Mastication training in adult patients with mitochondrial diseases: a pilot study.

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The aim of this pilot study is to assess the effect of low intensity mastication training in patients with a mitochondrial disease on masticatory performance, efficacy, endurance, bite force and the feasibility of this training .

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metabolic and nutritional disorders congenital
Study type	Interventional

Summary

ID

NL-OMON44341

Source
ToetsingOnline

Brief title
Mastication training in patients with mitochondrial disease.

Condition

- Metabolic and nutritional disorders congenital
- Inborn errors of metabolism

Synonym
Mitochondrial disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboudumc, afdeling Logopedie (kinderen), Afdeling Revalidatie
Source(s) of monetary or material Support: Ministerie van OC&W,Stofwisselkracht

Intervention

Keyword: mastication training, mitochondrial disease

Outcome measures

Primary outcome

1.Performance, using Mixing Ability Test: Mixing Index is derived.

2.Efficacy, using Test of Mastication and Swallowing Solids (TOMASS): Z-scores are calculated (table1) for total bites, total masticatory cycles, total swallows and total time.

3.Endurance, using the 6 Minutes Mastication Test (6MMT): Number of chewing cycles per minute and total number of chewing cycles are measured. The percentage difference between minute 1 and minute 6 is computed A numeric visual analogue scale (0-10) assess masticatory muscle pain and fatigue directly after the test and after 5 minutes.

4. Bite force, using VU University Bite Force gauge (VU-BFG): Maximum bite force is measured taking the highest score in Newton.

Secondary outcome

Secondary parameters are outcomes of the Mandibulaire functiebeperking vragenlijst (F1.1), and answers of the participants on the feasibility questionnaire (F1.2).

Study description

Background summary

Patients with mitochondrial diseases often complain about fatigue, muscle pain, loss of muscle strength and diminished endurance in physical activities. Easily

fatigued muscles during mastication is a frequently reported clinical symptom in patients with mitochondrial disease
Current usual care of these complaints during mastication is the adaption of food.
Although current usual care is based on compensatory strategies, aerobic training (cycling, during 8 weeks)) was found to have meaningful effects in skeletal muscle endurance in patients with a mitochondrial disease (mutation 3243 A * G), with no adverse effects of the training. Furthermore, a study on efficacy of low intensity mastication training using chewing gum was performed in patients with Duchenne muscular dystrophy, which showed improvement of the masticatory performance after a 4 week training (30 minutes, 3 times a day, 5 days a week).

Study objective

The aim of this pilot study is to assess the effect of low intensity mastication training in patients with a mitochondrial disease on masticatory performance, efficacy, endurance, bite force and the feasibility of this training .

Study design

Ten participants with mitochondrial disease will be asked to participate in the low intensity mastication training during 8 weeks.
A comparison group of ten adult participants with mitochondrial diseases (age and sex matched to the adults in the intervention group) will serve as control group.

Intervention

The intervention will consist of an 8 weeks low intensity mastication training using sugar free chewing gum. The instructions for training are 1 piece of sugar free chewing gum per exercise, 3 exercises a day of each 20 minutes, 5 days a week. Participants are free to choose the time of training, with an interval of at least 4 hours between the two exercises.
Participants are asked to keep a diary (f2) to check for compliance and potential complications.
Participants in the control group will be asked to do nothing additional to their daily routine. They are supposed to continue using the compensatory strategies (if applicable) they have already learned.

Study burden and risks

- Time investment: two times 20-30 minutes, at the start and end of the study;
- When assigned to the intervention group: 20 minutes, 3 times a day, 5 days a week, during 8 weeks chewing on a sugar free chewing gum. This burden is in

proportion because it is a low intensity training and the participant is free to choose the time of training, thereby fitting in his daily routine. Besides a two days rest period per week is included to increase compliance;
- It is possible to experience more fatigued muscles during mastication.
- It is possible to experience lack of energy caused by the intervention.
During training, there is an increased energy demand, which theoretically could increase the oxidative stress. However, this was not found in studies with endurance training in patients with a mitochondrial disease.

In conclusion the mastication training used in this study has an acceptable, low overall risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Genetically confirmed mitochondrial disease and aged >18.

Exclusion criteria

- Not able to participate on the measurements at baseline, due to physical problems.
- Problems with oral intake, defined as a Functional Oral Intake Scale (FOIS), score 1 * 4 (see Appendix 1 in Protocol) (Crary, 2005)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	06-02-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL64078.091.17