Analysis of the rehabilition program for ABI (Dutch: NAH)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON56588

Source
ToetsingOnline

Brief title
ARENAH

Condition

- Other condition

Synonym
Visual impairment through Acquired Brain Injury (ABI)

Health condition

Visuele klachten n.a.v. Niet-aangeboren hersenaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Koninklijke Visio
Source(s) of monetary or material Support: Visio Foundation

Intervention

Keyword: ABI, Effect measurement, Neuro-visual rehabilitation, Questionnaires

Outcome measures

Primary outcome

Primary parameters will include variations in lead time. Lead time is defined as the duration between the initial intake and the onset of the rehabilitation trajectory. The transition from the research to the rehabilitation phase can be readily identified through the first and second multidisciplinary meetings (MD1 and MD2).

In the first multidisciplinary meeting (MD1), the framework and assessments for the research trajectory are established in order to address the rehabilitation needs of the client. Typically scheduled one week after the intake, MD1 marks the initiation of the research trajectory. The second multidisciplinary meeting (MD2) takes place upon the completion of the research trajectory. During this meeting, the training sessions are precisely defined in terms of their nature and quantity, based on the rehabilitation needs and insights gathered from the research trajectory. MD2 therefore signifies the commencement of the rehabilitation trajectory.

Secondary outcome

Questionnaires are administered to clients (before and after the rehabilitation trajectory), and the answers will be compared. Depending on the rehabilitation needs, one or more questionnaires are administered in one of the following categories:

- Communication

- Orientation and Mobilization

- ICT

- Household

- Light and discomfort glare

- Psychosocial

- Managing of energy balance

- Leisure activity

- Self-care.

Furthermore, the following parameters are also taken into account: customer satisfaction, waiting list time, treatment outcomes, understanding of condition and limitation, and quality of life.

Study description

Background summary

The diagnosis of visual functions in people with acquired brain injury and visual problems (hereafter referred to as ABI clients) has significantly improved in recent years, leading to a sharp increase in the number of ABI clients seen by Visio annually. However, the diagnostic process that begins after the intake is completed can be long and arduous, particularly for newly referred clients who may be in poor condition and unable to sustain a lengthy process. These clients are often fatigued, both physically and mentally, which can make it difficult for them to process information. Therefore, it is crucial to balance what is feasible for the client with what is necessary for identifying their possibilities and limitations. By doing so, the client's efforts and questions can be balanced with the amount of diagnostics and the duration of the rehabilitation trajectory, without compromising the treatment outcome. This approach enables targeted, efficient, and faster rehabilitation, which prioritizes the client's needs and improves the overall effectiveness of

the organization.

Study objective

The aim of this project is therefore to measure the effect of the neuro visual rehabilitation and to (re)organize the care from Visio based on the client's request for help and condition.

Study design

This research project employs an experimental study design to investigate the effects of adjustments to the current rehabilitation process for ABI clients at Royal Visio. The study involves two research groups, with the first group serving as a control and already approved as a non-WMO application (2022.0495). The second group involves a rehabilitation trajectorie with specific adjustments:

- Research group 2: Visual Function Assessment (VFO) tailored to the specific needs of the client, with the application of guidelines for determining the need for Neuropsychological Assessment (NPO).

The NAH clients will be distributed across these two groups and compared using lead time (primary study parameter) and different questionnaires (secondary parameter). The specific questionnaire administered will depend on the rehabilitation question identified during the intake at Koninklijke Visio. These rehabilitation questions can be broadly divided into nine categories, with a PROM questionnaire developed for each category to assess changes in health or quality of life during the rehabilitation process at Visio. The duration of the study will depend on the length of the rehabilitation process for the client, plus an additional 15-30 minutes before and after the process to complete the questionnaires.

RECRUITEMENT
Upon registration with Koninklijke Visio (prior to the intake process), clients have provided given their written consent or objection to receiving information or being contacted in relation to potential participation in scientific research. Clients who have given permission for researchers to be contacted about participating in scientific research will be both assessed for eligibility and contacted by the researcher. During this telephone conversation, participation in the study will be clearly explained. In this conversation it will be clearly emphasized that the research is about shortening the research process. The advantages (shortened waiting list and a less strenuous research trajectory tailored to their specific needs) and the disadvantages (if in-depth research is necessary, a second appointment will have to be scheduled) will also be presented to the clients.

When the client is interested in participation, an information letter and consent form will be sent. Sufficient time (minimum of one week) will be given for clients to review and sign these. They will be contacted by telephone 1-2 weeks before their first appointment at Royal Dutch Visio to conduct the questionnaires. Before the start of the questionnaires, there will also be an opportunity given to ask any remaining questions.

Study burden and risks

The risks of this study are minimal. Of course, participation means that this will require time and energy from the participant. It is up to the participants to estimate whether participation is feasible for them. Additionally, participants can always end their participation if they want to. The researchers will make the participants aware of this. Furthermore, if deemed necessary or when the request for help is altered/expanded, the participant can always return to research trajectory for additional research. Therefore, the quality of care will not be altered through this research.

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

- Older than 18 years
- Good understanding of the Dutch or English language
- Clients of Royal Visio with visual impairment (through acquired brain injury)

Exclusion criteria

- Clients who do not have any form of acquired brain injury.
- Clients with complex psychiatric complaints
- Clients with extremely low strain capacity. An indication for this is them not being able to complete a 60 min interview/intake on the telephone.
- Limited life expectancy, for example those with terminal sickness or palliative care.
- Severe cognitive impairment: I.e. incapable to answer for oneself (without help); hetero anamnesis; incapacitated; severe anosognosia.
- Severe aphasia
- Psychiatric disorders

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-03-2024
Enrollment:	50
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	06-02-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL82600.018.23