Low-intensity parent- and clinician-delivered support for young autistic children in Aotearoa New Zealand: a randomised controlled trial

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The Lancet Regional Health - Western Pacific 2024;51: 101173

Published Online xxx
https://doi.org/10.1016/j.lanwpc.2024.101173

Summary

Background Aotearoa New Zealand does not provide publicly-funded intensive autism support. While parent-mediated supports are promising, children and families may also benefit from direct clinician support. We tested the efficacy of a low-intensity programme involving parent- and clinician-delivered support for autistic children.

Methods This single-blind, two-arm randomised controlled trial assessed outcomes of a six-month low-intensity parent- and clinician-delivered support (2–3 h per week) based on the Early Start Denver Model compared to a control group who received monthly support calls and assistance with referrals. Children aged 1–4.5 years who were autistic or showing signs of autism and their parents were randomised to the low-intensity or control group by a blinded statistician using the Urn minimisation method. Assessments were conducted at baseline and immediately following the support period (24-weeks post-baseline). The primary outcome was child engagement during an interaction with their parent. The trial was pre-registered with ANZCTR: U1111-1260-2529.

Findings From March 2021 to May 2023, 56 families were randomised to either the low-intensity or control group. Following drop-outs, 21 families in the low-intensity group and 24 in the control group were included in analysis. There was large and significantly greater improvement in children's engagement in the low-intensity group compared to the control group ($F(1, 43) = 21.47$, $p < 0.0001$, $\eta_p^2 = 0.33$). There was one recorded adverse event unrelated to the support and two adverse effects related to the support.

Interpretation A low-intensity parent- and clinician-delivered support can improve engagement between an autistic child and their parent during play. Low-intensity supports may be beneficial in areas where access to clinical autism supports is limited.

Funding Emerging Researcher First Grant from the Health Research Council of New Zealand.

Keywords: Autism; Low-intensity support; Parent coaching; Clinician support; Early start denver model

Introduction

Autism is a neurodevelopmental condition characterised by differences in information processing, social interactions, and preferences for routine.[1] Young autistic children and their families can benefit from the provision of timely, evidence-based clinical support (sometimes referred to as intervention or therapy). Such clinical supports can help family members to understand and be more responsive to the autistic child, improving outcomes for the whole family unit.[2]

Many promising approaches to early clinical autism support involve at least 10 h of weekly input from a trained clinician.[2] Such approaches are unfeasible in environments with limited clinical autism supports, such as Aotearoa New Zealand[3] ('New Zealand'). New Zealand is a relatively well-resourced country[4] and the Government does fund some clinical autism supports.

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Research in context

Evidence before this study

In many countries, including Aotearoa New Zealand, young autistic children and their families often do not access the level of support typically recommended to achieve optimal outcomes. In such circumstances, children and families might benefit from a small amount of direct clinician support per week, in addition to parent coaching. We searched PubMed and Google Scholar using terms related to "autism", "naturalistic developmental behavioural intervention", "Early Start Denver Model", "child", and "randomised controlled trial", and searched the reference lists of all relevant articles and meta-analyses. This search revealed that the three previous randomised controlled trials of combined parent- and clinician-delivered support for young autistic children have involved high clinician hours (>15 h per week), which is not feasible in lower-resourced areas.

Added value of this study

This study appears to be the first to rigorously examine the effects of a low-intensity (2–3 h per week) programme of parent and clinician-delivered support. Our findings indicate that children in the low-intensity support group were more engaged and used a greater amount and variety of language in an interaction with their parents compared to the control group. Parents in the low-intensity group were also better able to use strategies to support their child in this interaction than parents in the control group. Those in the low-intensity group also showed significant improvements in a range of other parent and child outcomes, while those in the control group did not. However, we cannot be confident that these improvements were statistically different for the low-intensity group compared to the control.

Implications of all the available evidence

This study showed that the low-intensity support improved parent–child interaction and parent's use of strategies to support their child. This suggests that low-intensity parent- and clinician-delivered support may be a beneficial approach in lower-resourced contexts. This research needs to be replicated with a larger sample of children to detect possible changes in more distal outcomes. Future studies should also prioritise neuro-affirming supports which have been co-produced with autistic people.

However, one-fifth of families of young autistic children report that they do not receive any clinical support, and those that do receive a weekly average of 2 h.[5] Parents and families also generally describe the overall quality of existing supports as poor.[3]

In parent-mediated approaches, clinicians teach parents strategies to support their autistic child. Such approaches typically involve 1–3 h per week or fortnight of input from the clinician across 3–9 months and may lead to improvements in some child and parent outcomes.[6–9] Parent-mediated approaches are well-suited to lower-resourced environments due to the relatively reduced time required with a clinician. In New Zealand, parent-mediated approaches are the primary type of support for young autistic children.[10] However, parents report feeling stressed and overwhelmed when required to be the sole providers of support[11] and want direct clinician support, in part, to alleviate this burden.[10] The provision of direct clinician support in addition to parent coaching may also improve child outcomes due to comparably higher implementation fidelity and the clinician's ability to focus on the child uninterrupted.[12–14]

Naturalistic Developmental Behavioural Supports (NDBSs) are a common approach for supporting young autistic children.[2] NDBSs use behavioural learning principles to teach developmentally relevant skills in the context of everyday life and routines. The Early Start Denver Model (ESDM) is one of the most well-researched NDBSs.[2] ESDM has a focus on developing positive child relationships and can be delivered by parents and clinicians.[15] Three randomised controlled trials (RCTs) have evaluated a combination of clinician- and parent-delivered ESDM.[12–14] These studies found greater improvements in child cognition[12], adaptive behaviour,[12,13] language[14] and gross motor skills[13] for the ESDM group. These combined approaches have resulted in greater child improvements than those generally seen in parent coaching alone.[9,16] However, they involved 15[14]–24[13] h of clinician input per week, which is unfeasible in countries like New Zealand. While not involving clinicians, Paediatric Autism Communication Therapy, a developmental approach, has similarly been delivered in tandem by parents and learning support assistants (LSAs) across six months[17] (PACT-G). LSAs and parents in the PACT-G group showed greater improvements in synchrony with the child, and children initiated more interactions compared to treatment-as-usual but there were no differences for the remaining outcomes.[17]

To our knowledge, the current RCT is the first to rigorously examine the effects of 2–3 h per week of parent- and clinician-delivered ESDM-based support for autistic and potentially autistic children under the age of 5. The clinician-delivered aspect is comparably low-intensity compared to previous related research,[12–14,16] as this support was designed to suit New Zealand. Responsive and engaging parent–child interactions are associated with positive outcomes for autistic children.[8,17] As such, the primary aim was to evaluate the effects of the low-intensity support in improving child engagement in an interaction with their parent

compared to a control group. We also examined a range of secondary child and tertiary parent and family outcomes.

Methods

Study design

This was a single-site (Wellington, New Zealand), single-blind (rater), two-arm ('low-intensity', 'control') randomised controlled trial. Ethical approval was obtained from the New Zealand Health and Disability Ethics Committee (20/NTA/170). The protocol was registered on the Australian New Zealand Clinical Trials Registry prior to the study commencing (Universal Trial Number: U1111-1260-2529). The CONSORT checklist for the trial is in Appendix 1.

Participants

Participants were recruited through the Victoria University of Wellington Autism Clinic, and advertisements were shared by other autism, health, and educational organisations within the Wellington region in New Zealand. The team aimed to recruit 58 children with a clinical diagnosis or showing signs of autism and their parents/caregivers ('parents'). A child was deemed to be showing signs of autism if they met the "autism spectrum" cut-off on the Autism Diagnostic Observation Schedule—second edition modules 1–3[18] (ADOS-2) or the "mild-to-moderate concern" cut-off on the toddler module.[19] Autistic or potentially autistic children were eligible for the trial if they: (a) were aged between 1 and 4.5 years; (b) did not have another serious medical, genetic, neurological or sensory condition; (c) were born after 32 weeks of pregnancy; (d) did not have a sibling/twin participating in the study; and (e) were not receiving ≥15 weekly hours of clinician-implemented early support. Parents were eligible to participate if they spoke sufficient English to consent and actively participate. Families were ineligible if they intended to move out of Wellington during the study, were participating in research evaluating NDBSs, or had previously received ESDM. Interested parents were provided with an information sheet and gave written consent to participate.

Randomisation and masking

Following pre-assessment, participants were randomly assigned to a group that received low-intensity parent- and clinician-delivered ESDM-based support ('low-intensity group') or a group that was assisted in accessing supports in the community ('control group'). Randomisation and data analysis were conducted by MH, a statistician masked to group assignment with no other involvement in the trial. Participants were randomly allocated to an "A" group or a "B" group using the Urn minimisation method,[20] minimising for differences in chronological age, in the randomizeR package (version 2.0.0) in r (version 4.1.2). Assessors were also masked to group assignments but clinicians delivering the support and parents were not. Assessors who became unmasked to group assignments did not code outcomes for that participant. Unmasking occurred for three of six assessors across eight (14%) of the 56 initially enrolled families.

Procedures

The trial involved pre-assessment, allocation to the low-intensity or control group, support provision, and a post-assessment after 24 weeks. All assessments and the clinician-delivered aspect of the low-intensity support took place in the Autism Resource Centre in Wellington. Children who did not have a clinical autism diagnosis participated in a clinician-administered ADOS-2 assessment,[18,19] and those who met or exceeded the relevant autism cut-off continued to pre-assessment. Each pre-/post-assessment included an in-person appointment for the observational and interview measures and a self-report assessment pack. All families completed a monthly log of hours and types of additional clinical supports accessed.

Participants in the low-intensity group received 2 h-long sessions per week of clinic-based clinician-implemented support and 18 h-long weekly home-based parent coaching sessions, spread across the 24-week period to allow for missed sessions. Parents were encouraged to observe the clinician-implemented clinic-based sessions. The clinician-implemented support and coaching were delivered according to the respective ESDM fidelity checklists.[15,21] While still adhering to fidelity, sessions were adapted to align with the Autism Clinic Guiding Principles, which were developed based on input from members of the autistic and autism communities in Wellington (Appendix 2). Across groups, a standard safety plan was followed in instances where there was a significant risk to the health and wellbeing of the child, their family, or the clinician (Appendix 3). Participants in the low-intensity group received an average of 80% (range = 55–99%) of their intended sessions. Only two families did not meet the predetermined minimum threshold of 60% session attendance, attending 55 and 59% of sessions, respectively.

All eight clinicians were trained and certified in clinician-implemented ESDM prior to or during the trial. Three clinicians had completed ESDM parent coaching training and internally trained the remaining clinicians in this approach. All clinicians participated in fortnightly peer supervision to reflect on fidelity and discuss parental or advisory group feedback and health and safety concerns related to the child and family. A second clinician used the ESDM fidelity scale[15] to score 8% of video-recorded clinician-implemented sessions (Mean fidelity: 84%; range: 74–92%). Parent coaching fidelity was coded live by a

second clinician for 6% of sessions using the parent coaching fidelity checklist[21] (Mean fidelity: 97%; Range = 81–100%). Parents in the low-intensity group reported implementing the ESDM techniques for an average of 7.8 h per week (range = 0–45.5 h per week).

Children and parents in the control group received monthly 30-min support calls from a researcher who listened to their concerns, gave generic advice, and supported requested referrals to community-based services. They received an average of 81% (range = 17–100%) of their intended support calls.

Families were able to seek support outside of the research. Ten families in the low-intensity group did not receive additional clinical support; the remaining 11 families received an average of 1.78 h per month (*SD* = 3.44; range = 1–18). Three families in the control group did not receive additional support; the remaining 21 families received an average of 3.19 monthly hours per month (*SD* = 2.84; range = 1–22). Further details of the type and number of additional supports are provided in Appendix 4.

Outcomes

Intraclass correlations (ICC) were calculated for all observational variables, with an assessor independently coding 20% of these data across timepoints. ICC scores of 0.75–0.9 and > 0.9 indicate 'good' and 'excellent' reliability respectively.[22]

Primary outcome

Child engagement was collected during a 10-min parent–child interaction that was recorded and coded in 10-s intervals by blind assessors using an adapted version of Bakeman and Adamson's measure.[23] To align with the types of engagement supported by ESDM, the number of intervals containing person engagement, and supported and coordinated joint attention were combined to generate an overall percentage engagement score (ICC = 0.797, 95% CI = 0.533–0.919).

Secondary outcomes

The parent–child interaction videos described above and an Eliciting Language Samples for Analysis—Toddler[24] (ELSA-T) interaction between the child and a blinded assessor were coded for the total number of utterances (ICC: parent–child interaction = 0.919, 95% CI = 0.786–0.970; ELSA-T = 0.936; 95% CI = 0.839–0.976) and the number of different words (ICC: parent–child interaction = 0.971, 95% CI = 0.925–0.989; ELSA-T = 0.988, 95% CI = 0.969–0.995) spoken by the child using EUDICO Linguistic Annotator software. The ELSA-T is a standardised, play-based expressive language and communication measure lasting 15–30 min. It involves eight activities such as pretend play, gross motor games, craft time, snack, and storybook time.

A blinded assessor administered the Mullen Scales of Early Learning[25] (MSEL) with the child. The MSEL is a standardised measure of developmental functioning for children aged 0- to 68-months-old. It involves manualised activities related to five subdomains: gross motor, visual reception, fine motor, expressive language, and receptive language. The duration varies from 15 to 50 min. The outcome analysed was the early learning composite, which considers scores across subdomains.

Parents completed the Vineland Adaptive Behaviour Scales—3rd edition[26] (VABS-III) during a semi-structured interview with an assessor. The VABS-III assesses child adaptive functioning across four domains: communication, daily living skills, socialisation, and motor skills. The outcome analysed was standard scores for all domains except motor skills.

The Social Responsiveness Scale—Second Edition[27] was originally included as a secondary outcome but was removed in September 2022 as it was no longer deemed appropriate by many in the autistic and autism communities in Australasia.[28]

Tertiary outcomes

The parent–child interaction videos were also coded for parent ESDM fidelity on the 13-item ESDM fidelity scale[15] by blind assessors (ICC = 0.764, 95% CI = 0.469–0.905). Each item was rated on a 5-point Likert scale from 1 = 'lack of use' to 5 = 'best possible example'. The outcome analysed was the average percentage of fidelity across items.

The MONSI-CC[29] was originally included as a tertiary outcome related to parent use of NDBI techniques but was removed prior to participant recruitment. The team could not access training and the measure was not deemed essential in addition to the ESDM fidelity scale.

The Autism Parenting Stress Index[30] (APSI) is a 13-item self-report scale measuring perceived stress for parents of autistic children across three domains: 'core social disability', 'difficult-to-manage-behaviour', and 'physical issues.' Items are rated on a 5-point Likert scale from 1 = 'not stressful' to 5 = 'so stressful that sometimes we feel we cannot cope'. The outcome analysed was the sum of scores across domains.

Parents completed the Parent Sense of Competence Scale[31] (PSOC), which measures parental sense of competence across two primary dimensions: satisfaction and efficacy. The 16 items are rated on a 6-point Likert scale from 1 = 'strongly disagree' to 6 = 'strongly agree'. The outcome analysed was the sum of scores across domains.

Parents completed the Family Quality of Life assessment, measuring their perceived satisfaction with their family's quality of life.[32] Parents completed 25 items covering five domains: family interaction, parenting, emotional well-being, physical/material well-being, and disability-related support. Items are rated on a 5-point Likert scale from 1 = 'very dissatisfied' to 5 = 'very satisfied'. The outcome analysed was the sum of scores across domains.

Treatment acceptability

Parents in the low-intensity group completed the Treatment Acceptability Rating Scale—Revised (TARF-R) at post-assessment.[33] It contains 17 items about perceived acceptability of the support across six subscales: reasonableness, effectiveness, willingness, side-effects, disruption/time, and affordability, each rated on a 7-point Likert scale with higher scores generally indicating greater acceptability, although some items are reverse coded. Total scores and mean acceptability scores per item were presented descriptively for the overall acceptability and each subdomain.

Adverse events

Adverse events and effects were recorded in a log. Clinicians kept a log of the proportion of time that children appeared to be upset or distressed during clinician-implemented sessions delivered to the low-intensity group.

Statistical analysis

The data analysis plan was registered on the Open Science Framework prior to the analysis of any data: https://osf.io/z2jm5/. When developing this plan, the team decided, for each outcome specified in the protocol, whether to analyse only the overall score (i.e., child engagement, MSEL, ESDM fidelity, APSI, PSOC, and FQOL) or only pre-specified subscales (i.e., number of utterances and different words for the parent–child interaction and ELSA-T, and the communication, daily living skills, and socialisation subdomains of the VABS-III). The proposed sample size was sufficient to detect changes in child engagement, the primary outcome measure, based on an estimated *Cohen's d* effect size of 0.81 for this outcome in a comparable study.[34] The team aimed to recruit 58 children, providing a two-tailed repeated measures ANOVA with over 90% power to detect a 0.81 effect size and allowing for ≤16 dropouts to retain power >80%. The analytic plan did not have the statistical power to correct for multiple outcomes. As such we pre-selected the primary outcome and included the secondary and tertiary outcomes as more exploratory tests.

Repeated measures 2 (support: low-intensity; control) × 2 (time: baseline; follow-up) ANOVAs were conducted in SPSS version 29.0. The criterion for statistical significance was 5%. Partial eta squared (η_p^2) was used to indicate the effect size for each ANOVA model, while Cohen's d was used for significant within group effects for significant ANOVA models only. A modified intention-treat-approach was used as all participants who completed the post-assessment were included regardless of whether they met minimum criteria for session attendance. Those who withdrew were offered the opportunity to participate in post-assessment, but none accepted. Due to the sample size, data were not imputed for participants who completed pre- but not post-assessment.

Role of the funding source

This study was funded by an Emerging Researcher First Grant from the Health Research Council of New Zealand awarded to HW, LvdM, and AJOW. The funder of the study had no role in study design, data collection, analysis, or interpretation.

Results

Ninety-eight children and parents were assessed for eligibility between March 2021 and May 2023 (Fig. 1). Of those, 56 families were randomised equally to the low-intensity and control groups, two fewer than intended due to time constraints. Seven families discontinued in the low-intensity group (2 prior to receiving support) and 4 in the control, resulting in 21 in the low-intensity group and 24 in the control group, all of whom completed post-assessment.

Participant demographics are displayed in Table 1, and correlations between outcome measures are in Appendix 5. Table 2 shows mean baseline, follow-up and difference scores by group, ANOVA results, and relevant effect sizes.

Fig. 2 shows the mean difference for the low-intensity and control groups over time for each primary, secondary, and tertiary outcome and relevant effect sizes.

For the primary outcome, there was a significant and large difference in child engagement between groups over time ($F(1, 43) = 21.47$, $p < 0.0001$, $\eta_p^2 = 0.33$). There was a significant and large (Cohen's d effect size) increase in engagement in the low-intensity group but not in the control.

For the secondary child outcomes, during the parent–child interaction, there was a significant and large difference in the number of utterances ($F(1, 43) = 13.31$, $p = 0.001$, $\eta_p^2 = 0.24$) and a significant and moderate difference in the number of different words ($F(1, 43) = 5.30$, $p = 0.026$, $\eta_p^2 = 0.11$) between groups over time. For number of utterances, there was a significant and large (Cohen's d) increase with the parent in the low-intensity group but not the control. For different words, there was a significant and moderate (Cohen's d) increase in the low-intensity group but not in the control. During the assessor–child interaction (ELSA-T), there was no significant difference in the total number of utterances or the number of different words between groups over time ($F(1, 43) = 0.50$, $p = 0.49$, $\eta_p^2 = 0.01$; $F(1, 43) = 0.06$, $p = 0.81$, $\eta_p^2 = 0.00$). For total utterances, there was a significant increase with the assessor in the low-intensity group but not the control. For different words, there were significant increases in the number of different words with the assessor in both the low-intensity and control groups. Regarding the VABS-III,

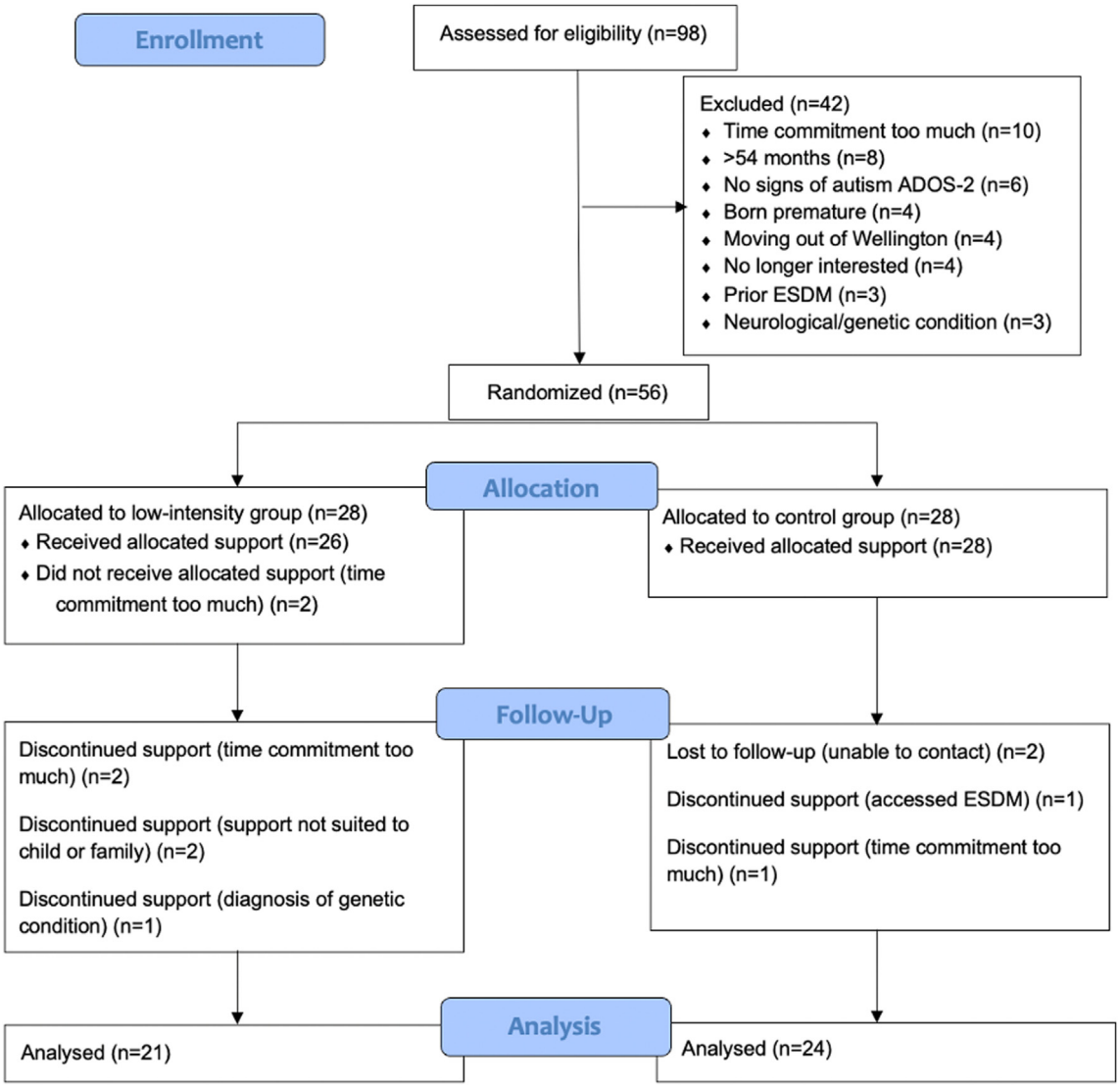

Fig. 1: **Trial profile**.

there were no significant differences in the communication (F (1, 43) = 2.74, p = 0.11, η_p^2 = 0.06), daily living skills (F (1, 43) = 2.76, p = 0.10, η_p^2 = 0.06), or socialisation subscales (F (1, 43) = 2.05, p = 0.16, η_p^2 = 0.05) between groups over time. For each subscale, there was a significant increase in the low-intensity group but not the control. There was no significant difference between the low-intensity and control groups in Early Learning Composite scores on the MSEL over time (F (1, 43) = 0.02, p = 0.90, η_p^2 = 0.00).

For the tertiary parent and family outcomes, there was a significant and large difference in parent ESDM fidelity between groups over time (F (1, 43) = 15.65, p < 0.0001, η_p^2 = 0.27). There was a significant and large (Cohen's d) increase in fidelity in the low-intensity group but not the control. There was no significant difference in APSI scores between groups over time (F (1, 43) = 0.82, p = 0.37, η_p^2 = 0.02). There was a significant decrease in APSI scores in the low-intensity group but not the control. There was no significant difference in PSOC scores between groups over time (F (1, 43) = 3.82, p = 0.06, η_p^2 = 0.08). There was a significant increase in PSOC scores in the low-intensity group but not the control group. There was no significant difference between the low-intensity and control groups in FQOL scores over time (F (1, 43) = 0.00, p = 1.0, η_p^2 = 0.00).

TARF-R scores for the low-intensity group are shown in Appendix 6. Mean acceptability scores per item were above the midpoint (4 = neutral acceptability) for total

	Low-intensity (n = 21) n (%)/m (sd)	Control (n = 24) n (%)/m (sd)
Child Sex		
Female	6 (29%)	7 (29%)
Male	15 (71%)	17 (71%)
Child Age (months)	41 (20–77)	43 (22–63)
Child Ethnicity[a]		
New Zealand European	10 (48%)	12 (50%)
Asian	6 (29%)	11 (46%)
Māori	1 (5%)	5 (21%)
Latin American	4 (19%)	1 (4%)
Pacific Island Nation	3 (14%)	
Eastern European		1 (4%)
Prefer not to say		1 (4%)
Participating Parent Education		
High school	5 (24%)	3 (13%)
Certificate/Trade	4 (19%)	7 (29%)
University	12 (57%)	14 (58%)
Participating Parent Employment		
Not employed	10 (48%)	7 (29%)
Part-time	5 (24%)	7 (29%)
Full-time	6 (29%)	10 (42%)
Family Income (NZD)		
<$80,000	8 (38%)	3 (13%)
≥$80,000	10 (48%)	16 (67%)
Prefer not to say	3 (14%)	5 (21%)

NZD, New Zealand Dollars. [a]Note: Children could have more than one ethnicity.

Table 1: **Participant demographics.**

acceptability and each sub-domain. Scores for disruption/time were comparably lower than those for the other subscales.

The one recorded adverse event involved a parent divulging significant mental health difficulties not related to the trial. Two adverse effects related to the trial resulted in withdrawal; one because the child was not comfortable in the clinic setting and one because the low-intensity support did not suit the family's parenting philosophy. The mean percentage of time clinicians perceived children to be upset/distressed during clinician-implemented sessions was 5% across children (range = 0–19%).

Discussion

Our findings suggest that the low-intensity parent and clinician-delivered support group showed significant improvements in child engagement (the primary outcome), total utterances, and different words in an interaction with their parents compared to the control group. Parents in the low-intensity group also showed greater improvement in their use of ESDM strategies than those in the control group. The effect sizes for these improvements were generally large, suggesting a meaningful change in parent–child interactions due to the provision of the low-intensity support. The effect sizes were greater than the mean effect size of improvements found in parent-mediated approaches alone.[9,16] As such, the addition of the clinician-delivered component may have resulted in benefits above and beyond those typically seen in parent-mediated support alone.

The parent–child interaction outcomes are proximal.[2] Parents were coached to be more responsive when interacting with their child, and clinicians modelled responsivity during their direct sesssions.[15] When assessing child outcomes with a parent following parent-mediated support, it is possible that observed child improvements may be primarily due to parents' improved abilities to elicit behaviours like engagement and communication. Young children spend a substantial amount of time interacting with their parents, and parent–child interactions are fundamental in supporting child development.[8,17] As such, these improvements in interaction may be meaningful, regardless of whether they immediately generalise to other individuals and contexts.

The effects of the low-intensity support on other, more distal[2] outcomes remain unclear. The low-intensity group showed significant improvements in a range of outcomes for which there was no improvement in the control group. This included child improvements in total utterances with an unfamiliar researcher and communication, daily living skills, and socialisation on the VABS-III, as well as parent reductions in stress on the APSI and improvements in their sense of competence on the PSOC. However, there was no evidence of significant interaction between groups over time for these variables. As such, we cannot be confident that these changes represent meaningful improvements for the low-intensity group compared to the control.

Both the low-intensity and control groups showed significant improvements in the number of different words with an unfamiliar researcher over time. This was the one area in which the control group showed significant improvements; however, this result may only represent the growth expected from natural language development over time. Neither group showed any significant improvement in developmental level on the MSEL or family quality of life. Comprehensive and intensive support may be needed to produce meaningful change in these most distal outcomes.[2]

There were strengths and limitations of this research. We followed gold-standard RCT procedures, such as blind randomisation, inclusion of blinded outcome measures, and a pre-registered data analysis approach. We included a broad range of outcome measures, and our study was sufficiently powered to detect improvements in proximal outcome variables pertaining to the parent–child interaction. Due to the

Outcome	Baseline	Follow-up				
	Mean (SD)	Mean (SD)	Mean difference (95% CI)	Cohen's d (95% CI)	ANOVA (F)	η_p^2
Child engagement (Primary)					21.47***	0.33
Low-intensity	38.19 (13.75)	61.71 (16.50)	23.52 (15.87; 31.17) ***	1.44 (0.81; 2.04)		
Control	45.67 (19.03)	45.13 (21.30)	−0.54 (−7.70; 6.61)	–		
Parent-child interaction–total utterances					13.31***	0.24
Low-intensity	19.57 (21.84)	50.24 (36.61)	30.67 (15.90; 45.44) ***	1.01 (0.47; 1.52)		
Control	38.75 (39.70)	32.83 (34.21)	−5.92 (−19.73; 7.90)	–		
Parent-child interaction–different words					5.30*	0.11
Low-intensity	15.19 (22.34)	36.57 (31.45)	21.38 (10.32; 32.45) ***	0.73 (0.24; 1.21)		
Control	24.29 (28.10)	28.38 (30.96)	4.08 (−6.27; 14.43)	–		
ELSA-T–total utterances					0.50	0.01
Low-intensity	27.10 (35.99)	60.76 (62.27)	33.67 (8.59; 58.75) **	n/a		
Control	37.50 (46.09)	59.17 (61.46)	21.67 (−1.79; 45.13)	n/a		
ELSA-T–different words					0.06	0.00
Low-intensity	16.19 (28.88)	39.14 (42.76)	22.95 (6.01; 39.89) ***	n/a		
Control	28.38 (46.13)	48.58 (67.60)	20.21 (4.36; 36.05) *	n/a		
VABS-III–communication					2.74	0.06
Low-intensity	58.10 (21.64)	72.00 (16.09)	13.91 (7.13; 20.68) ***	n/a		
Control	60.46 (25.30)	66.75 (21.03)	6.29 (−0.04; 12.63)	n/a		
VABS-III–daily living skills					2.76	0.06
Low-intensity	73.14 (16.11)	80.57 (12.00)	7.43 (1.17; 13.69) *	n/a		
Control	72.29 (13.80)	72.67 (16.28)	0.38 (−5.48; 6.24)	n/a		
VABS-III–socialisation					2.05	0.05
Low-intensity	69.00 (14.03)	75.29 (12.29)	6.29 (2.14; 10.44) ***	n/a		
Control	69.04 (8.92)	71.29 (9.95)	2.25 (−1.63; 6.13)	n/a		
MSEL–early learning composite					0.02	0.00
Low-intensity	54.71 (8.97)	57.48 (16.28)	2.76 (−3.50; 9.02)	n/a		
Control	61.79 (19.79)	64.00 (24.67)	2.21 (−3.65; 8.07)	n/a		
Parent ESDM fidelity					15.65***	0.27
Low-intensity	55.63 (9.94)	72.15 (9.09)	16.52 (11.93; 21.11) ***	1.48 (0.85; 2.01)		
Control	56.68 (11.27)	60.87 (10.13)	4.19 (−0.11; 8.48)	–		
APSI					0.82	0.02
Low-intensity	22.67 (10.37)	16.86 (6.60)	−5.81 (−11.27; −0.35) *	n/a		
Control	19.79 (12.25)	17.33 (13.20)	−2.46 (−7.56; 2.65)	n/a		
PSOC					3.82	0.08
Low-intensity	66.24 (10.65)	72.86 (9.18)	6.62 (1.35; 11.89) *	n/a		
Control	66.25 (10.46)	65.88 (12.84)	−0.38 (−5.31; 4.56)	n/a		
FQOL					0.00	0.00
Low-intensity	95.05 (13.41)	96.48 (12.96)	1.43 (−7.42; 10.28)	n/a		
Control	91.92 (12.97)	93.33 (21.35)	1.42 (−6.86; 9.70)	n/a		

*p ≤ 0.05. **p ≤ 0.01. ***p ≤ 0.001. Note: η_p^2 = partial eta squared; Cohen's d is only reported for significant within group changes within significant ANOVA models.

Table 2: **Mean baseline, follow-up, and difference scores by group, ANOVA results, and relevant effect sizes.**

sample size, it is likely that the study was underpowered to detect changes in more distal outcome variables. The exploratory examination of secondary and tertiary outcomes without correction for multiple comparisons also means that these findings should be interpreted with caution, including consideration of effect size and potential overlap of related outcomes. As such, we cannot determine with certainty whether the improvements in additional child and parent outcomes seen in the low-intensity group were meaningful. The sample size also meant that it was not possible to analyse whether, in line with the logic of the low-intensity approach, improvements in more distal child and family outcomes were mediated by changes in proximal outcomes such as child engagement and parent use of ESDM techniques. The combined nature of the support means it was also not possible to determine the relative contribution of the parent coaching and direct clinician components towards changes in child and family outcomes, only that the combined approach led to a significant effect on

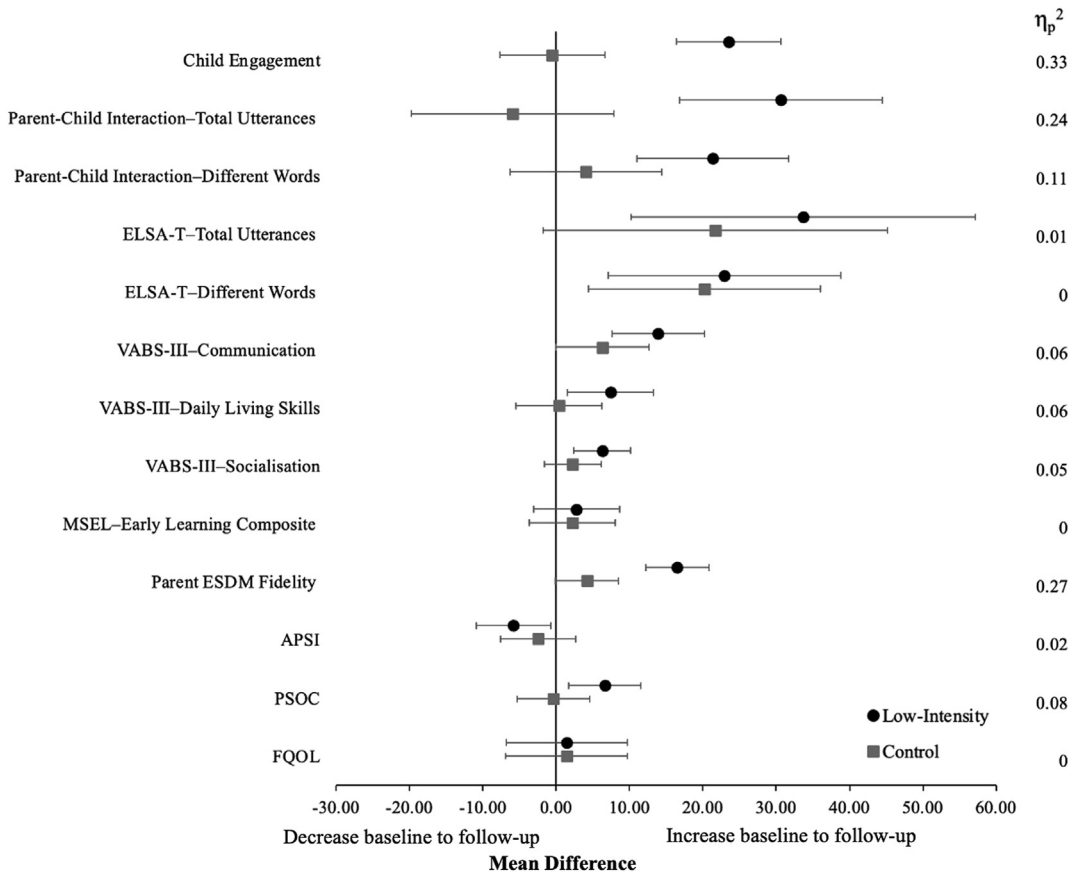

Fig. 2: **Mean difference between baseline and follow-up scores for the low-intensity and control groups over time for each primary, secondary, and tertiary outcome. Improvements were indicated by a positive mean difference from baseline to follow-up for all outcomes except for stress scores on the APSI for which improvements were indicated by a negative mean difference from baseline to follow-up**.

proximal outcomes. The participants in the trial represented a broad range of ethnicities, however, Māori were slightly underrepresented (13% in the sample compared to 17% of the population). There is a long wait for diagnosis in New Zealand,[3] thus, to recruit enough children for the trial, we included those who were undiagnosed but showing signs of autism on a gold-standard assessment tool.[18,19] ESDM is also suitable for undiagnosed children,[12] however, it is important to note that some child participants may never have reached the threshold for a clinical autism diagnosis.

The low-intensity support was intended to suit the New Zealand context, where access to clinical autism support is limited. The support was also adapted based on feedback from a local advisory group of autistic and non-autistic stakeholders. Participants in the low-intensity group generally found the support acceptable on the TARF-R.[33] Mean scores for the perceived reasonableness and effectiveness of the support, as well as family willingness to implement the procedures were particularly high. However, fifteen families were ineligible or withdrew because of the time commitment, and participating families found the low-intensity support somewhat disruptive.[33] It is hypothesised that these issues relate more to the need to travel to a clinic twice a week, for example, than the total number of weekly hours involved in the support. One family withdrew because their child did not like the clinic, and another because ESDM did not align with their parenting philosophy. Clinicians perceived that children were distressed for an average of 5% of the time during the clinician-implemented sessions, with one child experiencing distress almost 20% of the time. It is novel to measure child distress when receiving support services, so it is not possible to determine how this compares to other approaches. However, the fact that a small proportion of children appeared somewhat distressed during clinician-implemented sessions indicates that aspects of the low-intensity approach may not have been acceptable to them. As such, this support should be further adapted to be more accessible and suitable to all New Zealand children and families, including

potentially replacing the clinic component with community-based (e.g., home or preschool) direct clinician support and examining methods to further reduce distress for some children. To maintain rigour, future evaluations of adapted low-intensity approaches could include randomisation as part of a larger-scale community implementation.[35]

The low-intensity support was strengthened by its focus on responsiveness to the child's communication and interests and its alignment with guidance from a community advisory group. The researchers removed the SRS as a pre-post measure because the low-intensity support was never intended to "reduce autism characteristics", and many in the community find this outcome inappropriate.[28] However, the curriculum used to set goals[15] and some standardised outcome measures used in this study, including the MSEL[25] and the VABS-III,[26] are based on typical developmental norms. As such, they may encourage teaching autistic children to play, communicate, and socialise like their non-autistic peers instead of supporting their own unique communication style and sense of self.[1] Researchers should build on this current research by prioritising supports and outcome measures that are meaningful to the community, such as those related to quality of life, child and family mental health outcomes, and upskilling those around the child.[28] To further promote meaningful design and outcomes, future studies should also be co-produced with autistic people at all stages.[1]

Contributors

H.W contributed to study conceptualisation, funding acquisition, investigation, methodology, project administration, supervision, and writing. P.J. contributed to data curation, investigation, project administration, and writing. M.H. contributed to data curation, formal analysis, methodology, and writing. J.T. contributed to conceptualisation, investigation, and writing. L.P. contributed to methodology and writing. E.M. contributed to study conceptualisation, data curation, investigation, methodology, and project administration. G.D. contributed to data curation, investigation, project administration. S.P. contributed to study conceptualisation, methodology, and writing. L. v.d.M. contributed to study conceptualisation, funding acquisition, investigation, and writing. A.J.O.W contributed to study conceptualisation, funding acquisition, methodology, supervision, and writing.

Data sharing statement

Deidentified data are available for some study participants by request. Contact Hannah.Waddington@vuw.ac.nz for more information or to request these data.

Declaration of interests

H.W. is Clinic Lead, J.T. is Māori and Strategic Advisor, and G.D was Clinic Manager for the Victoria University of Wellington Autism Clinic in which this study was conducted and which historically delivered ESDM-based support. E.M., J.T., H.W., L.v.d.M., G.D., and P.J. are certified ESDM therapists. J.T. and H.W have attended ESDM parent coaching training. A.J.O.W has been awarded an NHMRC Investigator Grant, which is paid to his employer to support his salary. A.J.O.W is Clinical Director of Clinikids Telethon Kids Institute, which provides support to young autistic children. H.W. is a member of the Australasian Society for Autism Research Committee, Victoria University of Wellington representative on the Autism Experiences Wellington Trust, and a member of the Autism NZ Research Advisory group. H.W. and A.J.O.W. have received payment to attend conferences. L.v.d.M is a member Living Guidelines Group Aotearoa New Zealand Autism Guideline, Co-chair of the Australasian Autism Research Council, a member of the Victoria University of Wellington Autism Clinic Advisory Group, and the Chair of the Autism New Zealand Research Advisory Group.

Acknowledgements

The authors would like to acknowledge the invaluable contribution of the children and families who participated in the research. They would also like to acknowledge the broader Autism Clinic research team who assisted with data collection and with delivering support to children and families.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lanwpc.2024.101173.

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