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A systematic review exploring characteristics of lifestyle modification interventions in newly diagnosed type 2 diabetes for delivery in community pharmacy

Thando Katangwe, Debi Bhattacharya and Michael J Twigg

School of Pharmacy, University of East Anglia, Norwich, UK

Keywords
community pharmacy; diabetes; education; health promotion

Correspondence
Miss Thando Katangwe, School of Pharmacy, University of East Anglia, Norwich NR4 7TJ, UK.
E-mail: T.Katangwe@uea.ac.uk

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Abstract

Objectives The aim of this systematic review was to examine the characteristics of effective lifestyle modification interventions designed for patients with newly diagnosed type 2 diabetes mellitus (T2DM) in order to determine elements that have the potential to be delivered in the community pharmacy setting.

Key findings Seven studies, comprising three each of the interventions diet and structured education and one of supported exercise, were identified. Interventions were conducted in hospital diabetes clinics and clinics situated in both urban and rural areas. Interventions were delivered face to face by highly skilled personnel including physicians, nurses and dietitians. Duration of interventions ranged from 3 months to 5 years.

Summary Structured education and dietary interventions in newly diagnosed type 2 diabetes effectively controlled blood glucose levels without pharmacological intervention. Important characteristics included face to face, individualised and multicomponent interventions with a duration of at least 6 months. These characteristics demonstrate potential for delivery in a community pharmacy setting, given its current involvement in delivering face to face, individual services with diet and lifestyle components. Further research is required to provide evidence for ideal intervention duration and frequency as well as training requirements for pharmacists.

Introduction

Diabetes mellitus, highlighted as a global burden by the World Health Organisation, is one of the most common causes of major health and development challenges in the 21st century.[1–3] Globally, it is estimated that 422 million people are living with diabetes, a prevalence that has almost quadrupled since 1980.[2] This dramatic rise is largely attributed to an increase in type 2 diabetes mellitus (T2DM), primarily driven by modifiable risk factors including obesity and physical inactivity.[2,4,5] The progression of T2DM, often associated with the development of disabling and life-threatening complications, also threatens many health economies.[6] In England, where almost 3.1 million people are diagnosed with diabetes,[7] the National Health Service spends approximately £8.8 billion of its total annual expenditure on the management of T2DM.[8]

The management of T2DM requires a comprehensive approach to care including lifestyle modification and self-management strategies. At diagnosis, treatment guidelines recommend the initiation of pharmacological therapy, primarily metformin.[9,10] However, highly motivated patients with blood glucose levels near target are often given the opportunity to engage with lifestyle changes for a period of 3–6 months before embarking on pharmacotherapy.[11] In this medication-naïve population, the non-pharmacological interventions of education and support for making diet and physical activity modifications form an important element for achieving successful blood glucose control.[9,11] However, most of the evidence for these interventions is in the context of preventing disease progression and complications in the population with established T2DM.[12–16]

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Structured diabetes education in self-management and lifestyle changes is the cornerstone of non-pharmacological support for newly diagnosed people.[9,11,17] The time of diagnosis is considered a critical point for structured education to be offered to individuals and/or their carers.[9,18]. However, structured evidence-based education programmes are poorly attended. In the United Kingdom, recent figures demonstrate that 16.7% of people with newly diagnosed T2DM were offered education programmes with only 3.6% attending.[19] Similar problems of engagement have been identified in other countries such as the USA[20] and Germany, where almost 30–50% of eligible patients do not participate in diabetes education.[21,22] A diverse range of barriers to engaging with education programmes have been reported including programme timing, location, availability of transport and flexibility of programme delivery.[23,24] A number of strategies for improving participation in diabetes education have been suggested including physician endorsement of the programmes to patients.[25] However, in the United Kingdom, despite a significant increase in the number of referrals by physicians, attendance to structured education has remained <10%.[26]

There is therefore a need to explore new ways of delivering diabetes education in order to increase participation rates. In England, community pharmacy has been recognised for its accessibility, particularly to highly deprived populations and ethnic minority groups.[27] In these populations, obesity, the greatest modifiable risk factor for T2DM, has been shown to have the highest prevalence.[5] Community pharmacy setting could therefore be well placed to target low participation in this population. In England, current use of the community pharmacy setting in diabetes is primarily focused on established diabetes, with the provision of enhanced services such as medicine use reviews.[28,29] The involvement of community pharmacy in newly diagnosed diabetes is limited to the provision of the New Medicines Service, a service designed to improve adherence and persistence of newly prescribed medicines.[29,30] Community pharmacies in England may also provide opportunistic lifestyle interventions such as weight management, smoking cessation and brief alcohol interventions.[31,32] However, none of these interventions are tailored specifically to T2DM or include diabetes education. With evidence regarding the role of community pharmacists in established diabetes demonstrating positive clinical outcomes, there is potential for community pharmacists to be involved in the management of people newly diagnosed with type 2 diabetes.[33–38]

In order to explore whether community pharmacy has the potential to provide adequate support to patients who are newly diagnosed and medication naïve, there is a need to explore the characteristics of effective interventions in this population. The present systematic review aimed to examine the characteristics of successful diet and lifestyle interventions designed for patients with newly diagnosed T2DM such as type of intervention, style of delivery, resources, training requirements and settings in order to determine elements that have the potential to be delivered in the community pharmacy setting.

Methods

A narrative systematic review of published primary research exploring diet and lifestyle interventions in adults newly diagnosed with T2DM was performed. The protocol for this systematic review was registered on PROSPERO.

Search strategy

Relevant electronic databases were reviewed from inception to the 31st of March 2015 including, the Cochrane Central Register of Controlled Trials, Medline, EMBASE, AMED, Web of Science, SCOPUS and CINAHL Complete. The searches were re-run from inception to 24/08/2018 to find any additional work that might warrant inclusion. A search strategy limited to the English language was developed and modified for each database according to the medical subject headings used. Reference lists of all potentially relevant studies identified were hand searched for other potentially eligible studies. The search terms and a MEDLINE search strategy can be viewed in the supplementary file (Appendix S1).

Study selection

The study population included adults (>18 years) with newly diagnosed T2DM. Participants were considered 'newly' diagnosed if they were within the first 12 months of diagnosis at the start of the trial.[39] Duration of diagnosis was determined at recruitment stage by the clinical trial research team as described in each paper. For the purposes of exploring non-pharmacologically managed T2DM, only participants who were medication naïve were included. Studies were eligible regardless of setting in which they had been conducted. This was to ensure a wide range of interventions were captured.

Eligible interventions included diet, exercise, weight loss or education with usual practice or standard care as an acceptable comparator. Studies had to report at least one of the following outcomes of interest: time to initiation of medication treatment, glycosylated haemoglobin (HbA_1 or HbA_{1c}) (mmol/mol), weight (kg), body mass index (BMI) (kg/m^2)), blood pressure (mmHg) and total cholesterol (mmol/l). To be included, the study design had to be a randomized controlled trial, non-randomized controlled

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trial or controlled before-and-after study. Studies were excluded if they were focused on medication, for example medication reviews, effects of prescription medication or dietary supplements.

Screening and data extraction

An initial title screen was performed by the primary reviewer (TK) to exclude any records identified through the search that clearly did not meet the inclusion criteria. Following the title screen, two reviewers (TK plus MT or DB) independently reviewed the abstracts of the remaining papers. The full papers identified as potentially eligible from the abstract screen were then retrieved and screened for eligibility against the inclusion criteria independently by two review authors (TK plus MT or DB). Any disagreements were resolved through discussion and if necessary by arbitration by a third reviewer (MT or DB). The overall inter-rater agreement for the full-text screening process was calculated using Cohen's kappa coefficient.[40]

For each eligible paper, two reviewers (TK plus MT or DB) independently extracted data. Variations in data extraction were resolved by consensus, referring back to the original data. The data from the eligible studies were extracted using a tailored extraction form based on the EPOC data collection checklist.[41]

The following data were extracted:

- Publication details: title, authors, journal, year of publication, volume, pages.
- Population and settings: population description, setting, inclusion criteria, exclusion criteria, and recruitment methods.
- Methods: aim of the study, design and duration of participation.
- Participants: total number at the start of the trial, age, gender, ethnicity, socio- economic status, comorbidities, time since diagnosis and other treatment received.
- Intervention: type of intervention, setting, description of the intervention, description of standard care, duration of intervention, timing (e.g. frequencies of contact), delivery (e.g. intensity), method of follow-up, providers and resources requirements.
- Outcomes: whether reported, measurement tool/method, unit of measurement, length of follow-up, number or times of follow-up measurement.
- Analysis: number of withdrawals/exclusions/lost to follow-up (retention).
- Authors key results and conclusion.

Quality assessment

The methodological quality of each included paper was critically appraised using the EPOC criteria.[42] Each study was scored low, high or unclear (if not specified in the paper) for each of the criteria. Two reviewers (TK and MT) carried out the assessment independently. Blinding was not assessed as a quality criterion due to inability to blind participants and the objective nature of the outcome measure. The results were compared and any discrepancies resolved by discussion. The overall inter-rater agreement for the quality assessment was calculated using Cohen's kappa coefficient.[40] The quality assessment was used to determine the level of relevance of interventions to current practice.

Data synthesis

Due to the diversity of interventions in the included studies such as types of interventions and their duration, a narrative synthesis was adopted to summarise the results.[43] The textual approach of the synthesis provided an analysis of the relationships within and between studies and an overall assessment of the robustness of the evidence.

Results

Search results

The flow of studies through the screening process is provided in Figure 1. The main reason for exclusion at full-text screening of the 87 articles was that study participants were not newly diagnosed and/or medication naïve at the start of the trial. The overall inter-rater agreement for the full-text screening process was high, achieving a kappa score of 0.84. In total, seven published trials met the inclusion criteria and were thus eligible for data extraction.

Intervention characteristics

Types of intervention

The main characteristics of the population and interventions in the included studies are provided in Tables 1 and 2, respectively. All seven studies were randomised controlled trials conducted in Europe.[44–50] The study sample sizes ranged from 21 to 1139 and included participants with a mean age ranging from 46 to 56 years. Interventions were supported exercise,[44] diet[47,49,50] and structured education.[45,46,48]

Structured education was delivered in either a group or a individual setting. Laitinen *et al.*[48] reported a 12-month individual education intervention delivering tailored intensified dietary education following a 3-month basic education period offered to all study participants.

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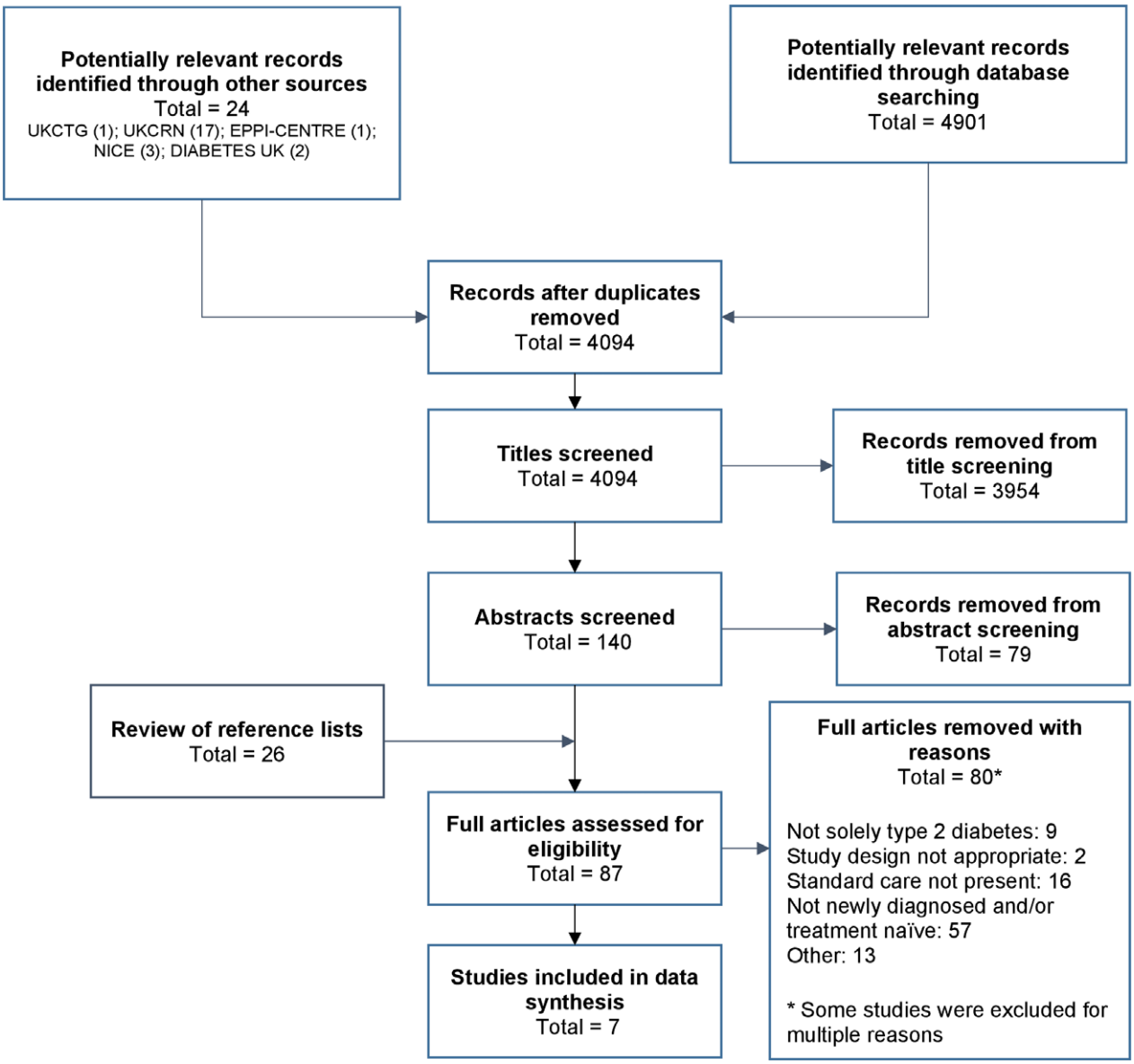

Figure 1 Adapted PRISMA flow diagram of study selection.

Heller *et al.* reported a 6-month group education intervention with sessions attended by four to six intervention participants, each with their spouse or friend.[46] The intervention which aimed to promote weight loss, encouraged healthy eating by teaching participants to make appropriate food choices. The study also included a 6-month follow-up post-intervention period. Hanefeld *et al.*[45] reported a 5-year multi-interventional intensified group education consisting of diet and physical activity interventions to promote weight loss as well as smoking cessation and alcohol interventions. Dietary interventions were aimed at restriction of carbohydrates, cholesterol and/or fat,[47,49] and increasing knowledge and appropriate consumption of low glycaemic index (GI) foods.[50] The intervention reported by Esposito *et al.*[49] also included physical activity advice which was offered to all study participants. Backx *et al.*[44] reported a 12-week supported exercise intervention consisting of a cardiorespiratory phase and interval training delivered at individualised training intensities.

Settings

Five studies defined intervention settings as diabetes clinics in secondary care[46–50] and one in diabetes clinics in urban or rural areas.[45] Backx *et al.*[44] who reported the

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Table 1 Characteristics of study participants

Study	Intervention	Total (intervention/ control) (*n*)	Age (years)	Gender (% males)	Time since diagnosis	Significant baseline differences between groups
Backx 2011[44]	Supported exercise	21 (11/10)	Median (range): 59.6 (44–69)	79%	<3 months	None
Esposito 2009[49]	Diet programme	215 (108/107)	Mean *Intervention*: 52.4 *Control*: 51.9	49%	Newly diagnosed	None
Frost 1994[50]	Diet programme	51 (25/26)	Mean (range) *Intervention*: 54 (52–56) *Control*: 56 (53–59)	71%	Newly diagnosed	Cholesterol
Hanefeld 1991[45]	Multi- intervention group education	1139[a] (382/378)	Mean (±SD): *Intervention*: 46.6 ± 5.6 *Control*: 46.2 ± 7.0	58%	Newly diagnosed	Fasting blood glucose
Heller 1988[46]	Group education	87 (40/47)	Mean (95% CI): *Intervention*: 56.5 (55–58) *Control*: 56.4 (53-59.9)	48%	Newly diagnosed	None
Hockaday 1978[47]	Diet programme	93 (39/54)	Mean (range): *Intervention*: 50 (24–65) *Control:* 53 (22–65)	56%	Newly diagnosed	% over ideal body weight
Laitinen 1993[48]	Individualised education	86 (40/46)	Mean (±SD): *Intervention:* 50.7 ± 7.7 (men) *Intervention:* 53.7 ± 6.3 (women) *Control:* 54.0 ± 6.6(men) *Control:* 54.4 ± 6.4 (women)	57%	Newly diagnosed	None

[a]Participants in this study were randomised to 3 arms including control (378), Intensified Health Education plus placebo (IHE) (382) and clofibric acid (379). For the purposes of this review we only examined the findings of participants in the control and IHE group.

supported exercise intervention was the only study which did not mention the intervention setting.

Delivery

All interventions were delivered face-to-face with some including telephone contact. Backx *et al.* used telephone contact to check on the progress of the standard care unsupported exercise participants and Heller *et al.* used telephone contact in the post-intervention follow-up period.[44,46] Dietary, physical activity and weight loss recommendations were delivered using a variety of methods including, visual, oral and written instructions.[45,46,48–50] Both group and individual education interventions used behaviour modification strategies such as goal setting to encourage weight loss or diet modification.[46,48] Heller *et al.*[46] (group education) also used progress mapping of weight, group discussion and attendance with spouse or friends. Laitinen *et al.*[48] (individualised education) included individually tailored dietary instructions, practical food preparation and behaviour modification strategies, for example self-motivation and recognition of situations which may pose a challenge to dietary control.

Frequency, duration and follow-up

The shortest intervention with the highest frequency of contact was reported by Backx *et al.*[44] who delivered 60-min supported exercise sessions, three times a week for 12 weeks. The shortest structured education intervention lasted for 6 months [46] and the longest lasted for 5 years.[45] Structured education and diet interventions were delivered at intervals ranging from three weekly to three monthly.[44–47,49,50] Duration of sessions was only described by Heller *et al.*[46] who reported delivering 90-min structured education sessions. The primary follow-up method used was clinic visits with self-reporting methods such as diaries used to record adherence to dietary recommendations.[44,47,50]

Resources and training requirements

Supported exercise was delivered by qualified exercise physiologists and physiotherapists and dietary advice was delivered primarily by dieticians, clinical nutritionists and diabetologists.[44–49] Diabetes education was delivered by diabetes nurse specialists.[46,48] Physicians were primarily

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Table 2 Intervention characteristics of included studies

Study	Intervention	Settings	Description	Length of intervention	Delivery	Provider	Frequency	Session duration	Standard care
Backx 2011[44]	Exercise	Not described	Supported exercise sessions consisting of a cardiorespiratory phase and interval training	12 weeks	Face-to-face	Exercise physiologist	Three times a week	60 min	Unsupported exercise (30 min five times a week)
Esposito 2009[49]	Diet programme	Teaching hospital diabetes clinic	Mediterranean-style diet (carbohydrate content of <50% of daily energy and 30% of calories from fat)	4 years	Face-to-face	Nutritionists and dietitians	Monthly for 1 year then bimonthly for 3 years	Unclear	Low-fat calorie restricted diet based on American Heart Association guidelines
Frost 1994[50]	Diet programme	Hospital diabetes clinic	Dietary education with emphasis on low GI foods	12 weeks	Face-to-face	Unclear	0, 4 and 12 weeks	Unclear	Standard advice based on the British Diabetic Association dietary recommendations
Hanefeld 1991[45]	Multi intervention group education	Diabetes clinics in urban or rural areas	Structured education including diet, antismoking and anti-alcohol education and ways to enhance physical activity	5 years	Face-to-face	Physicians; sports physicians and physiotherapists (group exercise sessions)	3 monthly intervals	Unclear	Participants were referred back to their local diabetes clinic for care by trained diabetologists
Heller 1988[46]	Group education	Hospital diabetes clinic	Group education including dietary advice, weight management and diabetes education	6 months Plus 6 months follow-up	Face-to-face and telephone contact during follow-up period	Diabetes specialist nurse; dietician	3 weekly	90 min	Initial visit with a doctor and tailored dietary advice from a dietician
Hockaday 1978[47]	Diet programme	University hospital diabetes clinic	High carbohydrate modified-fat (MF) diet	12 months	Face-to-face	Dietician	3 monthly intervals	Unclear	Classical low carbohydrate diet
Laitinen 1993[48]	Individual education	Hospital outpatient clinics	Individually tailored intensified dietary education	12 months	Face-to-face	Clinical nutritionist; diabetes specialist nurse; physician	2 monthly intervals	Unclear	Usual education at local health centres (at 2-3 month intervals)

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involved at diagnosis and initial clinic visits but had very little to do with delivering the interventions.[46,48] Training was only mentioned by Hanefeld *et al.*[45] who trained all participating staff to ensure standardisation of the intervention but there was no detail of what the training entailed.

Outcome measures

The outcome measures for each reported study are summarised in Table 3. The structured education intervention reported by Hanefeld *et al.*[45] reported a significantly smaller proportion of participants initiated on medication treatment at 2- and 5-years (9%, 33%) compared to standard care (34%, 54%) ($P < 0.01$). Similarly, the Mediterranean diet programme reported by Esposito *et al.* reported a significantly smaller proportion of participants initiated on medication at 18 months and 4 years (12% and 44%, respectively) compared to standard dietary advice (24% and 70%, respectively).[49] These were the only studies to have reported this outcome measure of interest. Secondary measures of interest reported by the studies, including blood pressure, BMI and cholesterol, were not used for the purposes of this review as data included participants who had been initiated on diabetes medication treatment during the intervention period.

The group and individual structured education interventions reported by Heller *et al.* and Laitinen *et al.*, respectively, were the only interventions reporting clinically significant reductions in both weight ($P < 0.002$ and $P = 0.05$ respectively) and HbA_1/HbA_{1c} ($P < 0.001$ and $P = 0.053$, respectively) compared to standard care.[46,48] Heller *et al.* who reported a 6-month education intervention with a 6-month follow-up period reported weight reductions which remained significantly greater than standard care during both the intervention and the follow-up period.[46] However, the reduction in HbA_1, which reached normal levels during the 6-month intervention period, was not maintained following the post-intervention follow-up period.[46] At 12 months, the HbA_1 levels of the intervention group not only reverted to diabetic levels but were also similar to the standard care group.[46] Laitinen *et al.*[48] reported a 3-month basic education offered to all the study participants which resulted in significant weight ($P < 0.01$) and HbA_{1c} ($P < 0.001$) reductions in both groups. However, during the 12-month intervention period, only individuals in the intervention group achieved further weight and HbA_{1c} reductions with overall significant reduction at the end of the 15-month period (($P < 0.05$) and (($P = 0.053$)).[48]

Total cholesterol was reported by Backx *et al.* in the supported exercise intervention, Hockaday *et al.* in the modified-fat diet, Frost *et al.* in the low GI diet intervention and Laitinen *et al.* in the individual structured education intervention.[44,47,48,50] Of the four interventions to have reported total cholesterol levels, only Hockaday *et al.* and Frost *et al.* reported significant reductions compared to standard care ($P = 0.01$ and $P < 0.05$, respectively). The modified-fat diet intervention, which consisted of moderate carbohydrate content, produced no additional benefits in achieving clinically significant weight loss when compared to standard low-carbohydrate diet.[47] The supported exercise intervention, despite producing significant within group differences, had no advantage over standard care in reducing BMI and HbA_{1c} in medication-naïve patients.[44] None of the studies reported blood pressure as an outcome.

Quality assessment

A methodological quality assessment of the included studies was conducted, the findings of which are reported in Table 4. The overall inter-rater agreement was substantial (kappa = 0.73). Sources of bias included significant baseline differences in outcomes of interest (Hanefeld *et al.*, Hockaday *et al.* and Frost *et al.*) and lack of reporting subsequent adjusted analysis (Hockaday *et al.* and Frost *et al.*). Hockaday *et al.* and Esposito *et al.* who reported using the same dieticians and/or nutritionists for delivering both the intervention and the standard care participants were rated high for contamination bias.[47,49] Unclear reporting of methods of randomisation and allocation concealment in most of studies precluded an adequate assessment of selection bias. Additionally, due to incomplete reporting, the only two studies addressing the outcome 'initiation of medication treatment' (Hanefeld *et al.* and Esposito *et al.*) could not be examined fully in order to investigate the effects of the intervention on the other outcomes in medication-naïve participants.[45,49]

Overall study attrition, assessed as incomplete data, was rated medium with most studies reporting low attrition rates. Four studies (Backx *et al.*, Heller *et al.*, Esposito *et al.* and Frost *et al.*) accounted for all randomised participants. In these studies, the proportion of missing data was similar in the intervention and control groups with reasons for attrition including dropouts, hyperglycaemic events, uncontrolled diabetes and death. However, the 5-year intervention reported by Hanefeld *et al.* was rated high risk of bias as it only accounted for those who failed to complete the study due to death. Hockaday *et al.* and Laitinen *et al.* were rated unclear as they reported the same number of participants at baseline and in the analysis and did not specify any attrition. Overall risk of bias across studies was rated medium and evidence deemed reliable for the purposes of extraction of effective components of lifestyle modification interventions in newly diagnosed type 2 diabetes.

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Table 3 Results of outcome measures of interest in the included studies

Study	Group	*N*	Baseline measurements	Follow-up measurement	Within group significance results	Between group significance results
Number of patients initiated on medication treatment. *N* (%)						
Hanefeld 1991[45]	Intervention (I)	Baseline 382 2 years: 334 5 years: 316	None	2 years: 29 (9%) 5 years: 104 (33%)	Not reported	$P < 0.01$ at 2 and 5 years
	Standard care (SC)	Baseline 378 2 years: 366 5 years: 329	None	2 years: 126 (34%) 5 years: 177 (54%)		
Esposito 2009[49]	Intervention (I)	Baseline 98	None	18 months: 12 (12%) 4 years: 43 (44%)	Not reported	$P < 0.01$ at 18 months and 4 years
	Standard care (SC)	Baseline 97	None	18 months: 23 (24%) 4 years: 68 (70%)		
HbA_{1c} mmol/mol [95 CI] (%)						
Backx 2011[44]	I	10	46 [39–69] (6.4)	42 [37–54] (6.0)	>0.007	N.S.
	SC	9	49 [38–63] (6.6)	50 [39–83] (6.7)	Not significant (N.S.)	
Heller 1988[46]HbA_1(%)	I	36	12.3 [11.4–13.2]	3 months: 8.6 [7.9–9.3] 6 months: 7.5 [7.0–8.1] 12 months: 9.0 [8.2–9.8]	Not reported	3 months: $P < 0.05$ 6 months: $P < 0.001$ 12 months: NS
	SC	39	12.7 [11.9–13.5]	3 months: 9.7 [9.0–10.4] 6 months: 9.5 [8.7–10.4] 12 months:9.9 [8.9–10.9]		
Laitinen 1993[48]	I	40	68 [±1] (8.4)	3 months: 54 [−4 to −8)] (7.1) 15 months: 49 [−6 to −12] (6.6)	3 months: $P < 0.001$	15 months $P = 0.053$
	SC	46	75 [±5] (9.0)	3 months. 62 [−2.0 to −4] (7.8) 15 months: 58 [−5 to −10] (7.5)	3 months: $P < 0.001$	
Total cholesterol (mmol/l)						
Backx 2011[44]	I	10	5.3 [3.8–7.8]	4.6 [3.5–5.7]	$P = 0.046$.	N.S.
	SC	9	4.8 [4.1- 6.4]	4.7 [4.1–5.2	N.S.	
Frost 1994[50]	I	25	6.2 [±0.3]	5.5 [±0.3]	$P < 0.05$	$P < 0.05$
	SC	26	5.6 [±0.2]	5.3 [±0.1]	N.S.	
Hockaday 1978[47]	I	39	6.2 [SE 0.20]	1 month: 5.2 [SE 0.19] 12 months: 5.6 [SE 0.21]	1 month: $P < 0.001$ 12 months: $P < 0.001$	12 months: $P = 0.01$
	SC	54	6.5 [SE 0.21]	1 month: 6.2 [SE 0.17] 12 months: 6.3 [SE 0.19]	N.S.	
Laitinen 1993[48]	I	40	6.3 [±1.4]	3 months. 6.1 [±1.2] 15 months: 6.0 [±1.0]	N.S.	N.S.
	SC	46	6.5 [±1.1]	3 months: 6.3 [±1.0] 15 months: 6.4 [±1.0]	N.S.	
Body mass index (kg/m^2)						
Backx 2011[44]	I	10	30.0 [25.3–40.1]	28.7 [23.1–39.4]	$P = 0.006$	N.S.
	SC	9	32.3 [26.4–40.5]	32.0 [25.0–41.2]	N.S.	

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Table 3 Continued

Study	Group	*N*	Baseline measurements	Follow-up measurement	Within group significance results	Between group significance results
Weight (kg)						
Backx 2011[44]	I	10	91.7 [74.3113.7]	87.9 [69.9-112.7]	$P < 0.007$	N.S.
	SC	9	102.5 [82.1-123.2]	101.1 [78.0-123.3]	N.S.	
Heller 1988[46]	I	36	86.9 [83.1-90.7]	3 months: −6 [−5 to −7]	Not reported	3 months: $P < 0.002$
				6 months: −7 [−5.5 to −9]		6 months: $P < 0.002$
				12 months:-5.5 [−4 to −6.5]		12 months: $P < 0.05$
	SC	39	86.1 [82.0-90.1]	3 months.: −3.5 [−1.5 to −5]		
				6 months: −2 [−1 to −5]		
				12 months: -3 [−2 to −4]		
Hockaday 1978[47]	I	39	82.2 [56-114]	1 month: −2.7 [+3 to −10]	1 month: $P < 0.001$	N.S.
				12 month: −4.6 [+3 to −33]	12 months: $P < 0.001$	
	SC	54	76.4 [51-99]	1 month.: −3.3 [+1 to −8]	1 month: $P < 0.001$	
				12 months: −3.8 [+8 to −20]	12 months: $P < 0.001$	
Laitinen 1993[48]	I	40	91.6 [±14.5]	3 months: 88.3 [±14.1]	3 months: $P < 0.01$	15 months $P = 0.05$
				15 months: 86.5 [±13.7]		
	SC	46	92.2 [±14.7]	3 month: 88.8 [±14.0]	3 months: $P < 0.01$	
				15 months: 90.2 [±14.3]		

NS, not significant.

Discussion

This review found that both structured education interventions and dietary interventions in newly diagnosed T2DM effectively controlled blood glucose levels without pharmacological intervention and positively affected clinically important outcomes such as weight and HbA_{1c}.[45,46,48,49] Characteristics of effective interventions included face to face, individualised, multicomponent education and diet interventions with a duration >6 months.

Rigorous systematic review methods were adopted for the conduct and reporting of this review. To minimise the risk of bias and errors, data screening, extraction and quality assessment were performed by two independent reviewers. The overall inter-rater agreement for screening and extraction (using Cohen kappa)[40] was good, achieving a kappa score of 0.84. Although the heterogeneity of included studies precluded a meta-analysis, findings are relevant to current practice and guidance has been provided regarding potential diabetes service innovations in community pharmacy settings.[9,11] A limitation of the review is the exclusion of non-English studies and the limited effort made in contacting corresponding authors for intervention details that were not included in the written reports.[44,45,49] Additionally, although the risk of bias across studies was rated medium, clinicians should exercise caution when consulting evidence from this review to inform future practice due to the lack of recent studies conducted in primary care settings.

The community pharmacy setting

In clinical practice, intervention setting is amongst the most important characteristics due to its potential to influence uptake and attrition.[1,23–26,51,52] In this review, two of the education interventions which demonstrated positive clinical outcomes were delivered in hospital outpatient settings.[46,48] Hospital settings may possess ideal characteristics for the implementation of diabetes interventions and achieve desired clinical outcomes but they often achieve a lower reach of the targeted populations than primary care settings.[51] Primary care settings have also demonstrated lower attrition rates than hospital settings.[51]

In recent years, in meeting primary care demands, the need to deliver diabetes education in alternative and convenient settings such as community pharmacies has been acknowledged.[18] The 5-year education intervention described in this review, conducted in both rural and urban areas[45] and the 4-year dietary intervention conducted in a city-based university clinic,[49] suggests that both local and high street community pharmacies could

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Table 4 Quality assessment of included studies

Study	Randomisation	Allocation concealment	Similar baseline characteristics	Similar baseline outcomes	Incomplete data	Blinding of assessors	Contamination	Selective outcome reporting	Other bias
Backx 2011[44]	Unclear	Unclear	Low	Low	Low	Low	Low	Low	Low
Esposito 2009[49]	Computer-generated random number sequence	Low	Low	Low	Low	Low	High	High	Low
Frost 1994[50]	Random number tables	Unclear	High	High	Low	Low	Unclear	Low	Low
Hanefeld 1991[45]	Unclear	Unclear	High	Low	High	Unclear	Unclear	High	Low
Heller 1988[46]	Unclear	Unclear	Low	Low	Low	Low	Low	Low	Low
Hockaday 1978[47]	Unclear	Unclear	High	High	Unclear	Low	High	Low	Low
Laitinen 1993[48]	Unclear	Unclear	Low	Low	Unclear	Low	Low	Low	Low

be well placed to deliver effective interventions. Additionally, the community pharmacy team, which tends reflect the culture of the local population, could play an important role in engaging ethnic minorities and other hard to reach groups thus also addressing cultural barriers identified by research.[23,51] In England, delivering diabetes education in community pharmacy setting would be in line with the current focus for the future of community pharmacy[53] to be a facilitator of personalised care for people with long-term conditions. However, to date, although community pharmacy has been identified as a favourable setting for the delivery diabetes education in countries such as the USA,[18,54] community pharmacies in England do not offer any diabetes education interventions.

The positive clinical outcomes of education interventions in this review demonstrate the potential to support people who are motivated to try non-pharmacological options before embarking on pharmacotherapy.[9,11,17] In this review, education interventions consisting of more than one component including diet, exercise, smoking cessation and alcohol interventions seemed to achieve wider clinical benefits in addition to effective blood glucose control in the management of T2DM, when compared to interventions focused on single components alone.[44,47,50] Therefore, based on this evidence[45,55] and in line with management guidance,[9] community pharmacy-based education interventions would have to deliver multicomponent diabetes education interventions. With community pharmacy currently delivering services such as smoking cessation, brief alcohol interventions and exercise advice, there is a potential to design education-based intervention without extra training requirements on these elements.[31]

When exploring the potential for community pharmacy to deliver diabetes education, it is also important to consider delivery characteristics of interventions that have shown effectiveness in controlling blood glucose in newly diagnosed type 2 diabetes. Majority of the interventions described in this review primarily used face-to-face delivery including one which also used telephone calls in the follow-up period. Face-to-face delivery has been shown to predict an increased likelihood of efficacy in diabetes education.[15] Face-to-face interventions, a commonly used delivery style in community pharmacy, would therefore be a more favourable option for this setting. The use of follow-up telephone calls, also used in community pharmacy interventions such as the New Medicine Service,[29,30] could also be easily implemented. Based on the evidence in this review, both group and individual education interventions demonstrated positive clinical outcomes, a finding in line with other research evidence.[16,56] Generally due to cost-effectiveness and the added advantage of patient networking, group-based education is more widespread and recommended as the choice delivery method in current treatment guidelines.[57,58] However, group-based interventions have been listed amongst the barriers to the uptake of diabetes education.[52] NICE guidance for the management of T2DM acknowledges that group sessions may not be popular with all patients and thus recommends the provision of individualised education for people unable or unwilling to participate in group education.[9] Therefore, based on this finding and in line with guidance, community pharmacy, which primarily delivers individualised interventions, could perhaps serve as an alternative option for a population which prefers individualised education. However, the cost-effectiveness of delivering individualised community pharmacy-based education would have to be considered.

Important intervention characteristics such as duration and frequency of contact described in this review, largely differed from current guidelines.[9,17] The interventions included in this review generally had a longer duration

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and higher frequency of contact than current practice guidance which recommends a single education intervention at the time of diagnosis with annual reinforcement.[9] Evidence shows that whilst single education interventions may improve weight loss and physical activity levels in the short term, they may not have any short or long-term effects on glycaemic control.[59,60] Previous research also suggests that increased contact time between participant and educator decreases glycaemic levels, with a decrease of 1% in HbA_{1c} for every additional 23.6 h.[12] Current community pharmacy interventions vary in both duration and frequency. For example, duration of services include ongoing (e.g. medicines use reviews),[28,29] 12 week (e.g. smoking cessation)[31,32] and one-off interventions (e.g. diabetes screening). Frequency of contact also ranges from annual (e.g. medicine use review),[28,29] two weekly (e.g. new medicines services)[29,30] and weekly contact (e.g. smoking cessation).[31,32] The variation displayed with current interventions delivered in the community pharmacy setting demonstrates potential to deliver diabetes education interventions with longer duration and regular frequency. Such interventions could also be linked with regular visits to pharmacies for other prescription or over-the-counter services.

Intervention facilitators and delivery skills are also important factors to consider in the delivery of structured education.[61] In this review, highly skilled personnel including physicians, diabetes nurses, dietitians and nutritionists were used to deliver the interventions. Although this reflects the multidisciplinary approach recommended by evidence,[62] the interventions did not reflect more recent guidelines which demonstrate the expansion of the role of facilitators over the recent years to include other disciplines such as pharmacists.[61] In the United States, the 2017 national standards for diabetes self-management education and support (DESMES) recommends that at least one of the team members responsible for facilitating DESMES services should be a registered nurse, registered dietitian nutritionist or pharmacist with training and experience.[61] Using community pharmacists as diabetes education facilitators could address barriers to attendance identified by research such as comorbidities and cultural beliefs.[23] People with T2DM often have comorbidities such as hypertension and high cholesterol which require regular medication often dispensed in community pharmacies.[9] Therefore, established relationships between patients and their pharmacists could be of potential benefit in decreasing attrition rates in education interventions.[51]

The training requirements for diabetes education facilitators were not clearly described in the interventions included in this review. However, due to the growing recognition of pharmacists as diabetes educators, particularly in the United States and Australia, courses have been designed to support this additional training need.[54,63] Evidence supports the need for facilitators to have specialised clinical knowledge in diabetes and behaviour change principles.[61,64] In England, although a thorough assessment of training requirements for community pharmacists may need to be undertaken, current established diabetes courses designed for healthcare professionals[65] and training programmes for diabetes educators[66] could be used to ensure that pharmacists have both specialised clinical knowledge and behaviour change skills. Behaviour change strategies identified by this review such as goal setting, and progress mapping may also shed some light into skills needed to deliver successful interventions.[67–70]

Conclusion

Structured education and dietary interventions in newly diagnosed type 2 diabetes effectively controlled blood glucose levels without pharmacological intervention. Important characteristics included face to face, individualised and multicomponent interventions with a duration of at least 6 months. These characteristics demonstrate potential for delivery in a community pharmacy setting, given its current involvement in delivering face-to-face individual services with diet and lifestyle components. Further research is required to provide evidence for ideal duration and frequency of education interventions for this population as well as training requirements for pharmacists.

Declarations

Conflict of interest

The Author(s) declare(s) that they have no conflicts of interest to disclose.

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Ethical approval

This publication is a systematic review and therefore ethical approval was not required as no primary research was undertaken.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Appendix S1. Bibliographic searches.

Appendix S2. PRISMA checklist.

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