UNIVERSITY OF SOUTH CAROLINA

Improvements on the Kinesia HomeView System for Parkinson's Patients

BIOMEDICAL ENGINEERING SENIOR DESIGN II

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I. INTRODUCTION

Parkinson's disease affects 50-60,000 people in the United States each year, making it one of the most common nervous system diseases of the elderly. Parkinson's disease is a slow progressing, neurodegenerative brain disorder in which the neurons responsible for producing dopamine are slowly damaged. An insufficiency of dopamine in the body can result in loss of smooth muscle control, tremors, automatic movements, irregular gait and a variety of other symptoms. The cause of this damage is still unknown; therefore the goal of treatment is to control Parkinson's symptoms. The current approach in the medical field used to assess patients is the Unified Parkinson's Disease Rating Scale, which is a set of questions doctors ask patients to evaluate their symptom progression. However, this method is subjective and often frustrating for Parkinson's patients.

In order to provide physicians with more objective and quantitative information, Great Lakes Neurotechnologies/CleveMed has designed the Kinesia HomeView System. This system consists of a patient kit, as well as a physician web interface (Figure 1). After speaking with a patient, the physician programs the device with individualized diaries, medications and exercises. The patient can then take the device home where it is utilized. The kit contains software that instructs the patient through a series of motor tasks (Figure 2). In diary mode, the patient can enter medication times and their overall estimation of their symptoms.

All information is recorded and later uploaded to the physician web interface. Algorithms on the physician interface generate a score (0-4) based on motor task symptom severity, which correlates to the Unified Parkinson's Disease Rating Scale (Figure 3). Scores can be tabulated over days, weeks and months. These scores are evaluated and interpreted, along with symptom trends and videos by the treating physician.

II. OBJECTIVES

GSTechnologies's purpose in pursuing this project was to aid CleveMed in producing a product with better user-interface and a more portable design. Our company evaluated the current human interface system, Kinesia HomeView, by conducting preliminary field tests on groups of people that represented a control

population as well as a test population. Upon completion of the testing, our company suggested improvements on the Kinesia HomeView to CleveMed for their discretion and implementation.

(1) Determine which aspects of the Kinesia HomeView need improvements
(2) Facilitate field studies to evaluate which aspects of interface demand more attention, and to compare survey results by age group
(3) Suggest improvements to CleveMed

III. METHODOLOGY

Before the device was obtained, we had the task of defining which portions of the Kinesia HomeView System we were to work on improving. After speaking with Joe Giuffrida, we decided to focus on issues with the patient kit interface and finger device ergonomics. We selected these particular parts of the device to investigate because the target patient pool is an elderly population and the device incorporates rather advanced technology.

After obtaining the device, we reviewed the tutorial packet and scheduled a training session with CleveMed. Maureen Phillips from CleveMed trained us on how to operate both the physician web interface as well as the patient kit. Each team member also took the opportunity to act as physician and patient in order to gain a thorough understanding of the system.

After gaining a thorough understanding of the device, our team identified the key areas of the patient kit to be evaluated. Applying our understanding, we formulated a participant questionnaire to be used in the studies.

Before beginning testing on the participant pool, we submitted an online application on the eIRB Research Portal for expedited review with human studies from the Institutional Review Board through the university. During the course of the application process we found that CITI training was required for all members of our team including advisors and mentors.

Due to scarcity of potential Parkinson's disease patients, our team decided to contact assisted living communities in the Columbia area for potential testing

candidates. The inadequate number of Parkinson's patients within these communities led our team to revise the original intention of our project which called for the testing of strictly Parkinson's patients. Our team justified the alteration of the patient pool by working under the assumption that any major issues with the device would be noticed by not only Parkinson's disease patients but also age matched individuals without Parkinson's disease. Included in the patient survey, participants were asked to identify if they were: (a) 18-25 (b) 26-30 (c) 31-50 (d) 51 & above.

Because our team was unable to gain approval from IRB committee, we were unable to test the device with the assisted living communities. Our team conducted field tests on volunteers that fell within the age groups. We performed the trials at the university over the course of several days. Each participant was briefed on the device and asked to sign consent before beginning testing the device. Upon finishing the exercise, each participant completed an anonymous survey about the functionality of the tablet interface and finger device. The consent form and questionnaire can be found in the Appendix.

IV. RESULTS

As discussed previously, the testing performed for the purpose of this project was preliminary testing. The specific aims were to identify the flaws of the device and to evaluate whether age, and therefore technological exposure, has an effect on the patients comfort level in operating the system. Throughout the course of the project, our team surveyed 20 subjects.

Our first evaluation of the data was to determine which aspects of the device interface would require the most improvement. Our team performed statistical analyses of each question. The questionnaire included a total of 18 questions: five devoted to subject information, three to device set-up, two to the "My Symptoms" portion, seven to the "My Tests" portion, and one overall question about the device. The results we compiled as a function of interface property are compiled Figures 4 and 5.

Our secondary evaluation of the data was focused on comparing survey results by age group. For the purpose of assessing the surveys, subjects were placed into 2 categories: a "Control" group, which included subjects from the ages of 18-30 and a

"Test" group, which included subjects from ages 30 and above. The significance behind the age divisions will be explained in the discussion portion of our paper. The device was evaluated by a subject pool of n=20, where 50% of the subjects fell in the "control" group and 50% fell in the "test" group.

The first step in evaluating the data by age was to decide if our assumption about technological exposure was valid, we hypothesized that test subjects of older age, would be less exposed to computer technology. Our hypothesis proved to be true, the test group averaged only 5.1 hours of computer use a day, where as the control group averaged 6.8. Which is a 28.6% difference. Neither group contained outliers.

The next step was to compare survey results with respect to age groups. Since there were two types of question formats the results have been summarized in two comparison graphs found in the appendix. Figure 6 is an evaluation of the yes/no-type questions; the percentages shown are the percent of subjects that indicated that a particular portion of the device needed improvement. Figure 7 is an evaluation of the rating-type questions (1-5 scale), the higher the numbers, the more difficulty the subjects had operating that portion of the device.

V. DISCUSSION

We divided subjects into either "Control" or "Test groups based on technological exposure with 18-30 being the most technologically savvy and 50 & above being least. From research, our team found that over 90 percent of Parkinson's patients are over the age of 50. With this knowledge, we concluded that the most relevant feedback we received would come from the 50 & above age group. We also found from the National Parkinson's Foundation that approximately 10 percent of Parkinson's suffers will exhibit symptoms before the age of 50. However, they also stated that often times Parkinson's disease before the age of 50 goes undiagnosed. From this information, we felt that the 30-50 age group should also be included as representation of early onset Parkinson's patients, and therefore placed into the "Test" group. Less than one percent of Parkinson's patients will exhibit symptoms before the age of 30; therefore, we chose age group 18-30 as our "Control".

Evaluation of the interface properties graphs reveals that the "My Tests" portion of the interface was the area that subjects had the most difficulty with. This is apparent

because for the Set-Up and "My Symptoms" portion of the interface a maximum of 15% of the total population indicated improvements were desirable. Whereas (for every property in question) under the "My Tests" evaluation, over 20% of subjects indicated improvements were desirable.

Evaluation of the Control vs. Test group's graphs proves the original theory, that indeed the "Test" group of subjects (representative of a Parkinson's Disease age-group) experienced more difficulty when working with the device, than did subjects of the "Control" group. As is obvious in the graphs, a higher proportion of "Test" group subjects had difficulty with every property in question. The only exception to this trend is a question involving a video of the symptoms, as well a question involving the instructions provided before each exercise.

Throughout the survey subjects were also allowed to comment on each aspect of the device. The follow list, summaries participant comments

- The video recording should have start-stop functionality
- It was difficult to fit into the screen when demonstrating the symptoms
- Subject was unsure of how to place the finger sensor on
- The finger device was too loose
- The spoken instructions were unclear
- For the color exercise, there needs to be an example or more detailed explanations, it's too quick
- Volume adjustment during instructions would be helpful, or a head phone jack

As stated earlier in this section, the results of this study reflect only preliminary findings, however our expectation is that our analysis will assist future groups working on the project to refine their testing methods.

VI. FUTURE STRATEGIES

Given our assessment of the device was rather preliminary, there are a number of specific areas of the Kinesia we would recommend future groups focus their research on. The first aim we would suggest is testing the device on actual Parkinson's patients, due to the time constraints our groups faced, our assessment of the device used a

rather limited test group. In the case that the IRB application is approved, a simple amendment through the IRB, to change the PI and study staff would allow future teams to work under our IRB approval. This would permit them to devote more time to recruiting appropriate test subjects.

Our team has been in contact with two communities that are willing to participate in trials- Still Hopes and Christopher Towers. We have recorded the contact information and will recommend that future teams pursue trials at these locations first.

In addition, from the results of our preliminary study, our group would suggest that future studies focus more attention on the "My Tests" portion of the device. Our survey posed broad based questions about all aspects of the device, but the questionnaire results indicate that most uncertainties arose when the subjects were actually performing the exercises. Therefore, a more in-depth questionnaire about all aspects of these tasks would be more effective.

A further advancement for this project could include developing and implementing solutions to the observed problems with the user interface and finger sensor. We were unable to develop and implement changes due to time constraints and lack of a disposable device.

The website aspect of the device could also be considered in future studies. Although we noticed several problems with the website, which physicians use, we did not have the time or resources to adequately formulate solutions.

VII. PROBLEMS FACED DURING TESTING

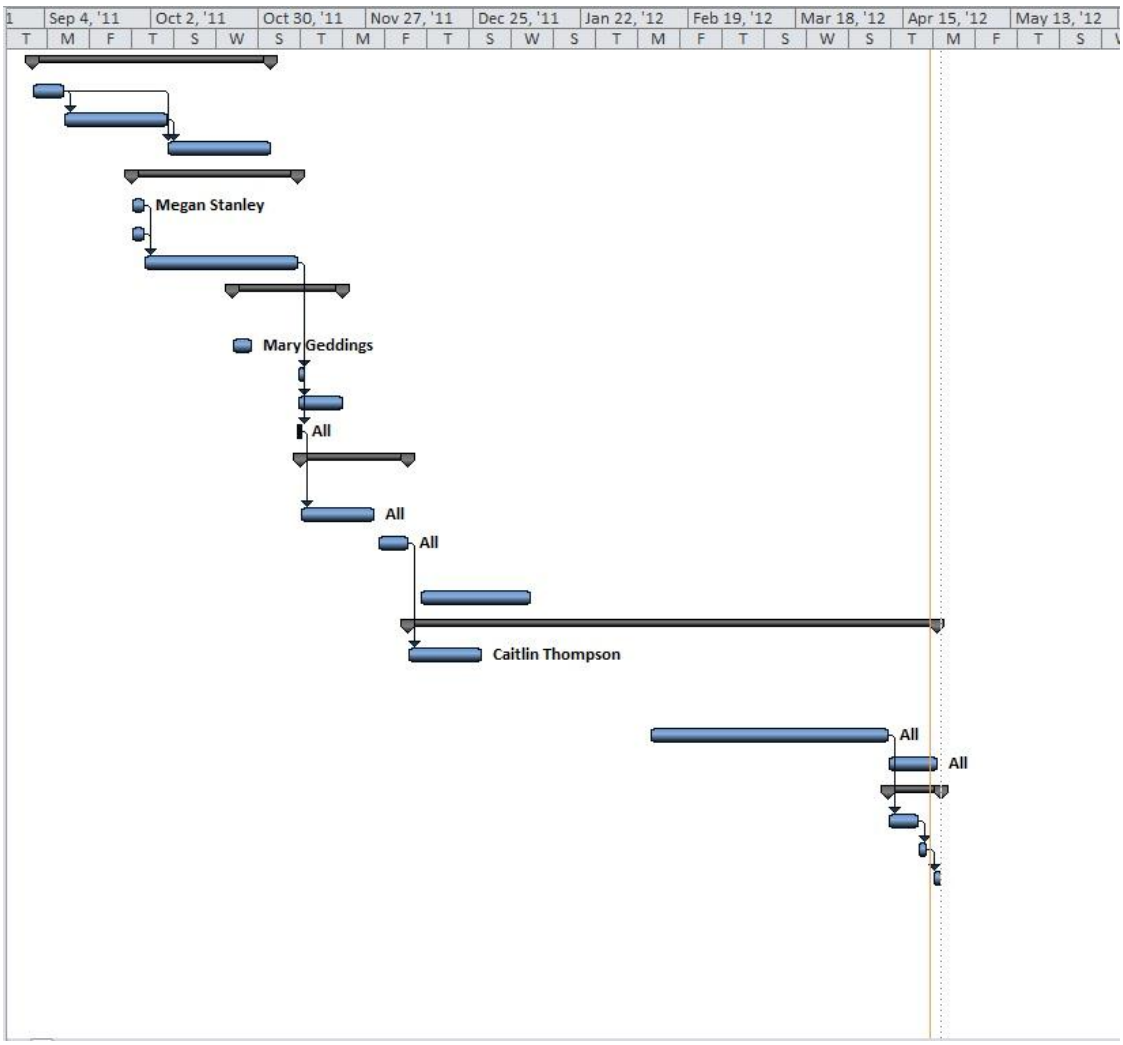
The initial delay in receiving our device held up the progression of our project significantly during the first semester, as you can see below in our timeline. Another problem we faced was that there is not a large population of Parkinson's patients. Although we were able to circumvent this problem, it altered the scope of our study. Additional delay in submitting the eIRB application led to a further delay in the project during the second semester. The CITI training, which we discovered had to be completed rather late in the process, was very time consuming. Also, because we were unable to provide the mentor and advisor with enough time to finish the CITI training, they did not have the ability to finish the training. The delay in the eIRB application, as

well as the CITI training, led to the inability to test in assisted living communities because of time constraints.

VIII. TIMELINE

	Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names
1		**Project Development**	**44 days**	**Thu 9/1/11**	**Tue 11/1/11**		**All**
2		Project Selection	6 days	Thu 9/1/11	Thu 9/8/11		
3		Research Project	19 days	Fri 9/9/11	Wed 10/5/11	2	
4		Research Parkinson's c	19 days	Thu 10/6/11	Tue 11/1/11	2,3	
5		**Obtaining Device**	**31 days**	**Tue 9/27/11**	**Tue 11/8/11**		
6		First contact with spor	3 days	Tue 9/27/11	Thu 9/29/11		Megan Stanley
7		Request for Kinesia Hc	3 days	Tue 9/27/11	Thu 9/29/11		
8		Awaiting arrival of Kir	28 days	Fri 9/30/11	Tue 11/8/11	6,7	
9		**Familiarizing the Team with the Device**	**20 days**	**Sun 10/23/11**	**Sun 11/20/11**		
10		Scheduled conferenc	5 days	Sun 10/23/11	Thu 10/27/11		Mary Geddings
11		Obtained login inform	2 days	Wed 11/9/11	Thu 11/10/11	8	
12		Tutorial of the Kinesia	9 days	Wed 11/9/11	Sun 11/20/11	8	
13		Appraisal of device by	1 day	Wed 11/9/11	Wed 11/9/11	8	All
14		**Planning for Second Semester**	**20 days**	**Thu 11/10/11**	**Wed 12/7/11**		
15		Compiled survey	13 days	Thu 11/10/11	Mon 11/28/11	13	All
16		Planned second semester testing	6 days	Wed 11/30/11	Wed 12/7/11		All
17		Winter break	22 days	Sun 12/11/11	Sun 1/8/12		
18		**Pre-test Planning**	**98 days**	**Thu 12/8/11**	**Mon 4/23/12**		
19		Obtained information on potential trial location	13 days	Thu 12/8/11	Mon 12/26/11	16	Caitlin Thompson
20		eIRB application	44 days	Thu 2/9/12	Tue 4/10/12		All
21		CITI training	9 days	Wed 4/11/12	Mon 4/23/12		All
22		**Testing and Results**	**10 days?**	**Wed 4/11/12**	**Tue 4/24/12**		**All**
23		Testing	6 days	Wed 4/11/12	Wed 4/18/12	20	
24		Compiled results	2 days	Thu 4/19/12	Fri 4/20/12	23	
25		Suggested improvements to CleveMed	2 days	Mon 4/23/12	Tue 4/24/12	24	

Timeline Spreadsheet



Timeline Layout

IX. BUDGET

Our team was able to print the consent forms and questionnaires for free. Testing facility was also free because we were able to use an empty classroom at the university. The Kinesia HomeView device was provided by CleveMed at no charge. These were the only anticipated costs for our overall project; therefore, our team spent no money.

X. ACKNOWLEDGEMENTS

Dr. Joseph Giuffrida: CleveMed/Great Lake Neurotechnologies

Maureen Phillips: CleveMed/Great Lake Neurotechnologies

Dr. Abdel E. Bayoumi: University of South Carolina Biomedical Engineering Department

Nick Metrokos:: University of South Carolina Biomedical Engineering Department

X!. REFERENCES

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(3)"Parkinson's Disease Information Page." National Institute of Neurological Disorders and Stroke (NINDS). Web. 11 Oct. 2011. <http://www.ninds.nih.gov/disorders/parkinsons_disease/parkinsons_disease.html

(4) "Tele-diagnostics for Remote Parkinson's Monitoring - Full Text View - ClinicalTrials.gov." Home - ClinicalTrials.gov. Web. 11 Oct. 2011. <http://clinicaltrials.gov/ct2/show/NCT01356056>.

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(6) "Parkinson's Disease" National Parkinson's Foundation. Web. 4 Mar 2012. < http://www.parkinson.org/Parkinson-s-Disease/PD-101>.

Appendix

Figure 1: Schematic of Kinesia HomeView

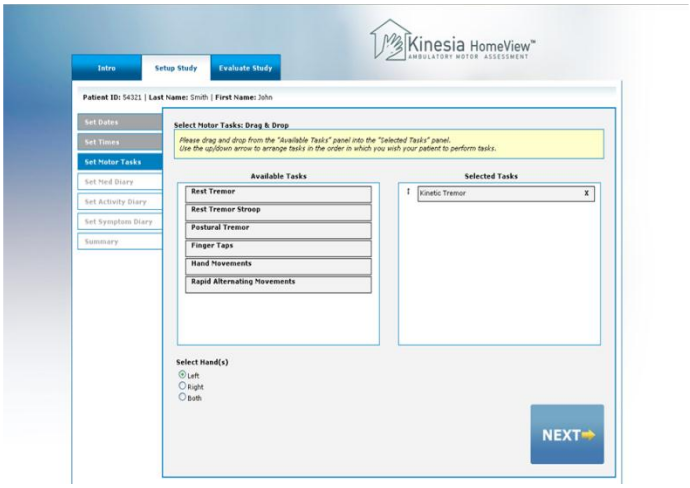

Figure 2: Physician Web Interface

Figure 3: Patient Results; Red indicates severe symptoms, green indicates less severe symptoms

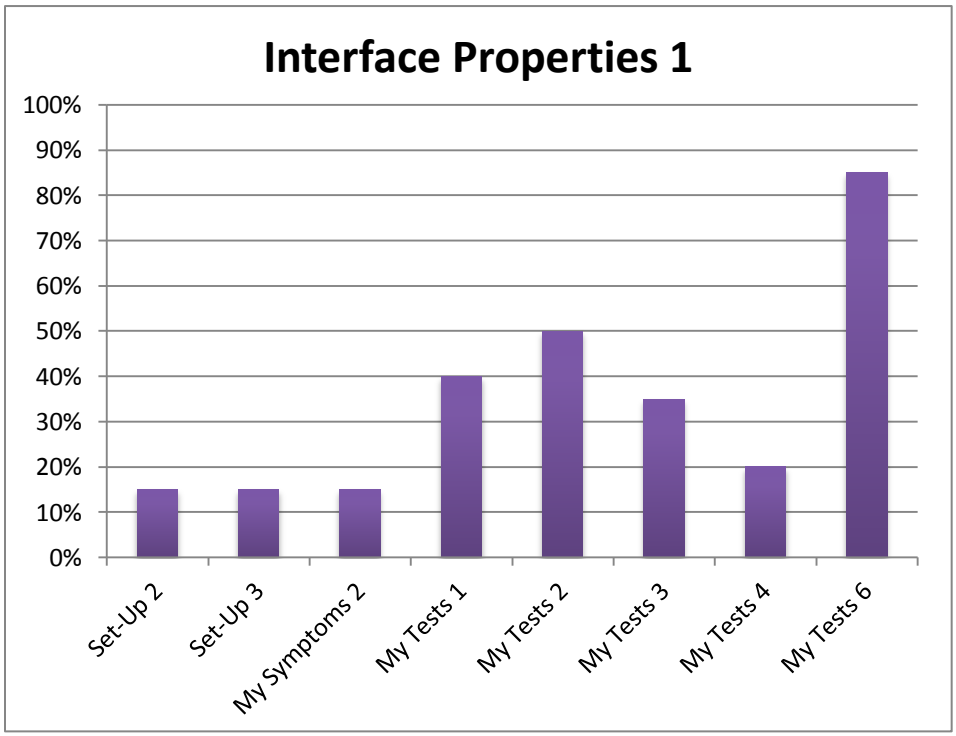

Figure 4: Interface properties results for yes/no-type questions

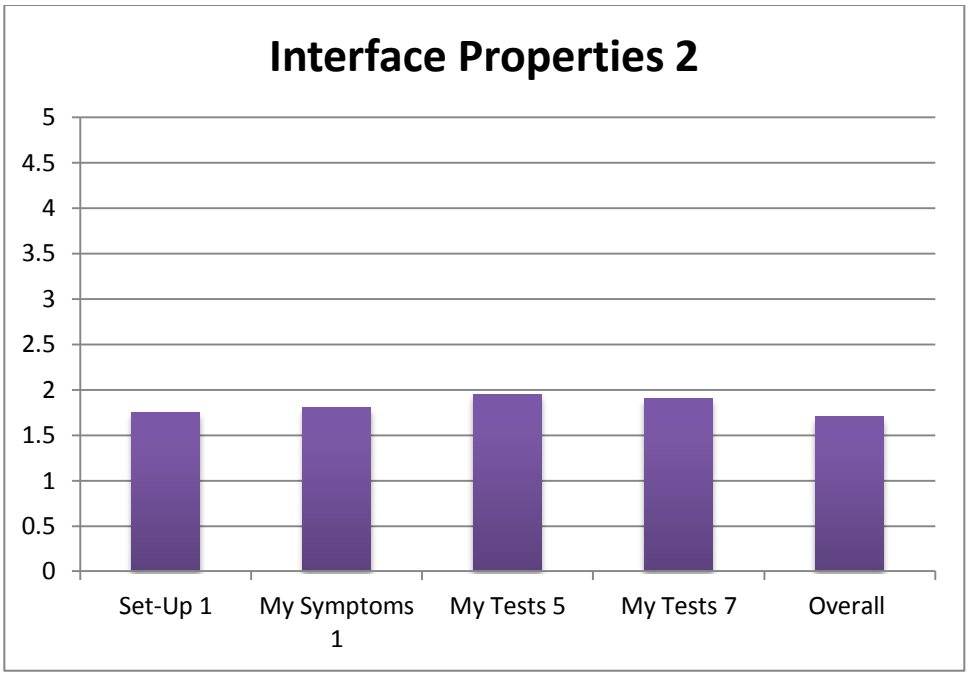

Figure 5: Interface properties results for rating-type questions

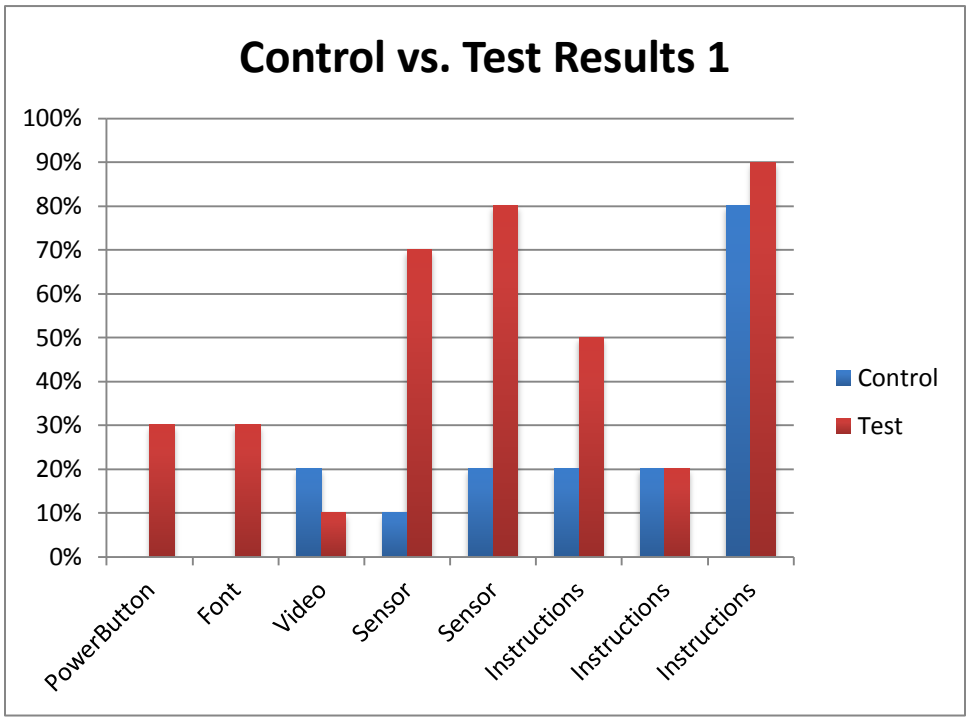

Figure 6: Age-Group results for yes/no-type questions

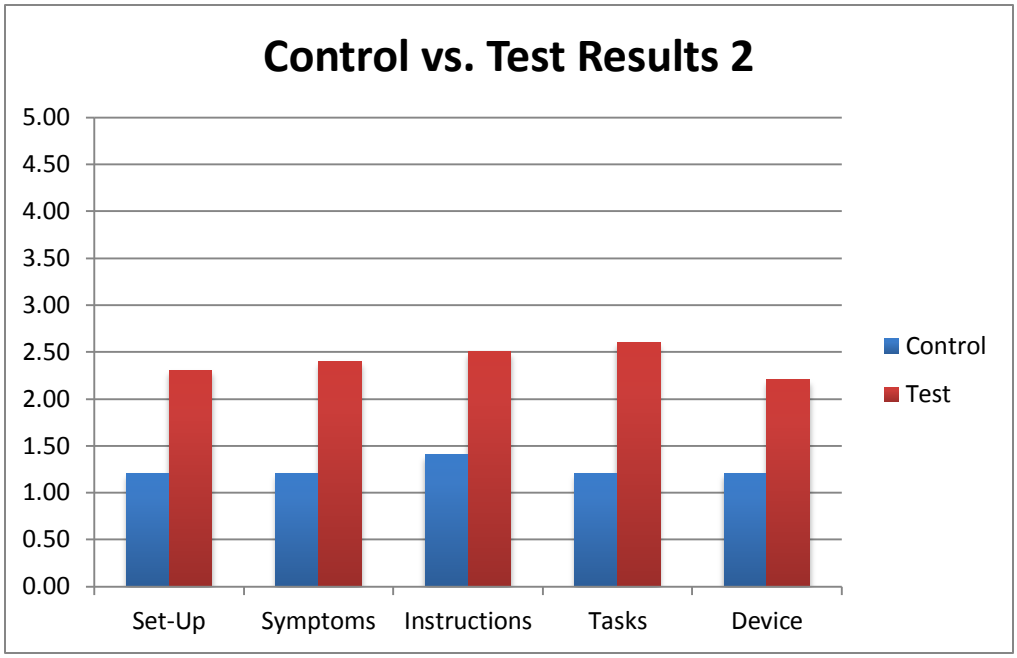

Figure 7: Age-Group results for rating-type questions

Kinesia HomeView Subject Evaluation Questionnaire

We thank you for taking the time out of your busy schedule to participate in our study. If you have any additional questions or comments, please feel free to contact us using the information given below.

uscgstechnologies@gmail.com
(803)528-0677

1. Estimate the amount of time you spend daily using computer technology (i.e. desktop, laptop, mp3, and tablet).

2. Do you have Parkinson's disease?

a) Yes
b) No
c) I do not wish to reply

3. If yes, how would you rate your disease progression?

a) Mild
b) Moderate
c) Severe
d) Severe & Debilitating

4. If yes, do you have your symptoms controlled by medication or other means?

a) Yes
b) No

Comments:

5. What age bracket are you a member of?

a) 18-25
b) 26-30
c) 31-50
d) 51 & above

6. Rate your overall ease with setting up the device (1 being very easy, 5 being very difficult).

1 2 3 4 5

7. Do you find the power button small and/or difficult to press?

a) Yes

b) No
Comments:

8. Do you find the font on the home screen easy to read?

a) Yes
b) No
Comments:

9. Rate your ease of understanding the symptoms rating scale (1 being very easy, 5 being very difficult).

1 2 3 4 5

10. Do you find the ability to make a video of your symptoms helpful?

a) Yes
b) No

11. Do you find the finger sensor well fitted?

a) Yes
b) No
Comments

12. At any time did the finger sensor feel too loose, too tight, or uncomfortable in any way?

a) Yes
b) No

13. Did you find the instructions at the beginning of each exercise easy to understand?

a) Yes

b) No
Comments:

14. Do you feel that the instructions at the beginning of each exercise provided you with enough information to perform the exercise?

a) Yes
b) No
Comments:

15. Rate the clarity of the verbal instructions (1 being very clear, 5 being very unclear).

1 2 3 4 5

16. Do you feel that the on-screen written instructions would be helpful?

a) Yes
b) No
Comments

17. Rate your overall ease of performing the tasks (1 being very easy, 5 being very difficult).

1 2 3 4 5

18. Rate your overall ease of using the device (1 being very easy, 5 being very difficult).

1 2 3 4 5

INFORMATION AND CONSENT FORM

Introduction:
You are invited to participate in a research study investigating the Kinesia HomeView System. This study is being conducted by Mary Geddings, Megan Stanley & Caitlin Thompson undergraduate students at the University of South Carolina under the supervision of Dr. Abdel Bayoumi a faculty member in the Department of Biomedical Engineering. You were selected as a possible participant in this research because you met the required criteria and were willing to volunteer your time. Please read this form and ask questions before you agree to be in the study.

Background Information:
The purpose of this study is to our purpose in pursuing this project, is to aid CleveMed in producing a product with better user interface and a more portable design. Approximately 50 people are expected to participate in this research.

Procedures:
If you decide to participate, you will be asked to:

1) Be given instructions to read over: 3 minutes
2) Set up the device: 30 seconds
3) Rate and record your symptom(s): 2 minutes
4) Add your medication: 30 seconds
5) Perform a series of 6 motor tasks, each lasting 25 seconds: 5 minutes
6) Fill out an anonymous survey

This study will take a maximum of 15 minutes over 1 session.

Risks and Benefits of being in the study:
The study is testing a noninvasive device so participant risks are almost negligible. Potential discomforts could include tired limbs and minimal muscle soreness. If at any time, you as a participant experience discomfort from a particular exercise please notify the PI and, you are free to terminate your participation in the study.

If you are a subject unaffected by Parkinson's Disease-there are no direct benefits to you for participating in this research. However if you do have Parkinson's Disease, this study may (upon request) be provided with an objective and numerical analysis of your symptoms, only the symptoms included in the tests will be evaluated.

Compensation:
In the event that this research activity results in an injury, such as limb fatigue, we will assist you by promptly terminating your trial and allowing you to rest. GSTechnologies will cover the costs of any medical care for research-related injuries. If you think you have suffered a research-related injury, please let us know right away.

Confidentiality:
Any information obtained in connection with this research study that can be identified with you will be disclosed only with your permission; your results will be kept confidential. In any written reports or publications, no one will be identified or identifiable and only group data will be presented.

We will keep the research results in a locked file cabinet, and only study staff will have access to the records while we work on this project. We will finish analyzing the data by April 24th, 2012. We will then destroy all original reports and identifying information that can be linked back to you. Video recordings obtained during your trial will be transferred directly from the device to a password-protected database (via an encrypted USB) that only study team members may access.

Voluntary nature of the study:
Participation in this research study is voluntary. Your decision whether or not to participate will not affect your future relations with University of South Carolina in any way. If you decide to participate, you are free to stop at any time without affecting these relationships.

Contacts and questions:
If you have any questions, please feel free to contact me, Caitlin Thompson, (or one of the researchers Mary Geddings at 803-225-2415 or Megan Stanley at 803-528-0677) at 513-607-0937. You may ask questions now, or if you have any additional questions later, the faculty advisor, Dr. Abdel Bayoumi (803-777-1845) will be happy to answer them.

You may keep a copy of this form for your records.

Statement of Consent:
You are making a decision whether or not to participate. Your signature indicates that you have read this information and your questions have been answered. Even after signing this form, please know that you may withdraw from the study at any time.

_____

I consent to participate in the study, complete the incorporated survey, and agree to have videos recorded throughout my participation

_____

Signature of Participant Date

_____

Signature of Parent, Legal Guardian, or Witness Date
(if applicable, otherwise delete this line)

_____

Signature of Researcher Date