Multi-country cOllaborative project on the rOle of Diet, FOod-related behaviour, and Obesity in the prevention of Depression (MooDFOOD)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON42605

Source
ToetsingOnline

Brief title
MooDFOOD

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, mood

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Het Zevende Kader Programma van de Europese Commissie (FP7-KKBE-2013-2-1-01).

Intervention

Keyword: depression, food intake, nutritional strategies, obesity

Outcome measures

Primary outcome

* The 12 month cumulative incidence of Major Depressive Disorder (MDD), defined according to the standard psychiatric DSM-IV criteria using MINI (Mini International Neuropsychiatric Interview): baseline, 6 and 12 months later1.

* Depressive symptomatology according the Inventory of Depressive Symptomatology2;3 baseline, 3, 6, 12 months later.

Secondary outcome

* Depressive Symptomatology assessed with the Patient Health Questionnaire (PHQ-9, Kroenke et al, 2001)

* Food intake (FFQ-GA2LEN)

* Food behaviour and sustainability:

* Food and eating behaviour: The Three-factor Eating Questionnaire (TFEQ-21; Cappelleri et al, 2009)

* Physical activity and sedentary behaviour with validated questionnaires (Short Questionnaire to Assess Health - Enhancing Physical Activity (SQUASH, Wendel-Vos 2003) and sedentary behaviour (SBQ67)

* Body weight perception: The Stunkard figure rating scale (Stunkard et al.,1983)

* Generalized Anxiety Disorder Assessment (GAD-7; Spitzer et al, 2006) for

anxiety symptoms

* Quality of life (EuroQol instrument, EQ-5D-5L, EuroQol group, 1990)

* Automaticity of good and bad health behaviours and compliance to

Mediterranean diet (Self-reported behavioural automaticity index (SRBAI)

* Behavioural functionality: activation, avoidance/rumination, work /school

impairment and social impairment (The behavioural activation for depression

scale (BADS)

Study description

Background summary

Depression is one of the most prevalent, severe and disabling disorders in the EU and places a heavy burden on individuals and families. Additionally, a large proportion of the EU population is overweight, which according to previous research, increases the risk of depression. Recent research has suggested that there is a bi-directional link between healthy nutrition and psychological health. It is yet unclear whether nutritional behavior influences the development of depression in a direct manner or whether other mechanisms like social environment or obesity are also involved as well. The MooDFOOD consortium would like to gain a better understanding of the psychological, lifestyle and environmental pathways underlying the multi-faceted, bidirectional links of food intake, nutrient status, food-related behaviour and obesity with depression. The aim of the intervention study is to investigate whether two different nutritional strategies (a multi*nutrient supplement and food*related behavioural change) are feasible and effective in preventing depression in high*risk overweight EU citizens. This will be studied in four countries across Europe (the Netherlands, United Kingdom, Germany and Spain). It is hoped that improving food-related behavior and nutrient status may offer opportunities to prevent depression, especially in people prone to being overweight.

Study objective

The main objectives of the trial are
* To develop innovative evidence*based, feasible, effective and sustainable

nutritional strategies for the prevention of depression in EU citizens.
* To establish the feasibility and effectiveness of nutritional strategies on the prevention of depression.
* To develop optimal, sustainable, and evidence*based nutritional strategies for the prevention of depression.
* To provide and promote guidelines and practical tools for stakeholders which will improve implementation and thus contribute to nutrition*related prevention of depression.

Study design

One-year long two*by*two factorial randomized placebo controlled prevention trial with two intervention conditions (a multi*nutrient supplement and a food* related behavioural change (FBC) intervention).

Intervention

* Multi-nutrient supplement: comprising 2 pills a) Omega 3 fatty acids: 1000 mg per capsule with a EPA/DHA ratio 3:1 (EPA > 700 mg per capsule, DHA > 100 mg per capsule) b) Multivitamin/minerals pill containing 100 mg calcium, 30 *g selenium, 400 *g B11-vitamin, 20 *g D-Vitamin.
* Placebo: Sunflower oil capsule with similar filling material and colour as the fatty acid capsule.
* Food related behavioral change (FBC): The intervention will consist of 21 sessions (15 individuals -30 minutes/each-; 6 group-based sessions -1h-) with a trained therapist who will target the determines and idiosyncratic triggers of unhelpful (e.g., mood related snacking) and helpful food related behavior.

Study burden and risks

* Participants will be assessed at baseline, 3, 6, 9 and 12 months (4 site visits and one optional site visit at 9 months). This will involve an hour long interview and anthropometric measurements.
* During the baseline assessment patients will be asked to fill in 12 questionnaires
* There is an optional blood draw which will be done at baseline, 6 and 12 months. It will involve 3 x 6ml and 2 x 8.5ml samples.
* Those allocated to the FBC will also need to attend 21, hour long behavioural therapy sessions spread over a period of 12 months with a therapist.
* All participants will be required to take a pill, either a placebo, or a multi-nutrient supplement every day for a year.

The contents of the multi-nutrient supplement will be similar to that available in over-the-counter supplements, hence well under maximum recommended daily dose, thereby presenting no health risks to the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 18*75 years, 2) BMI *25 - 40 kg/m2, 3) High depressive symptom score (PHQ-9 score > 5)

Exclusion criteria

1) Current clinical depression diagnosis (according to psychiatric DSM*IV criteria as determined with the MINI international neuropsychiatric interview);
2) Current use of antidepressant drugs or psychological interventions,
3) History of psychosis, bipolar disorder, substance, dependence or other severe, psychiatric disorder that requires specialized clinical attention,

4) History of bariatric surgery or current severe, life*threatening disease.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-09-2015
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	08-07-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	Dit wordt gedaan na goedkeuring onderzoek door METC
CCMO	NL52702.029.15