PROTOCOL

Effectiveness of JettProof Sensory Singlets for Autistic Children: A Single Case Series

Protocol Number (if applicable): N/A
Protocol Version: 2
Date: 18th July 2022

Document history:

Date of change	Summary of changes
1st April 2022	Pre-registration draft
25th May 2022	Revised draft for submission to HREC
1st June 2022	Modification (to HREC approved draft) to administer PSI-4-SF via hardcopy and Vineland-3 via Pearson's Q-global platform. Allocation of version number (1).
18th July 2022	Modification (to HREC approved draft) to remove University of Newcastle as a study site and University of Newcastle co-investigators.

Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

1. Table of Contents

PROTOCOL SYNOPSIS

Title	Effectiveness of JettProof Sensory Singlets for Autistic Children: A Single Case Series
Trial description	This study will utilize a single-subject ABA design with pre-intervention/baseline (one-week; standard care), intervention (three-weeks; includes acclimatization), and post-intervention/return-to-baseline (one-week; standard care) phases. The participants will comprise 10 children aged 2-to-11 years with a diagnosis of Autism Spectrum Disorder and sensory processing difficulties. The research methods include direct behavioural assessment, semi-structured interview, physiological recording, questionnaire, and experience sampling.
Objectives	• To determine whether JettProof sensory singlets reduce: 1) self-regulation and motor coordination difficulties in autistic children, and 2) caregiver effort and stress • To assess the feasibility of the study methods in preparation for a larger trial.

Outcomes and outcome measures	• Child self-regulation pre-to-post intervention as assessed by:
	  ○ Attainment of personalised self-regulation goals pre-to-post intervention as assessed by GAS
	  ○ Behavioural coding of self-regulation challenge tasks using the Lab-TAB
	• Child physiological stress arousal as measured by the Empatica E4, capturing heart rate variability, electrodermal responsivity and accelerometry data
	• Child motor coordination as assessed by the COMPS-2 and M-ABC-2
	• Child anxiety pre-to-post intervention as assessed by SCAS-P
	• Child daily affect pre-to-post intervention as assessed by caregiver experience sampling
	• Caregiver effort pre-to-post intervention as assessed by PES
	• Caregiver stress pre-to-post intervention as assessed by PSI-4-SF

	• Acceptability/feasibility of study methods as assessed by semi-structured interviews and caregiver experience sampling
Trial Population	10 children aged between 4 years 0 months and 11 years 11 months 30 days with a diagnosis of Autism Spectrum Disorder with heterogeneous profiles of sensory processing difficulties.
Description of sites enrolling participants	La Trobe University (Victoria, Australia).
Description of intervention	JettProof sensory singlets composed of CalmTex® fabric with a 360 degree stretch, fitted closely to the body and worn as a base garment or under other clothing for a minimum of 6 hours/day.
Trial duration	May 2022 – December 2022 (9 months).
Participant duration	Participants will be enrolled in the trial for 5 weeks and required to wear the JettProof sensory singlet for 3 weeks at a minimum of 6 hours per day. Caregivers will complete an eligibility screen over the phone (1 hour), attend six face-to-face assessment visits with their child (9 hours total), and complete daily experience sampling (2 minutes per input, 3.5 hours total).

GLOSSARY OF ABBREVIATIONS

ABBREVIATION	***TERM***
LTU	La Trobe University
OTARC	Olga Tennison Autism Research Centre
ANZCTR	Australian and New Zealand Clinical Trials Registry
HREC	Human Research Ethics Committee
REDCap	Research Electronic Data Capture
SRS-2	Social Responsiveness Scale-2nd Edition
SSP	Short Sensory Profile
PPECS	Pragmatics Profile of Everyday Communication Skills
Vineland-3	Vineland Adaptive Behaviour Scales-3rd Edition
M-ABC-2	Movement Assessment Battery for Children-2nd Edition
COMPS-2	Clinical Observations of Motor and Postural Skills
GAS	Goal Attainment Scaling
SCAS-P	Spence Children's Anxiety Scale-Parent Version
Lab-TAB	Laboratory Temperament Assessment Battery
PES	Parent Effort Scale
PSI-4-SF	Parent Stress Index-4th Edition Short Form

2. Administrative Information

2.1. Title

Effectiveness of JettProof Sensory Singlets for Autistic Children: A Single Case Series.

2.2. Trial Registration

2.2.A. Registry

This trial will be registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR) following approval from the La Trobe University (LTU) Human Research Ethics Committee (HREC).

Trial Identifier: To be confirmed

2.2.B. Data set

Data Category	Information
Primary registry and study identifying number	To be confirmed
Date of registration in primary registry	Following ethics approval
Secondary identifying numbers	N/A
Source(s) of monetary/material support	AusIndustry, Commonwealth Government of Australia Indasun Pty Ltd
Primary sponsor	La Trobe University
Secondary sponsor(s)	N/A
Contact for public queries	Prof Alison Lane
Contact for scientific queries	Prof Alison Lane
Public title	Effectiveness of JettProof Sensory Singlets for Autistic Children: A Single Case Series
Scientific title	Effectiveness of JettProof Sensory Singlets for Autistic Children: A Single Case Series
Countries of recruitment	Australia
Health condition(s) or problem(s) studied	Sensory processing and associated self-regulation and/or motor coordination difficulties among autistic children.
Intervention(s)	JettProof Sensory Singlet.

Data Category	Information
Key inclusion and exclusion criteria	Inclusion: age between 4 years 0 months and 11 years 11 months at trial entry; a caregiver-confirmed and corroborated diagnosis of Autism Spectrum Disorder made by a registered health professional and exceeding the cutoff for autism on the Social Responsiveness Scale-2nd Edition; current sensory processing difficulties as indicated by the Short Sensory Profile; caregiver has a compatible smartphone. Exclusion: current/previous use of JettProof and/or other garments for sensory processing needs; does not have sufficient functional language and/or communication to understand and assent to study procedures as indicated by the Pragmatics Profile of Everyday Communication.
Study type	Intervention, non-randomized, single-case series
Date of first enrolment	May 2022
Sample size	10
Recruitment status	Pending: participants are not yet being recruited or enrolled.
Primary outcome(s)	Outcome name: Child sympathetic nervous system activity (heart rate, heart rate variability, electrodermal activity, and motion-based activity) Metric/method of measurement: Empatica E4 Wristband Timepoint: pre-during-post intervention Outcome name: Child motor coordination Metric/method of measurement: Clinical Observation of Motor and Postural Skills-2nd Edition, Movement Assessment Battery for Children-2nd Edition Timepoint: pre-post intervention Outcome name: Child attainment of individualized self-regulation goals Metric/method of measurement: Goal Attainment Scaling Timepoint: pre-intervention goal formulation, ratings pre-during-post intervention

Data Category	Information
Key secondary outcomes	Outcome name: Child anxiety Metric/method of measurement: Spence Children's Anxiety Scale Timepoint: pre-post intervention Outcome name: Child daily affect Metric/method of measurement: smartphone-based experience sampling Timepoint: daily for duration of the trial Outcome name: Child self-regulation Metric/method of measurement: Laboratory Temperament Assessment Battery Timepoint: pre-during-post intervention Outcome name: Intervention acceptability Metric/method of measurement: smartphone-based experience sampling, semi-structured interview Timepoint: pre-post intervention Outcome name: Caregiver effort Metric/method of measurement: Parent Effort Scale Home Version, Parent Effort Scale Community Version Timepoint: pre-post intervention Outcome name: Caregiver stress Metric/method of measurement: Parent Stress Index Timepoint: pre-post intervention
Ethics review	Not approved.
Completion date	December 2022
Summary results	Not applicable.
Individual-participant level (IPD) sharing statement	There is no plan to share IPD.

3. Protocol Version

Issue Date:	16th March 2022

Protocol amendment number:	Pre-Registration DRAFT
Author(s):	Lane, A., Chetcuti, L.

4. FUNDING

AusIndustry	The trial is funded by an AusIndustry Innovation Connections grant in partnership with Indasun Pty Ltd. The design, conduct, management, analysis, and reporting of the study will be entirely independent of AusIndustry. Representatives from Indasun Pty Ltd will consult on study design and supply garments for the trial. The conduct, analysis, and reporting of the study will be independent of Indasun Pty Ltd.

5. ROLES AND RESPONSIBILITIES

5.1. CONTRIBUTORSHIP

Author Name	**Summary of contribution**
Prof Alison Lane La Trobe University	AL is the Principal Investigator and will provide all governance to the conduct of the study
Dr Lacey Chetcuti La Trobe University	LC is a Lead Co-Investigator and will contribute to study design, coordination, data collection and analysis
Caitlin Argent-Schutz Occupational Therapist	CAS is a Co-Investigator and will support Melbourne-based families with singlet use, and conduct research assessments at LTU
Claudia Madafferi La Trobe University	CM is a Research Assistant and will provide support to the research team
Perrin Date La Trobe University	PD is the OTARC Research Operations Coordinator with administrative control over the personal information contained in the OTARC participant registry
Michelle Ebbin JettProof (Director)	ME will manufacture and supply the singlets, train research staff to fit the singlet, and provide consultation and advice to research staff regarding singlet use
Dr Peter Scaife JettProof	PS will provide consultation to the research team regarding study design.

Author Name	Summary of contribution
Dr Heather Nuske University of Pennsylvania	HN will provide consultation to the research team on Lab-TAB implementation and data interpretation.
Assoc. Prof. Matthew Goodwin Northeastern University	MG will provide consultation to the research team on Empatica E4 implementation and data interpretation.

5.1.A. SPONSOR CONTACT INFORMATION

Study Sponsor	Olga Tennison Autism Research Centre (OTARC), La Trobe University (LTU)
Sponsor's Reference number (if applicable)	N/A
Contact name	Alison Lane
Address	C/O Olga Tennison Autism Research Centre (OTARC), La Trobe University, School of Psychology and Public Health, Bundoora, VIC 3083
Telephone	03 9479 2463
Email	a.lane@latrobe.edu.au

5.1.B. SPONSOR AND FUNDER

LTU is the trial sponsor will provide trial oversight and the medico-legal responsibility associated with the conduct of the trial. This study is funded by an AusIndustry Innovation Connections grant awarded to Indasun Pty Ltd known otherwise as JettProof. Representatives from Indasun Pty Ltd will consult on study design and supply garments for the trial. Indasun Pty Ltd will not have a role in the collection, analysis, and interpretation of data. Ausindustry will not have a role in the design of the study, collection, analysis, and interpretation of data or in the decision to submit the report for publication.

5.1.C. COORDINATING CENTRE

The Principal Investigator (see Section 5.1) is the Deputy Director of the Olga Tennison Autism Research Centre (OTARC) at LTU (Melbourne, Australia), which will provide its relevant facilities, assets, and infrastructure in service of this research project including its participant registry, for which the Research Operations Coordinator has administrative control.

5.1.D. RESEARCH TEAM

See section 5.1 for members. The Principal Investigator is responsible for the design, conduct, and completion of this research project, for preparation of the project protocol and revisions, for corresponding with the HREC and ensuring appropriate approvals have been obtained, for ensuring compliance with the project protocol and applicable laws and regulations and institutional policy governing the research, for preparation of progress, safety, compliance, financial, and a final reports to the HREC and study funder, for preparation of research publications and for managing the conduct of the Lead Co-Investigators and Co-Investigators.

The Lead Co-Investigator will contribute to preparation of the project protocol (and revisions), documentation, reports and publications and be responsible for recruiting participants, liaising with the Principal Investigator and other individuals consulting on the trial, for executing the project in accordance with the protocol and applicable laws and regulations and institutional policy, for maintenance of data systems and data verification, and for coordination with Co-Investigators to conduct research assessments, and will provide agreement on the final protocol.

The Co-Investigators will be responsible for implementing appropriate safety procedure and practices for the research project, liaising with caregivers of child participants including to monitor for adverse events, for implementing the study protocol of procedures and assessments, and will provide agreement on the final protocol.

The Research Assistants will support the Lead Co-Investigator and Co-Investigators to implement study procedures, including the completion of research assessments and associated data preparation and management.

5.1.E. Intervention Manufacturer

See section 5.1 for members. JettProof (see Section 5.1) will manufacture and supply sensory singlets for 10 child participants, train research personnel to (i) take body measurements for singlet sizing, (ii) put on the singlet, and (iii) strategies to improve child compliance in wearing the singlet (including provision of written materials as necessary, and consult on trial design and protocol development. Indasun Pty Ltd will not have a role in the decision to submit the research for publication.

5.1.F. Research Consultants

See section 5.1 for members. Research Consultants will provide technical advising and mentoring to the research team within their area(s) of expertise to ensure that the research project is able to deliver its objectives.

6. Introduction

6.1. Background and Rationale

Sensory processing difficulties are common among children on the autism spectrum and may be expressed as hyper- or hypo-reactivity to sensory input, and sensory seeking (American Psychiatric Association & Association, 2013). Such difficulties can limit engagement in daily activities and learning (Dunn, Little, Dean, Robertson, & Evans, 2016) and are associated with emotion dysregulation and anxiety (Lidstone et al., 2014), ultimately conferring risk towards mental health difficulties in autistic children. Sensory-based therapies are designed to address sensory processing difficulties by helping to organize and regulate reactions to sensory input (Lane, 2020). Sensory-based therapies include techniques such as: Ayres' Sensory Integration® therapy, unimodal sensory strategies (e.g., brushing, massage, swinging), sensory environment modifications and multi-sensory environments. Whilst sensory therapies are used frequently by occupational therapists with autistic children, the evidence for these therapies is mixed (Lane, 2020). Currently, best evidence is available for Ayres' Sensory

Integration® and Qigong massage with effects on self-regulation, parental stress and task engagement noted (Bodison & Parham, 2018).

Recently, there has been increased used of sensory garments to support regulatory function in autistic children and adults. Sensory garments made from stretch fabrics such as Lycra are worn close to the body and provide the individual with dynamic postural support and tactile input during daily routines including sleep. Testimonial data retrieved from one sensory garment manufacturer, JettProof, indicates that many customers report almost immediate benefits for the child when wearing the garments.

A total of 802 testimonials – posted by customers to the JettProof website between June 2015-October 2021 – were analyzed for prominent themes using NVivo software (Chetcuti & Lane, unpublished data). The results of our analysis revealed three key themes. The first theme, *acceptability,* revealed that most users found the garments comfortable and enjoyed wearing them alone or under other clothing; however, some testimonials mentioned needing an 'adjustment period' to acclimate to the garments. The second theme, *effects*, demonstrated multifaceted effects of JettProof sensory garments on: arousal, sensory processing, sleep, engagement/attention, and participation. Effects of JettProof garments were reported across settings (i.e., school, home, community, and clinical) and also for the broader family unit. Further, testimonials suggested a short duration of effect (i.e., only while wearing) and both immediate and delayed latencies. The third theme, *usage*, revealed that most users of JettProof garments were diagnosed with Autism Spectrum Disorder (ASD), or had other developmental or clinical presentations including: anxiety, Attention-Deficit Hyperactivity Disorder (ADHD), sensory sensitivities, and motor conditions (e.g., Dyspraxia). Further, testimonials indicated that most users wore JettProof sensory garments throughout the entire day and overnight, with others wearing the garments in challenging contexts (e.g., while at school).

Conclusions from our testimonial analyses were further endorsed in focus groups we conducted in December 2021 and January 2022 with three occupational therapists and a developmental psychologist who prescribe JettProof sensory garments for their autistic clients. These focus groups further enabled us to explore additional considerations clinicians take into account when prescribing these garments for autistic children. One view expressed among participants in the focus group was that the choice and regimen of JettProof sensory garments should be individualized and informed by the child. Another view was that garments should be used adjunctive to other therapies rather than as standalone support. Lastly, of the range of garments manufactured by JettProof, the singlet was the most strongly endorsed and prescribed by clinicians for autistic children.

Overall, the qualitative testimonial and focus group data suggest that JettProof garments may support the regulatory functioning of children on the autism spectrum. While there is currently no empirical evidence to support the efficacy of JettProof garments in particular, several studies published over the last decade have yielded promising results of a sensory t-shirt on the sleep of autistic children (Mische Lawson et al., 2022), and of a sensory vest on the gross motor control, posture, and behavioural challenges of autistic children and adolescents (Guinchat et al., 2020).

However, one study, focused solely on the outcome of stereotypic behaviour, did not find any significant changes related to the use of a full-body sensory suit (Watkins & Sparling, 2014).

The overall objective of our study, therefore, is to provide an empirical evaluation of the effectiveness of JettProof sensory singlets on the regulatory functioning of children on the autism spectrum, including in primary and secondary areas of interest: behavioural self-regulation, motor coordination, anxiety, daily affect, and sleep quality. Other objectives of our study are to explore effects on caregiver effort and stress, predictors of differential responsiveness, and the feasibility and acceptability of implementation and study methods prior to embarking on a larger scale trial.

6.2. Choice of Comparators

This single-subject case series will compare each participant's response to the intervention against their own baseline. No concomitant care or intervention is prohibited during the trial; rather, participants will continue their standard care with the addition of the intervention during the second, third and fourth trial weeks. The single-subject design is advantageous for intervention research with the autistic population in accounting for heterogeneity of clinical/phenotypic presentation and responsiveness to intervention –which otherwise impede firm conclusions in large-scale controlled trials that appraise intervention effectiveness at the group level. Moreover, by utilizing a single-subject design and the comparator of standard care, this research project will have ecological validity – i.e., mirroring 'real world' implementation by clinicians alongside other eclectic interventions – and generate findings that are relevant to clinical practice and policy. Other branded sensory garments or alternative sensory-based therapies were not included as comparators at this preliminary stage of evaluation and hypothesis generation.

6.3. Objectives

This study will test the use of JettProof sensory singlets among children with a diagnosis of Autism Spectrum Disorder. The primary objective of this trial is to evaluate the effects of JettProof sensory singlets – applied for at least 6 hours/day for a three-week period – on the self-regulatory and motor functioning of autistic children. We hypothesise that application of the JettProof sensory singlet will lead to a reduction in autonomic and behavioural markers of affective and motor dysregulation and the subsequent attainment of individualized goals, relative to standard care.

A second objective is to evaluate the effects of JettProof sensory singlets on additional outcomes related to sensory and motor functioning difficulties for autistic children and their caregivers. We hypothesize that, for children, the application of the JettProof sensory singlet will lead to a reduction in anxiety, less negative and more positive daily affect, and improvements in sleep quality for children and, for caregivers, a reduction in the levels of stress and perceived effort required to assist their children.

A third objective is to assess the feasibility and acceptability of implementing JettProof sensory singlets with autistic children. We anticipate that most children will wear the singlet for 6 hours/day or more during the full-scale intervention phase, and report that it is at least tolerable.

A fourth, exploratory objective is to determine whether there may be sensory characteristics of autistic children that predict differential response to JettProof sensory garments. We hypothesize that JettProof sensory singlets will evidence greater efficacy among children with a dysfunction in proprioceptive and/or vestibular sensory systems.

6.4. Study Design

This single-subject case series will utilize an ABA design, where the intervention phase (b) is sandwiched between an initial baseline period (a) and post-intervention/return-to-baseline period (a). Each baseline period will last for one-week and involve unrestricted standard care. The intervention period will last for three-weeks, allowing a one-week acclimatization period before a two-week full-scale wearing protocol (if tolerable to the child). The full-scale wearing protocol was defined – through analysis of existing testimonial data, and consultation with JettProof and prescribing clinicians – as a minimum 6 hours/day of continuous wear. The participants will comprise children aged 4 years 0 months to 11 years 11 months with an existing community diagnosis of autism spectrum disorder (see Section 6.8. for a full description of trial inclusion/exclusion criteria). Child participants will attend six face-to-face assessment sessions with their caregiver(s): upon study entry (week 0), during pre-intervention/baseline phase A (week 1), pre-intervention/acclimatization phase B (week 2), intervention phase A (weeks 3 and 4), and post-intervention/return to baseline phase A (week 5).

Methods: Participants, Interventions, Outcomes

6.5. Study Settings

The trial will be conducted at La Trobe University (Melbourne, Victoria, Australia).

6.6. Eligibility Criteria

6.6.A. Inclusion Criteria

Children will be eligible to participate in the trial if:

1. They are aged between 4 years 0 months and 11 years 11 months 30/31 days at trial entry, and
2. They have a DSM-5 clinical diagnosis of Autism Spectrum Disorder or equivalent DSM-IV diagnosis of Asperger's Disorder or Autism, and
3. They have a Social Responsiveness Scale-2nd Edition (SRS-2; Constantino & Gruber, 2012) total *t* score exceeding the cutpoint value of 60 associated with Autism Spectrum Disorder, and
4. They have current sensory processing difficulties as indicated by a total score that is more than two standard deviations below the normative mean on the Short Sensory Profile (SSP; McIntosh, Miller, Shyu, & Dunn, 1999), and
5. Their caregiver has a smartphone (iPhone or Android).

6.6.B. Exclusion Criteria

Children will be excluded from participation in the trial if:

1. They are using, or have previously used, JettProof sensory singlets and/or other garments designed for sensory-based needs, and/or
2. They did not have the language and/or communication skills to understand and assent to study procedures and indicate their discomfort reliably as indicated by the caregiver report Pragmatics Profile of Everyday Communication Skills (PPECS; Dewart & Summers, 1995) denoting children's every day and flexible use of language for a range of relevant functions: making requests for assistance, expressing upset, giving information, and asserting independence.

6.6.C. *Description*

CalmTex® is an innovative polyester and elastane sensory fabric used in the production of JettProof sensory singlets. This unique construction is breathable and moisture wicking, with a 360-degree knitted stretch that moves with the body. Fitted according to chest measurement, JettProof sensory singlets are non-restrictive, and are intended to be fitted closely to the body and worn as a base garment or under other clothing. A full dosage wearing regimen was defined for this trial, through consultation with the manufacturer and stakeholders, as a minimum of 6 hours/day of continuous wear but can be extended up to 24 hours/day.

6.6.D. *Criteria for Discontinuation/Modification*

Withdrawal of informed consent is possible at any time, without any obligation for the child or caregiver to give reasons for the decision. Tolerance, compliance, and adverse events will be monitored during each weekly assessment visit or by telephone call from a member of the research team. Should any serious adverse events or other concerns about wellbeing occur, the child will discontinue the intervention and return to standard care. In these such cases, the child will be invited to remain in the study and attend the remaining assessment visits.

6.6.E. *Strategies to Improve/Monitor Adherence*

After the researcher has supplied child participants their singlet and supported their first wear, they will provide the caregiver with strategies to support and encourage their child's singlet wearing and manage challenging behaviour should it arise. A researcher will telephone the caregiver at least three times during the intervention phase – once each during each of the acclimatization and full-scale wearing weeks – to check how the child is doing and troubleshoot any issues arising. During the intervention phase, the length of time the child spends wearing the singlet will be reported each day by the caregiver via a smartphone-based experience sampling app.

6.6.F. *Concomitant Care and Interventions*

No concomitant care or intervention is prohibited during the trial. Caregivers will be asked to disclose any medications their child is taking (including type and dosage) and any outside care accessed during the trial period (including type and duration). Caregivers will be provided a one-page document summary of the study and nature of the child's involvement to share this with any clinicians involved in their child's care, if they wish to do so.

6.7. OUTCOMES

6.7.A. PRIMARY OUTCOMES

The primary outcomes for this trial are:

- Child sympathetic nervous system activity (i.e., heart rate, heart rate variability, electrodermal activity, and motion-based activity) acquired from an Empatica E4 wristband, worn in the context of Laboratory Temperament Assessment Battery (Lab-TAB; H. Goldsmith et al., 2010) episodes conducted in weeks 1 through 5. Empatica E4 recordings have been shown to accurately predict affective behaviour in autistic children (Goodwin, Mazefsky, Ioannidis, Erdogmus, & Siegel, 2019) and has been validated against other stationary and wearable biosensors (Schuurmans et al., 2020; van Lier et al., 2020).
- Child motor coordination as measured by the standardized Movement Assessment Battery for Children-2nd Edition (M-ABC-2; Henderson, Sugden, & Barnett, 2007) and Clinical Observations of Motor and Postural Skills (COMPS-2; B Wilson, Kaplan, Pollock, & Law, 2000) in weeks 1 and 5. The M-ABC-2 is one of the most widely used motor assessments in research and clinical practice (Barnett, 2008) with evidence of inter-rater reliability, test-retest reliability, content- and concurrent validity (Henderson et al., 2007). The COMPS-2 was designed to supplement standardized measures of motor performance and has demonstrated good inter-rater reliability, test-retest reliability, and construct validity (Brenda Wilson, Pollock, Kaplan, Law, & Faris, 1992).
- Child attainment of individualized and meaningful intervention goals as measured by Goal Attainment Scaling (GAS; Kiresuk & Lund, 1994). Upon study entry, the caregiver of each child will be supported by investigators to formulate two GAS goals centred around self-regulation difficulties for their child and develop a five-point descriptive rating scale for completion in weeks 1 and 5. Use of GAS is common in research and clinical practice and is especially sensitive to capturing change in intervention studies (McLaren & Rodger, 2003).

6.7.B. SECONDARY OUTCOMES

The secondary outcomes for this trial are:

- Child anxiety as measured by the caregiver-reported Spence Children's Anxiety Scale-Parent Version (SCAS-P; Nauta et al., 2004) in weeks 1 and 5. The SCAS-P has strong properties (Nauta et al., 2004; Orgiles, Fernandez-Martinez, Guillen-Riquelme, Espada, & Essau, 2016) including good internal consistency and convergent, divergent and discriminant validity among autistic children (Magiati et al., 2017).
- Child affect and sleep reported daily by caregivers via smartphone-based experience sampling. The experience sampling method demonstrates high ecological validity, in that it captures real-life experiences and behaviours across a full range of momentary contexts while 'in-the-moment', thus circumventing potential biases from retrospective recall.
- Child reactivity and self-regulation as coded from behaviour during semi-structured Lab-TAB (H. Goldsmith et al., 2010) episodes in weeks 1 through 5. Being a direct observational method, the Lab-Tab will provide a method by which to build upon and complement caregiver

ratings of child affect. Lab-TAB episodes have been validated as effective for inducing emotional reactivity in autistic children (Macari, Vernetti, & Chawarska, 2021; Northrup et al., 2020) and used previously as a context for physiological recording (Nuske et al., 2022).

6.7.C. Other Outcomes

Other outcomes of this trial include:

- Intervention feasibility and acceptability indicated through duration of daily singlet wear – as captured through experience sampling – and semi-structured interviews conducted with children and their caregiver(s) in weeks 0 and 5. This will provide valuable first-hand insights into the feasibility and acceptability of JettProof sensory singlets.
- Caregiver effort expended to support their child as measured by the Parent Effort Scale (PES; Pfeiffer et al., 2017) in weeks 1 and 5. The PES has shown adequate internal consistency and test-retest reliability in an autistic sample (Bevans, Hallock, Piller, & Pfeiffer, 2022).
- Caregiver stress as measured by the Parent Stress Index-4th Edition Short Form (PSI-4-SF; Abiden, 2012) in weeks 1 and 5. The PSI-4-SF has shown good internal consistency and test-retest reliability in a variety of samples (Abiden, 2012).

6.8. Participant Timeline

Figure 1 shows the schedule of participation in the study.

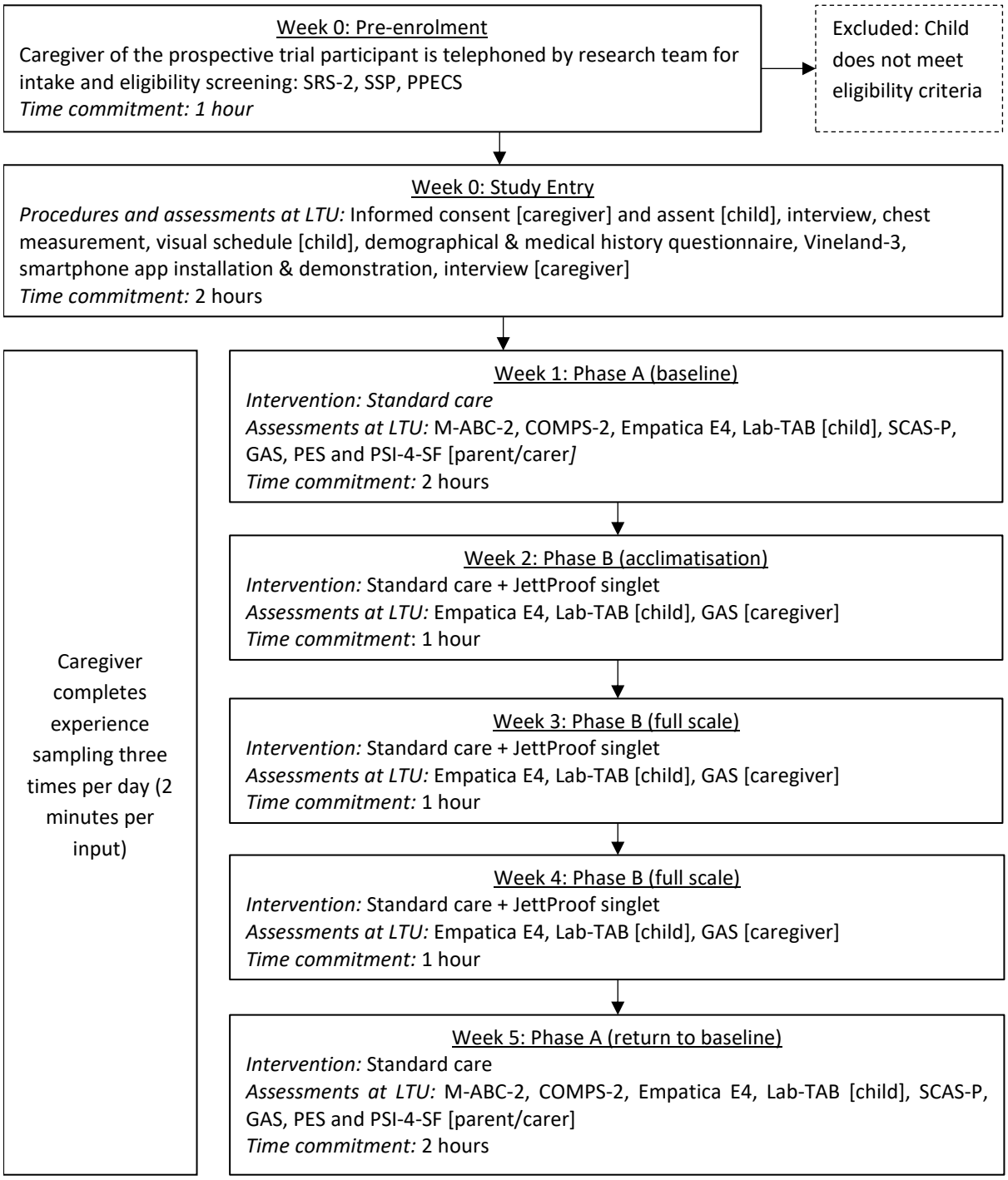

Figure 1. Schedule of Participation.

6.8.A. Intake and Characterization

Caregivers who express interest in having their child participate in the study will be telephoned by a member of the research team to conduct eligibility screening including verbal administration of the

SRS-2 (Constantino & Gruber, 2012), SSP (McIntosh et al., 1999) and PPECS (Dewart & Summers, 1995). This phone call will require a time commitment of approximately one hour for caregivers.

For those who meet trial eligibility criteria, an appointment will be made to attend LTU for a face-to-face assessment. Once an appointment has been made, caregivers will be emailed an appointment confirmation letter along with a Participant Information and Consent Form (PICF) that contains: a description of the purpose of the study, the study procedures and timeframe, the possible risks and potential benefits to participation, compensation for being involved, procedures to protect confidentiality and privacy, and the contact details of the research team and HREC.

On entry to the study (week 0), child participants will attend a face-to-face entry visit with their caregiver(s) which will involve a researcher taking caregiver consent and additional child verbal assent, taking the child's chest measurement (for supply of appropriate singlet size), conducting a brief interview with the child and caregiver to determine their motivations for participating. At this visit, children will be given a printed visual schedule of the study procedures and timeline in the form of a booklet to take home with them. Further, the researcher will work with the caregiver to identify one or two goals for their child during the intervention, support them to install a smartphone application (MyCap) for experience sampling and demonstrate its use, provide them with a hardcopy Demographic and Medical History Questionnaire, and navigate them to Pearson's Q-global web-based platform for completion of the Vineland Adaptive Behaviour Scales-3rd Edition (Vineland-3; Sparrow, Cicchetti, & Saulnier, 2016). Caregivers will complete these questionnaires on-site during their child's assessment visit or finish them at home before their child's next assessment visit. This assessment visit will require a time commitment of approximately two hours for the child and their caregiver(s).

6.8.B. Intervention Schedule

The end of the week 0 visit will mark the beginning of the trial period, and first intervention phase. Children will continue with their standard care for the first trial week (i.e., week 1; pre-intervention/baseline phase A), with no restrictions on concomitant care or intervention (including medications). Week 2 will be a period of acclimatization (pre-intervention/acclimatization phase B), allowing children to practice wearing the singlet and increase the duration of daily use in their own time. The researcher will telephone the caregiver during this week to check how they are doing and to troubleshoot any issues, completing a further follow-up call if needed. Weeks 3 and 4 will be the full intervention phase (intervention phase B), whereby children are encouraged to wear their singlet for as long as they feel comfortable. There will be no restrictions regarding wearing times or contexts, nor regarding access to outside care or interventions, during the intervention phases. Children will cease wearing their singlet and return to their standard care in week 5.

6.8.C. Assessment Schedule

Child participants will attend six face-to-face assessment visits (See Figure 1 & Table 1) with their caregiver(s) during each of the trial weeks. Assessment visits at weeks 1 through 5 will each involve a researcher fitting the child with an Empatica E4 wristband on the wrist or calf. Empatica E4 recordings will be taken while children watch a low-demand movie (Inscapes) to ascertain their physiological baseline, and while completing Lab-TAB (H. Goldsmith et al., 2010) episodes interspersed with a period

of free-play with their caregiver. Additional assessments conducted at weeks 1 and 5 include the M-ABC-2 and COMPS-2, and at week 5 an examiner-led interview to explore child and caregiver perceptions and experiences of the singlet. All assessment sessions will be video-recorded with consent from caregivers for later scoring.

The caregiver will be given a laptop during each of their child's assessment visits and navigated to a REDCap survey to complete: GAS (Kiresuk & Lund, 1994) in weeks 1 through 5, in addition to the SCAS-P (Nauta et al., 2004), PES (Pfeiffer et al., 2017). Additionally, the PSI-4-SF (Abiden, 2012) will be completed via hardcopy in weeks 1 and 5. Caregivers who do not manage to complete all survey measures during their child's assessment visit will be provided a survey return code, enabling them to return to the survey for later completion (within 24 hours). The PSI-4-SF may be taken home for completion and return at the child's next assessment visit. Assessment visits in Weeks 2, 3 and 4 will require a time commitment of around one hour for children and their caregiver(s). A longer time commitment of two hours will be required for visits in Weeks 1 and 5.

During the trial period, the caregiver will receive a push notification on their smartphone from their installed MyCap application three times per day (morning, afternoon, evening) to report their child's previous night's sleep (morning, only), current activity, affect, use of non-routine medications (evening, only), and singlet wearing (intervention phases, only). The resulting daily time commitment for caregivers will be approximately 6 minutes (2 minutes per day).

6.9. Sample Size

In this feasibility study, we will recruit 10 participants in order to provide initial insights into the intervention feasibility and protocol as well as preliminary effect size estimates in the context of pragmatic constraints (i.e., time, budget).

6.10. Recruitment

Recruitment into the study will be through existing participant registries at LTU, and announcements posted on social media, private therapy practices and University noticeboards. The final sample will be purposively selected to include children with a range of sensory processing challenges – as ascertained by the SSP (McIntosh et al., 1999) completed by caregivers at eligibility screening – to allow exploration of differential responsiveness.

7. Methods: Data Collection, Management, Analysis

7.1. Data Collection Methods

7.1.A. Plans for Assessment and Collection of Study Data

Study data will be collected through online survey platforms (REDCap, Pearson's Q-global) in lieu of/in addition to paper forms, smartphone-based experience sampling, and face-to-face assessments. The assessment schedule is outlined in Tables 1 and 2.

Table 1. Schedule of Assessments.

Trial Week	0	1	2	3	4	5
Caregiver-report measures						
Inclusion/ exclusion criteria	X					
SRS-2	X					
SSP	X					
PPECS	X					
Demographic and medical history questionnaire	X					
Interview	X					X
Vineland-3	X					
SCAS-P		X				X
PES		X				X
PSI-4-SF		X				X
GAS		X	X	X	X	X
ESM		X (Daily)	X (Daily)	X (Daily)	X (Daily)	X (Daily)
Child Assessment Measures						
M-ABC-2		X				X
COMPS-2		X				X
Interview	X					X
Physiological recording		X	X	X	X	X
Lab-TAB		X	X	X	X	X

Table 2. Summary of Measures.

Caregiver-Report Measures			
Measure	Description	Variable	Role
Demographic and Medical History Questionnaire	Caregiver-report on child and family background information and child medical history	Various demographic characteristics for child and family	Sample characterisation
Social Responsiveness Scale-2nd Edition (SRS-2; Constantino & Gruber, 2012)	Caregiver-report measure of child autism features	Total raw and *t* score	Eligibility; Sample characterisation
Short Sensory Profile (SSP; McIntosh et al., 1999)	Caregiver-report measure of child sensory processing	Domain raw scores; Domain standard scores; Sensory subtype (Lane et al., 2014);	Eligibility; Sample characterisation

		Overall score	
Pragmatics Profile of Everyday Communication (PPECS; Dewart & Summers, 1995)	Examiner-led interview to gain a qualitative picture of children's typical communicative behaviours.	Qualitative responses to interview questions	Eligibility; Sample characterisation
Vineland Adaptive Behaviour Scales-3rd Edition (Vineland-3; Sparrow et al., 2016)	Caregiver-report measure of child adaptive behaviour	Domain Age-Equivalence and Standard Scores (SS); Total SS	Sample characterisation
Spence Children's Anxiety Scale-Parent Version (SCAS-P; Nauta et al., 2004)	Caregiver-report measure of child anxiety symptoms	Total raw and *t* score; Subscale raw and *t* scores	Outcome
Parent Effort Scale (PES; Pfeiffer et al., 2017)	Caregiver-report measure of effort expended to support child participation in home and community activities	Subscale raw and standard scores; Overall raw and standard score	Outcome
Parent Stress Index-4th Edition Short Form (PSI-4-SF; Abiden, 2012)	Caregiver-report measure of caregiving stress	Domain standard scores; Overall standard score	Outcome
Goal Attainment Scaling (GAS; Kiresuk & Lund, 1994)	Caregiver-report measure of child goal attainment	Change scores	Outcome
Interview	Examiner-led interview to ascertain caregiver's motivations and experiences	Qualitative responses to interview questions	Feasibility/acceptability
Child Assessment Measures			
Assessment Tool	Description		
Movement Assessment Battery for Children-2nd Edition (M-ABC-2; Henderson et al., 2007)	Standardized direct assessment of child motor function	Component standard scores; Total standard score	Outcome
Clinical Observations of Motor and Postural Skills-2nd Edition (COMPS-2; B Wilson et al., 2000)	Observational direct assessment of child motor and postural skills	Domain score; Total score	Outcome

Empatica E4	Wearable biosensor to collect peripheral physiological arousal and motion activity	Heart rate; Heart rate variability; Electrodermal activity; Motion-based activity	Outcome
Laboratory Temperament Assessment Battery (Lab-TAB; H. Goldsmith et al., 2010)	Standardized direct assessment of child self-regulation	Task scores; Composite score	Outcome
Interview	Examiner-led interview to ascertain children's own motivations and experiences	Qualitative responses to interview questions	Feasibility/acceptability

7.1.B. Plans to Promote Participant Retention and Complete Follow-Up

Participants who deviate from the protocol will not be withdrawn from the trial. Upon trial completion, each participant will retain their singlets and be provided a $200 (AUD) gift voucher -- $100 AUD to the child and $100 AUD to the caregiver – to thank them for their time.

7.2. Data Management

All study data will be coded with a participant ID number in a location separate to identifiable personal information (e.g., consent forms, contact details). All participant information and data will be entered directly into REDCap (Research Electronic Data Capture – Vanderbilt University, hosted at LTU) by the investigators or caregivers through self-administered online survey. To ensure data quality, the database will be designed with branching logic, data validation, and range checks for data values, where possible. All hardcopy data will be stored in a locked filing cabinet at LTU. Access to data will be limited to research investigators as approved by the HREC. All data will be re-identifiable.

7.3. Statistical Methods

7.3.A. Outcome Analyses

This single-case feasibility study will combine visual and quantitative analyses of the data. For each participant, scores for each repeated outcome measure (i.e., Empatica E4 recordings, Lab-Tab, GAS, PES-H, PES-C, PSI-4-SF) will be graphically depicted as a time-series with standard deviation bands around each series and the global average for each outcome measure plotted as a reference line. Visual analysis will be employed for an initial examination of within-subject slope and level change across trial phases. Effect sizes will be computed through parametric methods (i.e., standard mean difference [Hedges *g*]) and non-overlap indices (e.g., Tau-U), with a *p*-value of $< .05$ indicative of statistical significance.

7.3.B. *Additional Analyses*

The sample will be characterized using descriptive methods (Demographic and Medical History Questionnaire, PPECS) and standard/raw scores (SSP, Vineland-3, M-ABC-2). Feasibility and acceptability of the intervention will be determined by participants' daily duration of singlet wear and qualitative responses to the semi-structured interview conducted post-intervention.

7.3.C. *Handling of Missing Data*

The last observation carried forward (LOCF) method (i.e., replacing each missing score with the last observed score preceding the missing score) will be used where for experience sampling ratings provided multiple times within a phase, and for measures administered multiple times across subphases within a phase (i.e., from pre-intervention/baseline to post-intervention/return to baseline, from acclimatization to full-scale intervention phases). Listwise deletion will be used in other cases of missing data.

Methods: Monitoring

7.4. Data Monitoring

7.4.A. *Data Monitoring Committee*

There is no data monitoring committee established for this feasibility trial due to the intervention having a low risk of mild adverse effects and very low risk of severe adverse effects.

7.4.B. *Interim Analyses*

Not applicable. No interim analysis is planned.

7.5. Adverse Events and Safety

The deep-touch compressive pressure produced by the singlet might cause minor physical discomfort and/or secondary physical sensations (e.g., itching, tingling) arising from the activation of sensory nerve endings in the skin. Qualitative work we have performed in preparation for this study – i.e., focus group discussions with clinicians who prescribe JettProof garments, thematic analysis of customer testimonials posted to the JettProof website – suggests that discomfort is experienced for a small proportion of wearers and is likely to resolve over time as acclimatization occurs. For this reason, children's first wear of the singlet will be supervised by a trained occupational therapist and a one-week acclimatization period will allow gradual increased exposure to the singlet before proceeding to full-scale wearing (i.e., ≥6 hours per day). A researcher will telephone each caregiver at least once per week during the intervention phase (i.e., three times in total) to monitor for the occurrence of any adverse events associated with the singlet.

Our qualitative work has indicated that caregiver attempts to doff JettProof garments (e.g., for laundering) may be met with child refusal, upset (e.g., crying) and other challenging behaviour (e.g., tantrum). As such, each family will be provided three singlets for the intervention phase, allowing

substitution while laundering. Further – in an effort to make trial events more predictable for child participants and ensure ample time for them to prepare for transitions across trial phases – each child will be given a printed visual schedule at the beginning of the trial to take home with them, that illustrates the sequence of study activities and singlet wearing. This schedule will be reviewed at each study visit with the child and with the caregiver by phone as needed by the trained occupational therapist research assistant. Lastly, a researcher will telephone each caregiver during their child's post-intervention/return to baseline phase to monitor for the occurrence of adverse events associated with *removal* of the singlet.

This study will utilize a series of semi-structured observational tasks based on the well-established Lab-TAB (H. Goldsmith et al., 2010), that have been designed to elicit mild negative emotional responses (i.e., anger, frustration, sadness, disappointment). These procedures have been used extensively in studies of the general child population (H. H. Goldsmith & Gagne, 2012) and among children with developmental disabilities such as autism (Macari et al., 2021; Northrup et al., 2020; Nuske et al., 2022), are brief (i.e., less than 5 minutes each), mirror what children might encounter in the real world, and have been shown to elicit no more than a mild emotional response in an autistic child sample with no lasting effects (Macari et al., 2021). We do not anticipate that these challenges will elicit a more-than-mild emotional response in the present child sample. A short verbal description of each episode will be presented to the primary caregiver prior to administration to allow truly informed consent. Should the primary caregiver anticipate a Lab-TAB episode will elicit *severe* challenging behaviour or emotional distress then the research assistant will co-design an alternative episode with the caregiver. A Lab-TAB task will be ended immediately should it elicit a more-than-mild emotional response or any challenging behaviour, and an adverse event will be recorded.

We do not anticipate any risk of psychological, emotional, physical, or social harm to caregivers or the research team.

Any adverse event occurring during this study will be documented and reported to the HREC in a detailed written report, identifying the participant by assigned code. A report would include an assessment of the severity and causality of the adverse event in relation to the treatment protocol, as well as detailed information regarding steps taken by the research team with regard to both the trial protocol and the participant involved. The severity of adverse events is graded as:

- Mild Adverse Event: event results in mild or transient discomfort; does not require hospitalization or treatment; does not limit or interfere with everyday activities
- Moderate Adverse Event: event is sufficiently discomforting so as to limit or interfere with daily activities; does not require hospitalization or treatment
- Severe Adverse Event: event results in significant symptoms that prevents normal daily activities; may require hospitalization or treatment

7.6. AUDITING

There are no plans for auditing trial conduct beyond the independent research governance requirements and annual reporting to the HREC. The investigators and institution will permit trial-related monitoring, audits, and regulatory inspections, providing direct access to source documents,

as required. A non-independent inspection of the study protocol and source data will be performed by the investigators on a regular and routine basis to ensure accuracy and compliance with GCP and HREC standards and processes.

8. Ethics and Dissemination

8.1. Research Ethics Approval

This protocol (in Pre-registered Draft form) has been submitted for review to the LTU HREC.

8.2. Protocol Amendments

All protocol amendments will be submitted to the institutional HREC for approval before implementation. The only exception will be when the amendment is necessary to eliminate an immediate hazard to the trial participants. In this case, the necessary action will be taken first, with the relevant protocol amendment following shortly thereafter. Once HREC approval has been granted, investigators and the ANZCTR will be updated.

8.3. Consent

Caregivers of potential child participants (i.e., who express interest in participating) will be contacted by a researcher to answer any questions and screen for eligibility, including verbal administration of the SRS-2 (Constantino & Gruber, 2012), SSP (McIntosh et al., 1999), and PPECS (Dewart & Summers, 1995). Caregivers whose children pass the eligibility screen and who give verbal consent to participate in the trial will be given an information and consent form – containing a description of the purpose of the study, the study procedures and timeframe, the possible risks and potential benefits to participation, compensation for being involved, procedures to protect confidentiality and privacy, and the contact details of the research team and HREC – and encouraged to discuss participation in the trial with their child, family, friends, and community practitioners if they wish to do so. At the child's first face-to-face assessment session, the caregiver and child will be given an opportunity to ask questions about the trial. Once all questions are answered, the caregiver will be asked to provide written consent on behalf of their child and the child will be asked to provide verbal consent to participate. Should consent not be obtained from either the caregiver or child, the child will be excluded from participating in the trial.

8.4. Confidentiality

The personal identifying information of potential participants will be recorded in an LTU-hosted REDCap participant database, including reasons for ineligibility or refusal to participate. Participants selected for inclusion in the study will be allocated a unique participant ID number, which will be recorded against their identifying information in the REDCap participant data to enable the reidentification of de-identified study data should a participant decide to withdraw their data from the trial. Electronic- (i.e., REDCap survey) and hardcopy data files will be labelled with each participant's unique participant ID number and stored separate participant's personal identifying

information in an LTU-hosted REDCap project database and/or locked filing cabinet at LTU. Participants' data will not be released outside of the study without the written permission of the participant (once aged older than 18 years) or their caregiver, except as necessary for monitoring by regulatory bodies and authorities. The study data will only be published in aggregated form.

8.5. Declaration of Interests

AL: none to declare.

LC: salary is wholly funded by project grant from AusIndustry.

CAS: salary is wholly funded by project grant from AusIndustry.

ME: has a direct financial interest as the Director of JettProof.

PS: has an indirect personal interest as an immediate family member of ME.

CM: none to declare.

PD: none to declare.

HN: none to declare.

MG: serves on the Empatica Scientific Advisory Board.

8.6. Access to Data

The sponsor, LTU, will retain ownership of the data collected. No limits will be imposed on the investigators' access to and use of the data, subject to HREC approval.

8.7. Ancillary and Post-Trial Care

There is no ancillary or post-trial care for participants in this trial.

8.8. Dissemination Policy

8.8.A. Trial Results

Findings from this trial will be disseminated via a manuscript submission to a peer-reviewed journal, traditional and social media outlets, and at academic and professional conferences. JettProof may communicate trial results to the public provided that this is not misleading and there is no disclosure of confidential information. There are no publication restrictions.

8.8.B. Authorship

Substantive contributions to the design, conduct, interpretation, and reporting of a clinical trial will be recognised through the granting of authorship on trial publications and outputs. Any authorship disputed will be addressed by the Principal Investigator. There are no plans to employ professional writers.

8.8.C. PUBLIC ACCESS

There are no plans for granting public access to the full protocol, participant-level dataset, or statistical code generated from the study.

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