Self-Management Education for Adults With Type 2 Diabetes

A meta-analysis of the effect on glycemic control

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OBJECTIVE — To evaluate the efficacy of self-management education on GHb in adults with type 2 diabetes.

RESEARCH DESIGN AND METHODS — We searched for English language trials in Medline (1980–1999), Cinahl (1982–1999), and the Educational Resources Information Center database (ERIC) (1980–1999), and we manually searched review articles, journals with highest topic relevance, and reference lists of included articles. Studies were included if they were randomized controlled trials that were published in the English language, tested the effect of self-management education on adults with type 2 diabetes, and reported extractable data on the effect of treatment on GHb. A total of 31 studies of 463 initially identified articles met selection criteria. We computed net change in GHb, stratified by follow-up interval, tested for trial heterogeneity, and calculated pooled effects sizes using random effects models. We examined the effect of baseline GHb, follow-up interval, and intervention characteristics on GHb.

RESULTS — On average, the intervention decreased GHb by 0.76% (95% CI 0.34–1.18) more than the control group at immediate follow-up; by 0.26% (0.21% increase - 0.73% decrease) at 1–3 months of follow-up; and by 0.26% (0.05–0.48) at ≥4 months of follow-up. GHb decreased more with additional contact time between participant and educator; a decrease of 1% was noted for every additional 23.6 h (13.3–105.4) of contact.

CONCLUSIONS — Self-management education improves GHb levels at immediate follow-up, and increased contact time increases the effect. The benefit declines 1–3 months after the intervention ceases, however, suggesting that learned behaviors change over time. Further research is needed to develop interventions effective in maintaining long-term glycemic control.

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Diabetes is a common, costly condition associated with significant morbidity and mortality (1,2). Recent studies have found dramatic increases in diabetes during the last decade (3). Diabetes self-management education (DSME), the process of teaching individuals to manage their diabetes (4), has been considered an important part of the clinical management of individuals with diabetes since the 1930s and the work of the Joslin Diabetes Center (5). The American Diabetes Association recommends assessment of self-management skills and knowledge of diabetes at least annually, and the provision or encouragement of continuing diabetes education (6). One of the diabetes-related objectives of *Healthy People 2010* (7) is to increase to 60%, from the 1998 baseline level of 40%, the proportion of individuals with diabetes who receive formal diabetes education. The goals of self-management education are to optimize metabolic control, prevent acute and chronic complications, and optimize quality of life, while keeping costs acceptable (8). There are significant knowledge and skill deficits in 50–80% of patients with diabetes (9), and ideal glycemic control (HbA_{1c} <7.0%) (6) is achieved in less than half of individuals with type 2 diabetes (10). A large body of literature has developed on diabetes education and its efficacy, including several important quantitative reviews showing positive effects of diabetes education. However, educational techniques have evolved over the last decade since these reviews (11–13), and they have shifted from didactic presentations to interventions involving patient "empowerment" (14,15), with participation and collaboration.

The objective of this study was to systematically review reports of published, randomized, controlled trials to ascertain the efficacy of DSME in adults with type 2 diabetes, provide summary measures of its effect on GHb, and identify predictors of effect. This quantitative review focusing on glycemic control follows an earlier work by Norris et al. (16) that provided descriptive details and a qualitative summary of the efficacy of DSME over a broad range of outcomes.

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Abbreviations: DCCT, Diabetes Control and Complications Trial; DSME, diabetes self-management education.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

RESEARCH DESIGN AND METHODS

Data sources

We searched the English-language medical literature published between January 1980 and December 1999 using the Medline database of the National Library of Medicine, the Educational Resources Information Center database (ERIC), and

the Nursing and Allied Health database (Cinahl), which commenced in 1982. The medical subject headings (MeSH) we searched were "health education" combined with "diabetes mellitus," including all subheadings. Searches were confined to the English language because in a recent study, effect sizes did not differ significantly in language-restricted meta-analyses compared with language-inclusive ones (17), and there is some evidence of lower quality in the non-English medical literature (18). Abstracts were not included because they generally had insufficient information to assess the validity of the study by the criteria used in this meta-analysis. Dissertations were also excluded because the available abstracts contained insufficient information for evaluation and the full text was rarely available. We reviewed titles of articles extracted by the search for relevance to the efficacy of diabetes education, and we retrieved the full-text articles for those that were potentially relevant. Because automated databases are incomplete (19,20), we manually searched journals expected to have the highest relevance. These journals were: *Diabetes Care*, *The Diabetes Educator*, *Diabetes Research and Clinical Practice*, *Diabetologia*, and *Diabetic Medicine*. Experts in the field of diabetes education were consulted for additional relevant citations.

Study selection

We selected reports of randomized controlled trials because this type of study design generally supports maximum validity and causal inference (21). We reviewed only studies in which all or most subjects had type 2 diabetes. If the type of diabetes was unclear, then the study was included if the mean age was >30 years because most of these patients were likely to have type 2 diabetes. To examine as broadly as possible the efficacy of diabetes self-management education, we included studies of subjects >18 years of age with type 2 diabetes, with any degree of disease severity and any comorbidity. We also included interventions in all settings, and we did not exclude interventions based on provider type, medium (written, oral, video, or computer), whether they were individual or group based, or duration and intensity. We included studies in which other interventions were delivered in addition to DSME only if the effects of the educational component could be examined separately. We included studies that reported GHb outcomes, including total GHb, HbA_1, or HbA_{1c}.

Data extraction

Data from eligible studies were extracted by one of the authors (S.L.N.), and all extracted data were checked by a second person (Phyllis Nichols). Extraction was not blinded to author or institution because there is no evidence that blinding decreases bias in the conduct of systematic reviews and meta-analyses (22,23). We included only data reported in the study; we did not attempt to contact the authors due the lengthy period of time over which these studies were published and concerns regarding recall bias in the information that might be provided (24). Data were abstracted on participant characteristics, including age, diabetes treatment (insulin with or without oral hypoglycemic agents, diet only, or diet plus oral hypoglycemic agents), baseline GHb, and psychosocial attributes.

We classified DSME interventions into one of the following categories by their primary educational focus, as described previously (16): knowledge or information; lifestyle behaviors (including diet and physical activity); skill development, including skills to improve glycemic control (e.g., self-monitoring of blood glucose) as well as skills to prevent and identify complications (e.g., foot care); and coping skills (to improve psychosocial function, including interventions that used empowerment techniques or promoted relaxation or self-efficacy). We subclassified studies with a focus on knowledge or information by primary type of educational approach, which could be didactic or collaborative. Didactic education occurred when the patient attended to the information but did not interact with the instructor or participate actively in teaching sessions. Collaborative education occurred when the patient participated actively in the learning process, which might include group discussions, or when teaching techniques included empowerment (14), individualized goal-setting, or modeling. We considered lifestyle, skill development, and coping skills education to be collaborative.

We extracted a number of other intervention characteristics, including individual versus group education, use of self-monitoring of blood or urine glucose, number of contacts of the patient with the educator, total contact time (number of contacts multiplied by duration of each contact, in hours), the time frame over which the intervention was delivered (in months), who delivered the intervention, whether computer-assisted instruction was given, and what treatment the control group received (type of intervention, if any; number of contacts; and total contact time). We also extracted health care system characteristics (including whether an interface with a primary care provider was documented) and setting (e.g., inpatient, outpatient clinic, home, or community center).

We assessed internal validity based on Cochrane methodology (25). We examined each study for potential selection, attrition, and detection bias because these biases are thought to have significant effects on measured outcomes in intervention studies (26). We noted attrition as a potential bias if >20% of initially enrolled subjects dropped out before data collection, and dropouts were not compared or were not found equivalent to completers at baseline.

GHb concentrations were measured with a variety of techniques. Most studies used ion-exchange methods and reported either HbA_1 or HbA_{1c}. A few studies measured total GHb by affinity chromatography. However, because within-group differences were used to calculate pooled effects, analytic bias among laboratories is largely removed. A formula based on sample comparison data was used to convert HbA_1 results to HbA_{1c} equivalents in six studies (27–32), where there was sufficient detail to determine the exact measurement technique and where the relationship to HbA_{1c} was established (33).

We stratified studies a priori by follow-up interval, because data from the diabetes education literature (16,34) and behavioral research in other fields (35–37) suggest that positive outcomes diminish over time from the end of an intervention. We categorized follow-up intervals as those occurring during the course of an intervention or immediately following the last educator-patient contact, 1–3 months from the end of the intervention, or ≥4 months from the end of the intervention. Each study contributed only one outcome measure to each follow-up stratum, using the most distal measure if the study reported more than

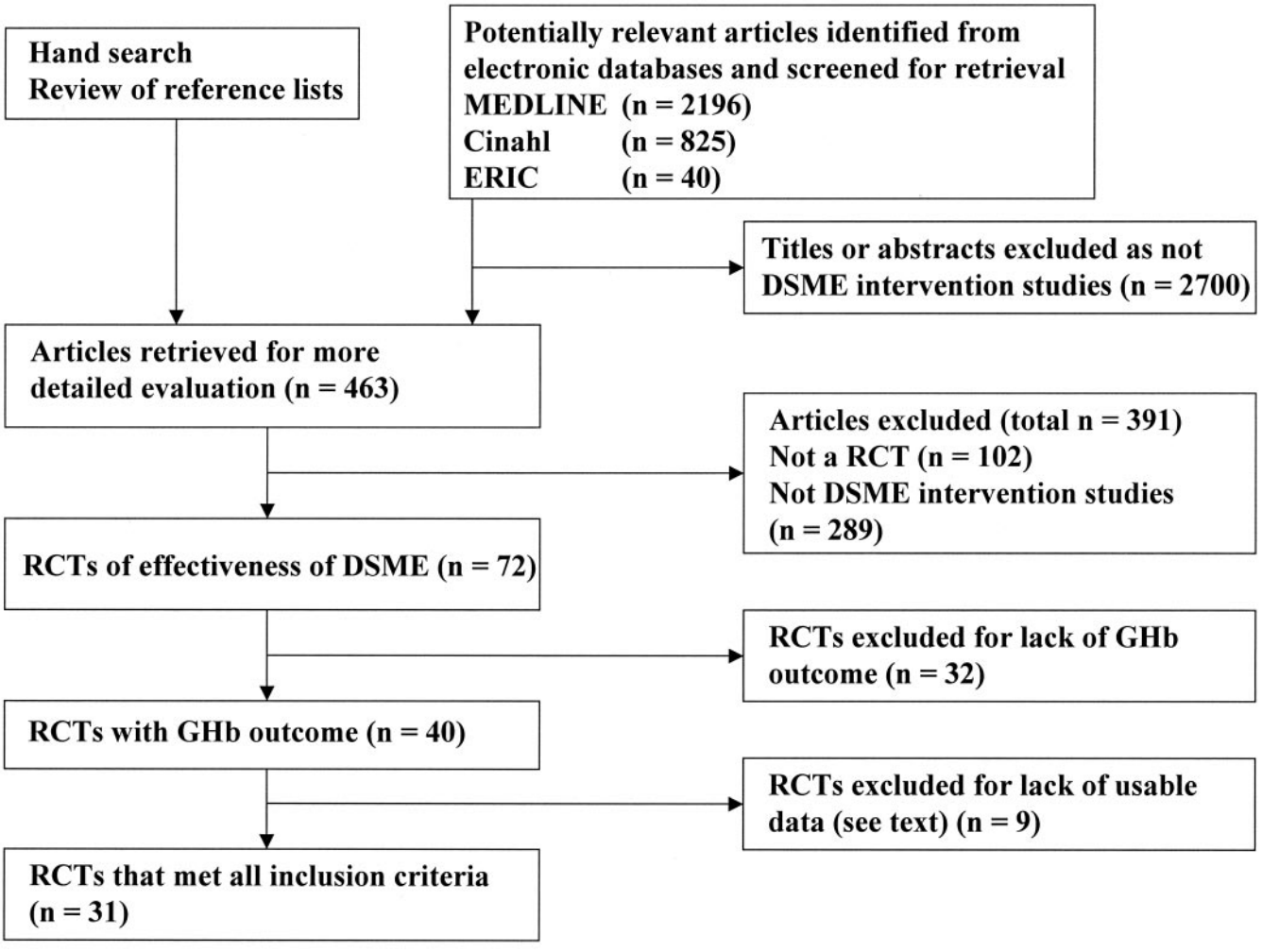

Figure 1—*Systematic review flow diagram.* n = *number of studies. Cinahl is the Nursing and Allied Health database; ERIC, Educational Resources Information Center database; RCT, randomized controlled trial.*

one GHb measure within a stratum. We performed analyses on the subgroup of studies where only usual care was delivered to the control group, because in some studies an intervention, usually less intensive, was delivered to the comparison group.

We calculated the mean difference between the intervention and control group (Δ) for each individual study, which is equal to $\Delta I - \Delta C$, where ΔI and ΔC are the absolute differences in GHb between each follow-up and the baseline measure for each study group. The estimate of variance of ΔI and ΔC was calculated from the GHb measures in each study group using the formula $V_{pre} + V_{post} - 2r(SE_{pre} \times SE_{post})$, where V_{pre} is the variance of the mean baseline GHb, V_{post} is the variance of the mean follow-up GHb, r is the correlation between the baseline and follow-up values, and SE_{pre} and SE_{post} are the standard errors of the baseline and follow-up groups, respectively. The variance of Δ was then calculated as the sum of the variance of ΔI and the variance of ΔC. Because no studies report r, and its true value is unknown, a sensitivity analysis was performed using values of 0.25, 0.5, and 0.75. Three studies (38–40) reported the SE of the difference for each of the intervention and control groups, and these values were used to calculate the variance of Δ for these studies.

If the mean baseline GHb value of either the intervention or control group was missing, we assumed that it was the same as the other group. If a study had several different intervention groups, we averaged GHb and variances within each study, weighted by the sample size (8,27,30,38,41–46). In several studies, GHb point estimates and CIs were not presented in numeric form, and they were estimated from graphs (28,30,47,48). If the SE was missing for the control or intervention groups at baseline or follow-up, then it was assumed to be the same as the value reported for the other group (27,29,30,42,43,49). In one study variance was calculated from the *P* value (50). If only the range was given as the measure of variation, then the SD was calculated as the range divided by 5.88 (6 SDs) (28). In several studies, the measure of variance was unclear or was assumed to be labeled incorrectly. In one study (40), we assumed that the stated variance was actually the SD; in a second (51,52), we assumed it to be the SE; in a third (47), we assumed a SD rather than a SE. In studies that involved crossover designs, fol-

Table 1—*Characteristics of eligible clinical trials*

Study	No. of patients	Duration of intervention (months)	Total contact time (h)	Follow-up intervals (months)*	Care delivered to the intervention group
Agurs-Collins, 1997 (78)	64	6	28	0, 3	Additional care†
Bloomgarden, 1987 (79)	345	19	NR	0	UC
Brown, 1999 (49)	247	12	NR	0	UC
Campbell, 1996 (38)	238	12	NR	−1‡, −1	Additional care
de Bont, 1981 (29)	148	6	NR	0	Additional care
de Weerdt, 1989 (39)	558	1	12	6	UC
d'Eramo-Melkus, 1992 (45)	82	3	14	0, 3	UC
Estey, 1990 (80)	60	2.5	1	0	Additional care
Falkenberg, 1986 (28)	46	3	16	6	Additional care
Franz, 1995 (57)	247	1.5	1.5	1.5, 4.5	Additional care
Glasgow, 1995 (50)	206	9	1	3	UC
Glasgow, 1992 (53)	102	2.5	NR	3	UC
Hawthorne, 1997 (73)	201	NR	NR	6	UC
Heller, 1988 (81)	87	6	7.5	−1, 0, 6	Additional care
Kaplan, 1985 (27)	76	2.5	20	15.5	Additional care
Korhonen, 1987 (30)	80	12	NR	−1, −1, 0	UC
Mazzucca, 1986 (31)	532	6	3.6	12	UC
McCulloch, 1983 (41)	44	6	NR	−1, 0	Additional care
Mulrow, 1987 (42)	120	10	NR	1	Additional care
Perry, 1997 (54)	70	6	NR	0	UC
Raz, 1988 (47)	51	12	NR	0	UC
Ridgeway, 1999 (40)	58	6	9	0, 6	UC
Scott, 1984 (55)	60	1	NR	0	UC
Trento, 1998 (82)	120	12	4	0	UC
Tu, 1993 (75)	31	1	NR	1.5	UC
Turnin, 1992 (56)	105	6	9	0	UC
Uusitupa, 1993 (51)	86	27	NR	−1, 0	UC
White, 1986 (48)	41	6	10	0	Additional care
Wing, 1986 (32)	50	10	NR	−1, 3	Additional care
Wing, 1988 (68)	20	10	NR	−1, 2	Additional care
Wise, 1986 (43)	88	6	2	6	UC
Total *N*	4,263				

*Follow-up is from the last educator-patient contact; †additional = control group received an intervention in addition to usual care; ‡follow-up of (−1) indicates that the measurement occurred during the course of the intervention. NR, not reported; UC, usual care.

low-up comparison was made before the comparison group received the intervention (53–56). One study (57) had two comparison groups, and the randomized control group was used as the comparison group.

For the meta-analysis, we report the results of random effects models, which account for variability among studies. We computed the between-study variance for the random effects model using the DerSimonian and Laird formula (58), and we report the *P* values for the χ^2 test to evaluate heterogeneity (Q).

The goal of the meta-regression was to determine whether Δ was influenced by the time frame over which the intervention was delivered, the length of follow-up, the initial GHb, the number of contacts with subjects, or total contact time. We examined interaction terms for all models. Mathcad 2001 Professional (MathSoft, Cambridge, MA) was used to perform the meta-analysis, and SAS (version 8.01; SAS Institute, Cary, NC) was used for the meta-regression.

RESULTS — The flow diagram for this review is depicted in Fig. 1. We found 72 randomized controlled trials that examined the efficacy of DSME on a variety of outcomes, and these have been previously reviewed with a narrative summary (16). Of these studies, 40 examined GHb outcomes. We excluded nine of these from the meta-analysis for a variety of reasons. Five were excluded for design issues: Noel et al. (59) compared choice versus no choice groups, and results for standard versus nutrition education were not presented separately; Anderson et al. (60) measured GHb after the intervention for both control and intervention groups in a cross-over design study; Gilden et al. (44) randomized only the two intervention groups and not the control group; Wing et al. (61) presented only combined data for the two groups at baseline and follow-up; and Boehm et al. (62) presented only percentage change. Three studies were excluded for GHb measurement issues: Pratt, Wilson, and colleagues (46,63) measured GHb in nanomoles per fructose equivalent, which is not compa-

rable to units used in all other studies, and the unit of measurement used by Lo et al. (64) was unclear. The study by Mazzuca et al. (31) was not included in the meta-analysis or the meta-regression because no measure of variation was reported, but it was included in the presentation of descriptive information (Tables 1–3 and the APPENDIX). The study by Arseneau et al. (65) fulfilled inclusion criteria but was felt to be conceptually different because the intervention involved an intensive 4-day course for both the intervention and control groups, with an additional individual dietary intervention for the intervention group. Analyses were performed with and without this study, with no change in the direction or significance of effect.

A number of studies had more than one follow-up measure. If these measures were reported in one of the predefined follow-up intervals (intermediate, 1–3 months, and ≥4 months), then they were analyzed within each stratum. If a study reported more than one measure within a stratum, then we used only the last measure. Thus, 37 estimates of GHb were included in the meta-analysis (total number of participants [*N*] = 3,731).

Meta-analysis

The characteristics of the clinical trials included in the meta-analysis are presented in Table 1, and summary demographic, intervention, and design characteristics, equally weighted by study, are presented in Table 2. (Further details on the individual studies are given in the APPENDIX.) Results for GHb outcomes are presented in Fig. 2 and Table 3, and those for the meta-analysis, stratified by follow-up interval, are presented in Table 4. In calculating pooled effect sizes, the results were insensitive to *r* in the range we expected (0.25–0.75); therefore, data are presented with a value of 0.5. For the three studies in which SE of the difference for each of the control and intervention groups was given (38–40), the median value of *r* was 0.65 for the intervention group and 0.61 for the control group. Heterogeneity (Q) was consistently significant ($P < 0.05$) for the immediate follow-up interval and when *r* was estimated to be 0.75. On average, the intervention decreased GHb by 0.76% (95% CI 0.34–1.18) more than the control group at immediate follow-up ($n = 2056$); by 0.26% (0.21% increase to 0.73% decrease) at 1–3 months of follow-up ($n = 922$); and by 0.26% (0.05–0.48) at ≥4 months of follow-up ($n = 1{,}893$). The subgroup of studies where the comparison group received usual care and no additional intervention constituted 58% of all studies, and results differed little from the overall results (Table 4).

Table 2—*Summary of demographic, setting, intervention, and design characteristics of included studies*

Variable	Mean
Demographics	
Age (years)	55 (35–67)
Using insulin (%)	16 (0–100)
Baseline GHb	9.4 (6.1–12.9)
Race/ethnicity (% NR)	77
Setting (%)	
United States	45
Clinic	88
Home	9
Senior center	3
Intervention	
Focus (%)	
Lifestyle	44
Knowledge	23
Skills (SMBG and foot care)	3
Coping skills	0
Mixed	30
Provider (%)	
Nurse	13
Dietitian	13
Physician with team	25
Team (nurse, dietitian, etc.)	20
Lay health care worker	3
Self (e.g. computer-assisted instruction)	7
NR	20
Duration (median) (months)	6 (1.0–27)
Number of contacts (median)	6 (1–36)
Total contact time (hours)	9.2 (1–28)
Individual (%)	32
Collaborative (%)	87
Theory-based (%)	39
Computer-assisted instruction (%)	6
Interface with primary care (%)	13 (65% NR)
Design and quality	
Recruitment (%)	
Random	3
Volunteers	58
Entire eligible population	19
Unclear	19
Comparison group: % Patients receiving usual care	58
Completion rate ≥80%	65

Data are means (range) or %, unless otherwise indicated. NR, not reported; SMBG, self-monitoring of blood glucose.

Meta-regression

Using Δ as the dependent variable, we performed a meta-regression to investigate potential treatment interactions, with patient age, baseline GHb, treatment (insulin, diet-only, or oral hypoglycemic agents), the number of contacts with the intervention subjects during the study, total contact time (in hours), time frame over which the intervention was delivered (in months), group versus individual presentation of the intervention, who delivered the intervention, educational focus (lifestyle, skills, knowledge, coping skills, or mixed), follow-up interval (in months), and setting in the U.S. versus other countries as the independent variables. None of the interactions was significant, except for total contact time, which was reported in addition to the number of contacts in 15 studies, with a total of 21 GHb measurements. In these studies, GHb was reduced by 0.04% (95% CI 0.01–0.08) for every additional hour of contact time, over the range of 1–28 h. This implies that on average, 23.6 h of contact between the educator and patient are needed to achieve a 1% reduction in GHb. We did not find any evidence that the studies in which contact time was reported differed from those in which it was unreported. Seven studies provided data on contact time for both intervention and control groups. One of these studies had a 26-h difference in contact time between study groups associated with a between-group difference in GHb of −1.8%. In the remaining six studies, there were small differences in contact time between groups, and a nonsignificant positive relationship was noted between the difference in contact time and improved GHb. There were insufficient data to examine the effects of psychosocial variables on GHb.

CONCLUSIONS — This meta-analysis provides evidence of the efficacy of DSME for individuals with type 2 diabetes on glycemic control, and it delineates the factors that contribute to its efficacy. GHb improves with DSME, with an average

Table 3—*Change in glycated hemoglobin after self-management training in type 2 diabetes*

Study	Baseline GHb	First follow-up interval*		Second follow-up interval*		Third follow-up interval*	
		Months	Net change GHb	Months	Net change GHb	Months	Net change GHb
Agurs-Collins, 1997 (78)	10.0	0	−.80	3	−2.60	—	—
Bloomgarden, 1987 (79)	6.6	0	−0.40	—	—	—	—
Brown, 1999 (49)	12.4	0	−2.00	—	—	—	—
Campbell, 1996 (38)	11.9	−1	−0.50	−1	−2.30	—	—
de Bont, 1981 (29)	9.2	0	−0.04	—	—	—	—
de Weerdt, 1989 (39)	9.2	6	−0.24	—	—	—	—
d'Eramo-Melkus, 1992 (45)	10.9	0	−1.87	3	−1.59	—	—
Estey, 1990 (80)	6.1	0	−0.40	—	—	—	—
Falkenberg, 1986 (28)	7.3	6	0.00	—	—	—	—
Franz, 1995 (57)	8.3	1.5	−0.30	4.5	−0.20	—	—
Glasgow, 1995 (50)	7.9	3	−0.10	—	0.00	—	—
Glasgow, 1992 (53)	7.4	3	−0.10	—	—	—	—
Hawthorne, 1997 (73)	NR	6	−0.34	—	—	—	—
Heller, 1988 (81)	12.7	−1	−0.70	0	−1.60	6	−0.50
Kaplan, 1985 (27)	7.5	15.5	−0.24	—	—	—	—
Korhonen, 1987 (30)	9.2	−1	−0.13	−1	−0.40	0	−0.04
Mazzucca, 1986 (31)	9.4	12	−0.78	—	—	—	—
McCulloch, 1983 (41)	12.9	−1	−0.80	0	−1.40	—	—
Mulrow, 1987 (42)	9.5	1	0.00	—	—	—	—
Perry, 1997 (54)	8.7	0	−0.40	—	—	—	—
Raz, 1988 (47)	9.6	0	−2.20	—	—	—	—
Ridgeway, 1999 (40)	12.3	0	−0.99	6	−0.14	—	—
Scott, 1984 (55)	8.7	0	−0.50	—	—	—	—
Trento, 1998 (82)	7.3	0	−0.21	—	—	—	—
Tu, 1993 (75)	NR	1.5	−0.46	—	—	—	—
Tumin, 1992 (56)	10.8	0	−0.80	—	—	—	—
Uusitupa, 1993 (51)	7.8	−1	−0.30	0	−0.20	—	—
White, 1986 (48)	11.3	0	0.40	—	—	—	—
Wing, 1986 (32)	10.5	−1	0.68	3	0.51	—	—
Wing, 1988 (68)	10.5	−1	0.49	2	1.06	—	—
Wise, 1986 (43)	8.7	6	−0.80	—	—	—	—

*Follow-up is from the last educator-patient contact, in months.

change of −0.76%, when measured at immediate follow-up. Duration of contact time between educator and patient was the only significant predictor of effect, with 23.6 h of contact time needed for each 1% absolute decrease in GHb.

This study has important implications for current clinical and public health practice and research. Glycemic control is an important predictor of many of the chronic complications of diabetes (66). According to the U.K. Prospective Diabetes Study (UKPDS), each 1% reduction in HbA_{1c} over 10 years is associated with reductions in risk of 21% for any end point related to diabetes, 21% for deaths related to diabetes, 14% for myocardial infarctions, and 37% for microvascular complications (67). No HbA_{1c} threshold value for risk of any complications was observed (67). Thus, the improvement in GHb of 0.76% at immediate follow-up is clinically significant.

The diminishing effect of DSME interventions with longer follow-up intervals after the end of the intervention is consistent with the literature in diabetes (16,34) and other behavioral interventions focused on weight loss and physical activity (35–37). It appears that long-term interventions may be required to maintain the improved glycemic control brought about by DSME programs. Because contact time was the only significant predictor of improved glycemic control, it appears that to achieve clinically meaningful effects, interventions must involve adequate time spent with patients. Other intervention characteristics did not influence outcomes in our analysis: educational focus (knowledge or lifestyle), group versus individual presentation, number of contacts, time frame over which the intervention was delivered, and who delivered the intervention. A variety of teaching techniques may thus be effective in improving glycemic control, and brief interventions, regardless of the number of contacts, appear to be less effective. Patient characteristics of baseline GHb and age also did not affect outcomes.

There was a wide range of effects on GHb noted in this review, and there are a number of potential reasons for this observation. The characteristics of the interventions varied widely, and they are undoubtedly only partly described by the variables that we examined. A number of other factors might explain the heterogeneity in outcomes: *1*) patient factors such as psychosocial mediators; *2*) intervention characteristics such as cultural rele-

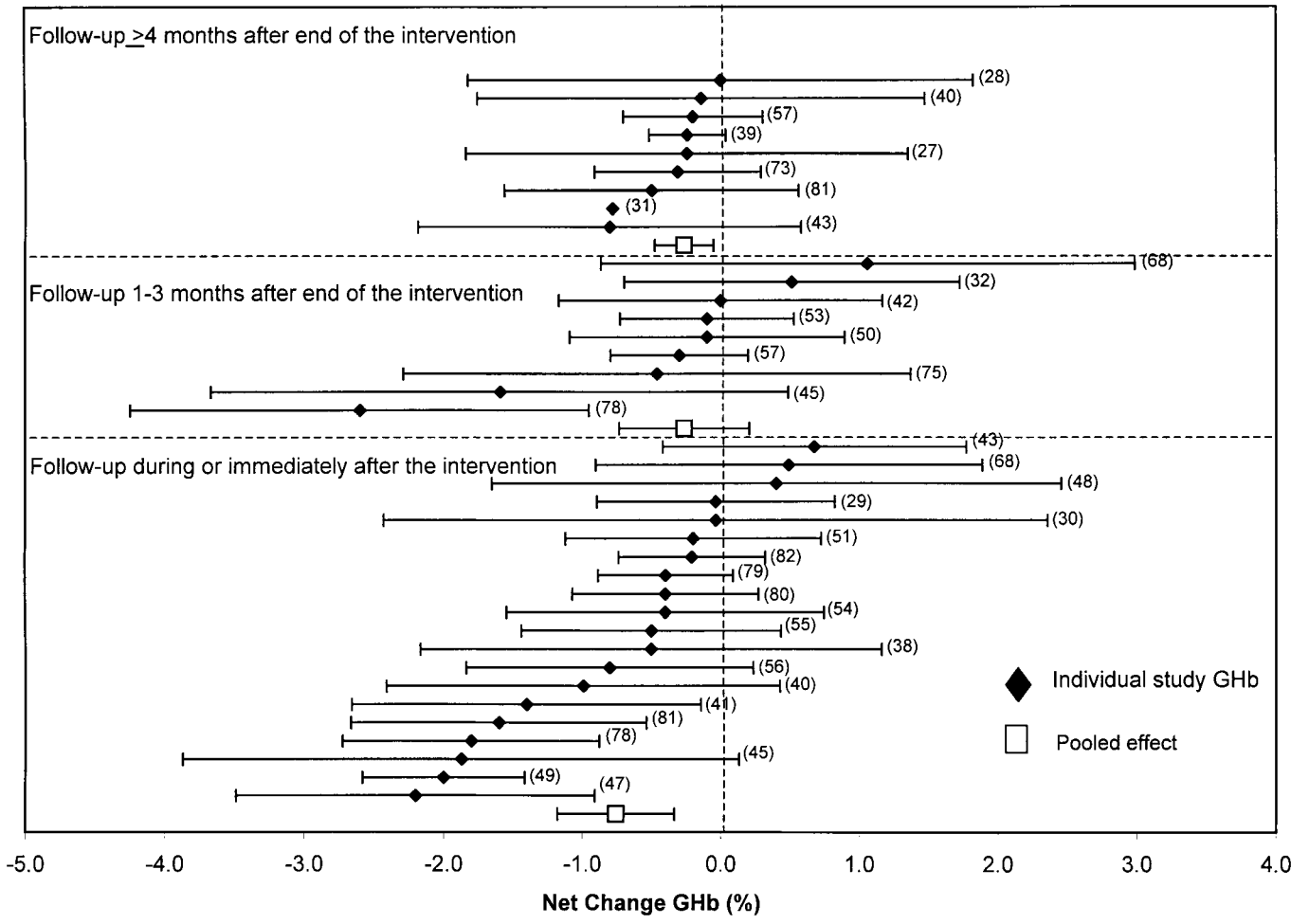

Figure 2—*GHb, stratified by follow-up interval. Net change in GHb is shown for each individual study, with lines extending from the symbols representing 95% CIs. Pooled results are for each follow-up interval, with* r = *0.5.*

vancy; and 3) contextual factors such as health care system structure and linkages to primary care. The care delivered to the control group also varied greatly, and improvements in GHb may be found in that group because of the Hawthorne effect, control group contamination, and unintended cointerventions. In several studies there were greater improvements in the control than the intervention group, leading to a net increase in $\Delta I - \Delta C$ (32, 48,68).

Several meta-analyses have been previously published on this subject. Brown's meta-analyses and meta-regression (11,12,69) support the efficacy of diabetes DSME, with positive effect sizes (from largest to smallest) for the outcomes of knowledge, dietary compliance, skill performance, metabolic control, psychological outcomes, and weight loss. She

Table 4—*Meta-analysis results*

Study group and follow-up interval	Number of studies	*Q* significance level	Point estimate (net change in GHb [%])	95% CI
All studies				
During or immediately after the intervention	20	<0.05	−0.76	−1.18 to −0.34
1–3 months	9	>0.10	−0.26	−0.73 to 0.21
≥4 months	8	>0.10	−0.26	−0.48 to −0.05
All studies where the comparison group receives usual care				
During or immediately after the intervention	12	<0.05	−0.91	−1.40 to −0.42
1–3 months	4	>0.10	−0.11	−0.57 to 0.36
≥4 months	5	>0.10	−0.28	−0.52 to −0.05

Appendix—*Additional characteristics of eligible clinical trials of the effectiveness of self-management education in type 2 diabetes*

Study	Age (years)	Baseline Control GHb	Patients on insulin (%)	In U.S. (yes/no)	Intervention	Care delivered to the control group	Inter-vention	No. of contacts	Total contact time (hours)	Individual or group	Didactic or collaborative	Theory-based (Y,N)	Sampling	Completion rate >80% (Y,N)
Agurs-Collins, 1997 (78)	62	10.0	50	Y	Didactic + participatory sessions: diet and activity	One class + mailed information	L	18	28	G	C	Y	V	Y
Bloomgarden, 1987 (79)	58	6.6	100	Y	Classes on general diabetes issues	UC	M	9	NR	G	C	N	E	N
Brown, 1999 (49)	54	12.4	25	Y	Weekly sessions + group support	UC	M	26	NR	G	Unclear	N	V	NR
Campbell, 1996 (38)	56	11.9	0	N	Individual sessions	Two group sessions	K	10	NR	G	C	N	V	N
de Bont, 1981 (29)	55	9.2	1.5	N	Individual sesions + home visits: low-fat diet	Same intervention, with low-carbohydrate diet	L	4	NR	I	C	N	Unclear	Y
de Weerdt, 1989 (39)	44	9.2	100	N	Collaborative education by health worker or patient	UC	K	4	12	G	C	Y	V	Y
d'Eramo-Melkus, 1992 (45)	56	10.9	0	Y	Didactic course + individual sessions	UC	M	12	14	G	C	Y	V	N
Estey, 1990 (80)	55	6.1	0	N	Group education + follow-up at home	3-day course, no follow-up	M	4	1	I	C	N	Unclear	Y
Falkenberg, 1986 (28)	66	7.3	0	N	Small group sessions: problem solving	1-day didactic teaching	K	8	16	G	C	Y	R	N
Franz, 1995 (57)	57	8.3	16	Y	Individual visits with dietician	Basic nutrition care	L	3	1.5	I	C	N	V	N
Glasgow, 1995 (50)	62	7.9	67	Y	Single visit: diet, goal-setting	UC	L	8	1	I	C	Y	V	Y
Glasgow, 1992 (53)	67	7.4	27	Y	Weekly sessions: problem-solving and self-efficacy	UC	L	10	NR	G	C	Y	V	Y
Hawthome, 1997 (73)	53	NR	NR	N	Culturally appropriate flashcards, by lay health care worker	UC	M	1	NR	I	D	Y	V	Y
Heller, 1988 (81)	56	12.7	0	N	Group sessions on weight loss	Individual sessions with dietician	L	5	7.5	G	C	N	E	Y
Kaplan, 1985 (27)	54	7.5	26	Y	Collaborative sessions on diet and activity	Same intervention, discuss general diabetes issues	L	10	20	G	C	Y	V	Y

Korhonen, 1987 (30)	56	9.2	0	N	Individual sessions on diet	UC	L	5	NR	I	C	N	E	Y
Mazzucca, 1986 (31)	58	9.4	70	Y	Home visits	UC	K	2.4	3.6	G	C	N	E	N
McCulloch, 1983 (41)	35	12.9	100	N	Meal demonstrations	Conventional diet teaching	L	3	NR	G	C	N	V	Y
Mulrow, 1987 (42)	54	9.5	0	N	Monthly small group meetings in diet and activity	Unclear	L	6	NR	G	C	Y	E	N
Perry, 1997 (54)	42	8.7	100	N	Monthly meetings, feedback	UC	L	6	NR	Unclear	C	N	V	Y
Raz, 1988 (47)	53	9.6	0	N	Didactic + small group sessions	UC	M	15	NR	G	D	N	Unclear	Y
Ridgeway, 1999 (40)	64	12.3	16	Y	Monthly group sessions on behavioral modification	UC	K	6	9	G	C	Y	E	N
Scott, 1984 (55)	NR	8.7	0	N	Group + individual sessions	UC	K	4	NR	G	D	N	V	N
Trento, 1998 (82)	61	7.3	0	N	Group sessions on diet, activity and blood sugar	UC	M	4	4	G	C	N	Unclear	Y
Tu, 1993 (75)	65	NR	89	Y	Weekly telephone calls after hospital discharge	UC	M	4	NR	I	C	N	V	Y
Tumin, 1992 (56)	45	10.8	80	N	Interactive computer program on diet	UC	L	36	9	I	C	N	NR	Y
Uusitupa, 1993 (51)	53	7.8	0	N	Individual sessions on diet, activity	UC	L	10	NR	I	C	N	V	Y
White, 1986 (48)	61	11.3	71	Y	Psychologist-led group sessions on diet and activity	Didactic teaching	L	10	10	G	C	Y	Unclear	N
Wing, 1986 (32)	54	9.9	50	Y	Weight loss program with focus on blood sugar	Behavioral weight control intervention	M	18	NR	G	C	N	V	Y
Wing, 1988 (68)	53	10.5	0	Y	Sessions on diet, activity and blood sugar	Same intervention, but no problem-solving	S	22	NR	G	C	Y	V	Y
Wise, 1986 (43)	56	8.7	0	N	Computerized knowledge assessment program	UC	K	2	2	I	C	N	V	Y

C, collaborative; D, didactic; E, entire accessible population recruited into the study; G, group; I, individual; K, knowledge; L, lifestyle; M, mixed; N, no; NR, not reported; R, recruitment of the study population by random sampling of the accessible population; S, skills teaching such as self-monitoring of blood glucose and foot care; UC, usual care; V, volunteers recruited into the study; Y, yes.

found an effect size of 0.41 for GHb (95% CI 0.31–0.52), indicating a small-to-moderate effect size. The effect peaked at 1–6 months after the intervention, with a decline to earlier levels after 6 months (69). Brown noted no difference in metabolic control by the length of the intervention (total minutes of contact) (69). However, Brown's work differs from this meta-analysis in that it included a variety of study designs, unpublished literature, the use of a checklist for quality assessment in the earlier meta-analysis (70) and a quality score in the later studies (71), the use of effect sizes, and the removal of outliers to achieve statistical homogeneity. Padgett et al. (13) reviewed the efficacy of diabetes education in 1988 and found that approaches based on diet instruction and social learning were the most effective interventions, and glycemic control and knowledge were associated with the most improved outcomes.

This study has several important limitations. This analysis was confined to English-language articles, which could introduce bias. However, Moher et al. (17) found that language-restricted meta-analyses overestimated treatment effect by only 2% on average, compared with language-inclusive meta-analyses, although the language-inclusive meta-analyses were more precise. Publication bias is always a concern in meta-analyses, and we performed exhaustive searches and contacted investigators in the field to obtain all published studies.

Only randomized controlled trials were included in this review, although an important body of literature on DSME exists with other study designs. Randomized controlled trials in this area of research are not always feasible, or even desirable, particularly when examining community-based educational interventions. Glasgow et al. (72) note the increasing importance of recognizing the complexity of disease determinants and multilevel system interventions. Classic randomized controlled trials emphasize efficacy, to the exclusion of factors influencing effectiveness, such as adoption (the proportion and representativeness of settings that adopt a policy or program), reach (the percentage and risk characteristics of persons who receive or are affected by a program), and institutionalization.

Threats to internal validity were common in the literature included in this meta-analysis. No study reviewed fulfilled all our criteria for the absence of selection, performance, attrition, and detection bias. Efforts to address allocation concealment were mentioned in only three studies (45,50,73), and one study randomized participants by month and year of birth (43). Attrition was >20% in one-third of the studies.

In the majority of included studies, the intervention group received significantly more contact time than the control group, but in only seven studies was contact time reported for both the intervention and control groups. Because contact time was shown to be an important predictor of effect for the intervention group, it is unfortunate that there were not sufficient data to provide adequate power to examine the relationship between the difference in contact time between the control and intervention groups and GHb. This important issue should be addressed in future evaluation studies, either by equalizing contact time between groups (e.g., with a sham counseling intervention), or by reporting contact time for the control and intervention groups and exploring the relationship with outcomes.

The studies included in this review use a variety of measurement techniques for GHb. The use of Δ in estimating pooled effects and in the meta-regression, and the conversion of HbA_1 to HbA_{1c} (where possible), minimized interlaboratory variation in outcome measures. However, there is likely some analytic variation in Δ between studies because GHb standardization efforts were not widespread until 1996, when the National Glycohemoglobin Standardization Program began efforts to make GHb determinations traceable to Diabetes Control and Complications Trial (DCCT) (74) values (66). Most of the studies included in this review predate these standardization efforts.

The results of this meta-analysis are likely generalizable to adult populations and geographic settings because a broad range of patient age and insulin utilization, intervention characteristics, and geographic settings were examined, with no evidence that these characteristics affect outcomes. Generalizability is likely limited to clinic settings because only four interventions were delivered outside the clinic: three in the home (56,73,75) and one in senior centers (46,63). Interventions focused mainly on lifestyle modification (diet and physical activity) and knowledge levels, with only one study (68) focusing exclusively on skills such as self-monitoring of blood glucose and none using coping skills as the only focus of the intervention. Results thus apply to lifestyle- and knowledge-focused interventions only.

Further research is needed to better define effective interventions for reducing GHb in persons with diabetes, particularly interventions aimed at long-term maintenance of initial behavior change. This work needs to focus on identifying the predictors and correlates of glycemic control (particularly psychosocial attributes such as depression, social support, and problem-solving skills) and on improving the quality of performance and reporting of DSME intervention studies. This research must provide adequate descriptive information, including demographic data, detailed descriptions of interventions (particularly contact time for both the intervention and control groups), and details of the health care delivery system. Measures of variance should be reported for all outcome measures and DCCT traceable GHb measures used (66,74). Allocation must be concealed when randomization is performed, and attention must be paid to minimizing attrition. Target populations must be described and scientifically sampled so that results are generalizable to specific populations.

Diabetes and its complications are responsible for a tremendous individual and public health burden of suffering at the present time, and the epidemic is projected to continue into the future (76). Definitive evidence of the benefits of improved glycemic control for reducing the diabetes burden exists (77). Thus, we are compelled to deliver diabetes care that improves glycemic control, and effective diabetes education is an integral part of comprehensive diabetes care.

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