EFFECTIVENESS OF DIABETES EDUCATION INTERVENTIONS ON PSYCHOSOCIAL OUTCOMES IN ADULTS WITH TYPE 2 DIABETES MELLITUS - PROTOCOL

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Background

Type 2 diabetes is a chronic disease which contributes a substantial individual and public health burden. Current estimates suggest that more than 180 million people worldwide suffer from diabetes, with the number expected to double by 2030 (1). Type 2 diabetes accounts for 85% of these cases. The global epidemic in type 2 diabetes is linked to a dramatic increase in risk factors such as obesity and physical activity (1).

Uncontrolled diabetes can lead to serious complications such as heart disease, stroke, kidney failure, blindness, and lower limb amputations. As many as 2.9 million deaths worldwide (5.2% of all deaths) in 2000 were attributed to diabetes (2). In Australia, approximately one million people have diabetes, with around half of all cases still undiagnosed (3). Estimated annual health system costs for type 2 diabetes alone are around $6 billion, though actual costs may be much higher due to indirect costs such as lost productivity (4).

Psychosocial problems such as depression, anxiety, and low quality of life or wellbeing are also common among people with diabetes (5, 6). There is evidence to suggest that these factors may directly and indirectly impact long-term outcomes such as metabolic control, cardiovascular status, and the development of diabetes complications (5).

Given the enormous costs to the individual and the community, preventing the complications of diabetes and improving patient outcomes is critical. Landmark studies such as the Diabetes Control and Complications Trial [DCCT] and the United Kingdom Prospective Diabetes Study [UKPDS] demonstrated that reducing blood glucose levels can delay or prevent the onset of diabetic complications.
(7, 8). According to the UKPDS, “each 1% decrease in haemoglobin A1c was associated with a 37% decrease in risk for microvascular complications and a 21% decrease in the risk of any end point or death related to diabetes” (9, p.409).

**Diabetes management and the role of education**

Diabetes education has long been recognised as playing a vital role in assisting the person with diabetes to manage their disease. The traditional approach to diabetes education has been one of the health professional imparting knowledge about diabetes and its management to the patient with diabetes (10, 11). However, it is now recognised that knowledge alone is insufficient to produce the behaviour changes necessary for effective self-management and thus metabolic control (10). This type of education also fails to address the complex personal and psychosocial aspects of living with diabetes (12).

More recently, the focus has been on developing education interventions with a greater behavioural and psychosocial component, enabling the patient to become an active participant in self care and decision-making (11). The goal of diabetes self-management education (DSME) is to provide the patient with the necessary knowledge and skills to effectively manage their condition and encourage behaviours that will “result in better choices, better health, and fewer complications” (10, p. 655). It is important that DSME address the individual’s underlying beliefs and attitudes about their disease, and endeavour to overcome existing psychosocial barriers (5, 13, 14).
Effectiveness of DSME on psychosocial outcomes

DSME has been shown to be effective at changing behaviour and improving metabolic control (13, 15). However, despite the evidence for the importance of addressing psychosocial barriers, few diabetes education interventions have successfully targeted this aspect of diabetes management (12). The recent DAWN study (6) suggested that the majority of diabetes education providers fail to meet the psychosocial needs of their patients. This is hardly surprising when the bulk of diabetes education research continues to focus primarily on metabolic outcomes, with psychosocial factors only included as secondary outcomes. In addition, many existing intervention studies are fraught with methodological problems, creating a high risk of bias and making meaningful interpretation of study results difficult.

Several reviews have examined the effectiveness of diabetes education at improving glycaemic control, diabetes-related knowledge, and self-management behaviours (12, 15, 16). However only a small proportion of studies included in the reviews assessed psychosocial outcomes, and many of these studies were of poor methodological quality. Only one review specifically examined the impact of different types of interventions on psychosocial outcomes (13). The results suggested that self-management education may have positive effects for psychosocial outcomes, though again the effects of the interventions were difficult to determine due to methodological limitations.

Recent studies investigating the impact of diabetes education on psychosocial outcomes have produced mixed results. Several studies failed to detect any significant difference between treatment groups across a range of outcomes such as quality of life (17), self-efficacy (18), satisfaction (18), wellbeing and empowerment (19). Others demonstrated significant improvements in these variables (20-22). Given the
diversity of results from these studies, there is a need to collate this evidence using a rigorous review methodology to provide clinicians with a single reliable source of evidence.

Objectives

The aim of this systematic review [SR] is to examine whether the context of diabetes education effects psychosocial outcomes in adults with type 2 diabetes mellitus.

Research question

This SR will be undertaken to answer the following research questions:

Is there a difference in psychosocial outcomes for adults with type 2 diabetes who participate in:

1. group versus individual diabetes education;
2. group versus other diabetes education; or
3. Individual versus other diabetes education?

Definition of terms

For the purposes of this review, the following definitions will apply:
**Type 2 diabetes** is a chronic disease characterised by an inability to effectively utilise insulin (insulin resistance), often associated with a concomitant reduction in insulin production, resulting in elevated blood sugar (hyperglycaemia) (1).

**Group/individual diabetes education** is any kind of education provided to a person with diabetes to enable them to adjust to and effectively manage their disease, avoid its complications, and maintain or improve their quality of life. It may be delivered on an individual basis or in a group format, and may include educational, behavioural, and psychosocial components.

**Psychosocial outcomes** are those aspects of a patient’s psychological and social functioning, such as quality of life and wellbeing, which may be affected by the diagnosis of and experience of living with diabetes, and in turn impact upon the person’s ability to successfully manage their disease.

**Criteria for considering studies for this review**

*Types of studies*

All randomised, quasi-randomised and clinical controlled trials that investigate the effectiveness of diabetes education on psychosocial outcomes will be eligible for inclusion in this review. Should there be insufficient randomised trials identified, consideration will be given to including studies using comparative designs. Studies undertaken in any county will be considered for inclusion; however, publications will be limited to the English language. All studies will be categorized according to the Joanna Briggs Institute Level of Evidence (Appendix 1).
Types of participants

This review will consider all studies that report relevant interventions involving individuals aged 18 years and over who have been diagnosed with type 2 diabetes. Given the changes in classification and diagnostic criteria for type 2 diabetes over the years, the diagnosis should have been based on standard criteria, such as the WHO criteria, that were current at the time of the trial (16). Ideally, this information should be included in the study report. Studies involving only participants with type 1 or gestational diabetes will not be included. Studies that include participants with both type 1 and type 2 diabetes will be included provided data from participants with type 2 diabetes is analysed separately.

Types of interventions

Trials will be considered for inclusion in the review if they report on any kind of group or individual diabetes education intervention, conducted in all settings, and delivered by any provider type. The interventions of interest are related to lifestyle modification and instruction on self-management behaviours, such as diet and exercise counselling, medication adherence, and blood glucose monitoring, as well as psychosocial counselling such as coping skills training, empowerment, and motivational interviewing. Interventions that specifically address insulin initiation will be excluded, as will those that involve specialised psychological therapies such as cognitive behavioural therapy, psychotherapy, and others. Studies with multiple component interventions will be included only if the effects of the educational component can be examined separately.
Types of outcome measures

The primary outcomes of interest will include:

- Quality of life
- Wellbeing
- Empowerment
- Self-efficacy
- Patient satisfaction
- Attitudes
- Health/illness beliefs and perceptions
- Anxiety
- Depression
- Stress
- Motivation
- Psychological adjustment

Secondary outcomes may include:

- Glycaemic control: glycated haemoglobin and fasting blood glucose
- Body weight / Body mass index
- Diabetes knowledge
- Self-management behaviours
- Cardiovascular outcomes: blood pressure, lipid profile
• Adverse events: e.g. increased hypoglycaemia
• Diabetes complications
• Diabetes-related morbidity and mortality
• Medication regimen: use of oral antihyperglycaemic agents
• Attendance for complication screening
• Cost effectiveness

Studies which do not use validated outcome measures will be excluded. Timing of outcome assessment will be classified as short term (4-6 months), medium term (6-12 months), or long term (>12 months).

**Search strategy for identification of studies**

Prior to commencing the review the Cochrane Collaboration, the Joanna Briggs Institute (JBI), National Health Service (NHS) Centre for Review & Dissemination (CRD) and the Agency for Healthcare Research and Quality (AHRQ) databases will be searched to ensure that a systematic review on this subject is not being undertaken. The search will identify both published and unpublished trials. In consultation with the medical librarian the Ovid databases will be searched to identify key words used in the titles and abstracts. As each database has its own indexing terms, individual search strategies will be developed for each database (Appendix 2). During the development of the search strategy, consideration will be given to the diverse terminology used and the spelling of keywords as this would influence identification of relevant trials.

The following databases will be searched:
• MEDLINE (to present) and PreMedline
• CINAHL (to present)
• PsycINFO (to present)
• The Cochrane Library (most recent issue)
• Evidence Based Medicine (EBM) Reviews (to present)
• Database of Abstracts of Reviews of Effects (DARE) (to present)

In addition, the reference lists and bibliographies of all identified trials and reviews will be searched for further references. Relevant reports, conference proceedings and unpublished literature (e.g. theses) will be searched and experts in the field will be contacted to identify any further trials or research in progress. Electronic searching of the full text versions of Diabetes Care (1998-present), Diabetes Educator (1980-present), Diabetic Medicine (1999-present), Diabetologia (1965-present), Patient Education & Counselling (1978-present), Diabetes Research & Clinical Practice (1985-present), and Diabetes Spectrum (1996-present) will be undertaken as these journals are electronically available in full text and have been identified as commonly publishing relevant papers.

Methods of the review

All studies identified by the search strategies will be entered into bibliographic software (Endnote™ 7.0). After removal of duplicate results, the titles, abstracts, keywords/MeSH terms and methods sections will be considered against the inclusion and exclusion criteria independently by two reviewers. When the paper appears to meet the inclusion criteria or the abstract is inconclusive, the full text of the
publication will be accessed for complete analysis using the Verification of Study tool (Appendix 3).

Studies that have been reported in more than one publication will only be included once. Any disparities in decision-making will be settled by a third reviewer.

**Assessment of methodological quality**

The methodological quality of the eligible randomised controlled trials will be assessed independently by two reviewers using the Joanna Briggs quality assessment tool for experimental studies (Appendix 4). Any disagreements will be resolved by discussion with a third reviewer. Each study will be critically appraised and methodological quality will be assessed for the following:

1. Detailed description of inclusion and exclusion criteria used to obtain the sample;
2. Evidence of allocation concealment at randomisation;
3. Validity of methods of outcome assessment;
4. Description of withdrawals and dropouts;
5. Potential for bias in outcome assessment.

**Data extraction**

Data extraction from the included trials will be undertaken and summarised independently by two reviewers using a data extraction tool (Appendix 5) that has been piloted prior to use. Discrepancies between reviewers will be resolved by discussion. Data will be collected relating to:
- Patient inclusion/exclusion criteria
- Study settings
- Patient demographics
- Description of the interventions; method, frequency of delivery of the intervention
- Content of the intervention
- Whether the intervention was targeted at psychosocial outcomes
- Description of theoretical model underpinning the education programme (if any)
- Description of the outcomes
- Follow up period
- The number and reasons for withdrawals and dropouts

Attempts will be made to obtain data missing from the trial report by contacting the authors.

**Data synthesis**

All calculations will be made using the Cochrane statistical package Review Manager (RevMan) Version 4.4. The studies will be assessed for clinical heterogeneity by considering the populations, interventions, and outcomes. Statistical heterogeneity will be investigated by calculating the $I^2$ statistic, and if this indicates a high level of heterogeneity among the trials included in an analysis, a random effects meta-analysis will be preferred for an overall summary. Where high levels of heterogeneity are found they will be explored by the pre-specified sub-group analyses and by sensitivity analyses excluding the trials most susceptible to bias based on the quality assessment: those with inadequate allocation concealment; high levels of post randomisation losses or exclusions; or unblinded outcome
assessment, or uncertain blinding or outcome assessment. Fixed effects meta-analysis will be used for combining study data if the trials are judged to be sufficiently similar.

Relative risks and 95% confidence intervals (CI) will be calculated for dichotomous data. Analysis of continuous data will be undertaken using the mean and standard deviation values to derive weighted mean differences (WMD) and their 95% CIs. Where synthesis is inappropriate a narrative analysis of results will be presented.

Where possible subgroup analysis will be undertaken to assess effects of duration and intensity of education programme, setting (e.g. primary or secondary care), delivery (type of provider), theoretical model underpinning the intervention, age (e.g. <65 years and >65 years), gender, and ethnicity.

**Potential conflicts of interest**

Nil.
REFERENCES


# APPENDIX 1

**JOANNA BRIGGS INSTITUTE LEVEL OF EVIDENCE FOR SYSTEMATIC REVIEWS**

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>Feasibility F(1-4)</th>
<th>Appropriateness A(1-4)</th>
<th>Meaningfulness M(1-4)</th>
<th>Effectiveness E(1-4)</th>
<th>Economic Evidence EE(1-4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SR of research with unequivocal synthesised findings</td>
<td>SR of research with unequivocal synthesised findings</td>
<td>SR of research with unequivocal synthesised findings</td>
<td>SR (with homogeneity) of Experimental studies (eg. RCT with concealed allocation) Or 1 or more large experimental studies with narrow confidence intervals</td>
<td>SR (with homogeneity) of evaluations of important alternative interventions comparing all clinically relevant outcomes against appropriate cost measurement, and including a clinically sensible sensitivity analysis</td>
</tr>
<tr>
<td>2</td>
<td>SR of research with credible synthesised findings</td>
<td>SR of research with credible synthesised findings</td>
<td>SR of research with credible synthesised findings</td>
<td>Quasi-experimental studies (eg. without randomisation)</td>
<td>Evaluation of important alternative interventions comparing all clinically relevant outcomes against appropriate cost measurement, and including a clinically sensible sensitivity analysis</td>
</tr>
<tr>
<td>3</td>
<td>SR of text/opinion with credible synthesised findings</td>
<td>SR of text/opinion with credible synthesised findings</td>
<td>SR of text/opinion with credible synthesised findings</td>
<td>3a. Cohort studies (with control group) 3b. Case-controlled 3c Observational studies without control groups</td>
<td>Evaluation of important alternative interventions comparing a limited number of outcomes against appropriate cost measurement, without a clinically sensible sensitivity analysis</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion without explicit critical appraisal</td>
<td>Expert opinion without explicit critical appraisal</td>
<td>Expert opinion without explicit critical appraisal</td>
<td>Expert opinion with explicit critical appraisal, or based on physiology, bench research or consensus</td>
<td>Expert opinion with explicit critical appraisal, or based on economic theory</td>
</tr>
</tbody>
</table>
APPENDIX 2

MEDLINE and PreMEDLINE (OVID) SEARCH STRATEGY

1. diabetes mellitus/ or diabetes mellitus, type 2/
2. insulin resistance/
3. glucose intolerance/
4. (obes$ adj diabet$).mp.
5. impaired glucose tolerance.mp.
6. glucose intolerance.mp.
7. insulin resistance.mp.
8. (mody or niddm or t2dm or dm2).mp.
9. (non insulins depend$ or noninsulin$ depend$ or noninsulin$depend$ or non insulin$depend$).mp.
10. ((type 2 or type ii) adj diabet$).mp.
11. ((nonketotic or non ketotic) adj diabet$).mp.
12. ((adult or matur$ or late) adj3 diabet$).mp.
13. metabolic syndrom$.mp.
14. plurimetabolic syndrom$.mp.
15. or/1-14
16. dermatomyositis/
17. myotonic dystrophy/
18. diabetes insipidus/
19. dermatomyositis.mp.
20. myotonic dystroph$.mp.
21. diabet$ insipidus.mp.
22. or/16-21
23. 15 not 22
24. education/
25. patient education/
26. teaching/
27. counseling/
28. self care/
29. health behavior/
30. behavior therapy/
31. patient compliance/
32. educat$.mp.
33. motivational interview$.mp.
34. behavi?or$ therap$.mp.
35. health education$.mp.
36. train$.mp.
37. teach$.mp.
38. counsel$.mp.
39. therap$.mp.
40. treatment$.mp.
41. intervention$.mp.
42. program$.mp.
43. or/24-42
44. group$.mp.
45. individual$.mp.
46. client$.mp.
47. or/44-46
48. 43 and 47
49. psycho$.mp.
50. "quality of life".mp.
51. lifestyle.mp.
52. behavio?r$.mp.
53. skill$.mp.
54. (self adj5 (care or manage$ or monitor$)).mp.
55. wellbeing.mp.
56. (self adj5 (efficac$ or confiden$)).mp.
57. empower$.mp.
58. (problem solving or problemsolving).mp.
59. coping.mp.
60. motivation$.mp.
61. (stage$ adj5 change).mp.
62. satisfaction.mp.
63. anxiety.mp.
64. depression.mp.
65. attitude$.mp.
66. perception$.mp.
67. belief$.mp.
68. locus of control.mp.
69. adjustment.mp.
70. or/49-69
71. 48 and 70
72. randomized controlled trial.pt.
73. controlled clinical trial.pt.
74. randomized controlled trials.sh.
75. random allocation.sh.
76. double blind method.sh.
77. single blind method.sh.
78. clinical trial.pt.
79. exp clinical trials/
80. (clin$ adj25 trial$).ti,ab.
81. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
82. placebos.sh.
83. placebo$.ti,ab.
84. random$.ti,ab.
85. research design.sh.
86. comparative study.pt.
87. exp evaluation studies/
88. follow up studies.sh.
89. prospective studies.sh.
90. (control$ or prospectiv$ or volunteer$).ti,ab.

91. or/72-95

92. (animals not humans).sh.

93. 91 not 92

98. 23 and 71 and 93
CINAHL (EBSCO) SEARCH STRATEGY

1. MH "Diabetes Mellitus, Non-Insulin-Dependent" or MH "diabetes mellitus"
2. MH "Insulin Resistance"
3. MH "glucose intolerance"
4. ( "type 2" or "type ii" ) and diabet*
5. obes* N5 diabet*
6. impaired glucose tolerance
7. insulin resistance
8. mody or niddm or t2dm or dm2
9. non-insulin-depend*
10. non-ketotic N5 diabet* or nonketotic N5 diabet*
11. adult N3 diabet* or matur* N3 diabet* or late N3 diabet*
12. metabolic syndrom* or plurimetabolic syndrom*
13. S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12
14. MH dermatomyositis
15. MH "myotonic dystrophy"
16. MH "diabetes insipidus"
17. dermatomyositis
18. myotonic dystroph*
19. diabet* insipidus
20. S14 or S15 or S16 or S17 or S18 or S19
21. S13 not S20
22. MH education
23. MH patient education
24. MH teaching
25. MH counseling
26. MH "self care"
27. MH "health behavior"
28. MH "behavior therapy"
29. MH "patient compliance"
30. educat*
31. motivational interview*
32. behav* therap*
33. health education
34. train*
35. teach*
36. counsel*
37. therap*
38. treatment*
39. intervention*
40. program*
41. S30 or S31 or S32 or S33 or S35 or S36 or S37 or S38 or S39 or S40
42. group*
43. individual*
44. client*
45. S42 or S43 or S44
46. S45 and S41
47. psycho*
48. "quality of life"
49. lifestyle
50. behav*
51. skill*
52. “self care” or “self manage*” or “self monitor*”
53. wellbeing or well-being
54. “self efficac*” or “self confiden*”
55. empower*
56. problem solving or problem-solving
57. coping
58. motivation*
59. stage* N5 change*
60. satisfaction
61. anxiety
62. depression
63. attitude*
64. perception*
65. belief*
66. "locus of control"
67. adjustment
68. S47 or S48 or S49 or S50 or S51 or S52 or S53 or S54 or S55 or S56 or S57 or S58 or S59 or S60 or S60 or S61 or S62 or S63 or S64 or S65 or S66 or S67
69. S46 and S68
70. random* clinical trial*
71. random* control* trial*
72. clinical control* trial*
73. random* allocat*
74. MH “Clinical Trials+”
75. MH “double-blind studies”
76. MH “single-blind studies”
77. PT "clinical trial"
78. singl* N25 blind* or singl* N25 mask* or doubl* N25 blind* or doubl* N25 mask* or trebl* N25 blind* or trebl* N25 mask* or tripl* N25 blind* or tripl* N25 mask*
79. AB “clin* N5 trial*”
80. AB “placebo*”
81. AB “random* “
82. MH "Study Design"
83. compar* stud*
84. evaluat* stud*
85. intervention* stud*
86. follow-up stud*
87. prospective stud*
88. AB ( control* or prospectiv* or volunteer* )
89. S70 or S71 or S72 or S73 or S74 or S75 or S76 or S77 or S78 or S79 or S80 or S81 or S82 or S83 or
    S84 or S85 or S86 or S87 or S88
90. animal* not human*
91. S89 not S90
92. S21 and S69 and S91
PsychINFO (EBSCO) SEARCH STRATEGY

1. DE "Diabetes Mellitus"
2. ( "type 2" or "type ii" ) and diabet*
3. obes* N5 diabet*
4. impaired glucose tolerance
5. insulin resistance
6. mody or niddm or t2dm or dm2
7. non-insulin-depend*
8. non-ketotic N5 diabet* or nonketotic N5 diabet*
9. adult N3 diabet* or matur* N3 diabet* or late N3 diabet*
10. metabolic syndrom* or plurimetabolic syndrom*
11. S10 or S9 or S8 or S7 or S6 or S5 or S4 or S3 or S2 or S1
12. dermatomyositis
13. myotonic dystroph*
14. diabet* insipidus
15. S14 or S13 or S12
16. S11 not S15
17. DE "Client Education" or DE "Education" or DE "Disease Management" or DE "Health Education" or DE "Health Knowledge" or DE "Health Promotion" or DE "Psychoeducation" or DE "Treatment Compliance"
18. DE "Counseling"
19. DE "Self Care Skills"
20. DE "Behavior Therapy"
21. educat*
22. motivational interview*
23. behav* therap*
24. health education*
25. train*
26. teach*
27. counsel*
28. therap*
29. treatment*
30. intervention*
31. program*
32. S31 or S30 or S29 or S28 or S27 or S26 or S25 or S24 or S23 or S22 or S21 or S20 or S19 or S18 or S17
33. group*
34. individual*
35. client*
36. S35 or S34 or S33
37. S36 and S32
38. psycho*
39. "quality of life"
40. lifestyle
41. behav*
42. skill*
43. self care or self manage* or self monitor*
44. wellbeing or well-being
45. self efficac* or self confiden*
46. empower*
47. problemsolving or problem-solving
48. coping
49. motivation*
50. stage* N5 change*
51. satisfaction
52. anxiety
53. depression
54. attitude*
55. perception*
56. belief*
57. "locus of control"
58. adjustment
59. S58 or S57 or S56 or S55 or S54 or S53 or S52 or S51 or S50 or S49 or S48 or S47 or S46 or S45 or S44 or S43 or S42 or S41 or S40 or S39 or S38
60. S59 and S37
61. random* clinical trial*
62. random* control* trial*
63. clinical control* trial*
64. random* allocat*

65. DE "Clinical Trials"

66. singl* N25 blind* or singl* N25 mask* or doubl* N25 blind* or doubl* N25 mask* or trebl* N25 blind* or trebl* N25 mask* or tripl* N25 blind* or tripl* N25 mask*

67. AB placebo*

68. AB random

69. AB random*

70. DE "Experimental Design"

71. comparat* stud*

72. evaluat* stud*

73. intervention* stud*

74. follow-up stud*

75. prospective stud*

76. AB (control* or prospective or volunteer*)

77. S76 or S75 or S74 or S73 or S72 or S71 or S70 or S69 or S68 or S67 or S66 or S65 or S64 or S63 or S62 or S61

78. animal* not human*

79. S77 not S78

80. S79 and S60 and S16
COCHRANE LIBRARY SEARCH STRATEGY

1. MeSH descriptor Diabetes Mellitus, Type 2, this term only

2. MeSH descriptor Glucose Intolerance, this term only

3. MeSH descriptor Insulin Resistance, this term only

4. (obes* near/ diabet*)

5. "impaired glucose tolerance"

6. "glucose intolerance"

7. "insulin resistance"

8. (mody or niddm or t2dm or dm2)

9. ((type 2 or type ii) near/ diabet*)

10. ((nonketotic or non ketotic) near/ diabet*)

11. ("non insulin* depend*" or "noninsulin* depend*" or "noninsulin*depend*" or "non insulin*depend*")

12. ((adult or matur* or late*) near/3 diabet*)

13. "metabolic syndrom*"

14. "plurimetabolic syndrom*"

15. (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14)

16. MeSH descriptor Dermatomyositis, this term only
17. MeSH descriptor Myotonic Dystrophy, this term only
18. MeSH descriptor Diabetes Insipidus, this term only
19. dermatomyositis
20. "myotonic dystroph*"
21. "diabet* insipidus"
22. (#16 OR #17 OR #18 OR #19 OR #20 OR #21)
23. (#15 AND NOT #22)
24. MeSH descriptor Education, this term only
25. MeSH descriptor Patient Education, this term only
26. MeSH descriptor Teaching, this term only
27. MeSH descriptor Counseling, this term only
28. MeSH descriptor Self Care, this term only
29. MeSH descriptor Health Behavior, this term only
30. MeSH descriptor Behavior Therapy, this term only
31. MeSH descriptor Patient Compliance, this term only
32. educat*
33. "motivational interview*"
34. "behav* therap*"
35. "health education"
36. train*
37. teach*
38. counsel*
39. therap*
40. treatment*
41. intervention*
42. program*
43. (#24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42)
44. (group* or individual* or client*)
45. (#43 AND #44)
46. psycho*
47. "quality of life"
48. lifestyle
49. behav*
50. skill*
51. (self near/5 (care or manage* or monitor*))
52. wellbeing
53. (self near/5 (efficac* or confiden*))
54. empower*
55. "problem solving" or problemsolving
56. coping
57. motivation*
58. stage* near/3 change*
59. satisfaction
60. anxiety
61. depression
62. attitude*
63. perception*
64. belief*
65. "locus of control"
66. adjustment
67. (#46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57
OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66)
68. (#45 AND #67)
69. (randomized controlled trial):pt or (controlled clinical trial):pt
70. MeSH descriptor Randomized Controlled Trials, this term only
71. MeSH descriptor Random Allocation, this term only
72. MeSH descriptor Single-Blind Method, this term only

73. MeSH descriptor Double-Blind Method, this term only

74. (#69 OR #70 OR #71 OR #72 OR #73)

75. (animals not humans)

76. (#74 AND NOT #75)

77. (clinical trial):pt

78. MeSH descriptor Clinical Trials explode all trees

79. (clin* near/25 trial*):ti,ab

80. ((singl* or doubl* or trebl* or tripl*) near/25 (blind* or mask*)):ti,ab

81. MeSH descriptor Placebos, this term only

82. (placebo*):ti,ab

83. (random*):ti,ab

84. MeSH descriptor Research Design, this term only

85. (#77 OR #78 OR #79 OR #80 OR #81 OR #82 OR #83 OR #84)

86. (#85 AND NOT #75)

87. ("comparative study"):pt

88. MeSH descriptor Evaluation Studies explode all trees

89. MeSH descriptor Follow-Up Studies explode all trees

90. (control* or prospectiv* or volunteer*):ti,ab
91. (#87 OR #88 OR #89 OR #90)

92. (#91 AND NOT #75)

93. (#76 OR #86 OR #92)

94. (#23 AND #68 AND #93)
APPENDIX 3

VERIFICATION OF STUDY ELIGIBILITY

THE INFLUENCE OF DIABETES EDUCATION INTERVENTIONS ON PSYCHOSOCIAL OUTCOMES IN ADULTS WITH TYPE 2 DIABETES MELLITUS

Author _______________________________________________ Year _________________________

Journal __________________________________________________________________________

Title _______________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

INCLUSION CRITERIA

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Randomised controlled trial</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quasi-randomised controlled trial</td>
<td></td>
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<tr>
<td>Comparative study with non-current controls</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
<th>Diagnosis of type 2 diabetes</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Group and/or individual diabetes education</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Does the study evaluate the effect of the intervention on psychosocial outcomes such as:</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Quality of life</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wellbeing</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Empowerment</td>
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<tr>
<td>Patient satisfaction</td>
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<tr>
<td>Attitudes</td>
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<tr>
<td>Health/illness beliefs/perceptions</td>
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<tr>
<td>Anxiety</td>
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<td></td>
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<tr>
<td>Depression</td>
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<td></td>
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<tr>
<td>Stress</td>
<td></td>
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<td></td>
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<tr>
<td>Motivation</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Psychological adjustment</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Other: ____________________________</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments: __________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________

Eligible: YES / NO

(Studies must score Yes to at least 1 question in each of the above four sections in order to be included in the review)
## APPENDIX 4

### JBI CRITICAL APPRAISAL CHECKLIST FOR EXPERIMENTAL STUDIES

**INFLUENCE OF DIABETES EDUCATION INTERVENTIONS ON PSYCHOSOCIAL OUTCOMES IN ADULTS WITH TYPE 2 DIABETES**

Reviewer _________________________________ Date ______________________
Author ___________________________________ Year ___________ Record Number ____________

<table>
<thead>
<tr>
<th></th>
<th>YES (3)</th>
<th>NO (2)</th>
<th>UNCLEAR (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the assignment to treatment groups random?</td>
<td></td>
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<tr>
<td>2. Were participants blinded to treatment allocation?</td>
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<tr>
<td>3. Was allocation to treatment groups concealed from the allocator?</td>
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<tr>
<td>4. Were the outcomes of people who withdrew described and included in the analysis?</td>
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<tr>
<td>5. Were those assessing outcomes blind to the treatment allocation?</td>
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<tr>
<td>6. Were the control and treatment groups comparable at entry?</td>
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<tr>
<td>7. Were groups treated identically other than for the named interventions?</td>
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<tr>
<td>8. Were outcomes measured in the same way for all groups?</td>
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<tr>
<td>9. Were outcomes measured in a reliable way?</td>
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<tr>
<td>10. Was there adequate follow-up (&gt;80%)?</td>
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<tr>
<td>11. Was appropriate statistical analysis used?</td>
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</tbody>
</table>

Overall appraisal: Include Exclude Seek further info

Comments (including reasons for exclusion):

____________________________________________________________________________________

____________________________________________________________________________________

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____________________________________________________________________________________

____________________________________________________________________________________
**APPENDIX 5**

**DATA EXTRACTION TOOL**

**INFLUENCE OF DIABETES EDUCATION INTERVENTIONS ON PSYCHOSOCIAL OUTCOMES IN ADULTS WITH TYPE 2 DIABETES MELLITUS**

Reviewer _________________________________ Date ______________________

Author ___________________________________ Year ___________ Record Number ____________

Method: ____________________________________________________________________________

Setting: ___________________________________________________________________________

Participants: _________________________________________________________________________

<table>
<thead>
<tr>
<th>PARTICIPANTS</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number in each group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Gender</td>
<td>M/F</td>
<td></td>
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<tr>
<td>Participants excluded from the study</td>
<td>Number: _____</td>
<td>Number: _____</td>
<td>Number: _____</td>
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<tr>
<td>Reason: __________</td>
<td>Reason: __________</td>
<td>Reason: __________</td>
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</tbody>
</table>
## INTERVENTION

<table>
<thead>
<tr>
<th>Description of intervention</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention delivered by (e.g. Nurse, CDE)</td>
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<tr>
<td>Frequency of delivery</td>
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<tr>
<td>Length of time for delivery of intervention</td>
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<tr>
<td>Method of delivery (e.g. group/individual session, face to face contact, telephone)</td>
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<tr>
<td>No. of follow ups</td>
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<tr>
<td>Duration of follow ups</td>
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<td></td>
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<tr>
<td>Schedule of follow ups (e.g. 3mths, 6mths)</td>
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## OUTCOME MEASURES

<table>
<thead>
<tr>
<th>Definition:</th>
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<tr>
<td>Outcome description</td>
<td>Scale / Measure</td>
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</table>
## RESULTS

### Dichotomous data

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group A number/total</th>
<th>Group B number/total</th>
<th>Group C number/total</th>
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<tbody>
<tr>
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### Continuous data

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group A mean &amp; SD (number)</th>
<th>Group B mean &amp; SD (number)</th>
<th>Group C mean &amp; SD (number)</th>
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<tbody>
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Author’s conclusions: ________________________________________________________________
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