# <u>The effect of waiting room's environment on the levels of anxiety</u> <u>experienced by children prior dental treatment</u>

# NCT03197129

**Protocol 23.3.17** 

#### Introduction

It has been estimated that about 11% of children and adolescents suffer from dental anxiety<sup>1</sup>. The level of the subject's dental anxiety is affected by environmental factors and by personality traits<sup>2</sup>.

Several dental stimuli can cause anxiety; one of them is the waiting in the waiting area<sup>3</sup>. The amount of time the patient has spent awaiting treatment and the nature of the waiting room environment influence the anxiety level prior treatment<sup>4</sup>.

Waiting room environment and atmosphere was the focus of several studies. Among the different methods to reduce anxiety in the waiting room were: exposure to positive images of dentistry<sup>5,6</sup>, aromatherapy<sup>7,8</sup>, and music<sup>9</sup>.

The Snoezelen environment consists of a multisensory adapted environment coupled with client-centered therapy. The original idea was to use the multisensory environment to function as leisure and relaxation to calm the patient with cognitive impairment<sup>10</sup>. A sensory adapted dental environment (SADE) has been developed, based upon the Snoezelen environment, and found to be suitable in reducing dental anxiety and maladaptive behaviors and facilitating a calming effect in the dental clinic among children during routine dental prophylactic cleaning<sup>11-13</sup>.

# Objective

The objective of the present study is to compare the effect of waiting room's environment on the levels of anxiety experienced by children, in SADE and traditional waiting rooms.

# Materials and methods

- Participants- boys and girls, ages: 3-10 years waiting to dental examination or dental treatment with/without conscious sedation. The participants will be recruited from the pediatric dental clinic in Hadassah Ein Kerem. Exclusion criteria: mentally unable to understand and answer the Venham Picture Test (VPT) to assess anxiety before treatment, accepted immediately without waiting.
- Waiting room- <u>The SADE waiting room</u>: a small waiting room (2.5mx2.5m) inside the clinic with 6 seats. All ceiling fluorescent lighting is removed. The adapted lighting consisted of slow-moving, repetitive visual color effects created by a projector, and a lighting column that children can touch and climb on. Auditory stimuli include rhythmic music, which is heard via loudspeakers. <u>The traditional waiting room</u>: a waiting area outside the clinic with ten seats in one row faces the reception desk in an area of 15 square meters. The area is air-conditioned, moderately well-lit, without posters or paintings on the walls, and no reading material.
- *Dental anxiety scale* Venham Picture Test (VPT) is widely used and easily administered<sup>14</sup>. In this test, children are presented with eight cards, with two figures on each card, one 'anxious' figure and one 'nonanxious' figure. They are

asked to choose the figure from each pair that describes how they feel at that particular time. All cards are shown in their numbered order. If an anxious figure is chosen, a score of one is recorded. If a nonanxious cartoon is chosen, a score of zero is recorded. A measure of anxiety is obtained by totaling the number of times the child picks the cartoons depicting the anxious state (minimum score, 0; maximum score, 8). The participants will be asked to answer while waiting in the waiting room just before entering the clinic.

- *Study design* The study is a parallel randomized trial. The participants will be randomly assigned to one type of waiting room.
- *Additional data-* gender, age, the lengths of waiting, the purpose of the visit (examination or treatment with/without sedation), dental experience, type of waiting room, child escort.
- *Safety-* there are no reports of adverse effect or risks using SADE. Cermak et al. reported that more than 95% of children accepted all components of SADE; 1 child stated that he did not like the music and requested that we turn it off, and 1 child reported that she did not like having the lights dimmed because she was afraid of the dark. Parents provided positive comments about the intervention as well<sup>15</sup>.

# Statistical analysis plan

Descriptive statistics – tabulate for the demographic and clinical characteristics. Chi-squared and Fisher's Exact tests - utilize to test the association between the categorical variables and waiting room type.

A T test with unequal variance - to test the association between VPT score and waiting room type.

Estimated unadjusted and adjusted slopes from linear regression to examine the association between VPT score and waiting time; as well as, waiting room type.

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