

# Mediterranean protocol diet rich in whole grains to treat the risk factor "Metabolic Syndrome" in cancer patients

<b>Submission date</b> 05/10/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 08/10/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Metabolic syndrome is a term used to describe a combination of factors which increase a person's risk of cardiovascular disease (disease of the heart and/or blood vessels). Many of these factors are linked with obesity, such as high blood pressure, cholesterol and body fat. Obesity is therefore considered to be the primary cause of metabolic syndrome, although there is evidence that it is related to insulin resistance. Insulin resistance is where levels of insulin are so high that the cells in the body stop reacting to it. This means that the body is unable to process sugars properly and so blood sugar can become very high (hyperglycaemia). Metabolic syndrome also puts people at risk of developing cancer, and so improving the factors which make up metabolic syndrome could potentially help prevent some cancers. The Mediterranean diet is considered to be one of the healthiest diets worldwide. Rich in fruit, vegetables and whole grains, it has been shown to reduce the risk of cardiovascular disease and can keep obesity under control. The aim of this study is to find out whether a Mediterranean diet that is also high in fibre can help to reduce the factors which make up metabolic syndrome in cancer patients.

### Who can participate?

Adult cancer patients showing signs of having metabolic syndrome.

### What does the study involve?

Participants are randomly allocated into two groups. The first group are given a diet rich in whole grains and omega 3 fatty acids for a period of six months. Throughout the study, participants are asked to keep a food diary and attend weekly meetings in order to provide support and encouragement. The second group are provided with general information about a healthy diet with the same nutritional recommendations as the first group at the start of the study. No additional sessions are offered to provide help and support throughout the study for these participants however. At the start and end of the study participants in both groups are measured to find out if they have lost weight, and undergo blood tests to check their blood fat, cholesterol and sugar levels.

What are the possible benefits and risks of participating?

Participants may benefit from resolution of their metabolic syndrome because of the change to their diet. There are no risks of participating in the study.

Where is the study run from?

National Cancer Institute "G. Pascale" (Italy)

When is the study starting and how long is it expected to run for?

May 2014 to July 2015

Who is funding the study?

National Cancer Institute "G. Pascale" Foundation (Italy)

Who is the main contact?

Dr Vincenzo Quagliariello

quagliariello.enzo@gmail.com

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Vincenzo Quagliariello

**ORCID ID**

<http://orcid.org/0000-0002-4557-5401>

**Contact details**

Via M. Semmola

Naples

Italy

80131

+39 331 776 7430

quagliariello.enzo@gmail.com

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## Study information

**Scientific Title**

Effects of Mediterranean-style diet on inflammation markers and reversion of metabolic syndrome in cancer patients: role of plasmatic calprotectin

## **Acronym**

OncoMedDiet

## **Study objectives**

A Mediterranean diet with higher grain fiber intake would reduce the components of the metabolic syndrome in cancer patients independently of cancer stage or therapy, compared to a habitual Mediterranean diet.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Not provided at time of registration

## **Study design**

Single-centre pilot randomised parallel trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised parallel trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Prevention

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Metabolic syndrome

## **Interventions**

Cancer patients were randomly assigned to either the intervention or the control diet. All participants in the study did not follow any kind of diet treatment eight months before the study. In addition, all participants did not practice physical exercise and maintained a constant weight at about 12 months and before the start of the study, each patient completed a daily food diary for initial screening test.

Intervention diet: Participants were given detailed information about the expected slimming, anti inflammatory and protective effects on its lipid and glucose homeostasis consuming suggested foods. In fact, we organized weekly meetings with cancer patients in order to accurately follow the course of the diet by using food diaries, providing also detailed explanations, psychological support and motivation throughout 6 months of diet. The caloric breakdown of the diet given in the intervention group was based on the following distribution: carbohydrates 50-55%, proteins 15-20%, total fat around 30% and saturated fat less than 10%.

Control diet: Participants followed general information about healthy food choices at baseline and at subsequent visits but were offered no specific individualized program. However, the general recommendation for macro-nutrient composition of the diet was similar to that for the intervention group (carbohydrates, 50-55%, proteins 15%-20% and total fat 30%.

## **Intervention Type**

Other

## **Primary outcome measure**

1. Metabolic syndrome markers (waist circumference, blood pressure, HDL-cholesterol, triglycerides, fasting blood glucose) measured using anthropometrics and blood analysis at baseline, 2, 4 and 6 months
2. Plasma calprotectin measured using blood analysis at baseline, 2, 4 and 6 months

## **Secondary outcome measures**

1. C-Reactive Protein measured by blood analysis at baseline 2, 4 and 6 months
2. Homocysteine measured by blood analysis at baseline 2, 4 and 6 months
3. Insulin measured by blood analysis at baseline 2, 4 and 6 months
4. HOMA-IR measured by blood analysis at baseline 2, 4 and 6 months
5. LDL-cholesterol measured by blood analysis at baseline 2, 4 and 6 months

## **Overall study start date**

06/05/2014

## **Completion date**

14/07/2015

# **Eligibility**

## **Key inclusion criteria**

1. Aged between 18 and 65 years
2. Oncology patients
3. Have at least three of the following characteristics:
  - 3.1. Waist circumference of at least 88 cm in women and 102 cm in men
  - 3.2. Low levels of serum high density lipoprotein cholesterol (HDL), specifically less than 40 mg /dL for men and less than 50 mg/dL for women (or taking drug treatment for reduced HDL-C)
  - 3.3. Hypertriglyceridemia with triglycerides level of at least 150 mg/dL (or taking drug treatment for elevated triglycerides is an alternate indicator)
  - 3.4. Systolic blood pressure of at least 130 mmHg and diastolic blood pressure of at least 85 mmHg (or taking antihypertensive drug treatment in a patient with a history of hypertension)
  - 3.5. Fasting plasma glucose value of 100 mg/dL or greater due to loss of glucose homeostasis (or taking drug treatment of elevated glucose is an alternate indicator)

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

150

**Key exclusion criteria**

1. Patients with cognitive and psychosocial problems
2. Genetic disorders
3. Smokers
4. Drug addicts or abusers of alcohol (consumption of at least  $\geq 500$  g/wk in the last year)

**Date of first enrolment**

10/06/2014

**Date of final enrolment**

13/01/2015

## **Locations**

**Countries of recruitment**

Italy

**Study participating centre**

**National Cancer Institute "G. Pascale"**

Department of Cardiology

Via M. Semmola

Naples

Italy

80131

**Study participating centre**

**National Cancer Institute "G. Pascale"**

Department of Abdominal Oncology

Via M. Semmola

Naples

Italy

80131

## **Sponsor information**

**Organisation**

National Cancer Institute "G. Pascale" Foundation

**Sponsor details**

Via M. Semmola

Naples

Italy

80131

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/04tfzc498>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

National Cancer Institute "G. Pascale" Foundation

**Results and Publications****Publication and dissemination plan**

Publication of results in the Journal of Nutrition, Cancer and Cardiovascular disease and presenting the abstract, posters and a discussions at the International Workshop on Cardiology (AICO-AIOM) and cancer in the next year.

**Intention to publish date**

01/09/2016

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Data sharing statement to be made available at a later date