Effectiveness of audiobooks for patients who hear voices: a pilot study

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Primary objective: the primary goal is to investigate the effect of audiobooks on quality of life, general psychopathology, the experienced power of the voices and the burden of the voices. Secondary objective: the second goal is to determine whether...

Ethical review	Not approved
Status	Will not start
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON34270

Source ToetsingOnline

Brief title Audiobooks for patients who hear voices

Condition

· Schizophrenia and other psychotic disorders

Synonym auditory hallucinations, hearing voices

Research involving Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen) **Source(s) of monetary or material Support:** Optelect Nederland B.V. stelt de audio apparatuur beschikbaar.,Stichting OLIM

Intervention

Keyword: auditory hallucinations, hearing voices, quality of life

Outcome measures

Primary outcome

The primary outcome is quality of life.

Secondary outcome

The secondary outcomes are:

- General psychopathology
- The power of the voices
- Beliefs about voices
- The frequency of use of the audio player
- The experience of the audio books

Study description

Background summary

Psychotic disorders are often accompanied by impaired concentration, both by disease and medication. Because of this, reading books is often impossible. By giving audiobooks to the patients, we offer an activity which was no longer possible. We want to know whether this intervention is associated with an increase in qulaity of life, decrease in general psychopathology and whether it reduces the burden of auditory hallucinations.

Study objective

Primary objective: the primary goal is to investigate the effect of audiobooks on quality of life, general psychopathology, the experienced power of the voices and the burden of the voices.

Secondary objective: the second goal is to determine whether the research is possible for patients woth psychotic disorders. This includes the feasibility of (1) the execution of the study in the proposed manner and (2) the

intervention itself.

Study design

In this study, we use a controlled design. The experimental groups receives and intervention consisting of the use of audiobooks for eight weeks. The control group receives no intervention. Both groups receive pre and post measurements.

The durations of the study for an individual patient is twelve weeks. The first four weeks are used for including the patient in the study and for the patient giving permission to participate. After these four weeks, the patients in the experimental group receive the audio player. All participants receive the questionnaires after inclusion and at the end of the period of intervention.

The total duration of the study is eight months. During the first six months, the inclusion and measurements are executed. The last two months are used for analysis and reporting.

Intervention

The intervention is providing audio books to patients who perceive auditive hallucinations (hearing voices).

The choice of books that the patients are listening to is left entirely to the participants. They are not obliged to listen to books with a certain subject or theme. Participants are also free to choose where they want to listen to books and how often and how long they want to do.

The way the audio books are offered by using daisy players (Digital Accessible Information System). This audio device uses daisy-roms. This method has the advantage of saving the entire book on a disk, as opposed to ordinary audio books on several disks. The daisy player has more options than the usual audio books, such as navigating the text and setting playback speed and volume. Patients can use the listening material of 'Loket Aangepast Lezen' (www.aangepast-lezen.nl). This form of adapted reading was originally designed for people with visual impairments, including blindness, visual impairment, or other reading disabilities. Patients will be supported in applying for the books when they need it.

Participants in the experimental group receive a daisy player for eight weeks. For patients in the control group, it is possible to use daisy players for eight weeks after the study to compensate for their investment. This offer goes beyond the investigation as described in this protocol.

Study burden and risks

The proposed intervention was not previously discussed in the scientific literature. The potential risks are not known. Investigations of a similar interventions, namely the effects of listening to music, have shown no adverse risks. Based on this knowledge, the researchers expect that the proposed intervention entails a negligible risk for the participating patients.

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

- Diagnosis of psychotic disorder

- Auditory hallucinations in particular hearing voices. Items 1, 9 and 10 of the Auditory Hallucination Rating Scale (AHRS) must be equal to or higher than 3

- Interested in reading (books, magazines, newspapers)

Exclusion criteria

- Not having Dutch as mother tongue
- Severe substance abuse
- Severe organic brain damage

Study design

Design

Primary purpose: Other	
Masking:	Open (masking not used)
Allocation:	Non-randomized controlled trial
Intervention model:	Other
Study type:	Interventional

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	24
Туре:	Anticipated

Ethics review

Not approved	
Date:	09-07-2010
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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 NL32701.097.10