

An adapted social communication intervention at home and education to promote social communication change in children with severe autism: the PACT-G RCT

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Scientific summary

The PACT-G RCT

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Scientific summary

Background

Prior evidence suggests that behaviours closely related to the intervention delivered for autism are amenable to change. However, it can be more difficult for many interventions to generalise treatment effects beyond the intervention's immediate context into other naturalistic contexts of the child's life or symptom reduction. We tested an early autism social communication intervention that was an adaptation of our original Preschool Autism Communication Trial (PACT) [Green J, Charman T, McConachie H, Aldred C, Slonims V, Howlin P, *et al.* Parent-mediated communication-focused treatment in children with autism (PACT): a randomised controlled trial. *Lancet* 2010;**375**:2152–60]. The original PACT intervention was delivered by a therapist alongside the child's parents in a clinic-based setting over 18 sessions. Trial work had shown that PACT produced a reduction in severity of autism symptoms (including social communication and restricted, repetitive and sensory behaviours) that was sustained over 6 years after the end of therapy, as well as an improvement in parent-child reciprocal social communication, parental well-being and parent-report child social outcomes. The adapted intervention – Paediatric Autism Communication Trial – Generalised (PACT-G) – consisted of simultaneous, parallel intervention delivery in the child's home and an educational setting, using a mixture of in-person and online delivery and extending the age of intervention up to 11 years (the age range for the PACT was 2–5 years). This method was designed to (1) make delivery easier for families, (2) focus more on child functioning in the educational setting (a key context for their development) than the PACT had, (3) extend the PACT intervention to some autistic children of school age and (4) facilitate maximal intervention effects within these different naturalistic settings (home and education) for the child beyond the clinic setting, on the basis that this might result in enhanced additive effects compared with the PACT on the overall child symptom outcomes measured in a research setting. An associated detailed mechanism study within the trial investigated the process by which there might be transmission of treatment effects within and across settings to an overall research-assessed effect.

Methods/design

The trial was a three-site, parallel-group, randomised controlled trial of the experimental treatment plus treatment as usual and treatment as usual alone as the control condition. The primary outcome was researcher-assessed severity of autism symptoms [using the Autism Diagnostic Observation Schedule, Second Edition (ADOS-2)] at the 12-month trial end point. Secondary outcomes were (1) child autism symptoms rated using the Brief Observation of Social Communication Change (BOSCC) in home, educational and research outcome settings; (2) child reciprocal dyadic social interaction with a parent in the home setting and an education staff member (usually learning support assistant) in the educational setting; (3) child language, well-being and reported functional outcome; (4) reported child disruptive behaviour across home and educational settings; and (5) parental self-efficacy and well-being. Outcomes were measured at baseline and the 12-month end point in all settings, with interim measurements (7 months) in the home and educational settings that were designed to test treatment effect mechanisms. The primary analysis estimated between-group difference in the primary outcome using an analysis of covariance, with a test of homogeneity of effect across preschool- and school-aged groups. The mechanism analysis used regression models to test for mediation on the ADOS-2 and BOSCC outcomes by the observed parent-child and education staff-child social interactions.

Interventions

The PACT-G is a caregiver-mediated intervention for enhancing social communication skills in children with autism. The intervention is designed to be delivered by a trained speech and language therapist to a nominated caregiver in the child's home setting or by a trained specialist professional in the child's educational setting. The intervention utilises video-feedback analysis of child interactions with the caregiver or adult to support implementation of individualised adult strategies with the child. These strategies have been previously evidenced, from our previous PACT and other studies, to be ones that enhance communication skills in children with autism. The intervention has parallel components within home and educational settings, and uses a combination of in-person and remote (teleconference) delivery. The control condition is treatment as usual.

Results

Children aged 2–11 years, who met the criteria for severe autism (a ADOS-2 total score of > 12), were randomised ($n = 249$; 122 in the PACT-G group and 127 in the treatment-as-usual group; 51 were female and 197 were male) and analysed by intention to treat, with just one participant lost to follow-up by the end point. Children received a median of 10 (interquartile range 8–12 sessions) out of 12 possible sessions at home (interquartile range 2–12 sessions) and 8 (interquartile range 5–10 sessions) out of 12 possible sessions in an educational setting (interquartile range 0–12 sessions). A total of 36% of sessions in the home setting and 34% of sessions in the educational setting were delivered remotely, usually by video conferencing, and the rest were delivered in person. Issues related to remote delivery or therapy environment led 5.5% of sessions in the home setting and 5% of sessions in the educational setting to be rated as 'unacceptable' in quality by therapists.

The treatment effect on the end-point ADOS-2 primary outcome was 0.04 (95% confidence interval -0.26 to 0.18 ; $p = 0.734$). The effect on the end-point BOSCC secondary outcome was -0.03 (95% confidence interval -0.31 to 0.25 ; $p = 0.85$). No treatment effect was seen on secondary child outcomes of language composite, repetitive behaviour, adaptive behaviour and child well-being. However, a significant treatment effect was found on proximal dyadic interactions [i.e. increased parent synchronous response with child (0.54 , 95% confidence interval 0.39 to 0.69 ; $p = 0.001$), increased child initiations with a parent (0.27 , 95% confidence interval 0.12 to 0.41 ; $p = 0.001$), increased learning support assistant synchronous response with child (0.32 , 95% confidence interval 0.14 to 0.49 ; $p = 0.001$), and increased child initiations with a learning support assistant (0.21 , 95% confidence interval 0.06 to 0.36 ; $p = 0.005$)]. Significant treatment effect was also seen on unblinded measures of increased parental well-being and decreased child disruptive behaviour across home and educational settings.

The mechanism study showed that the significant treatment effects found on child social communication initiation with dyadic partners in both the home setting (with a parent) and educational setting (with a learning support assistant) were mediated by an increase in the respective adult partner's synchronous responsiveness. There was no evidence of a mediation effect on end-point ADOS-2 symptoms, but there was evidence of an association between child social initiations with adults in both home and educational settings and, later, a BOSCC symptom outcome.

Discussion

In this trial, we have, to the best of our knowledge, carried out the largest mechanistic study yet undertaken within an autism intervention trial and one of the largest intervention studies of objectively assessed autism symptoms. Providing multicomponent PACT-G treatment for the child in home and educational settings in parallel did not produce the hypothesised improvement in the outcomes researcher-rated child autism symptomatology or adaptive behaviour. It did show significant planned

treatment effects on the more 'proximal' outcomes of adult-child reciprocal dyadic communication in both home and educational contexts, but at approximately half the ES found in the original clinic-delivered PACT. Our mechanism study replicated the same proximal effects of adult synchronous social response on child social communication, as found in the PACT, in both home and educational settings. Although in the PACT such proximal treatment effects with a parent had mediated significant and sustained subsequent child symptom change, in this study they did not transmit in the same way to child symptom effects on ADOS-2, but there was evidence of some effect on BOSCC.

We explore possible reasons why this PACT-G model of parallel treatment did not produce the full mediated treatment pathway that we found in the previous PACT. We consider factors such as reduced session dosage, the increased multicomponent complexity, impact of remote intervention delivery and impact of characteristics of therapy settings. We discuss the results in the context of other research on implementation of early home, education-based and multicomponent intervention for children with severe autism. We recommend future research areas to build on these results, including further work on remote delivery of complex intervention, dosage thresholds in psychosocial interventions, and multicomponent therapies in an educational setting, with the aim of extending social communication interventions for young children with autism in naturalistic settings.

Trial registration

This trial is registered as ISRCTN25378536.

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