

Understanding the effectiveness and underlying mechanisms of lifestyle modification interventions in adults with learning disabilities: a mixed-method systematic review

ABSTRACT

Background: Adults with learning disabilities have an increased disposition to unhealthy lifestyle behaviours which often occur simultaneously. Existing studies focus on complex interventions targeting unhealthy diet, physical inactivity, sedentary behaviour, smoking and alcohol use to reduce health risks in adults with learning disabilities. It is essential to understand how well these interventions work, what works, for whom, in what context and why. This study will address this by investigating the effectiveness and underlying mechanisms of lifestyle modification interventions for adults with learning disabilities.

Methods: This is a mixed-methods systematic review consisting of a network-metanalysis (NMA) and realist synthesis. Electronic databases (ASSIA, CINAHL, EMBASE, MEDLINE, and PsycINFO) will be searched from inception until January 2021 with no language restriction. Additionally, trial registries, grey literature databases and references lists will be searched. Studies related to lifestyle modification interventions on the adult population (>18 years) with learning disabilities will be eligible for inclusion. Two independent researchers will screen studies, extract data, and assess its quality and risk of bias using the Cochrane Collaboration's Risk of Bias Assessment Tool (RoB Version 2) and ROBINS-I. The overall quality of the studies will be assessed per the GRADE methodology. The NMA will incorporate results from RCTs and quasi-experimental studies to estimate the effectiveness of various lifestyle interventions. Where appropriate, a component NMA (CNMA) will be used to estimate effectiveness. The realist synthesis will complement and explain the findings of NMA and CNMA by including additional qualitative and mixed-method studies. Studies will be assessed on their rigour and relevance to programme theory development. Results from both syntheses will be incorporated into a logic model.

Discussion: The paucity of population-specific lifestyle interventions contributes to the challenges of behaviour change in adults with learning disabilities. This study will provide an evidence-base from which various stakeholders can develop effective interventions for adults with learning disabilities. The evidence will also help prioritise and inform research recommendations for future primary research so that people with learning disabilities live happier, healthier, and longer lives.

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1. BACKGROUND

The transition of care for adults with learning disabilities away from large institutions towards care in the community has led to an increased reliance on mainstream healthcare services. Consequently, reintegration into the community has exposed them to social and environmental pressures.⁽¹⁾ This is concerning as adults with learning disabilities engage in a cluster of health risk behaviours predominantly eating an unhealthy diet, physical inactivity, sedentary behaviour, smoking and alcohol use.^(2, 3) Gateway theories propose that engaging in one health risk behaviour increases the likelihood of engaging in multiple health risk behaviours.⁽⁴⁾ This increased disposition to unhealthy lifestyle behaviours, which rarely occurs in isolation, has an adverse impact on their health.⁽⁵⁾ Adults with learning disabilities experience higher comorbidity rates and premature mortality compared to the general population.^(6, 7) They have an increased risk of developing preventable diseases such as cardiovascular disease, obesity, type-2 diabetes, and some cancers.⁽⁸⁾

Research on the determinants of health supports the need to prioritise these health risk behaviours. Adults with learning disabilities have low fruit and vegetable consumption and higher fat intake. They spend a high proportion of their day sedentary^(9, 10) and engage in low levels of health-enhancing physical activity.⁽¹¹⁾ These unhealthy lifestyle behaviours create an imbalance in energy intake and expenditure, contributing to a high prevalence of obesity in adults with learning disabilities compared to the general population.^(1, 3, 12) Conflicting findings related to the prevalence of smoking and alcohol consumption in adults with learning disabilities exist as these rates appear to be similar to the general population.^(13, 14) As a leading risk factor for the development of cardiovascular disease and cancer, smoking aggravates secondary conditions such as type 2 diabetes, which are highly prevalent among adults with learning disabilities.⁽¹⁵⁾ Additionally, excessive alcohol consumption is associated with several concerns related to the risk of personal safety and interpersonal relationships in adults with learning disabilities due to their impaired judgement and risk-taking, and long-term physical and mental health issue.⁽¹⁶⁾ Furthermore, adults with mild learning disabilities are more vulnerable to social and environmental pressures⁽¹⁶⁾ than adults with more severe learning disabilities and the general population. Compared to these two populations, they have higher rates of obesity, smoking, alcohol consumption and clustering of unhealthy lifestyle behaviours⁽³⁾.

The latest review of multicomponent weight management interventions concluded that current interventions based on a health education approach are not effective in supporting a clinically meaningful weight loss (5-10% of initial body weight).⁽¹⁷⁾ It recommended weight management interventions adhere to clinical guidelines based on a daily energy deficit diet (EDD) of 600 kcal/ day to achieve a clinically meaningful effect.^(18, 19) Only two studies considering an EDD has achieved sustainable, clinically meaningful weight loss till date.^(20, 21) A systematic review of smoking and alcohol cessation interventions reported heterogeneity in study designs and intervention components, which precluded quantitative assessment of these interventions' effectiveness.⁽²²⁾ Similarly, in another systematic review of physical activity and dietary interventions, effect sizes were not quantified due to high

heterogeneity.^(23, 24) A review and meta-analysis of interventions on multiple lifestyle behaviours (nutrition and physical activity) reported moderate effects on anthropometric and physical activity outcomes.⁽²⁵⁾ However, the effects were only statistically significant for waist circumference, and it was not reported whether these were clinically meaningful.

There are some more limitations to existing systematic reviews. The reviews focused primarily on data from randomised controlled trials (RCTs) of single behaviours or health outcomes.^(23, 24) Thus, it did not consider that individual studies may report multiple effect sizes correlated with each other due to multiple outcome measures and/or the same outcome measures at multiple time points. Existing meta-analyses have limited comparisons between any lifestyle interventions versus control. Rather than lumping these interventions as a homogenous whole, it is critical to highlight that complex interventions are made up of diverse components instead and identify these effective components.

Therefore, our study will determine the effectiveness of lifestyle modification interventions and explain what works, for whom, in what circumstances and why. This is necessary to ensure interventions reflect the needs of adults with learning disabilities and effectively promote healthy lifestyles to improve overall health and wellbeing subsequently.

2. AIM AND OBJECTIVES

The aim of the review is to investigate the effectiveness and underlying mechanisms of lifestyle modification interventions in adults with learning disabilities.

The objectives are:

- To determine the effectiveness of different lifestyle modification interventions and the components within the interventions, in adults with learning disabilities.
- To establish how lifestyle modification interventions for adults with learning disabilities work, for whom they work, as well as why they may work in particular circumstances and not in others.
- To integrate the findings of the quantitative and qualitative syntheses using a logic model.
- To identify future research priorities to develop lifestyle modification interventions for the NHS and social care services to improve the health of adults with learning disabilities.

3. METHODS/DESIGN

3.1. Registration

This protocol is registered in the PROSPERO (ID: CRD 42020223290). The present protocol has been developed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) statement.⁽²⁶⁾

3.2. Data source and strategy

An extensive and comprehensive search of relevant studies will be performed through electronic databases. The following databases will be searched from inception to January 2021: Applied Social Sciences Index and Abstracts (ASSIA); Cumulative Index to Nursing and Allied Health Literature (CINAHL); EMBASE; MEDLINE, and PsycINFO. Registered and ongoing clinical trials will be searched in these databases: Cochrane Central Register of Controlled Trials (CENTRAL); ClinicalTrials.gov; International Standard Randomised Controlled Trials Number (ISRCTN); and Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre). Grey literature will be identified in Systems for Information in Grey Literature (OpenSIGLE) and Google Scholar. We will hand search reference lists of relevant systematic reviews and included studies.

The search strategy will be developed according to the PICOS framework defined by the review question domains which includes the health condition (learning disability), health risk behaviours (diet, physical inactivity, sedentary behaviour, smoking, alcohol) and interventions with desired outcomes. Existing systematic reviews and search words in papers within the related domains will be referred to develop a thorough search strategy. Alternative terms (e.g., exercise or lifestyle physical activity) will be used to maximise the identification of relevant papers. Search terms in truncated formats will permit more comprehensive terms and different sets of the terms to be searched for simultaneously. Appropriate Boolean operators will be used. The full search strategy will be adapted for each database and include medical subject headings (MeSH) and free text words. A version of search strategy, limited to human population, in MEDLINE is available (See Appendix).

3.3. Eligibility criteria

Population

We will include studies involving adults (age of 18 years and above) diagnosed with learning disabilities (or equivalent term, e.g., intellectual disabilities). To ensure consistency in the definition of learning disabilities across the studies, international definition which considers it a limitation in intellectual functioning (intelligence quotient < 70) and adaptive behaviour with onset before age 18 years will be followed. Each study will be judged on how appropriately adults with learning disabilities are defined, as criteria for its definition may differ across studies.

Interventions and Comparators

The review will include lifestyle behaviour change interventions on one or more of the following health risk behaviours: smoking (cigarettes or tobacco), alcohol consumption, diet, physical inactivity, and sedentary behaviour. There will be no restrictions related to the intervention settings (e.g., community or domiciliary setting). These interventions will be compared against active comparators, or control interventions, or treatment as usual arms (standard care at the time that an eligible study was done), or post-study arms.

Outcomes

This review will focus on the effectiveness of lifestyle modification interventions on the following outcome categories:

- Changes in lifestyle behaviours [smoking (e.g., number of cigarettes), alcohol use (e.g., number of units), diet (e.g., energy intake), physical activity (e.g., minutes per day and intensity), and sedentary behaviour (e.g., minutes per day)],
- Anthropometric measures (e.g., weight),
- Metabolic outcomes (e.g., lipoprotein profiles),
- Glycaemic control (e.g., blood glucose),
- Health-related quality of life/wellbeing,
- Attrition rate and reasons for drop out,
- Cost-effectiveness, and
- Adverse events.

Study design

The quantitative synthesis will include all comparative effectiveness studies (RCTs, quasi-experimental studies with control or comparator intervention, and uncontrolled pre-post design) involving lifestyle modification interventions in adults with learning disabilities. For the realist synthesis, we will use the studies included in the quantitative synthesis and published or unpublished studies of any methodological study designs (i.e., quantitative, qualitative, and mixed-methods), based on relevance to developing a programme theory.

3.4. Study selection and data extraction

Two reviewers will independently conduct the study selection, data extraction, and coding process. COVidence software and EndNote X9 will be used to streamline this process. Article titles and abstracts will be screened against the inclusion criteria by the reviewers. Full-text articles that appear to meet the inclusion criteria or where there is any uncertainty will be reviewed. The results of the search strategy and selection process will be recorded in a flow chart. Studies will initially not be restricted by study design to identify papers that may be relevant for the realist synthesis. Papers will then be identified that meet the criteria for the quantitative synthesis. Relevant systematic reviews will be stored for further handsearching. We will record the excluded studies and reasons for exclusions of full-text articles.

Any disagreement between the reviewers over particular studies' eligibility will be resolved through discussion with a third reviewer. Where multiple papers pertaining to the same study are identified (e.g., protocol paper and outcome paper or outcomes paper of the same study reporting on different follow-up time points), data will be extracted with care to avoid duplication of information. These studies will be linked together under one study identification number. We will contact the authors of papers included to request information on missing data or re-verify key characteristics such as aspects of an intervention, wherever appropriate.

Our data extraction form will be adapted from a previous review of lifestyle interventions⁽²⁵⁾ and the sample forms presented in the Cochrane Handbook.⁽²⁷⁾ It will be designed in

Microsoft Excel. Our Patient and Public Involvement (PPI) representatives will be consulted to ensure that all important data are captured. Broadly, the following data will be extracted from the relevant studies based on lifestyle modification behaviours targeted, including multiple behaviours:

- General study characteristics: authors, year, country, funder, study design, unit of allocation (individual, cluster, group)
- Sample characteristics: sample size, level of disability, age, sex, ethnicity, living status (alone or with carer/family)
- Intervention and comparator characteristics: intervention and comparator detail, whether the intervention is theory-based and extent to which theory has been used, behaviour change technique, behaviour targeted, delivery of intervention, setting, duration, frequency and intensity, definition of key parameters
- Outcomes: outcomes of interest, timepoints measured, follow up period, attrition rates, intervention fidelity.
- Data analysis and conclusions: method of analysis, key findings

The intervention components will be coded for whether the interventions were accessible for the population (e.g., provided easy read resources), whether behavioural recommendations were specified, whether the intervention is based on an explicit theory, and/or employed behaviour change techniques (BCTs). Based on the work by Michie et al.,⁽²⁸⁾ the extent to which theory has been used in the intervention design will be coded using a 19-item Theory Coding Scheme (TCS). This includes whether a theory or model was mentioned, how theories were used in theory development, how intervention evaluations tested the theory and the implications of the results for future theory development. We will also code the intervention and comparator treatments using the 93-item BCT taxonomy.⁽²⁹⁾ BCT will only be coded if there is sufficient description matching the technique definition. It will aid us in identifying the active components of the interventions and comparator treatments.

3.5. Quality and risk of bias assessment in studies

Two reviewers will independently assess the quality and risk of bias of the included studies using validated and study-design appropriate tools for papers included in the quantitative data synthesis. The risk of bias for RCTs will be assessed by the Cochrane Collaboration's Risk of Bias Assessment Tool (RoB Version 2).⁽³⁰⁾ It constitutes six domains: selection bias (adequate sequence generation and allocation concealment); performance bias (blinding of participants); detection bias (blinding of outcome assessors); attrition bias (clear account of dropouts and exclusions), and; reporting bias (selective outcome reporting). The risk of bias of non-randomised trials will be assessed using the Risk Of Bias In Non-randomised Studies - of Interventions (ROBINS-I) tool.⁽³¹⁾ These specifically evaluate risk of bias applicable to case- control or cohort studies. All studies will be judged as high, low, or unclear risk of bias.

The overall quality of included studies will be assessed per the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology⁽³²⁾ to inform the strength of conclusion of the effectiveness of lifestyle modification interventions. The evaluation

criteria include risk of bias, consistency (heterogeneity), directness (generalisability), precision (statistical significance of effect measures), and publication bias. The quality of evidence is graded as high, moderate, low, or very low.

3.6. Quantitative data synthesis

Descriptive summary

Characteristics of included studies will be described. We will provide a descriptive summary of findings, including contextual factors such as participant characteristics, outcomes which lack sufficient data or studies which were inappropriate to combine statistically. Moreover, we will visually present a network graph of the available evidence where each edge represents a head-to-head (direct) comparison for all outcomes, and the thickness is proportional to the number of direct comparisons.

Meta-analysis

Treatment effect sizes will be estimated for each outcome of interest. We will first estimate the treatment effect sizes of all interventions based on direct evidence. We will use standardised mean differences (SMD) for continuous outcomes data and odds ratio (OR) for dichotomous outcomes data. We will focus on the effects immediately post-intervention & at follow-up, where possible. Intervention follow-up is likely to vary across the studies. Individual effect sizes across studies will be pooled using random-effects model, which assumes that the between studies variance is varied across all pairs of intervention comparisons.

Subsequently, a Bayesian network meta-analysis will be conducted at the intervention-level. It will enable us to simultaneously compare multiple interventions in a single model using direct evidence and indirect evidence. The analysis will follow the general principles set out by the International Society for Pharmacoeconomics Outcomes Research (ISPOR) Taskforce.^(33, 34) We will fit both fixed and random-effects models. The Bayesian framework of our analysis will be based on minimally informative prior probability distribution to estimate a joint (posterior) probability distribution of the model parameters (intervention effect estimates and heterogeneity) by using Markov Chain Monte Carlo (MCMC) simulation. The convergence of the simulated model will be examined. We will report the results as the median of the posterior distribution along with 95% credible intervals (95% CrI).

Following the components-based approach developed by Welton and Freeman,^(35, 36) we will conduct a component network meta-analysis (CNMA) where active ingredients of interventions are modelled using a network meta-regression approach. CNMA allows assessment of the effectiveness of interventions and the components that contribute to improvements in modifiable health risk factors in adults with learning disabilities. Here, each intervention's effect will be dismantled by modelling component-specific effects to answer if interventions with a particular component or combinations of components are effective. The components will be classified based on theories and BCT codes. For example, an intervention based on social cognitive theory may also include multiple interacting active ingredients

comprising BCT ‘social support’ and ‘social incentive’. Accordingly, we will evaluate the following three models and report the odds ratios and 95% credible intervals for the relative effects between components:

- An additive main effects model: The model assumes that each intervention's effect is the sum of the effects of the component parts. No interaction between components exists. The model aids in understanding the effectiveness of an intervention containing certain specific components compared to interventions without the same components.
- An extended additive effects model: A two-factor interaction model which allows pairs of components to have either a larger (synergistic) or smaller (antagonistic) effect than would be expected from the sum of their effects alone. The model aids in understanding if interventions containing specific pairs of components are effective.
- A saturated CNMA model/full-interaction model: This model is the standard NMA model in which each of the different combinations of components is considered a distinct intervention with its own effect, regardless of whether it is made up of one or four components.

All interventions and components will be ranked to provide a probability of each interventions being considered the best in each outcome. Surface Under the Cumulative Ranking (SUCRA) score will also be calculated. We will assess the fit and parsimony of the various models using the deviance information criterion (DIC). The DIC is equal to the sum of the residual deviance's posterior mean and the effective number of parameters (measure of complexity). It can be viewed as a trade-off between the fit and complexity of the model.⁽³⁷⁾ We will report the common between-study variance (τ^2) value along with 95% CrI. A large τ^2 means that there are important differences between the true effects. Furthermore, a multivariate random effects meta-regression will be fitted to investigate whether heterogeneity may be further explained by the presence of effect modifiers. We will perform sensitivity analyses to evaluate the robustness of our findings. For example, use of different priors in the Bayesian NMA will be examined as results are suggested to be sensitive to the chosen priors in presence of small amount of data, or the influence of different studies (small population or low-quality studies) on our results will be examined.

The validity of NMA depends on two most important assumptions of transitivity and consistency. Transitivity means there is no effect modification of the intervention effects or that the prevalence of effect modifiers is similar among studies.⁽³⁸⁾ It suggests that intervention A is similar when it appears in A versus B and A versus C studies.⁽³⁹⁾ It can be examined by comparing the distribution of potential effect modifiers across the different comparisons.⁽⁴⁰⁾ This is slightly adapted for CNMA. Here, we can use studies comparing A versus B combinations of components (AB studies) and CD studies to learn about the relative effects of group of components A vs. group of components B. For both NMAs, we will

inspect the important characteristics, including inclusion/exclusion criteria for similarity in factors we consider most likely to be modifiers. These include age, gender, level of learning disabilities, and intensity and mode of delivery of the interventions.

Consistency refers to the equivalence, i.e., closed loops of direct and indirect evidence. Inconsistency occurs when there is a violation of this assumption due to discrepancy between this evidence. Node-splitting is a method used in the presence of complex networks for evaluating inconsistency between direct evidence and indirect evidence. We will also use model fit and selection statistics to assess inconsistency. Inconsistency assessments will be adapted accordingly to ensure that the assumption holds for CNMA. All statistical analysis will be conducted using the R software.

3.7. Realist synthesis

To complement and explain the results of the NMA, we will employ a realist approach⁽⁴¹⁾ to synthesise a broad and diverse body of literature (i.e. quantitative, qualitative and mixed-methods studies) in the form of a programme theory regarding complex causal mechanisms and how these interact with individuals' agency and social context to produce outcomes. In particular, we will follow the five key stages for realist reviews, as described by Pawson et al.,⁽⁴¹⁾ and captured in the RAMESES quality and publication guidelines⁽⁴²⁾: 1) locate existing theories; 2) search for evidence; 3) study selection; 4) extract and organize data, and; 5) synthesise the evidence and draw conclusions.

Phase 1: Locating existing theories

We will start by conducting initial scoping searches of key literature to identify available theories that may explain how lifestyle modification interventions for adults with learning disabilities work, for whom they work, and why they may work in particular circumstances and not in others. This exploratory searching differs from the more systematic literature searching that will be conducted in phase 2, as the objective here will be to quickly locate the range of possible theories that may be relevant. Identified theories will then be synthesised into an initial programme theory that will be discussed with our advisory and PPI groups and further refined based on their input.

Phase 2: Searching for evidence

After running preliminary scoping searches and developing a 'rough' programme theory, we will use the results of the literature search previously described to identify a relevant body of literature that might contain data with which to further develop and refine our programme theory. Given that the goal of a realist synthesis is to make sense of diverse evidence about complex interventions applied in different settings, we will seek to include (published and unpublished) studies of any methodological design, such as RCTs, controlled studies, uncontrolled studies, surveys, as well as qualitative studies of participants' views and experiences of interventions. Specifically, the realist review is likely to include evidence covering the following:

- Studies focusing on adults with learning disabilities (as previously defined) and reporting any intervention designed to change the following unhealthy lifestyle

behaviours: smoking, alcohol use, unhealthy diet, physical inactivity, and/or sedentary behaviour.

- Studies reporting barriers and facilitators to the implementation and uptake of lifestyle modification interventions in adults with learning disabilities.
- Studies that could provide opportunities for transferable learning (e.g., studies reporting interventions for adults with learning disabilities, but not targeting the above-mentioned lifestyle behaviours).

Phase 3: Study selection

The key consideration for selecting studies to be included in realist reviews is the extent to which these include data that can contribute to programme theory development. Therefore, standard quality appraisal checklists, that cannot capture issues like the conceptual richness of a study or its relevance to the review question, have been argued to be insufficient for realist reviews.⁽⁴¹⁾ Similar to previously published work,^(43, 44) we will assess potentially eligible studies based on their relevance to programme theory development (high/low) and, for those articles classified as ‘highly relevant’, we will also assess rigour and trustworthiness of findings. For instance, if an article reports the results of a qualitative process evaluation of an intervention conducted in the UK, it will be judged as ‘highly relevant’. However, if the study was based on a very small sample size, which did not allow for data saturation (i.e., further data collection might have yielded substantive new information), then the methodological rigour of the work will be scored as ‘low’. All screening and selection decisions will be made by a single reviewer, with a 10% random sub-sample of citations reviewed independently by a second, to ensure consistency in decisions.

Phase 4: Extracting and organising data

Main study characteristics (e.g., objectives, sample, study design, risk behaviour targeted) will be extracted into an Excel spreadsheet by one reviewer and checked for accuracy by a second. Full texts of included papers will be uploaded into NVivo QRS International (a qualitative data management software) and verbatim sections of text, namely those understood as contexts, mechanisms and their relationships to outcomes, will be coded. It is anticipated that quantitative data will be mostly used to shed light on the outcome patterns (e.g., changes in blood glucose levels and body weight), whereas qualitative data will provide a more in-depth understanding of contexts and mechanisms. We will start the coding and analysis process by using a set of ‘key’ papers, namely studies that are likely to have a major contribution to the development of our programme theory due to their high relevance and conceptual richness. The resulting coding framework will then be applied to the rest of the papers, moving from the ones that are more relevant and specific to our programme theory to those that are less relevant and specific.

Phase 5: Synthesising the evidence and drawing conclusions

In the final phase of the review, we will continue to use a realist logic of analysis to build context–mechanism–outcome configurations (CMOCs), while searching to identify relationships not just within the same articles, but across sources. For instance, we will seek to explain how and why context may have influenced observed outcomes, by comparing

interventions that have been successful in changing unhealthy lifestyle behaviours among adults with learning disabilities against those that have not. Such analysis will allow us to understand the behaviour of the most important mechanisms under different contexts and to build more transferable CMOCs. We will work with our steering/advisory and PPI groups to finalise our evidence informed framework of what works, for whom, and in what contexts in relation to lifestyle behaviour modification interventions for adults with learning disabilities and produce a set of actionable recommendations to inform policy and practice.

3.8. Logic Model

To bring together the findings from the two syntheses (NMA and realist review) in a meaningful way, we will develop a logic model. A logic model is a summary diagram which maps out the underpinning pathway and causal mechanism of how complex interventions work.⁽⁴⁵⁾ Logic models have predominantly been used in programme evaluations; however, more recently their importance to contribute to synthesising findings from systematic reviews has been recognised.⁽⁴⁶⁾ Our approach will combine data from both quantitative and qualitative designs, treated as textual (qualitative) data. The process involves charting, categorising the data, and thematic synthesis methods to develop a process-orientated logic model.⁽⁴⁷⁾ The logic model aims to portray how interventions operate. We will present our logic model to our PPI members and will ask them to provide their input on the relevance of the findings for adults with learning disabilities, how might the information help them improve these unhealthy behaviours in practice, to identify any gaps in the evidence, and what they think we should be doing to make it easier for them to improve these lifestyle behaviours. This is an essential step to inform the development of lifestyle modification interventions to be delivered in the NHS and social care services and improve the health of adults with learning disabilities.

4. DISCUSSION

Our study employs a mixed-methods approach to meet the objectives mentioned above. The NMA and CNMA will allow us to assess the relative effectiveness of different lifestyle modification interventions and the components that contribute to improvements in modifiable health risk factors, respectively. The realist synthesis will complement and explain the results of the NMA and CNMA and generate an in-depth understanding of the interventions. Lastly, the logic model will inform the pathway and causal mechanism associated with these complex interventions. To our knowledge, this protocol describes the first study of its kind.

We foresee some limitations while undertaking this study. Inconsistent reporting of intervention detail may be a challenge while coding theories or BCT. This will also influence the reporting of intervention components and the ability to run a NMA on all outcomes described. Diverse outcome measurements may limit our capacity to combine results from different studies in NMA. In case of CNMA, should there be a lack of studies comparing various combinations of components, it would impede our ability to disentangle the relative effects of the various components. It may also lead the model to have insufficient power and would have to be overcome by grouping components together in a clinically meaningful manner.

In conclusion, the paucity of population-specific lifestyle interventions contributes to the challenges of behaviour change in adults with learning disabilities. This study will provide an evidence-base from which various stakeholders can develop effective interventions for adults with learning disabilities. The evidence will also help prioritise and inform research recommendations for future primary research so that people with learning disabilities live happier, healthier, and longer lives.

5. ABBREVIATIONS

ASSIA: Applied Social Sciences Index and Abstracts

BCT: Behaviour Change Technique

CENTRAL: Cochrane Central Register of Controlled Trials

CINHAL: Cumulative Index to Nursing and Allied Health Literature

CMOC: Context Mechanism Outcome Configurations

CNMA: Component Network Meta-Analysis

EDD: Energy Deficit Diet

DIC: Deviance Information Criteria

EPPI-Centre: Evidence for Policy and Practice Information and Co-ordinating Centre.

GRADE: Grading of Recommendations Assessment, Development and Evaluation

ISPOR: International Society for Pharmacoeconomics Outcomes Research

ISRCTN: International Standard Randomised Controlled Trials Number

MCMC: Markov Chain Monte Carlo

NMA: Network Meta-Analysis

OpenSIGLE: Systems for Information in Grey Literature

OR: Odds Ratio

PPI: Patient and Public Involvement

PRISMA-P: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols

RCT: Randomised Controlled Trials

ROBINS: Risk of Bias In Non-randomised Studies of Interventions

SMD: Standardised Mean Difference

TCS: Theory Coding Scheme

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7. APPENDIX

MEDLINE Search Strategy

Condition	
1	((development* or learn*) adj2 disorder*).tw.
2	exp intellectual disability/
3	((learn* or development* or mental* or intellect* or cognitv*) adj2 (deficien* or disab* or disorder* or deficien* or difficult* or impair* or handicap* or retard* or sub?normal* or challenge*).tw.
4	(cretin* or feeble minded* or imbecil* or moron*).tw.
Health risk behaviours	
5	exp smoking/ or exp cigarette smoking/
6	((smok* adj2 (behavio?r or habit* or us* or consum*)) or (tobacco or cigarette)).tw.
7	exp binge drinking/ or exp alcohol consumption/
8	((alcohol or ethanol or drink*) adj2 (problem* or harm* or hazard* or depend* or binge or us* or consum* or misuse* or behavio?r or habit*).tw.
9	(unhealth* adj2 (food or diet*) adj2 (habit* or consum*).tw.
10	exp sedentary time/ or exp sedentary lifestyle/
11	((sedentary or passive or inactive or physical*) adj2 (life?style* or behavio?r* or liv* or li?e or time)).tw.
12	exp obesity/
13	((over or excess) adj2 weight).tw.
Interventions and expected outcomes	
14	exp behavior therapy/ or exp cognitive behavioral therapy/ or exp psychotherapy/ or exp family therapy/ or exp counseling/
15	((life?style* or behavio?r*) adj2 (modif* or interven* or change* or program*).tw.
16	((behavio?r* or cogniti* or CBT or psycho?therap* or psycho?educat or psycho?social or counsel*) adj2 (session* or therap* or technique* or modif* or interven* or change*).tw.
17	(health* adj2 (promot* or educat* or life?style*).tw.
18	exp health promotion/ or exp health education/
19	exp smoking cessation/
20	((tobacco or smok* or nicotine or replace* or relapse) adj2 (cessat* or stop or reduc* or prevent* or therap*).tw.
21	exp diet therapy/ or exp caloric restriction/ or exp low fat diet/ or exp low carbohydrate diet/ or exp portion size/ or exp nutritional support/
22	(health* adj2 (diet* or weight)).tw.

23	((calorie* or portion* or serv* or size*) adj2 (control* or reduc* or restrict*)).tw.
24	((diet* or nutri* or food or carb* or protein* or fat*) adj2 (educat* or guide* or habit* or intake)).tw.
25	exp physical activity/ or exp exercise/
26	(interven* adj2 (physic* or exercise*)).tw.
27	((moderat* or vigo?r*) adj2 (activit* or exercise* or train*)).tw.
28	((exercise* or physic*) adj2 (aerobic* or train* or fit* or active* or endur*)).tw.
29	((gym* or circuit* or aqua* or walk* or jog* or run* or swim* or weight* lift* or (strength or resist* or circuit* or aerobic*)) adj2 train*).tw.
30	((fat or body or weight) adj2 loss).tw.
31	((health or weight or obes*) adj2 (loss or reduc* or manage*)).tw.
Grouped terms	
32	or/1-4
33	or/5-13
34	or/14-31
35	32 and 33 and 34
36	limit 35 to humans