

Systematic reviews of and integrated report on the quantitative, qualitative and economic evidence base for the management of obesity in men

Clare Robertson,¹ Daryll Archibald,¹
Alison Avenell,^{1*} Flora Douglas,² Pat Hoddinott,^{1,3}
Edwin van Teijlingen,⁴ Dwayne Boyers,^{1,5}
Fiona Stewart,¹ Charles Boachie,^{1,6} Evie Fioratou,^{1,7}
David Wilkins,⁸ Tim Street,⁹ Paula Carroll¹⁰
and Colin Fowler¹⁰

¹Health Services Research Unit, University of Aberdeen, Aberdeen, UK

²Rowett Institute of Nutrition and Health, University of Aberdeen, Aberdeen, UK

³School of Nursing, Midwifery and Health, University of Stirling, Stirling, UK

⁴Centre for Midwifery, Maternal & Perinatal Health, Bournemouth University, Bournemouth, UK

⁵Health Economics Research Unit, University of Aberdeen, Aberdeen, UK

⁶Robertson Centre for Biostatistics, University of Glasgow, Glasgow, UK

⁷School of Medicine, University of Dundee, Dundee, UK

⁸Men's Health Forum England and Wales, London, UK

⁹Men's Health Forum Scotland, Glasgow, UK

¹⁰Men's Health Forum in Ireland, Dublin, Republic of Ireland

*Corresponding author

Declared competing interests of authors: none

Published May 2014

DOI: 10.3310/hta18350

Scientific summary

Management of obesity in men

Health Technology Assessment 2014; Vol. 18: No. 35

DOI: 10.3310/hta18350

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Obesity increases the risk of many serious illnesses such as coronary heart disease, type 2 diabetes and osteoarthritis. More men than women are overweight or obese in the UK and this difference is projected to continue. Men appear more likely than women to misperceive their weight, less likely to consider their body weight a risk for health and less likely to consider trying to manage their weight. Perceptions of dieting and weight-loss programmes as a feminised realm have been cited as a possible explanation for men's under-representation in weight-loss services. That men are under-represented suggests that methods to engage men in services, and the services themselves, are currently not optimal.

The aim of this study was to systematically review evidence-based management strategies for treating obesity in men and investigate how to engage men in these obesity services. The overarching objective was to integrate the quantitative, qualitative and health economic evidence base for the management of men with obesity and their engagement in weight-loss services, researching concurrently to systematically review:

- the clinical effectiveness and cost-effectiveness of interventions for obesity in men, and men in contrast to women
- the clinical effectiveness and cost-effectiveness of interventions to engage men in their weight reduction
- qualitative research with men about obesity management, and providers of such services for men.

Methods

We undertook six systematic reviews:

1. a systematic review of long-term randomised controlled trials (RCTs) of interventions with men only
2. a systematic review of long-term RCTs of interventions in which the results were presented separately for men and women
3. a systematic review of interventions for men, or for men and women compared, in the UK, including any setting, any study design and any duration
4. a systematic review of interventions to increase the engagement of men with services for obesity management, including any study design
5. a systematic review of economic evaluations of obesity interventions in which data were presented either for men only or for men compared with women
6. a systematic review of qualitative research with men with obesity, or with men compared with women, and with providers of services.

The reviews were integrated in a mixed-method synthesis.

Data sources

The following electronic databases were searched with no language restrictions from inception to January 2012 with an updated search of 15 databases carried out in July 2012: MEDLINE, MEDLINE-In-Process & Other Non-Indexed Citations, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews (CDSR), the Database of Abstracts of Reviews of Effects (DARE), the NHS Economic Evaluation Database (NHS EED), Health Technology Assessment (HTA), Applied Social Sciences Index and Abstracts (ASSIA), Education Resources Information Center (ERIC), Anthropology Plus, British Nursing Index,

Social Sciences Citation Index (SSCI), Health Management Information Consortium (HMIC), Conference Proceedings Citation Index – Social Science & Humanities (CPCI-SSH), Cost-Effectiveness Analysis Registry (CEA Registry), Research Papers in Economics (RePEc), ClinicalTrials.gov, CenterWatch, Current Controlled Trials and International Clinical Trials Registry. Subject-specific websites were also consulted and reference lists were searched. Additionally, we contacted professional health-care organisations and commercial organisations to identify published and unpublished UK studies.

Participants

Obese men with a body mass index (BMI) of ≥ 30 kg/m² (or overweight men with a BMI of ≥ 28 kg/m² with cardiac risk factors).

Study designs and interventions

Studies had to be carried out in societies relevant to the UK setting.

- Interventions explicitly promoting weight loss or weight maintenance as their main outcome. We considered lifestyle changes (e.g. diet, physical activity, behaviour change techniques or combinations of any of these) and orlistat for the management of obesity in men. Studies evaluating complementary therapy, over-the-counter non-diet products promoted for weight loss, or bariatric surgery, or examining a combination of interventions, for example smoking cessation and weight loss at the same time, were not included. We included RCTs with follow-up data of at least 1 year, but for UK studies any study design and length of follow-up were acceptable.
- Evaluations of interventions to increase the participation of men in any services aiming to reduce obesity, for example community outreach services, incentive schemes and web-based initiatives. Any study design was considered.
- Qualitative and mixed-method studies linked to RCTs and non-randomised intervention studies. UK-based, men-only qualitative studies not linked to interventions were also included.

Outcome measures

The primary aim of the evidence synthesis was to uncover how effective interventions work and to describe key intervention ingredients, processes and environmental and contextual factors that contribute to effectiveness. Outcome measures were weight, waist circumference, cardiovascular risk factors, disease-specific outcomes, adverse events, quality of life, process outcomes and economic costs.

We also aimed to identify the barriers and facilitators that men experience when engaging with a weight management intervention. The following a priori research questions were developed to initially guide our investigation:

1. What are the best evidence-based management strategies for treating obesity in men?
2. How can men's engagement in obesity services be improved?

In addition to these a priori research questions we also developed more detailed research questions, which emerged inductively from the initial findings of the effectiveness reviews:

1. How are men initially motivated to lose weight?
2. How are men attracted to taking part in the trial/intervention?
3. Are men consulted in the design of the intervention?
4. If it is found that interventions for men should be different from those for women, how should they be different and why?
5. Are group-based interventions for men found to be more effective for weight loss than interventions delivered to individual men?
6. Are certain features of diets found to be more attractive for obese men?
7. Are certain features of physical activity stated to be more attractive for obese men? How and why are these features more attractive?

8. What efforts are made to help men continue with the programme?
9. Do men state who they believe to be the best person/persons to deliver the intervention?
10. Are programmes deliberately involving partners/families more effective?

Study appraisal

For each systematic review one reviewer extracted data from the included studies and a second reviewer checked the data for omissions or inaccuracies. Two reviewers carried out the quality assessment.

Synthesis

For quantitative data we reported means or changes in means or proportions between groups. For continuous outcomes we reported the mean difference or standardised mean difference (different scales for the same outcome) and for dichotomous outcomes we reported risk ratio data with 95% confidence intervals (CIs). For the analysis of mean weight loss, the mean difference between men and women and the weighted mean difference were calculated for both men and women when more than one group was reported. Because of the inherent heterogeneity in studies of obesity interventions, when study results from more than one study could be quantitatively pooled we used random-effects meta-analysis.

We undertook a realist approach to integrating the qualitative and quantitative evidence synthesis, conceptualising interventions by the:

1. *context* that an intervention/programme will be situated within so that factors that might inhibit or enhance its effectiveness can be identified
2. *mechanisms* of the intervention/programme and how the intended programme beneficiaries will interact and react to the intervention processes and mechanisms
3. *outcomes*, both positive and negative, that may arise from an individual's engagement with the proposed intervention.

Both deductive and inductive analytical approaches were employed throughout the review process.

Results

Data were included for 1238 men from 11 trials and six linked reports for our review of men-only RCTs; 12,934 men and women from 20 RCTs and six linked reports for our review of RCTs in men and women; and 11,426 men and 63,990 women from 26 reports of UK interventions; five economic evaluations and two linked reports; 13 qualitative studies linked to interventions; and nine qualitative studies not linked to interventions. We found no eligible studies for our review of interventions to increase the engagement of men. We found some consistent findings across reviews and we present an integrated synthesis of our results. Our findings should be interpreted with the knowledge that the evidence base, particularly in the UK setting, is currently limited in the quality and number of studies and mainly reflects white, middle-class, middle-aged men. In addition, few UK studies included long-term data and our results may not necessarily be applicable to all men. We also had difficulties retrieving studies and it is possible that the studies that we found had more promising results than those that we were not able to access.

Types of effective interventions

Men may do well if physical activity is part of a weight-loss programme. One intensive supervised exercise programme produced a mean weight change after 1 year of -4.6 kg (95% CI -6.2 kg to -3.0 kg). Men may like exercise programmes and may be more likely to respond to them than women. Men enjoyed the use of pedometers to monitor their physical activity. Reducing diets tended to produce more favourable weight loss than physical activity alone (mean weight change after 1 year from a reducing diet compared with an exercise programme -3.2 kg, 95% CI -4.8 kg to -1.6 kg). Reducing diets are more effective if an exercise programme is also provided. Low-fat reducing diets, some with meal replacements, combined

with physical activity and behaviour change training gave the most effective long-term weight change [–5.2 kg (standard error 0.2 kg) after 4 years].

The type of reducing diet, such as increasing the protein content, was not shown to affect long-term weight loss in men. Some men expressed a dislike of 'strict' diets. However, for men, intermittent periods of very low-calorie dieting, as required, may be more effective than regular periods of dieting (mean difference after 2 years –10.5 kg, 95% CI –16.2 kg to –4.8 kg).

Interventions including behaviour change training improved long-term weight loss and maintenance for men (e.g. self-monitoring, goal setting, prompting self-monitoring, providing feedback, review of goals). Behaviour change training significantly improved weight-loss maintenance over the second year for men who had used exercise to lose weight over the first year (mean difference –3.1 kg, 95% CI –5.0 kg to –1.2 kg) but not for men who had used diet to lose weight over the first year (mean difference 0.6 kg, 95% CI –1.3 kg to 2.5 kg). Men might like less monitoring than women and too many sessions may be counterproductive. Support by telephone and mail could be useful (mean difference after 1 year –1.4 kg, 95% CI –2.7 kg to –0.1 kg).

After a very low-calorie diet, men may be less likely than women to do well with orlistat to help long-term weight-loss maintenance (for men: mean change after 3 years with orlistat –8.9 kg, with placebo –8.1 kg; reported as not significant).

Motivators to lose weight

Although fewer men joined weight-loss programmes, once recruited they were significantly less likely to drop out than women (difference 11%, 95% CI 8% to 14%). The evidence suggested that middle-aged men were motivated to lose weight once they perceived that they had a problem with their health, for example being diagnosed or labelled as obese by a health professional. The health benefits of losing weight can act as a further motivator for men. Trials found that successful weight reduction with low-fat reducing diets or physical activity advice or programmes, with or without behaviour change training, may improve health problems, for example erectile dysfunction in men with and without type 2 diabetes (reported $p = 0.06$ and $p = 0.001$ respectively). This type of intervention can also prevent diabetes (hazard ratio for diabetes incidence 0.43, 95% CI 0.22 to 0.81). Successful weight loss might increase the risk of osteoporosis for type 2 diabetics by reducing total hip bone density. The desire to improve personal appearance was also cited as a motivator, although men were also keen to avoid looking too thin.

Intervention setting and delivery and support

Group compared with individual programmes

Group-based weight management programmes were found to facilitate peer or social support amongst men with similar health problems, despite the fact that some men were initially reluctant to take part in a group. Some individual tailoring of advice or counselling for men could also assist with weight loss. Some men found that being accountable to oneself and having to account for food choices to others within the programme facilitated adherence. Some men stated that men-only group settings were important whereas others stated that this was unimportant or preferred mixed-sex groups. Group-based programmes can be logistically difficult with regard to scheduling; programmes offering evening meetings at fixed, regular times were desirable. Group-based financial contracts were reported to be significantly more effective for weight loss over 2 years than individual financial contracts (reported $p < 0.05$), although the size of the contract did not appear to be a significant influence.

Setting

Interventions situated in sporting contexts, for which men have a strong sense of affiliation and belonging, have been instrumental in engaging men. Interventions with football fans have had low dropout rates and have shown very positive responses from participants. Men largely welcomed the use of humour in intervention design or delivery, although it was recognised that men's health issues could be trivialised if

humour was used insensitively or inappropriately. Generally, men preferred interventions that were individualised, fact based and flexible, which used business-like language and which included simple to understand information.

Some men favoured programmes delivered by the NHS in comparison to commercial companies, and in contrast to female preferences, but data showed that commercial programmes were effective in helping men to lose weight. Weight-loss programmes delivered in the NHS for men only have so far been few, with limited follow-up, although feedback has generally been positive. The comparative effectiveness of NHS and commercial programmes for long-term weight loss was unclear for men. In a 1-year UK-based randomised trial of commercial and NHS-based programmes, only 31% of the participants were men. In this trial only one intervention from a commercial weight-loss organisation, in which 28% of the participants were men, resulted in significantly greater weight loss than in the comparator arm (adjusted mean difference -2.5 kg, 95% CI -4.2 kg to -0.8 kg).

Delivery

Studies generally did not report the sex of the person delivering the intervention and whether or not this was an influence. The benefits of internet-based advice for men were unclear (mean difference for internet-based advice after 1 year -0.9 kg, 95% CI -1.9 kg to 0.2 kg).

Support from family and friends

The effect of support from partners to aid weight loss was inconsistent. There was evidence to suggest that having a partner involved in a weight-loss programme might be beneficial for weight loss but the opposite effect was also found. Equally, the social role of food in maintaining relationships with family members or friends was raised as a barrier to weight loss. Participating in a weight-loss intervention appeared to encourage men's partners (not signed up to the intervention) to lose weight through a halo effect.

Economics

No evidence was retrieved relating to the cost-effectiveness of interventions to tackle obesity in UK men. Five studies in a European, Australian or American setting evaluated cost-effectiveness in men as a subgroup analysis. Formal meta-analysis of the studies was not possible because of heterogeneity in the study designs, modelling methods used and study populations. There was, however, some evidence that general practitioner counselling interventions were more cost-effective than interventions delivered by a dietitian. Lifestyle interventions also proved to be cost-effective as were group-based interventions. Orlistat was found to be cost-effective in addition to a lifestyle intervention and was particularly cost-effective if targeted at high-risk groups, especially people with type 2 diabetes. The results should be interpreted in the light of the variable methodological quality of the studies.

Strengths and limitations

The strengths of this study are the systematic and rigorous methods taken to review and integrate the evidence. Exhaustive searches were undertaken with the aim of identifying all relevant published and grey literature. Despite these efforts we identified limited data, especially for the UK, which were of moderate quality. Furthermore, the diversity of men was not well-represented by the narrow evidence base as the majority of participants considered by the included studies were white, middle class and middle aged. The results should therefore be interpreted with caution.

Conclusions

Implications for health care

1. Weight reduction for men is best achieved and maintained with the combination of a reducing diet, physical activity advice or a physical activity programme, and behaviour change techniques (e.g. self-monitoring, goal setting, prompting self-monitoring, providing feedback, review of goals). These key components differ from those found for women, with men preferring more factual information on how to lose weight and more emphasis on physical activity programmes. Weight-loss programmes can prevent type 2 diabetes and improve cardiovascular risk factors, erectile dysfunction, self-esteem and quality of life.
2. For some men, but not all, the opportunity to attend men-only groups may enhance the effectiveness of interventions. Individual tailoring and feedback may also be features of more effective services.
3. Weight-loss programmes for men may be better provided in social settings, such as sports clubs and workplaces, which may be more successful at engaging men. Innovative means of delivering services are needed for hard-to-reach groups.

Recommendations for research

1. Research is needed to examine the effectiveness and cost-effectiveness of new approaches to engaging men with weight-loss services and the best design for those services.
2. Men (and women) are a heterogeneous group. Rigorous methods are needed to test more complex interventions. Men should be consulted on how to optimise engagement and make interventions more user-friendly, and these services need to be formally evaluated. The experiences and perspectives of men (and women) who are black or from ethnic minority backgrounds, who are unemployed or on low incomes, who are gay, bisexual or transgender or who are from rural and/or remote locations need to be addressed. Rigorous feasibility studies and piloting with service user input at all stages is required before undertaking definitive RCTs.
3. Health concerns, which may prompt contact with health service staff, motivate men to address their obesity. Research is required to examine the most effective interventions delivered at these pivotal health service encounters when an obesity-related diagnosis is made.
4. Although we found relatively few long-term RCTs, there were even fewer UK studies that provided outcome data for men of more than a few months' follow-up. As was clear from our reviews, men would value longer-term support and there is a need to provide longer-term outcome data (at least 1 year of follow-up). These outcome data should include cardiovascular risk factors, the impact on comorbidities and quality of life and economic outcomes. There is also a need to look specifically at ways to enhance the maintenance of weight loss. The majority of the programmes did not make a distinction between support for the initial weight loss and a different or modified programme to help maintain that weight loss.
5. Qualitative research is needed with men to inform all aspects of intervention design, including the setting, optimal recruitment processes and reasons for, and how processes might minimise, attrition. Process evaluation of intervention studies should seek feedback on the marketing, content and delivery of interventions and how the macro, meso and micro context interacts with the intervention.
6. Future research studies should adhere to best practice guidelines for health economic decision modelling and particular attention should be given to assumptions regarding the continuation of treatment effect and the modelled link between weight loss and longer-term costs and outcomes (e.g. health events such as diabetes and myocardial infarction).

Study registration

This study was registered as PROSPERO CRD42011001479.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Five-year impact factor: 5.804

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: www.hta.ac.uk/

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 09/127/01. The contractual start date was in October 2011. The draft report began editorial review in April 2013 and was accepted for publication in August 2013. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

© Queen's Printer and Controller of HMSO 2014. This work was produced by Robertson *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

Editor-in-Chief of *Health Technology Assessment* and NIHR Journals Library

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the HTA Programme, UK

NIHR Journals Library Editors

Professor Ken Stein Chair of HTA Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andree Le May Chair of NIHR Journals Library Editorial Group (EME, HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck Chair in Public Sector Management and Subject Leader (Management Group), Queen's University Management School, Queen's University Belfast, UK

Professor Aileen Clarke Professor of Public Health and Health Services Research, Warwick Medical School, University of Warwick, UK

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Peter Davidson Director of NETSCC, HTA, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Professor Elaine McColl Director, Newcastle Clinical Trials Unit, Institute of Health and Society, Newcastle University, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Professor of Health Sciences Research, Faculty of Education, University of Winchester, UK

Professor Jane Norman Professor of Maternal and Fetal Health, University of Edinburgh, UK

Professor John Powell Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professorial Research Associate, University College London, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Please visit the website for a list of members of the NIHR Journals Library Board:
www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: nihredit@southampton.ac.uk