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Telehealth-delivered Naturalistic Developmental Behavioral Intervention with and without Caregiver Acceptance and Commitment Therapy for Autistic Children and their Caregivers: Protocol for a Multi-arm Parallel Group Randomized Clinical Trial

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Telehealth-delivered Naturalistic Developmental Behavioral Intervention with and without Caregiver Acceptance and Commitment Therapy for Autistic Children and their Caregivers: Protocol for a Multi-arm Parallel Group Randomized Clinical Trial

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Abstract

Introduction: Timely access to early support that optimizes autistic children's development and their caregiver's mental health is critical. Naturalistic Developmental Behavioral Interventions (NDBIs) and Acceptance and Commitment Therapy (ACT) are evidence-based supports that can enhance child learning and behavior, and adult wellbeing, respectively. The traditional face-to-face delivery of these approaches is resource intensive. Further, little is known about the benefit of parallel child- and caregiver-focused supports. The aims of this trial are to evaluate the effectiveness and social validity of telehealth-delivered, caregiver-implemented, child-focused NDBI and caregiver-focused ACT when delivered alone and in parallel, on autistic children's social communication and caregiver wellbeing.

Methods and analysis: The study will use a randomized, single-blind clinical trial with three parallel arms: NDBI; ACT; and ACT + NDBI. We will recruit a minimum of 78, 2-5 year-old autistic children and their families throughout Aotearoa New Zealand. Support will be delivered over 13 weeks using a combination of culturally enhanced web-based modules and online group coaching. Primary outcome variables include children's social communication/engagement with their caregiver as well as caregiver stress and will be evaluated using a repeated measures multivariate analysis of variance (MANOVA). Outcome variables are assessed at baseline (before randomization), immediately post-participation, and at 3-month follow-up.

Ethics and dissemination: The trial is approved by the Health and Disability Ethics Committee (2022 FULL 12058). The findings of this trial will be disseminated through peer-reviewed journals and national and international conference proceedings regardless of the magnitude/direction of effect. Additionally, data will be shared with stakeholder groups, service providers, and health professionals.

Registration: Australian New Zealand Clinical Trials Registry (ACTRN12622001134718)

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3 **Keywords:** Autism; Naturalistic Developmental Behavioral Intervention; Acceptance
4 and Commitment Therapy; early intervention; caregiver wellbeing
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Article Summary**Strengths and limitations of this study**

- This trial will consist of three support arms, thus enhancing our understanding of the relative and combined effectiveness, and social and cultural acceptability of ACT and NDBI.
- Telehealth-delivery offers an equitable and accessible method of delivering caregiver- and child-focused support, that has scarcely been examined.
- The ACT and NDBI programs developed for this study were created in consultation with the autistic community and the tangata whenua (indigenous people) of Aotearoa New Zealand.
- Our multi-arm RCT compares three active interventions, so all participants will receive support.
- The ACT and NDBI programs are currently only available in English which prevents non-English speaking caregivers benefitting from these supports.

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Telehealth-delivered Naturalistic Developmental Behavioral Intervention with and without Caregiver Acceptance and Commitment Therapy for Autistic Children and their Caregivers: Protocol for a Multi-arm Parallel Group Randomized Clinical Trial

Autism/takiwātanga (a te reo Māori term for autism meaning “my/their own time and space”)[1] is a form of neurodiversity characterized by differences in cognitive, sensory, and social processing. Reported rates of autism among children in Aotearoa New Zealand (NZ) have increased from 1.2% in 2014 to 2.5% in 2021.[2] This is reflective of an overall global trend suggesting that 1 in 44 children are autistic.[3]

The increased recognition and rates of autism accompany a contemporaneous rise in demand for services. This has resulted in an unmet need for support, posing a major challenge for health systems. For example, in NZ, there is a 2 to 3 year delay between primary caregivers or parents (henceforth, caregivers) seeking initial support and receiving a diagnosis.[4, 5] Consequently, many children do not receive support until school-age.[5] Timely, evidence-informed early supports can maximize learning and development for autistic children.[6, 7] Naturalistic Developmental Behavioral Interventions (NDBIs) are a category of supports informed by behavioral and developmental theories that are implemented within natural contexts. They teach skills in a developmentally sequential manner using behavioral techniques, naturalistic teaching strategies, and shared control between the adult and child.[8] NDBIs can be comprehensive, focusing on supporting skills in a range of developmental domains (e.g., adaptive behavior, language, play), or have a more specific focus (e.g., targeting social communication alone).[8] Common elements of NDBIs include an emphasis on relationship building, face-to-face interaction, following the child’s lead, use of positive affect, language modelling, responding to communicative attempts,

Identity-first language has been used in this protocol following consultation with the autistic community in Aotearoa New Zealand.

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2
3 natural rewards, and direct teaching. Many NDBI programs teach caregivers to be the
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5 primary support agents, thus providing opportunities for NDBI techniques to be implemented
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7 throughout the day and across environments. This may facilitate generalization and
8
9 maintenance of skills over time, as well as providing the most meaningful social context for
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11 learning.[9] Recent meta-analyses found evidence that NDBIs support development of social
12
13 communication, language, play, and cognition in young autistic children.[10, 11]
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15

16
17 While many support options for autistic children focus on improving child outcomes
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19 (child-focused supports), directly supporting the wellbeing of the family may also facilitate
20
21 meaningful change.[12] Parenting an autistic child brings much joy,[13] however, research
22
23 also suggests that caregivers of autistic children can experience high rates of stress and poor
24
25 psychological wellbeing.[14, 15] Although child-focused supports can lead to secondary
26
27 improvements in caregiver mental health, they do not directly provide caregivers with tools to
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29 manage their own wellbeing.[16]
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33 Acceptance and Commitment Therapy (ACT) is a third-wave cognitive behavioral
34
35 therapy that focuses on the way people respond to internal experiences (e.g., thoughts and
36
37 feelings) through six core processes: acceptance, defusion, contact with the present moment,
38
39 self-as-context, values, and committed action.[17] Recent systematic reviews suggest that
40
41 ACT for caregivers of autistic children can contribute to reductions in stress, depressive
42
43 symptoms, and anxiety; improvements in caregiver competence and quality of life;[18, 19]
44
45 and can enhance child wellbeing and behavior.[20]
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48

49 Māori, the tangata whenua (indigenous people) of NZ, continue to face significant
50
51 disparities in access to healthcare compared to non-Māori due to systemic racism and
52
53 economic hardship, stemming from the ongoing impacts of colonization.[21] This is true of
54
55 other indigenous populations globally, such as in Australia,[22], the USA, and Canada.[23]
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57 To address these inequities, it is essential for ethnic minorities to have access to culturally
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2
3 appropriate supports. However, both ACT and NDBI are culturally-bound therapies grounded
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5 in assumptions from Western society. As culture strongly influences understanding autism
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7 and supporting autistic people,[24] evidence-based Western support options may not be
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9 appropriate for people from non-Western cultures and may act as a barrier to indigenous
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11 populations accessing and/or benefiting from these supports.[25] Cultural considerations are
12
13 necessary to ensure the available supports also meet the needs of indigenous populations.
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17 Technological innovations have resulted in a surge in telehealth-delivered support,
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19 with the recent Covid-19 pandemic, and long waitlists for services, further highlighting the
20
21 need for remote access.[26] Telehealth provides consumers with additional ways to access
22
23 supports as programs can be accessed anywhere, any time, and at minimal cost.[26] This may
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25 help reduce inequities in healthcare access faced by Māori and other ethnic minorities. While
26
27 telehealth-delivered models of NDBI and ACT have been developed, no studies have
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29 examined the relative or combined effect of both caregiver-focused ACT and child-focused
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31 NDBI delivered via telehealth, nor those which have been culturally enhanced for use with
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33 indigenous and nonindigenous populations alike.
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38 The proposed study will evaluate: (1) the effectiveness of culturally enhanced
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40 telehealth-delivered, caregiver-implemented, child-focused NDBI and caregiver-focused
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42 ACT when delivered alone and in parallel, on children's social communication/engagement
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44 with their caregiver and internalizing and externalizing behavior, as well as caregiver mental
45
46 health and wellbeing; and (2) the social validity and cultural acceptability of telehealth-
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48 delivered NDBI and ACT. We hypothesize that: (1) telehealth-delivered NDBI will result in
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50 improvements in children's social communication/engagement as well as internalizing and
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52 externalizing behavior; (2) telehealth-delivered ACT will result in improved mental health
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54 outcomes for caregivers; (3) parallel delivery of NDBI and ACT will deliver the greatest
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56 benefits in children's social communication/engagement, and internalizing and externalizing
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behavior, as well as caregiver mental health, and be rated most favorably; (4) each program will result in improved outcomes for both Māori and non-Māori participants; and (5) caregivers will rate each program as acceptable, feasible, and culturally appropriate.

Methods

Design

This will be a multi-arm parallel group, single blind (rater), randomized clinical trial. Caregiver-child dyads will be randomly allocated to one of three support arms: ACT alone, NDBI alone, or NDBI + ACT. Randomization will be performed as block randomization with a 1:1:1 allocation using minimization and stratification by ethnicity (participants who self-identify as Māori or non-Māori). Participant flow throughout the trial is depicted in Figure 1. This study and protocol were developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT),[27] the Consolidated Standards of Reporting Trials (CONSORT)[28] statement, and the CONSORT extension for multi-arm parallel-group randomized trials.[29]

< Insert Figure 1 here >

Eligibility Criteria

Participants will include a minimum of 78 caregiver-child dyads who meet the following inclusion criteria: (1) the child has a formal diagnosis of autism or has been identified as having a high likelihood of being autistic by an appropriately qualified clinician and confirmed by a “high likelihood” score on the Social Attention and Communication Surveillance–Revised (SACS-R) or SACS-Preschool (SACS-PR)[30] instrument; (2) the child is between 2 years 0 months and 5 years 11 months of age at the first point of contact (i.e., screening) and is not attending primary school; (3) the primary caregiver speaks sufficient English to understand study requirements and written content, and to participate in group sessions; (4) the primary caregiver consents to randomization; (5) the child is not

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receiving > 15 hours a week of professionally-delivered support; (6) the primary caregiver is not currently engaged in another parenting program; and (7) the child does not have a sibling or twin already participating in the study.

Recruitment

Participants will be recruited throughout NZ using a flyer shared on social media and distributed to community and cultural organizations, support groups, and service providers. Referrals from service providers and self-referrals will be accepted via the program website or direct contact with the research team.

Setting

Screening will be conducted via phone. The administration of the SACS-R and SACS-PR will be conducted in person at prospective participants' homes, at university clinics, or via Zoom (those residing outside of university sites). Information and consent forms will be emailed or posted to eligible caregivers, depending on preferences. Caregivers will access web-based educational content via the program website (www.waioratariki.org.nz) and group coaching will be delivered via Zoom. Post-participation interviews will be conducted via Zoom or phone, and paper copies of assessment tools and outcome measures will be posted to caregivers or administered over the phone. Video recordings of caregiver-child interactions will be recorded by caregivers within their homes.

Randomization and Blinding

Computer-generated fixed block size randomization with an allocation ratio of 1:1:1, will generate a random allocation order, stratified by ethnicity. An independent statistician will conduct the randomization process and give the randomization schedule to an independent researcher who will enclose assignments in sequentially numbered sealed envelopes. When each caregiver has completed the enrolment phase the project coordinator

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will open the next envelope and inform the caregiver which condition they have been allocated to. This trial is single-blinded. Caregivers and therapists will be aware of the allocated condition, whereas outcome assessors will be blind to the allocation. An independent statistician who is blind to participant allocation will conduct key analyses of the specified primary and secondary outcome measures. Investigators will conduct subsidiary analyses after the blind is broken.

Programs of Support

Caregivers will engage in the ACT and NDBI programs over 13 weeks, including six (self-directed) web-based modules (released two-weekly) and seven caregiver group sessions conducted via Zoom. Caregivers will be randomly divided into cohorts of up to eight people who will participate in group sessions together. Group sessions will last up to 2 hours. Session one will orient caregivers to the program and introduce caregivers and facilitators. Subsequent sessions will include a module summary, discussion of homework and caregiver reflections, trouble-shooting, and tailoring strategies to the individual and their family. All group sessions will follow elements of Māori tikanga, such as opening and closing the session with a karakia (prayer) and draw on hui and pōwhiri processes (rituals of encounter)[31]. Te reo Māori terminology will be incorporated within program content and resources.

Group sessions will be co-facilitated by a caregiver of an autistic child who is not part of the study and a trained practitioner (i.e., psychologists, intern psychologists, or PhD students). Where feasible, groups that include Māori participants will be co-facilitated by a Māori caregiver of an autistic child. Caregiver co-facilitators will not need to be trained in ACT nor NDBI as their role is to relate to the experience of raising an autistic child and facilitate related conversations, as opposed to providing therapeutic advice. However, they will be provided with access to modules prior to coaching sessions. There will only be a

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small number of clinical and caregiver facilitators in order to maintain integrity in program delivery (i.e., to ensure consistent levels of training and performance).

Online modules will take up to 1 hour to complete. Web-based content is presented in a range of formats, including written text, video, pictures, comics, and audio files. Caregivers will receive guidance on strategies to practice in the home to assist in the application of newly learned skills. Caregivers will also be given the opportunity to engage in a therapist-monitored, online discussion forum with others in their cohort.

An outline of both programs is presented in Table 1.

ACTion in Caregiving

ACTion in Caregiving is a parent-focused program based on ACT, which was developed for this project to teach strategies to reduce caregiver stress. Each module and its associated group session will focus on one of the six core components of ACT.

Table 1

ACTion in Caregiving, Play to Learn, and ACTion in Caregiving + Play to Learn Program

Content

| Structure | ACTion in Caregiving Content | Play to Learn Content |
|------------------------------|---|--|
| Introductory group | Program overview, introductions to group members & facilitators | Program overview, introductions to group members & facilitators |
| Module 1/ Group 1 | Creative hopelessness (e.g., futility of controlling thoughts & feelings); acceptance/willingness in the context of unpleasant internal experiences; introduction to values | Engaging your child (e.g., face-to-face interactions) & following their lead (e.g., joining child-chosen activity) |
| Module 2/ Group 2 | Mindfulness (e.g., awareness of present moment with attitude of non-judgement) & application within daily life (e.g., mindfulness of the breath) | Engaging through play (with people & objects) & incorporating in everyday routines |
| Module 3/ Group 3 | Identifying caregiver cognitive fusion & techniques to facilitate defusion | Principles of learning (e.g., role of antecedents & consequences) as applied to teaching new skills using behavioral techniques (e.g., chaining) |

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|------------------------------|---|--|
| Module 4/ Group 4 | Introduction to self-as-context & applying awareness, acceptance, and defusion to this | Principles of learning applied to replacing behaviors that are harmful to the child, others, or property |
| Module 5/ Group 5 | Living by values (e.g., ongoing clarification of values & extent to which caregivers are currently living by these; using values as a guide for action) | Teaching non-verbal communication using behavioral techniques (e.g., modelling, creating opportunities) & visual supports |
| Module 6/ Group 6 | Taking action to live by values (e.g., goal-setting), while managing vulnerabilities & processes of psychological inflexibility (e.g., avoidance) | Teaching verbal communication using behavioral techniques (e.g., prompting, responding to speech/attempts) & visual supports |

The ACTion in Caregiving website includes te ao Māori (Māori worldview) imagery (e.g., koru designs) to symbolize parent growth, nurturing of their wellbeing, caregiver-child connections, and mindfulness. Established ACT techniques and metaphors have been adapted to suit a NZ audience. Participants will receive written instructions during the modules to engage in worksheets, experiential exercises (e.g., thought suppression strategies) and therapeutic activities (e.g., mindfulness meditations) to facilitate understanding of ACT concepts and consolidate learning.

Play to Learn

The Play to Learn program was created for this research, and is based on the principles of NDBI. Play to Learn is designed to teach caregivers strategies to support the development of a broad range of social communication skills in their children.

Te ao Māori imagery for the Play to Learn website utilizes ngutukākā (plant shaped like parrot beak) and mangōpare (hammer head shark known for its strength) border designs representing communication and strengthening social connections. The online modules include video exemplars of NDBI techniques which represent families from a diverse range of cultures (e.g., Māori, Pacific peoples). While completing the modules caregivers will be provided with relevant resources and directions regarding how to create their own resources (e.g., social stories). In addition, caregivers will be given several opportunities to share video

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recordings of themselves practicing the skills from Play to Learn, to receive feedback from facilitators.

ACT + NDBI

Families in the combined support group will participate in ACTion in Caregiving and Play to Learn programs concurrently. Group sessions will occur during alternate weeks.

Adherence Strategies

If caregivers have clinical questions between group sessions that are not confidential, they will be directed to ask these at the next group session or on the discussion forum so the answer is available to all caregivers in their cohort. If caregivers have not logged into the web-based program for 7 days they will receive a text or email from a researcher to ask if they require support. Follow up phone calls will be made by group facilitators if caregivers miss a group session, to clarify reasons for non-attendance and trouble-shoot barriers. Families will be able to continue to access the web-based content independently post-participation.

Outcome Measures

Outcome variables will be assessed at baseline (before randomization), immediately post-participation, and at 3-month follow-up. Table 2 shows the time points for data collection for each outcome measure.

Eligibility Assessment Measures

Screening Interview. Screening interviews will be completed to ascertain the safety and suitability of the program, collect demographic details, and to gather information about the child's presenting strengths and challenges and caregiver mental health.

SACS-R[32] and SACS-PR.[33] The SACS-R (24 to 30 months) and SACS-PR (31 to 60 months) observational developmental surveillance tools will be administered by a trained member of the research team if the child participant does not yet have a formal

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Table 2

Timeline of the study and data collection

| | Study Period | | | | | | | | | | | | | | | | |
|--|--------------|---------------|--------------------|----|----|----|----|----|----|----|----|-----|-----|-----|-----|--|-----------------------------------|
| | Enrolment | Randomization | Support (13 weeks) | | | | | | | | | | | | | Post-support (immediately after program participation) | Follow-up (3 months post-support) |
| Timepoints | – | 0 | W1 | W2 | W3 | W4 | W5 | W6 | W7 | W8 | W9 | W10 | W11 | W12 | W13 | W14 | W38 |
| Study procedures | | | | | | | | | | | | | | | | | |
| Eligibility screening (30 min) | X | | | | | | | | | | | | | | | | |
| SACS-R/SACS-PR (<30 min) | X | | | | | | | | | | | | | | | | |
| Informed consent (30 min) | X | | | | | | | | | | | | | | | | |
| Randomization | | | | | | | | | | | | | | | | | |
| | | X | | | | | | | | | | | | | | | |
| Supports | | | | | | | | | | | | | | | | | |
| ACT | | X | G | O | G | O | G | O | G | O | G | O | G | O | G | | |
| NDBI | | X | G | O | G | O | G | O | G | O | G | O | G | O | G | | |
| ACT + NDBI | | X | GO | GO | GO | GO | GO | GO | GO | GO | GO | GO | GO | GO | GO | | |
| Outcome data collection | | | | | | | | | | | | | | | | | |
| Child-caregiver interaction video (10 min) | X | | | | | | | | | | | | | | | X | X |

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|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Child engagement | X | | | | | | | | | | | | | | | | X | X |
| Child language | X | | | | | | | | | | | | | | | | X | X |
| Caregiver application of NDBI | X | | | | | | | | | | | | | | | | X | X |
| IOA | | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Vineland-3 (45 min) | X | | | | | | | | | | | | | | | | X | X |
| CBCL/1.5-5 (20 min) | X | | | | | | | | | | | | | | | | X | X |
| PSI-4-SF (5 min) | X | | | | | | | | | | | | | | | | X | X |
| DASS- 21 (10 min) | X | | | | | | | | | | | | | | | | X | X |
| PAAQ (10 min) | X | | | | | | | | | | | | | | | | X | X |
| PSOC (10 min) | X | | | | | | | | | | | | | | | | X | X |
| Caregiver log of NDBI and/or ACT practices (5 min weekly) | | | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Log of caregiver & child professional support received (5 min weekly) | | | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |

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|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Website analytics | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Therapist support fidelity rating scale | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| TARF-R (10 min) | | | | | | | | | | | | | | X |
| Post-support interview (30 min) | | | | | | | | | | | | | | X |

Note. SACS-R = Social Attention and Communication Surveillance–Revised; SACS-PR = SACS-Preschool; W = week; G = 1 hour group session (video); O = 1 hour online module; IOA = Interobserver Agreement; Vineland-3 = Vineland Adaptive Behavior Scales, Third Edition; CBCL/1.5-5 = Child Behavior Checklist for Ages 1.5-5; PSI-4-SF = Parenting Stress Index – Fourth Edition, Short Form; DASS-21 = Depression, Anxiety, and Stress Scale – 21; PAAQ = Parental Acceptance and Action Questionnaire; PSOC = Parent Sense of Competence Scale; TARF-R = Treatment Acceptability Rating Form-Revised; Approximate time for participants to complete assessments is noted in parentheses. Adapted from the SPIRIT (2013) template.

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diagnosis of autism. Assessors rate whether the child's behavior is consistent with autism or not across the SACS-R (≤ 30 months of age) or SACS-PR (> 31 to 60 months of age) items. A child is considered to have a "high likelihood" of autism if at least three of the key items are consistent with autism.[34] The SACS-R has demonstrated high diagnostic accuracy (positive predictive value [PPV] = 83%; negative predictive value [NPV] = 99%), high specificity (99.6%), and modest sensitivity (62%).[34] The SACS-R + SACS-PR has also demonstrated high diagnostic accuracy (PPV = 78%; NPV = 99.9%), sensitivity (96%), and specificity (98%).

Primary Outcome Measure – Child Engagement

The primary child outcome is the difference in the child's engagement with their caregiver across time points. Naturalistic, in-home, child-caregiver play episodes (10 min) will be video recorded by caregivers at each time point. An adapted version of Bakeman and Adamson's[35] method will be used to code three forms of child engagement (unengaged, passive engagement, and active engagement) during video observations.

Bakeman and Adamson's[35] procedure has excellent inter-rater reliability (intra-class correlation coefficients [ICC] = 0.94).[36]

Primary Outcome Measure – Caregiver

Parenting Stress Index - Fourth Edition, Short Form (PSI-4-SF).[37] The primary caregiver outcome is the difference in caregiver stress, as measured by the PSI-4-SF Parental Distress (PD) subscale, across time points. The PSI-4-SF is a 36-item abbreviated version of the caregiver-report measure. It evaluates stress in the child-caregiver system by summing scores across PD, Parent-Child Dysfunctional Interaction (P-CDI), and Difficult Child (DC) subscales to provide a Total Stress scale score. Higher scores indicate higher parenting stress. Within the current study, only the PD subscale will be administered as this is directly relevant

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to trial aims and has high validity and reliability ($\alpha = .88$), whereas P-CDI and DC subscales have been found to have poor validity for caregivers of young autistic children.[38]

Secondary Outcome Measures - Child

Child Behavior Checklist for Ages 1.5 – 5 (CBCL).[39] The CBCL is a 99-item caregiver-report measure of child internalizing and externalizing behavior and will evaluate change in child emotional and behavioral functioning across time points. Scores across seven subscales (Emotionally Reactive, Anxious/Depressed, Somatic Complaints, Withdrawn, Attention Problems, Aggressive Behavior, and Sleep Problems) are summed to provide composite scores for Internalizing, Externalizing, and Total Problem behavior scales. Higher scores are indicative of increased difficulties. The CBCL has strong construct validity, high internal consistency (Internalizing $\alpha = .89$, Externalizing $\alpha = .92$, Total Problems $\alpha = .95$), and high test-retest reliability ($r = .87 - .90$).[40]

Vineland Adaptive Behavior Scale, Third Edition (Vineland-3).[41] The Vineland-3 parent/caregiver rating form is a standardized measure of adaptive behavior. Four domain scores (Communication; Daily Living Skills; Socialization; and Motor Skills) and the global score (Adaptive Behavior Composite) will be measured across time points. Higher scores are indicative of more advanced adaptive behaviors. The Vineland-3 has adequate internal consistency (Communication $\alpha = .95$, Daily Living Skills $\alpha = .94$, Socialization $\alpha = .96$, Motor Skills $\alpha = .90$, Adaptive Behavior Composite $\alpha = .98$) and high test-retest reliability ($r = .73 - .92$)[41].

Systematic Analysis of Language Transcripts, New Zealand/Australia (SALT-NZAU).[42] The 10-minute video observations used for the child engagement measure will be transcribed and analyzed using the SALT- NZAU 20 software to detect change in speech and language from baseline. Analyses will include total number of utterances, total number of words, total number of different words, mean lengths of utterances in words and morphemes,

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percentage of grammatically accurate utterances, percentage of maze words, and percentage of intelligible utterances. Video coders will receive training in the SALT- NZAU 20 software and 20% of the videos will be coded separately by two coders to assess inter-rater reliability.

Secondary Outcome Measures - Caregiver

Depression, Anxiety, and Stress Scale-21 (DASS-21).[43] The DASS-21 will be used to evaluate change in caregiver psychological distress from baseline. The DASS-21 yields subscale scores on three dimensions (Depression, Anxiety, and Stress) as well as a Total Scale score, with higher scores indicating higher distress. The DASS-21 has been demonstrated to have high internal consistency (Depression scale $\alpha = .88$, Anxiety scale $\alpha = .82$, Stress scale $\alpha = .90$, Total scale $\alpha = .93$) and convergent and discriminant validity.[43]

Parental Acceptance and Action Questionnaire (PAAQ).[44] The PAAQ is a 15-item self-report measure of caregiver experiential avoidance and will be used to measure change from baseline. The PAAQ consists of two subscales, Unwillingness and Inaction, as well as a Total scale score. The Unwillingness subscale measures caregiver's ability to tolerate their child's experience of an unpleasant emotion and the latter evaluates the caregiver's ability to effectively manage their reactions to their child's affect. Higher scores indicate higher experiential avoidance. Items from the original version of the PAAQ that refer to child anxiety will be adapted to include a broader range of unpleasant child emotional states (e.g., anger, sadness).[45] The PAAQ shows satisfactory internal consistency ($\alpha = .67-.82$).[45]

Parent Sense of Competence Scale (PSOC).[46] The PSOC is a 16-item caregiver-report questionnaire which will be used to assess change in caregiver efficacy and satisfaction in their caregiving role from baseline. The PSOC yields a Total score as well as Efficacy and Satisfaction scores, designed to capture caregivers' perceived competence in child rearing and enjoyment derived from caregiving, respectively. Higher scores are indicative of higher

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3 caregiver efficacy and satisfaction. The PSOC has adequate internal consistency (Total score
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5 $\alpha = .79$, Efficacy score $\alpha = .76$, Satisfaction score $\alpha = .75$).[46]
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7 ***Process Measures***

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10 **Social Validity.** The Treatment Acceptability Rating Form-Revised (TARF-R)[47] is
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12 a 20-item self-report measure that will be completed post-participation to assess program
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14 acceptability. Ratings on six subscales (Effectiveness; Reasonableness; Willingness; Cost;
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16 Negative side-effects; Disruption/time) are summed to provide a total acceptability score,
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18 with higher scores indicating higher acceptability. The TARF-R has adequate internal
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20 consistency (Effectiveness $\alpha = .95$; Reasonableness $\alpha = .90$; Willingness $\alpha = .83$; Cost $\alpha =$
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22 $.71$; Negative side-effects $\alpha = .77$; Disruption/time $\alpha = .69$, Total $\alpha = .92$).[47, 48] In addition
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24 to the TARF-R, caregivers will be interviewed using a semi-structured interview schedule to
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26 further assess the social validity and cultural acceptability of the program.
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31 **Program Adherence and Implementation.** While receiving support, caregivers in
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33 each support arm will complete weekly logs of their engagement in ACT and/or NDBI
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35 practices at home, time spent engaging in these practices (mins), and amount of additional
36
37 professional support received (i.e., type and duration). The 10-minute video observations
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39 used for the child engagement measure and language analyses will also be analyzed to
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41 evaluate caregiver use of NDBI strategies. The same analysis will not be conducted for ACT
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43 strategies as they are not always observable; ACT implementation will be measured by
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45 weekly logs. Website analytics (e.g., frequency and duration of engagement with website
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47 modules) and group session attendance will provide a measure of support dosage. Finally,
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49 therapist procedural integrity in delivery of ACTION in Caregiving and Play to Learn group
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51 sessions will be assessed by an independent observer for at least 20% of sessions using a
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53 checklist.
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Interobserver Agreement. To assess interobserver agreement (IOA), 15-20% of all 10-minute caregiver-child video observations will be randomly selected and recoded by a second observer for child engagement, child language, and caregiver use of NDBI strategies. An autistic research assistant blinded to participant allocation will code 15-20% of original IOA coded videos. This is to obtain an autistic perspective on the data collected and strengthen interpretation. IOA will be calculated using ICC.

Patient and Public Involvement

Consultation with the autistic community (including autistic adults and caregivers of autistic children) has informed the development of the research questions, design, and measures. We also received input from the autistic community, and Māori and Pacific people regarding support implementation, website layout, functions, usability, content, and cultural appropriateness. We will provide participants with a summary of trial results and will seek patient and public involvement in the development of dissemination methods, such as how to communicate findings to the community.

Sample Size

Sample size estimates were calculated a priori (power = 0.80; alpha = 0.05) and indicated that a minimum of 78 participants (caregiver/child dyads; $N = 26/\text{group}$) is sufficient to detect a large effect ($d = 0.80$) for the primary analysis. Effect size estimates were based on Kasari[9] which demonstrated a strong effect size (Cohen's $d = 0.87$) following caregiver implementation of the JASPER program with autistic toddlers. This sample size allows for 15% attrition between pre- and post-participation.

Data Analysis Methods

Firstly, an exploratory analysis of the data will be conducted. Then the three support groups will be compared for equivalency across variables at baseline, starting with descriptive examination. Where descriptive examination suggests that one or more groups

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3 may differ substantively from the others, the statistical significance of such differences will
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5 be tested by independent sample *t*-tests and chi-square with alpha set at $p < .05$. If substantive
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7 differences are detected, these variables may be used as covariates in subsequent analyses.
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10 A repeated measures 3 (Groups; NDBI vs ACT vs NDBI + ACT) by 3 (Time;
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12 baseline vs post-support vs follow-up) multivariate analysis of variance (MANOVA) design
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14 will compare baseline scores for primary and secondary outcomes with scores post-support,
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16 and at follow-up. Caregiver and child outcomes will be analyzed separately. Depending on
17
18 the statistical significance of the MANOVA findings, post hoc procedures such as
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20 discriminant descriptive analysis (DDA) and discriminant ratio coefficients (DRC), will be
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22 used to describe differences among groups and identify which variables contribute to these
23
24 differences.[49] Point-biserial correlation will evaluate whether categorical variables (e.g.,
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26 self-identified ethnicity) moderate any significant outcomes. Descriptive statistics (e.g., linear
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28 regression) will be used to examine data gathered from process variables, including the
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30 relationship between process and outcome variables and differences in process variables
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32 across groups and time.
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37 Within and between group differences may also be analyzed by Modified Brinley
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39 Plots, Cohen's *d* (standardized mean difference) effect size with 95% Confidence Intervals,
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41 and the Percent Superiority effect size.[50, 51] The degree of clinically significant therapeutic
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43 change will be assessed by the Reliable Change Index.[52] A one-way ANOVA will be
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45 performed to compare caregivers' overall mean satisfaction with support received across
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47 groups. Point-biserial correlation will evaluate whether self-identified ethnicity classification
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49 and caregiver autistic/non-autistic identification, moderate effects. Post-participation
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51 interviews will be analyzed using inductive thematic analysis.
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55 We will conduct an intention to treat analysis, whereby multiple imputation is used to
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57 handle missing data. We will also conduct a per protocol analysis whereby participants who
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withdraw will not be included in the final comparisons. Depending on the sample size and number of partial completers we may conduct a separate MANOVA to determine the effect of supports for this group specifically. We plan to describe the reasons for missing data, clarify whether there are meaningful differences between individuals with complete and incomplete data, and any baseline characteristics which may predict non-completion.

Data Collection, Storage, and Protection

The research team will make every reasonable effort to collect data from enrolled caregivers across time points, including sending email reminders and phone calls. Access to the full participant dataset will be restricted to the research team. Each caregiver-child dyad will be allocated a unique ID code following study enrolment and information will be recorded under this code. Research data will be stored on secure password-protected servers at the University of Canterbury which are only accessible by approved members of the research team. Identifiable data and source documents will be retained for at least 10 years after the youngest child has turned 16 years old, then destroyed by secure deletion.

Data Monitoring and Harms

There are no anticipated serious adverse events for this trial, therefore a formal data monitoring committee is not required and no interim analyses or a priori stopping rules will be implemented. If any adverse events arise (e.g., worsening of outcomes for caregivers/children), these will be recorded by the research team and reported to the relevant ethics committees as well as being reported in relevant publications as it pertains to feasibility outcomes. Participants will be in regular contact with members of the research team. If there are any perceived risks (e.g., caregiver response to questionnaire indicates severe distress) we will advise participants to seek care from their healthcare professional and/or contact relevant statutory authorities, and pause involvement in the study if necessary. The study may end early for participants if the level of problem behaviors (e.g., aggression or self-harm) reported

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by the caregiver is considered to be unsafe towards them or other family members.

Involvement will also end immediately if the caregiver requests withdrawal. Caregiver reasoning for discontinuation will be recorded if they are contactable and provide an explanation.

Ethics and Dissemination

This study has been approved by the NZ Health and Disability Ethics Committee (2022 FULL 12058) and this trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12622001134718). Any substantive protocol modifications and amendments will be submitted to the NZ Health and Disability Ethics Committee for approval prior to implementation.

Potential caregiver participant will be given detailed information sheets describing the study and are requested to contact the research team to arrange further discussion and initial screening. If they agree to participate in the study, they will be provided with a consent form, but informed that their participation is voluntary and they can withdraw at any time without consequences. It will not be possible to obtain informed consent from child participants, given their age, therefore their assent to participate and be videoed will be obtained.

Trial findings will be disseminated through peer-reviewed journals and national and international conference proceedings regardless of the magnitude/direction of effect. Data will be shared with stakeholder groups and service providers. If the supports are shown to be effective and socially valid the web-based modules have the potential to be disseminated widely.

Word count: 4,564

Author contributions

LM, LME, HW, and MR designed the study. JvD, JH, LME, HW, LM, and LvN worked together to create the ACT and NDBI modules. NB and JvD drafted the statistical analysis

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plan. SM and AH provided cultural guidance and support. JvD drafted the initial protocol and manuscript and all authors contributed to refinement of the study protocol and approved the final manuscript. The sponsor and funders had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

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Competing interests

None to declare.

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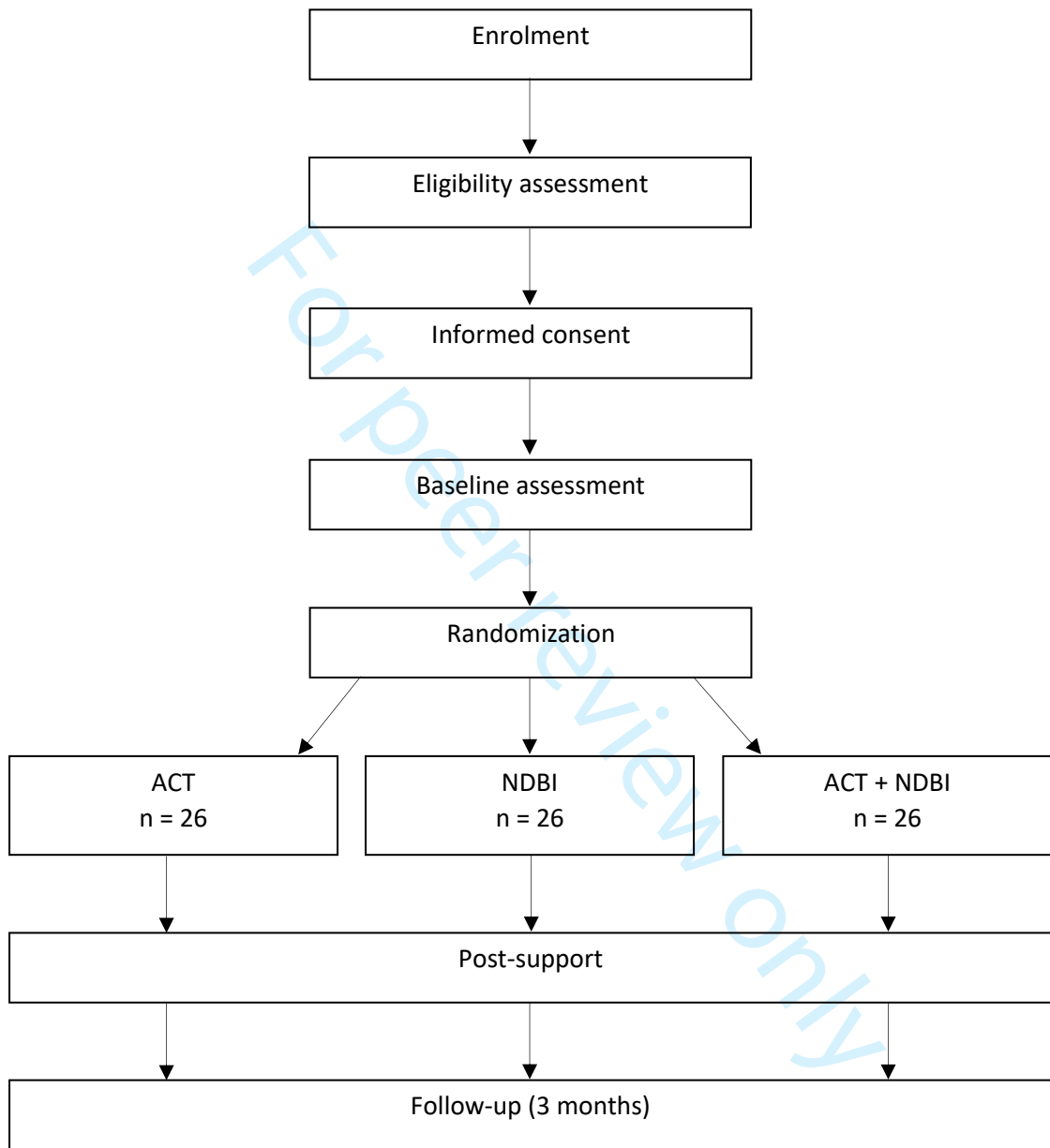
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Figure 1

Consort participant flow chart





STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|-----------------------------------|---------|--|---|
| Administrative information | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | _1_____ |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | _2_____ |
| | 2b | All items from the World Health Organization Trial Registration Data Set | _Trial registration data is available through ANZCTR (ACTRN12622001134718)_____ |
| Protocol version | 3 | Date and version identifier | _ANZCTR can be referred to for any new versions_____ |
| Funding | 4 | Sources and types of financial, material, and other support | _25_____ |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | _24-25_____ |
| | 5b | Name and contact information for the trial sponsor | _25_____ |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | _25_____ |

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| 1 | | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | _NA_____ |
| 2 | | | | |
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| 6 | Introduction | | | |
| 7 | | | | |
| 8 | Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | _5-7_____ |
| 9 | | | | |
| 10 | | | | |
| 11 | | 6b | Explanation for choice of comparators | _5-7_____ |
| 12 | | | | |
| 13 | Objectives | 7 | Specific objectives or hypotheses | _7-8_____ |
| 14 | | | | |
| 15 | Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | _8_____ |
| 16 | | | | |
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| 19 | Methods: Participants, interventions, and outcomes | | | |
| 20 | | | | |
| 21 | Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | _9_____ |
| 22 | | | | |
| 23 | | | | |
| 24 | Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | _8-9_____ |
| 25 | | | | |
| 26 | | | | |
| 27 | Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | _10-13_____ |
| 28 | | | | |
| 29 | | | | |
| 30 | | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | _23-24_____ |
| 31 | | | | |
| 32 | | | | |
| 33 | | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | _13_____ |
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| 37 | | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | _8-9_____ |
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| 1 | Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | _13-20_____ |
| 6 | Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | _14-16 (Table)____ |
| 9 | Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | _21_____ |
| 13 | Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | _9_____ |

Methods: Assignment of interventions (for controlled trials)

Allocation:

| | | | | |
|----|----------------------------------|-----|--|---------------------------------|
| 19 | Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | _9_____ |
| 25 | Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | _9-10_____ |
| 30 | Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | _9-10_____ |
| 33 | Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | _10_____ |
| 36 | | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | _NA (single-blinding only)_____ |

Methods: Data collection, management, and analysis

| | | | | |
|----|---------------------------------|-----|---|-------------|
| 1 | Data collection | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related | _13-21_____ |
| 2 | methods | | processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of | |
| 3 | | | study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. | |
| 4 | | | Reference to where data collection forms can be found, if not in the protocol | |
| 5 | | | | |
| 6 | | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be | _23_____ |
| 7 | | | collected for participants who discontinue or deviate from intervention protocols | |
| 8 | | | | |
| 9 | Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality | _23_____ |
| 10 | | | (eg, double data entry; range checks for data values). Reference to where details of data management | |
| 11 | | | procedures can be found, if not in the protocol | |
| 12 | | | | |
| 13 | | | | |
| 14 | Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the | _21-23_____ |
| 15 | | | statistical analysis plan can be found, if not in the protocol | |
| 16 | | | | |
| 17 | | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | _22-23_____ |
| 18 | | | | |
| 19 | | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any | |
| 20 | | | statistical methods to handle missing data (eg, multiple imputation) | _22-23_____ |
| 21 | | | | |
| 22 | | | | |
| 23 | Methods: Monitoring | | | |
| 24 | | | | |
| 25 | Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of | _23_____ |
| 26 | | | whether it is independent from the sponsor and competing interests; and reference to where further details | |
| 27 | | | about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not | |
| 28 | | | needed | |
| 29 | | | | |
| 30 | | | | |
| 31 | | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim | _23_____ |
| 32 | | | results and make the final decision to terminate the trial | |
| 33 | | | | |
| 34 | Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse | _23_____ |
| 35 | | | events and other unintended effects of trial interventions or trial conduct | |
| 36 | | | | |
| 37 | Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent | _NA_____ |
| 38 | | | from investigators and the sponsor | |
| 39 | | | | |
| 40 | | | | |
| 41 | Ethics and dissemination | | | |
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|----|-------------------------------|-----|---|----------------------------|
| 1 | Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | _24_____ |
| 2 | | | | |
| 3 | | | | |
| 4 | Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | _24_____ |
| 5 | | | | |
| 6 | | | | |
| 7 | | | | |
| 8 | Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | _24_____ |
| 9 | | | | |
| 10 | | | | |
| 11 | | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | _NA_____ |
| 12 | | | | |
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| 14 | Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, stored, and maintained in order to protect confidentiality before, during, and after the trial | _23_____ |
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| 18 | Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | _25_____ |
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| 21 | Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | _23_____ |
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| 24 | Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | _13_____ |
| 25 | | | | |
| 26 | | | | |
| 27 | Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | _24_____ |
| 28 | | | | |
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| 32 | | 31b | Authorship eligibility guidelines and any intended use of professional writers | _Not included_____ |
| 33 | | | | |
| 34 | | | | |
| 35 | | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | _NA_____ |
| 36 | | | | |
| 37 | | | | |
| 38 | Appendices | | | |
| 39 | | | | |
| 40 | Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | _Available on request_____ |
| 41 | | | | |
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| 1 | Biological | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular | _NA_____ |
| 2 | specimens | | analysis in the current trial and for future use in ancillary studies, if applicable | |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons [“Attribution-NonCommercial-NoDerivs 3.0 Unported”](https://creativecommons.org/licenses/by-nc-nd/3.0/) license.

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BMJ Open

Telehealth-delivered Naturalistic Developmental Behavioral Intervention with and without Caregiver Acceptance and Commitment Therapy for Autistic Children and their Caregivers: Protocol for a Multi-arm Parallel Group Randomized Clinical Trial

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|---------------------------------|---|
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| Primary Subject Heading: | Research methods |
| Secondary Subject Heading: | Paediatrics, Mental health, Health services research, Evidence based practice |
| Keywords: | MENTAL HEALTH, Developmental neurology & neurodisability < PAEDIATRICS, Clinical trials < THERAPEUTICS, Community child health < PAEDIATRICS |
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Manuscripts

STUDY PROTOCOL

Telehealth-delivered Naturalistic Developmental Behavioral Intervention with and without Caregiver Acceptance and Commitment Therapy for Autistic Children and their Caregivers: Protocol for a Multi-arm Parallel Group Randomized Clinical Trial

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STUDY PROTOCOL

Abstract

Introduction: Timely access to early support that optimizes autistic children's development and their caregiver's mental health is critical. Naturalistic Developmental Behavioral Interventions (NDBIs) and Acceptance and Commitment Therapy (ACT) are evidence-based supports that can enhance child learning and behavior, and adult wellbeing, respectively. The traditional face-to-face delivery of these approaches is resource intensive. Further, little is known about the benefit of parallel child- and caregiver-focused supports. The aims of this trial are to evaluate the effectiveness and social validity of telehealth-delivered, caregiver-implemented, child-focused NDBI and caregiver-focused ACT when delivered alone and in parallel, on autistic children's social communication and caregiver wellbeing.

Methods and analysis: The study will use a randomized, single-blind clinical trial with three parallel arms: NDBI; ACT; and ACT + NDBI. We will recruit a minimum of 78, 2-5 year-old autistic children and their families throughout Aotearoa New Zealand. Support will be delivered over 13 weeks using a combination of culturally enhanced web-based modules and online group coaching. Primary outcome variables include children's social communication/engagement with their caregiver as well as caregiver stress and will be evaluated using a repeated measures multivariate analysis of variance (MANOVA). Outcome variables are assessed at baseline (before randomization), immediately post-participation, and at 3-month follow-up.

Ethics and dissemination: The trial is approved by the Health and Disability Ethics Committee (2022 FULL 12058). The findings of this trial will be disseminated through peer-reviewed journals and national and international conference proceedings regardless of the magnitude/direction of effect. Additionally, data will be shared with stakeholder groups, service providers, and health professionals.

Registration: Australian New Zealand Clinical Trials Registry (ACTRN12622001134718)

1 STUDY PROTOCOL

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3 **Keywords:** Autism; Naturalistic Developmental Behavioral Intervention; Acceptance
4 and Commitment Therapy; early intervention; caregiver wellbeing
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STUDY PROTOCOL

Article Summary**Strengths and limitations of this study**

- This trial will consist of three support arms, thus enhancing our understanding of the relative and combined effectiveness, and social and cultural acceptability of ACT and NDBI.
- Telehealth-delivery offers an equitable and accessible method of delivering caregiver- and child-focused support, that has scarcely been examined.
- The ACT and NDBI programs developed for this study were created in consultation with the autistic community and the tangata whenua (indigenous people) of Aotearoa New Zealand.
- Our multi-arm RCT compares three active interventions, so all participants will receive support.
- The ACT and NDBI programs are currently only available in English which prevents non-English speaking caregivers benefitting from these supports.

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3 Autism/takiwātanga (a te reo Māori term for autism meaning “my/their own time and
4 space”)[1] is a form of neurodiversity characterized by differences in cognitive, sensory, and
5 social processing. Reported rates of autism among children in Aotearoa New Zealand (NZ)
6 have increased from 1.2% in 2014 to 2.5% in 2021.[2] This is reflective of an overall global
7 trend suggesting that 1 in 44 children are autistic.[3]

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15 The increased recognition and rates of autism accompany a contemporaneous rise in
16 demand for services. This has resulted in an unmet need for support, posing a major
17 challenge for health systems. For example, in NZ, there is a 2 to 3 year delay between
18 primary caregivers or parents (henceforth, caregivers) seeking initial support and receiving a
19 diagnosis.[4, 5] Consequently, many children do not receive support until school-age.[5]
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Timely, evidence-informed early supports can maximize learning and development for autistic children.[6, 7] Naturalistic Developmental Behavioral Interventions (NDBIs) are a category of supports informed by behavioral and developmental theories that are implemented within natural contexts. They teach skills in a developmentally sequential manner using behavioral techniques, naturalistic teaching strategies, and shared control between the adult and child.[8] NDBIs can be comprehensive, focusing on supporting skills in a range of developmental domains (e.g., adaptive behavior, language, play), or have a more specific focus (e.g., targeting social communication alone).[8] Common elements of NDBIs include an emphasis on relationship building, face-to-face interaction, following the child’s lead, use of positive affect, language modelling, responding to communicative attempts, natural rewards, and direct teaching. Many NDBI programs teach caregivers to be the primary support agents, thus providing opportunities for NDBI techniques to be implemented throughout the day and across environments. This may facilitate generalization and

Identity-first language has been used in this protocol following consultation with the autistic community in Aotearoa New Zealand.

1 STUDY PROTOCOL

2 maintenance of skills over time, as well as providing the most meaningful social context for
3 learning.[9] Recent meta-analyses found evidence that NDBIs support development of social
4 communication, language, play, and cognition in young autistic children.[10, 11]
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10 While many support options for autistic children focus on improving child outcomes
11 (child-focused supports), directly supporting the wellbeing of the family may also facilitate
12 meaningful change.[12] Parenting an autistic child brings much joy,[13] however, research
13 also suggests that caregivers of autistic children can experience high rates of stress and poor
14 psychological wellbeing.[14, 15] Although child-focused supports can lead to secondary
15 improvements in caregiver mental health, they do not directly provide caregivers with tools to
16 manage their own wellbeing.[16]
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26 Acceptance and Commitment Therapy (ACT) is a third-wave cognitive behavioral
27 therapy that focuses on the way people respond to internal experiences (e.g., thoughts and
28 feelings) through six core processes: acceptance, defusion, contact with the present moment,
29 self-as-context, values, and committed action.[17] Recent systematic reviews suggest that
30 ACT for caregivers of autistic children can contribute to reductions in stress, depressive
31 symptoms, and anxiety; improvements in caregiver competence and quality of life;[18, 19]
32 and can enhance child wellbeing and behavior.[20]
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42 Māori, the tangata whenua (indigenous people) of NZ, continue to face significant
43 disparities in access to healthcare compared to non-Māori due to systemic racism and
44 economic hardship, stemming from the ongoing impacts of colonization.[21] This is true of
45 other indigenous populations globally, such as in Australia,[22], the USA, and Canada.[23]
46 To address these inequities, it is essential for ethnic minorities to have access to culturally
47 appropriate supports. However, both ACT and NDBI are culturally-bound therapies grounded
48 in assumptions from Western society. As culture strongly influences understanding autism
49 and supporting autistic people,[24] evidence-based Western support options may not be
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2 appropriate for people from non-Western cultures and may act as a barrier to indigenous
3 populations accessing and/or benefiting from these supports.[25] Cultural considerations are
4 necessary to ensure the available supports also meet the needs of indigenous populations.
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10 Technological innovations have resulted in a surge in telehealth-delivered support,
11 with the recent Covid-19 pandemic, and long waitlists for services, further highlighting the
12 need for remote access.[26] Telehealth provides consumers with additional ways to access
13 supports as programs can be accessed anywhere, any time, and at minimal cost.[26] This may
14 help reduce inequities in healthcare access faced by Māori and other ethnic minorities. While
15 telehealth-delivered models of NDBI and ACT have been developed, no studies have
16 examined the relative or combined effect of both caregiver-focused ACT and child-focused
17 NDBI delivered via telehealth, nor those which have been culturally enhanced for use with
18 indigenous and nonindigenous populations alike.
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30 The proposed study will evaluate: (1) the effectiveness of culturally enhanced
31 telehealth-delivered, caregiver-implemented, child-focused NDBI and caregiver-focused
32 ACT when delivered alone and in parallel, on children's social communication/engagement
33 with their caregiver and internalizing and externalizing behavior, as well as caregiver mental
34 health and wellbeing; and (2) the social validity and cultural acceptability of telehealth-
35 delivered NDBI and ACT. We hypothesize that: (1) telehealth-delivered NDBI will result in
36 improvements in children's social communication/engagement as well as internalizing and
37 externalizing behavior; (2) telehealth-delivered ACT will result in improved mental health
38 outcomes for caregivers; (3) parallel delivery of NDBI and ACT will deliver the greatest
39 benefits in children's social communication/engagement, and internalizing and externalizing
40 behavior, as well as caregiver mental health, and be rated most favorably; (4) each program
41 will result in improved outcomes for both Māori and non-Māori participants; and (5)
42 caregivers will rate each program as acceptable, feasible, and culturally appropriate.
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STUDY PROTOCOL

Methods**Design**

This will be a multi-arm parallel group, single blind (rater), randomized clinical trial. Caregiver-child dyads will be randomly allocated to one of three support arms: ACT alone, NDBI alone, or NDBI + ACT. Randomization will be performed as block randomization with a 1:1:1 allocation using minimization and stratification by ethnicity (participants who self-identify as Māori or non-Māori). Participant flow throughout the trial is depicted in Figure 1. This study and protocol were developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT),[27] the Consolidated Standards of Reporting Trials (CONSORT)[28] statement, and the CONSORT extension for multi-arm parallel-group randomized trials.[29]

< Insert Figure 1 here >

Eligibility Criteria

Participants will include a minimum of 78 caregiver-child dyads who meet the following inclusion criteria: (1) the child has a formal diagnosis of autism or has been identified as having a high likelihood of being autistic by an appropriately qualified clinician and confirmed by a “high likelihood” score on the Social Attention and Communication Surveillance–Revised (SACS-R) or SACS-Preschool (SACS-PR)[30] instrument; (2) the child is between 2 years 0 months and 5 years 11 months of age at the first point of contact (i.e., screening) and is not attending primary school; (3) the primary caregiver speaks sufficient English to understand study requirements and written content, and to participate in group sessions; (4) the primary caregiver consents to randomization; (5) the child is not receiving > 15 hours a week of professionally-delivered support; (6) the primary caregiver is not currently engaged in another parenting program; and (7) the child does not have a sibling or twin already participating in the study.

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Recruitment

Participants will be recruited throughout NZ using a flyer shared on social media and distributed to community and cultural organizations, support groups, and service providers. Referrals from service providers and self-referrals will be accepted via the program website or direct contact with the research team.

Setting

Screening will be conducted via phone. The administration of the SACS-R and SACS-PR will be conducted in person at prospective participants' homes, at university clinics, or via Zoom (those residing outside of university sites). Information and consent forms (see supplementary file) will be emailed or posted to eligible caregivers, depending on preferences. Caregivers will access web-based educational content via the program website (www.waioratariki.org.nz) and group coaching will be delivered via Zoom. Post-participation interviews will be conducted via Zoom or phone, and paper copies of assessment tools and outcome measures will be posted to caregivers or administered over the phone. Video recordings of caregiver-child interactions will be recorded by caregivers within their homes.

Randomization and Blinding

Computer-generated fixed block size randomization with an allocation ratio of 1:1:1, will generate a random allocation order, stratified by ethnicity. An independent statistician will conduct the randomization process and give the randomization schedule to an independent researcher who will enclose assignments in sequentially numbered sealed envelopes. When each caregiver has completed the enrolment phase the project coordinator will open the next envelope and inform the caregiver which condition they have been allocated to. This trial is single-blinded. Caregivers and therapists will be aware of the allocated condition, whereas outcome assessors will be blind to the allocation. An

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independent statistician who is blind to participant allocation will conduct key analyses of the specified primary and secondary outcome measures. Investigators will conduct subsidiary analyses after the blind is broken.

Programs of Support

Caregivers will engage in the ACT and NDBI programs over 13 weeks, including six (self-directed) web-based modules (released two-weekly) and seven caregiver group sessions conducted via Zoom. Caregivers will be randomly divided into cohorts of up to six people who will participate in group sessions together. Group sessions will last up to 2 hours. Session one will orient caregivers to the program and introduce caregivers and facilitators. Subsequent sessions will include a module summary, discussion of homework and caregiver reflections, trouble-shooting, and tailoring strategies to the individual and their family. All group sessions will follow elements of Māori tikanga, such as opening and closing the session with a karakia (prayer) and draw on hui and pōwhiri processes (rituals of encounter)[31]. Te reo Māori terminology will be incorporated within program content and resources.

Group sessions will be co-facilitated by a caregiver of an autistic child who is not part of the study and a trained practitioner (i.e., psychologists, intern psychologists, or PhD students). Where feasible, groups that include Māori participants will be co-facilitated by a Māori caregiver of an autistic child. Caregiver co-facilitators will not need to be trained in ACT nor NDBI as their role is to relate to the experience of raising an autistic child and facilitate related conversations, as opposed to providing therapeutic advice. However, they will be provided with access to modules prior to coaching sessions. There will only be a small number of clinical and caregiver facilitators in order to maintain integrity in program delivery (i.e., to ensure consistent levels of training and performance).

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Online modules will take up to 1 hour to complete. Web-based content is presented in a range of formats, including written text, video, pictures, comics, and audio files. Caregivers will receive guidance on strategies to practice in the home to assist in the application of newly learned skills. Caregivers will also be given the opportunity to engage in a therapist-monitored, online discussion forum with others in their cohort.

An outline of both programs is presented in Table 1.

ACTion in Caregiving

ACTion in Caregiving is a parent-focused program based on ACT, which was developed for this project to teach strategies to reduce caregiver stress. Each module and its associated group session will focus on one of the six core components of ACT.

Table 1

ACTion in Caregiving, Play to Learn, and ACTion in Caregiving + Play to Learn Program

Content

| Structure | ACTion in Caregiving Content | Play to Learn Content |
|------------------------------|---|--|
| Introductory group | Program overview, introductions to group members & facilitators | Program overview, introductions to group members & facilitators |
| Module 1/ Group 1 | Creative hopelessness (e.g., futility of controlling thoughts & feelings); acceptance/willingness in the context of unpleasant internal experiences; introduction to values | Engaging your child (e.g., face-to-face interactions) & following their lead (e.g., joining child-chosen activity) |
| Module 2/ Group 2 | Mindfulness (e.g., awareness of present moment with attitude of non-judgement) & application within daily life (e.g., mindfulness of the breath) | Engaging through play (with people & objects) & incorporating in everyday routines |
| Module 3/ Group 3 | Identifying caregiver cognitive fusion & techniques to facilitate defusion | Principles of learning (e.g., role of antecedents & consequences) as applied to teaching new skills using behavioral techniques (e.g., chaining) |
| Module 4/ Group 4 | Introduction to self-as-context & applying awareness, acceptance, and defusion to this | Principles of learning applied to replacing behaviors that are harmful to the child, others, or property |
| Module 5/ Group 5 | Living by values (e.g., ongoing clarification of values & extent to which caregivers are | Teaching non-verbal communication using behavioral techniques (e.g., modelling, creating opportunities) & visual supports |

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currently living by these; using values as a guide for action)

| | | |
|------------------------------|---|--|
| Module 6/ Group 6 | Taking action to live by values (e.g., goal-setting), while managing vulnerabilities & processes of psychological inflexibility (e.g., avoidance) | Teaching verbal communication using behavioral techniques (e.g., prompting, responding to speech/attempts) & visual supports |
|------------------------------|---|--|

The ACTION in Caregiving website includes te ao Māori (Māori worldview) imagery (e.g., koru designs) to symbolize parent growth, nurturing of their wellbeing, caregiver-child connections, and mindfulness. Established ACT techniques and metaphors have been adapted to suit a NZ audience. Participants will receive written instructions during the modules to engage in worksheets, experiential exercises (e.g., thought suppression strategies) and therapeutic activities (e.g., mindfulness meditations) to facilitate understanding of ACT concepts and consolidate learning.

Play to Learn

The Play to Learn program was created for this research, and is based on the principles of NDBI. Play to Learn is designed to teach caregivers strategies to support the development of a broad range of social communication skills in their children.

Te ao Māori imagery for the Play to Learn website utilizes ngutukākā (plant shaped like parrot beak) and mangōpare (hammer head shark known for its strength) border designs representing communication and strengthening social connections. The online modules include video exemplars of NDBI techniques which represent families from a diverse range of cultures (e.g., Māori, Pacific peoples). While completing the modules caregivers will be provided with relevant resources and directions regarding how to create their own resources (e.g., social stories). In addition, caregivers will be given several opportunities to share video recordings of themselves practicing the skills from Play to Learn, to receive feedback from facilitators.

ACT + NDBI

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Families in the combined support group will participate in ACTION in Caregiving and Play to Learn programs concurrently. Group sessions will occur during alternate weeks.

Adherence Strategies

If caregivers have clinical questions between group sessions that are not confidential, they will be directed to ask these at the next group session or on the discussion forum so the answer is available to all caregivers in their cohort. If caregivers have not logged into the web-based program for 7 days they will receive a text or email from a researcher to ask if they require support. Follow up phone calls will be made by group facilitators if caregivers miss a group session, to clarify reasons for non-attendance and trouble-shoot barriers. Families will be able to continue to access the web-based content independently post-participation.

Outcome Measures

Outcome variables will be assessed at baseline (before randomization), immediately post-participation, and at 3-month follow-up. The Supplementary Table shows the time points for data collection for each outcome measure.

Eligibility Assessment Measures

Screening Interview. Screening interviews will be completed to ascertain the safety and suitability of the program, collect demographic details, and to gather information about the child's presenting strengths and challenges and caregiver mental health.

SACS-R[32] and SACS-PR.[33] The SACS-R (24 to 30 months) and SACS-PR (31 to 60 months) observational developmental surveillance tools will be administered by a trained member of the research team if the child participant does not yet have a formal diagnosis of autism. Assessors rate whether the child's behavior is consistent with autism or not across the SACS-R (≤ 30 months of age) or SACS-PR (> 31 to 60 months of age) items. A child is considered to have a "high likelihood" of autism if at least three of the key items

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are consistent with autism.[34] The SACS-R has demonstrated high diagnostic accuracy (positive predictive value [PPV] = 83%; negative predictive value [NPV] = 99%), high specificity (99.6%), and modest sensitivity (62%).[34] The SACS-R + SACS-PR has also demonstrated high diagnostic accuracy (PPV = 78%; NPV = 99.9%), sensitivity (96%), and specificity (98%).

Primary Outcome Measure – Child Engagement

The primary child outcome is the difference in the child's engagement with their caregiver across time points. Naturalistic, in-home, child-caregiver play episodes (10 min) will be video recorded by caregivers at each time point. An adapted version of Bakeman and Adamson's[35] method will be used to code three forms of child engagement (unengaged, passive engagement, and active engagement) during video observations.

Bakeman and Adamson's[35] procedure has excellent inter-rater reliability (intra-class correlation coefficients [ICC] = 0.94).[36]

Primary Outcome Measure – Caregiver

Parenting Stress Index - Fourth Edition, Short Form (PSI-4-SF).[37] The primary caregiver outcome is the difference in caregiver stress, as measured by the PSI-4-SF Parental Distress (PD) subscale, across time points. The PSI-4-SF is a 36-item abbreviated version of the caregiver-report measure. It evaluates stress in the child-caregiver system by summing scores across PD, Parent-Child Dysfunctional Interaction (P-CDI), and Difficult Child (DC) subscales to provide a Total Stress scale score. Higher scores indicate higher parenting stress. Within the current study, only the PD subscale will be administered as this is directly relevant to trial aims and has high validity and reliability ($\alpha = .88$), whereas P-CDI and DC subscales have been found to have poor validity for caregivers of young autistic children.[38]

Secondary Outcome Measures - Child

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Child Behavior Checklist for Ages 1.5 – 5 (CBCL).[39] The CBCL is a 99-item caregiver-report measure of child internalizing and externalizing behavior and will evaluate change in child emotional and behavioral functioning across time points. Scores across seven subscales (Emotionally Reactive, Anxious/Depressed, Somatic Complaints, Withdrawn, Attention Problems, Aggressive Behavior, and Sleep Problems) are summed to provide composite scores for Internalizing, Externalizing, and Total Problem behavior scales. Higher scores are indicative of increased difficulties. The CBCL has strong construct validity, high internal consistency (Internalizing $\alpha = .89$, Externalizing $\alpha = .92$, Total Problems $\alpha = .95$), and high test-retest reliability ($r = .87 - .90$).[40]

Vineland Adaptive Behavior Scale, Third Edition (Vineland-3).[41] The Vineland-3 parent/caregiver rating form is a standardized measure of adaptive behavior. Four domain scores (Communication; Daily Living Skills; Socialization; and Motor Skills) and the global score (Adaptive Behavior Composite) will be measured across time points. Higher scores are indicative of more advanced adaptive behaviors. The Vineland-3 has adequate internal consistency (Communication $\alpha = .95$, Daily Living Skills $\alpha = .94$, Socialization $\alpha = .96$, Motor Skills $\alpha = .90$, Adaptive Behavior Composite $\alpha = .98$) and high test-retest reliability ($r = .73 - .92$)[41].

Systematic Analysis of Language Transcripts, New Zealand/Australia (SALT-NZAU).[42] The 10-minute video observations used for the child engagement measure will be transcribed and analyzed using the SALT- NZAU 20 software to detect change in speech and language from baseline. Analyses will include total number of utterances, total number of words, total number of different words, mean lengths of utterances in words and morphemes, percentage of grammatically accurate utterances, percentage of maze words, and percentage of intelligible utterances. Video coders will receive training in the SALT- NZAU 20 software and 20% of the videos will be coded separately by two coders to assess inter-rater reliability.

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Secondary Outcome Measures - Caregiver

Depression, Anxiety, and Stress Scale-21 (DASS-21).[43] The DASS-21 will be used to evaluate change in caregiver psychological distress from baseline. The DASS-21 yields subscale scores on three dimensions (Depression, Anxiety, and Stress) as well as a Total Scale score, with higher scores indicating higher distress. The DASS-21 has been demonstrated to have high internal consistency (Depression scale $\alpha = .88$, Anxiety scale $\alpha = .82$, Stress scale $\alpha = .90$, Total scale $\alpha = .93$) and convergent and discriminant validity.[43]

Parental Acceptance and Action Questionnaire (PAAQ).[44] The PAAQ is a 15-item self-report measure of caregiver experiential avoidance and will be used to measure change from baseline. The PAAQ consists of two subscales, Unwillingness and Inaction, as well as a Total scale score. The Unwillingness subscale measures caregiver's ability to tolerate their child's experience of an unpleasant emotion and the latter evaluates the caregiver's ability to effectively manage their reactions to their child's affect. Higher scores indicate higher experiential avoidance. Items from the original version of the PAAQ that refer to child anxiety will be adapted to include a broader range of unpleasant child emotional states (e.g., anger, sadness).[45] The PAAQ shows satisfactory internal consistency ($\alpha = .67-.82$).[45]

Parent Sense of Competence Scale (PSOC).[46] The PSOC is a 16-item caregiver-report questionnaire which will be used to assess change in caregiver efficacy and satisfaction in their caregiving role from baseline. The PSOC yields a Total score as well as Efficacy and Satisfaction scores, designed to capture caregivers' perceived competence in child rearing and enjoyment derived from caregiving, respectively. Higher scores are indicative of higher caregiver efficacy and satisfaction. The PSOC has adequate internal consistency (Total score $\alpha = .79$, Efficacy score $\alpha = .76$, Satisfaction score $\alpha = .75$).[46]

Process Measures

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Social Validity. The Treatment Acceptability Rating Form-Revised (TARF-R)[47] is a 20-item self-report measure that will be completed post-participation to assess program acceptability. Ratings on six subscales (Effectiveness; Reasonableness; Willingness; Cost; Negative side-effects; Disruption/time) are summed to provide a total acceptability score, with higher scores indicating higher acceptability. The TARF-R has adequate internal consistency (Effectiveness $\alpha = .95$; Reasonableness $\alpha = .90$; Willingness $\alpha = .83$; Cost $\alpha = .71$; Negative side-effects $\alpha = .77$; Disruption/time $\alpha = .69$, Total $\alpha = .92$).[47, 48] In addition to the TARF-R, caregivers will be interviewed using a semi-structured interview schedule to further assess the social validity and cultural acceptability of the program.

Program Adherence and Implementation. While receiving support, caregivers in each support arm will complete weekly logs of their engagement in ACT and/or NDBI practices at home, time spent engaging in these practices (mins), and amount of additional professional support received (i.e., type and duration). The 10-minute video observations used for the child engagement measure and language analyses will also be analyzed to evaluate caregiver use of NDBI strategies. The same analysis will not be conducted for ACT strategies as they are not always observable; ACT implementation will be measured by weekly logs. Website analytics (e.g., frequency and duration of engagement with website modules) and group session attendance will provide a measure of support dosage. Finally, therapist procedural integrity in delivery of ACTion in Caregiving and Play to Learn group sessions will be assessed by an independent observer for at least 20% of sessions using a checklist.

Interobserver Agreement. To assess interobserver agreement (IOA), 15-20% of all 10-minute caregiver-child video observations will be randomly selected and recoded by a second observer for child engagement, child language, and caregiver use of NDBI strategies. An autistic research assistant blinded to participant allocation will code 15-20% of original

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IOA coded videos. This is to obtain an autistic perspective on the data collected and strengthen interpretation. IOA will be calculated using ICC.

Patient and Public Involvement

Consultation with the autistic community (including autistic adults and caregivers of autistic children) has informed the development of the research questions, design, and measures. We also received input from the autistic community, and Māori and Pacific people regarding support implementation, website layout, functions, usability, content, and cultural appropriateness. We will provide participants with a summary of trial results and will seek patient and public involvement in the development of dissemination methods, such as how to communicate findings to the community.

Sample Size

Sample size estimates were calculated a priori (power = 0.80; alpha = 0.05) and indicated that a minimum of 78 participants (caregiver/child dyads; $N = 26/\text{group}$) is sufficient to detect a large effect ($d = 0.80$) for the primary analysis. Effect size estimates were based on Kasari[9] which demonstrated a strong effect size (Cohen's $d = 0.87$) following caregiver implementation of the JASPER program with autistic toddlers. This sample size allows for 15% attrition between pre- and post-participation.

Data Analysis Methods

Firstly, an exploratory analysis of the data will be conducted. Then the three support groups will be compared for equivalency across variables at baseline, starting with descriptive examination. Where descriptive examination suggests that one or more groups may differ substantively from the others, the statistical significance of such differences will be tested by independent sample t -tests and chi-square with alpha set at $p < .05$. If substantive differences are detected, these variables may be used as covariates in subsequent analyses.

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A repeated measures 3 (Groups; NDBI vs ACT vs NDBI + ACT) by 3 (Time; baseline vs post-support vs follow-up) multivariate analysis of variance (MANOVA) design will compare baseline scores for primary and secondary outcomes with scores post-support, and at follow-up. Caregiver and child outcomes will be analyzed separately. Depending on the statistical significance of the MANOVA findings, post hoc procedures such as discriminant descriptive analysis (DDA) and discriminant ratio coefficients (DRC), will be used to describe differences among groups and identify which variables contribute to these differences.[49] Point-biserial correlation will evaluate whether categorical variables (e.g., self-identified ethnicity) moderate any significant outcomes. Descriptive statistics (e.g., linear regression) will be used to examine data gathered from process variables, including the relationship between process and outcome variables and differences in process variables across groups and time.

Within and between group differences may also be analyzed by Modified Brinley Plots, Cohen's *d* (standardized mean difference) effect size with 95% Confidence Intervals, and the Percent Superiority effect size.[50, 51] The degree of clinically significant therapeutic change will be assessed by the Reliable Change Index.[52] A one-way ANOVA will be performed to compare caregivers' overall mean satisfaction with support received across groups. Point-biserial correlation will evaluate whether self-identified ethnicity classification and caregiver autistic/non-autistic identification, moderate effects. Post-participation interviews will be analyzed using inductive thematic analysis.

We will conduct an intention to treat analysis, whereby multiple imputation is used to handle missing data. We will also conduct a per protocol analysis whereby participants who withdraw will not be included in the final comparisons. Depending on the sample size and number of partial completers we may conduct a separate MANOVA to determine the effect of supports for this group specifically. We plan to describe the reasons for missing data,

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clarify whether there are meaningful differences between individuals with complete and incomplete data, and any baseline characteristics which may predict non-completion.

Data Collection, Storage, and Protection

The research team will make every reasonable effort to collect data from enrolled caregivers across time points, including sending email reminders and phone calls. Access to the full participant dataset will be restricted to the research team. Each caregiver-child dyad will be allocated a unique ID code following study enrolment and information will be recorded under this code. Research data will be stored on secure password-protected servers at the University of Canterbury which are only accessible by approved members of the research team. Identifiable data and source documents will be retained for at least 10 years after the youngest child has turned 16 years old, then destroyed by secure deletion.

Data Monitoring and Harms

There are no anticipated serious adverse events for this trial, therefore a formal data monitoring committee is not required and no interim analyses or a priori stopping rules will be implemented. If any adverse events arise (e.g., worsening of outcomes for caregivers/children), these will be recorded by the research team and reported to the relevant ethics committees as well as being reported in relevant publications as it pertains to feasibility outcomes. Participants will be in regular contact with members of the research team. If there are any perceived risks (e.g., caregiver response to questionnaire indicates severe distress) we will advise participants to seek care from their healthcare professional and/or contact relevant statutory authorities, and pause involvement in the study if necessary. The study may end early for participants if the level of problem behaviors (e.g., aggression or self-harm) reported by the caregiver is considered to be unsafe towards them or other family members. Involvement will also end immediately if the caregiver requests withdrawal. Caregiver

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reasoning for discontinuation will be recorded if they are contactable and provide an explanation.

Ethics and Dissemination

This study has been approved by the NZ Health and Disability Ethics Committee (2022 FULL 12058) and this trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12622001134718). Any substantive protocol modifications and amendments will be submitted to the NZ Health and Disability Ethics Committee for approval prior to implementation.

Potential caregiver participant will be given detailed information sheets describing the study and are requested to contact the research team to arrange further discussion and initial screening. If they agree to participate in the study, they will be provided with a consent form, but informed that their participation is voluntary and they can withdraw at any time without consequences. It will not be possible to obtain informed consent from child participants, given their age, therefore their assent to participate and be videoed will be obtained.

Trial findings will be disseminated through peer-reviewed journals and national and international conference proceedings regardless of the magnitude/direction of effect. Data will be shared with stakeholder groups and service providers. If the supports are shown to be effective and socially valid the web-based modules have the potential to be disseminated widely.

Word count: 4,569

Author contributions

LM, LME, HW, and MR designed the study. JvD, JH, LME, HW, LM, and LvN worked together to create the ACT and NDBI modules. NMB, NM, and JvD drafted the statistical analysis plan. SM and AH provided cultural guidance and support. JvD drafted the initial protocol and manuscript and all authors contributed to refinement of the study protocol and

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approved the final manuscript. The sponsor and funders had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

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Competing interests

None to declare.

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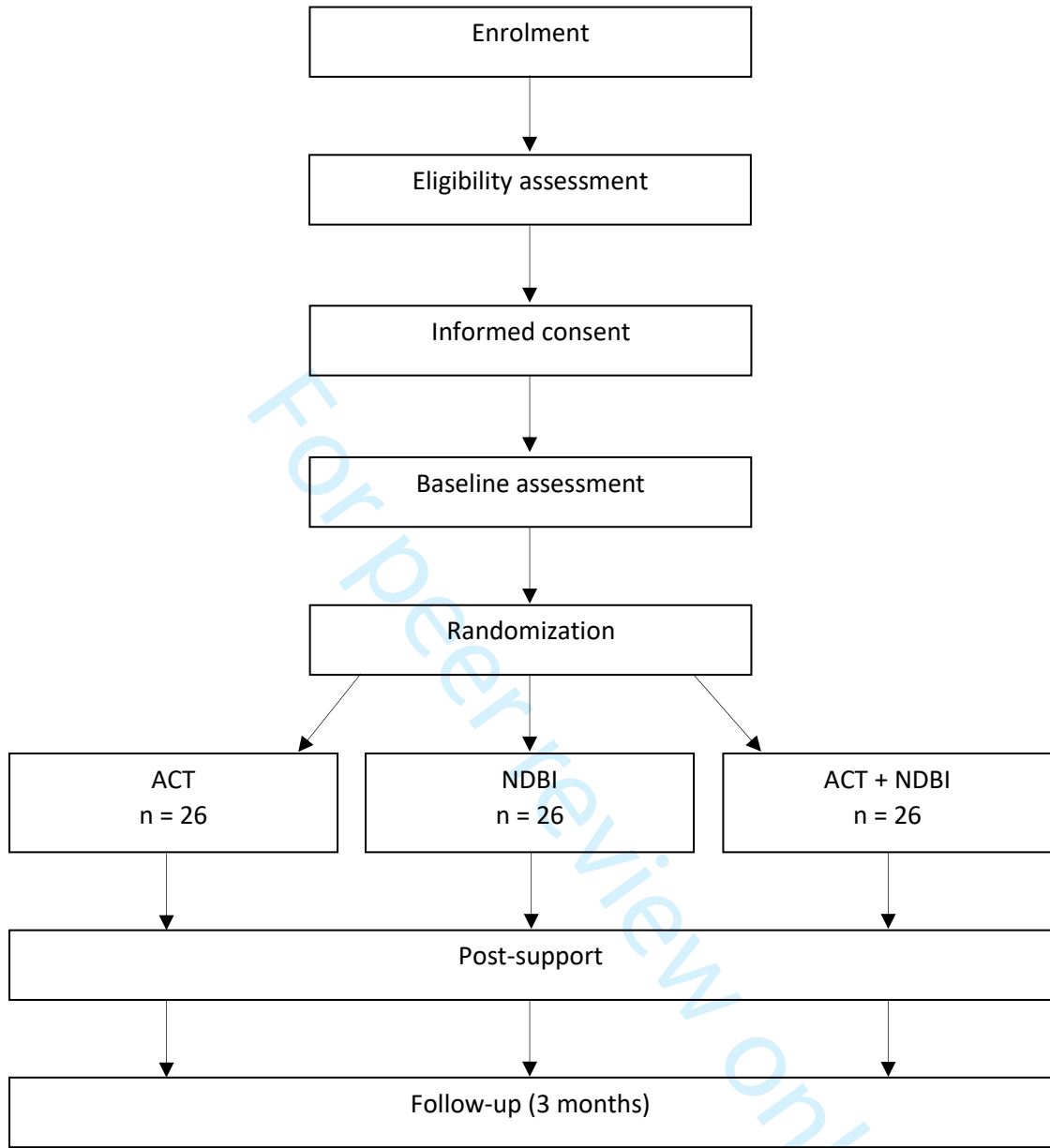
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1 STUDY PROTOCOL

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3 **Figure Legends/Captions**4
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6 Figure 1. Consort participant flow chart
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For peer review only

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Supplementary Table

Timeline of the study and data collection

| | Study Period | | | | | | | | | | | | | | | | | |
|--|--------------|---------------|--------------------|----|----|----|----|----|----|----|----|-----|-----|-----|-----|--|-----------------------------------|---|
| | Enrolment | Randomization | Support (13 weeks) | | | | | | | | | | | | | Post-support (immediately after program participation) | Follow-up (3 months post-support) | |
| Timepoints | – | 0 | W1 | W2 | W3 | W4 | W5 | W6 | W7 | W8 | W9 | W10 | W11 | W12 | W13 | W14 | W38 | |
| Study procedures | | | | | | | | | | | | | | | | | | |
| Eligibility screening (30 min) | X | | | | | | | | | | | | | | | | | |
| SACS-R/SACS-PR (<30 min) | X | | | | | | | | | | | | | | | | | |
| Informed consent (30 min) | X | | | | | | | | | | | | | | | | | |
| Randomization | | | | | | | | | | | | | | | | | | |
| | | X | | | | | | | | | | | | | | | | |
| Supports | | | | | | | | | | | | | | | | | | |
| ACT | | X | G | O | G | O | G | O | G | O | G | O | G | O | G | | | |
| NDBI | | X | G | O | G | O | G | O | G | O | G | O | G | O | G | | | |
| ACT + NDBI | | X | GO | GO | GO | GO | GO | GO | GO | GO | GO | GO | GO | GO | | | | |
| Outcome data collection | | | | | | | | | | | | | | | | | | |
| Child-caregiver interaction video (10 min) | X | | | | | | | | | | | | | | | | X | X |

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| Child engagement | X | | | | | | | | | | | | | | | | | X | X |
| Child language | X | | | | | | | | | | | | | | | | | X | X |
| Caregiver application of NDBI | X | | | | | | | | | | | | | | | | | X | X |
| IOA | | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Vineland-3 (45 min) | X | | | | | | | | | | | | | | | | | X | X |
| CBCL/1.5-5 (20 min) | X | | | | | | | | | | | | | | | | | X | X |
| PSI-4-SF (5 min) | X | | | | | | | | | | | | | | | | | X | X |
| DASS- 21 (10 min) | X | | | | | | | | | | | | | | | | | X | X |
| PAAQ (10 min) | X | | | | | | | | | | | | | | | | | X | X |
| PSOC (10 min) | X | | | | | | | | | | | | | | | | | X | X |
| Caregiver log of NDBI and/or ACT practices (5 min weekly) | | | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Log of caregiver & child professional support received (5 min weekly) | | | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Website analytics | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Therapist support fidelity rating scale | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| TARF-R (10 min) | | | | | | | | | | | | | | X |
| Post-support interview (30 min) | | | | | | | | | | | | | | X |

Note. SACS-R = Social Attention and Communication Surveillance–Revised; SACS-PR = SACS-Preschool; W = week; G = 1 hour group session (video); O = 1 hour online module; IOA = Interobserver Agreement; Vineland-3 = Vineland Adaptive Behavior Scales, Third Edition; CBCL/1.5-5 = Child Behavior Checklist for Ages 1.5-5; PSI-4-SF = Parenting Stress Index – Fourth Edition, Short Form; DASS-21 = Depression, Anxiety, and Stress Scale – 21; PAAQ = Parental Acceptance and Action Questionnaire; PSOC = Parent Sense of Competence Scale; TARF-R = Treatment Acceptability Rating Form-Revised; Approximate time for participants to complete assessments is noted in parentheses. Adapted from the SPIRIT (2013) template.

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Participant Information Sheet – Parent/Caregiver/Guardian

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Telehealth-delivered supports for enhancing the social communication of autistic children and caregiver wellbeing

Lead Researcher: A/Prof. Laurie McLay
Study Site: University of Canterbury
Contact phone number: (03) 369-3522
Ethics committee ref: 2022 FULL 12058

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We are inviting you and your child to take part in a study that focuses on the social communication of autistic children and caregiver wellbeing. Whether or not you and your child take part is your choice. If you or your child don't want to take part, then you don't have to. Your decision to take part or not will not affect the services or supports that you or your child receive. The Participant Information Sheet will help you decide if you would like to take part in this study. It sets out:

- Why we are doing the study
- What your participation would involve
- What the benefits and risks to you and your child might be, and
- What would happen after the study ends

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We have gone through some of this information with you over the phone and are happy to discuss it further and answer any questions you may have. You don't have to decide today whether you will take part in this study. Before you decide, you may want to talk about the study with other people, like your family, whānau, friends or healthcare providers. Please feel free to do this.

If you and your child agree to take part in this study, we will ask you to sign the Consent Form on the last page of this document. We will give you a copy of both the Participant Information Sheet and the Consent Form to keep. These materials are available in English only.

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3 This document is 15 pages long, including the consent form. Please make sure you have
4 read and understood all of the pages.
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8 VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY 9

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11 Being part of this study is your choice. It's also your child's choice. You and your child don't
12 have to take part in this study if you don't want to. If you and your child decide to take part,
13 and later change your mind, you can do that. If you and your child decide not to take part in
14 the study, or you decide to leave the study, you don't have to tell us why.
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20 WHAT IS THE PURPOSE OF THIS STUDY? 21

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23 Autistic children have a number of strengths, but can also experience difficulties related to
24 social communication. Social communication is a term used to describe a range of skills
25 including spoken and non-spoken (e.g., facial expressions, gestures) language which help
26 people to effectively interact and communicate with others. The development of these skills
27 can help build social relationships. Caregivers of autistic children can experience challenges
28 that negatively impact their wellbeing (e.g., contributing to increased stress). The wellbeing
29 of caregivers is essential to the wellness of children and whānau. Research shows that early
30 supports can optimise child development and caregiver wellbeing. The Play to Learn
31 programme has been developed for this research and is based on the principles of
32 naturalistic developmental behaviour interventions (NDBI). NDBI are evidence-informed
33 supports that are designed to facilitate children's social communication and behaviour. The
34 ACTION in Caregiving programme has also been developed for this research and is based on
35 the principles of Acceptance and Commitment Therapy (ACT). ACT is an evidence-informed
36 support shown to enhance adult wellbeing. In this study we hope to:
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- 50 1. Find out if the telehealth-delivered Play to Learn (for children) and ACTION in
51 Caregiving (for caregivers) programmes are effective in enhancing children's social
52 communication and caregiver wellbeing and self-confidence. Examples of telehealth-
53 delivered supports include web-based content and online coaching and support.
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- 55 2. Find out whether the Play to Learn and ACTION in Caregiving programmes are more
56 beneficial when delivered in combination than when they are delivered separately
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3. Understand whether these programmes and use of telehealth to deliver these programmes are acceptable to all caregivers, particularly Māori, Pacific, and autistic caregivers
 4. Find out whether any benefits from the Play to Learn and ACTION in Caregiving programmes are maintained over time

HOW IS THIS STUDY DESIGNED?

For this study, we will recruit approximately 78 autistic children and their caregivers. This study will start with an *assessment*. In addition to the screening interview you have done, we will ask you to complete some questionnaires. These questionnaires ask about your child's social development, emotions, and behaviour. They will also ask you about your own wellbeing and experiences related to parenting. We can give you a list of these questionnaires, if you would like to learn more about them before you sign the consent form.

Once you complete the assessment, your family will be randomly assigned to one of three groups that you will then participate in, either the: (1) Play to Learn programme; (2) ACTION in Caregiving programme; or (3) Play to Learn + ACTION in Caregiving programmes. A random assignment means we do not know ahead of time which group you will be assigned to; we let the computer decide where to put you. We have three different groups so that we can compare how helpful each support option is. It will not be possible to offer you support from a different group other than the one you have been randomly assigned to. This means you may receive one type of support and not another (e.g., ACTION in Caregiving and not Play to Learn).

Each programme will run for 13 weeks. During this time, you will be provided with a web-based toolkit which you can continue to access after completing the study. This web-based toolkit is available through the Waiora Tamariki website and includes multi-media content, activities, and resources. It is divided into six modules that focus on different programme topics. In addition to being available on your computer, the website will be mobile-optimised so you can access content using your phone. If you do not have internet access, and have concerns about the cost of internet data, we can provide you with mobile data packages to complete the study.

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3 As well as accessing the website, you will take part in small group coaching sessions
4 over Zoom. Each group will have up to eight caregivers. The sessions will align with the web-
5 based modules, and will include discussion about module content and activities, as well as
6 provide an opportunity for facilitators to help you tailor strategies to the needs of your child
7 and whānau. The identities of the people in these group meetings, and everything that is
8 said at the meetings, will be confidential. You should not discuss these meetings with
9 anyone who is not there.
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16 *Play to Learn*

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19 Play to Learn consists of a range of support strategies that are based on the
20 principles of NDBI. Play to Learn uses play- and routine-based learning strategies, which
21 means that opportunities for your child to learn new skills and behaviours are incorporated
22 into everyday activities and parent-child interactions, such as one-on-one play and care
23 routines (e.g., dressing, bathing, eating). It also includes behavioural strategies such as
24 modelling (i.e., demonstrating to your child how to perform a new skill/behaviour) and
25 rewards (e.g., praise, preferred items) to enhance children's social communication and
26 behaviour. A lot of research shows these strategies are effective in enhancing social
27 communication, language, learning, play and behaviour in young autistic children. In this
28 programme, you will be taught strategies to use with your child in your own home.
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37 *ACTion in Caregiving*

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40 ACTion in Caregiving is based on ACT and is designed to support adults to find ways
41 of effectively responding to challenging thoughts and feelings so they can break unhelpful
42 habits and create a meaningful life. ACTion in Caregiving teaches people a number of
43 strategies they can use to respond to unpleasant thoughts and feelings, allowing them to
44 take helpful action without being controlled by their emotional experiences. This can help
45 caregivers remain true to the caregiver/person they want to be in the face of parenting
46 stress. Research shows ACT can help to reduce stress and anxiety, and improve overall
47 mood, parenting self-confidence, and wellbeing in caregivers of autistic children. This has
48 also been shown to benefit children's wellbeing.
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57 Once you finish the programme, we will ask you to complete the same
58 questionnaires you completed during the assessment. This allows us to tell whether there
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3 have been any changes to your child's social communication, emotions, and behaviour,
4 and/or your own wellbeing and parenting experiences since receiving support through the
5 programme. We will also ask you to do a post-support interview after you finish the
6 programme. We will do this interview to see how families felt about the online programme,
7 what was helpful, and what could be improved.
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13 We will follow up to check how you and your child are doing and if the strategies are
14 still working 3 months after you finish the programme and will ask you to complete the
15 assessment questionnaires again.
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20 WHO CAN TAKE PART IN THIS STUDY? 21

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23 We are inviting you and your child to take part in this study because you have a child aged 2-
24 5 years who is autistic and is not yet attending primary school. Your child may have received
25 a diagnosis of autism, or may have been identified by a professional (e.g., paediatrician,
26 psychologist, psychiatrist) as highly likely to be autistic (e.g., awaiting diagnosis). If your child
27 does not have a diagnosis of autism, we will confirm there is a high likelihood with a
28 measure that checks for features of autism. We will discuss this with you by phone. You
29 cannot take part in this study if your child already receives more than 15 hours of support
30 per week through another early support intervention, or if you are currently completing
31 another parenting programme (e.g., Triple P). Only one child per family will be able to
32 participate in this study.
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44 WHAT WILL MY PARTICIPATION IN THIS STUDY INVOLVE? 45

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47 You will have already completed a screening interview to determine that this study is a good
48 fit for you and your whānau. For caregivers of children who are identified as likely to be
49 autistic (but not diagnosed), an assessment measure will be completed with you to confirm
50 this likelihood. This measure will take up to 30 minutes to complete. Please note that this
51 measure will not be used to make a diagnosis of autism, it will simply confirm there is a
52 possibility that your child is autistic. If your child does not meet our criteria for having a
53 likelihood of autism this does not mean that your child is not autistic. It only means that
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3 they may not meet our criteria for inclusion in this study. It will also have no effect on the
4 services that you receive.
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8 During the study we will ask you to complete a range of questionnaires relating to
9 your child's social development, emotions and behaviour, your own wellbeing and
10 experiences related to parenting. The time it takes to complete each questionnaire will
11 differ ranging from approximately 5 to 45 minutes. We expect it to take you up to 1.5 hours
12 maximum to complete all of the questionnaires. We will ask you to complete these
13 questionnaires again immediately after you finish the programme and then again 3 months
14 after the programme has finished.
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21 During the screening call we asked you to provide demographic information, such as
22 how you identify your child's ethnicity and whether or not you identify as autistic. This is so
23 we can evaluate whether the support programmes are acceptable and effective for people
24 from a range of ethnicities and both autistic and non-autistic caregivers. If you prefer,
25 information about whether you identify as autistic or not can be excluded from data
26 analyses (i.e., evaluation of programme effectiveness for autistic caregivers compared with
27 non-autistic caregivers). You can indicate this in the Consent Form at the end of this
28 document.
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36 The programme you participate in (i.e., to receive either Play to Learn, ACTion in
37 Caregiving, or Play to Learn + ACTion in Caregiving supports) will last for 13 weeks. During
38 this time, we will expect you to engage with the web-based module content. You will mostly
39 do this by yourself, though you will be able to contact a member of the research team at
40 any stage, and you can post questions in an online forum on the website. Each of the six
41 modules for the Play to Learn and ACTion in Caregiving programmes takes 1-2 hours to
42 complete and will include tasks to practise at home. The seven small group coaching
43 sessions for each of the Play to Learn and ACTion in Caregiving programmes will be up to 2
44 hours and will be delivered fortnightly via Zoom. For caregivers in the Play to Learn + ACTion
45 in Caregiving group, you will have access to both Play to Learn and ACTion in Caregiving
46 content, and the group coaching sessions will run on alternate weeks (i.e., Play to Learn one
47 week and ACTion in Caregiving the next). We will ask your permission to collect audio-visual
48 recordings of the small group coaching sessions. This is so we can evaluate the performance
49 of the facilitators (i.e., how well they followed the intended plan). These recordings will only
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3 be viewed by members of the research team for the sole purpose of observing facilitators
4 (i.e., participant information shared in the sessions won't be analysed). These recordings will
5 be deleted after they have been viewed.
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9 While you are completing the support programme, we will ask you to keep a weekly
10 log of the strategies you are using. We will also ask your permission to collect 10-minute
11 video samples of you and your child engaging in one-on-one play at home three times in
12 total (once during the assessment phase, once immediately after you finish the programme,
13 and once 3 months after the programme has finished). This is so we can observe the
14 outcomes of the programme on your child's social communication and behaviour. It will not
15 be possible to take part in this study if you do not agree to you and your child being
16 videoed.
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24 Your participation will last at least four months. This includes the assessment phase
25 and the programme itself.
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WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

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33 There is a small risk that the programme will cause you or your child distress. The new
34 strategies and expectations might upset your child or cause you emotional discomfort. If
35 you or your child experience distress while participating in this research, you can contact a
36 member of the research team for guidance. If we feel that you or your child are in danger,
37 then we may take steps that involve us contacting another agency and we will do our best
38 to discuss this with you at the time. We have a detailed safety plan for this study. The safety
39 plan also includes details on when we have to contact another agency. We can provide you
40 with a copy of the plan if you would like to see it.
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WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

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53 Your involvement in this study is likely to enhance your child's social development and/or
54 your wellbeing. If it does, you might notice other benefits such as to the overall wellness of
55 your whānau. If your child is communicating more and using adaptive behaviour, it is
56 possible that this will reduce your own stress. If your own wellbeing improves, it is possible
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3 that this might improve your child's interactions and behaviour. However, it is also possible
4 that the study will not help you or your child, and that you will get no benefits from it.
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6

7 If the programmes are effective, the website we have developed for this study will
8 be rolled out to families across Aotearoa/New Zealand who experience similar support
9 needs. So, this study might help other families of children who are autistic in the future,
10 including families who live in areas that are far away from clinics and specialist care.
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16 WHAT ARE THE ALTERNATIVES TO TAKING PART?

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18 You can choose not to take part in this study. In this case, you may seek out services from
19 another provider with expertise in autism or adult mental health and wellbeing.
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25 WILL ANY COSTS BE REIMBURSED?

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27 You will not have any expenses connected with this study.
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29
30
31

32 WHAT IF SOMETHING GOES WRONG?

33
34 If you or your child were hurt in this study you would be eligible **to apply** for compensation
35 from ACC, just as you would be if you were hurt in an accident at work or at home. This does
36 not mean that your claim will automatically be accepted. You will have to lodge a claim with
37 ACC, which may take some time to assess. If your claim is accepted, you will receive funding
38 to assist your recovery, or your child's recovery.
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45 If you have private health or life insurance, you may wish to check with your insurer
46 that taking part in this study won't affect your cover.
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51 WHAT WILL HAPPEN TO MY INFORMATION?

52
53 During this study, the researchers and other staff will keep records of information about you
54 and your child. This includes information gathered during interviews, weekly logs, analysis of
55 video recordings and questionnaires. We will also collect information on how often and for
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3 how long you used the website. You cannot take part in this study if you do not consent to
4 the collection of this information.
5

6
7 Identifiable Information:
8

9
10 Identifiable information is any data that could identify you or your child (e.g., name, date of
11 birth, address). The following groups may have access to your identifiable information, or
12 your child's identifiable information:
13
14

15 Associate Professor (A/Prof.) Laurie McLay (Principal Investigator, University of Canterbury)

16
17 Dr Lisa Emerson (Associate Investigator, University of Canterbury)

18
19 Dr Hannah Waddington (Associate Investigator, Victoria University of Wellington)

20
21 Dr Jenna van Deurs (Child and Family Psychologist, University of Canterbury)

22
23 Dr Jolene Hunter (Child and Family Psychologist, University of Canterbury)

24
25 Emeritus Prof Neville Blampied (Project Advisor, University of Canterbury)

26
27 Aaron Hāpuku (Associate Investigator, University of Canterbury)

28
29 Post-graduate research students identified for this project

30
31 Research assistants identified for this project

32
33 Child and family psychology interns or registered psychologists

34
35 Ethics committees or government agencies from New Zealand, if the study or site is audited.
36 Audits are done to make sure that participants are protected, that the study is run properly,
37 and the data collected is correct.
38

39
40 Rarely, it may be necessary for A/Prof. McLay to share your information, or your child's
41 information, with other people – for example, if there is a serious threat to safety, or to the
42 life or health of you, your child, or another person, or if the information is required in
43 certain legal situations.
44

45
46 De-identified (Coded) Information
47

48
49 To make sure your personal information is kept confidential, information that identifies you
50 or your child will not be included in any report generated by the researchers. Instead, you
51 and your child will be identified by a code. A/Prof. McLay will keep a list linking your code
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3 with your name, so that you can be identified by your coded data if needed. The list will be
4 stored in a password protected computer. Only the people named above (under
5 'Identifiable Information') will have access to this list.
6
7

8
9 The results of the study may be published or presented, but not in a form that would
10 reasonably be expected to identify you or your child.
11

12 Future Research Using Your Information

13
14 If you agree, your coded information may be used for future research related to autism
15 and/or the wellbeing of caregivers of autistic children.
16

17
18 You will not get reports or other information about any future research that is done using
19 your information.
20

21
22 Your de-identified information (and your child's) may be used for future research unless you
23 withdraw your consent. However, it may be extremely difficult or impossible to access your
24 information or withdraw consent for its use once your information has been shared for
25 future research.
26
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31 Security and Storage of Your Information

32
33 Your identifiable information will be stored for 10 years after the youngest participant in the
34 study has turned 16 years old. It will be stored on a secure, personal device. This storage is
35 password protected. Your coded information will be in a secure electronic online database.
36 This database is also password protected. Information collected on paper (e.g.,
37 questionnaires) will be stored in a locked filing cabinet in a secure office at the University of
38 Canterbury and will be destroyed after being coded and saved in the secure password-
39 protected online database. Only the people named above (under 'Identifiable Information')
40 will have access to the storage and database passwords. A/Prof. McLay will keep all your
41 password protected coded information for 10 years after the youngest participant has
42 turned 16 years old. All storage will comply with local and international data security
43 guidelines.
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54 Risks

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3 We will make every effort to protect your privacy and that of your child. However, we
4 cannot guarantee absolute confidentiality of your information. Even with coded and
5 anonymised information there is no guarantee that you or your child cannot be identified.
6
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9 Please note that other caregivers in the small group coaching sessions will have access to
10 any identifying information that is provided by you during the sessions or in the online
11 discussion forum. However, we ask that anything which is said at the meetings or online is
12 kept confidential. There will be up to eight caregivers in total in your group.
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14
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16 Rights to Access Your Information

17
18 You have the right to request access to information held by the research team about you
19 and your child. You also have the right to request that any information you disagree with be
20 corrected.
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23

24
25 If you have any questions about the collection and use of information about you or your
26 child, you should ask A/Prof. McLay.
27
28

29 Rights to Withdraw Your Information

30
31 You may withdraw your consent for the collection and use of your information at any time,
32 by informing A/Prof. McLay.
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35
36 If you withdraw your consent, your study participation will end, and the study team will stop
37 collecting information from you.
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40
41 If you agree, information collected up until you withdraw from the study will continue to be
42 used and included in the study. You may ask for it to be deleted when you withdraw unless
43 you withdraw after the study analyses have been undertaken. Once we start analysing data,
44 it may not be possible to delete your information.
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48 Ownership Rights

49
50 Information from this study may lead to discoveries and inventions or the development of a
51 commercial product. The rights to these will belong to the lead research investigators. You
52 and your family will not receive any financial benefits or compensation, nor have any rights
53 in any developments, inventions, or other discoveries that might come from this
54 information.
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WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

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6 If you change your mind about being in the study, you will need to talk to A/Prof. McLay.
7 You do not have to give a reason for not wanting to stay in the study. You can simply tell her
8 that you would like to withdraw. A/Prof. McLay may be able to give you information about
9 alternative services that could help you or your child. You can also contact the research
10 team again in the future if you wish though there is no guarantee that you will be able to be
11 included in the study at this point.
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18 CAN I FIND OUT THE RESULTS OF THE STUDY? 19

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21 You can ask to get results of the study. When we publish the results, we will send you a
22 summary in plain English. You can choose to get the results even if you leave the study
23 without finishing it.
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29 WHO HAS APPROVED THE STUDY? 30

31
32 An independent group of people called a Health and Disability Ethics Committee (HDEC)
33 approved this study. HDEC check that studies meet current ethical standards.
34
35
36

37 WHO IS FUNDING THE STUDY? 38

39 The study is being co-funded by *Cure Kids* and *A Better Start E Tipu e Rea: National Science*
40 *Challenge* (<https://curekids.org.nz/latest-grants/a-better-start-2021-successful-projects/>).
41
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45 WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS? 46

47 If you have any questions, concerns or complaints about the study at any stage, you can
48 contact:
49
50

51 A/Prof. Laurie McLay (Principal Investigator)

52 (03) 369 3522

53 laurie.mclay@canterbury.ac.nz
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55
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1
2
3 If you want to talk to someone who isn't involved with the study, you can contact an
4 independent health and disability advocate on:
5

6
7 Phone: 0800 555 050

8
9 Email: advocacy@advocacy.org.nz

10
11 Fax: 0800 2 SUPPORT (0800 2787 7678)

12
13 Website: <https://www.advocacy.org.nz/>
14
15

16 For Māori health support please contact:

17
18 Te Puawaitanga Ki Ōtautahi Trust

19
20 (03) 344 5062 or 0800 66 99 57

21
22 Email: reception@omwwl.maori.nz
23
24

25 You can also contact the Health and Disability Ethics Committee (HDEC) that approved this
26 study:
27

28
29 Phone: 0800 4 ETHIC

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31 Email: hdecs@health.govt.nz
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Consent Form: Parent/Caregivers/Guardians

Telehealth-delivered supports for enhancing the social communication of autistic children and caregiver wellbeing

Lead Researcher: A/Prof. Laurie McLay

Study Site: University of Canterbury

Contact phone number: (03) 369-3522

Ethics committee ref: 2022 FULL 12058

Please tick to indicate that you consent to the following

- I have read or have had read to me the Participant Information Sheet. I understand it.
- I had enough time to decide whether to take part in this study.
- I had the opportunity to use resources to help me ask questions and understand the study (these resources may have been a lawyer, whānau/family support, or friend).
- I am satisfied with the answers I received regarding the study. I have a copy of this consent form and information sheet.
- I understand that taking part in this study is my choice. I may withdraw from the study at any time, and it will not affect my child's medical care.
- I understand that I will be randomly assigned to receive support from one of three groups, either the: (1) Play to Learn programme; (2) ACTION in Caregiving programme; or the (3) Play to Learn + ACTION in Caregiving programme. I understand that it is not possible to choose my group or to receive support from a different group other than the one I have been randomly assigned to.
- I give permission to the research staff to collect and process the information I give them. This includes information I give them about my child's health.
- I give permission to the research staff to collect and analyse data according to whether I identify as autistic or not
- I give permission for audio-visual recordings of my child and I (e.g., during play interactions) to be collected and processed by research staff.

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- I give permission for audio-visual recordings of the group coaching sessions to be collected and processed by research staff.
 - I understand that my part in this study is private. No material that can identify my child or I will be used in any reports on this study.
 - I know whom to contact if I have any questions about the study in general.
 - I understand my responsibilities as a study participant.
 - The research team may contact me after I complete the study to gather additional information. Yes No
 - If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. Yes No
 - I agree to have my coded information, or that related to my child, used in future related research (e.g., research about children's social communication or caregiver wellbeing). Yes No
 - I agree to have my coded information, or that of my child, used in future research not connected to this study. Yes No
 - I would like to receive a summary of the study results. Yes No

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35

Declaration by participant:

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I hereby consent to take part in this study.

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Participant's name.....

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Signature..... Date.....

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Declaration by member of the research team:

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51

I have given verbal explanation of the research project to the participant and have answered the participant's questions about it.

52
53
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55

I believe that the participant understands the study and has given informed consent to participate.

56
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58

Researcher's name.....

59
60

Signature..... Date.....



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|-----------------------------------|---------|--|---|
| Administrative information | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | _1_____ |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | _2_____ |
| | 2b | All items from the World Health Organization Trial Registration Data Set | _Trial registration data is available through ANZCTR (ACTRN12622001134718)_____ |
| Protocol version | 3 | Date and version identifier | _ANZCTR can be referred to for any new versions_____ |
| Funding | 4 | Sources and types of financial, material, and other support | _22_____ |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | _22-22_____ |
| | 5b | Name and contact information for the trial sponsor | _22_____ |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | _22_____ |

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For peer review only

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|----|---|-----|--|-------------|
| 1 | | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | _NA_____ |
| 2 | | | | |
| 3 | | | | |
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| 5 | | | | |
| 6 | Introduction | | | |
| 7 | | | | |
| 8 | Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | _5-7_____ |
| 9 | | | | |
| 10 | | | | |
| 11 | | 6b | Explanation for choice of comparators | _5-7_____ |
| 12 | | | | |
| 13 | Objectives | 7 | Specific objectives or hypotheses | _7_____ |
| 14 | | | | |
| 15 | Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | _8_____ |
| 16 | | | | |
| 17 | | | | |
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| 19 | Methods: Participants, interventions, and outcomes | | | |
| 20 | | | | |
| 21 | Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | _9_____ |
| 22 | | | | |
| 23 | | | | |
| 24 | Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | _8_____ |
| 25 | | | | |
| 26 | | | | |
| 27 | Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | _10-13_____ |
| 28 | | | | |
| 29 | | | | |
| 30 | | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | _20-21_____ |
| 31 | | | | |
| 32 | | | | |
| 33 | | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | _13_____ |
| 34 | | | | |
| 35 | | | | |
| 36 | | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | _8_____ |
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| 1 | Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | _14-18_____ |
| 6 | Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | _Supplementary Table |
| 9 | Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | _18_____ |
| 13 | Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | _9_____ |

Methods: Assignment of interventions (for controlled trials)

Allocation:

| | | | | |
|----|----------------------------------|-----|--|---------------------------------|
| 19 | Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | _9_____ |
| 25 | Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | _9-10_____ |
| 30 | Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | _9-10_____ |
| 33 | Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | _9-10_____ |
| 36 | | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | _NA (single-blinding only)_____ |

Methods: Data collection, management, and analysis

| | | | | |
|----|---------------------------------|-----|---|-------------|
| 1 | Data collection | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related | _14-18_____ |
| 2 | methods | | processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of | |
| 3 | | | study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. | |
| 4 | | | Reference to where data collection forms can be found, if not in the protocol | |
| 5 | | | | |
| 6 | | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be | _20_____ |
| 7 | | | collected for participants who discontinue or deviate from intervention protocols | |
| 8 | | | | |
| 9 | Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality | _20_____ |
| 10 | | | (eg, double data entry; range checks for data values). Reference to where details of data management | |
| 11 | | | procedures can be found, if not in the protocol | |
| 12 | | | | |
| 13 | | | | |
| 14 | Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the | _18-20_____ |
| 15 | | | statistical analysis plan can be found, if not in the protocol | |
| 16 | | | | |
| 17 | | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | _19-20_____ |
| 18 | | | | |
| 19 | | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any | |
| 20 | | | statistical methods to handle missing data (eg, multiple imputation) | _19-20_____ |
| 21 | | | | |
| 22 | | | | |
| 23 | Methods: Monitoring | | | |
| 24 | | | | |
| 25 | Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of | _20_____ |
| 26 | | | whether it is independent from the sponsor and competing interests; and reference to where further details | |
| 27 | | | about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not | |
| 28 | | | needed | |
| 29 | | | | |
| 30 | | | | |
| 31 | | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim | _20_____ |
| 32 | | | results and make the final decision to terminate the trial | |
| 33 | | | | |
| 34 | Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse | _20_____ |
| 35 | | | events and other unintended effects of trial interventions or trial conduct | |
| 36 | | | | |
| 37 | Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent | _NA_____ |
| 38 | | | from investigators and the sponsor | |
| 39 | | | | |
| 40 | | | | |
| 41 | Ethics and dissemination | | | |
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|----|-------------------------------|-----|---|----------------------------------|
| 1 | Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | _21_____ |
| 2 | | | | |
| 3 | | | | |
| 4 | Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | _21_____ |
| 5 | | | | |
| 6 | | | | |
| 7 | | | | |
| 8 | Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | _21_____ |
| 9 | | | | |
| 10 | | | | |
| 11 | | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | _NA_____ |
| 12 | | | | |
| 13 | | | | |
| 14 | Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | _20_____ |
| 15 | | | | |
| 16 | | | | |
| 17 | | | | |
| 18 | Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | _22_____ |
| 19 | | | | |
| 20 | | | | |
| 21 | Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | _20_____ |
| 22 | | | | |
| 23 | | | | |
| 24 | Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | _13_____ |
| 25 | | | | |
| 26 | | | | |
| 27 | Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | _21_____ |
| 28 | | | | |
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| 31 | | | | |
| 32 | | 31b | Authorship eligibility guidelines and any intended use of professional writers | _Not included_____ |
| 33 | | | | |
| 34 | | | | |
| 35 | | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | _NA_____ |
| 36 | | | | |
| 37 | | | | |
| 38 | Appendices | | | |
| 39 | | | | |
| 40 | Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | _In supplementary materials_____ |
| 41 | | | | |
| 42 | | | | |

1 Biological 33 Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular NA
2 specimens analysis in the current trial and for future use in ancillary studies, if applicable
3

4 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.
5 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons
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