Supplements for reducing aggressive behavior in people with mild intellectual disabilities.

Published: 28-10-2013
Last updated: 22-04-2024

The objective of this pilot study is testing whether the supplementation of vitamins and minerals can reduce aggressive behavior and improve quality of life in people with mild intellectual disability. With sufficient results a follow-up research is...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38720

Source
ToetsingOnline

Brief title
Vitamins & minerals for reducing aggression

Condition

- Other condition

Synonym
attacking behaviour, Violence

Health condition

Agressief gedrag

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Regeling Veilig Werken in de Zorg

Intervention

Keyword: Aggression, Intellectual disability, Supplements, Vitamins and minerals

Outcome measures

Primary outcome

The reduction of aggressive behavior. .Aggression is measured on the basis of a daily score on the Modified Overt Aggression Scale (MOAS).

Secondary outcome

The effect of the supplements on the quality of life. It is also examined whether the effect of nutritional supplements on aggressive behavior is mediated by positive and negative affect. The positive and negative affect is measured daily, using two items derived from the abbreviated Positive And Negative Affect Schedule (PANAS). The Reactive and Proactive Aggression Scale (RePro) is used to distinguish between reactive and proactive aggression. The Intellectual Disability Quality of Life scale is used (IDQOL-16) for measuring the quality of life. The effects are controlled for sex, age, medication, sweets, alcohol consumption and tobacco consumption.

Study description

Background summary

Literature shows that most people with mild intellectual disability do not keep an optimal diet and have a higher degree of alcohol, tobacco and medicine consumption than the general population. In addition, they face a higher level

of stress. These factors can cause relative shortage of vitamins and minerals. A relative shortage of vitamins and minerals may provide a sub-optimal performance of a number of neurotransmitter systems, which may affect behavior. Earlier research has shown that supplementation of vitamins and minerals can help reduce aggressive behavior in certain target groups.
The research question of this study is: is supplementation of vitamins and minerals effective in reducing aggressive behavior in a population consisting of people with mild intellectual disabilities? The following assumptions are made:
* supplementation of vitamins and minerals will lead to a lesser degree of aggressive behavior in comparison with the placebo condition.
* The supplementation of vitamins and minerals will lead to a lower negative affect and higher positive affect as compared to the placebo condition.
* There is a positive correlation between negative affect and reactive aggression.
* The effect of nutritional supplements on aggression is partially mediated by negative affect.
* Supplementation of vitamins and minerals will lead to a higher quality of life compared with the placebo condition.

Study objective

The objective of this pilot study is testing whether the supplementation of vitamins and minerals can reduce aggressive behavior and improve quality of life in people with mild intellectual disability. With sufficient results a follow-up research is possible, in order to develop a treatment for reducing aggression in the social care.

Study design

The design is a randomised double-blind placebo controlled trial, studying the effect of the supplementation of vitamins and minerals on aggressive behaviour by people with a mild intellectual disability.

Intervention

The intervention group will receive daily a multivitamin and mineral tablet, during a period of ten weeks. The placebo group will receive an identical looking tablet containing starch. The baseline is measured in the week before the intervention starts.

Study burden and risks

The burden for the participant consists of the daily intake of a tablet and the communicating about their affect with their attendant. Further there are three

questionnaires to be filled in this will take about an hour.

Contacts

Public
Erasmus MC

Dr. Molewaterplein 50
Rotterdam 3015 GJ
NL
Scientific
Erasmus MC

Dr. Molewaterplein 50
Rotterdam 3015 GJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The pricipal inclusion criteria are: mild intellectual disability (IQ 50-85) with behavior problems; age 18 till 40, minimum once a week aggressive behavior according to the reports of the care institution, ten week from the beginning of the intervention.

Exclusion criteria

Exclusion criteria are; users of multivitamin supplements, pregnancy, swallowing problems

and users of medication with possible interactions with vitamins and minerals: digoxin, ACE-inhibitors methyldopa, sulfasalazin, levothyroxin, colestyramin, tetracycline antibiotics and warfarin.

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:	Will not start
Enrollment:	24
Type:	Anticipated

Ethics review

Not approved

Date:	28-10-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL45255.078.13