Vitamin D supplements to prevent depression and poor physical function in persons over 60 years.

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Depressive symptoms are common in older persons, often associated with poor physical function and vitamin D deficiency (serum 25-hydroxyvitamin D < 50 nmol/l). Simple and cheap interventions to prevent depression are lacking. Vitamin D deficiency...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24229

Bron
Nationaal Trial Register

Verkorte titel
D-Vitaal

Aandoening

depressive symptoms and poor physical functioning in older persons.

depressieve symptomen en matig fysiek functioneren bij ouderen.

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in the CES-D score (depressive symptoms), change in physical performance score, and change in the number of functional limitations as well as change in the degree of functional limitations.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Depressive symptoms are common in older persons, often associated with poor physical function and vitamin D deficiency (serum 25-hydroxyvitamin D < 50 nmol/l). Simple and cheap interventions to prevent depression are lacking. Vitamin D deficiency occurs in 50% of persons >65 yr and has been associated with an increase in depressive symptoms in many studies, as well as with functional limitations and declining physical performance. A prior randomized placebo-controlled trial on the effect of vitamin D supplementation in overweight persons showed a decrease in depressive symptoms. Vitamin D supplementation also had a positive influence on mobility tests in several clinical trials. A mechanistic explanation is available: the vitamin D receptor is present in muscle cells as well as in brain tissue, especially in the hypothalamus. The hypothesis is that vitamin D decreases depressive symptoms and improves physical performance and functional limitations in older persons. Secondary hypotheses are that vitamin D decreases anxiety, improves cognitive functioning and quality of life, and prevents the development of full-blown depression in older persons.

Objective of the study:

Primary objectives:

1. Does vitamin D supplementation improve depressive symptoms in older persons?

2. Does vitamin D supplementation improve physical performance and functional limitations in older persons?

Secondary objectives:

1. Does vitamin D supplementation decrease anxiety and improve cognitive function and quality of life in older persons?

2. Can vitamin D supplementation prevent the development of full-blown depression in older persons?

3. Is vitamin D supplementation a cost-effective strategy in the prevention of increasing depressive symptoms and functional limitations and declining physical performance?

Study design:

A randomized double-blind placebo-controlled intervention study on the effect of vitamin D 1200 IU per day versus placebo on depressive symptoms, physical performance and functional limitations. The duration of intervention and follow-up is one year.

Study population:

Potential participants are recruited in The Netherlands, aged 60 to 80 years, are recruited in general practices with the Center of Epidemiological Studies Depression Scale (CES-D). They are eligible when having mild depressive symptoms, i.e. a CES-D score of 16 or higher. Further inclusion criteria are the presence of at least one functional limitation and a serum 25-hydroxyvitamine D concentration between 15 nmol/l and 50 nmol/l in winter or 70 nmol/l in summer. Patients with a diagnosis of depression are excluded. According to the sample size calculation and drop out, 50 persons per group, i.e.100 persons are required. Because of uncertainty in the 25-hydroxyvitamin D assay during screening, 70 persons per group will be included, altogether 140 persons..

Intervention:

The patients are randomized into two groups: vitamin D 1200 IU (three tablets of 400 IU per day) or placebo (three tablets per day) for one year.

Primary study parameters/outcome of the study:

Change in the CES-D score, change in physical performance score after 12 months, change in the number of functional limitations as well as change of degree of functional limitations.

Secundary study parameters/outcome of the study:

Change in anxiety, cognition, quality of life, incidence of full-blown depression, timed up-and-go-test, costs.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Potential participants are screened with postal questionnaires and a screening visit to their general practice (short questionnaire and blood sample). After screening, they have to come 3 times to the general practice or health center at baseline, after 6 and 12 months. They have to complete questionnaires, perform physical performance tests, and a blood sample is drawn twice at baseline and 6 months. Assessments at 3 weeks, 3 months and 9 months are by telephone. The risk of the vitamin D treatment is negligible.

Doel van het onderzoek

Depressive symptoms are common in older persons, often associated with poor physical function and vitamin D deficiency (serum 25-hydroxyvitamin D < 50 nmol/l). Simple and cheap interventions to prevent depression are lacking. Vitamin D deficiency occurs in 50% of persons >65 yr and has been associated with an increase in depressive symptoms in many studies, as well as with functional limitations and declining physical performance. A prior randomized placebo-controlled trial on the effect of vitamin D supplementation in overweight persons showed a decrease in depressive symptoms. Vitamin D supplementation also had a positive influence on mobility tests in several clinical trials. A mechanistic explanation is available: the vitamin D receptor is present in muscle cells as well as in brain tissue, especially in the hypothalamus. The hypothesis is that vitamin D decreases depressive symptoms and improves physical performance and functional limitations in older persons. Secondary hypotheses are that vitamin D decreases anxiety, improves quality of life and prevents the development of full-blown depression in older persons.

Onderzoeksopzet

Primary outcomes:

1. Change in depressive symptoms (CES-D score) after 12 months;

2. Change in physical performance score after 12 months;

3. Change in number and degree of functional limitations after 12 months.

Secondary outcomes:

1. Change in depressive symptoms (CES-D score), after 6 months;

2. Change in physical performance score after 6 months;

3. Change in number and degree of functional limitations after 6 months;

4. Number of subjects with a full-blown major depressive disorder (CIDI score) after 6 and 12 months;

5. Change in anxiety (Beck Anxiety Index score) after 6 and 12 months;

6. Change in cognition (Stroop Colour-Word Test score) after 6 and 12 months;

7. Change in quality of life (EQ-5D and SF-36 score) after 6 and 12 months.

Onderzoeksproduct en/of interventie

Experimental group: 1200 IU of vitamin D per day, in 3 tablets of 400 IU, for 12 months. Active substance: Colecalciferol. Product name: Devaron.

Placebo group: 3 placebo tablets per day for 12 months. (similar to Devaron tablets in size, shape, taste etc., but no active substance).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a participant must meet all of the following criteria:

1. Age 60-80 yr;

2. At least one functional limitation;

3. Mild depressive symptoms;

4. Serum 25-hydroxyvitamin D ¡Ý 15 nmol/l and > 50 nmol/l in winter or > 70 nmol/l in summer;

5. Ability to comply with the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential participant who meets any of the following criteria will be excluded from participation in this study:

1. Full-blown depressive disorder;

2. Use of antidepressiva;

3. Serum 25-hydroxyvitamin D < 15 nmol/l and serum 25 hydroxyvitamin D > 50 nmol/l in

winter or > 70 nmol/l in summer;

4. Vitamin D (more than 400 IU/day) or calcium supplementation (more than 1000 mg/day);

5. Major life-threatening illness;

6. Living in an aged people¡¯s home or nursing home.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2013
Aantal proefpersonen:	140
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3675
NTR-old	NTR3845
Ander register	METC VUmc / Wetenschapscommissie EMGO+ Instituut VUmc / CCMO : 2012/354 / 2012/041 / NL41567.029.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A