphasized the focus about targets and the ADA, but retained the text about VA performance measures as targets, since the key questions given to us by VA concern efficacy at achieving target glycemic control levels.
Aron	Introduction	This evidence review is being performed by VA. Therefore, it is quite surprising that the recommendations of the American Diabetes Association are so prominently stated. The recent article in the New York Times related to conflicts of interest in determining performance measures should give us pause. I realize that this is in the introduction and meant to provide context, but I would rather have seen studies cited, e.g., DCCT and UKPDS rather than the ADA (or any other advocacy organization).	Text about ADA has been deemphasized.
Pogach	Background	I don't understand why performance measurement is pertinent to the introduction. Only NCQA recommends public reporting for A1c <7% (see Pogach, Engelgau, Aron JAMA 2007). Thus, I would recommend removing references to performance measures as being not relevant.	The text regarding performance measures is retained because VA's questions to us were framed in terms of target levels.
Aron	Study Identification/ Study Selection	Some of the criteria for study inclusion were not explicit. I am referring here specifically to the statement that studies not included in other meta-analyses/reviews were included in this one. The reasons why are not included.	The reasons were indicated in Table 1, and no change was made in the text.
Pogach	Study Identification/ Study Selection	I am not satisfied with the investigators' explanation that "we included studies rejected by Balk and/or by Welschen for a variety of reasons (italics mine)".	
Pogach	Study Identification/ Study Selection	If the investigators believe that their inclusion is still justified, in contrast to the AHRQ Evidence Synthesis (Balk report) the investigators should provide an explicit explanation of the reasons why they disagreed.	
Pogach	Study Identification/ Study Selection	The investigators frame the meta-analysis by noting that it is to address SMBG in individuals on oral hypo-glycemic medications. It is unclear to me whether the Kwan study included individuals on insulin; the Cho study did include 7 out of 40 control groups on insulin (4 insulin only) and 11 of 40 intervention group (6 insulin only). If these studies are included, this needs to be noted as a limitation of generalization of the study findings. In addition, the willingness and ability to use the internet to download meter results may prevent generalization to other populations with lower Socio-economic position.	We agree and the articles by Cho and Kwon were removed from the analysis.
Aron	Study Identification/ Study Selection	P17. "Initial screening of the articles resulted in 13 RCTs that measured the effect of SMBG compared to a group not receiving SMBG and monitored A1c levels with at least three months of follow-up. Two were excluded; one because the trial presented duplicate data, the other because the trial compared a control group of SMBG to an intervention group of SMBG plus other components. (Figure 1)" Unfortunately, this is not the case. The Cho study states: "We performed a diabetes education program again to standardize every patient's education for diabetes management and the method and frequency of self-monitoring of blood glucose (SMBG) according to glucose control." The control group used SMBG. The only difference was that the experimental group had the internet intervention. Why is this study included?	

Peer Review Comments Table 1. Continued

Reviewer	Section	Comment	Change
Pogach	Study Identification/ Study Selection	The investigators note that "Initial screening of the articles resulted in 13 RCTs that measured the effect of SMBG compared to a group not receiving SMBG and monitored A1c levels with at least three months of follow-up. Two were excluded; one because the trial presented duplicate data, the other because the trial compared a control group of SMBG to an intervention group of SMBG plus other components. (Figure 1)." By these criteria, the Kwon (2004) and Cho (2006) articles should be excluded, since the control group and intervention group each received the same number of monitoring strips and received the same instructions on monitoring. The intervention being tested was therefore the "Internet Based Blood Glucose Monitoring System", which essentially increased the frequency of access to the diabetes team; electronic case management in a sense. It's my perspective that the investigators are obligated to remove these studies from the main analysis.	We agree and the articles by Cho and Kwon were removed from the analysis.
Pogach	Study Identification/ Study Selection	The investigators note that "Eligible study designs included controlled clinical trials, RCTs, and systematic reviews/meta-analyses. Observational studies, case reports, non-systematic reviews, letters to the editor and other similar contributions were excluded." This review separately comments on observational studies done in veterans, but not observational studies of non-veterans. The investigators need to be consistent; either remove them or separately discuss all observational studies. I suggest excluding them as not being relevant to the meta-analysis as defined. In addition, the investigators, in their criteria for inclusion, do not include observational studies. None the less, they include older retrospective VA studies. If they choose to include VA studies, they should modify their inclusion/exclusion criteria to include others. Otherwise (and given that meta-analyses of RCTs have significant limitations as well), I would exclude them.	We have revised the methods and results to indicate that the observational studies in veterans were searched for and reported on as evidence regarding the effectiveness of SMBG in the VA patient population and delivery system, as opposed to the efficacy evidence from RCTs.
Aron	Study Identification/ Study Selection	P13 "Eligible study designs included controlled clinical trials, RCTs, and systematic reviews/meta-analyses. Observational studies, case reports, non-systematic reviews, letters to the editor and other similar contributions were excluded." However, in discussing studies in veterans, observational studies were included. It is not clear why they were included here and not elsewhere. The reasons should be made explicit. That also raises the question about using observational studies in non-veterans.	
Aron	Study Identification/ Study Selection	Inconsistencies aside, it is an interesting philosophical issue what the appropriate control group should be in studies like this. Individuals with diabetes have free access to SMBG, i.e., can do it without a prescription. What is usual care in this regard?	We agree this is an interesting question. We agree that the Cho and Kwon studies aren't comparing SMBG to no SMBG , so as indicated above, we deleted these. We interpreted VA's main interest as SMBG vs. no SMBG at all.
Pogach	Data Synthesis	A significant positive aspect of this study is to adjust for baseline A1c. This is welcome, and should be commented upon in more detail (see also data synthesis).	We have added text about this.
Pogach	Data Synthesis	The reviewer's perspective is that adjusting for baseline HbA1c is an appropriate consideration and can be defended (see Bloomgarden Z et al Lower Baseline Glycemia Reduces Apparent Oral Agent Glucose-Lowering Efficacy: A meta-regression analysis Diabetes Care 2006 29: 2137-2139. This should be commented upon in greater detail.	
Aron	Data Synthesis	It is an interesting issue whether or not to adjust for baseline A1c. I would have liked to see both adjusted and unadjusted analyses.	Only unadjusted pooled results are presented in Figure 2. Figure 3 presents the pooled result of studies adjusting for baseline levels of A1c at the individual study level. The meta-regression analysis assesses the relationship between baseline A1c and efficacy of SMBG. So all three kinds of analyses are already included in the report - unadjusted, adjusted at the individual study level, and adjusted at the pooled analyses level.

Peer Review Comments Table 1. Continued

Reviewer	Section	Comment	Change
Aron	Conclusions	To reiterate, it is not clear why observational studies are included and I don't see how one can draw the conclusion that veteran patients may not be receiving the full possible benefits of SMBG. I happen to agree with the conclusion, but that comes more from my experience in clinic than from these studies.	The reason for including observational VA studies has now been made clear.
Pogach	Conclusions	In multiple sections of the report the investigators state that "The results of the studies with Veterans do not negate the evidence from RCTs that the addition of SMBG and education can result in a decrease in A1c levels of about 0.3% absolute at six months and up to one year. As previously noted, I do not know why observational studies are included at all, and recommend that that the observational studies be removed.	Observational studies were included as the only available evidence of effectiveness in VA patients.
Pogach	Conclusions	The investigators, on multiple occasions state "that these studies do raise the question of whether veteran patients are receiving the full possible benefits of SMBG." It should be removed. Further, these statements indicate to me a pre-conceived bias, especially since the issue of SMBG efficacy, in individuals who are diet controlled or stable is controversial, and cannot be fully resolved by a meta-analysis. Furthermore, and this is more pertinent to the issue, the investigators indicated that "we draw no conclusion about the effect of frequency of SMBG monitoring on A1c values, and judge the strength of the evidence to be very low."	We disagree with the suggestion to remove the statement about effectiveness of SMBG in Veterans, as there is evidence to support no effectiveness.
Pogach	Future Research	One important limitation of the meta-analysis is that earlier studies from the early mid-90s used SMBG methodology that was much more inconvenient than current methodology. Glucose meters from that era required substantially more blood, transfer to the monitoring strip was more cumbersome, and data feedback from the meters less user friendly if present at all. All of these factors may have contributed to inconclusive results from early studies, and emphasizes the need for research in this area.	We have added this to future research
Pogach	Future Research	The investigators note: "The evidence is insufficient to draw conclusions about which components of SMBG (additional-education, algorithms or other techniques to adjust medication) and frequency of testing are most associated with better results. More research is needed." Agree, this limitation is important and should be better highlighted.	We added additional text on this.
Pogach	Future Research	"However, observational studies in the VA do not report differences in A1c levels between Veterans using or not using SMBG supplies. This raises the question about implementation: more research is needed to understand if implementation of SMBG in a typical VA clinic setting is sufficient for Veterans to receive the full benefit reported in clinical trials." The more pertinent issue is efficacy not effectiveness (see item 2). Please delete this statement.	We disagree, and note that VA's key question to us concerned effectiveness as well as efficacy.
Pogach	Future Research	"Additionally, data are needed about the cost-effectiveness of SMBG in a VA setting.". Unless I am mistaken doesn't cost effectiveness analysis depend upon efficacy data? This seems premature to me. Even if such data were available, it would also involve a number of assumptions that would have to be based upon Markov modeling.	We agree this would involve modeling, but disagree that such an effort is premature. Our analysis of efficacy data support that SMBG is efficacious, therefore a CEA analysis may help better determine which variables are most important in determining cost effectiveness and the identification of these important variables could then target new studies.
Pogach	Future Research	Impact of SMBG on medication adherence should be evaluated. Non-compliance with oral-antiglycemic medications is a recognized issue among veterans and among non-veterans. It is also possible the system interventions to improve adherence may not need to incorporate increased frequency of SMBG.	We have added this to future research.
Pogach	Future Research	I have noted my comments about the Cho/Kwon study design in the previous section. Nonetheless, although I have some reservations about the study design for the purpose of this meta-analysis given the author's inclusion/exclusion criteria, I think that the study design is actually more relevant to what is now considered usual care; e.g., most persons with type 2 diabetes with training in SMBG and some supplies. (Key question 4). This might be mentioned under future research; i.e., that usual care (infrequent) for SMBG be the control group for persons with diabetes on oral agents.	We added this to future research.

Peer Review Comments Table 1. Continued

Reviewer	Section	Comment	Change
Aron	Future Research	This section seems pretty generic for the most part. More problematic is that SMBG is viewed completely in isolation. Most diabetes interventions are complex and involve more than activity. Moreover, other outcomes are relevant, e.g., behavior change. Finally, what does pramlintide have to do with this? That seemed to come out of the blue.	We have revised the future research section and also deleted the reference to pramlintide.
Pogach	Future Research	I substantially disagree with the language of the research implications. "Our review of existing data support the beneficial effect of SMBG on A1c levels in the context of a clinical trial. Although improvement in A1c is modest, it is equivalent to that achieved with some of the newer medical therapies for diabetes, such as pramlintide.44,45" As noted previously, I believe that there is a bias by including the Cho and Kwan studies. However, based upon the main analysis of this study, it is probably most pertinent to note that the benefit of SMBG [including bundled interventions] for persons on oral hypoglycemic agents is similar to that found for diabetes education interventions, many of which included SMBG (Norris et al, Diabetes Care, 2002). Better designed prospective clinical trials, especially for individuals with stable glycemic control (e.g., at their target A1c) are necessary. Mentioning a specific medication is inappropriate. Please delete.	We have dropped the use of pramlintide as a reference for efficacy and have inserted the diabetes education.
Pogach	Future Research	I would recommend, as noted previously, that future research include alternative study designs to reflect the fact that SMBG is considered usual care for patients on medication (though not on diet alone).	We made this change.
Pogach	Future Research	Use of SMBG in context of VHA Health Buddy would be an appropriate area of investigation.	We added this to future research.
Pogach	Overall Evaluation	The investigators were thorough in their identification of possible trials for inclusion in their report, but the reviewer has concerns that the included randomized trials articles from Cho and Kwan did not meet the stated inclusion criteria. This introduces biases which are not fully addressed in their discussion/and conclusions. This is a significant flaw of the study as written, and it needs to be more fully addressed. If the investigators wish to justify their inclusion, then the reviewer suggests that the meta-analysis should be presented with and without these studies to permit comparison with the AHRQ evidence synthesis.	We agree that leaving in Cho and Kwon introduced biased and have therefore removed them from the analyses in this revision.

APPENDIX C. EVIDENCE TABLE

Evidence Table 1. Randomized Controlled Trials Evaluating the Self-Monitoring of Blood Glucose

Author, Year	Sample Size Enroll/ Follow-up	Dur. of Diabetes inYears	Mean Age	Mean Weight (kg) / BMI	% Women / Race	Delphi List Quality Criteria			Arm/ Group					Outcome	Adverse Events
						Method of Randomization / Allocation Concealment / Similarity at Baseline between groups	Eligibility criteria specified / Outcome assessor blind / Care provider blind / Patients blinded	Point estimates & measures of variability for primary outcome variable / Did analysis included intention to treat analysis	Sample Size entering	Components	# Visit	Freq of SMBG Times/ Week	Dur. of Tx		
Wing RR et al., 1986 [19]	50 / 45	NR	54	98 / NR	78% / NR	Yes	Yes	Yes	25	Exercise Counseling/Edu	20	Control	62 wks	A1c Fasting Glucose BMI/Weight loss	ND
						No	No	No	25	SMBG Exercise Pt Control led Counseling/Edu	20	5.4	62 wks		
						No	No								
							No								
Fontbonne A et al., 1989 [20]	208 / 164	13	55	73 / 27	42% / NR	No	Yes	Yes	68	Counseling/Edu	4	Control	6 mths	A1c BMI/Weight Loss	ND
						No	No	No	68	SMBG Counseling/Edu	4	7.5	6 mths		
						Yes	No								
							No								
Rutten G et al., 1990 [23]	149 / 127	8.1	63	75 / NR	65% / NR	No	Yes	Yes	83	NR	NA	Control	1 year	A1c BMI/Weight Loss	ND
						No	No	No	66	SMBG Dietician Counseling/Edu	Vari-able	NR	1 year		
						No	No								
							No								
Muchmore DB et al., 1994 [24]	29 / 23	5	59	99 / 34	61% / NR	Yes	Yes	Yes	14	Dietician Counseling/Edu	8	Control	44 wks	A1c BMI/Weight Loss HRQOL*	ND
						No	No	Yes	15	SMBG Dietician Counseling/Edu	8	3	44 wks		
						Yes	No								
							No								
Jaber LA et al., 1996 [25]	45 / 39	6	62	90 / 33	70% / African Ancestry	No	Yes	Yes	22	NR	2	Control	4 mths	A1c Fasting Glucose HRQOL*	Hypogly-cemia
						No	No	No	23	SMBG Pt Controlled Counseling/Edu	NR	8	4 mths		
						Yes	No								
							No								
Kibriya MG, et al., 1999 [27]	64 / 64	NR	50	60 / 24	45% / NR	No	Yes	Yes	32	Counseling/Edu	19	Control	18 mths	A1c Fasting Glucose	Hypogly-cemia
						No	No	No	32	SMBG Pt Control led Counseling/Edu	7	1	18 mths		
						No	No								
							No								
Schwedes U, et al., 2002 [29]	250 / 223	5.3	60	89 / 31	48% / NR	Yes	Yes	Yes	110+	Counseling/Edu	6	Control	24 wks	A1c BMI/Weight Loss HRQOL*	ND
						No	No	No	113+	SMBG Dietician Counseling/Edu	6	12	24 wks		
						Yes	No								
							No								
Guerci B, et al., 2003 [30]	988 / 689	8.1	62	83 / 30	45% / NR	No	Yes	Yes	344+	Counseling/Edu	5	Control	6 mths	A1c Fasting Glucose	Hypogly-cemia Other
						No	No	Yes	345+	SMBG Counseling/Edu	5	6	6 mths		
						Yes	No								
							No								
Davidson MB, et al., 2005 [32]	89 / 88	5.6	50	82.3 / 32.5	74% / African Ancestry, Hispanic, Other	No	Yes	Yes	45	Dietician Other	13	Control	6 mths	A1c BMI/Weight Loss	ND
						No	Yes	Yes	43	SMBG Dietician Other	13	36	6 mths		
						Yes	Yes								
							No								
Farmer A et al., 2007[33]	453 / 453	3	66	NR / 31.3	43% / NR	Yes	Yes	Yes	152	Usual Care	NR	Control	12 mths	A1c BMI/Weight Loss	Hypogly-ceima
						Yes	No		150	SMBG	NR	6	12 mths		
						Yes	No	Yes	151	SMBG Patient Control	NR	NR	12 mths		
							No								

ND=Not Described, NR=Not Reported, NA=Not applicable, *HRQOL=Health Related Quality of Life, +No entering sample size reported, this is the sample size completing the trial