Inclusion Criteria Worksheet: Diabetes & Medical Nutrition Therapy Education for Families with Children Who Have Type 1 Diabetes Mellitus

Reviewer: _____ **Date:** _____ **Record ID:** _____

	Yes	No	Unclear/Comments
Population: Patients with type 1 diabetes (If both type 1 and type 2 diabetes patients are included, results for type 1 must be explicit) **Exclude** Type 2 diabetes, gestational diabetes	Yes	No	
Population: Patients ≤ 18 yr. (or <20% of population over 18 yr.) OR families of patients ≤ 18 years	Yes	No	
Study design: RCT, CCT, cohort studies, interrupted time series, before-after study with concurrent controls, case control studies, uncontrolled before and after studies, case series [make a note of those that are <10 participants] **Exclude** secondary research, case reports	Yes	No	
Intervention: Education program that incorporates at least one of the following content areas: 1) Diabetes disease process and treatment options; 2) Nutritional management; 3) Physical activity; 4) Monitoring blood glucose, urine ketones (when appropriate), and using the results to improve control; 5) Utilizing medications; 6) Preventing, detecting, and treating acute complications; 7) Preventing (through risk reduction behavior), detecting, and treating chronic complications; 8) Goal setting to promote health and problem solving for daily living; 9) Psychosocial adjustment.	Yes	No	
Comparator: Education program vs. usual care OR another education program. **NOTE:** do not exclude based on this item; just make note of whether there is or isn't a comparison group.	Yes	No	
Is the description of intervention sufficient to reproduce? Note: Must include topics or content. Other characteristics: provider, length and # sessions, target audience, mode of delivery (e.g., in person or distance), group or individual, didactic/interactive, changes in treatment.	Yes	No	

Inclusion Criteria Worksheet: Diabetes & Medical Nutrition Therapy Education for Families with Children Who Have Type 1 Diabetes Mellitus (continued)

Outcomes: One or more of the following: 1) Metabolic control (as measured by HbA1c); 2) Hospitalization or ED utilization; 3) Complications (short & long term; e.g., diabetic ketoacidosis, episodes of hypoglycemia, retinal, renal, cardiovascular, neurological); 4) Knowledge; 5) Quality of life; 6) School attendance and performance; 7) Self confidence in ability to cope with disease; 8) Psychosocial outcomes **Exclude** life style outcomes (e.g., smoking, use of recreational drugs, participation in extracurricular activities)	Yes	No	
Final decision: Should this study be included?	**Yes**	**No**	**Unclear (Discuss)**
Results of discussion:			

Quality Assessment Form: (Jadad Scale for RCTs)

Study number _____ Initials of assessor: _____

Part 1 (from: Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control Clin Trials 1996;17(1):1-12.)

1. Was the study described as randomized (this includes the use of words such as randomly, random, and randomization)? _____
Yes=1 No=0

2. Was the study described as double-blind? _____
Yes=1 No=0

3. Was there a description of withdrawals and drop-outs? _____
Yes=1 No=0

Add one point if:

Method to generate the sequence of randomization was described, and was appropriate (e.g., table of random numbers, computer-generated, coin-tossing) _____

Method of double-blinding was described, and was appropriate (identical placebo, active placebo, dummy) _____

Subtract one point if:

Method of randomization was described, and was inappropriate (allocated alternately, according to date of birth, hospital number) _____

Method of double-blinding described, but was inappropriate (comparison of tablet versus injection with no double dummy) _____

OVERALL SCORE (maximum 5)

Score _____

Part 2 (from Schulz – JAMA 1995; 273:408-12)

Concealment of treatment allocation:

- ☐ Adequate
- ☐ Inadequate
- ☐ Unclear

Adequate:	e.g., central randomization; numbered/coded containers; drugs prepared by pharmacy; serially numbered, opaque, sealed envelopes
Inadequate:	e.g., alternation, use of case record numbers, dates of birth or day of week; open lists
Unclear:	Allocation concealment approach not reported or fits neither above category

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

Ref ID: _____
Author: _____
Year: _____
Reviewer: _____

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

Very Likely Somewhat Likely Not Likely

(Q2) What percentage of selected individuals agreed to participate?

80 - 100% Agreement 60 – 79% Agreement Less than 60% Agreement Not Reported Not Applicable

Rate this section (see dictionary)	Strong	Moderate	Weak

B) ALLOCATION BIAS

Indicate the study design

RCT (go to i) Quasi-Experimental (go to C) Case-control, Before/After study, No control group, or Other: _____ (Score Weak and go to C)

(i) Is the method of random allocation stated? Yes No

(ii) If the method of random allocation is stated is it appropriate? Yes No

(iii) Was the method of random allocation reported as concealed? Yes No

Rate this section (see dictionary)	Strong	Moderate	Weak

C) CONFOUNDERS

(Q1) Prior to the intervention were there between group differences for important confounders reported in the paper?

Yes No Can't Tell Not Applicable (Score Weak and go to D)

Please refer to your Review Group list of confounders.

Relevant Confounders reported in the study:

_____ _____ _____

_____ _____ _____

_____ _____ _____

(Q2) If there were differences between groups for important confounders, were they adequately managed in the analysis?

Yes No Not Applicable

(Q3) Were there important confounders not reported in the paper?

Yes No

Relevant Confounders NOT reported in the study:

_____ _____ _____

Rate this section (see dictionary)	Strong	Moderate	Weak

Note: Many studies report the results of multiple data collection tools. If you are interested in only one outcome of interest, measured by one tool, at one point in time, rate the components (validity and reliability of tool, blinding, withdrawals and drop-outs) based on that one tool. If you are collecting multiple outcomes of interest, scored by multiple tools (e.g. self-report AND assessor interview, SF-36 AND made-up questionnaire), at multiple points in time (e.g. 6-month follow-up AND 20-year follow-up) copy components of the EPHPP tool so that each data collection tool of interest is scored.

D) BLINDING

(Q1) Was (were) the outcome assessor(s) blinded to the intervention or exposure status of participants?

Yes No Not Reported Not Applicable

Rate this section (see dictionary)	Strong	Weak	Not Applicable

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown or are they known to be valid?

Yes No

(Q2) Were data collection tools shown or are they known to be reliable?

Yes No

Rate this section (see dictionary)	Strong	Moderate	Weak

F) WITHDRAWALS AND DROP-OUTS

(Q1) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

80 -100% 60 - 79% Less than 60% Not Reported Not Applicable

Rate this section (see dictionary)	Strong	Moderate	Weak	Not Applicable

G) **ANALYSIS**

(Q1) Is there a sample size calculation or power calculation?

Yes Partially No

(Q2) Is there a statistically significant difference between groups?

Yes No Not Reported

(Q3) Are the statistical methods appropriate?

Yes No Not Reported

(Q4a) Indicate the unit of allocation (circle one)

Community Organization/ Institution Group Provider Client

(Q4b) Indicate the unit of analysis (circle one)

Community Organization/ Institution Group Provider Client

(Q4c) If 4a and 4b are different, was the cluster analysis done?

Yes No Not Applicable

(Q5) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

Yes No Can't Tell

H) **INTERVENTION INTEGRITY**

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

80 -100% 60 - 79% Less than 60% Not Reported Not Applicable

(Q2) Was the consistency of the intervention measured?

Yes No Not reported Not Applicable

(Q3) Is it likely that subjects received an unintended intervention (contamination or cointervention) that may influence the results?

Yes No Can't tell

SUMMARY OF COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-3 onto this page.

A SELECTION BIAS

Rate this section (see dictionary)	Strong	Moderate	Weak

B STUDY DESIGN

Rate this section (see dictionary)	Strong	Moderate	Weak

C CONFOUNDERS

Rate this section (see dictionary)	Strong	Moderate	Weak

D BLINDING

Rate this section (see dictionary)	Strong	Weak	Not Applicable

E DATA COLLECTION METHODS

Rate this section (see dictionary)	Strong	Moderate	Weak

F WITHDRAWALS AND DROPOUTS

Rate this section (see dictionary)	Strong	Moderate	Weak	Not Applicable

G ANALYSIS
Comments _____

_____

_

_____

_

H INTERVENTION INTEGRITY
Comments

_____

_____

_

_____

_

WITH BOTH REVIEWERS DISCUSSING THE RATINGS:

Is there a discrepancy between the two reviewers with respect to the component ratings?
No Yes

If yes, indicate the reason for the discrepancy

1	2	3
Oversight	Differences in Interpretation of Criteria	Differences in Interpretation of Study

Data Extraction Form: Diabetes Education for Children with Type 1 Diabetes

Description of Study

Reviewer name:
Date entered:
Verifier's name:
Consensus reached:
Data updated:

Procite ID:
Author: Year:

Study ID: **Reviewer Name:** **Date entered:**

Type of publication:

Funding:

Country:

Study setting:

Single-centre	☑
Multi-centre	☑
Urban	☑
Rural	☑
Mixed	☑
Camp	☑
Unclear	☑

Study design:

Objective or hypothesis of study:

Author's primary outcome:

Measure of primary outcome:

Secondary outcomes:

Inclusion criteria for study:

Exclusion criteria for study:

Procite ID:
Author: **Year:**

Number Eligible: **Number of withdrawals:**

Number Enrolled:
Number Completed:

Number Excluded: **Out of how:**

How many excluded were from treatment group (n/N): **How many from treatment group (n/N):**

How many excluded were from control group (n/N): **How many from control group (n/N):**

Reasons for Exclusion: **Reasons Withdrawn:**

From where were subjects recruited?: (Drop down menu)

Hospital
Clinic
Home
Community
Existing support program
Diabetes centre
School

How were they recruited?: (Drop down menu)

Volunteers
Referrals
Existing patients
Poster/flyer
Administrative data
Chart review/Medical records

How was the control group selected?:

Authors' Conclusions:

Reviewer's Comments: **Verifier's Comments:**

Baseline Characteristics

Verifier's name:
Consensus reached:
Data updated:

Population ID:

Procite ID:

Reviewer Initials:

Group Name: Name of Group:

Number in Group:

Age Mean: Standard deviation: Reported ☑
Age- other measure: Other variance: Calculated ☑

Percent Male: Reported ☑
Calculated ☑

Weight or BMI:

BMI Mean: BMI SD:

Weight Mean: Weight SD:

HbA1C Unit of Measurement:

HbA1C Mean: HbA1C SD:

HbA1C Other Measure: HBA1C Other Variance:

Diabetes Duration: Standard deviation:

Percent Newly Diagnosed:

Comments:

Pop categorical	Population ID	Measures	Category	Numerator	Denominator	%	Mean	SD	Comments
(Auto Number)									

Interventions

Verifier's name:
Consensus reached:
Data updated:

Procite ID:

Group Name: Short Name:

Setting

- Hospital ☑
- Doctor's office ☑
- Home ☑
- Community ☑
- Support Program ☑
- School ☑
- Diabetes Center ☑
- Other ☑

Specify other:

Content

- Diabetes disease process and treatment options ☑
- Nutritional management ☑
- Physical activity ☑
- Monitoring (e.g. blood glucose, urine ketones) ☑
- Medication use ☑
- Preventing, detecting, treating acute complications ☑
- Preventing, detecting, treating chronic complications ☑
- Relationship Skills
- Goal setting to promote health and problem solving for daily living ☑
- Psychosocial adjustment ☑

Description of Intervention:

Theoretical Framework:

Enter the page number where this description is located:

Interventions

Procite ID:

Group Name: **Short Name:**

Study Duration:
Recruitment period:
Follow-up period:
Duration of program delivery:

Component 1:
Frequency of intervention component 1 (ie 2x/week):
Duration of component 1 (i.e. length of session):

Frequency of component 2:
Frequency of intervention component 2 (ie 2x/week):
Duration of component 2 (i.e. length of session):

Frequency of component 3:
Frequency of intervention component 3 (ie 2x/week):
Duration of component 3 (i.e. length of session):

Who delivered the intervention?
Primary deliverer (select one)

- Diabetes educator
- Physician
- Pediatric endocrinologist
- Nurse
- Nurse practitioner
- Psychologist
- Social worker
- Exercise physiologist
- Paramedic
- Camp counsellor
- Multidisciplinary team
- Research staff
- Peer group
- Lay person
- Computer game
- Video game
- Dietician
- Other (specify)
- NR
- N/A

Secondary mode(s) of delivery:

If other, please specify:

To whom was the intervention delivered?

- Parents
- Child
- Family
- Other
- Other (specify)
- NR
- N/A

Secondary deliverers:

If other, please specify:

What was the mode of delivery?
Primary mode of delivery (select one)

- Literature
- Meetings
- Clinic visits
- Personal counselling
- Club
- Computer game
- Presentation
- Class
- Support group
- Workbooks
- Phone calls
- Other (specify)
- NR
- N/A

Other recipient:

Specify other:

Outcomes

Verifier's name:

Consensus reached:

Data updated:

Procite ID:
Reviewer Initials:

Category (drop down menu):
- Knowledge
- Metabolic control
- Short-term complications
- Long-term complications
- Health care utilization
- Quality of life
- School attendance and performance
- Self-confidence in ability to cope with disease
- Psychosocial outcomes
- Adherence

Description of outcome:

Instrument used:

Method of Measurement (drop down menu):
- Patient self-report
- Parent self-report
- Observation
- 24 hr food frequency questionnaires
- Pill count
- Skill demonstration
- Laboratory records
- Medical records
- Other

Specify Other:

Frequency of Measurement:

Unit of Measurement (e.g. mg, score):

Outcome group ID	Outcome ID	Group	Time-point	Number	Mean	SD	Other Measure	Other Variance	Page Number	Comments
(Auto number)										