Comparative efficacy of lifestyle intervention strategies on weight outcomes in people with psychosis: a systematic review and network meta-analysis protocol

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Review question/objective: (i) To systematically review and rank the efficacy of different types of lifestyle intervention strategies on weight outcomes (weight, body mass index [BMI], waist circumference and waist-to-hip ratio) in people with psychosis. (The efficacy of different types of lifestyle intervention strategies will be ranked by comparing the effect size on weight outcomes in people with psychotic disorders.) (ii) To stratify lifestyle interventions that target weight outcomes (weight, BMI, waist circumference and waist-to-hip ratio) in people with psychosis, according to their inclusion of dietary information that adheres with Australian Dietary Guidelines (National Health and Medical Research Council. Eat for Health, Australian Dietary Guidelines Canberra National Health and Medical Research Council; 2013).

Specifically, the review question is: What lifestyle intervention strategies targeting weight outcomes (weight, BMI, waist circumference and waist-to-hip ratio) in people with psychosis compared to no treatment or various control conditions have the best efficacy?

Keywords Lifestyle interventions; nutrition interventions; schizophrenia; weight management psychosis

Background

The Survey of High Impact Psychosis (SHIP) found that in 2010, the 12-month-treated prevalence of psychosis in Australia was 4.5 people per 1000 in those between 18 and 64 years.[1] Other developed countries quote similar prevalence rates, with a systematic review and meta-analysis in the United Kingdom estimating the annual prevalence of psychosis between 1950 and 2009 to be four people per 1000 in 16-64-year olds.[2] In the United States, 4.2% of the population aged 18 years and over in 2014 was estimated to be living with psychosis.[3] A psychotic disorder is characterized by the experience of hallucinations, delusions or gross excitement and over activity, psychomotor retardation and catatonic behavior that causes distress and interferes with personal functions.[4] Schizophrenia spectrum disorders represent the main types of psychotic disorders.[4] While the magnitude of the figures quoted for the prevalence of psychosis may not seem high, the annual cost incurred per individual with psychosis is almost four times that incurred by a healthy Australian.[5] Despite a significantly higher disease burden, evidence suggests that there is poorer healthcare provision and access in people with psychotic disorders that may lead to unfavorable physical health outcomes.[6,7] Morgan *et al.*[1] found that one of the biggest concerns for people with psychosis who took part in the SHIP was their physical health.

The relationship between poor physical health and psychosis is well established.[8-11] Factors that contribute to poor physical health in people with psychosis through weight gain are anti-psychotic

medication use, poor diet or a diet that is inconsistent with dietary recommendations and low physical activity levels.[10,12] Excessive weight gain predisposes one to developing metabolic syndrome, a cluster of metabolic abnormalities that include hypertension, central adiposity, dyslipidemia and insulin resistance that increase the risk of cardiovascular disease two to threefold.[13,14] Cardiovascular disease is one of the single largest contributors to high mortality in people with psychosis.[11,15] Lifestyle factors such as a poor diet and low physical activity levels are modifiable through the use of various lifestyle intervention programs.[1,14,16] The risk of increased weight gain associated with the use of atypical anti-psychotic medications can also be mitigated by implementing lifestyle interventions.[10,17,18] The general consensus of what a lifestyle intervention entails seems to be a program that promotes improved nutrition and or increased physical activity through use of various strategies.[16,19,20]

A preliminary search of MEDLINE revealed that lifestyle interventions in people with psychosis have been researched widely.[16,19-27] More recent systematic reviews on lifestyle interventions in people with psychosis have confirmed the efficacy of these interventions in the reduction of weight, BMI and waist circumference.[16,19,20] Some meta-analyses have attempted to decipher what aspects of lifestyle interventions in people with psychosis are most efficacious at improving weight outcomes.[16,20-22,26] Many of these meta-analyses have not been successful at indicating efficacious characteristics of lifestyle interventions; two studies have however highlighted that lifestyle interventions characterized by an "individual approach" are more efficacious than "group based" lifestyle interventions.[16,21] A closer analysis of randomized controlled studies (RCTs) that were classified as those with an "individual approach" within the systematic reviews revealed that these studies were distinguished by their use of specific instructions or personalized goals that were reviewed regularly by a health professional because of the one-on-one attention participants received.[28-30] Studies classified as those with an "individual approach" were also more likely to offer participants supervised exercise.[28-30] Comparatively, an analysis of RCTs that were classified as "group based" lifestyle interventions within systematic reviews highlighted the use of generalized

information on healthy diet or physical activity that lacked the structured or personalized nature of prescribed information offered within the "individual approach."[31-35] Subsequently, corresponding monitoring that was offered with the highly structured diet and physical activity advice within the "individual approach" lifestyle interventions was generally not offered within the "group based" lifestyle interventions.[31-35]

Randomized controlled studies of lifestyle interventions analyzed in previous systematic reviews and meta-analyses are characterized by many features that do not exclusively fit into the dichotomous categories, "individual approach" or "group based".[16,19,20] Other important sub-categories within these lifestyle interventions are structured diet interventions, non-structured diet interventions, structured exercise interventions, non-structured exercise interventions and combination groups that merge two of the categories mentioned above such as structured diet and structured exercise interventions, structured diet and non-structured exercise interventions, non-structured diet and structured exercise interventions, and finally non-structured diet and non-structured exercise interventions.[16,19,20] These eight types of lifestyle interventions identified from analyzing some of the available RCTs will be compared against one another to assess efficacy of different intervention types. The use of dichotomous categories in comparing different types of lifestyle interventions in previous meta-analyses may have masked important features of successful lifestyle interventions; this may have been the reason why many of these studies were unsuccessful at identifying characteristics of successful lifestyle interventions.[18,20,22] The meta-analytic procedure can however only compare two intervention types and therefore may not be suitable in ranking the efficacy of different types of lifestyle interventions.[36] The use of the network meta-analytic procedure would help overcome this limitation as with this method, it is possible to provide a comprehensive estimate of the efficacy of multiple intervention types using both direct and indirect effects.[36] In addition, with the network meta-analytic procedure, it is possible to rank the intervention categories from the most efficacious to the least efficacious.[36]

In addition to this, none of the available systematic reviews and meta-analyses have identified nutritionally sound lifestyle interventions.[16,19-27] In view

of the current study, nutritionally sound lifestyle interventions will be defined as RCTs that offer dietary advice that complies with Australian Dietary Guidelines (ADGs) in terms of serves of various foods and food groups. It is important that dietary information offered to people with psychosis complies with the ADGs as these guidelines were written to promote health and wellbeing, while reducing chronic disease which are issues of concern in this population group.[1,37] The information obtained through this network analysis can be used to make recommendations on the design of future lifestyle interventions in people with psychosis who are living in the community and accessing services so as to improve health outcomes in this vulnerable group.

Inclusion criteria
Types of participants
The current review will consider studies that include community dwelling participants aged 18 years and over with a psychotic disorder. More specifically, "psychotic disorders" mainly include schizophrenia type disorders (International Statistical Classification of Diseases and Related Health Problems [ICD] codes F20-F29).

A diagnosis of a psychotic disorder will be regarded as valid for the purpose of this study if at least one of the conditions listed below are met:

- The diagnosis has been made using the Diagnostic and Statistical Manual of Mental Disorders or the ICD.
- The diagnosis has been confirmed by consulting the participant's physician.
- Participant's health records have been accessed to confirm diagnosis.
- Participants have been referred by their physician to take part in the study because they have a psychotic disorder.
- Participants with comorbid mental or physical illnesses will also be included provided they have a psychotic disorder.

Types of intervention(s)/phenomena of interest
The current review will consider studies designed to deliver lifestyle interventions, health interventions, health promotion lifestyle programs, health promotion programs, healthy living interventions, healthy lifestyle programs, interventions for health risk behaviors, weight management interventions, diet interventions, exercise interventions,

nonpharmacological lifestyle interventions or nutrition interventions.

The current review will exclude all lifestyle interventions that utilize the internet or mobile health (m-health) technology because lifestyle interventions that are delivered through the internet have high dropout rates and low utilization rates; hence, many studies are not efficacious.[38] Furthermore, well designed high-quality RCTs that deliver lifestyle interventions using m-health technology or delivered through the internet to a population with psychosis have not been identified because research in this area is still quite new.[38] This study will also exclude all lifestyle interventions carried out in inpatient settings because the needs of people in inpatient and outpatient settings differ vastly, and it has been identified in a previous systematic review that weight, BMI and waist circumference are only significantly decreased in RCTs carried out in outpatient settings.[20]

Outcomes
The current review will consider studies that include the following outcome measures: weight, BMI, waist circumference and waist-to-hip ratio. This is because weight was the single most reported weight outcome in previous RCTs; however, experts have concluded that BMI, waist circumference and waist-to-hip ratio are more meaningful weight outcomes in relation to overall health.[16,39,40] Weight will be included as an outcome measure in this study as it has been frequently reported; however, BMI, waist circumference and waist-to-hip ratio will also be included as outcome measures as they are more meaningful to the assessment of overall health.[39,40]

Types of studies
The current review will only include RCTs for inclusion.[41]

Search strategy
The search strategy aims to find published studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Third, the reference list of all

identified reports and articles will be searched for additional studies. Studies published in English will be considered for inclusion in this review. Studies published from 1985 to date will be considered for inclusion in this review. The 1985 cutoff point was decided upon because in studies prior to this, undesirable contingency weight management approaches were used, such as provision of cigarettes or coffee depending on whether the participants achieved the desired outcomes; these methods may currently be considered unethical in the practice of modern clinicians. In addition to this, RCTs delivering lifestyle interventions in people with psychosis have not been identified prior to the year 1985 in other systematic reviews; therefore, it would not be beneficial to include studies carried out before this date.[27]

The databases to be searched include The Cochrane Library, MEDLINE/PREMEDLINE, Embase, CINAHL, Scopus and PsycINFO. The Cochrane Library will be included in the database search because previous reviews and systematic reviews have been done on this topic; scanning reference lists of previous reviews and systematic reviews will ensure that all available RCTs are included in the current study because incomplete inclusion of research papers has been identified as a common problem among authors of this topic.[18]

Initial keywords to be used will be: lifestyle interventions, nutrition interventions, weight management psychosis and schizophrenia.

Assessment of methodological quality

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data extraction

Data will be extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives. Data extraction of all the

outcomes will be conducted simultaneously, as separate data extractions do not need to be conducted for each outcome (weight, BMI, waist circumference and waist-to-hip ratio). Where details of the included studies are inadequate to allow accurate grouping, authors will be contacted for more detail.

Data synthesis

Papers will, where possible, be pooled in network meta-analysis using Stat data analysis and statistical software, StataCorp, Texas, USA.[42] All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data), and their 95% confidence intervals will be calculated for analysis. Heterogeneity is typically presented through between-study variance in network meta-analyses; hence, this will be calculated and assumed to be common across the network.[43] Results will be presented in a number of ways; network plots will be used to present a weighted visual of the interventions used and direct comparisons available whereas contribution plots will be used to display the relative contribution of each intervention type to the network.[43,44] Network plots will also be used to evaluate the transitivity assumption which implies that effect modifiers do not differ across various interventions.[43] Additional assumptions will be presented using inconsistency plots that will display differences between the direct and indirect effects of various intervention types, comparison-adjusted funnel plots that will be used to assess small study effects if appropriate, and predictive interval plots will contain a summary of the relative mean effects, prediction estimates of future studies and impact of heterogeneity on each intervention.[43] A cumulative ranking probability plot will be used to rank the efficacy of all the intervention types by displaying the probability that each study type will occupy a specific rank.[43] Nutritionally sound lifestyle interventions will be identified by comparing the dietary information provided to the ADGs.[37] Studies will be classified as either compliant or non-compliant. Where statistical pooling is not possible, the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

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Appendix I: Appraisal instruments
MAStARI appraisal instrument

JBI Critical Appraisal Checklist for Randomized Controlled Trials

Reviewer_ Date_ .

Author _ Year_ _ _ _ _ _ _ _ _ _ _Record Number_ _ _ _ _ .

	Yes	No	Unclear	NA
1. Was true randomization used for assignment of participants to treatment groups?	☐	☐	☐	☐
2. Was allocation to treatment groups concealed?	☐	☐	☐	☐
3. Were treatment groups similar at the baseline?	☐	☐	☐	☐
4. Were participants blind to treatment assignment?	☐	☐	☐	☐
5. Were those delivering treatment blind to treatment assignment?	☐	☐	☐	☐
6. Were outcomes assessors blind to treatment assignment?	☐	☐	☐	☐
7. Were treatments groups treated identically other than the intervention of interest?	☐	☐	☐	☐
8. Was follow-up complete, and if not, were strategies to address incomplete follow-up utilized?	☐	☐	☐	☐
9. Were participants analysed in the groups to which they were randomized?	☐	☐	☐	☐
10. Were outcomes measured in the same way for treatment groups?	☐	☐	☐	☐
11. Were outcomes measured in a reliable way?	☐	☐	☐	☐
12. Was appropriate statistical analysis used?	☐	☐	☐	☐
13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?	☐	☐	☐	☐

Overall appraisal: Include ☐   Exclude ☐   Seek further info ☐

Comments (Including reason for exclusion)

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Appendix II: Data extraction instruments

MAStARI data extraction instrument

JBI Data Extraction Form for Experimental / Observational Studies

Reviewer _____ Date _____

Author _____ Year _____

Journal_____ Record Number_____

Study Method

RCT ☐   Quasi-RCT ☐   Longitudinal ☐

Retrospective ☐   Observational ☐   Other ☐

Participants

Setting

_____

Population

_____

Sample size

Group A _____ Group B _____

Interventions

Intervention A

_____

Intervention B

_____

Authors Conclusions:

_____
_____
_____

Reviewers Conclusions:

_____
_____
_____

Study results

Dichotomous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

Continuous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number