A case study of the usability evaluation and redesign of the upper extremities rehabilitation device for stroke patients

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Abstract: In current years, rehabilitation device integrates with digital technology to meet the need for therapy. This project selects a rehabilitation device as “Curamotion Exer III” which designed with digital technology and used in clinical. We evaluate the effectiveness and usability of the device. Based on the evaluation results, we can then generalize a design policy for the device. Five stroke patients received 24 sessions of upper extremity exercises via Curamotion Exer III in addition to regular conventional rehabilitation. Outcome measures include a questionnaire, Fugl-Meyer Assessment of Physical Performance. The results can be summarized three points: 1) after using this device, patients with upper extremity motor function impairment had improved. 2) patients are highly satisfied the effectiveness and usage of this device. 3) this device to improve the design proposal includes strengthening the stability of the device; adjusting the angle of rotation bearings; enhanced the range of the resistance and clearly marked resistance size; hand grip itself has a fixed component; the interface is easy to read and operate and placed in the appropriate operating position for patients; can transform different operating parts.

Key words: Therapy effectiveness, Usability evaluation, Upper extremity rehabilitation device redesign

1. Introduction

People with Cerebrovascular Disease may cause motor disturbances in one side of the body. Upper-extremity motor deficit is one of the main symptoms for the stroke patients [1]. About 85% stroke patients have function impairment on upper-extremity at the beginning stage of the stroke, and still about 40% patients have function impairment at the final stage of stroke [2]. In order to recover the function for daily life, the occupational therapy is needed for the stroke patients. During the occupational therapy, the doctor need to diagnose the stroke level of each stroke patient, then selected a suitable therapy product for rehabilitation to restore their movement function. Rehabilitation devices are essential tools in the process of rehabilitation therapy. Therefore, rehabilitation devices must be designed with users in mind. Such products can increase acceptance, and improve quality of life [3].

In recent years, the fields of ergonomics, occupational therapy and physical therapy have grown increasingly intertwined as professional knowledge and skills are blended to advance applications that optimize human well-being and performance. Ergonomics is not solely confined to the workplace, products and environments should match the abilities, needs, and perceptions of the user [3]. High quality, well-designed medical devices are
necessary to provide safe and effective clinical care for patients as well as to ensure the health and safety of professional and lay device users. In order to design good medical device, capturing the requirements of users and incorporating these into design is an essential component of it [4]. Furthermore, in the process of rehabilitation device development, the product designers should fully aware of the user’s needs, where users include not only patients and therapists, but also peripheral users such as caregivers, hospital stuff and technicians. In other words, the user's needs encompass more than just clinical effectiveness. The peripheral users, in this context, functions in the provision of clinical status and knowledge to the designer. Based on considerations of clinical status and user needs, the designer’s responsibility is then to design the rehabilitation device to meet the needs of all those concerned. Therefore, the usage assessment of the UERD by users is very important for the improvement and redesign of existing UERD for better function as well as performance. Charles Eames also stated that “Recognizing the need is the primary condition for design” [5].

With the development of digital technology, some of rehabilitation device combined with digital functions, in order to meet the demand of the treatment. These device are currently in clinical use, but have not been assessed the use and treatment effectiveness. This project selects a rehabilitation device as “Curamotion Exer III” which designed with digital technology and used in clinical. This study aimed to evaluate the effectiveness, usability and satisfaction of the device for stroke patients, and to summarize a guideline for improvement design of such devices. The results provide a reference for development of upper extremity rehabilitation device design with digital functions.

2. Methods

A pilot clinical trial was implemented to compare the therapeutic effectiveness between pre-, mid- and post-intervention Curamotion Exer III in rehabilitation. The usability and satisfaction of using Curamotion Exer III in rehabilitation were also assessed by stroke patients, and to summarize a guideline for improvement design of such device.

2.1 Effectiveness evaluation

Subjects. Stroke patients were recruited from the occupational therapy department of Chung Shan Medical University Hospital. Inclusion criteria were the following: (a) Hemiparetic with upper extremity dysfunction following a single unilateral stroke, (b) a history of first-time stroke (3-48 months post stroke), (c) the required upper extremity rehabilitation convalescent levels were Brunnstrom stage III to IV, i.e., having basic upper extremity synergies to perform joint movement voluntarily, (d) ability to communicate, (e) able to understand and follow instructions, (f) no serious problems with balance. Exclusion criteria were the following: (a) engaged in any other rehabilitation program during the study and (b) serious aphasia or cognitive impairment. Each patient gave informed consent. This study was approved by the Human Research Ethics Board of Chung Shan Medical University Hospital.

Locations and settings. This clinical trial was conducted in the occupational therapy department of the Chung Shan Medical University Hospital. Curamotion Exer III was used in this trial (Figure 1). It includes three functions, as following: a) Automatic 5-function LCD display indicates stride count, strides per minute, time exercised, calories consumed and scan of all functions. b) Resistance knob for adjusting the resistance of the unit. c) Handlebar radius: Arm length adjusts from 13” (33 cm) to 22” (56 cm).
Functional assessments. Fugl-Meyer Assessment of Physical Performance (FMA) [6]. It was used to evaluate the motor functions. The upper extremity motor test part with a possible highest score of 66 was adopted in the evaluation. The reliability of Fugl-Meyer Assessment is generally considered reliable [7].

Duration of intervention. The training comprised 24 sessions during 2 months, with each session lasting 30 minutes. The therapeutic effectiveness was evaluated before, middle and after completing the 24 training sessions. In addition to this training (Curamotion Exer III) in this study, all patients also received at least 1 hour of occupational therapy and 1 hour of physical therapy.

2.2 Usability evaluation
An interviewer-administered questionnaire was designed to evaluate usability and satisfaction of using Curamotion Exer III. The questionnaire included four parts:

1) effectiveness
   - How do you feel about the therapy effectiveness of the device in restoring the patient’s upper extremity movement functions?

2) ease of use
   - Do you have any usage problems in using the device for therapy?
   - Do you know how to use all the functions of the device?
   - Do you use the 5-function LCD display to assist you for therapy?

3) comfort
   - Is it comfortable for you to operate the device?

4) satisfaction
   - Do you satisfy with using the device in rehabilitation?

2.3 Data analysis
The characteristics of the study groups were described as mean and SD. All data were analyzed using paired-samples t-tests for pre- and post-therapy values. To analyze the interview data from occupational therapists and stroke patients, the recording was firstly transcribed verbatim. Similar opinions were combined and all unique responses were independently itemized for further discussion.
3. Results

3.1 Effectiveness evaluation of stroke patients

Characteristics of the stroke patients. A total of 7 post-stroke patients were admitted to the Occupational Therapy Department of Chung Shan Medical University Hospital. Of the 2 who did not finish, one was transferred out of the hospital, the other was not complete the final assessment. Five consecutively screened stroke patients finally completed the trial, with a mean age of 66.80 years (SD=14.11). The characteristics of the patients are shown in Table 1.

The result of the effectiveness treatment. Five subjects who completed 24 sections were analysis (Table 2). The result shown that statistically significant improvements in pair 1 ($t = -4.276$, $p<0.05$) that subjects had better improvements for upper extremity functions than pre-treatment. For an effect-size of 0.821, the value of 73% indicates that the average person in the mid-treatment would score higher than 73% of the pre-treatment that was initially equivalent.

Table 1. Characteristics of the stroke patients participating in the study

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects</td>
<td>5</td>
</tr>
<tr>
<td>Gender (male/female)</td>
<td>5/0</td>
</tr>
<tr>
<td>Age (years) (mean, SD)</td>
<td>66.8 (14.11)</td>
</tr>
<tr>
<td>Paretic side (left/right)</td>
<td>1/4</td>
</tr>
<tr>
<td>Time from stroke onset to involve intervention (years) (mean, SD)</td>
<td>0.58 (0.29)</td>
</tr>
<tr>
<td>FMA (UE) (pre-treatment) (mean, SD)</td>
<td>36.2 (20.96)</td>
</tr>
</tbody>
</table>

FMA (UE): The upper extremity portions of the motor subscale of the Fugl-Meyer Assessment

Table 2 Fugl-Meyer Assessment scores of Pre and post-intervention for all stroke patients

<table>
<thead>
<tr>
<th></th>
<th>number of subjects</th>
<th>Mean</th>
<th>SD</th>
<th>t</th>
<th>$\eta^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>pair 1</td>
<td>pre-treatment</td>
<td>5</td>
<td>36.2</td>
<td>20.96</td>
<td>-4.276*</td>
</tr>
<tr>
<td></td>
<td>mid-treatment</td>
<td>5</td>
<td>42.0</td>
<td>18.75</td>
<td></td>
</tr>
<tr>
<td>pair 2</td>
<td>mid-treatment</td>
<td>5</td>
<td>42.0</td>
<td>18.75</td>
<td>-0.701</td>
</tr>
<tr>
<td></td>
<td>post-treatment</td>
<td>5</td>
<td>44.2</td>
<td>23.41</td>
<td></td>
</tr>
<tr>
<td>pair 3</td>
<td>pre-treatment</td>
<td>5</td>
<td>36.2</td>
<td>20.96</td>
<td>-2.202</td>
</tr>
<tr>
<td></td>
<td>post-treatment</td>
<td>5</td>
<td>44.2</td>
<td>23.41</td>
<td></td>
</tr>
</tbody>
</table>

* P-value of difference at pre-gaming between three groups

3.2 Usability evaluation of stroke patients

Effectiveness. All five subjects agreed that the device is effective to improve their upper extremity functions.

Ease of use. a) Four subjects had difficulty to hold the handlebar, hence the need for additional bandages to tie their hand to hold the handlebar. One patient mentioned that he has been restored some hand movement ability, but still need a bandage to be fixed the hand on the handlebar. Because this way made him felt the hand operation more easy and more secure. b) When the patient hold the handlebar to rotate, the patient's forearm is always easy...
to bump into the rotating radius. c) The base of the device is not stable to operate because it might not be able to sustain heavy forces during operation. d) Resistance sizes are not clearly marked numbers on resistance knob, so some patients feel the strength of the resistance to change the resistance sizes. However, some patients firstly rotated the resistance knob to calculate the sizes of resistance, and adjusted to the appropriate size of resistance. e) Some patients unknown the all functions of this device. f) Automatic 5-function LCD display is too small and difficult to read internal display information.

Comfort. The operating height of the handlebar is too high to cause the burden on their shoulder.
Satisfaction. All patients are highly satisfied the effectiveness and usage of this device.

3.3 Design guidelines concerning the improvement of this device
Design guidelines can be summarized into the following points:

a) strengthening the stability of the device.
b) adjusting the angle of rotation bearings.
c) enhanced the range of the resistance and clearly marked resistance size.
d) the handlebar itself has a component for fixing the hand.
e) the interface is easy to read and operate and placed in the appropriate operating position.
f) transform different operating components.

4. The improvement design of this device
Based on the design guidelines, a design proposal is proposed, the design features are described as follows:

a) According to the usage need, the device can be changed into the vertical or the horizontal operation mode (Figure 2).
b) A screen will display the number of the resistance sizes, the number of turns, and operation time (Figure 2).
c) The square loop in the back of the device can assist user to pull the device (Figure 3).
d) The adjustment knob is placed on the bracket for adjusting the appropriate height (Figure 4).
5. Conclusions
This project selects the rehabilitation device as “Curamotion Exer III” which designed with digital technology and used in clinical. We evaluate the effectiveness and usability of the device. Based on the evaluation results, we can then generalize a design policy for the device. The results can be summarized three points: 1) after using this device, patients with upper extremity motor function impairment had improved. 2) patients are highly satisfied the effectiveness and usage of this device. 3) this device to improve the design proposal includes strengthening the stability of the device; adjusting the angle of rotation bearings; enhanced the range of the resistance and clearly marked resistance size; hand grip itself has a fixed component; the interface is easy to read and operate and placed in the appropriate operating position for patients; can transform different operating parts.

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6. References


