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Home health monitoring and personal lifestyle assistants to improve nutritional habits in adults: the Cook to Health trial, C2H

Evaluation clinique à domicile et utilisation d'outils connectés pour améliorer les habitudes alimentaires : l'essai européen Cook to Health, C2H

Christophe Moinard¹, Marie France Vaillant¹, Mariette Sicard², Paul Dancer², John Draper³, Cristina Andres-Lacueva⁴, Jean-Luc Bosson⁵, Jean Christian Borel⁶, Carole Rolland⁵, Marie Joyeux Faure⁶ Christophe Pison^{1,7}

- 1- Université Grenoble Alpes, Laboratoire de Bioénergétique Fondamentale et Appliquée, LBFA, Inserm1055, Saint Martin d'Hères, France
- 2- Groupe SEB – Headquarters, Ecully, France
- 3- Aberystwyth University, United Kingdom
- 4- Barcelona University, Spain
- 5- Université Grenoble Alpes, TIMC-THEMAS team, CNRS UMR 5525, Université Grenoble Alpes
- 6- IC@dom., Investigation Clinique à domicile, Meylan, France
- 7- CHU Grenoble Alpes, Service Hospitalier Universitaire Pneumologie Physiologie, Pôle Thorax et Vaisseaux, , France

Corresponding author: Pr. Christophe Moinard, Laboratoire de Bioénergétique Fondamentale et Appliquée, LBFA, Inserm1055, Saint Martin d'Hères, France, France. Phone + 33 4 76 51 44 90, christophe.moinard@univ-grenoble-alpes.fr

ABSTRACT

Introduction: Unhealthy lifestyles are major factors contributing to chronic conditions. By proposing suitable menu designs and easy recipes, *Open Food Service* internet app with connected food processors will bring easy solutions to cook and progressively develop healthy dietary habits at home. A randomized controlled trial will test in healthy subjects the ability of connected food processors to modify dietary habits and to improve metabolic homeostasis, assessed with a systems health monitoring, all at home.

Methodology and analysis: This is a prospective, randomized, single blind and 12 month controlled trial in Grenoble and Aberystwyth. Double consent using Zelen method of randomization is used. Healthy volunteers, 25-50 years old, living in a family, be the main person who prepares meals and be able to use the personal health monitoring devices are recruited, 100 in Grenoble and 60 in Aberystwyth. The principal objective is to evaluate the ability of connected cook devices to modify dietary habits measured by a clinically significant increase of 1 quintile in Alternate Healthy Eating Index-2010. Secondary objectives are a) to demonstrate feasibility to collect data and specimen at home over one year; b) to compare changes at 1 year in quality of life, body composition, physical activities, sleep duration, gut microbiote; c) to describe urinary metabolomics patterns that are able to report recent dietary habits.

Elementary descriptive analysis and integration of all data sets vertically and longitudinally and comparisons between groups will be carried out. The 2 studies are conducted separately and analysed in meta-analysis.

Keywords: Connected devices-AHEI 2010- clinical research at home

RESUME

Introduction: Les modes de vie Occidentaux sont des facteurs majeurs contribuant au développement des maladies chroniques. En proposant des menus adaptés et des recettes faciles à réaliser, l'application internet *Open Food Service* et ses outils de cuisine connectés proposent des solutions faciles pour cuisiner et développer progressivement des habitudes alimentaires plus saines à domicile. Un essai contrôlé randomisé testera chez des sujets sains la capacité des outils de cuisine connectés à modifier les habitudes alimentaires et à améliorer l'homéostasie métabolique des volontaires. Par ailleurs, l'ensemble de l'évaluation clinique se fera à domicile.

Méthodologie et analyse : Il s'agit d'un essai, randomisé, en simple aveugle et contrôlé sur 12 mois à Grenoble (n=100), France et Aberystwyth (n=60), Pays de Galles. Le double consentement est utilisé avec la méthode de randomisation de Zelen. Des femmes et des hommes, âgés de 25 à 50 ans, sans médication chroniques vivant en famille, et étant la principale personne à préparer les repas. L'objectif principal est d'évaluer la capacité des appareils de cuisine connectés à modifier les habitudes alimentaires mesurées par une augmentation cliniquement significative d'un quintile de *l'Alternate Healthy Eating Index-2010*. Les objectifs secondaires sont a) de démontrer la faisabilité de la collecte de données et d'échantillons à domicile pendant un an; b) de comparer les changements à un an dans la qualité de vie, la composition corporelle, les activités physiques, la durée du sommeil, le microbiote intestinale; c) de décrire des signatures métabolomiques urinaires qui seraient capables de prédire les habitudes alimentaires récentes.

Mots clés : outils connectés - AHEI 2010-Recherche Clinique à domicile

INTRODUCTION

Today, medicine mainly curative and reactive is primarily interested in sick people. Now, with our aging Western populations, we face a strong increase in chronic diseases incidence and prevalence that have a financial cost that becomes unbearable, for example, in France up to 11.3% of 2018 gross domestic product, *i.e.* 208 billion euros [1]. Immediate and decisive action is required to reverse these trends to avoid a collapse. The paradigm shift would be to move from a reactive to a proactive medicine that promote healthy life style to decrease incidence of chronic conditions through P4 Medicine that is Preventive, Participative, Predictive and Personalized [2–4].

However, unhealthy lifestyles are major factors contributing to chronic conditions that impose a huge financial burden in EU healthcare systems [5]. Insufficient daily physical activity, inadequate sleep duration [6] and poor diet [7] beside smoking and alcohol consumption are significant risk factors for cancers, cardiovascular, chest, metabolic disorders and leading causes of morbidity and premature mortality [8,9]. Epidemiological and clinical studies indicate that different conditions be prevented and sometimes reversed through adaptation of healthy habits [8,10–12]. Unfortunately, communication of Public Health failed to influence consumer to change their habits.

Hence, it is recognized as a gold standard that better nutrition will reduce the risk of chronic diseases which impact heavily on health spending [13]. Unfortunately, free-living individuals are often poor at judging the healthiness of their own diet (choice of meal constituents, cooking methods, portion sizes pattern of eating). Moreover, there is a lack of awareness of the contextual features influencing eating behavior and even where there is motivation to change, people have difficulty translating good intentions into healthy behaviors. Hence, their day-to-day constraints (lack of time, lack of knowledge, constraining family and cultural habits, personal tastes) make it difficult for them to comply and adopt the nationally recommended healthy lifestyles.

By proposing suitable menu designs and easy recipes for the whole meal and all the family, Open Food System (OFS) Internet apps will bring easy solutions to cook and progressively develop healthy dietary habits and lifestyles. OSF is a research program led by SEB and supported by the

French government for the development of semantic content, devices and innovative digital services that facilitate food preparation at home [14]. Regarding current digital services, like Yummly [15], they do not take completely into account the user profiles and are not connected to devices for meals preparation. The principal objective is to evaluate the ability of connected cook devices to modify dietary habits measured by a clinically significant increase in Alternate Healthy Eating Index-2010 (AHEI-2010).

METHODS AND ANALYSIS

Study design

This is a randomized controlled open study including 160 patients and performed in 2 sites (100 patients in Grenoble in France and 60 patients Aberystwyth in Wales). After control for inclusion / exclusion criteria at the inclusion visit, participants will be randomized according to the Zelen's method, i.e. participants are randomized in a 2 step-stage to be sure they will accept this close monitoring during one year [16]. We chose such design to avoid disappointment at being randomized to the control group, which participants may perceive as substandard care. This may influence outcomes (especially patient-reported outcomes) or even lead to withdrawal from the study, thereby possibly causing bias. Participants assigned to the intervention group will be informed about the program and the one-year follow-up. If they refused to participate, they will be proposed the control group with only questionnaires, physical activity and sleep duration measurements and blood / urine / stool samples collections. Volunteers assigned to the control group will be asked whether they consent to participate to a clinical study with questionnaires, physical activity and sleep duration measurements and biological follow-up. Participants will not be aware of the existence of the other group (Fig. 1).

Lifestyle intervention

The lifestyle intervention consists in connected cook devices and Internet apps connections. The particularity of these new tools is that they are equipped with the OFS system. OFS aims to develop

a standard ecosystem to facilitate food preparation at home via access to innovative content, appliances and services. New connected smart cooking appliances, with the ability to monitor cooking settings automatically for optimal results and preserve the nutritional value and organoleptic qualities of cooked foods are developed. Personalized nutrition coaching services will improve the health of consumers by providing targeted daily advice at home, highlighting the “at home” dishes realization with fresh produces and vegetables. In the control group, there will be no lifestyle intervention.

Objectives

Primary research objective

The main objective of this project is to assess whether the lifestyle intervention improves dietary habits measured by a clinically significant increase of 1 quintile in AHEI-2010), over a 1-year period in overweight healthy subjects.

Secondary research objectives

The secondary objectives of the project are: a) To demonstrate feasibility to collect data and specimen at home over one year, b) To compare between the 2 groups of volunteers changes over 1 year in quality of life, hematological and biochemistry homeostasis, body composition, daily physical activities, sleep duration and gut microbiote, c) Description of urinary metabolomics patterns that are able to report recent (12-48 hrs) dietary habits, d) Identify novel patterns within the streams of health and wellness data that indicate either optimal nutritional status, or transition states between optimal nutritional status and inadequate nutritional status.

Inclusion and exclusion criteria

Females and males, 25-50 years old, overweighed $25 < \text{BMI} < 30$, without any chronic medications, living in a family, be the main person who prepares meals and be able to use the personal health monitoring devices (*Table 1*).

Measured variables and measurement methods

SURVEYS. During the inclusion visit, after 6 months (M6) and at the final visit (M12), the

investigator suggests a face-to-face survey to each participant. It will deal with: personality, general health (SF36 questionnaire), life style, eating habits and particularly in the intervention group. Moreover, each participant will complete the Nutrinet questionnaire during one week at M0, M6 and M12.

PHYSICAL ACTIVITY AND SLEEP DURATION. Physical activity and sleep duration will be determined using ActiGraph GT3X+ accelerometer (ActiGraph, Pensacola, FL, USA) at M0, M6 and M12. Participants will be instructed to wear the accelerometer for 7 consecutive days. The accelerometer was worn on the dominant side of the hip during the day and non-dominant wrist during sleep [17,18].

BODY ANALYSIS. Body analysis includes weight assessment, Body Mass Index (BMI), fat mass percentage with an impedance meter will be determined at M0, M6 and M12. Moreover, all the subjects will have a weighing scale that could be used *ad libitum*. The volunteers will weigh themselves one time a month during one year at home

HEALTH EXAMINATION. Participants are asked to be on an empty stomach since 12 hours.

Clinical examination includes: anthropometric measures: weight, height, waist circumference, blood pressure series of three measures.

BIOLOGICAL PARAMETERS. - Hematological parameters will be measured at M0, M6 and M12: transaminases (ASAT, ALAT), creatinine, urea, total protein, albumin, Cholesterol HDL & LDL Friedwald, Cholesterol total, triglycerides, glucose, HS C-reactive protein, ferritin, Vitamin D total (25OH D2 + 25OD D3), and PaxGenes; - Urinary analysis will be performed at M0, M6 and M12, - Gut microbiote analysis will also be performed at M0, M6 and M12.

All evaluated parameters are summarized in Table 2.

Statistical considerations

Sample size: The main objective of this project is to significantly improve the AHEI-2010 [0-110] of 1 quintile, which has been shown to be associated with a significant reduction of chronic conditions. Based on the data collected by Chiuve et al. [19], mean AHEI-2010 score in men and

women 25-50 year old will be 50 ± 11.1 . In order to show a significant increase of 1 quintile (i.e. 7 points on the AHEI-2010 score) in the lifestyle intervention group, assuming that the common standard deviation is 11.1 using a two group t-test with a 0,050 two-sided significance level, a sample size of 41 in each group will have 80% power to detect such difference in means (nQuery Advisor v7). We further validated sample size calculation with data collected in France [20]. In the latter, mean AHEI-2010 score was 51.6 ± 8.3 , assuming a sex ratio of 1:1. In order to show a significant increase of 1 quintile (4.6 points in this population), 53 subjects per group are needed using the same methods.

Analyses will be performed using Stata software (version 13.0; Stata Corp, College Station, Texas) and respecting the recommendations of CONSORT Group for Trials Assessing Non pharmacologic Treatments. Descriptive statistics will include frequencies and percentages for categorical variables, and the median and interquartile range (25th-75th percentile) for continuous variables. A table (population description) with comparability of control and intervention group will be created without statistical test for this randomized study.

The main outcome (primary criteria) is the success rate defined by the gain of a quartile in AHEI-2010 score at 12 months compared to M0. It will be evaluated by a chi-square test. The AHEI-2010 score will also be tested as a relative change of the score in quantitative value ($M12 - M0 / M0$). An analysis of variance for repeated measures with intervention effect and time*intervention interaction will allow for testing of all measures for the score M0, M6, M12.

The data obtained from the devices under study concern only intervention group. We will observe these data thanks connected cook devices with the analysis of their quality. We will describe all variables separately. Moreover, in order to reduce information, we will make a Principal Component Analysis (PCA) for finding patterns in these high-dimensional data.

For secondary objective b), comparisons between control and intervention group will use the Mann-Whitney test for continuous variables, and Chi2 or Fisher's exact test when appropriate for categorical variables. SF36 questionnaire will be processed according to the user manual, in

particular for the management of missing data. For the secondary objective c) of urinary metabolomics validation to assess dietary habits, common tools for validation of a diagnostic test will be used (Se, Sp, PPV, NPV, positive and negative likelihood ratio) considering the repeated measures for a single individual (intra-correlation). The secondary objective d) will use the methods of longitudinal data analysis and cross correlation.

Data from the 2 sites (i.e. Wallish and French) will be analyzed separately and aggregated into a meta-analysis.

Patients and public involvement: No patients involved

Ethics

The study will be conducted in accordance with the Declaration of Helsinki and the recommendations for Good Clinical Practice. Written informed consent will be signed by all study participants before enrolment in the study once in control group and twice in intervention group corresponding to 2 consent forms (see online supplemental file). Patients have the right to withdraw from the study without incurring any prejudice at any time.

Sponsor and funding

The sponsor of the study is CHUGA, Grenoble, France and Aberystwyth University. The principal investigator is Christophe Pison. EIT Health will provide funding's. The funders are not involved in the design of the study and will not influence the execution, analysis and publication of results.

DISCUSSION

We postulate that intervention with the coaching on dietary habits using OFS will be associated to changes in dietary habits as measured by dietary records and dietary “fingerprints” evaluated by metabolomics approach. We suppose that OFS will be associated to durable

modification of dietary habits with a shift to increased consumption of healthier diet components (oily fish, whole grains, fruit, and vegetables) and a shift to decrease consumption of processed meats or deep-fried foods. It is well known that people living in couples have different eating habits of people living alone. The strengths of our work are the methodology used (assessments mainly at home) and the target (primary prevention in healthy subjects). Hence, we proposed to collect a large part of our data in “real life” with a personalized nutritional monitoring for interventional group. In addition, we decided to use Zelen randomization (with double blind consent) in order to avoid a sense of frustration in the control group. Finally, we follow our population over 1 year, which is a rather long interventional period compared to what is usually done.

The beneficial of the work could be measured at many levels: Health economy, sustainability of healthcare systems: personalized nutrition coaching services will improve the health of consumers by providing targeted daily advice at home, highlighting the “at home” dishes realization with fresh produces and vegetables, as promoted by the institutional and medical instances. Better nutrition and better health will reduce the risk of chronic diseases such as obesity and cardiovascular diseases, which impact heavily on health spending. A report by the French National Assembly estimated the cost of obesity for the health insurance, if we add the daily allowances of sick care costs, between 2 and 6 €billion / year (until 4.6% of current health expenditure). As recently summarized by Caroline K. Kramer [5], moderate weight loss is related to favorable clinical outcomes. A weight loss of 7% (modification of lifestyle) reduced diabetes progression (-58%). The data collected addressed to health professionals will also enable better guide diagnostics and more efficient care strategies; Quality of life: digital services will allow greater involvement of the whole family in the preparation of healthy and good food, as observed in previous consumer tests, facilitating social communication and exchanges within the home. These services are also paced to modern life, leaving less and less time for preparation of meals. The services will accompany the young adults in their cooking learning, as transmission of recipes and cooking know-how made by the parents has lessened. Regarding elderly, coaching facilitates their autonomy and their remaining

at home.

Strengths and limitations of the study

- This study is one of the few intervention studies of primary prevention in the field of nutrition.
- This study proposes an intervention solution which is not based on constraint and which could have a better compliance.
- Since the use of connected cooking devices in the intervention group is free, this can lead to greater variability in the population and in the expected results.

Ethics and dissemination. The protocol was approved by the French ethics committee the 7th December, 2016. The study started in March, 2017 completion achieved December, 2017 (end of inclusion) and December, 2018 (end of study). Dissemination plans of the results include presentations at conferences and publication in peer reviewed journals.

Trial registration number: NCT03169088

Abbreviations

AHEI	:	Alternative Healthy Eating Index
ANSM	:	National Agency for the Safety of Medicines and Health Products
API	:	Application Programming Interface
ASAT, ALAT	:	Transaminases
BMI	:	Body Mass Index
CE	:	European community
CHUGA	:	Grenoble Alpes University Hospital Center
eCRF	:	electronic Case Report Form
EIT	:	European Institute of Technology
EU	:	European Union
GGT	:	Gamma-Glutamyl Transférase
GDP	:	Gross Domestic Product
HDL	:	High Density Lipoprotein
HPS	:	Health Promotion Survey
HSP	:	Hosting Service Provider
IMC	:	Body Masse Index
LDL	:	Low Density Lipoprotein
NCDs	:	Non Communicable Diseases
OFS	:	Open Food System
PAL	:	Phosphatase Alcaline Totale
PCA	:	Principal Component analysis
P4 Medicine	:	Predictive, Preventive, Personalized, and Participatory Medicine

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Contributors

C.M., M-F. V., M.S., P.D., J.-L. B. and C.P. designed the study and protocol submission. C.M., M-F. V. and C.P. wrote the manuscript. M.S., P.D., A.L. J-L. B. J-C. B., C.R. and M-J. F. revised the manuscript.

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Competing interests

P.D. and M.S. are employed by Seb company. Others authors have no competing interest.

Volunteers consent for publication obtained

Ethics approval

The protocol was approved by The French Regional Ethics Committee (Comité de Protection des Personnes Sud Est V n° 16-CHUG-26).

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

- 1 Les dépenses de santé en 2019 - Résultats des comptes de la santé - Édition 2020 - Ministère des Solidarités et de la Santé. <https://drees.solidarites-sante.gouv.fr/etudes-et-statistiques/publications/panoramas-de-la-drees/article/les-depenses-de-sante-en-2019-resultats-des-comptes-de-la-sante-edition-2020> (accessed 10 Jan 2021).
- 2 Hood L, Flores M. A personal view on systems medicine and the emergence of proactive P4 medicine: predictive, preventive, personalized and participatory. *New Biotechnol* 2012;**29**:613–24. doi:10.1016/j.nbt.2012.03.004
- 3 Hood L, Auffray C. Participatory medicine: a driving force for revolutionizing healthcare. *Genome Med* 2013;**5**:110. doi:10.1186/gm514
- 4 Hood L, Price ND. Demystifying disease, democratizing health care. *Sci Transl Med* 2014;**6**:225ed5. doi:10.1126/scitranslmed.3008665
- 5 MARAGKOUDAKIS P. Cost of Non-Communicable Diseases in the EU. EU Sci. Hub - Eur. Comm. 2017. <https://ec.europa.eu/jrc/en/health-knowledge-gateway/societal-impacts/costs> (accessed 14 Aug 2020).
- 6 Buxton OM, Marcelli E. Short and long sleep are positively associated with obesity, diabetes, hypertension, and cardiovascular disease among adults in the United States. *Soc Sci Med* 1982 2010;**71**:1027–36. doi:10.1016/j.socscimed.2010.05.041
- 7 Afshin A, Sur PJ, Fay KA, *et al.* Health effects of dietary risks in 195 countries, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *The Lancet* 2019;**393**:1958–72. doi:10.1016/S0140-6736(19)30041-8
- 8 Li Yanping, Pan An, Wang Dong D., *et al.* Impact of Healthy Lifestyle Factors on Life Expectancies in the US Population. *Circulation* 2018;**138**:345–55. doi:10.1161/CIRCULATIONAHA.117.032047
- 9 Nyberg ST, Singh-Manoux A, Pentti J, *et al.* Association of Healthy Lifestyle With Years Lived

- Without Major Chronic Diseases. *JAMA Intern Med* 2020;**180**:1–10.
doi:10.1001/jamainternmed.2020.0618
- 10 Gooding HC, Shay CM, Ning H, *et al.* Optimal Lifestyle Components in Young Adulthood Are Associated With Maintaining the Ideal Cardiovascular Health Profile Into Middle Age. *J Am Heart Assoc Cardiovasc Cerebrovasc Dis* 2015;**4**. doi:10.1161/JAHA.115.002048
- 11 Sotos-Prieto M, Bhupathiraju SN, Mattei J, *et al.* Association of Changes in Diet Quality with Total and Cause-Specific Mortality. *N Engl J Med* 2017;**377**:143–53.
doi:10.1056/NEJMoa1613502
- 12 Hagan KA, Chiuve SE, Stampfer MJ, *et al.* Greater Adherence to the Alternative Healthy Eating Index Is Associated with Lower Incidence of Physical Function Impairment in the Nurses' Health Study. *J Nutr* 2016;**146**:1341–7. doi:10.3945/jn.115.227900
- 13 Dietary risks are leading cause of disease burden in the US and contributed to more health loss in 2010 than smoking, high blood pressure, and high blood sugar. *Inst. Health Metr. Eval.* 2014.<http://www.healthdata.org/news-release/dietary-risks-are-leading-cause-disease-burden-us-and-contributed-more-health-loss-2010> (accessed 14 Aug 2020).
- 14 Open Food System, Industrialisez vos recettes et créez de nouveaux services. <https://openfoodsystem.com/> (accessed 14 Aug 2020).
- 15 Yummly: Personalized Recipe Recommendations and Search. <https://www.yummly.com> (accessed 14 Aug 2020).
- 16 Flory JH, Mushlin AI, Goodman ZI. Proposals to Conduct Randomized Controlled Trials Without Informed Consent: a Narrative Review. *J Gen Intern Med* 2016;**31**:1511–8.
doi:10.1007/s11606-016-3780-5
- 17 Cole RJ, Kripke DF, Gruen W, *et al.* Automatic sleep/wake identification from wrist activity. *Sleep* 1992;**15**:461–9. doi:10.1093/sleep/15.5.461
- 18 Santos-Lozano A, Santín-Medeiros F, Cardon G, *et al.* Actigraph GT3X: validation and determination of physical activity intensity cut points. *Int J Sports Med* 2013;**34**:975–82.

doi:10.1055/s-0033-1337945

- 19 Chiuve SE, Fung TT, Rimm EB, *et al.* Alternative dietary indices both strongly predict risk of chronic disease. *J Nutr* 2012;**142**:1009–18. doi:10.3945/jn.111.157222
- 20 Andrianasolo RM, Hercberg S, Kesse-Guyot E, *et al.* Association between dietary fibre intake and asthma (symptoms and control): results from the French national e-cohort NutriNet-Santé. *Br J Nutr* 2019;**122**:1040–51. doi:10.1017/S0007114519001843

Figure Legends

Figure 1. Study protocol according to Zelen double consent model

Table 1 -Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> ▪ Consenting adults based in Grenoble area France without known chronic medications (except contraception) or recent surgical intervention or hospitalization (< 6 months); ▪ Be able to understand and follow the protocol and use the personal health monitoring devices; ▪ Be the owner of a electronic tablet (iOS or Android platform) and have a valid Internet connection with access from home; ▪ Be able to understand the study, its aim and methodology ▪ Be legally able to give consent. ▪ $25 \leq \text{BMI} < 30$ ▪ $25 \text{ y} \leq \text{Age} \leq 50 \text{ y}$ ▪ Live in a family and be the main person who prepares meals 	<ul style="list-style-type: none"> ▪ Vital prognosis engaged within 6 months; ▪ Smoker ▪ Being unable to understand, follow objectives and methods due to cognition or language problems; ▪ Be under chronic use of medications; ▪ Be likely to move away from the geographic inclusion zone (mainland France); ▪ Be unavailable (e.g. work commitment abroad) for the two months following inclusion; ▪ Pregnant women, feeding and parturient ▪ Playing sports at a high level ▪ Subject under administrative or judicial control ▪ All eating disorders ▪ Regimen without red meat

Table 2:

Visits	Pre- inclusion V0 -1 to 4 weeks	Inclusion V1 M0	Home visits	Visit V2 M6 ± 15 days	Home visits	Visit V3 M12 ± 15 days	Home visits
Information	✓	✓	✓				
Consent signature		✓					
Verification of eligibility criteria	✓	✓					
Medical history		✓					
Adverse events			✓	✓	✓	✓	✓
Clinical examination: Weight, height, blood pressure series of three measures		✓		✓		✓	
Impedancemetry / DEXA		✓		✓		✓	
Questionnaires:		✓		✓		✓	
Blood collection		✓		✓		✓	
Actimetry			✓		✓		✓
Urine/Stool collection for Immunomonitoring and omics assessments			✓		✓		✓
Activity and Food frequency questionnaires			✓		✓		✓

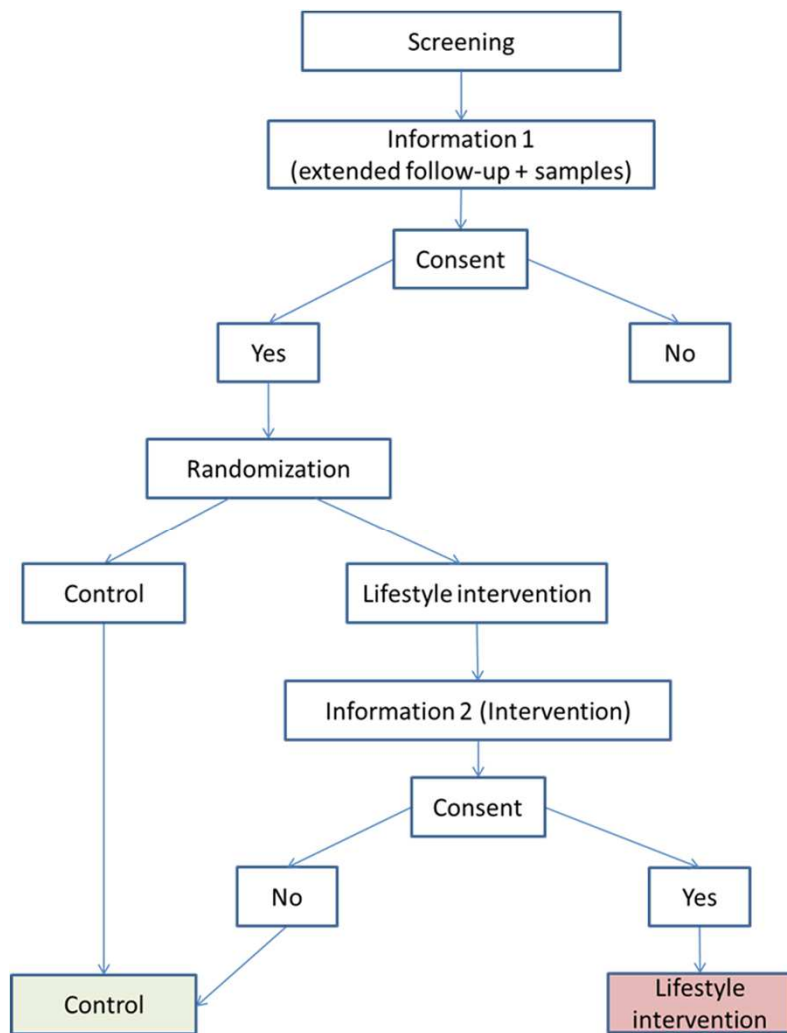


Figure 1. Study protocol according to Zelen double consent mode