

STUDY PROTOCOL

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OBESIAL: Protocol for a Prospective Interventional Real-World Study of a Multidisciplinary Obesity Management Programme

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Principal Investigator	Professor Mounira Chanegriha

Submission Statement

This document contains the full study protocol reviewed and approved by the National Institutional Ethics Committee of Algeria (Reference 11/AG/2025) and is submitted for ClinicalTrials.gov document upload.

OBESIAL: protocol for a prospective interventional real-world study of a multidisciplinary obesity management programme

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Abstract

Introduction

Obesity is a major public health challenge associated with substantial metabolic, cardiovascular, and socioeconomic consequences. In Algeria and across many African countries, obesity prevalence is increasing while structured multidisciplinary care pathways remain limited. The **OBESIAL** (Obesity Structured Intervention in Algeria) study aims to evaluate the clinical, metabolic, and organisational impact of a structured multidisciplinary obesity care pathway implemented under real-world conditions.

Methods and Analysis

OBESIAL is a prospective pragmatic study involving 300 adults with obesity recruited from healthcare facilities in Algeria and followed for 18 months. The primary comparison evaluates outcomes between participants receiving structured multidisciplinary care (G1, n=150) and those receiving non-structured usual care (G2, n=150). The structured pathway includes coordinated medical follow-up, personalised nutritional intervention, adapted physical activity, therapeutic education, and multidisciplinary support.

Within the structured care group, eligible participants will undergo a nested randomised comparison between G1a (lifestyle intervention plus GLP-1 receptor agonist therapy) and G1b (lifestyle intervention alone) to assess the additional effect of GLP-1 receptor agonist treatment.

The primary outcome is the proportion of participants achieving clinically meaningful weight loss ($\geq 5\%$ of initial body weight) at 18 months. Secondary outcomes include changes in body composition, metabolic parameters, treatment response, adherence, and obesity-related outcomes. Longitudinal analyses will be performed using mixed-effects models, while multivariable approaches will explore factors associated with treatment response.

The findings of the OBESIAL study are expected to provide evidence to support the development and optimisation of structured multidisciplinary obesity care pathways in Algeria and may offer relevant insights for other African healthcare systems.

Ethics and Dissemination

The study has received approval from the national institutional ethics committee in Algeria (Ref: 11/AG/2025). Written informed consent will be obtained from all participants before enrolment. Study findings will be disseminated through peer-reviewed publications and presentations at scientific meetings.

Keywords: adult obesity, multidisciplinary care, lifestyle interventions, GLP-1 receptor agonists, real-world study.

Introduction

Obesity is a major global public health challenge and a recognised risk factor for numerous non-communicable diseases, including type 2 diabetes, hypertension, cardiovascular diseases, and several types of cancer [1]. According to the World Health Organization (WHO), more than 1.9 billion adults worldwide are overweight, of whom over 650 million are living with obesity, with prevalence continuing to rise [2,3]. Beyond its clinical consequences, obesity also imposes a substantial economic and organisational burden on healthcare systems [1,2].

Multidisciplinary interventions integrating lifestyle modification, nutritional management, adapted physical activity, psychological support, and, when appropriate, pharmacological treatment or bariatric surgery have demonstrated effectiveness in obesity management [4,5]. However, most available evidence originates from high-income Western countries, limiting its applicability to low- and middle-resource settings, including North African countries [6].

In Algeria, obesity represents a major healthcare challenge. The national WHO STEPwise survey reported that 55.6% of adults aged 18–69 years are affected by overweight or obesity, with a higher prevalence among women than men (63.3% vs 48.3%) [7]. Obesity alone affects 21.8% of adults and nearly one-third of women [7]. Previous studies have also highlighted high obesity prevalence among women living in urban areas [8] and a concerning increase in overweight and obesity among children and adolescents [9,10]. This epidemiological trend is associated with a growing burden of metabolic and cardiovascular comorbidities [7,11]. Furthermore, increasing obesity rates among women of reproductive age may contribute to the intergenerational transmission of metabolic disorders, potentially amplifying the future burden of obesity and diabetes within the Algerian population [12].

Despite the recognition of obesity as a public health priority, evidence regarding structured multidisciplinary obesity care pathways evaluated under real-world conditions remains limited in Algeria. In addition, restricted access to innovative pharmacological treatments, including GLP-1 receptor agonists, highlights the need to optimise integrated and pragmatic care strategies.

The **OBESIAL (Obesity Structured Intervention in Algeria)** study was designed to evaluate the effectiveness and feasibility of a structured multidisciplinary obesity care pathway under real-world clinical conditions. It aims to assess its clinical, metabolic, and organisational impact, as well as its integration within the Algerian healthcare system. Beyond the national context, OBESIAL may also provide evidence relevant to other North African and African healthcare settings seeking to develop sustainable, pragmatic, and context-adapted obesity care models.

Objectives

Primary Objective

To evaluate, after 18 months of follow-up and under real-world clinical conditions, the effect of a structured multidisciplinary obesity care pathway (G1), compared with non-structured usual care (G2), on achieving clinically significant weight loss among adults living with obesity in Algeria.

Secondary Objectives

1. To evaluate, within the nested randomization conducted in the G1 group, the additional effect of a GLP-1 receptor agonist combined with lifestyle interventions (G1a), compared with lifestyle interventions alone (G1b), on achieving clinically significant weight loss.
2. To identify predictive factors associated with response to GLP-1 receptor agonist treatment.
3. To compare, after 18 months of follow-up, changes in metabolic parameters, particularly glycaemic and lipid parameters, between G1 and G2.
4. To compare changes in body composition between participants exposed to a structured multidisciplinary care pathway (G1) and those receiving non-structured care (G2).

Methods

Protocol Version

Version 1.0 dated 1 December 2025

Study Type and Design

OBESIAL is a hybrid-design study combining a prospective real-world cohort study with a nested randomized controlled trial. In the first phase, it consists of a prospective non-randomized study comparing, among adults living with obesity in Algeria, a structured obesity care pathway with non-structured usual care in order to evaluate the impact of an integrated multidisciplinary consultation in routine clinical practice.

In the second phase, after 6 months of follow-up, a nested randomized controlled trial will be conducted among participants within the structured care pathway who are eligible for pharmacological intervention. This component aims to compare the combination of a GLP-1 receptor agonist with lifestyle interventions versus continuation of lifestyle interventions alone.

The total follow-up duration for all participants will be 18 months.

Study Setting

The study will be conducted at the Mother and Child Hospital of the Army (MCHA), within a specialised unit providing a structured obesity care pathway in both outpatient and inpatient settings. This organisation enables integrated care coordination involving multiple medical and allied healthcare specialties.

Study Population

Sample Size

The target sample size was set at 300 participants based on the pragmatic nature of the study and the anticipated recruitment capacity within routine clinical practice. This sample size is expected to provide sufficient precision to detect a clinically meaningful difference in the proportion of participants achieving $\geq 5\%$ weight loss at 18 months between the structured and non-structured care groups. In addition, it allows for potential attrition commonly encountered in real-world longitudinal studies.

The planned sample size is also considered appropriate in the Algerian context, where obesity represents a major public health challenge, with an estimated prevalence of 21.8% reported by the WHO STEPwise national survey [7]. This epidemiological context supports the relevance and feasibility of recruiting the proposed number of participants.

Following referral by healthcare practitioners, participants will be recruited consecutively during specialised outpatient consultations or after scheduled hospital admissions related to obesity assessment or management and will be followed for a period of 18 months.

Group Allocation and Control of Confounding Bias

Participants will be allocated into two groups according to their actual exposure to the structured care pathway.

The primary comparison of the study is between the structured care pathway (G1) and usual non-structured care (G2). The nested randomised comparison within G1 is designed to explore the additional effect of GLP-1 receptor agonist therapy among eligible participants.

- Structured care group (G1): 150 participants receiving regular management within the OBESIAL structured care pathway, including coordinated medical follow-up, nutritional interventions, and a physical activity programme.
- Non-structured care group (G2): 150 participants receiving obesity management outside the structured pathway within comparable healthcare settings operating at the same level of the healthcare system as those involved in G1. Participants in G2 will present a baseline clinical profile comparable to that of G1, particularly regarding sociodemographic characteristics, obesity severity, and associated comorbidities.

Participants will be allocated into two groups according to their actual exposure to the structured care pathway.

To minimise selection bias and improve baseline comparability between groups, recruitment procedures will aim to ensure similar distributions of age, sex, body mass index (BMI), and obesity-related comorbidities across study groups. Residual confounding factors will be addressed during statistical analysis using multivariable regression models.

This design, representative of routine clinical practice, enables an internal comparison of the effects of a structured multidisciplinary care pathway on weight evolution, body composition, and obesity-related comorbidities.

Nested Randomized Controlled Trial

Within the structured follow-up group (G1), eligible participants (n=150) will be invited to participate in a nested randomized therapeutic intervention study. A computer-generated random allocation sequence will be generated by an independent investigator who is not involved in participant recruitment, treatment allocation, or clinical follow-up. Participants will be randomly assigned in a 1:1 ratio using fixed block randomization with blocks of four.

Allocation concealment will be ensured until eligibility has been confirmed and written informed consent for participation in the pharmacological intervention has been obtained.

Participants will be allocated into two subgroups:

- G1a (n≈75): initiation of GLP-1 receptor agonist therapy in addition to the structured care pathway, following provision of a second written informed consent specific to the pharmacological intervention.
- G1b (n≈75): continuation of optimised lifestyle interventions alone (nutritional management, physical activity, psychological and medical follow-up) integrated into the structured care pathway.

Due to logistical constraints, particularly the absence of an injectable placebo, double blinding will not be feasible. Therefore, the study will be conducted using an open-label design, consistent with its pragmatic objective of evaluating effectiveness under routine clinical practice conditions.

The primary analysis will follow the intention-to-treat principle, including all randomized participants analysed according to their initial allocation group regardless of treatment adherence or therapeutic modifications, in order to estimate effectiveness under real-world conditions.

Inclusion Criteria

- Adults aged 18–65 years
- BMI ≥ 30 kg/m²
- Written informed consent obtained prior to enrolment

Non-Inclusion Criteria

- Refusal to participate or inability to adhere to follow-up procedures
- Pregnancy at enrolment
- Severe or unstable comorbidities compromising safety or participation, including:
 - Recent acute cardiovascular event (<60 days)
 - Active malignancy
 - Severe unstable organic disease
- Previous bariatric surgery

- Obesity pharmacotherapy within the previous 90 days
- Known contraindication to planned therapeutic options
- Severe unstable psychiatric disorders
- Genetic obesity or obesity secondary to uncontrolled endocrine disease

Exclusion Criteria During Follow-up

- Pregnancy occurring during follow-up
- Initiation of chronic treatment associated with weight gain

A CONSORT flow diagram will be developed after completion of recruitment and follow-up, illustrating participant assessment, exclusion, randomization, follow-up, and analysis procedures in accordance with recommendations for nested randomized controlled trials.

Study Procedures and Follow-up Schedule

The overall study duration is 24 months, including participant recruitment and follow-up. Each participant will be followed for 18 months.

Participant recruitment will be conducted progressively and consecutively throughout the study period. Recruitment started in **January 2026** and will continue until the target sample size is achieved.

The OBESIAL study is organised into three successive phases to enable a pragmatic longitudinal evaluation of obesity management under real-world clinical conditions.

Phase 1: Baseline Assessment and Inclusion

Following verification of eligibility criteria and collection of written informed consent, participants will be allocated to G1 or G2 according to their actual care pathway, reflecting routine clinical practice.

At enrolment, all participants will undergo a baseline assessment adapted to their study group:

- G1: standardised multidisciplinary assessment including specialist consultations (endocrinology-diabetology, cardiology, pulmonology and stomatology), biological investigations, anthropometric measurements, nutritional assessment and psychological evaluation.
- G2: participants will receive standard obesity care available in routine clinical practice and will not benefit from the coordinated multidisciplinary OBESIAL pathway.

These assessments will establish an individual baseline profile for longitudinal follow-up and internal comparisons. Detailed assessment tools are presented in Appendices 1 and 2.

Clinical and Anthropometric Assessment

Baseline assessment includes medical and surgical history together with a comprehensive clinical examination performed by a physician trained in obesity management. Standardised anthropometric

measurements include body weight, height, BMI, waist circumference, hip circumference and waist-to-hip ratio.

Body weight will be measured using calibrated electronic scales by trained healthcare staff, with participants wearing light clothing and no shoes according to a standardised procedure. Measurements will be performed at baseline and at scheduled follow-up visits under similar conditions whenever feasible. The final 18-month assessment will be conducted within a predefined time window of ± 4 weeks.

Body composition will be assessed using bioelectrical impedance analysis and/or dual-energy X-ray absorptiometry (DEXA), according to availability and clinical indications.

Specialised Multidisciplinary Assessment and Screening for Comorbidities

This assessment applies exclusively to participants in G1.

Participants will undergo coordinated specialist consultations in endocrinology-diabetology, cardiology, pulmonology, and stomatology, organised within a one-day integrated multidisciplinary care pathway. This organisation enables a comprehensive and coordinated assessment of obesity-related comorbidities while optimising patient flow and improving adherence to follow-up.

Nutritional assessment will evaluate dietary habits, qualitative and quantitative intake, eating behaviour and meal patterns in order to identify contributing factors and establish personalised goals.

Psychological assessment will explore emotional, cognitive and behavioural dimensions affecting treatment adherence.

Screening for obesity-related comorbidities will follow a predefined protocol including electrocardiography, ambulatory blood pressure monitoring, echocardiography, abdominal ultrasound, liver FibroScan, pulmonary function testing and sleep respiratory polygraphy.

Biological Assessment

A standardised biological assessment will be performed for all participants including blood count, fasting glucose, oral glucose tolerance testing when indicated, HbA1c, insulin, C-peptide, lipid profile, renal, hepatic and phosphocalcic assessment, and uric acid.

Targeted investigations will be performed according to clinical indications. Exploratory biomarker analyses will include adipokines and inflammatory markers involved in energy homeostasis and will remain exploratory and hypothesis-generating.

An exploratory panel of biomarkers will also be analysed, including adipokines and interleukins involved in energy homeostasis (leptin, ghrelin, adiponectin, resistin, visfatin, IL-1, IL-6, IL-8, IL-10, IL-17, IL-18, IL-22, IL-23, and TNF- α), in order to improve understanding of underlying pathophysiological mechanisms and to explore potential biomarkers that may support future personalised management strategies.

Additional investigations may be performed when clinically indicated, particularly to exclude secondary causes of obesity or investigate specific clinical suspicions.

At the end of this phase, an individual multidimensional profile will be established for each participant. This profile will serve as the longitudinal reference framework for evaluating the impact of the OBESIAL programme on clinical, metabolic, nutritional, psychological, and functional outcomes.

Participants receiving non-structured follow-up (G2) will undergo a comprehensive assessment at baseline and at 18 months only, without intermediate evaluations, in order to preserve their usual care pathway and maintain the pragmatic nature of the study.

Phase 2 : Structured Intervention and Longitudinal Follow-up

Only participants in G1 will undergo the structured care pathway over 18 months.

The first six months will consist of first-line non-pharmacological interventions including:

- Individualised nutritional follow-up adapted to the sociocultural context, consisting of eight sessions, including nutritional education sessions lasting 30 minutes and evaluation sessions lasting 15 minutes.
- An individually tailored physical activity programme based on baseline functional capacity and associated comorbidities. Participants will be encouraged to attend supervised or structured physical activity sessions three times per week, with adjustments according to tolerance and clinical status.
- Psychological support provided according to individual needs, focusing on motivation, emotional eating, barriers to adherence, and behavioural change strategies. The frequency of psychological follow-up will be adapted to patient requirements, reflecting the pragmatic nature of the intervention.

The organisation of care is based on coordinated collaboration among physicians, dietitians, psychologists, organ specialists, adapted physical activity professionals, and surgeons, according to clinical indications.

Therapeutic patient education will be integrated throughout the care pathway to support patient understanding of obesity as a chronic disease, treatment adherence, self-monitoring, prevention of adverse effects, and long-term behavioural change.

Longitudinal Follow-up and Reassessments

Multidisciplinary reassessments are scheduled at months 3, 6, 9, 12, 15 and 18. Standard biological assessments will be repeated every three months, while DEXA assessment will be repeated every six months.

Proteomic and biomarker analyses will be exploratory and hypothesis-generating. They will aim to identify potential biological signatures associated with treatment response but will not be used to define the primary efficacy outcome.

At month 6, participant status will be reviewed during a multidisciplinary team meeting. Participants eligible for GLP-1 receptor agonist therapy will proceed according to the previously described nested randomization procedure.

Multidisciplinary Team Organisation

Care delivery will be coordinated by a multidisciplinary team including general practitioners, endocrinologists-diabetologists, dietitians, psychologists and psychiatrists, together with organ specialists according to obesity-related comorbidities, including cardiology, pulmonology, gastroenterology, rheumatology and stomatology.

Adapted physical activity interventions will be supervised by sports medicine physicians or physiotherapists, while functional capacity assessments will be performed by rehabilitation specialists. Metabolic and plastic surgeons will contribute according to indications validated during multidisciplinary discussions. Biological, pharmaceutical, epidemiological, statistical and administrative staff will support the analytical and organisational aspects of the study.

Patient and Public Involvement (PPI)

Following the initial phase, a limited number of participants may be invited to act as patient partners. Their role will include providing feedback on the care pathway, participating in selected non-decision-making multidisciplinary meetings and contributing to the co-development of organisational improvements aimed at enhancing coordination and intervention acceptability.

This involvement follows a Patient and Public Involvement (PPI) approach intended to improve the relevance, feasibility and patient-centred nature of the evaluated care model.

Multidisciplinary Review and Therapeutic Randomization at 6 Months (M6)

At 6 months of follow-up, each participant in the structured care group (G1) will undergo review during a multidisciplinary team meeting (MTM). This evaluation aims to assess response to lifestyle interventions, determine adherence to the programme, and discuss potential eligibility for bariatric surgery in accordance with current recommendations and the participant's informed preferences.

Participants considered eligible for bariatric surgery will not proceed to the pharmacological intervention and will continue within the standardised multidisciplinary preoperative pathway.

Participants eligible for GLP-1 receptor agonist therapy will subsequently enter the nested randomised intervention according to the previously described study procedures. Detailed eligibility criteria are presented in Appendix 3. The semaglutide treatment regimen is summarised in Table 1.

Table 1. Semaglutide dose escalation and treatment schedule

	First stage	Second stage	Third stage	Fourth stage	Maintenance up to 12 months
Dose (mg/week)	0.25	0.5	1	1.7	2.4

Participants initiating semaglutide will receive a dedicated therapeutic education session covering injection technique, dose escalation, expected benefits, prevention and management of gastrointestinal adverse effects, hydration, nutritional intake, preservation of lean body mass, and symptoms requiring medical attention.

Tolerance and adherence will be assessed prospectively at scheduled visits (months 1, 2, 3, 6, 9 and 12), allowing dose adjustments according to clinical response and tolerability.

Adverse events will be collected prospectively at each follow-up visit. Particular attention will be paid to gastrointestinal symptoms, dehydration, gallbladder-related symptoms, warning signs of pancreatitis, and treatment discontinuation. Serious adverse events will be reported to the principal investigator and the ethics committee in accordance with national regulations.

In cases of severe or persistent adverse effects, the dose may be maintained, reduced, temporarily interrupted, or discontinued according to clinical judgement.

Phase 3 : Final Multidisciplinary Assessment (M18)

At month 18, all participants will undergo a final multidisciplinary evaluation conducted by assessors blinded to participant group allocation and therapeutic status to minimise assessment bias.

The evaluation will include body weight and body composition, metabolic comorbidities, psychological status, quality of life, treatment adherence and participant satisfaction.

Comparative analyses will assess the overall impact of the structured care pathway and identify key components contributing to the effectiveness of the OBESIAL programme, and inform organisational adjustments for future implementation (Figure 1).

OBSIAL PROJECT

Impact of structured care vs usual care on obesity management

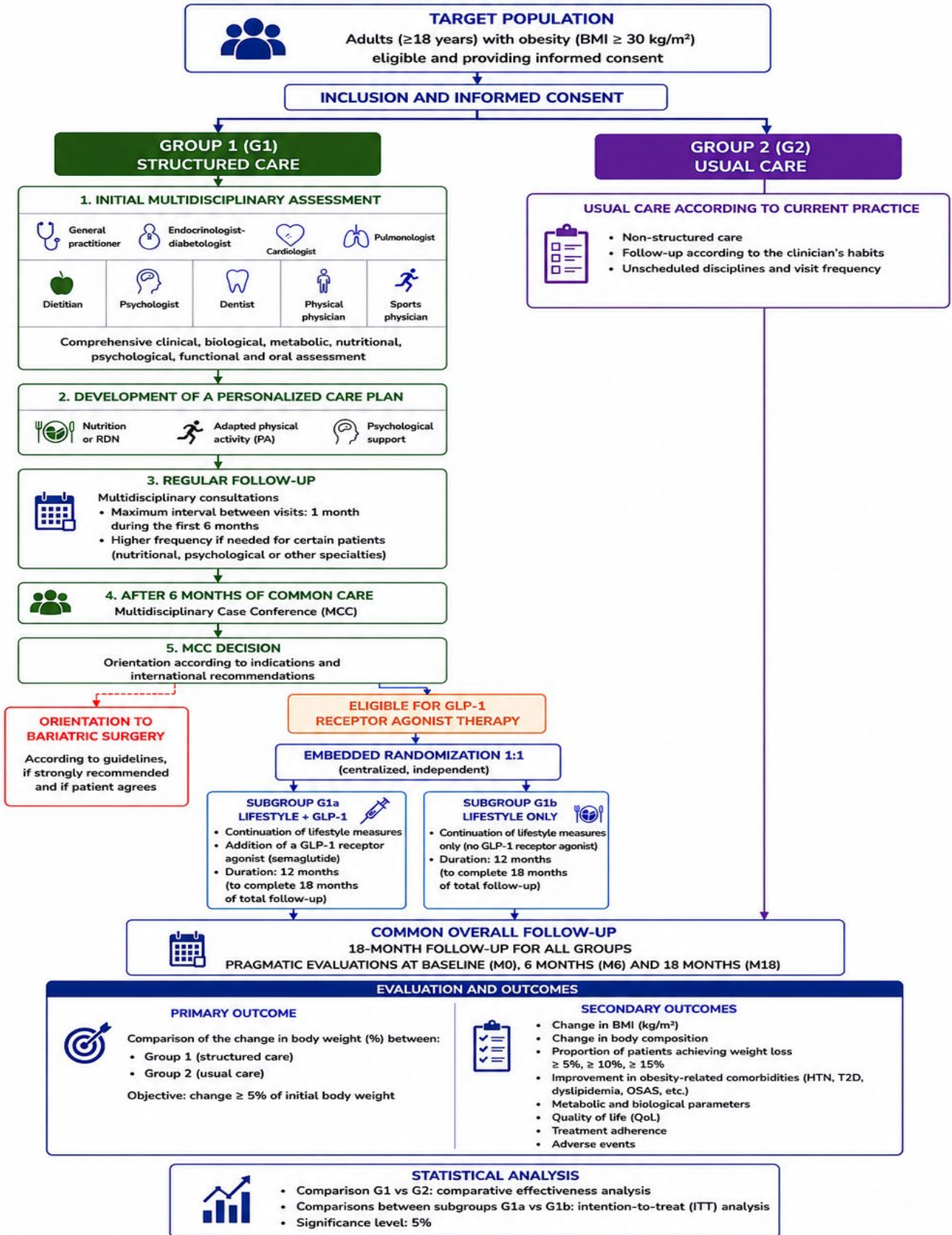


Figure 1: Flowchart of the OBESIAL Project

Statistical Analysis and Data Management

Objectives of the Analysis

The statistical analysis aims to evaluate, at 18 months, the effect of exposure to the structured care pathway on weight loss (primary objective) and to explore secondary effects on body composition, metabolic parameters, and response to GLP-1 receptor agonist therapy.

Statistical Analysis Plan

Statistical analyses will follow a predefined plan adapted to the prospective and pragmatic design of the study, including the nested randomized controlled trial.

Baseline participant characteristics will be summarised using descriptive statistics.

The primary outcome will be compared between the structured care group (G1) and the non-structured care group (G2) using logistic regression models, with adjustment for baseline age, sex, body mass index (BMI), and obesity-related comorbidities.

Longitudinal changes in weight, metabolic parameters, and body composition over the study period will be analysed using mixed-effects models for repeated measures.

The nested randomised comparison between G1a and G1b will be analysed according to the intention-to-treat principle.

Subgroup analyses will be performed among participants managed without pharmacological treatment to evaluate the independent effect of the structured care pathway.

Statistical significance will be set at $p < 0.05$. Statistical analyses will be performed using R software (version 4.5.2).

Data Collection and Management

Data will be collected prospectively using standardised case report forms specifically developed for the OBESIAL protocol and applied uniformly at each scheduled visit (baseline and months 3, 6, 9, 12, 15, and 18).

Collected data will include:

- Anthropometric measurements
- Clinical and metabolic parameters
- Nutritional and behavioural data
- Adherence indicators and follow-up measures related to the structured care pathway

Each case report form will be completed by healthcare professionals according to their field of expertise. Data consistency and completeness will be reviewed during multidisciplinary meetings. Standardised procedures will be applied at each visit to ensure longitudinal comparability of measurements.

For participants not receiving regular scheduled follow-up, data collection will be limited to two assessment points (baseline and month 18), in accordance with the study protocol. This organisation will be considered in the statistical analysis plan.

Data Analysis

1 - Descriptive Analysis

- Qualitative variables will be described using frequencies and percentages.
- Quantitative variables will be summarised using means, 95% confidence intervals, standard deviations, and medians, as appropriate.

2 - Univariate Analysis

Associations between variables will be explored using appropriate statistical tests:

- Pearson's chi-square test for comparison of proportions.
- Student's t-test for comparison of two means.
- Analysis of variance (ANOVA) for comparison of multiple means.

Results not reaching statistical significance will be considered non-significant (NS).

3 - Multivariable Analysis Using Logistic Regression

Multivariable logistic regression models will be used to identify factors independently associated with clinically meaningful weight loss and treatment response while controlling for potential confounding variables.

Missing Data Management

Missing data, expected mainly because of loss to follow-up or incomplete measurements, will be handled using multiple imputation by chained equations (MICE), incorporating sociodemographic, clinical, and follow-up variables into the imputation model. The primary analysis will follow the intention-to-treat principle, with missing outcome data handled under the missing-at-random (MAR) assumption.

Variables considered not applicable, particularly sex-specific variables, will not be imputed and will either be analysed within relevant subgroups or coded as "not applicable".

A complete-case analysis will be performed as a sensitivity analysis to assess the robustness of findings by comparing results obtained after multiple imputation with those derived from complete cases only.

Nested Randomization

At six months of follow-up, eligible participants requiring pharmacological treatment will undergo a centralised and independent 1:1 randomisation procedure comparing lifestyle intervention combined with GLP-1 receptor agonist therapy versus lifestyle intervention alone.

Safety, Anonymisation and Quality Control

Paper case report forms will be stored in secured archives within the department in accordance with confidentiality and personal data protection regulations. Each participant will be assigned a pseudonymised identification code for scientific data processing.

Data entry will be performed by trained personnel under the supervision of the methodological and statistical team following standardised procedures adapted to the local context.

Periodic internal quality checks will be conducted to ensure the completeness, consistency, and plausibility of collected data. These procedures will include the identification of outliers, duplicate entries, and missing data to support data reliability and integrity. Any discrepancies identified will be resolved through verification against source documents.

Planned Analyses

The primary analysis will assess the proportion of participants achieving clinically significant weight loss ($\geq 5\%$ of initial body weight) at 18 months.

Within the nested randomized trial, comparisons between G1a (lifestyle intervention plus GLP-1 receptor agonist therapy) and G1b (lifestyle intervention alone) will explore additional weight-loss thresholds ($\geq 10\%$ and $\geq 15\%$) to assess major therapeutic responses.

Additional exploratory analyses will assess determinants of adherence and changes in obesity-related metabolic outcomes, including glycaemic and lipid parameters.

Ethical Considerations

The OBESIAL protocol has been approved by the appropriate ethics committee. The study will be conducted in accordance with the principles of the Declaration of Helsinki and applicable national regulations. Written informed consent will be obtained from all participants before enrolment.

Randomisation of participants eligible for GLP-1 receptor agonist therapy at 6 months is performed for research purposes without withholding recognised standards of care. Therapeutic decisions will take into account medical indications, contraindications, and participants' informed preferences.

Confidentiality and protection of personal data will be strictly maintained.

Study Limitations

- The study is conducted within healthcare structures operating at a comparable level of care, which may limit the generalisability of findings to other organisational settings or healthcare systems. However, participant recruitment includes individuals from different regions across the country, increasing the heterogeneity of clinical profiles and strengthening the relevance of the identified operational criteria.
- Baseline and follow-up assessments differ between groups according to their real-world care pathway in order to avoid contamination between interventions and preserve the pragmatic nature of the study.
- Although the study includes a randomised component for the evaluation of GLP-1 receptor agonist therapy, it retains a pragmatic design reflecting routine clinical practice. Variability in access to GLP-1 receptor agonists and the duration of follow-up may limit the assessment of very long-term outcomes. Nevertheless, this variability also represents a strength by enabling evaluation of the feasibility, acceptability, and effectiveness of the model within the real-world Algerian healthcare setting.

Expected Outcomes and Future Perspectives

The OBESIAL study aims to demonstrate the feasibility and evaluate the clinical, metabolic, and organisational effectiveness of a structured multidisciplinary obesity care model in Algeria. It is expected to identify treatment response profiles, develop and validate a predictive score for response to GLP-1 receptor agonists under real-world conditions, and define operational criteria adapted to the national context.

As an exploratory component, the protocol includes the possibility of conducting proteomic analyses on collected biological samples to identify potential biomarkers associated with therapeutic response and improve understanding of the pathophysiological mechanisms underlying obesity.

The findings are expected to contribute to the optimisation of multidisciplinary care pathways and the development of personalised obesity management strategies adapted to the national context and potentially relevant at a regional level.

Conclusion

This prospective study conducted under real-world clinical conditions will provide original data on the clinical, metabolic, and organisational impact of a structured multidisciplinary obesity care pathway for adults in Algeria. By combining a pragmatic design with a targeted nested randomization for the evaluation of GLP-1 receptor agonist therapy, the OBESIAL protocol aims to generate findings that are directly applicable to routine clinical practice.

The results of this study may contribute to the development of recommendations adapted to both national and broader African contexts, supporting the optimisation of obesity care pathways and the implementation of personalised management strategies. Although conducted in Algeria, OBESIAL may also provide valuable insights for other African healthcare systems seeking to establish structured, multidisciplinary, and pragmatic models of obesity care.

The potential integration of proteomic analyses may further improve understanding of underlying pathophysiological mechanisms and facilitate the identification of biomarkers associated with therapeutic response, thereby strengthening the scientific and translational value of the study.

Ethics and Dissemination

Approval from research ethics committee

This study has been reviewed and approved by the appropriate national institutional ethics committee in Algeria (December 16, 2025; **Ref 11/AG/2025**) prior to participant enrolment (refer to appendix 1). The study will be conducted in accordance with the Declaration of Helsinki and applicable national regulations governing biomedical research involving human participants.

No independent data monitoring committee will be established because of the pragmatic nature of the study, the well-established safety profile of the intervention, and the moderate sample size. Safety monitoring will be performed throughout the study by the principal investigator in collaboration with the multidisciplinary clinical team.

Protocol amendments

Any substantial modifications to the study protocol, including changes to eligibility criteria, outcomes, or analyses, will be submitted for approval to the ethics committee before implementation. All protocol amendments will be documented and reported transparently in the final publication.

Informed consent

Written informed consent will be obtained from all participants prior to inclusion in the study. Participants will receive detailed information regarding the study objectives, procedures, potential benefits, and possible risks. They will be informed of their right to withdraw from the study at any time without affecting their standard medical care (refer to appendix 2).

Confidentiality and data protection

All participant data will be handled in strict confidentiality. Personal identifiers will be removed and replaced with unique study codes. Data will be stored securely with restricted access limited to authorized study personnel only. Electronic data will be password-protected, and any hard copies will be stored in locked cabinets within the research facility.

Declaration of conflicts of interest

All investigators will declare any potential conflicts of interest prior to study initiation. Any financial or non-financial relationships that could influence the interpretation of the study results will be transparently disclosed in the final manuscript.

Access to data

Access to the final dataset will be restricted to the principal investigator and designated members of the research team.

Dissemination policy

The results of the OBESIAL study will be disseminated through peer-reviewed scientific publications and presentations at national and international conferences. Summarized results may also be communicated to participating healthcare professionals and, where appropriate, to participants in a comprehensible format.

Contributors/Author contribution

Mounira Chanegriha conceived the study and is the principal investigator. She led the overall study design, defined the scientific objectives and methodology, coordinated the implementation of the project, and supervised all stages of the study. She drafted the initial version of the protocol and critically revised the manuscript.

Abdelkader Yah, Nardjess Laoufi, Housseem Baghous, Mustapha Hanba and Akli Taazibt are direct contributors to the project. They are involved in the practical implementation of the study, including participant recruitment, data collection, follow-up procedures, and delivery of the intervention. They contributed to data interpretation and critically reviewed the protocol.

All authors critically reviewed the manuscript and approved the version submitted for publication.

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This research did not receive any external funding. The study is supported by institutional resources only. No industrial sponsorship was involved.

Competing interest

The authors declare no competing interests.

Trial registration

Registration on ClinicalTrials.gov is planned prior to participant enrolment.

Data availability statement

No datasets have been generated or analysed at this protocol stage. Following study completion, anonymised datasets may be made available from the corresponding author upon reasonable request and in accordance with institutional regulations and ethical requirements.

Appendices

1. Appendix 1. Case Report Form for Participants in the Structured Care Group (G1)
2. Appendix 2. Case Report Form for Participants in the Non-Structured Care Group (G2)

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