OTO, A compressive armchair to perform deep pressure in children with ASD: a user-centered design and feasibility study

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Abstract

Background: Deep Pressure Therapy (DPT) is widely used to reduce anxiety in autism spectrum disorder (ASD) but evidence of its efficacy is limited.

Objective: To design a usable, non-stigmatizing compressive armchair which can be easily controlled, electronically, by the user.

Methods: We used a user-centered design to assess the usability of the device. We tested the device in a Day Hospital for children with autism spectrum disorder (ASD) in France with a convenience sample of 39 children with severe forms of autism spectrum disorder and intellectual deficiency. The compression armchair has four different cells which can be inflated to induce tailored pressure on the body. The pressure level is recorded electronically. We used Witteman design guideline. We measured System Usability Scale and time of use.

Results: The design was user centered. Usability was between good and excellent. The device was used by 39 children, for 3 to 20 minutes with one or two sessions each week, for 31 months in the center. The armchair takes up less space than the hug machine. Performing sessions with the chair is feasible.

Conclusions: This device opens perspective for controlled evaluation of deep pressure therapy to treat anxiety in ASD. First clinical impressions show a decrease of anxiety, a better emotional and attention regulation. Deep pressure therapy is widely used in occupational therapy and frequently requested by parents, but efficacy studies are too scarce to make evidence-based recommendations for its use.

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Authors

*These authors equally contributed

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Conclusions and Relevance: This device opens perspective for controlled evaluation of deep pressure therapy to treat anxiety in ASD. First clinical impressions show a decrease of anxiety, a better emotional and attention regulation. Deep pressure therapy is widely used in occupational therapy and frequently requested by parents, but efficacy studies are too scarce to make evidence-based recommendations for its use.

Keywords: Deep pressure therapy; proprioception; compression; autism spectrum disorder

Article

Introduction

Autism Spectrum Disorder (ASD) is defined by (1) persistent deficits in social communication and social interaction across multiple contexts and (2) restricted, repetitive patterns of behavior, interests, or activities (American Psychiatric Association, 2013). According to the American Psychiatric Association (2013), the prevalence of autism is 1%.

Sensory difficulties are frequently found in individuals with ASD (Kojovic et al., 2019). They could underly the pathophysiological processes that lead to impaired social development (Bonnet-Brilhault et al., 2018).

Proprioception is the sensory registration of the ongoing spatial configuration of the body. It includes

the position of the body segments in space, the force and the speed of movement, and the integration of gravity and body balance. Proprioception is known to impact behavioral regulation and motor control (Ayres, 1972 in Guinchat et al., 2020). Blanche et al. showed that Children with ASD present proprioceptive processing difficulties that are different from those of children with other developmental disabilities and their typically developing counterparts (Blanche et al., 2012). However, Morris et al., 2015 and Fuentes et al., 2011 did not confirm these proprioceptive difficulties in experimental paradigms. It is possible that the deficits rely mostly on multisensory integration (Robertson & Baron-Cohen, 2017).

Sensory Integration Theory

Sensory processing dysfunction theory in children with ASD was suggested by Ayres in 1972 using sensory integration theory (Lane et al., 2019). The presumed mechanism of sensory-based intervention is to maintain an optimal arousal between hypo- and hyper- stimulation (Case-Smith et al., 2015; Watling & Hauer, 2015).
Several techniques or devices can be used in sensory based interventions, in particular deep pressure therapy (DPT). Systematic reviews show that sensory integration therapies, that use play activities and sensory-enhanced interactions, have positive effects, but the evidence is not of sufficient quality to confirm these results (Case-Smith et al., 2015; Lane et al., 2019) whereas, the practitioners like the American occupational therapy association recommends the use of sensory strategies for individuals with ASD (Watling et al., 2011; Watling & Hauer, 2015).
In an online survey among 552 parents, Green et al. 2006 showed that sensory integration was the 3rd most used treatment after speech therapy and visual schedules, and before behavioral methods (Green et al., 2006). In a survey among 152 parents, Peña et al. 2021 reported a high acceptability of sensory based methods. These interventions were considered to be ‘very important’ or ‘important’ (Peña et al., 2021). Main barriers of dissemination were lack of recommendations, difficulty to use, or difficulty to access this kind of interventions (Peña et al., 2021). Among these techniques, deep pressure therapy was particularly studied.

Deep Pressure Therapy

Different devices and strategies can be used to deliver Deep Pressure Therapy to patients with ASD (Table 1)

Type of device	Principle	Level of evidence	N	Time of use	Measure of efficacy	Control	Efficacy	Acceptance	Cost	Autonomy of the patient
Weighted blankets	Weight	Systematic review, population based observational study	Observational: 1785; Interventional: 160	> 8h daily	Sleep, STAI, Electrodermal activity, Pulse rate	Nothing or light plastic chain blanket	Conflicting evidence	+++	+	+++
Therapeutic body wrap	Tightening	One RCT	48	45 min; 2/week	Aberrant Behavior Checklist irritability	Dry versus wet-sheet TBW	+ but no waiting -list comparative arm	+/-	+	- - -
Shape memory vest	Tightening	None, prototypes	None	Unknown	None	None	Unknown	Unknown	++	Unknown
Weighted vest	Weight	Systematic review of SCRD (k = 4)	13	30 min	In seat behavior, off-task behavior, on-task behavior, stereotypic behavior, problem behavior, engagement	Nothing	Conflicting evidence	+++	++	+++
Compression vest	Pressure by inflation	SCRD	3	20 min, daily? for 22-50 days	Stereotypies	Fully deflated vest or no vest	No efficacy	+++ ?	++	+++
Manual squeezing	Manual squeezing	SCRD	8	5-15 min, until 3/day for 3 months	Visual analogue scales (Calmness, Engaged, Responsivity, Happy, Communicative)	Nothing	+/-	+++	+	-
Hug or squeeze machine	Compression by a plate	RCT	12	20 min; one/week for 6 weeks	Conners' Parent Rating Scale, Electrodermal activity	Not receiving deep pressure in the disengaged hug machine	++	+	+++ (reusable)	-
Compressive garments	Tightening	Observational study	14	>1h-16h daily for 6 weeks	Aberrant Behavior Checklist, Sensory integration (Dun. Profile), postural sway, motor performance	Nothing	+ but no comparative arm	+++	+++ (tailored)	+/-
Sitting hug machine	Compression by a plate	SCRD	2	Not reported	Stereotypical behaviors	Nothing	+ but no comparative arm	+++	++ (reusable)	+++
Compression chair	Compression by inflated cushions	None, prototype	None	Unknown	None	None	Unknown	+++	++ (reusable)	+++

Table 1. Comparison of several devices used to induce deep pressure in children with ASD

k: number of included studies in a systematic review, STAI: State Trait Anxiety Inventory-10, RCT: randomized control trial, SCRD: single case research design

Hug or Squeeze Machine

Kraus used a pressuring apparatus consisting of two stacked air mattresses, to deliver deep pressure therapy to 23 typically developing college students during their exam period. They measured heart rate and self-reported anxiety using the State-Trait Anxiety Inventory (STAI). The control group did not receive deep pressure therapy. There was no objective difference between the two conditions. Subjectively, participants in the deep pressure group reported a relaxing effect. The baseline level of anxiety in this population was low. The authors do not exclude that the confinement alone may have induced subjective feelings of relaxation (Krauss, 1987).

Prof. Grandin. 1992 developed a hug device to allow self-administration of lateral body pressure. It specifically targets individuals with high levels of anxiety (Grandin, 1992). Edelson and colleagues tested this device on children with ASD (n=12) (Edelson et al., 1999). A control group received deep pressure via the disengaged Hug Machine. Participants had 20-minute sessions every week for 6 weeks. Arousal and anxiety was measured using Conners parents rating scale and Electrodermal activity (EDA). The hug device allowed to decrease the anxiety in both behavior and physiological measures. As pressure can be controlled by the individual, this device may be useful for children with marked anxiety. No side effects were reported.

The ergonomic of the device is an important issue (Lane et al, 2019; Edelson et al. 1999). Lo & Hang performed interviews with professionals and patients. They concluded that the ergonomic design of the device and its acceptability could be improved. For instance, it is necessary to lie down or to squat which can be difficult for some children. The system is very bulky. The controller is outside of the machine and cannot be activated autonomously. It is not possible to choose the part of the body that the individual or professional want to squeeze (Lo & Huang, 2018).

Lo and Huang proposed a sitting hug machine which is more compact, controllable by the patient or the therapist, who can press either the shoulders or bottom part of the body. Stereotypies decreased during intervention for 2 children (Lo & Huang, 2018).

Afif. 2021 designed a portable, inflatable hug machine (Afif et al., 2021). It was tested on 5 children with ASD. They measured heart rate variability. They found that the inflatable wrap model decreased heart rate but could not find this effect with a manual pull (Maula et al., 2021).

In the current study we aim to improve the design of the hug machine by (1) improving controllability of the pressure by the professional, allowing replicability and making the device useful for both care and research (2) improving controllability of the pressure by the user and allowing different pressure on bottom and top of the body (3) using pressure instead of restraint (4) making a more attractive and less stigmatizing device. This article describes the method of design, the device and evaluates the usability of the device.

Method

In a population with special needs such as ASD, gathering user feedback could be complicated by communication and social difficulties. It is important to have a tailored, user-centered strategy to improve acceptability and usability before assessing efficacy (Parsons & Cobb, 2014).

We used a validated method of user-centered design to report this process (Witteman et al., 2019). Beyond this method, it is important to assess the time of use of the device (Building Evidence for Technology and Autism, 2021) to show how it was accepted on the field.

The first usages of the device by the patient and the therapist were video recorded to improve the design of the device to the needs of the patient and the therapist.

We wanted to improve the design of the squeezing chair and keeping a very easy usage. A remote for the patient and a control panel for the therapist would improve control of the chair, and also enable digital monitoring and feedback on pressure use (location, time and level). We used the system usability scale (SUS) to measure how people perceived the usability of this system (Brooke, 1996).

Results

Design goal and process

The seat was designed by Alexia Audrain[1], furniture maker, to address the needs of individuals with ASD for deep pressure. The project was carried out in partnership with the medical-educative institute of Blain, France, over a period of 1.5 years. The educator, psychomotrician and the director of the center were involved in needs identification and design process.
A prototype was built using inflatable cushions, to understand the need of pressure, to verify the principle of action to get side pressure on the body and define the main technical characteristics (Figure 1).

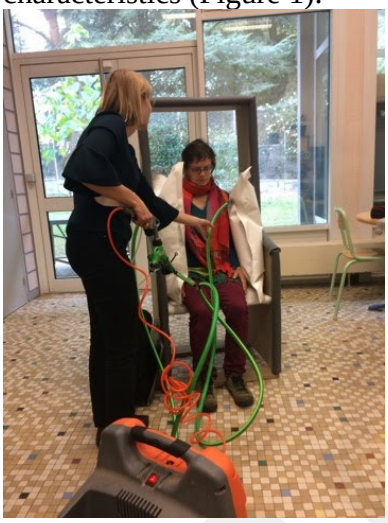

Figure 1: First Prototypes of the OTO Armchair

The prototype was tested with the socio medical team (around 10 professionals) and a convenience sample of 30 children. The designer observed during testing and asked questions about the experience of using the device.
Based on the test results, different models of compression chair were designed and sketched in 3 dimensions to validate the form, the materials, the colors of the prototype before construction. The first model was made in June 2019 and presented to medical educative center professionals, children and the graduation committee.
Following this, the model was presented to a general audience, another Medical-educative institute (Specialized educators, speech therapist, occupational therapist, psychologist), St Jean de Boizeau near Nantes, France; and was tested with 5 children. The device was also used with an adult (30 years) with ASD, without language.

Test within the hospital and modification

First meeting

In December 2020, OTO the squeezing armchair was presented to and tested by Tours

[1] https://www.oto-chair.com/

hospital teams before introducing it for use in the hospital. During this meeting adjustments were suggested by the medical team to enhance the experience of people with ASD.
New functionalities were added before the seat was introduced in the day care hospital:

- Access to pressure measurement in real time for the professional
- Logging of pressure measurement, action used, timestamp
- Seat operation monitoring and safety protocol in case of failure
- Remote control connected to the outside of the seat

Integration

The device was transferred to the Autism Day hospital of the Excellence Center of Neurodevelopmental Disorders in the university hospital of Tours, France in January 2021. After gaining consent from parents, 39 children with ASD tested the device to refine its performance. Suggested improvements following these tests include: cushions to be tailored to the morphology of participants, upper and lower cells deflation dissociated, control panel to set the pressure limit, the feedback light that needs to be deactivated for some user. The noise accompanying inflation and deflation was reduced.
A second group of modifications were made after two months and delivered in March 2021:

- A range of different sizes of back cushion
- New cells with a different design for upper and lower cells to adjust the squeezing effect.
- New valves, pipes and pump to reduce noise
- New remote design with 4 buttons to reduce air pressure independently in upper or lower cells, and a light that can be disactivated
- Addition of a tablet connected to the seat that lets the professional define the maximum pressure

Between April and November, the seat was used in the hospital and tested for two months in services in Rennes, Angoulème and Grandchamps-des-Fontaines. Based on the feature request from users in Tours, and feedback from three other services, some adjustments have been made:

- Enhanced experience: easier on/off process, enhanced pressure measurement
- Noise reduction with valves modification and firmware adjustment
- Control panel enhancement, addition of a second remote
- Safety: continuous monitoring of program execution, error handling and codification

Description of the end-product (Figure 2)

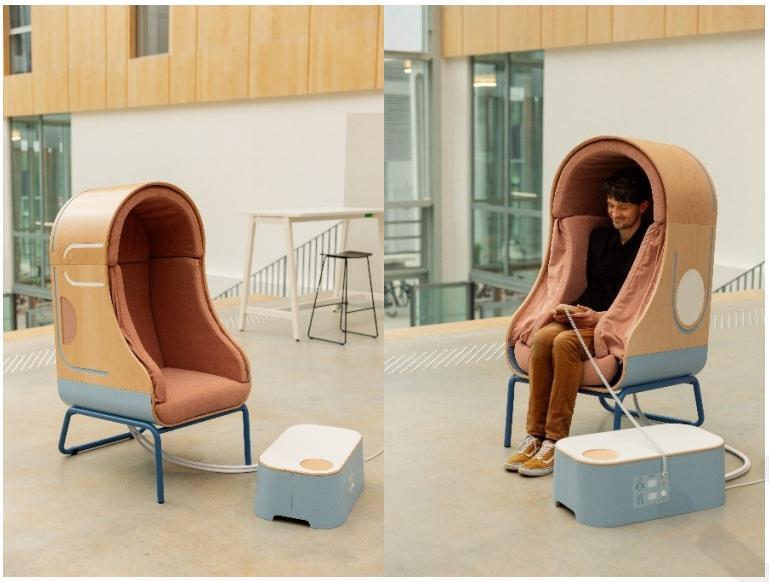

Figure 2: OTO, the Compressive Armchair to Perform Deep Pressure in Children with ASD (Final Product)

OTO is a squeezing armchair that uses inflatable cells to induce deep pressure on the legs and the trunk. The pressure is progressive, measurable, homogenous and can be tailored for each child. Four different inflatable cells allow for modulation through use differentiate pressions on either shoulders and arm or hip and thighs.
The pressure can be controlled by the user via a remote with simple pictogram, to improve autonomy and predictability for the child. The control panel allows the user to set maximum pressure level for upper and lower cells. The maximum default pressure is 60 mmHg for upper cells and 80 for lower cells. This corresponds to the pressure a swimmer perceives one meter under the water. The seat records the use of the device with accompanying time logs.
The sitting position makes the device less bulky and allow more freedom of movement for the user who does not need to lay down as they would in a hug machine. It allows the child to easily leave the armchair if uncomfortable. The footrest can be used to (1) rest the legs (2) as a step for smaller children to enhance stability (3) by the healthcare provider to have the same height and to keep eye contact.
Pastels colors were used to limit sensory stimulation. Edges were avoided to make the armchair safer and more attractive. The device was developed to look like a cocoon to induce a feeling of privacy, to limit the stigmatization of its use and to limit outside noise or light stimulation. The structure is made from beech wood with a metallic structure for the base. All cloth is removable and washable.

Evaluation of the product and the design

The armchair received several prizes from several committees

- The canopé (5k€), National innovation competition organized by Forinvest and Superior school of wood specialized in wood
- Great prize of health innovation (25 k€), St Pierre Fondation which is specialized in the children health with a jury of medical professionals.
- French laureate of James Dyson award specialized in design with a jury specialized of engineers.

- Startup and innovation day prize 2022 that recognize innovative startup
- Crédit Mutuel 4S Semeur d'innovation 2023
- Caisse d'épargne mon projet innovant 2021
- French Tech Tremplin for innovative company launched by people underrepresented in the tech industry
- Handitech-trophy organised with French Ministry of Health and French Ministry of digital technology

The technology readiness level is between 8 and 9 according to the Defense Acquisition Guidebook (2006), meaning that the system can be used for several patients. Minor bugs and user-interface issues with the control panel need to be rectified.

Usage

Recruitment was done between January and July 2023 in the ASD day Hospital in Tours. Thirty nine children between 3 and 12 years with ASD and intellectual deficiency were included. Four children had to stop using the chair due to difficulties tolerating noise, being in an enclosed space or continuing anxiety despite habituation. These children had difficulties in sensory modulation and motor and emotional regulation.
The first sessions were habituation sessions of around 5 minutes. This system was used for 3 to 20 minutes weekly or bi-weekly, with an average total of 272 hours of total use in the ward.

First Clinical Impression

First clinical impressions suggest an increase in pleasure and body relaxation, decrease of anxiety, better postural stability, better social contact (gaze and touch). When children came back to the group, it appeared that their attention and emotional regulation improved. However, in this population, there is marked intra and inter-person variability, a larger sample and controlled procedures are required to formally assess the efficacy of the device.

Usability of the Product

The SUS was measured in 9 professionals (3 psychomotricians, 3 nurses and 3 educators) in July 2022. A mean score of 81/100 was obtained (between good and excellent usability); corresponding to a B score in a scale between A (best) to F (worst) (Bangor et al., 2009).

Discussion

We have detailed the process of development of an ergonomic compressive chair to induce deep pressure in children with ASD. This design was user-centered according to the methodology of Witteman. The system is usable according to the SUS.

User-Centeredness

This device was accepted by the clinicians, patients and their family. The system was used by psychomotor/occupational therapists, but use by nurses was also possible and did not require the support of a technician. The goal was to increase acceptability, autonomy of the subject and decrease the stigmatization associated with ASD and this kind of care.
We began focus group with users and parents to compare sensory issues perspectives the acceptability of different devices proposed for DPT and sensory therapy among children with ASD, their parents and professionals.

Feasibility of Randomized Controlled Trials

Recruitment was easy enough to conduct a study to assess the rationale and efficacy of Deep Pressure Therapy in ASD. Other teams contacted us to test the device and be involved in an efficacy study. In children with most anxiety, the presentation of the device should be

progressive.

Armchair Use, Child Profile and Time of Use

According to the experience of the psychomotrician and analysis of the video by an independent clinician, usability was better for older children (> 8 years).
There were no side effects reported. Children could leave the armchair easily. If they experienced discomfort the therapist was able to deflate the cushion.
The system was used in a small room with limited visual and auditory stimulation.
Sometimes, we proposed to children to use a neck cushion to improve relaxation.
This device will enable further evaluation of deep pressure therapy. In future, we plan to properly characterize and report the data of the individuals including precise diagnostic information (ADI, ADOS), their sensory profile and proprioception deficits (Dunn -Kientz & Dunn, 1997); score on the EPSA scale (Le Menn-Tripi et al, 2019) and underlying pathophysiological processes (Heart-Rate Variability, Electro Dermal Activity) using a wearable monitoring device to measure physiological data. We are running focus groups and simulations assessed the acceptability of such device by children with ASD, professionals and parents that we plan to report also in future works.
We tested a wearable device tom measure physiological data in University Hospital of Tours. It was accepted by the patients and the data was usable (time-stamped). This evaluation highlighted that the device was less accepted by younger children, who showed more agitation during the application of pressure.

Limitation

This study does not allow any firm conclusions to be drawn about the efficacy of the device in reducing anxiety in ASD. However, this study showed that an efficacy study is feasible (Eldridge et al., 2016). It would be important to report the precise clinical profiles of children. Due to the design and preliminary study, French regulations do not allow the reporting of clinical data yet.

Implication for Occupational Therapy Practice

This device has the potential to facilitate the design of well conducted studies to better understand the rationale behind and efficacy of deep pressure therapy in ASD.

Conclusion

We describe the design process, end product and evaluation of a compression chair to induce deep pressure therapy in ASD. This device would allow the user better control over the pressure and facilitate high quality studies to understand the rationale (role of proprioception) and efficacy deep pressure therapy in reducing anxiety in ASD.

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Conflict of interests

Alexia Audrain has intellectual properties and the original idea of the device.

Suplementary Materials

https://drive.google.com/file/d/1IwkissN50LsGPEHsXeC1Wzs2iML4uIMq/view
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Supplementary Files