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Weight-Neutral Health Intervention (WIN) for adults with BMI ≥30 kg/m^2: protocol for a single-arm feasibility study

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ABSTRACT

Introduction Weight stigma and internalised weight bias are associated with poor mental, social and physical health. Weight-neutral approaches prioritise well-being and sustainable health behaviours. However, the feasibility and acceptability of weight-neutral interventions remain uncertain.

Methods and analysis Weight-Neutral Health Intervention (WIN) is an investigator-initiated single-arm feasibility study enrolling 56 adults with body mass index ≥30 kg/m^2 in the Capital Region of Denmark. The study investigates a codesigned weight-neutral health intervention. The 6-month intervention comprises 1 preparatory session and 11 group sessions led by trained practitioners, focusing on intuitive eating, body acceptance and self-compassion; optional components include support-network events, up to three individual online sessions and access to 'size-inclusive yoga' and 'body competence' courses. The primary feasibility outcome is follow-up completion. Recruitment proportion and adherence are secondary feasibility outcomes. These will be assessed using a set of predefined 'traffic-light' stop/go progression criteria. Exploratory feasibility outcomes include data completeness for other outcomes and participant engagement with the intervention. Exploratory clinical outcomes include questionnaire data (quality of life, depression, weight bias internalisation, eating behaviours, self-esteem, body image, stress and life satisfaction), clinical measures (weight, heart rate and blood pressure), biomarkers (blood samples and hair cortisol), 7-day actigraphy (physical activity and sleep) and serious adverse events. Qualitative interviews, focus groups and fieldnotes will be used to explore acceptability and contextual factors. If progression criteria are met, the study will inform the design of a pragmatic, multicentre, randomised trial. The exploratory outcomes will inform outcome selection, setting, sample size and procedures.

Ethics and dissemination Approved by the Regional Ethics Committee of the Capital Region of Denmark (H-25013213). Results will be disseminated through peer-reviewed publications, conferences and public platforms.

Trial registration number NCT06922630.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The Weight-Neutral Health Intervention was codesigned with adults with body mass index ≥30 kg/m² and health professionals experienced in weight-neutral practice, enhancing relevance and sensitivity to stigma-related concerns.
⇒ The present study protocol addresses a knowledge gap by evaluating the feasibility and acceptability of a weight-neutral health intervention using quantitative and qualitative methods and including both participant and practitioner perspectives.
⇒ Predefined 'traffic-light' progression criteria and prespecified exploratory outcomes provide a transparent basis for feasibility assessment and planning of a future randomised trial.
⇒ As a single-arm study, clinical outcomes are exploratory and cannot be used to establish causality or effectiveness.
⇒ Delivery in a university research setting by trained weight-neutral practitioners may overestimate feasibility relative to routine primary-care or municipal services, where resources and training opportunities will differ from the conditions of the study setting.

INTRODUCTION

Since the 1960s, average body mass index (BMI) has increased in most populations,[1 2] raising public health concerns due to the association between higher BMI and adverse health outcomes.[3] Within the dominant weight-centric paradigm, body weight is treated as a key indicator of health, and weight loss is framed as an appropriate and

achievable route to improved health.[4 5] Accordingly, behavioural weight loss interventions are commonly recommended for adults with a BMI ≥30 kg/m^2.[6] However, evidence suggests that even intensive lifestyle interventions are not efficient in sustaining substantial long-term weight reduction.[7] Furthermore, such interventions do not reduce the incidence of cardiovascular events[8] and may result in weight cycling and adverse outcomes such as self-criticism, disordered eating,[9–12] bone demineralisation[13] and increased risk of frailty fractures.[14] Newer pharmacological treatments, such as GLP-1 receptor agonists, have demonstrated substantial and sustained weight loss while treatment is maintained. However, uncertainties remain regarding long-term adverse effects, treatment adherence and post-treatment weight regain.[15]

Individuals with higher body weight frequently experience weight stigma, defined by the WHO as 'the social rejection and devaluation that accrues to those who do not comply with prevailing social norms of adequate body weight and shape'.[16] Weight stigma is pervasive in society and healthcare[17] and contributes to inequitable access to healthcare services.[16] Internalised weight bias (WBI)—when individuals adopt negative stereotypical beliefs about themselves[16 18]—has been identified as a mediator between perceived weight stigma and negative health outcomes.[19]

Weight-neutral health (WNH) approaches have emerged as alternatives to weight-centred approaches.[5] WNH approaches are closely related to weight-inclusive approaches, which are based on the premise that individuals can pursue health and well-being across a range of body sizes when supported by non-stigmatising care.[4 10] Within weight-inclusive approaches, body weight is neither assumed to be a proxy for health nor treated as a target of medical treatment or intervention.[4 10] WNH approaches often draw on the 'Health at Every Size' (HAES) framework,[20] which promotes balanced eating or intuitive eating,[21] body respect, compassion-based practices, life-enhancing movement and respect for body diversity and seeks to reduce weight stigma and the cultural emphasis on weight loss.[4]

Two systematic reviews compared HAES approaches[22] or WNH interventions[23] with waiting list or weight-centred programmes. These reviews indicate that HAES approaches and WNH interventions resulted in greater improvement in bulimia and greater improvement in disinhibition and restraint.[22 23] However, only some of the included studies were randomised, and sample sizes were generally small. Thus, the existing evidence base remains limited, highlighting the need for larger, long-term studies conducted in real-world settings.

It also remains unclear whether WNH interventions can be feasibly delivered and evaluated in a context where public and clinical attention is increasingly directed towards pharmacological weight-loss treatments. Recruitment and retention may be challenging if adults with higher body weight are reluctant to enrol in programmes that explicitly avoid weight loss as a goal. Similarly, healthcare professionals may vary in their acceptance of weight-neutral approaches, influencing referral patterns and engagement.

The present feasibility study—the WIN (Weight-Neutral Health Intervention) study—is part of the Lighthouse Consortium on Obesity Management (LightCOM) research initiative, which also includes the LightCARE,[24] LightWAY (NCT06321458) and LightBAR (NCT06309238) trials. The LightCOM consortium brings together studies across both weight-centred and weight-neutral paradigms within a shared framework for trial management and evaluation. While the other studies focus on weight-centric interventions, WIN aims to test a codesigned, weight-neutral alternative. Although weight-neutral approaches are relevant for individuals of all body sizes, the WIN study includes only participants with a BMI ≥30 kg/m² to align with the broader LightCOM framework. This paper presents the protocol for the WIN feasibility study.

METHODS

Study design

The WIN feasibility study is a single-arm, investigator-initiated study, assessing a codesigned weight-neutral health intervention for adults with a BMI ≥30 kg/m² in the Capital Region of Denmark. The study follows the Medical Research Council (MRC) framework for complex interventions[25] and the consolidated guidance for behavioural-intervention pilot and feasibility studies.[26]

Setting

The study will be conducted at the Research Unit for General Practice, University of Copenhagen, where all intervention sessions take place in dedicated facilities designed for seated discussions and light movement. Most assessments will occur on site, except for venous blood sampling, which is carried out at a collaborating hospital laboratory.

Participants

Recruitment and enrolment

Potential participants will be recruited through adverts on social media, podcasts and through general practitioner networks. Interested individuals will complete an online eligibility questionnaire. Those who meet the initial eligibility criteria are invited to a telephone screening (pre-screening). Eligible individuals will then attend an in-person information meeting for final screening, where written informed consent is obtained prior to final enrolment. The recruitment and enrolment process is illustrated in figure 1.

Inclusion criteria

Individuals will be eligible to participate if they

1. Are aged ≥18 years at screening.
2. Have BMI ≥30 kg/m^2.
3. Have residence in the Capital Region of Denmark.

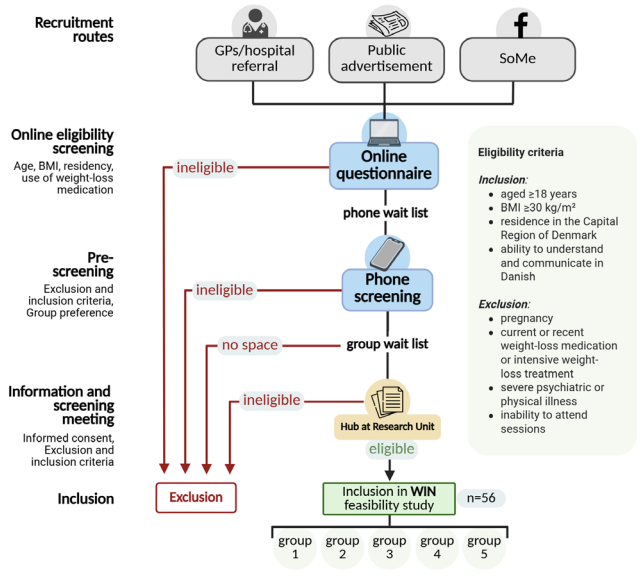

Figure 1 Recruitment routes, eligibility assessment and participant flow in the WIN feasibility study. Flow diagram illustrating recruitment, online eligibility screening, telephone screening and an in-person information and screening meeting. The figure presents inclusion and exclusion criteria, reasons for exclusion (ineligible or lack of group capacity), and participant flow to final inclusion (n=56) and allocation to one of five intervention groups. BMI, body mass index; GPs, general practitioners; WIN, Weight-Neutral Health Intervention; SoMe, Social Media.

4. Can understand and communicate in Danish.
5. Provide informed consent.

Exclusion criteria

Participants will not be eligible for the study if they

1. Are pregnant or planning to become pregnant during the intervention.
2. Are using weight-loss medications (WLM) or GLP-1 agonists, have used WLM within the previous 6 months, or have the intention to use WLM or to begin any other intensive weight-loss treatments during the WIN intervention.
3. Have undergone bariatric surgery within the past 12 months.
4. Are diagnosed with or treated for severe psychiatric or physical illness that may interfere with participation or may present a safety concern.
5. Are unable to attend group sessions.
6. Are deemed unable to complete a 2-hour group session, as assessed by the investigator at the clinical screening interview.
7. Are participating in another intervention trial involving weight-loss treatment.

Patient and public involvement

Given the variation in scope, structure and implementation contexts of WNH interventions, the intervention described in this protocol was developed through a codesign process[27] involving relevant stakeholders. Stakeholder engagement is a core component of the MRC framework for complex interventions[28] and is considered essential for enhancing acceptability and relevance in the target population.[29 30]

The codesign process aimed to adapt the HAES principles to a Danish primary care context and to Danish cultural norms.[31] Health professionals with basic experience in WNH participated in participatory sessions to both develop their competencies in the approach and contribute their clinical expertise to the design of intervention components and activities.

In parallel, individuals with higher body weight (BMI ≥30 kg/m²) who had lived experience with WNH were involved through semistructured interviews, a half-day workshop and a focus-group interview. This process facilitated the systematic identification of priorities, potential barriers, and key components for a WNH intervention in Danish primary care.[32] It was guided by a human-centred design approach[33–35] and is described in detail elsewhere.[27]

As described later, participants will contribute to the evaluation of the feasibility study through qualitative interviews, focus groups and a questionnaire assessing acceptability and experiences of the programme. Study findings will be shared with participants via email on completion for those who consent to receive study updates.

WIN practitioners

Three to four healthcare professionals (eg, nurses or clinical dietitians) with prior certification in weight-neutral approaches will deliver the core programme, with two additional practitioners (eg, physiotherapists or yoga instructors) providing the optional 'rest and movement' sessions.

All practitioners will receive intervention-specific training and ongoing supervision to maintain fidelity to the WIN intervention principles and a supportive, non-stigmatising approach.

Intervention

The WIN intervention is a 6-month, group-based programme (figure 2) designed to promote health and well-being through weight-neutral, stigma-aware care. It integrates HAES principles, intuitive eating, self-compassion and Acceptance and Commitment Therapy (ACT).[36] The overall aim is to help participants develop a more supportive relationship with food, body, movement and health.

The programme begins with one individual preparatory session (60 min) in which participants clarify personal values, hopes and possible barriers. This is followed by 11 2-hour group sessions (10–12 participants) co-facilitated by two practitioners. Each session combines brief psychoeducation, group reflection, mindfulness-based exercises and structured dialogue in smaller groups. Home assignments are included, including journaling tasks, to support integration between sessions.

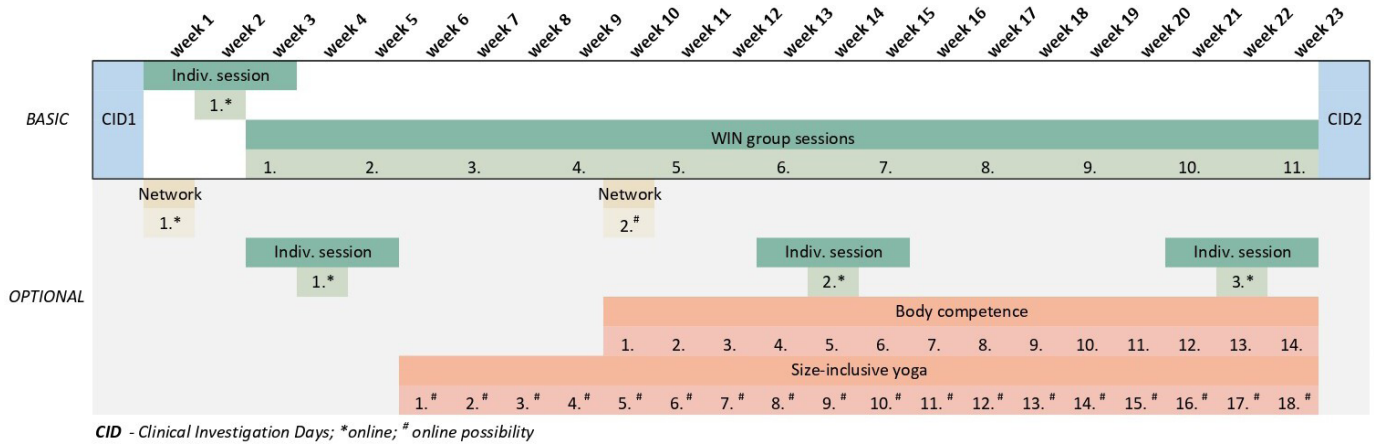

Figure 2 The WIN intervention programme. Schematic overview of the structure and timeline of the 6-month Weight-Neutral Health Intervention (WIN), including one individual preparatory session, 11 group-based sessions and CIDs. The figure also illustrates optional components, including individual online sessions, support-network events and movement-based activities.

Core session themes include

- Food and body in a diet culture—identifying internal rules and restrictions, guilt and permission to eat.
- Identifying eating patterns and binge-restriction cycles.
- Intuitive eating—reconnecting with hunger, fullness and satisfaction cues.
- Self-compassion and body respect—fostering kindness toward oneself and resilience to stigma.
- Rest and movement for well-being—introducing gentle, enjoyable, body-trusting activities.
- Sustaining change and self-care—consolidating learning, relapse prevention and social support.

Optional components

Participants may attend up to three 30 min individual online sessions for personal support, two support-network events designed to enhance understanding of WNH among relatives or peers and movement courses ('size-inclusive yoga' and 'body-competence'), adapted to individual preferences, abilities and comfort levels. All activities emphasise autonomy, accessibility and safety, consistent with trauma-informed and stigma-aware care principles.[37]

The intervention manual and materials will be refined iteratively during the feasibility phase. A comprehensive intervention description following the Template for Intervention Description and Replication checklist[38] will be published following feasibility evaluation to support replication and future implementation.

Concomitant care

Usual care continues. Initiation of intensive weight-loss treatment or WLM during the intervention discontinues group participation (individual sessions may continue) as this is not compatible with the weight-neutral principles.

Assessments and data collection

Assessments occur pre-intervention (clinical investigation day 1, CID1) and post-intervention (CID2), unless otherwise specified (table 1). Data include self-administered questionnaires, physical measurements (height, weight, blood pressure, heart rate), biological samples (venous blood, hair cortisol), 7-day SENS Motion actigraphy,[39] attendance logs and qualitative interviews/focus groups. Weight is measured but not disclosed to participants in line with weight-neutral principles. Study data will be handled using OpenClinica, an electronic database managed by the Copenhagen Trial Unit. This incorporates audit trails, data separation between intervention sites and data validation in accordance with Danish data protection regulations.

Feasibility outcomes and progression criteria

The main objective in the WIN study is to assess the feasibility of both the WIN intervention manual and the conduct of a later, larger pragmatic randomised trial. Feasibility outcomes will be assessed using a predefined traffic light system (green=go, amber=modify, red=stop), as illustrated in table 2.[40] The four most important feasibility outcomes are categorised as primary or secondary, reflecting their significance and importance in the decision to progress to a larger randomised trial.

Feasibility outcomes

Primary feasibility outcome

- **Follow-up completion**: The proportion of participants completing the CID2 assessment, defined as answering the 'Mental health component' of the 36-item Short Form survey (SF-36).[41] This measure is the putative primary outcome for a future randomised trial. A completion proportion of 80% or higher will indicate feasibility (green signal), 50%–79% will suggest that modifications may be required (amber signal), while less than 50% will indicate that the study procedures are not feasible (red signal).

Secondary feasibility outcomes

- **Recruitment proportion**: The proportion of individuals enrolled as participants (numerator, n) out of

Table 1 Assessments and timing

		Prescreening	Screening	CID1	CID2*
		Online and telephone	Preinclusion	Preintervention	Postintervention
Background	Sociodemographic information	Self-reported	IA		
	Medical history	Self-reported	IA		
Clinical	Height	Self-reported	Measured		
	Weight	Self-reported	Measured	Measured	Measured
	Office blood pressure and pulse rate			Measured	Measured
	SENS Motion actigraphy device (physical activity and sleep patterns)			Measured†	Measured†
Questionnaires	Short-Form 36			SAQ	SAQ
	Weight Bias Internalisation Score-Modified			SAQ	SAQ
	Intuitive Eating Scale-3			SAQ	SAQ
	Eating Disorder Examination Questionnaire			SAQ	SAQ
	Rosenberg Self-Esteem Scale			SAQ	SAQ
	Body Appreciation Scale			SAQ	SAQ
	Cantril Ladder Scale			SAQ	SAQ
	Major Depression Inventory-10			SAQ	SAQ
	Perceived Stress Scale-10			SAQ	SAQ
	Weight and diet history (background information) Acceptability Questionnaire (TFA based)			SAQ	 SAQ
Biomarkers	Hair sample (cortisol; chronic stress biomarker)			Laboratory	Laboratory
	Venous blood sample, routine analysis			Laboratory	Laboratory
Safety	Serious adverse events				IA

*CID2 data are collected until 4 weeks after the end of intervention. For questionnaire data, we will allow up to 8 weeks.
†7 consecutive days.
CID1, clinical investigation day 1; IA, Investigator assessed; SAQ, self-administered questionnaire.

those who passed the telephone screening (denominator, N). A proportion of 50% or higher will give a green signal, 20%–49% will give an amber signal, while less than 20% will give a red signal.

- **Adherence**: The proportion of participants who attend at least 2/3 of the planned sessions. We will assess:
  - Adherence midway assessed as the proportion of participants who attended at least four of the first six planned sessions (assessed at study week 12). A proportion of 60% or higher will give a green signal, 40%–59% will give an amber signal, while less than 40% will give a red signal.

Table 2 Progression criteria and sample size

Progression criteria	Definition	Red	Amber	Green	Implied sample size for 80% power	Implied sample size for 90% power
Primary feasibility outcome						
Follow-up completion	Proportion of participants who complete the SF-36 outcome questionnaire at CID2	<0.5	0.5–0.79	≥0.8	18	23
Secondary feasibility outcomes						
Recruitment proportion	Proportion of individuals enrolled as participants out of those who passed the telephone screening	<0.2	0.2–0.49	≥0.5	18	23
Adherence midway	Proportion of participants who attended at least 4 of the first 6 planned sessions	<0.4	0.4–0.59	≥0.6	42	56*
Adherence postintervention	Proportion of participants who attended at least 8 of the total 12 planned sessions	<0.3	0.3–0.54	≥0.55	25	36

*Chosen sample size.
CID2, clinical investigation day 2; SF-36, 36-item Short Form survey.

- Adherence at the end of the intervention assessed as the proportion of participants who attended at least 8 of the total 12 planned sessions (assessed at study week 23). A proportion of 55% or higher will give a green signal, 35%–54% will give an amber signal, while less than 35% will give a red signal.

Exploratory feasibility outcomes

Exploratory feasibility outcomes include participant burden, compliance, engagement and the practicality of the data-collection procedures. To evaluate follow-up completion, we will assess the proportion of participants who complete all required questionnaires at both CID1 and CID2, as well as the proportion willing to provide blood samples, hair samples and use and return the SENS actigraphy monitor at both assessment points. We will also record the proportion of participants who complete the physical assessments at CID1 and CID2.

To assess participant engagement and compliance, we will evaluate participation in optional programme components, including the 'rest and movement' sessions, the 'body competence' sessions and the optional 'support-network' events. Engagement with the online sessions will be examined by recording the proportion of participants who attend at least one online session with the WIN practitioner.

Exploratory clinical outcomes

- Questionnaires: SF-36 Mental Component Summary, SF-36 Physical Component Summary and all subscales[41]; Weight Bias Internalisation Scale–Modified[42]; Intuitive Eating Scale-3[43]; Eating Disorder Examination Questionnaire[44]; Rosenberg Self-Esteem Scale[45]; Body Appreciation Scale[46]; Cantril Ladder Scale[47]; Major Depression Inventory[48]; Perceived Stress Scale-10.[49]
- Physical and metabolic health: Physical activity and sleep (actigraphy), hair cortisol concentration (pg/mg hair) as a marker for chronic stress, blood pressure, heart rate and weight.
- Routine blood analysis will include haematology, electrolytes, organ markers, lipid and glucose metabolism markers, endocrine markers and inflammatory markers, analysed according to standard clinical laboratory procedures.

Safety

- Serious adverse events: Assessed as the proportion of participants with any adverse event that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect during the intervention period.[50]

Please refer to online supplemental table 1 for details on all outcomes and their assessment.

Statistical considerations

Sample size and progression criteria

We applied the approach proposed by Lewis *et al*[40] to estimate the minimum sample size required for each feasibility outcome. This method gives 80% or 90% power to assess whether the true value of a given parameter lies at or above the predefined 'green' threshold (ie, considered feasible; see table 2), the probability of observing a value at or below the 'red' threshold (ie, considered unfeasible) is ≤5%. In other words, it minimises the risk of incorrectly classifying a feasible study as unfeasible.

We applied this method to the four primary and secondary outcomes, resulting in a range of possible sample sizes. To optimise power and reduce the risk of type I error, we chose the largest calculated sample size. We will therefore include 56 participants in the WIN feasibility study.

Analysis

Feasibility outcomes will be reported descriptively as proportions with 95% CIs and assessed using the predefined traffic light progression criteria (see table 2). As this is a feasibility study, no formal hypothesis testing will be conducted for these outcomes. Exploratory clinical outcomes will be summarised descriptively using appropriate statistics (eg, means and SD, or medians and IQRs), with 95% CIs presented where relevant. Given the single-arm design and limited sample size, no formal statistical comparisons will be performed, and exploratory findings will be interpreted as preliminary. These results will serve to inform outcome selection, power calculations and the design of a future pragmatic randomised trial. Missing data will be reported and described.

Interpretation of progression criteria and feasibility outcomes

The primary and secondary feasibility outcomes will be assessed using the predefined traffic light progression criteria. Progression to a pragmatic randomised trial, where the current concept will be tested, will be considered appropriate if all indicators fall within the green zone. If any indicators fall within the amber zone, the study design will undergo revision in the relevant domain(s) before moving forward. If any indicators fall within the red zone, the relevant domain(s) will undergo major revision, and the study design and concept will need to be tested in another feasibility study before moving forward to a larger pragmatic trial.

The remaining feasibility outcomes, as well as the qualitative results, will explore whether the WIN intervention and manual in its current form is acceptable to the participants, or whether an intervention with, for example, more online participation, fewer or differently designed sessions may be more appropriate.

Qualitative inquiry and analysis

To further explore feasibility, acceptability and contextual factors influencing implementation, as well as participants' and practitioners' experiences of the intervention, the

study includes several qualitative components conducted during and after the intervention period. The qualitative inquiry is grounded in a constructivist epistemology, acknowledging that individual experiences are shaped by social and relational contexts.[51] We will draw on multiple qualitative data sources:

- Semistructured telephone interviews with participants who discontinue the intervention, focusing on reasons for dropout and perceived barriers to engagement[52];
- Post-intervention focus group interviews with 6–8 participants to explore experiences, acceptability and suggestions for refinement[51];
- Researcher-facilitated reflective debriefing with practitioners after each group intervention session to document tacit knowledge arising from actual intervention delivery.[53] The focus will be on documenting practitioners' immediate reflections on perceived challenges, required adaptations and session delivery;
- Post-intervention focus group interviews with all practitioners involved in delivering the intervention, focusing on reflections on implementation, feasibility and delivery experiences;
- Photo-elicitation interviews with a subsample of participants (7–10), conducted during the later stages of the intervention, in which participant-generated photographs of meaningful everyday moments will be used to prompt reflection and dialogue (not to document outcomes)[54 55];
- Fieldnotes and observations from intervention sessions and interviews, to capture interactions, atmosphere and contextual elements.

All interviews and reflective debriefing will be conducted by members of the research team, audio recorded with participant consent, transcribed verbatim using GoodTape software, and anonymised prior to analysis. Interview guides will be developed for each interview format and refined iteratively during the data generation period.

Sampling and recruitment

Participants for semistructured and focus group interviews will be purposively selected to ensure variation in gender, age, degree of intervention engagement and baseline characteristics, following the principle of information power.[56] Following this principle, the number of participants will not be determined in advance but will rely on the researcher's judgement of the sufficiency of data and analytical depth. Specifics of this process will be documented in the papers reporting the findings, respectively, to ensure transparency. Participants who discontinue the intervention will be invited to a brief exit interview. Practitioners involved in delivering the intervention will be invited to participate in a dedicated post-intervention focus group.

Analysis

Qualitative materials will be analysed abductively through a team-based analytic process, moving iteratively between inductive insights from the data and relevant theoretical perspectives.[57] The analytic process will involve familiarisation with transcripts, coding, development of themes, and discussion within the research team to enhance analytical rigour. Semistructured and focus group interviews will be analysed thematically to explore experiences, contextual influences on engagement and suggestions for intervention refinement.[58]

Photo-elicited interviews will be analysed using reflexive thematic analysis[58] to explore both patterned meanings across participants and how individuals make sense of WNH principles in everyday life.[58–60] Fieldnotes and debriefing will also be analysed thematically to assess intervention fidelity, delivery challenges and required adaptations. Findings across qualitative data sources will be synthesised to develop an integrated account of feasibility and acceptability.

To ensure quality and rigour consistent with the constructivist epistemology, the study will draw on the authenticity criteria articulated by Guba and Lincoln,[61] which evaluate the quality of constructivist inquiry based on whether the research is fair, deepens understanding, and has the potential to prompt action. Fairness will be pursued by seeking diverse participant and practitioner perspectives. Ontological and educative authenticity will be supported through dialogic methods, including focus groups and photo-elicitation interviews, that invite participants and practitioners to reflect on, articulate and potentially deepen their understanding of their own experiences of the intervention. Catalytic authenticity is inherent to the feasibility purpose of the study, as findings are intended to inform the further development of the intervention. Throughout, the research team will critically reflect on their own positioning and preconceptions in relation to health, bodies and WNH practice through reflexive journaling and peer debriefing, treating researcher subjectivity as an active resource rather than a source of bias to be controlled.

NVivo software will support systematic data management, coding and audit trails. Expanded methodological procedures (sampling strategies, topic guides, coding framework and researcher positionality and reflexivity)[62] will be described in subsequent publications.

DISCUSSION

To our knowledge, WIN is the first codesigned weight-neutral health intervention for adults with a BMI ≥30 kg/m². The participatory codesign process aimed to ensure that the intervention reflects the perspectives, challenges and preferences of the target population, enhancing its relevance, acceptability and sensitivity to stigma-related concerns. Unlike conventional weight-centred programmes, the WIN intervention seeks to strengthen body respect and self-compassion, reduce internalised weight bias and improve relationships with food, rest and movement. While the intervention cannot remove external weight bias or stigma, it may support participants

in navigating and resisting its effects, potentially reducing stress and supporting mental and physical well-being.

The programme was intentionally designed with flexibility in delivery and participation. Optional components (size-inclusive yoga, body competence sessions, online individual meetings and support-network events) allow participants to engage according to personal preferences, schedules and physical abilities. This flexibility acknowledges that movement and body-related activities may evoke ambivalence or past trauma for some individuals.[37] Although flexibility can enhance engagement and accessibility, it also introduces variability in exposure that must be considered when interpreting feasibility findings.

Guided by the MRC framework for complex interventions[25] and the consolidated guidance for behavioural-intervention pilot and feasibility studies,[26] the WIN study evaluates key uncertainties related to recruitment, retention, data procedures and acceptability. Quantitative feasibility indicators will be complemented by qualitative interviews and focus groups with participants and practitioners to explore experiences, relevance and barriers to engagement. This approach will provide a nuanced understanding of what facilitates or hinders participation and inform refinements to both the intervention and trial procedures.

If progression criteria are met, findings from the feasibility study will inform further development of the intervention, including a digital delivery platform (the WIN app). This will be followed by further feasibility testing. If progression criteria continue to be met, a proof-of-concept randomised controlled trial may be considered to assess preliminary effectiveness in a primary care setting. The feasibility study will provide key information to inform the design of subsequent trials. Future trials will be accompanied by a formal process evaluation to examine implementation fidelity, contextual factors and mechanisms of change.

In subsequent trials, or implementation of weight-neutral programmes in routine clinical practice (eg, municipal health programmes), practitioners may come from diverse professional backgrounds, but formal training in weight-neutral practice—such as certification in intuitive eating or other accredited education—will remain essential to maintain fidelity. Ensuring sufficient training capacity and institutional support will be key to sustainable implementation.

Although weight loss is not a goal of the intervention, body weight will be measured at baseline and follow-up to allow exploratory analysis and a comprehensive assessment of clinical measures. In line with weight-neutral principles, participants will not be informed of their weight and it will not be discussed during sessions.

Weight-neutral approaches are gaining international attention, yet the evidence base remains limited by small sample sizes, short follow-up and inconsistent outcome reporting. In Denmark, several municipalities have begun piloting weight-neutral programmes without systematic evaluation or research linkage. By applying rigorous feasibility testing, the WIN study provides essential groundwork for evaluation in a future trial and may contribute to evidence-informed policy decisions and practice in primary care.

Limitations include single-centre delivery in a university research setting and provision by trained weight-neutral practitioners rather than under routine primary care or municipal conditions. This controlled environment may enhance participant motivation and practitioner fidelity, potentially overestimating feasibility.

The present single-arm design does not assess participants' willingness to be randomised to different intervention approaches. Randomisation between a weight-neutral intervention and usual care or a specific weight-centric intervention may pose challenges to recruitment and retention. This will be an important consideration in the design of future trials.

The findings from this feasibility study will contribute to the development and evaluation of stigma-aware, participant-centred approaches in primary care. WIN will add to the evidence base needed to evaluate weight-neutral approaches alongside existing strategies in primary care.

ETHICS AND DISSEMINATION

The study is approved by the Regional Committee on Health Research Ethics for the Capital Region of Denmark (H-25013213) and the Capital Region's Data Protection Office (P-2025-18470). The intervention is considered non-invasive and low risk. All procedures follow the Declaration of Helsinki and Danish regulations. All participants provide informed consent for participation. Participants will be informed of potential emotional or physical discomfort and encouraged to report any distress to the research team. Blood samples are processed immediately after collection and destroyed per standard hospital protocols. Hair samples will be stored securely for cortisol analysis and destroyed after analysis. Personal data will be handled in accordance with the General Data Protection Regulation and local data protection legislation. Participants are covered by the Danish Patient Compensation. Participants will be reimbursed DKK 450 for attending the final CID2 assessment. No additional financial compensation will be provided. Study findings will be made publicly available, regardless of whether they are positive, neutral or negative. The findings will be disseminated through peer-reviewed journals, conferences and public platforms. A depersonalised dataset may be shared on request following publication. However, qualitative data (photographs, audio recordings, transcripts and field notes) will not be publicly shared, as they are not anonymised. Authorship will follow ICMJE criteria and reflect contributions from the LightCOM consortium.

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Contributors GAS, RKR, LBM, CTS, ALC, IOS and FBW outlined the feasibility study. PA performed the power calculations. JL and JE contributed with ethical approval and trial registration, as well as managing data collection and secure data storage. GAS prepared the first draft of the manuscript. CD, BLH, SR, GO, MBK, PA, SJ, KNB-M, ALC and FBW conceived the LightCOM project and secured funding, gave advice, provided feedback and contributed to the writing of the paper. CD is the trial sponsor and guarantor for the study. Figures created in BioRender by GAS and ALC. All authors read and approved the final version of the manuscript. Generative AI tools (ChatGPT (GPT-5, OpenAI) and Microsoft Copilot) were used to assist with language editing. All text and content were reviewed and approved by the authors, who take full responsibility for the final manuscript.

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Competing interests RKR declares a potential conflict of interest since, in addition to his work as a general practitioner and an associate professor, he receives a standard consultant fee when he occasionally teaches courses about weight-neutral health to nurses and staff in general practice. The courses are organised by Denmark's national association of general practitioners (PLO) under the national association of medical doctors in Denmark. LBM declares a potential conflict of interest in that she has a private practice where she offers therapy, supervision and courses about eating disorders and weight-neutral health. CD is, on behalf of his institution, the grant recipient of the LightCOM grant (NNF22SA0080921) from the Novo Nordisk Foundation, which covers the funding of the present study. Apart from that he has over the past 3 years received funding for other research projects from the Novo Nordisk Foundation, served as principal investigator on clinical trials conducted by Novo Nordisk and Amgen, received personal honorarium (lecturer, expert testimony, committee member) from Dagens Medicin, Dansk Lægemiddel Information, Empros Pharma, Novo Nordisk, AstraZeneca and Amylyx, and served in unpaid roles (meeting organiser or chairperson) for Novo Nordisk and Eli Lilly. None of these commitments have any relation to the current study. JE owns Novo Nordisk stocks. KNB-M has, over the past 3 years, served as co-investigator on a clinical trial conducted by Amgen AB, has received personal honorarium (as a lecturer) from Dagens Medicin, and has received research funds from Greater Copenhagen Health Science Partners to support research activities of CAG SHIFT, including part of the salary of a PhD student. GO received grants or contracts from the TRYG Foundation and VELUX Foundation. The remaining authors declare no conflicts of interest.

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