

The nutrition, cardiovascular wellness and diabetes project

Submission date 06/08/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/08/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/04/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Nutrition has been shown to be a very important factor in the development of different diseases, especially in diabetes and cardiovascular diseases, such as heart disease and stroke. The Mediterranean diet, which is rich in fruits and vegetables, as well as low in salt and saturated fat, has been shown to be very effective in preventing and treating these conditions. Unfortunately, in modern society, these healthy eating habits are becoming rarer. Previously, a large study was completed looking at the general eating habits of people in the Palermo region of Italy. The aim of this study is to look at the dietary habits and disease risk factors of a sample of people who took part in this study, and how their habits have changed over a four year period. The study will also investigate a possible link between the diet and a number of other diseases, including liver disease, thyroid disease, and mental illnesses which affect learning, memory, and thought processes.

Who can participate?

Healthy adults living in the Palermo region of Italy

What does the study involve?

Participants who took part in the previous study are asked to complete a number of questionnaires about their eating habits, general health and mental health. All participants then visit the clinic in order to be tested for a number of health conditions. At the clinic visit, participants have a blood test in order to check for diabetes, and scans of the neck arteries and liver are also performed. After four years, the questionnaires and tests are repeated at a visit to the clinic.

What are the possible benefits and risks of participating?

A potential benefit for participants is the early diagnosis of the diseases investigated in this study. There are no significant risks, other than the general risks relating to blood tests.

Where is the study run from?

Policlinico "P. Giaccone" University Hospital (Italy)

When is the study starting and how long is it expected to run for?
September 2014 to July 2015

Who is funding the study?
Associazione Onlus Nutrizione e Salute, Palermo (Italy)

Who is the main contact?
Professor Silvio Buscemi
silvio.buscemi@unipa.it

Study website
<http://www.facebook.com/progettoabcd>

Contact information

Type(s)
Public

Contact name
Prof Silvio Buscemi

ORCID ID
<http://orcid.org/0000-0003-0730-7649>

Contact details
Policlinico "P. Giaccone"
Centro Obesità, Malattie del Metabolismo e Nutrizione Clinica
Palermo
Italy
I-90127
+3 991 655 4580
silvio.buscemi@unipa.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Influence of nutritional factors on cardiovascular and metabolic risk

Acronym

The ABCD study (Alimentazione, Benessere Cardiovascolare e Diabete)

Study objectives

1. Nutritional factors independently influence cardiovascular and metabolic risk
2. Nutritional factors may also have important influences on other conditions as thyroid status, cognitive impairment, gallstones

Ethics approval required

Old ethics approval format

Ethics approval(s)

"Palermo 1" of the Policlinico "P. Giaccone" University Hospital, 11/03/2014, ref: 3/2015

Study design

Longitudinal observational study single-centre of a population representative cohort

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Community

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

1. Obesity
2. Type 2 diabetes
3. Atherosclerosis
3. Hypertension
4. Liver steatosis
5. Thyroid diseases
6. Tumors
7. Cognitive impairment

Interventions

The 2011 study was an observational, cross-sectional study carried out in Palermo, the largest city in Sicily, Italy. From March 28th to April 10th 2011, groups composed of physicians (n= 5) and dietitians (n= 13) alternated their presence inside the Forum, a shopping mall in Palermo, from 9:00 a.m. until 9:00 p.m., and investigated those customers who asked to participate in the investigations proposed on posters placed inside the Forum.

The Forum is the largest shopping mall in Palermo, and customers come from all parts of the city, suburbs and neighboring areas. Data provided by the Forum's administration show that the characteristics of their habitual customers were heterogeneous and representative of residents

of Palermo. Inclusion criteria were participants aged ≥ 18 , and with residence in Palermo. There was no incentive provided to the participants.

Participants were also asked to come to the Laboratory of Clinical Nutrition of the Biomedical Department of Internal and Specialized Medicine at the University of Palermo in the following weeks, up until July 15, 2011, to undergo blood sampling for assessment of blood chemistry and hormonal parameters. In particular, health and food frequency questionnaires, anthropometric and echo-carotid measurements were obtained. A total of 1,231 participants (465 males and 766 females) were selected.

The current study re-examines all participants from the original cohort study that it was possible to re-contact and who agreed to participate in the study. Furthermore, each participant was given the opportunity to present as a new participant in the study a relative or friend, but the number of new participants has been limited to the first 300 people.

Participants will be contacted (telephone, e-mail, letter) and evaluated at the University hospital during the period from 21 March 2015 to 31 July 2015. Nutritional and health questionnaires will be administered, also blood and instrumental exams will be performed.

Intervention Type

Other

Primary outcome measure

1. Insulin resistance measured using HOMA-Index [fasting blood concentrations of insulin (mU/L) x glycemia (mmol/L) / 22.5], at baseline and 4 years from the first observation
2. Carotid atherosclerosis measured using ecography to measure the carotid intima-media thickness. This is measured at baseline and 4 years from the first observation

Secondary outcome measures

1. Changes to the number and size of thyroid nodules are measured using ecography at baseline and 4 years from the first observation
2. Liver stenosis is measured by determining liver stiffness and controlled attenuation parameter (CAP) using a fibroscan at baseline and 4 years from the first observation
3. The level of mild cognitive impairment will be determined using mini-Mental State Examination (MMSE) score and clock-test score at baseline and 4 years from the first observation

Overall study start date

01/09/2014

Completion date

31/07/2015

Eligibility

Key inclusion criteria

1. Aged 18 years or over
2. Residents in Palermo area (Italy)
3. Having been part of the 2011 cohort or being a new participant introduced by a participant to the 2011 study (up to a maximum of 300 new participants)

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1000 participants

Total final enrolment

890

Key exclusion criteria

N/A

Date of first enrolment

21/03/2015

Date of final enrolment

31/03/2015

Locations

Countries of recruitment

Italy

Study participating centre

Centro Obesità, Malattie del Metabolismo e Nutrizione Clinica - Policlinico "P. Giaccone"

University Hospital

via del vespro, 129

Palermo

Italy

I-90127

Sponsor information

Organisation

University of Palermo - Dipartimento Biomedico di medicina Interna e Specialistica (DIBIMIS)

Sponsor details

via del vespro 129
Palermo
Italy
I-90127

Sponsor type

University/education

ROR

<https://ror.org/044k9ta02>

Funder(s)

Funder type

Charity

Funder Name

Associazione Onlus Nutrizione e Salute, Palermo (Italy)

Results and Publications

Publication and dissemination plan

We intend to publish both longitudinal and cross-sectional data as manuscripts in the form of original articles or reviews or book chapters. Also, data will be presented as oral presentations at scientific meetings. Data may also be spread by means of mass media but only after their publication on journal using peer review.

Intention to publish date

01/01/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2018	11/12/2020	Yes	No
Results article		01/03/2018	11/12/2020	Yes	No
Results article	Follow up results	01/11/2018	11/12/2020	Yes	No

Results article	results on association between dairy food intake and LDL- cholesterol levels	11/02 /2021	08/03 /2021	Yes	No
Results article		03/08 /2017	12/09 /2023	Yes	No
Results article		22/04 /2024	24/04 /2024	Yes	No