Effects of Virtual Reality System in Children With Developmental Delays

This study has been completed.

| Sponsor: | Ru-Lan Hsieh |
| Collaborators: |
| Information provided by (Responsible Party): | Ru-Lan Hsieh, Taipei Medical University |
| ClinicalTrials.gov Identifier: | NCT02184715 |

Purpose

The purpose of this study is to investigate the effects of virtual reality system on children with developmental delays.

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<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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<tbody>
<tr>
<td>Developmental Delays</td>
<td>virtual reality system</td>
<td>Phase 4</td>
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Study Type: Intervventional
Study Design: Health Services Research, Crossover Assignment, Single Blind (Outcomes Assessor), Randomized, Efficacy Study
Official Title: The Additional Therapeutic Effects of Virtual Reality System in Children With Developmental Delays

Further study details as provided by Ru-Lan Hsieh, Taipei Medical University:

Primary Outcome Measure:
- health of children (Pediatric Quality of Life Inventory) [Time Frame: changes from baseline at one and two months.] [Designated as safety issue: No]

Following the recruitment and baseline assessment, outcome measures were assessed before treatment (Time 0), at the end of first intervention in the fourth week (Time 1), and at the end of second intervention...
in the eighth week (Time 2).

Enrollment: 157
Study Start Date: January 2009
Study Completion Date: December 2011
Primary Completion Date: January 2011

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<th>Arms</th>
<th>Assigned Interventions</th>
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| Active Comparator: Virtual reality video game | virtual reality system  
Participants received rehabilitation treatment and additional virtual reality system (30 minutes of interactive virtual reality system play, two times per week, in eight sessions over a 4-week span) for 1 month, followed by rehabilitation treatment for 1 month  |
| Placebo Comparator: Virtual reality system | virtual reality system  
The participants were randomly assigned to either Group A or Group B. Group A received rehabilitation treatment and additional virtual reality system for 1 month, followed by rehabilitation treatment for 1 month; by contrast, the participants in Group B received rehabilitation treatment for 1 month, followed by rehabilitation treatment and additional virtual reality system for 1 month. |

Participants attended eight 30-minute sessions of virtual reality system for 4 weeks in addition to regular rehabilitation programs.

Eligibility

Ages Eligible for Study: 2 Years to 12 Years
Genders Eligible for Study: Both

Inclusion Criteria:

• confirmed to have developmental delays
• provided informed consent
• 2 to 12 years old

Exclusion Criteria:
- failed to provide informed consent

Contacts and Locations

Locations
Taiwan
Shin Kong Wu Ho-Su Memorial Hospital
Taipei, Taiwan, 111-01

Investigators
Principal Investigator: Ru-Lan Hsieh, MD

More Information
Responsible Party: Ru-Lan Hsieh, MD, Taipei Medical University
Study ID Numbers: HP-01
Health Authority: Taiwan: Department of Health