Prevention of communicative decline in the cognitively impaired. Intervention on disordered perceptive and productive functions.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30605

Source
ToetsingOnline

Brief title
Improving speech in the cognitively impaired

Condition

- Other condition
- Congenital and hereditary disorders NEC
- Congenital and peripartum neurological conditions

Synonym
cognitive disability ; mental disorder

Health condition

logopedisch: taal-spraakstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Instellingen voor VG-zorg

Intervention

Keyword: cognitive impairment, communication, hearing, speech

Outcome measures

Primary outcome

The specific function training will be given in two episodes of 3 months, with an intervening rest-episode, each followed by assessment of progress. Based on progress and motivation of the patient, in the second episode the same training will be continued as in the first, or a switch to another approach within the same function domain will be made.

Because in the literature hardly any reports are available on this type of function training in adults with mental retardation, with concomitant restricted motivation and trainability, a study design with randomized groups seems inappropriate. In order to track progress during treatment, a detailed protocol of assessment and registration of training will be developed and implemented.

Secondary outcome

not applicable

Study description

Background summary

Oral communication is the most direct form of communication between people. Patients with mental retardation have increased risks of communicative failure and consequent social isolation. In many patients these risks go beyond what would be expected on the basis of their level of cognitive functioning, but are caused by impairments in the preception and production of speech. This project focuses on patients with mental retardation who in addition show hearing impairment and/or specific impairment of speech production and perception skills.

Study objective

Aim of this project is to diagnose hearing impairment, and underlying disorders in speech perception and production, and to develop and implement adequate intervention techniques, which are subsequently evaluated. The ultimate goal is to prevent that in patients with MR hearing impairment and specific difficulties in listening and speaking communicative skills decline.
The study specifically focuses on input- and output functions. At the perceptual or input-side: hearing and auditory processing; at the production or output-side: articulation and speech motor control. The rationale is that in patients with mental retardation who suffer from specific difficulties in input- and output- functions, intervention to improve those functions will be most effective, and will prevent deterioration of communicative and social functioning.

Study design

The first phase of the study comprises screening from the larger group of patients with mild to moderate mental retardation those patients in whom communicative and social functioning stays behind their expectancy level. This will be based on medical records and on inventories of communicative skills and opportunities.
The second phase entails administration of an extensive battery of cognitive and speech-language tests, in order to assess the cognitive and speech-language profile; for a selection of patients also electro-encephalographic (EEG) recordings will be made.
The third phase is the intervention phase. Patients receive hearing aids including audiological and logopaedic support, or speech therapy comprising auditory processing or articulation and speech motor functions. A baseline-intervention-design will be implemented, in which half the patients start their intervention 3 months later, after a second assessment.
Phase four comprises evaluation of the intervention: assessments at 3-months

intervals to monitor progress, and a larger evaluation at the end of the intervention and 9 months later.
Also the communicative abilities will be assessed at the beginning an at the end of the project.

Intervention

The function-profile is the starting point for intervention. Patients receive hearing measures or speech therapy on the basis of their function profile. Thus, two types of treatment will offered: (1) hearing and speech perception; (2) articulation and speech motor skills. Treatments are derived from speech therapeutic intervention strategies for children.
The two types of treatment are the following:
1. Hearing and speech perception: Audiological intervention and specific speech perception training, in order to improve attention for speech sound, perception of phonological contrasts, and speech sounds in context.
2. Articulation and speech production: phonological therapy according to Metaphon; relevant parts of the Dutch Dyspraxia Program (Erlings-van Deurse e.a., 1993; derived from the Nuffield dyspraxia programme in English).

Study burden and risks

There are no physical health-risks. Substantial investment of time and exercise is required from the subjects. However, this could be experienced positively by the subjects, because of the personal attention during therapy, as well as the provisioned progress in communicative abilities.

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

Mild to moderate mental retardation (i.e. IQ level 35 to 70).
Adults.
Hearing impairment or speech impairment

Exclusion criteria

psychiatric disorder; acute medical condition

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-06-2007
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	hearing device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

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	NL16175.091.07