1) The checklist 'Attune & Stimulate' is a valid instrument to assess the arousal level of clients with SID. 2) Caregivers who are randomized to the intervention group that is instructed to use the A&S-checklist attune...

**Ethical review**
Approved

**Status**
Completed

**Health condition type**
-

**Study type**
Interventional

## Summary

### Brief title

TBA

### Health condition

Severe Intellectual Disability (SID)
Ernstig Meervoudige Beperking (EMB)
Difficulties in attunement with other people
Stressregulation (Stressregulatie)
Emotionregulation (Emotieregulatie)
Behavioural Problems (Gedragsproblemen)

### Sponsors and support

**Primary sponsor :**
This research is conducted within nine residential care organisations for people with an intellectual disabilities in the Netherlands. In this project we work together with care organisations Bartiméus, Ons Tweede Thuis, Cordaan en ASVZ, Accessibility, Prader-Willi Fonds, Stichting Down Syndroom and educational institutions VU, HvA, ROC Amsterdam and TU/e.

**Source(s) of monetary or material Support :**
ZonMW

### Intervention
Outcome measures

Primary outcome

The primary objective of this study is to investigate whether the checklist ‘Attune & Stimulate’ (in Dutch: Aansluiten & Stimuleren) results in a better attunement when used by caregivers of persons with severe intellectual disabilities compared to the attunement of caregivers who provide care as usual in the control group, and whether this results in a more optimal level of arousal in the clients.

Research question:
Does the use of the checklist ‘Attune & Stimulate’ results in better attunement of the caregivers to persons with severe intellectual disabilities than the attunement of caregivers who provide care as usual? And results this in more optimal level of arousal in the clients?

Primary study parameter(s):
Observed arousal level with the A&S-checklist
Observed applied recommendations of the A&S-checklist by the caregiver
Observed ‘responsive/child oriented behaviour’ of the caregiver with the Maternal Behavior Rating Scale (MBRS; Mahoney, 2008)

Secondary outcome

The secondary objective of this study is to test the construct validity of the new checklist ‘Attune & Stimulate’.

Research questions:
What is the correlation between the arousal observed with the A&S-checklist and related constructs?

Other study parameter(s):
b) Adaptive functioning - Vineland Screener 0-6 jaar (Vineland-S; Scholte, Van Duijn, Dijkxhoorn, Noens, & Berckelaer-Onnes, 2008) or Sociale redzaamheidsschaal (SRZ; Kraijer, Kema, & De Bildt, 2004).
c) Communication and influence - Subscale of the Quality Of Life of persons with Profound Multiple Disabilities (QOL-PMD; Petry, Maes, & Vlaskamp, 2008).
d) Subjective well-being - The Mood, Interest, and Pleasure Questionnaire (MIPQ; Ross & Oliver, 2003), Dutch translation (Maes, Penne, Petry, & Vos, 2015).
e) Physiological measurement of arousal - Skin conductance sensor sock (Frederiks, Croes, Chen, Bambang Oetomo, & Sterkenburg, 2015; Sterkenburg et al., 2017).
Study description

Background summary

Rationale: Persons with severe intellectual disabilities (SID) often experience social and behavioural problems, resulting in difficulties in the attunement with other people or in stress when they have new social experiences. Also parents and caregivers find it hard to attune to the wishes of their child/client. This can lead to social and behavioral problems for persons with SID. It is therefore important that caregivers and parents can identify and prevent behavioural problems, in order to enable persons with SID to build relationships.

Objective: The goal of the current study is to examine whether the checklist Attune & Stimulate’ (A&S) developed at the Vrije Universiteit Amsterdam (Doodeman, Blom-Yoo & Sterkenburg, 2018) is a valid tool that can support caregivers and parents in their daily contact with their child or client with SID (effectiveness).

Study design: A Randomised Controlled Trial which has one measurement and contains a group of caregivers using the Attune & Stimulate checklist and a control group with caregivers who do not use the checklist; they provide the care as usual. The measurement consists of a video of an interaction between the client and the caregiver, in which the client wears the skin conductance sensor sock (measuring level of arousal).

Study population: This study involves 140 adults with an IQ lower than 35 who live in group homes for this target group.

Intervention: The intervention is the checklist ‘Attune & Stimulate’ (Doodeman, Blom-Yoo & Sterkenburg, 2018).

Main study parameters: The attunement of the caregivers with the person with SID and the level of arousal of the person with SID.

Study objective

1) The checklist 'Attune & Stimulate' is a valid instrument to assess the arousal level of clients with SID.

2) Caregivers who are randomized to the intervention group that is instructed to use the A&S-checklist attune better (sensitive responsiveness) to the behavior of their client than the control group with caregivers not given the A&S-checklist.

3) Clients whose caregiver is randomized to the intervention group that is instructed to use the A&S-checklist show more behaviour in an optimum arousal level during the interaction-and relaxation-moment than clients whose caregiver is randomized to the control group not
given the A&S-checklist.

**Study design**

T0: Questionnaire – Minimum Data Set for Relatives and Professionals; The researchers in this project use the modules “Basis MDS fixed”, “Basis MDS relatives” and “Basis MDS professional” of the Minimum Data Set (MDS) for people with intellectual disabilities, variant adults fixed-Other (Kunseler, Schuengel, Embregts, & Mergler, 2016). The measured constructs are adaptive functioning, emotional development, communication and influence (as part of quality of life) and subjective well-being.

T1: Video recording and measurement of physiological arousal in session; The session consists of an observation-moment (15 minutes), an interaction-moment between caregiver and client (15 minutes) and a moment of relaxation (10 minutes). All three moments will be video recorded and the client wears a skin conductance sensor sock. Because of the Randomized Controlled Trial, there is a small difference between the instructions the caregivers of the control group and the caregivers of the intervention group are given;
- In the observation-moment, the caregivers of the control group are instructed to observe without the A&S-checklist and the caregivers of the intervention group are instructed to observe with the A&S-checklist, and;
- In the interaction-moment, the caregivers of the intervention group are instructed to take the recommended behavioural responses out of the second part of the checklist in their mind during the interaction, and the caregivers of the control group are instructed to interact with the client like they always do.

Afterwards, the recorded videos will be coded with;
1) the A&S-checklist to gain information about a) the arousal level of the client, and b) the applied recommended behaviours of the caregiver
2) the Maternal Behavior Rating Scale (Mahoney, 2008) to gain information about the ‘responsive/child oriented behaviour’ of the caregiver

**Intervention**

The ‘Attune & Stimulate’ checklist (Doodeman, Blom & Sterkenburg, 2018); developed for parents and professional caregivers of persons with SID, to support them in noticing signs of psychosocial stress and responding adequately.

The checklist consists of two parts. The first part requires users to observe behaviour of the person with SID (92 behavioural item-options) and rate the level(s) of arousal of each observed behaviour. In the second part of the A&S-checklist, the parent or caregiver is presented a selection of recommended behavioural responses to attune to the level of arousal of the child or client. These recommendations are based on analysis of the behaviour of therapists providing the Integrative Therapy for Attachment and Behaviour (ITAB;
Doodeman, Schuengel, & Sterkenburg, 2020; Sterkenburg, Janssen, & Schuengel, 2008). In a digital learning environment related to the A&S-checklist, parents and caregivers are trained to observe with the A&S-checklist and can get familiar with the recommended behavioural responses, by practicing with videos (1.5 hour training).

**Contacts**

**Public**
Vrije Universiteit Amsterdam
Tanja Doodeman

0205988955
Vrije Universiteit Amsterdam
Tanja Doodeman

0205988955

**Eligibility criteria**

**Inclusion criteria**

Clients:
- IQ lower than 35
- 18 years or older

Caregivers:
- In the function of coordinating caregiver, assistant caregiver, caregivers or trainees

**Exclusion criteria**

Caregivers;
Clients; none.

Caregivers;
1) work-relationship with the client for less than 3 months
2) in a function primarily focused on nursing (in Dutch, this function is called ‘ADL’er’)
3) interns *

* In the Netherlands, there is a difference between ‘leerlingen’ (referred to as ‘trainees’) and ‘stagiaires’ (referred to as ‘interns’). The main difference important for our study, is the
difference in involvement with a group home or day activity group. The first mentioned are more closely and for a longer period of time involved, because they stay for a long period of time, several days a week. The second mentioned are less closely and for a shorter period of time involved, because they stay for a short period of time and mostly only one day a week. For this reason, the ‘interns’ will be excluded from the study and the ‘trainees’ will be included in the study.

### Study design

#### Design

- **Study type:** Interventional
- **Intervention model:** Parallel
- **Allocation:** Randomized controlled trial
- **Masking:** Open (masking not used)
- **No intervention arm:** Active

#### Recruitment

- **NL**
- **Recruitment status:** Completed
- **Start date (anticipated):** 01-03-2019
- **Enrollment:** 140
- **Type:** Actual

#### IPD sharing statement

- **Plan to share IPD:** Yes

#### Plan description

We will work with the Minimum Data Set (MDS) which is intended sharing deidentified individual participant level data. Only when client representatives give permission to reuse data in various, similar studies.

### Ethics review

Approved
Study registrations

(Historical) registrations known in this register

In other registers

<table>
<thead>
<tr>
<th>Register</th>
<th>ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>NTR-new</td>
<td>NL7543</td>
</tr>
<tr>
<td>Other</td>
<td>VCWE FGB VU : FGB VCWE-2018-137R1</td>
</tr>
</tbody>
</table>

Study results

Summary results

The effect study is described in detail in the OSF pre-registrations:


The validation study is described in detail in the OSF pre-registration:


The first publication in the Attune & Stimulate project: