

REVIEW ARTICLE

Effectiveness of educational interventions for diabetes-related foot disease: A systematic review and meta-analysis

Aaron Drovandi^{1,2} | Leonard Seng¹ | Jonathan Golledge^{1,3} 

¹Queensland Research Centre for Peripheral Vascular Disease, College of Medicine and Dentistry, James Cook University, Townsville, Queensland, Australia

²School of Biomedical Sciences, Faculty of Biological Sciences, University of Leeds, Leeds, West Yorkshire, UK

³The Department of Vascular and Endovascular Surgery, Townsville University Hospital, Townsville, Queensland, Australia

Correspondence

Jonathan Golledge, Queensland Research Centre for Peripheral Vascular Disease, College of Medicine and Dentistry, James Cook University, Townsville, QLD 4811, Australia.

Email: jonathan.golledge@jcu.edu.au

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Abstract

This systematic review and meta-analysis pooled evidence from randomised controlled trials (RCTs) on the effectiveness of educational programs for people with or at risk of diabetes-related foot disease (DFD). A systematic search identified RCTs evaluating the effectiveness of educational programs in preventing or managing DFD. The primary outcome was risk of developing a foot ulcer. Secondary outcomes included any amputation, mortality, changes in cardiovascular risk factors, foot-care knowledge and self-care behaviours. Meta-analyses were performed using random effects models. Risk of bias was assessed using Cochrane's ROB-2 tool. Education programs were tested in 29 RCTs ($n = 3891$) and reduced risk of a foot ulcer by approximately half although the upper 95% confidence interval (CI) reached 1.00 (odds ratio [OR], OR 0.54; 95% CI 0.29, 1.00, $I^2 = 65\%$). Education programs reduced risk of any amputation (OR 0.34; 95% CI 0.13, 0.88, $I^2 = 38\%$) and HbA1c levels (standardized mean difference -0.73 ; 95% CI -1.26 , -0.20 , $I^2 = 93\%$) without affecting all-cause mortality (OR 1.09; 95% CI 0.57, 2.07, $I^2 = 0\%$). Education programs mostly significantly improved DFD knowledge (13 of 16 trials) and self-care behaviour scores (19 of 20 trials). Only one trial was deemed at low risk of bias. Previously tested education programs have mostly effectively improved participants' knowledge and self-care behaviours and reduced risk of foot ulceration and amputation. Larger high quality trials with longer follow-up are needed.

KEYWORDS

amputation, foot ulcer, glycated haemoglobin, patient education, quality of life

1 | INTRODUCTION

Diabetes-related foot disease (DFD) incorporates a range of complications, including foot ulcers and infections, affecting an estimated 20% of people with diabetes at some point in their life.¹ DFD has a detrimental effect on quality of life,² and carries a high risk of mortality, with 5-year mortality being 2.5 times higher than people with

diabetes without DFD, and is over 70% for those with a DFD-related lower limb amputation.¹

Treatment and prevention of DFD requires patients with diabetes to be integrally involved in their own health care. Patients usually receive education aimed at improving their knowledge about management, promoting their adherence to prescribed treatments, and participation in daily foot care activities.^{3,4} The International Working

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Group on Diabetic Foot (IWGDF) guidelines recommend a structured education programme delivered by a member of the health care team to patients individually or in small groups.^{4,5} Several previous reviews have attempted to examine the value of such educational programs but have lacked meta-analyses,^{6,7} or focused only on foot ulceration and amputation, omitting key outcomes related to the effectiveness of educational interventions such as their effect on patient knowledge and self-care behaviours.^{3,8-10} These previous analyses of a limited number of randomised controlled trials (RCTs) all found that educational programs trialled so far have insufficient evidence of their effectiveness.^{3,7,9,10} There is therefore widespread uncertainty about the value and best mode of delivery of DFD education.¹¹⁻¹⁶

The aim of this systematic review and meta-analysis was to assess the effectiveness of DFD-specific educational interventions on a wider range of DFD-related outcomes, including not only foot ulcer risk, but also ulcer healing, infection, amputation, mortality, modifiable risk factors, DFD-knowledge, foot self-care behaviours, health-related quality of life (HRQOL), and anxiety and depression. This was achieved through analysis of RCTs that tested any form of DFD-focused educational programme in people with or at risk of DFD.

2 | METHODS

This systematic review and meta-analysis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines,¹⁷ and was registered with PROSPERO (CRD42021275610).

2.1 | Search strategy

The PubMed, MEDLINE (Ovid), CINAHL and Cochrane Library databases were searched for English language articles describing RCTs testing educational interventions for people with DFD. The search string was developed by two authors (AD and LS) and last run on the 8 December 2022 with no start date restriction. The search string combined three term groups using the Boolean operators 'AND' and 'OR'; (1) 'diabetes' terms (e.g. diabetes), (2) 'DFD' terms (e.g. ulcer), and (3) 'education' terms (e.g. knowledge). The full search string is detailed in Supporting Information S1: Appendix 1. Reference and citation lists of eligible studies and identified systematic reviews were manually searched to identify additional articles not captured by the search strategy.

2.2 | Study selection

Eligible articles were published RCTs that evaluated the effect of DFD-focused educational interventions aimed at improving the knowledge and/or self-care behaviours of adults aged ≥ 18 years old diagnosed with diabetes. Excluded articles were non-RCTs, RCTs that described educational interventions that were more widely targeted at improving diabetes knowledge, and RCTs where DFD education

was only a minor component of the study intervention. Two authors (AD and LS) independently screened each article from the search strategy with the third author (JG) resolving disagreements. The primary outcome was the risk of diabetes-related foot ulcer. Secondary outcomes were foot ulcer healing, infection, any amputation, mortality, modifiable cardiovascular risk factors (HbA1c, low-density lipoprotein [LDL]-cholesterol, and systolic and diastolic blood pressure), participant knowledge about DFD, DFD-related self-care behaviours, HRQOL, and anxiety and depressive symptoms.

2.3 | Evaluation of risk of bias

Methodological quality and potential bias of included studies were assessed independently by two authors (AD, LS) using the Cochrane collaboration Risk of Bias (ROB)-2 tool for RCTs.¹⁸ Risk of bias tables were created to summarise the risk of bias for the five individual domains in the ROB-2 tool as 'Low risk' of bias; 'Some risk' of bias, or 'High risk' of bias. These domains were used to judge the overall risk of bias for each included study. A study was deemed at 'low risk' of bias if all domains were judged as low risk, at 'some risk' of bias if one or more domains were judged to be at some risk but none were judged as high risk, and 'high risk' of bias if one or more domains were judged to be at high risk.¹⁸ Following independent evaluation of each study, discussions were held between the two assessors to arrive at final consensus on the overall risk of bias. If consensus could not be reached, another author (JG) was consulted to act as a third independent assessor to reach consensus on the risk of bias.

2.4 | Data extraction

Standardised data extraction tables were developed to extract the following data from each study: title, authors, year published, country of publication, participant inclusion and exclusion criteria, number of participants in the intervention and control groups, duration of follow-up, loss to follow-up, the type of intervention and intervention setting, participant characteristics, details of the control management, the number of participants screened and excluded, the primary and secondary outcomes, study limitations, and additional relevant information. Of interest were the methods of communication between the study team and participants, specifics of the education interventions delivered, persons delivering the interventions, participant acceptability of the education, and feasibility and cost-effectiveness analyses. Two authors (AD and LS) extracted the raw data, with disagreements resolved with the third author (JG).

2.5 | Data analysis

Numerical data were reported as mean and standard deviation (SD) or median and interquartile range, and categorical data as number and percentage. Meta-analyses were performed for primary and secondary outcomes where at least three studies reported relevant data.

Meta-analyses were conducted using the Mantel-Haenszel statistical method and random effects models anticipating significant heterogeneity. Results are reported for specific outcomes and include odds ratio (OR) and 95% confidence intervals (CI) or standardized mean difference (SMD) and 95% CI. All statistical tests were two-sided, and a *p*-value <0.05 was considered statistically significant.

Heterogeneity was assessed using I^2 statistic values (0%–49%: low, 50%–74%: moderate, and 75%–100%: high).¹⁹ Leave-one-out sensitivity analyses assessed the impact of each study by excluding individual studies and recalculating the remaining pooled estimates. Sub-group analyses were performed to evaluate the impact of: length of follow-up (≤ 12 months vs. > 12 months), study quality ('low risk' and 'some risk' of bias vs. 'high risk' of bias), number of educational sessions (single vs. multiple), risk of DFD (very low, low and moderate risk vs. high risk), and participant foot ulcer history (no history vs. active or past foot ulcers).

Risk of DFD was based on the 2019 IWGDF guidelines.⁴ Participants of included trials were considered high risk if inclusion criteria included a past history of foot ulceration, lower-extremity amputation or end-stage renal failure (ESRF). Trials including people with active DFD were also considered to have involved high-risk participants. Where inclusion criteria were not reported (NR) participants were considered low risk. Publication bias was assessed by funnel plots comparing the summary estimate of each study and its precision (1/standard error) where at least 10 studies were included.²⁰ All analyses were conducted using Review Manager (RevMan) v5.3 (Copenhagen: Nordic Cochrane Centre. The Cochrane Collaboration, 2014).

3 | RESULTS

3.1 | Search results and study characteristics

Of 2424 unique records identified from the search strategy, 74 underwent full-text review, and 29 were found to be eligible for inclusion (Figure 1 and Table S1).^{21–49} The 29 eligible RCTs included 3891 participants from 16 countries, with sample sizes of 40 to 749 participants, and had follow-up durations ranging from 2 weeks to 26 months. Five studies recruited participants with active foot ulcers,^{25,32,37,48,49} six trials included past ulcer amongst the inclusion criteria,^{30,33,35,36,40,45} one trial included participants with ESRF and in the remaining trials the reporting of inclusion and exclusion criteria was very limited but did suggest high-risk participants were included (Table 1 and Table S2). Overall 12 trials were considered to have included participants at high risk of DFD^{25–27,30,32,34–38,40,48,49} (Table 1). Authors of five studies were contacted for additional data,^{21,24,25,42,49} but none responded.

3.2 | Description of interventions

The education programs were diverse, ranging from short, single individualised education sessions to multiple comprehensive group-based sessions (Table 2 and Table S3). Thirteen studies provided

a single education session of up to 2 h duration, nine delivered to individual participants,^{22,24,27,32,34–36,44,48} including two in the participants' homes,^{27,35} and four delivered a single education session to a group of participants.^{30,37,40,42} Ten included multiple group sessions,^{21,23,25,26,29,31,34,39,43,49} and one delivered multiple individualised one-on-one sessions to dialysis patients.³⁸ One was a transitional care programme with individualised education,³⁶ and one used text messaging for education.⁴¹ All programs included education on foot care activities, such as washing, drying, and inspecting the feet, toenail cutting, suitable footwear and water temperature, with 11 programs providing supervised practice of some of these activities.^{21,22,25,27,29,31,34,40,42,46,49} Most¹⁵ programs also included education on how diabetes affects the feet.^{21–23,25,26,29,30,35–37,39,40,42,43,46} Some programs included education on blood glucose control,^{23,26,38–41,43,44,49} provided written materials on DFD care,^{22,25,29,30,35,42,44,46,48} advice on healthy lifestyle (diet, exercise, weight management),^{21,23,25,38,39,43,49} support in overcoming barriers to foot care,^{21,24,29,31,32,42} advice on adhering to medications,^{23,39,43,49} and psychological support or stress management.^{21,25,29,49} Three studies provided foot care kits with resources needed for good foot health, such as nail clippers, moisturisers, 10 g monofilament, mirror and thermometer.^{34,42,46} Four programs also contacted participants by phone to answer questions, reinforce knowledge, and motivate foot care behaviours,^{31,35,42,48} two provided offloading footwear,^{26,30} and one implemented an instant messaging group to allow participants, physicians and nurses to instantly communicate.²⁵

3.3 | Control groups

Nineteen studies indicated 'usual', 'routine', or 'standard care' was provided to participants assigned to the control groups, with varying levels of description as to what this level of care involved.^{21,22,25,26,29,30,32,34–42,44,46,49} Of these, five studies simply indicated 'standard care' or 'routine care' with no further description,^{22,29,39,41,46} one study delivered group-based diabetes education sessions with a minor emphasis on foot care,²¹ eight provided education on general diabetes care such as insulin use and blood glucose measurement,^{25,34,37,38,40,42,44,49} two provided footwear and instructions on foot care,^{26,30} one provided wound care education,³² one provided an information leaflet,³⁵ and one provided education on foot care.³⁶ Five studies did not report on the management of the control group,^{23,24,31,43,48} and one reported 'no education'.²⁷

3.4 | Risk of bias of included trials

Overall, 14 trials were deemed to be at high risk of bias,^{23,24,26,29,30,32,34,36,37,42,45,47–49} 14 as having some risk of bias,^{21,22,25,27,28,31,33,38–41,43,44,46} and only one as low risk of bias (Figure 2).³⁵ A high risk of bias was commonly identified with the methods of randomisation, lack of allocation concealment, inappropriate analyses, missing data, and uncertainty on the integrity of

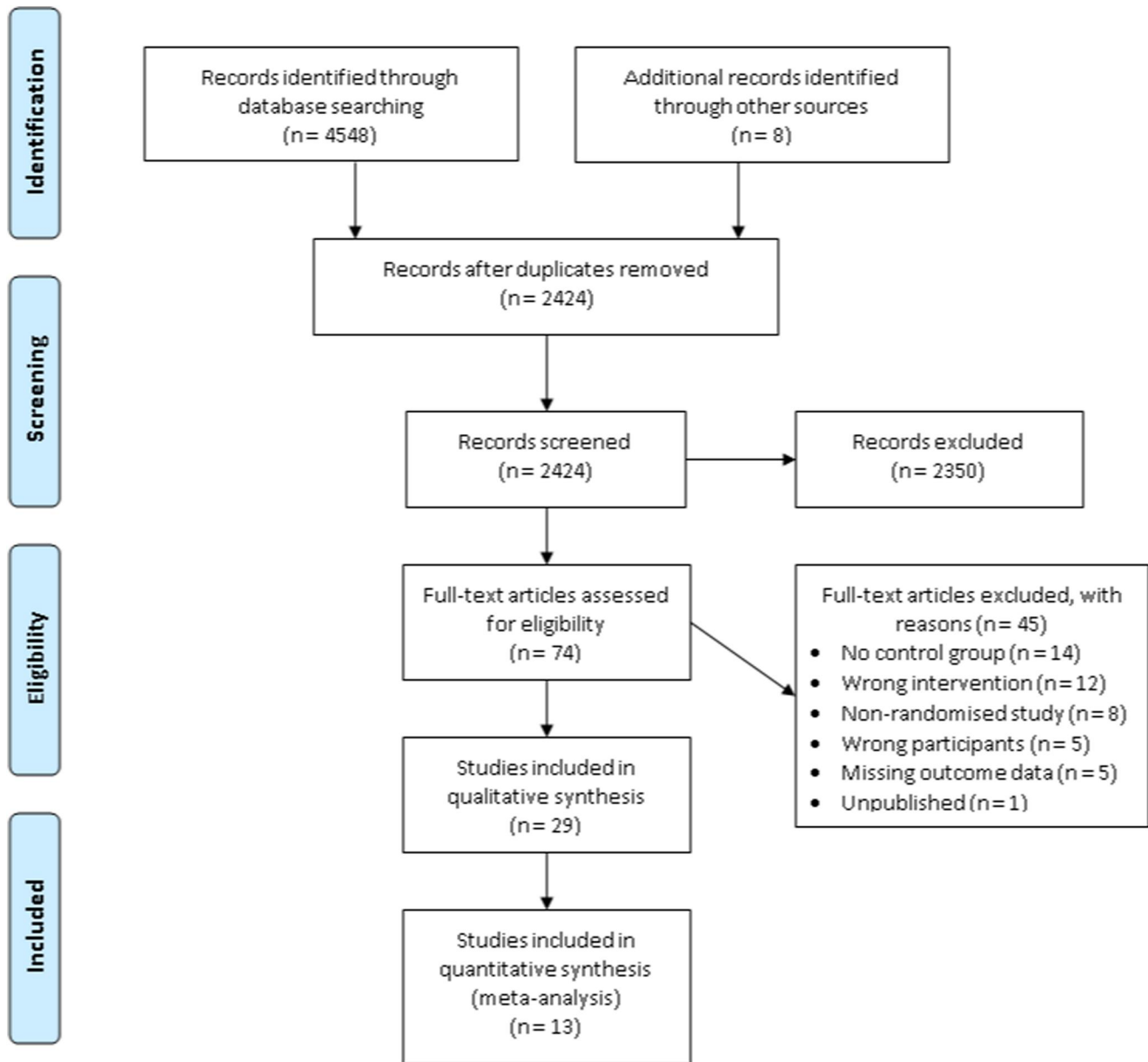


FIGURE 1 PRISMA flow diagram of the search results and number of eligible articles included. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

outcome assessment (Table S4). Publication bias could not be assessed due to the small number of studies reporting on each outcome.

3.5 | Effectiveness of education programs

3.5.1 | Foot ulcer risk

A meta-analysis of eight trials (intervention $n = 609$; control $n = 623$) found that the risk of a foot ulcer was halved by the education programs, but the upper CI was 1.00 (OR 0.54; 95% CI 0.29–1.00; moderate heterogeneity, $I^2 = 65\%$, Figure 3A; Table S5).^{23,26,30,34–37,40} Sensitivity analyses showed that there was no substantial change in OR or heterogeneity with removal of any individual study

(Table S6). Sub-group analyses suggested that findings were not substantially changed by differences in length of follow-up, risk of bias, number of educational sessions, or participants' risk of DFD, though was according to participant history of foot ulcers (Figures S1–S7). Neither trial that provided offloading footwear to participants found a significant reduction in foot ulcer risk.^{26,30} One education programme that provided a foot care kit reported that it significantly reduced the risk of a foot ulcer.³⁴

3.5.2 | Foot ulcer healing and infection

One study included participants with current foot ulcers and found that a self- and family-based management support programme

TABLE 1 Study characteristics and participant baseline demographics of included randomised controlled studies (n = 29).

Study	Country	Participants randomised	Duration of follow-up	Attrition	Type of intervention	Foot-ulcer history and DFD risk category	Intervention group				Control group			
							N ^a	Age	Female	Diabetes duration	N ^a	Age	Female	Diabetes duration
Barth (1991)	Australia	70	6 months	8 (11.4%)	Education programme with four ~2 h sessions on foot care	NR (assumed to be < high risk)	33 (of 38)	58 (9)	15 (45.5%)	8.7 (7.8)	29 (of 32)	59 (9)	12 (41.4%)	6.3 (6.0)
Bicer (2016)	Turkey	90	6 months	NR	A one-on-one 30-min DFD education session with a booklet	NR (assumed to be < high risk)	45	60.2 (9.9)	21 (46.7%)	13.3 (10.0)	45	61.0 (9.6)	31 (68.9%)	13.0 (8.1)
Bloomgarden (1987)	USA	749	18 months	483 (64.5%)	Group-based education programme with nine sessions (1 on DFD)	NR (assumed to be < high risk)	127 (of 145)	56 (12)	98 (77.2%)	13 (8)	139 (of 157)	59 (13)	93 (66.9%)	14 (9)
Borges (2008)	USA	112	1 month	19 (17.0%)	A 15-min DFD education intervention (Pies Somos)	NR though active foot ulcers were excluded (assumed to be < high risk)	55	NR	38 (69.1%)	NR	57	NR	40 (70.2%)	NR
Chen (2020)	China	180	3 months	29 (16.1%)	Intensive education programme to patients and family members	Active foot ulcer (high risk)	90	59.4 (10.1)	37 (41.1%)	6.0 [4.0–8.3]	90	59.9 (11.1)	31 (34.4%)	6.0 [5.0–9.0]
Cisneros (2010)	Brazil	53	24 months	14 (26.4%)	Group DFD education and offloading footwear	LOPS (assumed to be < high risk)	30	64.4 (9.2)	9 (30.0%)	14 (10)	23	59.8 (9.0)	11 (47.8%)	15 (10.5)
Corbett (2003)	USA	40	3 months	5 (12.5%)	Brief home-delivered education session on DFD	NR though active foot ulcer and amputation were excluded (assumed to be < high risk)	20	NR	NR	NR	20	NR	NR	NR
Dincer (2021)	Turkey	130	1 month	0	Mobile application for DFD education	NR though active foot ulcer were excluded (assumed to be < high risk)	65	49.5 (17.4)	31 (47.7%)	10.0 [1–504]	65	54.7 (13.6)	32 (49.2%)	11.0 [1–540]
Ebadi Fardazar (2018)	Iran	104	3 months	NR	Group-based, foot-focused education programme	NR though active foot disease was excluded (assumed to be < high risk)	52	60.1 (7.6)	31 (59.6%)	8.3 (5.9)	52	58 (8.1)	27 (51.9%)	8.6 (5.5)
Gershater (2011)	Sweden	131	6 months	33 (25.2%)	Participant-driven group education session on DFD	LOPS, past ulcer or minor amputation (high risk)	61	64 [37–78]	15 (24.6%)	NR	70	64 [35–79]	20 (28.6%)	NR
Hadi Sulisty (2018)	Indonesia	84	1 month	12 (14.3%)	Foot care camp including two half-days of DFD education	NR (assumed to be < high risk)	37 (of NR)	53.3 (7.8)	27 (73.0%)	NR	35 (of NR)	57.8 (6.0)	26 (74.3%)	NR
Heng (2020)	Singapore	60	3 months	18 (30.0%)	Collaborative patient education programme	Active foot ulcer (high risk)	33 (of 36)	55.2 (10.7)	14 (42.4%)	14.7 (9.5)	19 (of 24)	60.1 (10.6)	2 (10.5%)	16.0 (12.5)

(Continues)

TABLE 1 (Continued)

Study	Country	Participants randomised	Duration of follow-up	Type of intervention	Foot-ulcer history and DFD risk category	Intervention group			Control group			
						N ^a	Age	Female	N ^a	Age	Female	Diabetes duration
Kes (2021)	Turkey	51	6 months	Trans-theoretical model-based footwear programme	LOPS or PAD or past ulcer or foot deformity or amputation (high risk)	25	58.8 (10.5)	20 (80%)	26	60.1 (9.4)	16 (61.5%)	12.5 (4.5)
Liang (2012)	China	62	24 months	Foot care kit with education on use and regular education classes	Stated high risk but past ulcer and amputation excluded (assumed to be < high risk)	30 (of 31)	56.2 (22–70)	16 (53.3%)	29 (of 31)	55.8 (20–68)	10 (34.5%)	10.1 (5–25)
Lincoln (2008)	UK	178	12 months	A one-on-one 1-h education session	Recently healed foot ulcer (high risk)	87 (of NR)	63.5 (12.1)	24 (28%)	85 (of NR)	64.9 (10.9)	32 (38%)	NR
Liu (2019)	China	284	24 months	Transitional care plan including individualised education	LOPS or PAD or past ulcer or foot deformity or amputation (high risk)	142	58.2 (9.8)	57 (40.1%)	142	59.3 (8.7)	64 (45.1%)	8.7 (7.3)
Malone (1989)	USA	227	Variable 1–26 months	Single, group-based education session	Active DFD or previous amputation (high risk)	103 (of NR)	NR	NR	100 (of NR)	NR	NR	NR
McMurray (2002)	USA	91	12 months	Regular individualised education sessions by a diabetes educator	End-stage renal failure an inclusion criteria (high risk)	45 (of 49)	63.0 (13.5)	21 (46.7%)	38 (of 42)	60.9 (11.7)	17 (44.7%)	22.0 (11.7)
Mohammad (2018)	Saudi Arabia	60	3 months	Group-based education programme with seven 30-min sessions	NR (assumed to be < high risk)	30	48.4 (8.8)	19 (63.3%)	30	48.5 (8.2)	16 (53.3%)	8.6 (2.5)
Monami (2015)	Italy	121	6 months	Single 2-h group education session	LOPS or past ulcer or foot deformity (high risk)	60 (of 61)	72.0 (8.9)	20 (33.3%)	60	69.4 (11.3)	28 (46.7%)	15.9 (11.2)
Moradi (2019)	Iran	160	3 months	Daily text messages on behaviours to prevent foot ulcers	NR though past ulcer or amputation were excluded (assumed to be < high risk)	80	48.1 (9.7)	39 (48.8%)	80	47.3 (7.9)	43 (53.8%)	NR
Nguyen (2019)	Vietnam	119	6 months	Single 1-h group education and skills session	Past ulcer, foot deformity and PAD excluded (assumed to be < high risk)	59	62.5 (8.7)	49 (83.1%)	60	61.9 (10.0)	37 (61.7%)	10 [7–15]
Oyekanni (2020)	Nigeria	40	NR	Education programme with three weekly sessions	NR though past ulcer was excluded (assumed to be < high risk)	20	NR	13 (65.0%)	20	NR	14 (70.0%)	NR

TABLE 1 (Continued)

Study	Country	Participants randomised	Attrition	Duration of follow-up	Type of intervention	Foot-ulcer history and DFD risk category	Intervention group				Control group			
							N ^a	Age	Female	Diabetes duration	N ^a	Age	Female	Diabetes duration
Rahaman (2018)	India	127	26 (20.5%)	3 months	Education module including a short video and pamphlet	NR though past foot ulcer was excluded (assumed to be < high risk)	63	48.7 (11.7)	26 (41.3%)	9.3 (8.4)	64	44.1 (12.8)	31 (48.4%)	6.9 (6.3)
Satehi (2021)	Iran	90	NR	2 weeks	Teach-back group involved a 45-min session; multimedia group used the same content but was provided via various technologies	Past ulcer or LOPS or active ulcer not needing amputation (high risk)	30	55.6 (11.2)	NR	12.8 (7.8)	30	55.8 (11.7)	NR	13.0 (6.7)
Sharoni (2018)	Malaysia	76	5 (6.6%)	3 months	Group-based education programme to improve self-efficacy	NR (assumed to be < high risk)	38	70.1 (7.7)	14 (36.8%)	6.0 (12.0)	38	69.4 (7.4)	8 (21.1%)	5.0 (12.0)
Silva (2021)	Brazil	128	24 (18.9%)	3.5 months	Telephone-based education programme	NR though past foot disease was excluded (assumed to be < high risk)	50	61 (NR)	34 (68%)	8.5 (8.3)	52	65 (NR)	38 (73%)	8.3 (6.8)
Sonal Sekhar (2019)	India	210	75 (35.7%)	6 months	Clinical pharmacist-led education on foot care	Active foot ulcer (high risk)	70 (of NR)	58.6 (7.9)	15 (21.4%)	16.3 (7.1)	65 (of NR)	60.3 (8.4)	17 (26.2%)	18.7 (6.2)
Subrata (2020)	Indonesia	64	8 (12.5%)	3 months	Self- and family-based management support programme	Active foot ulcer (high risk)	27 (of 32)	51.0 (5.1)	8 (28.6%)	NR	29 (of 32)	51.2 (5.4)	12 (41.5%)	NR

Note: Data are presented as n (%), mean (standard deviation), median (range), or median [interquartile range]. DFD-risk categories were estimated using available data and assigned according to the 2019 International Working Group on Diabetic Foot Guidelines. Where level of risk was uncertain, the lowest reasonable level of risk was assigned. Age and diabetes duration are presented in years.

Abbreviations: LOPS, loss of peripheral sensation; NR, not reported; PAD, peripheral artery disease.

^aWhere studies did not report the baseline data of all randomised participants, the number of participants randomised to each group are reported. Where this was NR (Hadi Sulisty 2018, Lincoln 2008, Malone 1989, and Sonal Sekhar 2018), this has been indicated by the term '(of NR)'. For Bloomgarden (1987), participants were randomised before agreeing to participate, leading to large dropout. For Borges (2008), only the 'brief intervention group' and not the 'risk assessment group' was reported. For Heng (2020), follow-up was up to 3-months, earlier if the wound healed before this time.

TABLE 2 Characteristics of the educational interventions in the 25 randomised controlled trials in this systematic review and meta-analysis.

Study	Intervention characteristics										Intervention components							Other intervention components			
	I/G	Health staff involved	Number sessions	Total hours	Setting	Diabetes education	BGL education	Foot care education	Supervised FC practice	Written materials	Lifestyle advice	Personal strategies	Medication advice	Psychological/ stress support	Footwear provided	Point of care	Foot kit	Scales provided			
Barth (1991)	Group	Podiatrist & psychologist	4	9	Clinic																
Bteer (2016)	Individual	NR	1	<1	Clinic																
Bloomgarden (1987)	Group	NR	9	NR	Clinic																
Borges (2008)	Individual	NR	1	<1	Clinic																
Chen (2020)	Group	Nurse & physician	12	36	Clinic																
Cisneros (2010)	Group	NR	4	6	Clinic																
Corbett (2003)	Individual	Nurse	1	NR	Home																
Dincer (2021)	Individual	NA	NA	NA	Home																
Ebadi Fardazar (2018)	Group & individual	GP, diabetes expert, psychologist	4	3	Clinic																
Gershater (2011)	Group	Diabetes nurse	1	1	Clinic																
Hadi Sulisty (2018)	Group	NR	2	NR	Clinic																
Heng (2020)	Individual	Podiatrist	1	<1	Clinic																
Kes (2021)	Individual	Nurse	9	9	Clinic																
Liang (2012)	Individual	NR	1	NR	Clinic																
Lincoln (2008)	Individual	NR	1	1	Home																
Liu (2019)	Individual	NR	1	NR	Clinic																
Malone (1989)	Group	Podiatrist	1	NR	Clinic																
McMurray (2002)	Individual	Diabetes care manager	12	NR	Clinic																
Mohammad (2018)	Group	NR	7	3	Clinic																
Monami (2015)	Group	Doctor and nurse	1	2	Clinic																
Moradi (2019)	Individual	NA	NA	NA	Home																
Nguyen (2019)	Group	NR	1	1	Clinic																
Oyekunmi (2020)	Group	Nurse	3	NR	Clinic																
Rahaman (2018)	Individual	NR	1	NR	Clinic																

TABLE 2 (Continued)

Study	Intervention characteristics				Intervention components										Other intervention components			
	I/G	Health staff involved	Number sessions	Total hours	Setting	Diabetes education	BGL education	Foot care education	Supervised FC practice	Written materials	Lifestyle advice	Personal strategies	Medication advice	Psychological/stress support	Footwear provided	Point of care kit	Foot Scales provided	
Satehi (2021)	Individual	NR	1	<1	Clinic													
Sharomi (2018)	Group & individual	Nurse	2	1	Clinic													
Silva (2021)	Individual	NR	6	NR	Home													
Sonal Sekhar (2018)	Individual	Clinical pharmacist	1	<1	Clinic													
Subrata (2020)	Group	NR	24	20	Clinic													

Note: Studies shaded green, orange, and red indicate significant improvement in most, half, or less than half of reported outcomes respectively. I/G: Individual or Group education. Diabetes Education: provided education about diabetes, and DFD as a complication. BGL Education: education about controlling blood glucose levels, including insulin. Foot Care: educated on daily foot care activities. Supervised FC Practice: included supervised practice of daily foot care activities. Written materials: written materials on DFD care provided. Lifestyle advice: education on diet, nutrition, exercise, and weight loss. Personal Strategies: strategies for improving foot care including minimising risk factors and overcoming barriers. Medication Advice: education on adherence to prescribed medications. Psychological/stress support: psychological support or stress management provided. Footwear Provided: free offloading footwear provided. Point of care: point of contact was provided after the education sessions. Foot kit: a foot care kit was provided (nail clippers, foot cream, monofilament, mirror, water thermometer). Scales provided: weight scales was provided.

Abbreviations: BGL, blood glucose level; DFD, diabetes-related foot disease; FC, foot care; GP, general practitioner; NR, not reported.

significantly improved wound healing ($p < 0.001$).⁴⁹ One trial reported that the education programme significantly reduced the risk of foot infection.³⁷

3.5.3 | Any amputation

A meta-analysis of six trials (intervention $n = 467$; control $n = 454$) found that the education programs significantly reduced the risk of any amputation (OR 0.34; 95% CI 0.13–0.88, low heterogeneity, $I^2 = 38\%$; Figure 3B). Sensitivity analyses showed that there was no substantial change in OR or heterogeneity with removal of any individual study (Table S7). Sub-group analyses suggested that findings were not substantially changed by differences in length of follow-up, risk of bias, number of educational sessions, or participants' risk of DFD, though was according to participant history of foot ulcers (Figures S8–S14).

3.5.4 | Mortality

A meta-analysis of 10 trials (intervention $n = 532$; control $n = 542$) found the education programs did not affect the risk of mortality (OR 1.09; 95% CI 0.57–2.07, low heterogeneity, $I^2 = 0\%$, Figure 3C). Sensitivity and sub-group analyses did not substantially affect findings (Table S8 and Figures S15–S21).

3.5.5 | Modifiable cardiovascular risk factors

Of the risk factors of interest, only HbA1c was reported frequently enough to meet criteria for meta-analysis, with blood pressure reported in two trials and total cholesterol and body mass index reported in one trial.^{36,40} A meta-analysis of six trials (intervention $n = 484$; control $n = 488$) found the education programs significantly reduced HbA1c (SMD -0.73 ; 95% CI -1.26 , -0.20 , moderate heterogeneity, $I^2 = 93\%$, Figure 3D).^{23,34,36,38,40,41} Sensitivity and sub-group analyses did not substantially affect the SMD (Table S9 and Figures S22–S28). Two of the four programs that included blood glucose education significantly reduced HbA1c.^{38,41} Two trials reported on other modifiable risk factors, one which found that total cholesterol, LDL-cholesterol, high-density lipoprotein cholesterol, and triglycerides were not significantly improved compared to control, but found that systolic and diastolic blood pressure were significantly improved.³⁶ The other trial found that systolic and diastolic blood pressure were not significantly improved compared to control.⁴⁰

3.5.6 | DFD knowledge and self-care behaviours

Thirteen of 16 trials found that the education programs significantly improved DFD knowledge scores at the final follow-up, but meta-analysis was not possible due to heterogeneity in measurement tools

Study	Risk of bias domains					Overall
	D1	D2	D3	D4	D5	
Barth (1991)	-	-	+	+	-	-
Bicer (2016)	-	-	+	-	+	-
Bloomgarden (1987)	-	X	X	X	-	X
Borges (2008)	-	-	+	X	-	X
Chen (2020)	+	+	-	+	-	-
Cisneros (2010)	-	X	-	+	-	X
Corbett (2003)	+	-	+	+	-	-
Dincer (2021)	-	+	+	+	-	-
Ebadi Fardazar (2018)	-	-	X	-	-	X
Gershater (2011)	+	X	+	+	+	X
Hadi Sulisty (2018)	-	-	+	+	-	-
Heng (2020)	-	-	-	X	-	X
Kes (2021)	+	+	+	+	-	-
Liang (2012)	X	-	+	X	-	X
Lincoln (2008)	+	+	+	+	+	+
Liu (2019)	-	-	X	+	-	X
Malone (1989)	X	-	-	+	-	X
McMurray (2002)	-	-	+	+	-	-
Mohammad (2018)	-	-	+	+	-	-
Monami (2019)	+	-	+	+	-	-
Moradi (2019)	-	+	+	+	-	-
Nguyen (2019)	X	+	-	+	+	X
Oyekanmi (2020)	-	-	+	-	-	-
Rahaman (2018)	-	-	-	+	-	-
Satehi (2021)	-	+	+	X	-	X
Sharoni (2018)	-	+	+	+	+	-
Silva (2021)	+	+	X	+	-	X
Sonal Sekhar (2018)	-	-	-	X	-	X
Subrata (2020)	-	-	+	X	+	X

Domains:
D1: Bias arising from the randomization process.
D2: Bias due to deviations from intended intervention.
D3: Bias due to missing outcome data.
D4: Bias in measurement of the outcome.
D5: Bias in selection of the reported result.

Judgement
X High
- Some concerns
+ Low

FIGURE 2 Risk of bias outcomes for each randomised controlled trial included.

used (for example the Diabetes Foot Knowledge Questionnaire and the Modified Diabetic Foot Care Knowledge Questionnaire).^{21,22,24,27,28,31,32,34,36,38-41,43,44,46} One trial with high-risk participants³² and two trials with lower risk participants^{24,44} reported that the education intervention tested did not significant improve DFD

knowledge. Nineteen of 20 trials reported the education programs significantly increased participant DFD self-care behaviours but meta-analysis was not possible due to heterogeneity in measurement tools used (for example the Foot Self-Care Behaviour Scale and the Foot Care Practices Questionnaire).^{21,22,24,27-29,31-35,38,39,41,42,44-47,49}

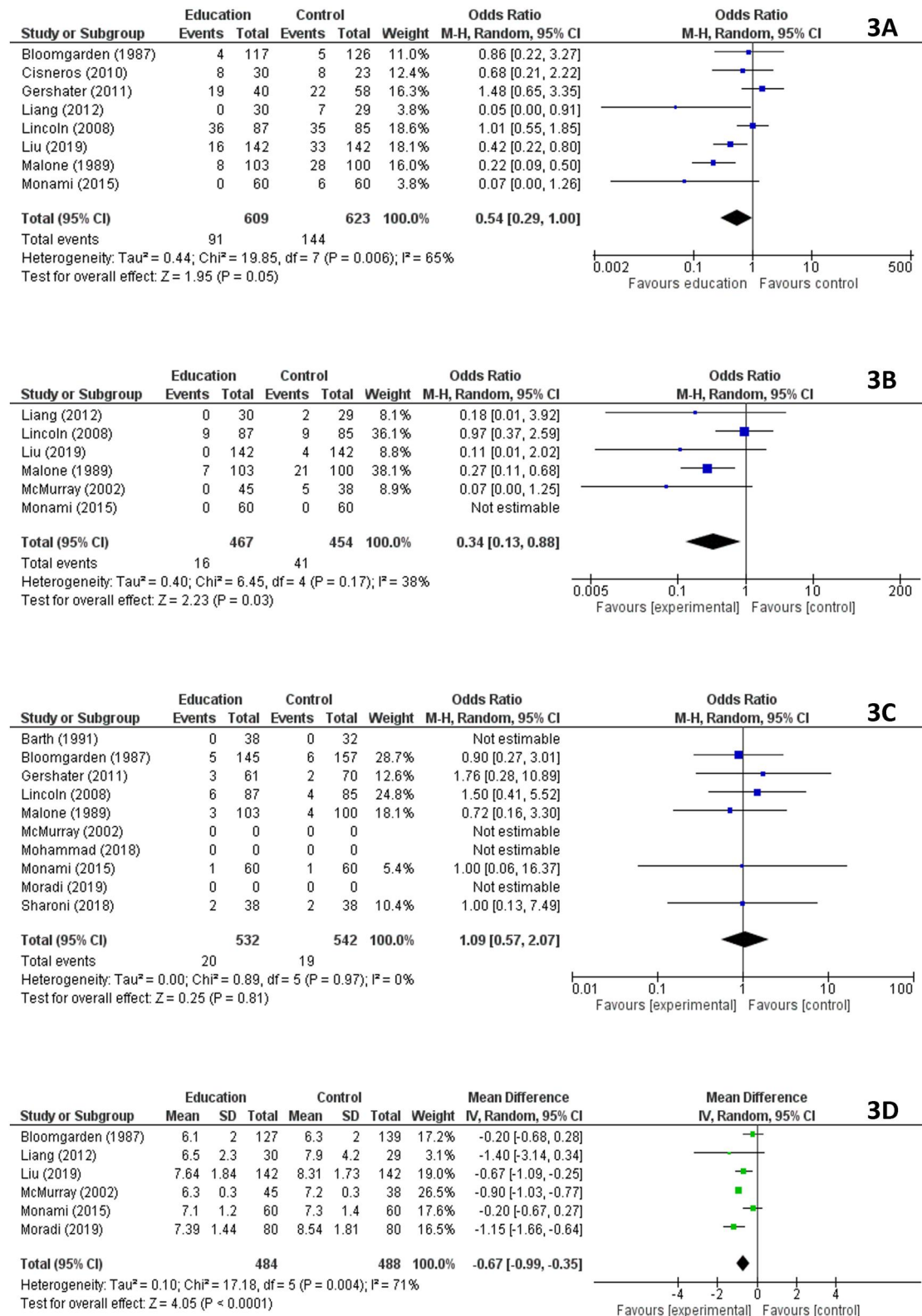


FIGURE 3 (A) Forest plot showing the effect of educational programs on risk of foot ulcers in people with diabetes-related foot disease. (B) Forest plot showing the effect of educational programs on risk of any amputation in people with diabetes-related foot disease. (C) Forest plot showing the effect of educational programs on risk of all-cause mortality in people with diabetes-related foot disease. (D) Forest plot showing the effect of educational programs on HbA1c control in people with diabetes-related foot disease.

One trial with lower risk participants found no significant improvement in DFD self-care behaviours.²⁴ Two studies found a positive correlation between DFD knowledge and DFD self-care behaviours ($p = 0.003$ ²¹ and $p < 0.01$).²⁴ All 10 trials that included supervised practice of foot care activities found the education programs significantly improved both DFD knowledge and self-care behaviour.

3.5.7 | HRQOL, anxiety and depression

HRQOL was measured in five trials using the Diabetic Foot Scale,³⁵ the Diabetes Quality of Life tool,³⁶ an adapted Diabetes Form 2.1,³⁸ the modified Foot-Specific Quality of Life tool,⁴⁶ or the Short-Form-36.⁴⁸ Three of the five trials reported the education programme significantly improved HRQOL.^{36,38,48} One trial reported the education programme significantly reduced symptoms of anxiety and depression while another reported no significant effect.^{25,35}

4 | DISCUSSION

This meta-analysis suggests that education programs increase knowledge about DFD, increase foot self-care behaviours, improve control of blood glucose and may reduce the risk of foot ulcers and any amputation. Further data from large high quality trials is required to confirm these findings because only one trial was considered low risk of bias,³⁵ many trials did not provide data for the meta-analyses and heterogeneity between trials was substantial. Most trials had concerns with the randomisation process or blinding and has small sample sizes. The incidence of foot ulceration and any amputation were only available for eight and six trials respectively. No trials reported on the type of amputation. Importantly, the upper limit of the 95% CI reached 1.00 for the meta-analysis on foot ulcer risk. Larger high quality trials are needed to rigorously test the benefit of education programs. Further research is also needed to clarify the key components of education programs, and how the programs are best delivered. Education programs varied in terms of whether they included education on blood glucose management, medication advice, daily foot care activities and free equipment such as offloading footwear and foot care kits. Due to the lack of outcome reporting it was not possible to perform sub-group analyses to examine which components of the education programs appeared to be most influential.

While most studies reported that participant knowledge on DFD increased as did their self-care behaviours, few studies reported both on foot ulcer incidence and DFD knowledge and self-care behaviours, making clear alignment of these subjective and objective outcomes difficult. Most trials had a short follow-up period and thus the longer-term effects of the education programs are unclear. The management of control groups within the included trials was heterogeneous with some involving aspects of DFD education. Thus participants in the control groups may have altered their behaviour and risk of foot ulceration and amputation due to enrolment in the trials.⁵⁰ Limited

description of the control groups was also noted, which has been noted as an ongoing limitation of behavioural and social science studies.⁵¹ The two studies with the longest follow-ups of 24 months that reported on both foot ulceration and DFD knowledge or self-care behaviours found significant reductions in foot ulcer risk compared to the control groups.^{34,36} Both of these studies included high-risk participants and provided comprehensive educational sessions covering a range of topics related to foot care.^{34,36} However, both of these studies were deemed to be at a high risk of bias.

Previous research involving surveys and interviews of health professionals with experience in treating DFD suggest that education programs need to deliver clear, structured and consistent information through a case manager.⁵²⁻⁵⁴ These findings align with the IWGDF guidelines, which recommend that education is repeated, and provided individually or in small groups.⁴ One study in this meta-analysis used text messages to educate participants, which significantly reduced HbA1c and improved DFD knowledge and self-care behaviours, highlighting the potential for telehealth as a medium for patient education.⁴¹ Prior reviews suggest that telehealth may be effective in monitoring and managing modifiable risk factors, monitoring the feet and prompting accelerated or advanced care in people with diabetes.^{9,55-57} Health professionals and patients had a positive view on telehealth and were willing to incorporate digital technologies into standard care.^{56,57} These findings suggest that telehealth can be an effective means to deliver education programs.

There are a number of strengths and limitations of this systematic review. Strengths include the large number of RCTs included and the systematic approach.^{17,18} Sensitivity and sub-group analyses were used to test the consistency of findings. Limitations included restricting eligibility to articles only in English, inability to perform meta-analyses for all outcomes and the heterogeneity in the design of the tested programs and the included trials. Marked heterogeneity was noted for most outcomes likely attributable to variation in the included populations, different study designs (e.g. varying follow-up) and distinct interventions tested.

5 | CONCLUSIONS

This systematic review and meta-analysis suggested that previously tested education programs increase participants' knowledge about DFD, increase participants' capacity in performing foot care activities, improve control of blood glucose and may reduce the risk of foot ulcers and any amputation. Further research is needed to identify which types of education programs are most effective, and if they are truly able to reduce the risk of DFD-related complications.

AUTHOR CONTRIBUTIONS

Aaron Drovandi conceive the research topic, conducted the search strategy, extracted the data, analysed the data, and wrote the manuscript. Leonard Seng conducted the search strategy, extracted and data, and revised the manuscript. Jonathan Golledge conceived the research topic, supervised the other authors in writing the

manuscript, and revised the manuscript. Jonathan Golledge and Aaron Drovandi are the guarantor of this work, and as such had full access to the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis. All authors contributed to the article and approved the submitted version.

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CONFLICT OF INTEREST STATEMENT

The authors have no potential or actual conflicts of interest to declare.

PRIOR PRESENTATION

This research has not been previously published or presented in any form.

DATA AVAILABILITY STATEMENT

All data generated for this systematic review and meta-analysis is available in the supplementary documents.

ORCID

Jonathan Golledge  <https://orcid.org/0000-0002-5779-8848>

PEER REVIEW

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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