Reducing Aggressive behaviour among People with an Intellectual Disability through Supplementation of Vitamins, Minerals and n-3 Fatty Acids

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The objective of this study is to test whether supplementation of vitamins, minerals and n-3 fatty acids may reduce aggressive behavior in people with intellectual disabilities. The research is relevant for the practice of social work. The…

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

Summary

ID

NL-OMON48658

Source
ToetsingOnline

Brief title
Reducing aggression through dietary supplements

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
aggression, aggressive behaviour

Research involving
Human

Sponsors and support

Primary sponsor: LUMC

Source(s) of monetary or material Support: Bonusan BV,innovatiefonds samenwerkende zorgverzekeraars en de Gemiva-SVG

Intervention

Keyword: Aggression, intellectual disability, nutritional supplements

Outcome measures

Primary outcome

The primary study parameter is the amount of aggressive behavior registered

with the Modified Overt Aggression Scale (MOAS).

Secondary outcome

The secondary study parameters are:

Aggressive- and anti-social behavior measured by the SDAS.

Quality of life measured by IDQOL-16

The cortisol status measured by hair analyses.

The micobiome measured with the aid of a feces analysis.

Study description

Background summary

Aggressive behaviour by intellectual disabled people is relatively common, with an estimated prevalence of in between 9% and 24%. The prevalence in institutionalized care recipients is even higher, reaching up to 45%. Aggressive behavior has consequences for both care recipients, as for the care workers. It contributes to stress and can lead to injury and illness. This becomes evident in a survey conducted by CNV on 112 social workers in care institutions for intellectual disabled people. More than 29% of the employees do not feel safe at work, 59% of the employees had to undergo a medical treatment because of an aggression incident and 88% of the social workers had to deal with physical aggression by clients (CNV, 2015). Aggressive behavior is more than physical aggression only. It is defined as: "any verbal, non-verbal

or physical behavior that is threatening or is causing actual physical damage (to the client themselves, others or property)" (Morrison, 1990).

Study objective

The objective of this study is to test whether supplementation of vitamins, minerals and n-3 fatty acids may reduce aggressive behavior in people with intellectual disabilities. The research is relevant for the practice of social work. The intervention with nutritional supplements can be combined with behavior-regulating medication or counseling methods to reduce aggressive behavior. Because of it's safety, the intervention is appropriate to apply to people with intellectual disabilities. An additional advantage is its low cost.

Study design

The study is a pragmatic multicenter randomized double-blind placebo-controlled intervention trial with an intervention period of 4 months. Since the washout period of several components of dietary supplements is unknown we chose a parallel design.

Intervention

The intervention consists of a daily supplementation of 2 multivitamin and mineral capsules "Multi Vital Forte" by Bonusan, supplemented with n-3 fatty acids "Omega 3 forte" in softgel capsules by Bonusan. The supplements or placebo's are provided 1x daily by the social care worker on location.

Study burden and risks

After completion of the informed consent procedure and a run in period of two weeks, the participant will spend two times an hour with the researcher for the completion of 2 questionnaires. The first time is at intake and it starts with a list of background information of the client, followed by a DHD-FFQ and a IDQOL-16. In addition a fecal sample is taken. In the last week the DHD-FFQ and IDQOL-16 are taken again and hair sample is also taken in addition to the stool sample. If the client is unable to complete the questionnaire in a meaningful way a social worker of the client is asked as a proxy.
For 16 weeks the participant will take one multi-vitamin mineral tablet and 2 softgel capsules with Omega 3 fatty acids daily. The use of the supplements '0737 MVF' and the 'Omega-3 forte' from Bonusan has not been associated with any significant risks.
The aggression will be recorded by the social worker using a MOAS form.

Contacts

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LUMC

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

intellectually disabled (IQ<80)
Residing, or day care at a social welfare organization.
Age 12 till 39
At least once a week aggressive behaviour.

Exclusion criteria

Pregnancy
Breastfeeding

People with: Williams syndrom, Wilson's desease, primary hyperparathyroidism and hemochromatosis.
Current use of multi vitamins, -minerals and omega-3 fatty acids supplementation and refusal to quit this at least two moths before the beginning of the intervention
Allergy for fish
The use of the following medication: levothyroxine, methyldopa en levodopa

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2018
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	28-11-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	20-04-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	24-07-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	14-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	25-04-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

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

Approved WMO

Date:	24-01-2020
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT03212092
CCMO	NL60839.058.17

Study results

Date completed:	01-02-2021
Actual enrolment:	185