

Feasibility of online courses on healthy eating, food-related behaviour and sustainable living

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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-OMON43972

Source

ToetsingOnline

Brief title

Feasibility of online courses

Condition

- Mood disorders and disturbances NEC

Synonym

Depressive symptoms; mood

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Europese Unie (Seventh Framework Programme)

Intervention

Keyword: Depression, Feasibility Studies, Intervention Studies, Nutrition Sciences

Outcome measures

Primary outcome

1. Feasibility of use of online courses and making changes in behaviour (per intervention; comparison between interventions; comparison between interventions and control group);
2. Comparison of feasibility in low versus high depressive symptoms group (per group; comparison between groups)

Secondary outcome

Secondary study parameters will be included as potentially confounding or modifying variables. These include:

Age

Gender

Country

Socio-demographics: educational level, money available for food, marital status, ethnic and cultural heritage, work situation, size of household, number of under-aged children living in the household

Life-style factors: BMI, alcohol use, smoking status, physical activity, sedentary behaviour, weight status

History of depressive disorder

Eating styles

Social context of eating

Depressive symptoms

Atypical depressive symptoms

Subjective health

Body dissatisfaction

Study description

Background summary

Depression is an important risk factor for general public health and strategies to prevent the development of depression are urgently needed. Nutrition and food-related behaviour are found to be associated with mental well-being and depression and might be factors that influence public health. Online interventions focused on promoting health behaviour are increasing and found to be effective and useful to reach large populations for preventive purposes. Knowledge of experiences and preferences of participants is crucial for successful implementation of these interventions. However, this information is missing.

In this study, we will explore the feasibility and perceived usefulness of behaviour change advice targeting nutrition and food-related behaviour. We will also explore if having depressive symptoms influences the feasibility of these advices. This is important because having depressive symptoms decreases quality of life, increases service use and has economic consequences. Furthermore, people with depressive symptoms have an increased risk of developing major depression. Feasibility of the nutrition and food-related behaviour advices in a sample of people with depressive symptoms needs to be investigated, because having depressive symptoms may reduce motivation for and compliance with recommendations. Feasible interventions for people with (high) depressive symptoms are needed in order to prevent negative consequences and the development of depression. The information of this study can be used to develop online interventions that are adopted to the level of depressive symptoms and that reach large groups of people from the general population, without leading to high numbers of drop-out and that are perceived as easy, both in content and in adopting the advices.

Study objective

The primary objectives are (1) to investigate the feasibility of online courses targeting nutrition and food-related behaviour and (2) to investigate whether the feasibility of the online courses is related to depressive symptoms. The secondary objective is to investigate the impact of a range of variables on feasibility outcomes.

Study design

A 8-week randomised controlled trial with 4 intervention groups consisting of online courses targeted at nutrition and food-related behaviour and one control group consisting of a online course targeting sustainability. This study is conducted in both the Netherlands and Denmark.

Intervention

The unguided online courses consist of advice, practical tips and exercises. Participants can decide for themselves what they want to read, use or fill out.

Study burden and risks

Participants have to follow a 8-week course, of which time investment is voluntary. Participants fill out online questionnaires at baseline, short questionnaires after 2,4,6, and 8 weeks, and a final questionnaire after 8 weeks. Post-intervention telephone interviews are conducted in a subsample of participants who volunteer for this.

Risks are very low, because people with a clinical diagnosis of depression and/or suicidal tendencies are excluded from participation and the intervention focuses on normal food products (and food behaviour) and sustainability. The courses have no therapeutic or diagnostic goal. Standards NEN7510, NEN2712 and NEN2713 are met.

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

Aged 18-70 years

Living in the Netherlands or Denmark

BMI 18.5 or higher and lower than 40

Exclusion criteria

Current (in past 6 months) clinical Major Depressive Disorder Episode

Current (in past 6 months) use of antidepressant drugs or psychological interventions

Anxiety or alcohol or substance/drug addiction in previous 6 months

Suicidal intentions as measured during the screening

Diagnosis of bipolar disorder, schizophrenia or psychosis, eating disorder (ever in life)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-09-2016
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO	
Date:	18-04-2016
Application type:	First submission
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

ID: 25393
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL55581.029.16
Other	NTR23799
OMON	NL-OMON25393