

PILOT STUDY ON THE CARE FOR CHILDREN WITH MODERATE TO SEVERE AGITATION, WITH OR WITHOUT THE USE OF A SEMI-SUPERVISED SUPPORT SOLUTION

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Context

According to the 2017 report by the General Inspectorate of Social Affairs on "The organisation and functioning of the psychiatric care system, 60 years after the circular of 15 March 1960", psychiatric illnesses affect more than one in five people every year. For minors treated in child psychiatry, by establishments financed by the Dotation Annuelle de Financement (public hospitals and the majority of private non-profit hospitals), in full- or part-time hospitalisation, the majority of disorders are psychological development disorders (32%) and behavioural and emotional disorders (24.6%).

Hospitalization is reserved for the most complex situations of acute crisis, as well as for children whose care by a multidisciplinary team several times a week is necessary to support their psychological development. In our study, we focus on one of the clinical manifestations regularly present: the state of agitation when its intensity is moderate to severe. "The state of agitation is defined as a disorder of psychological, motor and relational behaviour that leads to an intolerant reaction from those around. The care teams will then implement care actions that will be a graduated response adapted to the intensity of these states of agitation. In addition to the support of a carer, we propose to use the "Inner Garden" device developed in 2014 within the POTIOC laboratory of INRIA in Bordeaux (National Institute for Research in Digital Science and Technology). It is an interactive Zen garden that provides feedback (topographical, physiological) in different sensory modes.

Objectives

The main objective is to compare the treatment including the ambient sensory biofeedback solution "Inner Garden", compared to the treatment without this solution, on the regulation of behavioural disorders during a crisis requiring the removal of the child from group care. Nursing support with the Inner Garden tool in three wards will be compared to the practice in six other wards without this tool.

The secondary objectives are to compare the nursing support with the biofeedback tool in three wards with the practice in six other wards not equipped with this tool concerning:

- Adverse events related to aggression/violence in group care sessions;
- Children's emotional regulation over the care cycle (school year).

Methodology

Single-centre study comparing paramedical management with and without the "Inner Garden" biofeedback tool.

The study takes place over a school year (from November 2020 to July 2021) corresponding to a cycle of care in a children's hospital unit.

Inclusion criteria

- Children from 3 to 12 years;

- Cared for in the child hospitalization unit of the child psychiatry department of La Rochelle;
- Parent who is a member or beneficiary of a social security scheme ;
- Information of the child and the legal representative(s) and consent signed by the legal representative(s).

Exclusion criteria

- Refusal to participate by the child and/or legal representative(s)

Statistical analysis plan

The child psychiatry department is organized into three tripods, each comprising three inpatient units for children. A nurse-educator pair is assigned to each unit. Each pair takes care of three groups of three to five children per week.

In each tripod, one ward are equipped with the "Inner Garden" biofeedback tool and two ward does not have access to this tool and serve as control group.

To meet the main objective, a population homogeneity test will be carried out to compare between nursing support with the biofeedback tool and without the tool will focus on the number of moderate to severe crisis that did not allow the child to re-enter group care during the session.

To meet the secondary objectives, the comparison between nursing support with the biofeedback tool and without the tool will focus on:

- comparisons of means of emotional regulation-composite, emotional regulation, and emotional dysregulation scores measured at inclusion and visit 2 (ERC-vf : Emotion Regulation Checklist);
- A population homogeneity test to compare the number of adverse events related to aggression/violence during group care sessions.

Duration of the research

- Duration of the screening period: 2 months (17 August to end of October), corresponding to the period when the groups of children in the tripod units are formed
- Duration of the inclusion period: 5 days (2-6 November 2020)
- Duration of participation of each participant: 8 months (until 6 July 2021)
- Total duration of the research: 8.5 months

Expected benefits

This pilot study will determine the frequency of moderate to severe seizures managed by caregivers on children's inpatient units with and without the Inner Garden tool. These figures will be used as an estimate to calculate the number of children to be included in a comparative multi-centre study.

Through the reduction of times of tension, pain and anxiety, the Inner Garden should facilitate reintegration into group care, provide a less restrictive response to severe behavioral disorder by replacing constraint with relationship and/or observation (positive reinforcement). This tool makes it possible to better respect the distance and space sometimes required by the child and thus reduce the risk of injury when physical restraint is used (head butting). By helping to soothe, it may also help to reduce the risk of stigmatization of the child.

It may also make it easier for the child to regulate himself emotionally and behaviorally.

The Inner Garden is an additional tool for carers, which could help reduce their sense of helplessness in the face of unmanageable situations.