BMJ Open Transitioning care in youth-onset type 1 and type 2 diabetes: a scoping review protocol using the socio-ecological model framework

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ABSTRACT

Introduction The transition from paediatric to adult diabetes care in youth-onset diabetes (type 1 diabetes mellitus, Y-T1DM and type 2 diabetes mellitus, Y-T2DM) is associated with worsening glycaemic control, missed clinical visits, decreased medication adherence and the emergence of cardiometabolic complications. The socio-ecological challenges that influence transitioning to adult diabetes care may be distinct between Y-T1DM and Y-T2DM. The goal of this scoping review is to map the state of the literature on transitioning care in Y-T2DM compared with Y-T1DM and to identify the main sources and types of evidence available. The objectives are: (1) to identify the factors within the socio-ecological framework (individual, relationship, community, societal) associated with transitioning to adult care in Y-T2DM compared with Y- T1DM, and (2) to identify knowledge gaps related to transitioning to adult care.

Methods The scoping review protocol and reporting will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for scoping reviews quidelines. A systematic search of scientific databases (PubMed, Embase, Cumulative Index to Nursing and Allied Health, Scopus and APA PsycNet will be undertaken for articles between 1 January 1990 and 30 September 2022. Study designs will include peer-reviewed experimental and quasi-experimental published studies without language or country-specific restrictions. We will exclude articles on other diabetes subtypes and will exclude non-peer reviewed articles such as opinion papers, anecdotal reports or supplementary commentaries.

Analysis References will be collated, sorted and extracted using Covidence. Factors associated with transition from paediatric to adult diabetes care in Y-T1DM and Y-T2DM will be identified using the socio-ecological framework and results will be presented in narrative format, tables, and summary graphs.

Ethics and dissemination Ethical approval will not be applicable for this review.

Trial registration number https://osf.io/k2pwc.

INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disease due to defects in insulin secretion, action or both, resulting in abnormal

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This comprehensive review will broadly examine the factors associated with transitioning diabetes care in youth-onset type 1 diabetes mellitus versus youth-onset type 2 diabetes mellitus using the socio-ecological framework.
- ⇒ The inclusion of a wide age range relevant to transitioning diabetes care and conducting a search without language limitations across all ethnicities and various study designs will facilitate a rigorous evaluation of the current knowledge and potential knowledge gaps.
- ⇒ The broad nature of the scoping review will preclude an appraisal of the quality of identified relevant studies, the effect size of various factors and/or causal relationships.
- ⇒ The inclusion of peer-reviewed literature only could contribute to selection bias and will not include an assessment of contemporary web-based transition of care resources or local trends in practice.

carbohydrate metabolism and elevated blood glucose concentrations. DM is the third most common chronic disease in children, afflicting 1 in 400 of the 3 million youth less than 20 years old. In youth, there are two common types of DM, youth-onset type 1 DM (Y-T1DM) and youth-onset type 2 DM (Y-T2DM). T1DM is characterised by autoimmune β-cell destruction, resulting in an absolute deficiency of insulin and is the most common cause of vouth-onset DM occurring in 2 per 1000 youth.² In contrast, the pathophysiology of Y-T2DM is associated with progressive insulin resistance and relative impairment in insulin secretion. Overall, Y-T2DM is less prevalent (0.7 per 1000 youth) than Y-T1DM but prevalence rates have doubled in the last three decades and coincided with the childhood obesity epidemic.²⁻⁴ In the USA, annual incidence rates of Y-T2DM have increased by 5% per year between 2002



and 2016³ and depending on race/ethnicity, the probability of diagnosing Y-T2DM may be as high or higher than the chance of diagnosing Y-T1DM.²⁵ Incidence rates of Y-T2DM have also risen sharply in most developed countries⁴ ⁶⁻⁸ and rates are projected to increase more than fivefold over the next 15–30 years.⁹ Additionally, the natural history of Y-T2DM is distinct between Y-T1DM and Y-T2DM. Y-T2DM is associated with early onset of microvascular and macrovascular complications when most of the young adults are in their peak-productivity years.¹⁰ ¹¹

For youth with a chronic illness, transitioning to adult care is often fraught with anxiety and the uncertainty of adolescence and young adulthood. It is also a period when the inequalities in diabetes prevalence, control, and complications may be further magnified because of delays in care during the transition from paediatric to adult care. 12 The physiological changes during the adolescent and emerging adult period may contribute to challenges in transitioning to adult diabetes care. Adolescence is a time of expected increased experimentation, risky behaviours, mood instability, and invincibility when emerging adults are vulnerable to socio-ecological factors that may lead to poor health. ¹³ The challenges and socioecological factors that affect Y-T2DM versus Y-T1DM may differ significantly as they have distinct pathophysiology and mechanistic drivers of disease control. In Y-T1DM, the transition to adult diabetes care is associated with a negative psychological or affective experience. Studies have shown that emerging adults with Y-T1DM with adverse transitioning care experiences also have lower social network support, lower levels of self-care, poorer quality of life and emotional well-being and worse glycaemic control. 5 13 15-17 The transition in Y-T1DM is complex and includes burdensome self-management strategies such as multiple daily injections or insulin pump management and multiple daily blood glucose monitoring.

In contrast, few studies have examined the challenges during the transitioning of care in Y-T2DM. Diabetes selfmanagement in Y-T2DM is associated with a broad range of treatment strategies. For example, some Y-T2DM may be adequately managed on oral metformin while others require intensive insulin therapy with multiple daily injections. Management for Y-T2DM also includes treatment for obesity and nutritional guidance that encourages weight loss and increased activity. The social, emotional and societal challenges in transitioning care for Y-T1DM and Y-T2DM may be distinct and require further study. It is widely accepted that social determinants of health, such as food insecurity and lack of access to healthcare resources, are strong risk factors for poor diabetes outcomes, especially in youth with obesity and Y-T2DM.⁵ It is also appreciated that the transition to adult care in Y-T2DM is associated with >300% higher odds of poor glycaemic control and lapses in health insurance.¹² However, there are no studies comparing the range of factors influencing the healthy and safe transitioning to adult care in Y-T2DM compared with Y-T1DM. Deterioration in glycaemic control, increased emergency room

usage, higher hospitalisation rates, and increased rates of diabetes complications among older teens and young adults are unintended consequences of inadequate diabetes transition programmes. ¹² Therefore, to reduce the burden of youth-onset diabetes, it is critical to understand and address both the facilitators and barriers to transition to adult care.

The socio-ecological model is ideal for describing the complex framework between individual, relationship, community, and societal factors that may influence transition care in youth-onset diabetes. This model facilitates a broad assessment to highlight research gaps, and intervention areas within and across the multiple levels of the socio-ecological domain. Key mediating factors include individual and biological characteristics (eg, age, diagnosis, biological sex, glycaemic markers), relationship, and community factors (eg, resiliency, depression, anxiety, attitudes towards healthcare providers, social support systems, adverse childhood events) and societal factors (eg, structural racisms, food insecurity, poverty, medical infrastructure including community or private clinics, access to multi-disciplinary care).

Using the socio-ecological framework will facilitate consideration of barriers across multiple levels. For example, barriers to adult care may include health cultural factors-that include community and societal levels—such as assuming independent care for diabetes in adult provider practices that are well equipped to care for adult-onset T2DM but do not have the tools or experience to manage the rapidly progressive disease process of Y-T2DM. For example, over 50% of patients with Y-T2DM within 5 year of disease onset require multiple daily insulin injections²⁰ and would benefit from multidisciplinary diabetes care teams consisting of certified diabetes educators, nutritionists experienced in carbohydrate counting and psychologists. These resources may not be readily accessible to patients and may require multidisciplinary care coordination while maintaining work/school-life balance.²¹

This review will be the first to examine these factors associated with transitioning care in Y-T1DM compared with Y-T2DM using the socio-ecological framework. This framework includes accounting for social, economical, ecological, psychological, cultural, biological and behavioural factors that may be associated with transitioning of care in youth and young adults with T1DM and T2DM. A broad scoping review is a necessary first step in exploring key questions and areas of interest on transitioning care in youth-onset diabetes that should be addressed with future meta-analyses and systematic reviews. The scoping review will be conducted using the framework by Joanna Briggs Institute (JBI) manual for evidence synthesis, to elucidate socio-ecological factors influencing the transition to adult care in Y-T1DM and Y-T2DM.²² This protocol outlines the methodological framework that will be used to select and summarise studies on the transition to adult care in T1DM and Y-T2DM. The goal is to identify knowledge gaps, highlight the need for further research and



understand the multiple levels of socio-ecological factors associated with transition of children and youth with Y-T2DM to adult diabetes care.

Objectives

- 1. To identify the factors within the socio-ecological framework (individual, relationship, community, societal) associated with transitioning to adult care in Y-T2DM compared with those with Y-T1DM.
- 2. To identify knowledge gaps related to transitioning to adult care in Y-T2DM compared with Y-T1DM.

METHODS

A preliminary search for current systematic reviews or scoping reviews on Y-T2DM transitioning to adult care in MEDLINE, the Cochrane Database of Systematic Reviews and *JBI Evidence Synthesis*, was conducted and no existing scoping reviews on the topic were identified. The current scoping review will be reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for scoping reviews (PRISMA-ScR) guidelines. The proposed scoping review protocol was registered with Open Science Framework on 4 April 2022. The scoping review will be conducted in accordance with the JBI methodological framework. The analysis will follow the PRISMA-ScR guidelines and checklist. Example 2022.

Review questions

The two primary questions are:

- 1. What are the socio-cultural, behavioural and biological factors within the socio-ecological framework that are associated with transitioning from paediatric to adult care in Y-T2DM compared with Y-T1DM?
- 2. What are the knowledge gaps in transitioning to adult care in Y-T2DM compared with Y-T1DM?

Eligibility criteria

Participants

The eligibility criteria that will be used to guide the search and article review are listed in table 1 below.

To facilitate a broad, applicable global search, we will not employ language or country-specific restrictions. The selection of peer-reviewed articles only, will facilitate rigour and transparency in data reporting of published literature. Limitations of the scoping review include restricting the scope to the most common forms of youthonset diabetes (excluding other diabetes subtypes) as this was not our research question. We will exclude nonpeer reviewed articles such as opinion papers, anecdotal reports or supplementary commentaries, and we will not include an assessment of contemporary online transition of care resources or current local trends in practice. Although this increases the risk for selection bias,

Criterion	Inclusion criteria	Exclusion criteria
Population		
Participant characteristics	 Children/adolescents/young adults 0–25 years. All race/ethnicities. Diagnosis of Y-T2DM. Diagonsis of Y-T1DM. 	 Age ≥26 years. Diagnosis of other forms of diabetes (eg monogenic, neonatal, steroid-induced diabetes).
Concept		
Main outcome	Studies related to transitioning from youth to adult diabetes care in Y-T1DM and Y-T2DM.	Studies related to transition from hospital to outpatient care or in adult patients ≥26 years who are transitioning.
Variables	Social determinants of health.Psychological factors.Biological factors.	
Context		
Publication time period	1 January 1990 to 30 September 2022.	Prior to January 1990.
Language	All languages.	None.
Types of articles	Peer-reviewed published articles.	Non-peer reviewed articles.
Type of study designs	Experimental and quasi-experimental study designs including randomised and non-randomised controlled trials, case series, cohort, case-control, descriptive cross-sectional, observational prospective, longitudinal, case reports, qualitative research and cost-benefit analyses.	Commentaries, experiential articles, other reviews, anecdotal reports, supplementary commentaries, opinion papers and other unpublished studies.

this scoping review will represent a broad assessment of the published literature to help identify important knowledge gaps and research questions for systematic review.

Participants will include male and female children/ youth/adolescents ages 0-25 years with Y-T2DM and Y-T1DM. Articles that include children and youth between 0 and 25 years with Y-T2DM and Y-T1DM will help to identify relevant studies that focused on youth transitioning to adult care between 19 and 25 years. 11 The broad age range is necessary to allow section of studies that encompass transition care in paediatric diabetes. Current guidelines for transition care in diabetes recommend starting the transitioning process in adolescence, though there are no definitive recommendations on when to complete the transition process.²⁵ Since emerging adulthood is defined up to age 25 years, the transitioning process could extend to this age. Therefore, our study criteria will reflect the age range that will include adolescence and emerging adulthood. Y-T2DM is more common in racial/ethnic minorities. Therefore, the scoping review will be unrestricted and include all race/ethnicities and languages to capture the various cultural/subcultural, and environmental experiences associated with youth-onset diabetes around the world. Inclusion of all languages will facilitate identification of studies conducted in both English and non-English speaking participants and countries.

Patient and public involvement

There was no patient or public involvement in the generation of this protocol.

Concept

Articles to be considered will report on transitioning from paediatric to adult care in T1DM and Y-T2DM. Articles to be examined will include reporting on the domains of social determinants of health including but not limited to transcultural care, educational support, economic status, healthcare access, insurance status and clinical setting. We will also include articles reporting on psychological factors (eg, depressed mood and anxiety) and biological factors (eg, glycaemic control including haemoglobin A1c, glucose concentrations). Exclusion criteria include participants with other forms of diabetes, pre-diabetes or risk factors for T2DM (table 1).

Context

Contemporary studies published in all languages between 1990 and 2022 will be included to gather a comprehensive review of the range of factors associated with the increased prevalence of T2DM in the era of increased obesity and T2DM.

Types of sources

To undertake an expansive overview, a broad range of study designs will be included. Both experimental and quasi-experimental study designs including randomised and non-randomised controlled trials, case series, cohort, case—control, descriptive cross-sectional, observational prospective, longitudinal, case reports, qualitative

research and cost-benefit analyses studies published between 1 January 1990 and 30 September 2020 will be included. The search date range was chosen to capture the contemporary period associated with rise in prevalence rates of Y-T2DM and Y-T1DM.²⁶ This period also coincides with increased awareness of the need for directed care in transitioning youth with chronic diabetes.²⁷ In addition, systematic reviews and meta-analyses that meet the inclusion criteria will also be considered, depending on the research question. Experiential articles, other reviews, anecdotal reports, supplementary commentaries, opinion papers and unpublished studies will be excluded in the scoping review. The proposed start date will be October 2022 and we expect to complete the search and adjudication of articles by March 2023. The study status is pending start and the formal search will begin after protocol manuscript acceptance.

Search strategy

We will conduct a broad multidisciplinary search that includes the following electronic databases: PubMed, Cumulative Index to Nursing and Allied Health (CINAHL) and Embase. The literature search terms and keywords were developed collaboratively with the scoping review team and the National Institutes of Health (NIH) biomedical librarian. The librarian performed a preliminary search in PubMed using keywords and corresponding Medical Subject Heading (MeSH) terms. The preliminary search results were provided to the team members for their feedback to develop and refine a final search. We will use Embase, PubMed, CINAHL, Scopus and PsycINFO to facilitate a comprehensive search of the biomedical and socio-ecological literature. NLT (author and librarian) performed a preliminary search in PubMed using keywords and corresponding MeSH terms agreed on by all coauthors. The final PubMed search strategy and syntax will be adapted to run correctly in the additional databases to be searched (Embase, CINAHL, Scopus and APA PsycNet) and includes keywords and controlled vocabularies, when available, in the additional databases, including EMTREE for Embase, CINAHL subject headings in CINAHL and APA Thesaurus terms. Please note that Scopus does not have a thesaurus or controlled vocabulary terms. Publication date limits will be applied to the search to capture articles published between 1990 and 2022. The reference lists of all included sources of evidence will be searched to identify additional studies.

Outcomes of interest

The study outcomes and data to be extracted are listed in table 2. The outcomes include socio-ecological factors that act at individual, relationship, community and societal levels. These factors include the social determinants of health, psychological factors, health cultural factors and biological factors (table 2).

The final search terms are outlined in table 3 below. When the final search strategy is approved by the team members, the NIH librarian will follow the index terms



Scoping review title	Socio-ecological factors in transitioning from youth to adult diabetes care: a scoping review protocol	
Details and characteristics of evidence source	 Publication date. Primary and corresponding author. Primary institution and country. Number of participants. 	
Concept	Determinants of transition to adult care in youth/young adults with type 1 and type 2 diabetes.	
Context	Community and healthcare settings.	
Study design	Qualitative, quantitative or mixed.	
Study type	Experimental and quasi-experimental study designs including randomised and non-randomised controlled trials, case series, cohort, case-control, descriptive cross-sectional, observational prospective, longitudinal, case reports, qualitative research and cost-benefit analyses.	
Language	English, Spanish, etc.	
Details/results/outcomes to be extracted from evidence source	 Individual and biological factors (eg, biological sex, age, race/ethnicity, diagnosis of Y-T1DM and Y-T2DM, markers of glycaemic control). Relationship and community factors (eg, psychological and behavioural factors such as resiliency, anxiety, depression, self-management, medication adherence support, attitudes towards healthcare, health cultural attitudies, social support systems, adverse childhood events, relationship, community and societal). Societal factors (eg, structural racisms, food insecurity, poverty, medical infrastructure including community or private clinics, access to multidisciplinary care, other social 	

determinants of health).

Y-T1DM, youth-onset type 1 diabetes mellitus; Y-T2DM, youth-onset type 2 diabetes mellitus.

used to describe the articles to develop a full search strategy in PubMed. The final search will be conducted in PubMed, CINAHL, Embase, Scopus and APA PsycNet to include all identified keywords and index terms, adapted for each database. The reference list of all included sources of evidence will be screened for additional studies.

Selection of sources

Following the search, all identified citations will be uploaded into EndNote V.20²⁸ and duplicate citations will be removed. The remaining citations will be imported into Covidence²⁹ for all levels of screening. A clear decision on the screening and selection process as stated in this protocol will be discussed before reviewers begin screening to ensure that screeners have a shared understanding of the inclusion and exclusion criteria. All imported titles and abstracts will be screened by two independent reviewers for assessment against the eligibility criteria outlined in table 1. The full text of selected citations will be imported into Covidence and assessed in detail against the inclusion criteria by the two independent reviewers. Any disagreements that arise between the reviewers at each stage of the selection process will be resolved by a third reviewer to meet consensus. Reasons for excluding full text that do not meet the inclusion criteria will be recorded and reported in the scoping review.

Data charting

Data will be extracted from each study included in the scoping review by two independent reviewers. We will use the PRISMA-ScR²³ checklist and will present study screening and inclusion data in a PRISMA flow chart where the final number of included manuscripts will be listed. A sample data extraction tool (table 2) created to display the full list of data items to be extracted from the review. The Research Electronic Data Capture database will be used for collating and storing the extracted data. We will pilot the use of the data extraction tool to ensure understanding and proper use by the reviewers. Key pieces of information from each study will be collected and will include specific details about the participants, concept, context, study methods and key findings relevant to the review questions. Any disagreements between the two independent reviewers during the data extraction will be clarified with a third independent reviewer. If appropriate, authors of papers will be contacted to request missing or additional data, where required.

Synthesis of results

This scoping review will map the state of the literature on transitioning care in youth-onset diabetes and to identify the main sources and types of evidence available. Data on the synthesis and summary of the characteristics will be provided in aggregate and individually via narrative report. Key pieces of information from each study will

Table 3 Search strategy

Table 3 Search strategy		
Concept	Database and search terms	
Social determinants of health	#1 - "social determinants of health"(tiab) OR "Social Determinants of Health"(Mesh) OR "social factors in health"(tiab) OR "social health determinant" (tiab) OR "social determinant" (tiab) OR "social risk factor" (tiab) OR "social health determinant" (tiab) OR "social ceromoric seconomic determinant" (tiab) OR "socioeconomic factor" (tiab) OR "socioeconomic position" (tiab) OR "socioeconomic need" (tiab) OR "social determinants" (tiab) OR "social disadvantage" (tiab) OR "social disadvantage" (tiab) OR "social disadvantage" (tiab) OR "socioeconomic ration" (tiab) OR "socioeconomic factor" (tiab) OR "socioeconomic disadvantage" (tiab) OR "socioeconomic factor" (tiab) OR "socioeconomic disadvantage" (tiab) OR "financial instability" (tiab) OR "resource poor" (tiab) OR "socioeconomic disadvantage" (tiab) OR "financial instability" (tiab) OR "resource poor" (tiab) OR "socioeconomic disadvantage" (tiab) OR "financial instability" (tiab) OR "resource poor" (tiab) OR "food insufficienc" (tiab) OR "food insecurity" (tiab) OR "food insufficienc" (tiab) OR "food insecurity" (tiab) OR "food insufficienc" (tiab) OR "food insecurity" (tiab) OR "food insufficienc" (tiab) OR "food insecurities" (tiab) OR "food security" (tiab) OR "food insufficienc" (tiab) OR "food insecurities" (tiab) OR "food security" (tiab) OR "food insecurities" (tiab)	
Psychological factors	#9 - Anxiety(mh) OR anxiety(tiab) OR depression(mh) OR stress, psychological(mh) OR "psychological stress"(tiab) OR mental health(mh:noexp)OR resilience, psychological(mh) OR "psychological resilienc*"(tiab) OR psychosocial(tiab) OR "depressive symptom*"(tiab) OR feeding and eating disorders(mh) OR "eating disorder*"(tiab) OR binge-eating disorder(mh) OR "binge eating"(tiab) OR "loss of control eating"(tiab) OR suicide(tiab) OR suicide(tiab) OR suicide(mh) OR "suicide risk"(tiab) OR "cognitive function"(tiab) OR "executive function"(tiab) OR attention deficit disorder with hyperactivity(mh) OR "attention deficit disorder"(tiab) OR ADHD(tiab) #10 - #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9	
Diabetes mellitus	#11 - Diabetes mellitus, type 2(mh) OR "type two diabetes" (tiab) OR T2DM (tiab) OR "adult onset diabetes mellitus" (tiab) OR "youth onset diabetes mellitus" (tiab) OR diabetes mellitus, type 1(mh) OR "type 1 diabetes" (tiab) OR T1DM (tiab) OR diabetes mellitus (majr) OR diabetes (ti) OR diabetic* (ti)	
Child/adolescent/young adult	#12 - child(mh) OR adolescent(mh) OR young adult(mh) OR adolescen*(tiab) OR youth(tiab) OR teen*(tiab) OR child*(tiab) OR pediatric*(tiab) OR "school age"(tiab) OR "school aged"(tiab) OR girl*(tiab) OR boys(tiab) OR juvenile*(tiab) OR youngster*(tiab) OR paediatric*(tiab) OR "high school student*"(tiab) OR "college student*"(tiab) OR "emerging adult*"(tiab) OR "young adult*"(tiab) OR "young people"(tiab) #13 - #10 AND #11 AND #12 #14 - Date filters: from 1 January 1990 to 30 September 2022	



include specific details about the participants, concept, context, study methods and key findings relevant to the review questions. We will synthesise and integrate the emerging data by study design (qualitative, quantitative and mixed) and main outcome of interest (findings related to transition to adult care). Data items associated with transitioning to adult diabetes care will be categorised based on the socio-cultural, behavioural/psychological and biological factors within the socio-ecological framework. Descriptive statistics to report categorial and continuous data (eg, percentages, means (SD) and number (per cent) will be used for demographic data (including age, biological sex, race/ethnicity, presence of comorbidities) and to report the socio-ecological factors that are associated with transitioning care. We will also tabulate the socio-ecological levels investigated within the studies identified. To compare the categories of factor(s) between Y-T1DM and Y-T2DM, we will use rank-sum tests, tables and summary graphs.

Limitations

The goals of this scoping review are to broadly define and describe the factors associated with transitioning care. Due to the breadth and nature of studies being examined, it will not be feasible to conduct an appraisal of the literature, determine the direction of the association or extract effect size estimates. The goals of determining causation factors and effect size estimates are more suited for systematic review that we hope to complete after conducting this scoping review. The inclusion of peerreviewed literature only could contribute to selection bias and will not include an assessment of contemporary web-based transition of care resources or local trends in practice.

ETHICS AND DISSEMINATION

Ethical approval and completion of consents will not be applicable due to the absence of human participants. Results will be published in a peer-reviewed journal and presented at relevant academic conferences. Results will be used to write protocol for systematic review of socioecological determinants of transitioning from paediatric to adult care in youth with type 1 or type 2 diabetes. The search strategy will be made available publicly for transparency.

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Contributors AOU and STC conceptualised the research question and study design, wrote, and developed the search strategy and research protocol. SAD, TCDB, S-AA and NLT helped to design the search strategy and critically reviewed the study design and research protocol. All authors revised and approved the final submitted manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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