Short report: Examining the effect of a wearable, anxiety detection technology on improving the awareness of anxiety signs in autism spectrum disorder: a pilot randomized controlled trial

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Abstract
Anxiety is prevalent in autism spectrum disorder (ASD) and can negatively impact physical and mental health. Self-awareness of anxiety signs is a key barrier to success of anxiety interventions for many children. To address this, we conducted a randomized controlled trial to assess if the Anxiety Meter, a wearable, real-time anxiety detection technology can improve awareness of anxiety symptoms and the initiation of relaxation techniques in children with ASD. Twenty-eight children with ASD were trained on the use of the Anxiety Meter and taught a diaphragmatic breathing relaxation technique over three visits. On the fourth visit, participants were randomized to either receive feedback of their anxiety level or no feedback from the Anxiety Meter while completing a stress-eliciting task (public speaking) and asked to engage in deep breathing if anxious. Feedback from the Anxiety Meter was associated with increased likelihood of initiating deep breathing in response to anxiety. Although these results are limited by the relatively small sample size, they support the feasibility of using a wearable device and real-time feedback to improve anxiety symptom awareness.

Trial registration: ClinicalTrials.gov, NCT02160691. Registered 5 June 2014, https://clinicaltrials.gov/ct2/show/NCT02160691

Keywords: Autism Spectrum Disorder; ASD; Anxiety; Wearables; Intervention

Introduction
Anxiety is a prevalent, persistent, and disabling comorbidity associated with autism spectrum disorder (ASD). Anxiety concerns in ASD persist over the life span [1], and occur across all levels of functioning [2]. Anxiety profoundly impacts the psychosocial development and physical and mental health of children, and interacts with the core domains of ASD to increase functional impairment [3].

Treatment of anxiety in ASD remains a significant clinical challenge. There is evidence to suggest that Cognitive-Behavioural Therapy (CBT) may be effective for a subgroup of children with ASD with higher verbal ability; however, the optimal response to CBT is contingent upon children’s capacity for introspection, self-identification of emotional states, and communication – domains that are commonly impaired in ASD [4–6]. ASD is also associated with difficulty in self-awareness of physiological states [7], an additional barrier to mastering physiological awareness and management components of CBT. To address this gap, we evaluated the
efficacy of a wearable technology, the Anxiety Meter, in improving awareness of anxiety signs in children with ASD. The Anxiety Meter uses wearable sensors to sense changes in heart rate and translate these into a visual display of anxiety level which is presented to the user on a tablet.

**Methods**

**Trial Design**

The study was a parallel randomized control trial consisting of three training and one intervention visit to our lab at Holland Bloorview Kids Rehabilitation Hospital. Participants were randomized in a 1:1 fashion to either receive feedback on their anxiety level (treatment group) or no feedback (control group) from Anxiety Meter during the intervention visit. Due to the nature of the intervention, participants and investigators were not blind to the treatment allocation.

The study protocol was approved by Holland Bloorview’s research ethics board. Participants and their caregivers provided informed consent and assent as appropriate.

**Participants**

A total of 38 participants were recruited through the Province of Ontario Neurodevelopmental Disorders (POND) Network. Inclusion criteria were age between 8 and 18 years, primary diagnosis of ASD supported by the Autism Diagnostic Observation Schedule (ADOS-2) [8] and the Autism Diagnostic Interview-revised (ADI-R) [9], full-scale IQ greater than 50, and ability to complete modules three or four of the ADOS-2. Our exclusion criteria were taking beta-blockers (which can affect heart rate), previous experience with CBT, or starting new treatments within four weeks of study enrollment.

**The Anxiety Meter**

The version of the Anxiety Meter used in the study employed a wearable Shimmer2 unit (Shimmer Sensing Ltd.) connected via Bluetooth to record electrocardiogram (ECG) and respiration signals at a frequency of 256 Hz. The ECG data were used to compute anxiety levels [10] which were displayed on a tablet screen in the participant’s field of view. The anxiety level was displayed on a color gradient scale (green: calm, yellow: rising anxiety level, and red: anxious). A “blob” character, sound notification, and vibration signals alerted the participants once the anxiety level reached the yellow zone.

**Training**

During the first three visits, participants were taught diaphragmatic breathing by a psychologist or psychology intern trained in the Facing Your Fears program [11]. During the first visit, participants also watched a 15-minute baseline video and completed an anxiety-eliciting task (Stroop Color-Word Interference task [12]) to verify the presence of a cardiac anxiety response to anxiety-inducing stimuli. At the end of the third visit, the psychologist or psychology intern determined if participants mastered the breathing technique and use of the Anxiety Meter.
Intervention
During the intervention visit (figure 1), all participants watched a 30-minute baseline video. They then completed a public speaking preparation task (five minutes to prepare a talk). Participants then completed a two-minute intervention period where they reflected on their anxiety level and applied the relaxation technique if they felt anxious. Only the treatment group received feedback from the Anxiety Meter during this period. Participants then delivered a three-minute speech to three strangers. Finally, participants watched a fifteen-minute return-to-baseline video.

Measures
The primary outcome was the proportion of participants initiating diaphragmatic breathing during the intervention period. This was measured through self-report, supported by changes in respiration amplitude and rate. As an exploratory outcome, we examined whether or not the intervention improved symptom management (change in the State-Trait Anxiety Inventory (STAI) [13] score from baseline to the public speaking preparation task).

IQ was measured using the Wechsler Abbreviated Scale of Intelligence, Second Edition (WASI-II) [14]. General and separation anxiety, as well as attention-deficit symptom severity, were measured using the Child and Adolescent Symptom Inventory-5 (CASI-5) [15].

Analyses
The fisher’s exact test was used to compare the number of responders (i.e., those who initiated the breathing technique) in the treatment and control groups.

Results
53 children were assessed for eligibility, and 38 met criteria and were enrolled in the study. After the first visit, four participants were screened out as they did not display the heart rate response required for the Anxiety Meter (less than a two beats per minute difference between the average heart rate during the baseline and Stroop task). One participant was lost to follow-up and another participant withdrew. After the third visit, four participants were screened out because they did not master the breathing technique. Thus, 28 participants were eligible for the fourth visit. At the intervention session, two participants (one treatment and one control) did not complete the public speaking delivery task due to excessive anxiety. Thus, a total of 26 participants received the allocated intervention (table 1). Two participants in the treatment group and one control participant were excluded from the secondary analysis due to technical difficulties (figure 2).

Proportion of Responders
The proportion of participants who initiated deep breathing was significantly higher in the treatment group compared to the controls (treatment: 14:0; control 4:9; Fisher’s exact, p < 0.01). Of those who initiated deep breathing, 11/14 and 4/4 reported feeling calmer after deep breathing, in the treatment and control groups, respectively. In the treatment group, 11/14 participants reported that the Anxiety Meter reminded them to initiate deep breathing.
Comparison of the respiration data between the intervention and anxiety conditions supported the participants’ self-report of initiation of deep breathing (respiration amplitude: 18.6% increase in responders, 2.4% decrease in non-responders; respiration rate: 0.6% decrease in responders, 9.0% increase in non-responders).

When treatment and control groups were pooled, there was a significant increase in physiological measures from baseline to both anxiety conditions (heart rate, \( p < 0.001 \); respiration amplitude \( p = 0.01 \)), confirming that the study tasks did elicit states of arousal in participants. The treatment and control groups were not significantly different in baseline heart rate (treatment: 81.4 ± 7.9 bpm control: 84.7 ± 8.7 bpm) or the increase in heart rate from baseline to anxiety conditions (treatment: 6.7 ± 6.2 bpm, control: 7.2 ± 6.7 bpm). The change in self-reported anxiety level was not significant between the treatment and control groups (treatment: 1.4 ± 4.8, control: 0.00 ± 4.4; \( p = 0.47 \)).

**Discussion**

In this study, we evaluated the efficacy of a wearable technology, the Anxiety Meter, to improve awareness of anxiety states in children with ASD. Our results showed that using the Anxiety Meter was associated with an increased likelihood of initiating calming strategies under laboratory-induced stress conditions. This suggests that physiologically-informed alerts may be a promising approach for improving awareness of anxiety signs. This is particularly encouraging for children with ASD for whom difficulties with self-awareness is a barrier to benefiting from existing anxiety interventions. Another benefit of this approach is that physiological alerts can be delivered in real-time and in situ through inexpensive and commercially-available devices such as smartwatches. This can enable the integration of anxiety interventions in everyday situations, and continuous reinforcement of use of therapeutic techniques across multiple settings. In our study, the Anxiety Meter alerts were provided to the children directly. It is also possible to provide these to caregivers so that de-escalation strategies can be initiated in a timely manner.

**Limitations**

The findings of this study must be interpreted in the context of several limitations. First, our sample size was relatively small. Second, despite the randomized assignment of participants, the treatment and control groups were imbalanced in terms of IQ and sex, although the conclusions remained consistent when the groups were matched. Lastly, the controlled-laboratory settings limit the generalizability of the results to real-world settings. Future studies will explore the real-world use and feasibility of using the Anxiety Meter in clinical and educational settings.

**Conclusions**

The results of this study support the preliminary efficacy of using the Anxiety Meter to improve awareness of anxiety signs in children with ASD. Future studies are needed to replicate these results in larger samples and real-world environments.

**Acknowledgements**

We thank and acknowledge the time given by the families involved in the research study.
Funding
Funding was provided by the Ontario Brain Institute.

Abbreviations
ADI-R: Autism Diagnostic Interview-revised
ADOS-2: Autism Diagnostic Observation Schedule, Second Edition
ASD: Autism spectrum disorder
CASI-5: Child and Adolescent Symptom Inventory-5
CBT: Cognitive behaviour therapy
ECG: Electrocardiogram
POND: Province of Ontario Neurodevelopmental Disorders
STAI: State-Trait Anxiety Inventory
WASI-II: Wechsler Abbreviated Scale of Intelligence, Second Edition

Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate
Holland Bloorview’s Research Ethics Board approved the study. All participants provided informed consent.

Competing interests
AK and EA hold two patents for the Anxiety Meter, are involved in its commercialization, and will benefit financially from its sales.

Consent for publication
Not applicable.

Authors’ contributions
AZ, EA, and JAB designed and conceived of the study; AZ and JN analyzed the data. AZ, EA, JAB, and JN drafted and reviewed the manuscript as well as read and approved the final manuscript.

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Figures

**Figure 1** Schematic outline of protocol for intervention visit (visit 4)

CASI-5: Child and Adolescent Symptom Inventory-5; WASI-II: Wechsler Abbreviated Scale of Intelligence, Second Edition; STAI: State-Trait Anxiety Inventory

**Figure 2** CONSORT diagram from enrollment onwards

Consolidated Standards of Reporting Trials (CONSORT) flow diagram from enrollment to analysis.

Tables

**Table 1** Participant Characteristics. The statistics are reported as mean and standard deviation.

|                     | Treatment (n=14) | Control (n=12) |
|---------------------|-----------------|----------------|
| Age                 | 14.2 ± 1.9      | 13.0 ± 3.2     |
| Sex (male: female)  | 9.5             | 7.5            |
| Full-Scale IQ       | 107.0 ± 14.4    | 89.2 ± 18.6    |
| CASI-5: Generalized Anxiety | 72.0 ± 13.9 | 65.4 ± 14.9 |
| CASI-5: Separation Anxiety | 55.0 ± 17.5 | 59.8 ± 18.4 |
| CASI-5: Attention and Hyperactivity | 71.1 ± 8.8 | 63.9 ± 11.5 |
| Responders (yes: no) | 14.0            | 4.8            |