

Appendix 1: Secondary outcomes

The secondary outcomes are measured using standardized coding assessments of naturalistic observational videos (BOSCC, DCMA), performance-based standardized tests (MSEL), and parent-report-based standardized tests (VABS, DLFP, AFEQ, ISP, GHQ).

To assess social communication and interaction in the natural setting of parent-child interaction at home

Brief Observation of Social Communication Change (BOSCC) measures the same construct as the ADOS. It is a researcher coding assessment of autism symptoms based on child-adult interaction. It has good fidelity and results showed good construct validity [1]. The validity to measure the change was analysed in two small populations (N=20-50) and will have to be reanalysed in further trials [36,37]. It has the advantage to allow measure Dyadic interaction across different contexts. It was translated and retro-translated for the purpose of a previous study [2]

The scale is composed of 12 items scored from 0 to 5 according to the BOSCC algorithm. There is an overall score of 0 to 60 measuring core autism symptoms. A higher score indicates more autistic symptoms.

In the current study, a 12 minutes home-video will be recorded by the parents themselves. The parent will be provided with a simple protocol to follow using a standardized set of toys. The standardized set of toys given to the families at each time of assessment will include a cause and effect toy, shape sorter or puzzle, construction toys, miniature pretend play. The protocol includes 10 minutes time of natural play with children with the set of standardized toys and 2 minutes with bubbles play. A first unscored videotape would be done on the center (at T0) to train the parents to video record based on the protocol. In the week following, the parent will videotape at home a child-parent interaction according to the protocol with the standardized set of toys and send the video to the researchers via a secure platform. Professional may make up to two further requests if the video received is judged to not be of adequate quality. If the parent isn't able to send a usable video according to the protocol, the researcher completes a home visit to demonstrate and help the parent to do the video the third time. Two further videos will be done at home at 6 months (T1) and 12 months (T2) in order to assess Social communication interaction in a naturalistic setting.

All the video will be scored by trained researchers.

The same parent called the "referent parent" will be videotaped by a relative at each time of assessment. He/ she will be identified before the randomisation. It will also be the parent who receive PACT therapy if in the group of PACT intervention.

To assess dyadic communication in the natural setting of parent-child interaction at home

The *Dyadic Communication Measure for Autism (DCMA)* is a direct observation instrument of the communication between a parent and a child with autism [3]. It rates parental and child mutual shared attention, child communication (initiation and response) and parental communication style (synchronous/asynchronous).

Independent inter-rated reliability on synchrony has been reported and is good [3]. It was translated and retro-translated for the purpose of a previous study [2]

It can be used to code a number of acts of communication per timepoint. A higher score indicates better communication.

Coding will be done on the same 12 minutes home parent-child video described above in BOSCC at baseline, 6 months and 12 months.

To assess child cognitive development

The *Mullen Scales of Early Learning (MSEL)* is a direct observation standardized tool from birth to 68 months [4]. It measures verbal and non-verbal skills of the children, according to the success or failure in tasks of the MSEL protocol delivered by a trained researcher. The MSEL has been used extensively as a discriminative and evaluative measure in children with autism spectrum disorder, Fragile X syndrome, and speech delays [5–7]

The MSEL will be assessed on the center before the inclusion and at 12 months.

Internal consistency and concurrent validity are good [4]. It was translated and retro-translated for the purpose of a previous study [2]

The MSEL includes 124 items that measure five specific domains: 1) Gross Motor; 2) Fine Motor; 3) Visual Reception; 4) Expressive Language; and 5) Receptive Language. Scoring varies by item from 2-point scale (0 = does not meet criteria to 1 = meets criteria) to a 6-point scale. Results for each scale are described by T scores (M = 50, SD = 10), percentile ranks, and age equivalents. Four cognitive scales (Visual Reception, Fine Motor, Receptive Language, and Expressive Language) sum to represent an Early Learning Composite Score which measures overall cognitive functioning (M=100, SD=15). A higher score means better skills. This evaluation will be realized before inclusion and at 12 months.

To assess child language development

The “development of expressive language”, a standardised French Scale (Development du Language de Production In french_DLPF), is based on a self-administered parent-report [8]. This measure is standardised for age. Only the level 4 of the DLFP will be administered at each assessment to have a continuous score on expressive language. The DLFP was validated in a study [3]. Score is calculated based on the number of words in the naturalistic environment of the child as reported by the parents. A higher score means better language skills. This questionnaire will be completed by the referent parent at baseline and at 12 months.

It will complete the measure of functional communication with VABS-2 and standardised measure with MSEL.

Adaptative behavior

Vineland Adaptive Behaviors Scales second version (VABS-2) is a parent reported scale to measure the child’s daily personal and social skills [9]. This measure will be collected via a parental interview over videoconferencing before the inclusion and at 12 months. Videoconferencing model has been chosen

in our study to avoid multiples visits on the centre but also to evaluate, before the inclusion, if a long videoconferencing meeting could be done with the family on a technical point of view. A first assessment will be proposed to the parents. In case of technical difficulties during the first meeting, a second, and if necessary, a third meeting will be proposed. Tips to improve videoconferencing will also be provided to the parents. In case of failure of every remote assessment, the family will be considered as not eligible for the study as the remote PACT session require the ability to conduct a videoconferencing meeting.

This measure will provide an estimate of any assesses functional change in socialization, communication, motor and daily living skills, based on parent observation in the naturalistic settings of the child.

The VABS has well-established psychometric properties [9,10]. It is validated in french.

All of the items are rated on a three-point Likert scale, ranging from '0' (seldom or never present) to '2' (always present). Results for each scale are described by t scores (M = 50, SD = 10). An overall score is described by normalized score (M=100, SD=15). The range for each subscale is from 20 to 140. The subscales are summed to compute a total score, ranging from 80 to 560. The higher the scores are, the better adaptive functioning the children achieve.

To assess Parent's Stress, health, priorities and experience of the family

The psychometry of the following tools are described in the manual of each tool.

Autism Family Experience (AFEQ) [11] is a 48-item self-administered parent report about quality of life and priorities for early intervention. It is composed of 4 subscales: experience of being a parent (range 13-65), family life (range 9-45), child development understanding and relationships (14-70), child symptoms (12-60). The sum of all domains gives the total score (range 48 - 240). Each question is assessed using a 5-point Likert scale. Scores range from "always" (1) to "never" (5)". It was translated and retro-translated for the purpose of this study with the author. For the total score and the domain scores a higher score indicates a lower outcome. This questionnaire will be completed by the referent parent at baseline and at 12 months.

ISP (Parental stress index) is a 36-item self-administered parent report to measure the stress in the parent-child system. The PSI consists of three subscales: Parental Distress, Parent-child Dysfunction Interaction, and Difficult Child. Each subscale consists of 12 items rated from 1 (strongly agree) to 5 (strongly disagree), with subscale scores ranging from 12 to 60. The three domains combined form a Total Stress score (with a total score ranges from 36 to 180). We will use the short form of the 4th edition. A validated French version exists [12]. A higher score on the subscales and total stress score indicates increased levels of stress. This questionnaire will be completed by the referent parent at baseline and at 12 months.

General Health Questionnaire (GHQ-28) is a self-administered parent report, 28 item scaled version, assessing somatic symptoms, anxiety and insomnia, social dysfunction and severe depression. Each item is rated according to a Likert score method (1 to 4). The GHQ-28 global score range from 36 to 110 [13]. A higher score means more health problems. This questionnaire will be completed by the referent parent at baseline and at 12 months.

To assess implementation of the intervention

Professional adherence to the treatment:

All therapy training sessions with professionals will be videotaped and will be independently rated by the lead therapist using the PACT Fidelity Rating Scale (of the PACT manual) at regular intervals across the trial period. The PACT Fidelity Rating Scale measures how the therapists follow the PACT manual including the style of training.

Acceptability and feasibility of the PACT session

The therapist will collect the number of the session done with each parent. The quality of videoconferencing during each session with the professional will be rated. Quality of sound and quality of the image will be rated with a 4-points Likert scale. The number of disconnections along the session will also be collected.

The parents will self-report (likert-scale) the acceptability of videoconferencing training and implementation of PACT at home.

Parent PACT adherence at home

At 12 months, Parents will declare the average number of hours per day using PACT at home outside the PACT session with the therapist.

DCMA, coded on the 12 minutes home child-parent interaction will measure the parent's qualitative adherence of PACT intervention.

- 1 Grzadzinski R, Carr T, Colombi C, *et al.* Measuring Changes in Social Communication Behaviors: Preliminary Development of the Brief Observation of Social Communication Change (BOSCC). *J Autism Dev Disord* 2016;**46**:2464–79. doi:10.1007/s10803-016-2782-9
- 2 Touzet S, Occelli P, Schröder C, *et al.* Impact of the Early Start Denver Model on the cognitive level of children with autism spectrum disorder: study protocol for a randomised controlled trial using a two-stage Zelen design. *BMJ open* 2017;**7**:e014730.
- 3 Aldred C, Green J, Emsley R, *et al.* Brief report: Mediation of treatment effect in a communication intervention for pre-school children with autism. *Journal of autism and developmental disorders* 2012;**42**:447–454.
- 4 Mullen EM. *Mullen scales of early learning*. AGS Circle Pines, MN 1995.
- 5 Burns TG, King TZ, Spencer KS. Mullen Scales of Early Learning: The Utility in Assessing Children Diagnosed With Autism Spectrum Disorders, Cerebral Palsy, and Epilepsy. *Applied Neuropsychology: Child* 2013;**2**:33–42. doi:10.1080/21622965.2012.682852
- 6 Bishop SL, Guthrie W, Coffing M, *et al.* Convergent validity of the Mullen Scales of Early Learning and the differential ability scales in children with autism spectrum disorders. *American journal on intellectual and developmental disabilities* 2011;**116**:331–343.
- 7 Farmer C, Golden C, Thurm A. Concurrent validity of the differential ability scales, second edition with the Mullen Scales of Early Learning in young children with and without neurodevelopmental disorders. *Child Neuropsychology* 2016;**22**:556–69. doi:10.1080/09297049.2015.1020775

- 8 Bassano D, Labrell F, Champaud C, *et al.* Le DLPF : un nouvel outil pour l'évaluation du développement du langage de production en français. *Enfance* 2005;**57**:171. doi:10.3917/enf.572.0171
- 9 Sparrow SS, Cicchetti DV, Balla DA. *Vineland Adaptive Behavior Scales:(VABS)*. NCS Pearson 2005.
- 10 Chatham CH, Taylor KI, Charman T, *et al.* Adaptive behavior in autism: Minimal clinically important differences on the Vineland-II: Adaptive behavior and autism. *Autism Research* 2018;**11**:270–83. doi:10.1002/aur.1874
- 11 Leadbitter K, Aldred C, McConachie H, *et al.* The Autism Family Experience Questionnaire (AFEQ): An Ecologically-Valid, Parent-Nominated Measure of Family Experience, Quality of Life and Prioritised Outcomes for Early Intervention. *J Autism Dev Disord* 2018;**48**:1052–62. doi:10.1007/s10803-017-3350-7
- 12 Lacharité C, Éthier L. « Le stress parental chez les mères d'enfants d'âge préscolaire : validation et normes québécoises pour l'Inventaire de Stress Parental » Carl Lacharité, Louise Éthier et Christiane Piché. 2013;**17**:183–203. doi:10.7202/502077ar
- 13 Pariente P, Challita H, Mesbah M, *et al.* The GHQ-28 questionnaire in French : a validation survey in a panel of 158 general psychiatric patients. *European Psychiatry* 1992;**7**:15–20.