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Metabolic impact of a nutrition education program for the promotion of fruit and vegetable consumption with people with severe mental disorders

Submission date
07/03/2022

Recruitment status
No longer recruiting

Registration date
11/03/2022

Overall study status
Completed

Last Edited
22/05/2023

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Growing evidence suggests that diet combined with a healthy lifestyle has potential for the prevention and treatment of mental illness and may modify the effects of treatments. The introduction of a diet rich in fruit and vegetables is very beneficial for health, prevents heart disease and some types of cancer, and in general is associated with a higher quality of life and good mental health. The aim of this study is to determine the metabolic impact of a nutrition education program (Dietment) on metabolic parameters and the presence of metabolic syndrome. Metabolic syndrome is the medical term for a combination of diabetes, high blood pressure and obesity that increases the risk of heart disease, stroke and other conditions that affect the blood vessels.

Who can participate?
Patients over the age of 18 years with a severe mental disorder who participate actively in a community rehabilitation program

What does the study involve?
Participants are randomly allocated to the Dietment program or a control group. The Dietment program lasts 4 months (April to July 2019). It consists of a food education strategy aimed at promoting the consumption of food and vegetables and comprises 15 weekly group sessions (of 5–10 people) lasting 90 minutes each session. All sessions are conducted by the same dietitian-nutritionist. In the control group, three voluntary group sessions are offered to the participants' relatives as support agents to facilitate the change of habits (60 minutes).

What are the possible benefits and risks of participating?
The international recommendation of five portions of food and vegetables a day has been shown to be beneficial for mental health and may offer benefits in reducing heart disease risk factors. There are no potential risks due to the intervention.

Where is the study run from?
Osona Psychopedagogical Medical Center, with the collaboration of the Vic University Hospital (Spain)

When is the study starting and how long is it expected to run for?
September 2018 to September 2020

Who is funding the study?
Agency for Management of University and Research Grants (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
AGAUR grant number 2017 DI 55

Study information

Scientific Title
Metabolic impact of a nutrition education program for the promotion of fruit and vegetable consumption with people with severe mental disorders (DIETMENT)

Acronym
DIETMENT

Study objectives
A food education program based on the stages of change model for severe mental disorders reduces the development of metabolic syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/09/2018, the Clinical Research Ethics Committee of the Osona Foundation for Health Research and Education (FORES) (C. Francesc Pla “El Vigatà”, 1, 08500 Vic, Barcelona; +34 (0)937027710; fores@chv.cat, lsolerdelcoll@chv.cat), ref: 2018974

Primary study design
Interventional

Study design
Randomized community-based clinical trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Metabolic syndrome

Interventions
For randomization the Zenon algorithm (equiprobable randomization 1:1 through R Software) is used, considering the variables of age, gender, functionality, and primary mental health diagnosis.

The Dietment intervention program lasts 4 months (April to July 2019). It consists of a food education strategy aimed at promoting the consumption of food and vegetables and comprises 15 weekly group sessions (of 5–10 people) lasting 90 minutes each session. All sessions are conducted by the same dietitian-nutritionist.

In the control group, three voluntary group sessions are offered to the participants’ relatives as support agents to facilitate the change of habits (60 minutes).

Intervention Type
Behavioural

Primary outcome(s)
Metabolic syndrome, defined using the following criteria:
1. Abdominal perimeter measurement of the Spanish population (94.5 cm in men and 89.5 cm for women)
2. Blood pressure (BP) >130/85 mmHg, triglyceride (TG) >150 mg/dl; glycaemia >100 mg/dl
3. HDL-cholesterol (<40 mg/dl for men and 50 mg/dl for women)
Subjects prescribed medication for hypertension, dyslipidemia or impaired glucose tolerance /diabetes are considered as having the respective risk factors. For a diagnosis of MetS, at least three abnormal components are required. Measured at baseline and after a mean of 5 months post-intervention.

Key secondary outcome(s)
Measured at baseline and after a mean of 5 months post-intervention:
1. Glycated haemoglobin (%), total cholesterol (mg/dl), LDL cholesterol (mg/dl), HDL cholesterol (mg/dl) and triglycerides (mg/dl) measured using blood samples
2. Body mass index (BMI) [weight (kg)/size (m^2)]

Completion date
30/09/2020

Eligibility

Key inclusion criteria
Individuals over the age of 18 years with a clinical diagnosis of a severe mental disorder (SMD) who participated actively in a community rehabilitation program

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
74

Key exclusion criteria
1. Users of the residential services
2. Substance use disorder
3. Dementia
4. Relapse of mental disorder
5. Moderate to severe intellectual development disorder
6. Individuals with a diet that contraindicates the consumption of foods and vegetables

Date of first enrolment
08/09/2019

Date of final enrolment
30/01/2020

Locations

Countries of recruitment

Spain

Study participating centre
Osona Psychopedagogical Medical Center
C. Josep Maria Selva 2
Vic
Spain
08500

Sponsor information

Organisation
Agency for Management of University and Research Grants

Funder(s)

Funder type
Government

Funder Name
Agència de Gestió d'Ajuts Universitaris i de Recerca

Alternative Name(s)
Agency for Management of University and Research Grants, Agencia de Gestión de Ayudas Universitarias y de Investigación, Agència de Gestió d'Ajuts Universitaris i de Recerca (AGAUR), AGAUR

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/06/2021	10/03/2022	Yes	No
Results article		29/03/2022	22/05/2023	Yes	No
Thesis results		29/11/2022	10/03/2022	No	No