Diet and Aggression: Reducing aggression among chronic psychiatric inpatients through supplementation of multivitamins, minerals and n-3 fatty acids

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The main objective in this study is to test the hypothesis that suppletion with vitamins, minerals and n-3 fatty acids in long-term psychiatric inpatients will reduce the number of aggressive incidents.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON47917

Source
ToetsingOnline

Brief title
Diet and Aggression

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
aggressive behaviour among long-term psychiatric inpatients; escalation of aggressive behaviour

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw,Atrium Innovations, eigenaar en producent van het merk Orthica,Atrium innovations;eigenaar en producent van het merk Orthica

Intervention

Keyword: aggression, long-stay psychiatric inpatients, nutritional supplements

Outcome measures

Primary outcome

The main parameter in this study is the number of aggression incidents in each arm as registered with the Staff Observation Aggression Scale-revised (SOAS-R, Nijman et al., 1999). As incidents differ in severity and consequences, they will be divided in major and minor incidents, major incidents are: severe threats, fighting, assault on patients or staff, self-harm, suicide attempt ; minor incidents are: verbal aggression, threats, non-compliance with hospital rules, aggression towards objects, disinhibited [sexual] behaviour. In our pilot study in institutions for long-term psychiatric inpatient care (Hazewinkel et al., in preparation) we 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:

* facilitators and barriers of nutritional supplement acceptation by long-stay

psychiatric inpatients (see J)

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

costs of incidents

* patient quality of life as measured with the WHOQL-bref

* patient self-report aggression levels as measured with the AVL-AV

* patient observer rated affective symptoms as measured with the vCPRS

* patient observer rated aggression levels as measured with the SDAS

Study description

Background summary

Aggressive incidents frequently occur among long-term psychiatric inpatients (n=12.201 in The Netherlands Knispel et al., 2013). Incidents, such as verbal aggression towards persons, aggression towards objects, threats, non-compliance with hospital rules, disinhibited (sexual) behaviour, fighting, assault on patients or staff, self-harm and suicide attempt; follow from a wide range of causes such as psychosocial stressors, patient history, psychopathology, resistance to treatment, and being institutionalized. The magnitude of the aggression problem becomes evident in a review of 122 studies conducted in various psychiatric settings, showing that severe aggressive incidents occurred on average 5.8 times per 100 occupied bed days, amounting to 21 (standard deviation [SD]=42) serious events per bed per year (Bowers et al., 2011). The large SD indicates extreme variability across studies. A pilot study in 3 chronic inpatient wards (in Oegstgeest, The Hague, and Amsterdam) within the present study demonstrated an incidence rate of 112 aggression incidents per patient per year. This number can be divided in 35 major incidents (severe threats, fighting, assault on patients or staff, self-harm, suicide attempt), and 77 minor incidents (verbal aggression, threats, non-compliance with hospital rules, aggression towards objects, disinhibited [sexual] behaviour) (Hazewinkel et al., in preparation). Aggression has serious consequences; incidents can have physical consequences, may cause stress, and can be traumatic for patients as well as staff (Nijman et al., 2005; Bowers et al., 2011; Arnetz et al., 1997). Consequences of aggression can also be expressed in terms of financial costs. Finally, aggression is one of the reasons long-term psychiatric inpatients remain admitted involuntarily. Policymakers prioritize aggression reduction in (mental) health care. Containment of aggression and its consequences is achieved through (coerced) medication,

observation, show of force, restraint, seclusion, time-out, and security policies like locking ward doors, but also through aggression-anticipation and environment- and client-focused approaches (Bowers et al., 2011). However, further reduction of aggressive incidents remains necessary as becomes evident from initiatives like the petition *handen af van ggz verpleegkundigen* (www.handenafvanggzverpleegkundigen.nl), and the action plan against aggression in care (http://www.rijksoverheid.nl/nieuws/2012/03/22/ministers-presenteren-gezamenlijk-actieplan-tegen-agressie-in-de-zorg%5B2%5D.html), an initiative of the ministries of *Volksgezondheid, Welzijn en Sport* (VWS), *Binnenlandse Zaken en Koninkrijksrelaties* (BZK), *Veiligheid & Justitie* (VJ), and social parties.
The need for aggression reduction is also felt strongly among nursing staff, as is reflected in responses to a short anonymous online survey we conducted among psychiatric nurses (n=19), who unanimously endorsed the need for new methods for reducing aggression.
A number of randomised controlled trials (RCTs) demonstrated anti-aggressive effects of multi-ingredient formulae, including multiple vitamins, minerals, and n-3FA (i.e., omega-3 fatty acids), see figure 1. An RCT of vitamins and minerals in 62 juvenile delinquents showed a 28% (95%CI: 18-45%) decrease in violent and nonviolent offences over a 13-week period (Schoenthaler et al., 1997). A subsequent RCT of vitamins and minerals in 80 frequently disciplined schoolchildren showed a 47% (95%CI: 29-65%) reduction in the number of violent and nonviolent delinquent acts during a 4-month period (Schoenthaler et al., 2000). An RCT of vitamins, minerals, and n-3FA in 231 prisoners showed a 26% (95%CI: 8-44%) reduction in the number of offences and antisocial behaviour during a 2-39 week period (Gesch et al., 2002). Another vitamin, mineral, and n-3FA-RCT in 221 young adult prisoners demonstrated an incidence rate ratio of 0.60 (95%CI: 0.37-0.96) during a 1-3 month period (Zaalberg et al., 2010). Finally, a pilot study with 12 treatment resistant schizophrenia patients demonstrated reduced agitation and psychopathology and increased functioning upon n-3FA supplementation (Legare et al., 2007).
Chronic psychiatric inpatients are known to have poor nutritional status (Francis et al., 2010; Grol et al., 2005). This is the result of energy-dense and nutrient-poor diets, low appetite, and insufficient outdoor activities but also of the detrimental effect of psychotropics on appetite and gastrointestinal function, and possible interactions with food and nutrients (Gray et al., 1989). Based on the high prevalence of aggression and the poor nutritional status of this patient group, we hypothesize that the aggression reducing effect of vitamin-, micronutrient-, and n-3FA-supplementation in this group may be substantial. Providing nutritional supplements to this patient group may result in reduction of aggression, decrease of costs related to aggression, and increase in patients* quality of life.

Study objective

The main objective in this study is to test the hypothesis that suppletion with vitamins, minerals and n-3 fatty acids in long-term psychiatric inpatients will

reduce the number of aggressive incidents.

Study design

The proposed study is a pragmatic multicentre randomised double-blind placebo controlled intervention trial with an intervention period of 6 months. As the wash-out period of nutritional supplements is in some cases unknown, we propose a parallel design.

Intervention

During six months, one group will receive three capsules daily: 1 Orthica Fish EPA Mini en 2 Orthica Multi Energie, the other group will receive three placebo capsules daily.

Study burden and risks

Patients who agree to participate will enter a two-week run-in phase in which they will take three placebo capsules daily. After this run-in phase the use of three capsules per day will be evaluated, if this evaluation is positive participants will be randomised (baseline) to active or control condition. Participants will then start the daily use of three nutritional supplement capsules daily or three placebo capsules daily which will continue for six months.
At three moments (baseline, two months post baseline and six months post baseline) three questionnaires will be administered: the Aangepaste Versie van de Agressievragenlijst (AVL-AV, Hornsveld et al., 2009), a 12 item self report questionnaire about feelings of aggression; the Dutch version of the World Health Organization Quality of Life Questionnaire (WHO-QL-bref, De Vries & van Heck, 1996), a 26-item observer rated quality of life instrument; the verkorte Comprehensive Psychopathological Rating Scale (vCPRS, Montgomery et al., 1979), a 25-item observer rated questionnaire measuring affective symptoms. Also, at baseline and at six months post baseline two bloodsamples (25cc each) will be taken to determine nutrient status and patient background information (BMI, bloodpressure, drug use, information regarding diagnosis and treatment from the medical file, and social demographic information) will be collected . All data-collection will take place at the department where the patient resides.
Within the study aggression incidents will be registered by nursing staff in the department using the Staff Observation Aggression Scale-revised (SOAS-R, Nijman et al., 1999). As registration of severe incidents is already part of standard care, this registration will not form any burden for the patient.
Also, at 4 time points (baseline, two weeks post baseline, two months post baseline and six months post baseline), nursing staff will fill in the Social Dysfunction Aggression Scale (SDAS, Wistedt et al., 1990), measuring the observed level of aggression and social dysfunction.
The risks of participating in this study are minimal, the risk of blood

collection is that of a small local hematoma, feeling light headed, fainting or local infection. The use of the supplements Orthica Soft Multi and Orthica Fish EPA MAX has not been associated with any significant risks. Burden associated with participation is also minimal with questionnaires at three time points and blood sample collection at two points. Participants will be compensated for their time. Potential benefits of participating in this study are a direct and indirect increase in quality of life through improved nutrition as well as reduction of aggressive incidents.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

residing at a facility for long-term psychiatric inpatient care

age 18 or over

Exclusion criteria

Pregnancy
Breastfeeding
Known contra-indication for using the supplements used in this study (as specified in the Summary of Product Characteristics; SPC)
Expected discharge or transfer to a not included institution within the next eight weeks
Current use or use in the past eight weeks of nutritional supplements and refusal to quit this use for the duration of the study, with the exception of vitamin B1 (thiamine) and vitamin D
Contra-indication for the use of pork-gelatin
Failure to complete the two-week run-in phase

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-04-2015
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	17-04-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	03-02-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	12-12-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	28-08-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	01-12-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	30-10-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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: 27374
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT02498106;NTR5176
CCMO	NL51850.058.14
OMON	NL-OMON27374