

# Italian Society of Endocrinology Prevention Study

<b>Submission date</b> 16/10/2003	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/10/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/02/2008	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

**Scientific Title**

**Acronym**  
ISEPS

**Study objectives**

Randomized controlled trial designed to test the hypothesis that an intensive life style intervention is able to prevent the metabolic syndrome in 20-50 years old subjects affected by visceral obesity. Follow-up 5 years.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Visceral obesity, metabolic syndrome

### **Interventions**

Intervention: Individual intensive counseling to induce life-style change as described in detail in the article: "Validation of a counseling strategy to promote the adoption and the maintenance of physical activity by type 2 diabetic subject by Di Loreto et al (PubMed reference PMID: 12547870)

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

Prevention of metabolic syndrome

### **Key secondary outcome(s)**

Reduction of body weight  
Reduction of CHD risk

### **Completion date**

30/06/2010

## **Eligibility**

### **Key inclusion criteria**

Men and women with visceral obesity  
20-50 years old

Waist >88cm (women)

Waist >102cm (men)

Without metabolic syndrome (according to the Adult Treatment Panel III [ATPIII] classification)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

Not provided at time of registration

### **Date of first enrolment**

01/06/2004

### **Date of final enrolment**

30/06/2010

## **Locations**

### **Countries of recruitment**

Italy

### **Study participating centre**

**DIMI**

Perugia

Italy

06126

## **Sponsor information**

### **Organisation**

Italian Society of Endocrinology

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Foundation of Italian Society of Endocrinology

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration