



Clinical Study on Deep Pressure Therapy

The Snug Vest's Effects on Anxiety and Behaviour in Children with Autism Spectrum Disorder*

Study by:

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Mitacs



**snug
VEST**

Abstract

Background Deep Pressure Therapy devices are widely used in the treatment of autism, yet little scientific evidence exists to support their effectiveness.

Purpose We tested the effects of an inflatable garment that applies pressure to the torso (the "Snug Vest").

Method We conducted an ABAB withdrawal design to test the effects of the vest in 7 children (5-9 years-old) with Autism Spectrum Disorder. We compared treatment ("on-days", wearing the vest inflated vs. "off-days", wearing the vest deflated or not at all), and intervention

time point (prior to, directly following, and after a delay).

Findings We found a significant interaction between treatment and time point for parents' subjective ratings of attention and for salivary cortisol levels, and a significant effect of the vest on naive coders' ratings of problem behaviors. We found no effect on blood pressure or heart rate.

Implications These findings suggest that the garment can have beneficial effects on the functioning of some children with autism.

Purpose

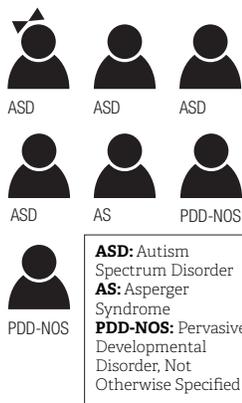
The purpose of this research is to test the effects of the Snug Vest, an inflatable garment, that applies pressure to the torso on behavioural and physiological function using ABAB method.

Method

The study involved an

ABAB withdrawal design

to test the effects of the vest on 7 children with Autism Spectrum Disorder



— 5–9 years old —

The study compares **treatment** on:

ON DAYS **OFF DAYS**

{wearing the vest inflated}

{wearing the vest deflated or not at all}

and **intervention time points**.

Day 1

No vest

Day 2

Inflated vest

Day 3

Deflated vest

Day 4

Inflated vest

Day 5

No vest

Measures

1 Parent questionnaires:



- Pre-session questionnaire
- Pre-experiment questionnaire
- Sensory profile
- Vineland adaptive behaviours scale
- Post-session phone questionnaire

2 Physiological measures:



a. Salivary cortisol

Measured beginning of, end of, & 20 mins. following, each intervention period.



b. Blood pressure

Measured beginning of, end of, & 20 mins. following, each intervention period.



c. Heart rate

Continuous recording during intervention period.

3 Behavioural observation:



Participants were **video recorded during the intervention period**.

Two naive coders per child identified and coded a range of problem behaviours.

Intervention Session

the 20 minute intervention session comprised of 3 activities:

1 Computer game

Designed to challenge sustained attention (Continuous Performance Task).

2 Card sorting game

Zelazo, 2006.

3 Jigsaw puzzle

Data Analysis

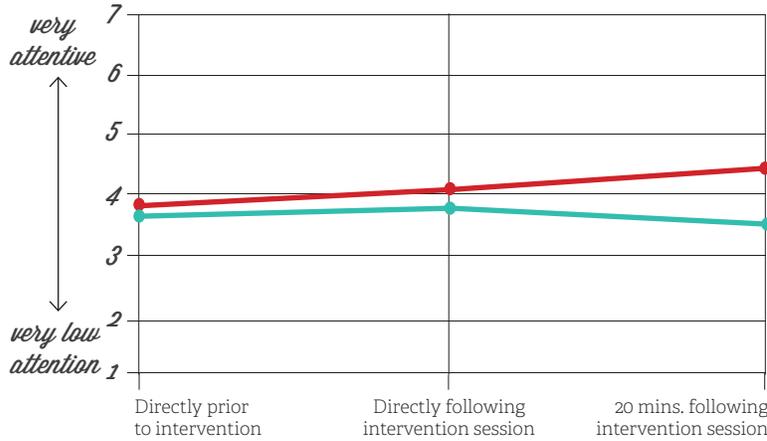
All data was entered into IBM SPSS statistics software, V.21 for analysis. Because many participants demonstrated elevated anxiety and behaviour problems on the first day, Day 1 data is excluded from analysis. Data analyzed using 2 x 3 repeated measures analysis of variance (ANOVA) with treatment (on-days, off-days) and time points.

Results

1 Parent questionnaire

Mean parent rating of child's attention:

Parents indicated that their children were more attentive on **“on” days** (day 2&4) and less attentive on **“off” days** (day 3&5). Attention rating on a 7-point Likert scale.



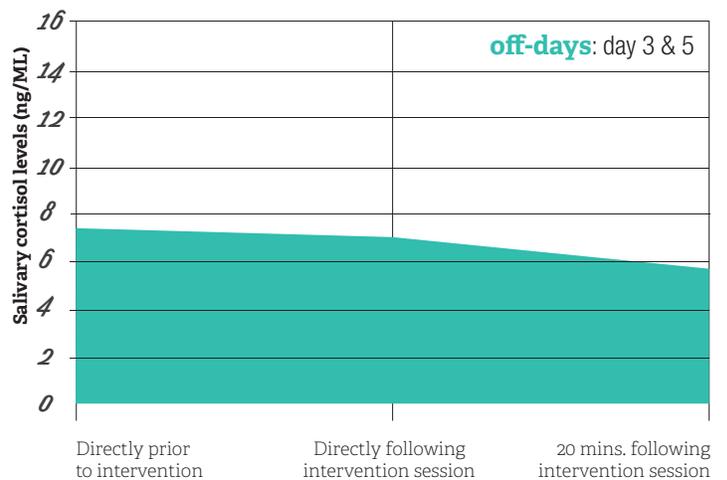
“ We found a significant interaction between treatment and time point, such that parents indicated that their children were more attentive directly after and two hours following the intervention session on days when their children wore the vest inflated, but less attentive on days when their child wore the vest deflated or not at all. ”

— Kayla D. Ten Eycke

2 Physiological measures

a. Mean Participant Salivary Cortisol Levels:

Salivary cortisol levels (in nanograms per milliliter) decreased during intervention session and decreased post intervention, regardless of **“on”** & **“off”** days. There was a significant interaction between time point and treatment condition. Cortisol is a major glucocorticoid, produced in the adrenal cortex, which rises in response to stress.



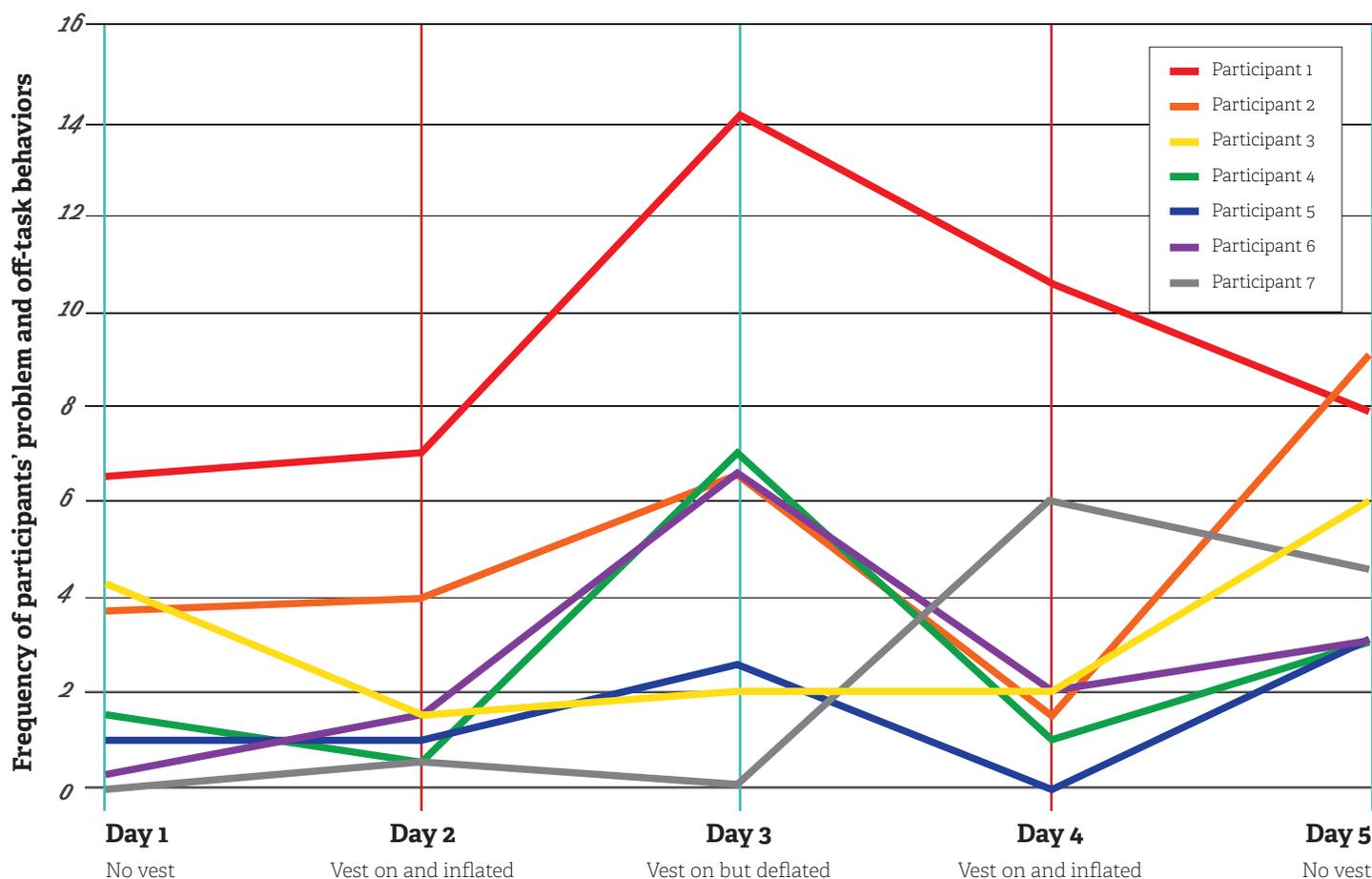
b & c. Blood Pressure & Heart Rate:

No significant differences found

3 Behavioural observation

Naive Coders' Ratings of Problem Behaviours:

Two naïve raters scored the frequency of participants' problem and off-task behaviors over the intervention session. Based on a paired samples t-test with treatment ("on" & "off" days) as the independent variable, coders observed significantly more problem behaviors on "off" days ($M = 5.4$ $SD = 3.1$) compared to "on" days ($M = 2.8$ $SD = 2.8$), $t(6) = 3.556$, $p = .012$.



Discussion:

“Whereas the majority of previous studies have found no effect for deep pressure treatments, the present study provides tentative support for such treatment. ...To the best of our knowledge, this is the first study to use such a

comprehensive set of assessments. Further research using extended treatment and more varied outcome measures is necessary to corroborate the current findings and ascertain their generalizability to real-life contexts.”

— Kayla D. Ten Eycke



Beta Trial Feedback

Study on Usability, Efficacy, and Performance of Snug Vest for Children with a range of disorders

Study by:

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(Product researchers / developers)



Sponsored by:

NRC-IRAP



National Research
Council Canada

Approved by:



Health Canada
Santé Canada

Research Ethics Board

Abstract

Background Prior to commercialization of Snug Vest, we gathered feedback for better understanding of product use and to make final improvements on product.

Purpose We gathered feedback on usability, efficacy, and performance of a Snug Vest - Deep Pressure vest.

Method We conducted a 28-day study in a real-life context: home or school-based setting, to collect data from 15 children (6-9 years old) with a range of disorders. An initial phone call was made with each caretaker prior to starting the trial. The children were instructed to fill out worksheet booklets and caretakers

(parents, therapists, or teachers) filled in questionnaires for 4 weeks. On the 28th day, a phone interview was conducted for follow-up.

Findings The results show that most children benefited from using the Snug Vest. No major product changes were needed prior to commercialization.

Implications Feedback suggests that Snug Vest can be beneficial to reduce amount of time, and occurrences of symptoms experienced throughout the week. Due to small sample size, this beta study serves as a pilot for conducting larger clinical and efficacy testing in the future.

Purpose

To analyze if the vest was working as intended, find out the frequency of use, and extract information for how to improve the product. We wanted to test the vest in real-time environments including home with parents, classrooms with teachers, and therapy center with occupational therapists.

Method

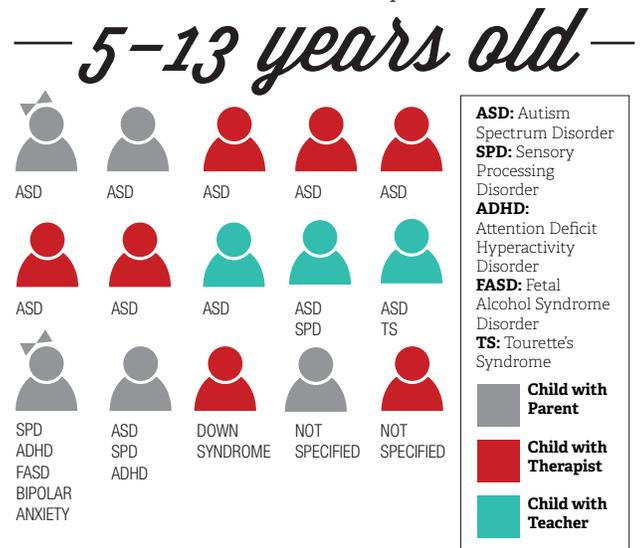
Each participant was given a **beta kit** to complete the study. The beta kit consisted of:

- A beta Snug Vest & pump
- Instructions manual and CD
- Warranty sheet
- Worksheet booklet
- Stationery kit (marker, coloured pencils, post-its).

Caretakers including parents, teachers, and therapists were asked to fill out weekly questionnaires and worksheets with their children, followed by a phone interview as outlined in the 28 day schedule.

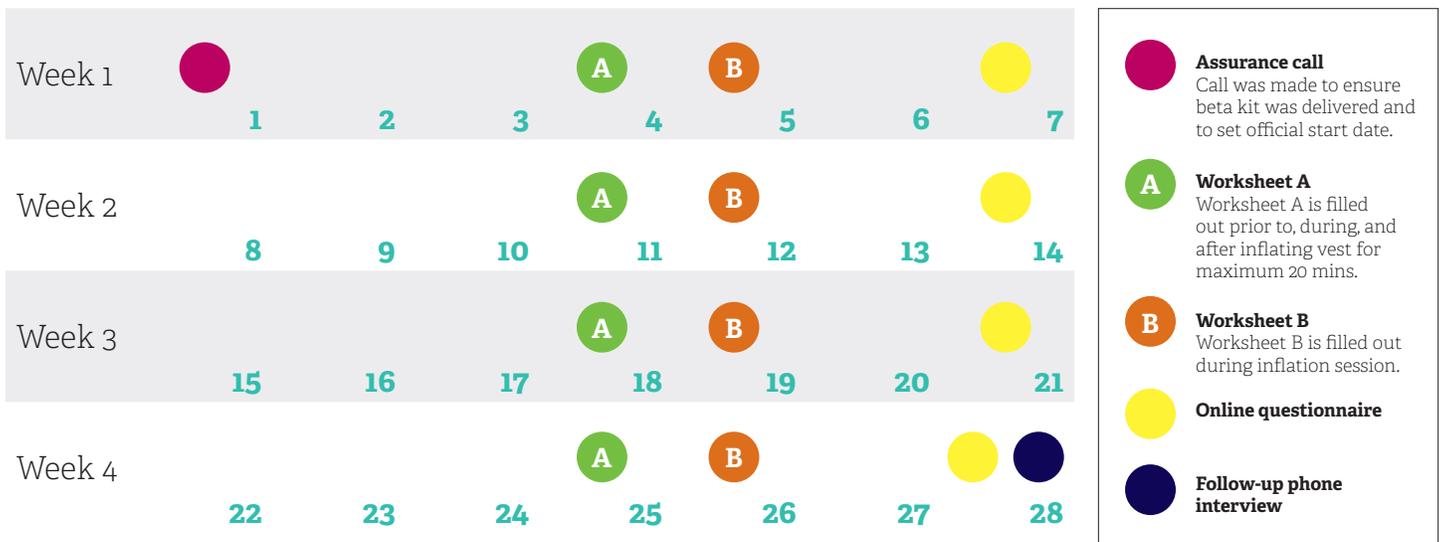
15 **15 children** participated in this study with a range of disorders. See below:

8 **8 caretaker** fully completed all 4 weekly questionnaires.



28 Day Schedule

The beta trial asked the caretaker/ parent to fill out weekly questionnaires from Qualtrics. Children were asked to fill in worksheet booklets that gave us information on the efficacy and performance of Snug Vest. The booklet also included additional time logs, journals, and worksheets for reference.



Measures

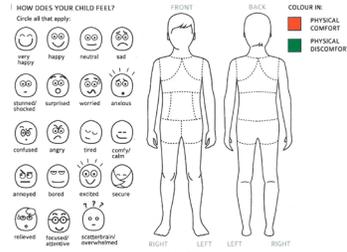
1 Usability



Caretakers' Questionnaire

Questionnaire was taken to determine if each component of the vest and pump were satisfactory.

2 Efficacy



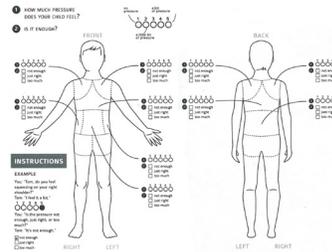
a. Caretakers' Questionnaire

Caretakers filled in questionnaire to see if child's symptoms were better or worse each week.

b. Worksheet A

Children circled how they felt prior to, during, and after 20 minute inflation session. Children also used orange pencil to colour areas of physical comfort, and used green pencil to colour areas of discomfort.

3 Pressure performance



a. Caretakers' Questionnaire

Caretakers filled in questionnaire to determine how satisfied they were with pressure distribution of vest.

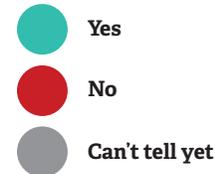
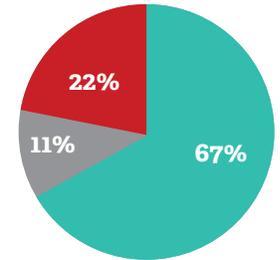
b. Worksheet B

Child was shown a front and back view of child's silhouette, where it sectioned off shoulders, chest, stomach, and sides. Child was asked how much pressure they felt and if it was enough pressure while wearing Snug Vest.

User Benefits

We asked caretakers if user benefited from wearing Snug Vest on the fourth week.

Most users benefited, while a small portion of caretakers required more time to determine whether they will benefit from Deep Pressure.



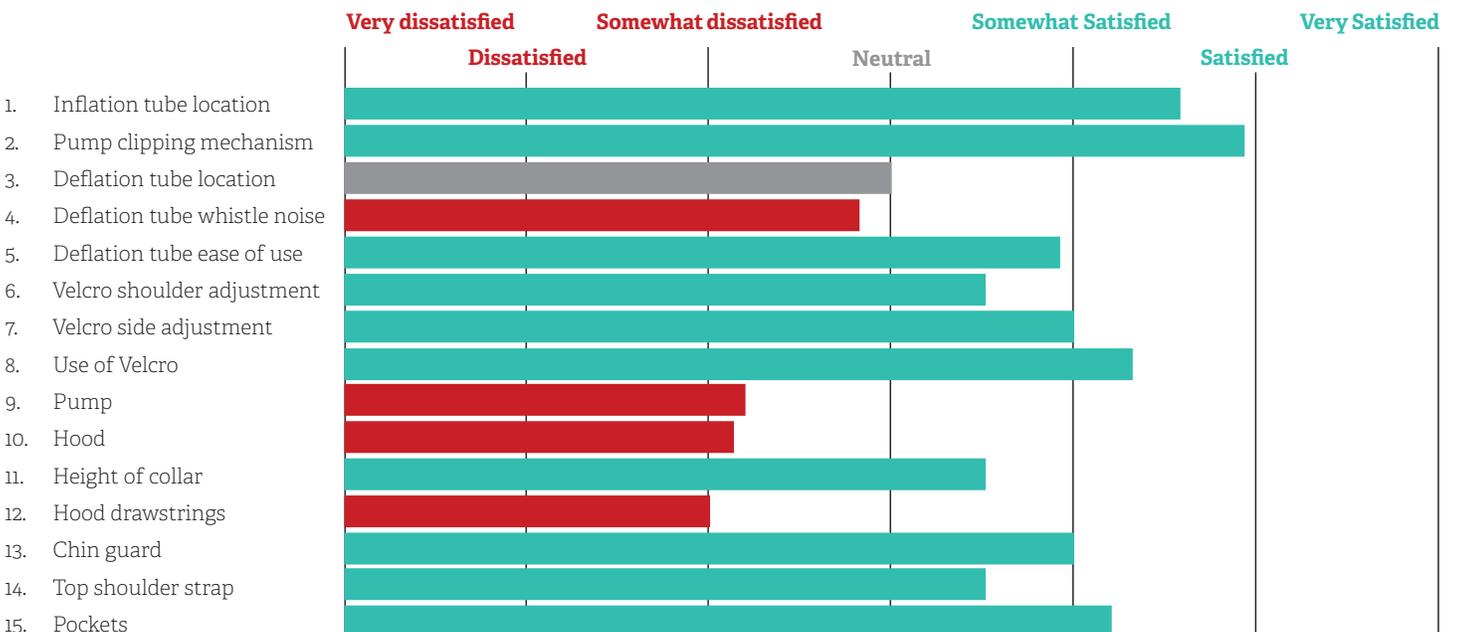
Responses recorded from 9 participants

Results

1 Usability

Caretakers' Questionnaire on 15 Snug Vest Features

On average, 12 features were **"satisfactory"** and 4 features including deflation tube whistle noise, pump, hood drawstrings, and hood were **"not satisfactory"**. On the commercialized Snug Vest 2013 version, we replaced the beta pump with a higher quality pump with faster inflation rate. We also eliminated the hood drawstrings for safety purposes and are looking for detachable hood options and alternative deflation tubes that are less noisy while retaining current fast deflation rate.

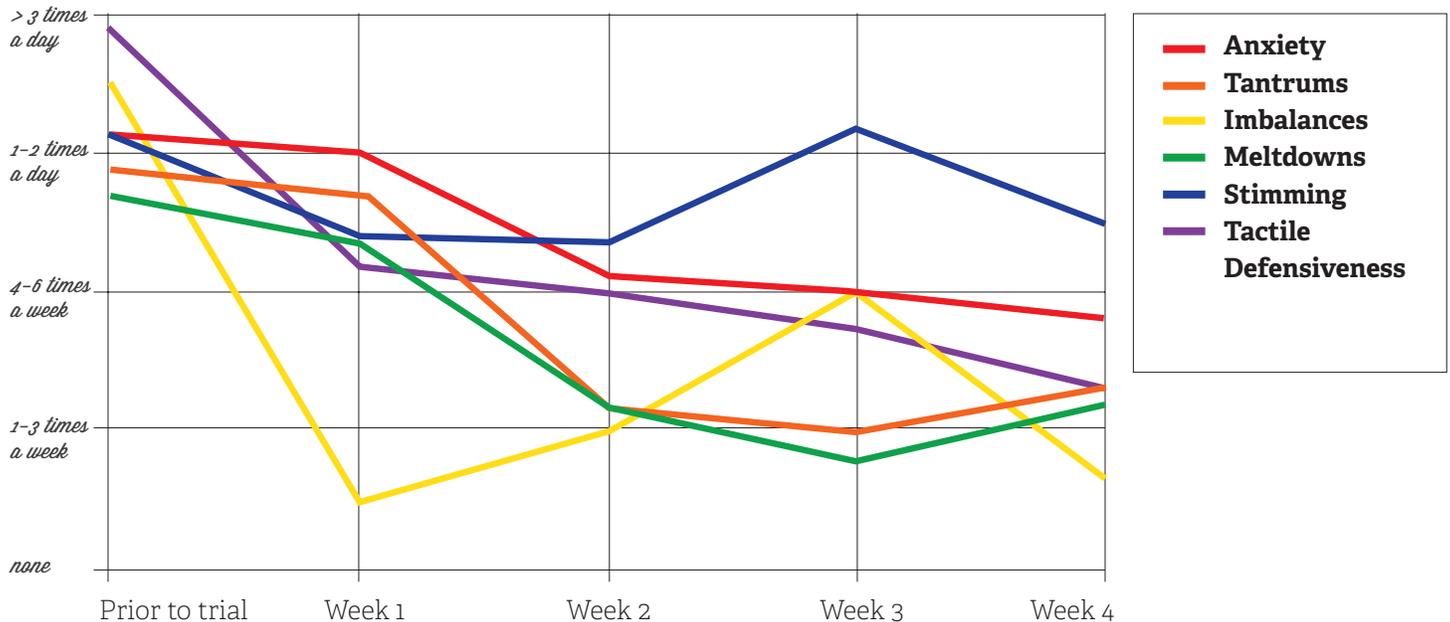


2 Efficacy

a. Parent Questionnaire

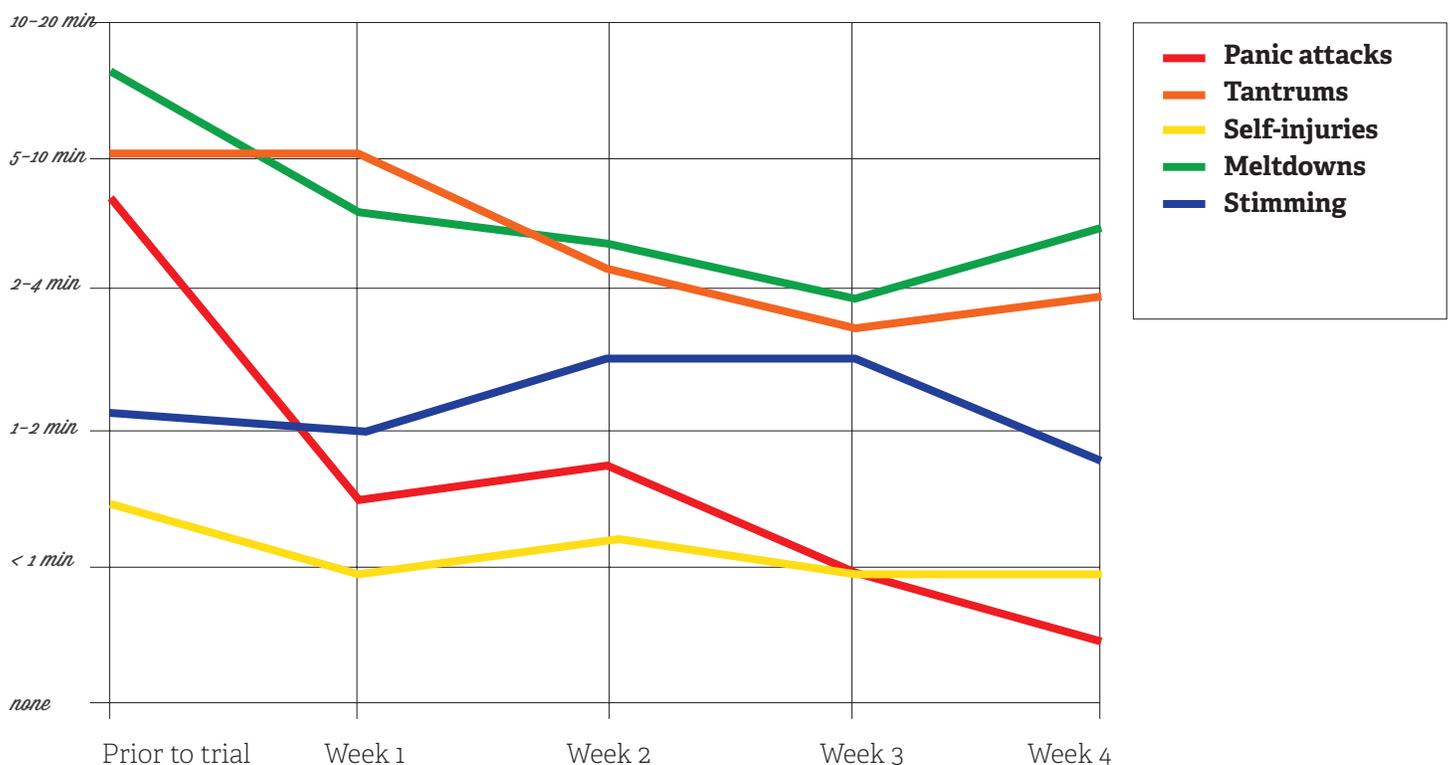
Symptom's Occurrences Throughout The Week

Based on parent's feedback, there were positive outcomes that show decrease in anxiety, tantrums, meltdowns, and tactile defensiveness occurrences throughout the weeks after starting the trial. There were neither positive nor negative results for imbalances and stimming.



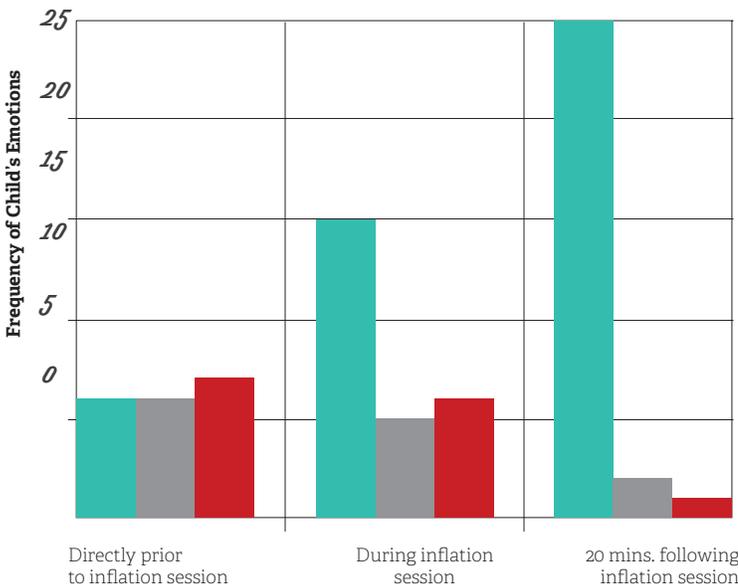
Amount of Time Participant Experiences The Symptoms

The data shows that the amount of time children experience tantrums, and panic attacks decreased; while there were no positive nor negative changes in meltdowns, stimming, or self-injuries.



b. Child's Emotions Prior to, During, and After Inflation Session (Worksheet A)

On Worksheet A, children were asked to circle different emoticons that corresponded to how they felt at the moment. In total, children had more positive emotions after inflating vest.



Positive emotions
Very happy, happy, comfortable/calm, excited, secure, relieved, focused.

Neutral emotions
Neutral, tired.

Negative emotions
Anxious, confused, angry, annoyed, bored, scatter-brained.

A VEST ON - INFLATED 10MIN INTO 20MIN INT

2/3 HOW DOES YOUR CHILD FEEL?
Circle all that apply:

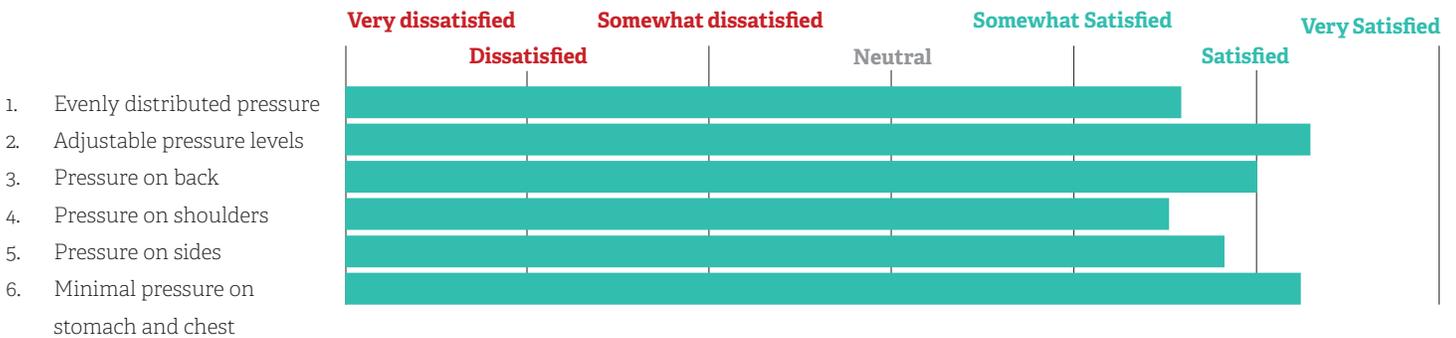
Worksheet A Example

very happy, happy, neutral, sad, stunned/shocked, surprised, worried, anxious, confused, angry, tired, comfy/calm, annoyed, bored, excited, secure, relieved, focused/attentive, scatterbrain/overwhelmed

3 Pressure Performance

a. Parent Questionnaire on 6 Deep Pressure Benefits

On average, all 6 deep pressure benefits were **“satisfactory”**. Based on the questionnaires, participants were most satisfied with adjustable pressure levels. The least satisfying pressure benefit was pressure on shoulders.



b. Pressure mapping (Worksheet B)

Out of the 3 children that completed this exercise, on average, all 3 mentioned that pressure was **“just right”** throughout sides, stomach, chest, upper and lower back regions. On average, pressure was **“not enough”** on the shoulders.

Shown on the right is an example of a child who filled out Worksheet B with their caretaker. Question 1 asked how much pressure the child felt and second question asked if pressure was enough.

B VEST ON - INFLATED 10MIN INTO 20MIN INT week one

1 HOW MUCH PRESSURE DOES YOUR CHILD FEEL?
no pressure, a lot of pressure

2 IS IT ENOUGH?
seems a little too tight on the shoulders

DATE: Tues

BACK

LEFT RIGHT

INSTRUCTIONS

EXAMPLE
You: "Tom, do you feel squeezing on your right shoulder?"
Tom: "I feel it a lot."
You: "Is the pressure not enough, just right, or too much?"
Tom: "It's not enough."
 not enough
 just right
 too much

Time Logs and Journals

Caretakers filled out optional time logs and journals in the worksheet booklet to keep track of Snug Vest usage. In the timelogs and journals, caretakers expressed how Snug Vest has helped the child in different activities throughout the week.

“ We had a lovely family meal at Pizza Hut. Theo coped brilliantly after wearing the vest. Even though the restaurant was busy, he managed 1.5 hours there. ”

— Day 27, Wiggs, Mother

“ During therapy sessions, if he wore the vest, I found that he would be doing more directed tasks and interact more with me rather than wandering around the clinic. ”

— Day 28, Lang, OT

Time Log Example

Time Log				week four
Date	Time in * min 20 min	Time out * min 30 min	Reason for inflation, activities/tasks	Observations
May 1	10 am	10:10	-Tom had meltdown -help focus on hwk	I noticed Tom get more relaxed wearing the vest and he seemed to stay relaxed for a few hours after
July 31	6pm	6:30pm	- Theo had meltdown	Theo calmed down quickly with the vest on.
August 1	10 am	10:22am	- Calm Theo for reading	Theo was very settled and explained his book to me.
August 1	4:11pm	4:32pm	- Calm Theo for swimming	Theo calmed down enough to go in the swimming pool safely.
August 2	9:44am	10:21am	- Calm Theo to go out	Theo was very settled, no jumping about wanting to go.
August 2	1:47pm	2:27pm	- Calm Theo when changing out	Theo was calm and seemed very happy. Didn't want to take the vest off!
August 2	7:32pm	7:58pm	- Calm Theo for bedtime	Theo was a little overstimulated but soon settled with the vest on.
August 3	9:17am	9:39pm	- Help Theo to get dressed.	Theo was calm enough to try dressing himself - manage trousers, socks, shoes.
August 3	6:14pm	6:35pm	- Calm Theo for dinner	Theo was very settled after being very active before dinner.
August 4	8:31am	8:56pm	- Calm Theo for bedtime	Theo was very relaxed with his vest on.

* Note: If Tom wore the vest for 10 minutes, he would not be able to wear the vest again until 10:40 as you should wait 30 mins between inflation.

Journal Example

JOURNAL week four

Feel free to add anything that comes to mind. It can be about your thoughts on the vest such as what you like or dislike, what your child said about the vest, or how their day went.

Write as frequently as you like. Daily is not necessary.

Fill in the date here (Wed, 23)
I really noticed that the vest helped Tom today. He was upset after school in a very bad mood and couldn't sit still but...

July Day 1 IGO stimmi vest seemed to help.

July Day 2 Asked for vest today. Good sign!

July Day 3 Needed lots of hugs and squeezes today. After use, asked for further squeezes.

July Day 4 Very hyper today. Put on vest, seemed calmer.

July Day 5 Over stimulated today. Much more relaxed after use of vest.

July Day 6 Away.

July Day 7 Away.

Discussion

“ In general, we received mostly positive feedback on usability, efficacy and performance of Snug Vest. We are happy to see that children with a range of disorders are benefiting from wearing the vest, not just limited to autism spectrum disorders. For areas where we received less satisfactory feedback, we have already improved on aspects

of Snug Vest including: pump, instruction manual, and clear labelling. We hope to improve pressure on shoulders in the future. Due to the limited sample size, we believe that this study serves as a pilot for conducting larger clinical and efficacy testing in the future. With every Snug Vest we make, we truly hope that the vest will benefit all users. ”

— Snug Vest Team, October 2014