Diet and aggression

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27374

Source
NTR

Health condition

chronic psychiatric inpatients
aggression
nutrition
n3-fatty acids
vitamins
minerals

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

Sponsors and support

Primary sponsor: Leids Universitair Medisch centrum
Source(s) of monetary or material Support: ZonMw
Atrium Innovations Inc.
Leids Universitair Medisch Centrum

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary parameters are:

• patient barriers and facilitators in the acceptation of nutritional supplements, which will be identified in a short semi-structured interview.

• costs of time spent by staff members on aggression incidents and additional costs of incidents

• patient self-report aggression levels as measured with the Aangepaste Versie van de Agressie Vragenlijst (AVL-AV) (Hornsveld et al., 2009)

• patient observer rated aggression levels as measured with the Socil Dysfunction and Aggression Scale (SDAS) (Wistedt et al., 1990)

• patient observer rated affective symptoms as measured with the Verkorte Comprehensive Psychiatric Rating Scale (vCPRS) (Asberg et al., 1979)

• patient quality of life as measured with the World heath Organization Quality of Life (WHOQL-bref) (De Vries et al., 1995)

Study description

Study objective

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

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

age 18 or older

residing at a facility for long-term psychiatric care

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-01-2016
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-04-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47917
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results