

Scoping Review Protocol

1.0 TITLE

Effects of intermittent fasting (IF) on glycaemic control in people with type 2 diabetes mellitus (T2DM): A scoping review protocol

1.1 Identification:

Prepared for registrations to Open Science Framework

1.2 Date submitted:

2.0 PROTOCOL INFORMATION

2.1 Authors:

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2.3 Dates:

Anticipated start date of search: October 2020

Anticipated completion date: October 2021

3.0 OUTLINE

Diabetes mellitus is a chronic metabolic disorder that occurs when the body cannot produce enough insulin or cannot utilise the insulin produced (Karroubi & Darwish, 2015). Diabetes mellitus is a global pandemic that has a prevalence rate of 440 million (World Health Organisation, 2020). In New Zealand (NZ) alone, the costs due to diabetes mellitus is projected to rise to \$1.7 billion (NZ) by 2021/22 (Ministry of Health, 2009). Finding additional management tools to support people with type 2 diabetes mellitus (T2DM) is an important health strategy to help reduce the burden put on the health system by the rising prevalence rates (Karroubi & Darwish, 2015). The leading risk factor for T2DM is obesity and therefore lifestyle changes such as diet control and weight loss are the leading management strategies (Horne et al., 2012). A fasting tool, intermittent fasting (IF), has been used as part of weight loss strategies for the purpose of reducing weight and improving other health outcomes, but has recently gained the interest of health practitioners and researchers worldwide for its effects on glycaemic levels, as an additional management tool (Arnason et al., 2017).

IF is a dietary intervention that restricts caloric foods for certain amounts of time throughout the day (Arnason et al., 2017). However, in health practice and research the term ‘intermittent fasting’ seems to be used interchangeably to describe similar but different ways in which it is practiced or observed. This is important as it can make generalising claims and collating data harder as there can be many confounding factors with each variation.

With the increasing interest in IF for management of glycaemic levels, there have been many blogs and articles written that are self-reported experiences from people who have tried IF. Most of the practices related to the use of IF for glycaemic control seem to be based on the data from animal studies and case reports with a very limited number of human clinical trials conducted. Despite the limited number of human clinical trials there seem to be some medical practitioners already prescribing IF to their patients with T2DM (Fung, 2016; Intensive Dietary Management, 2020). With medical practitioners prescribing and people beginning to use IF as a management tool the question is raised, what extent of empirical evidence is available regarding the use of intermittent fasting in improving glycaemic control in people with type 2 diabetes mellitus? Subsequent questions that are raised are, is there any standardized format for IF and is there a standard definition? Another question that is raised is, are safety and efficacy issues being considered when prescribing such practices for people with diabetes as the risk of hypoglycaemia in some fasts such as Ramadan are quite high (Al-Arouj et al., 2010). For this reason, the current project will undertake a scoping review to examine the extent of empirical evidence investigating the potential role of IF in affecting glycaemic control in people with T2DM. Furthermore, the research team will investigate the variations in IF being practiced and explore the evidence to determine if there is an agreement on a standard definition of IF.

4.0 AIMS

Undertake a scoping review to examine the extent of peer review empirical evidence available regarding the effects of intermittent fasting of glycaemic control in people with type 2 diabetes mellitus. In addition, determine the existence of various definitions of and protocols of intermittent fasting being practiced.

4.1 Primary objectives

- To examine the extent of peer reviewed empirical evidence reporting effects of intermittent fasting on glycaemic control in people with type 2 diabetes mellitus.
- To determine different types of protocols being practiced as intermittent fasting.
- To determine the existence of various definitions of intermittent fasting.
- To provide recommendations for future research.

5.0 PROTOCOL DESIGN

The framework for the scoping review used in this research will be the five stage framework created by Arksey and O'Malley (2005), with further improvements and recommendations by Levac et al. (2010), Pham et al. (2014) and Peters et al. (2015). The five stages of the framework for this study will be as follows: identifying the research question, identifying relevant studies, selecting studies, charting the data and collating, summarising and reporting the results (Levac et al., 2010). The decision to incorporate the optional sixth stage of consultation will be determined after assessing the preliminary data at stage five. If considered to be necessary and feasible, appropriate stakeholders such as healthcare professionals managing T2DM will be consulted.

5.1 Stage 1: Identifying the research question

The following research question was developed by the author (JS) and co-authors (SS and DR): What empirical evidence is available regarding the use of intermittent fasting in affecting glycaemic control in people with type 2 diabetes mellitus?

5.2 Stage 2: Identifying relevant studies

In order to identify relevant and appropriate studies the following databases will be examined: PubMed, ScienceDirect and EBSCO Health. The other potential source would be Embase and Web of Science, if feasible with regard to funding the subscription for these search engines.

5.2.1 Search parameters

The initial search will include all relevant empirical studies that are published in English. The search will be followed by a review of text words used in the title, abstract and keywords, all index terms used will be noted. Furthermore, a second search will be conducted using the index terms on all databases identified earlier. Lastly, as recommended by Joanna Briggs Institute (JBI) Manual (Peters et al., 2020) the reference list of included studies will be reviewed to find any further sources. The 'related articles' tab on PubMed will also be utilised to find any additional sources. Additional databases like NZResearch (2020) will be used along with clinical trial registries such as ClinicalTrials.govt, The Australian New Zealand Clinical Trials Registry (ANZCTR) and the International Clinical Trials Registry Platform (ICTRP).

5.2.2 Grey literature

Grey literature is research that is published on non-peer reviewed platforms (magazines, blogs or newspapers) or has been produced by individuals or organisations outside the realm of academic publishing in non-commercial ways (Adam et al., 2016). The quality of a large proportion of grey literature cannot be verified as there is no formal quality assessment applied

to grey literature. As the aim of this study is to determine the extent of empirical evidence available in supporting the role of IF in glycaemic control for people with T2DM, including grey literature would not be appropriate to meet the aim of this study and therefore will not be included in the scoping review.

5.2.3 Initial search terms and key phrases

Preliminary searches were made to assess the available literature and the nature of the literature. EBSCO Health was also used to gather any relevant MeSH tags in order to further refine the search terms. This was done to arrive at the appropriate search syntaxes that would yield the most appropriate and relevant sources feasible to manage the research in the decided time frame. The following search terms identified from this process will be used for the search strategy: intermittent fasting, type 2 diabetes mellitus, alternate day fasting, glycaemic control, 5:2 diet, time restricted fasting. The keywords will be revised and refined as the researchers become more familiar with the literature and if it is felt necessary after the preliminary assessment by the team.

The title or abstract must include any of the following combinations:

- Intermittent fasting AND type 2 diabetes
- Intermittent fasting AND definition OR meaning OR concept
- Intermittent fasting AND type 2 diabetes AND define*
- Intermittent fasting or alternate day fasting or time restricted feeding AND diabetes mellitus type 2
- “intermittent fasting” AND diabetes mellitus type 2
- “intermittent fasting” or “alternate day fasting” or “time restricted feeding” AND diabetes mellitus type 2
- “intermittent fasting” AND type 2 diabetes
- Intermittent fasting AND glycaemic control AND type 2 diabetes

5.3 Stage 3: Study selection

Stage three involves selecting appropriate studies to include in the scoping review. The studies need to be appropriate to meet the aims and objectives of the study and answer the research question (Levac et al., 2010). As per methodological guidelines the title and abstract will be screened first in order to make sure study selection meets inclusion criteria, which are outlined below. This process will be iterative and will involve using a snowball technique. Searches will continue to be reviewed and refined until a saturation point is achieved meeting all inclusion criteria.

The study selection process will first be piloted on 20-25 articles to achieve a 95% selection consistency between lead author and co-author, any discrepancies will be resolved by the second co-author using either percentage or consensus agreement. The search strategy will be created and refined through the help of a librarian specialist.

Inclusion criteria

1. Studies published in last 10 years
2. Studies published in English
3. Studies looking at IF and effects on glycaemic control in people with T2DM
4. Studies on obesity if glycaemic control was also assessed
5. Studies looking at safety and efficacy issues around IF in people with T2DM

Exclusion criteria

1. Studies looking at Ramadan and any religious fasting
2. Studies looking at animal trials
3. Studies looking at effect of IF only on obesity
4. Any studies on T1DM
5. Studies looking at effects of IF on other health outcomes
6. Grey literature

5.3.1 Rationale for inclusion/exclusion criteria

Only studies published in the last 10 years will be included. This is because this is an emerging topic with the majority of studies published 2012 onwards. Studies looking at religious fasting such as Ramadan will be excluded as this excludes the consumption of non-caloric beverages, which is different to therapeutic fasting. Furthermore, conditions during Ramadan can vary significantly depending on the geographical location, this includes; length of fast, temperature, humidity and weather. Therefore, the data from one place at one particular time cannot be compared globally. Animal studies will also be excluded as the aim of this study is to determine the extent of empirical evidence available in supporting the role of IF in glycaemic control for people with T2DM. Hence, including animal studies would not be appropriate to meet this aim. Health conditions other than T2DM will be excluded because they are beyond the scope of this review and not directly related to the research question. Type 1 diabetes mellitus (T1DM) will be excluded from this review as the aim of the scoping review is to look at glycaemic control in T2DM. People with T1DM have insulin dependence and IF may not be advisable for people with T1DM. Finally, grey literature will be excluded from this review as the lack of critical appraisal and formal assessment of quality makes it unfit to meet the aim of this study, which is to look at peer reviewed empirical data only.

5.4 Stage 4: Charting the data

Data will be managed using the Microsoft programmes such as Word and Excel. The online referencing system, Mendeley, will be used to manage citations. Critical appraisal is not required as per Arksey and O'Malley's (2005) framework, however it is becoming an emerging trend to provide information on the quality of all or a subset of studies. The critical review and analysis will depend on the type of data that is found during this stage. Appropriate tools such as Critical Appraisal Skills Programme (CASP) guidelines will be used if necessary to aid the critical review process. Appropriate reporting guidelines such as, CONSORT, AMSTAR 2 and STROBE may be used if feasible and considered appropriate when undertaking a quality assessment of a subset of studies (Von Elm et al., 2009; Schulz et al., 2010; Shea et al., 2017). If a critical appraisal is used, it will not be done to exclude studies. If feasible, we may undertake quality appraisal of the clinical trials or studies related to any important theme or concept that would emerge.

A form for charting data will also be used, data items included will relate to the guiding research question and objectives. The form will include the following information: author, year, origin, aim, purpose of the study, population, sample size, intervention, methodology, outcomes and key features. The form and data extraction process will be piloted by the author and one of the co-authors who will independently extract and chart data for the first five to ten studies. Any disagreements will be reviewed by the second co-author. The team will then meet to determine if our approach is consistent and identify if any changes to the data charting form are required.

5.5 Stage 5: Collating, summarising and reporting the data

Given the nature of a scoping review and the potential heterogeneity of material included, it is not possible to predetermine what the most ideal method of collating, summarising and reporting the results will be. So this will be determined after the data has been charted. As recommended by Peters et al. (2020) appropriate numerical and narrative methods such as, reporting frequency of occurrence, categories and concept distribution, study characteristics, definitions and descriptive analysis will be used.

The Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist and guidelines will be followed (Tricco et al. 2018) in reporting the scoping review.

5.6 Stage 6: Consultation

The decision to incorporate the optional sixth stage will be determined after assessing the preliminary data after stage five. If considered to be necessary and feasible, appropriate stakeholders such as healthcare professionals managing T2DM, qualified endocrinologists or physicians practicing IF and managing T2DM will be consulted. Appropriate community networks such as Diabetes NZ, people living with T2DM and Maori or Pacific communities will also be consulted if considered necessary. The main purpose would be to seek suggestions on appropriate platforms for knowledge transfer and/or to formulate future research direction.

6.0 DISSEMINATION AND ETHICS

This review protocol and scoping review will not involve recruitment of any human or animal participants (in trials, experiments or otherwise) or use any copyrighted materials. Furthermore, only publicly available data and literature will be used for this review. For this reason, it has been deemed that this scoping review does not require ethical approval, a position confirmed by the Unitec Research Ethics Committee (UREC).

7.0 DECLARATIONS

Nil.

8.0 FUNDING SUPPORT

The study will be funded by the post-graduate research fund from the Unitec Institute of Technology to cover the cost of accessing necessary journal articles

9.0 AUTHORS' CONTRIBUTIONS

Jagjeet Sandhu:

- Creation and design of the scoping review
- Creating the protocol, and revising it with input from co-authors
- Development of screening and data extraction forms
- Performing searches
- Screening papers for the eligibility criteria and appraising
- Extracting and exporting data

- Mapping of results
- Interpretation of data, with support from co-authors
- Drafting of the scoping review, and revising it critically for important intellectual content

Dr Shamim Shaikh:

- Contribution to the concept and design of the scoping review
- Refining the protocol, and revising it critically for important academic content
- Providing support with the development of data extraction forms, interpretation of data
- Screening papers for the eligibility criteria and appraising
- Refining the scoping review critically for important academic content
- Resolving disagreements in the screening and selection of studies
- Manuscript editing, preparation and submission

Dr Dianne Roy:

- Input to the creation and design of the scoping review
- Refining the protocol, and revising it critically for important academic content
- Refining the scoping review critically for important academic content
- Resolving disagreements in the screening and selection of studies
- Manuscript editing, preparation and submission

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