**Evidence-Based Practice Group Answers to Clinical Questions**

# "NeuroCatch® Platform and Cognitive Brain Function"

**A Rapid Systematic Review**

By

**WorkSafeBC Evidence-Based Practice Group**

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*July 2021*

**Clinical** WORK SAFE BC WORKING TO MAKE A DIFFERENCE **Services – Worker and Employer Services**

## About this report

**NeuroCatch® Platform and Cognitive Brain Function**

**Published:** July 2021

### About the Evidence-Based Practice Group

The Evidence-Based Practice Group was established to address the many medical and policy issues that WorkSafeBC officers deal with on a regular basis. Members apply established techniques of critical appraisal and evidence-based review of topics solicited from both WorkSafeBC staff and other interested parties such as surgeons, medical specialists, and rehabilitation providers.

### Suggested Citation

WorkSafeBC Evidence-Based Practice Group, Martin CW. NeuroCatch® Platform and Cognitive Brain Function. Richmond, BC: WorksafeBC Evidence-Based Practice Group; July 2021.

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## Background and Objective

Recently, through the First Responders Mental Health Committee, the Board was asked to review a medical device called the NeuroCatch® Platform. No further information was provided with the exception of the company's website (https://www.neurocatch.com/). Upon receiving this request, the Evidence-Based Practice Group (EBPG) gathered further information regarding this device through the company's website in order to collect, if any, published evidence, characteristics of the device, as well as potential keywords that can be used for the purpose of conducting a literature search as part of this systematic review towards investigating the efficacy/effectiveness of this device. Hence, information provided in this Background and Objective section mainly derives from the company's website.

According to its website, the NeuroCatch® Platform is a Health Canada approved Class II medical device that offers a simple and objective way to measure cognitive brain function (https://www.neurocatch.com/). *It should be noted that an approval for a Class II medical device by Health Canada does not require prove of efficacy/effectiveness in its stated purposes (Canada Medical Device Regulation. https://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/index.html)*[179]. NeuroCatch® is designed to measure the cognitive brain function of patients by measuring event-related brain potentials through electroencephalogram (EEG) scanning. The results of the scan are thought to provide objective measurements of specific brain functions including auditory sensation, basic attention and cognitive processing. It is proposed that these measurements can be employed to identify areas for improvement, customize the treatment and/or recovery plan, as well as for understanding how the brain is functioning at the time of scan. *Important note: This statement suggesting that the NeuroCatch® Platform may function as a measurement tool and that it may provide something akin to a diagnosis, renders it necessary for there to be quantitive studies/data which can provide the necessary data/information to assess validity and reliability of this device as a measurement tool, as well as data on its sensitivity, specificity and responsiveness*[182,195].

Per information available from the producers, NeuroCatch® conducts a rapid 6-minute EEG scan to measure and report on cognitive brain function as measured by three event-related potentials (ERPs) parameters, i.e.: (https://www.neurocatch.com/the-neurocatch-platform/)

1. N100 (Auditory Sensation). The N100 response is induced by auditory tones that elicit a negative peak, typically occurring around 100 milliseconds after hearing the tones. The N100 represents sensory and perceptual processing of the tones.
2. P300 (Basic Attention). The P300 is a positive peak that occurs around 300 milliseconds after hearing unexpected tones. The P300 response is sensitive to unpredictable events that require attention, contextual updating and memory processes. The P300 is a physiological representation of information processing systems within the brain.
3. N400 (Cognitive Processing). The N400 is a negative peak that occurs around 400 milliseconds after hearing a mismatching word. The N400 response is sensitive to semantic language processing during speech perception. The N400 is a physiological representation of language comprehension systems within the brain.

ERPs are an application of EEG that specifically time-lock such electrophysiological activity to a stimulus or a behavioral response. The amplitude and latency of changes in voltage provide insight into the magnitude and timing of information processing in the brain[114,184].
The NeuroCatch® system consists of three electrodes embedded in a thin mesh cap worn by the patient, whereby these electrodes receive EEG signals elicited through audio sequences that play a variety of tones and word pairs for 6 minutes. During this time, NeuroCatch® records how fast the brain reacts to these sounds, as well as the strength of that response. The NeuroCatch® data processing software takes selected EEG scan data, processes it, and uses a proprietary algorithm to identify those three distinct peaks in the ERP data (https://www.neurocatch.com/for-practitioners/healthcare/). The company further claims that NeuroCatch® offers a scientific, evidence-based approach for the clinical utilization of ERPs (https://www.neurocatch.com/the-neurocatch-platform/).
In the company website, NeuroCatch® listed six studies, five on traumatic brain injury related patients and one on dementia, using the NeuroCatch® Platform (https://www.neurocatch.com/science/). However, only one study, titled "Assessing Repeatability of NeuroCatch® Platform Measurements: An Initial Assessment", assessed feasibility. This was a small study (n=10 healthy subjects), and was completed on February 1, 2018 (https://clinicaltrials.gov/ct2/show/NCT03421405?term=NCT03421405&draw=2&rank=1). *It should be noted that although this study was completed as of February 1, 2018, subsequent searches on medical literature databases failed to identify the publication of this study.*

Given the above background, the EBPG conducted a systematic review of literature for the purpose of investigating the efficacy/effectiveness of NeuroCatch® Platform in measuring brain cognitive function.

## Methods

- A comprehensive and systematic literature search was conducted on July 16 and July 19, 2021.
- The search was done on commercial medical literature databases, including the Cochrane Database of Systematic Reviews® (2005 to July 14, 2021), ACP Journal Club® (1991 to June 2021), UK York University Database of Abstracts of Reviews of Effects® (1st Quarter 2016), Cochrane Clinical Answers® (June 2021), Cochrane Central Register of Controlled Trials® (June 2021), UK NHS Health Technology Assessment® (4th Quarter 2016), UK NHS Economic Evaluation Database® (1st Quarter 2016), BIOSIS Previews® (1969 to 2008), Embase® (1974 to 2021 July 15) , Medline Epub Ahead of Print®, Medline In-Process, In-Data-Review & Other Non-Indexed Citations®, Medline Daily Update®, Medline® (1946 to July 15, 2021), Joanna Briggs Institute Evidence-based Practice Database® (Current to July 07, 2021) and the American Psychological Association PsycInfo® (1806 to July Week 1 2021), that are available through the Ovid® search platform.
- Combinations of keywords were employed in this literature search. These keywords included:
  1. (neurocatch **ADJ** platform) **OR** (neurocatch platform)
  2. neurocatch
  3. (healthtech connex)

4. ((n100 **OR** (auditory **ADJ** sensation)) **AND** (p300 **OR** (basic **ADJ** attention)) **AND** (n400 **OR** (cognitive **ADJ** processing))) **AND** (objective **ADJ** cognitive **ADJ** assessment)
5. ((n100 **OR** (auditory **ADJ** sensation)) **AND** (p300 **OR** (basic **ADJ** attention)) **AND** (n400 **OR** (cognitive **ADJ** processing))) **AND** (cognitive **ADJ** assessment)
6. ((n100 **OR** (auditory **ADJ** sensation)) **AND** (p300 **OR** (basic **ADJ** attention)) **AND** (n400 **OR** (cognitive **ADJ** processing))) **AND** ((measure **OR** measuring) **AND** (cognitive **ADJ** brain **ADJ** function))
7. (event-related **ADJ** potential) **AND** (objective **ADJ** cognitive **ADJ** assessment)
8. (event-related **ADJ** potential) **AND** (cognitive **ADJ** assessment)
9. (event-related **ADJ** potential) **AND** ((measure **OR** measuring) **AND** (cognitive **ADJ** brain **ADJ** function))
10. (brain **ADJ** vital **ADJ** signs) **AND** (cognitive **ADJ** assessment)
11. ((quantitative **ADJ** electroencephalography) **OR** (quantitative **ADJ** electroencephalogram)) **AND** (objective **ADJ** cognitive **ADJ** assessment)
12. ((quantitative **ADJ** electroencephalography) **OR** (quantitative **ADJ** electroencephalogram)) **AND** (cognitive **ADJ** assessment)

- No limitations, such as on the language or date of publication, were implemented in any of these searches.
- Manual searches were also conducted within the website of the NeuroCatch® Platform, and within the references of studies that were retrieved in full.

## Results

- Search results:
    - To date, there are no published studies identifiable through the above searches regarding the topics of: the NeuroCatch® Platform, the utility of combining the ERP component of N100 with P300 and with N400 in cognitive assessment, as well as on the concept of "brain vital sign" (promoted by the company) for the purpose of cognitive assessment.
    - 164[1-164] published studies were identified on ERP and cognitive assessment and one[165] study on ERP and brain function.
    - Thirteen[166-178] published studies were identified on quantitative EEG and cognitive assessment.
    - Upon examination of the titles and abstracts of the above combined 178[1-178] identified studies, two[37,114] studies were thought to be relevant and were retrieved in full for further appraisal.
    - Two[180,181] white papers, published by researchers employed by the manufacturer of the NeuroCatch® Platform and available through the company's websites (https://www.neurocatch.com/science/) were also retrieved.
    - A further twelve[183-194] studies were retrieved in full as a result of manual searches.

  - As such, overall, there were 16[37,114,180,181,183-194] studies retrieved in full for this systematic review investigating the efficacy/effectiveness of the NeuroCatch® Platform as a measurement tool for brain cognitive function.
- Of the two[37,114] studies identified from the literature searches, Connolly's paper[37] did not provide any data and will not be discussed further. A low-medium quality systematic review (*clear search strategy and reported results, but lacking critical appraisal for all of the included primary studies*) investigating whether event-related potentials (ERPs) during higher cognitive processing could detect subtle, early signs of neurodegenerative diseases (Alzheimer's disease and mild cognitive impairment) was reported by Paitel et al[114] . The authors found that the majority of primary studies were investigating EPRs of N200, N250, N400 and P300, either as stand alone or in combination (***none of the primary studies investigated the specific combination which the NeuroCatch® Platform uses for detecting brain vital sign, i.e. N100, N400 and P300***). The authors reported high heterogeneity regarding the ERPs components involved, the placement of EEG electrodes, as well as the amplitude and latency effects reported. The authors concluded that there were patterns of reduced amplitude and delayed latency in pathological aging, consistent with Alzheimer's disease-related brain atrophy and cognitive impairment. These effects were particularly evident in advanced disease progression (i.e., Alzheimer's disease more than mild cognitive impairment). *It should be noted that this systematic review did not report on the validity and reliability aspects of the ERPs as a measurement tool and how these ERPs (standalone ERP or in various combinations) performed in investigating disease progression.*
- The two[180,181] white papers on the NeuroCatch® Platform posted on the company's website did not provide any data relevant to the objective of this systematic review nor do they provide any rationale for the choice of using the three specific ERPs parameters, nor is there data to justify how these three ERPs would work together in measuring cognitive brain function. These two white papers will not be discussed further.
- With regard to (mild) traumatic brain injury, at present, there are no unique EEG features identified for effectively and reliably diagnosing this condition[185,194].

## Summary and Conclusions

- At present, there is no published study reporting data to support the efficacy/effectiveness of NeuroCatch® Platform as a measurement tool for brain cognitive function.
- At present, there is no published study reporting data to support the advantage of "brain vital sign" (involving the 3 ERPs parameters of N100, P300 and N400) in measuring brain cognitive function.

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## Appendix 1

**WorkSafeBC - Evidence-Based Practice Group Levels of Evidence** [adapted from 1,2,3,4]

| | |
|---|---|
| **1** | Evidence from at least 1 properly randomized controlled trial (RCT) or systematic review of RCTs. |
| **2** | Evidence from well-designed controlled trials without randomization or systematic reviews of observational studies. |
| **3** | Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 centre or research group. |
| **4** | Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included |
| **5** | Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees. |

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