TRACKING AGITATION AND EMOTIONAL REACTION THROUGH THE TULLY WEARABLE DEVICE

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ABSTRACT

The paper represents a report on a solution and technology validation study realized by Stressless SRL and Faculty of Psychology, Babes-Bolyai University Cluj-Napoca, through the Developmental Psychology Laboratory. The preliminary validation study was conducted over a 5 months period on a group of 15 children, out of which 10 were diagnosed with ADHD and 3 formed the typically developing group. The aim of the study was to test and validate an emotional and stress detection technological solution in the form of a wearable device, developed by Stressless SRL. The results of the study show that firstly that there is a clear difference between the behavioural reaction to stress of children diagnosed with ADHD and those in the typically developing group. Secondly that several biomarkers, specifically heart rate variability, galvanic skin response and movement intensity are valuable contributors to the realisation of a calculated general Agitation/Emotion Score, having a strong correlation with the observable agitation and hyperactivity. And thirdly, the study showed that the solution developed by Stressless SRL has a very strong predictive potential for the detection of high intensity emotional events.

INTRODUCTION

The ADHD disorder in children

Attention Deficit Hyperactivity Disorder (ADHD) is a neurodevelopmental psychiatric disorder, that is associated with higher levels of inattention, impulsivity and/or hyperactivity, which are not appropriate for a person's age, therefore affecting *two broad areas of executive functioning* – inattention and hyperactivity / impulsivity (Tavakoulnia, Guzman, Cibrian, Lakes, Hayes & Scuck, 2019). It can affect both children and adults and it is diagnosed during childhood, being persistent through adulthood. *According to the American Psychiatric Association* (2013), children with ADHD can be predominantly hyperactive, inattentive or a combined type between these two, the hyperactivity resulting in inability to control impulses and leading children to squirm, fidget or bounce when sitting (Ricci, Terribili, Giannini, Errico, Pallotti, Galasso, Tomasello, Sias & Saggio, 2018).

They often experience challenges in school as a result of this inability to control their impulses and maintain their attention. ADHD prevalence is different among countries, but it averages somewhere around 5% (Saval et al., 2017). In 2015 it was estimated to affect about 51.1 million people globally (Jiang, Xing, Zhang, Huang, Gao & Chen, 2019). Regarding children and teenagers, in 2011 *The Centers for Disease Control and Prevention* (CDC) showed that 11% of patients between 4 and 17 years are affected by ADHD in the US, as a result of the survey applied. Also, by using the diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders (DSM-V), it has been proven to affect about 5 – 7% of the children (Jiang et al., 2019). According to *adhd-institute.com*, it has been estimated that ADHD affects, globally, around 2.2% children and adolescents (<18 years), and around 2.8% of adults (with ages between 18 and 44 years).

In Romania, statistics from 2014 reported by the Government (2016) emphasize that 5015 children and adolescents are affected by this disorder, with 589 of them being between 0-4 years, 3744 were 5-14 years and 682 being over 15.

The benefits of diagnosis

Early diagnosis of ADHD can result in improving the performance of patients in different fields: education, career development and psychosocial development (Jiang et al., 2019). Regarding the diagnosis, there are different auxiliary methods that can be used, among which we can mention the following: *Clinical rating scaling*, *Cognitive-neurophysiology technology*, *Electroencephalography* (EEG) and *Brain imaging*.

There are different current existing methods for *ADHD alleviation*, most of them are trying to increase the engagement of the patient with the purpose of increasing the focusing skill (Alchalabi, Eddin & Shirmohammadi, 2017). Current strategies for treating children with ADHD focus primarily on *pharmacological treatments* as they decrease the symptoms for more than 80% of patients, but there are some limitations regarding the effectiveness of this way of treatment, as it does not include the adherence to behavioural treatments. Also, as Brown (2018) highlights in his article, **medication alone does not change behaviours**.

There is also a need for building academic skills, teaching social skills, emotional regulation or coping with anger and frustration. So therefore, a combination of methods and a collaboration between caregivers, schools and specialists can increase the quality of life for these children.

In the meantime, specialists are working to find new solutions for increasing the quality of life for people who are in these situations, so more can be read about different types of technology used in research, such as the use of brain EEG signals, cognitive training and multimedia digital games (see Alchalabi, Eddin & Shirmomahammadi, 2017).

Wearable devices for ADHD and more

Wearables refer to smart autonomous battery-powered measuring devices that are worn close to and / or on the surface of the skin and transmit information regarding the physical, behavioural, psychological or social activity of the user, based on different signals received from the body, mainly called **neurofeedback**. In the case of ADHD, neurofeedback focuses on reinforcing the behaviors and sensations associated with attentiveness.

Wearables have been used to monitor user's *metabolism* and *sleep patterns*, *physical* and *psychological stress* and / or *cognitive feedback* (Gersak, Vitulic, Prosen, Starc, Humar & Gersak, 2019). As of usage, wearables have been put to work in a number of fields, such as research, medicine and health management, professional environments, education and have been used as a tool for the detection of emotions and stress (Gersak et al., 2019). Another plus is represented by the fact that, as Schaefer et al. (2014) mentioned in their article, pre-adolescent children find wearables acceptable and are relatively compliant using them. Also, it is thought that young people represent enthusiastic recipients of digital technology and digital health interventions (DHIs) because they are hardened digital technology consumers (Johnson, Fuchs, Horvath & Scal, 2015). Furthermore, there has been a number of researchers who have worked on designing better and more accurate wearable devices, different games, applications and technologies to support the increasing need and overlapping of traditional methods.

On the other hand, current wearables are limited regarding their acquisition rate, do not always function in real-time situations as accurate as they should, are prone to errors, have limited energy autonomy, are dependent on environmental conditions and most of them are not validated by research studies. Despite these limitations, they have the capacity to work in real-life situations and would bring us more ecological results. Devices used until now take the form of *belts*, *glasses*, *bracelets* and some of them will be presented, summarily, in the next paragraph.

Examples of wearables

BlurtLine (Smit & Bakker, 2015) is an interactive belt designed to support children with ADHD in regaining control over their impulsive speaking in class situations, by monitoring the wearer's *breathing patterns*. After a certain intensity level is passed, it issues a signal by vibrating, making the child aware.

CASTT (*Child Activity Sensing and Training Tool*; Sonne, Gronbaek & Obel, 2015) is an assistive technology composed of a wearable band to measure the heart rate, accelerometers on the arms and feet to sense movement, an EEG headset and a smartphone, designed to help children with ADHD in regaining attention by using a quiz application that triggers simple mathematical questions, as to encourage the child to return to the task.

The Empowered Brain System (Vahabzadeh, Keshav, Salisbury & Sahin, 2018) is a combination of modern *smart glasses* and *educational modules*, composed of a *camera*, *microphone*, *touchpad*, *blink sensor*, *gyroscope* and *accelerometer*, targeting socioemotional and behavioural management skills.

WatchMinder presents itself as a watch-life device that allows the user to create discreet cues that remind them to do specific tasks. The task customization is made by the user. We can include an example such as receiving notifications for taking medications. Similar functionality is provided by other wristband devices such as Sqord or Re-vibe (FokusLabs, 2016) (Bieganski, 2017).

T.Jacket also gives the user reminders to perform certain tasks. However, unlike the WatchMinder, the current device is a jacket-like wearables clothing. The reminders are delivered via pressure applied by the jacket (like a hugging sensation; Bieganski, 2017).

Awareness as a form of monitoring and intervention in ADHD

While most of the wearable devices being designed with a target population encompass mostly people with autism spectrum disorder (ASD), these devices have the potential to provide the same benefits to children and adolescents suffering from ADHD. This type of device represents a useful tool in assessing, monitoring and intervention since it can be used in parallel with other intervention methods such as *cognitive behavioural therapy* (CBT) (Tavakoulnia et al., 2019). Monitoring physiological activity in children with ADHD may help them become more self-aware of their internal changes and emotions (Taj-Eldin et al., 2018). Moreover, providing a pattern of physiological and behavioural activation *may help in anticipating and predicting* when an episode of increased intensity would occur, as is the case with people with ASD (Taj-Eldin et al., 2018).

As for the intervention component, monitoring physiological activity can help parents and caregivers better understand the child's emotional states and what internal changes occur in this process, so they can help them implement suited coping and emotion regulation techniques (Taj-Eldin et al., 2018).

Wearables and this type of technology in particular (autonomous battery-powered measuring devices), can be employed for a better understanding of the physiological and emotional responses in real-time, which would increase the quality of task engagement, drive new trends in peer-to-peer interactions and increase the learning outcomes by inspiring a new form of pedagogy. Also, with the latest impact of adoption of internet and mobile technologies (especially in the current context of the health crisis) in most developing countries, wearable technology is a feasible solution to manage and monitor children’s task engagement.

METHODS

Research Design Overview

The aims of this paper are threefold:

- ***First***, to describe the testing and validation done on the emotion management technology solution developed by STRESSLESS SRL, the TULLY wearable device, through concurrent verification of biomarkers data information and human information data and through deep data analysis of un-labelled data
- ***Second***, to describe the process of creating the observational protocol, used in the testing sessions of children with specific manifestations of ADHD disorder;

- ***Third***, to provide new information for practitioners, but also as reference literature, regarding the wearable-type devices.

By creating this observational code, the research team (consisting of various specialists: psychologists, psychotherapists, researchers, research assistants and technology and data analysis specialists) aimed at using a wearable tool for monitoring the participants during the 4 test sessions and comparing the children's reactivity read by the bracelet with the one *read* by our observers. The psychology department of the research team had the task of developing the observational tool by choosing the right items, applying them in test sessions, choosing the right tests for the target population, preparing and analysing the data needed for the psychology aspects included in this report, while the Stressless team insured accurate data collection, processing and statistical and deep data analysis for the solution validation part of the report.

Wearable Device Description

TULLY is a Patent Pending battery powered wearable device in the form of a bracelet, worn on the wrist. It is designed to provide a tool for emotion recognition and management. It offers an "external observer" input and an early warning signal, helping children learn to identify and control high intensity emotional manifestations. Tully integrates an optical PPG sensor, an accelerometer, a contact-based galvanic skin response sensor and an embedded temperature sensor and continuously monitors a set of physiological and movement indicators, including heart rate (BPM), heart rate variability (HRV), blood oxygen concentration (SpO_2), skin electrical conductivity – galvanic skin response (GSR), temperature (T) and movement (A). Data is processed and stored locally on the device, on an embedded flash memory chip and accessed through USB as a mass storage device. Using all this input Tully's algorithm calculates an Agitation Score, interprets the stress levels and alerts the wearer when an emotional flare becomes imminent, guiding the child, through biofeedback, back to calm state.

TULLY was developed by the lead partner in this research project, SC STRESSLESS SRL, over a 3 years period, between 2017 and 2020.

First Phase of the Preliminary Validation Study

During the first phase of the testing the main instrument used was the Developmental Neuropsychological Assessment (NEPSY; Korkman, Kirk, & Kemp, 1998) is a child friendly assessment battery divided in five functional domains (attention and executive functions, language and communication, sensorimotor functions, visuospatial functions, learning and memory) used to assess neuropsychological functioning in children aged 3-16 years old.

In order to have a complex perspective over the main characteristics of ADHD there have been four sessions during the first phase of this study including both structured and unstructured tests, but also individual and group activities (2 children).

Session one had four structured tests from NEPSY: design copying, visual attention, narrative memory, visuomotor precision which lasted for approximately 30 minutes.

This session started with *Design Copying*, a subtest of visuospatial processing. Children had to copy a 2-dimensional design as good as possible. The subcomponent assessed include inductive visual reproduction.

The session continued with a subtest of attention and executive functions – *Visual Attention*. Firstly, children had to draw a line over every cat they saw on the page. The page has multiple elements on it: flowers, dinosaurs, faces, rabbits, trees, apples, houses, trains, and so on. Secondly, children had to draw a line over two faces with specific characteristics they saw on another sheet with multiple faces expressing different facial characteristics. The subcomponents assessed include selective and sustained attention.

The third type of activity is a subtest of learning and memory – *Narrative Memory*. Children had to pay attention to a short story and then they had to tell the story back using the same words. If they struggled to remember part of the information, they received help twice. If they didn`t remember all the information required, they received more helping questions in order to fill in the gaps. The subcomponents assessed include descriptive memory under free and cued-recall conditions.

The last activity of this session was a subtest of sensorimotor functions – *Visuomotor Precision*. Children had to reach destination in two mazes without lifting the pencil from the paper and without exceeding the contour. The subcomponents assessed include fine motor speed and precision.

Session two had three unstructured tests: mathematical calculations, text transcription and a puzzle of 70 pieces and lasted for approximately 30 minutes.

This session started with *Mathematical Calculations*. Children had to sum or extract from 14 given exercises. They had to solve only those exercises they knew – they have previously learnt at school. The components assessed include sustained attention processes and inhibition of prepotent responses.

The session continued with *Text Transcription.* Children had to copy a verse from a popular poem studied at school. The components assessed include monitoring and self-regulation, but also sustained attention processing.

The last activity of this session was to assemble a *puzzle of 70 pieces* without seeing it before. The components assessed include recognition of part-whole relationships and visual orientation.

Session three had five structured tests from NEPSY: memory for names, auditory attention and response set A+B, design fluency, sentence repetition and long-term memory of names and lasted for approximately 45 minutes.

This session started with memory for names, a subtest of *Memory and Learning*. Children had to listen and pay attention to eight pictures of different children faces and memory their names. Then, they were asked three times in a row to remember their names without any help. The subcomponents assessed include working memory and immediate recall of simple stimuli.

The second type of activity was auditory attention and response set A+B, a subtest of *Attention and Executive Functioning*. Firstly, children had many coloured squares and had to put into a box a red square when heard "red". They also had to ignore any other words (colours) they heard and just do nothing. Secondly, children had the same colored squares in front of them and had to put into the box a yellow square when they heard red, a red one when they heard yellow and a blue one when they heard blue. Again, they had to ignore any other words they heard and just do nothing. The subcomponents assessed include selective and sustained attention, the inhibition of prepotent responses and monitoring and self-regulation processes.

This session continued with design fluency, a subtest of *Attention and Executive Functioning*. Children had to draw different shapes joining at least three out of five dots, having structured areas but also, unstructured ones. The subcomponents assessed were selective and sustained attention processes, creativity and nonverbal problem solving.

The fourth activity was sentence repetition, a subtest of *Memory and Learning*. Children had to repeat different sentences after the instructor. The sentences had increased levels of difficulty, starting from short, simple sentences like "Good night." and finishing with long, complex ones like "Next Wednesday at 2 PM our soccer team will play a game on the stadium". The subcomponents assessed include working memory and immediate recall of simple and complex stimuli and repetition.

The last activity of this session was long term memory of names, a subtest of *Memory and Learning*. Without any help, children had to remember the names of the eight children presented at the beginning of this session, 30 minutes earlier. The subcomponents assessed include working memory and delayed recall of simple stimuli.

The last session was a group session including two children playing together four types of unstructured activities: Tower of Friendship, Word Memory, Jenga and Guess What It Is. This session lasted for approximately 30 minutes.

Children started with the game *the Tower of Friendship*. Every child received a pair of shoelaces tied to the elastic. They had to build a pyramid out of the six plastic glasses they picked up together from the floor with the shoelaces. The game was over when they built the pyramid. There are no winners or losers. The subcomponents assessed include verbal and behavioural inhibition, sustained attention, hand dexterity, fine motor precision and problem solving.

This session continued with *Word Memory Game*. One of the children had to say a word, any word, and then the other one had to recall that word and add another one and so on. They had to recall and add as many words as possible. The game ended when they couldn`t remember the words they have said before. There are no winners or losers. The subcomponents assessed include sustained attention, phonological processing and decoding, expressive and/or receptive labelling of common objects, working memory and immediate and delayed recall of simple stimuli and repetition of words.

The third group activity was *Jenga*, a well-known game among children and adolescents. Children had to build a tower from wood, colored pieces and then extract one after one and put it over the top of the tower. When the tower falls, the game ends. There are no winners or losers. The subcomponents assessed include inhibition, vigilance, sustained attention, planning and problem solving.

The last activity of this session was the game G*uess What It Is*. Children were blindfolded one by one and had to draw what his/her colleague told them to, but only using words to describe the object without saying its name. The game ended when they finished the drawing. There are no winners or losers. The subcomponents assessed include hand and finger dexterity, fine motor speed and precision, comprehension of oral instructions, inhibition and spatial orientation.

Observational protocol - Tool Creation, Item Source, Customization for Task

The observational code used in this report study is based on noting the frequency of occurrence for a given event. The observation was made for a period of 30-40 minutes, depending on the tasks performed by the children. The tool consists of *30 items* divided into 4 categories (*interaction with the evaluator, motor activity, verbal behaviours, relationship with the task*) for an easier item categorization of several behaviours with simultaneous occurrence and efficient rating during the observation procedure (too see the instrument, check *Appendix1*).

Items were formed with a specific operationalization in the context of the applied tasks, insisting on the observable behavioural manifestations. In an initial form, the toll had 3 main categories (inattention, hyperactivity, impulsivity) a categorization made after the 3 clusters of symptoms specific for ADHD, according to the DSM-IV manual (APA, 2013).

Tool creation and the source of the 30 items

- *Vanderbilt Assessment Scale (VAS)*

Given the nature of the *NEPSY tests* (Korkman, Kirk & Kemp, 1998) and the behavioural tasks used in these experimental sessions (testing executive functions: motor, working memory, attention, etc.), we wanted to include in the observational code items that specifically follow the child's interaction with the tasks, as well as his reaction. *Vanderbilt Assessment Scale* (VAS) is a parent and teacher rating tool of Attention-Deficit/Hyperactivity Disorder created in 2002 by the American Academy of Pediatrics (AAP) and the National Initiative for Children's Healthcare Quality (NICHQ; McGoey, DuPaul, Haley & Shelton, 2007). The scale has good psychometric properties with a Cronbach's alpha coefficient of > .90 (parent) and >.89 (teacher) (Wolraich et al., 2002; Wolraich et al., 2013). It's been proven that the teacher scale correlates highly with a diagnosis of ADHD (Austerman, 2015). From the rating for teacher's assessment (teacher informant), we took over the following items, which we considered to be congruent with the possible manifestations within the sessions:

Nr 2. "Has difficulty sustaining attention to tasks or activities" but more specifically, we divided this item into two observable behaviours: distracted by external stimuli and unfocused, searching look.

Nr 4. "Does not follow through when given directions and fails to finish activities (not due to refusal or failure to understand)" which we divided into 2 items: he/she does not do what is asked of him/her and the lack of completion of the task.

Nr 8. "Is easily distracted by extraneous stimuli"

Nr 10. "Fidgets with hands or feet or squirms in seat" which we divided into 3 items: fidgets with hand, kicks his / her legs or fidgets with feet and changes position/ squirms in seat.

Nr 11. “Leaves seat in classroom or in other situations in which remaining seated is expected” customized as “he/she stands up, when remaining seated is expected”.

Nr 12. “Runs about or climbs excessively in situations in which remaining seated is expected” customized as “he/she walks around the room, when remaining seated is expected”.

Nr 15. “Talks excessively” to which we added: “Talks excessively and fast”.

Nr 16. “Blurts out answers before questions have been completed” which we simply put as “talk over the evaluator”.

We think that is important to mention that all the taken items were rated on a Likert scale, instead we only used their training to observe the frequency of a behaviour.

- *Child Behaviour Checklist (CBCL)*

We also created task-specific items, being inspired by *Child Behaviour Checklist—Parent and Teacher Report Forms*, instrument included in the Manual for *ASEBA* school-age forms & profiles (Achenbach, 2001). A recent study of anxiety and ADHD symptoms in children with ASD by Llanes, Blacher, Stavropoulos & Eisenhower, (2018) mentioned that the CBCL has good psychometric properties, showing strong discriminant and predictive validity as well as construct validity with BASC-2.

We studied the ADHD items from CBCL (nr 2. “Inattentive”, nr 3. “Can’t concentrate”, nr 4. “Fidgets”, nr 5. “Can’t sit still” nr 6. “Impulsive”, nr 8. “Falls to finish”, nr 12. “Unusually load”, nr 13. “Talks too much”) and we decided to add the following items to our list: he/she swings from the front to the back, he/she raises the tone, he/she jumps or slams into the chair, he/she skips steps in the task.

- *Other tools taken into consideration (HPC – D) and (VWU)*

We looked at other common behavioural assessments used in practice by the psychologist on our research team such as *Questionnaire addressed to parents regarding behavioural problems during homework (HPC – D)* and *Behaviour during psychological evaluation (VWU).* From the first tool *(HPC – D),* we searched items of interest such as “7. Premature interruption of the task, 10. Dreams / plays during tasks, 11. Slightly distracted by noise / other stimuli, 14. Needs a long time to complete homework or 17. Finishes too fast”. This tool is presented in the manual “*Copilul hiperactiv si incapatanat*” or “The hyperactive and stubborn child” (Dopfner, 2004), book addressed to parents, educators, psychologists, psychotherapists and teachers offering support in educating children with hyperactive and oppositional behavioural problems.

It is notable that some concepts are also found in the other instruments presented above and most of the descriptions did not represent a concrete operationalization, so we created the following: he/she plays with his/her hands, he/she plays with the objects around him/her, change the pace of task execution.

From the second tool mentioned (*Behaviour during psychological evaluation),* we noticed that the assessment insists on things like: motor skills, distractibility and concentration, cooperation, adult attention-grabbing behaviour, understanding instructions, working speed, frequency of evaluator interventions. This instrument is part of the book "*Program terapeutic pentru copiii cu probleme comportamentale de tip hipercibernetic si opozant*" (THOP) or "Therapeutic program for children with behavioural problems of hyper-cybernetic and opposing type" (Dopfner, Schurmann & Frolich, 2010), a program that combines therapeutic strategies and integrates them into family, kindergarten and school interventions. As a result, we introduced the following items: *Fine motor agitation* (which includes fine movements such as: finger movement, touching the face, scratching), *Change the subject of the discussion, Asks for rehearsal or repeats what it was told, Asks for reinsurance* and *Interventions from the evaluator.*

Customization for Task

- *Before applying the observational code – A priori*

Before starting the tasks and making the observation within them, the research team also thought about the *appearance of other possible behaviours* during the tasks and the interaction of the children with the relevant materials. Considering the experience of the clinical psychologist (member of the research team) with children with ADHD and the mentions brought by her regarding some specific manifestations within this specific practice context, we decided to include in the observation list the following items: *blinks repetitively, emits various sounds, describes what he/she is doing, invades the personal space of the evaluator, throws objects*. The application of these items has proven to be useful in practice, having a high occurrence in the context of performing tasks that test executive functions and that require the use of cognitive load.

- *After applying the observational code – First session*

In an **initial meeting**, involving *two children*, two observers noted the children's behaviour using the observation items selected, and coded behaviours based on an early draft of the legend, which describes the behaviours encompassed in the items presented in the grid.

The **discrepancies** have only appeared at the level of categorizing the behaviour or including new behaviours in the existing items. After these dissimilarities were addressed and corrected, the revised legend was being used thenceforth in coding the behaviours and the observation grid applied by only one observer. Also, during the first session, **new behaviours** were observed that did not belong to the list of items. The *necessary changes were made* after a discussion with the clinical psychologist and the entire team. So, **3 final items** were introduced: *inappropriate comments, he/she contorts in unusual positions, he/she hits the furniture.*

Intensity scaling (used for comparison of the reactivity recorded by the bracelet)

After the observational code has been revised, each element was assigned a certain **weight**. In this process, the two observers together with the therapist each assigned weights separately from one another. They were instructed to take into account the way all ten children behaved during the four sessions, making use of the existing recordings when necessary. The clinical psychologist (the therapist) offered advice on the items in the scale that represent a typical manifestation of ADHD in an order of specificity. The agreement between members was high, with only a few numbers of items having assigned different weights. The discrepancies occurred only between two members and were resolved by discussing the reasoning behind every member's choice and ultimately agreeing on a single weight to be used.

Thereby, **3 types of weights** were decided, **weight 1** is assigned to items of items of low intensity in terms of hyperactivity or impulsivity (eg. fine motor skills); **weight 2** is assigned to items of items of medium intensity, having a lower recurrence but a greater magnitude in terms of disturbance of tasks by impulsivity (eg. change the subject of discussion); and **weight 3** is assigned to items of high intensity, items that require significant energy consumption and that are very specific to the manifestations of hyperactivity (eg. he/she walks around the room).

The actual intensity of each behaviour was also estimated on a 1-4 scale, where 1 corresponded to very low intensity (for example for No. 10, Fidgeting, corresponding to only fingers' movement) and 3 to the maximum intensity observed (for Fidgeting would be full body fidgeting); 4 was reserved for behaviours that were conducted in a continuous manner at high intensity, over the course of at least one full minute.

The sum of the behavioural items, weighed by their impulsivity related strength, was defined as the "Agitation Score" (AS), and used as comparison basis with the data generated by the wearable device. Additionally, in order to capture very rare (one apparition) but high impact behaviours that were not included in the standard items, an extra 5 points was added to the (like "the test subject left the room") was added to the Agitation Score.

Setting and data collection

We applied the observation code in all four conducted sessions, with a length of *30 minutes* for the first two sessions, and *40 minutes* for the next two. The observation involved one observer being a member of the setting in which the sessions took place. Before the sessions began, the children were introduced to the observers, who were presented to them as student practitioners whose purpose was to learn and take notes on the way the therapist was to conduct the activities.

The participants have been placed a wearable device on one wrist and had to wear it until the end of each session. The child was left alone with the therapist and the observer, while his parents were waiting in the next room. The observer was placed facing the child, who was sitting on a sofa, while the therapist was sitting in an armchair, placed to the right of the child. A camera was placed facing the child in order to record the sessions. Each parent gave his consent for his child to be filmed by signing an agreement.

The observers were instructed to note every behaviour displayed by the children by drawing a straight line in the checkbox assigned to a particular behaviour and minute since the probe began. A signal given by the therapist informed the observer to start the chronometer at the beginning of the session; if the time expired and the child was still performing the task, the observer signalled to the therapist that they should end the session. If the child became very agitated and aggressive or repeatedly asked to return to his parents, the session was interrupted by the therapist.

Second Phase of the Preliminary Validation Study

The second phase of the study involved collected un-labelled behavioural information during at home activities. The children that completed the 4th exercise in the First Phase were included in this one, and were given a device for use at home. They were instructed to use them during online school or homework. The Agitation Score, calculated based on the Tully algorithm, was used compared with a set of Baseline value, estimated during the first session with the device, when measurements were done for a minimum period of 30 minutes of complete calm, under the supervision of the parents. The following sessions were evaluated comparing the Agitation Score with the average and the +1 Standard Deviation values of the Baseline Agitation Score.

In addition to the Baseline AS we also implemented two measures to evaluate the emotional level – we asked the parents to observe their children's behaviour whenever possible and fill up the observation sheet. We also modified the device, adding an alert button and asking the children to press it when they fill emotionally overwhelmed. However these methods generate inconclusive results because of the rare use and uncertain timing (for the parents' observations) and because of the incorrect use for the children's self-alert (either almost continuous pressing or almost complete ignorance of this action).

Study Participants

To carry out the study, participants were included in the study if they were children ages between 6 and 14 and they had a diagnostic of ADHD. Their parents were asked to confirm that the children had been fully assessed and diagnosed prior to this study, providing the latest medical report where the diagnosis was given. A number of 20 children diagnosed with ADHD were initially recruited from different schools from Cluj County, but because of the COVID-19 Pandemic situation some of them dropped out from the study. 12 children started the study in Phase 1 and 10 children (male to female ratio 8:2, mean age 8.60, range 7-12 years, standard deviation 1.713) completed all 4 tests within Phase 1 and participated also in Phase 2. Two of them were on medication but were not taking medication when the data was recorded, except for the first session, and eight of them were not taking any medication for ADHD, even if prescribed. Six of the children present comorbidities and were diagnosed with other disorders besides ADHD: Oppositional Defiant Disorder (2 children), Unspecified behavioural and emotional disorders with onset usually occurring in childhood and adolescence (1 child), Mathematics disorder (1 child), Autism Spectrum Disorder (1 child), Specific reading disorder (1 child), Anxiety Disorder, unspecified (1 child), Mixed disorder of conduct and emotions (1 child). During Phase 2 we added data from 3 typically developing group subjects, children without any condition diagnosed or identified – male to female ratio of 1:2 and ages between 11 and 14 years old, in order to add an additional comparison data point.

PRELIMINARY VALIDATION STUDY DATA

Study details

The study was realized over the course of a 6 months period, between July and December 2020, as follows:

- During July – August we developed the final version of the study plan, created the 4 tests, and recruited the participants
- In September we realized the on-boarding of the participants, prepared and signed the necessary documentation and went through the first two pilot testing sessions
- October – November covered the first phase of the study. We realized a total number of 38 sessions, totalling 18 hours of data
- The first data analysis was realized during the first week of December, and the second phase of the study started immediately afterwards, took place for two weeks, until the 20th of December, and generated over 245 hours of data.

Data collection and processing details

We extracted BPM, SpO2 and sympathetic (LF)/parasympathetic (HF) nervous system response information from the Photoplethysmogram recorded by the optical sensor. De-trending and de-noising the raw input data was done in real-time through real-time multilevel discrete wavelet decomposition/recomposition. The on-board accelerometer was used to help filter out unfavourable samples and record high motion excursions. This system yielded a net processed data point density of around 3-4 points per minute.

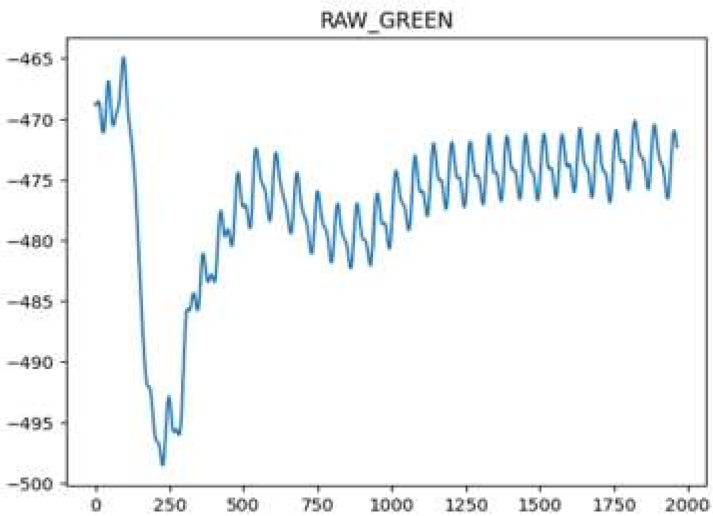

Figure 1

Figure 1 shows a raw PPG signal for a 20 second capture window.

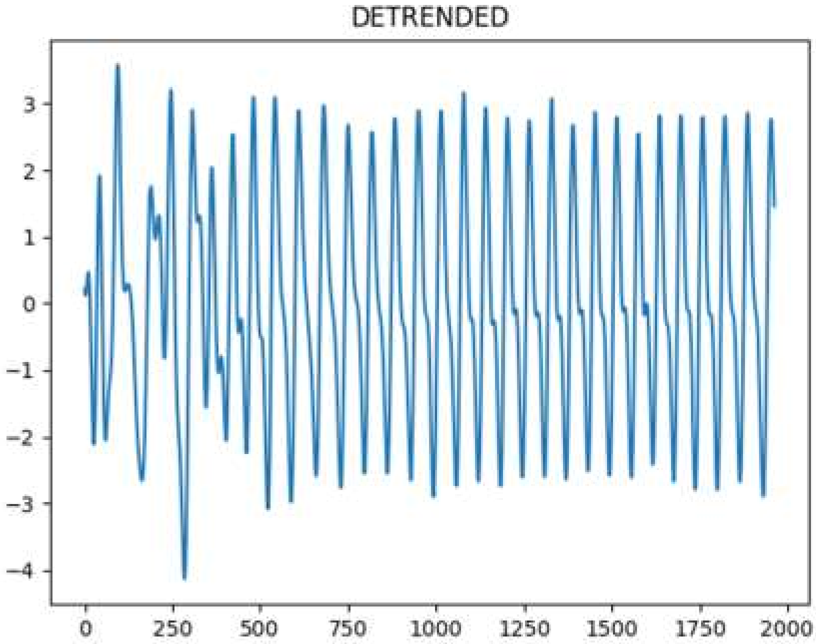

Figure 2

Figure 2 shows the same raw data, but de-trended.

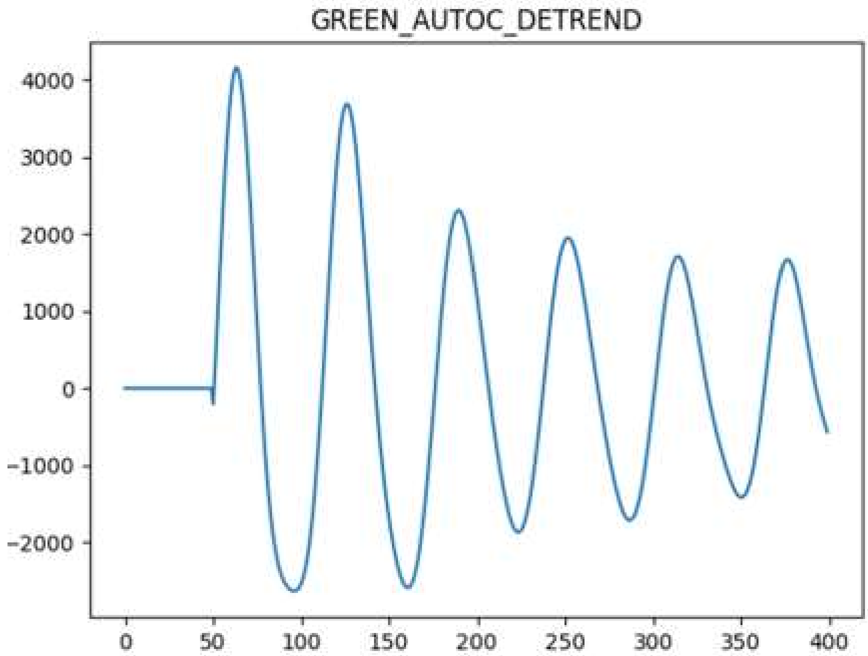

Figure 3

Figure 3 shows the strong autocorrelation of the de-trended signal corresponding to the measured heart rate and its frequency harmonics.

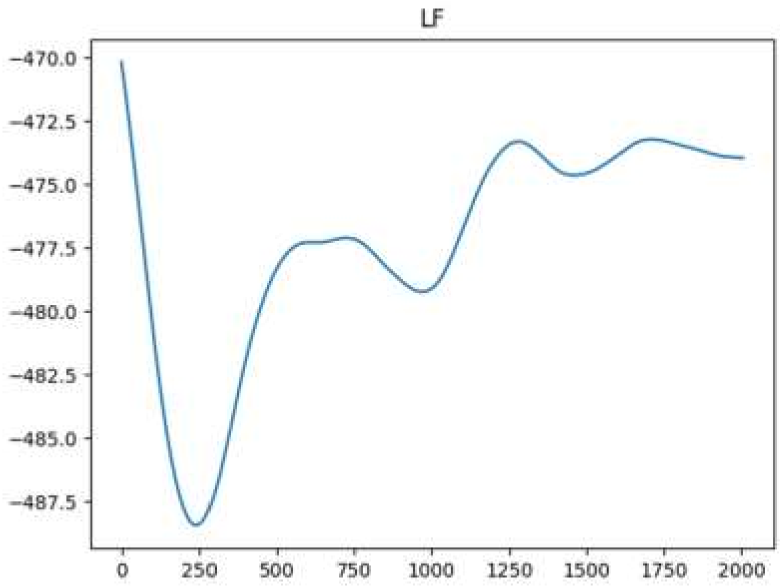

Figure 4

Figure 4 shows the low frequency content of the PPG (sympathetic nervous system response) as recomposed by the wavelet analysis stage.

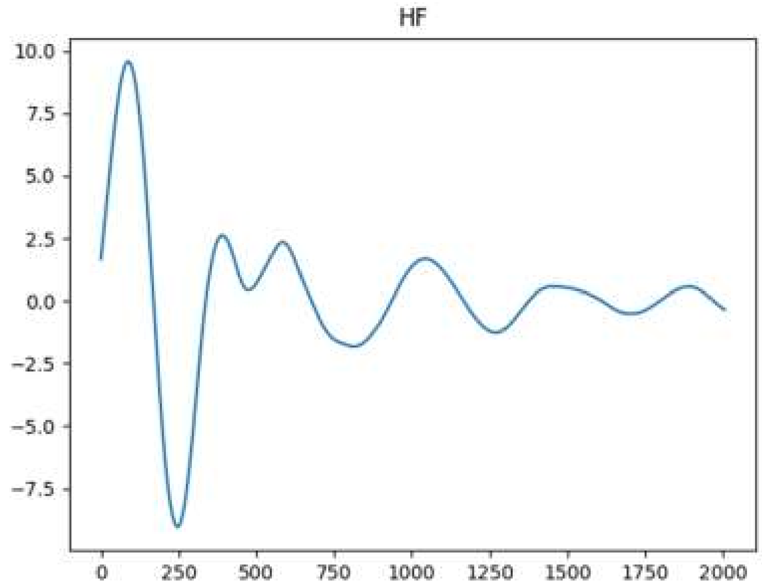

Figure 5

Figure 5 shows the HF (parasympathetic nervous system response) as recomposed by the wavelet analysis stage. In our analysis we used the ratio of HF to LF components as an indication of heart rate variability.

Data analysis

Good level of correlation were evident between the observed agitation levels and the HRV indicator. Figure 6 shows a convolution of the HRV data against the original observed agitation levels. It is also visible that the HRV indicator can serve as a rough indicator for the raise in observed agitation, as both agitation peaks were preceded by increase in the HRV calculated levels (outside the graph for the first peak).

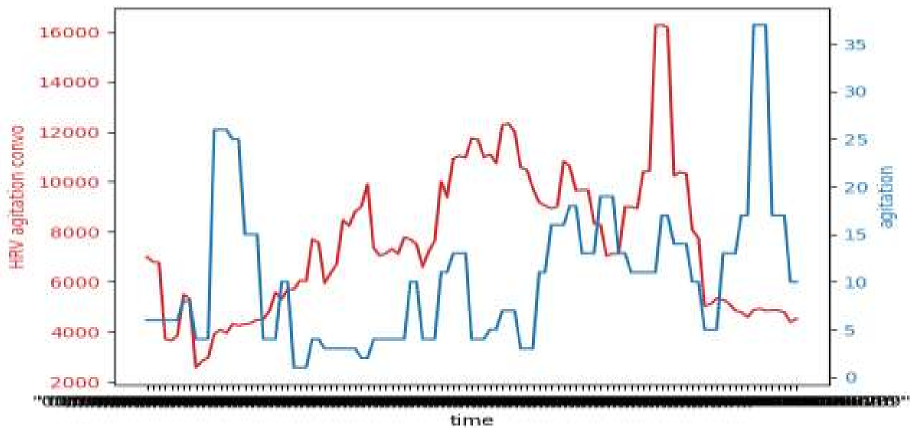

Figure 6

The GSR signal manifested increased variation tracking very closely the timing of recorded stress. Figure 7 shows the levels of GSR variation and that of the observed levels of stress/ agitation. All the AS spikes deviating from the blue agitation line are very closely followed by the GSR indications, but because they happen almost simultaneous, this biomarker, although valuable in the composition of the Tully algorithm, is not sufficient for a stress indication by itself.

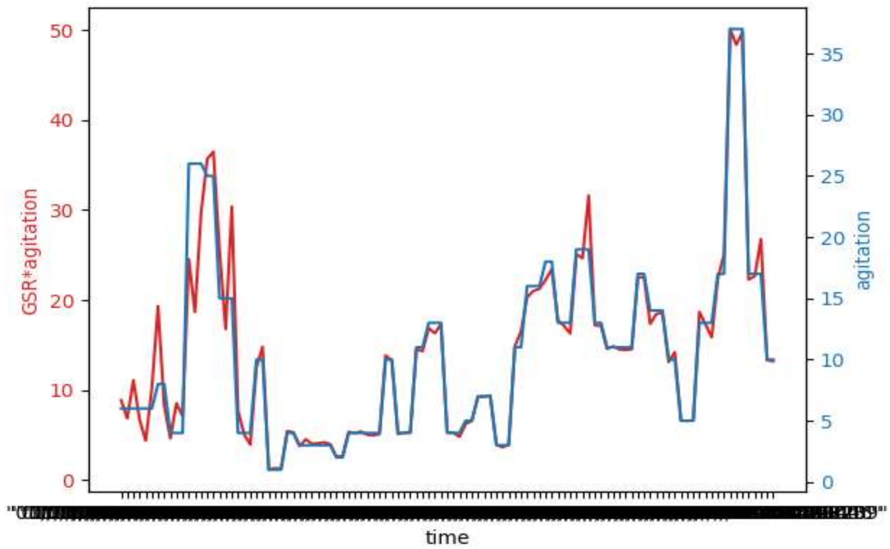

Figure 7

Similarly, the motion sensor also showed a promising indication of stress levels (figure 8), marking its value in the algorithm composition.

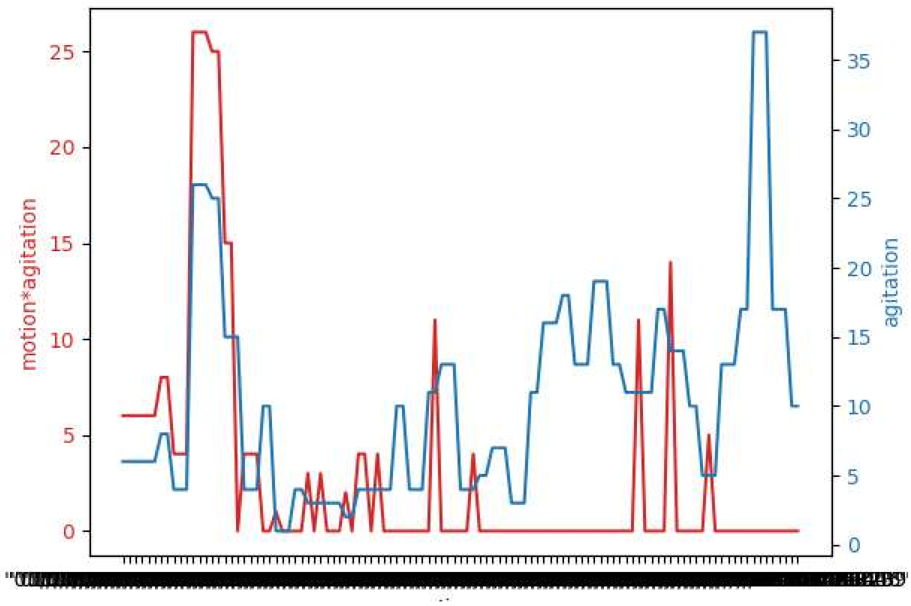

Figure 8

When we analysed at the covariance matrixes of the HRV (Figure 9), GSR (Figure 10) and Motion Data (Figure 11) strong correlation was identified at approximately the same lags.

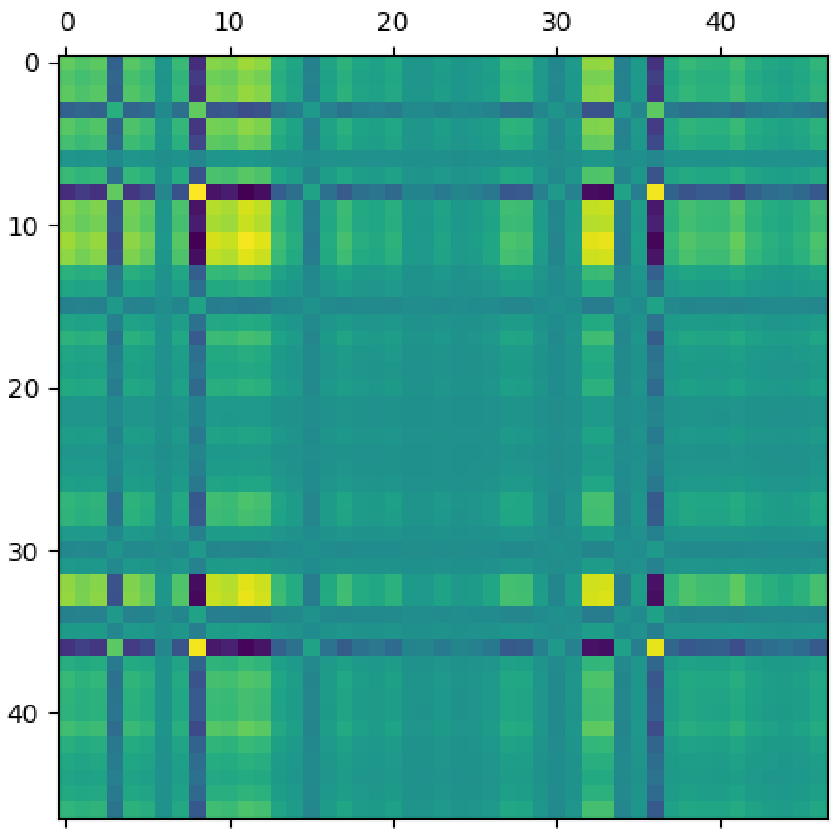

Figure 9 - Covariance matrix of HRV and observed agitation)

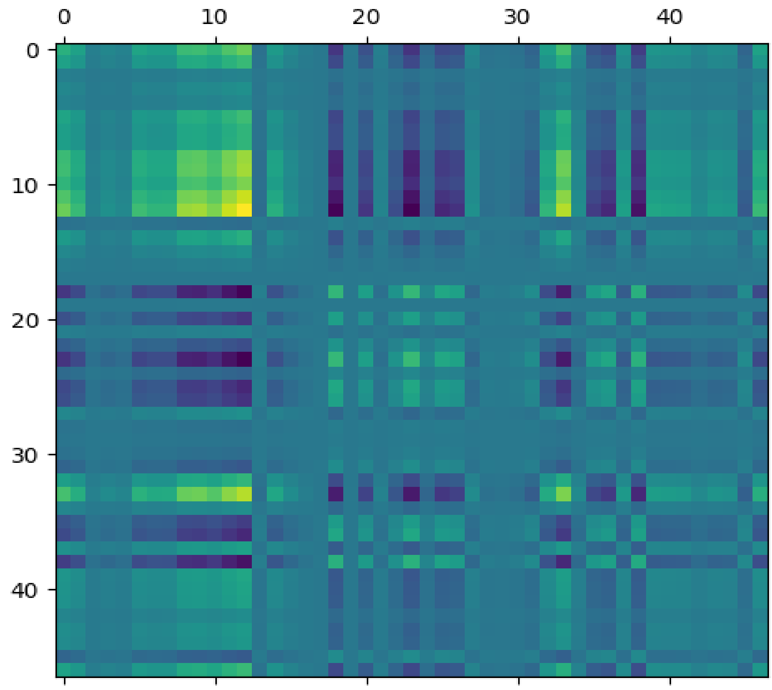

Figure 10 - Covariance of GSR and observed agitation

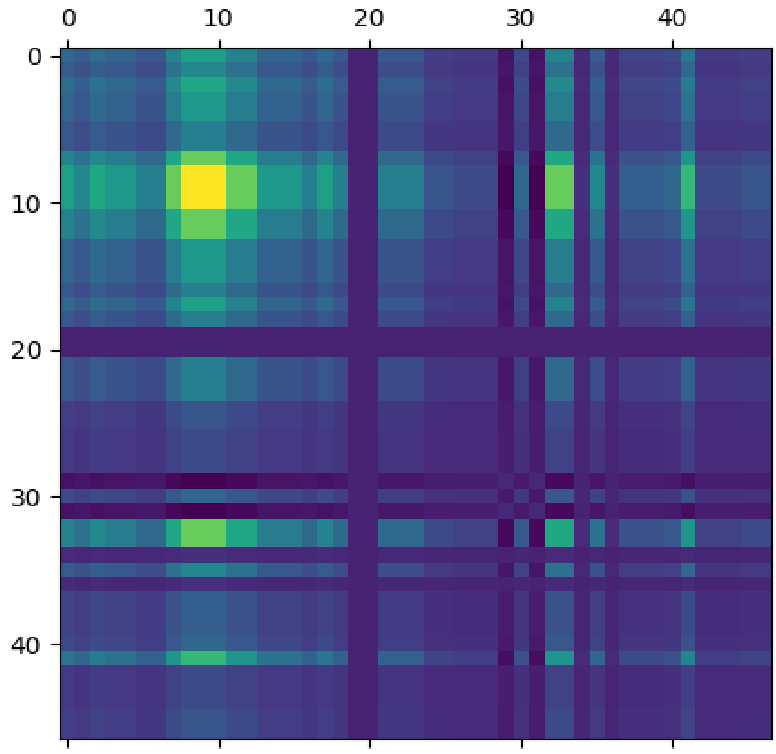

Figure 11 - Covariance of motion and observed agitation

Moving forward, we analysed the AS (Agitation Score), based on statistical inferential analysis of our data. While the exact details of the algorithm, a cross product of all biomarkers collected, are confidential information, the major contributors to it are HRV, GSR and motion data. Plotting this indicator in Figure 12, we were able to observe that Agitation Score (blue line) varied by at least one standard deviation at moments of peak observed agitation (green line). The following 4 graphs (12a – 12d) show the very strong predictive abilities of our algorithm in the case of 4 different users and tests, observed during the study's Phase 1. Also one case of time displacement of the indicators is visible in figure 12a, which could have appeared due to the somewhat subjective evaluation of the observed agitation and also to the fact that the time interval of data collection was very different between the biomarkers that form the basis of the AS calculation (one reading at 10-20 seconds, depending on actual physiological indicators' intensity) and that of the agitation observed by the research assistants (one reading at approximately every minute).

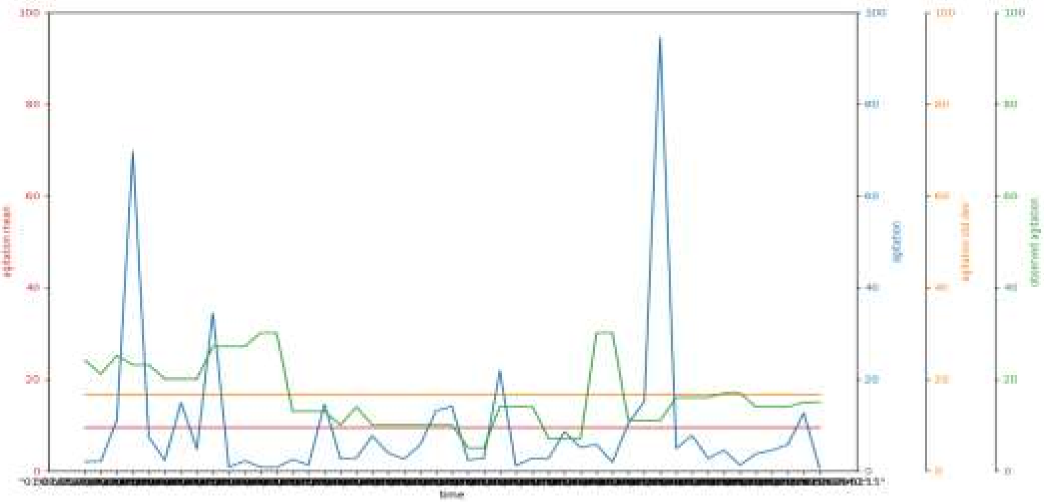

Figure 12a – AS and observed agitation over time in the case of one specific user and test

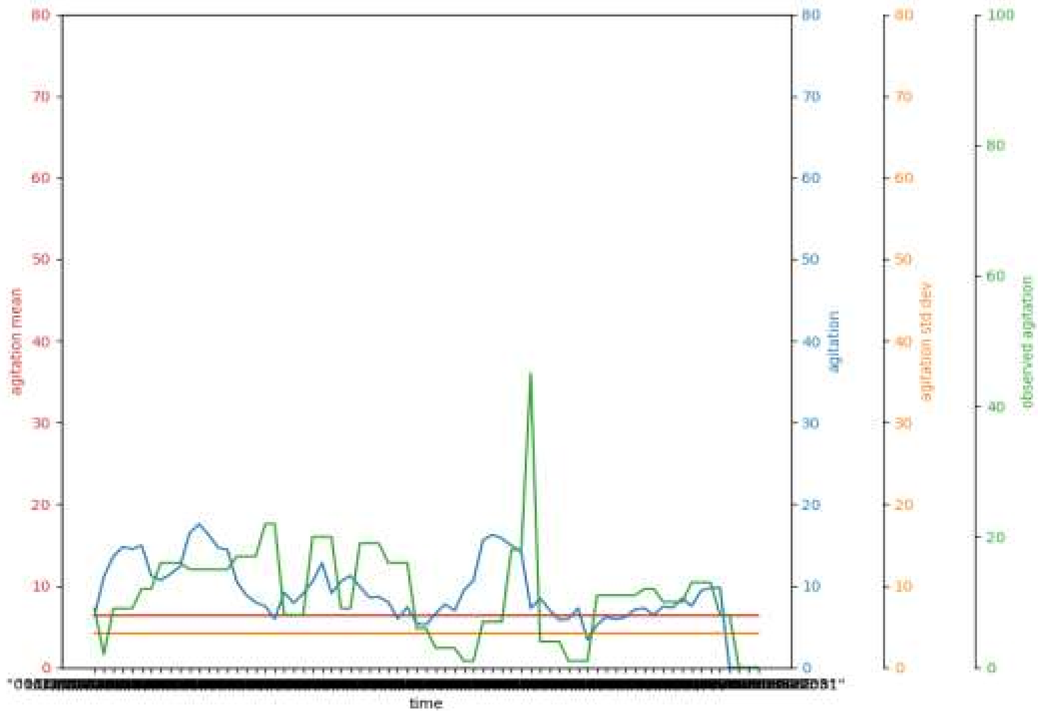

Figure 12b – AS and observed agitation over time in the case of a second specific user and test

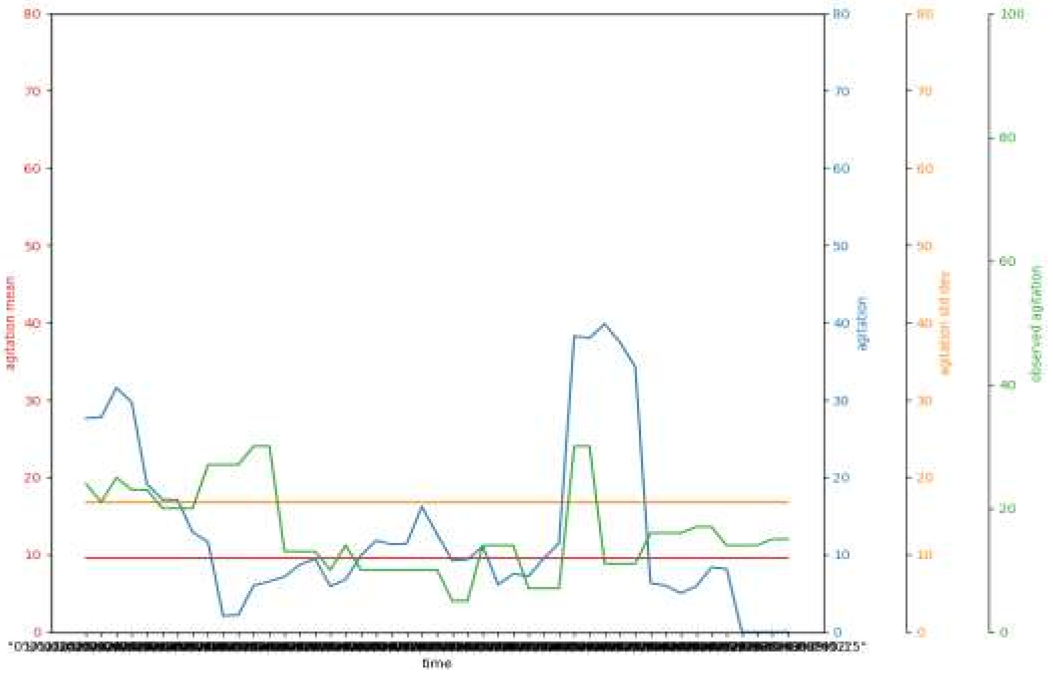

Figure 12c – AS and observed agitation over time in the case of a third specific user and test

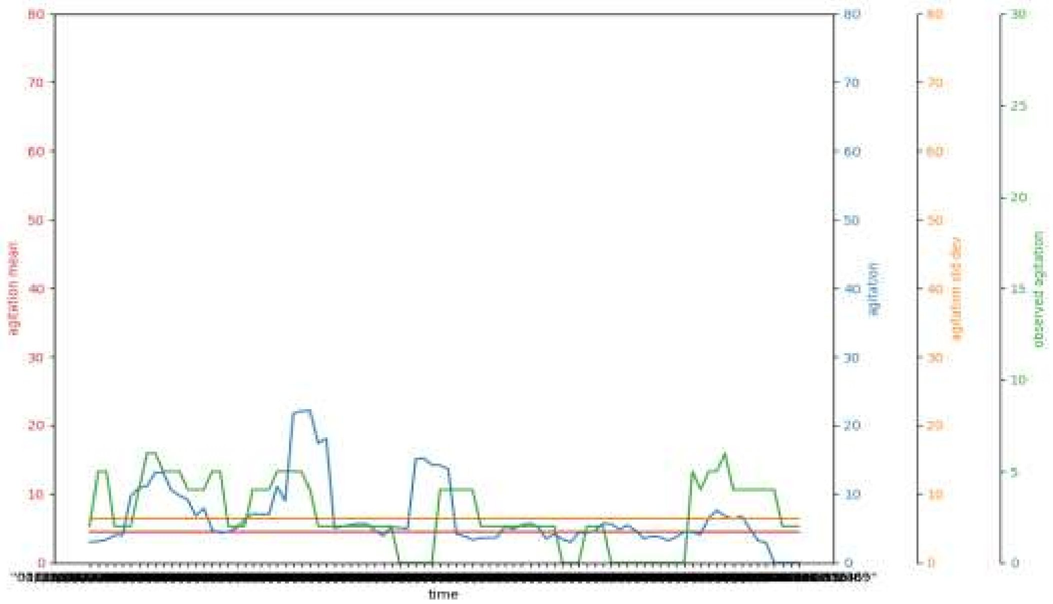

Figure 12d – AS and observed agitation over time in the case of a fourth specific user and test

Calculating the Agitation Score is however only the first component of the Tully detection algorithm. It also includes an adaptive baseline estimator on a case-by-case basis, and the algorithm is calibrated based on a known period of "maximum calmness and restfulness". In addition to this, instead of a cross product of sensor data, the complete algorithm uses a bounded time-lag cross-correlation with lag bounds chosen so as to not exceed a reasonable interval for agitation onset. For the analysis of the Phase 2 of this study a lag bound of 60 seconds was chosen.

An additional input come from a secondary calibration of the baseline standard deviation over a period of a few minutes at the beginning of each session, when the user is at their most calm moment, and to constantly compare this baseline value with the initial “maximum calmness” data and to update it as necessary. The following graphs show the high intensity emotional events registered by the wearable device (the peaks in the AS line), over an extended period of intellectual challenge and mental stress of 2 to 5 hours, during online school. The graphs illustrate 4 cases of users diagnosed with ADHD and 2 users from the typically developing group.

For all users diagnosed with ADHD (Figures 13 – 16) there are multiple excursions of the AS indicator crossing the agitation alert threshold, set at one standard deviation from the mean of the baseline AS indicator (orange line) and also the analysis AS threshold, set at the mean of the Agitation Score for each session (red line).

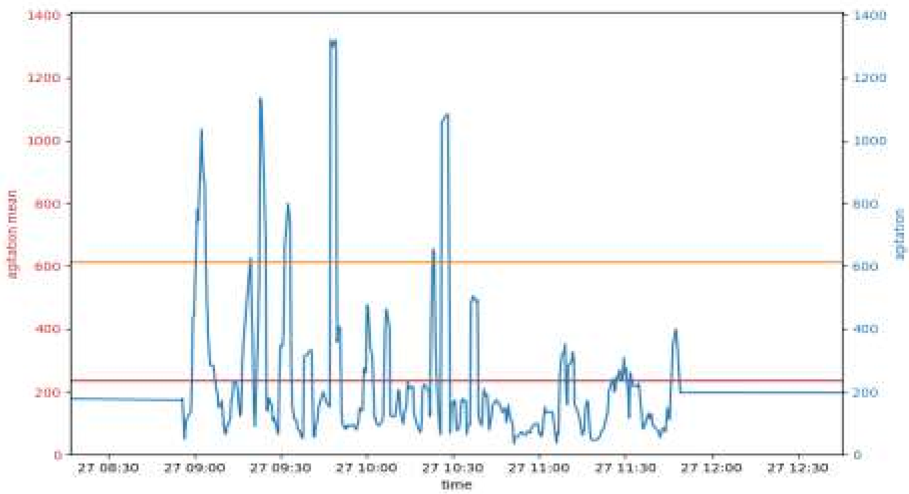

Figure 13 – AS evolution for a user diagnosed with ADHD

Figure 14 – AS evolution for a user diagnosed with ADHD

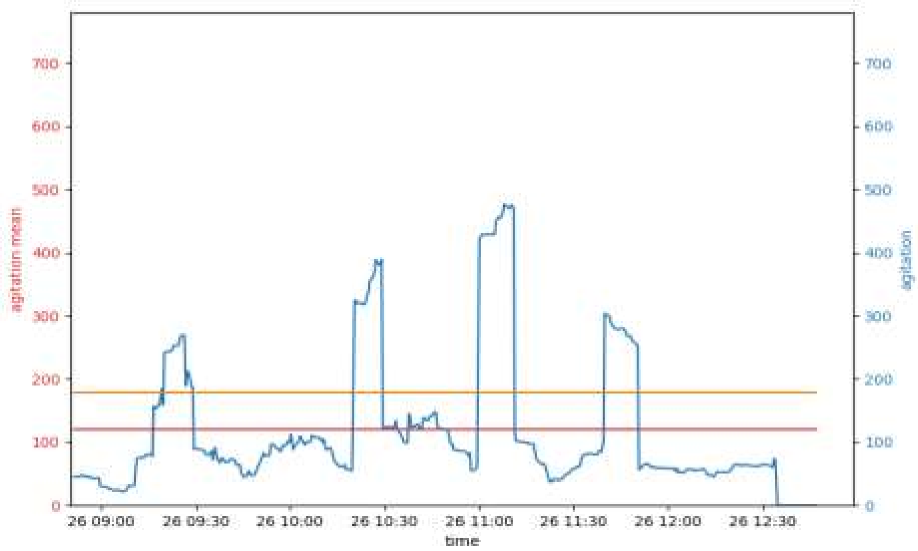

Figure 15– AS evolution for a user diagnosed with ADHD

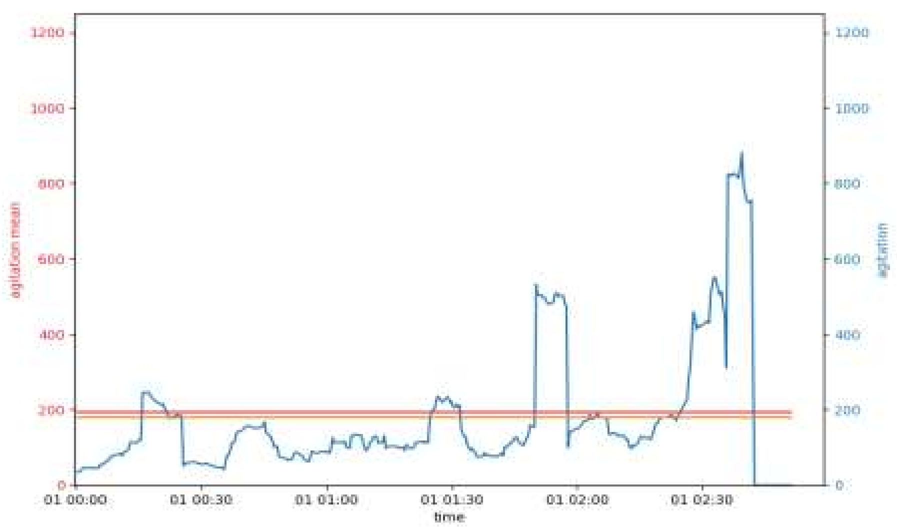

Figure 16 – AS evolution for a user diagnosed with ADHD

Among the above figures, a specific situation is visible in Figure 16, where not only the AS peaks, but also the mean of the entire session is above the alert threshold, the baseline +1 standard deviation AS, indicating extremely high intensity emotional response from the user, and clearly visible escalating trend of their emotional state.

The users in the typically developing group (Figures 17 and 18) show no similar excursions above the 1SD alert threshold. One of the users' data (Figure 17) show some variation over the course of the 5 hours of the session, which, according to information received from their parents is explainable by unusual stressing school activities (multiple tests and/or oral examination) but even in this case the AS level is clearly below the alert threshold. In the other presented session (Figure 18) the AS is actually mostly below the average baseline value.

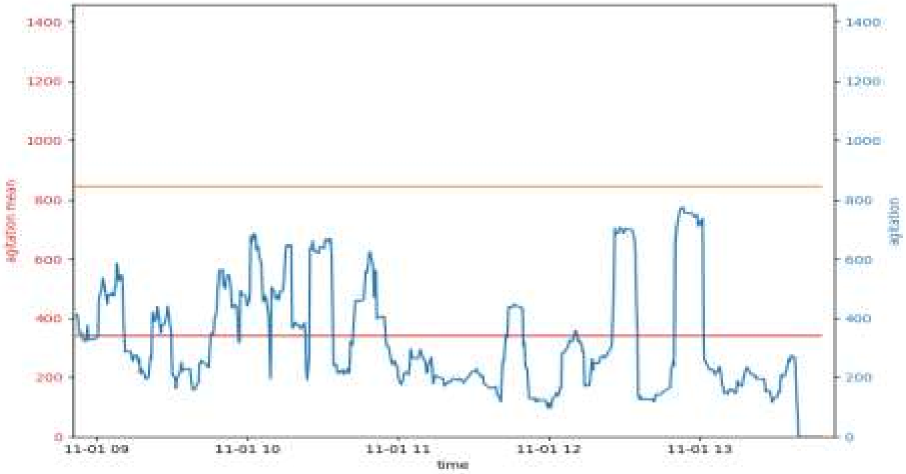

Figure 17 – AS evolution for a user NOT diagnosed with ADHD

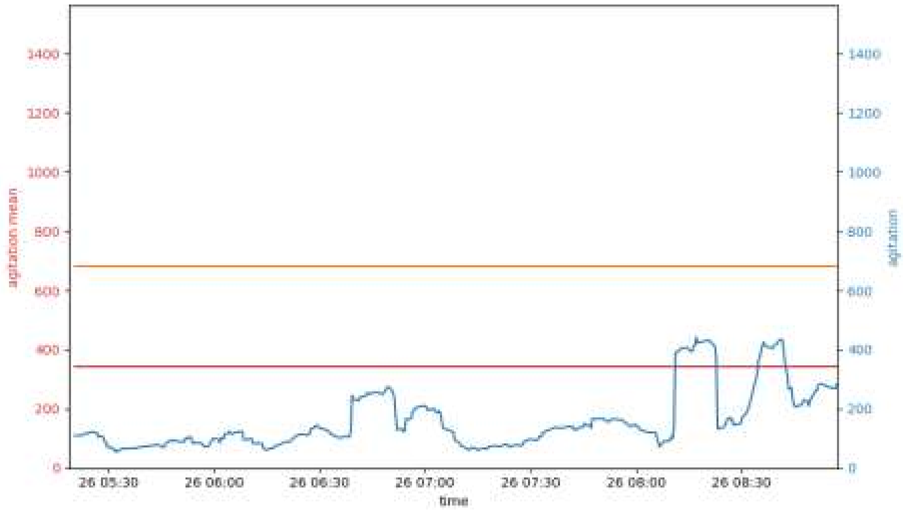

Figure 18 – AS evolution for a user NOT diagnosed with ADHD

CONCLUSIONS AND FURTHER DEVELOPMENT

1. The analysed data show a clear difference between the behavioural reaction to stress and agitation in the case of users diagnosed with ADHD and users in the typically developing group, not diagnosed with any mental-related condition. In the case of all users diagnosed with ADHD at least one instance in which the Agitation Score reached peaks above the alert threshold defined by the calm state baseline was present for all sessions which included an element of intellectual challenge and mental stress. In the same type of sessions the users not diagnosed with ADHD did not experience a similar escalation of their emotional state.

2. Several of the tracked biomarkers, especially Heart Rate Variability (HRV), skin conductivity (GSR) and movement indicator (M) proved to be highly correlated with the agitation level witnessed directly by trained observers, proving their value as components of a detection algorithm.

3. Further on, the Tully detection algorithm developed by Stressless SRL, on the basis of multiple physiological indicators monitored in a dynamic state and processed on-board of the wearable device is a reliable solution for an emotional reaction forecasting tool. We can conclude that the first step of the Tully emotional monitoring and management is valid.

4. The wearable device's aim is both to collect accurate data on the users' emotional state and to offer the user an early warning in the case of approaching emotional events and to guide, through biofeedback, the users' actions towards regaining a calm state. The first-mentioned functions were validated through the study described in this report, but a continuation of this study is necessary to validate the latter functions and to quantify the effects of using the device, both from the point of view of stress and agitation control and from that of the overall task completion level.

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Appendix1.

Date:

Time:

		00	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
INTERACTIONS WITH THE EVALUATOR	Asks for repetition, repeats what has been told to him/her																																									
	Changes the subject of the discussion																																									
	Inappropriate comments / remarks																																									
	Talks over the evaluator																																									
	Invades the evaluator's personal space																																									
	Interventions from the evaluator																																									
	He doesn't do what is asked of him/her																																									
	He/ she evaluates him/herself, asks for reinsurance																																									
	TOTAL:																																									
MOTOR. ACTIVITY	He/She waves his/her arms																																									
	Motor agitation																																									
	Throws objects, drops materials																																									
	Plays with his/ her hands																																									
	Plays with the surrounding objects																																									
	Kicks his/her legs																																									
	Stands up when expected to stay seated																																									
	Walks around the room																																									
	He/She contorts his/herself																																									
	He/She swings his/her body																																									
	Changes position																																									
	Jumps, slams into the chair																																									
	Hits the furniture																																									
	Blinks repetitively / excessively																																									
	TOTAL:																																									
VERBAL BEHAVIORS	Emits different sounds																																									
	Raises his/her voice																																									
	Talks a lot, fast																																									
	TOTAL:																																									
RELATIONSHIP WITH THE TASK	Unfocused, searching gaze																																									
	Distracted by external stimuli																																									
	Skips stages																																									
	Change of rhythm / pace																																									
	Describes what he/she is doing																																									
	Unfinished tasks																																									
	TOTAL:																																									