Tracking Intervention Efficacy in Autistic Individuals using Wearable Biometrics on Autonomic Arousal and Sleep

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1. Summary

Summary: This white paper discusses the use of Philia Labs' PhiliaHealth™ biometrics to objectively measure the efficacy of interventions in autistic individuals. PhiliaHealth was used to track autonomic arousal and sleep patterns during therapy sessions, particularly the Anxiety Reduction Technique (A.R.T.). Data was shared retrospectively with the therapists and participants.

Key Points:

- **Objective:** Address the unmet need for easy-to-use, objective physiological measures that can demonstrate the real-world efficacy of mental health interventions, especially in autistic individuals.
- **Intervention:** The study involved an 8-week program where biometric data, such as sleep efficiency and autonomic nervous system (ANS) activity, was monitored to evaluate the impact of somatic therapy on autistic participants.
- **Benefits:**
    - For Autistic Individuals/Caregivers: Enhanced ability to monitor therapy progress, pinpoint stress causes, and predict emotional dysregulation.
    - For Therapists: Ability to develop and refine interventions, measure efficacy with data-backed insights, and communicate treatment outcomes more effectively.
- **Methods:** The study employed a mix of quantitative and qualitative measures, including psychometric assessments and biometric data collected via the Philia Health monitoring program.
- **Results:** Biometrics provided detailed insights into participants' responses to therapy, with significant improvements in sleep quality and autonomic balance observed in several cases.
- **Conclusions:** Philia Labs' biometrics offer a valuable tool for enhancing the efficacy of interventions in autistic populations by providing objective data that supports therapeutic outcomes and reduces stakeholder stress.

If you wish to find out more about using our monitoring program for your clinical study, reach out to us at contact@philialabs.com.au

Notes:

At the time of writing, the authors have used the term "autistic individuals" to refer to autistic people in alignment with the inclusive description used by Australian advocacy organisations and scientific literature.

2. Background and Motivation for study

Autism is a complex developmental condition involving persistent challenges with social communication, restricted interests and repetitive behaviour. Autistic individuals tend to demonstrate extraordinary strengths such as an above average ability to remember facts, visual thinking, paying close attention to details that others might miss as well as being honest, focused and creative. At the same time, autistic individuals face challenges in communication and social interaction that are a consequence of atypical integration of sensory and information processing. This causes a cognitive and emotional overload state that is associated with decreased parasympathetic (or rest-and-digest) nervous activity when compared to neurotypical individuals (Zadok, Golan et al. 2023).

Over time, decreased parasympathetic and increased sympathetic tone results in poor sleep (Monroe 1967, Lichstein and Rosenthal 1980, Sapolsky 2004, Richdale, Chetcuti et al. 2023, Richdale and Haschek 2024), psychological inflexibility (Uddin 2021), depression and anxiety (Hufnagel, Chambres et al. 2017, Freeman, Sheaves et al. 2020). Autistic people, in particular females, operate at a much higher level of stress and experience poorer sleep than neurotypical people (Richdale, Haschek et al. 2021), meaning that the prevalence of anxiety and depression in Autistic Australians is twice the rate the general population (Richdale, Haschek et al. 2021).

In the realm of autism support and intervention, there is a critical need for research that evaluates the effectiveness and impact of various programs and supports. Mental health interventions and sensory supports are among the key areas requiring rigorous evaluation, particularly in terms of their influence on autistic students' academic and personal outcomes over extended periods (Richdale, Chetcuti et al. 2023). The authors observe that despite the availability of body-focused therapies for the general population, there is a notable absence of neurodivergent, body-oriented approaches tailored specifically for individuals with autism. This gap is significant, as autistic individuals often experience alexithymia, poor interoception, and emotional blocks that hinder their access to conventional body-focused therapies (Benevides, Shore et al. 2020, Goodall and Brownlow 2022).

A related but separate unmet need to new and existing therapies in autism is the lack of easy to use and objective physiological measures from which real-world evidence behind therapies can be demonstrated. Measures which demonstrate a shift in autonomic nervous activity towards a greater vagal tone (Hufnagel, Chambres et al. 2017, Moon, Yang et al. 2021, Yarger, Sarkar et al. 2024) are required to enable autistic individuals, caregivers and providers personalise interventions and receive more support from disability organisations.

Physiological measures on sleep and autonomic nervous system (ANS) activity can provide information on the body's response to interventions (Epel, Crosswell et al. 2018, Crosswell and Lockwood 2020) that improve autistic individuals' ability to self-regulate and function independently. The authors consider these measures to be important information in supplementing interviews and questionnaires during therapies.

This whitepaper describes a case study of Philia Labs' wearable monitoring program to empirically measure the efficacy of a somatic therapy (Anxiety Reduction Technique) that has been developed by one of the co-authors, Ms Holly Bridges of License to Think (Bridges, Smith et al. 2024).

Objective measures of nervous system activity and sleep metrics could supplement interviews and questionnaires, providing additional data for therapist to aid their patients with treatment. This white

paper led by Philia Labs focuses on the wearable monitoring program and its benefits to therapists and clients to positively influence mental health outcomes. We will also describe stakeholder feedback – caregivers and therapists - on the use of the wearable and the data provided in the discussion.

3. Methods

3.1. Participants

The study involved seven participants, 3 females and 4 males, who comprised 6 children and one adult, with Autism and/or ADHD. Over fifteen weeks, they participated in online A.R.T. sessions. The outcomes aligned with Autism CRC's clinical recommendations, showing improvements in sleep, psychological flexibility, and emotional adaptability (Adams, Girdler et al. 2023). Participant information is shown in Table 1.

Table 1: Summary of Participant Information

Code	Identified Sex	Age	Reported Diagnosis / Medical Conditions, Medication, Location
ZEBR01	Female	16	ADHD, Neurodevelopmental Disorder, Anxiety • Medication: None • Location: USA
*ZEBR02	Male	16	ASD (level 2), ADHD, Postural orthostatic tachycardia syndrome (POTS) **ZEBR02 Left study in the initial stages due to ill health*
ZEBR03	Female	59	ASD (level 2), (ASD level 3 for social functioning), ADHD, Fibromyalgia, Sjogren's Syndrome, Raynaud's Disease, Lupus, Chronic Fatigue Syndrome, Low Blood Pressure, Breathing difficulties, Allergies, Digestive Problems, PTSD. • Medication: Dexamphetamine • Location: Australia
ZEBR04	Male	9	ASD (level 3), Global Developmental Delay, Sensory Processing Disorder, Language disorder, Hyperlexia, Dyspraxia, Echolalia • Medication: None • Location: Australia
ZEBR05	Female	12	ASD (level 2), ADHD, Audio Processing Deficits, Delayed Speech, Dysgraphia, Asthma, Seizures • Medication: Melatonin • Location: Australia
ZEBR06	Female	17	ASD (level 2), ADHD, Reconstructive Respiratory Surgery, Breathing Issues Digestive Issues • Medication: None • Location: Australia
ZEBR07	Male	16	Autism Spectrum Disorder, Without Intellectual or Language Impairment, and Associated with Other Neurodevelopmental Conditions and Associated with Emotional Conditions, Requiring Support, (ASD: Level 2), Developmental Coordination Disorder, Specific Learning Disorder, Dyscalculia, Generalised Anxiety Disorder, Depressive Type 1 Diabetes, Chiari and Syringomyelia, Vocal Tics • Medication: Insulin/Insulin pump, Abilify, Clonidine, Lamatrogine, Hydroxyzine • Location: USA
ZEBR08	Male	10	ASD (level 2), ADHD • Medication: Melatonin • Location: Australia

Following the latest guidelines in autism research, this evaluation prioritised co-participant consent, involvement, and assessment. A mixed-methods strategy was adopted, integrating both quantitative and qualitative data to thoroughly analyse the A.R.T. treatment program and ensure the co-participant's perspective was included (Bridges, Smith et al. 2024). The study employed wearable biometric devices used at home and conducted treatments in a home environment, facilitating a non-intrusive investigation. Insights were gained through thematic analysis and independent psychometric assessments before and after the treatment, highlighting the co-participant's views.

3.2. Intervention

Developed by Holly Bridges (Bridges, Smith et al. 2024), the Anxiety Reduction TechniqueTM is a somatic therapy that is aims to stimulate the vagus nerve through a combination of guided proprietary physical movements that predominantly stimulate the dorsal section of the vagus nerve. It is based on the polyvagal theory (Porges 2009).

The intervention comprised eight sessions conducted over five weeks. It began with an onboarding session to discuss intervention details, followed by an initial one-hour session to explain the modality's science and philosophy, and set expectations. The intensive week included five two-hour sessions, each at the same time daily, where participants learnt somatic exercises tailored to them. Two follow-up sessions were conducted to modify home exercises, assess progress, and gather feedback from schools, family, and friends. Post-research debrief sessions were held approximately six weeks after the follow-up sessions. Throughout, participants had the flexibility to participate with or without parents and/or carers and could choose whether to be on camera.

3.3. Measures

This study employed a mixture of quantitative and qualitative measures. These used included Participant feedback reports, psychometric measures and the biometrics from the PhiliaHealth™ monitoring program. To prevent bias in participant feedback in the interventions, the measures were provided to the therapists and participants after the study was completed.

3.3.1. Participant Feedback

Participant feedback was collected throughout the treatment process, including before, during, and after treatment. The therapist used mostly open-ended questions to gauge whether perceived physical changes and visible improvements in behaviour and capacity could be observed. Parents or caregivers of minors also provided feedback to corroborate these observations.

3.3.2. Psychometric Measures

The Adaptive Behaviour Assessment System 3rd Edition (ABAS-3) was used to assess adaptive skills before and after treatment. It covers areas like Conceptual, Social, and Practical skills, focusing on everyday activities needed for functioning and interacting with others. The survey gathers information from various sources such as parents, family members, teachers, and supervisors to understand an individual's functionality across different domains. A higher score indicates a better ability to adapt, with percentile norms (Figure 8). The general adaptiveness composite score from this survey was compared before and after treatment to evaluate therapy effectiveness.

The WHO-5 Well Being Scale was administered three times during the study. This scale measures wellbeing over the last two weeks through five positively worded items rated on a 6-point scale. Scores are transformed to a scale of 0% to 100%, with lower scores indicating poorer wellbeing. A change of 10% between pre- and post-treatment is considered significant.

3.3.3. Biometric Measures

As part of PhiliaHealth's wearable-agnostic approach, Biostrap's EVO Wristband device (Figure 1) was used in a research capacity. The EVO is a non-invasive optical sensor that monitors changes in arterial pulse volume using photoplethysmography (PPG). The Wristband is a low-power device that will not cause electroshock or burns. The materials that were exposed to the patient's wrist are ABS plastic, optically clear, medical grade PC plastic, silicone and aluminium clasp. No allergic reactions have been reported in prior investigations. The raw bio-signals recorded by the wristband device are transferred to an iPhone or Android Mobile Phone via Bluetooth and stored in Amazon Web Service cloud servers belonging to Biostrap (USA) and Philia Labs (Australia) for further data processing to estimate biometrics. By using the chosen participant code e.g. ZEBR01, all biometric data were de-identified of participant information.

Figure 1: Biostrap EVO wearable and mobile app

Four nocturnal / sleep biometric measures were included. These are time asleep, sleep efficiency, and an indicator of sympathetic and parasympathetic arousal during sleep. To reduce bias, the data was not revealed in the mobile app and only shared with the co-authors after the post-intervention phase was completed.

3.3.3.1. Total Sleep Time and Sleep Efficiency

Time asleep was measured in minutes spent in light or deep sleep. Sleep efficiency was calculated as the time spent asleep divided by the total time in bed, with 80% considered healthy (Figure 7). These two metrics are chosen in accordance with clinical guidelines on measuring insomnia using actigraphy (Riemann, Baglioni et al. 2017) and meta-analyses that demonstrate that these parameters are impaired on autistic children (Elrod and Hood 2015), adolescents (Díaz-Román, Zhang et al. 2018) and adults (Morgan, Nageye et al. 2020).

3.3.3.2. Indicators of Sympathetic and Parasympathetic Arousal

The ANS is subdivided into two large components: the sympathetic and the parasympathetic nervous system, also known as the fight-or-flight mechanism and the relaxation response. Pulse or heart rate variability (HRV) is a measure of the variation in time between each heartbeat and represents the parasympathetic activity (Shaffer and Ginsberg 2017). Yarger et al's meta-analysis indicates a significant and moderate relation between HRV and anxiety in autistic individuals (Yarger, Sarkar et al. 2024), where a lower HRV indicates a higher state of anxiety.

The quality of sleep is also of primary importance due to the association with several pathophysiological conditions and mood disorders (Espie and Morin 2012, Poon, Ho et al. 2024). Autistic individuals generally show altered hypothalamic pituitary adrenal (HPA) axis and autonomic functions, generally with a tendency towards hyperarousal and hyper-sympathetic state. While resting heart rate is easier to understand for the layperson, it is harder to interpret clinically whether changes in heart rate are due to reduced sympathetic arousal or increased parasympathetic arousal. Measuring correlates of the parasympathetic and sympathetic arousal may better assist estimating sleep quality as part of mental health interventions (Kalmbach, Anderson et al. 2018, Kalmbach, Cuamatzi-Castelan et al. 2018).

The nocturnal HRV was measured using optical signals from the wrist worn device in the following way: The root mean square of successive differences (RMSSD) of the interbeat interval was calculated every 10 minutes over a period of 45 seconds, which was the maximum window length of the chosen wearable.
To assess sympathetic arousal during sleep, Philia Labs' novel measure of muscle sympathetic arousal was used based on changes in skin blood flow (Buxi, Senior et al. 2020, Udhayakumar, Rahman et al. 2023). This measure calculates the area under the curve of a binary indicator of high or low sympathetic arousal across the total sleep time.

By measuring both sympathetic and parasympathetic arousal, stakeholders and clinicians can obtain a more detailed and accurate assessment of the impact on interventions on the ANS. In particular, the balance between sympathetic and parasympathetic arousal during sleep is a predictor of sleep quality (Kalmbach, Cuamatzi-Castelan et al. 2018) and anxiety and fatigue in neurotypical individuals (Crosswell, Mayer et al. 2024).

4. Results

4.1. Synopsis of Psychometric and Biometric Results

A synopsis of the results is given in Table 2 and Table 3 according to pre- and post-intervention changes in psychometric and biometric data respectively.

Table 2: Synopsis of Results for Pre and Post Treatment for Psychometrics.

	ZEBR01	ZEBR03	ZEBR04	ZEBR05	ZEBR06	ZEBR07	ZEBR08
Psychometrics							
WHO-5 Score indicating general wellbeing							
Pre-treatment	40	44	28	52	44	56	64
Post-treatment	52	64	16	68	52	76	72
Difference	**+12**	**+20**	**-12**	**+16**	+8	**+20**	+8
ABAS-3 GAC (General Adaptive Composite) Score indicating adaptive behaviour (percentile rank in bracket)							
Pre-treatment	82 (12)	83 (13)	78 (7)	64 (1)	61 (0.5)	87 (19)	69 (2)
Post-treatment	84 (14)	74 (4)	81 (10)	74 (4)	64 (1)	82 (12)	80 (9)
Difference	+2 (+2)	-9 (-9)	+3 (+3)	+10 (+3)	+3 (+0.5)	-5 (-7)	+11 (+7)

Table 3: Synopsis of Results for Pre and Post Treatment for Biometrics. Statistically significant changes are in bold.

	ZEBR01	ZEBR03	ZEBR04	ZEBR05	ZEBR06	ZEBR07	ZEBR08
Biometrics							
Time Spent Asleep per Night (Median ± Mean Absolute Deviation hh:mm)							
Pre-treatment	7:24 ± 0:59	6:18 ± 1:09	7:34 ± 1:20	6:13 ± 2:29	5:55 ± 1:05	7:30 ± 1:44	6:35 ± 1:43
Post-treatment	**7:43 ± 0:34**	6:23 ± 1:52	6:04 ± 2:20	**7:19 ± 0:51**	5:54 ± 0:44	7:23 ± 1:41	6:22 ± 1:24
p-value Kruskal-Wallis	**0.008**	0.92	0.131	**0.022**	0.788	0.722	0.715
ANOVA	0.091	0.881	0.329	**0.027**	0.431	0.693	0.735
Sleep Efficiency per Night (Median + MAD %)							
Pre-treatment	97 ± 3	82 ± 4	90 ± 3	90 ± 6	91 ± 6	92 ± 4	88 ± 6
Post-treatment	98 ± 2	84 ± 6	92 ± 5	**85 ± 3**	**93 ± 4**	97 ± 3	81 ± 5
p-value T-test	0.426	0.332	0.934	**0.029**	**0.023**	0.739	0.127
p-value Kruskal-Wallis	0.319	0.511	0.744	0.114	0.115	0.634	0.355
ANOVA	0.325	0.609	0.571	0.075	0.075	0.929	0.243
Pre and Post difference in mean T-test SA							
Mean difference	-0.062	-0.001	0.12	-0.029	-0.084	-0.115	-0.101
p-value	0.407	0.992	0.174	0.701	0.439	0.093	0.254
Pre and Post difference in mean T-test for HRV (RMSSD milliseconds)							
Mean difference	-5.4	**-10.5**	**-29.9**	+8.2	+9.4	**+13.8**	+15.1
p-value	0.152	**0.037**	**0.002**	0.191	0.271	**0.014**	0.077

All in all, each participant has shown a heterogeneity in biometric and psychometric changes, but an improvement in their self-reported information.

According to the WHO-5 score difference, six out of seven participants showed an improvement in well-being, with four showing significant improvements with increases of 12 to 20%. Two participants almost reached the threshold for significant improvement with an 8% increase. Five out of seven participants reported improvements in general.

In terms of Biometrics, four out of seven participants showed increases in median sleep length by 10 to 42 minutes, with two showing statistically significant changes. Six out of seven participants showed 1-7 percentage points increase in median sleep efficiency, with two showing statistically significant changes.

As for the correlate of sympathetic arousal, five out of seven participants showed a decrease in sympathetic nervous activity during sleep, though none of the changes were statistically significant. For HRV, which is a correlate of parasympathetic arousal, four participants showed improvements, with one being statistically significant. Two out of seven participants showed decreases in HRV, both of which were significant.

In order to provide context for the significance of the ABAS-3 changes, pre-and-post scores with respect to the percentiles are shown in Figure 8.

4.2. Selected Individual Results

To demonstrate how the response to intervention was recorded, the individual results for four subjects (ZEBR01, ZEBR03, ZEBR05 and ZEBR08) are described in this document. These include both qualitative (feedback during interviews on the therapy and use of the device) as well as quantitative (changes in psychometric and biometric data). The multi-dimensional data is presented to show the supporting role played by biometric data in capturing heterogenous responses to the intervention.

An in-depth description for all subjects is presented in (Bridges, Smith et al. 2024).

4.2.1. ZEBR01

Qualitative: The desired outcomes for the Intensive phase were to 'get my life together, help to not be so frustrated; less family conflict; less stress and anxiety'. Post Intensive, ZEBR01 was 'less anxious' and could get 'calmer faster'. They were more able to regulate emotions, tolerate uncertainty; were physically stronger with better endurance; and 'better quality sleep'.

Quantitative: ZEBR01's WHO-5 score increased by 10%, indicating a significant improvement in wellbeing. Regarding the ABAS-3, their sense of wellbeing improved in two out of five areas and remained stable in the other three. During the treatment phase, their sleep efficiency and duration were at their highest. Post-treatment, the median time spent asleep increased by 12 minutes, reaching 7 hours and 50 minutes, while maintaining excellent sleep efficiency at 97-98%. Their nocturnal SA steadily decreased during the treatment phase, indicating increased sympathetic withdrawal during sleep (Figure 2). However, nocturnal HRV showed a downward trend, suggesting the presence of other stressors impacting their recovery.

Caregiver's feedback on reasons to use PhiliaHealth™ :

- Monitor parasympathetic and sympathetic states during and after therapy.
- For people with poor interoception, this can be a useful tool to understand when their body is in a "good" and "bad" state.
- Identify stressors and triggers as well as identify how they are feeling independently and pre-emptively i.e. 'This is what I'm feeling, how I can regulate?'
- Try to get into a more relaxed state [using biofeedback].

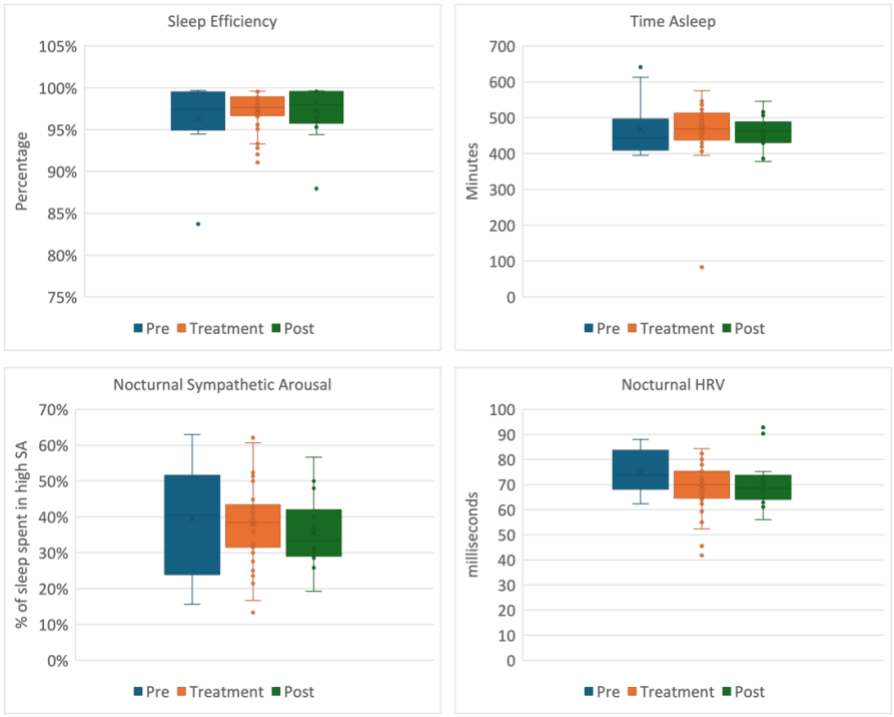

Figure 2: Biometric changes for ZEBR01

4.2.2. ZEBR03

Qualitative: Desired outcomes for the Intensive were to 'have energy and regain ability to manage my everyday life' to get back to work and become economically independent; learn how to regulate and hopefully achieve some integration between mind, body and soul; fix 'autistic burnout'. Post-treatment, ZEBR03 would 'wake up with clarity. Every day would become clearer and steadier'. There was a 'a lot more clarity of thought'; a 'massive improvement' in interoception; 'in knowing when to go to the toilet and when (they were) cold'.

Quantitative: Psychometric evaluation shows that ZEBR03's WHO-5 score improved from 44 to 64, but their ABAS-3 percentile declined from the 13th to the 4th percentile. At first glance, the biometric data suggest a non-response, which doesn't align with their reported experiences. Post-phase sleep patterns fluctuated, with median sleep efficiency rising from 82% to 84%. The distribution of sleep efficiency also increased, indicating less movement during sleep. There was no change in nocturnal SA, but nocturnal HRV decreased from 35ms to 25ms (Figure 3). It might be necessary to extend the observation and treatment period to reconcile the reported experiences with the biometric data.

Participant's feedback on reasons to use PhiliaHealth™ :

- Use as a prompt to do exercises taught during the therapy to achieve more interoception and more contact with their body.
- Carer or adult could use data retrospectively:
- If the 'device says that they've had a bad night sleep, this will prompt them to review the past day and try to determine root causes.'
- If 'they are feeling bad, but the device indicates that they did have a good night's sleep, then they'd focus more on what's happening in the present or will happen'.
- Identify triggers that could lead to anxiety.

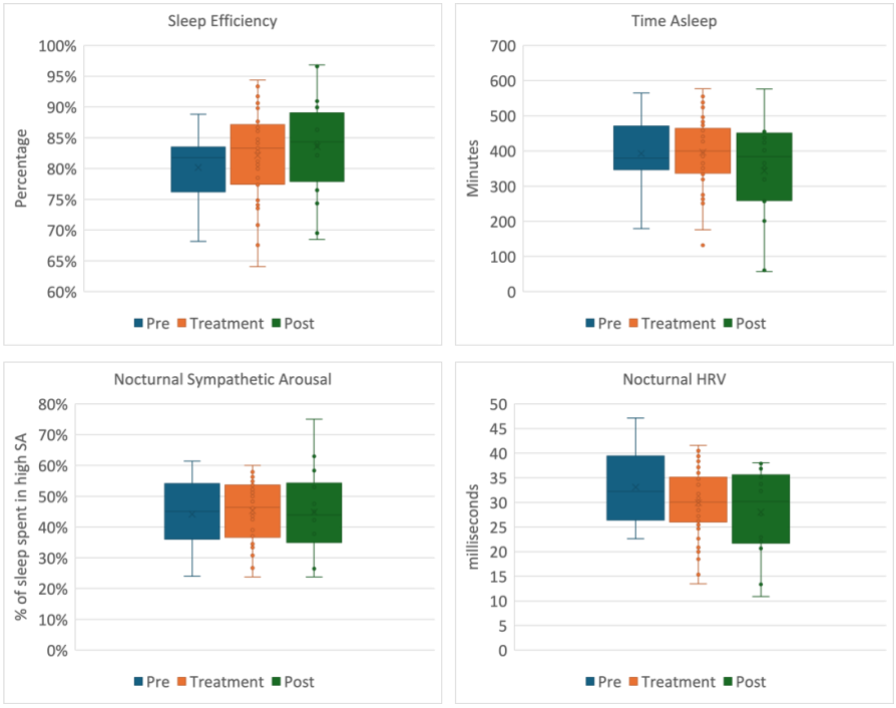

Figure 3: Biometric changes for ZEBR03

4.2.3. ZEBR05

Qualitative: Desired outcomes reported by ZEBR05 were to sleep better; better concentration; and to fix their Restless-Leg Syndrome. Post-treatment, parent/carer reports suggested that there was a reduction in Restless-Leg Syndrome. Both the co-participant and parent/carer reported sleep had significantly improved and that the client was no longer taking melatonin. Changes in physical capacity were indicated by having improved memory; being able to know if they were doing the correct pose in drama class and being able to listen to three instructions at once and that they were more organised and less frazzled.

Quantitative: Psychometric evaluations for ZEBR05 indicated a decline in their WHO-5 score from 28 to 16, but an improvement in their ABAS-3 percentile from the 7th to the 10th. Their biometric data show sleep efficiency consistently above 80%, with a significant increase in median sleep duration from 5 hours and 52 minutes to 8 hours and 26 minutes (Figure 4). Although their nocturnal SA increased during the treatment phase, it showed a downward trend post-treatment. Conversely, their HRV exhibited an opposite trend. The post-treatment combination of SA and HRV metrics suggests a shift towards increased vagal tone during sleep, indicating intervention efficacy and a higher quality sleep for ZEBR05.

Caregiver's feedback on reasons to use PhiliaHealth™ :

- Caregiver would sit with their child after an episode emotional dysregulation and show "here's what the watch said" to help their child understand what fight or flight looks like.
- Parent would use data in telehealth sessions with therapist.
- Use as an advocacy tool e.g. at school to get support, even though the child is good at masking their stressed state.

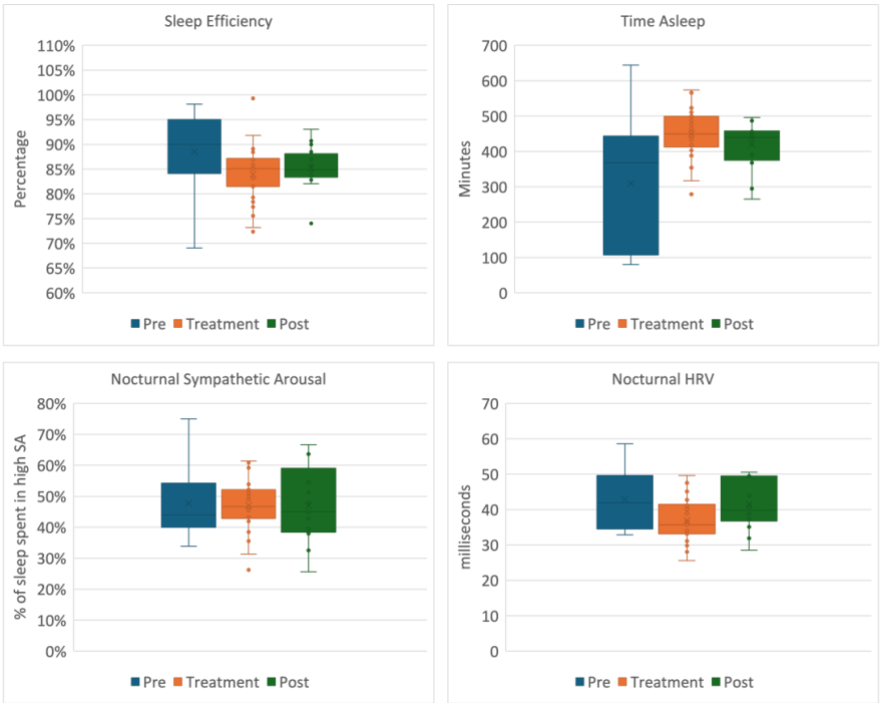

Figure 4:Biometric changes for ZEBR05

4.2.4. ZEBR08

Qualitative: ZEBR08's desired outcomes were to have more inner calm and to be able to learn. Post intensive treatment, ZEBR08 was dealing with math problems better; coping better with stress and was generally more relaxed. Their temperament was more even, there were less hiccups in the day and they were waking up happier and more refreshed. ZEBR08 reported having more energy, clearer vision and that their eyes hurt less. Handwriting was less painful; balance and coordination were greatly improved.

Quantitative: ZEBR08 demonstrated an 8% increase in their WHO-5 well-being score. Their adaptiveness improved significantly from the 2nd to the 9th percentile, though remaining below average. Biometrically, their median sleep duration decreased slightly by 13 minutes, yet their sleep efficiency increased by 7% (Figure 5). Similar to ZEBR07, despite less sleep time, improvements in nocturnal SA and HRV indicated a statistically significant shift towards increased vagal tone during sleep.

Caregiver's feedback on reasons to use PhiliaHealth™ :

- To know the effect of interventions e.g. weighted blanket on the quality their dependent's sleep.
- Be better at pinpointing what a stress trigger is and see what patterns are e.g. if their dependent hates Italian [the language].
- Wear watch during therapy sessions and see what changes.
- Wear the watch during sessions to observe the effect of changes on biometrics

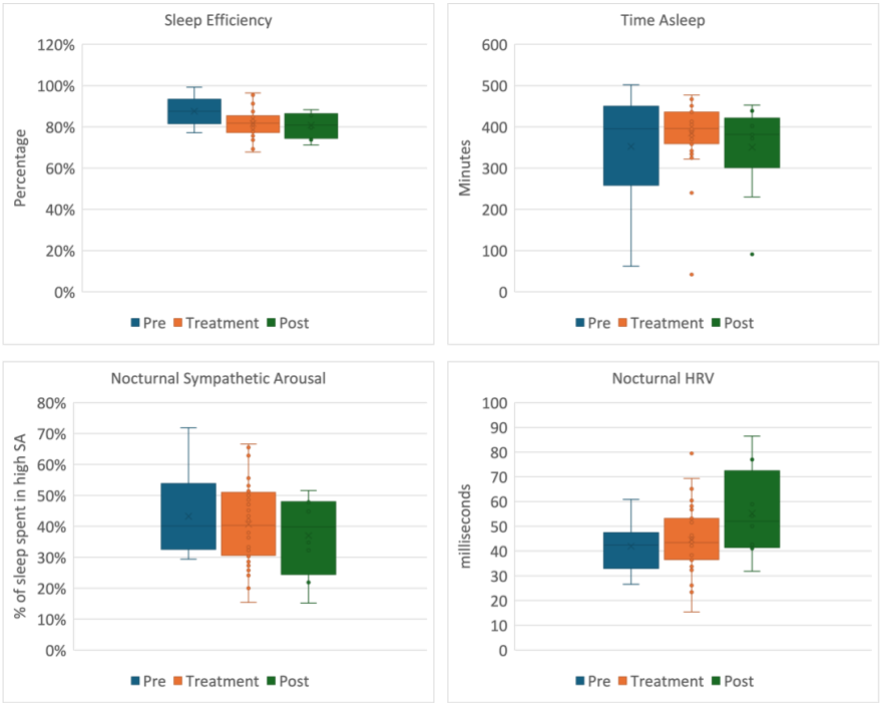

Figure 5: Biometric changes for ZEBR08

4.3. Trends of Participants' Nocturnal Autonomic Arousal

The participants' week-by-week trends on rest and digest or parasympathetic (HRV) and fight-or-flight or sympathetic arousals (SA) are shown in Figure 6. A richer picture emerges In contrast to the pre-during and post-treatment distributions in Figure 2-Figure 5. The data was intentionally processed and visualised after the treatment was completed, which prevented any change in interventions during the treatment.

The following observations are made with the correlate of parasympathetic arousal (HRV):

- ZEBR01: seemed to respond well to the treatment, given the sudden decline in SA in the treatment phase. Their HRV also fluctuated with a downward trend, which could have been correlated with the social anxiety faced when they returned to school.
- ZEBR03: did not appear to have responded to the treatment. However, they suffered more co-morbidities as reported in Table 1.
- ZEBR04: seemed to respond well to the treatment phase but shows increasing nocturnal sympathetic arousal from week 5 onwards.
- ZEBR05: showed a shift to sympathetic dominance before the treatment started. From week 3, they showed an increase in HRV, with another increase in week 7. Their SA showed a downward trend from weeks 2 to 6, with an increase in week 7.
- ZEBR06: showed an increase in SA and decrease in HRV from week 6 onwards, which suggested that a stressor may have occurred here.
- ZEBR07: showed a steady decrease in SA and a steady increase in HRV, suggesting uninterrupted improvement.
- ZEBR08: showed a similar trend to ZEBR07, except that the HRV started increasing after week 6.

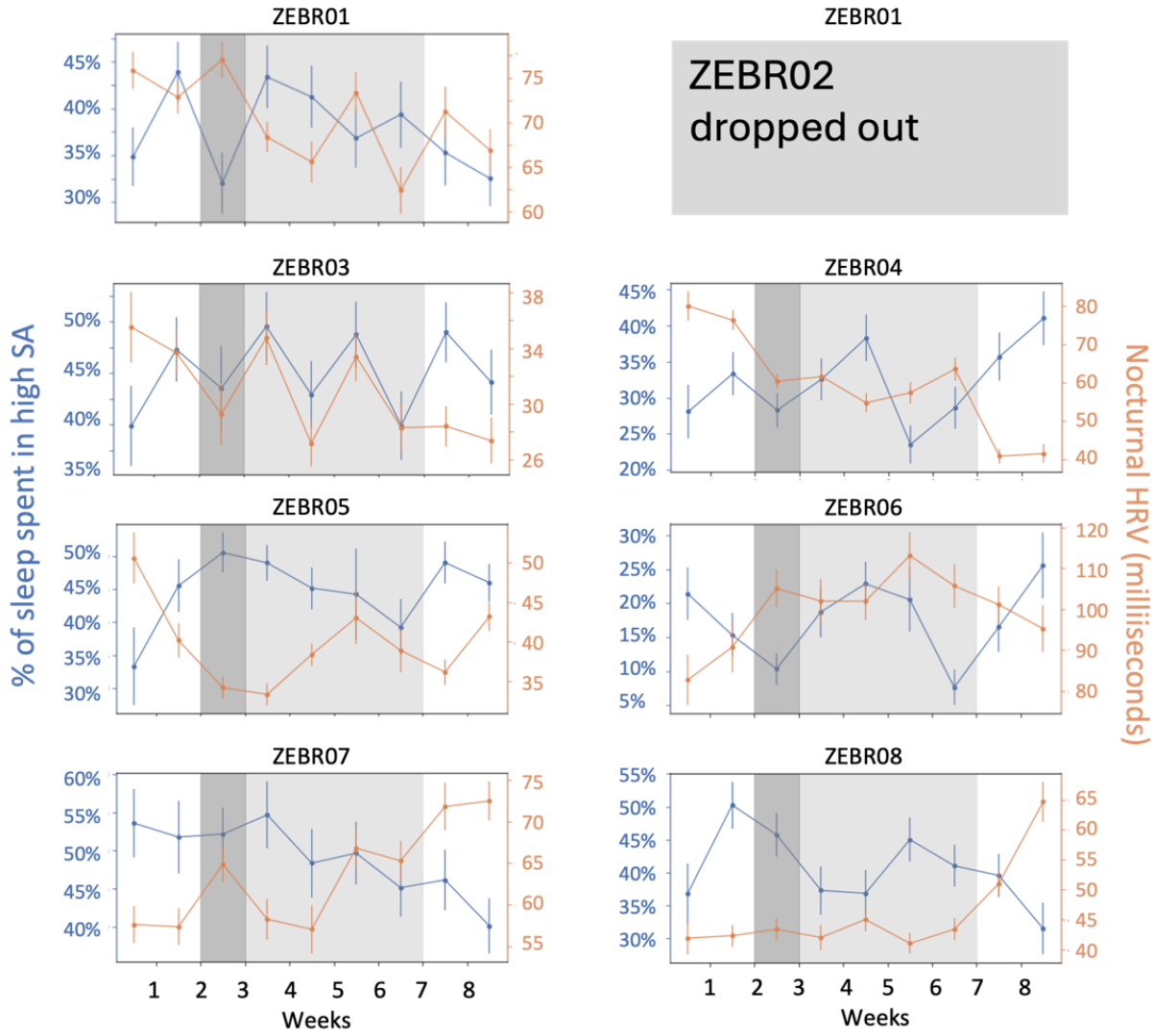

Figure 6: Trends of autonomic arousal correlates across weeks. The grey phases correspond to treatment, while the white phases in weeks 1-2 and 7-8 correspond to pre- and post-treatment.

5. Discussion

This investigation reports the use of wearable biometrics on sleep and autonomic arousal to demonstrate therapy efficacy of an in-home therapy in an autistic population. While the efficacy of the therapy is discussed separately in (Bridges, Smith et al. 2024), the perspectives of the therapist and the participants or their caregivers are discussed.

5.1. Perspective of Therapists

The biometric and psychometric data (section 3.3) was shared only after the treatment phase to prevent bias in the therapists' observations during interviews with participants and carers. Retrospectively, the therapist co-authors (Dr Smith and Ms Bridges) surmised the following benefits of using the *Philia Health* monitoring system in future interventions:

- **Biometric data** serves as essential evidence to document therapy efficacy and advocate for new therapies within the research and autistic communities, acknowledging the individuality of each person on the spectrum. For four participants, improvements in parasympathetic arousal (HRV) and sleep length were consistent with both interview and psychometric data, highlighting the importance of selecting appropriate baseline and post-treatment measurement phases.
- **Clients with poor interoception** may not notice changes in their autonomic nervous system. For one participant, biometric data showed better coping with daily activities, improved well-being, and more restorative sleep, facilitating agreement on progress between therapist and client. In cases where clients struggle to articulate their feelings, biometric measures can be valuable in assessing therapeutic success.
- **Comparing changes** to baseline data and adjusting therapy accordingly can help therapists manage high caseloads more effectively. The format used in Figure 6Figure 1, which therapists found useful, should be expanded to include sleep data.

The therapists reported that they'd like the following features in clinical practice, which Philia Labs is working on:

- Measure correlates of sympathetic and parasympathetic arousal during the day:
  - during intensive sessions to see the effect of the sessions.
  - during the day to understand when stress triggers occur.
- Provide easy to interpret reports
  - on changes from one week to the next, with respect to baseline. In particular, Figure 6 was pointed out as an interesting format.
  - These should enable communication of more pertinent information with other health providers working with the client, which should lead to better decisions and health outcomes.

5.2. Perspective of Participants or their Family Caregivers

The caregivers only had access to the biometric results after the treatment to prevent interference with the treatment and demonstrating its efficacy. However, in clinical practice, the top reasons cited by caregivers to use biometric data were

- Biometric data facilitates more informed discussions between therapists and clients/caregivers
- This would allow the caregiver or participant to advocate for additional support. This time their claims could be backed by empirical evidence.
- Monitor for agitations or potential periods of emotional dysregulation, which can reduce overall stress in the family.

Concerns reported were:

Data sharing should be done with the caregiver's consent. A high level of trust was observed between the recruited participants and the therapist in this investigation.
The wearable should be sensory-friendly. The ABS silicone was reported to be acceptable to most participants, but Philia Labs will be mindful that others may prefer different materials or colours.

User-friendly explanations on how to interpret the data should be provided to caregivers for them to focus on acting appropriately, rather than having to fork out additional time in an already busy schedule.

6. Conclusions and Outlook

This white paper describes the use of objective biometrics on nocturnal autonomic arousal and sleep actigraphy as measures of therapeutic efficacy of a novel somatic therapy (Anxiety Reduction Technique by License to Think) in an autistic cohort.

The benefits of the biometrics to the stakeholders are:

- **For autistic individuals / caregivers:**
  - A better way to monitor therapy progress and advocate for themselves / loved ones.
  - A better way to find the best therapies that work for themselves / loved ones.
  - A better way to pinpoint specific causes of stress to implement appropriate coping mechanisms
  - A way to predict periods of emotional dysregulation to implement appropriate coping mechanisms and reduce all stakeholder stress
- **For therapists:**
  - Develop new interventions / therapies
  - Measure efficacy of interventions
  - More pertinent data to document and communicate treatment efficacy to other stakeholders and efficiently arrive at the right decisions

If you wish to find out more about using our monitoring program for your clinical study, reach out to us at contact@philialabs.com.au

7. Revision History

Version	Effective Date	Prepared/Updated by	Reviewed by	Description
01	16/07/2024	See author list	See reviewer list	First version
02	16/07/2024	DB	See reviewer list	Graphics modified
03	15/08/2024	DB	Alexandra Crosswell	Shortened version

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9. Appendix

Appendix A – Methods

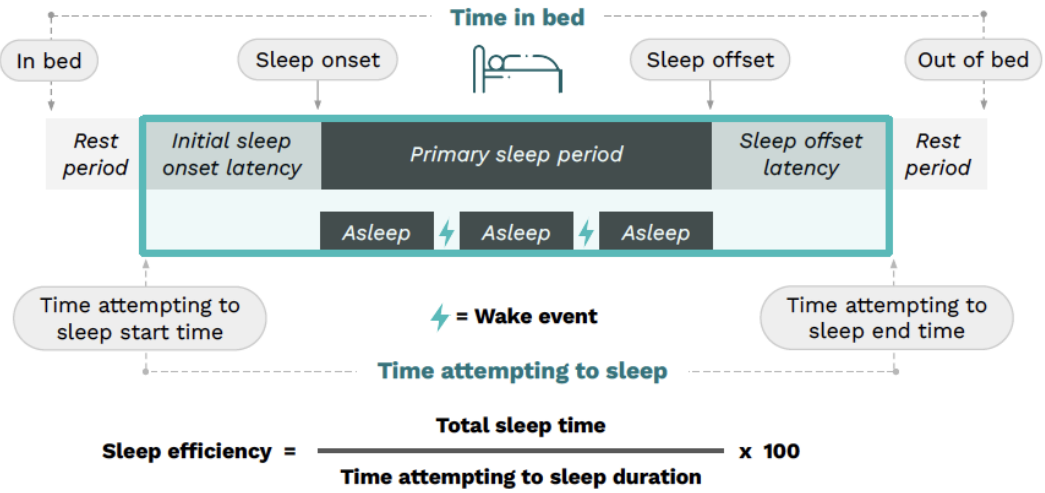

Figure 7: Time asleep and sleep efficiency definition (Source: Digital Medicine Development, Core Measures of Sleep)

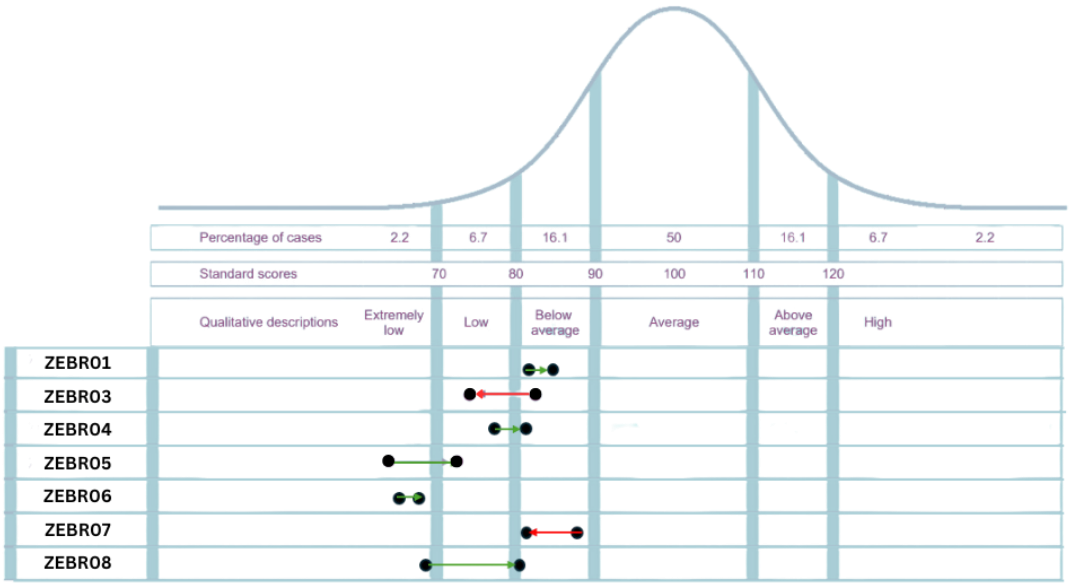

Figure 8: ABAS-3 changes, Pre-and-Post scores with respect to the percentiles

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