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Author:
McLaughlin, Joanna C

Title:
Mixed methods investigation of the public health impact of pre-surgical health optimisation interventions in elective arthroplasty

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Mixed methods investigation of the public health impact of pre-surgical health optimisation interventions in elective arthroplasty

Dr Joanna Clare McLaughlin

November 2023

A dissertation submitted to the University of Bristol in accordance with the requirements for award of the degree of Doctor of Philosophy
in the Faculty of Health Sciences, Bristol Medical School

Word count: 60,135

Abstract

Commissioning policies in some areas of England influence National Health Service patients' access to hip and knee replacement surgery based on their body mass index. Delay or denial of surgery is intended to promote weight loss as part of 'health optimisation'. This thesis comprises four studies which investigate the impact of these restrictive policies.

A descriptive study of National Health Service body mass index policies for access to hip and knee replacement revealed high and rising use of restrictive policies, with variability by geography and content. In 2021, 67.9% (72/106) of commissioning groups in England had body mass index policies, 66.7% of which were restrictive.

Use of interrupted time series analysis in a natural experimental study demonstrated an association between policy introduction and a reduction in surgical provision. Patients of lower socio-economic status were disproportionately affected, likely due in part to lower use of independently-funded surgery.

A qualitative study of key informants in policy decision-making and implementation for health optimisation demonstrated that short-term financial pressures were key drivers in the use of restrictive policies. Participants highlighted strong concerns about using body mass index for rationing, inadequate provision of weight management services, and exacerbating health inequalities.

A scoping review of available health economic models for valuing obesity reduction from behavioural interventions identified 44 models, 32 of which had been used only once. Only four models complied with existing expert recommendations, limiting decision-makers' ability to justify the development and implementation of weight management services needed for equitable health optimisation.

The thesis concludes that restrictive policies should no longer be used to limit access to surgery, but that future research and practice developments can strengthen alternative approaches. Shared decision-making and equitable provision of integrated support for health improvement during the surgical pathway could contribute as one element of wider policies to address obesity.

Acknowledgements

This research within this thesis was undertaken for my Doctoral Fellowship which was funded by the National Institute for Health and Care Research (NIHR) - award number 301469. The fellowship was completed with the support of the South West Public Health Specialty Training Programme through permission to take three years ‘out of programme for research’.

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The National Joint Registry’s research committee and centre staff for their role in facilitating the study in Chapter 4 and for providing dissemination opportunities. Thank you to the patients and staff of all the hospitals in England who have contributed data to the National Joint Registry, and to the Healthcare Quality Improvement Partnership (HQIP). The views expressed represent those of the author and do not necessarily reflect those of the National Joint Registry Steering Committee or the HQIP who do not vouch for how the information is presented. HQIP and the NJR take no responsibility for the accuracy, currency, reliability and correctness of any data used or referred to in this report, nor for the accuracy, currency, reliability and correctness of links or references to other information sources and disclaims all warranties in relation to such data, links and references to the maximum extent permitted by legislation. HQIP and NJR shall have no liability (including but not limited to liability by reason of negligence) for any loss, damage, cost or expense incurred or arising by reason of any person using or relying on the data within this report and whether caused by reason of any error, omission or misrepresentation in the report or otherwise. This report is not to be taken as advice. Third parties using or relying on the data in this report do so at their own risk and will be responsible for making their own assessment and should verify all relevant representations, statements and information with their own professional advisers.

Lastly - thank you to the participants in the qualitative study. Without your time and enthusiasm to share your insights on health optimisation, this work would not have been possible.

COVID-19 Statement

This statement details the impact of the COVID-19 pandemic on the completion of this thesis.

Chapter 7 details one element of a study initiated for this research which was closed before completion, with the agreement of the NIHR, the study sponsor (University of Bristol) and the Clinical Research Network. The originally planned study had been reliant on patient recruitment from a regional health optimisation service. However, the impact of COVID-19 on staff redeployment within the participant identification centres, and on the referral rates of patients into this service, meant that study completion was not feasible. The full details are provided in Chapter 7. Under the guidance and approval of the fellowship supervisors, independent assessors and the funder, the work comprising the studies in Chapters 3 to 6 was expanded in response to the reduction in the work on the study in Chapter 7.

Author's declaration

I declare that the work in this dissertation was carried out in accordance with the requirements of the University's *Regulations and Code of Practice for Research Degree Programmes* and that it has not been submitted for any other academic award. Except where indicated by specific reference in the text, the work is the candidate's own work. Work done in collaboration with, or with the assistance of, others, is indicated as such. Any views expressed in the dissertation are those of the author.

SIGNED: [redacted] DATE: 29.11.23

Publications of work presented in this thesis

This thesis is an ‘integrated thesis’ prepared under the University of Bristol guidelines, whereby some or all of the content of the peer-reviewed publications of the research have been included within the relevant chapters. In the overview section at the beginning of each chapter the publication on which the chapter is based is indicated. Below is a list of the publications which resulted from the work in this thesis, in the order in which they are presented in the thesis. The thesis author (JM) is the first author for each of them, performed the analyses and wrote and submitted the manuscript drafts. The authors’ contributions were confirmed at publication. The contributions of the co-authors are gratefully acknowledged.

First author: Last authors:. A. Judge.

Publications

- McLaughlin J, Elsey J, Kipping R, Owen-Smith A, Judge A and McLeod H. Access to hip and knee arthroplasty in England: commissioners’ policies for body mass index and smoking status and implications for integrated care systems. BMC Health Serv Res. 2023 Jan 24;23(77).

- McLaughlin J, Kipping R, Owen-Smith A, McLeod H, Hawley S, Wilkinson, JM and Judge A. What effect have commissioners’ policies for body mass index had on hip replacement surgery?: an interrupted time series analysis from the National Joint Registry for England. BMC Med. 2023 Jun 13;21(1):202.

- McLaughlin J, Kipping R, Owen-Smith A, McLeod H, Hawley S, Wilkinson JM and Judge A. What effect have NHS commissioners’ policies for body mass index had on access to knee replacement surgery in England?: An interrupted time series analysis from the National Joint Registry. PLoS One. 2022 Jun 29;17(6):e0270274.

- McLaughlin J, Sillero-Rejon C, Moore T and McLeod H. Study protocol: “Health Economic Models for Estimating the Benefits of Obesity Reduction and Weight Loss: a Scoping Review” – Registered on The Open Science Framework (OSF) Registry. 2023 Jun 13, https://doi.org/10.17605/OSF.IO/4U53Y

- McLaughlin J and Judge A. Linkage of routinely collected healthcare data and bespoke research questionnaire data to best serve NHS patient study participants. International Journal of Population Data Science. 2022 7(3). (Abstract).

Conference contributions

- McLaughlin J, Kipping R, Owen-Smith A, McLeod H, Wilkinson JM and Judge A. What effect have clinical commissioning group policies for thresholds of weight loss and body mass index had on access to knee replacement surgery in England? An analysis from the National Joint Registry for England. 24.3.22: World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Disease 2022, (virtual) – poster presentation and abstract publication: Aging Clin Exp Res (2022) 34 (Suppl 1):S35–S474. P759 S363.

- McLaughlin J, Kipping, R, Owen-Smith A, McLeod H, Wilkinson JM and Judge A. What effect have clinical commissioning group policies for thresholds of weight loss and body mass index had on access to knee replacement surgery in England? An analysis from the National Joint Registry for England. 19.5.22: Academy of Medical Sciences Clinical Academics in Training Annual Conference (CATAC) 2022, (Bristol) – poster and mini-oral presentation – winner of poster presentation competition.

- McLaughlin J. Investigating the effectiveness of pre-surgical 'health optimisation' public health interventions for obesity and smoking in elective hip and knee replacement surgery from health service and patient perspectives. 1.9.22: UK-RiME (Research in Musculoskeletal Epidemiology) Annual Showcase 2022, (Winchester) – oral presentation and winner of Early Career Researcher presentation competition.

- McLaughlin J. and Judge A. Linkage of routinely collected healthcare data and bespoke research questionnaire data to best serve NHS patient study participants. 7.9.22: International Population Data Linkage Network conference 2022, (Edinburgh) – oral presentation.

- McLaughlin J, Kipping R, Owen-Smith A, McLeod H, Wilkinson JM and Judge A. What effect have clinical commissioning group policies for thresholds of weight loss and body mass index had on access to knee replacement surgery in England? An analysis from the National Joint Registry for England. 8.9.22: Society for Social Medicine and Population Health Annual Scientific Meeting 2022, (Exeter) – oral presentation, awarded top ten abstract and invited to author a summary blog.

- McLaughlin J, Kipping R, Owen-Smith A, McLeod H and Judge A. Do we risk causing health inequalities by asking patients to lose weight before surgery? Insights from an interview study with NHS policy-makers, clinicians and commissioners. 22.11.22: NIHR Academy Members Conference 2022, (Leeds) – poster presentation.

Wider dissemination and media contributions

- Press releases were issued for two of the publications listed on page xi. These generated interview requests from journalists and substantial media reporting of the study findings and implications. Example media articles include:
    - Morris L. NHS BMI policies linked to surgery health inequalities. The National Health Executive [Internet]. 2022 Jul 4; Available from: https://www.nationalhealthexecutive.com/articles/nhs-bmi-policies-linked-to-surgery-health-inequalities
    - Morris S. Knee replacements stall in regions of England with weight rules for patients. The Guardian [Internet]. 2022 Jun 29; Available from: https://www.theguardian.com/society/2022/jun/29/knee-replacements-stall-in-regions-of-england-with-weight-rules-for-patients

- NHS Elect (national membership and consultancy organisation for the NHS) Perioperative Care for Older People Network – webinar delivered on findings and implications of the quantitative studies in this thesis - June 2022. Available to NHS Elect members.

- Guest speaker on a podcast episode for 'Anaesthesia on Air' the podcast series from the Royal College of Anaesthetists and the Centre for Perioperative Care. Released October 2022. Available from: https://www.rcoa.ac.uk/events-professional-development/education-professional-development/podcasts/pre-surgical-health

- McLaughlin J, Madigan C, Avery L. and Durrand J. Pre-surgical health optimisation as a wide-reaching preventative healthcare intervention (PHS0375). Evidence submission to the consultation for the UK Parliament Select Committee's Prevention Inquiry. March 2023. Available from: https://committees.parliament.uk/work/7205/prevention-in-health-and-social-care/publications/written-evidence/?SearchTerm=mclaughlin&DateFrom=&DateTo=&SessionId=

- Winner of UK Society for Social Medicine & Population Health's Research Summary Competition 2023. Blog authored for the Society's website June 2023. Available from: https://socsocmed.org.uk/blog/ssm-featuring-2022s-top-scoring-abstracts-joanna-mclaughlin/

- Television interview for an episode of ITV's 'Tonight' current and consumer affairs series. Hip and knee joint replacement in the UK – due for release in November 2023. Available from: https://www.itv.com/watch/tonight/1a2803

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List of Abbreviations

ARC	Applied Research Collaboration
ASA	American Society of Anesthesiologists
BMI	Body mass index
BNSSG	Bristol, North Somerset, South Gloucestershire
CCG	Clinical commissioning group
CI	Confidence interval
CSU	Commissioning Support Unit
CVD	Cardiovascular disease
ESCAPE-Pain	Enabling Self-management and Coping with Arthritic Pain using Exercise
FCP	First contact physiotherapist
FOI	Freedom of Information
GP	General practitioner
ICB	Integrated care board
ICER	Incremental cost-effectiveness ratio
ICP	Integrated care partnership
ICS	Integrated care system
IMD	Index of multiple deprivation
IRAS	Integrated Research Application System
IVF	in vitro fertilisation
LSOA	Lower Layer Super Output Areas
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NJR	National Joint Registry for England, Wales, Northern Ireland and the Isle of Man

OECD	Organisation for Economic Co-operation and Development
ONS	Office for National Statistics
OSF	Open Science Framework
OYSG	One You South Gloucestershire
PPI	Patient and public involvement
PROMS	Patient-reported outcome measures
QALY	Quality-adjusted life year
REC	Research Ethics Committee
SD	Standard deviation
SWD	Systemwide Dataset
UK	United Kingdom
USA	United States of America

Glossary

Arthroplasty	A surgical procedure to restore the function of a joint, including hip and knee joint replacements.
Body mass index	A measure used in the categorisation of obesity. An adult's body mass index (BMI) is calculated by dividing their weight in kilograms by the square of their height in metres.
Clinical commissioning group	The statutory NHS bodies charged with planning and commissioning the healthcare services for their locality. They were formed in 2012 and replaced by integrated care boards in 2022.
Health optimisation (pre-surgical)	The systematic efforts to improve a patient's health and well-being in preparation for a potential surgical procedure and recovery. This can include medical optimisation e.g. correction of anaemia and uncontrolled diabetes, risk factor reduction regarding behavioural change e.g. smoking cessation, alcohol misuse and weight management, and elements of psycho-social well-being e.g. loneliness and anxiety.
Independently-funded surgery	Surgical procedures undertaken which are not funded by the NHS. Includes hip and knee replacement procedures paid for as private treatment or provided through private healthcare insurance.
Integrated care board	The statutory NHS organisation responsible for NHS planning, budget management and service provision of healthcare within an integrated care system area.
Integrated care partnership	The statutory committee formed between the integrated care board and the local authorities within the integrated care system area.

Integrated care system	Statutory partnerships of organisations that come together to plan and deliver joined up health and care services within the integrated care system area. 42 such systems were formed in England in 2022.
Local authority	A government organisation responsible for all the public services and facilities in a particular local area in England.
Obesity	An abnormal or excessive fat accumulation that presents a risk to health. A body mass index of 30 kg/m^2 or above is considered obese.
Perioperative care or perioperative medicine	Patient-centred, multidisciplinary, and integrated medical care of patients from the moment of contemplation of surgery until full recovery.
Policymakers (healthcare)	People working in roles who help to set a course or define a principle that governs how a healthcare organisation acts. They may have a direct role in making policy for the NHS, or be focused on influencing the policy making of others. They can operate at a local, regional, national or international level. Healthcare commissioners are included as policymakers.
Prehabilitation (pre-surgical)	Health improvement directed at patients from the point of confirmation of their decision to proceed with surgery to the time of the surgical procedure.
Preoperative assessment	The process of nurse-led assessment of a patient's fitness and readiness for surgery in the standard pathway to elective surgery.
Restrictive body mass index policy	A commissioning policy which uses a patient's body mass index to determine their eligibility for elective surgery. Includes policies which deny or delay access to surgery, or require weight loss or engagement with weight management interventions, for patients above a threshold of body mass index.

Teachable moment (healthcare)	Situations whereby a patient’s circumstances create a salient opportunity to engage them in communication about improving their health.

Chapter 1. Introduction

1.1 Overview

This chapter provides the context for the thesis by outlining the issue of obesity in England, the role of healthcare delivery in health improvement opportunities, and the concept of ‘health optimisation’ for obesity in the pre-surgical setting. The chapter also specifies the thesis aim and objectives, provides an overview of the methodological approach and an outline of the structure of the thesis.

1.2 Obesity

The World Health Organisation defines obesity as an abnormal or excessive fat accumulation that presents a risk to health. To measure obesity, an adult’s body mass index (BMI) can be calculated by dividing their weight in kilograms by the square of their height in metres. A BMI of 30 kg/m^2 or above is considered obese (1).

Obesity levels have been rising globally - the worldwide prevalence of obesity almost tripled between 1975 and 2016 (1). The latest Health Survey for England reports that in 2021, 26% of adults in England were living with obesity and a further 38% were overweight. Obesity was more prevalent in adults living in more deprived areas (range 20 to 34% by area) (2).

As a major contributor to multiple health conditions such as diabetes, cardiovascular disease, many cancers and musculoskeletal disorders such as osteoarthritis, obesity represents a significant public health problem (1). Given that healthcare costs for people with obesity are estimated to be 36% higher than for those of a healthy weight (3), obesity is also a major economic concern for the National Health Service (NHS). The treatment of obesity and its associated comorbidities accounts for £6.5 billion of NHS expenditure per year (4). The NHS is the publicly financed health system of the United Kingdom (UK).

The causes of obesity are multifactorial and range from individual factors including genetics, behavioural and psychological characteristics and health conditions, to social and environmental factors including the built environment, food and agriculture policy and the economic climate. Figure 1 summarises the categories of the recognised causes of obesity (5). Many of the modifiable factors are ultimately related to the access people have to healthy lifestyles which enable them to meet guidelines on dietary intake and physical activity – this is intrinsically linked to an individual’s socio-economic conditions (1).

Figure 1: Causes of obesity (reproduced from Safaei et al. 2021 (5))

The most recent UK government strategy 'Tackling Obesity' places emphasis on individuals' responsibility to achieve a healthy weight (6). Multiple collaborative reports from cross-organisational groups call for increased government action to prevent obesity through a recognition of the need to improve the lived environment and address policy measures for food, activity and health (7,8).

Public health leaders highlight the importance of behaviour change in equitable health improvement. Behavioural causes of ill health are associated with socio-economic deprivation; unhealthy diet and physical inactivity are England's second and fourth main behavioural causes of shortened life expectancy (9). Tackling the social causes of these behaviours is necessary for equitable health improvement as the success of individual interventions on behaviour is also socially patterned, while environmental improvements have their largest effects in areas of higher deprivation (10).

1.3 Weight management

For adults already living with overweight or obesity, there are national guidelines outlining the provision of weight management interventions (11,12). In England, the tiered weight management pathway, spanning the provision of advice to accessing specialist treatment, has achieved limited and variable service provision over the last decade (13). Tier 1 covers universal health promotion services such as healthy lifestyle campaigns. Tier 2 weight management interventions are commissioned by local authority public health teams and typically include 12-week-long behavioural and lifestyle group courses delivered in community settings, in some cases by commercial providers. An online, digital equivalent is now available from the NHS via referral from primary care for all adults with obesity-associated co-morbidities (14). For individuals requiring additional intervention for weight management, healthcare commissioning organisations are responsible for Tier 3 specialist weight management services which may include dietitian and psychotherapist input, and Tier 4 bariatric surgery. Patients are required to have engaged with each lower tier before accessing the next (12). A recent development in weight management options in England is the approval of the use of the injectable pharmacological treatments such as semaglutide for NHS patients with obesity. These medications act through appetite reduction and metabolic profile improvements to support weight loss in specialist management settings for obesity, though are currently only recommended for up to 2 years of NHS-funded treatment (15).

The NHS has been identified as a major setting within a whole systems approach through which to tackle obesity in the UK. Action should be taken through three mechanisms; supporting behaviour change, shaping wider determinants of health, and reducing health inequalities (8). Following devolution in 1999, the four countries of the UK have taken different policy approaches to healthcare planning and delivery (16). This thesis focuses on NHS care within England, specifically the role of NHS service design to support behaviour change in England.

1.4 Supporting behaviour change in the NHS

Opportunistic delivery of information and advice for health improvement forms the main mechanism by which the NHS is intended to support large numbers of people with behaviour change for weight management. The Making Every Contact Count programme involves widespread training of frontline NHS staff to provide brief advice and interventions to patients in opportunistic encounters, including for obesity. The programme was designed to benefit from people’s heightened receptiveness to advice given by healthcare professionals (17). A commitment to better training healthcare professionals in their ability to effectively and confidently deliver this advice, along with better funded weight management services targeted to those with the highest need, was made in the NHS Long Term Plan published in 2019 (18).

1.5 Behaviour change before elective surgery – health optimisation

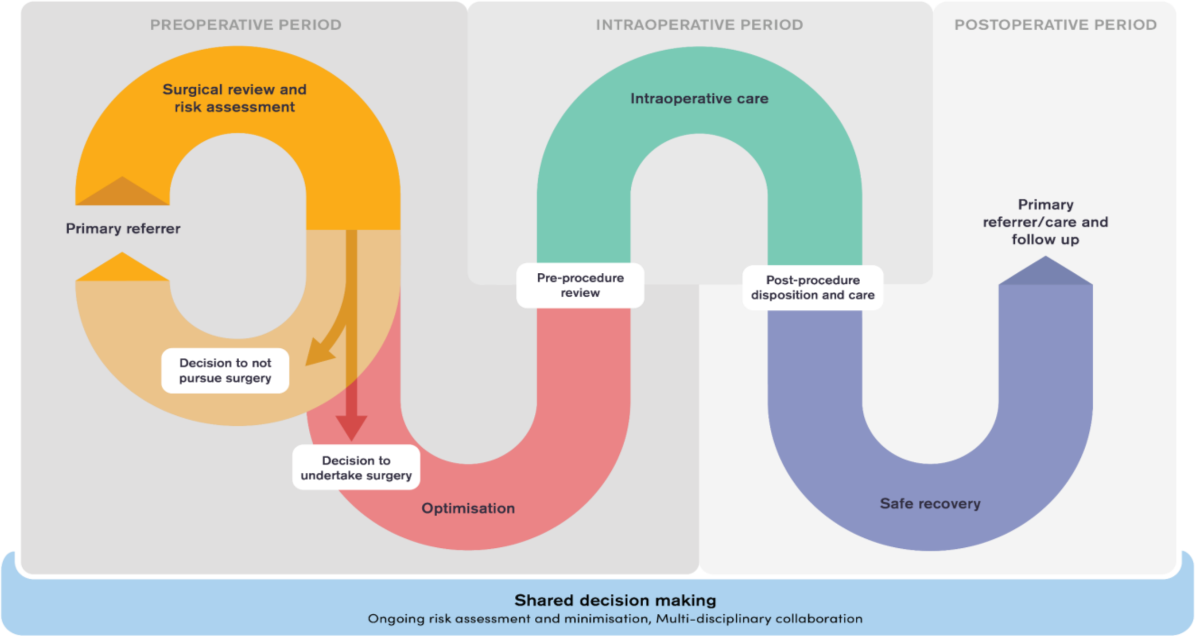
The concept of the ‘teachable moment’ is applied to situations whereby a patient’s circumstances create a salient opportunity to engage them in communication about improving their health (19). As a major event in a patient’s life, contemplation of surgery has been identified as a teachable moment where patients may be more receptive to addressing their lifestyle and behaviours, including weight loss. Leverage of this moment is considered a key opportunity to offer health improvement (20).

Elective (rather than emergency or urgent) surgery is a focus of the approach to using healthcare interactions to support behaviour change. This is due to the high numbers of NHS patients receiving elective surgery each year, the strength of the teachable moment, and the high cost of surgical complications and post-operative care (21–23).

Various terms have been used to describe the formalisation of screening for, assessing, and managing health improvement opportunities for surgical patients. In the pre-surgical setting, the terms ‘prehabilitation’ and ‘health optimisation’ are often used interchangeably to denote the systematic efforts to improve a patient’s health and well-being in preparation for their surgical procedure and recovery. This can include medical optimisation e.g. correction of anaemia and uncontrolled diabetes, risk factor reduction regarding behavioural change e.g. smoking cessation, alcohol misuse and weight management, and elements of psycho-social well-being e.g. loneliness and anxiety (21). This thesis uses the term prehabilitation to refer to health improvement directed at patients who have confirmed their decision to proceed with surgery. The term health optimisation is used in this thesis to encompass health improvement directed at patients contemplating surgery as well as those who have made the decision to proceed with surgery.

'Perioperative care' or 'perioperative medicine' are the terms for 'patient-centred, multidisciplinary, and integrated medical care of patients from the moment of contemplation of surgery until full recovery' (24). 'Pre-operative assessment' refers to the existing process of nurse-led assessment of a patient's fitness and readiness for surgery in the standard NHS pathway to elective surgery (25). Both these practices incorporate health optimisation in the pre-operative period. Proponents of health optimisation suggest reframing surgery waiting lists as 'preparation lists' given their length and the opportunity for patients to engage in health optimisation while they wait (22). Figure 2 reproduces the Australian and New Zealand College of Anaesthetists & Faculty of Pain Medicine Perioperative Care Framework, which illustrates the internationally accepted overall approach to perioperative care for surgical patients, and identifies the optimisation period between the decision to undertake surgery and the surgical procedure itself (26).

Figure 2: The Perioperative Care Framework (reproduced from the Australian and New Zealand College of Anaesthetists & Faculty of Pain Medicine (26))



Preoperative assessment and optimisation are considered to be key to good outcomes in surgery (22) and an important element in improvements to population health more widely (20). NHS England is the national body for the NHS in England and sets the operational priorities for the health system. Within the standard NHS contract for NHS secondary care providers, NHS England has introduced five core requirements related to the identification and optimisation of modifiable risk factors for surgery, which are mandated to be implemented by March 2024. Figure 3 presents these five core requirements, reproduced from the published guidance (23). Weight management is one of the recommended interventions in the optimisation to be offered to all patients. The guidance gives recognition that 'different organisations and systems will have different approaches to meeting these requirements', including the setting in which optimisation is offered.

Figure 3: NHS England's five core requirements for early screening and risk assessment for inpatient surgery, (adapted from NHS England guidance 2023 (23)**)**

Five core requirements

1. Screening for perioperative risk factors should be undertaken as early as possible in the patient pathway
2. Patients identified through screening assessment as having risk factors for poor perioperative outcome should receive proactive personalised support to optimise their health prior to surgery
3. All patients waiting for surgery should be contacted by their Trust at least every three months to check that they still want their procedure and that there have been no changes to their health status
4. Patients waiting for surgery should only be given a surgery date after they have had a preliminary perioperative risk assessment and been confirmed as ready for surgery from a general health point of view
5. Patients must be involved in shared decision making conversations to discuss the benefits, risks and outcomes of the surgery itself as well as the postoperative recovery period

1.6 Healthcare commissioning and policy decision-making

Decisions over healthcare policy in England are made at a number of levels. National-level guidance is provided through NHS England and the National Institute for Health and Care Excellence (NICE). NICE is an executive non-departmental public body, sponsored by the Department of Health and Social Care which delivers evidence reviews and assessments of health technologies, translated into recommendations and guidance for practice (27). While NICE guidance is considered to represent the gold standard of care in England, decisions over healthcare delivery are made by commissioning bodies in each locality in England. In 2012 clinical commissioning groups (CCGs) were formed to fulfil this role. These were the statutory NHS bodies charged with planning and commissioning the healthcare services for their locality, including elective hospital care and community care. Health and wellbeing boards in each locality facilitated joint decision-making between local authorities and healthcare systems. Mergers between some CCGs took place meaning that by April 2021 there were 106 CCGs in England (28).

In July 2022, CCGs were dissolved and 42 integrated care boards (ICBs) were formed in their place in England. Each ICB is situated within an integrated care system (ICS). ICSs are based on place-based partnerships which bring together the key organisations and groups in a locality to collaborate in decision-making and delivery of healthcare, health improvement and prevention. This includes local NHS services, local authority teams and the voluntary and community sector. ICSs comprise the ICB, which is the statutory NHS organisation responsible for NHS planning, budget management and service provision of healthcare within the ICS area, and an integrated care partnership (ICP) which is the statutory committee formed between the ICB and the local authorities within the ICS area. The ICP must produce an integrated care strategy for the population of the ICS in alliance with local stakeholders and organisations concerned with healthcare and wellbeing in the region (29).

The localised approach to planning and commissioning healthcare means that localised variation can arise. The commissioners have a statutory duty to commission healthcare ‘to meet the reasonable needs of the persons for whom they are responsible’, but latitude in decision-making is granted (30). CCGs, and now ICSs are able to design their own pathways to surgery, including eligibility for referral, mechanisms for triage and assessment, and approaches to health optimisation.

1.7 Intended effects of health optimisation for obesity in elective surgery

Pathways to surgery across the NHS are increasingly incorporating health optimisation interventions to encourage eligible patients to lose excess weight (21). In the NHS England guidelines referred to in Figure 3, weight management is one of the recommended universal intervention pathways (23). Health optimisation which addresses obesity in elective surgery patients is intended to provide a number of benefits (19–21):

1. Health improvement in the short term which
    a. Improves existing pathology/symptoms, increases quality of life and lessens the need for healthcare interaction.
    b. Improves the safety and outcomes of the surgery.
2. Initiation of behavioural change which is maintained in the long term to provide health benefits realised through the prevention of other pathology, or improvement in the safety and outcomes from healthcare interactions over a lifetime.

1.8 Joint replacement surgery

Hip and knee osteoarthritis is a leading contributor to the global burden of disease (31,32) and hip and knee replacement (arthroplasty) are two of the most common high-cost elective surgical procedures provided in the NHS (33). Approximately 100,000 hip and 120,000 knee procedures are undertaken in the UK each year (34). Osteoarthritis is a condition associated with increasing age in which the cartilage surface of the joints becomes degraded which may result in joint pain, stiffness and reduced function. Other risk factors for the development of osteoarthritis are female sex, obesity and joint injury (35).

The initial management pathway of osteoarthritis (36) involves advice on therapeutic exercise and weight management, followed by topical, oral and transdermal analgesia. If self-management and analgesia are not effective, the third line of treatment is referral to specialist care where patients may be considered for arthroplasty. In England, NICE guidance for people with osteoarthritis promotes behavioural management to achieve positive changes including the offer of interventions to support weight loss for patients who are overweight or obese (36). In 2015, NICE's osteoarthritis quality standard specified that commissioners "ensure that they commission services in which adults with osteoarthritis are not referred for consideration of joint surgery until they have been supported with non-surgical core treatments for at least 3 months" (37).

Hip or knee replacement procedures are highly effective at reducing pain and improving functional outcomes in patients with end-stage osteoarthritis (38,39). In the UK, one in 10 people can expect to receive a hip or knee replacement at some point in their lifetime (40). Demand is increasing with an ageing population and rising levels of obesity (41); even before the delays in access to surgery arising from the COVID-19 pandemic, more than half a million people were on the waiting list for elective orthopaedic surgery in England and Wales (42).

In line with rising levels of obesity, joint replacement patients have become increasingly young and more obese over time (43). Due to the high number of patients referred for surgery, and the role of obesity in the development and progression of osteoarthritis, hip and knee replacement patient pathways have been a prime focus for health optimisation for obesity. Commissioning organisations may consider the intended benefits of health optimisation to be important in addressing the financial and waiting list pressures faced due to high demand (44). Careful consideration of health inequalities is needed in alterations in access to joint replacement surgery. Analysis in 2021 revealed that groups already facing health inequalities, including those of lower socio-economic status and those from ethnic minority backgrounds, have a higher need for surgery yet face reduced access and poorer outcomes (45).

1.9 Restricting access to joint replacement surgery using BMI

Policies determining health optimisation practices for joint replacement surgery patients have been noted to vary across commissioning localities in England for many years (46). Policies range in severity from a recommendation that overweight patients are offered advice on weight management, to mandated extra waiting periods to engage with weight management, to the most stringent including BMI thresholds for surgical referral (47,48). Policies using obesity status or BMI to delay or deny access to joint replacement surgical referral, or which otherwise place mandatory requirements on patients to attempt to lose weight, are referred to as 'restrictive policies' within this thesis.

The Royal College of Surgeons stated that commissioning policies should be based on clinical need and not factors such as a patient's weight (49), yet around 50% of England's CCGs in 2016 restricted access to joint replacement based on BMI (46). A recent update to NICE guidance for the management of osteoarthritis is explicit that people should not be excluded from referral for arthroplasty because of being overweight or obese (36), yet BMI thresholds remain in use.

Where BMI thresholds limit access to surgery, it has been suggested that restrictive health optimisation policies present an interplay between rationing for resource preservation and health improvement (44,46,50). Existing literature highlights the ethical concerns around imposing thresholds for surgery and the rationing of healthcare based on lifestyle-related factors such as BMI (44,51). Public consultations undertaken by some CCGs considering the introduction of restrictive health optimisation policies found public support for restrictive approaches. Respondents framed obesity as an issue of personal responsibility and therefore a fair means of rationing healthcare, prioritising care for those who have ‘looked after their health’ (52).

Despite the longstanding use of commissioners’ policies regarding BMI-based restrictions for joint replacement surgery, few evaluations of their impact have been published and the evidence base for their effectiveness remains unclear (21,53,54). An understanding of the health economic impact of such policies is critical to allow balanced decision-making in their role in rationing of access to surgery, but is currently unaddressed.

Assumptions in health optimisation in need of investigation

The aim and objectives of this thesis were informed by my identification and categorisation of a number of assumptions within restrictive health optimisation approaches in need of further investigation, based on the background literature review (Chapter 2). In order for a restrictive health optimisation policy for obesity reduction in joint replacement patients to be effective in the short term, the following assumptions need to hold true:

1. Policy introduction results in patient engagement with weight loss
    a. Patients must be informed about the requirements
    b. Patients must accept the requirements and take steps to achieve weight loss
2. Patients can successfully lose weight
    a. Self-directed change is effective
        and/or
    b. Support services are available, acceptable, accessible and effective
3. BMI reduction is effective in
    a. improving joint symptoms or their course, thereby reducing the need for treatment
        and/or
    b. improving the safety and outcome of treatment
4. The benefits of delaying or denying access to surgery outweigh the costs

To be effective in the long term:

5. BMI reduction is maintained and results in sustained health improvement

Within these assumptions, consideration also needs to be given to differential effects on patients based on their demographics and characteristics. Health inequalities may result where there is a heterogeneous effect from a policy. Negative effects on health inequalities from health optimisation could result from different groups in society facing:

1. Higher obesity prevalence; restrictive policies disproportionately reduce access to NHS surgery for these groups. This is exacerbated when the ability to pursue independently-funded treatment also varies for these groups.

2. Lower engagement with health optimisation; patient capacity to engage with health improvement may be influenced by differences in their available time, resources and the health, mobility and social support needed.
3. Lower rates of successful health improvement in the short and long term; those that do engage with weight management may have lower success rates due to competing demands, capacity and resources, and higher exposure to obesogenic environments.

1.10 Aim and objectives

The aim of this thesis is to explore the restrictive approach to health optimisation for obesity in elective joint replacement healthcare delivery in the NHS in England. To guide future policy use, decision-makers require high-quality evidence on the impact of health optimisation approaches, to understand whether restrictive approaches increase inequalities in access to surgery and whether there are wider public health benefits to be gained by reshaping or extending their use. The thesis employs a mixed methods approach to meet the following objectives:

Objective 1:

i. *To ascertain the prevalence, trend in use and nature of commissioning policies in England that alter access to hip and knee replacement surgery based on patients' body mass index.*
ii. *To consider the implications of the transition to integrated care systems for policy prevalence and nature.*

Objective 2:

i. *To assess the association between the introduction of body mass index policies for hip and knee replacement patients and changes in trends in surgical rates and patient characteristics.*
ii. *To assess the association of body mass index policy introduction with impact on inequality in access to hip and knee replacement surgery and use of independently-funded surgery.*
iii. *To examine any differences in association related to the level of severity of the policy.*

Objective 3:

i. *To investigate the views of key informants about the appropriateness and effectiveness of current health optimisation interventions.*
ii. *To explore key informants' views on the role of evidence in health optimisation policy development and implementation.*
iii. *To explore key informants' views on the current and potential impact of health optimisation policies on health inequalities.*

Objective 4:

i. *To identify and describe the variation in economic models used recently to evaluate the long-term cost-effectiveness of policies or interventions to prevent or reduce overweight and obesity.*

ii. *To consider the implications of health economic modelling approaches for policy making in obesity reduction and prevention, including health optimisation approaches.*

Objective 5:

i. *To determine which weight loss support services or self-management were used by patients referred to secondary care for hip or knee osteoarthritis, why, and for how long, and any effect on the body mass index of others in the patient's household.*
ii. *To collate this information with routinely collected NHS data to explore associations between patient engagement and success with health optimisation and their baseline characteristics (sociodemographic information, clinical diagnosis) and their clinical and patient-reported outcome measures up to 1 year later.*

1.11 Methodology overview

The multifaceted nature of health optimisation invited complexity in my choice of methodology to meet the thesis objectives. Examination of the measurable policy position and associations between policy introduction and patterns in the provision of related surgical procedures (Objectives 1 and 2) required quantitative study. The 'empirical' epistemology involved in meeting these quantitative research objectives employed statistical techniques and consideration of cause and effect within studies intended to offer objectivity in their interpretation of the health and care context of health optimisation (55). The objectives centred on the way in which health optimisation policy is constructed and experienced (Objectives 3 and 5) were approached with qualitative research methods which offered greater depth of understanding of the meanings of the phenomenon of health optimisation (55). Objective 4 concerned the investigation of health economic modelling, contingent on the examination of health economic approaches using evidence synthesis methodology. Overall, therefore, the thesis employed mixed methods research methodology, which was chosen as a 'pragmatic' approach to research questions best explored through both quantitative and qualitative methods (56). It is acknowledged that academic discourse offers debate over the exact criteria for research meeting the mixed methods paradigm; in the context of this thesis I have considered mixed methods research to be defined as 'an approach to knowledge that attempts to consider multiple viewpoints, perspectives and positions, always including quantitative and qualitative standpoints' (57). Methodological detail is provided separately for each study presented in the thesis.

1.12 Structure of the thesis

The thesis is structured in eight chapters. Figure 4 depicts the ordering and headline content of each chapter. Following this introduction chapter, Chapter 2 provides a review of the literature regarding the current evidence base for health optimisation, the role of obesity and weight loss in patient and population outcomes, and the interventions available to support weight loss through behaviour change. Chapter 3 addresses Objective 1. It presents the descriptive study undertaken to determine the current and historic prevalence of restrictive policies in use in England for hip and knee replacement surgery. Chapter 4 presents the natural experimental study which made use of these data on the policy situation to investigate the association between policy introduction and changes in the rate and characteristics of hip and knee replacement surgery. This study addresses Objective 2.

Chapter 5 presents the qualitative study undertaken to address Objective 3. The study used interviews to investigate key informants' insight into the reasons for policy introduction and the effects seen from policy use. Chapter 6 addresses Objective 4 and presents a scoping review of health economic models available to address the health economic aspects of health optimisation policy use. Chapter 7 presents the design and methodology of a study intended to address Objective 5, and addresses the learning gained from this experience despite cessation of the study. Chapter 8 summarises the key findings from each preceding chapter, and discusses the thesis strengths and limitations. It then defines the impact and implications of the thesis findings, questions for future research and draws a conclusion.

Figure 4: Structure of the thesis

Chapter 1&2
Introduction and Literature Review

Research question:
What impact do restrictive pre-surgical health optimisation interventions for obesity in hip and knee replacement patients have on patient outcomes, are they cost-effective, and do they risk causing health inequalities?

Chapter 3
What is the prevalence and nature of body mass index policy use in hip and knee replacement surgery in England?

- Descriptive study of clinical commissioning groups' body mass index policy position from 2012-2021 (Objective 1)

Chapter 4
What effect has body mass index policy use had on access to hip and knee replacement surgery?

- Interrupted time series natural experiment studies examining associations between body mass index policy introduction and hip and knee replacement surgery rates and characteristics (Objective 2)

Chapter 5
What explanation and insight can key informants give on the reasons for policy use and considerations for health optimisation's future?

- Qualitative interview study with managerial and clinical professionals (Objective 3)

Chapter 6
How are health optimisation policies' purported effects on obesity reduction estimated and valued?

- Scoping review of health economic models available to value obesity reduction (Objective 4)

Chapter 7
What was the experience of the initiation of further methodology to address the research question?

- Report on intended methodology for further examination of elements of patient experience and outcomes, and wider learning gained from initiation of a questionnaire and data linkage study (Objective 5)

Chapter 8
Discussion and Conclusion

Chapter 2. Literature review

2.1 Overview

This chapter begins with a review of the literature on the key underlying assumptions for restrictive health optimisation in joint replacement surgery:

- that weight loss is beneficial for patients' general health and specifically for osteoarthritis (section 2.4)
- that obesity or higher body mass index are significant risk factors for poorer joint replacement outcomes (section 2.5)
- that weight loss is beneficial before joint replacement surgery (section 2.6)
- that referral to weight management behavioural support programmes is effective (section 2.7)

The chapter then addresses the available literature on the existing evidence for health optimisation approaches, including trials of pre-operative interventions in various settings, and the incorporation into clinical guidelines (section 2.8). Focusing on restrictive health optimisation policies, the chapter finishes with an examination of the literature regarding their acceptability (section 2.9), their impact on joint replacement surgery provision and costs and health inequalities (section 2.10). The key findings from each section, their implications for the thesis, and the evidence gaps remaining are presented in a summary table at the end of the chapter (section 2.11).

2.2 Methods

Searches for relevant literature for the context of this thesis were prepared with a subject librarian. Searches were made of the Ovid Medline and Cochrane Library electronic databases in the first instance. The search terms used are presented in Table 1. These terms were informed by the keywords from relevant literature already identified and were combined with relevant medical subject heading (MeSH) headings within the Medline search. Top-tier evidence sources were prioritised using filters for systematic reviews and meta-analyses and by purposive searches for evidence summaries from NICE and the Centre for Perioperative Care. Where recent evidence sources of these types were unavailable, the search was extended to include empirical studies including randomised trials, cohort studies and programme evaluations.

Hand searches were made of the reference lists and citations of the key literature identified via the electronic database searches. Specific searches were made for clinical and commissioning guidelines related to the search topics including through searches for grey literature using Google Search.

An Expert Advisory Group was formed for the purposes of my fellowship comprising clinical, academic and commissioning professionals with direct involvement in developments in health optimisation in the UK. Regular meetings with this group, along with my attendance at relevant conferences such as the Evidence-based Perioperative Medicine Conference and the UK Society for Behavioural Medicine Conference, and webinars and newsletters from the Centre for Perioperative Care and NHS England ensured awareness of key literature and updates in this topic.

The electronic searches were run in 2021 and 2022 and refreshed between August and October 2023.

Table 1: Search terms used in literature review

Main search term	Alternative search terms
Health optimisation	Optimisation, optimization, prehab*, pre-operative, peri-operative, pre-admission
Obesity	Obes*, overweight, body mass index, BMI, lifestyle
Weight loss intervention	Diet*, behavio* change, weight management, weight control, weight loss, reduction, risk management, intervention, program*, trial, pathway
Arthroplasty	Osteoarthritis, OA, joint replacement, hip replacement, knee replacement, orthop* surgery
BMI threshold	Body mass index threshold, cutoff, eligibility, referral criteri*, surgery denial, delay, withhold*, restrict*, barrier, mandatory, ration*

2.3 Knee and hip replacement surgery equivalence

This thesis considers both hip and knee joint replacement, as these procedures are generally subject to the same health optimisation policies at a locality level. However, these conditions are not without their differences in their relationship to obesity and weight loss. As detailed in section 2.4, obesity is a more significant risk factor for knee osteoarthritis and arthroplasty than for hip osteoarthritis. An observational study of the outcomes of hip and knee replacements over four years in the American College of Surgeons National Surgical Quality Improvement Program database concluded that the impact of obesity on postoperative complications is more profound for hip than knee replacement (58). Differences in practice are seen at the level of individual clinicians; a survey of American orthopaedic surgeons found that where given the choice, they were more likely to not perform hip replacements on patients with morbid obesity than knee replacements (59).

Clinical guidelines and recommendations also acknowledge this heterogeneity; however, NICE determined that evidence for weight loss in knee osteoarthritis could reasonably be applied to osteoarthritis in other joints given the systemic effects of obesity and the fact that osteoarthritis is a multi-joint disease (36).

2.4 Evidence weight loss improves general health and osteoarthritis in people with obesity

2.4.1 Prevention of ill-health and osteoarthritis

A recent large-scale prospective cohort study provided strong evidence for the health benefits of weight loss. The study examined the association between weight loss and the reduction of obesity-related outcomes in 500,000 patients in the UK Clinical Practice Research Datalink GOLD database. It found that intentional weight loss was associated with a reduced risk of developing type 2 diabetes, hypertension, dyslipidaemia, obstructive sleep apnoea and osteoarthritis six years later. The study also showed that even modest weight loss (5-10% of initial body weight) was associated with significant health benefits, though a 13% weight loss was necessary to significantly reduce the risk of osteoarthritis (60). A 2021 review of the benefits of larger amounts of weight loss (≥10% of body weight) also reported significant beneficial impacts on health-related quality of life with reductions seen in cancer risk, cardiovascular disease, sleep apnoea and osteoarthritis (61).

The cohort study authors do note however that "some changes occurring over a significant time period before diseases become symptomatic, such as cardiac remodelling associated with heart failure, may not be reversed by weight loss" (60). While cartilage degradation is considered to have a reversible phase (62), once symptomatic joint changes are present in osteoarthritis they are likely to be irreversible and weight loss may instead offer only a reduction in symptom progression.

The mechanisms through which obesity causes and affects the progression of osteoarthritis are not fully understood. Increased body weight causing increased force through joints is seen to be a logical explanation as each unit of weight lost results in a fourfold reduction in the load exerted on the knee per step (63). Systemic effects of obesity also play a role, however, as evidenced by the increased prevalence of osteoarthritis in non-weight-bearing joints in patients with obesity, thought to be mediated through inflammation (64).

2.4.2 Improvement in osteoarthritis

A 2007 meta-analysis of four randomised controlled trials of weight loss through diet and exercise for osteoarthritis patients reported that weight loss of 5% has a clinically relevant effect on disability (65). A synthesis of two more recent systematic reviews of randomised controlled trials of knee osteoarthritis interventions for diet-induced weight loss found that the interventions produced only modest weight loss and therefore only small improvements in pain scores which were not deemed to be clinically significant (66).

A further randomised controlled trial published after the completion of the systematic reviews in 2022 used osteoarthritis patients as the target for a weight loss intervention. Comparing six-month exercise and advice programmes with and without an additional dietitian-led intervention, the authors found that both programmes offered improvements in pain and function and that the additional dietary component modestly increased the level of improvement. The programmes were delivered remotely using video calls (67).

Two large prospective cohort studies, of circa 1400 patients each, have also investigated the effects of weight loss in patients with diagnosed knee osteoarthritis. One observed patients actively enrolled in a community-based weight loss programme for osteoarthritis (68) while the other used data from existing longitudinal cohort studies of osteoarthritis patients and did not determine the mechanism of any weight loss observed (69). Both studies had similar findings. At all levels of weight loss, including less than 5% of body weight, patients experienced improvements in quality of life and pain. A clinically significant improvement in physical function was recorded in patients who lost more than 10% of their body weight evidencing a dose-response effect of weight loss.

The 2022 randomised controlled trial did not report any health economic data (67). A 2021 systematic review of health economic analyses of lifestyle interventions for hip and knee arthritis identified only one study using dietary intervention, and this had produced no clinical effect and was therefore not cost-effective. Two further dietary programmes were delivered in combination with exercise interventions and in these cases, the interventions were cost-effective provided a 5-10% weight loss was achieved (70). A limitation of these studies was that a short term time horizon was used in each case, therefore there were no data on the maintenance of any weight loss.

2.4.3 Weight loss and the need for joint replacement surgery

A prospective cohort study of Australian adults has shown that higher BMI is associated with a higher risk of the need for a total joint replacement; a hazard ratio of 2.49 (95% CI 1.81–3.44) and of 1.65 (95% CI 1.08–2.51) for knee and hip joints respectively. The hazard ratios were even higher when impaired physical performance was already present (71). A modelling study using Irish healthcare and population data estimated that 43% of knee and 20% of hip replacements were attributable to obesity (72).

For health optimisation to be effective in reducing the amount of surgery required, weight loss must succeed in reducing the need for surgery for patients with obesity. In a cohort study of overweight and obese adults with no current osteoarthritis diagnosis, every 1% weight loss was associated with a 2% reduction in the risk of knee replacement and a 3% reduction in the risk of hip replacement if they had hip pain at baseline (73). However, consideration needs to be given to the timing of weight loss in its importance in reducing the risk of progression to joint replacement for osteoarthritis patients. A randomised trial (n=5125) in the United States of America (USA) for an intervention offering intensive lifestyle interventions to achieve 7% weight loss in diabetic patients with overweight or obesity, showed no difference in progression to knee replacement against the standard care. When the analysis was restricted to those without any knee pain at baseline, the weight loss intervention gave a 29% reduction in the risk of knee replacement indicating weight loss may be most beneficial earlier in the osteoarthritis pathway (74).

2.5 Evidence that obesity is associated with arthroplasty outcomes

2.5.1 BMI's association with arthroplasty outcomes

Aside from the role of achieving weight loss in the prevention and progression of osteoarthritis, the logic of health optimisation approaches during the perioperative period also relies on the assumption that surgical outcomes are poorer for arthroplasty patients who are obese. NICE completed an evidence review on this question for the purposes of informing their update to the osteoarthritis management guidance (36,75). Fifteen relevant cohort studies were included in the analysis and examined outcomes of mortality, health-related quality of life, surgical complications, post-operative patient-reported outcome measures (at 6 months or 1 year) and reoperation or revision to the prosthesis. While meta-analysis was not possible between these studies, NICE concluded that the substantial improvements in quality of life achieved in all BMI categories meant that in general, total joint replacement benefits outweighed the marginally higher risk of adverse events seen in higher BMI categories. Mortality was not seen to be increased with higher BMI.

2.5.2 BMI thresholds and arthroplasty outcomes in very high BMI

Multiple individual studies report associations between obesity and various surgical outcome measures, leading review authors to conclude that there is evidence that wound infection, joint infection, dislocation and revision are associated with obesity to some degree (76). Studies have since sought to address the evidence for a logical threshold of BMI in determining clinically significant increased risk. A cohort study of around 18,000 joint replacement patients noted a gradual increase in joint infection risk with increasing BMI, but did not recommend the use of any BMI thresholds (77).

Studies of exclusively patients in the highest BMI categories (BMI ≥40 kg/m^2) undergoing knee replacement have found that there are substantial increases in the risk of perioperative complications including infection, and length of stay (78,79). A UK cohort study of 493,710 total knee replacements in the National Joint Registry (NJR) examined the association of obesity with surgical outcomes. Noting that where differences in revision rates and patient-reported outcome measures are associated with higher BMIs, Evans et al. report that the outcomes achieved still reach recognised thresholds of acceptability and that therefore there is 'no support for rationing total knee replacement based on increased BMI' (80).

Due to the fact that the highest improvements in patient-reported outcome measures and quality of life are seen in patients with higher BMI (81), the increased costs associated with surgery in this group still allowed Chen et al. to conclude in their economic analysis that total knee replacement offers good value in patients with BMI ≥40 kg/m^2, including those with multiple comorbid conditions, at a $55,000 per quality-adjusted life year willingness-to-pay threshold (82). A UK analysis of knee replacement procedures estimated an overall cost of £5623 per quality-adjusted life year gained and found no significant effect of BMI on costs or outcomes (83).

2.5.3 The obesity paradox

Observation of an 'obesity paradox' in the outcomes of joint replacement surgery has been noted in the literature, further complicating the ability to recommend BMI thresholds for these patients. Examination of BMI as a continuous measure in its association with complication rates from hip replacement in patients younger than 60 reveals a U-shaped curve. The lowest risks are observed in the BMI 35-40 kg/m^2 range, contrary to the expectation that patients with a 'healthy' BMI would experience the best outcomes. No such U-shape was observed in older patients, and complication rates were noted to be generally higher in females (84).

Zhang et al. highlight that the issue of patient selection - whereby only the healthiest patients with obesity are operated on - may skew the available data on BMI-associated risk of mortality in joint replacement surgery. They suggest that the obesity paradox whereby patients with obesity are seen to have less risk of mortality than patients with lower BMI may be an artefact of this selection (85). A review of the evidence for the obesity paradox within joint replacement patients noted the high number of studies reporting the paradox, and the consistency in their findings, but considered that improvements in baseline comorbidities data were still necessary to determine whether the paradox is a true effect or a result of confounding (86).

2.6 Evidence for benefits from weight loss before arthroplasty

2.6.1 Consensus on whether weight management should be included in pre-operative care for arthroplasty

Expert opinion in a review article in 2019 noted that while there was some evidence that obesity was a risk factor for poorer outcomes in knee arthroplasty, the situation remained controversial regarding how to address obesity in arthroplasty patients. Citing Liu et al.'s 2015 review of weight loss interventions in this patient group (87), the limited evidence for pre-operative interventions was highlighted. In one case, poorer post-operative outcomes had been reported following diet-based pre-operative interventions. The authors concluded that while weight loss should be routinely recommended, the appropriate intervention to achieve this was uncertain (88).

A UK-based Delphi process study to determine a consensus on pre-operative care for knee replacement patients was completed in 2021 (89). A strength of the study was its inclusion of osteoarthritis patients and commissioners alongside the clinical experts. Weight management was deemed 'important' but not one of the 12 'very important' elements of pre-operative knee replacement education such as rehabilitation and pain management. There was also consensus that it was important that patients with a BMI of 27 kg/m^2 or over should be referred to a weight management programme. This recommendation was described as likely to be costly and challenging to implement in practice, and a research recommendation was made for an investigation into whether specific subgroups of patients benefit from weight management.

2.6.2 Existing guidance on weight loss for osteoarthritis patients

NICE guidance for the management of osteoarthritis states that people who have excess weight or are obese should be advised to lose weight in order to improve their quality of life, physical function and pain. Patients should be supported to choose a weight loss goal and counselled that any amount of weight loss will be beneficial but that losing 10% of their body weight will be better than 5% (36). Clinicians are directed to the NICE guidelines for the management of obesity with regard to the interventions that can be offered to support patients in weight loss (11).

Where osteoarthritis patients have been referred for joint replacement surgery, there is no further specific guidance on weight loss. The 'Preoperative Assessment and Optimisation for Adult Surgery' guidance provided in 2021 by NHS England in collaboration with many other clinical professional bodies, makes only small references to obesity. The guidance states that shared decision-making should be undertaken with patients and that discussions should include 'modifiable risks which include physical inactivity, poor nutrition, and obesity (90). Related publications from the guidance authors further state that all elective surgery patients 'should receive general dietary, exercise and lifestyle advice' (22).

2.6.3 Quantifying the effect of weight loss on arthroplasty outcomes

Studies examining the evidence for the benefits of weight loss on the outcomes of arthroplasty itself are limited. The two studies identified on this topic focus only on patients with a BMI ≥40 kg/m^2, which therefore limits their applicability to arthroplasty patients in the UK. While literature in section 2.5.2 concluded that joint replacement surgery is itself cost-effective in patients with a high BMI despite their heightened risks, these studies suggest that if substantial weight loss is possible then this would be a cost-effective intervention before surgery. Kostic et al. compared the clinical and economic implications of surgical and non-surgical weight loss strategies for patients considering a total knee replacement. The study findings were that proceeding to arthroplasty without prior weight loss was not 'economically efficient' and that bariatric surgery before joint replacement offers good value. The use of non-surgical weight loss strategies was seen to increase the number of patients proceeding to joint replacement as their lower BMIs increased their eligibility for surgery (91). A retrospective cohort study by Keeney et al. sought to determine how much weight loss was necessary to improve surgical outcomes for arthroplasty patients. They concluded that only a loss of at least 20 pounds (9 kg) would produce a clinically significant effect for patients with a BMI ≥40 kg/m^2 (92).

Godziuk et al. provided a review of the pre-operative weight loss recommendations for knee replacement patients from various international organisations and the evidence behind them in 2021. They report that while some studies have found benefits for weight loss in osteoarthritis, they have tended to exclude patients with higher BMI (≥40 kg/m^2) or patients with advanced joint disease. The authors concluded that the current evidence base is not strong enough to make broad recommendations about weight loss approaches in this patient group, but that assessment of body composition, co-morbidities and other individual patient needs should be at the core of decisions (93).

2.6.4 Evidence for weight loss resulting in a return to normal risk

There is little published evidence examining whether outcomes in patients who were formerly obese are equivalent to outcomes in patients with equivalent BMI at the time of surgery but who had never been obese. A cohort study by Inacio et al. following circa 15,000 joint replacement patients with obesity in the USA investigated differences between those who had lost, gained or maintained their weight in the year before surgery (94). Weight loss was recorded in 12.4% of the knee replacement patients and 18% of the hip replacement patients. They found no significant difference between the groups for their main outcomes of interest which were surgical site infection and readmission rates. A limitation of this study was that no further outcomes were measured and the authors acknowledged that there may be other outcomes which are sensitive to the effects of weight loss such as speed and ease of rehabilitation.

2.6.5 Concerns over the effects of weight loss

Literature does raise concerns over the potential harm of advising intentional weight loss in the pre-operative period. Undernutrition and deconditioning are potential consequences of rapid weight loss with inadequately managed calorie restriction (95). Hip and knee replacement patients with malnutrition experienced worse outcomes from their joint replacement surgery (96). In a review of dietary interventions in joint replacement patients, the authors cited evidence that patients with obesity are already at risk of nutritional deficiencies and therefore caution must be taken in ensuring appropriate pre-surgical dietary advice is provided, particularly where the goal is weight loss. A safer approach would be to address weight loss earlier in osteoarthritis where surgery is not yet a concern (97). Studies of the differential effects of rapid and gradual weight loss indicate benefits on the preservation of resting metabolic rate with more gradual change (98). Where restrictive health optimisation may incentivise patients to attempt rapid weight loss to lessen any delay to their surgery, the approach may be responsible for metabolic compromise.

In the longer term, a study of knee replacement patients with initial BMI ≥40 kg/m^2, showed that significant weight loss (≥5% BMI loss) before surgery led to a “rebound” in weight gain, and subsequently the risk of needing revision surgery (99).

2.7 Effectiveness of referrals to behavioural change interventions for weight loss

2.7.1 General weight management interventions

Where health optimisation pathways are dependent on referring patients to existing behavioural change programmes, the literature on the effectiveness of these programmes is informative in gauging how successful health optimisation may be. NICE guidance on dietary, lifestyle and behavioural interventions was created in 2014 (12). The evidence summaries published alongside these guidelines concluded that ‘overall, the evidence broadly supports the recommendation that lifestyle weight management programmes that include components addressing diet, physical activity and behaviour change are effective at reducing weight among overweight and obese adults’ but do not provide data on levels of expected weight loss within these interventions, and also cautioned that the evidence for the long-term effectiveness (>12 months) of lifestyle weight management programmes was weak (100).

The Office for Health Improvement and Disparities in England collects a minimum dataset from local authority-commissioned tier 2 (community-based, lifestyle-focused) weight management services. Data were available from 87% of local authorities in England in 2022 revealing that 134,445 adults had been referred to these services with 65% of these consequently enrolling on services. Weight loss was achieved by 43% of those who undertook an intervention, though only 37% completed the interventions offered and only 16% lost at least 5% of their initial body weight (101). These figures represent a very small proportion of the number of adults eligible for weight management interventions; an expansive cohort study in England (n= 1,811,587) found that only 3% of adults recorded as overweight or obese in primary care had been referred to a weight management intervention in the years 2007 to 2020 (102). A limitation in the interpretation of this study is that reliance on a primary care record of being overweight or obese creates an underestimate of the total proportion of patients referred to weight management given that many of them will not be identified in records. It cannot be assumed, therefore, that joint replacement patients will access weight management services through primary care in the pre-operative period without additional facilitation.

A systematic review undertaken in 2021 sought to review all previous meta-analyses of non-surgical weight loss interventions for adults with a BMI ≥25 kg/m^2. The review separated interventions into categories including diets, behavioural change therapy, technological interventions and combination interventions. Behaviour change interventions included techniques such as self-monitoring, goal setting and habit changing in lifestyle factors such as diet or physical activity or motivational interviewing. In the technology intervention studies, participants received weight management support through the use of apps or online platforms, or by telephone in interventions ranging from 4 to 120 weeks. Meta-analyses of these intervention types revealed only minimal weight loss (<2 kg). In contrast, the meta-analysis of diet studies found that commercial diet interventions such as Weight Watchers group meetings, reported higher weight loss of around 8 kg in the short term, although weight regain was reported in studies with 12-month follow-up data. Meta-analysis of combination interventions – whereby participants received multimodal interventions covering at least two of diet, physical activity, lifestyle modification, behaviour change or counselling, concluded that meal replacement plus individual support was most effective, offering around 6 kg weight loss (103). An earlier systematic review of group-based intervention delivery reported that such settings were effective for modest weight loss at 12 months, particularly in men-only groups (104).

In a separate systematic review in 2022, Madigan et al. examined the behavioural change weight management interventions provided in UK primary care, finding 34 trials with follow-up data of at least 12 months. The mean difference in weight between the intervention and the comparators of no treatment or minimal intervention was -2.3 kg (95% confidence interval −3.0 to −1.6 kg) at 12 months, falling to -1.8 kg (−2.8 to −0.8 kg) at 24 months. Participants who had ≥12 contacts during interventions lost significantly more weight than those with fewer contacts. The authors concluded that primary care behavioural weight management interventions are effective for the general population but did not analyse the interventions' costs or the equity of delivery and effect (105).

2.7.2 Cost-effectiveness of weight management interventions

NICE undertook cost-effectiveness analyses of weight management interventions in 2013 and determined that weight regain is the key factor in whether or not interventions are cost-effective. Interventions were only cost-effective where weight loss is maintained for at least three years. A loss of 0.6 BMI points maintained over a lifetime was found to be cost-effective for all adults who are overweight or obese (106). A recent systematic review of randomised trials of behavioural weight management programmes found that few studies followed up their participants for more than five years. Despite some weight regain, the meta-analysis of 124 trials showed that weight loss resulted in reduced cardiometabolic risk factors five years after the programme's end (107). A health economic analysis from the same group recommended that programmes offering initial weight loss and despite subsequent regain would be cost-effective if delivered for under £560 per person (108). Changes in joint disease were not directly addressed in these studies. In their health economic study of 2019, Losina et al. concluded that adding an intensive diet and exercise weight management intervention to usual osteoarthritis care is highly cost-effective with an 8-year programme giving the best cost-effectiveness (109).

2.7.3 Weight loss through brief intervention

Achievement of weight loss with minimal time input from pre-operative clinicians may be of importance to the design of health optimisation programmes. Discussion and advice on weight management may be raised as a 'brief intervention' by a clinician in a healthcare interaction that is part of the surgical pathway. In a trial where the brief intervention comprised a 30-second interaction in primary care, the mean weight loss at 12 months was 2.43 kg, which was 1.43 kg (95% CI 0.89 to 1.97 kg) more than in the comparator (110). Notably this brief intervention required the clinician to achieve the offer of referral to an effective weight management programme, ensure that the patient left with an appointment, and offer follow-up and is therefore reliant on the availability of weight management programmes.

2.7.4 Self-directed weight loss without formal intervention

Where no formal intervention is available or acceptable, self-directed efforts at weight loss may form the necessary mechanism of effect when a pre-operative patient is given the advice to lose weight. The high proportion of adults making weight loss attempts and the rising prevalence of obesity is evidence of the fact that the majority of weight loss attempts do not result in lasting weight reduction; a 2021 survey reported that 43% of adult Britons are actively trying to lose weight (111). Attempts at weight loss are even higher in groups with obesity; 76% with a BMI $\geqslant$30 kg/m^2 (112).

2.7.5 Inequalities in weight loss interventions

Any inequalities in weight management interventions would contribute to the impact on inequalities of health optimisation. Differences could be seen within intervention uptake, adherence, attrition or weight loss outcome. A 2022 systematic review of inequalities in randomised controlled trials of behavioural weight management interventions found no gradient in inequalities based on these factors (113). However, only 56 of the 103 trials included collected the necessary data to examine inequalities and randomised controlled trials are not the usual setting for weight management delivery within health optimisation. A trial in 2016 examining the inequalities in uptake of a commercial open-group behavioural weight-loss programme offered via primary care referral in England did find that uptake was lower in males, younger people and people living in more deprived areas. The authors concluded that a substantial proportion of the lower uptake by males was due to practitioner bias in which patients were offered the intervention (114).

Inequalities have also been noted in the referral to weight management programmes in the general population. In the large cohort study of referrals to weight management in England, geographical inequalities were observed in referral rates and patients with lower BMIs (but still eligible for intervention) were less likely to receive referrals (102). Within osteoarthritis, a study of 1,273 knee replacement patients in Canada found that the use of recommended non-surgical treatments (including weight loss) had been lower in older patients, men and those with lower levels of education and income (115).

2.8 The evidence for health optimisation in elective care

2.8.1 Theory of behaviour change - the teachable moment

Lawson and Flocke conceptualise the ‘teachable moment’ in the theory of behaviour change within health and wellbeing (116). In healthcare interactions, the teachable moment is generally viewed as a favourable occasion in which a patient is receptive to education or advice from their clinician, when interventions may work better than if they were introduced at another moment. The authors describe the concept within the Health Beliefs model whereby cues to action and perceived threats and benefits to health can influence behaviour. They argue that these moments could be created to the benefit of healthcare interaction outcomes. Literature has specifically described the teachable moment in the perioperative encounter – whereby a patient's contemplation of surgery provokes a wider consideration of their health and an opportunity for their clinician to recommend actions they could take to make improvements and lower their surgical risk (117,118).

Lifestyle and behavioural change are key targets in which to engage patients in the pre-operative period and so information and encouragement to address these issues may be provided in person by a clinician, or in standard written information. A review of patient information sheets provided to knee replacement patients found that in 2021, 59 acute Trusts in England provided such leaflets, and 47% of these included information on lifestyle interventions (119). Only publicly available resources were searched for, therefore it is unclear what proportion of other Trusts provide such information. It is also unclear what impact the provision of leaflets of this type has as evaluations have not been published.

2.8.2 Patient-reported motivation for weight loss in osteoarthritis

Teachable moments need to align with motivation on the patient's behalf for the behaviour change in question. Evidence shows osteoarthritis patients do consider weight loss to be a worthwhile pursuit; in one study from an orthopaedic outpatient setting, 56% of adults reported trying to control their weight (120). In a survey study of pre-operative patients in general in the UK (n=299) 73% were either overweight or obese. Substantial patient motivation for weight loss was reported by these patients, in line with the value of the teachable moment in this setting. Patients prioritised benefits to their peri-operative outcomes over long-term health improvement. However, the low confidence levels for successful weight loss observed in participants led authors to conclude that structured support for behavioural change would be required to facilitate change over and above advice alone (121). Levett et al. provided expert opinion in a review of the evidence for psychological interventions in prehabilitation. While they conclude that evidence is not yet available from trials of psychological interventions in the pre-operative period, they may play a role in improving low self-efficacy which may produce benefits when offered in concert with weight management interventions (122).

Perceived difficulties with weight loss are often attributed in part to difficulty exercising due to osteoarthritis symptoms, which may lead patients to rely on joint replacement to facilitate later weight loss (123). Studies examining the patterns in weight changes following joint replacement do not support the contention that improved pain and function will naturally produce weight loss after surgery; a scoping review in 2021 found a split in studies reporting post-surgical weight loss or gain for patients with obesity (124).

Where restrictive policies are in use, the mandatory nature of engagement with weight loss may change the patient's perception of the teachable moment offered by the contemplation of surgery. The authors of a qualitative study interviewing patients facing a mandatory health optimisation programme whereby patients with a BMI over 30 kg/m^2 were delayed in accessing referral to elective surgical care for six months reported that patients described negative experiences. Patients could choose to access weight management support services during the extra six months. Participants reported that they found the situation stigmatising and felt that obesity was in part a consequence of their wider environment rather than only a personal responsibility

(125). In contrast, patients in another small qualitative study which I led in 2019, prior to the start of the thesis work, of a similar programme, found that addressing weight loss before surgery was broadly acceptable and an expected recommendation from their clinicians (126).

2.8.3 Evidence from existing trials of health optimisation for obesity in elective care

The most comprehensive review of health optimisation literature has been published in an evidence summary by the Centre for Perioperative Care in 2020 (127). The review considered a broad definition of perioperative care across all surgery types, of which prehabilitation including nutritional interventions was one individual element. The review concluded that overall there is strong evidence for perioperative care in reducing length of stay, complication rates and post-surgery intensive care. Effects were also seen in the costs of healthcare and in patient satisfaction and empowerment. When the evidence for prehabilitation was considered separately, the strongest evidence of impact was for reductions in complications, length of stay, readmissions and healthcare costs. None of the analysis of prehabilitation reported on direct interventions or outcomes regarding obesity or BMI and therefore the impact of prehabilitation was centred on physical activity, smoking cessation and alcohol reduction interventions rather than dietary or behavioural weight loss interventions. The main systematic review identified in the publication for evidence within hip and knee replacement surgery was that by Cabilan et al. from 2016, which likewise did not address any evidence regarding health optimisation for obesity (128).

In a systematic review of randomised controlled trials of prehabilitation, published in 2021, Perry et al. included 178 studies across all types of major elective surgery. Although 11 studies involved prehabilitation interventions for weight loss, these were generally restricted to bariatric surgery patients and there was no evidence reported for hip and knee replacement patients. Overall the authors reported that the quality of evidence for prehabilitation interventions remained too low to draw firm conclusions about their effect (129).

Pritchard et al. looked at whether the perioperative encounter is successful in promoting increased physical activity over the medium to long term after surgery, which may be an analogous element of health improvement. Despite a meta-analysis of 57 trials, the results were not precise enough to conclude that longer-term physical activity definitely increased as a result of pre-operative interventions. The authors noted the importance of expanding analyses to better understand the differential effects on patient groups in order to consider health inequalities within prehabilitation interventions (130).

Most recently, a systematic review addressed behavioural interventions for prehabilitation and included 67 trials. Some evidence was reported that these interventions reduce length of stay by 1.5 days, with the main pre-surgical measures showing improvement from the interventions being physical function and smoking cessation. Four of the trials addressed body mass index and none of these reported a difference in BMI between groups at the point of surgery. The review also sought to determine whether there was evidence that the interventions resulted in long-term retention of behaviour change, and whether there was any impact on health inequalities. The only measure reported with enough completeness at 12 months post-surgery was smoking cessation; no difference was maintained at this time point. None of the studies reported on socio-economic status or inequality therefore no conclusions could be drawn on this measure (131).

An individual trial of pre-surgery interventions in the Fit-4-Surgery programme centred in Southampton reported specifically on patients' behaviour change intentions (132). The intervention included sessions on physical activity, alcohol consumption, smoking and diet. A majority of patients (60%) reported that they planned to make behaviour changes and in those who completed post-operative questionnaires (n=234), 46% self-reported more physical activity and 41% self-reported dietary improvement. The trial included elective major surgery but did not include orthopaedic patients, therefore, the results may not be directly applicable to arthroplasty and there was also no measurement of changes in BMI.

2.8.4 Health optimisation interventions in osteoarthritis patients

General health optimisation programmes

The PREP-Well project introduced a community-based prehabilitation service for patients referred for major elective surgery, including joint replacement, thought to be the first of its kind (133). It was developed by a cross-health sector partnership including primary care, secondary care, commissioners and public health in the north of England in 2018. The service was offered in parallel to the existing pathway to surgery and was not mandatory, therefore it did not form a restrictive health optimisation approach. The service design sought to make use of the teachable moment of impending surgery. Lifestyle risk factors including obesity, smoking, alcohol use and physical activity, as well as modifiable clinical risk factors such as anaemia and sleep apnoea, were assessed and then addressed in supervised sessions across a median of 8 weeks. The intervention for obesity comprised brief advice on a healthy diet, followed by onward referral to the existing local weight management services. The evaluation of the 12-month pilot phase reported that of the 159 referrals to the service, 75 patients (47%) agreed to participate. Overall there were positive findings from the service – the concept proved practical and could be delivered at a cost of £52 per patient per week. The mean cost per patient was £404.86 (standard deviation £285) although orthopaedic patients were noted to have the highest cost by specialty. The majority of participants reported satisfaction with the service and an improved risk factor profile. Health-related quality of life was measured using the EuroQol 5D tool and participants showed an average of a 45% improvement at three months after surgery from service entry. No comparison of EuroQol 5D changes in a control group or in those declining participation were reported however. Of those agreeing to participate, only three patients had obesity therefore there is limited evidence for the effectiveness of the service for this specific risk factor. The use of clinical champions to screen patients, dedicated funding and a project manager were key features likely to have contributed to the success of the service, and these were included in the stated costs per patient.

A further individual trial found benefits from a health optimisation programme, although the outcome reporting does not make it possible to determine the impact of interventions for obesity within the overall effect (134). The trial was for a cohort of hip and knee replacement patients in the USA; a pre-operative optimisation protocol was used to highlight modifiable risk factors to the patient's surgeon 4-6 weeks before surgery. The post-implementation cohort had a shorter average length of stay than their pre-implementation counterparts (1.9 days vs 2.2 days, $P < .001$) and lower direct healthcare costs. However, it was not recorded which interventions, if any, patients with obesity pursued and with what success, nor whether the surgeons advised or required any additional time before surgery to allow the obesity to be addressed. Given that only 13% of the cohort (n=40/314) had obesity, it is unlikely that weight loss played a significant role in the observed outcomes of the optimisation intervention.

Health optimisation for obesity programmes

In the recent systematic review of randomised controlled trials of preoperative behaviour change interventions, 11 studies were identified which included interventions addressing physical activity and dietary intake (131). Only one of these studies was undertaken in orthopaedic patients. In this study, Liljensøe et al. trialled an 8-week low-energy diet in patients with obesity before total knee replacement, comparing this with standard care. While the intervention group showed an average of 10% body weight loss, there were no significant differences in the outcomes of their knee surgery after one year. The weight reduction was retained at one year, and in comparison, the control group saw no change in their weight (135). Weight loss was only measured post-operatively and therefore it was not possible to determine whether pre-operative weight loss was different between the groups. With only 38 patients in each study arm, this trial provides only very limited evidence for the impact of the intervention and is not representative of the type of behavioural weight management interventions available to patients in the UK as a first-line.

An earlier systematic review in 2021 sought to identify evidence from all trials of pre-operative non-surgical weight loss interventions for patients with obesity due to have hip or knee replacement surgery (136). The review included non-randomised trials, and dietary interventions in addition to the behavioural interventions which were the sole focus of the other recent systematic review. The review used a comprehensive search strategy and found seven studies which met the inclusion criteria comprising two randomised trials and five single-arm case series. Four of the studies used medically monitored low-calorie diets, one used pharmacological interventions while the remaining two used counselling and behavioural change alone. Overall analysis with the systematic review of all seven studies estimated that such interventions produced pre-surgical weight loss in the range of 5 to 32.5 kg but could not conclude whether there had been an impact on surgical outcomes.

Both of the randomised trials included in the review were for low-calorie meal-replacement diets and were considered to have had a high risk of bias due to a lack of blinding in the trial assessors. One was the Liljensøe et al. study described above, while the other used a three-month programme of meal-replacement shakes compared against dietary advice to reduce daily calorie intake by 500kcal (137). The intervention group achieved an average weight loss of 7.56 kg, however, even the dietary advice group achieved an average weight loss of 5.18 kg and this may be more analogous to weight management programmes offered in surgical pathways in England. Lipid profile and insulin resistance showed greater improvements in the intervention group but there was no difference in post-surgical co-morbidity measures, though this was a small study of 40 patients in total.

The main study using behavioural change counselling and dietary advice for an intervention was Lingamfelter et al.'s 2020 case series study from the USA (138). It reported outcome measures from patients (n=133) who agreed to work with a dietitian as they were ineligible for joint replacement surgery until they could reach a BMI threshold of 40 kg/m^2. A mean weight loss of 7.7 kg was achieved, with 92% of the patients losing weight. Surgery was then possible for 64% of the patients, however, it is not clear whether outcomes or characteristics were considered for patients ineligible for surgery due to their BMI but who did not receive dietitian input. A further issue was that patients lost to follow-up (22/133, 17%) were excluded from the analyses and reasons for their failure to complete the intervention were not provided.

Two earlier studies were not included in either of the systematic reviews, though they are of relevance as they address behavioural interventions of the type that may be offered in the UK. The first was a small study (n=16) which randomised total knee replacement patients with obesity to a behavioural weight management programme either before or after their surgery. While both groups achieved weight loss and improvements in function and patient-reported outcomes at the 26-week follow-up, it was noted that the post-surgical intervention was more effective for weight loss (139). A related qualitative study by this group found that knee replacement patients' preferences for a weight management programme were that it starts before surgery, is at least 6 months in duration, is delivered remotely, and focuses both on diet and exercise. The primary motivation participants gave for weight loss included symptom improvement in order to delay or reduce the need for surgery, but was most commonly to alter physical appearance (140).

The second study was for an intervention which included 12 weeks of dietitian-led weight management alongside exercise and pain medication for knee osteoarthritis patients and was investigated in a randomised controlled trial in Denmark (141). The groups in the trial either received joint replacement surgery prior to the intervention or did not. At the 12-month follow-up, non-surgical patients had lost an average of 2.5 kg, while surgical patients had no change in weight. The group receiving surgery had greater pain relief and functional improvement after 12 months, however, most of the non-surgical group did not go on to have surgery in the year after the intervention.

2.8.5 Digital pre-operative interventions

Recent trials of pre-operative interventions increasingly use digital tools such as smartphone apps, web-based tools and wearable monitoring devices. A 2022 review by Seward and Chen could identify no research on mobile health weight loss interventions before orthopaedic surgery, but found evidence that more generally, weight loss interventions delivered on smartphone apps combined with counselling produce short-term results of around 5 kg of weight loss (142).

A 2021 scoping review sought to identify literature regarding peri-operative digital behaviour interventions, including dietary intake. The majority of studies identified were interventions for smoking cessation and were feasibility studies rather than trials. No studies were identified that reported outcome measures regarding weight loss or BMI. From the limited, available evidence the authors noted that participant satisfaction measures were high with these digital interventions, but that small number of participants and study designs prevented any synthesis of other outcome measures (143).

A trial is planned in the UK to randomise 200 pre-operative hip and knee replacement patients to lifestyle intervention via a smartphone app, to include dietary change and physical activity, but thus far only the protocol is available (144).

2.8.6 Evaluations of restrictive health optimisation programmes

A lifestyle management programme introduced for osteoarthritis patients with a BMI over 35 kg/m^2 in Wales had stated aims of reducing BMI, improving general health, improving surgical outcomes and reducing the overall cost of elective orthopaedic pathways. Patients became eligible for referral to a surgeon for consideration of hip or knee replacement if their symptoms persisted despite achieving a 10% weight loss or a BMI below 35 kg/m^2. Patients who failed to achieve this weight loss could be considered for surgical referral in a multi-disciplinary team meeting. The clinical impact was evaluated only in an unpublished service evaluation, referenced in qualitative work by Law et al. It noted small, nonsignificant improvements in BMI, body weight, and hip and knee function scores (145). Attrition in the use of the intervention had been high; only 14% of those referred completed the 32-week intervention despite 87% of patients attending the first session of the programme. The qualitative study aimed to understand the reasons for the low impact of the programme and used focus groups and interviews with patients and professionals involved in the programme. Patients reported having been discouraged from participation by inconvenience, cost, lack of readiness to change and embarrassment. In combination with the findings from the professionals, a recommendation was made that the delay to the referral for surgical opinion should be ceased and that shared decision-making and increased psychological support may increase participation. It was also recommended that the programme focus on patients earlier in the orthopaedic pathway before symptoms became severe enough to require surgery.

In a feasibility study I led before the start of the thesis work, of the evaluation of a mandatory 12-week additional wait before joint replacement for patients with obesity in one CCG in England, data were available that indicated while 37% (184/502) of patients were eligible for health optimisation, only 28% of this comparatively deprived patient group accepted referral to the support offered (54). Patients who accepted referral to support and completed the programme had a larger median reduction in BMI than those who did not accept referral (− 1.8 BMI points vs. − 0.5). Forty-nine per cent of patients who accepted support were subsequently referred to surgery, compared to 61% who did not accept referral to support. Data on surgical outcomes or longer-term measures of health were not available. In my accompanying qualitative study of the same health optimisation programme in 2019, positive experiences were reported by some patients who had accepted referrals for support who found the group sessions on offer to be acceptable and beneficial in their efforts at weight loss (126). Their motivations for weight loss included symptom improvement and avoidance of surgery. Patients who did not accept referrals mostly stated that their reasons had been that they had no confidence in weight management programmes having already had multiple failed attempts at dieting in the past. A limitation of this small study was that patients with low engagement in health optimisation may have been less likely to respond to the study invitation.

Qualitative studies of weight management programmes directed at knee osteoarthritis patients, without any alteration to surgical referral eligibility, have been more positive. In one programme, patients reported positive experiences and achieved improvements in knee pain and function. Adequate social and professional support for patients in the programme was deemed crucial for the programme's success (146). Despite having no restrictive element, in the PREP-Well study in England, 50% of patients declined the offer of prehabilitation before surgery (35% of whom were orthopaedic patients). They cited travel difficulties, cost, time commitments during working hours and discomfort with group environments as reasons for declining (133).

2.9 Ethical dimensions of restrictive health optimisation policies

2.9.1 Personal responsibility

Published ethics literature has considered whether rationing NHS elective surgery on the basis of obesity is considered just on the premise that obesity is a modifiable state within the personal responsibility of individual patients. A review of commissioners' stated reasons for using restrictive health optimisation approaches and an exploration of the possible support for these reasons based on ethical dimensions was published by Pillutla et al. in 2018 (44). Commissioners stated in multiple cases that they considered rationing on the grounds of personal responsibility to be the acceptable reason for restricting access to surgery for patients with obesity. Pillutla et al reported that policymakers should avoid the use of this justification as financial motivations alone are insufficient in proceeding with the use of restrictive policies. They acknowledged that commissioners could instead focus on the potentially valid justification for rationing in cases where obesity has clear prognostic implications for the surgery in question. However, they cautioned that the evidence base for the clinical impact of restrictive health optimisation on the effectiveness of elective surgery was lacking and needed to be addressed to allow continued use of rationing in this way. The authors concluded that restrictive policies must not seek to deny patients access to healthcare services outright or to disadvantage specific patient groups, therefore there must be a reasonable expectation that such policies will result in obesity reduction allowing achievement of eligibility for surgery where still needed.

Authors considering the wider policy situation of personal responsibility argue that if it is to play a role in healthcare, the concept must be rethought in order to reflect the chronic, multi-factorial nature of issues such as obesity (147). Adding to the concern that restrictive health optimisation practice is unethical is the recognition that the ability of different groups in society to achieve necessary weight loss thresholds within weight control programmes will be far from equal (51). Bærøe and Cappelen argue that the provision of adequate support for weight loss helps to address the concept of avoidability in personal responsibility while assessing the effort made to attempt weight loss, e.g. by course attendance, is more ethical than judgements based on weight loss results (148).

In two publications by Coggon et al., the ethical dimensions of government and public health policy aiming to address obesity by framing the issue as one of personal responsibility are addressed. The authors examined the implications of the evidence showing that interventions and approaches reliant on high agency in individuals who were overweight have only a limited impact on population health and were considered likely to cause inequalities in society. Individual agency is affected by socio-economic deprivation where personal resources are required to make lifestyle changes (10). Further debate was invited on the ethical acceptability of such interventions acknowledging that the values and agency of all involved in public health intervention strategies must inform the decisions over the moral and health value of interventions within socio-political realities (149,150).

Empirical data from an analogous scenario – weight loss incentive programmes for employees, indicated that acceptance is higher amongst the public for programmes with reward-based incentives over those which are penalty-based. The author concluded that '[weight control] programs should be designed to engage, not to frustrate those most in need of health improvement' (51) which in the case of health optimisation would suggest avoidance of punitive delays for joint replacement surgery.

2.9.2 Weight stigma

Literature considering the acceptability and ethical dimensions relevant to restrictive health optimisation approaches also includes the issue of weight stigma. Batterham et al. publish on the impact of stigma in obesity, and the evidence that this worsens health and increases mortality. The authors advocate instead for a switch from focusing on weight loss, to focusing on health gain (151,152). The same group undertook a review in 2022 which highlighted the pervasiveness of weight stigma and the strong evidence against the belief that such stigma has any beneficial effect in promoting weight loss. Negative attitudes towards patients with obesity were reported by 69% of doctors and 37% of dietitians in a USA study, including in those specialising in obesity (153). The review authors cautioned that weight stigma must be addressed by public health and healthcare policymakers to ensure that obesity is treated as a chronic, progressive disease rather than an issue of personal responsibility, causing worsening inequality. Their recommendations also emphasise the importance of co-production of research, interventions and policy with people living with obesity to meaningfully improve outcomes and equality (154).

Given that most stigmatised behaviours are more prevalent in groups already facing health inequalities, policies which are punitive of these behaviours have a direct effect on worsening these health inequalities. Arguing for personal responsibility in health improvement is rarely seen outside risk factors unrelated to stigmatised behaviours (155).

2.9.3 Public attitude

In a survey investigation (n=101) of the UK public attitude to personal responsibility in healthcare, while participants agreed that people owe a duty to themselves (94%) and to society (64%), there was disagreement with the position that people should be held responsible for their past choices. Participants were more in favour of expecting people to commit to contributing to their health through prospective changes to their lifestyles, leading the authors to conclude that 'lifestyle contracts' could be an acceptable way of incorporating personal responsibility into healthcare provision (156).

2.9.4 Professionals' responses to restrictive health optimisation or rationing

A report and position statement from the Royal College of Surgeons in England in 2017 is actively critical of restrictive health optimisation policies for elective surgery. After surveying the CCGs in England to determine the prevalence and variation of restrictive health optimisation policies in place, the statement strongly denounced the creation of geographical inequalities in access to surgery (49,50). It suggested that the ability of the NHS to pursue rationing in overweight patients without fear of reputational repercussions is because such patients are perceived to be ‘soft targets’, responsible for their own weight. The statement also concluded that rationing care by such means is in contradiction to government commissioning guidance and that such policies should not be continued. BMI threshold use in orthopaedic surgery has been described as actively coercive in nature, and the acceptability of cutoffs for high BMI on the grounds of surgical safety where no such cutoffs exist for low BMI, despite evidence of higher surgical mortality in underweight patients has been challenged (157). Other academic commentators have also concluded that restrictive health optimisation is illogical and unethical, in part because it is unreasonable to assume patients with obesity have not tried to lose weight previously, and also that denying surgery to ‘healthy’ obese people likely worsens their prognosis (158).

In 2017 an NHS Clinical Senate also debated the use of restrictive policies which delay access to surgery until patients lose weight. NHS Clinical Senates are multi-professional assemblies which act as a source of independent advice and guidance to NHS commissioners (159). Their deliberations produced a position statement that these policies ‘are not supported and risk widening health inequalities […] Delay to surgery alignment to cost savings was not evidenced and was felt, at best, to delay rather than limit expenditure’. They also noted that perceived inappropriate financial motivations for restriction within the NHS was damaging to patient engagement and were clear that any interventions that delay surgery should be ‘purely for the benefit of the patient with mutual agreement between patient and clinician’ (160).

Despite these assertions from the Royal College of Surgeons and the NHS Clinical Senate, audits of the continued use of restrictive health optimisation in joint replacement surgery in 2017 and 2018 found use had increased and both publications again called for an end to the use of such approaches considering them to be in contradiction to existing NICE guidance for the management of osteoarthritis (46,47). Current NICE guidance states explicitly that people should not be excluded from referral for arthroplasty because of being overweight or obese (36).

2.9.5 Response in guidelines

There is evidence that formal guidelines have been created with an awareness of these issues of inequality. The NICE osteoarthritis guidelines highlight that because both osteoarthritis and obesity are more common in people in lower socio-economic groups ‘access to surgery on the basis of BMI has been raised by stakeholder groups as an important equality issue’ (36).

Midgely’s recent expert review on the implications of restricted access to knee or hip replacement on the basis of obesity concludes that “considering rising obesity levels in society, the association between osteoarthritis, and the rising demand of joint arthroplasty surgery, it is imperative that we improve our approach. There is significant variance and often absence of holistic support services to help this group of patients who continue to struggle greatly” (161).

2.10 Current evidence on BMI threshold policies in arthroplasty

2.10.1 Prevalence of use

Literature from international settings, mostly the USA, reports on the evidence for the impact of using a BMI threshold for arthroplasty. A survey in 2021 (n=675) questioned orthopaedic surgeons in the USA whether they had had an upper limit of BMI over which they would not operate. The survey reported that BMI thresholds were in common usage; 49.9% of surgeons had a BMI threshold of 40 kg/m^2, 24.5% at 45 kg/m^2, and 8.3% at 50 kg/m^2 (59). These thresholds represented individual surgeons' practices rather than thresholds chosen by their institutions. The majority of institutions did not have their own threshold (70.4% 455/646). A further survey published in 2023 found that BMI thresholds were in use in 54% (n=19/35) of orthopaedic institutions in one region of the USA. (162). The use of thresholds was seen to be slightly lower in a similar survey of knee surgeons in Denmark (n=41); 44% used a BMI threshold of 40 kg/m^2 and 46% required their patients to attempt to lose weight in the pre-operative period if needed. The lower figures may reflect the earlier date of this survey (2012) and the increasing use of BMI thresholds over time. Surgeons performing higher volumes of surgery were less likely to consider BMI a contra-indication to surgery (163).

Cross-sectional studies in the UK seeking to determine the prevalence of restrictive BMI-threshold policy use in joint replacement surgery have also reported an increase in use over time. The Royal College of Surgeons audited policy use in 2016 and found 34% of CCGs were restricting access to surgery through lifestyle factors including BMI (50). An audit in 2017 focusing on hip and knee replacement reported that 47% of CCGs then had a BMI threshold in place (46), with a similar figure reported in a freedom of information request study to all CCGs in 2018 (47). All audits reported the BMI thresholds themselves to be variable, ranging from 25 to 40 kg/m^2.

2.10.2 Impact of BMI threshold use

Inappropriate restriction in access to surgery

Arnold et al. studied a cohort of 3449 hip arthroplasty patients and determined their patient-reported outcome measures at one year. Responding to the hypothesis that BMI thresholds are a valid tool in avoiding operating on patients who would fail to see improvement from joint replacement, they calculated the impact that different thresholds would have had on the cohort. Even at a threshold as high as 45 kg/m^2, 21 patients would have been denied a meaningful improvement in their pain score in order to avoid one failed improvement (164). Three other similar studies looked instead at rates of thirty-day complications and ninety-day complications of knee replacement surgery by BMI. In their application of varying BMI thresholds, both concluded that while thresholds would reduce the number of complications, a significant number of patients would be denied surgery that would have been complication-free (165–167). The positive predictive value of using BMI over 30 kg/m^2 to predict a major complication in surgery was only marginally higher than that which would be achieved by a coin toss (167).

Authors at one institution in the USA where patients are denied arthroplasty until 'a reasonable attempt at reducing the BMI to below 40 kg/m^2 is made' undertook an observational study of 125 patients seeking arthroplasty but whose BMI was over the threshold (168). They found that almost 80% of the patients did not manage to meet the target BMI, and 59% of those denied arthroplasty did not seek a second opinion elsewhere.

In a similar study, Springer et al. concluded that restricting arthroplasty for morbidly obese patients did not incentivise weight loss, and only 20.1% of patients ultimately underwent surgery, and the majority of those remained morbidly obese (169). A third study of a cohort of similar patients by Wilson et al. also reported that 80% of patients were not successful in losing weight to achieve the BMI 40 kg/m^2 threshold, but also found that enforcement of the threshold was variable between individual surgeons (170). Springer et al. also reported that surgeons may make the decision to operate in spite of a patient having a BMI above a stated threshold where they were satisfied that the patient had already made unsuccessful weight loss attempts (169). In contrast, a study in Canada found that analysis of waiting times for joint replacement surgery showed some but not all individual surgeons instigated longer waiting times for obese patients, suggesting that even where formal BMI threshold policies are not used, clinician decisions over access to surgery may be based on BMI (171).

Positive reports of thresholds triggering interventions and improvements

The success reported by Lingamfelter et al. in the study also discussed in section 2.8, was within the context of a patient pathway which restricted access to joint replacement surgery until patients reached a BMI threshold of 40 kg/m^2 in the USA (138). Patients (n=133) agreed to work with a dietitian and 92% of the patients lost weight. Surgery was then possible for 64% of the patients and was deemed successful in all cases leading the authors to conclude that formal weight management support for patients with obesity could improve access to surgery. The significant limitations of this study must again be acknowledged as the failure to include patients lost to follow-up in the analyses makes the strength of the evidence very limited through this bias.

2.10.3 Impact of threshold policies on costs and inequalities

Vale of York CCG in England introduced a BMI threshold of 30 kg/m^2 for access to joint replacement surgery in 2016, which added a delay of one year before surgery for any patient above this threshold (exception circumstances were specified). Patients who needed to lose weight to meet the threshold could be supported in primary care through the existing weight management service options. The CCG reported that the policy had saved £2.2 million in the first year; however, scrutiny of the report raised concerns that this cost-saving represented a combination of deferment rather than prevention of surgery, and also an increase in the use of independently-funded surgery by those who could afford it. Healthwatch York surveyed people in the region to understand public opinion on the policy and heard from patients who had experienced financial and emotional distress as a result of delays to their surgery. Recommendations from their report in 2019 were that improvements to data collection were necessary to adequately gauge the policy's cost-effectiveness and that improvements should be made to support pathways to address barriers to engagement with weight loss. An emphasis was placed on co-production with patients and the importance of considering disadvantaged groups of patients (52).

BMI thresholds are deemed likely to have had a direct negative impact on health inequalities. Wang et al. examined the demographic data of 21,297 USA adults aged over 50 and reported that the application of a BMI threshold of 35 kg/m^2 for arthroplasty would result in a disproportionate reduction in eligibility for surgery in Black patients, women, those of lower socio-economic status and lower educational attainment (172). The existing health inequalities experienced by these groups would be compounded by the use of BMI thresholds in access to surgery.

In an expert commentary by Iacobucci in 2017, the author associates the rise seen in the rationing of hip and knee replacement in the NHS with a rise seen in individual funding requests for this procedure. Individual funding requests represent a resource-intensive process in themselves (173). A year later the same author noted the increase in the number of these individual funding requests being rejected and also some evidence that independently-funded procedures were increasing as a result (174).

In the ‘how recommendations may affect practice’ section of NICE’s osteoarthritis guidance (36) it is stated that following their guidance not to base referrals for arthroplasty on factors such as a patient being overweight or obese could have resource implications. It is noted that ”current practice is inconsistent. If all centres adopt these recommendations, then it may lead to an increase in the number of referrals for surgery and subsequently more joint replacements done overall”.

2.11 Summary of the literature

A summary of the key findings from each element reviewed in the literature for this chapter, along with the implications the findings have for the thesis and the evidence gaps remaining, are presented in Table 2.

Table 2: Summary of literature review findings, implications and evidence gaps

Element reviewed	Key findings	Implications for the thesis	Evidence gaps remaining
Evidence that weight loss improves general health and osteoarthritis in people with obesity	• Strong evidence that even modest weight loss improves general health in the short and long term • 10-20% weight loss reduces the risk of osteoarthritis and joint replacement • 5-10% weight loss in patients with diagnosed osteoarthritis produces cost-effective improvements in symptoms and quality of life • Weight loss was more effective in patients with lower levels of obesity and joint symptoms	• Weight loss is an evidenced intervention for osteoarthritis patients which can be expected to improve their joint symptoms and overall health • Weight loss at the stage of lower levels of overweight and obesity and of less severe osteoarthritis symptoms is recommended	• Questions remain over the systemic effects of obesity and the reversibility of its effects on early joint pathology • Long-term follow-up of osteoarthritis patients successful in weight loss is lacking, therefore evidence for the impact of weight regain is unclear
Evidence that obesity is associated with arthroplasty outcomes	• Risk of poor outcomes from arthroplasty due to obesity is marginal and surgery offers substantial benefits and is cost-effective for most patients even of a very high BMI • BMI thresholds for clinically significant risks of complications or contraindications for surgery could not be identified	• BMI thresholds for arthroplasty surgery are not justified on the grounds of surgical outcomes and cost-effectiveness	• Selection bias for healthier patients with obesity in referrals for surgery may be a cause of an underestimation in the role of high BMI in surgical outcomes
Evidence for benefits from weight loss in arthroplasty	• Clinical experts agree that weight management is important in pre-operative preparation • NICE recommend osteoarthritis patients with obesity are supported to lose at least 10% of their body weight • Concerns remain on the challenges of implementation and the potential unintended consequences of weight loss which include malnutrition and rebound weight gain	• Existing health optimisation guidelines do not provide recommendations on how weight loss should be achieved pre-operatively and what level of weight loss to pursue • Patients with obesity and with symptomatic osteoarthritis are generally considered to be	• Improved evidence is required on the optimum approach to pre-operative weight loss in arthroplasty, with measurement of unintended effects • Examination of weight loss effects by subgroups of patients is required to inform recommendations

	• Studies of the impact of pre-operative weight loss have provided insufficient evidence on intervention impact	homogeneous groups in recommendations, which is contrary to the empirical findings on the role of weight loss	• Body composition rather than BMI should be studied in pre-surgical weight loss approaches and outcomes • Comparison should be made of never-obese and formerly-obese patient outcomes to determine the impact of weight loss
Knee vs hip	• Obesity has a higher association with knee than hip osteoarthritis and risk of arthroplasty • Guidelines and recommendations generally do not differentiate between patient groups	• Investigation into arthroplasty health optimisation is limited by the grouping of hip and knee osteoarthritis patients	• Hip and knee patient analyses should be separated to determine whether different recommendations should be made between groups
Effectiveness of referrals to behavioural change interventions for weight loss	• Lifestyle weight management programmes are evidenced in supporting modest amounts of weight loss in the short-term • Weight regain is the key factor in whether programmes are cost-effective • Existing referrals into these programmes in England are low and show inequalities in access and effect	• Health optimisation approaches reliant on referral into existing lifestyle behavioural weight management programmes must account for the modest short-term impact of these interventions, the uncertainty over their long-term maintenance, and the potential for inequalities associated with their uptake	• Separation must be achieved between examining the impact of weight management interventions in the short term for arthroplasty and in the long term for general health and cost-effectiveness • Weight management intervention trials lack data which allow examination of inequalities in uptake and outcome
The evidence for health optimisation in elective care	• The ‘teachable moment’ is the basis for pre-operative behavioural change • Weight loss is perceived as an important but challenging goal by patients	• There is limited evidence for the effectiveness of pre-surgical weight loss interventions for surgical and long-term outcomes for	• The paucity of high-quality evidence for pre-operative weight loss interventions, must be addressed; long-term measures and impact

	• Health optimisation interventions show evidence of positive effects on length of stay and quality of life but long-term and obesity-related measures and inequalities are not reported • In interventions for pre-joint replacement weight loss, weight loss of 5 to 32 kg is achieved but conclusions could not be drawn on the impact on surgical outcomes • Evaluation of restrictive health optimisation shows mixed results. In cases where support was provided, uptake and adherence was low due to inconvenience, cost, readiness to change, low confidence in success, and embarrassment.	hip and knee replacement patients • Many interventions rely on intensive support or dietary replacement which are not representative of the weight management interventions routinely on offer in England • Patient engagement with interventions is low	on inequality are notably lacking in current studies • Digital intervention evidence is in its infancy
Ethical dimensions of restrictive health optimisation policies	• Personal responsibility for obesity is used as justification for restricting access to surgery by policy decision-makers but is likely to cause inequalities • Prognostic implications of obesity may be an acceptable reason to delay surgery if there is a reasonable expectation that the delay will result in weight loss • Weight stigma drives the perceived acceptability of restrictive practice, but reduces the likelihood of weight loss in those affected • Key professional organisations have taken formal positions against restrictive policies and rationing by obesity as illogical and unethical	• Restrictive policies are contrary to professional guidelines and position statements • Strong evidence of patient benefit, without a negative impact on health inequalities, would be required to reconsider the justification for restrictive approaches • Professional and organisational attitudes regarding personal responsibility in obesity are likely drivers in policy use	• Co-production of research with those affected by obesity is essential to produce acceptable, effective recommendations for health optimisation • The role of weight stigma in restrictive policy use needs to be evidenced and highlighted

Current evidence on BMI threshold policies in arthroplasty	• BMI threshold policies are in use for arthroplasty in around half of the settings surveyed • Policy introduction may result in short-term reduction in cost of surgery provision but this was considered deferment rather than reduction in need • There is strong evidence that BMI threshold use inappropriately restricts access to surgery for those who would benefit from arthroplasty • 80% of patients with a BMI over 40 kg/m^2 are unsuccessful in losing weight to become eligible for surgery • Racial and socio-economic disparities are worsened by use of BMI thresholds	• Restrictive policies are in use internationally • Restrictive policy introduction must be examined for short-term reductions in surgery and worsening of health inequalities • Provision of weight management support is not expected to have high uptake and adherence	• Research into health optimisation must prioritise patient and public involvement and qualitative investigation to understand the inequalities in impact and how these may be mitigated • Long-term investigation of restrictive policy impact on healthcare system costs is lacking

Chapter 3. Policy position descriptive study

3.1 Overview

This chapter presents the work to collect and analyse data on the policy situation across England regarding BMI related restrictions in access to hip and knee replacement surgery. These policies were known to vary by commissioning locality and an understanding of their prevalence, nature and trends in their introduction was key to the methodology and interpretation of the findings of the subsequent chapters.

The study in this chapter has been published:

McLaughlin J, Elsey J, Kipping R, Owen-Smith A, Judge A and McLeod H. Access to hip and knee arthroplasty in England: commissioners' policies for body mass index and smoking status and implications for integrated care systems. BMC Health Serv Res. 2023 Jan 24;23(77).

3.2 Objectives

The study aimed to meet the following objective:

Objective 1:

i. *To ascertain the prevalence, trend in use and nature of commissioning policies in England that alter access to hip and knee replacement surgery based on patients' body mass index.*
ii. *To consider the implications of the transition to integrated care systems for policy prevalence and nature.*

3.3 Background

Clinical commissioning groups (CCGs) were the statutory NHS bodies responsible for the planning and commissioning of healthcare services for their local area for the decade from their formation in 2012. CCGs set their own referral criteria for hip and knee arthroplasty leading to variation in policies across England, and these may include criteria for BMI thresholds. In some cases, 'health optimisation' is cited as the reason for policy introduction – whereby patients are offered extra support and/or an extra period of time before surgical referral to address weight management in order to improve their overall health as well as their surgical outcome (21). In other cases, policies are used to restrict access to surgery without necessarily offering health improvement support opportunities, heightening the risk of increasing health inequalities through rationing of surgery and raising ethical concerns (44,50).

The Royal College of Surgeons reported that the proportion of CCGs with mandatory BMI upper thresholds for referral for hip and knee arthroplasty was 13% in 2014, rising to 22% in 2016 (50). Further survey of CCGs by the Association of British HealthTech Industries (46) revealed that by 2017 this figure had risen again to 47%. The high prevalence of these policies is despite the position of the Royal College of Surgeons that all commissioning policies should be based on clinical need and “patient-specific factors (including age, sex, smoking, obesity and comorbidities) should not be barriers to referral for joint surgery” (49). A decision published by an NHS Clinical Senate was that “NHS bans delaying surgery until patients stop smoking or lose weight are not supported and risk widening health inequalities” (160).

The 106 CCGs in England were replaced by 42 integrated care systems (ICSs) in 2022. This evolution marked a move away from local general practitioner membership bodies being responsible for strategic commissioning to one based on collaboration between organisations (29). This change provided an opportunity for decision-makers to reassess the role of local commissioning policies to restrict access to hip and knee arthroplasty which have been inherited from CCGs by the ICSs. This study collated policy information from each current and historic CCG and assessed the extent to which policies inherited by the new ICSs place limitations on access to arthroplasty based on BMI.

3.4 Methods

3.4.1 Study design

To ascertain and describe the policy positions of CCGs in England over time and to provide a cross-sectional overview of the current policy position of each locality, policy data were collected from each CCG for a descriptive analysis. Estimations were made of the policy position of each new ICS based on the findings for the policy situation of their constituent CCGs.

3.4.2 Data collection

Lists of CCGs in existence by calendar year were obtained from information published online by the Office for National Statistics (175). All published policies that related to NHS patient referral for elective hip and knee arthroplasty surgical opinion (including generic policies that address all referrals for elective surgery) in effect any time from January 2013 to June 2021 were searched for. Each policy was specifically reviewed for BMI criteria. Other access criteria e.g., symptoms scoring, were not collated.

‘BMI policies’ were defined as those policies with criteria designed to alter, limit or delay access to surgery for patients based on their identification as overweight or obese including via body mass index. For each policy identified, the following data were recorded: start and end date, BMI threshold, extra waiting time or other requirement for access to surgical referral, nature of support services offered to patients for weight management, mandatory or optional elements of patient engagement with policy thresholds.

To identify the policies, a search protocol was developed and applied to each of the 106 current (June 2021) and 143 historic (formed at any point from 2013 but no longer in existence by June 2021 due to mergers) CCGs in England (175). Searches were made of CCG websites (formal websites for the organisations, of the format www.[CCG name].nhs.uk) and search terms were used in an internet search engine where CCG websites were unavailable or held no reference to relevant policies. The searches were completed in May to June 2021. The search protocol is included in Appendix 1.

To determine the policy situation for CCGs with no available online policy information, and to check the accuracy of the identified policy information, Freedom of Information (FOI) requests were sent to each current CCG by email in June 2021. The requests asked CCGs to verify or amend the data collected through the online searches. Repeat requests were sent to CCGs in July 2021 where they did not initially respond with information about their component historic CCGs.

3.4.3 Analysis

Policies were categorised based on their criteria and content, ranging from advice to patients to denial of access to surgery. These four categories are further detailed in Table 3.

Descriptive statistics were reported on the prevalence and nature of policies, as well as differentiating between historic and current policies.

For each ICS the policy type likely to have been inherited from its constituent CCGs was identified by determining the most common (modal) policy of the CCGs.

Mapping software (ArcMap Version 10.7.1) was used to present the geographical distribution of policies in CCGs in June 2021 and the estimated distribution of policies for ICS organisations in 2022 in choropleth maps. CCG regions with obesity prevalence higher than the England national average (as reported in the Public Health Outcomes Framework in 2021) (176) were indicated on the maps to allow assessment of association with policy severity.

3.5 Results

3.5.1 Data sources and data completeness

Policy information was available online for 84.9% (90/106) of current CCGs in June 2021. Many historic CCGs that subsequently merged into new CCGs did not have publicly available archived websites and so policy information was only available online for 35.0% (50/143) of historic CCGs. The internet searches therefore returned policy information for 56.2% (140/249) of CCGs overall.

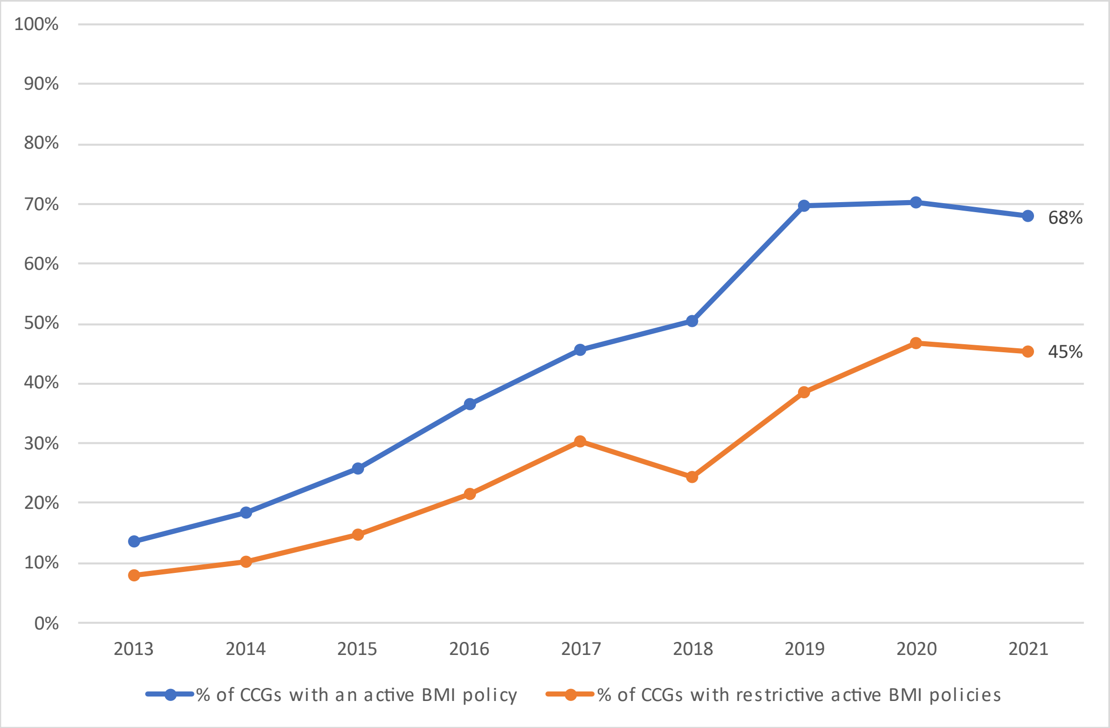
Responses to FOI requests were received from 94.3% (100/106) of current CCGs. With prompting to include information about their constituent, historic CCGs, FOI information was gained for 92.0% (229/249) of CCGs overall. One current CCG only provided partial information about their policies and one other current CCG had no policy information available online and did not respond to the FOI request. Policy information was unavailable or only partially available for 12 of the historic CCGs. In combination, the internet searches and FOI data gave complete policy information for 99.1% (105/106) of current CCGs and 94.4% (235/249) of all current and historic CCGs.

3.5.2 Changes in policy prevalence and severity over time

Between 2013 and 2021, the prevalence of BMI policies increased from 14% to 68% of CCGs (Figure 5). Many of the mergers in CCGs occurred in 2018 and this resulted in a sharper increase in policy prevalence by percentage, as CCGs without policies tended to become subject to the policies of other constituent CCGs in the newly formed

CCG. The stringency of these policies generally increased over time. By 2021, 45% of CCGs were using policies that required extra waiting time before surgery for BMI (Figure 5).

Figure 5: Percentage of clinical commissioning groups with a body mass index policy in place for arthroplasty by year (total n=106 in 2021)



3.5.3 Prevalence and nature of policies in 2021

In June 2021, 68% (72/106) of CCGs had an active BMI policy for arthroplasty referral. Policies ranged in severity from stating patients should be given advice on weight management without any restriction in access to surgery (22/106, 20.8%), to denying access to surgery until patients met a particular BMI threshold (12/106, 11.3%). In total 48/106 (45.2%) of CCGs had restrictive policies in place involving extra waiting time or mandatory BMI thresholds for surgery (Table 3). There were no differences between arthroplasty BMI policies for hips and knees within individual CCGs.

Table 3: Prevalence and content of hip and knee arthroplasty policies for body mass index (106 clinical commissioning groups in England 2021)

<table>
<tr><th colspan="2"></th><th>n</th><th>%</th></tr>
<tr><td colspan="2">Policy situation unknown</td><td>0</td><td>0.0</td></tr>
<tr><td colspan="2">Policy introduced but now inactive</td><td>11</td><td>10.4</td></tr>
<tr><td colspan="2">No policy</td><td>23</td><td>21.7</td></tr>
<tr><td colspan="2">Policy introduced and still active of which:</td><td>72</td><td>67.9</td></tr>
<tr><td>1</td><td>advice given to lose weight and directed to optional support</td><td>22</td><td>20.8</td></tr>
<tr><td>2</td><td>engagement required with weight loss attempts but no outcome requirements or delay to surgery</td><td>2</td><td>1.9</td></tr>
<tr><td>3</td><td>mandatory extra waiting time to surgery, but no penalty for engagement or outcome</td><td>36</td><td>34.0</td></tr>
<tr><td>4</td><td>access to surgery denied until BMI threshold is met</td><td>12</td><td>11.3</td></tr>
</table>

Of the 72 policies in use in 2021, 50% (36/72) specified an extra waiting time requirement for accessing surgery. This extra waiting time was added to the patient pathway before they could be listed for surgery. When recorded, the range in extra waiting time was three months to one year, with six months the most common duration. In a further 16.7% (12/72) of policies patients were required to meet a particular BMI threshold before being able to access surgery rather than wait a specified extra time period.

Eight six percent (62/72) of policies in use in 2021 specified a BMI threshold, ranging from 25 to 45 kg/m^2; in some cases only to identify which patients would be offered advice on weight management (Table 4). ‘Not specified’ indicates that all patients were subject to the same restrictions regardless of BMI. Common examples of this included access to lifestyle interventions for three months prior to surgery, whereby all patients would have the opportunity to improve an aspect of their lifestyle, including weight loss if appropriate.

Sixty nine percent (50/72) of policies specified a BMI threshold for whether it was mandatory for a patient to engage with weight management, wait for extra time before surgery or meet a mandatory BMI threshold (Table 4). Notably, a third of the CCG policies (15/50) which required that patients wait longer before surgery, engage with weight management or successfully lose weight to meet a certain threshold, used thresholds of $\leq$30 kg/m^2. This means that patients who were overweight but not obese were impacted by the restrictions as well as patients with obesity.

Table 4: Use of body mass index (BMI) thresholds in weight management policies for hip and knee arthroplasty n=72

Body mass index threshold kg/m²	**BMI threshold for policy application/ patient eligibility of any kind**		**BMI threshold for mandatory engagement* or extra wait for access to surgery**		**BMI threshold for access to surgery**	
	n=72		n=38		n=12	
	n	%	n	%	n	%
Not specified**	10	13.9	5	13.2	-	-
25	15	20.8	10	26.3	0	0.0
30	10	13.9	4	10.5	1	8.3
35	27	37.5	18	47.4	2	16.7
40	7	9.7	1	2.6	6	50.0
45	3	4.2	0	0.0	3	25.0

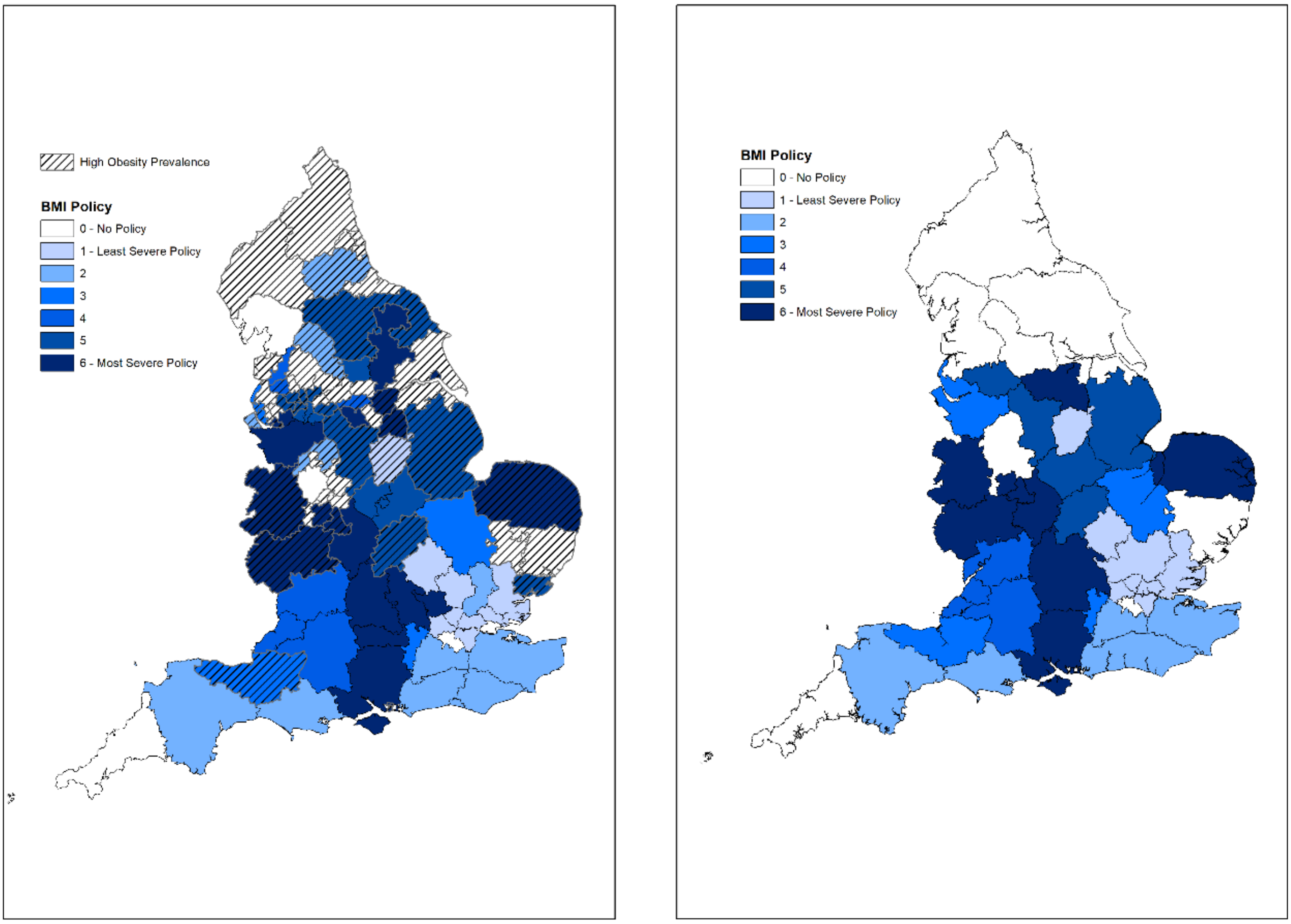
* Includes mandatory participation with weight management services and/or mandatory weight loss to reach a % weight loss or a specified BMI threshold

** all patients were subject to the same restrictions regardless of BMI e.g. all patients given access to lifestyle improvement services for 3 months before surgery

3.5.4 Geographical distribution of policy use

There was marked geographical variation in the current BMI policies (Figure 6). There was no association evident between the choice of policy severity and the population prevalence of obesity in CCGs. The figures also display the estimated uptake of these policies into the new ICS geography. For BMI policies 40.5% (17/42) of ICSs are estimated to have a policy in place that mandates extra waiting time ahead of surgery or a requirement to meet a BMI threshold in order to access surgery (3 with category 2, 5 with category 3 and 3 with category 4).

Figure 6: Left: clinical commissioning groups' BMI policy prevalence and severity in 2021 overlain with population obesity prevalence*. Right: estimated integrated care system BMI policy prevalence and severity



* 'high prevalence' = higher than the England national average as reported in the Public Health Outcomes Framework in 2021 (176)

3.6 Discussion

3.6.1 Summary of findings

Complete data on the prevalence and content of commissioners' policies for BMI that determine access to elective hip and knee arthroplasty were available for 105/106 (99.1%) of CCGs in 2021. Prevalence of policy use was high and rising: 67.8% (72/106) of CCGs had a policy for BMI in 2021. There was high variation in policy content and severity, with 45% of CCGs using restrictive policies that require extra waiting time or achievement of weight loss before surgery. Policy severity did not appear to be associated with high prevalence of obesity. This study estimated that 40.5% (17/42) of integrated care systems have a restrictive policy in place that mandates extra waiting time ahead of surgery or a requirement to meet a BMI threshold in order to access surgery.

Recent NICE guidance for osteoarthritis is explicit that people should not be excluded from referral for arthroplasty because of overweight or obesity (36). In this context, the study findings that commissioners' policies do not align with NICE guidance show that the restrictions in access to surgery imposed by many localities are problematic.

3.6.2 Strengths and limitations

This study used a comprehensive search of all CCGs that achieved high data completeness and provided detailed information on the content and variation in policies. A limitation is that future ICS policy positions could only be estimated as no formal mechanism for deciding which of the constituent CCG policies the ICS would retain was evident. With high variation in policy content, it is challenging to directly equate policy categories to conformity with relevant NICE guidelines.

3.6.3 Relation to other work and further context

Variations in musculoskeletal commissioning policies (177) and arthroplasty access criteria (46,47) have been previously documented in England, and BMI thresholds for arthroplasty are also in use internationally (167,178). The proportion of hip and knee arthroplasty patients with obesity is 49% in the UK (34), meaning policies with BMI criteria have implications for the majority of patients.

Access to elective surgery may be purposefully limited for patients with obesity through policies produced by healthcare commissioners. The available evidence indicates that hip and knee arthroplasty is cost-effective for almost every patient who receives treatment (179) and a recent analysis of the National Joint Registry found no evidence of poorer outcomes in arthroplasty patients with high BMI (80). Sustained, significant weight loss is difficult to achieve and literature reports that very few patients denied access to arthroplasty due to their BMI go on to lose sufficient weight to qualify for surgery (136,170). BMI policies that limit access to surgery are therefore not justified on clinical grounds and instead risk widening health inequalities given that patients' ability to pursue independently-funded treatment varies with their affluence (180). The use of policies that require patients to lose weight before accessing surgery should be based on evidence, yet there is currently no strong evidence that pre-surgical weight loss improves surgical outcomes. Indeed, short-term pre-surgical weight loss raises concerns about deconditioning and post-surgical rebounds in weight in arthroplasty patients (99).

In contrast, evidence is mounting for the beneficial role of 'prehabilitation' for patients in the peri-operative period to improve their overall health (21,132,181). These interventions include support for exercise and weight management but do not restrict access to surgery based on patient engagement or success.

Whilst it is healthcare commissioners who set surgery access policies, it is generally local authorities who commission community-based weight management services. Financial pressures on local authorities in recent years have led to the reduction or decommissioning of these services in some regions (182). This leaves a potential mismatch for patients facing a BMI threshold to access surgery and the access to services to support them in reaching these thresholds. Longstanding variation in both the surgery access policies and the support provided for weight management in different regions is highly likely to be the cause of health inequalities. National mapping of weight management services in 2015 revealed that only 61% of local authorities had a 'tier

2’ weight management service available. Additional funding for the financial year 2021/22 supported local authorities in increasing their provision of weight management services, although the continuation in the provision of these services without recurrent additional funding was not clear at the time of this study (183,184). The improved integration of health, care and community organisations resulting from the introduction of ICSs (185) may reduce the disconnect between healthcare commissioning policies targeting BMI and the regional alignment of resources for health improvement interventions.

3.7 Conclusion and implications for thesis

Integrated care systems are now the clinically-led statutory NHS bodies responsible for the planning and commissioning of healthcare services for their local area (185). It is unclear as yet on their approach to setting policy where their constituent CCGs had differences in policies, but the estimates from this study indicate that restrictive BMI policies governing access to hip and knee arthroplasty that are unsupported by NICE guidance will be in use in 40.5% of ICSs. It is the recommendation of this study that ICS decision-makers take this transition opportunity to ensure that integrated, complementary weight management support services are available and to reassess their continued use of restrictive BMI threshold policies for surgery. This chapter has provided the baseline information on the BMI policies in use across England in the decade since 2012. These data were a necessity for the interrupted time series analyses presented in the following chapter (Chapter 4), examining the associations in access to surgery and policy introduction dates, and in informing the design of the qualitative study reported in Chapter 5.

Chapter 4. National Joint Registry analyses

4.1 Overview

Chapter 3 has presented the work to determine the body mass index policy situation across England over time, regarding restriction in access to hip and knee replacement surgery. Policy introduction varied by clinical commissioning group (CCG), with different CCGs introducing policies of various levels of severity across a range of dates from 2012 onwards. This variation in the timing and severity of policy introduction, along with the fact that CCGs with no policy introduction can be viewed as a control group, formed a before-after natural experimental study.

This chapter presents the natural experimental study undertaken to analyse National Joint Registry data using an interrupted time series approach. Analyses were undertaken separately for data on hip and knee replacement operations, but as they share the same underlying methodology the study background, methods, discussion and implications are reported in common.

The studies in this chapter have been published:

- *McLaughlin J, Kipping R, Owen-Smith A, McLeod H, Hawley S, Wilkinson, JM and Judge A. What effect have commissioners' policies for body mass index had on hip replacement surgery?: an interrupted time series analysis from the National Joint Registry for England. BMC Med. 2023 Jun 13;21(1):202.*

- *McLaughlin J, Kipping R, Owen-Smith A, McLeod H, Hawley S, Wilkinson JM and Judge A. What effect have NHS commissioners' policies for body mass index had on access to knee replacement surgery in England?: An interrupted time series analysis from the National Joint Registry. PLoS One. 2022 Jun 29;17(6):e0270274.*

4.2 Objectives

The study aimed to meet the following objective:

Objective 2:

i. *To assess the association between the introduction of body mass index policies for hip and knee replacement patients and changes in trends in surgical rates and patient characteristics.*
ii. *To assess the association of body mass index policy introduction with impact on inequality in access to hip and knee replacement surgery and use of independently-funded surgery.*
iii. *To examine any differences in association related to the level of severity of the policy.*

4.3 Background

Policies determining health optimisation practices for hip and knee replacement surgery patients vary across commissioning localities in England. Policies range in severity from a recommendation that overweight patients are offered advice on weight management, to mandated extra waiting periods to engage with weight management, through to the most stringent with BMI thresholds for surgical referral (47,48). Despite the longstanding use of commissioners' policies regarding BMI-based restrictions for hip and knee replacement surgery, few evaluations of their impact have been published and the evidence base for their effectiveness remains unclear (21,53,54).

The aim of this study was to examine the impact of policy introduction on inequalities and patient access to elective hip and knee replacement surgery in England. Data from the National Joint Registry were used in a natural experimental study design with interrupted time series analyses to model the effect that the introduction of these polices has had on trends in rates of elective hip and knee replacement surgery. Difference in outcomes between CCGs with and without BMI policies were examined. The *a priori* hypothesis (186) was that policy introduction would be associated with a reduction in the rate of surgery provision and that stricter policy introduction would be associated with a greater reduction in the rate of surgery.

4.4 Methods

4.4.1 Study design

The study had a quasi-experimental natural experiment design (187,188). The Medical Research Council's guidance on using natural experiments to evaluate interventions relevant to population health defines the scenarios in which natural experimental designs are an appropriate choice (189). Based on this guidance, a natural experimental study design was deemed suitable in this case as it was possible to obtain appropriate data from exposed and unexposed populations of patients from an intervention introduced organically by commissioning bodies outside of the researcher's control. The study scenario also meets the other pre-requisites for a natural experimental approach – that there is scientific uncertainty about the size or nature of the effects of the intervention, and that the intervention's principles have the potential for generalisability.

The impact of the introduction of CCG health optimisation policies was examined by investigating trends in rates of surgery and in patient characteristics before and after introduction using interrupted time series analyses. The timing of introduction of health optimisation policies, and the level of policy severity, varied by CCG. Whilst CCGs ceased as organisations in July 2022 and were replaced by integrated care boards (29), the study uses data relating to commissioning by CCGs prior to this change.

Data source

The source of the surgery data was the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR). The NJR is a nationwide initiative which was launched in 2003 by the Department of Health and Social Care. Its purpose is to record, monitor, analyse and report on performance outcomes in joint replacement surgery to improve service quality and enable research analysis (34). It is mandatory for surgeons and their hospital to register all hip and knee replacement activity in the NJR whether the procedures are funded by the NHS or independently. The registry collects comprehensive data on surgical techniques, implant types, and patient outcomes and contains data on over 2 million patients since 2003, covering 96% of primary hip and knee replacements (34).

The NJR contains anonymised patient data on age, gender, procedure type and date, BMI and American Society of Anesthesiologists (ASA) grade. ASA grade is a physical status classification system used as an aid in determining anaesthetic risk; grade 1 indicates normal health, and grade 5 indicates poorest health (190). Information on the patient's residential area, as defined by the 2011 census Lower Layer Super Output Areas (LSOA) is also available. LSOAs are defined as geographical areas of similar population size, with an average of 1,500 residents (191). Data available from the Office for National Statistics (ONS) were used to identify the LSOAs nested in each CCG locality (192). The dataset prepared for the NJR's 2019 annual report (193) was used for the analyses, which therefore did not require further cleaning or coding. As a measure of socio-economic deprivation, the index of multiple deprivation (IMD) score was used; a relative measure of deprivation based on LSOAs. The IMD rank for a patient's LSOA was used to categorise patients into quintiles based on the national ranking of local areas, with quintile 1 being the most deprived group and quintile 5 being the least deprived group. Patient-reported outcome measures (PROMS) comprising pre and post-operative Oxford Hip Score and Oxford Knee Score questionnaire data were linked to the NJR dataset at the patient level. The Oxford Hip and Knee Scores are validated joint-specific measures of pain and function scored 0-48 with 0 indicating the most severe symptoms (194). Information on relevant CCG policy content, introduction and cessation dates was gathered in July 2021 through collection of policy documentation from CCG websites supplemented with Freedom of Information requests to each CCG (48). This is detailed in Chapter 3.

Statutory approvals

The NJR Research Committee and the Healthcare Quality Improvement Partnership (HQIP) Data Access Request Group granted approval of the request for the necessary NJR data access for this study (study reference RSC2021/01). With support under Section 251 of the NHS Act 2006, the Ethics and Confidentiality Committee (ECC), (now the Health Research Authority Confidentiality Advisory Group) allows the NJR to collect patient data including where consent is indicated as 'Not Recorded'.

Participants and inclusion criteria

The study sample consisted of 605,221 patients who had a primary knee replacement (total or uni-compartmental) and 849,686 patients who had a primary hip replacement, between January 2009 and December 2019 inclusive in England and recorded in the NJR. Inclusion criteria were patients age 40+ years with osteoarthritis as a primary reason for surgery.

Outcome measure

The primary outcome was the rate of provision of primary hip or knee replacement surgery for each CCG. For each annual quarter in each CCG, rates (expressed as per 100,000 persons aged 40+) of surgery were determined by aggregating the number of eligible primary hip or knee replacement procedures in the CCG locality (numerator) and using the aggregated ONS count of the population aged 40+ years living in each of these CCG localities in 2019 as the denominator (195).

Secondary outcomes measures were the proportion of independently-funded operations, the proportion of operations performed in patients with obesity (BMI ≥30 kg/m^2) and the mean pre-operative Oxford Hip or Knee Score. For BMI and Oxford Hip or Knee Score calculations, only the individual records with a BMI record in the range 12 to 60 kg/m^2 or a recorded Oxford Hip or Knee Score were retained respectively.

Intervention

The intervention was the date the CCG introduced a health optimisation policy on access to hip or knee replacement surgery. It was considered that ≥18 months of data post-policy introduction were sufficient to allow for policy implementation and possible influence of existing waiting lists. CCGs were excluded where their policy start date was unknown, policies were stopped and restarted, or where insufficient post-policy introduction data were available. Appendix 2 illustrates the data flowchart for the analysis.

Control

Each CCG that introduced a policy, acted as its own control, through a comparison of trends in outcomes in the time period before policy introduction and the time period after it was introduced. To account for potential external influencing factors, data from CCGs with no policy introduction over the time period of interest were included to control for secular changes in outcomes, using a difference-in-differences controlled interrupted time series study design (186). This approach provides a test of the differential effects of the intervention timepoint between the intervention and control groups.

Effect modification variables

Analyses were stratified according to: BMI, IMD deprivation quintile, and whether patients received public (NHS) or independently-funded surgery. NHS-funded surgery was delivered in both NHS and private sector hospitals but was not categorised separately. To explore heterogeneity according to the severity of CCG policy, policies were categorised as 1 (mild – patients receive advice only), 2 (moderate – patients are subject to additional waiting time before surgery) or 3 (strict – patients must be below a BMI threshold to be eligible for surgery).

4.4.2 Statistical Analyses

Before-and-after analysis: Interrupted time series analysis was used to examine the impact of policy introduction by calculating trends in the quarterly rates of surgery for each CCG individually. Segmented linear regression models were used to estimate the trend before policy introduction, and how this trend changed after policy introduction, also allowing for an immediate step change at the date the policy was introduced (186). The post-intervention counterfactual was estimated as the continuation of the pre-policy introduction period trend.

Visual assessment of these graphs of quarterly rates during the study period showed no ‘level change’ in rates of operations evident after policy introduction. Instead, post-policy introduction trends for the change in slope in rates showed a change for the majority of intervention CCGs. This was considered the ‘effect size’. Random effects meta-analysis was used to pool the change in slope across CCG groups, stratifying according to whether the CCG policy was mild, moderate or strict. Data are presented as Forest Plots.

Controlled interrupted time series: Outcomes for intervention and control group settings were further compared using segmented linear regression of the differences between the groups (186,196). The difference between the rate of surgery in intervention and control CCG groups was calculated for each quarter and models were fitted to combined data from the pre- and post-intervention periods. The difference between the rate of surgery in the intervention group and its counterfactual value for each quarter in the period after policy introduction was calculated; the counterfactual was estimated as the continuation of the pre-policy introduction period trend. Absolute and relative differences were calculated at 3 and 5 years post-policy introduction in the control group and the intervention group counterfactual.

Pooled analysis: Data on rates of surgery for all intervention CCGs were then pooled, with the policy introduction date being considered time 'zero' for alignment in each CCG. A single-segmented linear regression model was then fitted to obtain an overall national effect for all CCGs in England of the impact of health optimisation policy introduction.

To control for secular effects, non-policy control CCGs were randomly matched to policy CCGs and assigned their policy start date. Policy and non-policy CCG data were then pooled, and a controlled interrupted time series analysis was conducted, to compare differences in trends before and after policy introduction for an overall national effect of intervention compared to control CCGs. The Newey-West standard error model was used to address the autocorrelation in the data detected with the Durbin-Watson test (P<0.001) (197,198).

Interrupted time series analyses were completed with the same methodology using the secondary outcome measures of: proportion of independently-funded operations, proportion of operations performed in patients with obesity (BMI 30+) and mean pre-operative Oxford Hip or Knee Score.

Stratifications of the trends in surgery data for the time series analyses were also conducted by policy severity categories.

All statistical analyses were conducted using Stata/MP version 16.1.

4.4.3 Patient and public involvement (PPI)

The Patient Experience Partnership in Research (PEP-R) group is a regional facilitated group (199), most of whom have had joint replacement, that provide patient and public input into research. The group were engaged in the proposal of this research, and during the study design and analysis which shaped the categorisation of policy severity. The group were engaged in planning the dissemination of the study results.

4.5 Results

4.5.1 Policy prevalence and inclusion

Of the 181 CCGs in continuous existence from 2013 to 2019, 19 (10.5%) were excluded due to incomplete policy information or complex policy activity timelines (e.g., stops and starts to policy use) and 32 (17.7%) were excluded due to <18 months of outcome data post-policy introduction due to policy introduction dates that were later than mid-2018. 130 CCGs were therefore included in the analyses, of which 74 (56.9%) had no policy (control CCGs), and 56 (43.1%) had a policy (intervention CCGs). Of those with policies: 26 (46.4%) had mild (advice only) policies, 14 (25.0%) had moderate (extra waiting time) policies and 16 (28.6%) had severe (mandatory BMI threshold) policies. Policy introduction dates ranged from mid-2013 to mid-2018. Appendix 3 details the CCGs included in the analysis, their policy types and start dates.

4.5.2 Knee replacement analyses

Descriptive information and demographics

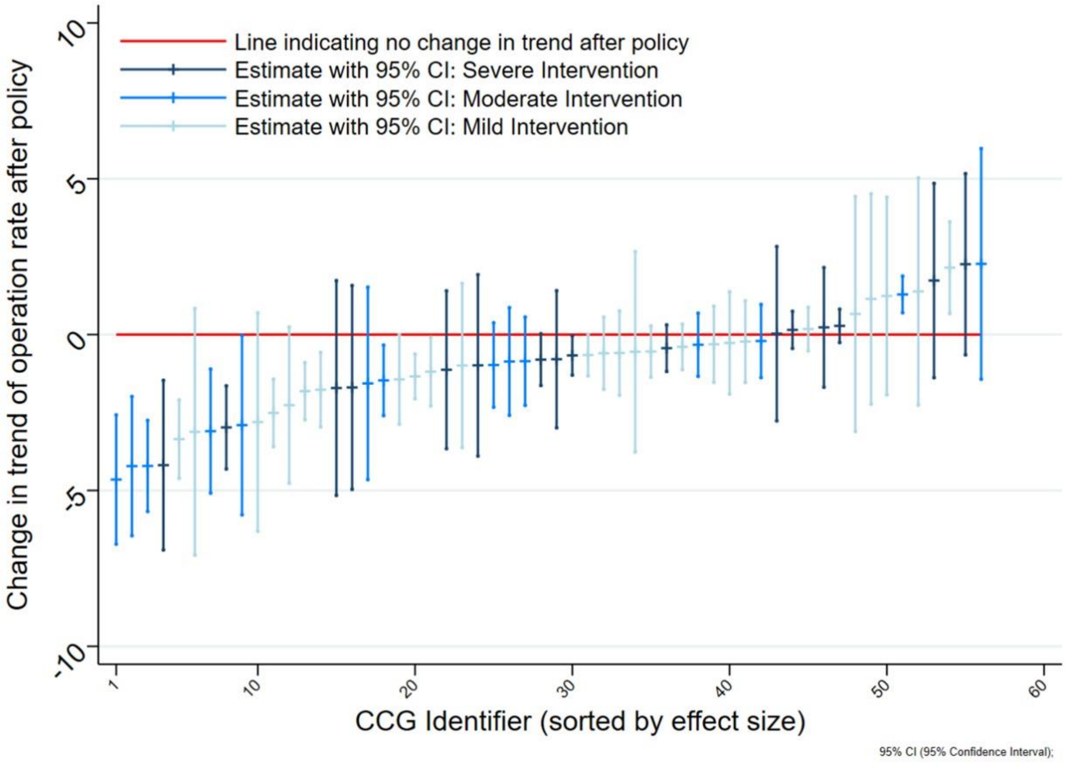
Within the included CCGs, a total of 481,555 patients aged 40+ years had a primary total or uni-compartmental knee replacement between January 2009 and December 2019 in England, with osteoarthritis as a primary reason for surgery. The mean age of patients was 69.6 years (SD 9.13) and 275,626 (57.2%) were women. BMI was not recorded for 25.3% of patients. The mean BMI of patients with a BMI record was 30.9 kg/m^2 (SD 5.46), 431,856 (89.7%) operations were NHS-funded, and 28,496 (5.9%) of patients who received operations were from the 10% most deprived areas.

Overall rates of surgery increased over time from 42.2 per 100,000 population aged 40+ per quarter year in 2009 to a peak of 75.7 in 2017, before declining to 59.6 in 2019. This was consistent across intervention and control CCG localities. There were approximately 11,000 operations in each quarter across control and intervention CCGs in total.

Primary outcome in intervention CCGs: change in rate of surgery following policy introduction

Interrupted time series analysis for individual CCGs in the intervention group (n=56) showed heterogeneity in the effect of policy introduction on the rate of knee replacement operations; rates were expressed per 100,000 population aged 40+ per quarter year. Where a change in trend was observed it was consistent with the time point of policy introduction identified *a priori*. Figure 7 illustrates the heterogeneity in effect sizes on a caterpillar plot. Effect sizes ranged from a change in post-introduction from pre-introduction trend in rate of operations of -4.65 to +2.27. Most CCGs (75%) had a decrease in rate of operations following policy introduction (effect size estimate <0), and two CCGs (4%) showed evidence of an increase in rate of operations (effect size estimate 95% C.I lower bound >0). The immediate change in slope observed after policy introduction for each CCG was independent of differences in the date of policy introduction (e.g. effects were observed for a CCG introducing a policy in 2014, as for a CCG introducing the policy in 2018).

Figure 7: Caterpillar plot of effect size* in CCGs with policies of any severity n=56



*'Effect size' is regression model coefficient for change in pre- to post-policy introduction trends in rate of knee replacement operations per 100,000 aged 40+, per quarter.

In meta-analysis, the overall effect size of policy introduction was -0.92 (95% CI -0.57 to -1.29) operations per quarter per 100,000 patients aged 40+ years. A forest plot of the effect size meta-analysis is included as Appendix 4.

Comparison of primary outcome in control and intervention CCGs

The interrupted time series analysis of pooled data for all intervention and all control CCGs with alignment of their policy start dates is presented in Figure 8. The figure illustrates the trends in operation rates pre- and post-policy introduction for the control and intervention CCGs. Before policy introduction both the intervention and control CCGs had an increasing trend in the rate of primary knee replacement surgery per 100,000 population aged 40+ per quarter. Intervention CCGs had a higher rate of surgery than the control CCGs in any given quarter before policy introduction.

From the point of policy introduction, control group CCGs had no directional change in their trend; rate of surgery continued to increase over time, although at a reduced rate. In contrast, for the intervention CCGs there was a reversal in trend at the point of policy introduction, which was sustained over time resulting in the mean rate of surgery becoming lower for intervention CCGs in any given quarter than for control CCGs. There was no evidence that intervention CCGs had a level change in the rate of operations immediately following policy introduction.

Figure 8: Interrupted time series analyses of rate of knee replacement surgery per 100,000 population aged 40+ from pooled data for all intervention and control CCGs (n=130)

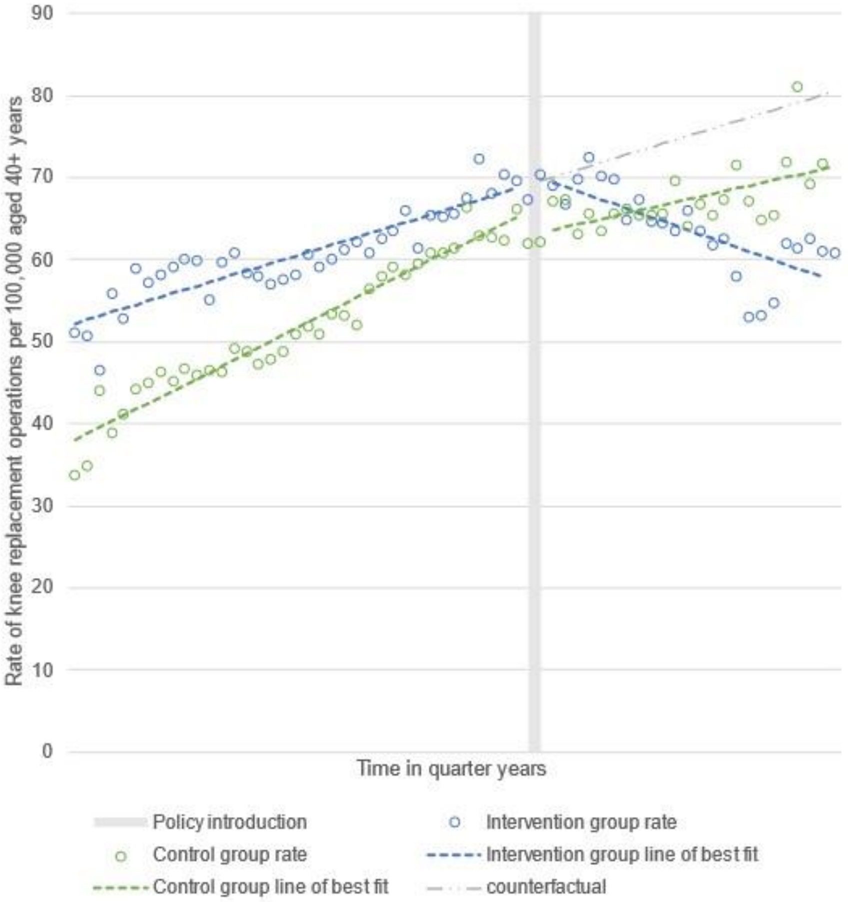


Table 5 presents the interrupted time series segmented linear regression model outputs for the control and intervention CCGs. There was strong evidence that there was a change in trend from the pre- to post-policy introduction period for the intervention CCGs: trend change -0.98 per quarter, 95% confidence interval (CI) -1.22 to -0.74, P<0.001.

For illustration, at 3 years after policy introduction, the modelled rate of operations per 100,000 aged 40+ per quarter in the intervention group was 64.1. This is a 4.6% reduction from the rate at the time of policy introduction (67.2). The predicted rate at 3 years in the counterfactual scenario (where the intervention group rate continued at the preintervention trend) is 74.6; an 11% increase from the rate at the time of policy introduction. The actual rate at 3 years in the intervention group was therefore 14.1% less than would have been expected had no policy introduction occurred. The modelled actual rate at 5 years is 59.9; 10.9% lower than the rate at the time of policy introduction, and 23.5% lower than the predicted counterfactual rate at 5 years (78.3).

The controlled interrupted time series difference-in-differences analyses results are also presented in Table 5. They indicate that the rate of knee replacement operations decreased by an additional 0.56 (95% confidence interval -0.76 to -0.36) operations per 100,000 aged 40+ per quarter in the intervention CCGs compared to the control CCGs.

Table 5: Interrupted time series segmented linear regression and difference in difference analyses before and after policy introduction in intervention and control CCGs

		Pre-policy introduction period			Policy introduction			Post-policy introduction period					
Outcome		Quarterly trend	95% CI		Level change	95% CI		Quarterly trend	95% CI		Change in quarterly trend compared to pre-intervention	95% CI	
Rate of knee replacement surgery in 100,000 population aged 40+ years	Intervention	0.46	0.36	0.55	1.30	-1.56	4.16	-0.52	-0.76	-0.29	-0.98	-1.22	-0.74
	Control	0.76	0.68	0.83	-2.97	-5.53	-0.42	0.34	0.17	0.50	-0.42	-0.57	-0.27
	Difference in differences; intervention rate minus control rate	-0.30	-0.40	-0.20	4.28	0.89	7.66	-0.86	-1.07	-0.65	-0.56	-0.76	-0.36

Baseline differences between intervention and control CCG groups

Intervention group CCGs had higher mean baseline rates (per 100,000 aged 40+) of surgery (2009 quarter 2), than those which did not; 47.3 (SD 16.2) compared to 38.2 (SD 16.1). Table 6 shows the differences between the groups when 'baseline' is considered to be 18 months before the policy introduction date. CCGs that went on to introduce policies had patients who were more affluent, similarly obese, and more independently-funded operations. The 'policy introduction date' for control CCGs is the date of policy introduction from a randomly paired intervention CCG.

Changes in patient characteristics after policy introduction

There were changes in patient characteristics after policy introduction in intervention CCGs, indicating that there was a differential impact of policies on patient groups. Table 6 presents the patient characteristics in the CCGs at baseline, at 18-months post-policy introduction and at 3-years post-policy introduction. Post-policy introduction, patients in intervention CCGs were more likely to be: less deprived, higher ASA grade (i.e. poorer health) and independently-funded.

Table 6: Surgery rate and patient characteristics of intervention and control CCGs before and after policy introduction

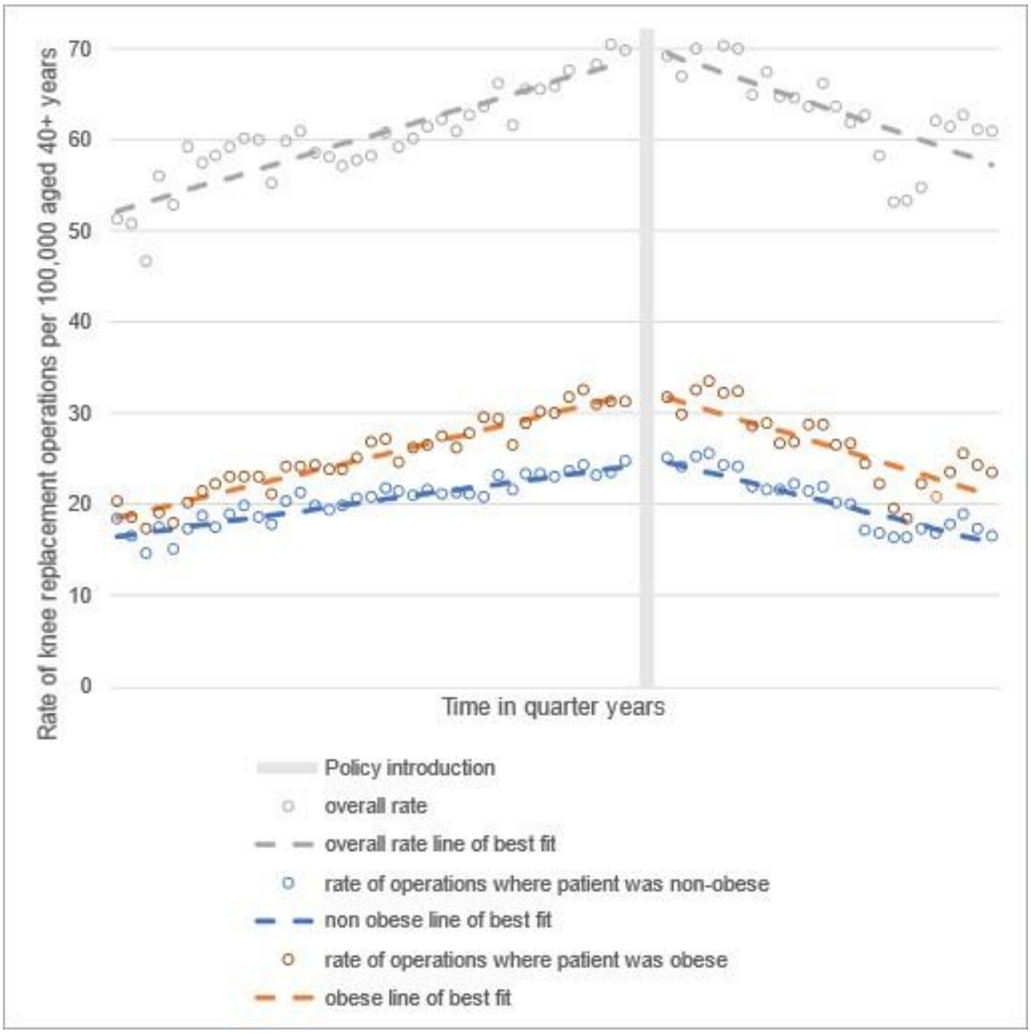
	Control CCGs (no policy introduced during study period)			Intervention CCGs (policy introduced during study period)		
Operation and patient characteristics	baseline 18m pre	18m post	3y post	baseline 18m pre	18m post	3y post
	N=74	N=74	N=37	N=56	N=56	N=30
Knee replacement operations rate per 100,000 population aged 40+ years per quarter (mean)	61.36	63.58	69.65	65.69	70.19	63.55
Age (mean)	69.35	69.42	68.85	69.86	69.82	69.94
Gender (% male)	41.8%	42.0%	39.9%	41.2%	42.4%	39.2%
BMI missing (%)	27.9%	20.8%	22.2%	23.9%	21.5%	22.9%
BMI (mean kg/m^2)	31.23	30.82	31.05	31.12	30.76	30.76
Underweight: BMI below 18 kg/m^2 (%)	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%
Healthy weight: BMI 18 to 24.9 kg/m^2 (%)	8.9%	10.2%	9.7%	10.7%	9.1%	9.1%
Overweight; BMI 25 to 29.9 kg/m^2 (%)	33.0%	33.4%	31.9%	33.2%	35.0%	35.3%
Obese category 1: BMI 30 to 34.9 kg/m^2 (%)	32.2%	32.1%	30.9%	32.3%	32.3%	31.9%
Obese category 2: BMI 35 to 39.9 kg/m^2 (%)	17.7%	17.9%	18.4%	16.1%	17.7%	15.6%

Obese category 3: BMI 40+ kg/m^2 (%)	8.2%	6.3%	9.1%	7.7%	5.9%	8.1%
Independently-funded surgery (%)	8.9%	10.3%	8.3%	11.1%	12.5%	13.8%
ASA* Grade (mean)	2.10	2.14	2.14	2.08	2.14	2.11
1 – normal health (%)	8.4%	6.9%	7.9%	8.7%	7.4%	8.2%
2 (%)	73.7%	72.3%	70.8%	74.7%	71.1%	72.6%
3, 4 or 5 – poorest health (%)	17.8%	20.8%	21.4%	16.7%	21.5%	19.3%
Index of Multiple Deprivation (mean score)	16026	16158	15787	18979	18919	19728
Most deprived 20% (quintile 1)	17.8%	18.8%	19.3%	10.8%	11.1%	8.9%
More deprived 20-40%	24.0%	22.5%	25.3%	16.3%	16.4%	16.80
Mid 20% deprived	21.3%	20.0%	18.9%	22.1%	22.5%	20.9%
Less deprived 20-40%	19.3%	21.3%	18.6%	25.2%	25.4%	23.8%
Least deprived 20% (quintile 5)	17.5%	17.4%	17.9%	25.6%	24.7%	29.5%

* American Society of Anesthesiologists

Stratification of the interrupted time series analyses of pooled data for all intervention CCGs (displayed in Figure 9) showed the policy introduction was associated with a reduction in the rate of operations done for all demographic groups, including in non-obese patients – a group which should not have been affected by the BMI policies. The denominator in each rate is the total CCG population aged 40+.

Figure 9: Stratification of rate of knee replacement operations by obesity in intervention CCGs



4.5.3 Hip replacement analyses

Descriptive information and demographics

Within the 130 CCGs, a total of 480,364 patients aged 40+ years had a primary hip replacement between January 2009 and December 2019 in England, with osteoarthritis as a primary reason for surgery. The mean age of patients was 68.9 years (SD 10.4) and 290,996 (60.6%) were women. BMI was not recorded for 26.3% of patients. The mean BMI of patients with a BMI record was 28.6 kg/m^2 (SD 5.23), 415,550 (86.5%) operations were NHS-funded, and 23,398 (4.9%) patients who received operations were from the 10% of most deprived areas.

Overall rates of surgery increased over time from 41.6 per 100,000 population aged 40+ per quarter year in 2009 to a peak of 72.6 in 2018, before declining to 59.5 in 2019. This pattern was consistent across intervention and control CCG localities. There were approximately 11,000 operations in each quarter in total (mean 10,775, range 7,889 to 13,581).

Primary outcome in intervention CCGs: change in rate of surgery following policy introduction

A similar heterogeneity in effect size was seen as in the knee replacement analyses. In interrupted time series analysis for individual CCGs in the intervention group the effect sizes ranged from a change in post-introduction from pre-introduction trend in rate of operations of -1.85 to +2.86. The caterpillar plot of effect sizes is included in the appendices as Appendix 5. Effect size was associated with policy severity; in meta-analysis (random-effects) within policy categories, the effect size was -0.17 (95% CI -0.57 to 0.23), -0.07 (95% CI -0.48 to 0.33) and 0.17 (95% CI -0.12 to 0.46) operations per quarter per 100,000 patients aged 40+ years in strict, moderate and mild policies respectively (Appendix 6).

Comparison of primary outcome in control and intervention CCGs

The overall pattern of difference in the primary outcome between the control and intervention CCGs is seen in hip replacement as in knee replacement. The interrupted time series analyses of rate of hip replacement operations per 100,000 population aged 40+, per quarter for pooled data by level of severity of body mass index policy are presented in Figure 10. The figure illustrates the trend in operation rates pre- and post-policy introduction for the control and intervention CCGs, including by stratification of policy severity.

From the point of policy introduction, control group CCGs had no overall directional change in their trend; rate of surgery continued to increase over time. There was an association with an increase in the upward trend in the post-policy introduction period (p=0.007). In contrast, for the intervention CCGs there was a downward trend in rate of surgery over time. This accelerated at the point of policy introduction and was then sustained over time resulting in the mean rate of surgery becoming lower for intervention CCGs than for control CCGs. This finding was most pronounced in the strict policy category of intervention CCGs.

Figure 10: Interrupted time series analyses of rate of hip replacement operations per 100,000 population aged 40+, per quarter by level of severity of body mass index policy; none (n=74), mild (n=26), moderate (n=14), strict (n=16)

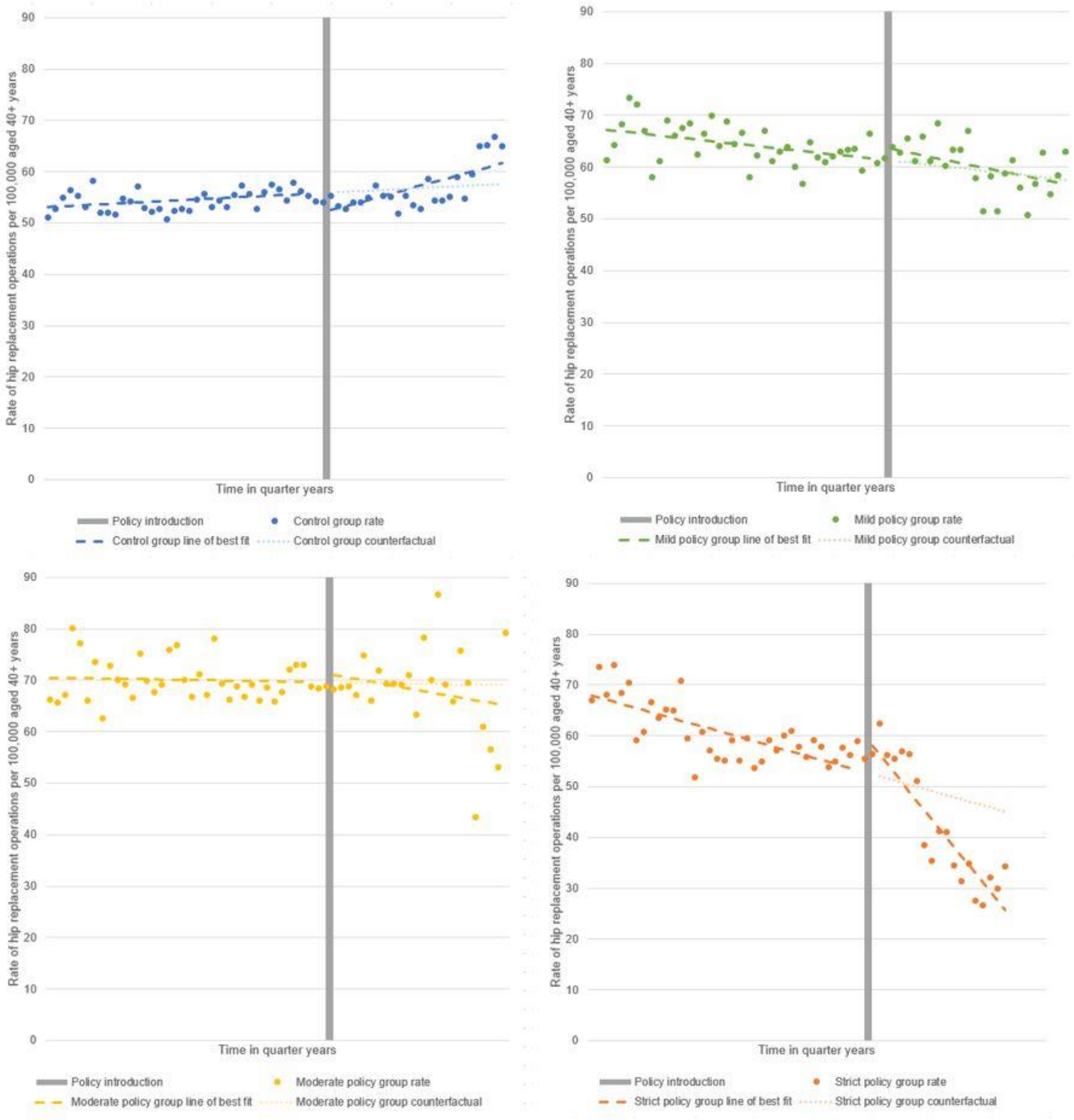


Table 7 presents the interrupted time series segmented linear regression model outputs for the control and policy categories of intervention CCGs. The largest change in trend from the pre- to post-policy introduction period was for the strict BMI policy CCGs: trend change -1.39 per quarter (95% CI -1.81 to -0.97, P<0.001). There was no equivalent post-policy introduction change evident in the mild and moderate BMI policy CCG groups. When the strict policy group was compared to the control group in difference-in-differences analysis, the difference in operation rates between the groups widens consistently over time; by -2.43 (95% CI -3.17 to -1.69, P<0.001) operations per 100,000 aged 40+ per quarter in the post-policy introduction period (Table 7).

Table 7: Interrupted time series segmented linear regression and difference in difference analyses before and after policy introduction for hip replacement surgery in intervention and control CCGs

		Pre-policy introduction period			**Post-policy introduction period**					
Outcome		Quarterly trend	95% CI		Quarterly trend	95% CI		Change in quarterly trend compared to pre-intervention	95% CI	
Rate of hip replacement surgery in 100,000 population aged 40+ years	Control	0.07	-0.01	0.14	0.40	0.16	0.63	0.32	0.09	0.56
	Mild	-0.16	-0.30	-0.02	-0.29	-0.50	-0.09	-0.14	-0.37	0.10
	Moderate	-0.02	-0.17	0.13	-0.26	-0.75	0.24	-0.23	-0.74	0.27
	Strict	-0.41	-0.54	-0.27	-1.80	-2.22	-1.34	-1.39	-1.81	-0.97
	Difference in differences; **strict** rate minus control rate	-0.48	-0.60	-0.37	-2.91	-3.67	-2.15	-2.43	-3.17	-1.69

Baseline differences between intervention and control CCG groups

Intervention group CCGs had higher mean rates (per 100,000 aged 40+) of surgery at the start of the time period (2009 quarter 2), than control group CCGs; 45.5 (SD 16.8) compared to 34.7 (SD 16.9). Table 8 shows the differences between the groups when 'baseline' is considered to be 18 months before the policy introduction date. In CCGs that went on to introduce policies, their patient cohorts were similarly obese to CCGs without policies, but their cohorts were more affluent and had more independently-funded operations. These differences in characteristics of the CCGs were sustained over time; CCGs choosing to introduce a BMI policy had higher rates of hip replacement and operated on a lower proportion of patients from the most socio-economically deprived areas (quintile 1) at all points in calendar time (Appendix 7).

Changes in patient characteristics after policy introduction

Changes in patient characteristics were associated with policy introduction in intervention CCGs compared to control CCGs, indicating a differential impact of policies on different patient groups. Table 8 presents the patient characteristics in the CCGs at baseline, at 18-months post-policy introduction and at 3-years post-policy introduction. Patients in intervention CCGs were more likely to be: less deprived, independently-funded and a healthy weight at baseline, and these differences were maintained into the post-introduction period. The 'policy introduction date' for control CCGs was the date of policy introduction from a randomly paired intervention CCG.

Table 8: Operation rate and patient characteristics of intervention and control CCGs before and after policy introduction

	Control CCGs			Intervention CCGs		
	(no policy introduced during study period)			(policy introduced during study period)		
Operation and patient characteristics	baseline 18m pre	18m post	3y post	baseline 18m pre	18m post	3y post
	N=74	N=74	N=37	N=56	N=56	N=30
Hip replacement operations rate per 100,000 population aged 40+years per quarter (mean)	57.6	54.1	55.4	62.2	65.7	62.9
Age (mean)	68.4	68.1	68.3	68.8	68.6	69.1
Gender (% male)	40.3%	42.5%	40.6%	39.0%	39.8%	37.7%
BMI missing (%)	33.9%	37.0%	36.0%	26.4%	25.1%	28.7%
BMI (mean kg/m^2)	28.6	28.4	28.9	28.3	28.6	28.3
Underweight: BMI below 18 kg/m^2 (%)	0.3%	0.7%	0.4%	0.3%	0.7%	0.7%
Healthy weight: BMI 18 to 24.9 kg/m^2 (%)	21.5%	22.7%	20.1%	23.6%	22.2%	24.9%

Overweight; BMI 25 to 29.9 kg/m^2 (%)	38.9%	40.7%	38.9%	39.9%	38.0%	34.4%
Obese category 1: BMI 30 to 34.9 kg/m^2 (%)	26.3%	22.9%	25.7%	24.1%	26.4%	27.5%
Obese category 2: BMI 35 to 39.9 kg/m^2 (%)	9.7%	9.7%	10.3%	9.3%	8.9%	9.7%
Obese category 3: BMI 40+ kg/m^2 (%)	0.03	3.3%	4.6%	2.9%	3.8%	2.7%
Independently-funded surgery (%)	12.2%	11.8%	10.1%	15.5%	15.6%	16.8%
ASA* Grade (mean)	2.06	2.05	2.06	2.04	2.04	2.03
1 – normal health (%)	12.9%	12.8%	12.5%	13.1%	12.6%	13.6%
2 (%)	68.4%	70.2%	69.9%	70.2%	70.8%	69.9%
3, 4 or 5 – poorest health (%)	18.7%	17.0%	17.6%	16.6%	16.6%	16.5%
Index of Multiple Deprivation (mean score)	16672	16492	16388	19001	19215	20317
Most deprived 20% (quintile 1)	17.3%	17.4%	18.9%	11.7%	10.2%	7.2%
More deprived 20-40%	22.2%	21.8%	21.1%	15.9%	15.8%	15.4%
Mid 20% deprived	19.2%	21.3%	19.0%	21.3%	22.7%	21.3%
Less deprived 20-40%	22.3%	21.4%	23.5%	25.2%	24.3%	24.1%
Least deprived 20% (quintile 5)	18.9%	18.1%	17.5%	25.9%	26.9%	32.0%
Pre-op Oxford Hip Score (mean)	16.9	17.6	17.6	18.1	18.5	18.4
Post-op Oxford Hip Score (mean)	38.4	38.8	38.1	39.6	39.5	39.4
Difference in pre to post op score (mean)	21.5	21.3	20.6	21.5	21.0	21.0

* American Society of Anesthesiologists

Figure 11 presents the interrupted time series analysis of the proportion of independently-funded operations performed between the control and strict policy groups. While the strict policy group showed an upward trend in the proportion of independently-funded surgery even in the pre-policy introduction period, the point of policy introduction was associated with a stronger, sustained upturn in the proportion. For illustration, at 3 years post-policy introduction the proportion of independently-funded surgery in the strict policy group is over double that of the control group (21.0% (SD 7.4%) and 10.1% (SD 9.5%) respectively).

Figure 11: Interrupted time series of proportion of independently-funded hip replacement operations from pooled data for strict policy CCGs (n=16) and control CCGs (n=74)

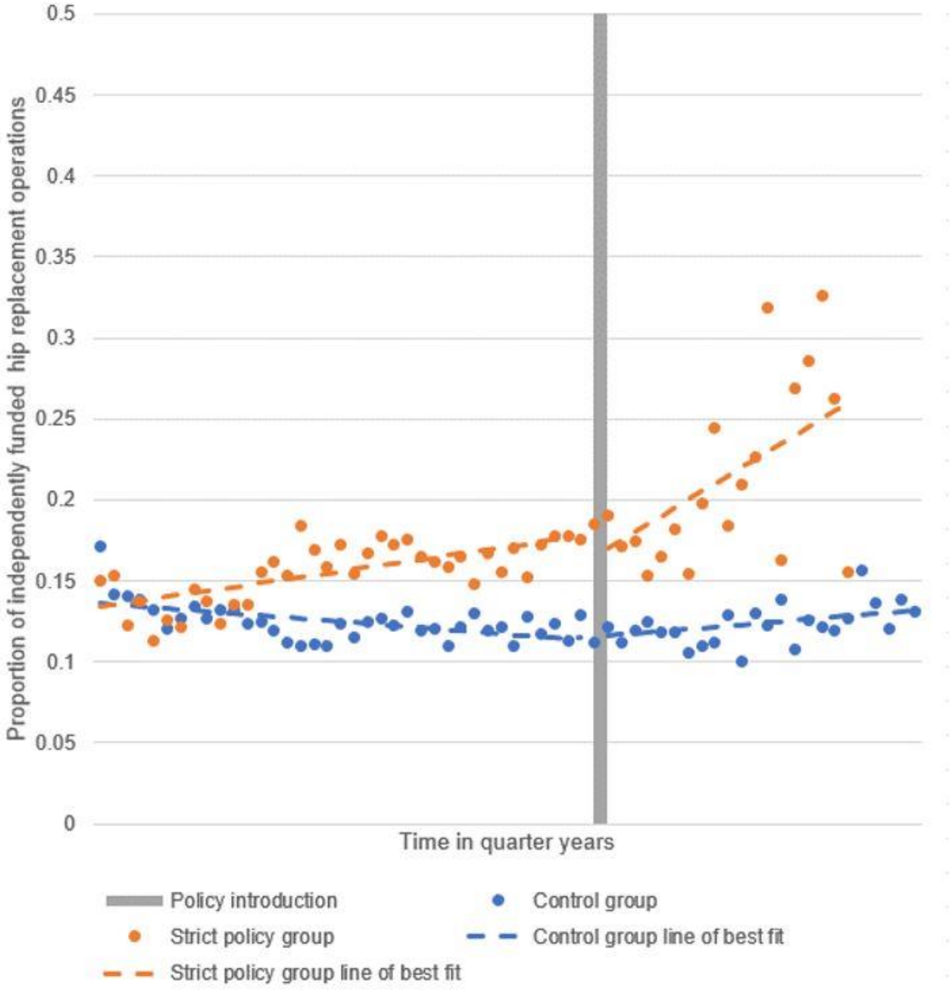


Figure 12 presents the interrupted time series analysis for the proportion of operations performed in patients with obesity (BMI 30+ kg/m^2). The proportion in the control group remained at approximately 26%, whereas the proportion in the intervention CCGs was higher in the pre-policy period but followed a downward trend into the post-policy introduction period. When the intervention group CCG analyses are stratified by policy severity, the reduction in the intervention group is shown to be driven by reductions in the mild and strict policy types. In contrast, following policy introduction in the moderate (extra waiting time) policy group there is an association with an increase in trend in this proportion.

Figure 13 presents the interrupted time series analysis for the mean Oxford Hip Score measured pre-operatively. The mean score in the control group remained at approximately 17, whereas the mean score in the intervention CCGs was already higher (indicating less severe symptoms) in the pre-policy period and showed an upturn in the trend in the post-policy introduction period. When the intervention group CCG analyses are stratified by policy severity, the increasing trend in the intervention group is shown to be driven by reductions in the mild and strict policy types. In contrast, following policy introduction in the moderate (extra waiting time) policy group there is a decrease in the trend of the mean score (indicating more severe symptoms).

Figure 12: Interrupted time series of proportion of hip replacement operations where the patient had obesity (BMI ≥30 kg/m²) from pooled data for a) intervention CCGs (n=56) and control CCGs (n=74) and b) stratified by policy severity

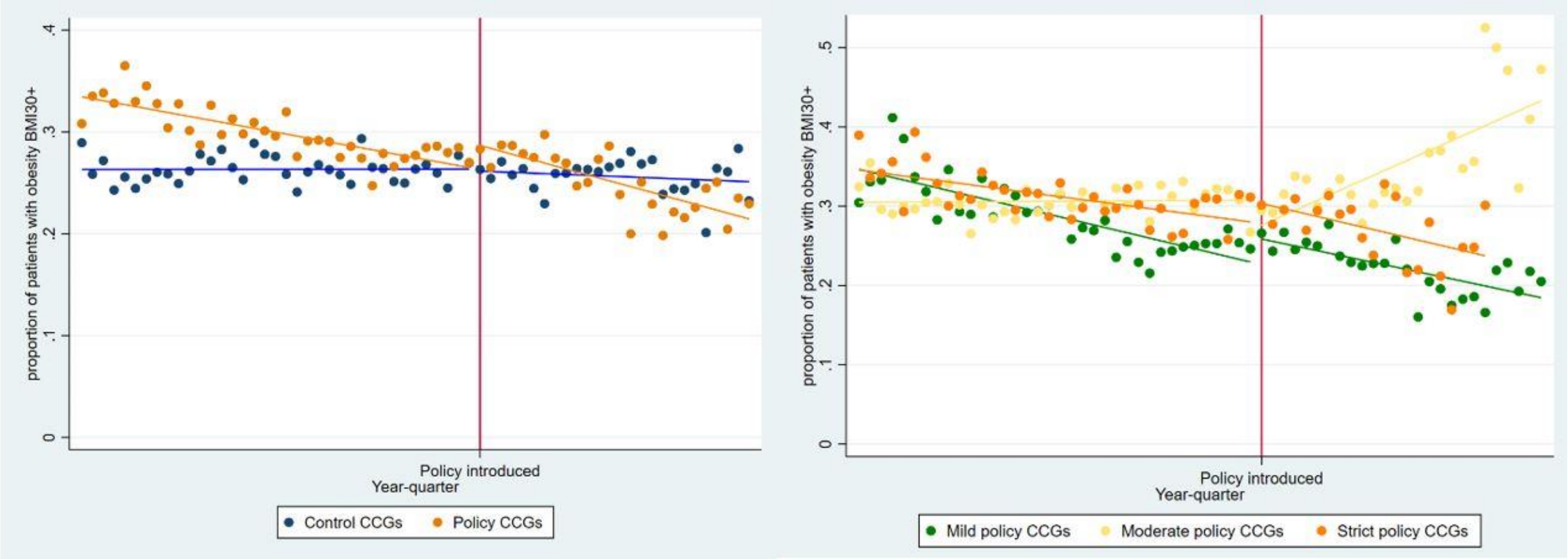
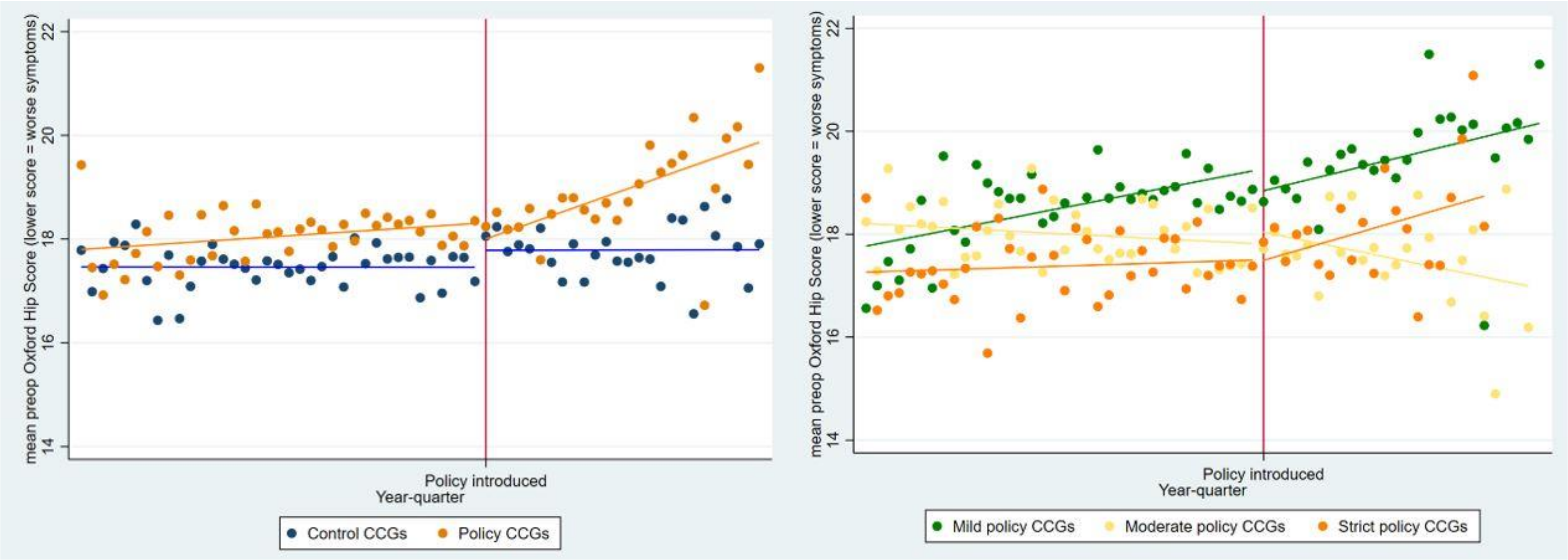


Figure 13: Interrupted time series of mean pre-operative Oxford Hip Score (lower score = worse symptoms) from pooled data for a) all intervention CCGs (n=56) and control CCGs (n=74) and b) stratified by policy severity



4.6 Discussion

4.6.1 Summary of key findings

- Analysis of circa 1 million hip and knee replacement operations comparing intervention and control policy areas with varying policy introduction dates formed a natural experiment.
- There was an overall association between BMI policy introduction and a sustained downturn in the trend of the rate of surgery (primary outcome); this was in contrast to the continued upward trend in control areas.
- The effect size was most marked with strict policy use (policies requiring patients with obesity to meet a BMI threshold to access surgery).
- An unexpected decrease in operations for non-obese patients alongside obese patients was also observed.
- Clinical commissioning groups that introduced BMI policies had higher rates of surgery and populations with lower levels of socio-economic deprivation at baseline compared to those that did not.
- The impact observed on secondary outcomes raises concerns over inequalities; after policy introduction, patients receiving surgery are more likely to be less socio-economically deprived and have independently-funded surgery.
- Stratification by policy severity revealed that extra waiting time (though not deemed 'most severe') had an association with worsening mean pre-operative symptom scores and obesity.

4.6.2 Interpretation and relationship to the existing literature

The interpretation of a reduction in the rate of surgery may be positive or negative in nature. In line with their stated purpose, BMI policies may have reduced the need for surgery for some patients where successful weight loss provided significant relief of their arthritis symptoms. However, considering that literature reports low rates of success with weight loss efforts and maintenance (an average of 3% weight loss in adults adhering to lifestyle weight loss programmes and weight regain common at one year (12,103,200)) and a recommendation for at least a 10% reduction in body weight for osteoarthritis patients with obesity to gain meaningful relief in their arthritis outcomes (75,201), this number is likely to be small. This explanation is also unlikely given the downward trend in rates of surgery for patients that were not obese. Health optimisation policies may also reduce the need for surgery by supporting symptom improvement and quality of life through mechanisms which are not directly related to weight loss, including increased exercise and the opportunity for shared decision-making (21).

An alternative, less positive explanation for the reduction in the rate of surgery would be that the BMI policies prevent access to surgery for some patients who would have received benefits to their quality of life from joint replacement but were unable or unwilling to lose sufficient weight to reach eligibility thresholds. Existing literature suggests that patients with BMI ≥40 kg/m^2 rarely find it possible to lose significant weight through lifestyle and pharmacological interventions alone when advised to do so for surgery, and that their response to being asked to lose weight may be to cease their pursuit of care for their joint symptoms despite needing surgery

(202,203). This may account for some of the reduction in rate of surgery in the obese patient group. This explanation is supported by literature from the USA reporting that very few patients denied joint replacement due to their obesity manage to lose sufficient weight to qualify for surgery (170).

Strict policy introduction was associated with an increase in the proportion of independently-funded surgery and the proportion of more affluent patients receiving surgery. These findings raise the concern that the use of BMI policies for joint replacement surgery risks widening health inequalities by increasing the link between access to surgery and socio-economic circumstances. The need for surgery is higher in patients of lower socio-economic status, and evidence that BMI eligibility criteria for joint replacement may worsen racial and socio-economic disparities has been reported previously (172). Data from these analyses show surgery rates decreased most in more deprived groups (data on ethnicity were not available).

There is also some evidence from these analyses that BMI policies that impose extra waiting time on patients are counterproductive in certain key measures; patterns in the post-policy introduction period suggest that this type of policy introduction was associated with worsening symptoms (pre-operative Oxford Hip Score) and increasing obesity in the surgical patient population. Existing literature shows evidence that waiting longer for elective surgery gives worse outcomes and loss of quality of life (204). The proportion of patients with obesity was seen to decrease in the mild and strict policy categories, though it is noted that this was a pre-existing trend.

The rise in surgery rates in the control CCG groups over time is consistent with expectations of a greater need for surgery in an ageing and increasingly obese population in England (205). The introduction of a moderate or strict policy in one CCG may also result in the referral of affected patients to neighbouring CCGs with less severe policies, raising pressure on their service provision. This may account for some of the rise seen in the control group. The number of patients on existing waiting lists prior to policy implementation may influence the timing of policy impact but this association could not be analysed in this study.

4.6.3 Strengths and limitations

This study has used a powerful quasi-experimental design. Pooled data between 130 CCGs, with alignment of policy start dates which were spread over many different years, provides reassurance that the change is due to the introduction of these policies, and not other wider external influencing factors that may have occurred at a single time point. The use of interrupted time series analysis ensures that pre-existing pre-intervention trends and secular trends are controlled for. A further strength of this study is the use of a large mandatory national dataset, capturing 96% of all hip and knee replacement procedures including those that are independently-funded (34), and for this study, the IMD 2015 was linked to all patients. BMI data are less complete in the registry – missing for approximately 25% of records. Some surgery eligibility policies also included restrictions on patients who smoke. As the NJR does not collect data on smoking status, no analysis was possible on this.

The COVID-19 pandemic’s impact on elective surgery has been significant. While this study limited data analysis to the pre-pandemic period to avoid the impact of the pandemic on the interrupted time series analysis, the pandemic itself alters the immediate applicability of the study findings.

As the primary data source is a registry of surgery, this analysis cannot comment on the patients who did not receive surgery through choice or exclusion. Analysis of changes in the rates of surgery gives important insight into the impact of BMI policy introduction, but further research is needed to determine the mechanism of effect and the impact on the quality of life of patients who did not receive surgical referrals.

There are multiple options for interrupted time series analyses – this study benefitted from a novel approach which allowed powerful pooling of data between CCGs by using an alignment to 'time zero' of disparate policy introduction dates across time, and random matching of control CCGs with these dates to allow direct comparison of two overall groups. The inherent methodological issues with interrupted time series analyses were addressed in the study design; seasonality was reduced by the non-calendar time alignment of quarters, and as recommended, a pre-specified technique - the Newey-West standard error model, was used to address data autocorrelation (206).

4.6.4 Policy and research implications

This study strengthens the evidence for the assertion in the newly updated NICE guidelines for the management of osteoarthritis (36) which state that BMI should not be used to deny patients access to hip or knee replacement surgery. The guidance also notes that as "osteoarthritis is more common in people in lower socio-economic groups […] obesity is also more common in people in lower socio-economic groups […] access to surgery on the basis of BMI has been raised by stakeholder groups as an important equality issue" (207). Despite the NICE guidance's stance that obesity should not preclude referral to surgery in osteoarthritis, it has been reported previously that CCG referral criteria are inconsistent in respect of NICE guidance (47). There is no consistent evidence that patients with obesity have substantially worse outcomes from joint replacement surgery (208–210), nor that weight loss before joint replacement surgery has any effect on infection or readmission rates (87,94,135). A study of joint replacement patients in the USA suggests that using even a high BMI threshold of 40 kg/m^2 may prevent one operation with complications yet deny complication-free operations to 14 others (167).

NHS commissioning has now moved from CCGs to integrated care boards in England and it remains to be seen what action they will take where they have inherited strict policies from their former CCGs. Clinical commissioning groups that introduced BMI policies had higher rates of surgery and more affluent populations at baseline compared to those that did not, and it is possible that these factors may have been drivers for policy introduction. While policies to limit access for obese patients may be driven by short term financial pressures, there is currently no evidence that treatment should be withheld on cost-effectiveness grounds. Economic modelling, which did not assess BMI, has concluded that compared to no replacement, knee replacement was cost-effective for 99.9% of patients receiving surgery (179); the basis for local policies to ration this treatment appears limited.

With the concerns over the unintended effects of health optimisation policies that target access to surgery raised here, policies could instead focus on supporting long-term lifestyle changes within existing waiting times, avoiding the risks of punitive restrictions on access to surgery (117,126).

As noted in the limitations, this study could only analyse data for patients in receipt of surgery. Research is needed that specifically determines the impact of policies on the group of patients that did not go on to have surgery as they are at high risk of health inequality. Examination of policy implementation rigour and resource may elucidate the reasons behind the heterogeneity in effect size seen in this study, and the unexpected impact on non-obese patients. It will also be important to extend research into areas of elective surgery other than orthopaedics which are affected by health optimisation policies, as the impact may differ given the varied mechanisms by which BMI may be associated with different pathologies.

4.7 Conclusion and implications for thesis

This chapter forms a key methodological component of the thesis and offers a novel, robust quantitative analysis of the impact of the use of BMI health optimisation policies over time. The evidence presented in the form of interrupted time series analyses associates BMI health optimisation policy use with problematic reductions in access to hip and knee replacement surgery and heightened health inequalities. Policy recommendations follow from these findings that increased efforts should be made to ensure progress is made to align commissioning decision-making with existing NICE guidance regarding avoidance of the use of BMI in restricting access to surgery. The mechanism for the reduction in the rate of surgery, and barriers and facilitators to the introduction or removal of BMI policies can best be understood through qualitative study of this topic. The following chapter (Chapter 5) presents the qualitative work undertaken for this thesis to extend this understanding and contextual appreciation of the findings of this chapter.

Chapter 5. Qualitative study

5.1 Overview

Earlier chapters of the thesis have presented the background situation whereby health optimisation policies incorporating mandatory BMI thresholds or extra waiting time have increasingly been used in the NHS and the variation that exists in these policies across England. This chapter presents the qualitative interview study with key professional informants with insight into decision-making in health optimisation policy making. The study background, methods, results, discussion and implications are reported.

5.2 Objectives

This study aimed to meet the following objective:

Objective 3:

i. *To investigate the views of key informants about the appropriateness and effectiveness of current health optimisation interventions.*
ii. *To explore key informants' views on the role of evidence in health optimisation policy development and implementation.*
iii. *To explore key informants' views on the current and potential impact of health optimisation policies on health inequalities.*

5.3 Background

The Royal College of Surgeons states that BMI should not be used to ration arthroplasty, and recently updated NICE guidelines advise that BMI should not preclude patients from referral (36). Chapter 3 recounts that despite this guidance, around half of CCGs in England in 2021 had a restrictive policy regarding BMI in place for arthroplasty (48). The recent formation of integrated care boards from CCGs in 2022 presented an opportune moment for commissioners and policymakers to reassess their policy positions.

Chapter 4 presents the findings from the natural experimental study examining differences in joint replacement surgery rates and demographics associated with BMI policy introduction. The chapter reports a sustained downward trend in the rate of hip and knee arthroplasty from the point of policy introduction in contrast to the upward trend maintained in the control group. The association with worsening pre-operative symptom scores and rising obesity in localities which introduced extra waiting time before surgery – counterproductive to the policies' stated purpose - is also noted. A disproportionate reduction in surgery rates in the most socio-economically deprived groups, coupled with a rise in the proportion of independently-funded surgery undertaken was also evident, raising concerns about health inequalities.

Given the geographical variation in policy prevalence and approach and the concerning associations seen with restrictive policy use, an investigation of the reasons for the introduction and continued use of these policies is warranted. Individual commissioning groups have the power to decide upon and implement their own BMI policies regarding access to elective surgery. The role of the evidence base in guiding these decisions is unclear. In the course of my professional experience, the use of public consultations and Health Equity Impact Assessment techniques was evident in some settings, but no consolidated approach to evidence-based policy making concerning this topic was apparent. This qualitative study sought to address some of these gaps in the understanding of views of policy decision-making, including reasons for regional variation, relevant to this topic of health improvement in the pre-operative period.

5.4 Methods

5.4.1 Qualitative approach and research paradigm

A qualitative approach was chosen to meet the study objectives. The philosophical underpinnings of qualitative research centre on the importance of understanding the subjective experiences and perspectives of individuals - in this case, key informants with experience and insight into healthcare policy decision-making. Working within the paradigm of interpretivism, most qualitative researchers conceptualise knowledge as socially constructed and seek to explore the meanings and beliefs that individuals ascribe to their experiences (211). In addition, the constructivist paradigm emphasises the co-construction of reality between the researcher and participants, accepting that multiple interpretations of reality may exist. Qualitative researchers view reality as subjective and context-dependent, with individuals actively constructing their own meanings and interpretations (212). In this paradigm, the researcher is seen as a co-creator of knowledge (213).

By using qualitative methods researchers can capture the richness and depth of the social world, providing a comprehensive understanding of the factors influencing complex phenomena such as policy decision-making (214). Semi-structured interviews provide a means to explore these subjective experiences and gain in-depth insights into the research topic and were chosen as an appropriate approach to data collection in this study (211). The technique of conducting semi-structured interviews allows for a balance between structure and flexibility, as it involves open questioning guided by identified themes while allowing for probes to elicit more elaborate responses and uncover new topics of interest. The semi-structured nature of the interviews used in this research enabled me to explore the research topic in a consistent and systematic manner while also allowing for the exploration of unexpected or emergent themes (215). Observational qualitative techniques were also considered for their potential role in exploring the interactions between multiple decision-makers in organisational settings; however, the policy decision-making settings and time points are difficult to identify and were often historic at the point of the study.

Qualitative interviewing enables researchers to explore the perspectives of multiple stakeholders involved in healthcare policy decision-making (211). This approach allows for a comprehensive understanding of the decision-making process and the various factors that influence policy choices, including providing the opportunity to explore the context and values that shape healthcare policy decision-making (216). It allows researchers to consider the broader societal and ethical implications of policy choices, taking into account the values and preferences of different stakeholders. This is particularly important in healthcare, where decisions often involve trade-offs and the allocation of limited resources (216).

5.4.2 Researcher characteristics and reflexivity

Reflexivity is the consideration of the influence of a researcher's personal and professional background and experience on their research. Reflection on the existing pre-conceptions and focused interests held by the researcher, shaped by their individual circumstances, can aid in the conscious appreciation of how these elements may shape the data collection and analysis decisions and style of the researcher (217).

I, the thesis author, am a medically qualified public health specialty registrar (qualifications MBChB, MSc, MFPH) who had experience in research into health optimisation prior to the completion of this research study. I also had operational input into a regional health optimisation policy introduced during a local authority public health training placement in 2019 where I co-led the public health appraisal of the potential impact of a policy to delay access to surgery for patients with obesity. I also led the evaluation of the policy impact after its introduction, including a qualitative study with patients, healthcare professionals and commissioners who had experience in the creation, implementation and delivery of the policy (54,126).

Participants in this study were aware of my clinical and public health background although I chose to primarily identify myself as a doctoral research fellow for the purposes of this study. I used my professional qualifications in my correspondence signature details therefore participants would also have been aware of my medical background. I acknowledge the influence that my previous experience of working with commissioners and clinicians to develop and evaluate a health optimisation policy, and also of interviewing patients with positive and negative experiences of the policy's implementation, will have had on the development of the topic guide, and my analysis of the data. This experience will have shaped my background views and opinions on which aspects of health optimisation policies needed detailed attention in this study. It may also have led me to assume that health optimisation policies were more deeply considered and of greater salience to the participants than was the case. To counter this possibility, the topic guide and interview approach were designed to promote early exploration of the participants' background level of engagement with health optimisation and also to ensure that open, non-judgement based questioning allowed participants to raise a broader range of issues than may have been anticipated. As the conclusion of the previous work evaluating a historic policy was that of equipoise, and with the awareness of the variation which had been present in the accounts of the patients and clinicians interviewed, I was left in a position of informed curiosity about the wider experiences of key informants in this policy topic. The background section of this chapter addresses the rationale for undertaking further qualitative work on this topic. While acknowledging the advantages of researchers working with peers as research subjects and in familiar settings, consideration was given to the disadvantages of this arrangement (218). Peer review through discussion with my experienced qualitative supervisor focused on returning to an emphasis on reflexivity at key points during the analysis phase.

5.4.3 Statutory approvals

Approval from the Cornwall and Plymouth NHS Research Ethics Committee (REC) and from the Health Research Authority for this study was granted for up to 30 interviews, by means of an Integrated Research Application System (IRAS) application submission; REC approval reference: 21/SW/0106, IRAS project ID: 294970. This process included review of the content and suitability of the processes in place for informed consent for participation in this study, and the confidentiality of participant information. The study documents and approval letter are provided in Appendix 8, Appendix 9, Appendix 10 and Appendix 11.

5.4.4 Context and sampling strategy

There was no central site for this study. Health optimisation policies are in place in many areas of England and could potentially be introduced by any commissioning region. Therefore key informants from any relevant NHS healthcare delivery or policy making setting across England were included in the scope; regional or national. In the year of the study's data collection, integrated care boards were newly formed from clinical commissioning groups, therefore participants drew on their experiences and identities within both these contexts. An understanding of individuals' views and experiences in all the major organisational settings which had influence and responsibility for determining health optimisation approaches in England were of interest. At the national level, these settings included NHS England and the Centre for Perioperative Care. Based on previous experience investigating the creation and delivery of a health optimisation policy, the following professional groups were considered to be the sources of key informants for this study; health optimisation pathway leads, healthcare and public health commissioners and policymakers focused on elective care, pre-operative interventions, health inequalities and health improvement, and clinicians including general practitioners, orthopaedic surgeons and anaesthetists.

I have used the term 'policymakers' in this chapter in alignment with the definition given in guidance from The Health Foundation: 'People working in healthcare policy roles help to set a course or define a principle that governs how an organisation acts. They may have a direct role in making policy for the NHS, or be focused on influencing the policy making of others. They can operate at a local, regional, national or international level' (219). Healthcare commissioners are policymakers themselves, but are specifically people involved in the delivery of policy making as part of their role in planning and allocating funding for healthcare services in their locality. In this study, this included commissioners within CCGs, and now ICBs, responsible for decision-making over health optimisation policy, described in section 1.6 of this thesis.

5.4.5 Sampling strategy

Potential participants were initially selected through purposive sampling, which is a targeted approach seeking to recruit participants with a range of perspectives relevant to the phenomena under study (214). The sampling frame included commissioners, policymakers, managers and clinicians known to have worked in different regions of England with and without restrictive health optimisation policies in place. Other individuals were approached due to their roles within national NHS or NHS-associated organisations with a remit in health optimisation or pre-operative prehabilitation policy development and delivery. Following a process of ‘snowballing’ (214), further invitations were made where participants suggested other potential participants with relevant involvement in health optimisation, or clinical experience in divergent policy regions of England. Invitations were issued in sets of five. It was estimated that up to 30 interviews would yield sufficient data; data collection and eventual sample size were informed by the concept of ‘information power’ (220) with sampling, participant recruitment and analysis conducted in parallel to allow a continuous assessment of the data collected. When the concurrent data analysis suggested a consolidation of emergent themes and multiple informants from each professional group had been interviewed no further invitations were issued and sampling was deemed to be complete.

Invitations were sent via email directly to the potential participants using publicly available contact information. Participants contacted me to indicate their availability for an individual semi-structured interview. Participants were required to return a completed consent form via email prior to interview commencement and their consent was confirmed verbally at the start of the interview. Participants had at least 72 hours to consider the information before being asked to consent. The consent form (Appendix 10) requested that participants read and ticked (electronically) statements indicating that they had read the relevant version of the Participant Information Sheet (Appendix 11) and had the opportunity to ask questions and have these answered fully; that they understood that their participation was voluntary; that they understood that the data they provided could be stored and used in its anonymised form for reports, publications, and/or teaching materials from the research and by other researchers for further research.

5.4.6 Data collection methods

Semi-structured Interviews were conducted using a topic guide developed by me with supervisory input from my qualitative supervisor AOS. The scope of the interview topic guide and priority subtopics were informed by relevant literature, my prior professional experience and patient and public involvement group engagement (detailed in Chapter 4). The main topics are outlined in Table 9. The full topic guide is included in Appendix 9.

Table 9: Interview topic guide summary

Topic headline	Subtopics
Introduction and participant background	• Professional role • What is health optimisation • Experience of any regional policies
The current evidence base for health optimisation interventions	• Policy development process • Role of evidence base • Key drivers • Role of integrated care systems
The role of inequalities in health optimisation	• How inequalities are considered in policy development • Potential impact on health inequalities
Best practice in health optimisation	• What works well • What are the challenges
Current and historic health optimisation policy landscape	• Regional differences, reasons and consequences • Parallels with other policy areas
The impact of health optimisation rates on provision of surgery	• Patterns in access to arthroplasty and possible relation to policy introduction
The future of health optimisation and research needs	• Scope of health optimisation in the NHS • Role of national policy • Next steps for health optimisation

I carried out the interviews by video call (using Microsoft Teams) or in person at a time convenient to the participant.

Remote interviewing through video call is acknowledged to offer both advantages and disadvantages compared to traditional face-to-face interviews (221) and these are summarised below. The impact of remote interviewing is currently an element of active discussion in qualitative methodology literature (214). The associated advantages are that it offers convenience and flexibility and requires no travel time or costs. The reduction in participant time necessary to conduct the interview may offer access to a more diverse sample of participants and increase positive response rates to study invitations. Potential disadvantages are that technical issues can disrupt the interview interaction and that the remote, two-dimensional nature of the interaction may reduce the personal connection and non-verbal cues available between the interviewer and participant. These factors may reduce the quality of the data collected. There may also be reduced privacy for the participants, and therefore confidentiality issues may arise depending on the environment available. As the participants in this study were all professionals already regularly using video calls to conduct their roles, and the participants were offered face-to-face interviews as an alternative, it was decided that including remote interviewing in this study was appropriate.

Participants were advised that the interviews were anticipated to last for 45 to 60 minutes. All data collection sessions were audio-recorded on an encrypted digital audio recorder and the recordings were uploaded as soon as possible to the University of Bristol's Research Data Storage Facility.

5.4.7 Data processing and analysis

In line with the statutory approvals granted for this study, personal identity data were stored separately and securely with restricted access to maintain confidentiality. I fully transcribed the Interviews and I then anonymised and checked the transcripts for accuracy against the recordings. Overall, I took a grounded approach to analysis, consistent with the iterative approach to generating theory from empirical data as initially explicated in the development of grounded theory by Glaser and Strauss (222).

The processes I used for the thematic analysis of the data were based on recommendations described by Braun and Clarke (223). All transcripts were read and reread to gain familiarity with the data. Initial ideas were documented before open coding using qualitative data analysis software (NVivo) was applied to blocks of text. The analysis thus took an inductive approach. Independent coding of a subsample of transcripts by my qualitative supervisor was undertaken to enhance the rigour of analysis; differences in interpretation were discussed until agreement was reached for an initial coding framework which was then applied to all transcripts. Data analysis ran in parallel with sampling and data collection so that emerging themes could be followed up and synthesised. The coding framework was kept under review and updated to this effect, with re-coding of earlier transcripts where necessary. Negative cases, where informants held divergent views or experiences, were re-analysed to gain further insights. Codes were amalgamated into major themes for the purposes of creating matrices to show the coded extracts by source for each theme. Further analysis of these matrices facilitated the interrelation of emergent themes and the comparison of findings across participant groups and between individual participants. The analysis refined the themes and these were written out into a descriptive account.

Following the advice of Ritchie et al. (211), recurrent and overarching elements in the participants' accounts of their stance on health optimisation were identified and used to populate a matrix with a separate row for each participant. The accounts were re-read to determine the way in which these elements manifest in each account to complete the matrix and to allow inspection for a typology. Figures were created to visually illustrate the categorisation and frameworks applicable to individual elements of the analysis.

5.5 Results

5.5.1 Invitation response and final sample

Invitations to participate were sent to 25 potential participants in batches of five. Twenty of the 25 responded to agree to participate and all completed an interview. No response was received from the other five. Many participants identified themselves as holding a number of roles. For example, the three general practitioners had past or present commissioning responsibilities, and seven of the eight commissioners and policymakers had clinical backgrounds and experience. Six of the eight commissioners and policymakers had a specific remit in policy or pathway development for health optimisation-related approaches in their locality; the other two had wider remits and experience centred on health inequalities and elective and personalised care. The participants' primary roles (those in which they spent the majority of their professional time) are shown in Table 10.

Table 10: Study participants' primary roles

n	Primary role
3	General practitioners
3	Orthopaedic surgeons
2	Public health professionals
4	Other secondary care clinicians (anaesthetists, geriatricians)
8	Commissioners and policymakers

The participants worked across seven regions of England but some also drew on experiences of recent employment in other regions.

One participant opted for an in-person interview at their workplace; the remainder were conducted via video conference. The interviews lasted for a median of 45 minutes (range 37 to 56 minutes). There were no significant technical issues with the video interviews.

Interviews took place between June and September 2022 inclusive, which is immediately after the formation of integrated care systems. Data analysis began during the data collection phase and the coding and initial descriptive analysis were completed by December 2022.

5.5.2 Results of data analysis

The final coding framework is included in Appendix 12.

The results of the data analysis are reported under the following main themes:

- Health optimisation as a concept
- Health optimisation approaches seen in practice
    - Drivers for the use of different health optimisation policies
- Participants' views on health optimisation policies and practices
    - A typology of participants' views
- Future for health optimisation

The data are presented with the use of illustrative quotes labelled with the participants' number and '**M**', '**C**' or '**B**' to denote whether the participant's current role was managerial, clinical or both respectively.

Ellipses [...] are used to denote text omitted for the purposes of clarity and brevity.

5.5.2.1 Health optimisation as a concept

Health optimisation in the surgical context was described by participants as an approach to improve patients' health in the period before surgery. Participants offered broad and narrow definitions of the scope of health optimisation, with some actively distinguishing between the two. Approaches targeting a select few risk factors such as obesity and smoking formed a narrow approach, whereas in the broader definition, a much wider consideration of multiple modifiable factors influencing patient health and well-being was included. These participants offered their views on the need to address both specific medical issues as well as a patient's overall health within health optimisation efforts.

> *"[Health optimisation is] the balance between a medical/clinical intervention, which is disease-specific versus a more holistic approach to getting patients' health better which could be mental, physical or otherwise." (I18 - B)*

Three main purposes of health optimisation were described. The first was to improve measures of health in the short-term which could improve surgery safety and outcomes. There was broad agreement on this, with 14 participants directly citing this purpose in relation to obesity.

> *"You are likely to recover better from surgery if you were a healthier weight." (I14 - M)*

A secondary purpose was to reduce referrals for surgery. A participant with frontline experience of health optimisation delivery offered examples of reduced demand for surgery achieved through the mechanism of health optimisation stimulating better patient-centred care, empowerment and opportunity for shared decision-making.

> *"[Perioperative assessment] services […] from around the country are all seeing about one in seven patients choosing not to go ahead with their operation. […] we are providing far too many interventions for people when the risks outweigh the benefits." (I15 - B)*

In three accounts, clinicians involved in perioperative care described that this shared decision-making would lead some patients to decide against surgery based on their health and chances of an acceptable level of outcome and recovery. In two other accounts, managerial participants linked a reduction in surgery directly to improvements in symptoms triggered by the health optimisation intervention.

> *"If you help them lose the weight, for example, someone who's got knee pain doesn't necessarily have knee pain anymore." (I7 - M)*

However, one of these participants noted that this purpose was more rational for some types of surgery than others.

> *"If people do lose weight, the need for the operation can go away because it's it is all related to the excess weight […but] it depends what the surgery is." (I2 - M)*

Finally, participants of all backgrounds recognised that health optimisation policies played a role in longer-term health improvement and need for healthcare, though none of the participants stated this as the primary purpose.

> *"[…] giving them as much quality of life back as possible and that they maintain that for as long as possible. That's all about getting ahead of the demand curve for much more severe interventions that we see later on in someone's life." (I14 - M)*

5.5.2.2 Health optimisation approaches seen in practice

When participants were asked to describe health optimisation policies in their own region, the examples given ranged from holistic highly structured approaches with consideration given to targeted extra support for groups most in need/ under-served, to narrow eligibility criteria for limited support. Five participants had direct experience of regions using policies of the most restrictive nature where BMI thresholds for access to surgical referral had been introduced, in some cases without access to associated behavioural change support services.

> *"There is a requirement to be at a certain BMI in order to undergo some procedures." (I16 - M)*

Other policies offered weight management support to patients without requiring their engagement or extra waiting time for surgery, and there were also policies whereby BMI or weight was only one, optional element of a holistic approach to improving a patient's overall health and wellbeing.

> *"We've got about 7 triage criteria, including high BMI and including [deprivation], high alcohol consumption, learning disabilities, smoking. […] a patient's [approached], to see if they […] want to take up the offer, their details are then passed down to the regional hub [to] contact them." (I17 - C)*

The delivery of support for behaviour change for patients was generally from services located separately from hospital-based preoperative assessment and surgical outpatient services, and participants described the work needed to identify and link these existing services.

> *"[…] a lot of interface work across community and secondary care as well and trying to utilise services which exist out there in the community rather than setting up parallel services within secondary care." (I11 - C)*

Two clinical participants spoke of holding their own unofficial approaches to health optimisation where they had the autonomy to delay patients' access to surgery based on their own conceptions of the importance of addressing obesity prior to surgery.

> *"We don't have BMI cut off […but] I still impose a kind of soft BMI target […] encourage them strongly to reduce down to 35. […] I don't treat it as a hard cut-off, if they've got advanced knee disease and been working hard and going in the right direction, I would list them at that point." (I10 - C)*

When asked about health optimisation more narrowly defined as pre-surgical approaches to address overweight and obesity, participants spoke of varying experiences across the regions in which they had worked, and of a lack of formal guidelines on which healthcare settings could base their provision.

> *"There have been lots of pockets of work done around the UK on perioperative, […] different Trusts have done different things." (I9 - M)*

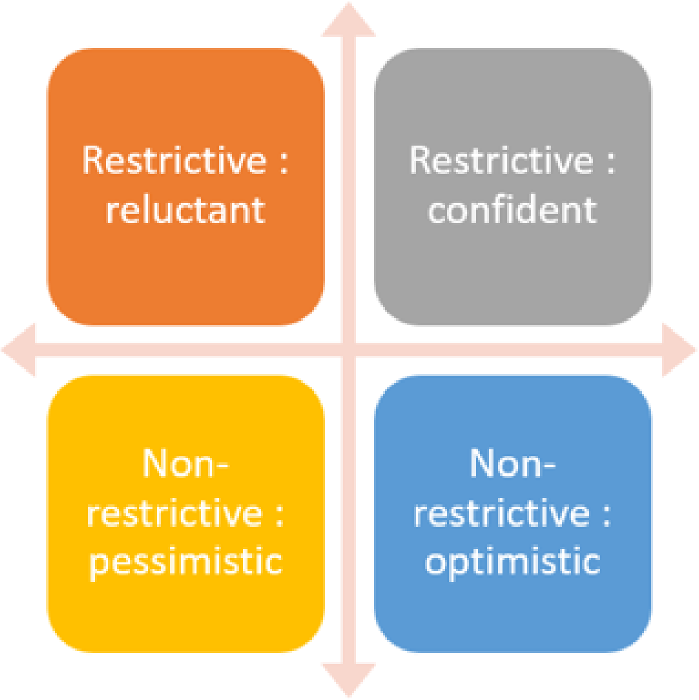
Drivers for the use of different health optimisation policies

Participants' accounts demonstrated two key continua that were important in defining organisational decision-making related to health optimisation policy choice. These are the level of restrictiveness chosen in a policy, and the level of confidence or optimism in the potential for the policy to offer the purported benefits. Participants described numerous drivers acting on a local level which moved the organisational position along each continuum. Figure 14 presents these continua on a pair of axes illustrating the way in which the resultant organisational positions on health optimisation policy could be seen to vary. The themes regarding the drivers and contextual factors identified in the participant accounts from which the figure was devised are expanded upon and illustrated with quotes in the remainder of section 5.5.2 below the figure.

The vertical axis represents the level of restrictiveness chosen in the policies that participants described. At the most restrictive, policies are introduced that mandate strict BMI thresholds for eligibility for surgical referral or extra requirements regarding engagement with behaviour change and weight loss. Non-restrictive policy could include a recommendation for ad hoc advice to patients on weight management, with or without the offer of optional additional support, without any other alteration to their care pathway experience.

The horizontal axis represents the organisational confidence or optimism in the potential for a health optimisation approach to offer the purported benefits. For example, participants described that an organisation with little confidence that health optimisation will offer health improvement makes a choice over the restrictive nature of the health optimisation approach chosen based on the other requirements of their situation. Conversely, other participants described that an organisation confident in the impact of a non-restrictive, holistic policy may introduce such a policy if their context allows.

Figure 14: Axes of restrictive nature of policies and organisational attitude to their chances of impact



Restriction driven by short-term financial considerations

The primary driver for the introduction of health optimisation policies falling into all quadrants above was identified by most participants as a financial consideration. All participants mentioned financial considerations within their accounts, though there was variation in the focus within these and in the confidence expressed that financial benefits would actually accrue. Managerial participants described the use of restrictive policies as tools in the rationing of elective surgery in response to NHS resources and waiting list pressures within local regions.

> *"It's what pressure was placed on them to do something. […] It'll be cost or waiting list time. […] in the end it all comes down to money […] you save money and you're saying it's because 'you don't meet criteria.'" (I4 - B)*

A clinician identified an explicit consideration of encouraging/requiring patients to pay for their own treatment.

> *"If you want to qualify for your hip or knee replacement, you just can't have it done free unless your BMI is 30. If you wanna have it done at BMI 35 go and see a private surgeon." (I17 - C)*

Two commissioners expressed confidence that restrictive health optimisation policies could offer financial benefits through their intended mechanisms of health improvement and shared-decision making.

> *"There's gonna be a huge cost benefit. […] we're not gonna be operating unnecessarily on people who have a better alternative than surgery. We're gonna be reducing length of stay, reducing complication rates." (I9 - M)*

Clinical participants based in secondary care also spoke of the costs of last-minute cancellations to operations which would be avoided where health optimisation approaches offer earlier assessment of patients.

> *"Operations have been cancelled [last] minute [because] they haven't realised that the patient is overweight." (I7 - M)*

Some participants suggested that as rationing was a necessary part of addressing scarce resources in the NHS, thresholds may come to play a role in decision-making.

> *"If you can only provide limited resource across every service, you do need to prioritise and decide if you're going to give a knee operation to everyone, or whether you're gonna have some cuts off and pick the winners." (I10 - C)*

A participant concerned with the unintended effects of restrictive policies was sceptical about whether rationing decisions had been based on anything other than the short-term financial results of restricting access to surgery.

> *"It's a sort of un-thought-through fairly blunt, financially oriented tool for saving money […] some bright spark in a management consultancy type of role will have sort of done some back of fag packet calculations. […] work out how many people are on the elective waiting list who are overweight." (I8 - M)*

The strength of these financial and rationing motivations was described by several participants as exacerbated in recent times by pressures on the NHS and the wider economy. One managerial participant noted the specific correlation between increased financial pressure and increased use of threshold policies over time.

> *"They're a thing that we've seen grow over time in terms of their use, particularly as financial pressures on the NHS have increased […] NHS finance directors are just going, no, I don't care. […] everything's on fire and I just have to try and make the books balance." (I14 - M)*

A region being in extreme financial difficulties - 'special measures', was suggested as a powerful driver for restrictive policy use by another managerial participant.

> *"Special measures pushes you further and further in this [restrictive] direction" (I8 - M)*

On the converse, two participants within national organisations described improvements in decision-makers' capacity to innovate and pursue non-restrictive policies as linked to the lack of financial pressures on a regional system.

> *"If […] they are flushed with money, they're more likely to experiment with new ways of thinking, […] it fundamentally depends on how successful your commissioners are in banking the money." (I18 - B)*

Health optimisation driven by longer-term economic considerations

Financial savings were spoken of as a powerful motivator by most participants whatever the primary purpose of a health improvement-related policy.

> *“But in this world you can trace most things back to money, and therefore, if we can demonstrate a financial saving aligned to improved well-being measures then everyone's winning.” (I16 - M)*

Several participants expressed confidence that while financial considerations and demand management were intrinsic needs, decisions over the use of restrictive policies were not made solely as a short-term reaction to financial difficulty.

> *“I don't think that those sorts of policies come in because people want to ration care […] we've chosen to look at patients who've been put on a waiting list and are waiting for big operations […] because [that’s] the most likely return on investment.” (I12 - B)*

Some of these participants spoke of a further economic consideration that health improvement triggered by presurgical health optimisation may also represent a longer-term, wider financial benefit where behavioural changes lasted beyond the peri-surgical period.

> *“You reduce complications. You reduce length of stay and you save money later. And you improve their long-term health, which obviously therefore also makes them more productive in society and all those things.” (I12 - B)*

However, participants raising this element highlighted that it was of secondary importance to policy decision-makers due to the lack of short-term tangible savings offered.

> *“There's going to be a requirement for a lot of investment in this without an immediate return on your funding […] at the moment that's done on an annual budget cycle, and it's very difficult to accept that you're gonna make a loss […] in this financial year.” (I16 - M)*

Managerial participants also described conflict in the way that current commissioning arrangements may incentivise acute Trusts to undertake surgery and offer no direct reward for long-term health improvement:

> *“There’s disincentives to […] trying to keep patients out of hospital, cause actually hospitals make money by doing more, so you end up with this perverse sort of setup.” (I19 - M)*

Perceived strength of the evidence base as a driver for policy type

The evidence base for health optimisation was another theme prominent in participants' accounts of the reasons behind differing policy choices. The evidence base was described as immature and lacking in local specificity, with few published evaluations of health optimisation programmes for commissioners to work from.

> *“Where there’s big variation in anything, that generally suggests that there isn't a clear right or wrong way of doing things. Or if there is, people aren't aware of it […] Therefore organisations and areas create their own approaches.“ (I3 - B)*

As such, decision-makers’ own interpretation of the evidence, and willingness to introduce policies of unproven value were felt to have influenced the choice of policy type in different areas.

> *“Particularly with an area like BMI where there is a lot of, um, controversy […] I think it's very much kind of down to the group who are interpreting that evidence - their experiences, their sort of personal experience and prejudices.” (I6 - C)*

A participant with experience in a local policy decision-making process described decision-makers as being willing to ‘cherry-pick’ evidence to support their policy choice, and that a lack of a need to provide rigorous evidence-supported rationales for new policies facilitated this.

> *“It becomes more of a political conversation […] if people need to make decisions […] I've seen examples of where people sort of fit scientific evidence and or lack of it, to managerial [needs].” (I8 - M)*

Policy position driven by differences in advocacy and reputational concern

Participants’ accounts suggested that differences in the characteristics of the systems and decision-makers in the regions resulted in variations in their ability to use innovative policies or to implement changes. The availability of local support for different policy approaches was felt to influence the uptake of policy approaches. A participant who identified as a champion for health optimisation spoke of the role as by no means sufficient in itself, but as one important part of the reason that policies could progress in some areas faster than in others.

> *“That enthusiast, if they're a clinician, needs to have buy-in and they need to […] get system change.[…] I think if you've got the kind of perfect coming together of the enthusiasts, the people who've to listen and the pots of money available, it's gonna happen.” (I17 - C)*

In contrast, a public health participant described the role of advocacy against policy choices in dissuading organisations from using restrictive approaches.

> *“There are people like me in some places that stamp their feet up and down quite a bit harder, and others that […] are prepared to let it wash, or aren't in the right place at the right time and by the time the decision’s made they can't change it.” (I8 - M)*

Differing levels of tolerance of risk to reputation, and confidence in public support were also factors which were suggested to have influenced the choice of more restrictive policies for some regions.

> *“One of them is the risk appetite, so, some Trusts are less risk averse than others. […] A lot of Trusts aren't. [...] so don't want to take anything that might be outside the norm.” (I7 - M)*

Two managerial participants speculated that commissioners took decisions where they were reassured that they were not ‘going first’, and geographical proximity and media attention became factors in the choice of region to emulate.

> *“And other CCGs then spotted it. And thought fine, we can now do it.” (I1 - M)*

Concerns over possible individual legal challenges, patient advocacy against rationing and negative media attention were described as ineffective barriers to the imposition of a restrictive policy in some settings. Commissioners could be unresponsive to patient and public groups where they faced greater pressure from overall NHS issues. A managerial participant described the very high level of legal challenge that would be needed to achieve impact against the use of restrictive policies.

> *“The problem is that as NHS leaders are under so much pressure locally that […] judicial reviews are the only thing that really get attention.” (I14 - M)*

5.5.2.3 Participants’ views on health optimisation policies and practices

Participants demonstrated individual views on the effectiveness and fairness of health optimisation policies which did not always reflect the position taken by the organisation in which they worked. Individual views on the effectiveness of health optimisation included opinions on the evidence for the benefit of promoting weight loss before surgery, the strength of the ‘teachable moment’, and barriers to the effectiveness of policies in practice. Participant opinions on the fairness of health optimisation policies included the role of personal responsibility for patients in addressing their weight, the need for clinical autonomy in providing individualised patient care, and the impact on health inequalities.

Evidence of the benefits of promoting weight loss before surgery

When considering the effectiveness of health optimisation in theory, most participants were supportive of the idea that decreasing obesity ahead of surgery was an important concept and felt that health optimisation could thereby achieve improvements in patients’ surgical and longer-term outcomes in some cases.

> *“To help, support and motivate people to make changes to their behaviours, their health that will not only improve their surgical outcomes but improve their life in general.” (I3 - B)*

Those already working in settings with non-restrictive health optimisation policies offered positive views on the evidence position.

> *“The evidence base is, is growing and is generally supportive. […] in terms of reducing harm after surgery. […] some of the prehab studies have looked at [sustained health benefits in the long term] and again report positive things about it.” (I12 - B)*

Two orthopaedic surgeons also shared examples of successful avoidance of surgery but emphasised that this is not common and that delay to the need for surgery was more likely than total avoidance.

> *“The exceptions that stand out in your mind, but I've definitely had some people who've been discharged from the clinic because they say actually now it's manageable.” (I13 - C)*

Clinical participants were not wholly positive about the validity of using surgical outcomes as a reason for weight loss and spoke of the overstatement of the benefits of BMI reduction on readiness for surgery. Concerns were expressed that delays to surgery could result in health optimisation having an effect opposite to that intended.

> *“If you end up delaying their surgery to try and get them down to that BMI then their pathology progresses, […] the longer people are in pain […] the poorer their pain outcomes are after surgery […] you've got to also think about an element of deconditioning […] there’s potentially some real pitfalls.” (I6 - C)*

Exceptions were made in very high ranges of BMI where immediate anaesthetic risk and surgical practicalities became significant issues, but overall there was low support offered for the clinical validity of hard cut-offs in BMI by participants from all groups.

> *"What's the difference between a BMI of 34.9 and a BMI of 35.1? Probably not very significant, but yet we've picked an arbitrary cut-off." (I10 - C)*

Two participants also noted concerns of malnutrition or psychological health where they perceived that patients felt they must engage in crash diets to achieve surgical referral.

> *"You don't want people to just restrict calories down and down and down to lose weight because they can lose muscle mass as well." (I6 - C)*

The teachable moment

Some participants were confident in the theory of the 'teachable moment' whereby the pre-surgical window provided a meaningful opportunity to engage patients in weight management.

> *"I think that it is a great opportunity. It's a teachable moment. […] Generally, having an operation is a major experience in anybody's life. They want it to go well." (I3 - B)*

However, in the specific context of joint replacement surgery, clinicians' views regarding immobility due to joint pain and the impact this has on BMI were prominent. Participants emphasising this aspect shared views which ranged from it being unreasonable to impossible to ask patients with significantly impaired mobility to lose weight without providing them with the improved function that surgery/relief of arthritis pain may offer first.

> *"It becomes a bit of an unachievable goal I think, and ultimately demotivating for people […] if you say well your BMI has got to be 30 or less and they say well that's great - I can't exercise and I'm already eating relatively healthily. What do you want me to do?" (I6 - C)*

Two participants involved in health optimisation service design spoke of the impact of offering shared decision-making to empower patients to make suitable decisions over ways in which to address their weight.

> *"The model that works best is to have, you know, a more coaching style or supportive approach and also an understanding of the mental health elements of care [...] one that addresses and takes the social determinants into consideration." (I19 - M)*

In contrast, two participants with roles in secondary care described the need for restrictive policies to require patient engagement as an important factor in the success of health optimisation.

> *"We want to reduce obesity and we want to take opportunities to do that and patients waiting for surgery, it might be seen as a lever and so you know, that teachable moment in a slightly more punitive way, as it were, gives patients something to aim at." (I12 - B)*

A manager described the concern raised to them by frontline clinical staff who opposed requirements for them to be gatekeepers who would need to communicate the restrictive measures to patients. There was a worry that this would be damaging to clinician-patient relationships.

> *"If you turn us into the police, who determine whether you can have an operation or not based on your weight and exercise. You're going to give us a bad reputation with patients." (I1 - M)*

Barriers to effectiveness

Participants also expressed scepticism over the effectiveness of health optimisation in practice. The current climate of very long waiting lists for surgery and the inability to be able to give patients a surgical date to work towards in their health improvement goals were given as reasons that limit health optimisation's success in practice.

> *"If people don't see an endpoint to their timing for surgery, they disengage from what you're asking them to do because they don't see the point." (I17 - C)*

Other key issues raised were the necessity of suitable, well-resourced support services for behavioural change, and that these were substantially lacking across many regions. As a result many clinicians described having low confidence that patients could successfully lose weight before surgery.

> *"We know that the majority of patients that we would ask to lose weight struggle to do so." (I13 - C)*

Three clinicians emphasised the lack of suitability of existing support services and that diverse options would need to be offered to achieve engagement by all.

> *"I think, lots of people are helped by things like Weight Watchers and all the rest of it. But if you are a single parent with three kids, you can't get to Weight Watchers […] blanket rules don't work. You have to tailor your interventions to the patients that you're treating." (I12 - B)*

The obesogenic environment was cited as another reason for low confidence in significant and lasting weight loss, even in the cases where weight management support was available, especially where this was short-term in nature.

> *"About 10% of them [attending community weight management services] lose 5% body weight, which is not insignificant. A lot of them then put it back on because they live in obesogenic environments." (I8 - M)*

Personal responsibility

In line with the obesogenic environment faced by patients, in many cases, participants were not supportive of the idea that obesity was an issue of personal responsibility. They raised the concern that it was not fair to restrict access to surgery based on a patient's BMI or willingness to engage with weight management services.

> *"This is not people who aren't trying to lose weight but as I say they are, they are not able to do that via knowledge or just the economic situation they find themselves and they're not empowered to make the change." (I16 - M)*

In contrast, some clinicians did support the role of the patient in responsibility for their health and losing weight to be eligible for surgery. Associated with this belief, a few participants described an appreciation of the need to ration NHS service provision, and supported the use of an objective threshold for a modifiable risk factor such as BMI.

> *"Having a BMI cut-off, I don't think is [unfair], because by and large most surgeons regardless of where in the country they are, would encourage you to lose weight if you're particularly obese prior to your surgery." (I10 - C)*

Clinical autonomy and individualised assessment

Two surgeons described support for BMI thresholds from another angle, due to their concerns over the situation regarding individual surgeon-level outcome metrics by which they were monitored. They noted that with policy variation by geography, they could be disadvantaged by operating on patients of greater complexity, due to their obesity, if their region was non-restrictive.

> *"[…] and outcomes are obviously published, so you know for elective arthroplasty you know that's quite a big… you will be on the line as a surgeon if you're operating on people who you know are going to have adverse outcomes." (I6 - C)*

In contrast, many participants described concerns with using individual level BMI as a sole determinant of access to surgery. A need to retain clinical autonomy, and to share meaningful communication on the risks of higher BMIs with patients was considered the appropriate arrangement by some participants.

> *"There has to be a bit of latitude in terms of how you implement it, […] weighted risk, I suppose, comes into play, you know, in terms of saying, actually, would it be worth just taking that risk of saying, well, the BMI isn't quite where it needs to be and where's patient choice in that as well." (I19 - M)*

These concerns translated into discomfort with any threshold rules; instead, individual patient assessments were the preferred approach to ensure clinical decisions were made fairly.

> *"I'm not really not convinced in the sort of moral and scientific validity in applying that sort of anaesthetic risk in a sort of a 'what should the policy on this be for a cohort of people?' It's a sort of a patient by patient, person, type of conversation that needs to be part of an informed consent process." (I8 - M)*

Health inequalities

Health inequalities were a key concern for many participants. Participants raised concerns that geographical inequalities would be caused by the 'postcode' lottery, whereby some regions had more restrictive or better-supported approaches than others.

> *"I don't agree with it for lots of reasons. […] it's a blunt tool, […] I think it will amplify health inequalities. […] I guess whoever wrote those policies must have assumed that patients would be given help to reduce their weight […] but I doubt very much that that's consistent." (I12 - B)*

Also prominent in discussions were the differences in demographic groups' ability, and agency to engage with weight management support on offer or to undertake self-directed behavioural change.

> *"I think there would have to be more targeted and perhaps more high-level support for the more deprived areas to avoid driving an increase in health inequalities." (I17 - C)*

The use of obesity as a discriminatory factor in surgical access was deemed a strongly problematic issue of equity within the NHS by one participant discussing the NHS's legal duties.

> *"By applying the 'you can't have your hip operation until you've lost weight you fatso' […] less poor people are gonna get hip operations and that's not right. Dear The NHS, you have a legal duty to redress inequalities. This policy is structurally failing that duty." (I8 - M)*

The ability for some to fund their own private treatment to be able to avoid delay to their surgery should they wish was also raised as a driver of health inequalities that would result from restrictive policy use.

> *"People on waiting lists, 65% say that private care is simply not an option for them […] it will be the people who are in poverty, who are from ethnic minorities, women, who will be affected the most by that. And so this two-tier system of more well-off people gonna end up going private." (I14 - M)*

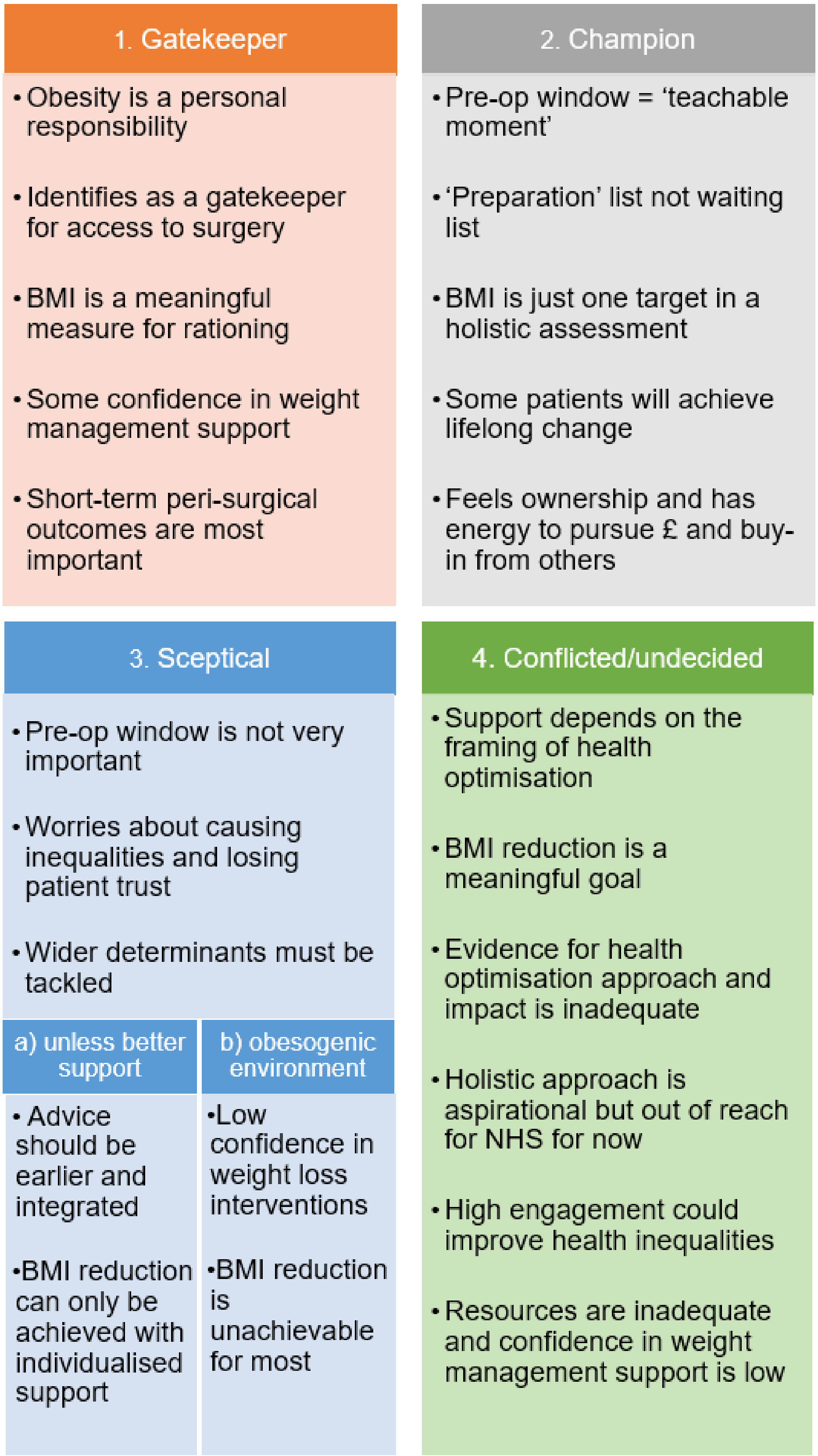
Development of a typology of participants' views on health optimisation

A typology was devised to describe the range of attitudes that were demonstrated towards health optimisation in this group of participants and is presented in Figure 15. Appendix 13 gives the detail of the categories for the matrix used to develop the typology.

Five types were included in the typology, two of which were felt to reflect subtypes of a single category. Participants could be described as a 'Gatekeeper' where they had prominent opinions on the importance of restricting access to surgery based on modifiable risk factors, a 'Champion' where they were optimistic and motivated about increasing the use of health optimisation in healthcare settings, 'Sceptical' where they foresaw more potential significant harm than benefit through the adoption of health optimisation approaches (sub-divided into those who did and didn't think this could be mitigated by adequate provision of support services) and a final type who were 'Undecided/conflicted' and felt the need for increased evidence, resourcing and careful framing of health optimisation approaches.

Based on the dominant views expressed in the individual interviews, participants were labelled within the typology. Table 11 provides my categorisation of the participants across the types within the typology and provides some example quotes for each. The participants within the ‘Gatekeeper’ type had primary roles as surgeons, those within the ‘Champion’ type were the most numerous (n=8) and had primary roles in policy making, perioperative medicine and pathway transformation. The participants within the ‘Sceptical; unless better support’ subtype formed the second largest group and were primarily based in public health and primary and community care, while those in the ‘Sceptical; obesogenic environment’ had primary roles in policy development and inequalities. The participants in the ‘Conflicted/undecided’ type were leads in secondary care services centred on surgery.

Figure 15: Typology of participants' stance on health optimisation



1. Gatekeeper

- Obesity is a personal responsibility
- Identifies as a gatekeeper for access to surgery
- BMI is a meaningful measure for rationing
- Some confidence in weight management support
- Short-term peri-surgical outcomes are most important

2. Champion

- Pre-op window = 'teachable moment'
- 'Preparation' list not waiting list
- BMI is just one target in a holistic assessment
- Some patients will achieve lifelong change
- Feels ownership and has energy to pursue £ and buy-in from others

3. Sceptical

- Pre-op window is not very important
- Worries about causing inequalities and losing patient trust
- Wider determinants must be tackled

a) unless better support

- Advice should be earlier and integrated
- BMI reduction can only be achieved with individualised support

b) obesogenic environment

- Low confidence in weight loss interventions
- BMI reduction is unachievable for most

4. Conflicted/undecided

- Support depends on the framing of health optimisation
- BMI reduction is a meaningful goal
- Evidence for health optimisation approach and impact is inadequate
- Holistic approach is aspirational but out of reach for NHS for now
- High engagement could improve health inequalities
- Resources are inadequate and confidence in weight management support is low

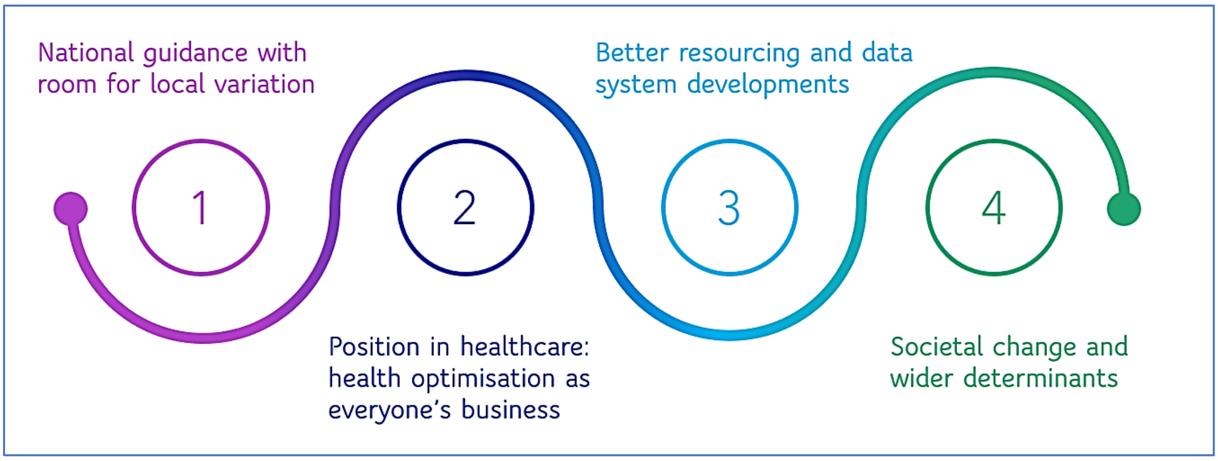
Table 11: Participant categorisation across the typology and example quotes

Type	n	n by role	Detail	Example quotes
1. Gatekeeper	2	2 clinical	Surgeons	*"I have to say that I quite like having a cut-off […] patients seem to find it very useful […] it's a hard line that they can see they're above." (I10-C)*
2. Champion	8	4 managerial, 1 clinical, 1 both	Programme leads, anaesthetists	*"We need to support patients with their lifestyle habits and exercise and food […] very much on an individual basis rather than putting a flat sort of rule for everyone." (I9-M)* *"That's about all of the enthusiasts coming together and starting to basically, convince commissioning people […] if you distil it all down it's an absolute no brainer." (I17-C)*
3. Sceptical				
a) Unless better support	5	3 managerial, 1 clinical, 1 both	Public health, GP, geriatrician, improvement programme leads	*"I don't think the system is geared to help everybody with a body mass index of 32 or 33 to come down, I think the services will be swamped." (I11-C)* *"[…] such a multifactorial problem […], it's very hard to deal with and that's why they're there. If they were easy to deal with, we'd have dealt with them by now." (I4-B)*
b) Obesogenic environment	2	2 managerial	Policy and inequalities	*"Weight management isn't the answer to obesity […] the answer to obesity is way upstream of weight management." (I8–M)* *"It's not just a case of it being, being a problem for the individual it's actually systemically, it's helping to drive health inequalities." (I14-M)*
4. Conflicted/undecided	2	1 clinical, 1 both	Surgeon, secondary care service lead	*"There may be some examples if the evidence is strong enough, where we probably should have a strict threshold." (I3-B)* *"We haven't come up with a clear pathway locally, despite us having been trying to do that for some time and some very strongly held views either one way or the other on this. […] So a real kind of lack of consensus locally and nationally as well." (I15-C)*

5.5.2.4 Future for health optimisation

Participants' accounts demonstrated four key elements regarding progress towards best practice for health optimisation in the NHS. Figure 16 illustrates these elements and their progression. As a starting point, there are issues of evidence gaps to be addressed. Evidence-based national guidelines could play a role in improving health optimisation practice while leaving room for beneficial local variation in approaches. Following this, implementation of this guidance would require decisions over the position within the healthcare service for health optimisation. This would include efforts to integrate the approach at all levels of care: making health optimisation 'everyone's business'. Thirdly, progress would be reliant on adequate resourcing for implementation, particularly in improving access to suitable weight management support, and with the data and digital systems necessary to make health optimisation pathways work efficiently. Finally, health optimisation can account for only one avenue for addressing obesity and health improvement more generally – societal change and action on the wider determinants of health must play their role. Expansions on the themes within these elements with the use of illustrative quotations follow the figure.

Figure 16: Summary of key elements identified by participants as important targets, barriers and drivers for best practice in health optimisation in the future



1. National guidance with room for local variation

To improve understanding and good practice in health optimisation, participants raised the need for certain areas of the evidence base to be addressed which could inform national guidance on the topic. Three participants with roles in health optimisation delivery spoke of the challenges in evaluating health optimisation, but along with commissioner participants, spoke of a need for generating evidence in two key areas. Evidence gaps were noted in the long-term maintenance of any health improvement or prevention achieved pre-operatively and in the effects of any policies on health inequalities.

> *"It comes back to understanding the long-term impact of these interventions, aligned with achieving the required immediate impact. So they're off the waiting list. Fantastic[...] let's not stop there, let's continue to monitor a cohort of individuals who are undergoing some of these interventions and see what the long-term implications are." (I16 - M)*

The risks in over-simplistic positive interpretations of reductions in surgery rates following the introduction of a health optimisation policy was a specific issue that one participant felt should be addressed in policy evaluation regarding inequalities.

> *"So you're looking at 'ohh we saved money and all these people didn't need an operation in the first place'. […] you then want to look well where are they going? How many private operations are happening at the same time." (I4 - B)*

Intrinsic issues around the impact of obesity on surgical outcomes and longer-term health were raised as an additional area requiring further research.

> *"Even the evidence for losing weight having a positive impact is actually poor as well, in that any risk that you accumulate [in arthroplasty] for being overweight appears to stick with you even when you lose the weight." (I13 - C)*

There were conflicting views on the position of variation in policies between regions. For some, the issues of geographical inequality, and the importance of national guidance on evidence-based interventions meant that they were in favour of a single national approach to health optimisation.

> *"I think if there was a single policy, then it'd be more likely to be acted upon and resourced. So I think it probably would be helpful. It would cut down on perceived unfairness. […] I think it would be welcomed on balance." (I3 - B)*

A participant with experience in a region without a health optimisation policy proposed that guidelines could protect against individual clinician approaches dictating whether or not a patient would receive health optimisation.

> *"It's left to individual professional people […] in an ad hoc unstructured, way, […] those with time and interest will do it. Those that don't have time or interest won't." (I3 - B)*

A participant working in the field of policy making identified that without a national policy, the recent formation of integrated care systems could result in 'policy equalisation' whereby integrated care systems adopt the strictest policy type of their constituent former CCGs.

> *"I certainly have seen it happen in the IVF space […] you see CCGs just equalising down to the lowest common denominator, which in most cases is no IVF offered to anyone, or higher BMI limits, or whatever it might be." (I14 - M)*

Although most participants felt that national policy would be a useful development, some were sceptical of its reach if it were perceived to be too remote from frontline healthcare.

> *"What one would hope is that national guidance would lead to somewhat […] more consistency, which clearly that would be a good thing. I suppose it depends on whether or not NHS England get the guidance right or not and actually, consult with […] clinical commentators. My fear is that they won't." (I8 - M)*

Others described the value in retaining regional flexibility to better respond to the local demographics and available service provision.

> *“I think the flexibility is crucial, […] if it's done properly and each system is assessing the needs of their population and putting the money where the population needs the most, that is the goal. That is the aim of having localised healthcare systems.” (I5 - M)*

2. Position in healthcare: health optimisation as everyone’s business

Participants were invited to share their views on where health optimisation should be positioned within healthcare. Most participants described that health improvement opportunities should be offered to patients earlier in their care, in an integrated way, without any mandatory element to engagement.

> *“I wouldn't want to use the word mandatory, but I would want to use […] ‘this is standard care’.” (I1 - M)*

Several participants extended this view and spoke of an aspiration to move towards making health improvement everyone’s business, included in healthcare within all settings, and considered the default.

> *“Just everybody’s responsibility, and that nudge all the way along. Hopefully then because it forms a continuous, you know, constant thing.” (I4 - B)*

A need for medical education (including medical undergraduates and inclusion of health optimisation onto curricula for professional healthcare qualifications) was raised by two participants as a route to better equipping a wider range of clinicians to deliver health optimisation.

> *“Perioperative medicine isn't really taught in medical school […] surgeons can be very focused on their one specialty and not looking at the patient as a whole.” (I9 - M)*

Health optimisation beyond surgery

Some participants already involved in health optimisation services shared views on the possible future scope of health optimisation in the NHS and looked ahead to extensions of health optimisation beyond the current emphasis on surgical patients.

> *“So we want to do more of this pre and post-op and way outside the context of elective surgery as well.” (I8 - M)*

An ambition to capture as many patients as possible by avoiding limiting input to those who definitely need surgery was described in the considerations for the positioning of the health optimisation.

> *“The best time to intervene would be at the point that the GP refers them into hospital […] ‘cause then you've got your 100% pool of patients that might end up needing an operation.” (I12 - B)*

A surgeon expressed a view that aligning health optimisation with preparation was not necessary.

> *“It shouldn't be about surgery it should be about their overall health. So I don’t think surgery is particularly relevant to it.” (I10 - C)*

While others felt that the association was actively inappropriate if surgery were used as the goal within restrictive policies.

> *“You shouldn't even be talking about ‘you're going to get an operation’ […] that you're gonna get this reward for being good, which is absolutely ridiculous.” (I4 - B)*

Primary and community care

While an ambition to achieve integration of health optimisation into all services and levels of care was prominent in many accounts, the setting suitable for initiating health optimisation with patients was most commonly described as within primary care. One secondary care participant highlighted that this is because in theory GPs should have more established relationships with their patients.

> *“Though I'm quite happy to have that conversation with patients, I'm cognisant of the fact that you know 5 minutes before they’d never met me.” (I11 - C)*

GP participants themselves acknowledged that health optimisation sits best within their service.

> *“I think we're well situated to have those conversations about needing to be as fit as possible for an operation […] we can talk to them when it gets really tough and instead encourage them, […] if there are any problems that come up, then you know we're in a position to monitor that.” (I6 - C)*

A commissioner designing a health optimisation service was working to this effect.

> *“It should be from or it should be aligned to general practice.” (I1 - M)*

Other participants were, however, sensitive to further burdening primary care with additional tasks. In acknowledgement of the existing pressures in primary care, two commissioners described an alternative model where a new perioperative service could offer health optimisation as part of the patient pathway to surgery.

> *“We're trying to minimise the involvement of primary care because we know how much pressure there is on them. […] so that they can just refer into the peri-op service and it not then have to come back to the GP to then be referred again for surgery.” (I9 - M)*

Whether delivered through primary care or by a separate service after referral from primary care, the community setting of interventions and support on offer was described as desirable by several participants.

> *“I think gradually most of it could be community-based […] it's what funding we get within the peri-op service as to whether we employ them ourselves or whether we, support other services to employ those people to do that work for us.” (I9 - M)*

Voluntary/third sector and peer support were also mentioned as valued as providers of health optimisation, in order that patients benefit from professional expertise and relatable first-hand experience in their communities.

> *“You need to be engaging with people like your social prescribers, your GPs, your community providers, your third sector providers, your local county councils, […] personalised care. […] it, should be part of everybody's programme.” (I7 - M)*

3. Better resourcing and data system developments

Effective, accessible support services that cater to the individual needs of patients were highlighted as key to successful health optimisation delivery, reflecting the need to address the issues already described with current weight management and lifestyle services (section 5.5.2.3). A public health participant cautioned that to meet health optimisation’s potential, significant extra resourcing for high-quality behavioural change support services would be necessary given that current local public health commissioning could not meet the needs of large increases in patient referrals.

> *“We're way off the ability to sort of treat our way out of an obesity and overweight epidemic. And if the NHS wants to increase the throughput of people through Tier 2 weight management services, that's great. And I really want that, but I haven't got any more money to put into it.” (I8 - M)*

Several participants emphasized the need for the NHS and wider care digital infrastructure to be modernised to reach the right patients, allow integrated care and better measurement of outcomes.

> *“We know what we're seeing at secondary care level fairly well, but there isn't that same level of knowledge at primary care and the ability to tie that into health inequalities data.” (I16 - M)*

A lead in a health optimisation service discussed some of the existing efforts towards increased digitisation, leading to increased reliance on patients’ self-assessment:

> *“We’ve got a complete electronic health record in my Trust. So we're sending patients questionnaires to complete electronically - that brings with it a whole host of challenges.” (I12 - B)*

A GP participant emphasised the way in which system developments should streamline health optimisation processes to avoid a lack of uptake by clinicians, or insufficient data for evaluations.

> *“And all I want to do is press two buttons and off it goes. You do that. Great. If it's that I've gotta do this and then I've got to put down the ethnicity, and then I've gotta work out the….. No. It's gonna fall away.” (I4 - B)*

The role of integrated care systems

The establishment of ICSs was seen to be a potential driver for a more systemic approach to health optimisation with the ability to better consider the wider determinants of health. Several managerial participants recounted hopes that ownership of health optimisation by a particular system within the NHS could drive progress and credited well-functioning systems with an improved ability to consider systemic outcomes and manage the overall financial decisions for greater overall benefit. This aligned with the aspiration expressed by some participants to move towards the systematisation of health improvement and to value long-term health outcomes achieved through pre-surgical interventions.

> *"We're seeing in the shift with our ICSs, as a shift more towards outcomes rather than activities, and how you manage, use the total pot of money you've got, to manage for the best outcomes of your local population rather than how many hip replacements you've successfully delivered." (I14 - M)*

Funding and oversight of programmes at the ICS level were described by clinicians interested in health optimisation approaches to be a possibility in improving standardisation and therefore disparities in care.

> *"I'm not sure how it's gonna work out, but if we can get the teams together and get a successful bid at a higher ICB level for recurrent funding [for a health optimisation programme], then that would be a good start." (I17 - C)*

4. Societal change and wider determinants

Despite differing opinions on where health optimisation fits into healthcare pathways, participants from all backgrounds expressed the view that healthcare can only contribute so much to overall well-being, and that work is needed to improve people's environment and opportunities before they reach the health service. This would include conscious health improvement by individuals.

> *"We need to be working with people at every stage of their lives to be able to drive a better publicity campaign around what people can do to improve their health, and what is and isn't possible through healthcare." (I15 - B)*

However, participants also maintained that healthcare can play a role in systemic change for health improvement, particularly if patients were reached early in their interactions with healthcare.

> *"While addressing poverty is difficult and beyond probably the remit of healthcare, doing health optimisation is at least an element of where we can impact […] positively on people's lives. […] reduce health inequalities." (I3 - B)*

5.6 Discussion

5.6.1 Summary of key findings

This qualitative study of the views of key informants in the field of health optimisation for elective surgery focused on the current impact and future implications of policies for obesity in patients considering joint replacement surgery. There is high variation in the health optimisation policies used in this setting, ranging from restrictive BMI threshold policies to holistic support for health improvement not contingent on surgery.

Personal stances on health optimisation coupled with the features of a locality, including financial and service pressure, attitude to risk and evidence base, and availability of support services, help to explain the choice of policy approach in a region, accounting for the variation seen in policy use. Finance and resources were cited as the main driver in the introduction and choice of policy type and a major consideration in why the policy might be delivered successfully with benefits to patients or otherwise. Overall, the dual elements in the policy approach in a region could be described regarding the level of restriction used in health optimisation policy and the organisational confidence in the approach's effects (Figure 14).

A typology was devised of individual professionals' views on health optimisation: a 'Gatekeeper' with prominent opinions on the importance of restricting access to surgery based on modifiable risk factors, a 'Champion' who is optimistic and motivated about increasing the use of health optimisation in healthcare settings, 'Sceptical' where more potential significant harm than benefit through adoption of health optimisation approaches is foreseen (sub-divided into those who do and do not think this could be mitigated by adequate provision of support services), and 'Undecided/conflicted'. Participants sceptical of health optimisation were mostly those working in primary and community care and public health which may represent their proximity to weight management services and experience of their limitations. The group of champions of health optimisation were in positions of influence in local policy and service design, and their attitude may be reflective of their positive experiences where health optimisation is available in an established and better-resourced setting. The conflicted/undecided participants gave prominence to the paucity of evidence for health optimisation approaches and impacts. These differing viewpoints illustrate the need to be responsive to the heterogeneity in practitioners' and policymakers' experiences, and therefore attitudes, to health optimisation in future decision-making and approaches to further implementation.

Participants' views on the future direction for best practice in health optimisation were described over four sequential elements. Participants identified gaps in the evidence that need to be addressed which could then support the introduction of national guidance retaining flexibility for localised approaches. Health optimisation could then be more fully implemented across the NHS, not solely in surgical patients and with an increased reach through initiation in primary care and integration throughout all healthcare settings. There was wide acceptance for a broad approach to support for health improvement in the pre-surgical setting, that is adequately resourced, patient centred and purposefully designed and monitored to improve health inequalities. The use of BMI as a measure remains contentious and raises concerns over unintended consequences of health optimisation where it forms a threshold for access to care. Integrated care systems were described as a potential vehicle through which to improve health optimisation and better address wider determinants of health and societal elements of obesity.

5.6.2 Strengths and limitations

The qualitative design of this study, with the use of semi-structured interviews, allowed a deep exploration of key informants' nuanced and often conflicted views on a topic under-researched to date. The major strength of the study was the broad range of the study participants' professional roles and practical experiences. Many of the participants had leading roles and first-hand experience of health optimisation at national and/or regional levels meaning they were key informants in the consideration of the policy making and practicalities of health optimisation. Others were based in front-line roles which left them managing patients or systems subject to health optimisation policies outside of their control, giving them insight into the direct impact on patients and their care pathways. Sampling across different geographical regions in the context of a variation-filled policy landscape allowed the analysis to bring together the key elements common to underlying attitudes and decision-making while exploring the differences between policy impact. Findings from this study inform the evidence base for the wider understanding of policy creation and decision-making relevant to other areas of rationed healthcare access as well as address the specific questions remaining around health optimisation approaches.

A discussion of the strengths and limitations of remote interviewing is covered in the methods section. Use of video calls for interviewing was considered overall to be a strength of this study as the resultant participant sample was diverse in geography and seniority and no technical issues were encountered. Reflexivity, and the resultant considerations made in this study's data analysis are also described in the methods section.

The timing of the study was a strength as it collected data during a key time in policy evolution with the formation of integrated care systems. While this study was undertaken, uncertainty in NHS funding, pressures and future approaches to weight management and health improvement left participants grappling with the need to differentiate between policy relevance to date and what is feasible to aim for in the future of health optimisation, and this is reflected in the findings. A study limitation was the requirement for me to undertake all data collection which restricted the sample size. This prevented an in-depth case study approach. It is notable that commissioners in localities receiving negative attention on the restrictive policies that had been introduced were noted by other participants to be reticent to further discuss their policy use, and this may have been a factor in the lack of response to invitations from the small number of people invited to the study who chose not to participate. Nonetheless, study participants did address the negative experiences faced by commissioners where there had been experience of restrictive policy use.

A limitation of this study is that it did not directly address patient and public views on health optimisation. These perspectives are important aspects in the full interpretation of the current and future potential impact of health optimisation approaches. Previous studies have reported related qualitative research with patient participants (125,126), and public consultations have reported public opinion on health optimisation approaches (described in section 1.9). The analysis of the data from this study was informed by these prior findings and by engagement with my fellowship's patient and public involvement group; one of our meetings focused specifically on discussing the key findings from this study, their relevance, meaning and potential further research requirements.

5.6.3 Existing literature and contextual policy development drivers

In the UK, NICE is intended to provide a rigorous evidence-based process for guideline creation, removing some of the burdens on local settings to synthesise the evidence needed for particular topics and to negotiate the decision-making needed in its interpretation (224). It remains the case that commissioners can and will take policy decisions which contradict the recommendations NICE makes (225) as is evident here in some localities' decisions over health optimisation. A recent analysis of policies for accessing elective musculoskeletal procedures in the NHS in England examined variation across 14 localities (177). The authors concluded that evidence was cited inconsistently across the policy documents, and that variation in specifications and requirements was recurrent, despite the existence of NICE guidance for many procedures covered. In order to counter the local variation in policy making, particularly with regard to its deviation from national guidance, the authors suggested that more central support is required to promote consistency and that this is critical where the evidence base is deemed uncertain for a particular policy (177).

Existing literature makes clear the ‘evidence-policy’ gap, whereby multiple factors play into policymakers' decision-making, including many which are not conducive to evidence-based policy making, such as ‘the tendency of policymakers to base judgements on their beliefs, and shortcuts based on their emotions and familiarity with information’ (226). Where policies are created in the setting of a regional organisation structure, there is a push-pull between evidence quality and relevance and this is reflected in the experiences and interpretations of the participants in this study.

With the responsibility for evidence services and support now based primarily in public health local authority settings – serving the region’s NHS commissioning bodies in turn, much attention is paid to evidence’s local relevance where rigorous peer-reviewed evidence sources may be deemed to have limited local replicability (227). The speed and hierarchical nature of decision-making in local settings present an added challenge for evidence-based policy making in public health topics (227). With democratic political decision-making remaining reliant on local knowledge and evidence, even the presence of good guidelines does not protect against practices which may not reflect broader scientific conclusions in healthcare public health; Kelly et al. interviewed elected members and public health officers to elucidate the reality that ‘there is an interchange of ideas going on and that guidelines and evidence contribute to that interchange but to do not determine it’ (228).

To investigate local evidence-informed policy making, Gabbay et al. conducted qualitative research with 52 participants working with UK healthcare commissioning organisations, using interviews, meeting observation and document review in 2020. Their research concluded that in response to the ‘multi-transactional environment characterised by interactive, pressurised, under-determined decisions’ faced by commissioners, professionals in this field ‘repeatedly re-interpreted and recrafted the available evidence’ to fulfil the demands of their roles (229). This characterisation is reflected here in this study within the themes of selective use of evidence and policy decision-making dominated by financial considerations. A survey study of orthopaedic surgeons’ decisions over the use of BMI threshold policies for elective joint replacement surgery in the USA reported many of the same themes participants in this study raised as drivers of restrictive policy use; poor outcomes, financial considerations, and the well being of the patient. In the USA setting individual hospital BMI thresholds were another element of the autonomy afforded to individual surgeons (59).

The requirement for policymakers and commissioners to evaluate the impact of new policies in a rigorous fashion is limited, and it is often the case that no published reports are made available. This raises the question of whether the impact of the policy is truly understood, even within the local setting of its implementation, and makes it difficult for other organisations to learn from what has gone before. Participants in this study highlighted the difficulties in evaluating health optimisation. Recent research has concluded that ‘overall, research use in public health policy making and evaluation is limited’ (230), in part due to the basis of intervention decisions made to meet perceived short-term opportunities (231).

This study identified the impact of interventions on health inequalities as a key consideration in health optimisation's future. McMahon's review of 2022 regarding what shapes local health system actors' thinking and action on social inequalities in health reports that 'inequalities continue to be problematised in narrow and reductionist ways to fit both with pre-existing conceptions of health, and the institutional practices which shape thinking and action'. Where systems were more positive in their approach, the factors linked with success were related to the identity of the system leader – their beliefs, values and ability to counter dominant norms (232), with concerns over the role of media providing further influence (231). The perception of obesity as a question of personal responsibility by key actors forms a key element of the ethical dimension of policy making for related interventions and barriers to healthcare provision (149) – reflected in particular in the 'Gatekeeper' type within the typology reported in this study.

It is noted that while there are no current plans for specific national guidance on health optimisation for obesity, national requirements and policy provisions on peri-operative care are increasing in line with an NHSE programme of work and the foundation of the Centre for Perioperative Care. The Centre for Perioperative Care is a partnership between patients and the public, and other professional stakeholders including Medical Royal Colleges and NHS England (233). There are many other relevant contemporary policy directives such as those regarding action on health inequalities above which will shape the future choices made by commissioners regarding their approach to health improvement in the pre-operative setting (234). Further relevant NHS initiatives such as 'My Planned Care' and elements in the NHS Elective Recovery Plan reflect the move towards universal, digitally centred support for patients on long waiting lists which may also influence access to health improvement support for NHS patients (235,236).

5.6.4 Future research and policy implications

The key findings from this study along with their policy implications and associated remaining research needs are summarised in Table 12.

Table 12: Summary of the study's key findings and implications

Key finding	Policy implication	Research needs
Finance and resources are primary drivers in the choice of health optimisation approach.	Financial pressures can influence decision-making towards more restrictive NHS policies. Commissioners must be sure of the value and effectiveness of tackling obesity in this setting and should use evidence of the cost-effectiveness of health optimisation interventions.	Rigorous evaluation of long-term cost-effectiveness of health optimisation interventions, which account for outcomes across a broad scope of health and wellbeing measures, would inform better decision-making over resource use. The feasibility of better integration of health optimisation into primary care needs examination.
Strong concerns around the role of BMI, concordant with current NICE guidance to avoid its use in determining access to surgery.	Alignment of current and future policy making to de-emphasise BMI as an individual decision-making tool.	Evidence gaps remain on the equivalence of patients at a healthy BMI with and without former obesity which should be addressed to guide health optimisation approaches. Exploration of factors that can influence retraction of inappropriate policies could be further explored qualitatively.
Local variation in policy approach is high and multi-factorial in cause.	National guidance would have a role in reducing variation. The existing wealth of health optimisation experience and willing leadership across the country could be shared across the integrated care system setting to encourage best practice.	Gaps in the evidence-base which drive variation and should inform national guidance must be addressed. Natural variation can be explored to provide opportunities for comparison and therefore evidence generation.
The nature of weight management support on offer is a key concern regarding the feasibility and effectiveness of health optimisation.	For effective policy, the provision of behavioural change support, integrated with prevention, should be central and adequately resourced. A focus on long-term outcomes and maintenance of benefits is key.	Shifting approaches to weight management in the NHS need to be researched in the context of pre-surgical provision to determine the impact of this setting.
Health optimisation policy choice could influence health inequalities in either direction.	Inequalities must be adequately measured in all policy introductions and pathways designed to mitigate differential benefits of the support on offer.	Longer-term measurement of the impact of the various pathways on offer, including new digital approaches would provide evidence of the broader impact of health optimisation.

5.7 Conclusion and implications for the thesis

This chapter shows that variation in health optimisation policy approach, experience and intent are prominent features in the policy landscape for this topic, reflective of the measured formal variation in restrictive policy use presented in Chapter 3. Insights from key informants indicate that financial drivers are a major element in policy decision-making. Participants' acknowledgements of the limited evidence base for the impact of health optimisation on patient outcomes and inequalities is reflective of the concerning quantitative changes associated with restrictive policy introduction in the natural experimental design of Chapter 4. Addressing the evidence and policy implications for the areas of concern around these factors would inform policy direction and interventions. Recommendations in the field of health optimisation policymaking need to be shaped with recognition of the complex landscape of the reality of local pressures, clinician autonomy, and changing weight management approaches and resourcing seen in these qualitative accounts. Having highlighted in this chapter the need for a stronger evidence base for obesity interventions including health optimisation, alongside reliable gauging of the impact of interventions on health inequalities central to decision-making over health optimisation in the future, the following chapter (Chapter 6) takes the next step by assessing the methods used to estimate the long-term cost-effectiveness of such interventions.

Chapter 6. Health economic scoping review

6.1 Overview

The previous chapter presented qualitative research which examined the views and experiences of key informants on the use of health optimisation policies in healthcare. A central finding was that decisions over the use and nature of such policies are driven by the perceived potential for cost savings from reducing obesity and consequently, the need for joint replacement for some patients. A further theme described the immaturity of the evidence base for the impact of health optimisation interventions and the effects of obesity reduction over the longer term, and between different demographic groups. These findings highlight the importance of economic evidence for health optimisation in future policy decision-making.

Evidence for the health economic impact of health optimisation should inform policy decision-making over its role in elective care. This chapter assesses the availability of health economic modelling for the measurement of the value of health optimisation. There is no single recommended model for estimating the cost-effectiveness and wider economic benefits of obesity reduction. The chapter begins with a brief introduction to the analysis of cost-effectiveness, NICE's approach to assessing value for money, and the role of economic modelling for a chronic condition such as obesity. It then presents the methodology and results of a scoping review into the modelling available to estimate the health economic effects of obesity reduction and prevention. Following this, a discussion is made of the implications of health economic modelling approaches on policy making for obesity intervention and population-level decision-making pertinent to health optimisation.

The protocol for the study in this chapter has been published in an online registry:

- *McLaughlin J, Sillero-Rejon C, Moore T and McLeod H. Study protocol: "Health Economic Models for Estimating the Benefits of Obesity Reduction and Weight Loss: a Scoping Review" – Registered on The Open Science Framework (OSF) Registry. 2023 Jun 13, https://doi.org/10.17605/OSF.IO/4U53Y*

Author's initials are used in the reporting of the scoping review methodology in this chapter to denote the contributions of the co-authors.

6.2 Objectives

This study aimed to meet the following objective:

Objective 4:

1. *To identify and describe the variation in economic models used recently to evaluate the long-term cost-effectiveness of policies or interventions to prevent or reduce overweight and obesity*
2. *To consider the implications of health economic modelling approaches for policy making in obesity reduction and prevention, including health optimisation approaches.*

6.3 Background

6.3.1 Health economics in healthcare decision making

Health economics is the application of economic principles and methods to study the level and distribution of health resources under conditions of scarcity and uncertainty. Health economic analysis forms a central component of NICE's health technology evaluations, giving consideration to the value for money offered by new interventions compared with established practice in the NHS (237). Health economic analysis techniques permit the expression of the costs and the impact of a policy or intervention in standardised terms which then allows more meaningful comparisons between different options. Policymakers concerned with obesity and its impact on health need to make decisions about the provision of interventions for overweight and obesity and rely on economic modelling to estimate their cost-effectiveness (7).

Cost-effectiveness is a comparative analysis between intervention and control groups, examining the costs and outcomes measured in each, with the results expressed as an incremental cost-effectiveness ratio (ICER). ICERs quantify the additional cost for each additional unit of outcome gained through an intervention (238). In cost utility analysis, outcomes are measured using quality-adjusted life years (QALYs). QALYs are a measure of health-related quality of life over time: one QALY is one year of life lived in perfect health. Fractions of QALYs thereby represent years of life lived in various states of ill health (237). QALYs are NICE's preferred unit of health gain and QALY-based ICERs are used by NICE to determine a decision rule for estimating cost-effectiveness through the application of a threshold which represents the willingness to pay – this is generally considered to be between £20,000 and £30,000 per QALY gained (239).

6.3.2 The role of health economic modelling

In some cases directly measured data are available of the costs and outcomes of an intervention – for example where these have been measured in a randomised controlled trial or in whole population statistics. Where direct measurement is not feasible, estimations of an intervention's costs and outcomes are necessary instead. Health economic modelling is a technique which fulfils the need to extrapolate from measured data from trials of interventions in specific settings, to different populations of patients or over longer timeframes. Models use existing literature to estimate the value of the disutility, in terms of impact on mortality and health-related quality-of-life, to an individual caused by a certain state of ill health (240). The direct costs of intervention delivery may also be derived from literature or service provision documentation, and national tariffs exist for the healthcare costs associated with specified health events (241).

Uncertainty is inherent in health economic modelling – decisions must be made over the sources of data used to create the model (judgement uncertainty) and statistical uncertainty results from the decisions made in the choice of a model's structure and parameters (242). A balance must also be struck between the use of comprehensive, complex models specific to an individual health setting, and models with more limited outputs which are more generalisable across interventions to allow meaningful comparisons to be drawn between different options (243). Brennan et al. (2006) provide a taxonomy of models structures used in the economic evaluation of health interventions (244), and where modelling seeks to account for the complexities of interventions influencing population level public health, systems-level modelling may be used (245).

Model structure

Approaches to modelling vary in response to the levels of data availability, uncertainty and resource availability. Modelling approaches can be categorised into types, each having suitability for economic analysis in specific circumstances (246). The simplest approaches include decision trees whereby the potential pathways an individual may follow in the context of an intervention, are represented as branches on a tree with their associated probabilities and outcomes. Events in the decision tree are assumed to be independent of each other (247).

Where increasing complexity is required, state transition models are a widely used approach within health economic evaluation. They are broadly categorised into Markov models and individual-level microsimulations (248). Markov models offer advantages over the linear nature of decision trees, through their ability to incorporate recurrent events. Individuals experiencing the events are still assumed to be independent of each other and are considered to be in one of a set of health states e.g. obese or not obese, over fixed time cycles e.g. one year. Fixed probabilities determine the transition of individuals between states estimated from empirical study of the relevant health conditions. An inherent limitation of Markov models is that all individuals in a particular state are assumed to be a homogeneous group, and probabilities of transitioning between states do not vary over time (249).

When an individual's pathway cannot be adequately represented in a manageable number of branches on a decision tree, or states in a Markov model, individual sampling models can be used (248). The introductory and literature review chapters of this thesis have described the evidence base for the multitude of health conditions and events that can be considered to be linked to an individual's obesity status. Considering all individuals in the state of 'obese' to be homogenous is clearly overly simplistic – the health conditions likely to affect a teenager living with obesity at a relatively low BMI are very different to those expected to affect an older adult living with obesity for many decades and already experiencing comorbidities (5).

To include estimates of the heterogeneity between individuals with the same overarching diagnoses, multi-state life tables may be employed in modelling. In this technique, additional demographic elements such as an individual's employment status, marital status and level of socio-economic deprivation are incorporated into the probabilities of them transitioning into different health states. Additionally, microsimulation modelling refers to the use of computational models capable of simulating the trajectories of high numbers of single individuals over time through multiple health states with complex interactions between the individual's characteristics and their changing health states (248). A full set of model types and their descriptions are provided in Appendix 14.

Perspectives and time horizons

Key elements in health economic modelling are those of the choice of perspective and of the time horizon to be modelled. Perspective is the lens through which the costs and benefits of an intervention are considered. Commonly used perspectives are those of the healthcare system, whereby only costs directly related to healthcare are included, and the societal perspective which includes wider considerations such as the use of informal care and costs to employers. NICE specifies that NHS and personal social service costs is the preferred perspective for economic evaluation (237). Narrower perspectives may allow for more specific estimates on costs to particular systems, and therefore improve comparability between model outputs. However where decision-making is required on a population level, recognition is required that no intervention acts on one system in isolation. Guidance was published this year to aid in considering the 'systems modelling' needed for complex public health issues (245).

Time horizons within modelling are the length of time over which an intervention's costs and benefits are assessed. Shorter time horizons may be chosen where short-term outcomes are the main ones of interest, or where there is considered to be too much uncertainty over the longer term impact of an intervention. Complementary to broader perspectives, longer time horizons can offer decision-makers more complete information on the role of an intervention or policy in population health. In the case of obesity interventions, the patients' lifetime is the most appropriate modelling time horizon (250). This reflects the recognition of obesity as a chronic, relapsing health condition, with health impacts at all phases in the life course (251).

6.3.3 Health economic modelling in obesity

Schwander et al.'s 2016 systematic review of obesity intervention economic modelling identified four broad approaches to simulating obesity-associated events in 72 different published models (252). With a trend for each research team to build their own model, the comparison of results between models was difficult. The variation in economic modelling suggests that overall consensus is lacking about the most appropriate approach, which may undermine confidence in current estimates of intervention cost-effectiveness and the development of future interventions.

Modelling for obesity raises particular complexities. Figure 17 summarises the elements of the mechanism of an obesity intervention which must be understood and accurately estimated in order for a model to meaningfully quantify its value.

Figure 17: Estimations required within obesity interventions

01

What effect does the intervention have on recipients' body mass index?

02

What does a change in body mass index mean for health?

03

What is the value of this change in health?

Body mass index (BMI) is the measure used in the NHS to determine an individual's obesity status (11), though models may instead assess change in weight or in category of obesity status. In determining the effect of an intervention on BMI, information on outcomes may be available directly from trials of the intervention, or assumptions may need to be made regarding changes in intermediary factors such as calorie intake and physical activity levels.

Decisions must also be made over how BMI will be assumed to change over time after an intervention is complete. In NICE's analyses, the rate of weight regain was identified as the most important factor in the cost-effectiveness of weight management interventions (106). To accurately model weight regain, data from lifelong follow-up of weight management intervention recipients would be needed; however 10-year follow-up is a typical maximum that studies have offered (253). Long term health benefits such as reduced lifelong cardiometabolic risk may result from weight loss in a limited time period even if weight regain occurs (107).

The impact of a change in BMI on health is equally complex. Modelers must make decisions over the breadth of clinical conditions and risk factors to include in their consideration of the impact of a change in BMI on a person's health. Cardiovascular disease (CVD) and type 2 diabetes were the most common obesity-associated events included in models identified in Schwander et al.'s 2016 systematic review (252). All other events were present in only a minority of models despite the strong evidence of association between obesity and other pathologies; for example, certain types of cancer, hypertension, and osteoarthritis. In a recent study using a Mendelian randomisation approach to investigate the health consequences of body mass index, 240 health conditions and events were included as meaningfully associated with obesity; failure to include relevant pathologies in modelling may lead to substantial underestimation of an intervention's effects (254).

Expert recommendations on modelling in obesity

Recommendations following an expert panel rating of key elements in health economic obesity models were published in 2020 (250). These are summarised in Table 13.

Table 13: Overview of key expert recommendations for health economic obesity models modified from Schwander et al. 2020 (250)

Model aspect	Expert panel recommendations
Time horizon	Lifetime time horizon is optimal Both short and long-term results should be presented
Obesity associated events	No consensus was reached on which clinical events to include. Events with a strong association with obesity and a clear causal relationship to obesity should be included.
Model type	Microsimulation (individual patient) models were the preferred approach.
Event simulation approach	Risk equation approaches were preferred for simulating clinical events.
External validation	External validation is important.

6.3.4 Rationale and aim

The literature review in Chapter 2 identified a paucity of health economic studies of health optimisation interventions. Published guidance including expert recommendations regarding the modelling of obesity interventions more generally highlighted the multitude of available models and the lack of clear direction towards any particular approach (250). It was therefore unclear how the cost effectiveness of health optimisation interventions should be addressed, and which health economic models could be used by health optimsation decision-makers to inform their commissioning and resource distribution. A scoping review would allow the identification of relevant health economic models used in publications in recent years as the last systematic review of models was completed eight years ago. Description and analysis could then be made of the nature of the models, and whether they meet the expert recommendations. Additionally, the scale and approach to the incorporation of examining interventions' impact on health inequalities could be examined.

6.4 Methods

A scoping review to provide an overview of the use of economic models for the long-term cost-effectiveness of policies or interventions to prevent or reduce overweight and obesity was considered to be the appropriate methodology for investigating this topic. While a systematic search for evidence is an essential component, an assessment of methodological limitations or risk of bias of the evidence included within a scoping review is generally not performed (255). The choice of this methodology was based on an initial pilot search of relevant published modelling study articles which confirmed that there was high diversity in interventions studied and a rapid proliferation and evolution of the types of models used in their methodology.

The methodology and reporting for the scoping review were based on guidelines from the Joanna Briggs Institute (255). The specific terms for the objective, search strategy and inclusion criteria were informed by the most recent systematic review on the topic of modelling obesity in adults (252) and by a more recent review examining the modelling of interventions for children (256). The study protocol was documented in advance of the data collection and was registered on the Open Science Framework platform (257).

In the first stage, all publications using relevant health economic models were identified to allow reporting on the frequency and nature of model usage.

In the second stage, the models themselves were retrieved from the publications to allow reporting on the content of the models and their comparison against the existing expert recommendations.

6.4.1 Stage 1 – Identifying recent publications using relevant modelling

Search strategy

A search was conducted for recent studies meeting predetermined eligibility criteria that have applied or described economic modelling to evaluate policies or interventions for the prevention or reduction of overweight and obesity. The inclusion and exclusion criteria are detailed in Table 14.

The electronic search strategy (Appendix 15) was developed to include a range of search terms and headings and was informed by the search strategy used in other reviews on the topic of obesity intervention (252,256). As the most recent systematic review on this topic was published in 2016, the search was performed to capture publications published from 2015 onwards. The searches were performed within the MEDLINE, PsycINFO and Web of Science databases.

Table 14: Inclusion and exclusion criteria

	INCLUSION CRITERIA	EXCLUSION CRITERIA
POPULATION	• General population of adults, which will include people living with overweight or obesity • Clinical populations receiving treatment for obesity or overweight	• Populations limited to specific comorbidities e.g. pregnant women with obesity • Populations of children alone, or studies on family interventions which report only on the children's outcomes • Populations outside the Organisation for Economic Co-operation and Development (OECD)
INTERVENTION	• Interventions or policies targeting behavioural risk factors (e.g. calorie intake, sugar intake) for preventing or reducing obesity and/or overweight • Hypothetical scenarios where level of obesity in the general population is altered without consideration of a specific intervention	• Interventions or policies aimed only at altering physical activity or improving nutrition where weight management is not the primary intent • Evaluations of medication/surgery interventions without 'usual care' or behaviour change interventions as a comparator
COMPARATOR	• No intervention or policy • Current practice • Hypothetical simulation	
MAIN OUTCOMES	• The incremental health effects (e.g. utilities) and cost for a time horizon of at least 10 years • Perspective that includes healthcare	• Short-term time horizons alone (<10 years) • Uncosted health outcomes only
STUDY TYPES	• Any study type incorporating economic modelling of cost-effectiveness of interventions/policies for the management or prevention of overweight and/or obesity • Publication on or after 1.1.2015	• Studies where the health outcomes and cost are calculated through methods other than economic models • Reviews, editorials, commentaries, protocols and methodological articles

Data collection

Identified references were downloaded into reference management software (Zotero (258)), deduplicated and then exported onto a web-based study selection platform (Rayyan (259)) for screening.

Screening

The titles and abstracts of the references were screened by two reviewers blinded to each other's decisions (myself and CSR). When independent findings differed, consensus was achieved through discussion with my health economics supervisor (HM). References which evidently did not meet inclusion criteria were excluded. Full-text articles were obtained for all remaining references. These were examined to determine whether they met the inclusion and exclusion criteria. All references excluded at this second stage were documented along with reasons for exclusion.

Where review articles were returned by the search, the citations included in the reviews were checked for relevant studies to be screened for inclusion. The review articles themselves were not eligible for inclusion. Hand searches were also made of the citations within the included references.

Data extraction

A bespoke electronic form was developed, piloted, and then used to extract the following data from the full-text document for each included study:

- The first and corresponding authors' name and affiliation
- Year of publication
- Type of publication e.g. journal article
- The location of the study population (country)
- Study design
- Study setting (e.g. clinical, community)
- Population characteristics (e.g. age, sex, co-morbidities)
- Intervention or scenario examined
- Comparator
- Behavioural risk factor targeted (e.g. diet, physical activity)
- Time horizons used
- Model used
- Modification to the model (if applicable)
- Approach (if any) to examining health inequalities related to intervention

6.4.2 Stage 2 – Examining the models' content

Data collection

A list of models to be retrieved for analysis in Stage 2 was produced from the Stage 1 data by removing duplicate models and identifying likely multiple versions of individual models.

Retrieval of the models for analysis

The primary source of each model identified in the references from Stage 1 was identified and retrieved where possible, including relevant supplementary material and technical documents. If the primary source was unavailable, the most recent and complete reference describing the model was retrieved. These primary sources were examined for citations of further, or updated, models eligible for inclusion in the final list of models for

Stage 2. Where multiple versions of a model were identified this was documented and through discussion between the reviewers (myself, CSR, HM) a decision was made over which version(s) to include in Stage 2.

Data extraction

Data were extracted using a bespoke electronic form. To minimise bias and errors, data extraction was performed by two reviewers independently (myself and CSR). Disagreements were resolved through discussion or referral to a third reviewer (HM) where necessary. The following data were extracted:

- Model name
- Year
- Author
- Primary reason for the model's development
- Relevance to weight loss, obesity reduction or prevention
- Model Type (e.g. Markov, microsimulation)
- Model population inputs (e.g. demographics and comorbidities)
- Behavioural risk factors modelled (e.g. dietary change, calorie intake)
- Model intervention inputs (e.g. weight loss effect, intervention costs)
- Health effects and events modelled
- Approach to event simulation
- Costs (e.g. health sector costs, societal costs).
- Utilities (e.g. Quality Adjusted Life Years)
- Annual discount rates
- Economic perspective
- Time horizons
- Validation

Table 15 shows the terms by which the models were categorised into model types in the data extraction. Appendix 14 contains the full explanation of the categorisation and definitions of model types.

Table 15: Categorisation of model types, adapted from Briggs et al. 2016 (260)

Model type category	Model type
Decision tree model	Decision tree
State transition model	Comparative risk assessment
	Markov models without interaction
	System dynamics models
	Markov chain models and Markov individual event history models
	Microsimulation models
Disease event simulation	Agent-based simulation
	Discrete event simulation

Table 16 shows the definitions used for the terms by which the models were categorised by the approach they took to event simulation of health outcomes based on weight loss, BMI change or obesity status change.

Table 16: Categorisation and definition of model event simulation approaches

Event simulation approach	Definition
Risk equation	Base risk is calculated as an equation of risk factors and the intervention effect is simulated by the change of risk factors
BMI-related relative risk of disease incidence	An incidence estimate (e.g. age-specific incidence) is used as base risk and the intervention effect is simulated by applying a relative risk for BMI or obesity status to the base risk
BMI function	Base risk is calculated as a function of the baseline BMI which is then directly influenced by the intervention effect on the BMI

Data analysis

Descriptive summary statistics were produced for each of the main categories of data extraction using the statistical software STATA 17 (261). All percentages are presented to the nearest whole number.

Where models were used across multiple included studies, with variation in the way in which they had been used, variables were represented in the affirmative if any of the studies had used that variable in their modelling. For example, where a model is indicated to have used several health events as outcomes, not all of these health events may have been used in all the included studies which used the model.

An overview of the models was created and considered against the relevant expert panel recommendations published by Schwander et al. (2020) regarding the nature and content of models relating to obesity reduction (250). The recommendations are clear on four of the elements; a lifetime time horizon should be used, microsimulation is the preferred model type, risk equations are the preferred event simulation approach, and the model should be validated. Less clarity was possible over the health events to be included in the model; I considered models to have met this element of the recommendations if they included mortality, CVD and diabetes as a minimum, reflective of the main health events used in models identified in the 2016 systematic review (252).

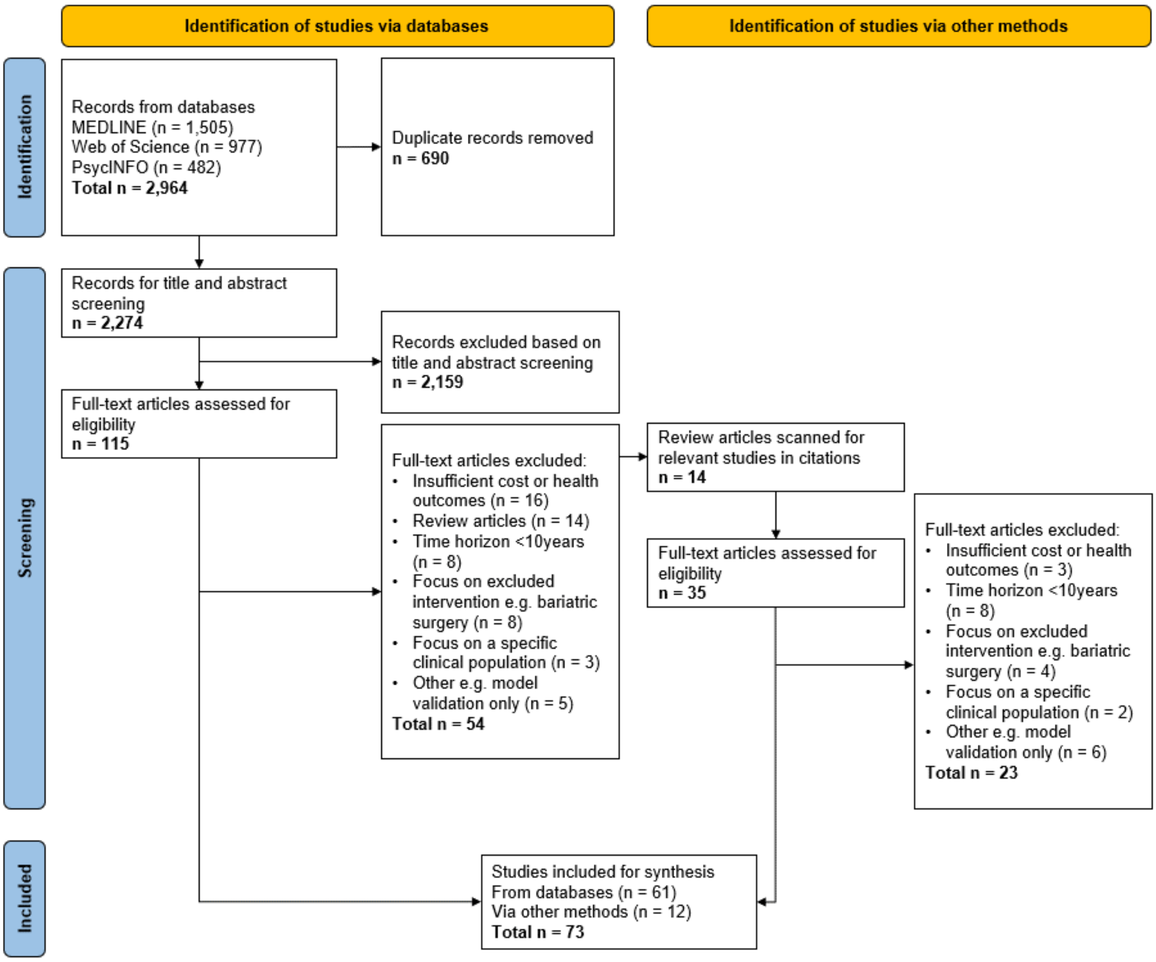
6.5 Results

6.5.1 Scoping review stage 1 results – recent studies using relevant modelling

How many studies were found?

The search strategy was run in May 2023. Figure 18 displays the PRISMA flow chart detailing the search strategy output and the exclusions made from the results. After screening and full-text articles assessment, 73 studies were included in the final selection. These are detailed in Appendix 16. The majority (n=61) were identified through searches of the electronic databases. Three author groups published three papers each, six author groups published two papers each, and the remainder of the included references were published singly.

Figure 18: PRISMA flow chart



When were they published and in which country?

A mean of nine studies were published in each year of the search timeframe. Most of the studies were based in North America (36%), followed by Australia or New Zealand (26%) and the United Kingdom (21%).

What were they looking at?

Fifty-eight of the studies (79%) assessed the impact of an intervention – actual or hypothetical. The remainder modelled the impact of existing (10%, n=7) or changing (11%, n=8) patterns in population obesity on health.

Table 17 displays the range in the types of interventions modelled. Individual-level interventions for weight management (26%, n=15) or for more general health improvement (21%, n=12) - commonly diabetes prevention programmes, were mostly based on measured outcomes from trials or evaluations of existing interventions. Population-level interventions were mostly hypothetical in nature and assessed changes in taxation or subsidy for food, drink or fuel (28%, n=16), or examined the impact of regulation of the food and drink industry (12%, n=7). The remainder (9%, n=5) considered the impact of the hypothetical achievement of existing dietary guidelines and sugar reduction strategies without specifying the mechanism for this achievement.

Table 17: Actual and hypothetical interventions modelled

Intervention	Examples	n (%)	of which were hypothetical
Taxation or subsidy	Sugar-sweetened beverage tax, vegetable subsidy	16 (27%)	15 (94%)
Individual weight management intervention	In person or digitally delivered group weight management course. Includes usual care.	15 (26%)	2 (13%)
Health improvement or prevention intervention	Diabetes prevention programme, mass healthy lifestyle campaign	12 (21%)	3 (25%)
Regulation	Food labelling, sugar-sweetened beverage reformulation	7 (12%)	5 (72%)
Population dietary change	Achievement of government dietary guidelines or sugar reduction strategy	5 (9%)	5 (100%)
Active transport	Policy introduction to support active transport use	3 (5%)	3 (100%)
	TOTAL	58	

Which populations did they use?

In their choice of population to model in the studies, 74% (n=54) used the national population of their study setting country in a given year, while 10% (n=7) created hypothetical populations. The remainder of studies (16% n=12) used a population of clinical trial participants.

70% (n=51) made no exclusions within the population regarding an individual's obesity status, 18% (n=13) considered the overweight or obese population, 11% (n=8) considered only the obese population, and one study (1.3%) considered a population with a 'healthy BMI' only. Regarding age, 64% (n=47) of the studies included only adults (18+ years), 32% (n=23) included the total population without age distinction, and 4% (n=3) included only adults 50 years old or more.

What perspective was taken over what time horizon?

The majority of studies undertook modelling using a healthcare only perspective (60%, n=44). Three studies (4%) considered social care in addition to healthcare. Thirteen studies (18%) used a societal perspective, and 11 studies (15%) used a healthcare and societal perspective. In two studies (3%) the perspective taken was not clear.

A lifetime time horizon was used in 46 (60%) of studies. The shortest maximum time horizon used reflects the study inclusion criteria and was therefore ten years (18%, n=14). The remaining studies (22%, n=17) used maximum time horizons of between 15 and 35 years.

Were health inequalities examined?

In 34 (47%) of the studies there was an examination of the differential effect of the impact of obesity and health effects on population subgroups, amounting to a consideration of health inequalities within the modelling. The most common stratification was by socio-economic deprivation (n=15), while others considered inequality by geography, race, age and sex.

How many different models did they use and what was the broad nature of these models?

There were 44 separate models in use across the 73 studies. In 24 studies (33%) the authors had created a new model for the purposes of their study. Of these, 22 were not reused by any other study included in the review. The remainder of the studies (67%, n=49) used a model which had already been previously published – mostly by a group other than that of the study authors (47%, n=34). Overall, 35 studies (48%) used a model developed by their own author group.

Table 18 lists the models used in order of frequency, naming the 12 models which were used multiple times: one model was used 10 times, and 32 models were only used once. Models were named here with the primary author's surname if they had not been assigned a name by their author.

Table 18: Frequency of model use

Model name	Frequency of use	% of included studies
ACE-Obesity (Assessing Cost-Effectiveness in Obesity) Policy model	10	14%
School for Public Health Research Diabetes Prevention model	5	7%
ACE-Prevention (Assessing Cost-Effectiveness in Prevention) model	4	6%
Dall	4	6%
CVD-PREDICT (Cardiovascular Disease Policy Model for Risk, Events, Detection, Interventions, Costs, and Trends) model	3	4%
UK Health Forum model	3	4%
Brown	2	3%
Chen	2	3%
CHOICES (Childhood Obesity Intervention Cost-Effectiveness Study) model	2	3%
CRE-Obesity model	2	3%
PRIMEtime-CE	2	3%
The Cardiovascular Disease (BMI) Policy model	2	3%
Models used once only	32	44% (1% each)

6.5.2 Scoping review stage 2 results – nature of the models

This section presents the data extracted from the 44 models found to have been used across the 73 studies. The frequency of model use across the studies does not feature in the data presentation – all models are presented with equal weight. Appendix 17 provides the details of all the models included in the review.

What were the model types?

Of the 44 models, 42 (96%) were categorised as state transition models (microsimulation, Markov, multistate life table or comparative risk assessment models). There was also one disease event simulation model (2%) and one decision tree model (2%). Models were sub-categorised within the state transition model category. Microsimulation models were the most common (41%, n=18), followed by Markov models (34%, n=15).

There were differences in the way in which the models estimated the change in incidence and prevalence of health events – their event simulation approach. Most models (68%, n=30) used a risk equation approach, taking into account multiple risk factors and changes in these risk factors with alterations in BMI to calculate likelihood of health events. The remaining models used much simpler approaches – either applying the relative risk of various health events to individuals based on their BMI (14%, n=6) or calculating health outcomes as a direct function of an individual's BMI alone (14%, n=6). One other model (2%) used estimates of the direct effects of reduced sugar sweetened beverage consumption on each health outcome.

What were the outputs and perspectives of the models?

Quality-adjusted life years (QALYs) were the primary health economic measure in 27 (61%) models. Other models used either a combination of health-adjusted life years (HALYs) and/or disability-adjusted life years (DALYs) (n=6, 14%), or made direct cost calculations based on health status (n=6, 14%) or BMI (n=5, 11%). Two models (5%) reported only on estimates of years lived with or without disability and did not formally cost these outcomes. Where costs were included beyond healthcare costs, in order of frequency these were: costs to industry e.g. for product reformulation or food labelling (n=3), costs to employers e.g. to implement workplace health initiatives (n=2), and single uses of participant time engaged in interventions and food costs.

Regarding the time horizons available within the models, 26 (59%) offered a lifetime time horizon and 9 (21%) offered short term (<10 years) estimates. Where no lifetime horizon was offered, the maximum time horizon ranged from 10 years to 35 years.

For two models (5%) the perspective taken was not clearly stated. Use of a healthcare only perspective was most common (55%, n=24), and one further model used a health and social care perspective (2%). The remainder took societal perspectives, either with (23%, n=10) or without healthcare (16%, n=7). The component outcomes used in the societal perspectives are further detailed in the outcomes section below.

What were the inputs of the models?

Three of the models (7%) did not provide information on the demographic and other baseline variables included in their models. Within the other 41 models, 40 (98%) used age, 39 (95%) used sex and 17 (42%) used ethnicity as their demographic inputs. Thirteen models (32%) used a measure of deprivation or education level, 34 models (83%) used baseline BMI or weight as an input variable and 13 models (32%) incorporated baseline comorbidities or health status. Thirty-one models (76%) used a further input variable. In order of frequency, these variables were: Type 2 diabetes status (n=14), blood pressure (n=13), smoking (n=11), cholesterol (n=10), nutrition or dietary intake (n=9), HbA1c (n=7), triglyceride (n=3), substance misuse (n=3), family history of health (n=3), physical activity (n=2), GP attendance (n=2) and disability (n=1).

How was the interventions' effect on obesity status modelled?

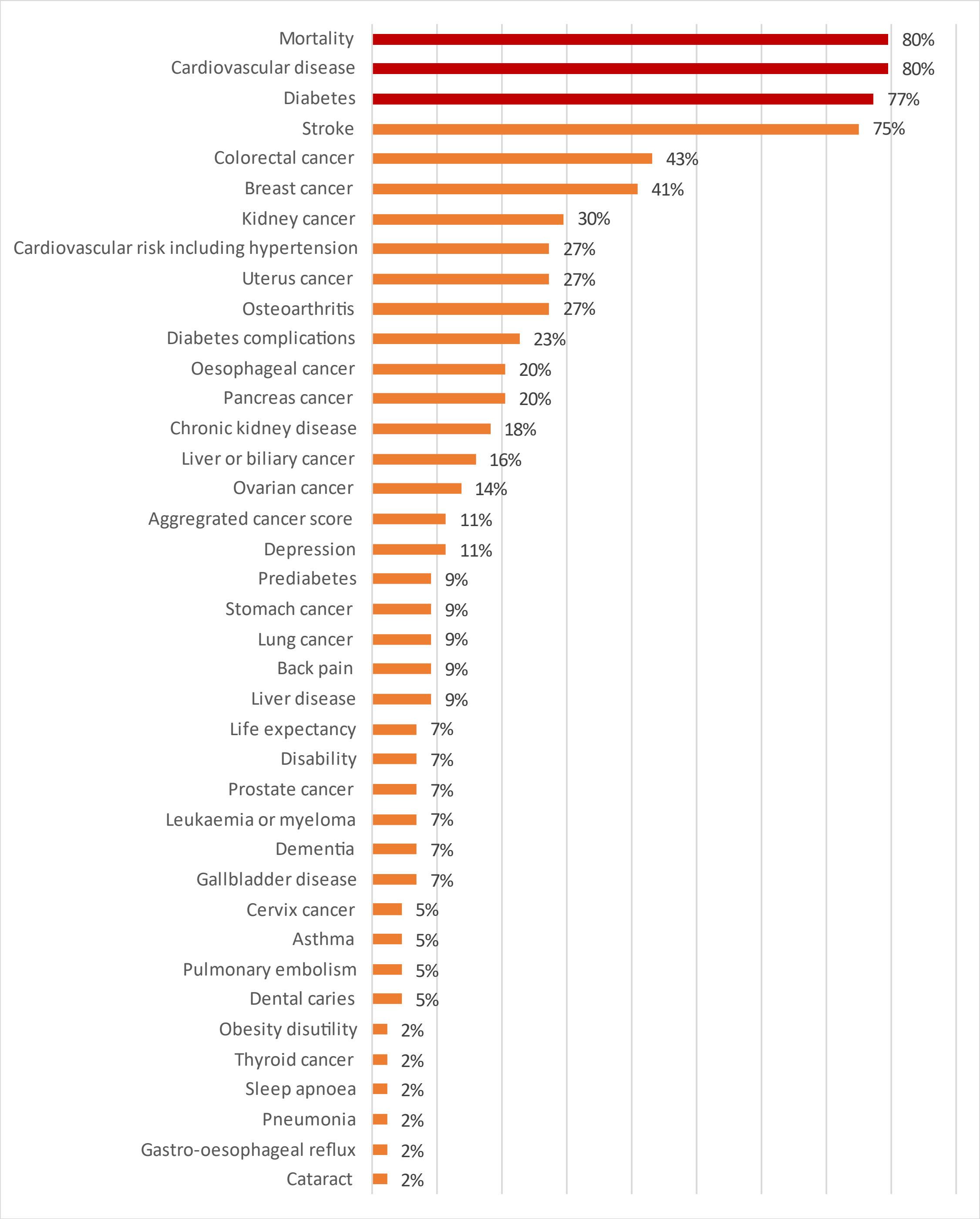
In their approach to modelling the impact of obesity reduction, 39 of the models (89%) used BMI change from baseline. Only four models (9%) also included a measure of BMI change maintenance. The other models used change in obesity status from baseline (n=4, 9%), or were examining the impact of current obesity prevalence without modelling any changes (n=1, 2%).

Models examining interventions used changes in purchasing (n=2), changes in calorie consumption (n=16) and change in physical activity or use of active transport (n=5) as applicable.

Which health events and outcomes were modelled?

Four models (9.1%) did not specify which health events they measured. Models which did specify the health events which had been included used up to 32 different health events (range 1 to 32, mean 8.5, SD 6.3). The percentage of models including each of the health events is presented in Figure 19. The most commonly included health events were mortality (n=35, 80%), cardiovascular disease (CVD) (n=35, 80%), diabetes (n=34, 77%) and stroke (n=33, 75%). Fifteen different types of cancer were included across the models, including aggregate variables of common cancers; the most commonly included were colorectal cancer (n=19, 43%) and breast cancer (n=18, 41%). Osteoarthritis was included in 12 models (27%). Depression was included in 5 models (11%).

Figure 19: Percentage of models including each health event, n=44



Additional, non-health outcomes were included in the model output where a societal perspective was taken. In order of frequency the additional outcomes were: productivity (n=8), tax (n=5), absenteeism (n=4), use of informal care (n=2), employment (n=2), and there were single uses of income and health insurance.

Where described, models used published estimates of population attributable fractions of obesity for each health event, or individual observational studies reporting on incidence and prevalence of chronic conditions and health events in patients with obesity. Other than in some microsimulation models, chronic conditions were considered to be independent of each other for the purposes of modelling. None of the models included differential costs for the severity of each condition, e.g. differences in patients who do and do not undergo surgery for their osteoarthritis, though in the case of diabetes, some models included an additional consideration of diabetic complications (n=10, 23%).

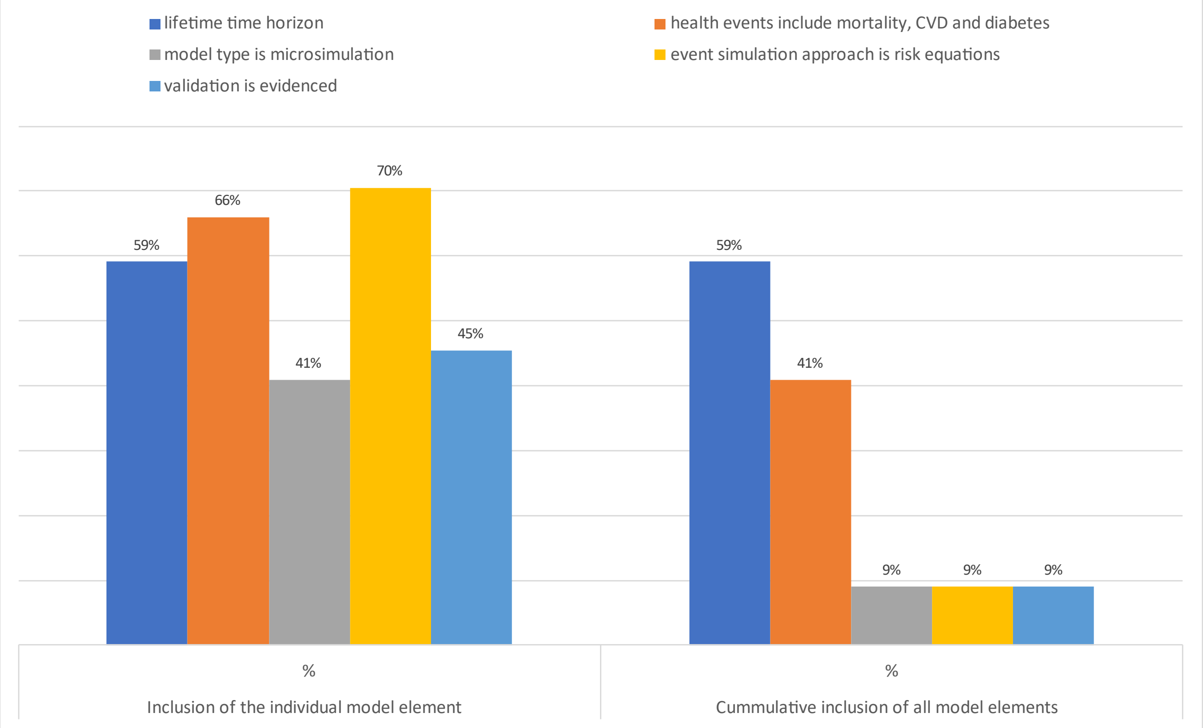
Were the models validated?

Twenty (46%) of the models provided evidence of validation either alongside the published modelling outputs, or in separate publications.

How did the models compare to the expert recommendations?

Figure 20 displays the percentage of the models which included each of the 5 model elements which are in line with the expert recommendations. Only four of the models met all 5 elements: the CVD-PREDICT model (262), Choi et al.'s model (263), the UK Health Forum model (264) and the School for Public Health Research Diabetes Prevention Model (265). Only 18 of the models (41%) met 2 or more of the elements. The element most commonly unfulfilled was the recommendation to use a microsimulation modelling approach (n=18, 41%), followed by the recommendation to provide validation of the model (n=20, 46%). A majority of models met each of the other elements: use of a lifetime horizon (n=26, 59%), inclusion of key health events (n=29, 66%) and a risk equation approach to event simulation (n=31, 71%).

Figure 20: Percentage of models meeting elements of the expert recommendations, n=44



6.6 Discussion

6.6.1 Summary of the key findings of the scoping review

This scoping review of the health economic modelling of interventions or policies for obesity reduction and prevention included 73 studies, across which 44 models were in use. Approximately a third of the studies created their own new model, and in studies making use of existing models only six models were used more than twice overall, reflective of a lack of consensus on modelling approaches.

When considered against the expert recommendations for modelling of this type, only 18 models (41%) met two or more of the five key elements, and only four models (9%) met all five. These four models were not the most recently published – one was available as early as 2017. There was a high variation in the health events included in the models. Around two-thirds of the models included the core health events of mortality, CVD and diabetes, but the inclusion of a wider range of health events was rare. Under half of the studies considered health inequalities in their reporting.

6.6.2 Strengths and limitations of the scoping review

The search strategy and data extraction for this study were strengths in this review as they followed the systematic approach, with blinded double assessment, recommended in established guidelines. A comprehensive search for studies across eight years and all OECD countries over multiple databases was completed. The opportunity to draw on the methodology and findings of a previous, though non-recent, systematic review also advantaged the validity of the review's approach. The diversity and high volume of economic models identified during the methodological design for this study meant that the evidence base presented is at the level of a scoping review rather than a systematic quality and risk of bias assessment that would have been possible in a more mature research field. However, this problematic diversity, including continued re-invention of models rather than re-assessment and improvements to existing models, is a key finding.

Limitations of the approach include the fact that not all models capable of modelling obesity are straightforwardly identifiable as such through electronic searches and some models may therefore not have been included in the review – for example, modelling of wider health interventions that may include relevant lifestyle assessment, such as in the NHS Health Checks programme (266). However, it is likely that models developed primarily for the study of obesity are the strongest models available and these will have been included here.

Likewise, modelling publications may not always report on the full capability of the model, and it is possible that the results here may underestimate the potential of the models to fulfil the content of the expert recommendations. For example – a model may be capable of providing output for differing time horizons other than the ones reported in a study's results but this will not be reflected in this review's results.

The ability to draw on existing published expert recommendations for the modelling of obesity interventions provided rigour to this review's consideration of the nature of the models. Within these recommendations, four of the five offered clear measures; however, when considering the health events that a high-quality model should include, there was no specified list of events and therefore the choice here of core events as a proxy measure for this recommendation was necessary. The choice of mortality, CVD and diabetes is a very limited selection given that existing literature can support the association of obesity with many other health events

(254). The fact that a third of models examined in this review did not meet this measure indicates that the choice of events was not overly unambitious.

6.6.3 Relationship to existing literature

The background and methods sections describe the way in which this study was informed by publications from Schwander et al.'s group. The problematic lack of consensus in modelling of obesity, and the trend for author groups to design their own new models rather than use or modify one of the multitude of existing models, is evidenced here in this review to have continued since observations to this effect were noted by this group in their systematic review in 2016 (252). Despite their subsequent publication of expert recommendations for modelling obesity (250), this review has demonstrated that a majority of models in use in recent years fail to meet these recommendations. Schwander et al.'s other publications place emphasis on the issues of variations in the approaches to event simulation, and in the deficit of replication studies demonstrating the reproducibility of model results informing confidence in external validity of existing models (267,268).

Analogous review studies have been published in the field of childhood obesity. While this review excluded studies concerning this population, there are similarities in the findings presented in this field. Mahdi et al. recently undertook a systematic review and critical appraisal of the evidence on the methods for the economic evaluation of obesity prevention dietary interventions in children (256). As noted in this scoping review that only four models include weight loss maintenance in their modelling, Mahdi et al. concluded that improvement in the consideration of weight regain was an important recommendation in future evaluation methodology. The issue that wider sets of outcomes are not well measured in economic evaluations of obesity interventions was also reported on by this group and again reflects the findings of this scoping review. Earlier work by another group studying childhood obesity economic evaluation also makes recommendations aligned with the findings of this scoping review (269). To address the deficits they identified in modelling, they recommended that conceptual approaches addressing the complexity of obesity and its impact, and methods for the measurement of intervention effects must be improved to allow a comprehensive understanding of the economic impact of obesity (269).

Tremmel et al.'s systematic review of cost-of-illness studies for obesity concluded that variation in the obesity-related diseases included in the studies they found, along with inadequate inclusion of wider costs related to productivity and informal care use, also highlights issues with consensus in modelling in this field (270). Cost-of-illness studies published more recently have expanded on the measures they include in their work to estimate the burden of disease of overweight and obesity, emphasising the importance of the choices on the inclusion of model inputs in conclusions over obesity interventions (271–273).

Challenges in the processes and interpretation of the reviews themselves of health economic studies have been recognised in existing literature. Jacobsen et al. published an obesity-specific review of recent reviews of economic evaluations and noted the lack of a standardised approach on how best to summarise cost-effectiveness evidence in this field (274).

6.6.4 Implications for policy, practice and research

The UK's Institute for Government recently reported on the repercussions of high obesity rates and concluded that obesity policy has failed to redress obesity prevalence and the inequalities within it. The report specifically addressed the role of health economic modelling in responding to this policy issue and stated that the government should "improve different types of evidence […] produce larger, more sophisticated and more robust models" (7).

Choice of interventions for obesity – the value of health optimisation within a holistic policy response

Obesity interventions range from individualised weight loss support (e.g. bariatric surgery), to population-level tax, legislation, and structural and behavioural prompts to prevent obesity (e.g. fast food advertising restrictions and sugar taxation). In the UK, the tiered weight management pathway, spanning advice to specialist treatment, has achieved limited and variable service provision over the last decade (13) and obesity prevalence has continued to rise (7). There has been a notable lack of boldness in engaging the more impactful public policy instruments.

The qualitative study chapter in this thesis (Chapter 5) highlights the importance of how health optimisation is framed in the consideration of its value for money. Some policymakers focused on its role in short-term outcomes for access to elective surgery, while other key informants emphasised its value as a trigger for lifelong obesity reduction which would offer far wider economic benefits. Participants from all backgrounds described a lack of confidence in the existing weight management support on offer to patients, both in terms of its availability and its efficacy.

Current resources are focused on short-term individual-level interventions (often 12-week weight management group courses), rather than "addressing stigma and ensuring treatment efficacy including long-term health outcomes" and focusing on interventions requiring little individual agency to help address inequalities (275). Recent excitement is high over new injectable appetite-suppressant pharmacological treatments (liraglutide and semaglutide), but this is another targeted, time-limited offering, and unforeseen concerns such as associations with suicidality have already surfaced (276). Despite the policy rhetoric about providing an integrated pathway for weight management, cumulatively, the interventions on offer do not provide an adequate, coherent response to obesity (7,275).

It is far easier to implement time-limited individual-level interventions and model associated short-term proxy outcomes, compared to population-wide structural/environmental-level policies, which may generate the required long-term health benefits. Providing a typical 12-week weight management programme is at odds with obesity being a complex chronic disease and these interventions cannot be relied upon to lead to permanent weight loss in the majority of people (7). Properly funded obesity prevention is clearly an urgent priority, but there is also a need to support those already living with obesity. Long-term or lifelong weight management pathways are essential, recognising that mental health and health-related quality of life support must be intrinsic (277). Well-designed health optimisation interventions may be able to support these needs.

In order to justify the higher investment required for a holistic approach, decision-makers need assurance about value for money. This is reliant on the availability of suitable economic models that can give confidence in the long-term value of different interventions (7). Decisions over the value of health optimisation therefore also require that modelling can elucidate its long-term, population-level health economic impact.

Addressing the modelling challenges - the trouble with simplistic modelling of short-term interventions

Working from Hall et al.'s seminal energy imbalance model published in 2011 (278), estimates are that obesity prevalence in the UK could be halved through a relatively modest daily reduction of 241 kcal for men and 190 for women (279). The issue is that interventions that elicit this calorie reduction in the short term should not be conflated with lifelong changes in populations due to appetite regulation responses undermining dietary change. Models rely on heroic assumptions which translate short-term drops in calorie intake to assumed obesity reduction long into the future. For example, in 2019 Amies-Cull et al. modelled that a hypothetical 5% sugar reduction programme would reduce calorie intake by 19kcal and provide a 5.5% reduction in obesity in adults in the UK – but caution that all this could be undone through unanticipated changes in eating habits (280).

Current interventions often focus on short-term weight loss outcomes without evidencing long-term maintenance, despite it having been over ten years since NICE stressed concerns over weight loss maintenance as the key factor in intervention cost-effectiveness (106) and overwhelming evidence that obesity must be treated as a chronic disease. This approach can give policymakers unwarranted reassurance that investment in these types of interventions is sufficient.

A counter-view suggests that short-term, individual-level interventions are good value for money in themselves and that it is appropriate for their outcomes to be extrapolated to assume long-term benefits for whole populations. Additionally, even where proponents are less optimistic about long-term maintenance of weight loss, the 'legacy effect' for type 2 diabetes is used to argue that interventions are worthwhile even where they do not yield permanent weight loss, due to the metabolic benefits of any time spent at a healthier weight (281). Jebb and Aveyard's group reported recently that 'despite weight regain, behavioural weight management programs reduce cardiometabolic risk factors with effects lasting at least 5 years after program end' (107).

The potential value of improved modelling and data

Addressing the issue detailed above of inappropriate, heroic assumptions about the long-term impact of short-term reductions in BMI would reduce current overestimates of the ease of achieving the behaviour change required to cause and maintain weight loss. While cost-*effectiveness* can be demonstrated based on short-term improvements, this approach may mislead policymakers, and while resources used on short-term interventions may be justified in isolation, this ignores the opportunity cost of not developing and instigating more ambitious and holistic combinations of population- and patient-level approaches. By prioritising long-term maintenance and scalability to whole populations through low-agency interventions, meaningful improvements in obesity rates may be achievable, and model development should prioritise the provision of evidence for interventions within this approach.

If coherent long-term population-level policies were implemented, which cumulatively achieved a sustained reduction in BMI, the benefits to society are likely to be much greater than that suggested by current economic modelling. Current models tend to only include the major obesity-associated outcomes: cardiovascular disease, cerebrovascular disease, some cancers and type 2 diabetes. When a Mendelian randomisation approach used 240 health-related outcomes instead of just the main four, the effect of a BMI change on quality-adjusted life-years was around 300% greater than typically predicted. The authors concluded that previous cost-effectiveness studies have likely underestimated the effect of BMI on quality of life and, therefore, the potential cost-effectiveness of BMI interventions (254). The impact of BMI on mental health, musculoskeletal health and productivity are just three of the major factors often missing from current models. For example, the recent evaluation of Transport for London’s ban on fast food advertising (282) suggested that the largest cost savings resulted from the prevention of osteoarthritis (29%), yet osteoarthritis is not included in the recent cost modelling of major interventions such as the NHS Health Checks (266).

Complexity and limited data availability

A challenge to the improvement of modelling is the complexity of obesity itself and the limited long-term data availability from trials and evaluations. Despite this difficulty, modelling more outcomes with more granular insight into demographic groups is essential. Collaborative efforts could collate the outcome evidence used across different models, and alterations to trial outcome reporting could allow for improved insight into the impact on health inequalities. If intervention development and the associated modelling of long-term outcomes and system effects are approached holistically then this would support a move away from the piecemeal intervention evaluation which perpetuates the current obesity policy approach.

Inequalities matter

To tackle health inequalities alongside the choice of interventions which offer good value, models must move away from one-size-fits-all assumptions in intervention effects and the utility of resultant health states for different groups. Integrated care system and NHS policymakers are adopting the 'CORE20PLUS5' approach which requires the prioritisation of those in society most in need of accelerated healthcare improvement (234). However, current models fail to consider the underrepresentation and effectiveness of obesity interventions among groups facing greater health inequalities. This lack of nuance hinders the understanding of which interventions contribute most to addressing health inequalities. Policymakers now seek this information for informed health spending decisions.

Large-scale government initiatives to reduce health inequalities have proved successful in the past when political will drives programmes to be integrated, broad and adequately funded (283). In the current climate of rolling major international concerns, health economic modelling to showcase the economic and health inequalities case for ambitious additional obesity reduction investment could help to galvanise political leadership. In recognition of the wider societal impact of obesity, reflected in the inclusion of outcomes such as productivity, employment and absenteeism in some of the models assessed in this scoping review, the economic case for obesity intervention investment can be more responsive to governmental priorities for economic growth.

Recommendations for future research and practice

1. Collaborative efforts are required between economic modellers and obesity intervention researchers. Obesity intervention studies could better provide long-term follow-up data to avoid heroic assumptions in modelling the long-term maintenance of short-term interventions' effects.

2. Central support for model development, open-source data, model availability and external validation could expedite the collation of the best available input data and assumptions, and prevent the continued proliferation of models which do not meet expert recommendations.

3. To prevent underestimation of the value of holistic obesity policy approaches, models should incorporate a much broader range of elements, including multiple health outcomes and societal impact. Models should prioritise the ability to examine health inequalities within obesity interventions. Incorporating model inputs that reflect the social determinants of obesity and the obesogenic environment can provide a more accurate representation of the complex interactions between individual behaviours, societal influences, and intervention effectiveness over the long term.

6.7 Conclusion and implications for the thesis

Examination of the current landscape of health economic modelling in interventions and policies for obesity reduction and prevention in this chapter supports the need for improved modelling approaches and data availability to better address the design and commissioning of interventions for obesity. The fact that osteoarthritis is not included as an obesity-related outcome in almost three quarters of the available health economic models despite its large contribution to the cost-effectiveness estimates in the models where it is featured, is indicative of the substantial barriers to health economic decision-making in the area of health optimisation for joint replacement surgery.

Health economic modelling, while not a solution in itself, is certainly necessary for improved policy decision-making, and the current lack of consensus in modelling approaches and the availability of models meeting existing expert recommendations hinders progress at present.

Collaborative efforts between researchers, clinicians, public health professionals and policymakers can pave the way for more effective obesity policy response, by improving the recognition of the potential value of interventions with long-term impact. Health optimisation policies' design, commissioning and evaluation are reliant on an adequate understanding of the breadth and value of their effects on health and inequalities.

Chapter 7. Intended further methodology

7.1 Overview

This chapter presents the aims and methodology of a work package within the fellowship intended to provide additional data and analysis on elements of patient experience and outcomes from health optimisation.

This study was named the 'HIO-Joint Study' (Health Improvement Opportunities for Joint arthritis patients). The health optimisation intervention under study was a pilot programme offering weight management support to hip and knee osteoarthritis patients in one sub-region alone of a CCG. The outcome data was to have been routinely collected healthcare usage and clinical data held in the CCG's 'Systemwide Dataset', linked with research questionnaire data collected from service users.

Significant progress was made in initiating this study; however, a number of issues beyond the control of the research resulted in the study becoming non-viable. These limitations that prevented the completion of the recruitment and data collection for this study are discussed, along with the learning gained by myself and my collaborators which was shared with the academic community, and implications for wider research of this type.

The work in this chapter has been presented orally at The International Population Data Linkage Conference, Edinburgh, 7.9.2022 and the abstract published:

- *McLaughlin J and Judge A. Linkage of routinely collected healthcare data and bespoke research questionnaire data to best serve NHS patient study participants. International Journal of Population Data Science. 2022 7(3). (Abstract).*

7.2 Objectives

The objective of the intended study was as follows:

Objective 5:

i. *To determine which weight loss support services or self-management were used by patients referred to secondary care for hip or knee osteoarthritis, why, and for how long, and any effect on the body mass index of others in the patient's household.*
ii. *To collate this information with routinely collected NHS data to explore associations between patient engagement and success with health optimisation and their baseline characteristics (sociodemographic information, clinical diagnosis) and their clinical and patient-reported outcome measures up to 1 year later.*

7.3 Background

Setting

Bristol, North Somerset, South Gloucestershire Clinical Commissioning Group (BNSSG CCG) introduced a health optimisation intervention for the South Gloucestershire (intervention) region alone in autumn 2020 in the form of the 'Health Optimisation pilot'. The health optimisation intervention directs patients at the point of consideration of hip or knee primary replacement to the 'One You South Gloucestershire' (OYSG) service which would offer weight management interventions and support. The main interventions offered are vouchers for 12 weeks of slimming group sessions and one-to-one support from specialist healthy lifestyle advisors. OYSG is a local authority-commissioned service. The non-intervention (control group) areas (Bristol and North Somerset) did not have this service. The service was suspended in late 2020 and restarted in April 2021 due to the impact of COVID-19.

Design and rationale

The introduction of a hip and knee surgery health optimisation intervention for only one of three localities allows for a natural experimental design. This would examine outcomes and patient experience between the intervention and non-intervention areas, with the advantage that all areas access the same hospitals and surgeons. The spillover effect on household outcomes would also be measurable (e.g. changes in patients' family members BMI).

The datasets from the National Joint Registry in Chapter 4, although extremely valuable to our understanding of the effectiveness of health optimisation interventions, have missing BMI data for approximately 25% of patients and no information is available about patients who decide against surgery nor on if/how patients engaged with the health optimisation intervention or undertook self-management.

Use of the new System Wide Dataset (SWD) and related CCG held routinely collected data (284) covering the BNSSG CCG region that incorporates primary, secondary, mental health and community care routinely collected data is a novel research technique offering efficient and in-depth patient-level data access regarding their use of services and clinical outcomes such as surgery completed. Current routinely collected data does not include any information on several key elements related to the health optimisation intervention. In order to address this, patients recognised as being potentially eligible for health optimisation would be invited to participate in the research study. Their participation would involve the completion of a baseline questionnaire, and follow-up questionnaires 4 months later and 1 year later to provide additional data. Linkage of questionnaire data and SWD data would allow research questions unanswered by routinely collected data to be addressed for the first time.

7.4 Intended methods

Patient identification

The service and provider landscape for hip and knee osteoarthritis patients in BNSSG is complex. Patients presenting to primary care may be reviewed by a General Practitioner (GP) or a First Contact Physiotherapist

(FCP). Those who are identified as in need of further intervention or support by community-based services may be referred for physiotherapy in the form of one-to-one sessions and/or an ‘ESCAPE Pain’ course. ESCAPE stands for ‘Enabling Self-management and Coping with Arthritic Pain using Exercise’, it is run as a 5-week long group course, virtually or in person. There are three providers of community services for physiotherapy and ESCAPE courses. Patients may also be directed to make use of the ‘GetUBetter’ app by the primary care team which provides evidence-based digital self-management support for common musculoskeletal conditions. As detailed above, South Gloucestershire patients may be referred to the One You service from primary or community care for support with weight management and smoking.

Though the System Wide Dataset includes a field which identifies a patient as having an osteoarthritis diagnosis, this does not include information on the site of the osteoarthritis, nor when it was diagnosed. In order to identify the relevant cohort of patients (adults with a hip or knee osteoarthritis diagnosis with a recent referral for community-based intervention or support or to secondary care for surgical opinion) it is necessary for a list of these patients to be produced by each of the community providers, of those referred to use the GetUBetter app, and those referred to a physiotherapy or ESCAPE course by a primary care practitioner or through self-referral. By capturing a list of unique identifiers for osteoarthritis hip or knee patients from all the following, the overall cohort of hip and knee osteoarthritis patients requiring a referral from primary care in the study period would be identified:

- Patients using the GetUBetter app
- Patients referred to the three community physiotherapy providers
- Patients referred to the One You South Gloucestershire service (the health optimisation service)

These five settings would act as Participant Identification Centres. A unique patient identifier such as the NHS number is needed. Some services do not collect NHS number and their own patient identifier would be collected instead provided the Commissioning Support Unit (CSU) would be able to recognise this identifier and match it to a record.

Recognising patients eligible for health optimisation (BMI ≥ 30 kg/m^2)

The community providers do not have complete, recent data on BMI, therefore it is not possible for them to identify health optimisation eligible patients from within the overall hip and knee osteoarthritis cohort. The majority of patients in the cohort will be overweight or obese and therefore eligible to participate based on the prevalence of obesity in adults in the region (176). Patients within the overall hip and knee osteoarthritis cohort would be invited to determine their own eligibility for the study based on their weight and height when they received a study information pack from the community providers. Through consultation with the providers, this was deemed the most suitable way to make efforts to include patients with no or low engagement in health optimisation opportunities in the study.

Sampling

Inclusion criteria: all BNSSG NHS patients aged over 18 referred from primary care to community services for intervention and support for hip or knee osteoarthritis from the study start date (October 2021) eligible for health optimisation (current smokers and/or a BMI of 30 or above). In the year prior to the study, there were 7310 referrals for hip or knee secondary care in BNSSG and 2705 hip or knee arthroplasty surgeries were completed.

Sample size

Table 19 shows the sample size calculation made for the study, using the primary outcome of ≥5% reduction in weight (dichotomous). The assumption made for the expected incidence in the intervention group is drawn from published literature on the outcomes of the use of commercial slimming group interventions (285). The assumption made for the expected incidence in the control group is drawn from published literature on the prevalence of successful weight loss amongst the general population of adults who are overweight or obese where this weight loss is maintained for at least a month (286). With an alpha value of 0.5 and power of 80%, the estimated sample size needed is 510 with a 1:2 ratio from intervention to control groups.

Table 19: Sample size calculation based on ≥5% reduction in weight as the dichotomous, primary outcome

Expected incidence in intervention group	35%		alpha	0.5
Expected incidence in control group	23%		power	80%
			Intervention: control ratio	1:2
Sample size needed from intervention group	170			
Sample size needed from control group	340			
Total	510			

Table 20 shows that the potential recruitment per month based on all hip/knee referrals = 102 in total (32 from the intervention group, eight of whom will actually use the health optimisation service) and 70 from the control group. Therefore it was estimated that six months of recruitment would be needed to meet the sample size.

Table 20: Estimates of the number of patients expected to be eligible and to participate in the study

	Hip/knee secondary care referrals per year (2019/2020)	Per month	Of which are health optimisation eligible (33%)	Of which take up health optimisation support offer (25%)	Potential numbers accepting study invitation (50% of those eligible for health optimisation)
South Gloucestershire (Intervention area)	2260	188	63	16	32 (8 health optimisation support users)
Bristol and North Somerset (Non-intervention area)	5050	421	140	n/a	70

Assumptions were made as follows:

- Hip and knee osteoarthritis diagnoses are likely to be in the 45+ age group (287).
- The obesity rate is 33% in those aged over 45 in England (288), therefore at least one-third of the cohort would be eligible for health optimisation.
- 25% of those offered a health optimisation referral will accept it (54).
- Response rate to the study invitation letter and initial survey is 50% (source: communication with the trial manager at the University of Bristol Musculoskeletal Research Unit).

Recruitment

The 'patient identification' section details the way in which potential participants would be identified via Participant Identification Centres (PICs). Members of the patient's direct care team would identify potential participants and provide them with a study invitation pack containing an invitation letter, participant information sheet and contact details to allow the potential participant to raise any questions with the research team. An individually wrapped teabag would also be included in each pack as a small non-monetary incentive for potential participants to read the pack's contents. The pack would be either posted to potential participants or handed to them in person at a suitable face-to-face clinical session. Where providers have a recorded mobile phone number for potential participants, a text message would be sent by the provider at the time that the invitation pack is prepared for posting to alert the recipient to the forthcoming invitation.

The patient identifiable details necessary to post or give the packs to the potential participants, and to send the text message notification of invitation, would only be held by the community service team caring for the patient. The invitation letter contained the details needed for potential participants to confirm their eligibility for the study. If they are not eligible then they are thanked for their time and informed that there is no need to read the remainder of the pack's contents.

Data collection

Routine data collection for the overall hip and knee osteoarthritis cohort

The System-Wide Dataset and related CCG held routinely collected data (SWD) would provide some information for the cohort identified. This information would include the key sociodemographic information relevant to investigating inequalities, comorbidities and service usage:

- Age
- Ethnicity
- Gender identity
- Sex at birth
- Religious belief
- Sexual orientation
- Index of Multiple Deprivation score
- Local authority
- GP practice
- Primary care network
- Primary language
- Marital status
- Has a carer
- Homelessness
- Housebound
- Lives in a nursing or residential home
- Is a carer
- Learning difficulties
- Autism
- Physical disabilities
- Visual impairment
- Veteran
- Co-morbidities including diabetes and pre-diabetes, hypertension, dementia, 'SAD' stress, anxiety, mild/mod depression
- Frailty
- Polypharmacy
- Activity codes for primary, community, emergency and critical care, inpatient and outpatient episodes

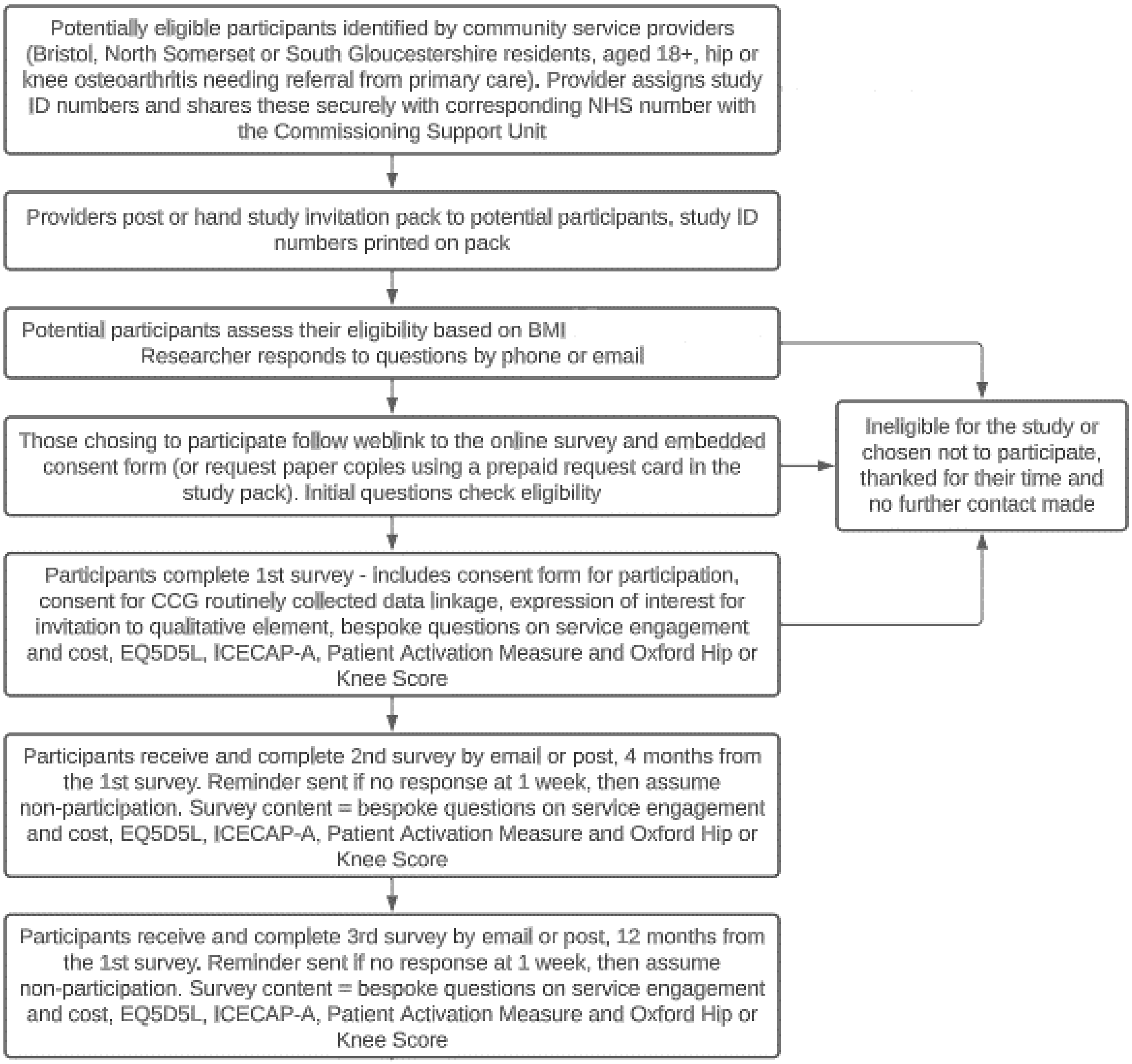
Additional data collected for the purposes of research

The domains in the questionnaires were based on the findings of a pre-fellowship feasibility study and the advice of the Expert Advisory Group for my fellowship. The questionnaires contained bespoke questions on engagement with weight loss, reasons for this choice, services used, success of the interventions, impact on household members, cost to patients and intention to continue or maintain weight loss in the future. The participants would also complete the standard EQ-5D-5L tool (289), ICECAP-A tool (290), NHS Patient Activation Measure (291) and Oxford Score tool (194) with each questionnaire to give data on changes in their clinical symptoms, capability and quality of life. These tools are commonly used in this research setting, for example in the recent STAR study (292). The bespoke elements of the questionnaires were developed by myself with the use of an existing, validated questionnaire used to collect cost information from arthritis patients (293). The questionnaires were then reviewed with the study's hip and knee patient PPI group and amendments were made in response. The questionnaires were then piloted by PPI group members with relevant lived experience using fictional data. Questionnaires would primarily be completed electronically using the secure REDCap software approved by the University of Bristol, with the option to complete a paper version if preferred. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies (294).

Participant consent for linkage of their questionnaire data to SWD data would be requested at the point of recruitment to the study. This linkage would be made with the assistance of the CSU to avoid the need for disclosure of personal identifiable information to the research team.

Figure 21 outlines the participants' interactions and timings and contents of the questionnaires during study participation.

Figure 21: Participant flow chart



Analysis

SWD and questionnaire data would be collated through the use of a pseudonymisation key provided by the CSU and the study ID number on the questionnaires to allow the determination of the outcome measures listed below. The analysis would compare intervention-area patients to non-intervention-area patients. Levels of patient engagement with the health optimisation pilot programme would be categorised as high-level, mid-level, and low.

Descriptive statistics on service use, patient outcomes, cost and patient demographics would be reported (with suppression of small numbers). Regression modelling would be used to describe the association of being in the intervention area with patient outcomes and characteristics. Changes in these outcomes would also be described using data from pre- and post-intervention, for both intervention and non-intervention patients.

Primary outcome

- ≥5% reduction in weight

Secondary outcomes

- Engagement with weight management health optimisation interventions (including self-management)
- Clinical treatment decision for joint symptoms at one year: referred onwards for primary arthroplasty surgery or opting for conservative management
- Inequality in access to health optimisation or primary arthroplasty surgery (including social deprivation, ethnicity, age, sex, obesity)
- Reasons for engagement or non-engagement with health optimisation interventions (including self-management)
- Which health optimisation services patients used and to what extent
- Their experience of these services or of self-management or non-engagement, including of personal financial costs
- Reasons for discontinuation of service use
- Changes in patient-reported outcome measures (PROMS) - Oxford Hip or Knee Score, EQ5D5L, ICECAP-A and Patient Activation Measure (measures of quality of life, capability and activation)
- Effect on BMI of others in the household
- Amount and cost of other musculoskeletal-related health service activity (including primary care, outpatient care and inpatient care including surgery)
- Quality-adjusted Life Years (QALYs) gained based on the benefits of healthier weight and reduced smoking over the lifetime
- Cost per QALY of the health optimisation intervention
- Outcomes of surgery (complications, length of stay, re-operation, and associated costs)

All patients would have a minimum of 18 months follow-up from the time of referral.

7.5 Results

Progress achieved

Following collaboration with BNSSG and the CSU to design a protocol for the study and agree on access to the necessary data and staff support, Health Research Authority and NHS Ethics approval were gained for this study (Appendix 8) and six Participant Identification Centres were recruited. The study was included in the Clinical Research Network's portfolio. Work with the study's PPI group was completed to create the participant-facing documents, including participant information sheets, consent forms, study invitation packs, and the study questionnaires themselves. Digital versions of the patient questionnaires were created using REDCAP. Permission was granted for the use of existing validated questionnaires which formed part of the suite of questionnaires (EQ5D, ICECAP and Oxford Hip and Knee scores). Recruitment and data collection were opened in Autumn 2021 and some responses (<50) were received showing that there were no core functional issues with the study processes.

Study cessation

A number of issues beyond the control of the research resulted in the study becoming non-viable. These issues along with the mitigating measures taken to try to address them are outlined in Table 21. An overall statement about the impact of COVID-19 on the thesis is provided on page vii.

Table 21: Factors leading to study cessation

Issue encountered	How this affected the study	Mitigating measures taken
COVID-related redeployment of staff within the participant identification sites.	Ethical approval was contingent on invitation packs being sent out by staff directly involved in a patient's care. Without their capacity, reduced numbers of invitations were sent.	The study was included on the CRN portfolio - contact was maintained with the CRN throughout to try to identify any resource available to assist in the recruitment processes for the study but no hands-on resource was available.
Challenges were faced in operationalising the data collection and linkage processes due to decisions over data controllership of the combined dataset.	Data collected from patient questionnaires would not be linked to the patient's routinely collected NHS data as planned.	18 months of liaison with NHS Digital's Independent Group Advising on the Release of Data (IGARD) failed to elucidate the changes they would require in order to make final approvals for data linkage, despite full HRA and NHS Ethics approval of the study protocol being in place in advance.
Unexpectedly low referral rates into the health optimisation intervention service under investigation; referral rates were only 15% of those expected.	Insufficient health optimisation referrals prevented adequate numbers of patients to approach for recruitment.	Multiple efforts were taken by BNSSG to raise awareness of the service amongst potential referrers, and changes were made to facilitate electronic referrals directly from GP IT systems during primary care consultations. Referral rates did not increase.
Low return rates from the study invitation packs that were successfully issued.	There was inadequate data collection to allow a comparison between the intervention and control areas.	The invitation pack contents were reviewed twice by the study PPI group and improvements were made.

7.6 Discussion

Sharing learning

With the support of the PPI group involved with this study, the intended methodology, the study aims and limitations encountered which prevented the study completion were presented orally at The International Population Data Linkage Conference, Edinburgh, 7.9.2022 and the abstract was published in the journal publication of the conference proceedings (295). The presentation generated audience discussion on the difficulties faced by researchers aiming to work with NHS data, and also the aspiration to be able to link research data with NHS data for the benefit of study participants' time commitment and recall quality.

The study was created in collaboration with BNSSG CCG to strengthen their evaluation of various musculoskeletal interventions offered to their osteoarthritis population. The routinely-collected data held by BNSSG on intervention use by demographics, and association with referral to the waiting list and/or receipt of arthroplasty will be used for internal analysis.

The additional questionnaire data was intended to give insight into patients' motivations, engagement, success and the household impact of any lifestyle changes made, and consideration can be given to how this information may be better understood by commissioners if changes to routinely collected data can be made. BNSSG's research team are engaged in ongoing internal and collaborative efforts with Health Data Research UK to address the challenges faced by researchers and commissioners in data use in this setting. The experience from this study has been used as a case study to inform their approach to future arrangements.

The data linkage design could offer an important advantage of a reduction in the participants' time and recall accuracy needed in completing questionnaires due to the ability to omit duplicate demographic and healthcare usage fields. Further potential advantages include the ability to compare participants with patients who decline participation in the questionnaires, and long-term follow-up of patient outcomes due to the continuation of routinely collected data.

7.7 Conclusion

There are research barriers to the full understanding of pathways and experiences of hip and knee care in patients who smoke/ have high BMI.

The linkage between routinely collected NHS data and bespoke research questionnaires was deemed ethically acceptable and could offer significant advantages in combining demographics, healthcare usage, outcomes and experience data of a cohort. Systemic decision-making to specify and streamline acceptable processes for this data linkage are important next steps.

7.8 Implications for thesis

The NIHR Academy, as the funder of the fellowship, confirmed that they supported the closure of this study in light of the factors described above, and the scope and success of the remainder of the fellowship work packages reflected in the other chapters of this thesis. The significant level of successful work undertaken in designing, preparing, gaining approval and opening this study provided me with valuable learning and experience in research skills and knowledge to build upon in the future, in line with the training elements intended as an outcome of my doctoral fellowship.

Chapter 8. Discussion

8.1 Overview

This chapter begins with a reiteration of the rationale and aim for this thesis. It then summarises the main findings of the studies presented in the thesis and synthesises the conclusions to be drawn from them in the context of the existing literature.

The first study was a descriptive study of clinical commissioning groups' health optimisation policy position regarding body mass index for hip and knee replacement from 2012-2021 (Chapter 3). The second was a natural experimental study which used interrupted time series analysis to examine associations between body mass index policy introduction and hip and knee replacement surgery rates and characteristics (Chapter 4). The third study was a qualitative interview study with key informant professionals (Chapter 5). The fourth study was a scoping review of the health economic models available to value obesity reduction from behavioural interventions (Chapter 6). Also presented in Chapter 7 was the experience and wider learning from the initiation of further methodology centred on patient questionnaire and routinely collected data which could provide further insight into patient experiences of health optimisation in the future.

Following the summary and synthesis of the findings from these studies, the chapter details the strengths and limitations of the thesis and the implications of the thesis findings for future research, policy and practice. Finally, an overall conclusion from the thesis is presented.

8.2 Review of the rationale and aim of the thesis

Policies determining health optimisation practices for joint replacement surgery patients have been noted to vary across commissioning localities in England for many years (46). Restrictive policies use obesity status or BMI to delay or deny access to joint replacement surgical referrals and are purported to be beneficial to patients through their encouragement of health improvement through weight loss. A recent update to NICE guidance for the management of osteoarthritis is explicit that people should not be excluded from referral for arthroplasty because of being overweight or obese (36), yet restrictive policies remain in use.

To guide future policy use, decision-makers require high-quality evidence on the impact of health optimisation approaches, to understand whether restrictive approaches increase inequalities in access to surgery and whether there are wider public health benefits to be gained by reshaping or extending their use. The aim of this thesis was to explore the use and impact of the restrictive approach to health optimisation for obesity in elective joint replacement healthcare delivery in England. The five thesis objectives are detailed in section 1.10 (Chapter 1). These were chosen based on the evidence gaps identified in the literature review (Chapter 2), feasibility work I had undertaken previously (54) and from engagement with the expert advisory group and patient and public involvement group for the thesis research work.

8.3 Summary and synthesis of main findings

The key findings of each study within the thesis are presented in Table 22 alongside the relevant thesis objectives.

The descriptive study in Chapter 3 successfully collected comprehensive policy data from England's 106 commissioning groups in 2021 and confirmed that restrictive policies remained prevalent in England. Forty-five per cent of commissioning groups had a restrictive policy based on BMI in place for hip and knee replacement surgery, and within these policies, the BMI threshold in use ranged from 25-45 kg/m^2. This provided firm evidence of geographical inequality in access to joint replacement surgery for patients with obesity. These policy data were categorised by policy severity and along with their introduction dates, they provided the necessary information to fulfil the design of the natural experimental study in Chapter 4.

Chapter 4 examined the changes in the rate of joint replacement surgery separately by hip and knee, over time from 2009 to 2019, applying interrupted time series analysis to determine changes in the trends in relation to the introduction point of health optimisation policies. The fact that policy introduction dates varied by locality meant that the changes in trends seen were unlikely to have been due to other wider external influencing factors that may have occurred at a single calendar time point. Therefore these studies provided strong evidence of an association between the introduction of restrictive policies and downturns in the rate of surgery. The lack of obesity reduction and the worsening of mean pre-operative symptom scores indicated that the reduction in surgery was not likely to have been due to symptom relief from weight loss. In addition, the findings raised concerns over worsening health inequalities as groups of lower socio-economic status were disproportionately affected by policy introduction. This was likely to be partially explained by the rise in the proportion of independently-funded surgery which may have allowed more affluent individuals to avoid NHS restrictions.

The quantitative findings from Chapters 3 and 4 required qualitative investigation to address the explanations for choices over policy introductions, and further insight into the likely detrimental effects on health inequalities. Chapter 5 presented the qualitative study which met these objectives. With topic guides informed by the prior studies, along with input from the patient and public involvement group, 20 interviews were completed to collect data from key managerial and clinical informants. Each had experience of health optimisation policy decision-making or delivery, and thematic analysis of the interviews provided important insight into policy development and implementation. Financial drivers, often in response to short-term pressures, were described as a primary factor in a locality's choice of a restrictive policy. The concerns participants highlighted over the impact on health inequalities due to disproportionate effects on disadvantaged groups in society, and inequities in these groups' abilities to access and engage with weight management support, reinforced the equity issues suggested in the quantitative work. Participants identified a cause for optimism in the potential for alternative, non-restrictive approaches to health optimisation in the setting of elective care. Improvements in the evidence base for the effectiveness and value of interventions, along with assurance for adequate provision of weight management services and holistic support, were described as future needs of health optimisation best practice.

The need for policy decision-makers to be able to evidence the cost-effectiveness of behavioural interventions for weight loss used in health optimisation, and to more accurately estimate the wider benefits that obesity reduction may offer a population from a societal as well as a healthcare perspective, was prominent in the qualitative findings. This entails modelling the long-term impact on costs and outcomes of typically short-term weight management interventions. Existing literature from 2016 highlighted the lack of consensus in the necessary health economic modelling for the analysis of obesity reduction interventions. Chapter 6 presented the scoping review of more recently available models for health economic estimation of this kind. The findings of 44 separate models, most of which had been used only once in a publication, and only four of which were compliant with expert recommendations, make clear the difficulties still faced by decision-makers associated with the current limited evidence base. Those seeking to present adequate estimates of the full, potential value of health optimisation weight management interventions do not yet have adequate modelling to make the case for suitable funding for the holistic health optimisation approaches viewed as best practice by the qualitative study participants.

Chapter 7 presented the intended methodology for the further investigation of elements of health optimisation patient experience and outcomes, and the wider learning gained from the initiation of a questionnaire and data linkage study. The study initiation demonstrated that the data linkage necessary for investigations of this type was deemed ethically acceptable and could offer advantages in future evaluations of the impact of health optimisation interventions.

Overall, the thesis findings provide new evidence against the use of restrictive health optimisation policies and for the outstanding needs of decision-makers seeking to pursue alternative approaches which may be more equitable and cost-effective. The implications of these findings for research, policy and practice are considered in the following sections.

Table 22: Objectives and key findings of the studies in the thesis

Chapter number and study	Objectives	Key findings
Chapter 3 **Descriptive study of clinical commissioning groups' body mass index policy position from 2012-2021**	*Objective 1:* i. *To ascertain the prevalence, trend in use and nature of commissioning policies in England that alter access to hip and knee replacement surgery based on patients' body mass index.* ii. *To consider the implications of the transition to integrated care systems for policy prevalence and nature.*	• Data were available through internet searches and Freedom of Information requests to ascertain the BMI policy position of 105/106 (99.1%) of commissioning groups in England in 2021. • 45% of commissioning groups had a restrictive BMI policy in place for hip and knee surgery. • There was high variation by geography in policy content and severity, this was not associated with the prevalence of obesity. • Estimates are that 40.5% of integrated care systems continue to use a restrictive policy.
Chapter 4 **Interrupted time series natural experiment study examining associations between body mass index policy introduction and hip and knee replacement surgery rates and characteristics**	*Objective 2:* i. *To assess the association between the introduction of body mass index policies for hip and knee replacement patients and changes in trends in surgical rates and patient characteristics.* ii. *To assess the association of body mass index policy introduction with impact on inequality in access to hip and knee replacement surgery and use of independently-funded surgery.* iii. *To examine any differences in association related to the level of severity of the policy.*	• There was an overall association between BMI policy introduction and a sustained downturn in the trend of the rate of surgery; this was in contrast to the continued upward trend in control areas. • The effect size was most marked with policies requiring patients with obesity to meet a BMI threshold. • An unexpected decrease in operations for non-obese patients alongside obese patients was also observed. • The impact observed on outcomes raises concerns over inequalities; after policy introduction, patients receiving surgery are more likely to be less socio-economically deprived and have independently-funded surgery. • Extra waiting time policy introduction had an association with worsening mean pre-operative symptom scores and obesity.
Chapter 5 **Qualitative interview study with managerial and clinical professionals**	*Objective 3:* i. *To investigate the views of key informants about the appropriateness and effectiveness of current health optimisation interventions.* ii. *To explore key informants' views on the role of evidence in health optimisation policy development and implementation.*	• Financial considerations are primary drivers in the choice of health optimisation approach. • Participants had strong concerns about the use of BMI in patient assessment and restriction, concordant with current NICE guidance to avoid its use in determining access to surgery. • Personal attitudes coupled with the features of a locality, including financial and service pressure, attitude to risk and evidence base,

	iii. To explore key informants' views on the current and potential impact of health optimisation policies on health inequalities.	and availability of support services account for the variation seen in policy use. • The nature and extent of weight management support on offer is a key concern regarding the feasibility and effectiveness of health optimisation. • Health optimisation policy choice could influence health inequalities in either direction.
Chapter 6 **Scoping review of health economic models available to value obesity reduction**	*Objective 4:* *i. To identify and describe the variation in economic models used recently to evaluate the long-term cost-effectiveness of policies or interventions to prevent or reduce overweight and obesity.* *ii. To consider the implications of health economic modelling approaches for policy making in obesity reduction and prevention, including health optimisation approaches.*	• The scoping review identified 73 studies, with 44 models for the health economic modelling of obesity reduction. • Approximately a third of the studies created their own new model, reflective of a lack of consensus on modelling approaches. • Models rarely included health events beyond mortality, CVD and diabetes, such as osteoarthritis and mental health. • Under half of the studies reported on health inequalities. • Only four models (9%) complied with existing expert recommendations, limiting decision-makers' ability to evidence the resourcing needs of effective, equitable weight management interventions within health optimisation.
Chapter 7 **Report on intended methodology for further examination of elements of patient experience and outcomes, and wider learning gained from initiation of a questionnaire and data linkage study**	*Objective 5:* *i. To determine whether weight loss support services or self-management were used by patients referred to secondary care for hip or knee osteoarthritis, why, and for how long, and any effect on the body mass index of others in the patient's household.* *ii. To collate this information with routinely collected NHS data to explore associations between patient engagement and success with health optimisation and their baseline characteristics, clinical and patient-reported outcome measures up to 1 year later.*	• Study cessation was necessary due to low referral rates into the health optimisation service and challenges in operationalising the data collection and linkage processes due to decisions over data controllership of the combined dataset. • The linkage between routinely collected NHS data and bespoke research questionnaires was deemed ethically acceptable and could offer significant advantages in combining demographics, healthcare usage, outcomes and experience data of a cohort. • Systemic decision-making to specify and streamline acceptable processes for this data linkage are important next steps for research in this setting.

8.4 Strengths and limitations of the overall thesis

The strengths and limitations of the individual studies within this thesis have been presented within the chapter for each study along with context and comparisons with the relevant existing literature. Here the strengths and limitations of the overall thesis are discussed.

Mixed methods approach

A key strength of this thesis is the use of multiple methods across four studies to approach the investigation of the research question from different angles, using the most appropriate methodology to address each objective. These methodological choices are discussed in section 1.11 and within each study's chapter. The combination of quantitative, qualitative and health economic elements has allowed exploration of important facets of the evidence base and policy and practice implications of health optimisation policy use. Each study's findings informed the next in turn. Triangulation of evidence provided from each methodology has provided additional rigour to the thesis' conclusions. The work to complete this thesis has been supported by my strong supervisory team, each able to provide expert guidance which encompassed all the different methodologies employed.

Engagement in parallel with key audiences and contributors

From the stage of the initial scoping of the work for this thesis to the drawing of conclusions and dissemination, I have pursued a broad range of academic and health and care organisation collaborations and interactions. These have resulted in timely and wide-reaching communication of the key findings of the thesis and ensured valuable impact from the completed work. Examples have included the presentation of the study findings at health optimisation working groups and health inequalities groups within the NHS, and contributions to varied conferences in the form of a symposium and through oral and poster presentations (detailed on pages xi and xiii). Networking with multiple researchers in the field of health optimisation and prehabilitation at the conferences resulted in contributions of the thesis study findings to submissions to the UK Government Select Committee call for evidence in their ongoing inquiry into prevention in healthcare (296), to consultations on NICE guidance, and to the curriculum development for perioperative care qualifications led by the Centre for Perioperative Care (233). Journal publications of the studies have also achieved significant media attention (297–300) supported by the use of press releases, provision of journalist interviews including a filmed interview for mainstream television broadcast, invited authorship of a blog (301) and participation in a Royal College of Anaesthetists podcast as a guest speaker (302). Further detail is provided in the 'Wider dissemination and media contributions' section on page xv.

The thesis work has been undertaken in the context of ongoing engagement with a patient and public involvement group with lived experience of osteoarthritis and obesity. The group contributed their expertise to support key points in the fellowship design, implementation and interpretation. This ensured the salience of the study objectives to those potentially affected by health optimisation policies, tailoring of the methods, and increased strength and perspective in the interpretation of the study findings. The group made particular contributions to insights into the future research needs and the thesis findings' implications for patients and the public, covered in the following sections.

An expert advisory group comprised of academics, clinicians, commissioners and policy leads with expertise in health optimisation was formed for the duration of the research. The group met three times for the purposes of guiding the content and progression of the studies within this thesis, as well as the interpretation and dissemination of the findings. This approach has been another key strength of the thesis as the studies were undertaken at a pivotal time in health optimisation policy and practice evolution. Maintaining an awareness of developments in the field, upcoming changes to guidance and practice, and key informants' insight into ongoing uncertainties has allowed deeper interpretation and heightened applicability of the recommendations drawn from the work.

Health inequalities

Academic investigation into the impact of health optimisation could focus on clinical effectiveness and cost-effectiveness alone. A further strength of this thesis is that in line with a public health perspective of the issue of obesity and the role of health and care services in contributions to health improvement opportunities, specific consideration to health inequalities has been given within all aspects of the thesis. In the quantitative studies, outcome measures were chosen to examine patient demographics representative of socio-economic status, and the use of independently-funded surgery. Direct investigation of participant views and insights into health optimisation’s relationship to health inequalities was undertaken in the qualitative work, and the health economic work ensured that in scoping the available health economic models, reporting on their incorporation of assessments of inequality was a focus. The scoping review represents an important initial step towards identifying issues to be addressed when undertaking future modelling to assess cost-effectiveness of both short-term weight management interventions, including health optimisation interventions, and also the more complex lifelong weight management pathways which are needed to reduce obesity at population level. The study initiated as described in Chapter 7 sought to collect data with granular knowledge of demographic factors in patients using a health optimisation service, although this was not ultimately feasible due to low patient referrals to the service and barriers to data linkage and collection.

COVID-19

While the timing of the work of this thesis had the benefit of alignment with important developments in policy and practice developments in health optimisation, it has also faced the limitation that is presented by the major upheaval to health and care systems caused by the COVID-19 pandemic. An important consideration in the methodology for investigating the impact of a policy or intervention is the way in which significant extrinsic factors are accounted for. One option within the quantitative studies would have been to include the time period of the pandemic and the subsequent recovery phase. This would have had the advantage of allowing the analyses to examine the interaction of health optimisation with a sudden cessation and then slow recovery of elective surgery. However, to maintain the important clarity in the interpretation of the surgical rates data in the interrupted time series analyses, the time period chosen ended in December 2019 to protect against the impact of the pandemic. The low number of surgical procedures during the excluded time period of 2020 to 2021 would have presented significant uncertainties in the suitability of analyses and interpretation. While this separation may represent a limitation of the thesis, the results remain applicable to the current health and care landscape now that elective care recovery is well underway. The quantitative interpretation of the impact of restrictive policy use is likely to be generalisable to this recovery period and beyond, though the qualitative understanding of the future for health optimisation acknowledges that health inequalities within patients waiting for surgery are likely to have been further exacerbated by the pandemic's effects.

As discussed in Chapter 7, one study was initiated but not completed in part due to very low referral rates into the health optimisation service under investigation. Although the time period in question fell after the COVID-19 pandemic, the redeployment of clinical staff involved with referrals into the service, in consequence of COVID-19 recovery efforts, was identified as a factor in the low use of the service. An alternative study design could have used a higher number of patient identification centres across multiple regions offering different health optimisation services. Limitations to clinical services were a national rather than a local issue however, and so it is likely that the pursuit of such a study is possible only when further recovery to elective services is complete.

Non-surgical patients

A limitation in the design of the work in this thesis is that the quantitative data include only those patients who underwent surgery. The literature review and findings in the qualitative study highlight the concerns over the unmeasured outcomes for patients actively denied access to surgery, or who feel unable to pursue a surgical referral due to the negative effect on their healthcare interactions caused by restrictive policy use. Understanding the explanations for patients' diversion from joint replacement surgery is important in elucidating the full impact of restrictive policy use. Patients who do not receive healthcare are consequently more difficult to study using routinely collected data. The National Joint Registry which provided the data for the natural experiment study in this thesis is admirably complete in its records of surgical patients, but does not provide any data on patients referred for surgery who then are not listed or who leave waiting lists. A cohort study of patients referred to secondary care for a surgical opinion on the management of their osteoarthritis could provide insight into a more complete group of these patients and guide recommendations on interventions within health optimisation provision and is something that should be addressed in future research.

The qualitative study in this thesis used a sufficient but not large sample size due to the necessity of undertaking the data collection alone and within a limited timeframe. The breadth of experience and position of the managerial and professional participants who were interviewed allowed for rich data collection and the specific objectives were therefore achieved. However, the study did not include patient or public participants and the views of these groups should be investigated to more fully inform future plans for health optimisation and could be compared against the views shared by the professional participants in this study.

8.5 Implications for future research

Address a wider scope of settings for health optimisation

Examination of differences in health optimisation policy and outcomes within Scotland, Wales and Northern Ireland is necessary to gauge the UK-wide generalisability of the findings of this thesis which studied only England's NHS health optimisation landscape.

The work within this thesis has focused on osteoarthritis and joint replacement care as the setting for health optimisation as this was seen to be the most common setting for restrictive policy use in England. Future research should investigate both the prevalence of different types of health optimisation policy use in other healthcare settings within the NHS, and the associated policy impact. The scope is wider than that of elective surgery alone – restrictive health optimisation policy use in other rationed care, e.g. fertility treatment provision, will also be relevant to the full consideration of the impact and future use of restrictive approaches. Investigation of restrictive policy use in non-NHS settings, including internationally, would also give insight into the role of the healthcare system in place, the population demographics and linked societal considerations in determining the impact of health optimisation on obesity.

Address the groups not visible in routinely collected data

An acknowledged limitation of this thesis was the inability to consider groups of patients who did not access surgery, as only patients with completed surgery featured in the available routinely collected data. Future research should pursue improvements to the representativeness of routinely collected data for wider populations, or where this is not possible, directly investigate the experience and outcomes of under-represented groups of patients. The literature review for this thesis identified that selection bias in surgical patients is thought to account for an underestimation of the risks of high BMI in surgical outcomes – the implication being that less healthy patients with obesity are excluded from surgery more often. An understanding of the reasons for patients' inability or unwillingness to engage with health optimisation services would give vital insight into the health inequalities impact of health optimisation and how this may be mitigated in policy and practice. Groups excluded from surgery or who are under-served in health improvement interventions and support are likely to be those already facing health inequalities and stigma.

Qualitative research should form a central component of investigations of the differential impact of health optimisation on groups within society. Qualitative techniques will aid in the understanding of low engagement with health improvement in the pre-surgical window. The thesis literature review identified some evidence from studies of patient preferences for health optimisation and this can be built upon; however, improved sampling of under-represented groups is essential. Close consideration should be given to the prominence in the ethics discourse around health optimisation of attitudes to personal responsibility for health improvement and the role of obesity stigma. High-quality qualitative investigation would result in an improved understanding of how effective and equitable health optimisation services may be co-produced with the patients facing barriers to service use.

Never-obese equivalence to formerly obese

The literature review for this thesis, and the analysis of the available data on BMI as a factor in health optimisation and surgical outcomes, highlighted an important gap in the evidence. Health optimisation policy decision-making is influenced by an assumption that weight loss is beneficial in all patients who are overweight or obese ahead of surgery. The nuance of differences in mechanism and speed of weight loss related to individual patient outcomes should be better understood to mitigate against unintended consequences of weight loss in surgical patients. An initial phase in research could address targeted investigations of the assumed equivalence of patients at a particular BMI who were formerly obese and those who were never obese. The literature review also suggested that weight loss in health optimisation may be more effective and better value for money if offered to patients with lower BMIs and less severe osteoarthritis symptoms. Criticism over the use of BMI in itself as a measure should be heeded; different measures of body composition could be seen to be more meaningful than BMI in determining risks and recommendations for patients (98,303).

While the findings of this thesis are hoped to drive the cessation of BMI-based denial or delay to surgery due to health optimisation policy use, evidence of the differences in needs and outcomes between patients of different BMIs and previous levels of obesity is still much needed. The current NHS England guidance on pre-surgical risk assessment supports the use of a patient's obesity status, in concert with their other characteristics, to deliver meaningful individual-level risk communication for patients contemplating elective surgery (23).

Alternative, non-restrictive approaches to health optimisation

As health optimisation becomes increasingly incorporated into NHS care pathways, in line with the five requirements for NHS providers outlined in the introduction chapter, there will be a proliferation in the approaches, services and evaluations available. Research must reliably distinguish between the impact of different types of health optimisation, and contribute to the improvements necessary in the use of standardised outcome measures. Plans in place for the Centre for Perioperative Care to facilitate the development of a core outcome set for the reporting of health optimisation prehabilitation interventions (304) were communicated at the most recent World Congress of Prehabilitation Medicine (July 2023). This will galvanise increased comparability in health optimisation evaluations. Health inequalities should be prominent in these considerations in light of the concerns identified over the impact of health optimisation, and the lack of health inequalities measures in health economics modelling reported within this thesis. Options to allow longer-term outcome measures to be incorporated into evaluations will also be critical in meaningfully evaluating the impact of different health optimisation interventions. The findings in Chapter 7 demonstrate that data-linkage of routinely collected data may be an acceptable method to patients for studying long-term healthcare usage and outcomes, though this technique still faces barriers in information governance processes.

Co-production of health optimisation interventions and policy would best be done between all key stakeholders in the field, including patients and public representatives as well as academic and provider colleagues. The findings from the qualitative study in this thesis identify key drivers, barriers and concerns in the ongoing use of health optimisation and can inform the approaches taken. Future qualitative research should also address the feasibility of the increased involvement of primary care in health optimisation's delivery, to address the recommendations described by managerial and clinical participants in the qualitative study in Chapter 5. Future interventions may seek to include novel options in weight management such as injectable appetite-suppressant treatments (e.g. semaglutide) and the continued shift to digital and remote intervention provision. Important trials are already underway such as a trial in the UK which will randomise 200 pre-operative hip and knee replacement patients to lifestyle intervention via a smartphone app, to include dietary change and physical activity (144). The effects of these changes in intervention approaches must be elucidated in future research to allow ongoing quality improvement in health optimisation.

8.6 Implications for policy and practice

8.6.1 For patients and the public

While restrictive policies remain in use for joint replacement surgery in some localities of England, thousands of patients face negative impact on their health and wellbeing. The geographical variation seen in policy use creates inequalities by location as well as by personal circumstance. The combination of the higher prevalence of obesity in people living with lower socio-economic status, and the fact that joint replacement surgery is available through independently-funded healthcare for those who can afford it, means restrictive policy use has a double effect on worsening health inequalities in the NHS.

Public consultations on restrictions in access to healthcare based on obesity have shown support for the narrative of personal responsibility in health (section 1.9). Where this public support for restriction is centred on the perceived easing of financial pressures on the NHS, future discourse needs to be informed by the thesis findings of the likely worsening of outcomes and increased costs of eventual healthcare after the application of restrictive policies, and of the counter-productive effects of obesity's stigmatisation already evident in existing literature (section 2.9.2).

Patients will have increasing opportunities to engage with non-restrictive approaches to health optimisation as progress is made towards NHS England's requirements for earlier risk assessment and increased health optimisation in surgical pathways (305). There are benefits to be gained from well-designed and well-resourced behavioural support if this is in concert with holistic care and forms a part of shared-decision making and risk communication as is intended (306). Patients and the public should be aware of the risk of unintended consequences of inappropriately rapid and unguided weight loss before surgery, alongside future developments in the evidence for specific, measurable increased risks in prognosis at different levels of body mass index or body composition.

8.6.2 For health and care services and public health

Suggested in the literature review, evidenced within the thesis studies, and supported by existing NICE guidance and professional organisations' position statements, is the conclusion that BMI thresholds for joint replacement surgery are not justified and likely worsen health inequalities. Their use should be ceased. Policy decision-makers within England's integrated care systems can take the opportunity offered by the recent re-organisation of commissioning responsibilities to ensure that integrated, complementary weight management support services are available for all and to reassess their continued use of restrictive BMI threshold policies for surgery. The novel evidence presented in the work of this thesis should accelerate the reconsideration of such policies by ICSs and provide important evidence for those advocating for change in line with existing position statements from key bodies.

Increased resource and demand pressures are the reality for the NHS and these risk influencing decision-making towards more restrictive policies. Commissioners and policy decision-makers must recognise that stigma and individual attitudes to personal responsibility for obesity may shape their views on acceptability which contradict empirical evidence and ethics analyses (154,155,275).

Alignment is needed of current and future policy making with the evidence from literature, guidelines and qualitative findings to de-emphasise BMI as an individual decision-making measure. Moves should be made away from BMI as anything other than a preliminary indicator in population level screening that indicates that a patient may benefit from further, individualised consideration of their health and nutrition status. Guidelines are clear that BMI should not present a barrier to patient or clinical autonomy or the provision of recommended healthcare (36).

Rising demands on existing community-based weight management intervention options under the responsibility of public health services will be better addressed by integrated approaches. Necessary improvements to data availability and health economic modelling would support more equitable, cost-effective allocation of resources for obesity intervention, which in some cases may involve higher cost, more intensive interventions or targeted approaches. Systemic decision-making to specify and streamline acceptable processes for timely, comprehensive data collection and linkage of routinely-collected data are critical next steps.

NHS England's five core requirements for screening and risk assessment are an important new driver for health optimisation in elective care (23). It is noted that these requirements retain flexibility for providers to decide on where and how these processes are implemented within surgical pathways, and provide little detail on how obesity may be best addressed once identified. Commissioners and service providers should position the assessment and support for weight management as early in patient pathways as is possible, in line with the findings from literature and professionals' qualitative insight that this is where it is likely to have the most benefit. More generally, primary care was deemed the appropriate site for health optimisation within the health and care system by many of the key informants in the qualitative study (Chapter 5) and this aligns with public health principles favouring early intervention and prevention for population benefit. The significant service pressures already faced by primary care providers in the NHS mean that processes for increased initiation and delivery of health optimisation within primary care pathways require careful consideration and further research into feasibility.

Services and interventions need to be shaped to promote long term follow up and maintenance of behavioural change for weight management within the context of health optimisation. Initially, new services must facilitate data collection to allow measurement of whether there are medium and long-term effects from these interventions. It is crucial that these data support examination of any differential effects between groups in society in order to allow future decisions for the mitigation of health inequalities.

Qualitative findings within this thesis indicated that flexibility for differences in approaches by locality is valued, but also that national guidelines to ensure minimum standards and avoidance of deleterious approaches would be valuable and welcomed if created in concert with all key stakeholders. The existing wealth of health optimisation experience and willing leadership across the country could be better shared across ICS settings. This would encourage continuous improvement towards best practice and facilitate the integrated, adequately resourced provision of behavioural change support and obesity prevention. The integration and shared responsibility for health and wellbeing across sectors including public health represented in the ICS structures should increase the prominence of the role of wider determinants of health and of broader obesity policy in shaping the need for health and care services to play a role in reducing obesity.

8.7 Conclusion

This thesis provides a mixed methodology investigation of restrictive pre-surgical health optimisation policies for obesity in hip and knee replacement patients. Overall it finds that restrictive policies should no longer be used in this context. It adds to the evidence base and highlights current issues in policy and practice in several key ways. It quantifies the high prevalence of policy use despite guidance to the contrary, and provides strong evidence that restrictive policy use is associated with inappropriate reductions in access to surgery including worsening of health inequalities due to differential access to surgery. It reports valuable qualitative insight into the financial motivations behind restrictive policy use, what is needed for future best practices to appropriately and equitably incorporate health optimisation for obesity into healthcare pathways, and provides evidence for the deficits in current health economic modelling for valuing obesity reduction in this setting.

Future research needs to strengthen the evidence base and clarify the practice implications for delivering health optimisation through alternative, non-restrictive approaches focusing on shared decision-making and adequately resourced, integrated support for patients. The contributions of this thesis guide the reconsideration of the use of restrictive policies and the ongoing efforts to use health optimisation to provide one element within wider policy to address obesity, without detriment to health inequalities.

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Appendices

Appendix 1: Search protocol

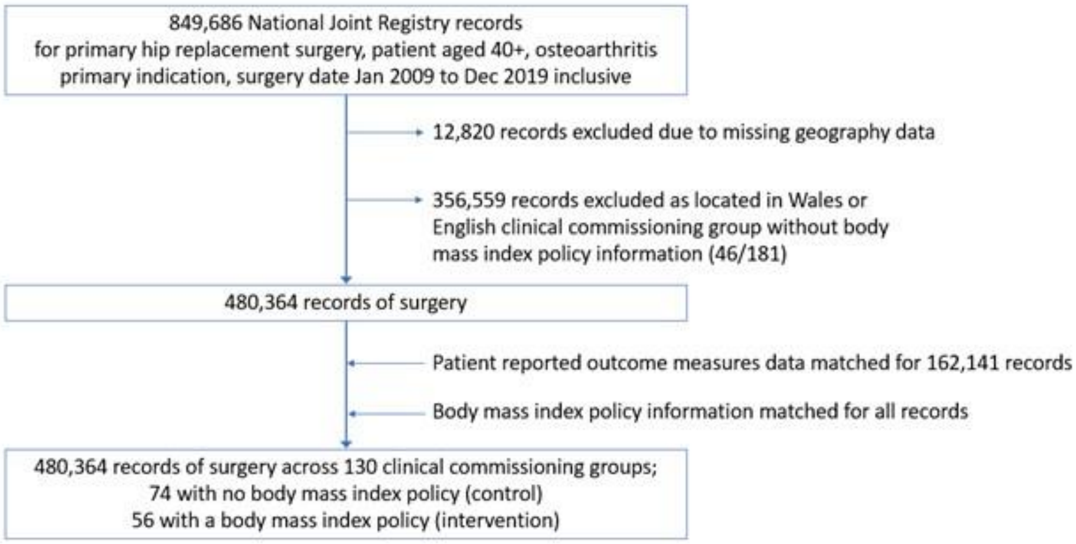
Ten clinical commissioning group websites were searched to determine the key search terms that returned relevant policy information.

The following search terms were used in Google search engine for each named clinical commissioning group:

“Hip and knee surgery, elective surgery, joint replacement surgery, arthroplasty, elective orthopaedic surgery, pre surgical health optimisation, prehabilitation, presurgical weight loss, BMI/body mass index criteria for surgery, BMI/weight/overweight/obesity eligibility or thresholds for surgical referral.”

Each individual clinical commissioning group website, including archived websites available for historic clinical commissioning groups, was checked manually for any further relevant policy documentation available.

Appendix 2: Flow chart of National Joint Registry record exclusions and data linkage



Appendix 3: Details of clinical commissioning group policies on weight loss and body mass index thresholds for joint replacement surgery for CCGs in existence from Jan 2013 to Dec 2019

Policies started less than 18 months prior to Dec 2019 are not included

Policy categories: 0 (no policy introduction), 1 (mild – patients receive advice only), 2 (moderate – patients are subject to additional waiting time before surgery) or 3 (strict – patients must be below a BMI threshold to be eligible for surgery).

CCG	CCG Name	Policy category 0-3**	Policy start date m/d/y
E38000004	NHS BARKING AND DAGENHAM CCG	0	
E38000005	NHS BARNET CCG	0	
E38000006	NHS BARNSLEY CCG	2	01/01/2018
E38000007	NHS BASILDON AND BRENTWOOD CCG	0	
E38000010	NHS BEDFORDSHIRE CCG	1	02/01/2016
E38000011	NHS BEXLEY CCG	0	
E38000014	NHS BLACKBURN WITH DARWEN CCG	0	
E38000015	NHS BLACKPOOL CCG	0	
E38000016	NHS BOLTON CCG	0	
E38000020	NHS BRENT CCG	0	
E38000021	NHS BRIGHTON AND HOVE CCG	2	04/01/2018
E38000023	NHS BROMLEY CCG	0	
E38000024	NHS BURY CCG	0	
E38000025	NHS CALDERDALE CCG	0	
E38000026	NHS CAMBRIDGESHIRE AND PETERBOROUGH CCG	0	
E38000027	NHS CAMDEN CCG	0	
E38000029	NHS CANTERBURY AND COASTAL CCG	1	12/01/2017
E38000030	NHS CASTLE POINT AND ROCHFORD CCG	0	
E38000031	NHS CENTRAL LONDON (WESTMINSTER) CCG	0	
E38000034	NHS CHORLEY AND SOUTH RIBBLE CCG	2	11/01/2017
E38000035	NHS CITY AND HACKNEY CCG	0	
E38000037	NHS CORBY CCG	0	
E38000038	NHS COVENTRY AND RUGBY CCG	3	02/01/2016
E38000040	NHS CROYDON CCG	1	04/01/2013
E38000043	NHS DARTFORD GRAVESHAM AND SWANLEY CCG	1	12/01/2017
E38000044	NHS DONCASTER CCG	2	01/01/2017
E38000045	NHS DORSET CCG	1	06/01/2017
E38000048	NHS EALING CCG	0	
E38000050	NHS EAST LANCASHIRE CCG	0	
E38000051	NHS EAST LEICESTERSHIRE AND RUTLAND CCG	3	11/01/2017
E38000053	NHS EAST STAFFORDSHIRE CCG	1	11/01/2017
E38000054	NHS EAST SURREY CCG	1	01/01/2016
E38000057	NHS ENFIELD CCG	0	
E38000059	NHS FAREHAM AND GOSPORT CCG	0	
E38000062	NHS GLOUCESTERSHIRE CCG	2	10/01/2015
E38000064	NHS GREATER HUDDERSFIELD CCG	0	
E38000066	NHS GREENWICH CCG	0	

E38000068	NHS HALTON CCG	3	06/01/2017
E38000069	NHS HAMBLETON RICHMONDSHIRE AND WHITBY CCG	0	
E38000070	NHS HAMMERSMITH AND FULHAM CCG	3	11/01/2014
E38000072	NHS HARINGEY CCG	0	
E38000073	NHS HARROGATE AND RURAL DISTRICT CCG	2	10/01/2016
E38000074	NHS HARROW CCG	3	11/01/2014
E38000077	NHS HAVERING CCG	0	
E38000078	NHS HEREFORDSHIRE CCG	0	
E38000080	NHS HEYWOOD, MIDDLETON AND ROCHDALE CCG	0	
E38000081	NHS HIGH WEALD LEWES HAVENS CCG	0	
E38000082	NHS HILLINGDON CCG	3	11/01/2014
E38000084	NHS HOUNSLOW CCG	3	11/01/2014
E38000085	NHS HULL CCG	2	08/01/2016
E38000087	NHS ISLE OF WIGHT CCG	0	
E38000088	NHS ISLINGTON CCG	0	
E38000089	NHS KERNOW CCG	0	
E38000090	NHS KINGSTON CCG	1	04/01/2013
E38000091	NHS KNOWSLEY CCG	0	
E38000092	NHS LAMBETH CCG	0	
E38000097	NHS LEICESTER CITY CCG	3	11/01/2017
E38000098	NHS LEWISHAM CCG	0	
E38000099	NHS LINCOLNSHIRE EAST CCG	1	06/01/2013
E38000100	NHS LINCOLNSHIRE WEST CCG	1	06/01/2013
E38000101	NHS LIVERPOOL CCG	0	
E38000102	NHS LUTON CCG	1	03/01/2017
E38000104	NHS MEDWAY CCG	1	12/01/2017
E38000105	NHS MERTON CCG	1	04/01/2013
E38000106	NHS MID ESSEX CCG	0	
E38000108	NHS NENE CCG	0	
E38000113	NHS NEWHAM CCG	0	
E38000117	NHS NORTH EAST ESSEX CCG	2	09/01/2016
E38000118	NHS NORTH EAST HAMPSHIRE AND FARNHAM CCG	0	
E38000119	NHS NORTH EAST LINCOLNSHIRE CCG	0	
E38000120	NHS NORTH HAMPSHIRE CCG	0	
E38000122	NHS NORTH LINCOLNSHIRE CCG	0	
E38000124	NHS NORTH NORFOLK CCG	3	09/01/2017
E38000127	NHS NORTH TYNESIDE CCG	0	
E38000128	NHS NORTH WEST SURREY CCG	1	01/01/2016
E38000130	NHS NORTHUMBERLAND CCG	0	
E38000135	NHS OLDHAM CCG	0	
E38000136	NHS OXFORDSHIRE CCG	1	09/01/2016
E38000137	NHS PORTSMOUTH CCG	0	
E38000138	NHS REDBRIDGE CCG	0	
E38000140	NHS RICHMOND CCG	1	04/01/2013
E38000143	NHS SALFORD CCG	0	
E38000146	NHS SHEFFIELD CCG	2	07/01/2016
E38000150	NHS SOMERSET CCG	0	

E38000151	NHS SOUTH CHESHIRE CCG	0	
E38000154	NHS SOUTH EASTERN HAMPSHIRE CCG	0	
E38000156	NHS SOUTH KENT COAST CCG	1	12/01/2017
E38000157	NHS SOUTH LINCOLNSHIRE CCG	1	06/01/2013
E38000161	NHS SOUTH SEFTON CCG	0	
E38000163	NHS SOUTH TYNESIDE CCG	0	
E38000164	NHS SOUTH WARWICKSHIRE CCG	3	12/01/2017
E38000165	NHS SOUTH WEST LINCOLNSHIRE CCG	1	06/01/2013
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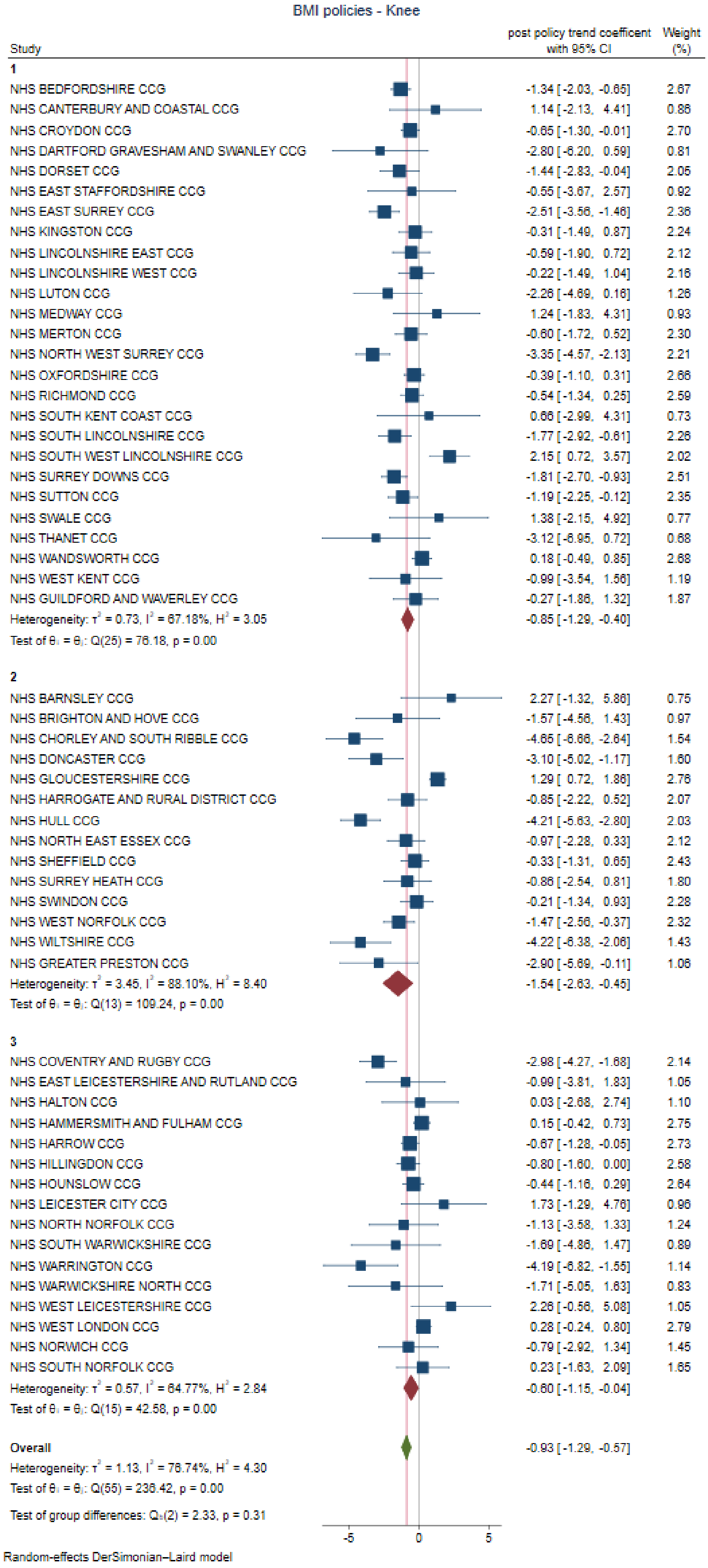
E38000168	NHS SOUTHEND CCG	0	
E38000170	NHS SOUTHPORT AND FORMBY CCG	0	
E38000171	NHS SOUTHWARK CCG	0	
E38000174	NHS STOCKPORT CCG	0	
E38000176	NHS SUNDERLAND CCG	0	
E38000177	NHS SURREY DOWNS CCG	1	01/01/2016
E38000178	NHS SURREY HEATH CCG	2	01/01/2016
E38000179	NHS SUTTON CCG	1	04/01/2013
E38000180	NHS SWALE CCG	1	12/01/2017
E38000181	NHS SWINDON CCG	2	06/01/2013
E38000182	NHS TAMESIDE AND GLOSSOP CCG	0	
E38000184	NHS THANET CCG	1	12/01/2017
E38000185	NHS THURROCK CCG	0	
E38000186	NHS TOWER HAMLETS CCG	0	
E38000187	NHS TRAFFORD CCG	0	
E38000189	NHS VALE ROYAL CCG	0	
E38000192	NHS WALTHAM FOREST CCG	0	
E38000193	NHS WANDSWORTH CCG	1	04/01/2013
E38000194	NHS WARRINGTON CCG	3	06/01/2017
E38000195	NHS WARWICKSHIRE NORTH CCG	3	04/01/2017
E38000196	NHS WEST CHESHIRE CCG	0	
E38000197	NHS WEST ESSEX CCG	0	
E38000198	NHS WEST HAMPSHIRE CCG	0	
E38000199	NHS WEST KENT CCG	1	12/01/2017
E38000200	NHS WEST LANCASHIRE CCG	0	
E38000201	NHS WEST LEICESTERSHIRE CCG	3	11/01/2017
E38000202	NHS WEST LONDON CCG	3	11/01/2014
E38000203	NHS WEST NORFOLK CCG	2	04/01/2015
E38000205	NHS WIGAN BOROUGH CCG	0	
E38000206	NHS WILTSHIRE CCG	2	03/01/2018
E38000214	NHS GUILDFORD AND WAVERLEY CCG	1	01/01/2016
E38000215	NHS NORTH CUMBRIA CCG	0	
E38000218	NHS NORWICH CCG	3	09/01/2017
E38000219	NHS SOUTH NORFOLK CCG	3	09/01/2017
E38000226	NHS FYLDE AND WYRE CCG	0	
E38000227	NHS GREATER PRESTON CCG	2	11/01/2017
E38000228	NHS MORECAMBE BAY CCG	0	

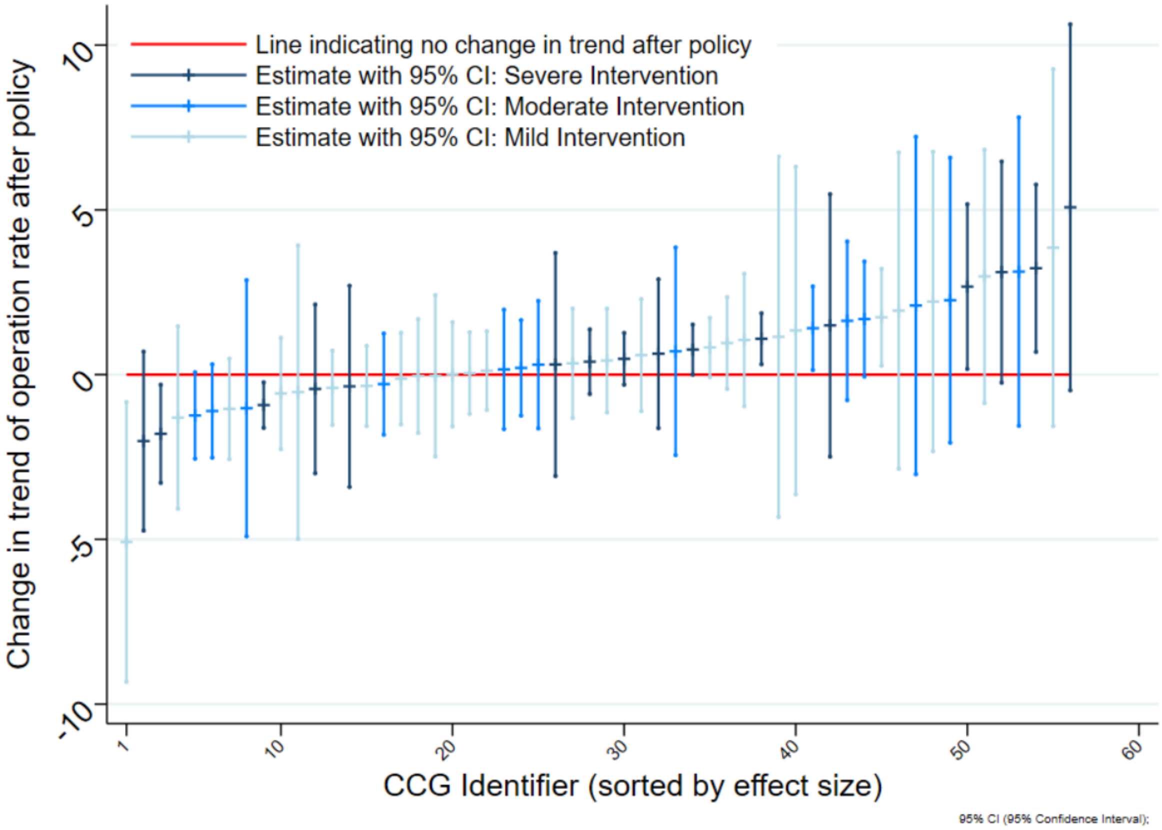
Appendix 4: Knee replacement: Forest plot of effect size by policy category (1= least severe) and with overall meta-analysis result for the intervention CCGs (n=56)

'Effect size' is regression model coefficient for change in pre- to post-policy introduction trends in rate of knee replacement operations. Policy severity is categorised as: 1 (mild – patients receive advice only), 2 (moderate – patients are subject to additional waiting time before surgery) or 3 (strict – patients must be below a BMI threshold to be eligible for surgery).



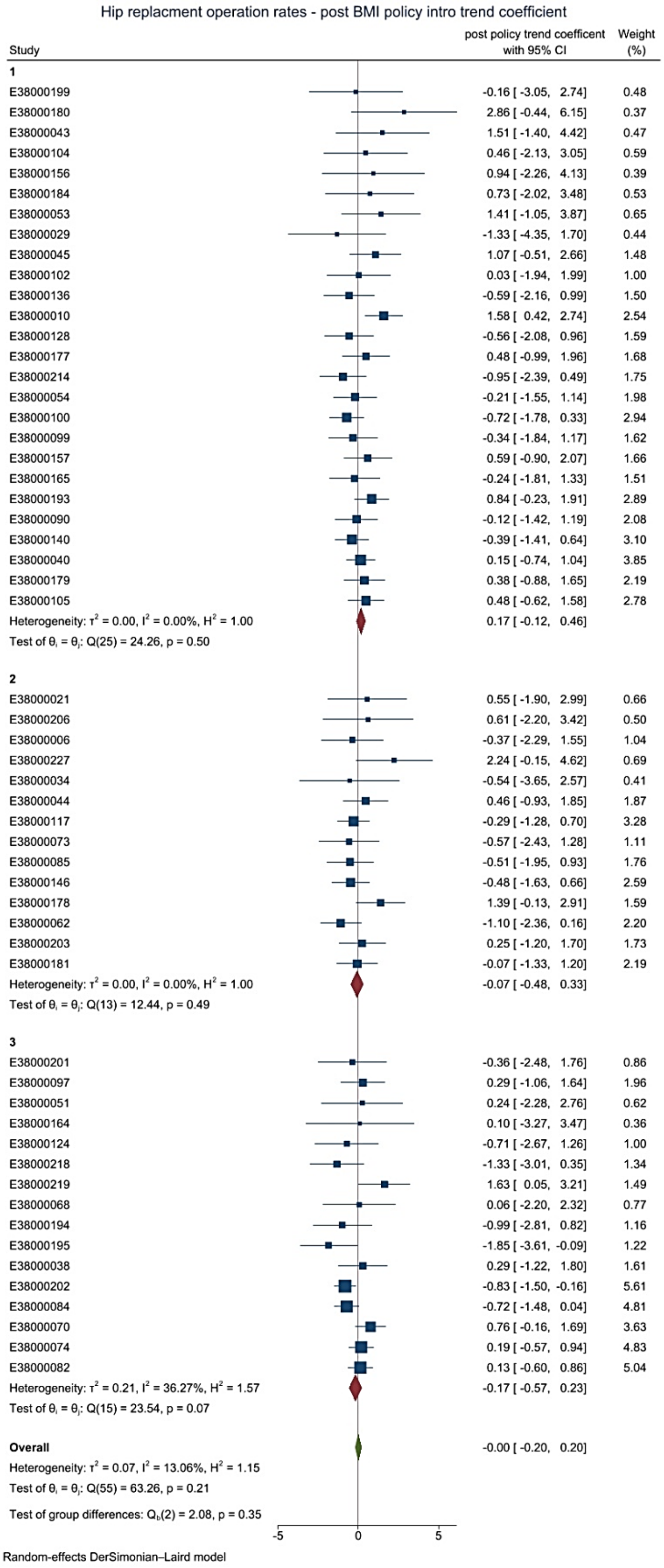
Appendix 5: Caterpillar plot of effect size in CCGs with policies of any severity n=56

'Effect size' is regression model coefficient for change in pre- to post-policy introduction trends in rate of knee replacement operations.



Appendix 6: Hip replacement: Forest plot of effect size by policy category (1= least severe) and with overall meta-analysis result for the intervention CCGs (n=56)

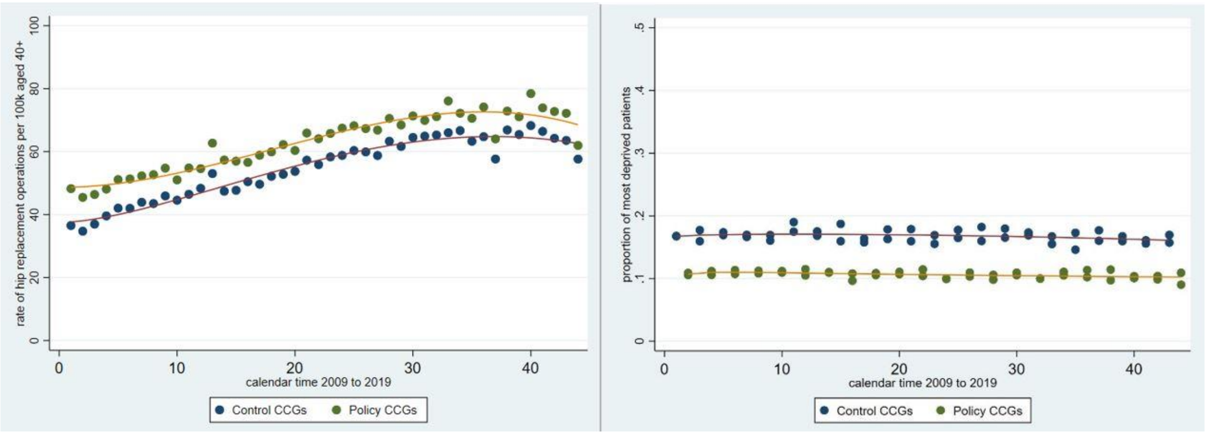
Policy severity is categorised as: 1 (mild – patients receive advice only), 2 (moderate – patients are subject to additional waiting time before surgery) or 3 (strict – patients must be below a BMI threshold to be eligible for surgery).


Hip replacment operation rates - post BMI policy intro trend coefficient

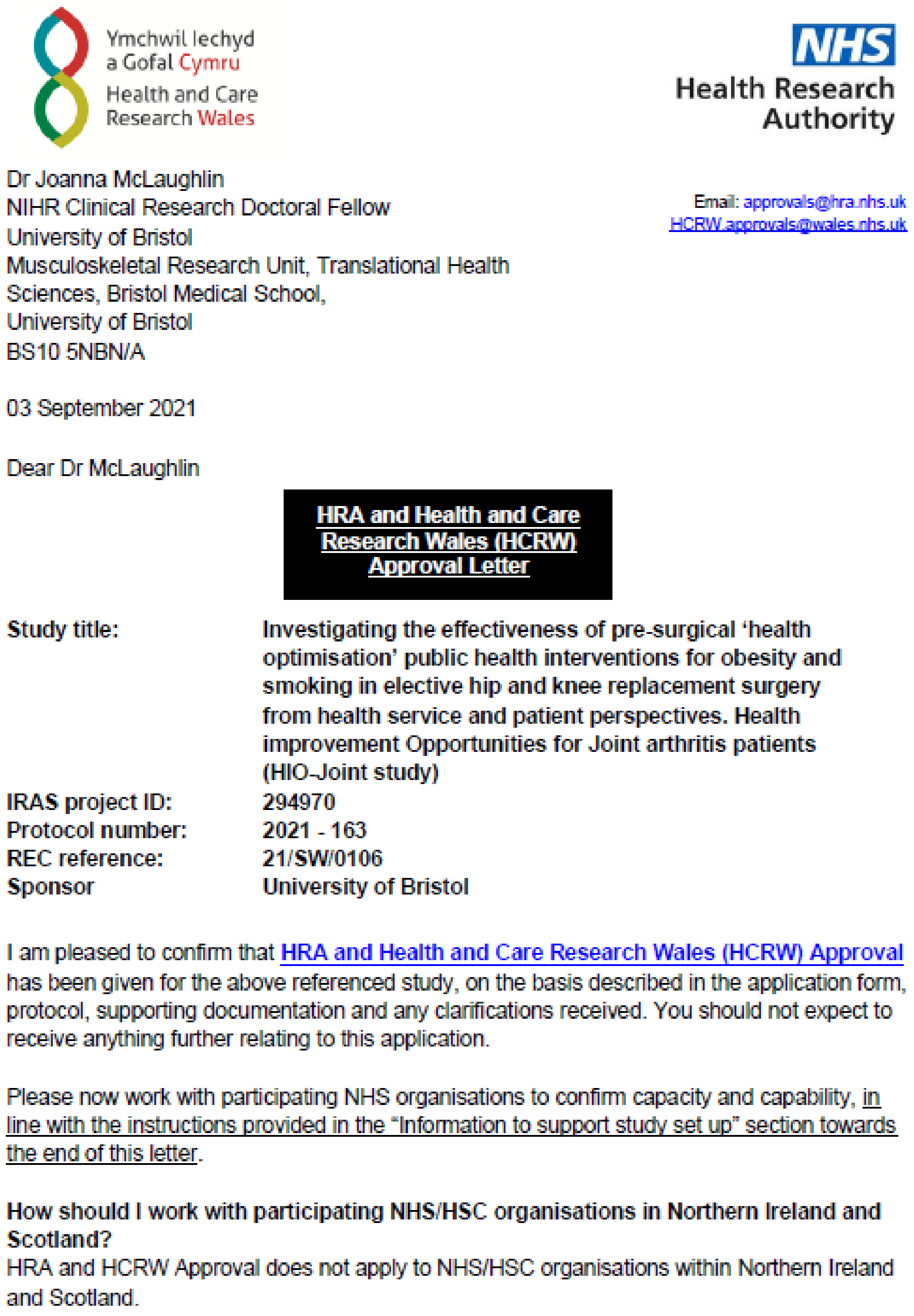
Study	post policy trend coefficent with 95% CI	Weight (%)
1		
E38000199	-0.16 [-3.05, 2.74]	0.48
E38000180	2.86 [-0.44, 6.15]	0.37
E38000043	1.51 [-1.40, 4.42]	0.47
E38000104	0.46 [-2.13, 3.05]	0.59
E38000156	0.94 [-2.26, 4.13]	0.39
E38000184	0.73 [-2.02, 3.48]	0.53
E38000053	1.41 [-1.05, 3.87]	0.65
E38000029	-1.33 [-4.35, 1.70]	0.44
E38000045	1.07 [-0.51, 2.66]	1.48
E38000102	0.03 [-1.94, 1.99]	1.00
E38000136	-0.59 [-2.16, 0.99]	1.50
E38000010	1.58 [0.42, 2.74]	2.54
E38000128	-0.56 [-2.08, 0.96]	1.59
E38000177	0.48 [-0.99, 1.96]	1.68
E38000214	-0.95 [-2.39, 0.49]	1.75
E38000054	-0.21 [-1.55, 1.14]	1.98
E38000100	-0.72 [-1.78, 0.33]	2.94
E38000099	-0.34 [-1.84, 1.17]	1.62
E38000157	0.59 [-0.90, 2.07]	1.66
E38000165	-0.24 [-1.81, 1.33]	1.51
E38000193	0.84 [-0.23, 1.91]	2.89
E38000090	-0.12 [-1.42, 1.19]	2.08
E38000140	-0.39 [-1.41, 0.64]	3.10
E38000040	0.15 [-0.74, 1.04]	3.85
E38000179	0.38 [-0.88, 1.65]	2.19
E38000105	0.48 [-0.62, 1.58]	2.78
Heterogeneity: $\tau^2 = 0.00$, $I^2 = 0.00\%$, $H^2 = 1.00$	0.17 [-0.12, 0.46]	
Test of $\theta_i = \theta_j$: Q(25) = 24.26, p = 0.50		
2		
E38000021	0.55 [-1.90, 2.99]	0.66
E38000206	0.61 [-2.20, 3.42]	0.50
E38000006	-0.37 [-2.29, 1.55]	1.04
E38000227	2.24 [-0.15, 4.62]	0.69
E38000034	-0.54 [-3.65, 2.57]	0.41
E38000044	0.46 [-0.93, 1.85]	1.87
E38000117	-0.29 [-1.28, 0.70]	3.28
E38000073	-0.57 [-2.43, 1.28]	1.11
E38000085	-0.51 [-1.95, 0.93]	1.76
E38000146	-0.48 [-1.63, 0.66]	2.59
E38000178	1.39 [-0.13, 2.91]	1.59
E38000062	-1.10 [-2.36, 0.16]	2.20
E38000203	0.25 [-1.20, 1.70]	1.73
E38000181	-0.07 [-1.33, 1.20]	2.19
Heterogeneity: $\tau^2 = 0.00$, $I^2 = 0.00\%$, $H^2 = 1.00$	-0.07 [-0.48, 0.33]	
Test of $\theta_i = \theta_j$: Q(13) = 12.44, p = 0.49		
3		
E38000201	-0.36 [-2.48, 1.76]	0.86
E38000097	0.29 [-1.06, 1.64]	1.96
E38000051	0.24 [-2.28, 2.76]	0.62
E38000164	0.10 [-3.27, 3.47]	0.36
E38000124	-0.71 [-2.67, 1.26]	1.00
E38000218	-1.33 [-3.01, 0.35]	1.34
E38000219	1.63 [0.05, 3.21]	1.49
E38000068	0.06 [-2.20, 2.32]	0.77
E38000194	-0.99 [-2.81, 0.82]	1.16
E38000195	-1.85 [-3.61, -0.09]	1.22
E38000038	0.29 [-1.22, 1.80]	1.61
E38000202	-0.83 [-1.50, -0.16]	5.61
E38000084	-0.72 [-1.48, 0.04]	4.81
E38000070	0.76 [-0.16, 1.69]	3.63
E38000074	0.19 [-0.57, 0.94]	4.83
E38000082	0.13 [-0.60, 0.86]	5.04
Heterogeneity: $\tau^2 = 0.21$, $I^2 = 36.27\%$, $H^2 = 1.57$	-0.17 [-0.57, 0.23]	
Test of $\theta_i = \theta_j$: Q(15) = 23.54, p = 0.07		
Overall	-0.00 [-0.20, 0.20]	
Heterogeneity: $\tau^2 = 0.07$, $I^2 = 13.06\%$, $H^2 = 1.15$		
Test of $\theta_i = \theta_j$: Q(55) = 63.26, p = 0.21		
Test of group differences: $Q_b(2) = 2.08$, p = 0.35		

Random-effects DerSimonian–Laird model

Appendix 7: Changes in (left) calendar time of rate of hip replacement operations per 100,000 population aged 40+, per quarter and (right) of proportion of patients from the most socio-economically deprived areas (quintile 1) from pooled data



Appendix 8: Health Research Authority and NHS Research Ethics Committee approval letters



Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

NHS
Health Research
Authority

Dr Joanna McLaughlin
NIHR Clinical Research Doctoral Fellow
University of Bristol
Musculoskeletal Research Unit, Translational Health
Sciences, Bristol Medical School,
University of Bristol
BS10 5NBN/A

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

03 September 2021

Dear Dr McLaughlin

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Investigating the effectiveness of pre-surgical 'health optimisation' public health interventions for obesity and smoking in elective hip and knee replacement surgery from health service and patient perspectives. Health improvement Opportunities for Joint arthritis patients (HIO-Joint study)**
IRAS project ID:	**294970**
Protocol number:	**2021 - 163**
REC reference:	**21/SW/0106**
Sponsor	**University of Bristol**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **294970**. Please quote this on all correspondence.

Yours sincerely,
Sharon Northey

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Mr Adam Taylor*

NHS
Health Research Authority
South West - Cornwall & Plymouth Research Ethics Committee
Level 3
Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 02071048033/53

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

24 August 2021

Dr Joanna McLaughlin
NIHR Clinical Research Doctoral Fellow
University of Bristol
Musculoskeletal Research Unit, Translational Health Sciences, Bristol Medical School, University of Bristol
BS10 5NB

Dear Dr McLaughlin

Study title:	**Investigating the effectiveness of pre-surgical 'health optimisation' public health interventions for obesity and smoking in elective hip and knee replacement surgery from health service and patient perspectives. Health improvement Opportunities for Joint arthritis patients (HIO-Joint study)**
REC reference:	**21/SW/0106**
Protocol number:	**2021 - 163**
IRAS project ID:	**294970**

The Research Ethics Committee (REC) reviewed the above application at the meeting held on 17 August 2021. Thank you for attending to discuss the application.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Number	Condition	Response
1	*The focus groups may uncover potentially sub-standard practice and this should be explained to the participants. This study involves looking at several different services there is the potential that some participants may identify some issues with some services. It should be mentioned in the PIS that if any sub-standard practice is uncovered then it will be reported to that service.*	
2	*It should be made clear in the PIS that this study is a part of a PhD for Dr Joanna McLaughlin.*	

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials** are registered on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland)being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [HIO-Joint study Insurance PL letter]	1	05 July 2021
Interview schedules or topic guides for participants [Topic guide for service users focus groups]	2	05 July 2021
Interview schedules or topic guides for participants [Topic guide for service users interviews]	2	05 July 2021
Interview schedules or topic guides for participants [Topic guide for professionals interviews]	2	05 July 2021
IRAS Application Form [IRAS_Form_07072021]		07 July 2021
Letter from funder [NIHR letter of intention to fund for Fellowship]		23 December 2020
Letters of invitation to participant [Invitation letter for recruitment to questionnaires study]	4	01 July 2021
Letters of invitation to participant [Invitation letter for recruitment to patient qualitative study]	2	01 July 2021
Letters of invitation to participant [Invitation letter for recruitment to professional qualitative study]	2	01 July 2021
Non-validated questionnaire [PDF of eligibility and general questions instrument in REDCap]	1	05 July 2021
Non-validated questionnaire [PDF of Overweight Baseline instrument in REDCap]	1	05 July 2021
Non-validated questionnaire [PDF of Smoker Basline instrument in REDCap]	1	05 July 2021

feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 294970	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

[redacted]

pp Dr Stephen Coles
Chair

E-mail: cornwallandplymouth.rec@hra.nhs.uk

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments "After ethical review – guidance for researchers"
Copy to:	Mr Adam Taylor

Appendix 9: Interview topic guide

Outline topic guide: HIO-Joint Study key informant interviews

Please bear in mind this is a live document which will be updated as the research is ongoing.

Researcher introduces research, takes consent, etc.

Introduction / background

- To start off can you tell me a bit about your professional role?
    - Probe – experience with health optimisation policy/interventions
- What do you think of when you think about a typical health optimisation policy?
    - Probe – setting, target groups, support offered, thresholds and rules

Perspective on the current evidence base for health optimisation interventions

- How do you think the policies were developed?
- Ideological vs evidence based?
- How evidence-based do you think the current health optimisation policies are?
    - (If indicates that evidence base is lacking) What are the key gaps in the evidence base that concern you?
    - How typical is this evidence-base situation when you consider other health care policies?
- What are the key drivers for health optimisation policies?
    - Why are they introduced?
    - What is important in their continued use?

Inequalities

- How much emphasis do you think is given to the consideration of inequalities in health optimisation policy making?
    - Inequalities improved if interventions are inclusive and tailored? Or inequalities worsened if access to surgery is more difficult for some?

Perspective on best practice in health optimisation

- What works well in health optimisation policies?
    - Who do you think is best placed to raise health optimisation/health improvement opportunities with patients?
    - Which patient groups or conditions may be best served by health optimisation?
- What are the challenges with the policies?
    - Which patient groups or conditions may be most challenging for health optimisation?
    - Is health optimisation inappropriate in some settings and groups?

Perspective on current and historic health optimisation policy landscape

- Do you know of any differences between regions/anywhere that does it differently?
    - What do you think drives variation in health optimisation policies across the UK?
    - What is the consequence?
    - Awareness of media attention on the policies?
- Parallels with any other health care policy situation?

Perspective on the future of health optimisation and future research

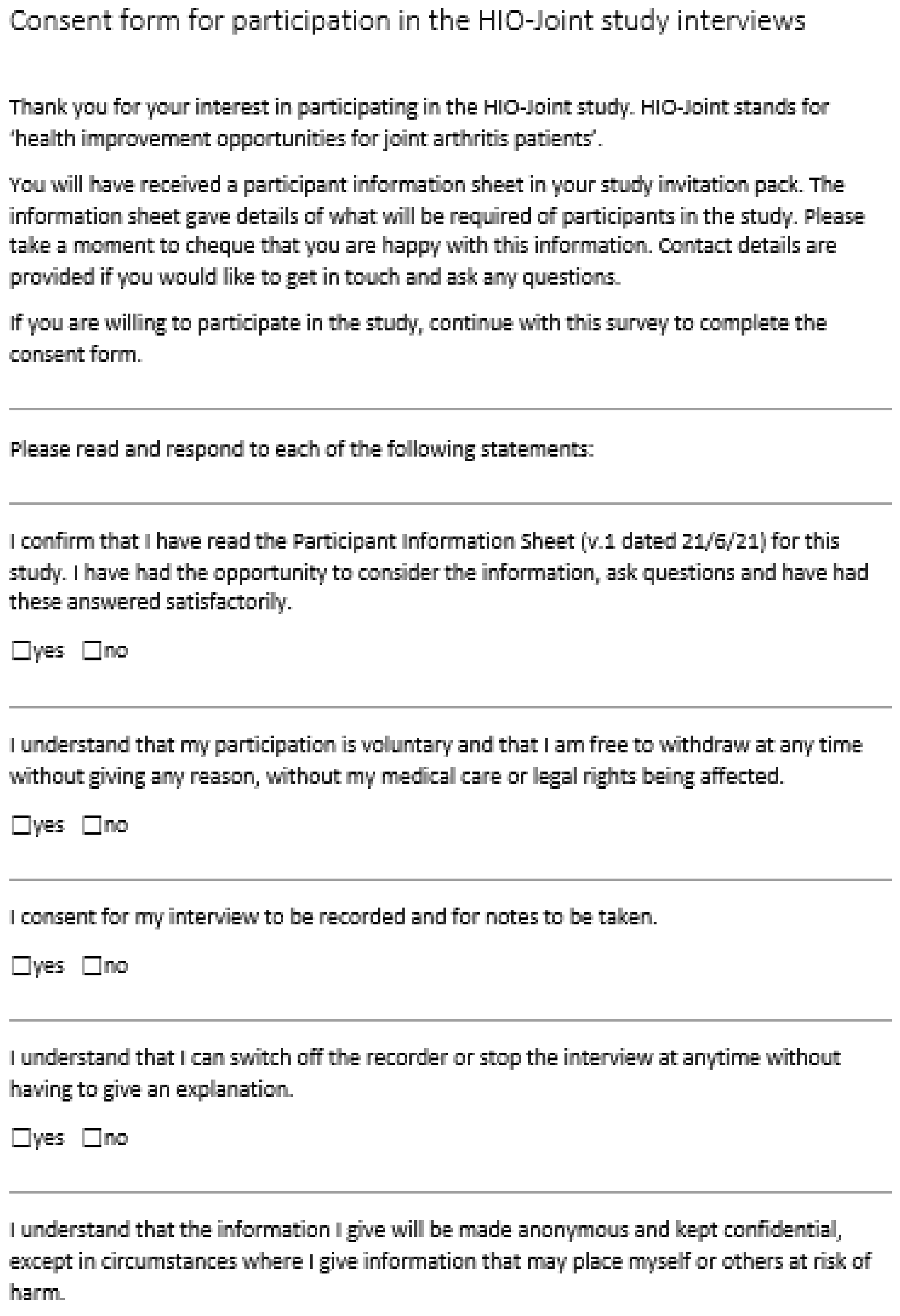
- How widespread should health optimisation be in the NHS?
- How important is it for there to be consistency/a single NHS policy for health optimisation?
- (If indicates that there is a role for health optimisation policy in the NHS) What barriers to policy making need to be addressed?
    - Barriers to policy implementation and possible solutions
- What are the next steps in improving evidence-based policy making for health optimisation?
    - Further research that is needed
    - How best to communicate/disseminate evidence

Final questions and closure

Researcher asks for any further comment, thanks participant and stops recorder

Version 2 5/7/21

Appendix 10: Consent form for qualitative study



Consent form for participation in the HIO-Joint study interviews

Thank you for your interest in participating in the HIO-Joint study. HIO-Joint stands for 'health improvement opportunities for joint arthritis patients'.

You will have received a participant information sheet in your study invitation pack. The information sheet gave details of what will be required of participants in the study. Please take a moment to cheque that you are happy with this information. Contact details are provided if you would like to get in touch and ask any questions.

If you are willing to participate in the study, continue with this survey to complete the consent form.

Please read and respond to each of the following statements:

I confirm that I have read the Participant Information Sheet (v.1 dated 21/6/21) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

☐yes ☐no

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

☐yes ☐no

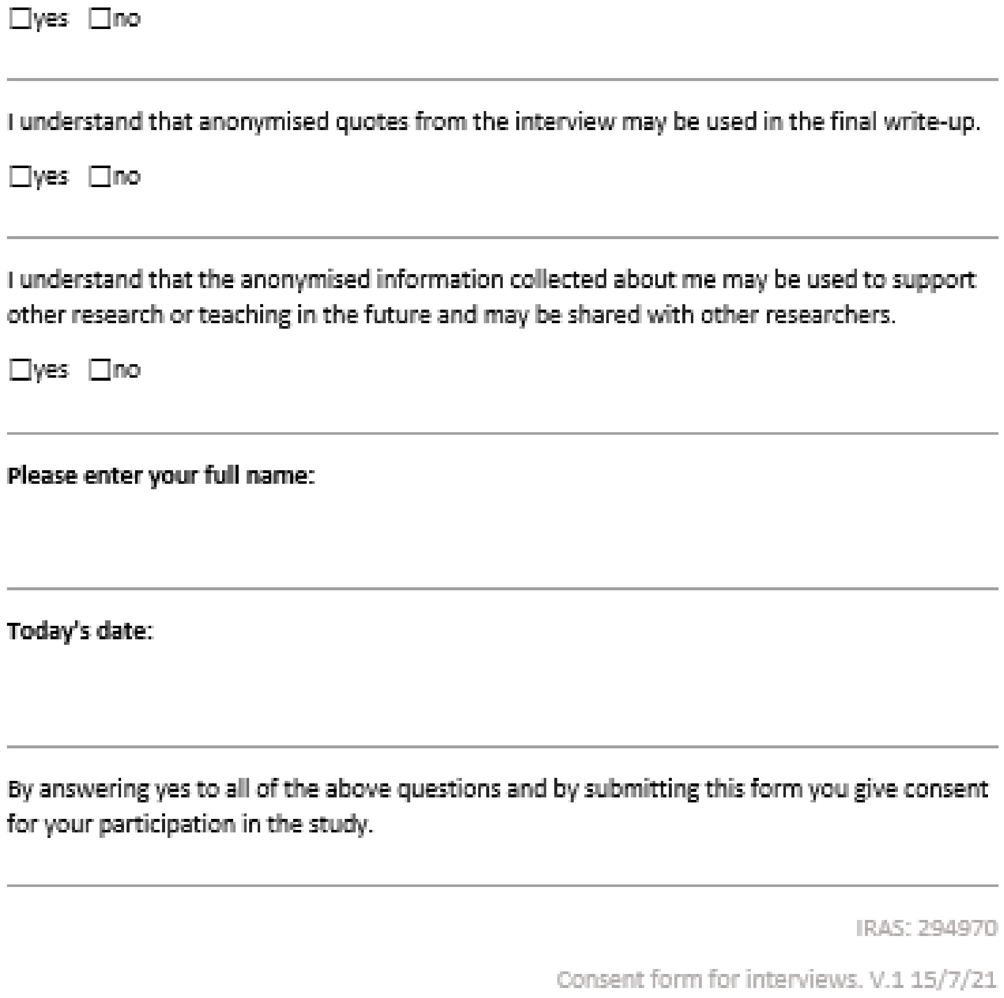
I consent for my interview to be recorded and for notes to be taken.

☐yes ☐no

I understand that I can switch off the recorder or stop the interview at anytime without having to give an explanation.

☐yes ☐no

I understand that the information I give will be made anonymous and kept confidential, except in circumstances where I give information that may place myself or others at risk of harm.



☐yes ☐no

I understand that anonymised quotes from the interview may be used in the final write-up.

☐yes ☐no

I understand that the anonymised information collected about me may be used to support other research or teaching in the future and may be shared with other researchers.

☐yes ☐no

Please enter your full name:

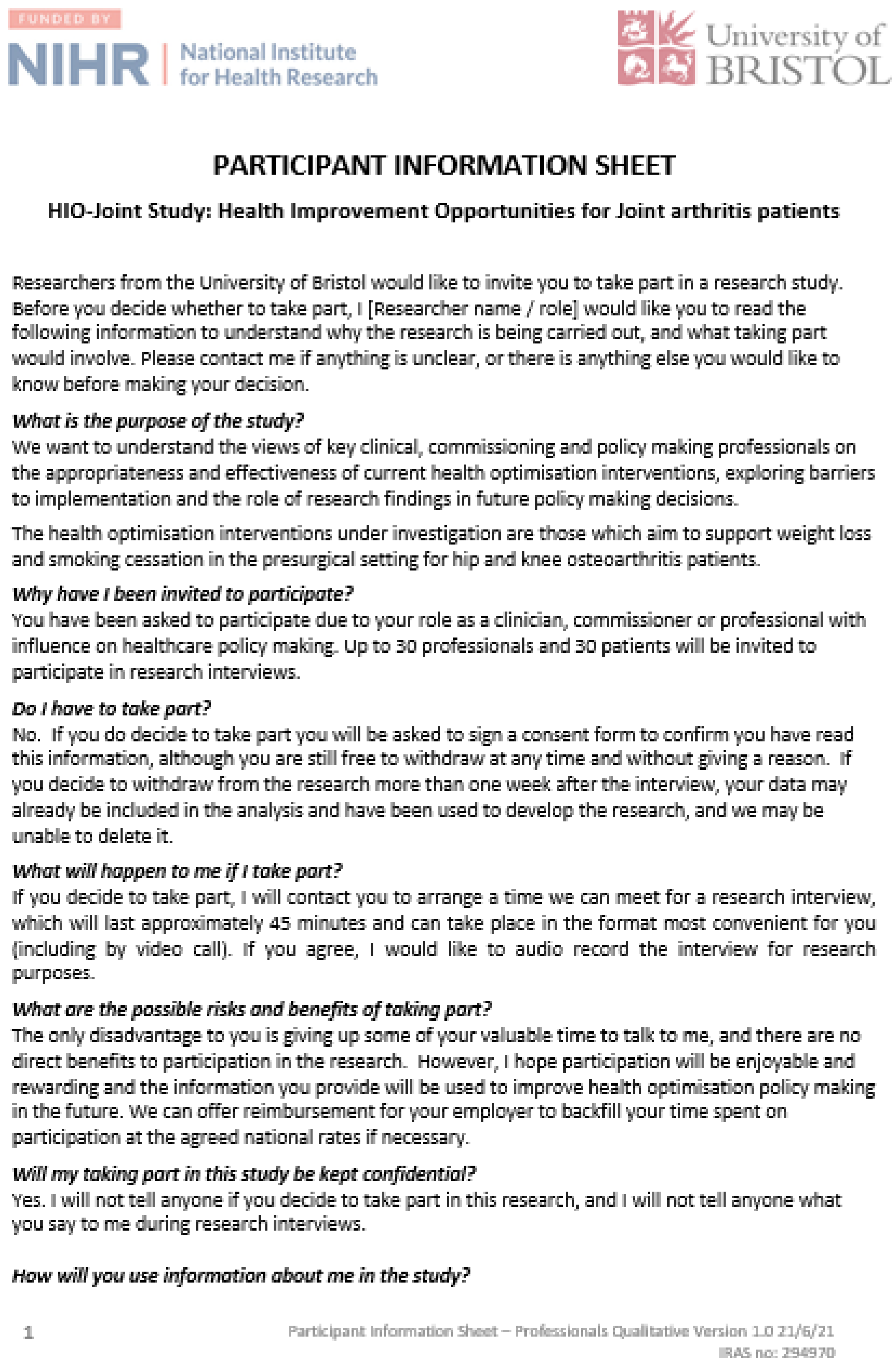
Today's date:

By answering yes to all of the above questions and by submitting this form you give consent for your participation in the study.

IRAS: 294970

Consent form for interviews. V.1 15/7/21

Appendix 11: Participant information sheet



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University of BRISTOL

PARTICIPANT INFORMATION SHEET

HIO-Joint Study: Health Improvement Opportunities for Joint arthritis patients

Researchers from the University of Bristol would like to invite you to take part in a research study. Before you decide whether to take part, I [Researcher name / role] would like you to read the following information to understand why the research is being carried out, and what taking part would involve. Please contact me if anything is unclear, or there is anything else you would like to know before making your decision.

What is the purpose of the study?
We want to understand the views of key clinical, commissioning and policy making professionals on the appropriateness and effectiveness of current health optimisation interventions, exploring barriers to implementation and the role of research findings in future policy making decisions.

The health optimisation interventions under investigation are those which aim to support weight loss and smoking cessation in the presurgical setting for hip and knee osteoarthritis patients.

Why have I been invited to participate?
You have been asked to participate due to your role as a clinician, commissioner or professional with influence on healthcare policy making. Up to 30 professionals and 30 patients will be invited to participate in research interviews.

Do I have to take part?
No. If you do decide to take part you will be asked to sign a consent form to confirm you have read this information, although you are still free to withdraw at any time and without giving a reason. If you decide to withdraw from the research more than one week after the interview, your data may already be included in the analysis and have been used to develop the research, and we may be unable to delete it.

What will happen to me if I take part?
If you decide to take part, I will contact you to arrange a time we can meet for a research interview, which will last approximately 45 minutes and can take place in the format most convenient for you (including by video call). If you agree, I would like to audio record the interview for research purposes.

What are the possible risks and benefits of taking part?
The only disadvantage to you is giving up some of your valuable time to talk to me, and there are no direct benefits to participation in the research. However, I hope participation will be enjoyable and rewarding and the information you provide will be used to improve health optimisation policy making in the future. We can offer reimbursement for your employer to backfill your time spent on participation at the agreed national rates if necessary.

Will my taking part in this study be kept confidential?
Yes. I will not tell anyone if you decide to take part in this research, and I will not tell anyone what you say to me during research interviews.

How will you use information about me in the study?

1

Participant Information Sheet – Professionals Qualitative Version 1.0 21/6/21
IRAS no: 294970

The University of Bristol is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are my choices about how my information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, your data saved from this study may be used for future research.

Where can I find out more about how my information is used?

You can find out more about how we use your information:

- at http://www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/
- by asking one of the research team
- by sending an email to data-protection@bristol.ac.uk , or
- by calling the University's Data Protection Officer on (0117) 3941824.

What will happen to the results of this research study?

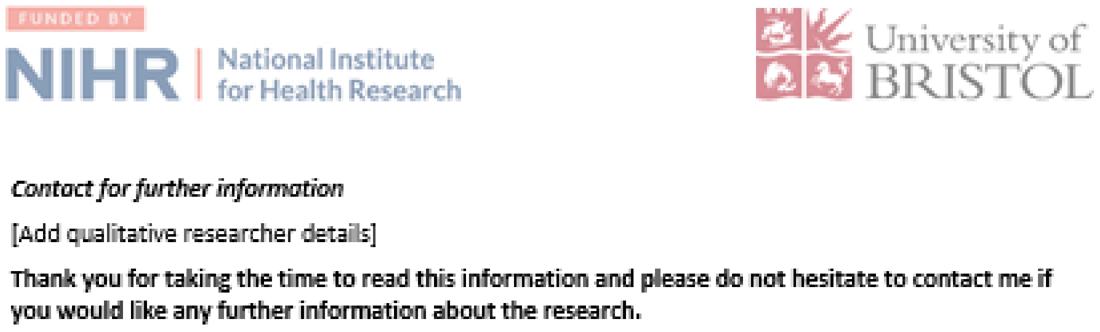
The results of the study will be published in academic journals and presented at academic conferences. The results of the study will also be circulated to participants and relevant professional organisations. However, you will not be identified in any presentation of the research findings.

Who is organising and funding the research?

The research is organised and sponsored by the University of Bristol. It is funded by The National Institute for Health Research. This study has been reviewed by [TBC] Research Ethics Committee.

What if there is a problem?

We hope there will not be any problems with the conduct of the study. However, if you have any concerns, you should ask to speak to the lead qualitative researcher (TBC – contact details below) who will do her best to answer your questions or direct you to the appropriate place to escalate your complaint.



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University of BRISTOL

Contact for further information

[Add qualitative researcher details]

Thank you for taking the time to read this information and please do not hesitate to contact me if you would like any further information about the research.

Appendix 12: Coding framework

1.0 Definition of health optimisation
broad
narrow or finite
2.0 Commissioning of HO
2.1 barriers to policy intro
2.1.1 systemic issues
data or digital issues
lack of support service capacity
source of funding or ownership for HO efforts
system pays secondary care to operate
2.1.2 opposition to HO policies
clinician or PH opposition
surgeon individual outcomes
legal or patient advocacy
media attention
2.1.3 lack of quick wins
2.2 drivers for policy introduction
2.2.1 financial or rationing
2.2.2 acceptability and ease
ease and low cost
personal responsibility motivation
spread of policies between CCGs
2.2.3 hoped for benefits to patients
health improvement
longer term or non-surgical
short term surgical or reduction in demand
systematise health improvement
impact on inequalities
patient experience
2.3 ethics justice and morality
2.4 impact of organisations
2.4.1 impact of ICS or ICBs changing NHS attitude
2.4.2 national requirements or policy
2.5 need for HO or prehab specialists
2.6 policy retraction
2.6.1 general
2.6.2 retraction of BMI threshold policies
2.7 reasons for variation
2.7.1 appetite for risk
2.7.10 spare funding

  - 2.7.11 system structure allows it
  - 2.7.12 vocal dissenters
  - 2.7.2 differences in demographics
  - 2.7.3 engagement with public health
  - 2.7.4 enthusiasts and advocates
  - 2.7.5 evidence isn't clear
  - 2.7.6 political will and organisational priorities
  - 2.7.8 pre-existing differences in resource or services
  - 2.7.9 service pressures
    - role of special measures
- 2.8 role of evidence base
  - 2.8.1 BMI
    - BMI as a practical or managerial consideration
    - BMI as a risk factor or BMI reduction as a benefit
      - benefits of exercise
      - need for holistic approach
        - problematic weight loss malnourishment
    - use of BMI as a measure of obesity
    - use of BMI thresholds
      - negative
      - positive
  - 2.8.2 difficulty in HO evaluation
    - use of rate as outcome measure
  - 2.8.3 evidence is in support
  - 2.8.4 evidence is not in support or is lacking
  - 2.8.5 need to be pragmatic and evidence informed rather than based
  - 2.8.6 not UTD with the evidence
  - 2.8.7 selective or inappropriate use of evidence

- 3.0 Health optimisation delivery at present
  - 3.1 approach and practicalities
    - 3.1.1 eligibility and timing for HO
      - LT follow up
    - 3.1.2 employment of HO staff
    - 3.1.3 formal screening physiological or blood testing
    - 3.1.4 issues with weight management and exercise interventions
      - difficulty knowing what exists
      - successful
      - support availability
        - efficacy of support
        - peer support or group settings
      - unsuccessful
        - medicalisation of obesity and exercise
        - surgery needed for weight loss or exercising or difficulty exercising
    - 3.1.5 presentation to or reception by patients
      - 3.1.5.1 clinician approaches
        - advice given
        - risk stratification and communication
        - setting a goal
        - shared decision making
          - patient choice
        - targeted approaches
      - 3.1.5.2 communication skills and trust
        - clinician prejudice & negative experiences of healthcare
        - patient initiated
        - patient perceived injustice or rationing
      - 3.1.5.3 teachable moment empowerment or selling the benefits
        - avoidance of surgery as a goal
      - 3.1.5.4 unwilling or uninterested patients
        - clinicians short on time
  - 3.2 COVID

impact on commissioning and evidence
impact on healthcare
move to digital or remote
negative impact of long waiting lists
3.3 Other related program and policy areas
3.4 unofficial HO approaches
3.5 Variation in delivery across UK
4.0 Perceived impact of HO delivery
4.1 health improvement
spillover impact
4.2 impact on clinician patient relationship
4.3 impact on healthcare service use
4.3.1 delay or reduced need for surgery
4.3.2 readiness or fitness for surgery
importance of timing
importance of pre-surgical window
waiting well
4.3.3 reduced primary care use
4.3.4 enforcement of rules
out of area patients
4.3.5 independently-funded surgery
4.3.6 inappropriate barrier to access
4.4 Inequalities
HO negative impact on inequalities
postcode lottery
variation in engagement or accessibility
digital exclusion
socio-economic deprivation
cost as a factor in engagement
cost of living worsening situation
impact on outcomes
HO positive impact on inequalities
5.0 Future direction and recommendations
5.1 how HO should be delivered
5.1.1 where HO should be set
prevention and role of public health in HO
targeted or individualised approach
voluntary sector role
who is best placed to deliver HO
5.1.2 making HO the default
5.1.3 mandatory nature of HO or offering choice
5.1.4 new approaches digital
5.2 need for societal or broader change
active transport obesogenic environment
intervention in childhood
wider determinants
5.3 what changes are needed to deliver HO well
5.3.1 need for support services and resource allocation
5.3.2 need for national policy and evidence
5.3.3 need for synergistic synchronised alignment in message and support
5.3.4 medical education and staff health
5.3.5 acceptability and advocacy
5.4 what should HO deliver
broader remit
everyone should know or be involved with HO
include post op and long term
not just smoking and weight

Appendix 13: Elements informing the creation of the typology of participants' stance on health optimisation

View on the role of individual patients in changing their risk factors	Definition of health optimisation and relevance of the surgical teachable moment
Appropriateness of group-level thresholds and policies	Value of reducing BMI
Clinician autonomy and role in decision-making	Setting and approach to health optimisation
Feasibility and efficacy of behaviour change	Evidence base strength and limitations

Appendix 14: Definitions of 'model type' categories used in data extraction – reproduced from study protocol (257)

Model Type	**Definition**
Decision tree	Simulate possible decisions and outcomes using branches to represent each potential event.
Comparative risk assessment (CRA)	These are commonly aggregate-level models that use population-attributable fractions to estimate how parameters describing the relationship between a risk factor and disease outcome would change following an intervention. Individuals can be simulated when combined with microsimulation.
Markov models without interaction	Markov models simulate how a population or individual moves between predefined health or disease states at a specific time interval (for example, annually). This incorporates a time component and allows for modelled populations to remain in a health state from one time interval to the next, and to loop back from a diseased state to a healthy state (recur), all based on a given transition probability.
System dynamics models	System dynamics models allow for populations to interact both with each other and with their environment. The probabilities of events occurring in the model (the system) change through feedback as the model runs, governed by algebraic or differential equations.
Markov chain models and Markov individual event history models	In discrete or continuous time Markov chain models, state transition probabilities can depend on (interact with) the proportion of different populations in different disease states, and on the time that has elapsed in the model.
Discrete event simulation (DES)	Discrete event simulation (DES) is an extremely flexible modelling structure that simulates a system changing over time with a sequence of discrete individual events. Rather than simulating populations or individuals through states for a fixed length of time, multiple future events are in competition and the model jumps to whichever event occurs next based on predefined probabilities.
Agent-based simulation (ABS)	ABS models apply rules to agents or groups of agents, and responses depend on individual agent characteristics which can change either over time or following interactions with other agents or the environment. This is compared to system-based rules found in DES

Multistate life tables	Use of multistate life tables can be made with decision tree, comparative risk assessment, and Markov models with no interaction. Multistate life tables are defined as life tables that model an individual’s, or proportion of a population’s, probability of developing a given disease at different ages and subsequent case fatality rates once the disease is acquired. These can simulate multiple diseases simultaneously and can be used to add a temporal component to decision tree or CRA models.
Microsimulation	Use of microsimulation can be made with individual-level decision tree, comparative risk assessment, and Markov models. In order to overcome the complexity of modelling multiple diseases and heterogeneous populations in decision tree, CRA, and Markov model structures, an alternative approach is to use individual patient simulation models (microsimulation). These allow for a population of heterogeneous individuals to move through the model based on probabilities appropriate to their characteristics (such as demographic factors or physiological characteristics). The model is run at the individual level with all members, or randomly selected members of a predefined population, being simulated until either a prespecified outcome occurs or a certain length of time has elapsed (e.g., death or reaching age 100).

Appendix 15: Search strategy terms for the health economic scoping review

	OVID MEDLINE(R) ALL <1946 TO CURRENT>
1	body weight changes/ or weight gain/ or weight loss/
2	("body fat" or overweight or over-weight or obes* or adiposity or "body composition" or weight or BMI or "body mass index").tw,kf.
3	1 or 2
4	exp models, economic/
5	*models, theoretical/
6	*models, organizational/
7	markov chains/
8	exp decision theory/
9	(markov* or monte carlo).tw,kf.
10	econom* model*.tw,kf.
11	(decision* adj2 (tree* or analy* or model*)).tw,kf.
12	(microsimulation? or micro-simulation?).tw,kf.
13	discrete event? simulation?.tw,kf.
14	or/4-13
15	3 and 14
16	limit 15 to (english language and humans and yr="2015 -Current")

Appendix 16: Table of studies included in the scoping review

First author	Year	Location of study	Scenario	Aim	Intervention	Model used	Reference
Ahern	2022	UK	intervention	models individual weight management intervention	weight loss programme	School for Public Health Research Diabetes Prevention Model.	(307)
Ahern	2017	UK	intervention	models individual weight management intervention	weight loss programme	UK Health Forum	(308)
Amies-Cull	2019	UK	hypothetical change	models population obesity reduction impact	sugar reduction	PRIMEtime-CE	(280)
An	2022	N America	hypothetical intervention	models population obesity reduction impact	food labelling	Au	(309)
Ananthapavan	2020	Australia/New Zealand	intervention	models individual weight management intervention	health improvement/prevention intervention	ACE-Obesity Policy model	(310)
Ananthapavan	2022	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	food labelling	ACE-Obesity Policy model	(311)
Ananthapavan	2022	Australia/New Zealand	intervention	models individual weight management intervention	health improvement/prevention intervention	ACE-Obesity Policy model	(312)
Arrospide	2022	Europe (non-UK)	no change, no intervention	models population obesity impact	models impact of obesity	Arrospide	(313)
Avenell	2018	UK	intervention	models individual weight management intervention	weight loss programme	UK Health Forum	(264)
Bastro-Abreu	2019	Other	intervention	models population obesity reduction impact	SSB tax	CHOICES (Childhood Obesity Intervention Cost-Effectiveness Study) model	(314)

Basu	2020	N America	hypothetical intervention	models population obesity reduction impact	SSB ban	Basu	(315)
Bates	2022	UK	hypothetical change	models population obesity impact	models impact of obesity	School for Public Health Research Diabetes Prevention Model.	(316)
Bjornelv	2021	Europe (non-UK)	no change, no intervention	models population obesity impact	models impact of obesity	Bjornelv	(317)
Blakely	2020	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	dietary taxes and subsidies	Blakely	(318)
Bourke	2018	Other	hypothetical intervention	models population obesity reduction impact	SSB tax	ACE-Prevention	(319)
Boyers	2021	UK	intervention	models individual weight management intervention	weight loss programme	UK Health Forum	(320)
Breeze	2017	UK	hypothetical intervention	models population obesity reduction impact	multiple	School for Public Health Research Diabetes Prevention Model.	(321)
Brown	2017	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	active transport	Brown	(322)
Brown	2017	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	fuel tax	Brown	(323)
Brown	2017	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	active transport	ACE-Obesity Policy model	(324)
Chen	2016	N America	intervention	models individual weight management intervention	health improvement/prevention intervention	Chen	(325)
Chen	2022	N America	intervention	models individual weight management intervention	health improvement/prevention intervention	Chen	(326)

Choi	2017	N America	hypothetical intervention	models population obesity reduction impact	food subsidy	Choi	(263)
Cleghorn	2019	Australia/New Zealand	hypothetical intervention	models individual weight management intervention	weight loss programme	BODE (Burden of Disease Epidemiology, Equity and Cost-Effectiveness) Programme model	(327)
Cobiac	2017	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	dietary taxes and subsidies	ACE-Obesity Policy model	(328)
Crino	2017	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	SSB reformulation	ACE-Obesity Policy model	(329)
Dall	2015	N America	intervention	models individual weight management intervention	health improvement/prevention intervention	Dall	(330)
Fallah-Fini	2017	N America	no change, no intervention	models population obesity impact	models impact of obesity	Fallah-Fini	(331)
Galvain	2021	UK	usual care	models individual weight management intervention	usual care	Galvain	(332)
Goryakin	2019	Europe (non-UK)	hypothetical intervention	models population obesity reduction impact	active transport	OECD SPHeP-NCD (Strategic Public Health Planning for NCDs) model	(333)
Gray	2018	UK	intervention	models individual weight management intervention	weight loss programme	The Cardiovascular Disease (BMI) Policy model	(334)
Gulliford	2017	UK	usual care	models individual weight management intervention	usual care	Gulliford	(335)
Huse	2020	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	SSB promotion ban	ACE-Obesity Policy model	(336)
Kao	2020	N America	hypothetical intervention	models population obesity reduction impact	SSB tax	ACE-Prevention	(337)

Kent	2019	UK	intervention	models individual weight management intervention	weight loss programme	PRIMEtime-CE	(338)
Kianmehr	2022	N America	hypothetical change	models population obesity reduction impact	models impact of weight loss	BRAVO (Building, Relating, Assessing, and Validating Outcomes) diabetes microsimulation model	(339)
Kingston	2021	Australia/New Zealand	no change, no intervention	models population obesity impact	models impact of obesity	Kingston	(340)
Lal	2020	Australia/New Zealand	hypothetical change	models population obesity reduction impact	dietary change	ACE-Obesity Policy model	(341)
Lal	2017	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	SSB tax	CRE-Obesity model based on the Assessing Cost-Effectiveness in Prevention (ACE-Prevention) obesity model	(342)
Laxy	2020	N America	hypothetical intervention	models individual weight management intervention	health improvement/prevention intervention	CDC-RTI diabetes computer simulation model	(343)
Liu	2022	N America	hypothetical intervention	models population obesity reduction impact	SSB tax	Liu	(344)
Liu	2020	N America	intervention	models population obesity reduction impact	food labelling	CVD-PREDICT (Cardiovascular Disease Policy Model for Risk, Events, Detection, Interventions, Costs, and Trends) model	(345)
Long	2019	N America	hypothetical intervention	models population obesity reduction impact	SSB tax	CHOICES (Childhood Obesity Intervention Cost-Effectiveness Study) model	(346)
Long	2015	N America	hypothetical intervention	models population obesity reduction impact	SSB tax	ACE-Obesity Policy model	(347)
Lymer	2018	Australia/New Zealand	intervention	models individual weight management intervention	weight loss programme	NCDMod	(348)

Mantilla-Herrera	2018	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	food labelling	CRE-Obesity model based on the Assessing Cost-Effectiveness in Prevention (ACE-Prevention) obesity model	(349)
Michaud	2017	N America	intervention	models individual weight management intervention	weight loss programme	Michaud	(350)
Mytton	2018	UK	intervention	models individual weight management intervention	health improvement/prevention intervention	Mytton	(351)
Neumann	2016	Europe (non-UK)	hypothetical intervention	models individual weight management intervention	health improvement/prevention intervention	Neumann	(352)
Nomaguchi	2017	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	SSB tax	ACE-Prevention	(353)
Nuijten	2018	N America	intervention	models individual weight management intervention	weight loss programme	Nuijten	(354)
Pitt	2020	N America	hypothetical intervention	models population obesity reduction impact	meat price increase	Pitt	(355)
Robinson	2020	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	alcohol pricing	ACE-Obesity Policy model	(356)
Rognoni	2020	Europe (non-UK)	intervention	models individual weight management intervention	weight loss programme	Rognoni	(357)
Sanchez-Romero	2016	Other	hypothetical change	models population obesity reduction impact	sugar reduction	The Cardiovascular Disease (BMI) Policy model	(358)
Schell	2020	N America	no change, no intervention	models population obesity impact	models impact of obesity	Schell	(359)

Shangguan	2021	N America	hypothetical change	models population obesity reduction impact	sugar reduction	CVD-PREDICT (Cardiovascular Disease Policy Model for Risk, Events, Detection, Interventions, Costs, and Trends) model	(360)
Smith	2016	N America	intervention	models individual weight management intervention	health improvement/prevention intervention	Smith	(361)
Sonntag	2017	Europe (non-UK)	no change, no intervention	models population obesity impact	models impact of obesity	DC-Obesity	(362)
Springmann	2016	Global	hypothetical change	models population obesity reduction impact	dietary change	Springmann	(363)
Su	2018	N America	hypothetical change	models population obesity reduction impact	models impact of weight loss	Dall	(364)
Su	2016	N America	intervention	models individual weight management intervention	health improvement/prevention intervention	Dall	(365)
Su	2015	N America	no change, no intervention	models population obesity impact	models impact of obesity	Dall	(366)
Thomas	2017	UK	intervention	models individual weight management intervention	health improvement/prevention intervention	School for Public Health Research Diabetes Prevention Model.	(367)
Thomas	2022	UK	intervention	models population obesity reduction impact	advertising ban	School for Public Health Research Diabetes Prevention Model.	(368)
Veerman	2016	Australia/New Zealand	hypothetical intervention	models population obesity reduction impact	SSB tax	ACE-Prevention	(369)
Verhaeghe	2016	Europe (non-UK)	hypothetical change	models population obesity reduction impact	models impact of weight loss	Verhaeghe	(370)

Vreman	2017	N America	hypothetical change	models population obesity reduction impact	sugar reduction	Vreman	(371)
Walter	2022	Europe (non-UK)	usual care	models individual weight management intervention	usual care	Walter	(372)
Wilde	2019	N America	hypothetical intervention	models population obesity reduction impact	SSB tax	CVD-PREDICT (Cardiovascular Disease Policy Model for Risk, Events, Detection, Interventions, Costs, and Trends) model	(373)
Willems	2020	Europe (non-UK)	intervention	models individual weight management intervention	health improvement/prevention intervention	ToyBOX study model	(374)
Wilson	2015	N America	intervention	models individual weight management intervention	weight loss programme	Archimedes model	(375)
Zomer	2016	UK	hypothetical change	models population obesity reduction impact	models impact of weight loss	Zomer	(376)

Appendix 17: Table of the models included in the scoping review

Model name	**Health economic measure(s)**	**Model type**	**Event simulation approach**	**Time horizon(s)**	**Validation**	**Reference**
ACE-Obesity Policy model	HALYs QALYs	Multistate life tables	Risk Equation / Change in Risk Factors	Lifetime	Y	(310)
ACE-Prevention	DALYs HALYs	Multistate life tables	Risk Equation / Change in Risk Factors	Lifetime	Y	(265)
An	Direct BMI to cost calculation	Microsimulation	BMI Function / Change in BMI	Short term, Long term	N	(309)
Archimedes model	QALYs	Microsimulation	Risk Equation / Change in Risk Factors	Short term, Long term	Y	(377)

Arrospide	QALYs	Discrete event simulation	Disease Incidence Estimate /BMI Group related RR	Lifetime	Y	(313)
Basu	QALYs	Microsimulation	Others / Others	Long term, lifetime	N	(315)
Bjornelv	Direct BMI to cost calculation	Markov models without interaction	BMI Group Function / Change in BMI Group	Short term, Long term, Lifetime	N	(317)
Blakely	HALYs	Multistate life tables	Risk Equation / Change in Risk Factors	Lifetime	Y	(318)
BODE (Burden of Disease Epidemiology, Equity and Cost-Effectiveness) Programme model	QALYs	Multistate life tables	Risk Equation / Change in Risk Factors	Lifetime	Y	(378)
BRAVO (Building, Relating, Assessing, and Validating Outcomes) diabetes microsimulation model	QALYs	Microsimulation	Risk Equation / Change in Risk Factors	Short term, Long term, Lifetime	Y	(379)
Brown	HALYs	Multistate life tables	Disease Incidence Estimate / BMI related relative risk (RR)	Lifetime	N	(322)
CDC-RTI diabetes computer simulation model	QALYs	Markov chain models and Markov individual event history models	Risk Equation / Change in Risk Factors	Lifetime	Y	(380)
Chen	Direct health status to cost calculation	Microsimulation	Risk Equation / Change in Risk Factors	Short term, Long term	N	(326)
Choi	QALYs	Microsimulation	Risk Equation / Change in Risk Factors	Lifetime	Y	(263)
CHOICES (Childhood Obesity Intervention Cost-Effectiveness Study) model	Direct BMI to cost calculation	Microsimulation	BMI Function / Change in BMI	Short term, Long term	N	(381)
CRE-Obesity model	HALYs	Multistate life tables	Risk Equation / Change in Risk Factors	Long term, lifetime	N	(342)
CVD-PREDICT (Cardiovascular Disease Policy Model for Risk, Events, Detection, Interventions, Costs, and Trends) model	QALYs	Microsimulation	Risk Equation / Change in Risk Factors	Short term, lifetime	Y	(262)
Dall	Direct health status to cost calculation	Microsimulation	Risk Equation / Change in Risk Factors	Lifetime	Y	(366)

DC (Differential Costs)-Obesity	Direct BMI to cost calculation	Markov chain models and Markov individual event history models	Risk Equation / Change in Risk Factors	Lifetime	N	(362)
Fallah-Fini	QALYs	Markov models without interaction	Risk Equation / Change in Risk Factors	Lifetime	N	(331)
Galvain	QALYs	Markov models without interaction	Risk Equation / Change in Risk Factors	Lifetime	N	(332)
Gulliford	QALYs	Markov models without interaction	Risk Equation / Change in Risk Factors	Lifetime	N	(335)
Kingston	only uses DFLE (uncosted)	Markov chain models and Markov individual event history models	Disease Incidence Estimate /Obesity related RR	Lifetime	N	(340)
Liu	DALYs	Multistate life tables	Risk Equation / Change in Risk Factors	Lifetime	N	(344)
Michaud	Direct health status to cost calculation	Markov models without interaction	Disease Incidence Estimate / BMI related relative risk (RR)	Lifetime	N	(350)
Mytton	QALYs	Microsimulation	Risk Equation / Change in Risk Factors	Lifetime	Y	(382)
NCDMod	Direct health status to cost calculation	Microsimulation	Risk Equation / Change in Risk Factors	Long term	Y	(383)
Neumann	QALYs	Markov models without interaction	Risk Equation / Change in Risk Factors	Lifetime	N	(352)
Nuijten	Direct health status to cost calculation	Decision tree	Disease Incidence Estimate /Obesity related RR	Short term, Long term	Y	(354)
OECD SPHeP-NCD (Strategic Public Health Planning for NCDs) model	Mortality and years lived in good health	Microsimulation	Risk Equation / Change in Risk Factors	Long term	N	(384)
Pitt	QALYs	Microsimulation	BMI Function / Change in BMI	Long term	N	(355)
PRIMEtime-CE	QALYs	Multistate life tables	Risk Equation / Change in Risk Factors	Short term, Long term, Lifetime	Y	(385)
Rognoni	QALYs	Markov models without interaction	Risk Equation / Change in Risk Factors	Lifetime	Y	(357)

Schell	Direct BMI to cost calculation	Markov models without interaction	BMI Group Function / Change in BMI Group	Lifetime	N	(359)
School for Public Health Research Diabetes Prevention Model	QALYs	Microsimulation	Risk Equation / Change in Risk Factors	Long term, lifetime	Y	(265)
Smith	QALYs	Markov models without interaction	Risk Equation / Change in Risk Factors	Short term	N	(361)
Springmann	Direct health status to cost calculation	Comparative risk assessment	Risk Equation / Change in Risk Factors	Long term	N	(363)
The Cardiovascular Disease (BMI) Policy model	QALYs	Microsimulation	Risk Equation / Change in Risk Factors	Long term, lifetime	Y	(334)
ToyBOX study model	QALYs	Markov models without interaction	Disease Incidence Estimate /BMI Group related RR	Long Term	N	(386)
UK Health Forum	QALYs	Microsimulation	Risk Equation / Change in Risk Factors	Long term, lifetime	Y	(264)
Verhaeghe	QALYs	Markov models without interaction	BMI Function / Change in BMI	Long Term	N	(370)
Vreman	DALYs	Microsimulation	Risk Equation / Change in Risk Factors	Long Term	Y	(371)
Walter	QALYs	Microsimulation	Risk Equation / Change in Risk Factors	Long Term	N	(372)
Zomer	QALYs	Markov models without interaction	Risk Equation / Change in Risk Factors	Long Term	N	(376)