Music intervention for people with an intellectual disability

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The overall aim of this RCT is to examine whether an individual music intervention can improve the challenging behavior, quality of life, emotional wellbeing and EF of adults with a mild to moderate ID.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20982

Bron
Nationaal Trial Register

Verkorte titel
Music-ID

Aandoening

Intellectual disability, challenging behavior

Ondersteuning

Primaire sponsor: Stichting Philadelphia Zorg
Overige ondersteuning: Stichting Philadelphia Zorg

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is challenging behavior, quality of life, emotional wellbeing and EF.

Toelichting onderzoek

Achtergrond van het onderzoek

This randomized controlled trial compares the effect of an individual music intervention with care as usual on emotional and behavioral problems and executive functioning among people with mild to moderate intellectual disability and challenging behavior. Furthermore, the self-reported feelings before and after each session will be analyzed. The design of this study is a RCT with two arms: a music intervention and a care as usual (CAU) group. A pre-post-follow-up design will be employed.

Doel van het onderzoek

The overall aim of this RCT is to examine whether an individual music intervention can improve the challenging behavior, quality of life, emotional wellbeing and EF of adults with a mild to moderate ID.

Onderzoeksopzet

A pre-post-follow-up design will be employed.

Onderzoeksproduct en/of interventie

Participants that are included are randomized to one of two conditions: music intervention or CAU.
• Music intervention (experimental group)
This intervention consists of sixteen music session within a maximum of 10 weeks. The music sessions will be carried out by musical caregivers, which can be professional caregivers, relatives, volunteers or professional music coaches. Additionally, there will be two scheduled meetings for the musical caregivers for intervision purposes. The music intervention will be provided in accordance with a training manual for musical caregivers. This training manual is especially developed for this study, with the input of different advisory groups.
In the manual intervention procedures are specified. The setting, general goals, contents of the music sessions and basic principles of the intervention as well as exemplifications will be outlined. By use of this protocol the intervention is standardized, but the protocol leaves enough flexibility to tailor the intervention to the characteristics and needs of the participants.
• CAU (control group)
Participants randomized into the experimental condition will receive both the musical intervention and CAU, while participants who are randomly allocated to the control group will receive only CAU during the study. Care as usual might include musical activities on facility-level, as music is a central theme among facilities of Stichting Philadelphia Zorg. However, individual musical activities will be postponed. Participants in the control group will be offerend musical activities at the end of the study, if they are still interested in this.
• Extra-music intervention

Ten participants who are randomized into the experimental condition will receive a specific music intervention, where there is a maximal musical input. They will be exposed to music as often as can be. By this manner, it is possible to examine the effect of additional music.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Mild or moderate ID (35-70)
- Age: 18 years or older
- VG-6 indication (or problems often accompanied by a VG-6 indication)
- Mentally competent to consent to participate in this research

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Inability to participate in an intervention for at least one hour
- Hearing impairment, which cannot be corrected with a hearing aid
- Serious medical condition which limits participation (e.g. dementia)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-05-2021
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-03-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8482
Ander register	non-WMO: METc VUmc : 2018.439 (A2020.028)

Resultaten

Samenvatting resultaten
We aim at publishing this study’s findings in international scientific peer-reviewed journals. Results will be presented at international scientific conferences and national conferences within the field of disability research.