Retrospective study of the effects of the longevity diet and the fasting-mimicking diet on body composition, risk factors for age-related diseases



Thank you for reaching out to **Valter Longo Foundation**, and the affiliated specialty clinic with an expert dietary and scientific team specializes in cutting edge science-based nutrition and fasting protocols to prevent and manage major chronic diseases such as Cancer, Heart, Neurodegenerative and Autoimmune Diseases, Diabetes, and extend healthy longevity.

Our clinic offers appointments, which involve providing nutritional counseling and Individualized Nutritional Protocols based on evidence-based study. These appointments are with our Registered Dietitians and Molecular Biologist. Each individual patient case is different, and therefore, cases can be reviewed and discussed by the Dietitian and Biologist in consultation.

The information needed to set up an initial consult is provided to us by you, via the attached forms. Feel free to add any additional information you feel is relevant to you, including medical history or recent lab work or consultation notes.

Once we receive these forms, we can move forward in setting up an appointment.

Please complete the forms attached, and email back to: nutrizionisti@fondazionevalterlongo.org

Thank you, and do not hesitate to reach out if you have any questions!

Valter Longo Foundation

www.fondazionevalterlongo.org nutrizionisti@fondazionevalterlongo.org

We welcome you and look forward to meeting you soon!



Treatment Contract - Policies and Limitations

The Fondazione Valter Longo (<FVL=) provider-patient relationship is extremely important to us, and communication is critical to maintaining this relationship in good standing. This Agreement explains howwe will work together. This Agreement is made between FVL and you (<you= or <Patient=).

FVL through its Registered Dietitians and Molecular Biologists offers nutrition guidance and recommendations for lifestyle management nutrition guidance of disease in exchange for certain fees paid by you according to the terms and conditions described below and pursuant to article. 3 of the italianlaw n. 396/1967, and This assignment begins from the signing of this form and is intended as conferred until the end of the professional service requested.

AGREEMENT

PATIENT: As used in this Agreement, the term Patient means a person for whom Fondazione Valter Longo (FVL) will provide services. FVL reserves the right to accept or decline patients based upon provider9 capability to appropriately manage the lifestyle medicine needs of its patients.

CONSULTATION SERVICES: FVL will see you for consultation with recommendations for nutrition and lifestyle management (diet, nutrition, physical activity, stress management, and sleep) of your conditions. All patients must have a Primary Care Provider who is the primary physician managing their care and with whom FVL9s provider can communicate and coordinate care.

Patients must share and discuss the recommendations for lifestyle management (diet, fasting, nutrition, mimicking fasting, physician activity, stress management, and sleep) received from anyhealthcare provider at Fondazione Valter Longo with their personal doctors and/or primary physician and/or specialist that are managing their care prior to moving forward with recommendations/direction. Prior to moving forward with any recommendations/direction received from any healthcare provider at Fondazione Valter Longo. patients must obtain the approval of their Primary Care Provider and/or Specialist (if applicable) managing their care. Patients hereby acknowledge they will not hold the Foundation, its clinic, employees or healthcare providers (<HCP=s) responsible if they do not follow the instructions as stated in this Agreement and/or move forward without their Primary Care Provider and/or Specialist approval.

EXCLUDED SERVICES: Our HCPs or providers are not Primary Care Providers (PCP) and do not provide primary care services. We do not accept responsibility for ongoing management of your entire care, writing/refilling prescriptions medications, nor providing urgent care services. Our meeting is a consultation and does not constitute an agreement on FVL9s part to treatment or ongoing treatment.

FONDAZIONE VALTER LONGO ONLUS ò C.F 95196780100 ò P.IVA 025666109990 ò IBAN: IT29V0538731870000047148247 ò SEDE LEGALE: VIA BORGOGNA, 9, 20122, MILANO, ITALY ò <u>INFO@FONDAZIONEVALTERLONGO.ORG</u> ò WWW.FONDAZIONEVALTERLONGO.ORG



AVAILABILITY: Our services, including lifestyle medicine or lifestyle management, do not include, and should not be considered to include, emergecy or urgent medical or psychiatric care. For medical or psychiatric emergencies, you must call an emergency or urgent care provider. For urgent medical problems you must seek care from your primary care physician, an urgent care clinic, or emergency department setting. We will make every effort to address your lifestyle medicine or lifestyle management concerns. Please allow 5-7 working days for us to respond to your questions.

HEALTHCARE PROVIDER REFERRAL NOTE:

In order for us to work directly with you, we would prefer to receive from your current healthcare provider (either your primary care physician, oncologist, endocrinologist, or other core healthcare provider) a referral note or prescription form prior to your initial appointment for nutrition guidance.

CONFIDENTIALITY: FVL keeps records of appointments and the content of the appointments. They arein a secure electronic medical record system. Information you disclose will be kept confidential, unless you specifically authorize its release or unless the disclosure or release is permitted or required under State or Federal applicable law or regulation or professional standards of practice or conduct. Specifically, your right to confidentiality may not be maintained if there is reasonable concern of: 1) abuseor neglect of a child, dependent or elder adult, 2) danger of harm to yourself or to others, 3) grave disability (i.e., inability to care for yourself), 4) as required by law or regulation, or 5) pursuant to legal proceedings.



Your Privacy Rights.

FVL will adhere to its obligations regarding your privacy rights as identified in FVL9sPrivacy Disclaimer. **Please make sure to read the FVL Privacy Disclaimer carefully** to understand your privacy rights, our obligations related to your privacy, and the circumstances when we may be permitted or required to share, use, disclose, or release your information.

PHI Release Authorization:

I, _______(patient's name) authorize FVL to disclose or release my protected health information, including my medical information, lab tests and results, and medical chartsand records to Professor Valter Longo Ph.D. and Nutritional Biologist Romina Cervigni Ph.D. for purposes of review of such information and consultation with FVL or Create Cures Foundation and its health care providers regarding my treatment or plan of care.

Signature____

Date _____

METHODS OF COMMUNICATION: You acknowledge that FVL communications may include email, fax, mobile application (<app=), telemedicine, telehealth, text messaging, telephone, and cell phone, and suchcommunications by their nature cannot be guaranteed to be secure or confidential. If you initiate a conversation in which you disclose personal information or protected health information, then you authorize the practice, FVL, to communicate with you regarding the information or PHI in thesame manner or format. Please be aware that transmitting confidential health information by email or text has a number of risks and we advise use of the Patient Portal provided as much as possible. We cannot guarantee the security or confidential information not caused by gross negligence or wanton misconduct on the part of FVL, or breaches of confidentiality caused by the patient. Your signature below signifies your acceptance of these terms.

INSURANCE/BILLING/CO-PAYS: You are responsible for knowing your insurance benefits. Nutrition consultation and follow-ups, and some treatments/procedures/labs may not be covered by healthinsurance plans. Covered procedures vary with each insurance company. If you have a specific concern regarding your coverage, contacting your insurance company is the most assured way of checking coverage information.

Patient is responsible for payment in full of all amounts billed by FVL for or related to its services provided Patient. Patient will be responsible for any amount not paid by his eventual insurance.

FONDAZIONE VALTER LONGO ONLUS ò C.F 95196780100 ò P.IVA 025666109990 ò IBAN: IT29V0538731870000047148247 ò SEDE LEGALE: VIA BORGOGNA, 9, 20122, MILANO, ITALY ò <u>INFO@FONDAZIONEVALTERLONGO.ORG</u> ò WWW.FONDAZIONEVALTERLONGO.ORG



CANCELLATION POLICY: We understand that emergencies arise, however, appointments are pre- arranged, and it is patient9s responsibility to keep or cancel your appointment with a minimum of 48 hours9 notice in advance. You will be charged for appointments which are not cancelled within this timeframe.

VITAMINS and SUPPLEMENTS: Because some nutrients and vitamins should not be taken without continued monitoring, and new research is occurring in this field every day, supplement and vitamin recommendations shall expire 6 months from the initial recommendation unless otherwise discussed.

PATIENT ARBITRATION CLAUSE:

It is understood that any dispute as to medical malpractice, that is as to whether any medical services rendered under this contract were unnecessary or unauthorized or were improperly, negligently or incompetently rendered, will be determined by submission to arbitration in Italy as provided by Italian law, and not by a lawsuit or resort to court process except as Italian law provides for judicial review of arbitration proceedings. Both parties to this contract, by entering into it, are giving up their constitutional right to have any such dispute decided in a court of law before a jury, and instead are accepting the use of arbitration.

Our goal is to provide medical care to our patients in a way that will avoid disputes. We know that most problems occur as a result of miscommunication. If you have concerns about your care, please discuss them with us.

Please understand that by agreeing to the arbitration clause you are specifically giving up your right to litigate any Dispute in court along with the right to have your case or Dispute tried before a jury.

NOTICE: BY SIGNING THIS CONTRACT YOU ARE AGREEING TO HAVE ANY ISSUE OF MEDICALMALPRACTICE DECIDED BY NEUTRAL ARBITRATION IN ITALY AND YOU ARE GIVING UP YOURRIGHT TO A JURY OR COURT TRIAL.

I,_____(patient name) have read, review and

understand the foregoing Patient Arbitration Clause and I hereby agree that all Disputes between me andFVL shall be decided by binding arbitration according to the terms of the Italian law. I specifically agreethat all Disputes as well as all gateway issues, including without limitation any issue related to whether any Dispute must be arbitrated, shall be delegated exclusively to, and decided exclusively by, the arbitrator in binding arbitration.

Signature_

Date ____

FONDAZIONE VALTER LONGO ONLUS ò C.F 95196780100 ò P.IVA 025666109990 ò IBAN: IT29V0538731870000047148247 ò SEDE LEGALE: VIA BORGOGNA, 9, 20122, MILANO, ITALY ò <u>INFO@FONDAZIONEVALTERLONGO.ORG</u> ò WWW.FONDAZIONEVALTERLONGO.ORG



TERMINATION: Both you and FVL shall have the absolute and unconditional right to terminate the Agreement, without cause. Notwithstanding any other provision of this Agreement, if your decision to terminate this agreement, or take other action related to FVL or its provider, is based on a grievance withone or more of our providers, you will give them an opportunity (not less than 15 days from the date younotify FVL or the provider of your grievance) to make it right, to cure the issue or problem giving rise to your grievance. If FVL or the provider is unable to cure or otherwise resolve your grievance, you may terminate this agreement by providing written notice of termination or intent to take other action. If FVL elects to terminate this Agreement, FVL will provide you thirty (30) days written notice, and you should follow-up with your Primary Care Provider.

FVL has a right to determine whom to accept as a patient, just as you have the right to choose your physician. There are certain circumstances in which FVL may choose to terminate this Agreement. Such circumstances may include, but are not limited to the following: (1) You fail to pay fees and charges whenthey are due, (2) You fail to sign the arbitration agreement, (3) You have performed an act that constitutesfraud, (4) You fail to adhere to the recommended treatment plan, (5) You are disruptive, abusive, or present an emotional or physical danger to the staff or other patients of FVL.

NON-DISCRIMINATION: FVL and its providers will not discriminate against you, or terminate this Agreement, on the basis of sex, race, color, religion, ancestry, national origin, disability, medicalcondition, genetic information, marital status, sexual orientation, citizenship, primary language, immigration status, or any other protected status.

NO WAIVER: No waiver of a breach of any provision of this Agreement will be construed to be a waiver of this Agreement or any right of the non-breaching party under this Agreement, whether of a similar or different nature, and no delay in acting with regard to a breach shall be construed as a waiver of that breach or any right of the non-breaching party under this Agreement.

LIMITS OF SERVICE: We do not provide primary care, psychiatric, emergency or urgent care, disability or workers compensation evaluations and treatments. If you have not received services from our office for a continual period of 12 months, and you request to start services again, you will be considered a newpatient.

MISCELLANEOUS: This Agreement shall be governed by, and construed in accordance with, the laws of the Italy, and to the extent not preempted, the substantive laws of Italy. Should any provision of this Agreement be declared or determined to be invalid or illegal, the validity of the remaining provisions shall not be affected, and the invalid or illegal provision shall be deemed not to be a part of this Agreement and will be governed in accordance with the Italian laws. This document contains the entire agreement between the parties with respect to the subject matter of this Agreement. Any failure to enforce any provision of this Agreement will not constitute a waiver of thatprovision or of any other provision. This Agreement may not be amended, nor any obligation waived, except by a writing signed by both parties.



CONSENT TO TREAT

| l, | in | (p | atient name) born |
|----|------|------|-------------------|
| in | IN | , on | located |
| | , at | | , with have |

readand understand the foregoing and consent to evaluation and treatment

Name (Print)_____

| Signature | |
|-----------|--|
| | |
| - | |

Date _____



PRIVACY DISCLAIMER

[ART. 12, REG. (UE) 679/2106]

Dear Sir or Madam,

we invite you to carefully read the contents of the present privacy disclaimer, prepared by FONDAZIONE VALTER LONGO ONLUS with the purpose of describing use, disclose, or release of your medical information or protected health information and how you can get access to this information and with respect to the Regulation (EU) 2016/679. Please review it carefully.

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CONTROLLER

FONDAZIONE VALTER LONGO ONLUS VAT 02566610990 Registered Office: Via Borgogna, 9 - Milano Privacy Office: Via Belgirate, 15 - Milano privacy@fondazionevalterlongo.org

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3

DATA PROCESSED

DATA PROVIDED

In order to process your health information, medical records and results to Fondazione Valter Longo Onlus (hereinafter <Company=), we will ask you to submit some information.

In particular, you may be asked to provide the following information (the following list is not comprehensive but is indicated merely as an example): your name and surname, your contact information (such as address, telephone number, email), data relating to the chosen payment method.

Granting such information together is required in order to process the professional service requested to the Foundation; the failure to communicate such data may determine the impossibility to proceed.

PARTICULAR CATEGORIES OF PERSONAL DATA

The Company generally avoids to collect and process particular categories of personal data. Among those categories are included data that reveal your ethnic or racial origin, your political position, your religious or philosophical convictions, or your trade union affiliation or genetic data, biometric data aimed to identify uniquely a natural person, data on wealth or sexual life or sexual orientation of the person.

Whenever, in specific cases, the Company should collect or anyway process particular categories of personal data, in order to achieve the purposes mentioned below, we will always process such data in accordance with dispositions of law and with the requirements as indicated in the present privacy disclaimer.

The Company will process your data pursuant to Articles 6 and 9 of the Regulation (EU) 679/2016 and on the basis of the consent under Article 7:



LEGAL BASIS FOR THE PROCESSING

- a. CONSENT [art. 6, (1)(a), art. 7, and, if applicable, art. 9, (2)(a)] the Company will process certain data solely upon your prior, free and express consent. You'll have the faculty to withdraw your consent at any time with effect for the future.
- b. PROCESS YOUR SERVICE [art. 6, (1) (b)] in order to process the professional service with the Company, we need to have access to certain data.
- c. PROTECTION OF LEGITIMATE INTERESTS PURSUED [art. 6, (1)(f)] the Company will process certain data in order to protect its interests or third parties interests. Such principle, however, shall be applied except where such interests are overridden by your interests.

The Company will process your data only for the purposes permitted by the law.

This regards the following purposes: (i) purposes prior approved by you; (ii) data processing in order to process your donation; (iii) fulfillment of legal duties to which we are subject (included requirements set forth by the relevant Authorities); (iv) protection of our legitimate interests or of third parties legitimate interests, except where such interests are overridden by your interests; (v) exercise of our rights and fulfillment of our duties under social safety and protection laws; (vi) establishment, exercise or defence of a legal right or claim; (vii) for relevant public interest reasons.

Among the others, we will process your data for the specific purposes as listed below. Please take note that this is not a comprehensive list of any single purpose, but merely an exemplification aimed to explain the aforementioned purposes.

 $\underline{41}$ purposes of processing related to the work relationship with the $\underline{\text{company}}$

a. MAIN PURPOSE. The main purpose of processing your data regards the processing of your donation to the Company, made through our website.

4.2 PURPOSES OF PROCESSING IN ORDER TO RESPECT LEGAL REQUIREMENTS.

The Company is subject to several legal requirements. If necessary, your data will be processed to guarantee the compliance with those requirements.

- a. DATA SAFETY. Data safety represents a relevant legal requirement. If necessary, we will process also your data in the context of the essential measures to evaluate and guarantee data safety.
- b. INTERNAL COMPLIANCE MANAGEMENT. Within the context of compliance management (intended as the respect of any rule and disposition of law) we will evaluate - for example - if you had received appropriate advices when you requested the services and if our personnel had behaved properly and accordingly to law requirements.
- c. LEGAL REQUIREMENTS. The Company is subject to several legal requirements. We will process your data as needed to the extent to be respectful of such requirements and we could forward your data to the competent Authorities, if set forth by communication law requirements. We could also process your data in case of law suit, if required.

4

PURPOSES OF DATA PROCESSING



The Company - Pursuant to art. 5, co. 1, lett. e) of Regulation (EU) 679/2016 - will store your data only for the period of time needed to processing the data for purposes for which they are processed.

In the event that the data are processed for different purposes, the same data will be automatically erased or saved in a format that doesn⁹t allow to reach a straight conclusion on your identity, as soon as the last specific purpose will be complied.

For a correct data erasing under Regulation (EU) 679/2016, the Company implements a storage policy of your data in accordance with what provided for the storage requirements of documents for fiscal purposes and with respect to the general rules on limitation period of the contractual claims. Therefore, the Company will delete data concerning the services provided upon expiry of a ten years period as sets forth by the law.

Your persona data - in general - will remain under the Company, but could be communicated, even without your consent, to supervisory bodies, law enforcement or judiciary, Ministry of Finance, Revenue Agency, ministerial bodies and competent Authorities, Local bodies, regional and provincial tax commissions, at their express request that will treat them as independent data controllers for institutional purposes and / or by law during investigations and controls.

Your data may also be communicated to third parties (for example, partners, freelancers etc.), as independent data controllers, for the performance of activities instrumental to the aforementioned purposes.

6

DATA SHARING

In your quality of data subject, you shall exercise certain rights toward us as provided by Regulation EU 679/2016 and other applicable rules concerning data protection.

The present § 7 contains clarification regarding your rights as data subject under Regulation EU 679/2016.

In particular:

7.1 DATA SUBJECT RIGHTS.

In your quality of data subject, you have the following right toward the Company:

- a. <u>RIGHT OF ACCESS</u>. At any time you can ask to have information about your data as stored by us. Such information regards, among the others, the categories of data processed, the purposes of processing, the origin of the data in case we didn9t obtained such data directly from you, as well as the recipients to who we may have transferred your data, if applicable. You could obtain a free copy of your data. If you wish to have further copies, the Company reserves the right to ask a remuneration for them.
- b. <u>RIGHT OF RECTIFICATION</u>. At any time you can ask a rectification of your data. As a consequence, the Company will adopt appropriate actions to make your data as stored and processed by us on an ongoing basis to be kept correct, complete, updated and pertinent, on the basis of the most updated data granted.

5

STORAGE PERIOD OF YOUR DATA

7

DATA SUBJECT RIGHTS



- c. <u>RIGHT TO ERASURE</u>. At any time you can ask the erasure of your data, subject to conditions as provided by the law. For example, that could happen as set forth in Article 17 of Regulation EU n. 679/2016:
 - if your data are no longer necessary in relation to the purposes for which they were collected or otherwise processed;
 - if you withdraw consent on which the processing is based and there is no other legal ground for the processing;
 - if you object to the processing and there are no overriding legitimate grounds for the processing;
 - if your personal data have been unlawfully processed, unless the processing is necessary: (i) for the fulfilment of a legal requirement that pretends the processing of your data; in particular for what it regards the period of storage of the documents as set forth by the law; (ii) for the establishment, exercise or the defence of a legal right or claim.
- d. <u>RIGHT TO RESTRICTION OF PROCESSING</u>. At any time you can obtain a restriction of processing your data if:
 - you contest the accuracy of the personal data, for a period enabling us to verify the accuracy of the personal data;
 - the processing is unlawful and you oppose to the erasure of the personal data and request the restriction of their use instead;
 - we no longer need the personal data for the purposes of the processing, but they are required by you for the establishment, exercise or defence of legal claims;
 - you have objected to processing pending the verification whether the legitimate grounds of the controller override those of the data subject.
- e. <u>RIGHT TO DATA PORTABILITY</u>. At any time you have the right to receive a copy of your data as they have been prior provided directly to the Company on your explicit request, we will transfer your data if it is technically workable to another controller.
- f. <u>RIGHT TO OBJECT</u>. At any time you can object, on grounds relating to your particular situation, to the processing of your data pursuant to point e) or f) of Article 6, (1) of Regulation EU n. 679/2016, or whenever personal data are processed for direct marketing purposes. In such case, we will no longer process your data. This last condition is not applicable if we can demonstrate that compelling legitimate grounds for the processing which override your interests, rights and freedoms or for the establishment, exercise or defence of legal claims.
- g. <u>RIGHT TO OBTAIN A COPY OF THE SAFEGUARDS</u>. At any time you can obtain a copy of the appropriate safeguards implemented for what it regards the data transfer toward third countries, if applicable.
- h. <u>RIGHT TO WITHDRAW THE CONSENT AT ANY TIME</u>. At any time you can withdraw the consent, if the processing is based on your consent, without prejudice to lawfulness of the processing based on the consent granted prior to the withdrawal, by sending a request to the address afore indicated (see § 1) or otherwise with technical procedures made available by the Company for the relevant processing.



| 7.2 TERMS OF FULFILMENT. |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Company always tries its best to manage the request within a 30 (thirty) days period. Nevertheless, such period could be extended for reasons related to the specific right of the data subject or to the complexity of his request. |
| 7.3 RESTRICTION RELATING TO THE COMMUNICATION OF INFORMATION PENDING THE FULFILLING OF REQUIREMENTS PERTAINING RIGHTS OF THE DATA SUBJECTS. |
| In certain situations, we may not be able to provide you with the information about your data due to legal provisions. In case we shall be obliged to decline your request of information, we will explain the reasons for our denial. |
| 7.4 claims to authority. |
| In case you won9t consider exhaustive the feedback provided by the Company to your requests and/or notifications, you have the right to notify a claim to the competent authority with regard to data protection, pursuant to Article 77 of Regulation EU n. 679/2016. |

| Name: | | _ | |
|------------|------|-------|--|
| | | | |
| Tax Code | | | |
| Address: | City | State | |
| Telephone: | | | |
| Email: | | | |
| | | | |

Date: _____

Signature: _____

If not signed by the patient, please indicate relationship to the patient (check one, if applicable):

____Parent or guardian of minor patient who could not have consented to health care.

____Guardian or conservator of an incompetent patient.

____Beneficiary or personal representative of deceased patient.

Retrospective Clinical Study on the Effects of the Longevity Diet and Fasting-Mimicking Diet on Body Composition, Age-Related Disease Risk Factors, and Aging Markers.

1. Introduction

Aging is often accompanied by numerous chronic degenerative conditions that compromise the quality of life and lead to dependency. However, a favorable interaction between genetic and environmental factors could lead to a significantly higher life expectancy, free from conditions that significantly compromise both the quality and duration of life, highlighting that increased longevity is not necessarily accompanied by one or more pathological conditions.

It is widely accepted that the quality and quantity of nutrition are essential factors in maintaining health and preventing diseases (1-3). Making healthy and conscious dietary choices can indeed alter the course of life in terms of both duration and health.

Numerous epidemiological studies have demonstrated the critical role of a proper dietary regimen in the risk of developing age-related diseases (4). Furthermore, recent studies have highlighted how short periods of extreme calorie reduction with adequate nutrient intake (5 days, fasting-mimicking diet, FMD) can impact metabolism, producing numerous beneficial effects in both healthy individuals and those with chronic degenerative conditions such as cancer, cardiovascular diseases, diabetes, and autoimmune diseases (5-7). Theories about senescence usually focus on the aging process and not on the ability of organisms to stay young. The longevity diet (8) proposed in this study is intended to be effective in achieving the goal of extending youth for as long as possible, optimizing protection, regeneration, and rejuvenation while minimizing diseases. It is based on five pillars that support the scientific evidence of the program: basic research, epidemiology, clinical studies, centenarian studies, and complex systems studies. Essentially, the longevity diet incorporates the dietary tradition of healthy centenarians, characterized by simplicity and products typical of their region of origin.

This type of diet generally consists of three isocaloric meals and one snack (for normal-weight individuals) or slightly hypocaloric meals (in the case of overweight or obesity). The diet consists of 50-60% of calories from complex carbohydrates, 30-35% of calories from mostly unsaturated fats, and 10-11% of calories from proteins, primarily from plant sources and fish, and occasionally from eggs, dairy, and meat, especially for those over 65. The diet is formulated to provide all necessary nutrients, including vitamins and minerals.

The fasting-mimicking diet is a dietary intervention in which normal food is replaced with a standardized, highly hypocaloric vegan diet for a limited period of 5 consecutive days. This diet is designed to stimulate the same processes normally activated during fasting while minimizing the side effects of total food deprivation.

This retrospective clinical study aims to investigate the two different approaches: the longevity diet and the fasting-mimicking diet, to assess both their feasibility and effectiveness when used individually or in combination.

1.1 Background and Hypotheses

The Italian population has moved away from the traditional Mediterranean diet and now predominantly follows a Western-style diet that is hypercaloric, rich in saturated fats, animal protein, and sugars (12). We hypothesize that a return to the original Mediterranean diet with modifications based on the scientific evidence of recent decades (longevity diet), and/or short periods of fasting-mimicking diet (5 days), can improve the overall health conditions of the population (9-11).

2. Objectives and Purpose of the Study

Primary Objective: To evaluate whether the longevity diet and the fasting-mimicking diet, either individually or in combination, can reduce the percentage of body fat in a cohort of subjects stratified by gender, age, body mass index, and defined physio-pathological states.

Secondary Objectives: To assess whether the longevity diet and the fasting-mimicking diet, either individually or in combination, can positively influence parameters related to the general health status of the analyzed sample, including (i) percentage of lean mass, (ii) phase angle as an indirect indicator of muscle function and cellular integrity, (iii) waist and hip circumference, (iv) total cholesterol, HDL, and LDL.

This is a retrospective, observational, single-center study to evaluate the effect of specific nutritional interventions (fasting-mimicking diet (FMD) and longevity diet (LD)) on reducing body fat. To achieve this, retrospective data from bioimpedance, anthropometric, and clinical analyses of subjects who underwent at least one of the two nutritional interventions (individually or in combination) at the Valter Longo Foundation in Milan from 2019 to 2022 will be analyzed. In particular, information from subjects who underwent at least two nutritional visits with bioimpedance analysis with a gap of at least 3 months between them will be considered. The subjects will be characterized based on (i) the type of nutritional intervention (FMD only, LD only, or combinations of LD and FMD); (ii) the duration of the nutritional intervention (short, medium, or long); (iii) the degree of obesity (normal weight, overweight, and obese); and (iv) physio-pathological status.

4. Data Collection and Analysis

Data will be collected retrospectively from the electronic medical records of the Valter Longo Foundation. Bioimpedance analysis, anthropometric measurements, and clinical parameters including lipid profiles will be used to assess changes in body composition, body fat percentage, lean mass percentage, phase angle, waist circumference, hip circumference, and blood lipid levels.

5. Statistical Analysis

Statistical analyses will be performed using appropriate statistical software packages. Descriptive statistics will be used to summarize baseline characteristics, and paired t-tests or non-parametric equivalents will be used to compare pre- and post-intervention measurements. Analysis of variance (ANOVA) will be used to compare outcomes across different subgroups based on type of intervention, duration, degree of obesity, and physio-pathological status. Correlation analyses may also be performed to explore associations between changes in body composition and other variables. A p-value of less than 0.05 will be considered statistically significant.

6. Ethical Considerations

This study will be conducted in accordance with ethical principles and regulations governing clinical research. All data will be de-identified and handled in compliance with data protection regulations. Informed consent will be obtained from all subjects included in the study.

7. Conclusion

This retrospective clinical study aims to investigate the effects of the longevity diet and the fasting-mimicking diet, either individually or in combination, on body composition, age-related disease risk factors, and aging markers. The study will provide valuable insights into the potential benefits of these dietary interventions in promoting health and longevity, which could have significant implications for public health and wellness.