Review title

Weight loss interventions for overweight/obese adults with chronic musculoskeletal pain: a mixed methods systematic review protocol

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Review question/objective

The objective of this mixed methods review is to develop an aggregated synthesis of qualitative and quantitative data on weight loss interventions for overweight/obese adults with chronic musculoskeletal pain in an attempt to derive conclusions and recommendations useful for clinical practice and policy decision making

The objective of the quantitative component of this review is to quantify the effectiveness of weight loss interventions on weight, pain, and physical and/or psychosocial function in overweight/obese adults

with chronic musculoskeletal pain.

The objectives of the qualitative component of this review are to explore the perceptions and experiences of overweight/obese adults with chronic musculoskeletal pain of the link between their weight and pain and the effectiveness and appropriateness of weight loss interventions and sustainability of weight loss efforts

Background

Independently, overweight and chronic pain are prevalent conditions that have widespread implications for the individual, health care resources and the economy.[1,2] These two conditions frequently occur simultaneously and the association appears to be bi-directional, this adds to the complexity of managing either condition independently. Studies to assess the effectiveness of weight loss interventions on individuals with co-existing chronic musculoskeletal pain have shown that weight reduction can be achieved and is associated with lower pain scores[3,4], however no systematic review has been conducted to determine the most effective intervention or participants' perceptions of the appropriateness and sustainability of interventions to inform clinical practice.

The World Health Organisation (WHO) defines obesity as “abnormal or excessive fat accumulation that may impair health”.[5] Obesity is categorised using Body Mass Index (BMI). A BMI ≥25 indicates that a person is overweight and a BMI ≥30 is deemed as obese.[6] This growing global public health problem has been associated with 3.4 million adult deaths annually and is linked to the development of type 2 diabetes, coronary heart disease (CHD) and some cancers.[5]

Worldwide prevalence of overweight/obesity has risen markedly in recent decades with rates more than doubling in some developed areas; globally 1.9 billion adults are overweight, 600 million of these are obese.[5] The United Kingdom (UK) has one of the highest levels of overweight/obesity in Europe; 66.6 % of men and 57.2% of women in England were classified as overweight/obese in 2012 (24% of men and 25% of women were obese).[8,9] Cohort studies carried out by the Centre for Longitudinal Studies found that at age 42 those in the 1970 birth cohort were markedly more likely to be overweight or obese compared to individuals in the 1958 birth cohort at the same age, highlighting the increase in adult obesity in the UK.[10] Obesity has been shown to reduce quality of life and limit ability to perform activities of daily living (ADLs),[11] it is also linked to higher levels of mental illness. [10] National Health Service (NHS) costs associated with obesity are currently estimated to be in excess of £5 billion annually. [10,12]

The causes of overweight/obesity in the general population are increased calorie intake and lack of physical exercise. However the Foresight Report describes this as a simplistic view and reports that overweight/obesity is the result of complex interaction between biological factors, psychological factors and a changing social environment wherein work patterns have become more sedentary and physical activity has decreased combined with an increase in the availability of food.[12] In 2013 the American Medical Association classified obesity as a disease.[13]

The International Association for the Study of Pain define pain as “An unpleasant sensory and emotional experience associated with actual or potential tissue damage”.[14] Chronic pain is persistent pain, which lasts over 12 weeks or after the time that healing would have been thought to occur after trauma or surgery.[15] Approximately 5 million adults in the UK annually develop chronic pain that impacts on their ability to work, thereby having an effect on business and the economy[2]. Although the total cost

of chronic pain is unknown the cost to the exchequer annually is in excess of £12.3 billion for back pain alone and 2.7 million people with chronic musculoskeletal pain are in receipt of incapacity benefit.[15,16] While back pain and osteoarthritis (OA) (particularly of the knee) account for 50% of chronic pain, other conditions such as rheumatoid arthritis, migraine, chronic daily headache and neck pain are also common. Five per cent of the UK population suffer from widespread chronic pain often referred to as fibromyalgia.[16] The 2011 Health Survey England (HSE)[17] and the National Pain Audit[18] found that chronic pain is more common in women, increases with age and is more likely to be reported by those in the lowest economic quintile. People reporting chronic pain also reported higher levels of anxiety and depression with a positive correlation between increasing pain and anxiety and depression scores.[17,19] Chronic pain sufferers are prone to have difficulty sleeping, socialising and are also more likely to become unemployed.[16]

Although no cause-effect relationship has yet been established there is growing acknowledgement of a link between obesity and chronic pain conditions.[20-27] For these individuals difficulties arise in everyday activities such as walking, climbing stairs and driving which result in a decline in independence, leading to reduction in mental health, with depression and social isolation being known to affect these patient groups.[28] As chronic pain interferes with daily functioning of obese individuals, it can have a negative effect on weight loss.[11]

The mechanical-structural nature of the relationship between obesity and chronic pain is generally accepted,[22] however it is not the definitive explanation for this comorbidity. In addition to mechanical explanations metabolic factors may be involved in altered pain sensitivity among obese individuals.[29] Furthermore evidence suggests that poor general health behaviours may have a role to play in the development and persistence of the comorbidity. Obesity may contribute to the development/maintenance of pain while the presence of pain may be a risk factor for the development/maintenance of obesity. Treatment needs to address both aspects of the comorbidity.[30,31]

National Institute for Clinical Excellence (NICE) recommend that overweight and obese adults are offered Lifestyle Weight management programs[6] while weight reduction is advocated as an integral component of chronic pain management.[20,30] Weight loss interventions may have an additional positive impact on pain by reducing mechanical-structural factors, metabolic factors, systemic inflammation and increasing health related quality of life (hrQol).[32] Interventions designed to target weight may have added positive effects, e.g. reduction of mental distress, such as anxiety or depression, both of which are strongly correlated with obesity and chronic pain.[10,175] Improvement in mental health may enable individuals who are overweight or obese with co-existing chronic pain to sustain positive changes and maintain new patterns of behaviour.

Physical activity is a primary intervention for overweight/obesity, however, many overweight/obese individuals report chronic pain acts as a barrier to physical activity and thus weight loss.[11] Individuals with higher BMI have been shown to have increased prevalence of chronic pain.[33] Physical activity is also used as a treatment technique for those with chronic pain; however, obesity can be a barrier to physical activity for individuals who are obese with chronic pain.[34,35] The cause and consequence relationship between obesity and chronic pain can become a vicious cycle that impacts on the function, health and well-being of this population. The rising prevalence of both obesity and chronic pain is a worldwide concern, as alongside patient health and well-being concerns there is an increased financial burden on healthcare and economic systems.[33,36,37]

The complex relationship between chronic pain and overweight/obesity appears to be bi-directional in nature; for example increased weight may cause an individual to experience pain that reduces activity or pain may restrict activity which results in increased weight that produces more pain, therefore a break in this cycle could have positive outcomes for individuals. A comprehensive search has failed to identify any systematic reviews that have been completed or any protocols for systematic reviews currently in progress on the effectiveness, appropriateness and sustainability of weight loss interventions in an overweight/obese population with co-existing chronic musculoskeletal pain. This review will bring together quantitativeand qualitative evidence to increase knowledge of the effectiveness of interventions in this population and understanding of individual perceptions of the links between overweight/obesity and chronic pain, the effectiveness,and appropriateness of weight loss interventions and sustainability of weight loss efforts. This review should inform future interventions for the promotion of healthier lifestyles, thus increasing weight loss and decreasing chronic pain in a more sustainable manner. In addition to individual positive health outcomes, there is potential for wider societal and economic benefits[33,37] e.g. considerable savings could be made on healthcare spending on care of patients with OA knee if cases attributed to overweight/obesity (currently 26.4%) were reduced.

Inclusion criteria

Types of participants

The quantitative and qualitative components of this review will consider studies that include male or female adult participants (aged 18 or over) of any ethnic origin who are overweight/obese and have co-existing chronic pain. We will consider studies that include participants diagnosed with chronic musculoskeletal pain conditions such as, chronic lower back pain (CLBP), OA or rheumatoid arthritis (RA), as well as those who suffer non-specific or widespread musculoskeletal pain conditions. The diagnosis of overweight/obesity should be consistent with the WHO definition (BMI ≥25 overweight; BMI ≥30 obese)[5] The diagnosis of chronic pain should be consistent with the BPS definition (persistent pain, which lasts over 12 weeks or after the time that healing would have been thought to occur after trauma or surgery).[15]

Studies that include participants with; chronic pain related to cancer; pregnant or breast-feeding women; or syndromic obesity will be excluded from the review.

Types of intervention(s)/phenomena of interest

The quantitative component of the review will consider studies that evaluate weight management treatment programmes. Interventions can include bariatric drugs (e.g. orlistat), surgery (e.g. gastric banding), and lifestyle modifications such as diet, physical activity or psychological interventions delivered as part of a multi or single component study. Comparator: intervention will be compared with no treatment (true control) or usual care in any experimental study design.

The qualitative component of this review will include studies that explore the perceptions and experiences of co-existing overweight/obesity and chronic musculoskeletal pain, engaging with weight loss interventions and sustaining weight loss efforts long-term.

Types of outcomes

The quantitative component of this review will consider studies that include the following outcome

measures - primary outcome: weight; any objective validated measure of adiposity (BMI, waist circumference). Secondary outcomes; pain - any validated measure of pain - numeric rating scale (NRS)/ visual analogue scale (VAS); adverse effects; psychological health - measured using standard scales (e.g. Hospital Anxiety and Depression Scale (HADS); physical and/or psychological function, quality of life (e.g. Health Related Quality of Life (HRQol)); use of analgesic medication (e.g. Naproxen, Codiene, opiods); contacts with health care professionals and hospital admission.

Types of studies

The quantitative component of the review will be restricted to experimental study designs including randomised controlled trials and quasi-experimental trials for inclusion.

The qualitative component of the review will consider qualitative studies of experience and perceptions including (but not limited to) designs such as interview studies, focus group studies, ethnography, phenomenology, grounded theory and action research.

Search strategy

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilised 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. Thirdly, the reference list of all key identified reports and articles will be searched for additional studies. Only studies published in English will be considered for inclusion in this review. Studies published 1990- present will be considered for inclusion in this review. This time frame was selected as overweight/obesity rates have been increasing steadily during this period.[3]

The databases to be searched include:

The Cochrane Library, MEDLINE, CINAHL, PubMED, Scopus, PsycINFO, EMBASE, Education Resources Information Centre (ERIC), Web of Science

The search for unpublished studies will include:

Clinical trials registries (e.g. clinicaltrials.gov), dissertations indexed with ProQuest Dissertations & Theses

Initial keywords to be used will be:

Overweight, obesity, obese, chronic pain, chronic lower back pain, chronic joint pain, osteoarthritis, rheumatoid arthritis, chronic widespread pain, fibromyalgia, persistent pain, chronic headache, weight loss, weight management, weight control, diet control, exercise therapy, exercise, structured exercise, cognitive behavioural therapy, CBT, pain coping skills training, bariatric surgery, gastric surgery, gastric bypass, gastric banding, orlistat, experiences, perceptions

Assessment of methodological quality

Quantitative papers selected for retrieval will be assessed by two independent reviewers for

methodological validity prior to inclusion in the review using standardised 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.

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

Data extraction

Stage 1 data extraction

Quantitative data will be extracted from papers included in the review using the standardised 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.

Qualitative data will be extracted from papers included in the review using the standardised data extraction tool from JBI-QARI (Appendix IIThe data extracted will include specific details about the phenomena of interest, populations, study methods and outcomes of significance to the review question and specific objectives.

Stage 2 data extraction

The results of each single method synthesis included in the mixed method review will be extracted in numerical, tabular or textual format. For example, for syntheses of quantitative data, this will consist of appropriate elements of the meta-analysis Forest plot or, where applicable an evidence table; for qualitative reviews, it will consist of appropriate elements of the QARI-view table.

Data synthesis

Stage 1 data synthesis for each single-method synthesis

Treatment effect sizes will, where possible be pooled in a meta-analysis using Comprehensive Meta-analysis (CMA) and Stata. All results will be subject to double data entry. We anticipate most of the data from each study will be effect sizes expressed either as odds ratios (for categorical data) and/or the mean difference between baseline and follow- up (for continuous data). Pooled effects sizes (and associated 95% confidence intervals) will be quantified in a weighted fashion using the inverse variance approach. Heterogeneity will be quantified using I-squared and Tau-squared statistics. If appropriate, heterogeneity sources will be explored with subgroup analyses and/or meta-regression approaches. 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.

Qualitative research findings will, where possible be pooled using JBI-QARI. This will involve the

aggregation or synthesis of findings to generate a set of statements that represent that aggregation, through assembling the findings (Level 1 findings) rated according to their quality, and categorising these findings on the basis of similarity in meaning (Level 2 findings). These categories are then subjected to a meta-synthesis in order to produce a single comprehensive set of synthesised findings (Level 3 findings) that can be used as a basis for evidence-based practice. Where textual pooling is not possible the findings will be presented in narrative form.

Stage 2 data synthesis for mixed method synthesis

The findings of each single-method synthesis included in this review will be aggregated according to the JBI Reviewers' Manual Methodology for JBI Mixed Methods Systematic Reviews[38]. This will involve the configuration of the findings to generate a set of statements that represent that aggregation through coding any quantitative findings to attribute a thematic description to all quantitative data; assembling all of the resulting themes from quantitative and qualitative syntheses; and the configuration of these themes to produce a set of synthesised findings in the form of a set of recommendations or conclusions

Conflicts of interest

None

Acknowledgements

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Appendix I: Appraisal instruments

QARI Appraisal instrument

JBI QARI Critical Appraisal Checklist for Interpretive & Critical Research

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Is there congruity between the stated philosophical perspective and the research methodology?	☐	☐	☐	☐
2. Is there congruity between the research methodology and the research question or objectives?	☐	☐	☐	☐
3. Is there congruity between the research methodology and the methods used to collect data?	☐	☐	☐	☐
4. Is there congruity between the research methodology and the representation and analysis of data?	☐	☐	☐	☐
5. Is there congruity between the research methodology and the interpretation of results?	☐	☐	☐	☐
6. Is there a statement locating the researcher culturally or theoretically?	☐	☐	☐	☐
7. Is the influence of the researcher on the research, and vice- versa, addressed?	☐	☐	☐	☐
8. Are participants, and their voices, adequately represented?	☐	☐	☐	☐
9. Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?	☐	☐	☐	☐
10. Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?	☐	☐	☐	☐

Overall appraisal: ☐ Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

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_____

_____

MAStARI Appraisal instrument

JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Was the assignment to treatment groups truly random?	☐	☐	☐	☐
2. Were participants blinded to treatment allocation?	☐	☐	☐	☐
3. Was allocation to treatment groups concealed from the allocator?	☐	☐	☐	☐
4. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
5. Were those assessing outcomes blind to the treatment allocation?	☐	☐	☐	☐
6. Were the control and treatment groups comparable at entry?	☐	☐	☐	☐
7. Were groups treated identically other than for the named interventions	☐	☐	☐	☐
8. Were outcomes measured in the same way for all groups?	☐	☐	☐	☐
9. Were outcomes measured in a reliable way?	☐	☐	☐	☐
10. Was appropriate statistical analysis used?	☐	☐	☐	☐
	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

Appendix II: Data extraction instruments

QARI data extraction instrument

JBI QARI Data Extraction Form for Interpretive & Critical Research

Reviewer _____ Date _____

Author _____ Year _____

Journal _____ Record Number _____

Study Description

Methodology

Method

Phenomena of interest

Setting

Geographical

Cultural

Participants

Data analysis

Authors Conclusions

Comments

Complete Yes ☐ No ☐

Findings	Illustration from Publication (page number)	Evidence		
		Unequivocal	Credible	Unsupported

Extraction of findings complete Yes ☐ No ☐

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:

_____

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Reviewers Conclusions:

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