

Fitness for swallowing

Speech therapy for swallowing disorders in adults with intellectual disability through biofeedback: does it work?

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Primary purpose: study the feasibility of a new treatment option based on biofeedback in people with intellectual disabilities. Secondary purpose: explore effects of treatment for swallowing problems in people with intellectual disabilities.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45655

Source

ToetsingOnline

Brief title

Fitness for swallowing

Condition

- Other condition

Synonym

dysphagia, swallowing disorders

Health condition

slikstoornis

Research involving

Sponsors and support

Primary sponsor: De Trans

Source(s) of monetary or material Support: deels gesubsidieerd door De Trans en aanvullende financiering uit synergiefonds van Espria (concern met verschillende zorgorganisaties waar De Trans deel van uit maakt) en een ontwikkelafpraak met het Zorgkantoor Drenthe. Silverfit heeft een scholing beschikbaar gesteld om de apparatuur te kunnen gebruiken. De apparatuur is aangeschaft door De Trans. Er zijn verder geen afspraken met Silverfit gemaakt.

Intervention

Keyword: biofeedback, intellectual disability, speech therapy, swallowing disorders

Outcome measures

Primary outcome

There are a number of types of outcome measures:

- insight in minimal developmental age and minimum language comprehension level where the training is feasible.
- pre- and post-treatment severity and type of swallowing problems.
- physiological data on basistonus, swallow strength and timing.

Secondary outcome

not applicable

Study description

Background summary

Swallowing disorders are common in adults with intellectual disability. It is estimated that more than eight percent of all adults with intellectual disabilities are dealing with swallowing difficulties. Swallowing problems are more common within the 24-hour care for people with intellectual disabilities. Recent research showed that almost 50% of adults in such a setting are dealing with swallowing problems. These problems range from mild to very severe.

Swallowing problems affect the enjoyment of food and drinking. Treatment options for swallowing problems these people are minimal. Following such therapy requires the patient insight into their own actions, the ability to follow instructions and practice independently and maintain skills. Experiences with biofeedback are positive and can help to learn the correct swallowing techniques.

For some time the SilverFit Rephagia program is available. The program uses visual exercises on a computer screen. This research has the primary goal to examine how the SilverFit Rephagia program is an appropriate training for adults with intellectual disabilities

Study objective

Primary purpose: study the feasibility of a new treatment option based on biofeedback in people with intellectual disabilities.

Secondary purpose: explore effects of treatment for swallowing problems in people with intellectual disabilities.

Study design

It concerns a feasibility study on the use of training to a new audience.

Because especially looks at whether the study is suitable, and in addition, it is expected for the control group in terms of enhanced zero, there is no use is made of a control group.

For insights to provide for whom the training is and is not appropriate and how to act any effects of the training, we are using a multiple case study.

Intervention

Training on the basis of biofeedback where serious gaming is combined with sensory information from the swallowing activities. The intention is to achieve improvement in timing, strength and coordination of the swallowing process. Participants follow a speech therapy with SilverFit Rephagia for 6 weeks with a frequency of twice a week.

Study burden and risks

The risks to participants are small. There is a small risk in choking, therefore not larger than in regular life of the participant.

It is possible that the participant has to do with skin irritation caused by the pad, which is stuck on the neck and throat.

The training takes less than half an hour per session.

The expectation is improvement of swallowing skills of the participants who follow the training.

Because of the expected improvement of the swallowing skills, there will be a reduction of the severity of dysphagia. So it makes the skills needed for

eating and drinking better and a decreasing chance of choking.

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

There is at least a mild intellectual disability.

There is a swallowing disorder, determined by speech therapy research.

Exclusion criteria

tube feeding through nose, stomach or intestine

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-05-2017

Enrollment: 20

Type: Actual

Medical products/devices used

Generic name: Silverfit Rephagia

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 13-04-2017

Application type: First submission

Review commission: METC Brabant (Tilburg)

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

CCMO

ID

NL60602.028.17