Diet and aggression

Gepubliceerd: 21-04-2015 Laatst bijgewerkt: 15-05-2024

multivitamin-, mineral-, and n-3 fatty acids supplementation is effective in aggression reduction in chronic psychiatric inpatients.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27374

Bron
NTR

Aandoening

chronic psychiatric inpatients
aggression
nutrition
n3-fatty acids
vitamins
minerals

langdurig opgenomen psychiatrisch patienten
agressie
voeding
n3-essentiele vetzuren
vitaminen
mineralen

Ondersteuning

Primaire sponsor: Leids Universitair Medisch centrum
Overige ondersteuning: ZonMw
Atrium Innovations Inc.
Leids Universitair Medisch Centrum

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main parameter in this study is the number of aggressive incidents in each arm, registered with the Staff Observation Aggression Scale- Revised Version (SOAS-R) (Nijman et al., 1999). As incidents may differ in severity and consequences, we make a distinction between minor (verbal aggression, threats, non-compliance with hospital rules, aggression towards objects, disinhibited [sexual] behaviour) and major (severe threats, fighting, assault on patients or staff, self-harm, suicide attempt) incidents. We carried out a pilot study to determine the prevalence of aggressive incidents among long-term psychiatric inpatients. This study yielded an estimate of 112 incidents per patient per year: 65 verbal aggression incidents, 12 incidents in which aggression was aimed at objects, 8 self-harm incidents, and 27 incidents in which physical aggression was aimed at others. We also monitored the time spent by nursing staff on each of these four types of incidents; verbal aggression took 80 minutes, aggression towards objects cost 77 minutes, self-harm cost 222 minutes, and physical aggression towards others cost 335 minutes per incidents. Based on these results, major incidents will be weighted by a factor 3.8.

Toelichting onderzoek

Doel van het onderzoek

multivitamin-, mineral-, and n-3 fatty acids supplementation is effective in aggression reduction in chronic psychiatric inpatients.

Onderzoeksopzet

SOAS-r will be used continuaously throuhghout the trial to register aggressive incodents.

t0, baseline: blood sampling (to monitor compliance), AVL-AV, SDAS, vCPRS, WHOQL-bref

t1, 2 weeks: SDAS

t3, 2 months: AVL-AV, SDAS, vCPRS, WHOQL-bref

t4, 6 months: blood sampling (to monitor compliance), AVL-AV, SDAS, vCPRS, WHOQL-bref

Onderzoeksproduct en/of interventie

During the six-month intervention, one group will receive two daily supplements :

• Orthica Soft Multi, containing vitamins (B1, B2, B3, B5, B6, B11, B12, C, D, E, Beta Carotene) and minerals (Calcium, Iodine, Copper, Magnesium, Selenium, Iron, Zinc, Potassium, Chrome, Manganese).

• Orthica Fish EPA MAX, containing n-3FA (EPA and DHA).

Both supplements are soft gel capsules and are available to the general public without prescription. Both supplements can be used as an addition to the existing diet. Patients can continue their normal dietary pattern and use of medication. The other group will receive two placebo capsules daily. Both supplements and placebos will be distributed through patients' Baxters, which are filled by the local pharmacist.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

age 18 or older

residing at a facility for long-term psychiatric care

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

pregnancy

breastfeeding

known contra indication for treatment with the supplements used in this study

expected discharge or transfer within the next eight weeks

current use of nutritional supplements and unwillingness to quit

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-01-2016
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-04-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47917
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5030
NTR-old	NTR5176
CCMO	NL51850.058.14
OMON	NL-OMON47917

Resultaten