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Efficacy and safety of momordica charantia in patients with type 2 diabetes mellitus: systematic review and meta-analysis protocol

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Citation

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Review question

The aim of this systematic review and meta-analysis is to evaluate the efficacy and safety of Momordica charantia Linn in the management of patients with type 2 diabetes mellitus. To this end, the proposed systematic review and meta-analysis will answer the following questions:
1. Does Momordica charantia Linn safe and effective in lowering fasting blood glucose among patients with type 2 diabetes mellitus?
2. Does efficacy and safety of Momordica charantia Linn differ with respect to frequency of consumption and dosage?
3. What clinical and study methodological characteristics explain the heterogeneity in results for questions 1 and 2 above?

Searches

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized. An initial limited search of MEDLINE/PubMed and CINAHL will be undertaken followed by an analysis of the text words contained in the title and abstract, and of the index terms used to describe article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. No language restriction will be imposed during identification of studies. Studies published up to 30th March 2018 will be considered for inclusion in this review. The searches will be re-run just before the final analyses and further studies retrieved will be included.
Database to be searched for studies include:
• The Cochrane Library
• MEDLINE/PubMed
• Scopus
• CINAHL
The search for unpublished studies will include google, Google Scholar and university digital library systems for dissertations and theses. Initial keywords to be used will include Momordica charantia, bitter gourd, bitter melon, type 2 diabetes, clinical trial combined using Boolenic logic terms ‘AND’, ‘OR’ and ‘NOT’.

Types of study to be included

Randomized controlled trials (RCTs) including cluster RCTs, controlled before-after (CBA) studies, prospective and retrospective comparative cohort studies will be included in the systematic review. Cluster randomized, cluster non-randomized, or CBA studies will be included only if there are at least two intervention sites and two control sites. Cross-sectional studies, case series and case reports studies will be excluded.

Condition or domain being studied

Pre-diabetes and Type 2 diabetes among adults men and women.

Participants/population

Inclusion criteria: The review will consider adult patients (18years and above) who have been diagnosed with pre-diabetes and/or type 2 diabetes mellitus. Both Men and Women will be included. There will be no restriction of countries. The disease should fit the standard diagnostic criteria valid at the time of trial been conducted. It is therefore, expected that the authors would have provided diagnostic criteria used in their studies. Alternatively, reviewer definition could be adopted. Pre-diabetes diagnosed based on the ADA's FPG cut-off values of 5.6-6.9 mmol/L (100-125 mg/dL) (with IFG on two days or IFG on one day in addition to eligible HbA1c), HbA1c of 5.7-6.4% (39-58% mmol/mol) (ADA, 2010). Diabetes mellitus will be diagnosed according to the standard diagnosis criteria given by American Diabetes Association (ADA) or WHO criteria as below;
HbA1C ?6.5%. The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay. OR; FPG?126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h. OR; A 2-h plasma glucose ?200 mg/dl (11.1 mmol/l) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water. OR; In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ?200 mg/dl (11.1 mmol/l) (ADA, 2017, 2011, 2010, 2003; Eastman and Vinicor, 1997; WHO, 1985)
Exclusion criteria: The exclusion criterion for this study includes studies conducted on patients younger than 18 years, those with follow up duration of less than four weeks and studies conducted on patients with concomitant endocrinopathy affecting their blood glucose levels.

Intervention(s), exposure(s)

Mono herbal preparation of Momordica charantia in any dose and dosage for administered orally, alone or in combination with oral hypoglycaemic agents, or both.

Comparator(s)/control

Placebo or treatment with or without active medications, such oral hypoglycaemic agents or other herbal or nutritional preparations.

Primary outcome(s)

Change in Fasting blood glucose levels (FBG) from the baseline to last follow up, Change of Glycosylated haemoglobin A1c (HbA1c) from the baseline to last follow up, Change in Post pradial glucose level (PPG) from baseline to follow up and Development of any types of Adverse effects during the study window.

Timing and effect measures
The follow up time of the included study should be at least four weeks for primary outcomes.

Secondary outcome(s)

Change of the following parameters from the baseline value to the value of the last follow up
- Serum cholesterol
- Body weight and body mass index (BMI)
- Renal pro?le and liver pro?le as well as changes in lipid profile

Timing and effect measures
The follow up time of the included study should be at least four weeks for secondary outcomes.

Data extraction (selection and coding)

Data will be extracted from studies included in the systematic review using the standardized data extraction tool from JBI-MAStARI. The data extracted will include specific details about the interventions, populations, study methods and outcomes of interest to the review questions/objective.

Risk of bias (quality) assessment

Selected papers will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized Cochrane risk of bias tool. The bias will be graded as low, high or unclear. Any disagreements that arise between the reviewers will be resolved through discussion, with a third reviewer.

Strategy for data synthesis

Quantitative data will be, where possible, pooled in statistical meta-analysis. Data will be entered into Excel and then imported to SPSS software. After labeling the data values in SPSS, it will be imported to Stata version 13.0 (Stata corp, LP, college station, TX) for analysis using meta comand. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated. Heterogeneity will be assessed statistically using I^2 test. Subgroup analyses will be conducted using different study designs and dose. Sensitivity analysis will also be conducted as deemed necessary. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures presentation where appropriate.

Analysis of subgroups or subsets

If the necessary data are available, subgroup analyses will be done for pre-diabetes and type 2 diabetes. Separate presentation will be done for different type of studies, type of dose and dosage form, and different type of participants with respect to age, diseases stage, presence of co-morbidies and sex.

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Pharm-Bio Technology and Traditional Medicine Centre (PHARMBIOTRAC), World Bank African Centre of Excellency (ACE II).

Conflicts of interest

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English

Country
Uganda

Stage of review
Review_Ongoing

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Subject indexing assigned by CRD

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Diabetes Mellitus, Type 2; Humans; Hypoglycemic Agents; Momordica charantia; Phytotherapy

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08 February 2018

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

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

Versions
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