

Developmental and Sequenced One-to-One Educational Intervention (DS1-EI) for autism spectrum disorder and intellectual disability: 2-year of a randomized, singleblind controlled trial

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Objective: to explore whether an appropriate intensive educational implementation for children with a very low IQ and behavioral impairments is possible and could either compromise or potentialize other global therapeutic interventions

Design: Randomized, single-blind multicentric controlled trial, aiming to compare the educational and clinical outcomes of two groups: TAU group benefited of the usual schooling and the usual institutional care of their institution (30 to 35 hours per week). **DS1-EI group** was exposed to an intensive (10 hours/week) structured one-to-one pedagogic workshop during which children benefited from individual, sequential and developmental pedagogy. They continued to receive the usual care of their institutions for the remaining time (e.g. speech therapy, social-skills group activities, occupational therapy). Thus, usual care was reduced compared to the control group, but schooling time was increased and individualized in a developmental structured and interactive way.

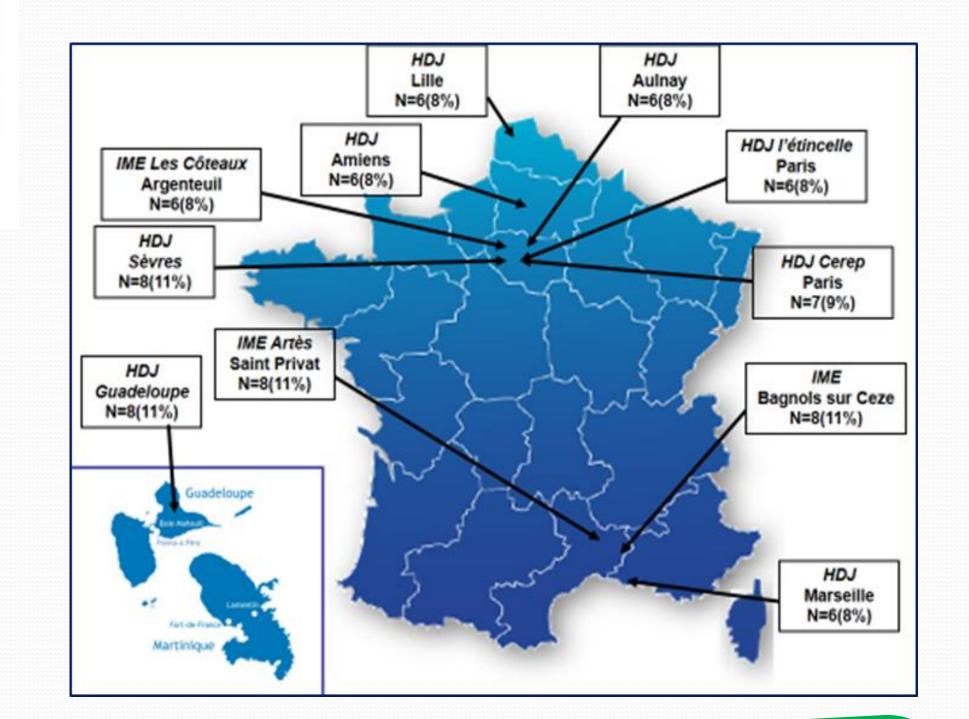
■ **Variables**: Primary variables: CARS, PEP-3 were blindly assessed at o, 18 and 36 months; school abilities were assessed at o and 36 months. Secondary variables: VABS, CGAS were assessed at o, 12, 24 and 36 months.



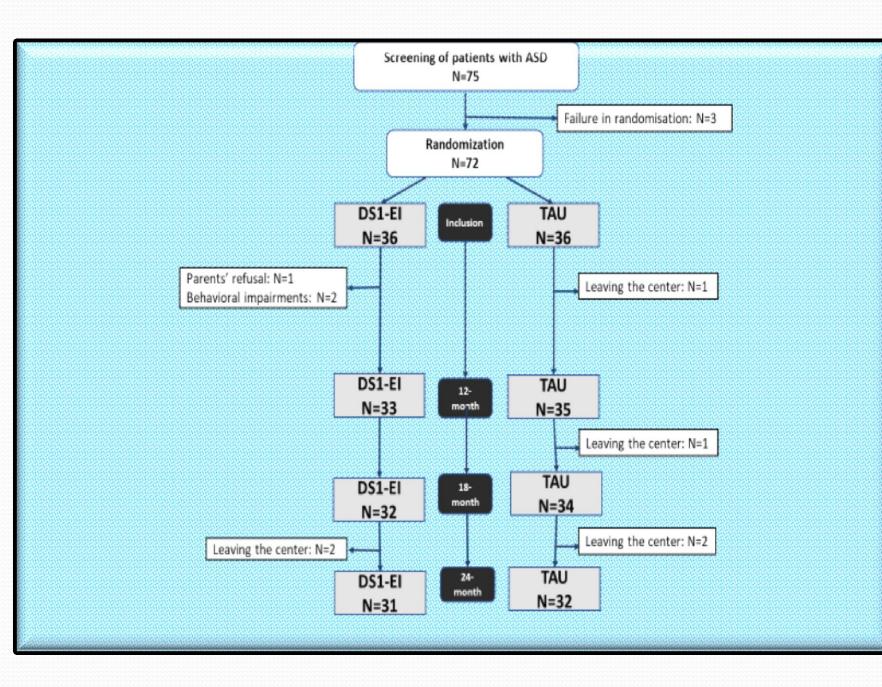
Inclusion & randomization per site:

We implemented in 11 French child care institutions (day-care hospitals and medico-social institutes), a new model called the DS1-EI. In each institution, 5-to-9-year-old children were recruited in dyads matched by developmental quotient and

The intervention was based on intensive schooling in small classrooms (3-4 children), promoting social skills through gathering moments with early social play with peers, alternating with sequenced individual learning adapted to the developmental abilities of each child, interactive through one-to-one condition, supporting positive interactions and encouraging spontaneous communication randomized to the treatment-as-usual (TAU) group or the DS1-EI group (combined with half-time TAU).

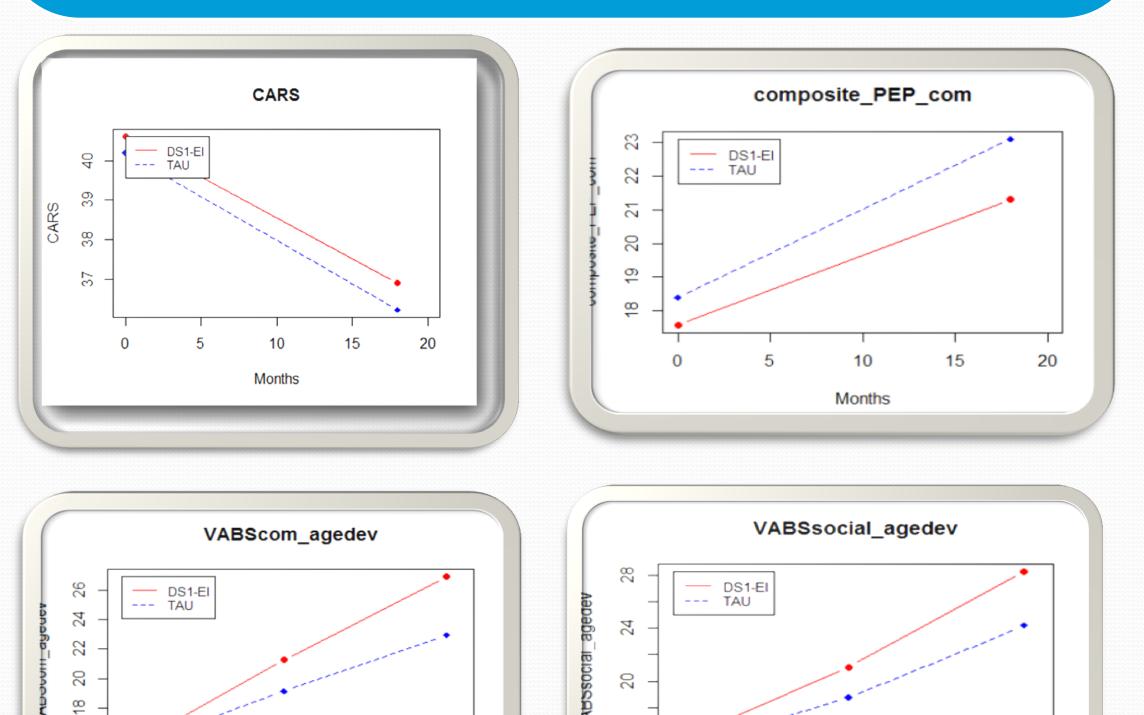






Flow-chart: At baseline, 72 participants were randomized. Nine patients (5 in the DS1-EI group and 4 in the TAU group) dropped out of the study.

Clinical characteristics: no difference between groups after randomization: severe autism (mean CARS > 40), severe intellectual disability (mean VABS developmental age at communication or socialization = 15 months, for a mean chronological age of 7 years). Using linear mixed models, both intent-to-treat (ITT) and per-protocol (PP) analyses at the 12-, 18and 24-month outcomes showed no significant group-by-time interaction effect. However, we found **significant improvements over time in most primary and secondary variables in both groups** (p<0.01 for PEP₃, CARS, VABS, CGAS...)



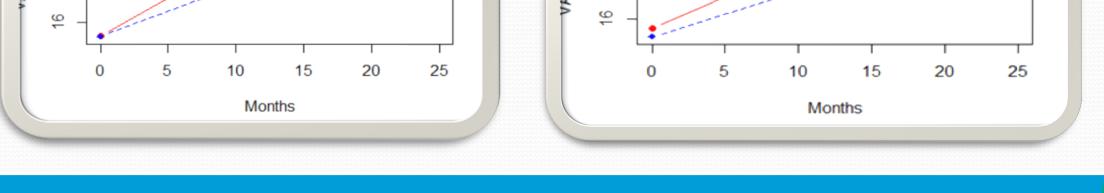
No significant differential evolution between the two groups for the clinical outcome variables, except a trend (p=0.085) for a group*time interaction in VABS-communication in favor of DS1-EI group.

Last minute: 3-years outcome

School primary outcomes were significantly improved in both groups but significantly better in the DS1-EI group (p<0.001).

At the end of the study, DS1-EI group participants were more likely to be oriented in mainstream classrooms than those of the TAU group (p=0.002).

School inclusion at 36 months (ITT analyses)





We found significant improvements over time for most variables in both groups. This means that the integrative care provided in daycare hospital and medico-educational institutes allows most children to improve their verbal communication, non-verbal communication and social skills. This is in line with Baghdadli et al. (2012) largest observational 3-year follow-up study using CARS and VABS, showing that children with ASD improved significantly their developmental and interactional skills in French institutional healthcare nor 36 months.

Conclusions and perspectives

The study did not show that DS1-EI was superior to TAU in treating children with ASD and ID over 24 months. However, the low dropout rate shows that an adapted intensive educational model is feasible without compromising other therapeutic interventions, and should be promoted since children who benefited the program acquired better academic skills and were more likely to be oriented in mainstream classrooms This study indicates that DS1-EI protocol is a culturally deployable program and that it should be compatible to most French context and practice.