

BMJ Open Outcomes of participating in the Let's Play programme on 0–5-year-old autistic children's engagement and caregivers' stress: study protocol for a parallel randomised controlled trial

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ABSTRACT

Introduction Vast empirical evidence highlights the importance of early identification, diagnosis and support for autistic children. Caregivers of autistic children often experience high levels of psychological distress; hence there is a need for parallel child and caregiver support. Autism New Zealand's Let's Play programme is a caregiver-mediated, community-based programme based on the principles of developmental and relational interventions (henceforth, developmental). Developmental interventions are evidence-based supports designed to enhance children's learning within the context of developmentally appropriate, naturalistic settings (eg, everyday routines, play). We aim to evaluate the effects of the Let's Play programme on autistic children's engagement and caregiver stress.

Methods and analysis This study will be a single-blind (rater) randomised controlled trial with two parallel arms: immediate programme access (intervention) versus a waitlist control. Participants will be 64 caregivers of children aged 0–5 years with diagnosed or suspected autism, allowing for 20% attrition, based on power calculations. The Let's Play programme will be delivered over 9 weeks using a combination of small group workshops and in-home coaching. Primary outcome variables include child engagement and caregiver stress. Caregivers will complete measures at three time points (baseline, immediately post-programme and at the 6-month follow-up), and effectiveness will be analysed using generalised estimating equation models and intention-to-treat and per protocol analyses.

Ethics and dissemination This trial was approved by Aotearoa New Zealand Ministry of Health's Health and Disability Ethics Committee (2022 FULL 13041). Findings will be communicated nationally and internationally via conferences, journal publications and stakeholder groups (eg, service providers for autistic children). Results will be shared regardless of magnitude or direction of effect.

Trial registration number ACTRN12622001139763.

INTRODUCTION

Autism, or *takiwātanga* (te reo Māori term derived from 'tōku/tōna anō takiwā' meaning

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The programme being evaluated was designed by early intervention educators with extensive experience supporting autistic children and their families.
- ⇒ Members of the autistic community have been involved in developing both the intervention programme and evaluating this study protocol.
- ⇒ This randomised controlled trial includes a wide range of quantitative and qualitative outcome variables for children and their caregivers, including caregivers' perceptions of the intervention programme's feasibility, acceptability and adverse effects.
- ⇒ Most outcome measures are completed at three time points (ie, baseline, post-programme, and 6-month follow-up) allowing the research team to evaluate change from pre- to post-programme and maintenance over time.
- ⇒ Currently, the intervention is only available in English, limiting access.

my/his/her own time and space),^{1,2} is a form of neurodivergence where individuals have social attention and communication differences from their non-autistic peers.^{3,4} There are limited data on the rates of autism diagnosis in Aotearoa New Zealand (ANZ),^{5,6} but estimates suggest a substantial increase in recent years from 1.2% in 2014 to 2.5% in 2021 (approximately 21 000 children).⁷

Parenting autistic children can be a joyful experience.⁸ However, caregivers of autistic children often experience poorer mental health and higher stress levels than caregivers of non-autistic children.^{9–12} High levels of parenting stress can have negative impacts on the caregiver-child relationship and child development.¹³ Early identification of autism and early access to appropriate support services can improve social, academic and

behavioural outcomes for autistic children^{4 14–17} and caregiver well-being.^{18–20}

While there is increasing evidence of the importance of early support, many families in ANZ face barriers to access, associated with difficulty gaining referrals, long waitlists and financial cost.^{21 22} This issue is further compounded by a lack of professionals with the relevant training to deliver such services. Caregiver-mediated programmes provide a time-efficient and cost-efficient alternative to clinician-implemented services,²³ particularly when confronted with professional skill shortages.²⁴ Further, caregivers are often well-placed to support their own child's development by enabling learning opportunities across different settings and throughout the day.²⁵

Developmental interventions are a form of early support, designed to enhance children's learning and development through their interactions with other people¹⁹ and within the context of developmentally appropriate, naturalistic settings and daily activities.¹⁶ Evidence shows that developmental interventions, including those that are caregiver-mediated, can have significant positive effects on young autistic children's social communication and engagement^{26–30} and caregiver communication, responsiveness and interaction.^{19 26} However, in most intervention studies, caregiver coaching has been provided using a one-to-one model of direct support^{24 31–33}; a resource-intensive model for community providers.

Group coaching provides an alternative, more efficient service delivery model, while enabling the simultaneous benefits of social learning and support for participating caregivers.^{34–36} Preliminary evidence suggests that group caregiver coaching is a feasible and socially valid method of delivering support for caregivers of autistic children.^{35–37} However, to the best of our knowledge, no randomised controlled trial (RCT) has evaluated the effects of group coaching in developmental interventions when delivered by community providers (ie, outside of university-based research programmes). Moreover, we were unable to identify any studies that have evaluated the effect of such interventions on caregiver well-being. Recent systematic reviews call for further methodologically rigorous evaluations of interventions for autistic children and their caregivers.^{27 30}

Autism New Zealand is a charitable organisation that develops and provides education and support programmes for autistic individuals, their families and health and education professionals. The Let's Play programme is a newly developed, caregiver-mediated, developmental-relational intervention. Using a combination of group workshop sessions and individual home visits, caregivers are taught the importance of attunement (ie, building positive relationships through caregiver responsivity)³⁸ to support their child's development of foundational learning skills (eg, joint attention, communication and problem-solving skills). The programme emphasises the positive impact that caregivers can have on children's development and techniques they can use in everyday routines.

AIMS AND OBJECTIVES

Primary objectives

This paper describes the protocol for an RCT comparing a waitlist control (WLC) condition to the 9-week Let's Play programme. The primary research objectives are to evaluate the effects of the Let's Play programme on young autistic children's social engagement with their caregivers and parental stress, in comparison to treatment-as-usual (WLC).

Secondary objectives

The secondary caregiver-focused research objectives are to evaluate the effect of programme participation on caregivers' psychological distress (ie, symptoms of depression, anxiety and stress) and parenting self-efficacy. Secondary child-focused research objectives include evaluating the effect of programme participation on children's social responsiveness, quality of life, behaviour and communication. The social acceptability, cultural responsiveness and feasibility of the programme will also be evaluated through qualitative analyses of interviews with caregivers.

Hypotheses

We hypothesise that caregiver participation in the Let's Play programme will result in: (1) an increase in child social engagement during caregiver-child interactions; (2) a reduction in parental stress and psychological distress; (3) increased parenting self-efficacy; (4) improvements in child social responsiveness, quality of life, behaviour and communication; and (5) caregivers will rate the programme as socially acceptable and culturally responsive.

Research questions

1. What is the effect of the Let's Play programme on children's level of engagement in caregiver-child interactions?
2. What is the effect of the programme on caregiver stress?
3. What is the effect of the programme on caregiver psychological distress and parenting self-efficacy?
4. What is the effect of the programme on children's social responsiveness, quality of life, behaviour and communication?
5. Do caregivers judge the programme to be socially and culturally acceptable and feasible?
6. Are programme benefits maintained at the 6-month follow-up?

METHODS

Trial design

This trial is a two-arm parallel group, superiority framework, single blind (rater), RCT that combines quantitative and qualitative methods. Families will be randomly allocated to the Let's Play programme or the WLC group (9-week waiting period followed by programme access). Random allocation will be achieved using computer-generated block randomisation. **Figure 1**

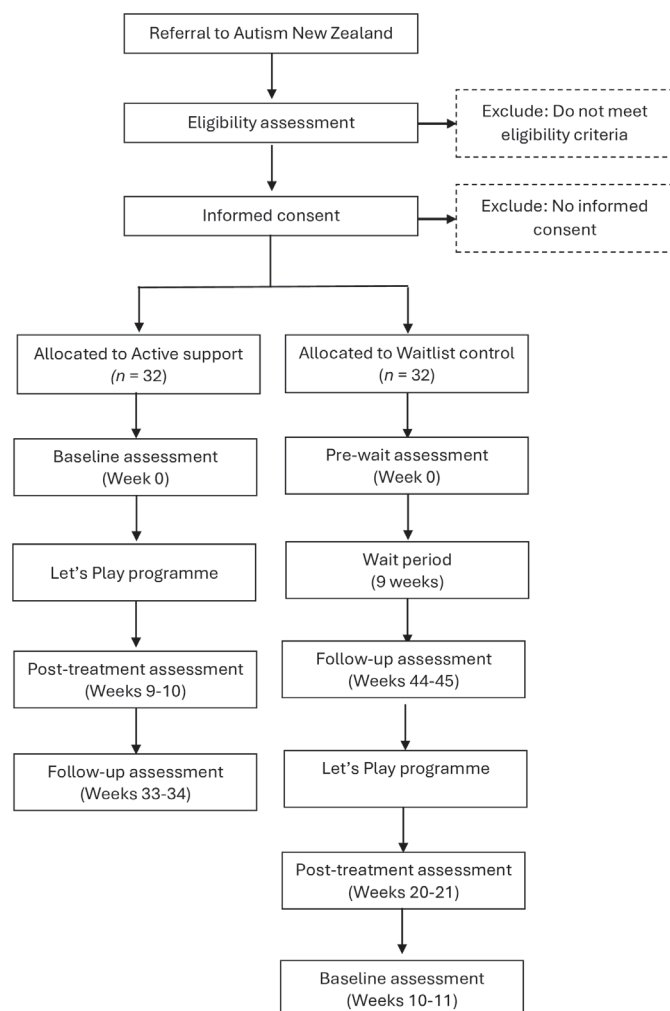


Figure 1 Consolidated Standards of Reporting Trials participant flow diagram.

shows the Consolidated Standards of Reporting Trials (CONSORT)^{39 40} participant flow diagram. The date of the first participant enrolment in this trial was 13 October 2022, and the date of final data collection was 23 May 2024.

Eligibility criteria

Participating caregivers will: (1) have a child who has received an autism diagnosis or who has been identified as having a high likelihood of autism by an appropriately qualified clinician (eg, developmental paediatrician) and is awaiting diagnostic assessment; (2) have a child who is aged 5 years 11 months or younger; (3) consent to randomisation; and (4) consent to participating in the research evaluation. Potential participants will be excluded if: (1) they are actively participating in another parenting programme; (2) their child is receiving ≥ 15 hours of professional support per week through another service provider (eg, speech language therapy, occupational therapy, early intervention delivered by a professional who is not a member of the Let's Play programme team); or (3) they do not speak sufficient English to be able to understand the consent processes and workshop content.

Recruitment and consent

Referrals for the Let's Play programme are received from Early Childhood Educators, medical professionals and other service providers. Referred families will be screened by Autism New Zealand to ensure they meet eligibility criteria for the Let's Play programme at which point Autism New Zealand staff will share information about the research evaluation and provide them with a copy of the Study Information Sheet. With the families' consent, Autism New Zealand staff will forward their details onto the research team. A member of the research team will then contact the family to share information about the study. Families will select one caregiver to complete the study measures. Due to children's age, assent (or proxy-assent from a caregiver) will be sought. See online supplemental material 1 for a copy of the caregiver consent form.

Setting

The Let's Play programme involves a combination of group workshops and inhome coaching. Group workshops will be conducted in person at the Autism New Zealand Auckland community clinic (single site).

Randomisation and blinding

A statistician, not involved with recruitment or data collection, will use computer-generated balance treatment group randomisation with fixed block size of 4, to generate allocation order. The allocation order will be copied into opaque, numbered envelopes by an independent research assistant. The lead investigator will be advised when to open the next envelope and reveal condition allocation by the research team member recruiting participants.

The trial will be single-blinded, in that the participating families and Autism New Zealand facilitators will know which condition each family is in; however, researchers coding quantitative outcome measures will not. Questionnaires and videos provided to coders will be carefully named to not reveal condition or assessment time point. A blinded statistician will conduct the main statistical analyses. After these analyses, unblinded research team members will run secondary analyses. There is no intention to unblind the statistician or coders. The post-programme interviewers may be unblinded to participant condition through participants' question responses.

Let's Play programme

The Let's Play programme will be delivered from November 2022 to November 2023 by four Autism New Zealand staff (three qualified specialist teachers and one caregiver of an autistic child). Programme facilitators all participated in a 2-day training workshop. During this time, the facilitators were taught about the theoretical underpinnings of the programme, the fundamentals of programme delivery (eg, group coaching, inhome coaching) and use of specific coaching strategies (eg, use of video feedback and modelling). This was followed by

joint delivery of the programme between an experienced and trainee facilitator, during which time the trainee is provided with feedback and guidance. Each programme will include 6–10 families. Families will select one family member to consistently attend the programme. The programme will be delivered for nine consecutive weeks and will include three 3-hour group workshops, five 1-hour inhome coaching visits and an end-of-programme group celebration.

The Let's Play programme focuses on three target areas: (1) caregivers' play skills, (2) caregivers' communication techniques and (3) the well-being of the family. The programme teaches caregivers the value of play and provides them with a repertoire of techniques they can apply during interactions within everyday routines to support their child's communication, social reciprocity, shared attention, imitation, emotion regulation, planning and problem-solving.

Group coaching workshops

Each group coaching session focuses on a different component of play. In each session, the facilitators work through a presentation that describes: the theory underpinning the play and/or communication techniques, examples of how the techniques can be used, exemplar videos and group discussions. Printed handbooks are also provided that include workshop content and reflective homework tasks (eg, brainstorming when and how caregivers could use techniques at home). Where applicable, each of the child's primary caregivers was invited to attend the workshops, with an expectation that at least one caregiver would attend all three sessions. Children did not attend group coaching workshops.

Inhome coaching visits

During home visits, facilitators will provide one-on-one coaching as caregivers implement the techniques described during workshops. Caregivers can demonstrate use of techniques synchronously or via recorded video to receive feedback on use of strategies, alternative strategies and fidelity of implementation. Facilitators will also discuss the achievements and challenges the family has faced that week, help them to reflect on these experiences and provide guidance on next steps.

The framework for programme delivery is presented in [table 1](#). Coaching and caregiver manuals are available on request.

WLC participants will not have access to Let's Play programme materials while on the waitlist and will be invited to take part in the next available Let's Play programme. While control participants are on the waitlist, they can access treatment as usual. Most families referred to Autism New Zealand have recently received a formal autism diagnosis for their child or are awaiting further assessment. They are unlikely to be accessing regular, autism-specific care yet; however, they might seek professional input (eg, general practitioner appointments).

Measures

All participants will be asked to complete measures during baseline, post-programme and follow-up. The WLC group will also complete the measures again before starting the programme, to assess any changes during their 9-week wait period. As per the intention-to-treat (ITT) principle, participants who choose to withdraw from the study will be invited to complete the study measures at the subsequent assessment time points to limit missing data. The timeline of data collection is presented in [table 2](#).

Primary child outcome measure

The primary child outcome measure will be change in children's level of engagement during caregiver-child interactions across the three time points. At each time point, caregivers will be asked to film a 10-minute video of one-on-one play with their child. Coders will use whole and partial interval measures adapted from Bakeman and Adamson's⁴¹ method. For each 10-second video segment, they will code whether the child is engaged: (a) with their caregiver for ≥ 7 s (total engagement; whole interval) and (b) in three mutually exclusive engagement states (ie, unengaged, passive engagement and active engagement) for ≥ 3 s (partial interval). The dependent variables will be the percentages of 10-second intervals each participant demonstrates total engagement and the preceding engagement states during video observations. Past implementations of Bakeman and Adamson's coding method have suggested high inter-rater reliability (eg, intraclass correlation of 0.94).⁴²

Primary caregiver outcome measure

The primary caregiver outcome measure is change in stress levels across the three time points. The Parenting Stress Index (Fourth Edition, Short Form) is a self-report measure used to assess parental stress levels.⁴³ The measure consists of three subscales: Parental Distress (PD), Parent-Child Dysfunctional Interaction and Difficult Child. Subscale scores are combined to give a total stress score (ie, higher scores indicate higher parental stress). Prior research suggests the PD subscale has good reliability (Cronbach's $\alpha=0.88$) when completed by caregivers of autistic children, but the other two subscales do not. Hence⁴⁴, only the PD subscale will be used in the analyses for this trial.

Secondary outcome measures

Participating caregivers will be asked to complete the Depression, Anxiety and Stress Scale-21⁴⁵ and Parenting Sense of Competence Scale⁴⁶ at each time point, as a measure of change in psychological distress and parenting self-competence, respectively. Caregivers will also complete the Social Responsiveness Scale, Second Edition Preschool Form⁴⁷ as a measure of their child's social communication behaviours; the Paediatric Quality of Life Inventory Generic Core Scales (V4.0),^{48 49} as a measure of their child's quality of life; and the Strengths and Difficulties Questionnaire (SDQ)⁵⁰ as a measure

Table 1 Let's Play programme delivery format

Week	Component	Content description
0	Pre-programme home visit	Prior to joining the programme, each family is visited by a Let's Play facilitator who explains the programme. If caregivers are interested in participating and provide consent, a baseline coaching video (1–2 min) is filmed at this visit.
1	Group session 1 <i>The basics of play</i>	The families in the cohort meet for the first time and their pre-programme videos are shared. The facilitators explain the importance of high-quality, engaged play for child development. The first main play strategy is introduced: <i>Pattern, Memory and Variation</i> (PMV). Using this technique, caregivers can create/adapt a game where there are predictable, repetitive roles for them and their child (pattern), which they can initiate using a memory catchphrase (eg, short phrase, song or gesture; Memory), and alter (variation). The facilitators show example videos from families in previous Let's Play programmes. They also discuss the importance of self-care.
2	Home visit 1	Each family is assigned a facilitator. The facilitators visit the families' homes to help them implement the PMV strategy. The facilitator recaps the strategy with the caregiver and then films a video (1–2 min) of the caregiver trying the technique with their child. The facilitator uses the video as a coaching tool by asking the caregiver to watch and reflect on their attempt, brainstorming how to apply all three PMV components, suggesting/demonstrating ideas, etc. During or after this discussion, additional videos (1–2 min) may be filmed.
3	Group session 2 <i>Following your child's lead</i>	A group check-in is performed whereby the caregivers report how they went applying PMV and share any celebratory moments. The facilitators share the caregiver-child play videos from the first home visit. The second main play strategy is introduced: <i>Turning a Me Game into a We Game</i> . This strategy involves caregivers identifying what independent play their child enjoys, deducing the child's motivation for engaging in that play and then figuring out a way they could create a role for themselves to join in. The facilitators share example videos from other families who have completed the programme. They also talk to the caregivers about the levels of quality engagement and how they can foster high-quality play (eg, have toys especially for caregiver-child play) and adapt their language to their child (eg, reducing language and commenting rather than questioning). They then talk more about self-care.
4	Home visit 2	The facilitators revisit their families to help them implement Turning a Me Game into a We Game. The procedure mirrors that for home visit 1, and at least one video (1–2 min) of the caregiver using the technique with their child is filmed.
5	Group session 3 <i>Using everyday routines</i>	The group does a check-in where each caregiver is asked to report on how their week went and whether they have any celebratory moments to share. A video clip is shown from each family's second home visit. Then the third main play strategy is introduced: <i>Everyday Routines</i> . The facilitators explain how play can be used to teach new skills and routines in everyday life using example videos. They also provide examples of personalised books to help their child understand new or stressful situations (eg, getting a haircut). Caregivers are also asked to reflect on what long-term goals they have for their child.
6	Home visit 3	Akin to the previous home visits, the facilitators visit the families' homes to help them practice a daily routine or use/create a personalised book. They follow the same coaching strategy. At least one video (1–2 min) of the caregiver doing a daily routine or reading a personalised book with their child is filmed.
7	Home visit 4	The facilitators help the caregivers with consolidation of play skills, working with professionals and goal-setting. The caregivers can request specific help.
8	Home visit 5	Continuation of content covered in home visit 4.
9	Celebration	Group meeting to celebrate progress and achievements. Caregivers are invited to bring their child with them to this session. The facilitators show two videos from each family: a baseline or early programme video and their best home visit example of quality engagement.

of their child's behaviour. Caregiver-child play videos will also be analysed using the Systematic Analysis of Language Transcripts, New Zealand/Australia V.16.⁵¹ These measures are described in greater detail in online supplemental material 2.

Process measures

Social validity

The Treatment Acceptability Rating Form-Revised (TARF-R)⁵² is a self-report measure, completed by caregivers post-programme, to measure perceived acceptability of the programme. Ratings on six subscales (effectiveness; reasonableness; willingness; cost; negative side-effects; disruption/time) are summed to provide a total treatment acceptability score. The TARF-R has adequate internal consistency ($\alpha=0.69-0.95$).^{52 53} In addition to completing

the TARF-R, a subset of caregivers will be interviewed. We will ensure Māori (Indigenous people of ANZ) caregivers are invited so we can specifically look at their perceptions of the cultural acceptability of the programme. Topics covered will include cultural acceptability, method of programme delivery and content; enablers and barriers to access; and suggestions for improvement.

Programme engagement, implementation and additional supports

Four measures will be used to ascertain caregivers' implementation of strategies. First, caregivers will record a weekly log reporting the Let's Play techniques they use with their child and approximately how long (min) they use them for. In this same log, they will record other professional services they have accessed (eg, speech or occupational therapy) and the length of appointments

Table 2 Timeline of the Let's Play programme and data collection

Study period															
Time points	Enrolment	Pre-wait baseline		Programme (9 weeks)									Post (immediately post-programme)		Follow-up (6 months post-programme)
		W12	W0	Baseline	W1	W2	W3	W4	W5	W6	W7	W8	W9	W9/10	W33/34
Study procedures															
Eligibility screening	X														
Informed consent	X														
Randomisation	X														
Let's Play programme															
Group workshop			X		X		X		X						
Home visit				X			X		X	X	X				
Group celebration													X		
Outcome data collection															
Caregiver-child interaction video (10 min)	C		X										X		X
Child engagement	C		X										X		X
Child language (SALT-NZAU)	C		X										X		X
Caregiver implementation of Let's Play techniques	C		X										X		X
IOA	C		X										X		X
PSI-4-SF (15 min)	C		X										X		X
DASS-21 (10 min)	C		X										X		X
PSOC (10 min)	C		X										X		X
SRS-2 (20 min)	C		X										X		X
PedsQL (5 min)	C		X										X		X
SDQ (10 min)	C		X										X		X
Caregiver log of Let's Play techniques (10 min weekly)				X	X	X	X	X	X	X	X	X	X		X
Caregiver log of professional support services accessed by caregiver and child (10 min weekly)	C			X	X	X	X	X	X	X	X	X	X		X
Therapist procedural integrity				X	X	X	X	X	X						

Continued

Table 2 Continued

Time points	Study period														
	Pre-wait baseline			Programme (9 weeks)									Post (immediately post-programme)		Follow-up (6 months post-programme)
	Enrolment	W12	W0	W1	W2	W3	W4	W5	W6	W7	W8	W9	W9/10	W33/34	
TARF-R (10 min)													X		
Post-programme caregiver interview (30 min)													X		
Adapted from the standard protocol items: Recommendations for Interventional Trials (SPIRIT) template. ^{57 58} C, waitlist controls only; DASS-21, Depression, Anxiety, and Stress Scale-21; IOA, interobserver agreement; PedsQL, Pediatric Quality of Life Inventory Generic Core Scales; PSI-4-SF, Parenting Stress Index – Fourth Edition, Short Form; PSOC, Parenting Sense of Competence Scale; SALT-NZAU, Systematic Analysis of Language Transcripts, New Zealand/Australia; SDQ, Strengths and Difficulties Questionnaire; SRS-2, Social Responsiveness Scale Preschool Form, Second Edition; TARF-R, Treatment Acceptability Rating Form-Revised; X, all participants.															

(min) that week. Second, a record of the number of workshop sessions and home visits the caregivers attend will be used as a measure of support dosage. Third, the 10-minute caregiver-child interaction videos will be used to assess caregivers' implementation of taught strategies with their child. And fourth, an independent observer will use a checklist to assess whether the Let's Play programme facilitators delivered the programme with fidelity for at least 15% of the workshop sessions and home visits.

Interobserver agreement

To ascertain the reliability of video coding for child outcomes, 15–20% of videos will be coded by a second trained coder, blinded to participants' treatment conditions. Additionally, therapist procedural integrity will be checked for 20% of the observed sessions. This will be judged in-person during group workshops and home visits. Intraclass correlation coefficients will be used to calculate interobserver agreement.

Data management plan

Participating families will be assigned a unique six-digit participant code to deidentify all their data. A password-protected file will include the key linking the participating families and their contact details to their unique participant code. Any coding will be stored in locked filing cabinets at the Autism New Zealand Auckland community clinic or the University of Canterbury. Such documents will be scanned and stored on a password-protected computer and backed up in a password-protected cloud storage system before being destroyed. Only members of the research team will have access to data collected for this trial. Videos will also be kept in a password-protected cloud storage system. These videos will only be accessible to the individual families and to the research team members coding the videos. The Data Management Plan is included in the in the Australian New Zealand Clinical Trials Registry (ANZCTR; ACTRN12622001139763).

Patient and public involvement

Māori Research Leaders from the University of Canterbury were consulted in the development and evaluation of this trial protocol. Autism New Zealand consulted with Māori staff and a Pasifika advisor from the ANZ Ministry of Education while developing the Let's Play programme. They have also received programme feedback from an autistic advisor at Autism New Zealand, a research advisory group of academics and health professionals, a community advisory group of autistic adults and caregivers of autistic children and participants in previous programmes. This feedback has been applied in the development of the Let's Play programme.

Sample size

An a priori, two-tailed power calculation was conducted to estimate sample size using G*Power software (V.3.1.9.6).^{54 55} The power calculation estimated a minimum of 52 families will be needed to detect a medium-sized effect ($d=0.80$; $\alpha=0.05$; power=0.80). To

account for potentially 20% attrition, this was increased to 64 families (ie, 32/condition). This power calculation was based on the primary child outcome measure (ie, the child's level of engagement in caregiver/child interactions). While the error and power rates are standard, the effect size was based off Kasari *et al*⁵⁶ who reported a strong effect of Joint Attention, Symbolic Play, Engagement and Regulation, Naturalistic Developmental Behavioural Intervention (JASPER NDBI) participation on increasing children's joint attention ($d=0.87$).

Data analysis methods

The Standard Protocol Items: Recommendations for Interventional Trials^{57 58} statement was used to inform the study protocol. CONSORT^{39 40 59} statements will be used to guide the reporting of research outcomes. Data will be checked by two members of the research team to ensure it is correctly inputted. Only members of the research team will be permitted access to research data.

Participant flow will be presented, giving the numbers of participants who were randomly assigned, received intended treatment and were analysed for the primary outcomes (ITT) and numbers who complied with the treatment protocol (per protocol; PP). Reasons for losses and exclusions after randomisation will be given. A table showing the baseline demographic and clinical characteristics for each treatment group will then be presented. ITT analyses will form the basis for the principal analytic reporting, whereas PP will give a lower level of evidence which reflects the effects of treatment when taken in an optimal manner.

For each primary and secondary outcome, results for each group and estimated effect sizes and 95% CIs will be presented. Generalised estimating equation models using exchangeable correlations and robust Huber-White sandwich estimators will be used to analyse the longitudinal clustered data comparing baseline, post-programme and follow-up scores for each of the primary and secondary outcome measures. Regression diagnostics and model assumptions will be checked. Caregiver and child outcomes will be analysed separately. Caregiver and child ethnicity will be included as separate factors to evaluate the effectiveness of the programme for Māori versus non-Māori, though the extent to which this is possible may depend on the number of Māori participants.

We will describe the number and reasons for missing data, including explaining any identifiable differences between those with complete and missing data and whether there are any baseline characteristics that are associated with non-completion of the programme. Sensitivity and post-hoc procedures may be employed, depending on patterns of any missing data or partial compliance with treatment. All analyses will be performed using Stata SE V.17.0,⁶⁰ and two-tailed $\alpha=0.05$ will define significance. Finally, post-programme interviews will be analysed using inductive thematic analysis, to identify key themes.

Data monitoring and harms

Serious adverse effects for families participating in this trial are not expected; hence, there will be no formal data monitoring committee, interim analysis or a priori stopping rules. If adverse effects are seen during the trial, the research team will record these in detail, report them to the ethics committee and discuss them in any resulting outputs. Immediately post-programme, participating families will be asked to indicate whether they perceived any adverse effects of participating using the TARF-R measure and interviews.

During the trial, participating families will be in regular contact with programme facilitators and the research team whose members have considerable training and experience working with autistic children and their caregivers and will be able to assist in risk identification and management. Autism New Zealand and the research team will communicate risks identified to each other. If a risk does arise, families will be conducted within 24 hours, encouraged to contact their healthcare professional (eg, general practitioner) and/or contact relevant statutory authorities. They may also be temporarily or permanently removed from the trial. In these instances, the research team will work closely with the families to determine how to proceed. If families would like to withdraw from the research, they can do so immediately, without repercussions. They will still be able to access the Let's Play programme if they have commenced. The research team will also clarify whether they would like the data they have contributed to be removed or if they want to stop contributing from that point onwards (ie, their baseline data can be retained for analyses).

ETHICS AND DISSEMINATION

This trial was approved by ANZ Ministry of Health's Health and Disability Ethics Committee, (HDEC; ref #13041). This trial has been registered in the ANZCTR (ACTRN12622001139763). Any changes to the study protocol will be reported to HDEC, logged publicly on ANZCTR and explained in research outputs. Whether the findings are supportive of our hypotheses or not, the findings will be disseminated and communicated in peer-reviewed journals, as well as both national and international conferences. The results will also be communicated to participating families, stakeholder groups, health professionals and support service providers. There are no external restrictions being placed by the funders or sponsors.

PROTOCOL DATE AND VERSION

Protocol version (v1.1; September 21, 2022) received ethics approval on October 6, 2022. Subsequent changes can be found on the ANZCTR. Protocol version (v1.1; September 21, 2022) received ethics approval on October 6, 2022. Subsequent changes can be found on the ANZCTR.

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