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# The Effect of an Exercise Regimen on the Psychological Health of Parkinson's Disease Patients

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The Effect of an Exercise Regimen on the Psychological Health Of  
Parkinson's Disease Patients

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Author Note

This study and paper serve as Alexander Stephens' senior thesis for the Lee Honors College, Western Michigan University.

### Abstract

This paper reports a study on the effect of an exercise regimen on the psychological health of Parkinson's disease patients. The 11 participants of the study were Parkinson's disease patients who were participants of a six-week exercise program titled 'Delay the Disease,' which was specifically designed for Parkinson's disease patients. The participants of the study were given the Geriatric Depression Scale twice before the start of the exercise regimen, and once per week for the duration of the six-week exercise regimen. They were also given a quality of life questionnaire at the beginning and end of the regimen. The data was evaluated visually for each participant, due to the small number of participants. The results show that there could be an improvement in the depression of Parkinson's patients with exercise, however the data are not statistically significant.

*Keywords:* Parkinson's disease, exercise, depression, quality of life

## The Effect of an Exercise Regimen on the Psychological Health Of Parkinson's Disease Patients

One percent of the population over age 65 (Hemmerle, Herman, & Seroogy, 2012), and more than one million Americans suffer from Parkinson's disease (PD), which is more than suffer from multiple sclerosis, muscular dystrophy, and Lou Gehrig's disease combined (Parkinson's Disease Foundation, 2012). There is no cure for PD, and while there is a great deal of research going into finding a cure, it does not seem that one will be developed in the near future. Since a cure is not on the horizon, it is imperative that we find ways to reduce the effects of this debilitating disease, and increase not only the lifespan of those who suffer from the disease, but the quality of life (QOL) as well.

One of the most common non-motor symptoms of PD is depression, with Poewe (2007) saying that 30%-40% of patients with PD also can be diagnosed with depression. In addition Vladejic and Vladejic (2011) stated that 5%-25% of PD patients can be diagnosed with major depressive disorder, while less severe depressive mood is present in 40-60% of patients. Also, Slaughter et al. (2001) stated that one in three PD patients experience depression during the course of their disease.

While there are wide ranging figures for the levels of depression in PD patients, the frequency of depression in the general population and elderly people is better studied and documented. Depression prevalence in the general population is around 7%, and is around 11% in the elderly (Hemmerle, Herman, & Seroogy, 2012). It is clear that there is a difference between the prevalence of depression in the general population compared to the PD population, with the PD population being more affected.

Therefore, if one wants to improve the QOL for PD patients, obviously one of the first things to look at is how to reduce their levels of depression. In today's society, one of the first ways that doctors think of to decrease depression and depressive symptoms is through drug therapy. There have been numerous trials involving PD patients and a wide variety of drugs where the researchers attempted to decrease their levels of depression. Unfortunately, in double-blind studies, the placebo effect has been rather large, and no study has demonstrated the efficacy of any antidepressive medications of any kind for treating depression in Parkinson's patients (Poewe, 2007).

Since drug therapy has not been shown to be effective in treating depression in PD patients, the study of more alternative approaches is necessitated. According to Hirsch and Farley (2009), PD patients avoided exercise for many years because it was believed it would have no effect on PD and could actually worsen the disease. However, Fisher et al. (2008) showed in their research that exercise could have a neuroprotective effect in early PD patients, by normalizing corticomotor excitability. This normalization would lead to an increase in the quality of life, but could exercise also have an effect on depression? According to Ahlskog (2011), there have not been many studies that have assessed the efficacy of exercise on cognition in PD patients, but the few that there have been showed a favorable effect. Additionally, there are not many studies about the effect of exercise on depression in PD patients, however according to M. Aan Het Rot et al. (2009) exercise has been shown to be effective in treating depression in the general population.

The lack of research surrounding the effect of an exercise regimen on the level of depression in PD patients, and the fact that there is a very high prevalence of depression in PD patients is what led to this research. The purpose of this study was to determine if an exercise

regimen specifically designed for Parkinson's disease patients could have a positive effect on both depression levels and the QOL of the patients.

## **Method**

### **Participants**

The potential participants of this study were the participants of the Delay the Disease (DTD) exercise program who had been previously diagnosed with Parkinson's disease. Karen Freshwater recruited participants of the Delay the Disease program from the Bronson Methodist Hospital Neurology department, where she is employed. All of the participants of the DTD program were read a recruitment paragraph, which is shown in Appendix A. The participants of the program who were interested in taking part in the research study were then given a copy of the WMU and the Bronson Methodist Hospital informed consent documents, which can be found in Appendices B and C respectively. Both documents were read aloud to the potential participants after they were handed a paper copy. Because the intent was to measure the effect of exercise on their QOL, a participant was excluded from the study if they were already exercising frequently (>2 times per week), or if they were receiving any psychological or medical treatment for depression at the beginning of the study. The participants who agreed to give consent were given a questionnaire to determine if they met the aforementioned exclusionary criteria. This questionnaire can be found in Appendix D. In total, 11 participants of the DTD program met the entire criteria for inclusion in the study and gave their consent to be a part of the study. All of the participants were 60 years or older at the beginning of the study.

### **Confidentiality of Data**

In order to protect the identity of the participants, each participant was assigned a random number using a random number generator. The names were placed next to a number in a table,

of which there were only two copies. An example of this kind of table can be found in Appendix E. In addition, during administration of both the GDS and PDQ-39, the questionnaires were placed into manila folders with the participants' names on them. They were asked not to put their names on the questionnaires. After each administration of a questionnaire, the number that corresponded to the participant was placed on the questionnaire and said questionnaire was removed from the folder. At the end of the study, the table containing the names and their corresponding numbers were destroyed, leaving only random numbers on any of the data.

### **Setting**

All aspects of this research took place at the Bronson Athletic Club in Kalamazoo, Michigan in the fall of 2012. This is where the DTD exercise program was held as well. The participants were read and given the informed consent document in a private conference room. All questionnaires were administered in a private location at the athletic club before one of their exercise classes.

### **Materials**

There were two questionnaires used in this study. One measured the level of depression in the participants (Geriatric Depression Scale), and a second assessed the QOL of the participants (Parkinson's Disease Questionnaire 39).

**Level of depression.** The Geriatric Depression Scale (GDS) is a questionnaire that was used to assess the level of depression in the patients. The scale was designed to assess the level of depression in elderly patients, and because all of our participants were over 60, the choice of this scale was logical. A copy of this questionnaire can be found in Appendix F. This questionnaire determines the level of depression in the participants through 30 yes or no questions. For each question, there is an answer (either yes or no) that is indicative of

depression. The number of questions where the answer given indicates some depression is summed, and the sum of these scores indicates the overall level of depression. A total score from zero to ten indicates no depression, a score between 11 and 20 indicates mild depression, and a score from 21 to 30 indicates severe depression. The GDS has been found to have 92% sensitivity and 89% specificity, when the GDS is evaluated against other diagnostic criteria (Kurlowicz 1999).

**Quality of life.** The Parkinson's Disease Questionnaire-39 (PDQ-39) was used to assess the QOL of the patients. A copy of this questionnaire can be found in Appendix G. This questionnaire determines the quality of life of PD patients through 39 questions that determine the difficulty the patient faces in eight different categories. The 39 questions individually correspond to one of eight categories: mobility, activities of daily living, emotional well-being, stigma, social support, cognitive impairment, communication, and bodily discomfort of the participants. The answers to each question are scored from zero to four. These scores are summed for each category, with a higher number indicating more difficulty in that category. The scores are reported as a percentage of the highest possible score for that individual category. The PDQ-39 has been shown previously to be a reliable and valid discriminate instrument (Gwady-Sridhar & Stafkey-Mailey, 2006).

### **Data Collection**

The GDS was administered once a week over an eight-week period, while the PDQ-39 was administered to the participants at the beginning and end of the exercise regimen. After the participants completed the questionnaires, the measures were scored using their corresponding scoring guide. The GDS scoring guide can be found in Appendix H, and the PDQ-39 scoring guide can be found in Appendix I. Each questionnaire was graded by three of the researchers,

who individually recorded all of their grades in a data table prepared in Microsoft Word. The table that was used to compile each researchers' GDS grades can be seen in Appendix J, while the table that each researcher used to compile the PDQ-39 grades they found can be found in Appendix K.

### **Interobserver Agreement**

Three different researchers graded all of the questionnaires at three different times, and each observer recorded their scores on different data sheets. The GDS data was then compiled onto one data sheet, which can be found in Appendix L. There was too much data with the PDQs to compile all of it onto one data sheet, however it was visually inspected to ensure all researchers had the same grade for each participant. If any of the scores were different, they were re-graded by all three of the observers until all of the scores were identical. Therefore, any interobserver agreement for this study below 100% was unacceptable.

### **Dependent Variables**

The dependent variables that were measured were the GDS scores and the PDQ-39 scores for each participant, and thus each participants' level of depression and QOL.

### **Independent Variable**

The independent variable was the Delay the Disease exercise program. The researchers from WMU had no involvement in the exercise program itself. Two employees of Bronson Athletic Club ran the program. The two employees that ran the program were Sheri Shon and Laura Steurer. They are both certified personal trainers, and are the only two people in Michigan who are certified to teach the Delay the Disease program. Between the two of them they have over 40 years of experience teaching one on one and group based exercise classes. They do not

have CITI training, however they did not help in the research portion of this program. The exercise program was designed to improve strength and control in Parkinson's patients. This was done through a variety of exercises including seated exercises, walking and balance exercises, cardiovascular exercises, and strength training. The program involved two of these exercise classes per week (Tuesday and Thursday) for six weeks. The program was designed to be implemented for six continuous weeks, however what should have been week five of the intervention was Thanksgiving week. The Bronson Athletic Club was closed the week of Thanksgiving, so the participants were not able to do the exercise class or fill out the questionnaires. Therefore, the intervention was actually spread out over a seven-week period, though the exercise program took place during only six of the weeks.

### **Research Design**

A multiple baseline across groups design was used. There were two groups of participants in the DTD program. Both groups met twice per week for six weeks on Tuesday and Thursday; however they both had the class at different times, although they met in the same place, with the same instructors. Both of the groups had a two-week baseline period, followed by a six-week intervention period.

### **Research Procedures**

**Baseline.** During the baseline phase, all of the participants were given the GDS twice. It was completed two weeks before the beginning of the program, and again one week before the beginning. Each participant was given the PDQ-39 one time during the baseline period. All of the questionnaires were administered by one of the researchers. If at anytime during the baseline or the intervention phase of the experiment, the GDS indicated that the participant was either moderately or seriously depressed they were given a handout that discussed the dangers of

depression, and provided resources for the participant to seek help. A copy of this handout can be found in Appendix M.

**Intervention.** The GDS was given once per week directly before one of the exercise periods during the intervention period. The PDQ-39 was given to each participant one time during the intervention phase, directly before the final class of the exercise program.

## **Results**

### **Analyses Conducted**

There were only 11 of 30 participants of the exercise program who met all of the inclusion criteria to be a part of the study. Unfortunately, 11 was not enough participants to have statistically significant results. However, we were hoping to be able to average the data we did collect, and still be able to show a change in the levels of depression and quality of life.

Regrettably, it was extremely difficult for some of the participants to attend the classes every week. As we administered measures directly before the classes, this made it very difficult for us to collect data. We ended up only collecting enough scores on the GDS (at least seven of eight scores) to make any kind of analyses for five of the 11 study participants, and we collected both PDQ-39 scores for only three of the original 11 participants. Because of the extremely low, the best analysis we could do was to plot scores of the five participants with seven or more GDS score. These plots were visually inspected, and some general conclusions could be drawn.

Additionally, the slope of the GDS scores v. time was calculated. A positive slope was indicative of an increase in GDS score over time, while a negative slope was indicative of a decrease in GDS score over time. Also, the PDQ scores were plotted for the three participants that completed both PDQs.

### **Level of Depression**

The five participants that completed the GDS at least seven times were participants 77, 11, 42, 30, and 29. The GDS score dropped immediately after the start of the intervention, however it gradually climbed back up to baseline levels by the end of the intervention. Unfortunately, the slope of the line of best fit for the intervention GDS scores was 0.6571. This indicates that the score actually increased during the intervention. Figure 1 shows a graph of the results for participant 77.

The GDS score for participant 11 was the same as baseline the first week of the intervention, however it gradually fell over the course of the intervention, ending with a new low at the final GDS score, which was week five of the intervention not week six. The slope of the line of GDS scores against time during the intervention reflects this decrease in GDS score, with a slope of -0.4. Figure 2 shows a graph of the results for participant 11.

The GDS score for participant 42 dropped immediately after the first week of the intervention, and continued a gradual drop throughout the course of the intervention, ending with a new low at the final GDS score, which was also week five of the intervention not week six. This decrease in GDS score was reflected in the graph of this participants results. The slope was -1, which indicates a decrease over time in the GDS score. Figure 3 shows a graph of the results for participant 42.

There was a sharp rise in the baseline score for participant 30 from week one to week two, then a drop back to the initial baseline level the first week of the intervention. The GDS score then varied between six and seven for the entirety of the intervention, ending at six, which was the same as the first baseline measurement. The slope of the best-fit line of GDS score against time was 0.0857, which indicates that the GDS score increased very slightly over time for this participant. Figure 4 shows a graph of the results for participant 30.

There was only one baseline measurement taken for participant 29, and it was 13. There was a drop in the score immediately after the start of the intervention that continued for the first two weeks of the intervention, there was then a spike in the score in week three of the intervention, however there was a sharp drop back down in week six, and there was a gradual decrease in score from week six to week eight. The slope of the best fit line for the GDS score against time was  $-0.5429$ , which indicates a decrease in GDS score over time. Figure 5 shows a graph of the results for participant 29.

### **Quality of Life**

The three participants who completed the PDQ-39 at the beginning and the end of the study were participants 77, 30, and 29. The difficulty scores for participant 77 decreased for two of the categories of the PDQ from week one to week six, while their difficulty scores increased for five of the categories, and stayed the same for one of the difficulty categories. The difficulty scores decreased from 37.5% to 30.0% for mobility and 29.16% to 12.5% for activities of daily life from week one to week six. The difficulty scores increased from 0% to 4.16% for emotional well being, from 0 to 16.6 for social support, from 12.5% to 37.5% for cognition, from 8.3% to 41.6% for communication, and from 16.6% to 33.3% for discomfort over the same time period. The difficulty scores for stigma were unchanged over this time period. Figure 6 shows a graph of these results.

The difficulty scores for participant 30 decreased for two of the categories of the PDQ from week one to week six, while the difficulty scores increased for two of the categories, and stayed the same for the other four categories. The difficult score for emotional well-being decreased from 8.3% to 4.16% and the difficulty score for stigma decreased from 12.5% to 6.25% from week one to week six. The difficulty score for cognition increased from 12.5 to 25%

and the difficulty score for mobility increased from 0% to 7.5% from week one to week six. The difficulty scores for activities of daily life, communication, discomfort, and social support were unchanged over this time period. Figure 7 shows a graph of these results.

The difficulty scores for participant 29 decreased for three of the categories of the PDQ from week one to six, while the scores for two categories increased over the same time period. Three of the difficulty categories stayed the same from week one to week six. The difficulty score for cognition decreased from 50% to 43.75%, the difficulty score for discomfort decreased from 41.6% to 33.3%, and the difficulty score for stigma decreased from 18.75% to 0% from week one to week six. The difficulty score for activities of daily life increased from 16.6% to 25% and the difficulty score for emotional well being increased from 12.5% to 16.6% over the same time period. The difficulty scores for mobility, communication, and social support remained unchanged from week one to week six. Figure 8 shows of a graph of these results.

## **Discussion**

### **Interpretation of Results**

At the beginning of the study, we thought that an exercise regimen would decrease the level of depression in Parkinson's patients, as well as increase their quality of life.

Unfortunately, we were not able to gather enough data to either confirm nor reject our hypothesis. However, with the data that we were able to gather we can make some broad associations.

By looking at the data for the five participants who did complete the GDS at least seven times, there are a few inferences that can be made. First, none of the participants' GDS scores were higher at the end of the intervention than they were at the baseline. Additionally, at no point during the study was there a GDS score for any of the participants that was higher than their

highest baseline score. This is very important, because it shows that more study can be done on this topic, without risking the mental health of the participants. Third, three of the five participants whose data was graphed showed a negative slope for the line of best fit of GDS score against time during the intervention phase. This indicates that the GDS score decreased over time for those three participants. While there were not enough participants to truly show a statistical difference, these differences show that exercise could have a positive effect on the psychological health of PD patients.

There were some inferences that could be made from the GDS scores of the five participants who completed at least seven questionnaires; unfortunately the same could not be said for the PDQ results. The PDQ measured the difficulty that the participants had with eight different categories of their lives. The point of analyzing the data from the three participants who completed the PDQ at week one and week six was to hopefully find some correlation with time that was common between all three of them. However, there is not a single category of the eight that the PDQ tested that changes in the same way with time between all three of the categories. However, there were only three complete results so this is not that surprising.

### **Limitations**

There were obviously some major limitations that had an impact on the outcome of this study. First and foremost, there were simply not enough participants in the study. If there were more participants, then a few of them missing the tests every once in a while would not have a major effect on the average. However, we only had eleven participants, who met the inclusion criteria. Therefore every time one of them missed one of the questionnaires, it was harmful to our analyses. A second limitation of the study was that the exercise program was not run for six consecutive weeks. Taking a week off for Thanksgiving could have had a major effect on our

results. A third limitation of the study was that all of the GDS scores we observed were very low at the baseline. The study was designed to see if exercise decreased depression, however only one of our five participants was actually even remotely depressed at the beginning of the study. Thus, while there was an observed drop in average score, all of them, with the exception of one participant, remained in the same category of “not depressed” on the GDS grading scale. A fourth limitation of the study was that we only administered the PDQs twice between the baseline and the intervention phases. It would be ideal to administer that questionnaire at least as frequently as we administered the GDS. However, the PDQ was considerably longer than the GDS, and we worried about testing effects on the participants. Additionally, even though we administered the GDS more frequently than the PDQ, we did not get enough baseline data to get a really significant result. With only two baseline data points, we can't conclude that the scores were steady in the baseline, or that the intervention caused a change in the depression scores. Another limitation of this study was that the exercise regimen was only six weeks long. Perhaps a longer regimen would produce more dramatic results. A final major limitation of this study is that both of the assessments used were self-report measures. Self-report measures are notoriously unreliable, because they rely on the participant being totally honest every time they take the questionnaire. They are also very susceptible to changes in mood or thought. While this is not necessarily a comprehensive list of the limitations of this study, these are the main limitations of our research study.

### **Future Research**

There is without a doubt room for future research on this topic. The results of the GDS questionnaires for the five participants who completed at least seven of the questionnaires are

very promising. The fact that three of the five participants showed a decrease in GDS scores over time is a good sign. Also, the results, or lack thereof, of the PDQs for the three participants who completed the questionnaire at the beginning of the program at the end should not discourage further research. The utter lack of any similarities between the three results should not discourage further study because three data points is not nearly enough to say that there is no correlation. Additionally, the fact that the results of the GDS are promising should give promise for the future study on the effect of exercise on QOL, because QOL increases with a decrease in depression.

There are a few things that any future research should change from this study. It is most likely inevitable that the research will have to make use of self-assessment questionnaires. Any other type of assessment would probably require too much of a time commitment, both from the researchers and the participants. One thing that any other study obviously must have is more participants. This would allow any future researchers to make statistically significant progress, instead of claims based on anecdotal evidence. Also, any future research should attempt to find a QOL assessment that can be administered more frequently than the PDQ. This would also help the future research to get statistically significant findings. Future research should also attempt to have participants who are already depressed. This would allow them to show an actual decrease in depression, instead of just a decrease in depression score within non-depressed people. Additionally, any future research should run the exercise program for six straight weeks, without any breaks, or they could also do a longer exercise regimen, to see if that would have a greater effect. Finally, any future research should have more baseline data as well.

All of the suggestions previously described for future research would allow the researchers to make more sound claims, and have better data than this study. While this study

was not a total failure, we did show that there *could be* a relationship between an increase and exercise and a decrease in depression, we did not have enough data to make any statistically significant claims. It is my hope that some future research can be conducted to show that there is indeed a relationship between exercise and a decrease in depression in PD patients, because it is absolutely imperative that we improve the quality of life of these patients who suffer for years, sometimes decades, with this terminal illness.

## References

- Ahlskog, J.E. (2011). Does vigorous exercise have a neuroprotective effect in Parkinson's disease? *Neurology*, 77(3), 288-294.
- Fisher, B.E., Wu A. D., et al. (2008). The effect of exercise training in improving motor performance and corticomotor excitability in people with early Parkinson's disease. *Archives of Physical Medicine and Rehabilitation* 89(7):1221-1229.
- Gwadry-Sridhar, F., & Stafkey-Mailey, D. (2006). A review of the validity and reliability of the Parkinson's disease questionnaire (pdq-39). *Value in health*, 9(3), A88. Retrieved from [http://www.journals.elsevierhealth.com/periodicals/jval/article/S1098-3015\(10\)64578-0/abstract](http://www.journals.elsevierhealth.com/periodicals/jval/article/S1098-3015(10)64578-0/abstract).
- Hemmerle, A.M., Herman, J.P., & Seroogy, K.B. (2012). Stress, depression and Parkinson's disease. *Experimental Neurology*, 233(1), 79-86.
- Hirsch, M.A. (2009). Community-based rehabilitation for Parkinson's disease: From neurons to neighborhoods. *Parkinsonism and Related Disorders*, 15S3, S114-S117.
- Hirsch, M.A., & Farley, B.G. (2009). Exercise and neuroplasticity in persons living with Parkinson's disease. *European Journal of Physical and Rehabilitation Medicine*, 45, 215-229.
- Kurlowicz, L. (1999). The geriatric depression scale. *The Hartford Institute for Geriatric Nursing*, (4).
- Parkinson's disease foundation. (2012). Retrieved from [http://www.pdf.org/en/parkinson\\_statistics](http://www.pdf.org/en/parkinson_statistics).

- Poewe, W. (2007). Depression in Parkinson's disease. *Journal of Neurology*, 254(Supplement 5), 49-55.
- Rot, A.H.M., et al. (2009). Physical exercise and depression. *Mount Sinai Journal of Medicine*, 76, 204-214.
- Slaughter, J.R., Slaughter, K.A., Nichols, D., Holmes, S.E., & Martens, M.P. (2001). Prevalence, clinical manifestations, etiology, and treatment of depression in Parkinson's disease. *The Journal of Neuropsychiatry and Clinical Neurosciences*, 13, 187-196.
- Vladejic, S.D., & Vladejic, S.S. (2011). Parkinson's disease: Frequency of depressive syndrome. *European Psychiatry*, 26(Supplement 1), 701.

## Appendix A

Recruitment Paragraph that Was Read to Participants of the  
Delay the Disease Exercise Program

You are invited to participate in a research study on the effect of an exercise regimen on the psychological health of Parkinson's disease patients. If you chose to participate in this study you will be asked to complete four questionnaires before the start of the exercise program, seven questionnaires during the exercise program, and one questionnaire six weeks after the end of the exercise program. If you choose to participate you will be given an informed consent document that will outline in more detail the procedures, risks, and benefits of this study. If you choose to participate in this study you may withdraw at anytime, and this will not affect your participation in the exercise program itself.

## Appendix B

## Western Michigan University Informed Consent

**Western Michigan University  
Department of Psychology**

**Principal Investigator:** R. Wayne Fuqua, PhD  
**Student Investigator:** Alex Stephens  
**Student Investigator:** Jeralee Briggs  
**Title of Study:** The effect of an exercise regimen on the psychological health of Parkinson's disease patients

You have been invited to participate in a research project titled, "The effect of an exercise regimen on the psychological health of Parkinson's disease patients." This project will serve as Alex Stephens' senior thesis for the requirements of the Lee Honors College. This consent document will explain the purpose of this research project and will go over all of the time commitments, the procedures used in the study, and the risks and benefits of participating in this research project. Please read this consent form carefully and completely and please ask any questions if you need more clarification.

**What are we trying to find out in this study?**

The purpose of this study is to track the depression levels of Parkinson's disease patients as they take part in the Delay the Disease exercise program. Delay the Disease aims to improve muscle control for Parkinson's disease patients. This study will find out if Delay the Disease is also useful for improving psychological health.

**Who can participate in this study?**

We are asking you to participate because:

- You are a Parkinson's disease patient, and
- You are enrolled in the Delay the Disease program at the Bronson Athletic Club

**Where will this study take place?**

This study will take place at the Bronson Athletic Club.

**What is the time commitment for participating in this study?**

Three questionnaires will be given by one of the investigators before the beginning of the exercise program, and will be spaced at least one week apart. During the exercise program a questionnaire will be given once per week before the beginning of the exercise program by one of the investigators. The exercise program lasts six weeks, with two sessions per week. This is a total of twelve sessions. This questionnaire will be given a total of nine times.

In addition, there will be a different questionnaire that will be given at the beginning of the study, at the end of the study, and three months after the beginning of the study. We estimate that each questionnaire will take less than 10 minutes.

**What will you be asked to do if you choose to participate in this study?**

If you decide to take part in this research program, we will ask you to complete questionnaires several times throughout the exercise program.

**What information is being measured during the study?**

All information obtained will be kept confidential and only used for research purposes. This information includes:

- The level of exercise before the beginning of the study
- Whether or not you are currently receiving any psychological treatment.
- Responses provided on the:
  - Geriatric Depression Scale (GDS)
  - Parkinson's Disease Questionnaire-39 (PDQ-39)

**What are the risks of participating in this study and how will these risks be minimized?**

If you elect to participate in this study by completing periodic questionnaires, we do not think this activity will add risks above and beyond those risks that are inherent in any exercise program. Confidentiality is a risk with any research study but we do our best to make sure your information stays private. You will be assigned a random number, which corresponds to your name. There will only be one key, which will identify participant to number, and this key will be destroyed at the end of the study. You will be asked to put your name on their questionnaires. Immediately after data collection, this data will be transferred to a table, which will report the results of the questionnaires next to the random number that corresponds to the person who filled out said questionnaire. In order to ensure proper grading of the questionnaires, they will be graded by two of the investigators and the grades will then be compared. The questionnaires with the names on them will then be destroyed, so only the table will be left. All information collected will be identified only with the random number that has been assigned to the participant. All information will be kept in a locked drawer on Western Michigan Universities' campus.

**What are the benefits of participating in this study?**

There will be no direct benefit to you for taking part in the study.

**Cost, Payment, and Compensation**

You will not be paid for taking part in this study. You do not have to pay money to take part in this study. You will have to pay the cost of the Delay the Disease exercise program whether or not you take part in the study.

**Who will have access to the information collected during this study?**

Only the lead researcher and the co-researchers will have access to any identifying information. The data that will be collected will be the results of the PDQ-39 and the GDS questionnaires. That data will be stored and kept only by members of the research study, and will not have any identifying information on the data itself. At the completion of the study all identifying information will be destroyed, and only the data will remain.

**What if you want to stop participating in this study?**

You may feel free to withdraw from the research portion of this study at any time, and still participate in the Delay the Disease program. If you chose to withdraw from the research portion of the study, you may contact the principal investigator or one of the co-investigators. Any of the investigators can also decide to stop your participation in the study without your consent.

Should you have any questions prior to or during the study, you can contact the primary investigator, R. Wayne Fuqua at (269) 387-4474 or wayne.fuqua@wmich.edu. You may also contact the Chair, Human Subjects Institutional Review Board at 269-387-8293 or the Vice President for Research at 269-387-8298 if questions arise during the course of the study.

This consent document has been approved for use for one year by the Human Subjects Institutional Review Board (HSIRB) as indicated by the stamped date and signature of the board chair in the upper right corner. Do not participate in this study if the stamped date is older than one year.

-----  
I have read this informed consent document. The risks and benefits have been explained to me. I agree to take part in this study.

---

Please Print Your Name

---

## Appendix C

### Bronson Methodist Hospital Informed Consent

#### **Informed Consent**

- Study:** The effect of an exercise regimen on the psychological health of Parkinson's patients
- Principle Investigator:** Karen Freshwater, PA-C
- Co-Investigators:** Alex Stephens  
Jeralee Briggs, MS

#### **Introduction**

We are asking you to take part in a research study. We are asking you because:

- You are a Parkinson's disease patient, and
- You are enrolled in the Delay the Disease program at Bronson Methodist Hospital

Taking part in this study is your choice. You may decide not to take part. If you join the study, you can leave at any time. You will not be punished or lose benefits to which you are otherwise entitled if you do not take part in the study.

#### **Purpose of Study**

The purpose of this study is to track the depression levels of Parkinson's disease patients as they take part in the Delay the Disease exercise program. Delay the Disease aims to improve muscle control for Parkinson's disease patients. This study will find out if Delay the Disease is also useful for improving psychological health.

#### **What does this study involve?**

If you decide to take part, we will ask you to complete questionnaires several times throughout the exercise program. The exercise program will last 6 weeks.

#### **What if I don't want to be in the study?**

You may feel free to withdraw from the research portion of this study and still participate in the Delay the Disease program.

#### **Risks and Benefits**

We do not think there is any extra risk if you take part in the study. Confidentiality is a risk with any research study but we do our best to make sure your information stays private. There may be risks to the exercise program that your clinical care staff will discuss with you.

There will be no direct benefit to you for taking part in the study. We assume that the Delay the Disease program will benefit your Parkinson's Disease.

### **Cost, Payment, and Compensation**

You will not be paid for taking part in this study. You do not have to pay money to take part in this study. You will have to pay the cost of the Delay the Disease exercise program whether or not you take part in the study.

Bronson Methodist Hospital will not pay for the medical treatment of other injuries or illnesses, or pay any other type of compensation. You will not receive money if you are injured. You will not receive any money for wages lost because you were:

- Hospitalized
- In physical therapy
- Getting other recovery services.

You will not receive any money for pain, suffering, or for any other loss of income.

### **Release of Protected Health Information for Research Purposes**

All information obtained will be kept confidential and only used for research purposes. This information includes:

- basic demographic information
- responses provided on the
  - Geriatric Depression Scale (GDS)
  - Parkinson's Disease Questionnaire-39 (PDQ-39)

### **What will be done with this information?**

Your information may be used and shared with others:

- To do the study and evaluate the results
- To make sure the study is correctly performed
- To meet the reporting requirements of government agencies or for legal actions

Others who may see your health information during this study include:

- The Bronson Methodist Hospital Institutional Review Board and its staff
- Agencies of the federal, state, or local government. This includes the Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) and the Office for Human Research Protection.

If the information is shared with others and leaves Bronson Methodist Hospital, we cannot promise that others will keep it private. The information will be shared only if necessary.

If the results of this study are published, or presented at medical meetings, you will not be identified in any way.

### **How long will this authorization last?**

This authorization will last until study completion, and for a maximum of 7 years.

**Contact Information**

If you have any questions about this study, you should call the principal investigator, *Karen Freshwater*, at (269) 341-7500.

The Bronson Methodist Hospital Institutional Review Board (IRB) has approved this consent form and study. The IRB is a group of scientific and non-scientific people. The IRB reviews, approves, or disapproves research involving people by following Food and Drug Administration (FDA) rules. If you have any questions about your rights as a participant in this research study, you should contact James W. Carter, MD, Chairman, Bronson Methodist Hospital Institutional Review Board at:

- Address:  
301 John Street (Box 92)  
Kalamazoo, MI 49007
- Phone:  
(269) 341-7898 between the hours of 8am and 4:30pm

**Signatures****Research Participant:**

I have read this form or had it explained to me in words I can understand. All my questions about the study and my participation in it have been answered. I have been told of my rights as a research subject. I can decide not to be a part of this or withdraw my consent. This will not affect my treatment in any way. I know that I will receive a copy of this signed and dated consent form. By signing this consent form, I have not waived any of the legal rights I would have as a subject in a research study. If my ability to consent for myself changes, either my legal representative or I may be asked to give consent again before I can continue to take part in this study.

Name (Print legal name): \_\_\_\_\_

Signature of Participant: \_\_\_\_\_

Date:

\_\_\_\_\_

**Legally Authorized Representative (if applicable):**

Name (Print legal name): \_\_\_\_\_

Signature of legally authorized representative: \_\_\_\_\_

Date: \_\_\_\_\_

Check Relationship to Subject:

Parent    Spouse    Child    Sibling    Legal Guardian  

Other: \_\_\_\_\_

**Principal Investigator (or Designee):**

I have given this participant (or his or her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. This participant indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name (Print legal name): \_\_\_\_\_

Title:

\_\_\_\_\_

Signature of Primary Investigator or Designee: \_\_\_\_\_

Date:

\_\_\_\_\_

Appendix D

Exclusionary Criteria Questionnaire

Name: \_\_\_\_\_

Please estimate the number of times that you exercise per week in the space provided below. For our purposes, exercise is defined as any activity that raises your heartbeat for at least 30 minutes.

Answer: \_\_\_\_\_ times per week

Do you currently receive any psychological or medical treatment for depression?

If so, how often do you receive treatment?

## Appendix E

Table Used to Assign Participants a Random Number

Participant Name	Number
	77
	11
	42
	33
	30
	29
	23
	93
	4
	53
	86
	97
	76
	71
	43
	49
	72
	42

## Appendix F

## The Geriatric Depression Scale Questionnaire

**Directions:** Circle either yes or no for the question above the answers.

1. Are you basically satisfied with your life?  
Yes                      No
2. Have you dropped many of your activities and interests?  
Yes                      No
3. Do you feel that your life is empty?  
Yes                      No
4. Do you often get bored?  
Yes                      No
5. Are you hopeful about the future?  
Yes                      No
6. Are you bothered by thoughts you can't get out of your head?  
Yes                      No
7. Are you in good spirits most of the time?  
Yes                      No
8. Are you afraid that something bad is going to happen to you?  
Yes                      No
9. Do you feel happy most of the time?  
Yes                      No
10. Do you often feel helpless?  
Yes                      No
11. Do you often get restless and fidgety?  
Yes                      No
12. Do you prefer to stay at home, rather than going out and doing new things?  
Yes                      No
13. Do you frequently worry about the future?  
Yes                      No
14. Do you feel you have more problems with memory than most?  
Yes                      No

15. Do you think it is wonderful to be alive now?  
Yes                      No
16. Do you often feel downhearted and blue?  
Yes                      No
17. Do you feel pretty worthless the way you are now?  
Yes                      No
18. Do you worry a lot about the past?  
Yes                      No
19. Do you find life very exciting?  
Yes                      No
20. Is it hard for you to get started on new projects?  
Yes                      No
21. Do you feel full of energy?  
Yes                      No
22. Do you feel that your situation is hopeless?  
Yes                      No
23. Do you think that most people are better off than you are?  
Yes                      No
24. Do you frequently get upset over little things?  
Yes                      No
25. Do you frequently feel like crying?  
Yes                      No
26. Do you have trouble concentrating?  
Yes                      No
27. Do you enjoy getting up in the morning?  
Yes                      No
28. Do you prefer to avoid social gatherings?  
Yes                      No
29. Is it easy for you to make decisions?  
Yes                      No
30. Is your mind as clear as it used to be?  
Yes                      No

Appendix G

The Parkinson's Disease Questionnaire





## Appendix H

## Guide for Scoring the GDS

1. no
2. yes
3. yes
4. yes
5. no
6. yes
7. no
8. yes
9. no
10. yes
11. yes
12. yes
13. yes
14. yes
15. no
16. yes
17. yes
18. yes
19. no
20. yes
21. no
22. yes
23. yes
24. yes
25. yes
26. yes
27. no
28. yes
29. no
30. no

One point is given for each of the above answers. Scoring goes as follows:

Normal: 0-9

Mild Depressive: 10-19

Severely Depressive: 20-30

## Appendix I

## Guide for Scoring the PDQ-39

*Coding system for questions*

All questions on the PDQ-39 are coded in the same way.

0 = Never

1 = Occasionally

2 = Sometimes

3 = Often

4 = Always (or cannot do at all, if applicable)

Dimension of PDQ	Number of Questions	Question Numbers	Total Possible Points
Mobility	10	1 to 10	40
Activities of Daily Life	6	11 to 16	24
Emotional well-being	6	17 to 22	24
Stigma	4	23 to 26	16
Social Support	3	27 to 29	12
Cognition	4	30 to 33	16
Communication	3	34 to 36	12
Bodily Discomfort	3	37 to 39	12

*Scoring for each dimension*

Each dimension is calculated as a scale from 0 to 100

0 = no problem at all; 100 = maximum level of problem

Formula for scoring each dimension:

$(\text{Sum of Scores of Each Question in Dimension}) / (\text{Total Possible Points in Dimension}) \times 100$

## Appendix J

## GDS Score Tracking Sheet for Each Researcher

Evaluator\_\_\_\_\_

Questionnaire Type\_\_\_\_\_

Questionnaire Number\_\_\_\_\_

Participant Number	Score
77	
11	
42	
33	
30	
29	
23	
93	
4	
53	
86	
97	
76	
71	
43	
49	

Appendix K





Appendix M

Handout that Was Given to Participants Whose Scores Indicated Depression

Dear {insert participant's name here},

Through the course of our evaluation, our metric has shown that you suffer from major depression. This is a very serious psychological condition, and is one that should be treated swiftly. We recommend that you seek psychological or medical treatment as soon as possible. Below are some of the resources in the area for seeking this treatment.

Best,

Alex Stephens  
Western Michigan University

Resources:

Elizabeth Upjohn Community Healing Center  
2615 Stadium Drive  
(269) 343-1651

Kalamazoo Community Mental Health & Substance Abuse Services  
Substance Abuse Coordinating Agency  
3299 Gull Road, Nazareth Campus  
(269) 553-8150

Kalamazoo Psychology  
122 West South  
(269) 349-4219

Mid-American Psychological Services  
8036 Moorsbrige, Portage  
(269) 327-1438

New Directions Counseling  
Ronald Grant  
5380 Holiday Terrace  
(269) 372-0961

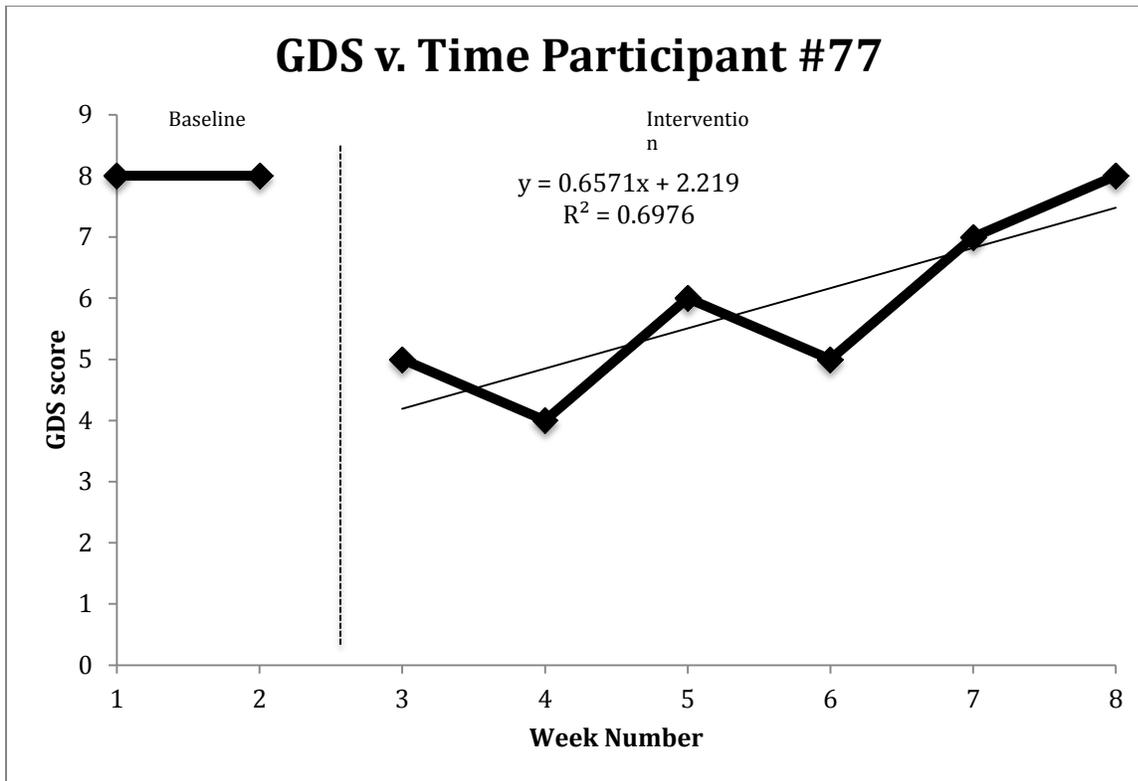
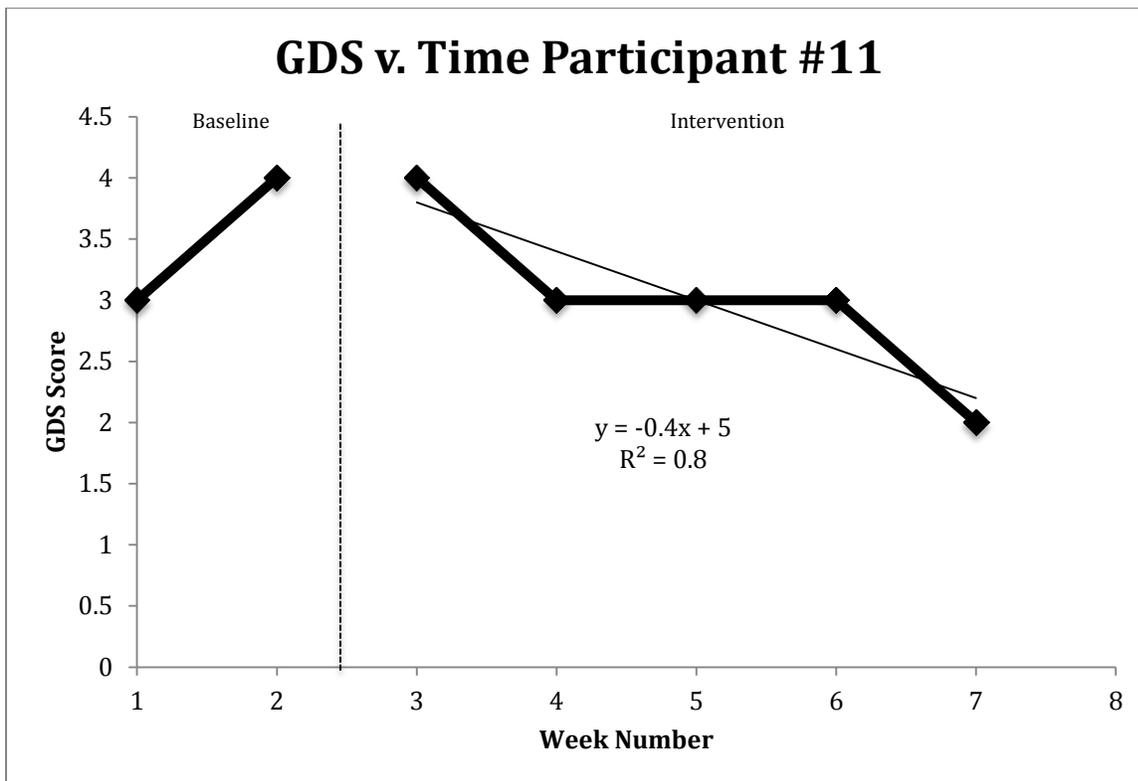
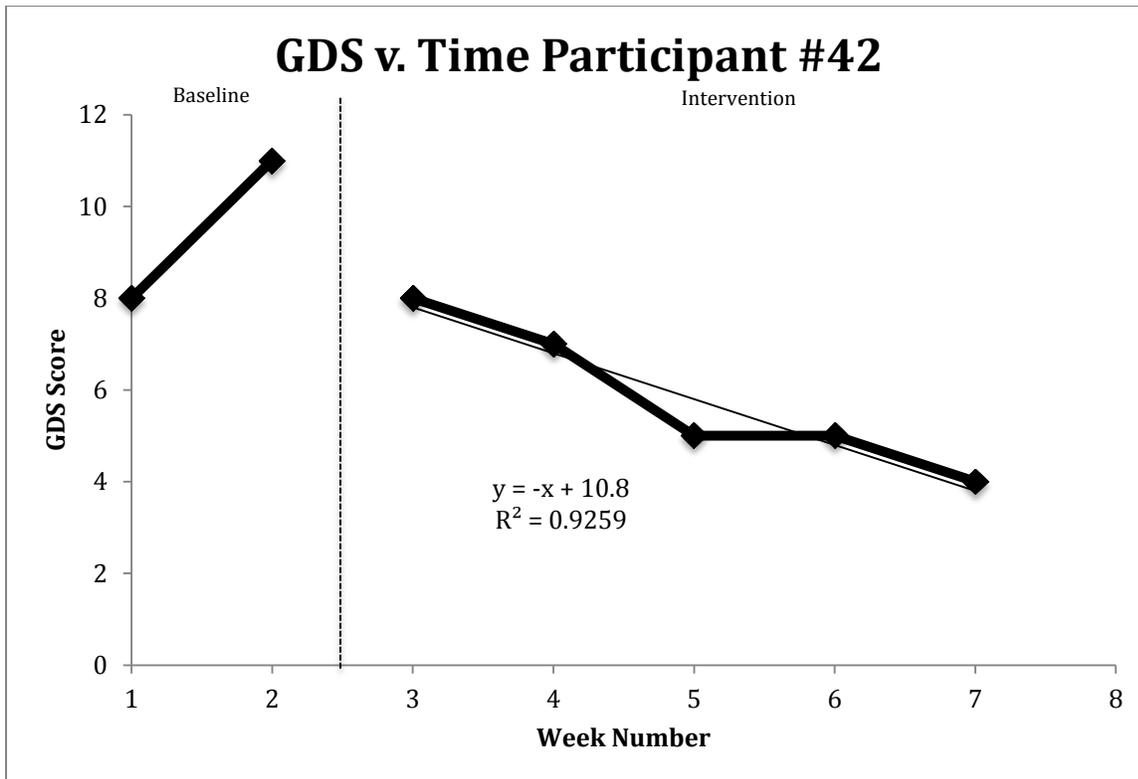


Figure 1. Overall GDS scores for Participant 77 from week 1 to week 8 of the study.



*Figure 2.* Overall GDS scores for Participant 11 from week 1 to week 7 of the study. GDS scores for this participant from week 8 were not collected because the participant did not go to the final exercise class.



*Figure 3.* Overall GDS scores for Participant 42 from week 1 to week 7 of the study. GDS scores for this participant from week 8 were not collected because the participant did not go to the final exercise class.

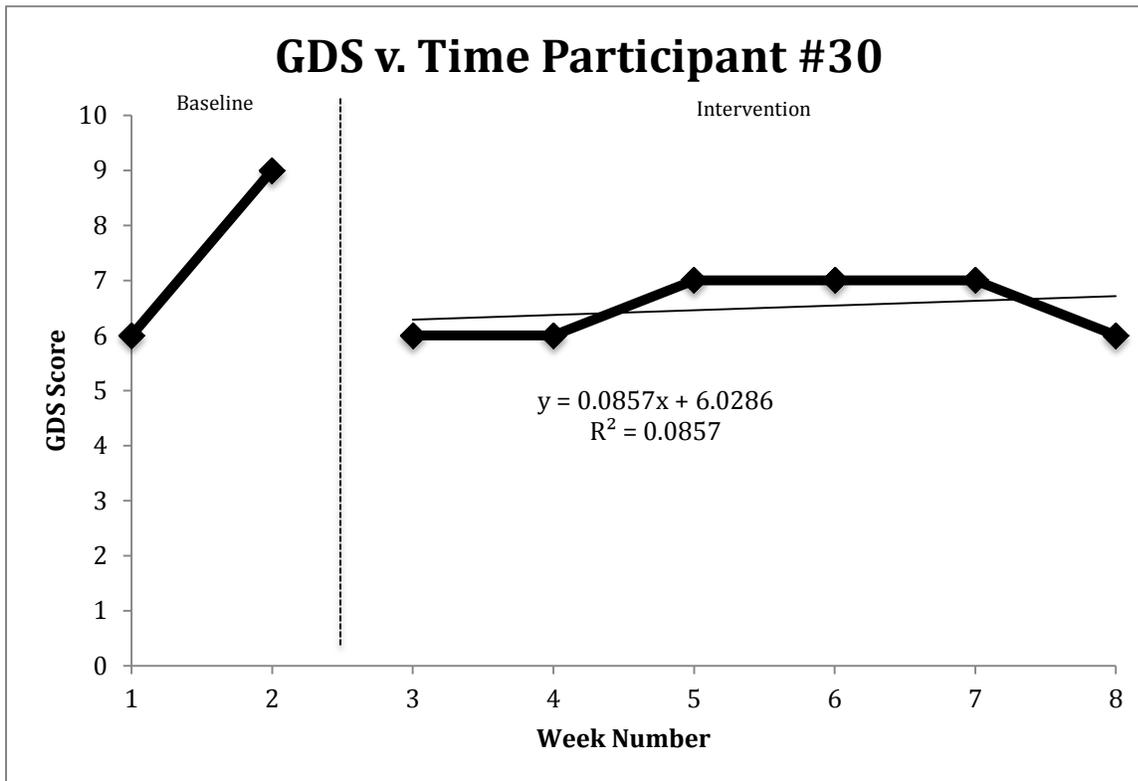


Figure 4. Overall GDS scores for Participant 30 from week 1 to week 8 of the study.

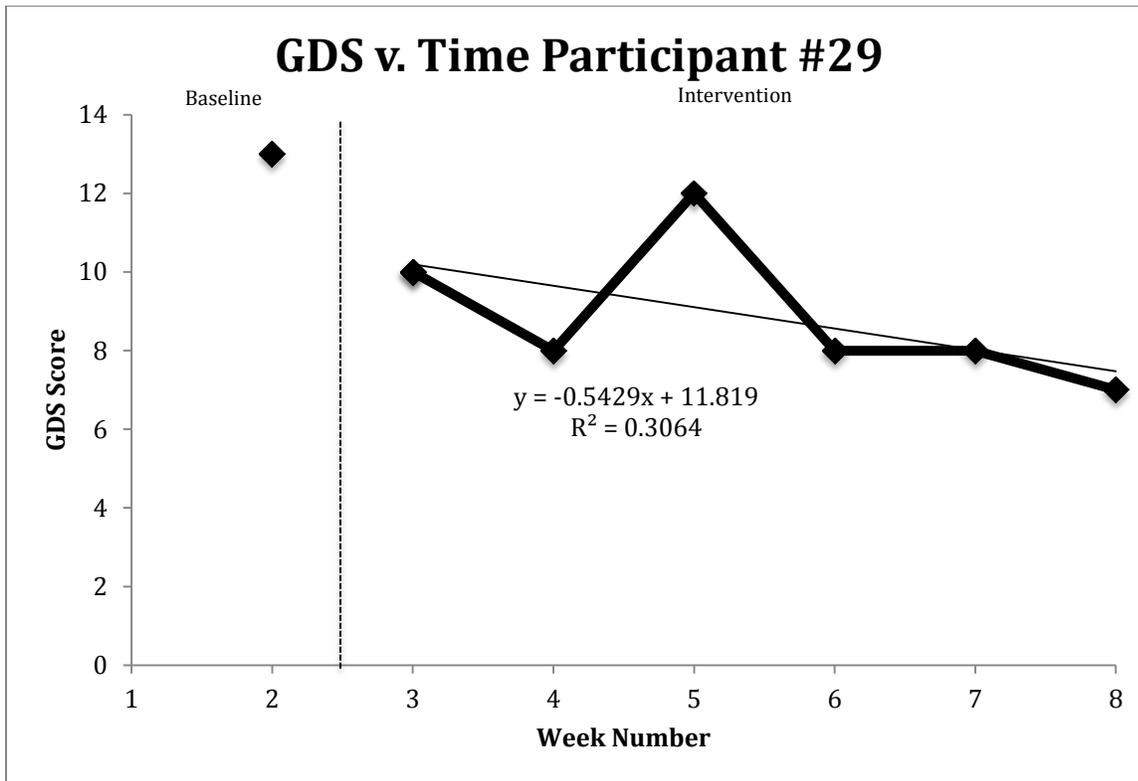


Figure 5. Overall GDS scores for Participant 29 from week 2 to week 8 of the study. GDS scores for this participant from week 1 were not collected because the participant signed up for the exercise class late.

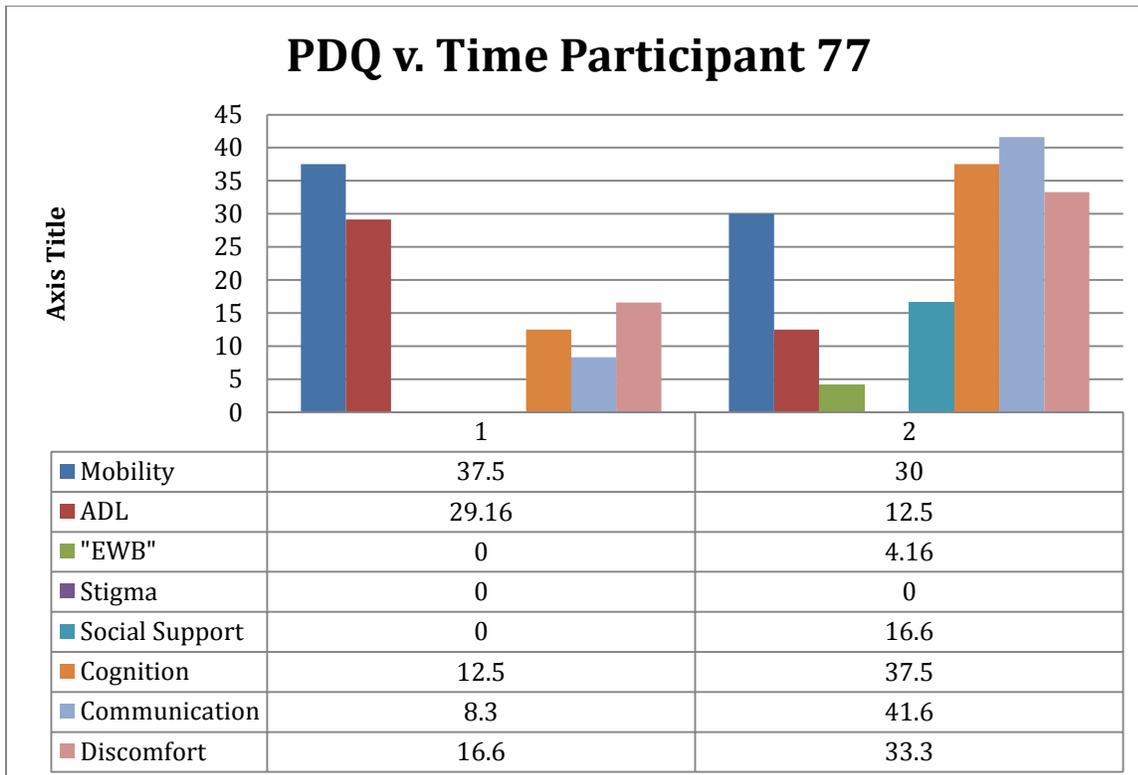


Figure 6. The change in the eight different categories of the PDQ from the beginning of the exercise regimen to the end for participant 77.

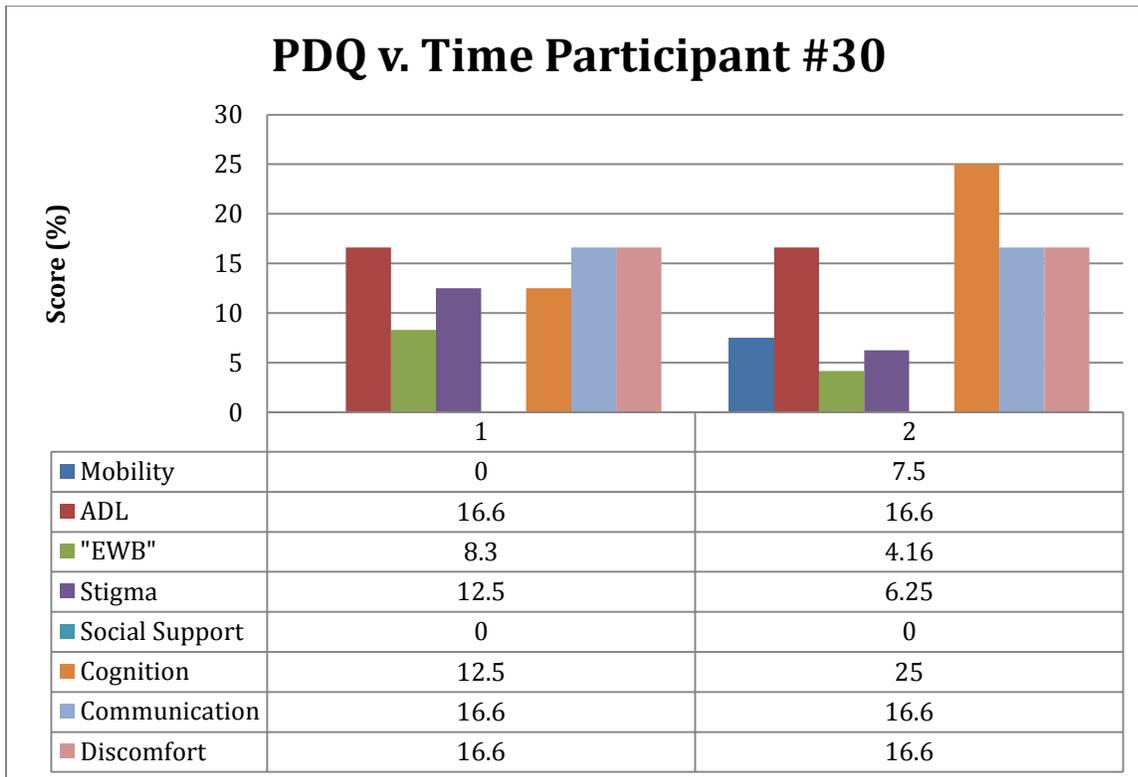


Figure 7. The change in the eight different categories of the PDQ from the beginning of the exercise regimen to the end for participant 30.

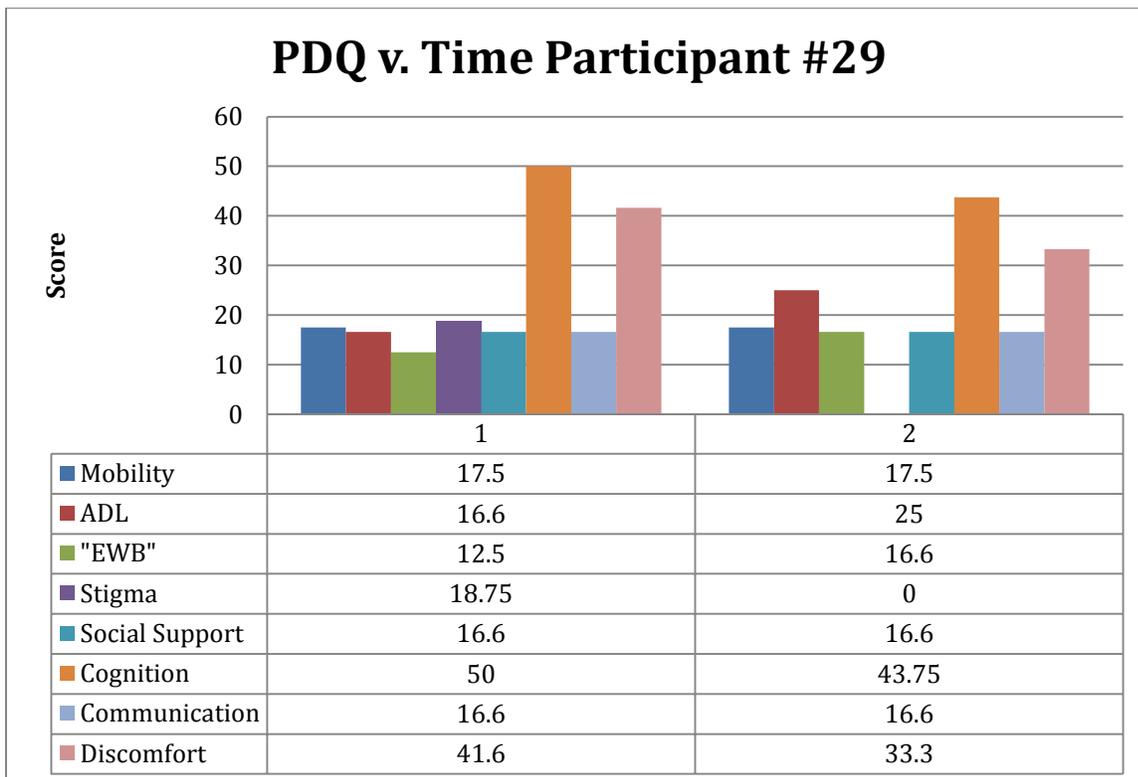


Figure 8. The change in the eight different categories of the PDQ from the beginning of the exercise regimen to the end for participant 29.