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Review article

Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control

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ABSTRACT

Objective: Assess effect of diabetes self-management education and support methods, providers, duration, and contact time on glycemic control in adults with type 2 diabetes.
Method: We searched MEDLINE, CINAHL, EMBASE, ERIC, and PsycINFO to December 2013 for interventions which included elements to improve participants' knowledge, skills, and ability to perform self-management activities as well as informed decision-making around goal setting.
Results: This review included 118 unique interventions, with 61.9% reporting significant changes in A1C. Overall mean reduction in A1C was 0.74 and 0.17 for intervention and control groups; an average absolute reduction in A1C of 0.57. A combination of group and individual engagement results in the largest decreases in A1C (0.88). Contact hours ≥10 were associated with a greater proportion of interventions with significant reduction in A1C (70.3%). In patients with persistently elevated glycemic values (A1C > 9), a greater proportion of studies reported statistically significant reduction in A1C (83.9%).
Conclusions: This systematic review found robust data demonstrating that engagement in diabetes self-management education results in a statistically significant decrease in A1C levels.
Practice implications: The data suggest mode of delivery, hours of engagement, and baseline A1C can affect the likelihood of achieving statistically significant and clinically meaningful improvement in A1C.

Contents

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1. Introduction

Current estimates suggest that almost 50% of people with diabetes do not achieve and sustain the recommended target of <7.0% for glycated hemoglobin (A1C) [1] and only 14.3% are at target goals for A1C, blood pressure, low-density lipoprotein cholesterol, and nonsmoking [2]. The American Diabetes Association 2015 Standards for Care as well as the American Association of Clinical Endocrinologists recognize diabetes self-management education (DSME) as an integral aspect of the care for people with diabetes [1,3] in concert with pharmacotherapy that can involve multiple medications and dosing algorithms [3]. Nonetheless, recent studies estimate that among those newly diagnosed with diabetes, less than 7% of individuals with private insurance [1] and less than 5% of those covered by Medicare [4] actually participate in DSME. Thus, although the systematic review work by Norris and colleagues [5,6] indicated that DSME resulted in clinical improvement, it appears to be an underutilized element of diabetes care. Notwithstanding the potential of tight glycemic control to reduce complications [7], heightened awareness that tighter glycemic control with antihyperglycemic medication can be associated with increased risk of hyperglycemia [8] suggested that a current review of the potential for clinical benefit from DSME which examined DSME characteristics of DSME interventions to explore which, if any were associated with efficacy, was warranted.

The National Standards for Diabetes Self-Management Education and Support define diabetes self-management education as a collaborative and ongoing process intended to facilitate the development of knowledge, skills, and abilities that are required for successful self-management of diabetes [9]. Alternatively termed diabetes self-management training or DSMT, for clarity, DSME will be the term used in this paper. Evidence from randomized controlled trials and observational studies suggest that DSME is cost-effective [10,11] and associated with favorable changes in knowledge [12–16], clinical outcomes [13,14,16–18], self-efficacy and other psychosocial outcomes [16,19–21], screening for complications [15,22], risk factors for cardiovascular events [22,23], and quality of life [22,24]. However, the association between DSME and improvements in clinical endpoints and patient-centered outcomes has not consistently been shown in clinical trials or systemic reviews [5,6,17,25–29]. Differences in the methods and providers of DSME [30], duration and intensity of interventions, educational setting, demographic and clinical characteristics of DSME recipients [30], and variations in the quality of the research are proposed as factors that may contribute to these inconsistent results [5,6,27,31,32]. While lending itself to systematic review, this diversity of engagement is a hindrance to meta-analysis.

This is a systematic review of published, randomized controlled trials to evaluate the impact of DSME compared with usual care or a minimal educational intervention on A1C levels in adults diagnosed with T2DM. Because glycemic control has been shown to strongly predict the microvascular and macrovascular complications of diabetes [7], we chose A1C as the clinical endpoint of this study. We assessed changes in A1C levels that might be attributed to the mode of delivery, provider type, duration, and baseline A1C.

2. Methods

2.1. Data sources

Our research protocol was reviewed and approved by the members of the 2013 Research Committee of the American Association of Diabetes Educators (AADE). Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines were followed [33] with the PICOS framing. Only studies published in peer reviewed journals were included.

2.2. Search strategy

We searched MEDLINE accessed through PubMed, the Cumulative Index to Nursing and Allied Health Literature, EMBASE, Educational Resources Information Center, and PsycINFO. Our search strategy used the National Library of Medicine Medical subject headings including "type 2 diabetes," "self-care education," "self-management," and "behavior change." We reviewed the titles and abstracts (when available) of articles identified by the systematic search as potentially relevant to evaluation of DSME. All articles considered potentially relevant were retrieved and reviewed for inclusion in this review.

Our search included English-language articles published from January 1, 1997 through December 31, 2013. January 1, 1997 was selected as the search initiation date because this was the year that Congress authorized Medicare coverage of outpatient diabetes self-management training in the Balanced Budget Act of 1997 which resulted in Medicare coverage for up to 10 hours of DSME in the first year of engagement. The systematic database searches were supplemented with manual searches of citations from relevant reviews, systematic reviews, and meta-analyses because searches of online databases can be incomplete [34].

2.3. Study selection

This systematic review included was restricted to randomized controlled trials (RCT), which are associated with optimal validity and inference about causal relationships [35]. Our review was limited to studies that included participants 18 years or older, with any A1C level, all intervals of diabetes duration, and any comorbid health conditions because it is not uncommon for people with diabetes to be managing multiple conditions. In an effort for this to be as comprehensive review as possible, trials enrolling participants with type 1 and type 2 diabetes mellitus were included if results were reported separately for participants with T2DM or if the percentage of participants with type 1 diabetes was less than 50% of the sample. DSME interventions provided in any setting, by any method or provider, for any duration and contact time were eligible for inclusion, though not every study reported on each of these elements. However, because A1C was the clinical endpoint of the review, to be eligible, studies were required to report outcomes for A1C level.

Studies eligible for inclusion were also required to meet the definition of DSME defined by the National Standards for Diabetes Self-Management Education and Support [9]. This definition is not

Table 1
Characteristics of eligible studies included in the systematic review.

Publication	Baseline age, mean (Years)		Baseline A1c		Change in A1c		Intervention				Control	No. randomly assigned		No. at final FU		Final FU (months)	Overall retention rate	Bias rating	Unique interv.
	IG	CG	IG	CG	IG	CG	Mode	Provider	Duration (months)	Est contact time (hours)		IG	CG	IG	CD				
Agurs-Collins et al. [54]	62.4	61.0	11.0	10.0	−1.1	1.5	C	Team	6	27	• One class on glycemic control • 2 mailings on nutrition	32	32	30	25	6	86.0	1	Y
Anderson et al. [24]	55.5	55.7	7.7	7.5			I	Team	24	NR	• Metabolic assessments	156	154	122	126	24	80.0	3	Y
Battista et al. [56]	60.0	59.0	7.9	7.7	−0.6	−0.3	I	Single	24	4	• Conventional care by endocrinologist	51	50	44	44	24	87.1	3	Y
Beverly et al. [57]	59.9	58.4	8.5	8.3	−0.5	0	G	Team	NR	4	• Attention control of 2 two-hour classes on dyslipidemia and hypertension	68	67	58	63	12	90.3	2	Y
Brown et al. [18]	54.7	53.3	11.8	11.8	−0.92	−0.16	G	Team	12	52	• Wait-list control	126	126	117	112	12	90.9	2	Y
Carter et al. [125]	52	49	9	8.8	−2.18	−0.9	R	Single	9	NR	• Standard of care	37	37	26	21	9	63.5	1	Y
Chen et al. [58]	59.2	58.7	8.97	8.53	−0.81	−0.05	I	Single	<1	1	• Invitation to attend outpatient, hospital-based education in group and individual settings	125	125	104	111	3	86.0	2	Y
Choe et al. [59]	52.2	51.0	10.1	10.2	−2.1	−0.9	I	Single	12	NR	• Usual medical care	41	39	36	29	24	81.3	2	Y
Clifford et al. [61]	70.5	70.3	7.5	7.1	−0.5	0	I	Single	12	2.75	• Usual care	99	99	92	88	12	91	2	Y
Cohen et al. [62]	69.8	67.2	7.8	8.1	−0.41	−0.20	G	Team	6	15.5	• Standard of care at individual clinic visits about every 4 months	50	49	48	48	6	97.0	1	Y
Cooper et al. [63]	59.0	59.0	8.4	7.9	0.1	1.0	G	Single	2	16	• Usual care for 6 months followed by educational intervention	30	23	23	36	6	100	2	Y
Crasto et al. [64]	62.6	60.3	7.9	8.0	−0.8	−0.2	C	Team	18	6	• Usual care by HCP according to local guidelines	94	95	89	89	18	94.2	2	N
Deakin et al. [67]	61.3	61.8	7.7	7.7	−0.6	0.1	G	Single	1.5	12	• Routine care plus diabetes education and review with RD (30 min), RN (15 min), and GP (10 min)	157	157	150	141	14	92.7	2	Y
Farsaei et al. [69]	53.4	52.9	9.3	8.9	−1.8	0.10	I	Single	3	NR	• General education provided by nursing staff	87	87	87	87	3	100	2	Y
Gallegos et al. [126]	52.0	49.5	10.36	9.44	−2.32	0.33	C	Single	12	39	• Routine care consisting of monthly visit with physician	29	28	25	20	12	78.9	2	Y
Goudswaard et al. [74]	62.6	58.7	8.2	8.8	−1.0	−0.4	I	Single	6	2.5	• Usual care by physician	25	29	24	26	18	92.6	2	Y
Huang et al. [127]	56.6	56.9	8.0	8.4	−0.7	−0.2	C	Single	12	4	• Routine care	93	100	75	79	12	79.8	1	Y
Jacobs et al. [128]	62.7	63.0	9.5	9.2	−1.8	−0.8	I	Single	12	NR	• Usual medical care	94	125	72	92	12	74.9	1	Y
Jarab et al. [76]	63.4	65.3	8.5	8.4	−0.8	0.1	I	Single	2	>2.7	• Usual medical services provided by clinic	85	86	77	79	6	91.2	2	Y
Johansen et al. [77]	59.0	58.0	7.5	7.6	−0.8	0.2	G	Team	24	8.4	• Standard care according to current ADA and national guidelines	60	60	49	57	24	88.3	2	Y
Kim et al. [79]	56.2	56.6	9.4	9.1	−1.3	−0.4	C	Team	7.5	13.7	• Delayed intervention	41	42	40	39	7.5	95.2	3	Y
Ko et al. [80]	53.3	54.1	9.4	9.2	−1.5	−0.5	C	Team		15	• Group education on diet, exercise, insulin, and monitoring with usual clinical care	219	218	160	148	48	70.5	1	Y

Koev et al. [146]	NR	NR	9.1	8.7	−0.48	0.17	G	NR	<1	7.5	• No structured group education	NR	NR	NR	NR	6	NA	0	Y
Krass et al. [81]	62.0	62.0	8.9	8.3	−1	−0.3	I	Single	6	NR	• 2 visits with pharmacist at beginning and end of study	176	159	149	140	6	86.3	4	Y
Less et al. [82]	56.6	58.6	7.95	8.03	−0.63	0.59	C	Single	6	NR	• Usual care provided by health centers	159	159	158	135	6	92.1	3	Y
Lorig et al. [83]	51.0	51.0	6.44	6.44	−0.01	0.126	R	Single	1.5	NR	• Usual care	60	50	35	38	6	86.6	3	Y
Lorig et al. [84]	52.9	52.8	7.44	7.38	−0.41	−0.05	C	Single	1.5	15	• Usual care	219	198	179	173	6	84.4	3	Y
Lujan et al. [86]	58.0	58.0	8.21	7.71	−0.46	0.3	G	Single	6	16	• Verbal information or 1–2 pamphlets on diabetes self-management at routine clinic visits	75	74	71	70	6	94.6	2	Y
Maislos et al. [132]	58.0	63.0	11.6	11.1	−1.8	−0.3	I	Team	6	NR	• Usual care	48	34	41	23	6	76.8	2	Y
McMurray et al. [87]	63.0	60.9	6.9	6.9	−0.6	0.3	I	Team	12	NR	• Standard diabetes care while at dialysis	49	42	45	38	12	91.2	3	Y
Mehuys et al. [88]	63.0	62.3	7.7	7.3	−0.6	−0.1	I	Single	6	NR	• Usual pharmacist care	153	135	148	132	6	97.2	3	Y
Miller et al. [89]	72.1	73.0	7.2	7.4	−0.5	0	G	Single	2.5	20	• Wait-list control	45	47	45	47	2.5	100	3	Y
Mohamed et al. [133]	52.0	55.0	8.67	8.61	−0.8	−0.19	G	Single	NR	16	• Educational toolkit	215	215	109	181	12	67.4	1	Y
Mollaoglu et al. [90]	53.2	51.8	9.5	9.7	−2.0	−0.1	C	Single	2	1	• Wait-list control	25	25	25	25	2	100	3	Y
Moriyama et al. [91]	66.4	65.2	7.44	7.28	−0.59	−0.03	I	Single	12	7	• Educational textbook with usual care	50	25	42	23	12	86.7	2	Y
Munshi et al. [92]	75.0	75.0	9.3	9.0	−0.7	−0.3	I	Team	6	2.1	• Attention control with 11 calls during first 6 months with no diabetes education, advice, or strategies discussed	70	30	67	26	12	93.0	2	Y
Oh et al. [134]	59.2	62.0	8.8	8.3	−1.1	0.7	R	Single	3	7.2	• Routine care	25	25	20	18	3	76.0	2	Y
Partapsingh et al. [93]	NR	NR	8.5	8.2	0.6	1.1	I	Single	4	NR	• Routine care	61	61	58	61	11	97.5	1	Y
Philis-Tsimikas et al. [136]	52.2	49.2	10.5	10.3	−1.4	−0.6	G	Single	10	32	• Usual medical care	104	103	55	71	10	60.9	1	Y
Piatt et al. [94]	69.7	68.6	7.6	6.9	−0.6	−0.1	G	Single	1.5	NR	• Usual medical care	30	51	27	46	12	90.1	3	Y
Piatt et al. [41]	69.0	66.3	7.4	7.1	−0.3	−0.5	G	Single	1.5	NR	• Usual medical care	30	51	15	24	36	48.1	2	N
Piette et al. [95]	60.0	61.0	9.5	9.2	−0.8	0	R	Single	12	7.6	• Usual care	146	146	132	140	12	93.2	2	Y
Pimazoni-Netto et al. [149]	54.5	58.4	10.29	10.01	−2.26	−1.29	I	Team	3	10	• FU visits at weeks 6 and 12 and 2 hours of education on diabetes, nutrition, and exercise at baseline	32	31	32	29	3	NA	1	Y
Polonsky et al. [137]	48.8	53.4	10.2	10.4	−2.3	−1.7	G	Team	<1	28	• Usual diabetes care plus quarterly mailings for 12 months	89	78	65	52	6	74.5	1	Y
Prezio et al. [96]	47.9	45.7	8.9	8.7	−1.6	−0.9	I	Single	12	7	• Wait-list control	90	90	78	78	12	86.7	2	Y
Rachmani et al. [97]	57.4	56.8	9.5	9.6	−1.3	−0.7	I	Single	NR	1.5	• Standard consultation	71	70	65	64	48	91.5	2	Y
Rachmani et al. [42]	NR	NR	9.5	9.6	−1.2	−0.4	I	Single	NR	1.5	• Standard consultation	71	70	56	54	96	78.0	1	N
Rosal et al. [19]	62.7	62.4	7.7	9.3	−0.85	−0.12	C	Team	2.5	31.5	• Simple booklet about lifestyle factors in diabetes management and recommendations for diet, physical activity, and self-monitoring blood glucose	15	10	14	9	6	92.0	2	Y
Rosal et al. [14]	NR	NR	8.85	9.11	−0.88	−0.35	C	Team	11	51	• No intervention, usual care	124	128	NR	NR	12	NA	1	Y

Table 1 (*Continued*)

Publication	Baseline age, mean (Years)		Baseline A1c		Change in A1c		Intervention				Control	No. randomly assigned		No. at final FU		Final FU (months)	Overall retention rate	Bias rating	Unique interv.
	IG	CG	IG	CG	IG	CG	Mode	Provider	Duration (months)	Est contact time (hours)		IG	CG	IG	CD				
Rothman et al. [98]	54.0	57.0	11.0	11.0	−2.5	−1.6	C	Single	12	7.7	• 1-h management session by pharmacist plus usual care	112	105	99	95	12	89.4	2	Y
Samuel-Hodge et al. [101]	57.0	61.3	7.8	7.8	−0.5	0	C	Team	12	25	• 2 educational pamphlets from ADA and 3 bimonthly newsletters with general health information and study updates by mail	117	84	101	69	12	84.6	3	Y
Sarkadi et al. [102]	66.4	66.5	6.5	6.5	−0.3	0.1	G	Team	12	NR	• Wait-list control	39	38	33	31	24	83.1	3	Y
Scain et al. [150]	59.3	59.5	6.8	6.7	−0.3	0.2	G	Single	1	8	• Usual care	52	52	NR	NR	12	NA	1	Y
Skelly et al. [106]	60.5	63.7	9.2	9	−1.27	−0.54	I	Single	NR	6	• Phone call at midpoint between baseline and final evaluation and a copy of Taking Charge of Your Diabetes	23	18	22	17	~2	95.1	2	Y
Sone et al. [107]	59.4	59.4	7.68	7.8	−0.15	−0.1	I	Team	36	19.5	• Conventional care	1105	1100	990	983	36	89.5	3	Y
Song et al. [139]	51.0	49.5	9.4	9.0	−2.3	−0.4	C	Team	3	14.5	• 1-hour of diabetes education, medical nutrition therapy, recommendation for physical activity provided by diabetic education nurse and usual medical care	25	24	20	19	3	79.6	1	Y
Spencer et al. [108]	50.0	55.0	8.6	8.5	−0.8	0	C	Single	6	24	• Wait-list control • Contact by phone once per month to update contact information	72	92	59	77	6	82.9	2	Y
Sperl-Hillen et al. [50]	61.6	63.3	8.14	8.0	−0.51	−0.24	I	Team	3	3	• Usual care	246	134	209	108	6.8	81.3	2	Y
Sperl-Hillen et al. [50]	61.2	63.3	8.07	8.0	−0.27	-0.24	G	Team	1	8	• Usual care	243	134	195	108	6.8	80.4	2	Y
Sun et al. [110]	51.0	51.0	7.1	7.0	−0.85	0	I	Team	6	12	• All study participants were provided diabetes education materials used in lectures given by nutritionists including information on diabetes management, behavior and lifestyle changes, physical activity, healthy eating, and low-glycemic foods	100	50	97	49	6	97.3	2	Y
Tan et al. [111]	54.0	54.0	9.9	9.6	−1.15	0.07	C	Single	3	1.5	• Usual care	82	82	78	73	3	92.1	2	Y
Tang et al. [22]	54.0	53.5	9.24	9.28	−1.14	−0.95	C	Team	NR	2.5	• Usual care	202	213	186	193	12	91.3	2	Y
Taveira et al. [113]	62.2	66.8	8.1	7.9	−0.9	0	G	Team	1	8	• Standard of care	64	54	58	51	4	92.4	2	N
Taveira et al. [112]	60.2	61.4	8.3	8.5	−0.9	−0.1	G	Team	6	18	• Standard of care	44	44	44	41	6	96.6	1	Y
Taylor et al. [141]	55.5	54.8	9.5	9.5	−1.14	−0.35	C	Single	12	11.75	• Usual care plus diabetes pamphlets and Medic Alert pamphlet	84	85	61	66	12	75.1	1	Y
Thom et al. [142]	56.3	54.1	10.05	9.55	−1.07	−0.3	I	Single	6	NR	• Usual care including access to nutritionist and diabetes educator through referral	148	151	122	114	6	78.9	1	Y
Toobert et al. [153]	NR	NR	7.43	7.4	−0.36	−0.02	G	Team	6	111	• Usual medical care	163	116	137	108	6	87.8	2	Y
Toobert et al. [143]	55.6	58.7	8.4	8.2	−0.5	0.1	G	Team	12	159	• Usual medical care	142	138	109	108	12	77.5	1	Y

Trento et al. [154]	62.0	61.0	7.4	7.4	0.1	0.9	G	Team	24	6.7	• Usual medical care every 3 months	56	56	43	47	24	80.4	2	Y
Trento et al. [45]	62.0	61.0	7.4	7.4	−0.4	1.2	G	Team	48	12.5	• Usual medical care every 3 months	56	56	45	45	48	80.4	2	N
Trento et al. [46]	62.0	61.0	7.4	7.4	−0.1	1.6	G	Team	60	15.8	• Usual medical care every 3 months	56	56	42	42	60	75.0	1	N
Walker et al. [114]	55.7	55.4	8.6	8.7	−0.23	0.13	R	Single	12	1.9	• Active control including print materials on self-management by mail	262	264	228	216	12	84.4	2	Y
Wattana et al. [115]	58.4	55.1	8.08	8.09	−0.68	−0.07	C	Single	NR	9.5	• Wait-list control	79	78	75	72	6	93.6	2	Y
Weinger et al. [51]	51.8	54.7	9.12	9.09	−0.82	−0.42	G	Single	1.5	10	• Attention control using didactic curriculum and same length of time and amount of contact with HCPs and homework	74	75	66	70	12	91.3	2	Y
Weinger et al. [51]	56.2	54.7	8.9	9.09	−0.37	−0.42	G	Single	6	4.5	• Attention control using didactic curriculum and same length of time and amount of contact with HCPs and homework	73	75	66	70	12	91.9	2	Y
Welch et al. [116]	54.4	57.5	9.0	8.5	−1.6	−0.6	I	Team	12	7	• Attention control consisting of seven 1-h visits over 12 months to review diabetes education booklets with clinic staff	25	21	21	18	12	84.8	2	Y
White et al. [117]	53.0	58.0	10.5	10.1	−2.1	−1.2	I	Team	NR	460	• One-time disease management session with pharmacist and usual medical care	112	105	NR	NR	12	88.9	2	Y
Williams et al. [119]	58.4	56.4	8.7	8.9	−0.8	−0.2	R	Team	6	5.5	• Quarterly newsletter with general health information and usual medical care	57	60	48	55	6	85.8	3	Y
Young et al. [121]	67.0	67.0	7.9	8.0	?	?	R	Team	12	NR	• Conventional treatment	394	197	332	176	12	85.6	2	Y

	Baseline Age, Mean (Years)		Baseline A1c		Change in A1c		Intervention				Control	No. Randomly Assigned		No. at Final FU		Final FU (Months)	Overall Retention Rate	Bias Rating	Unique Interv.
	IG	CG	IG	CG	IG	CG	Method	Provider	Duration (Months)	Est Contact Time (Hours)		IG	CG	IG	CG				
Adolfsson et al. [53]	62.4	63.7	7.4	7.1	−0.1	0.3	G	Single	7	12.5	• Routine care	50	51	42	46	12	87.1	3	Y
Agema et al. [122]	55.6	61.7	7.7	8.4	0.06	−0.66	I	Single	NR	NR	• Routine clinical care	30	30	18	14	2.4	53.3	2	Y
Anderson et al. [55]	61.0	61.0	8.74	8.41	−0.3	−0.28	G	Team	1.5	12	• Wait-list control	125	114	117	108	1.5	94.1	1	Y
Anderson et al. [123]	NR	NR	7.6	8.4	0.06	−0.66	R	Single	12	NR	• Usual primary care	146	149	94	117	12	71.5	0	Y
Anderson-Loftin et al. [124]	58.9	55.7	7.5	8.3	−0.5	−0.3	C	Team	6	10	• Referral to local 8-h traditional diabetes class and phone fu at 3 months by RA to maintain contact	49	48	38	27	6	67.0	1	Y
Cade et al. [38]	65.4	66.2	7.3	7.5	0.3	0.1	G	Single	1.75	14	• Standard care consisting of a single 15–30 min appointment with RD	162	155	86	108	12	61.2	1	N
Christian et al. [60]	53.0	53.4	8.08	8.29	−0.14	−0.46	I	Single	9	NR	• Health education materials plus usual care	155	155	141	132	12	88.1	2	Y
Crowley et al. [65]	56.0	57.0	8.0	8.0	−0.2	−0.1	R	Single	12	2.8	• Usual medical care plus written educational materials at baseline	182	177	180	172	12	98.1	2	Y
Davies et al. [66]	59.0	60.0	8.3	7.9	−0.15	−0.12	G	Single	<1	6	• Enhanced standard care	437	387	404	345	12	90.9	3	Y
Khunti et al. [40]	59.4	61.0	8.3	7.7	−1.32	−0.81	G	Single	<1	6	• Enhanced standard care	437	387	332	272	36	73.3	2	N

Table 1 (*Continued*)

	Baseline Age, Mean (Years)		Baseline A1c		Change in A1c		Intervention				Control	No. Randomly Assigned		No. at Final FU		Final FU (Months)	Overall Retention Rate	Bias Rating	Unique Interv.
	IG	CG	IG	CG	IG	CG	Method	Provider	Duration (Months)	Est Contact Time (Hours)		IG	CG	IG	CG				
Edelman et al. [68]	63.0	60.8	9.2	9.2	−0.9	−0.6	G	Team	12	14	• Usual medical care	133	106	122	89	12.8	88.3	2	Y
Frosch et al. [70]	56.7	54.3	9.4	9.8	−0.5	−0.6	R	Single	NR	2.5	• Brochure on diabetes self-care	100	101	83	87	6	84.6	2	Y
Gabbay et al. [144]	65.0	64.0	7.46	7.36	−0.01	0.04	I	Single	12	NR	• Usual care	150	182	NR	NR	12	NA	1	Y
Gary et al. [71]	59.0	56.0	7.7	8.0	−0.2	−0.8	I	Team	24	NR	• Mail and phone FU by NHCP every 6 months with reminders about preventive screening and informational mailings every 3–4 months	269	273	235	253	24	90.0	2	Y
Gary et al. [52]	59.0	57.0	8.8	8.5	−0.3	NR	I	Single	24	4.5	• Usual medical care plus quarterly diabetes newsletter	NR	NR	38	34	24	NA	1	Y
Gary et al. [52]	59.0	57.0	8.4	8.5	−0.25	NR	I	Single	24	6	• Usual medical care plus quarterly diabetes newsletter	NR	NR	41	34	24	NA	1	Y
Gary et al. [52]	60.0	57.0	8.6	8.5	−0.8	NR	I	Team	24	10.5	• Usual medical care plus quarterly diabetes newsletter	NR	NR	36	34	24	NA	1	Y
Glasgow et al. [73]	62.0	61.0	7.4	7.5	−0.1	0	R	Single	2	1	• Health risk appraisal, feedback, and brief, generic health habit change counseling	174	161	153	148	2	89.9	4	Y
Glasgow et al. [72]	~58.2	58.7	8.13	8.06	−0.18	−0.06	R	Single	2	NR	• Enhanced usual care	331	132	260	115	4	81.0	4	Y
Glasgow et al. [39]	~58.2	58.7	8.14	8.16	0.02	−0.12	C	Team	12	6	• Enhanced usual care	331	132	244	114	12	77.3	3	N
Hawthorne et al. [75]	52.0	54.0	8.4	8.6	−0.1	0.04	I	Single	NR	NR	• Usual medical care	112	89	106	86	6	95.5	2	Y
Keeratiyutawong et al. [78]	NR	NR	8.9	7.9	−0.73	0.21	G	Single	<1	10	• Written diabetes materials at baseline and 5 videos about diabetes care at clinic visits	45	45	40	41	6	90.0	2	Y
Keyserling et al. [47]	58.5	59.2	10.7	11.3	0.1	−0.6	C	Team	12	6.6	• Educational pamphlet mailings	67	67	54	57	12	82.8	2	Y
Keyserling et al. [47]	59.8	59.2	11.0	11.3	−0.1	−0.6	I	Single	6	3.3	• Educational pamphlet mailings	66	67	59	57	12	84.2	2	Y
Kim et al. [129]	56.6	54.7	7.4	7.41	−0.33	0.17	I	Single	4	10.8	• Booklet with basic educational advice on usual care for diabetes	27	27	21	22	4	79.6	1	Y
Ko et al. [130]	55.0	56.0	8.6	8.4	−0.5	−0.2	I	Single	12	2.5	• Usual medical care	90	90	90	88	12	98.9	2	Y
Krier et al. [131]	54.2	56.2	9.6	10.0	−0.4	−0.9	I	Single	9	0.75	• Physician FU every 3 months	21	18	14	9	9	59.0	1	Y
Lorig et al. [85]	67.7	65.4	6.74	6.7	-0.11	-0.17	G	Single	1.5	15	• Usual care	186	159	161	133	6	85.2	3	Y
Mayer-Davis et al. [48]	58.9	62.4	9.7	9.6	−0.84	−1.12	C	Single	12	4	• Usual care delivered by study nutritionist on diet and physical activity	NR	NR	47	56	12	NA	1	Y
Mayer-Davis et al. [48]	59.7	62.4	10.2	9.6	−1.56	−1.12	I	Single	12	26	• Usual care delivered by study nutritionist on diet and physical activity	NR	NR	49	56	12	NA	1	Y
Osborn et al. [135]	56.9	58.4	7.76	7.45	−0.48	−0.27	G	Team	<1	1.5	• Usual care including medical treatment, physician monitoring, and optional support group w group-based didactic diabetes education	59	59	48	43	3	77.1	1	Y

Rosenbek Minet et al. [20]	57.1	55.8	7.02	7.03	0.14	0.26	I	Team	12	3.75	• Usual care following 4-day educational course also provided to IG	173	176	145	153	24	85.4	2	Y
Ruggiero et al. [99]	NR	NR	8.9	8.5	−0.59	−0.24	I	Single	6	2	• Treatment as usual plus basic diabetes education handbook	25	25	24	18	6	84.0	2	Y
Rygg et al. [100]	66.0	66.0	7.1	6.9	−0.1	0.2	G	Team	2.25	15	• Wait-list control	73	73	64	69	12	91.1	3	Y
Sacco et al. [138]	52	52	8.4	8.5	−1.0	−0.7	R	Single	6	4.7	• Treatment as usual from board-certified endocrinologist	31	31	21	27	6	77.4	1	Y
Sevick et al. [103]	NR	NR	7.7	7.5	−0.6	−0.2	G	Team	6	NR	• Attention control including group seminars on general diabetes education and stress management and receipt of lay diabetes magazine	147	149	120	126	6	93.5	3	Y
Shibayama et al. [104]	61.0	62.0	7.3	7.4	0.1	0	I	Single	12	5	• Usual care	67	67	61	59	12	89.6	2	Y
Sixta et al. [105]	54.5	52.8	7.32	7.65			G	Single	2.5	15	• Wait-list, usual care	63	68	NR	NR	6	80	2	Y
Skelly et al. [49]	68.5	68.0	8.44	8.11	−0.44	−0.56	I	Single	6	4	• Attention control based on weight and diet control program with 4 modules delivered in 60-minute sessions	60	60	54	55	9	90.1	3	Y
Skelly et al. [49]	65.0	68.0	8.33	8.11	−0.75	−0.56	I	Single	6	5	• Attention control based on weight and diet control program with 4 modules delivered in 60-minute sessions	60	60	54	55	9	90.1	3	Y
Sperl-Hillen et al. [43]	62.0	62.0	8.11	8.09	−0.35	−0.42	I	Team	3	3	• Usual care	246	134	232	124	12.8	93.7	2	N
Sperl-Hillen et al. [43]	62.0	62.0	8.07	8.09	−0.31	−0.42	G	Team	1	8	• Usual care	243	134	227	124	12.8	93.1	2	N
Steed et al. [140]	59.2	60.3	8.39	8.65	−0.26	−0.15	G	Team	4.25	15	• Wait-list control	65	59	53	53	3	73.4	1	Y
Sturt et al. [109]	62.0	62.0	8.9	8.8	−0.5	−0.4	I	Single	3	12.25	• Delayed intervention	114	131	88	114	6.5	82.4	3	Y
Taylor et al. [151]	58	67	7.69	7.69	−0.29	0.72	I	Team	3	4.5	• Standard medical care	20	19	NR	NR	4	NA	1	Y
Thomas et al. [152]	51.4	52.2	8.9	9.0	−0.7	−0.5	G	Single	NR	3	• Usual care	54	61	NR	NR	6	NA	1	Y
Toobert et al. [44]	55.6	58.7	8.4	8.4	0	−0.6	G	Team	24	171	• Usual medical care	142	138	97	93	24	58.9	1	N
Whittemore et al. [118]	57.6	57.6	7.7	7.6	−0.2	−0.1	I	Single	6	NR	• Standard diabetes care every 3–4 months with HCP	29	24	26	23	6	92.5	2	Y
Wolever et al. [120]	53.1	52.8	7.9	8.1	−0.4	0.1	I	Single	6	7	• No intervention	30	26	27	22	6	87.5	3	Y

prescriptive but rather is process oriented; DSME interventions had to include elements and activities intended to improve participants' knowledge, skills, and ability to perform self-management activities that had the potential to improve glycemic control. The DSME intervention was also required to adhere to a process of informed decision-making that included goal setting in 1 or more areas of self-management, with goals tailored to individual participants and collaboratively established between the provider(s) of DSME and the person with diabetes. Interventions that provided only medical nutrition therapy or medication management were excluded.

2.4. Data extraction

Data for all eligible publications were abstracted by the first author and confirmed by a second reviewer using a standardized, structured evidence table. Any discrepancies in the evidence summary were resolved by consensus among the 3 authors. Data abstraction was not blinded to author, institution, year of publication, or journal. We included only data reported in each publication, although we contacted authors to clarify information about the educational method, duration of the intervention, estimated contact hours, and reductions in A1C for 17 publications. We used data (mean, standard deviation, and sample size) reported in 19 publications to calculate the statistical significance of changes in A1C from baseline to follow-up [36]. Even within the context of randomized clinical trials, DSME was found to be a heterogeneous intervention and so we used the information provided by the authors to parse the studies by mode of delivery, provider type, duration, and baseline A1C in an effort to understand the contribution of these factors on the impact of DSME on glycemic control. Examination of these DSME characteristics was undertaken to determine whether any was associated with efficacy of the intervention.

Information recorded about each study included a description of the intervention and comparison group(s), clinical and demographic characteristics of participants, and characteristics of the DSME intervention. Mode of delivery and DSME provider type, estimated maximum contact hours for DSME, follow-up interval and frequency, statistical methods, clinical outcomes, and study limitations noted in the publication were recorded.

2.5. Mode of delivery

Modes of DSME delivery were classified into 1 of 4 categories: (1) individual education, (2) group education, (3) a combination of individual and group education, and (4) DSME primarily delivered by remote methods, with subject contact conducted online or by telephone.

2.6. Provider type

DSME was provided by a diverse group of healthcare professions including physicians, nonphysician healthcare professionals (e.g., credentialed diabetes educator, dietitian, exercise physiologist, registered nurse, pharmacist, physical therapist, occupational therapist, psychologist, or a social worker) as well as non-healthcare professional (NHCP) such as community health workers and health navigators. However, for purposes of this systematic review, DSME was categorized as being delivered by a solo (S) or a team (T) provider (i.e., two or more individuals were involved with provision of DSME to the study participants).

2.7. Duration of DSME

Efficiency of care is of economic concern with respect to diabetes and other conditions the maximum contact time per subject during the DSME intervention was determined for all studies reporting this information. Because current Medicare policy in the US caps reimbursement for DSME at 10 hours in the first year of DSME engagement and 2 hours per year thereafter, we examined the efficacy of DSME in studies in which the engaged participants in programs of DSME involving $<$ or $=$ 10 hours compared with those studies involving >10 hours of DSME. Table 1 lists duration of DSME intervention as well as length of follow-up. Final A1C measure was taken at final follow-up which in many cases was after DSME intervention.

2.8. Baseline A1C

Another parameter that varied widely among the RCT reviewed was the participant characteristic of baseline A1C and therefore the impact of this variable was examined in the context of this systematic review. Outcomes for both the proportion of studies with statistically significant differences as well as the average improvement in A1C observed was evaluated in terms of quartile of baseline A1C.

2.9. Assessment of study quality and validity

The evaluation of study quality was modelled after earlier systematic reviews [5,6] and determined by information reported in each publication. Internal validity was evaluated for selection, performance, attrition, and detection bias as defined by the Cochrane Collaboration Criteria [37]. These included appropriateness of the statistical methodology employed as well as the number of subjects enrolled and randomized to the intervention group (IG) and control group (CG) at baseline and follow-up. Studies were assigned a score ranging from 0 to 4, with a score of 4 indicating that the study met the criteria for each of the 4 potential sources of bias and a score of 0 indicating that none of the criteria were met.

Studies were evaluated for the presence of statistically significant differences between the IG and CG at baseline as a measure of selection bias. If significant baseline differences were reported, the statistical analysis was reviewed to determine if measures had been taken to adjust for potential confounders. Most studies reported their methods of randomization. However, selection bias was a concern for studies that enrolled participants selected from an accessible population who volunteered to participate in the study or were convenience samples. We also examined studies for performance bias to determine the risk of possible contamination between the IG and CG and identification of treatment differences between the IG and CG other than the DSME intervention.

Whenever possible, we recorded retention rates reported in the publication or calculated these rates based on data reported in the article as a measure of attrition bias. Retention was considered as a possible source of bias for studies with retention rates $<$80%, while retention rates $\geq$80% were considered acceptable to reduce the risk of attrition bias, which is consistent with the Cochrane Collaboration Criteria [37].

We evaluated each publication for detection bias attributable to systematic differences in outcomes between the IG and CG that might be due to lack of blinding of participants, investigators, intervention providers, and study personnel who performed the outcome assessment and statistical analysis. We also considered the use of indirect measures of A1C (e.g., self-report) as an additional source of detection bias.

2.10. Categorization of interventions

The majority of eligible publications reported the effect of a single, discrete DSME intervention on a defined population with ≥1 follow-up assessments of A1C at varying time intervals 3 months or greater. Each of these was considered a unique intervention. Outcomes from some studies were reported in multiple publications with the first publication describing the DSME intervention, study population, and initial follow-up results for A1C. Subsequent publications reported A1C results for longer follow-up intervals for the same participants and DSME intervention. The initial publication was classified as a unique intervention while the additional follow-up data on A1C reported in subsequent publications were not. They were included in our assessment of changes in A1C attributable to the unique DSME intervention described in the initial publication. Finally, several studies compared 2 or 3 methods of DSME to the control condition within a single publication. Each intervention arm of the publication was counted as a unique intervention delivered to different groups of participants. This categorization plan allowed us to evaluate the effects of DSME at the level of unique intervention.

2.11. Evaluation of changes in A1C

The studies expressed changes in A1C between the IG and CG in various ways, including absolute A1C at baseline compared with A1C levels at each follow-up assessment, absolute or relative change from baseline, and/or percent of participants who met glycemic targets at each follow-up compared with baseline. For the purpose of this review, we evaluated changes in A1C by 2 methods. First, we calculated the percentage of unique interventions that reported a significant difference in A1C between the IG and the CG at 1 or more follow-up assessments, with interventions that did not achieve a significant difference between the IG and CG at any follow-up assessment categorized as not significant. Second, we examined the changes in A1C between the IG and CG for all unique interventions and calculated the absolute difference in A1C between IG and CG for a given category of intervention or patient population. We examined variations in the percentage of statistically significant and not significant interventions and degree of change in A1C for all unique interventions and unique interventions associated with a significant decrease in A1C by method of DSME, DSME provider, duration of DSME, and maximum contact time associated with the delivery of DSME. Differences in A1C utilizes the term 'change' rather than 'reduction' to simplify capture all outcomes including those from studies in which there was an observed increase in A1C in the CG.

3. Results

Our study selection process yielded a total of 3095 non-duplicated publications, with 2821 excluded and full-text review

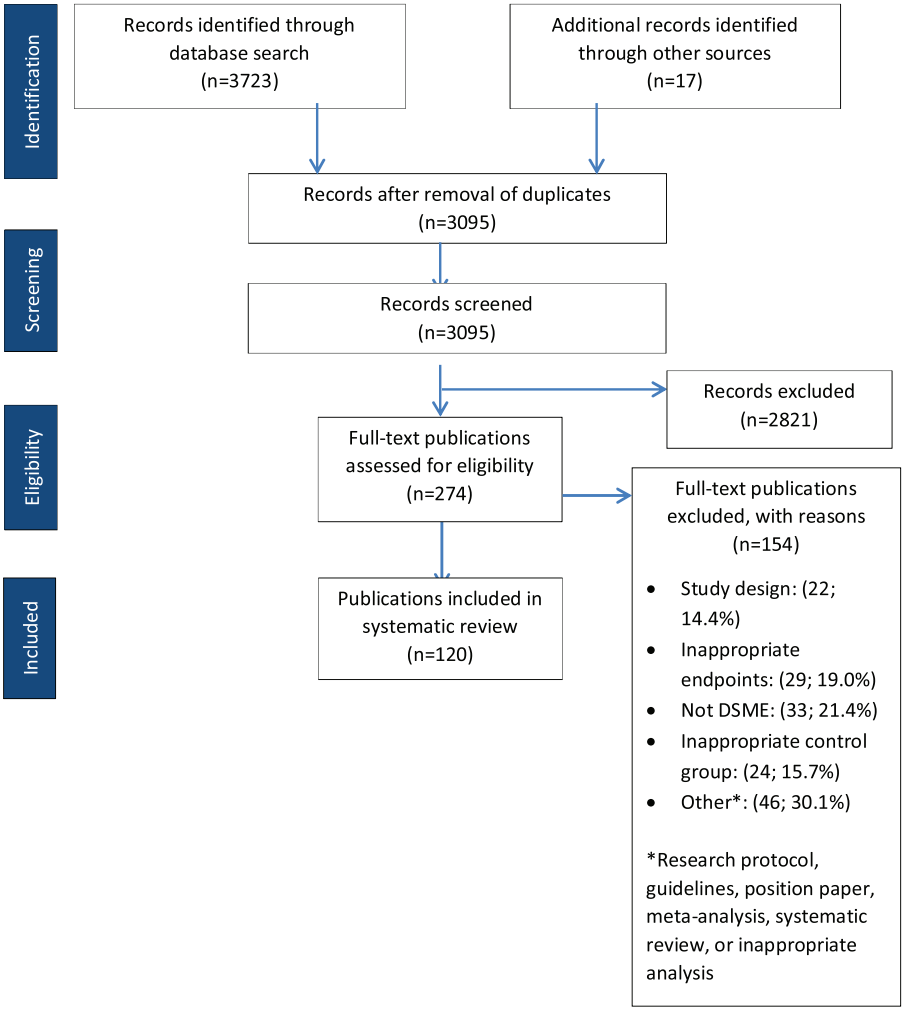

Fig. 1. Summary of evidence identification and selection for study inclusion.

completed for 274 articles. In addition to excluding publications that were not primary clinical trials (Other Reasons), the most common reasons for exclusion from this review were failure of the intervention to meet established criteria for DSME or omission of A1C as a study endpoint (Fig. 1). We identified 118 unique DSME interventions published in 120 articles that met our inclusion criteria. Nine publications reported additional follow-up results for a unique intervention delivered to the same population [38–46]. These publications were counted as non-unique interventions.

Six publications compared 2 methods of DSME to control [43,47–51] and 1 trial compared 3 methods of DSME [52] to the control group(s). Each IG arm in these 7 publications was counted as a unique intervention.

A total of 11,854 and 11,093 participants were enrolled in an IG and CG, respectively, with a mean age of 58.5 years (standard deviation [SD], 5.21; range, 47.9–75.0) for the IG and 58.7 (SD, 5.35; range, 45.7–75) for the CG. The median age at baseline was 58.5 years for both IG and CG participants and the median baseline A1C was 8.4 for both the IG and CG, with a mean of 8.55 (SD, 1.11; range, 6.4–11.8) for IG and 8.48 (SD, 1.08; range, 6.4–11.8) for CG participants.

Retention rates were ≥80% for 71.2% of the interventions [18–20,22,24,47,49–51,53–121], <80% for 18.6% [122–143], and insufficient data were available to determine retention rates for 12 interventions (10.2%) [7,14,48,52,144–152]. Higher subject retention rates were associated with interventions that reported a significant change in A1C following DSME at 94.5% compared with 80.0% for those that were not associated with a significant change in A1C.

Follow-up A1C results of greater than 3 months duration were reported for 11,584 IG participants and 10,466CG participants. A total of 73 (61.9%) unique interventions demonstrated significant differences between the IG and CG [14,18,19,22,24,50,51,54,56–59,61–64,67,69,74,76,77,79,81,82,84–98,101,102,106,108,110–114,117,119,125–128,130,132–134,136,137,139,141–143,146,149,150,153,154] compared with 45 (38.1%) interventions that resulted in no significant differences (Table 1) [20,47–49,51–53,55,60,65,66,68,70–73,75,78,80,83,99,100,103–105,109,118,120–124,129,131,135,138,140,144,151,152].

3.1. Characteristics of interventions

Because of intervention heterogeneity, it was not appropriate to conduct a meta-analysis. Interventions differed with respect to a number of factors with potential to impact outcomes such as clinical and demographic characteristics of participants; mode of DSME delivery, DSME provider, estimated maximum duration and maximum contact hours; frequency and duration of follow-up assessments; and quality (Table 1). Individual DSME was delivered in 49 (41.5%) of the studies [20,24,47–51,56,58–61,69,71,74–76,80,81,87,88,91–93,96,97,99,104,106,107,109,110,116–118,120,122,128,129,131,132,142,144,149,151], with 35 (29.7%) administering the intervention in a group setting [18,50,51,53,55,57,62–64,66–68,77,78,83,86,89,94,100,102,103,105,112,113,133,135–137,140,143,146,150,152–154], 21(17.8%) providing DSME as a combination of individual and group education [14,19,22,47,48,54,79,82,85,90,98,101,108,111,115,124,126,127,130,139,141], and 10.2% engaging people primarily through remote education [65,70,72,73,84,114,119,121,123,125,134,138]. One study did not report the mode of DSME delivery [95]. Single DSME providers were used in 71 (60.2%) of interventions [48,49,54,56,58–61,63,65–67,69,70,72–76,78,80,81,83–86,88–91,93–99,104–106,108,109,111,114,115,118–123,125–129,131,133–136,138,141,142,144,150,152] and 46 (39.0%) studies [14,18–20,22,24,47,50–55,57,62,64,68,71,77,79,87,92,100–103,107,110,112,113,116,117,124,130,132,137,140,143,149,151,153,154] provided team-based DSME. One study did not report the provider of DSME. [146] Median DSME duration was 6 months (mean, 8.14; SD, 6.75; range, 1–36). Eleven interventions [22,57,70,75,97,106,115,117,122,133,152] did not report or provide sufficient information to determine DSME duration. Mean DSME contact time was 18.26 (SD, 51.10; range, 0.75–460) hours in 92 interventions [14,18–20,22,47–58,61–68,70,73,76–80,83,85,86,89–92,96–101,104–117,119,120,124,126,127,129–131,133–141,143,146,149–154], while 26 (22.0%) interventions [24,59,60,69,71,72,75,81,82,84,87,88,93–95,102,103,118,121,123,125,128,132,142,144] did not report or provide adequate information to calculate mean DSME contact time.

3.2. Percentage of interventions with significant changes in A1C

Eighty-six percent of interventions based on combination DSME achieved significant improvements in A1C [14,19,22,54,79,82,85,90,98,101,108,111,115,126,127,130,139,141], which was higher than group, individual, or remote modes of DSME delivery (Fig. 2). Examination of changes in A1C associated with DSME provider revealed that 69.6% of team interventions [14,18,19,22,24,50,51,54,57,62,64,77,79,87,92,101,102,107,110,112,1-13,116,117,130,132,137,139,143,149,153,154] were associated with significant changes in glycemic control compared with 56.3% of DSME interventions conducted by a solo provider (Fig. 3) [56,58,59,61,63,67,69,74,76,81,82,84–86,88–91,93–98,106,108,111,114,115,119,125–128,133,134,136,141,142,150]. While the

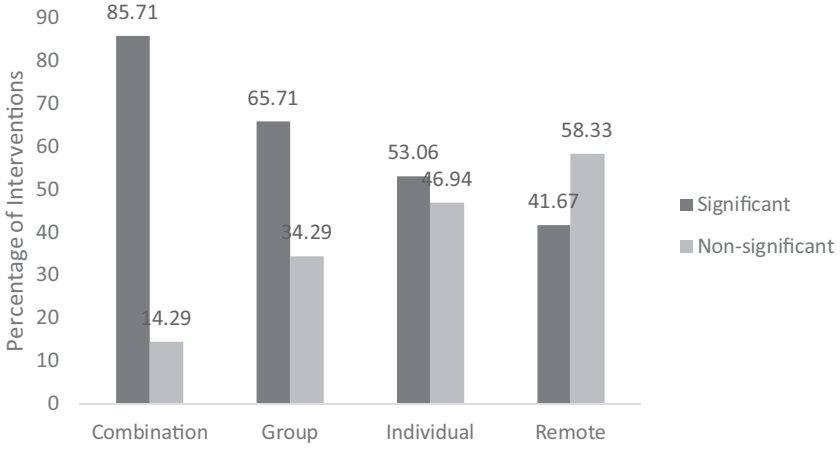

Fig. 2. Mode of delivery.

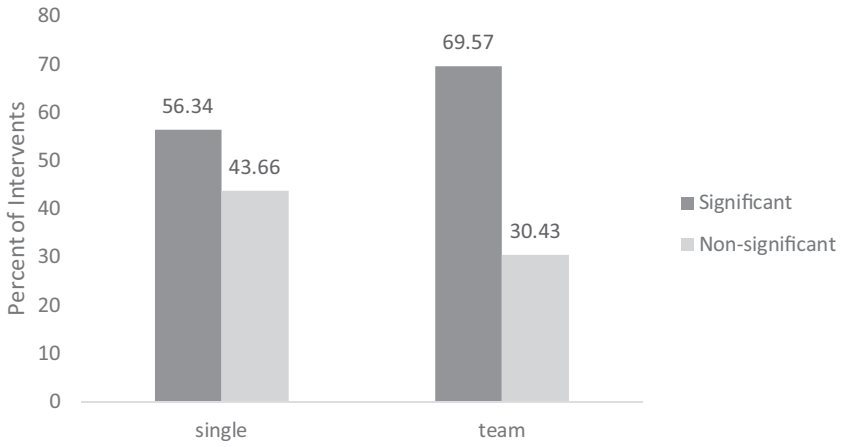

Fig. 3. DSME provider.

proportion of interventions reporting statistically significant differences between IG and CG was greater for those interventions provided by a team versus a solo provider, Pearson's chi-square analysis did not find these proportions to be significantly different ($p = 0.08$). In addition the mean change in A1C of −0.74 was the same regardless of whether the provider was a single individual or a team.

In order to examine the effect of baseline A1C on response to DSME, we calculated quartiles for baseline A1C with the first quartile consisting of participants with A1C <7.7%, the second quartile ranging from 7.7% to ≤8.3%, the third quartile ranging from >8.3% to ≤9%, and A1C >9% comprising the top quartile. A greater percentage of studies that enrolled participants with higher baseline A1C levels reported significant changes in A1C following exposure to DSME (Fig. 4) [18,22,51,54,59,69,79,90,92,95,97,98,106,111,117,126,128,130,132,136,137,139,141,142,146,149].

We also evaluated the effect of intervention duration on changes in A1C by calculating quartiles for length of DSME delivery duration. The 4 quartiles for DSME delivery duration were ≤2.5 months, >2.5 to <6 months, >6 to <12 months, and >12 months. Six (60%) of interventions in the top quartile for DSME duration achieved a significant improvement in A1C [24,56,64,77,107,154] compared with 17 (65.4%) interventions provided for durations of 2.5 or fewer months (Fig. 5) [19,50,51,58,63,67,76,84,85,89,90,94,113,130,137,146,150]. DSME contact time >10 hours was associated with significant improvements in A1C in 86 (70.27%) interventions [14,18,19,54,62,63,67,79,85,86,89,101,107,108,110,112,117,126,130,133,136,137,139,141,143,153] compared with 31 (56.4%) interventions with DSME contact times ≤10 hours [22,50,51,57–59,61,64,74,77,90–92,96–98,106,111,113–116,119,127,128,134,146,149, 150,154] (Fig. 6). Pearson chi-square analysis found the ratio of significant to non-significant change in A1C to be significantly greater for those interventions engaging participants in DSME for more than 10 hours as compared to those engaging participants in DSME for 10 hours or less ($p = 0.04$).

3.3. Overall changes in A1C

The overall mean reduction in A1C for all participants randomized to DSME was 0.74 (SD, 0.63) with a range of 0.6 to −2.50 and a median of −0.60 versus a mean decrease of 0.17 (SD, 0.50), range 1.5 to −1.7, and median of −0.12 for all CG participants (Table 2). Combination DSME was associated with the greatest change in A1C compared with group, individual, and remote interventions. There were no differences in the mean change in A1C between single or team DSME providers while DSME hours that exceeded 10 were associated with a slightly higher overall mean reduction in A1C (Table 2). Additional details about the median and range for overall changes between the IG and CG associated with DSME method, provider, and contact hours are summarized in Table 2.

3.4. Significant reductions in A1C

As an approach to examining the real potential for DSME to affect glycemic control, when we limited our assessment to

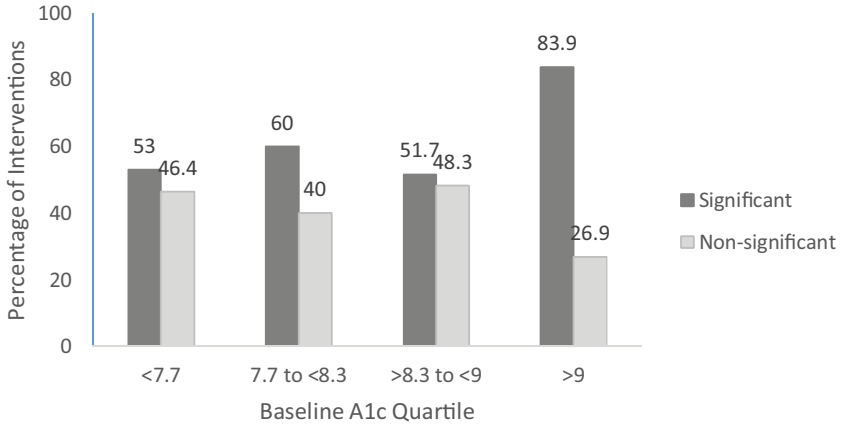

Fig. 4. Baseline A1c.

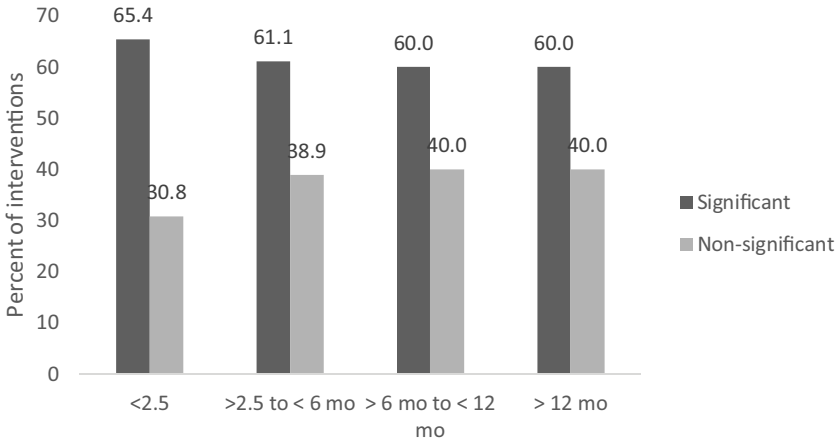

Fig. 5. Duration of DSME intervention.

interventions associated with a statistically significant decrease in A1C at 1 or more follow-up assessments, the overall mean A1C reduction for participants exposed to DSME was −0.80 compared with −0.21 for all CG participants (Table 2). Our examination of changes in A1C by method of DSME limited to studies that reported a significant decrease in A1C revealed the largest mean reduction for combination DSME at 1.22 compared with a mean reduction of 0.14 for participants randomized to a CG, followed by individual interventions that resulted in a mean reduction of 1.14 for IG participants versus −0.37 in the CG. The smallest reduction in A1C levels was evident for group DSME (Table 2).

There were only nominal differences between DSME delivered by a single provider compared with a team for interventions demonstrating significant decreases in A1C between the IG and the CG (Table 2). The improvement in glycemic control for DSME interventions resulting in significant decreases in A1C was slightly higher for interventions that offered ≥10 contact hours with a mean decrease of −1.01 for participants exposed to more than 10 hours of DSME and −0.96 for participants who received ≤10 hours of DSME (Table 2).

Examination of the range of A1C reductions for the 69 studies that reported significant decreases revealed reductions that exceeded 2% in the IG regardless of DSME method, provider, and contact hours. In comparison, A1C levels for participants randomized to a CG in these 69 studies ranged from a maximum of −1.7 for group, team, and contact hours >10 to an overall increase of 1.5 for combination, team, and more than 10 contact hours (Table 2).

4. Discussion and conclusions

4.1. Discussion

Since the authorization of Medicare coverage for outpatient diabetes self-management training in 1997, many randomized controlled trials have been conducted to evaluate the impact of DSME on clinical outcomes in individuals with T2DM. These studies are vary with respect to a number of parameters including methods and provider(s) of DSME, duration and intensity of as well as content included in the education, follow-up interval and participant characteristics. While not lending itself to meta-analysis, this systematic review confirms that DSME is associated with significant improvements in glycemic control. Notably, 61.9% of interventions achieved statistically significant and clinically relevant improvements in A1C for participants engaged in DSME compared with those who received no DSME. In addition, the overall mean reduction in A1C for all participants randomized to DSME was 0.74 compared with 0.17 for all participants randomized to a CG. It is worth noting this absolute improvement in A1C of 0.57 is clinically meaningful and in the range of improvement seen with the additional of several medications that may be added to a primary glycemic control treatment regime. To explore the real potential of DSME to improve glycemic control, we did a subanalysis including only those studies that reported a statistically significant decrease in A1C level with DSME as a surrogate indicator for quality. Here the reductions in A1C ranged from −0.1 to −2.50 for DSME compared with a range of change for CG

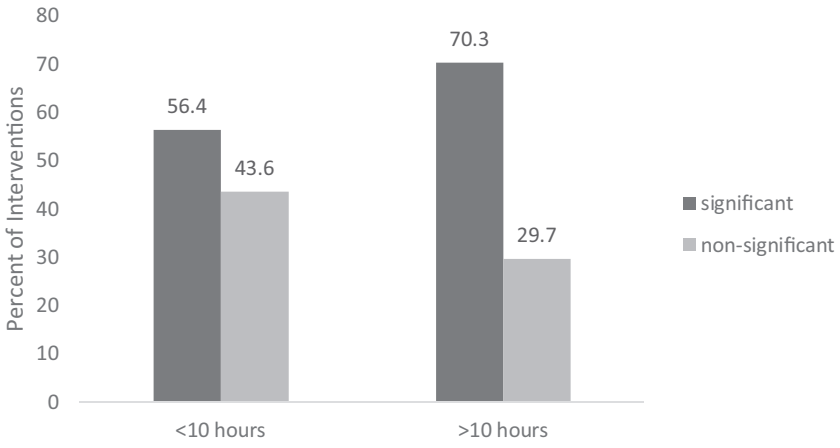

Fig. 6. Maximum DSME contact time.

Table 2
Change in A1C for intervention and control groups by DSME method, provider, and contact hours: all studies and studies with significant decrease in A1C between intervention group and control group.

	Interventions (*n*)	Mean (SD)		Median		Range		Absolute difference in A1C with the addition of DSME
All Studies								
		IG	CG	IG	CG	IG	CG	
Total	118	−0.74 (0.63)	−0.17 (0.5)	−0.60	−0.12	−2.5 to 0.6	−1.7 to 1.5	0.57
Mode								
• Combination	22	−1.10 (0.6)	−0.22 (0.62)	−0.88	−0.20	−2.5 to 0.1	−1.6 to 1.5	0.88
• Group	33	−0.62 (0.46)	−0.10 (0.42)	−0.50	−0.10	−2.3 to 1.0	−1.7 to 1.0	0.52
• Individual	47	−0.78 (0.63)	-0.28 (0.46)	−0.60	−0.27	−2.3 to 0.1	−1.3 to 0.9	0.50
• Remote	12	−0.50 (0.67)	−0.17 (0.46)	−0.22	−0.08	−2.2 to 0.2	−0.9 to 0.7	0.33
Provider								
• Single	69	−0.74 (0.63)	−0.17 (0.49)	−0.60	−0.10	−2.5 to 0.6	−1.6 to 1.1	0.57
• Team	46	−0.74 (0.64)	−0.18 (0.54)	−0.60	−0.20	−2.3 to −0.1	−1.7 to 1.5	0.56
Contact hours								
• ≤10	55	−0.71 (0.55)	−0.25 (0.47)	−0.60	−0.20	−2.5 to 0.1	−1.6 to 0.9	0.46
• >10	36	−0.84 (0.65)	−0.15 (0.55)	−0.80	−0.12	−2.3 to 0.1	−1.7 to 1.5	0.69
Studies with significant decrease in A1C								
	Interventions (*n*)	Mean (SD)		Median		Range		Absolute difference in A1C with the addition of DSME
		IG	CG	IG	CG	IG	CG	
Total	69	−0.80 (0.58)	−0.21 (0.47)	−0.69	−0.16	−2.5 to −0.01	−1.7 to 1.5	0.59
Mode								
• Combination	18	−1.22 (0.65)	−0.14 (0.63)	−1.1	−0.1	−2.5 to −0.4	−1.6 to 1.5	1.08
• Group	22	−0.71 (0.46)	−0.13 (0.40)	−0.6	−0.02	−2.3 to −0.23	−1.7 to 0.3	0.58
• Individual	24	−1.14 (0.6)	−0.37 (0.42)	−1.0	−0.3	−2.3 to −0.2	−1.3 to 0.3	0.77
• Remote	5	−0.86 (0.85)	−0.03 (0.85)	−0.8	0.1	−2.2 to −0.01	−0.9 to 0.7	0.83
Provider								
• Single	38	−1.03 (0.62)	−0.18 (0.45)	−0.8	−0.1	−2.5 to −0.01	−1.6 to 0.7	0.85
• Team	30	−1.00 (0.63)	−0.25 (0.56)	−0.9	−0.2	−2.3 to −0.2	−1.7 to 1.5	0.75
Contact hours								
• ≤10	30	−0.96 (0.56)	−0.26 (0.47)	−0.8	−0.20	−2.5 to −0.2	−1.6 to 0.7	0.70
• >10	25	−1.01 (0.65)	−0.16 (0.56)	−0.9	−0.10	−2.2 to −0.2	−1.7 to 1.5	0.85

participants ranging from 1.5 to −1.7. The United Kingdom Prospective Diabetes Study (UKPDS) revealed that a 0.9% decrease in A1C was associated with a 25% reduction in microvascular complications, a 10% decrease in diabetes-related mortality, and a 6% reduction in all-cause mortality [7].

We found that the magnitude of reductions in A1C in participants exposed to DSME exceeded that of usual care by more than 0.5% for all modes of delivery other than primarily remote. However, our findings on remote interventions must be interpreted with caution due to the small number of studies that offered remote DSME ($n = 12$). With the advancement of technology in the realm of web and remote applications they should continue to be explored and the potential remains to be determined.

Importantly the most favorable effect on A1C is associated with combination DSME with 0.88% reduction in A1C compared with the control group. There was no difference in the mean improvement in A1C between single and team DSME providers.

There was evidence to suggest that contact hours exceeding 10 were more often associated with DSME interventions resulting in additional, statistically significant, decreases in A1C. Although the difference between A1C declines in the ≤10 hours and >10 hours was small, a much greater proportion (70.3%) of studies providing ≥10 DSME hours demonstrated a statistically significant

change in A1C compared with usual care. Further analysis by method, provider, baseline A1C, duration of diabetes, and other demographic and clinical characteristics may shed additional light on this topic and provide useful policy information regarding reimbursement for DSME. Currently, the Centers for Medicare and Medicaid Services authorizes reimbursement for 1 hour of individual DSMT and 9 hours offered as group education over 12 months, with 2 hours of follow-up education in either group or individual settings reimbursed during each subsequent year. Although additional research is needed to better establish parameters for the optimal number of hours for different modes and provider types of DSME, the data in this systematic review are a first step in providing some guidance.

Of note, our review demonstrates that DSME benefited all participants regardless of baseline A1C level. However, almost two-thirds (65.6%) of studies that enrolled participants with baseline A1C levels ranging from >8.3 to ≤9.0 reported a significant difference between the IG and CG and 78.1% of studies that enrolled participants with baselines A1C levels >9.0 reported significant improvements in glycemic control in the IG compared with the CG. Although the recommendation of the American Diabetes Association [1] and others [155] is to engage individuals with diabetes when they are first diagnosed, it is our opinion that the results of this review suggest that this may not be the case. Instead, we suggest that the best time to engage individuals in DSME is when they are ready to engage, i.e., when they are receptive or motivated to engage in diabetes self-management strategies. Overall, our findings suggest that current DSME interventions can be improved through careful choice of method and possibly, provider and contact time, although these findings will need to be confirmed in randomized controlled trials and observational studies.

Factors that may contribute to differences in observed outcomes include the components and focus of the DSME intervention, which was another area of intervention heterogeneity among studies. For example, studies varied in their comprehensiveness in terms of coverage of the seven AADE7™ Self-Care Behaviors. In addition, subject demographics and clinical characteristics and the structure of the healthcare system in which the DSME was offered varied substantially between studies, including subject race/ethnicity, duration of diabetes, different countries, and different health care delivery systems.

The methodological limitations of the studies that were a part of this systematic review included lack of blinding of assessor, healthcare providers, and participants; potential for contamination between the IG and CG, unintended co-interventions, and the failure to describe strategies to properly conceal study group allocation. Most studies compared more intensive DSME with basic care and education due to ethical concerns about withholding education from the CG. This could have diminished the observed effects of DSME. There were also inconsistencies in the manner in which glycemic control was measured and reported. In addition, studies used diverse statistical methods to analyze their findings, with some relying on multivariate analyses that controlled for possible confounders while others used Student's *t*-test for independent samples to compare mean A1C between study groups or Pearson's chi-square analysis to compare the percentage of participants who met a discrete endpoint such as a prespecified value for A1C reduction. A number of studies failed to provide a detailed description of the DSME intervention and characteristics of the study population and most studies relied on volunteer participants, which limits generalizability of their results.

There are several limitations to this systematic review. First, we restricted our selection of publications to English-language only articles, though this is not considered to introduce systematic bias. [147] We also limited studies to those that assessed changes in A1C levels, although DSME is a behavioral intervention which focuses on self-management endpoints. This review included only randomized controlled trials and the generalizability of these findings to real-world settings may be limited the studies though studies settings included several community based interventions. Threats to internal validity were substantial with only 3 studies fulfilling the 4 quality assessment criteria that indicated no known selection, performance, attrition, or detection bias. By virtue of the definition of DSME, it is not feasible to blind providers to random assignment and few studies successfully blinded participants to randomization. However these limitations are representative of the field having been present in systematic reviews conducted in past decades [5,6,25,147] and the conclusions noted by Norris and co-workers [5,6] remain relevant 14 years later.

4.2. Conclusion

The clinical implication of the favorable impact of DSME on reductions in glycemic control is critically important because glycemic control is among the strongest predictors of disease progression and development of microvascular and macrovascular complications in individuals with T2DM [148]. The data from the UKPDS [7], suggests that this level of additional improvement in A1C would be associated with better outcomes of significance to patients. This systematic review demonstrates that all methods of DSME, delivered by either by a solo or team provider achieved greater reductions in A1C compared with CG participants.

4.3. Practical implications

Quality diabetes care should include engagement in DSME because it enhances the glycemic control seen with usual care. Effective DSME must integrate practical and feasible educational interventions that can be implemented in diverse settings. Having people with diabetes participate in DSME should occur when they are receptive to such engagement to maximize the potential of the intervention to have an impact. Because DSME is currently a heterogeneous intervention there is a need to assess and evaluate its ability to generate clinically significant changes in long-term physiological outcomes, behavioral endpoints, and patient-reported outcomes. In order to be relevant in today's healthcare marketplace, DSME must be relatively low-cost and cost-effective [5,145], as well as a satisfying experience for recipients [5]. Our results suggest that DSME has the potential to achieve clinically meaningful reductions in A1C, with resultant complication risk reduction. There is an imperative for methodologically rigorous research conducted with diverse subject populations in various real-world clinical and community settings to identify the methods, providers, duration, and contact time that will yield the most robust effects. Primary care physicians should refer their patients to receive diabetes self-management education using the diabetes education algorithm which defines 4 critical time points for delivery and key information on the self-management skills that are necessary at each of these critical periods [156]. Sample referral forms with information needed for reimbursement are available at: https://www.diabeteseducator.org/docs/default-source/legacy-docs/_resources/pdf/general/Diabetes_Services_Order_Form_v4.pdf.

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submit the manuscript for publication, reviewed all studies included in the analysis, and prepared this manuscript.

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