PROSPERO International prospective register of systematic reviews

Review title and timescale

1 Review title
Give the working title of the review. This must be in English. Ideally it should state succinctly the interventions or exposures being reviewed and the associated health or social problem being addressed in the review.
Systematic review of outcome measures in randomized controlled trails of pediatric diabetes management

2 Original language title
For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3 Anticipated or actual start date
Give the date when the systematic review commenced, or is expected to commence.
01/05/2012

4 Anticipated completion date
Give the date by which the review is expected to be completed.
30/06/2016

5 Stage of review at time of this submission
Indicate the stage of progress of the review by ticking the relevant boxes. Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. This field should be updated when any amendments are made to a published record.

The review has not yet started ×

Review stage	Started	Completed
Preliminary searches	No	Yes
Piloting of the study selection process	No	Yes
Formal screening of search results against eligibility criteria	No	Yes
Data extraction	No	Yes
Risk of bias (quality) assessment	No	Yes
Data analysis	No	Yes

Provide any other relevant information about the stage of the review here.

Review team details

6 Named contact
The named contact acts as the guarantor for the accuracy of the information presented in the register record.
Sunita Vohra

7 Named contact email
Enter the electronic mail address of the named contact.
svohra@ualberta.ca

8 Named contact address
Enter the full postal address for the named contact.
Department of Pediatrics, University of Alberta 1702 College Plaza 8215 - 112 Street NW Edmonton, AB Canada T6G 2C8

9 Named contact phone number
Enter the telephone number for the named contact, including international dialing code.
+1 780-492-6445

10 Organisational affiliation of the review
Full title of the organisational affiliations for this review, and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

University of Alberta Department of Pediatrics

Website address:
www.care.ualberta.ca

11 Review team members and their organisational affiliations

Give the title, first name and last name of all members of the team working directly on the review. Give the organisational affiliations of each member of the review team.

Title	First name	Last name	Affiliation
Dr	Sunita	Vohra	CARE Program, Department of Pediatrics, University of Alberta, Edmonton, Canada
Dr	Muhammad Zafar	Hydrie	CARE Program, Department of Pediatrics, University of Alberta, Edmonton, Canada
Mr	Hai Chuan (Carlos)	Yu	CARE Program, Department of Pediatrics, University of Alberta, Edmonton, Canada
Dr	Samaneh	Khanpour Ardestani	CARE Program, Department of Pediatrics, University of Alberta, Edmonton, Canada
Dr	Mohammad	Karkhaneh	CARE Program, Department of Pediatrics, University of Alberta, Edmonton, Canada

12 Funding sources/sponsors

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Any unique identification numbers assigned to the review by the individuals or bodies listed should be included.

Alberta Innovates Health Solutions; Canadian Institute for Health Research

13 Conflicts of interest

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

Are there any actual or potential conflicts of interest?

None known

14 Collaborators

Give the name, affiliation and role of any individuals or organisations who are working on the review but who are not listed as review team members.

Title	First name	Last name	Organisation details
Dr	Susanne	King-Jones	CARE Program, Department of Pediatrics, University of Alberta, Edmonton, Canada
Dr	Liliane	Zorzela	CARE Program, Department of Pediatrics, University of Alberta, Edmonton, Canada

Review methods

15 Review question(s)

State the question(s) to be addressed / review objectives. Please complete a separate box for each question.

How well were the primary outcomes identified and reported in pediatric diabetes randomized controlled trials?

What were the psychometric properties of the instruments used to measure outcomes in these trials?

16 Searches

Give details of the sources to be searched, and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.

The following electronic bibliographic databases are included in the search: MEDLINE, EMBASE, CINAHL, The Cochrane Library, Cochrane SR, and Cochrane Central Register of Controlled Trials (CENTRAL). Search terms were related to diabetes (e.g. diabetes mellitus, juvenile onset). The terms were combined with the MEDLINE filter for randomized controlled clinical trials and pediatrics (under 21 years old). The search terms will be adapted for use with other bibliographic databases in combination with database-specific filters for controlled trials, where these are

available. The search will be limited to English-language studies. Studies published between January 2001 and May 2012 will be considered.

17 URL to search strategy

If you have one, give the link to your search strategy here. Alternatively you can e-mail this to PROSPERO and we will store and link to it.

I give permission for this file to be made publicly available
Yes

18 Condition or domain being studied

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

Diabetes mellitus type 1 results when the pancreas no longer produces significant amounts of the hormone insulin, owing to the destruction of the insulin-producing beta cells of the pancreas. The subsequent lack of insulin leads to increased blood and urine glucose. The classical symptoms are polyuria (frequent urination), polydipsia (increased thirst), polyphagia (increased hunger), and weight loss. Type 1 diabetes is treated with insulin replacement therapy—either via subcutaneous injection or insulin pump. Treatment of diabetes focuses on lowering blood sugar or glucose (BG) to the near normal range, approximately 80–140 mg/dl (4.4–7.8 mmol/L). Diabetes mellitus type 2 is an intricate metabolic disorder with heterogeneous etiologies and is increasing in prevalence. Social, behavioral and environmental risk factors can trigger the disease in genetically susceptible people. Insulin resistance and insulin secretory failure are the main mechanisms involved in its pathophysiology. Lifestyle modification (nutritional and exercise) beside pharmacological therapy, such as insulin and oral antihyperglycemic medications (e.g metformin) are key management approaches.

19 Participants/population

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Pediatric patients 0-20 years of age.

20 Intervention(s), exposure(s)

Give full and clear descriptions of the nature of the interventions or the exposures to be reviewed

We will include any RCTs looking at interventions aimed at managing diabetes (e.g. different insulin regimens, educational therapies, etc). We will exclude diabetes prevention trials as well as trials assessing diabetes diagnostic tools. We will also exclude pilot studies, secondary studies, and studies validating psychometric properties of measurement tools.

21 Comparator(s)/control

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group).

Any comparator will be allowed, including placebo and usual care.

22 Types of study to be included

Give details of the study designs to be included in the review. If there are no restrictions on the types of study design eligible for inclusion, this should be stated.

Randomized controlled trials (RCTs) will be included; we will exclude pilot studies, multi-stage trials, trials of diagnostic tools, and secondary reports/follow up studies.

23 Context

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

Any setting dealing with pediatric health care will be included.

24 Primary outcome(s)

Give the most important outcomes.

This study aims to assess the quality of reporting, heterogeneity in selecting and validity of outcome measures presented by authors of pediatric diabetes trials. This study will not restrict the outcomes being assessed as the goal is to identify current trends in pediatric diabetes research reporting. Some examples of the outcomes often assessed include glycemic control, as measured by HbA1c levels, as well as insulin doses and hypoglycemic episodes.

Give information on timing and effect measures, as appropriate.

We will not include an assessment of effect or timing.

25 Secondary outcomes

List any additional outcomes that will be addressed. If there are no secondary outcomes enter None.

None.

Give information on timing and effect measures, as appropriate.

None.

26 Data extraction (selection and coding)

Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.

Duplicate articles will be removed prior to review. Two reviewers will then individually screen article titles and abstracts for inclusion. Full text of potentially included articles will be obtained and assessed for inclusion using preset criteria. Data will be extracted by one reviewer and verified by a second reviewer. Where disagreement between reviewers exists, the reviewers will attempt to reach consensus through discussion and a third reviewer will be consulted where necessary. Data to be extracted include: age and gender of participants, study design, condition, interventions and controls under study, details of outcomes and outcome measurement tools, and details of safety/harms assessment.

27 Risk of bias (quality) assessment

State whether and how risk of bias will be assessed, how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.

Because we are focusing on outcome reporting, risk of bias will not be assessed.

28 Strategy for data synthesis

Give the planned general approach to be used, for example whether the data to be used will be aggregate or at the level of individual participants, and whether a quantitative or narrative (descriptive) synthesis is planned. Where appropriate a brief outline of analytic approach should be given.

For the purpose of this systematic review data combining may not be feasible. If appropriate, count data will be presented using proportions and will be analyzed using descriptive statistics and Chi-squared tests.

29 Analysis of subgroups or subsets

Give any planned exploration of subgroups or subsets within the review. ‘None planned’ is a valid response if no subgroup analyses are planned.

None planned.

Review general information

30 Type and method of review

Select the type of review and the review method from the drop down list.

Intervention, Systematic review, Other

Methodologic

31 Language

Select the language(s) in which the review is being written and will be made available, from the drop down list. Use the control key to select more than one language.

English

Will a summary/abstract be made available in English?

Yes

32 Country

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved. Use the control key to select more than one country.

Canada

33 Other registration details

Give the name of any organisation where the systematic review title or protocol is registered together with any unique identification number assigned. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here.

34 Reference and/or URL for published protocol
Give the citation for the published protocol, if there is one.
Give the link to the published protocol, if there is one. This may be to an external site or to a protocol deposited with CRD in pdf format.

I give permission for this file to be made publicly available
Yes

35 Dissemination plans
Give brief details of plans for communicating essential messages from the review to the appropriate audiences.
We plan to submit a paper to a peer reviewed journal relevant to pediatric diabetic medicine.

Do you intend to publish the review on completion?
Yes

36 Keywords
Give words or phrases that best describe the review. (One word per box, create a new box for each term)
diabetes type 1 or type 2

reporting

outcomes

37 Details of any existing review of the same topic by the same authors
Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

38 Current review status
Review status should be updated when the review is completed and when it is published.
Ongoing

39 Any additional information
Provide any further information the review team consider relevant to the registration of the review.

40 Details of final report/publication(s)
This field should be left empty until details of the completed review are available.
Give the full citation for the final report or publication of the systematic review.
Give the URL where available.