CHARACTERISTICS OF ALLI® USERS AND EFFECT OF DRUG ON QUALITY OF LIFE

by

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DEDICATION

I would like to dedicate my thesis to my whole family. I would like to express my appreciation to my mother and father for the unconditional support they have shown me throughout my whole life. I am honored to have you as my parents. Thank you for always encouraging me to follow my dreams.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

Introduction

This study was designed to explore characteristics of overweight and obese Alli® users and how the drug affected their quality of life.

Methods

This obesity drug's impact was investigated through a qualitative survey questionnaire. The population of interest was overweight or obese individuals (BMI ≥ 25) who were currently taking Alli®. The sample consisted of volunteers living in and out of the United States who met the criteria for the study; currently taking Alli® and the ability to answer basic questions about their usage, compliance, weight loss, side effects and quality of life. Furthermore, individuals had to be ≥ 18 years of age to participate. Fliers were developed to recruit participants through several different methods. The only successful method was through the social networking site Facebook. Participants volunteered to complete a short online survey that was developed through the program Qualtrics®.

Results

A total of 16 individuals responded to a request for participation in the study. All of the participants were female. In addition, the majority were also white, from the US and between the ages of 25 and 34. Most participants (57%) in this study had a BMI >40, with ~87% of participants with a BMI ≥30. The BMI range was between 26.9 and 57.6. The most common side effects documented were gastrointestinal (GI) problems. A significant association between race and quality of life for discrimination was seen with a p value .03.

Conclusion

Due to the small sample size, the results are not representative of the whole population; therefore, results should not be generalized to the population. However, this paper illustrates general patterns related to daily life functioning to medication use occurring in a sample of overweight/obese individuals. Recruitment through social media has the potential to reach more participants than traditional methods. Even though this study did not acquire many participants, social networking was the only recruiting method that worked. Social networking continues to become more popular and needs to be considered as a method of recruiting subjects for research.

Chapter 1

INTRODUCTION AND LITERATURE REVIEW

There is a growing concern that the obesity epidemic is sweeping the world and specifically the United States (US). Today, obesity is common among all age groups, especially the adult population. Approximately 72.5 million adults in the US are obese (1). The National Health and Nutrition Examination Survey (NHANES) results from 2007-2008 indicate an estimated 68% of US adults ≥ 20 years of age are either overweight (Body Mass Index [BMI] 25-29.9) or obese (BMI ≥ 30) (2-4). Evidence suggests the prevalence of obesity has not continued to increase at the same rate over the past 10 years as previously documented (3). The current efforts to prevent weight gain are continuing to proceed because of the increased risk of several diseases associated with obesity (5). These diseases include diabetes, hypertension, heart disease, lung disease, and certain types of cancer.

The latest available figure from Marketdata Enterprises, Inc, a US Weight Loss and Diet Control Market Company, estimated the US weight-loss market was worth approximately $55 billion in 2006, with expected growth of a few billion dollars each year (6). Roughly $147 billion are spent on treating the diseases that are associated with obesity (1). Behavioral therapy, dietary management, and pharmacological treatments have been utilized over the years. Since many individuals have not maintained significant weight loss when using behavioral therapy and dietary management, people have turned to pharmacological treatments (7). The history of weight-loss medication usage is fraught with instances of harsh side effects, abuse, and relapse. In 2008, rimonabant was removed from the market due to mood/psychological alterations,

nausea, upper respiratory tract infections and many other adverse side effects (8). Similarly, a meta-analysis of fenfluramine, with or without phentermine, found high levels of pulmonary hypertension and valvular heart disease. Fenfluamine was also removed from the market due to the harsh side effects. Every drug poses a risk of side effects and the research has been ongoing for a weight-loss drug that shows a higher benefit for the patient than a risk. In 2008, Klonoff and Greenway (5) reported on two drugs that were approved for long-term use and had demonstrated effectiveness in large scale trials; Meridia® (sibutramine) is a norepinephrine and serotonin reuptake inhibitor that enhances satiety, and Xenical® (orlistat) is a lipase inhibitor that reduces fat absorption. Historically, sibutramine and orlistat were recommended for individuals with a BMI $\geq$ 27 and at least one risk factor for obesity (9). Even the National Institutes of Health (NIH) had supported the use of medications as an adjunct to lifestyle therapies for individuals with a BMI $\geq$ 30 with no obesity related co-morbidities or a BMI $\geq$ 27 with one obesity-related risk factor (10). However, on October 28, 2010, Meridia® was pulled from the market due to severe side effects associated with heart complications leaving orlistat as the only prescription medication to be currently available for weight-loss (5).

Orlistat was the first and only obesity prescription medication to become available over-the-counter (OTC). It was approved by the Food and Drug Administration (FDA) for OTC use in 2007 (9). The prescription dosage is 120mg, whereas the OTC dosage is 60mg. The prescription strength tablets reduce triglyceride absorption by 30%, whereas the OTC tablets reduce triglyceride absorption by 25% (5). Orlistat 60mg (Alli®) is still the only prescription weight-loss drug available for OTC use. Wyatt et al (11) suggested the OTC treatment for obesity would change many features of the "current obesity treatment paradigm" and the obesity field. First, Alli® would be the only OTC weight-loss treatment available for weight

management. This would provide patients with an evidenced-based, FDA approved medication. Patients are overwhelmed with untested and unapproved weight-loss OTC medications daily, and this would allow healthcare professionals to educate patients on the approved medication available to them without a prescription. Second, patients are not forced to consult a healthcare professional before use. However, if patients do seek help, the healthcare provider needs to be able to answer any questions the patient may have. In addition, the authors proposed that having an OTC medication for obesity will not only help patients but also lead to obesity being labeled as a disease.

The introduction of OTC weight-loss treatments for obese individuals may help reach a wide variety of people. Many overweight individuals believe that they are able to solve their weight issues themselves with "self-help" strategies (12). One study found that 70% of overweight individuals indicated that they were unlikely to visit a physician for help with weight loss because the majority (52%) believed they could do it themselves (13).

Orlistat's Mechanism of Action

The prescription drug Xenical® and its OTC counterpart Alli® have the same properties including the mechanism of action. The only difference between the prescription version and OTC version is the dosage. Both drugs are considered pancreatic lipase inhibitors (10). The detailed mechanism of inhibition has been studied for pancreatic lipases using the substance tetrahydrolipstatin (THL) (14,15). THL is derived from lipstatin and appears to be a general inhibitor for mammalian lipases and fat absorption. The inhibition is due to a covalent bond between THL and Ser152 which is one of the residues in the catalytic triad (Ser152-HIS263-Asp176) of this enzyme. Trp252 is part of the flap that covers the catalytic triad (15). The flap must be opened before inhibitors can react with Ser152.

Alli® reduces the body's capacity to absorb dietary fat by approximately 25%. The enzyme lipase, responsible for breaking down dietary fats, is blocked by the drug. When fat is not broken down, the body cannot absorb it, causing the body to excrete it, resulting in fewer calories being absorbed. Drugs that inhibit fat absorption may negatively affect fat soluble vitamins as well. Lipase is also used to break down and absorb fat-soluble vitamins. Orlistat has been shown to decrease plasma concentrations of fat-soluble vitamins (A, D, E, K and beta-carotene) in individuals consuming the drug for an extended period of time (16).

In the *XENical in the Prevention of Diabetes in Obese Subjects (XENDOS) study*, plasma concentrations for all fat-soluble vitamins assessed (vitamins A, D, E, K), except 1,25-hydroxyvitamin D, were significantly decreased in the orlistat group as compared to the placebo group after 4 years of treatment (17). Two studies using healthy individuals consuming orlistat for a short period of time found that concentrations of vitamin E and beta-carotene, but not vitamin A were significantly reduced (18, 19). McDuffie et al (20) studied obese adolescents who were receiving orlistat as well as a prescribed multivitamin supplement. They found a significant decrease in absorption for serum vitamin D and E compared to baseline.

Research conducted on orlistat and fat-soluble vitamins display varying results. However, each study found a significant decreased absorption in one or more fat-soluble vitamins. Therefore, there is an increased awareness to the possible decreased absorption of fat-soluble vitamins while consuming orlistat and most individuals consuming this medication are advised to consume a multivitamin or fat-soluble supplement to compensate for the lost vitamins (9). It is still unclear why there are varying results for fat-soluble vitamin concentrations with orlistat. However, researchers believe it may be due to genetic factors, for example African Americans are known to be at risk for vitamin D deficiency (20). It may also be due to varying

consumption of food containing these vitamins. The quality of research conducted on fat-soluble vitamins is lacking, additional high-quality studies are needed. More research is also needed to determine specific causes of vitamin depletion. It is still important for individuals who consume orlistat to also take a multivitamin to help prevent any vitamin deficiencies. The educational materials in the Alli® starter kit recommends every consumer take a multivitamin once daily, at bedtime (21).

Side Effects of Orlistat

A risk/benefit analysis is performed on every drug before it can be recommended for use. With every medication, the benefits have to outweigh the risks prior to marketing. One aspect of drugs that can turn people away is the side effects. Side effects can occur with every medication, however, most weight-loss medications produce mild side effects, i.e. dizziness, abdominal pain, and increased heart rate, that usually improve with continued use (10, 22). Xenical® and Alli® have been shown to display several different side effects among consumers, including abdominal cramping, intestinal discomfort, diarrhea, flatulence, and leakage of oily stool. Both medications are recommended to be consumed with a reduced-calorie, low-fat diet accompanied with exercise and a multivitamin. These suggestions, especially reducing fat, may help reduce some of the side effects produced by the medication. Even though the adverse side effects increase in response to the amount of fat consumed, they typically diminish over time as the patient gains experience taking the medication (22).

Weight-loss Outcomes

Obesity medications have received a great deal of attention for providing only moderate amounts of weight loss among users when compared to individuals not taking weight-loss medications. There are mixed results on how much weight loss each individual can expect while

taking medication that promotes weight loss. The promotional materials in the Alli® starter kit, suggest that individuals taking Alli® can expect to lose 2-3 more pounds for every 5 pounds they lose from diet alone (21). However, published evidence indicated that, within a 6-month period, people on orlistat with a reduced-calorie diet who adhered well to the program, lost an average of 2.3 kg (~5 lb) in addition to the 2.1 kg (~4.6 lb) lost with diet alone (a total of ~10 lb) (23). The majority of people lose 5-10 pounds over a 6-month period. In a meta-analysis, Rucker et al (24) found that 15 orlistat trials from 1 to 4 years duration resulted in a weight-loss of approximately 2.5-3.2 kg (~5.5-7 lb) more than diet-only placebo participants. According to the Weight-Control Information Network (WIN) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), individuals taking weight-loss medications can expect an additional 4.5 kg (10 lb) weight loss as compared to non-drug obesity treatments (10). Hauptman et al (25) investigated the long-term efficacy and tolerability of orlistat. They discovered that patients who consumed 120 mg and 60 mg dosages of orlistat for an extended period of time lost significantly more weight than those taking a placebo. Even though both forms of orlistat generated weight loss, after 1 year the 120 mg dosage produced the highest percentage of weight loss from initial body weight. At the end of year two, 22.8% and 16.5% of subjects who completed the 2 years of treatment of 120 mg and 60 mg dosages of orlistat, respectively, lost more than 10% of their initial body weight compared to 8.8% in the placebo group. In general, research indicates individuals consuming 120 mg or 60 mg dosages of orlistat can expect only moderate amounts of weight loss while consuming the medication.

Schwartz et al (9) studied the use of OTC 60 mg orlistat in terms of proper dosing procedures without physician supervision or nutrition counseling. The study used 237 subjects (202 female, 34 male) who were ≥ 18 years of age and completed at least one interview at a

specific pharmacy. The subjects purchased an orlistat package which contained one bottle of 90 orlistat 60 mg pills and education materials. The average price of the orlistat package was between $35-$45. The educational materials included a diet success planner, a fat wheel, a fat counter, a booklet on how to lose weight with orlistat and a personal food diary. These materials were used to support successful weight-loss and lifestyle information while taking orlistat. Data were collected at each pharmacy visit and via telephone interviews at 14, 30, 60, and 90 days into the program. During the first pharmacy visit, demographic, medical, and diet history questionnaires were collected and height and weight measurements were obtained. The mean initial weight of the subjects was 195.3lb. The telephone interviews were used to collect information about product use, adverse side effects, usefulness of educational materials, contact with a doctor or pharmacist, use of multivitamins, and satisfaction with the product. The recommended dosage is three pills per day. On average, two to three pills were consumed each day with meals and the pattern of use was consistent for all interviews. The majority of participants were female and approximately 27% had used a weight-loss drug in the past. Orlistat was reportedly used 90% of the days in the program. In addition, 74% of the participants reported taking multivitamins, 79% reported utilizing at least one of the education materials, 83% achieved weight loss at 3 months, 80% reported being satisfied with the product, and the most common side effect was GI problems, such as abdominal pain, fecal urgency, and flatulence. Previous studies demonstrated the significance of prescribing weight-loss drugs combined with lifestyle adjustments, but this study provided evidence that OTC medications combined with self-education materials showed "meaningful and satisfying weight-loss" at 3 months. Approximately, 80% of individuals reported being satisfied or very satisfied with the amount of weight loss achieved. Measured and self-reported weight loss were gathered. A total

of 106 participants were weighed at the pharmacy. The mean weight loss was 2.5 ± 0.4 kg (~4.6-6.4 lb) within the first 30 days and 4.6 ± 0.7 kg (~8.6-11.7 lb) after at least 60 days of consuming orlistat. Moreover, for measured weight loss, 46.3% of subjects achieved >5% weight loss >60 days after enrolling. For self-reported weight loss, 46.5% of subjects interviewed achieved >5% weight loss at 90 days.

Purpose of the Study and Research Questions

Alli® is still relatively new and there are many questions that need to be answered to fully understand the impact of the medication on consumers. The purpose of this research was to explore characteristics of overweight and obese Alli® users and how the drug affected their quality of life. In addition, other questions were explored.

- How much weight-loss was achieved from Alli® between 0-12 months?
- What was the average amount of time individuals took Alli®?
- How were quality of life functions (physical, emotional, social) affected by the use of Alli®?
- What was the daily dosage consumed?
- What side effects were experienced most often?

Operational Definition

For the purpose of this study, the term "quality of life" refers to the individual's perceptions and beliefs about their self-esteem, physical health, discrimination, work life, and activities of daily living (ADL), which include personal hygiene and grooming, self-feeding, dressing and undressing, functional transfers, bowel and bladder management, and ambulation.

Chapter 2

METHODS

Participants

The population of interest was overweight or obese individuals (BMI ≥ 25) who have used Alli®. The sample consisted of volunteers living in and out the US who met the criteria for the study; currently taking Alli® and the ability to answer basic questions about their usage, compliance, weight loss, side effects and quality of life. Furthermore, individuals had to be ≥ 18 years of age to participate and there were no gender exclusions. A goal of 100 volunteer participants was desired due to resources and subject availability.

A flyer was developed to recruit participants (SEE APPENDIX A). The flyer was posted in several places, including apartment complexes and businesses in the community, on the University of Delaware (UD) College of Health Sciences Website, on the social networking sites Facebook and Twitter, and on two free classified advertisement websites, Craigslist and UD classifieds.

Upon completion of the survey, each participant was asked if they wanted his/her name entered into a drawing to receive a $50 gift certificate to Barnes and Noble. One participant was chosen and the gift certificate was sent to the email address provided in the survey.

Survey Development and Validation

A 35-question online survey tool was developed for this study. The questionnaire had three distinct sections; demographic information (5 questions), Alli® questions (22 questions), and a quality of life items (5 questions). Three additional questions were asked in the survey (height, weight, flyer placement) (SEE APPENDIX B).

The demographic portion consisted of five questions; gender, race, age, educational status and current living location. The Alli® question portion consisted of 22 questions concerning compliance, weight-loss, usage, side effects, educational materials, vitamins, and meal choices. The quality of life portion consisted of five questions assessing physical function, self-esteem, activities of daily living (ADL), social, and work functioning. All questions began with the phrase, "Since taking Alli®…". Each question had 3 response options, yes, somewhat, and no, except the question about work which had an option for currently unemployed. The three additional questions consisted of where they saw a flyer, their height and their body weight the day they completed the survey.

Survey response rates are highly variable. Rates vary from 30-70% for individual participants (26). For this study, an electronic survey method was chosen because research has shown sensitive items acquired through Web-based surveys have a higher completion rate, especially related to health behaviors (27). Qualtrics® (UD survey tool) was used to create and distribute the survey online.

To establish face validity, the survey was evaluated by six professionals in the nutrition field, three professionals specializing in research and surveys, one professional survey creator and statistician. The instrument was pilot tested on 10 lay individuals for clarity and comprehensiveness. Any questions and/or comments that were mentioned by one of the individuals were addressed. Overall, only a few changes were made to the survey from the comments received.

Survey Procedures

The survey was posted on Qualtrics® from April 28th to June 15th. After participants read the flyer, they were able to decide if they wanted to participate in the survey. Each flyer

had the Web address clearly noted and the participant could access it from any computer. Each survey participant remained anonymous and only the researcher and advisor had access to the answers given. After completing the survey, the participant was asked if he/she wanted to enter into a drawing for a $50 gift certificate to Barnes and Noble. Participants were asked to give basic identifying information, i.e. email address, for easy contact if they were chosen. A UD Information Technology (IT) employee kept this information confidential and chose a winner at the end of the study who was emailed the gift certificate.

Statistical Analysis

The data were first summarized using descriptive statistics. Participant answers were compiled into patterns to show similar results among participants. Chi-square and t-test statistical assessments from Qualtrics® and Statistical Package for the Social Sciences version 19.0.0.1 (SPSS Inc. an IBM company, 2010, Chicago, IL) were used to test the associations between several survey questions. This research study was approved/exempt by the UD Institutional Review Board (IRB).

Chapter 3

RESULTS

A total of 16 individuals responded to a request for participation in the study. One participant did not complete the weight and height questions appropriately and had to be excluded for that portion of the analysis. Another participant had an initial BMI of 22, classifying the individual as normal weight and was excluded from the results as well.

Demographics

All of the participants were female (n=15, 100%). In addition, the majority were also white (n=11, 73%), from the US (n=10, 67%), and between the ages of 25 and 34 (n=6, 40%) (Table 1). Most participants were employed and were generally well educated; 53% (n=8) reported having completed some college, 13% (n=2) reported having a 4-year college degree, and 21% (n=3) reported having a master's, doctoral or professional degree. Most participants (n=8, 57%) in this study had a BMI >40, with ~93% (n=13) of participants with a BMI ≥30. The BMI range was between 26.9 and 57.6. The average amount of weight loss as a result of using Alli® was 17.79 lb over the time period of a few weeks to 1 year. The average weight loss per week was approximately 2.0 lb. However, one participant lost 34 lb in 3 weeks which elevated the average weight loss among all participants. With the accomplished weight loss, 87% were either very satisfied (n=6, 40%) or somewhat satisfied (n=7, 47%) with their weight loss (Figure 1). The majority of participants (n=11, 73%) were first time users of the medication.

Product Usage

Alli® is the first weight-loss medication to be provided OTC, therefore, there is no need to consult a physician before using the medication. However, 33% (n=5) consulted a physician

and 7% (n=1) consulted a pharmacist prior to using the medication (Figure 2). The rest of the participants, 53% (n=8) and 7% (n=1), consulted no one or a family member, respectively.

In the questionnaire, participants were asked if they used any of the reference booklets provided in the starter kit. Approximately, 73% (n=11) used at least one resource (Figure 3). In addition, 53% (n=8) used three or more resources provided and 27% (n=4) did not use any starter kit resources.

Participants were asked to identify how many Alli® pills they consumed daily. There was minimal variability in the responses for each day. Monday, Tuesday, Wednesday, Thursday, and Friday had the same range of 1-3 pills. Saturday and Sunday had two different ranges of 1-5 and 2-5 pills, respectively. This may be due to decreased diet adherence on the weekend. Most participants reported consuming three pills on a regular basis throughout the week, which is the recommended dose.

Diet/Vitamin Use

There are several recommendations for how and when Alli® should be consumed. One recommendation is to take Alli® with meals. According to the survey, 67% (n=10) of participants always took Alli® with their meals and 27% (n=4) sometimes took Alli® with their meals (Figure 4). A second recommendation is to consume a low-fat diet while taking Alli®. Surprisingly, 100% reported they either always (n=8, 53%) or sometimes (n=7, 47%) consumed a low-fat diet while taking the medication (Figure 5). A third recommendation is to take a multivitamin while taking Alli®. The majority of participants reported that they always (n=8, 53%) or sometimes (n=5, 33%) consumed a multivitamin (Figure 6). However, 50% (n=7) reported they did not consume fat-soluble vitamins (A, D, E, K) separately (Figure 7). Only 29%

(n=4) consumed all four pills separately, but 50% (n=7) consumed at least one fat-soluble pill daily.

Side Effects

There was a high degree of variability for the side effect questions. Seven different side effects were assessed. Some participants reported that they never experienced stool leakage (n=7, 47%), cramping (n=8, 53%), flatulence (n=3, 20%), urgency to use the restroom (n=6, 40%), nausea and/or vomiting (n=14, 93%), fatigue (n=8, 53%), and diarrhea (n=4, 27%) (Figures 8-14). Research has shown that adverse side effects from Alli® usually diminish over time as the patient gains experience with the medication (28). Only 33% (n=5) reported their side effects diminished over time. Three participants stated that stool leakage, cramping, and diarrhea diminished whereas two participants reported a decrease in flatulence one participant reported a decrease in urgency to use the restroom, fatigue, and nausea and/or vomiting (Figure 15).

Quality of Life

Quality of life was studied using five questions. The majority of participants reported that their self-esteem (n=8, 53%), physical health (n=9, 60%), and ADL (n=9, 60%) improved after taking Alli® (Figures 16-18). Only 40% (n=6) of the participants stated that discrimination against them improved and 27% (n=4) reported their work life improved (Figures 19, 20). Even though several participants felt their quality of life improved after taking Alli®, there were still several participants who felt their quality of life did not improve. Approximately, 33% (n=5) reported no changes in quality of life for self-esteem, discrimination, and work life. In addition, 27% (n=4) reported no changes in quality of life for physical health and ADL. It is not

surprising that several participants showed no improvement in quality of life because many had such a small amount of weight loss.

Race and Discrimination

A chi-square test was used to assess the association between race and perceived discrimination after using Alli® (Table 2). Race was merged into two categories, white/Caucasian, not Hispanic and all other races. There were 11 participants that were white and 4 participants that were another race. Participants were asked if they felt less discrimination against them since taking Alli®. The chi-square test generated a significant p value of .03 (p value < .05) indicating a greater number of non-white/Caucasian participants felt less discrimination over time.

Educational Status and First Time User

A chi-square test was used to assess the association between educational status and first time use of Alli® (Table 3). Educational status was merged into two categories (less than high school through some college was one category and 2-year college degree through professional degree was the other category). There were nine participants in the first category and six participants in the second category. The participants answered if they were or were not a first time user of Alli®. The chi-square test generated a p value of .06 which is not significant. However, it is approaching significance, indicating participants with a college degree or higher were more likely to be a first time users of Alli® than non-college degree participants.

Other Testing

There were no significant differences when comparing age vs. BMI, education vs. BMI, age vs. weight loss, and education vs. weight loss (all p's > .05).

Chapter 4

DISCUSSION

The information found from this study illustrated the types of reactions and problems that occur among individuals using Alli®. Even though we cannot make any generalizations because of the small sample size, the results of this study pose some key questions that need to be addressed in future work. Due to the disappointing response rate, this study can only be viewed as a pilot study that would help to direct future research to expand on some of the patterns found among the participants.

The instrument used was created specifically for this study and the questions were carefully picked to understand how individuals reacted to the medication. It is not surprising that only females participated and the majority of participants were generally well-educated, employed, white women between the ages of 25 and 34. The BMI range was between 26.9 and 57.6 with the majority having a BMI classification over 40. Alli® has been known to cause small weight loss totals and harsh side effects. This study found that weight loss was highly variable among participants. The average weight loss among participants was 17.8 lb with a range of 0 lb to 40 lb. Still, the majority of participants (n=13, 87%) were at least somewhat satisfied with the amount of weight that they lost. One individual achieved a normal BMI after consuming Alli®.

Most participants were first time users of the medication and the majority did not consult anyone before starting the program. For the most part, the medication was used appropriately in terms of the dosing instructions and recommendations. Perhaps this is because 73% of the

participants used at least one reference booklet from the starter kit. Alli® is a medication that can comes with a "starter kit". The starter kit is meant to provide the consumer with information so they do not have to consult a professional before consuming the medication. The starter kit has Alli® weight-loss capsules, an Alli® pill shuttle, and seven reference booklets. These resources are designed to help the consumer use the product correctly and maximize the expected weight loss. The starter kit is an all-inclusive resource so the medication could truly be an OTC treatment not needing assistance from a professional. The majority of participants followed a low-fat diet and consumed some type of vitamin daily. This is consistent with the recommendations given by healthcare professionals as well as the Alli® starter kit. Consuming a low-fat diet can increase weight loss while reducing the adverse side effects. Multivitamin consumption is also suggested because the medication can reduce fat-soluble vitamin absorption in the body.

All of the side effects discussed in previous research were reported by the participants. However, an interesting addition to this study was identifying which side effects diminished over time. Researchers have found that adverse side effects from Alli® reduce with continued use, but many users were not continuing to use Alli® long enough to assess this effect (28). The most common side effects experienced by Alli® users are GI tract issues, such as stool leakage, cramping, and flatulence. Alli® targets the GI tract by reducing the body's capacity to absorb dietary fat. As a result, fat is not broken down and the body cannot absorb it, causing the body to excrete it. If a low-fat diet is followed, adverse side effects are reduced and a greater amount of weight loss is usually achieved. On the other hand, if a high-fat diet is consumed, adverse side effects will be enhanced and weight loss will be minimal.

A few questions were designed to help gain an understanding of how Alli® affects individuals physically, emotionally, and socially. These questions were based on how each participant felt about themselves. For three out of the five questions, the majority of participants showed improvement in their quality of life (self-esteem, physical health, and ADL). The three questions that showed the most improvement among the participants all dealt with them personally. It is surprising that quality of life would be impacted when the majority of participants were still obese after losing only a small amount of weight with Alli®. The two questions (discrimination and work life) that showed little improvement among the participants were based on other individuals as well as the participant. In general, Alli® seemed to help many participants function better physically and emotionally.

In this study, the association between race and discrimination was significant. However, to understand this significance, an extra question may need to be asked if the individual felt discrimination before taking the medication. If all participants felt discrimination before taking Alli®, a detailed analysis would be important to see which races felt the discrimination against them improved the most. Nevertheless, it is still important to note that individuals who are overweight/obese feel discrimination against them and losing even small amounts of weight may help improve how they feel socially. A second association between educational status and potential first time users of Alli® was approaching significance. The six participants who had a 2-year college degree or higher were strictly first time users, whereas the less educated participants had four individuals who were repeat users. A larger sample is needed to determine if this pattern would continue. Still, it is interesting that all of the participants with a higher education were first time users. These individuals may have researched the product and followed the instructions more thoroughly increasing their weight-loss results and decreasing

their adverse side effects. All six of the participants with higher education used the educational materials in the starter kit and four out of the six consulted someone before taking the medication.

A few t-tests were also conducted comparing age vs. BMI, education vs. BMI, age vs. weight loss, and education vs. weight loss. There were no significant differences between any of the tests; however these categories are important to keep in mind. With an increased sample size, these associations may have potential to show significance.

Overall, this study found several interesting patterns among participants. Unfortunately, the small sample size inhibited many of the associations from showing possible significant results. Other associations that were assessed had p values nearing significance that may have benefitted from a larger sample. Future research could consider evaluating similar questions to determine if significance could be found.

Study Limitations

The online survey method was convenient and inexpensive. Web-based surveys generally have lower respondent errors and increased question completeness (29). Since March 2011, ~78% of North Americans now have access to the Internet which has grown ~157% between 2000-2011 (30). Technical problems and security issues still pose as a problem for some users and can decrease response rate (29).

One of the main issues was recruiting participants. We knew it would be a hard population to recruit, so a recruitment plan was set prior to the start of the study. Several methods for recruiting were planned. The first and most logical idea was to post fliers in pharmacy areas or ask pharmacy counter staff to hand out a flyer to anyone who purchased Alli®. It had been shown in previous research that posting fliers in pharmacy areas was a

successful method for recruiting subjects (9). Numerous pharmacies were contacted, including Walgreens, Rite Aid, CVS, and Costco. The only pharmacy that responded to our request was Costco. An initial contact at a Delaware Costco pharmacy indicated that approximately 100 refills of Alli® were purchased each month. However, when asked if counter staff could hand out a flier or if fliers could be posted near the product, Costco declined to participate due to legal concerns. Other methods were then used to try and create a larger sample.

After the pharmacies declined to help, other recruiting strategies were developed. Craig's List was used to recruit individuals across the country. However, several spam emails were sent to my email address as well as my advisor's email address. This caused me to remove the flyer from Craig's List approximately 5 days after posting it. Fliers were also posted on bulletin boards around the UD campus. The bulletin boards are used by numerous individuals in the community and there is no way of stopping them from taking down your flyer to make room for their postings. Unfortunately, the fliers were taken down quite often. It was extremely hard to monitor the bulletin boards to makes sure a flier was constantly posted. As the initial attempts were not acquiring participants, social media through Facebook and Twitter were used. Facebook had 10+ support group dedicated to Alli® users. Fliers were posted in each support group inviting users to fill out the survey. Twitter can be used to connect with individuals and publish links. Links to the survey were published, however it was not able to find the specific Alli® users needed for the study. Facebook was much easier to identify Alli® users through the support groups, therefore more time and energy for recruitment was used on Facebook instead of Twitter.

We were curious to assess the best method of recruitment. A question was added to the survey for each individual to explain where they saw a flyer. Unfortunately, only one method

proved successful, online social networking. Future researchers in this area may want to recruit participants through online surveys. Recruitment through social media would be an interesting/important topic to research as social networking becomes more popular. It has the potential to reach more participants in a faster manner. This study was able to contact individuals who lived in and out of the US. Future research could look at the differences between individuals living in and out of the US who consume Alli®.

Marketing research through Twitter can be used in the survey research process (31). Links can be published to connect participants to a research survey and invitations can be sent to specific Twitter users. According to Henning, if social media is used in the survey process it can help produce "higher quality research". Market Action Research (MAR) is a market research company founded in August 2011 (32). It is the first company to use social media to launch viral research campaigns. MAR is using social media pages from specific businesses to understand consumer insights through surveys. It is much easier and quicker to connect with consumers through social media than traditional research methods. Another area beginning to use social media is academia (33). Researchers in all academic areas are using social media tools to identify research opportunities, form research collaborations, review literature, collect data, and disseminate findings.

Recruiting more participants may have been easier with more incentives. However, this thesis project was not part of a grant and therefore generated no income to provide to the participants. Nevertheless, one $50 gift certificate was given to a randomly chosen participant.

There may be other reasons why individuals did not participate in this study. For instance, several news articles were released in April 2011 that discussed GlaxoSmithKline (GSK), the company that owns Alli®, would be selling the line of medication (34). GSK is

hoping to find a contact to invest in the medication and sell the line by late 2011. In 2010, sales began to fall when reports stated the medication caused liver damage. Non-profit consumer advocacy groups have been petitioning to the FDA to remove Alli® and Xenical® from the market because liver damage and pancreatitis can develop from the medications (34). Recently, Alli® sales have declined from previous years and GSK would like to sell as soon as possible (35).

Conclusion

Generalizing to the population of interest was not appropriate with the small sample size, but general comparisons/patterns among the individuals were made. The information found from this study illustrated what type of results and problems occur among individuals using Alli® and could be expanded on in future research. This study also demonstrated that recruiting through social media may be a new viable recruiting method. Even though a significant number of participants were not attained, social networking was the only recruiting method that worked. As social networking continues to become more popular, research may be able to use the online method to recruit a wider variety of participants.

TABLES

Table 1. Characteristics of participants who completed the survey

	N[a]	Mean or %
Sex (%)		
Female	15	100%
Race (%)		
White/Caucasian, not Hispanic	11	73%
Asian	1	7%
Hispanic	3	20%
Age (years) (%)		
18-24	2	13%
25-34	6	40%
35-44	4	27%
45-54	3	20%
Educational Status (%)		
High School/GED	1	7%
Some College	8	53%
2-Year College Degree	1	7%
4-Year College Degree	2	13%
Masters Degree	1	7%
Doctoral Degree	1	7%
Professional Degree	1	7%
Residing Place (%)		
United States	10	67%
Not in the United States	5	33%
Initial Weight (lbs)[b]	14	226.4
Initial BMI (%)[b]		
25-39.9	6	43%
>40	8	57%
Initial BMI (kb/m^2)[b]	14	39
Weight loss (lbs)[b]	14	17.8

[a]Data from 15 participants who used the medication and completed the survey.

[b]Data missing for one subject.

Table 2. Chi Square testing comparing race and discrimination

		Race		
		African American or Black, Asian, Hispanic, Native American or Alaska Native, Native Hawaiian or Pacific Islander, Other	White/Caucasian, not Hispanic	Total
Since taking Alli®, do you feel less discrimination against you?	Yes	1	5	6
	Somewhat	3	1	4
	No	0	5	5
	Total	4	11	15

		Race
Since taking Alli®, do you feel less discrimination against you?	Chi Square	6.90*
	Degrees of Freedom	2
	p-value	0.03

**Note: The Chi-Square approximation may be inaccurate - expected frequency less than 5.*

Table 3. Chi Square testing comparing educational status and Alli® users

		Educational Status		
		Less than High School, High School/GED, Some College	2-Year College Degree, 4-Year College Degree, Masters Degree, Doctoral Degree, Professional Degree (MD, JD)	Total
Are you a first time user of Alli®?	Yes	5	6	11
	No	4	0	4
	Total	9	6	15

		Educational Status
Are you a first time user of Alli®?	Chi Square	3.64*
	Degrees of Freedom	1
	p-value	0.06

**Note: The Chi-Square approximation may be inaccurate - expected frequency less than 5.*

FIGURES

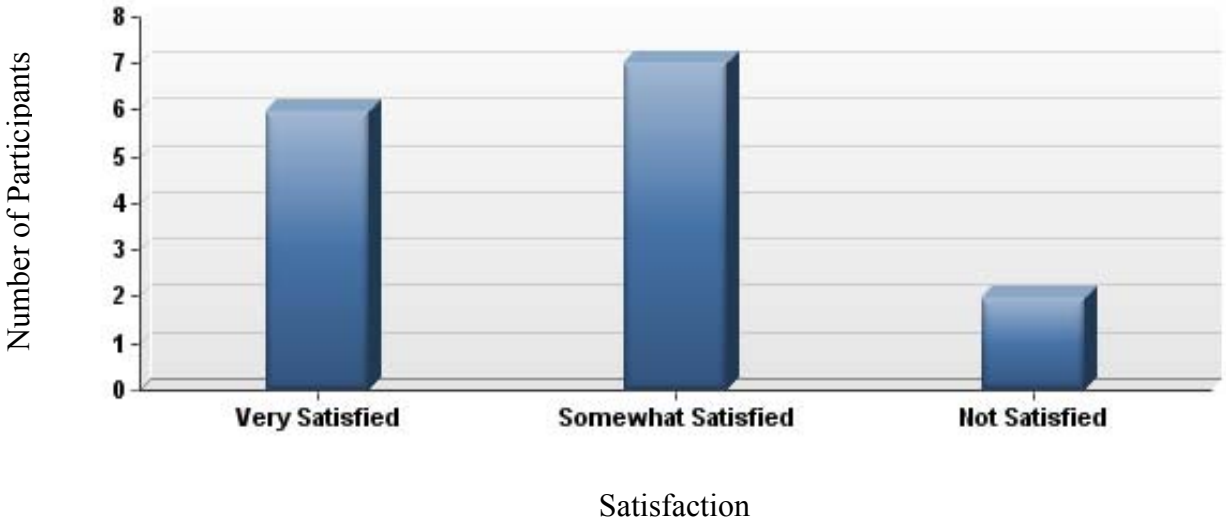

Figure 1. The number of participants that were very satisfied, somewhat satisfied, or not satisfied with their weight loss.

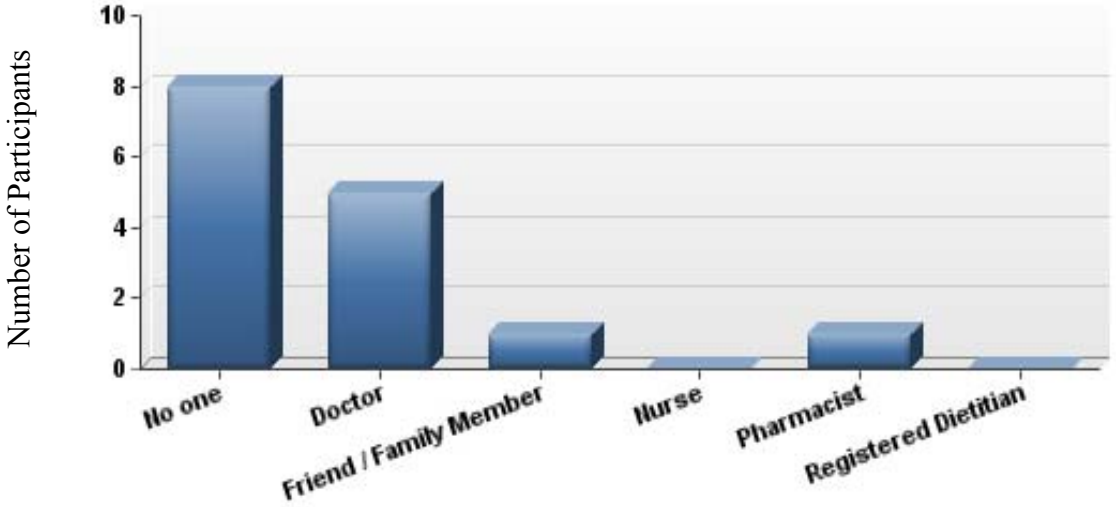

Figure 2. The number of participants that consulted a specific individual before taking Alli®.

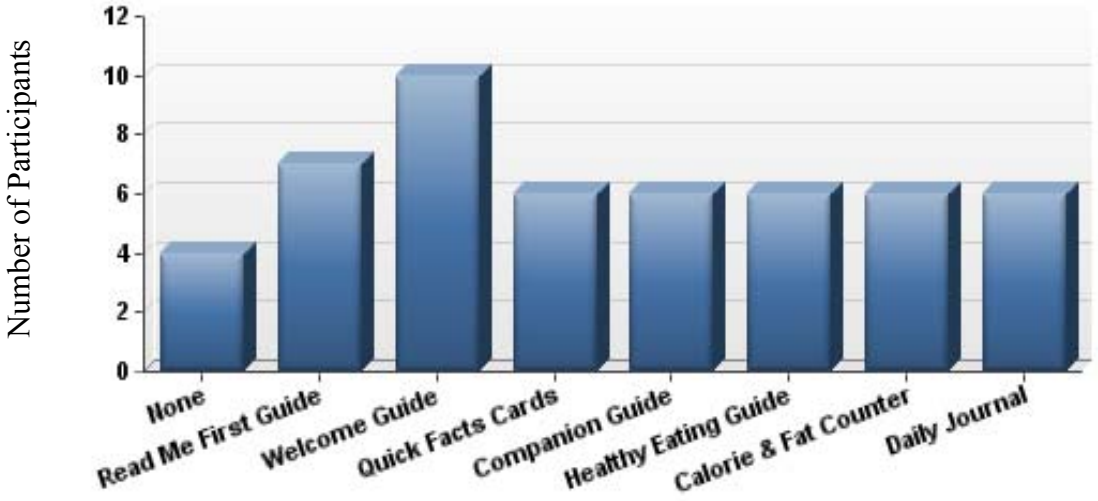

Figure 3. The number of participants that used specific educational materials from the Alli® starter kit.

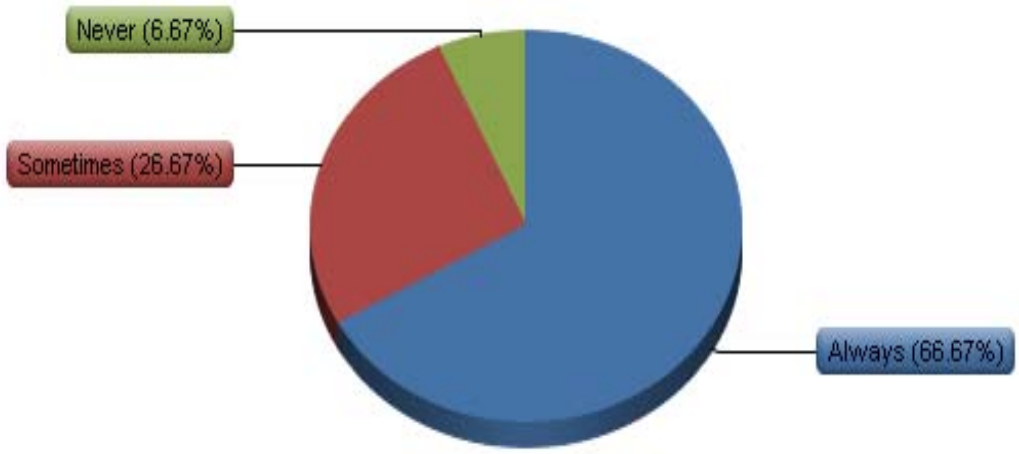

Figure 4. The percentage of participants who always, sometimes, or never consumed Alli® with meals.

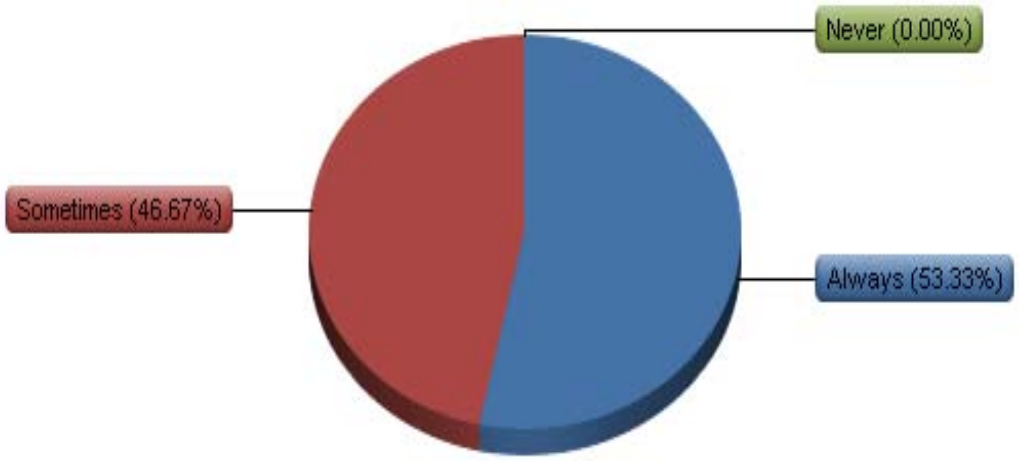

Figure 5. The percentage of participants that always, sometimes, or never consumed a low-fat diet while taking Alli®.

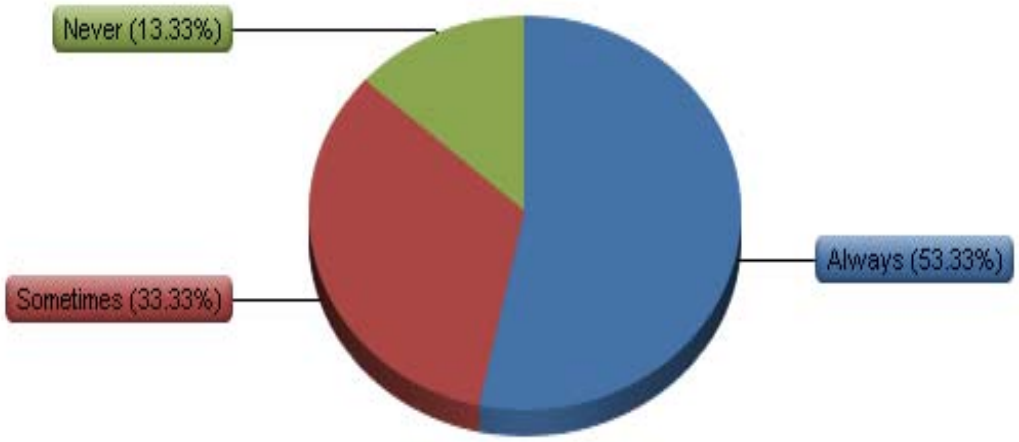

Figure 6. The percentage of participants who always, sometimes, or never consumed multivitamins while taking Alli®.

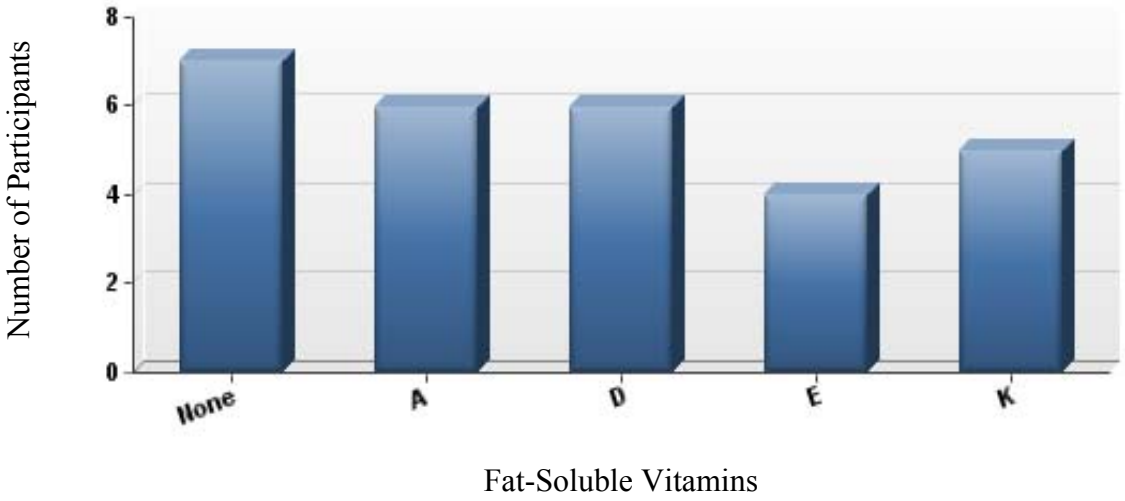

Figure 7. The number of participants consuming fat-soluble vitamins A, D, E, and K.

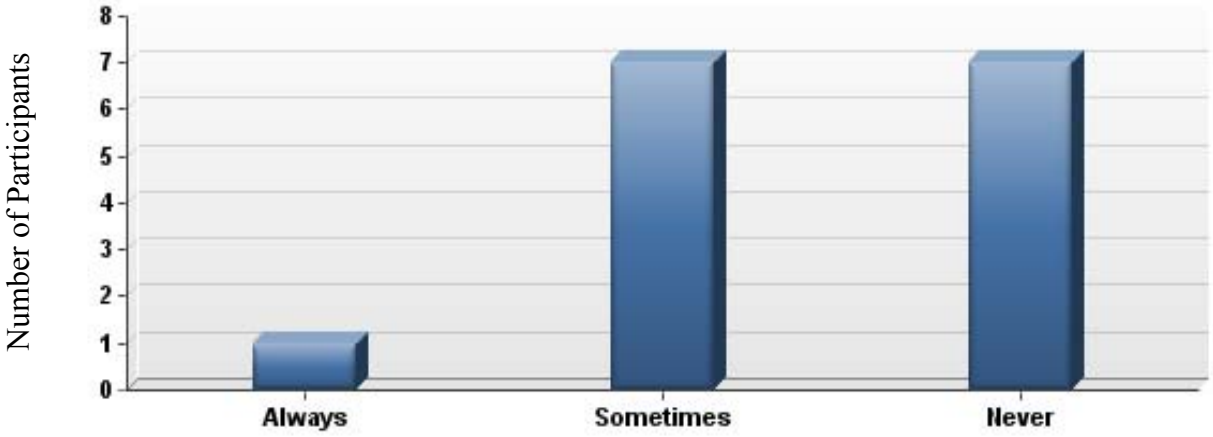

Figure 8. The number of participants that always, sometimes, or never experienced stool leakage while taking Alli®.

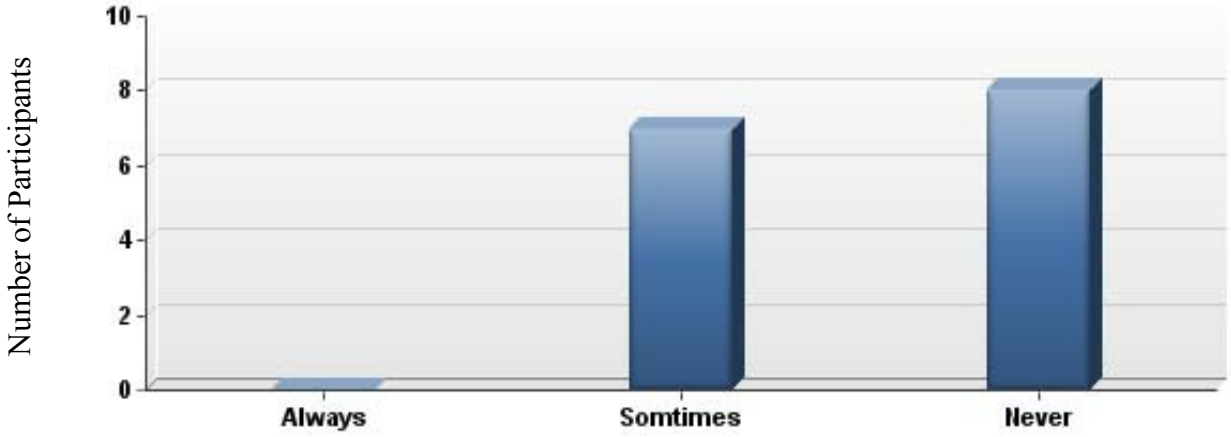

Figure 9. The number of participants that always, sometimes, or never experienced cramping while taking Alli®.

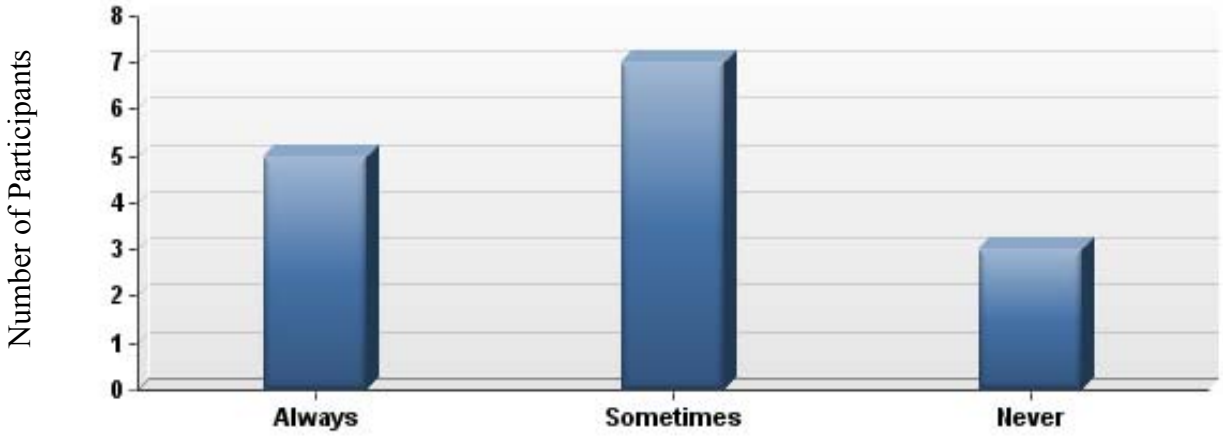

Figure 10. The number of participants that always, sometimes, or never experienced flatulence (gas) while taking Alli®.

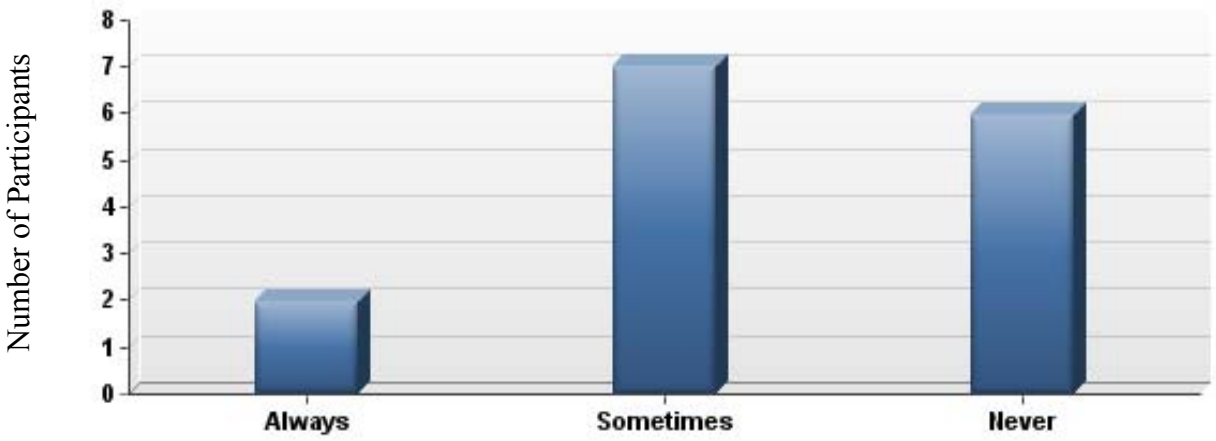

Figure 11. The number of participants that always, sometimes, or never experienced urgency to use the restroom while taking Alli®.

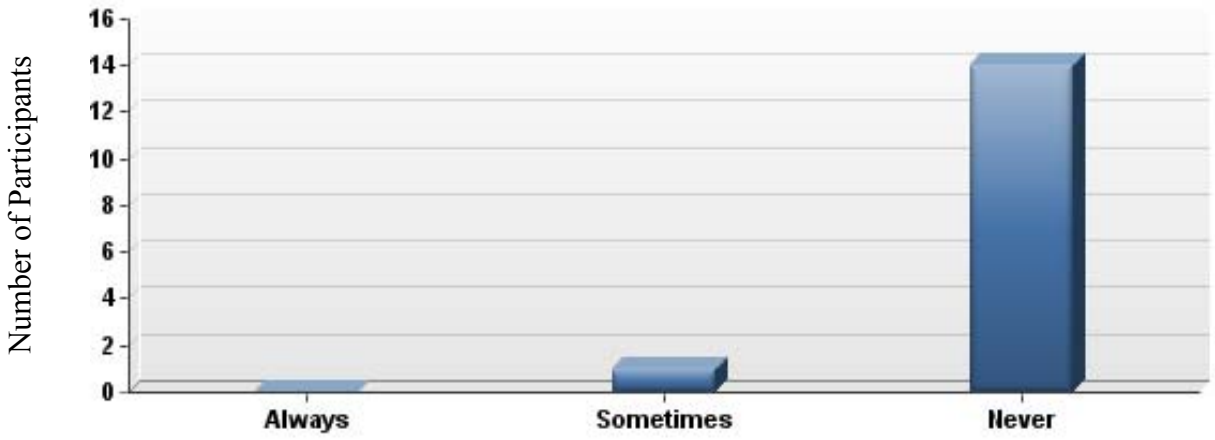

Figure 12. The number of participants that always, sometimes, or never experienced nausea and/or vomiting while taking Alli®.

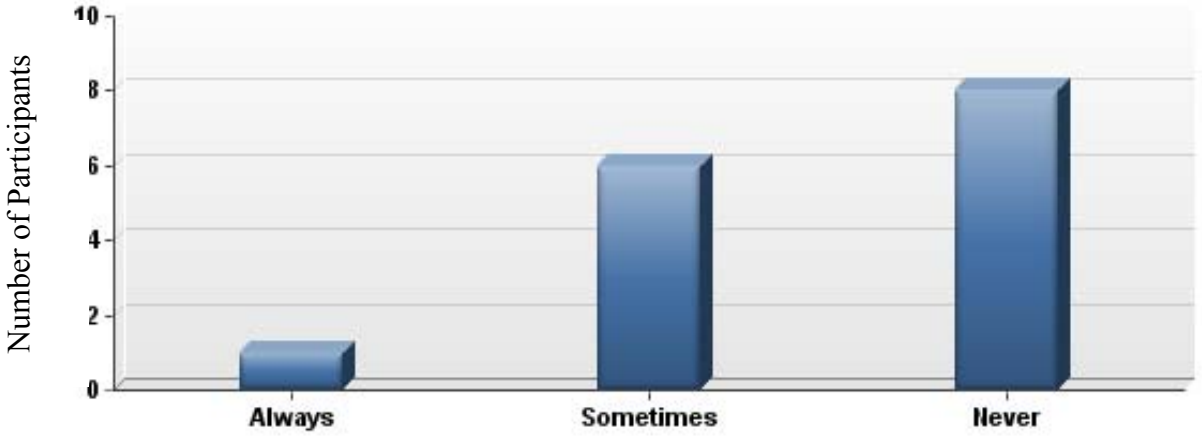

Figure 13. The number of participants that always, sometimes, or never experienced fatigue while taking Alli®.

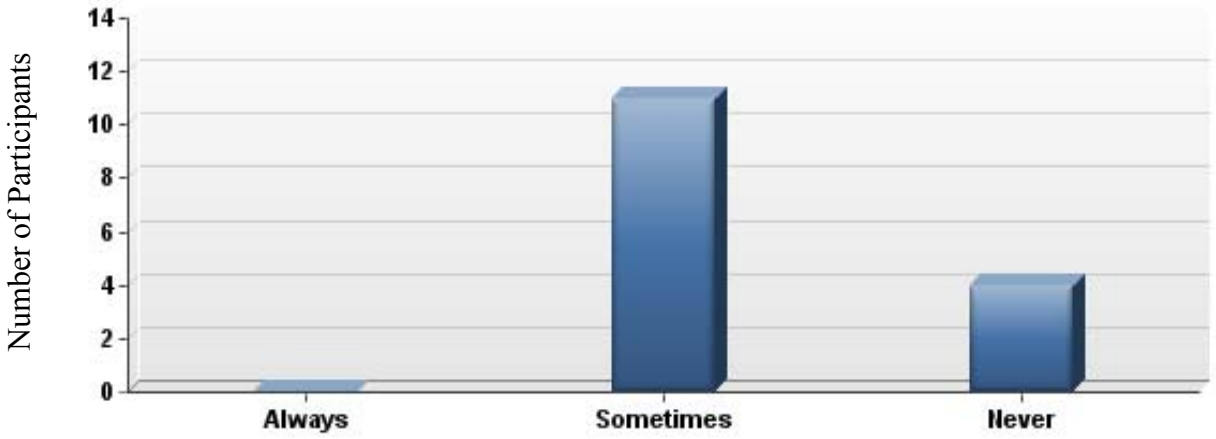

Figure 14. The number of participants that always, sometimes, or never experienced diarrhea while taking Alli®.

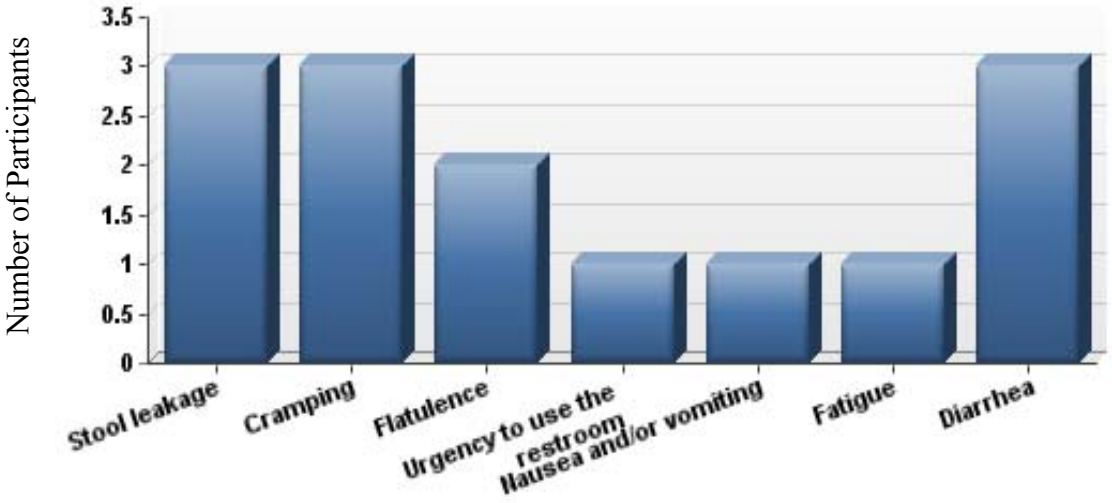

Figure 15. The number of participants that had specific side effects diminish over time while taking Alli®.

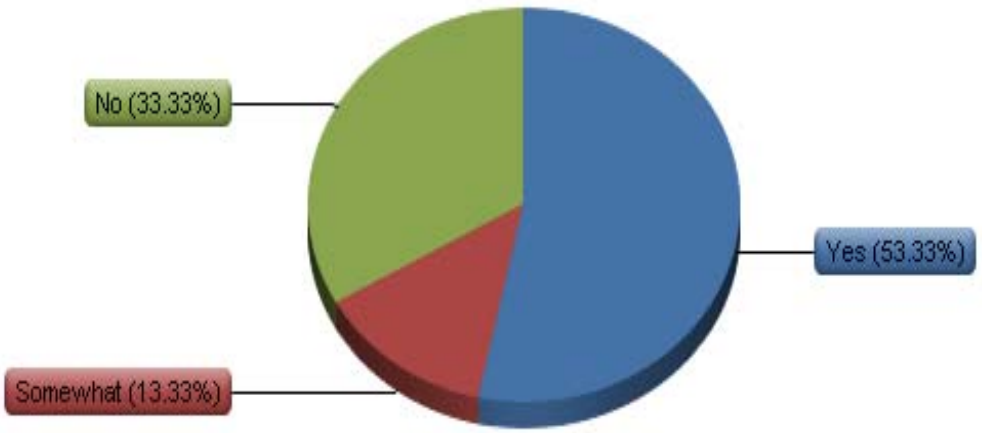

Figure 16. The percentage of participants whose self-esteem improved, somewhat improved, or did not improve while taking Alli®.

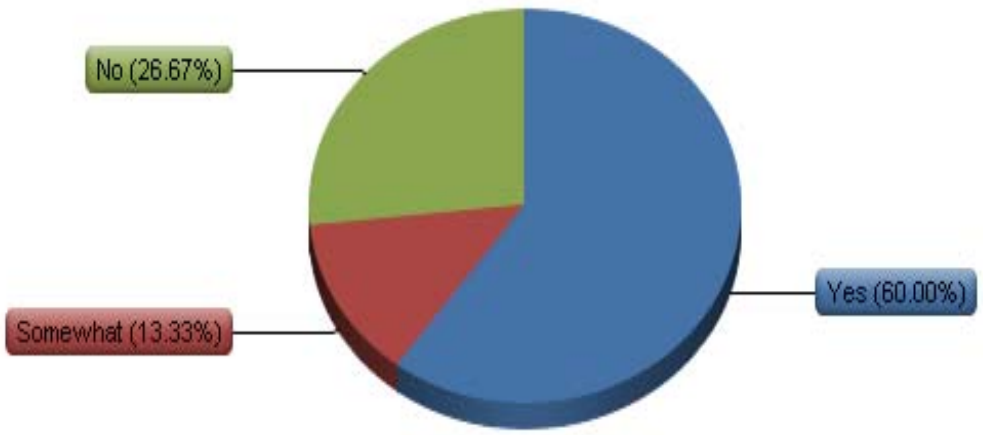

Figure 17. The percentage of participants whose physical health improved, somewhat improved, or did not improve while taking Alli®.

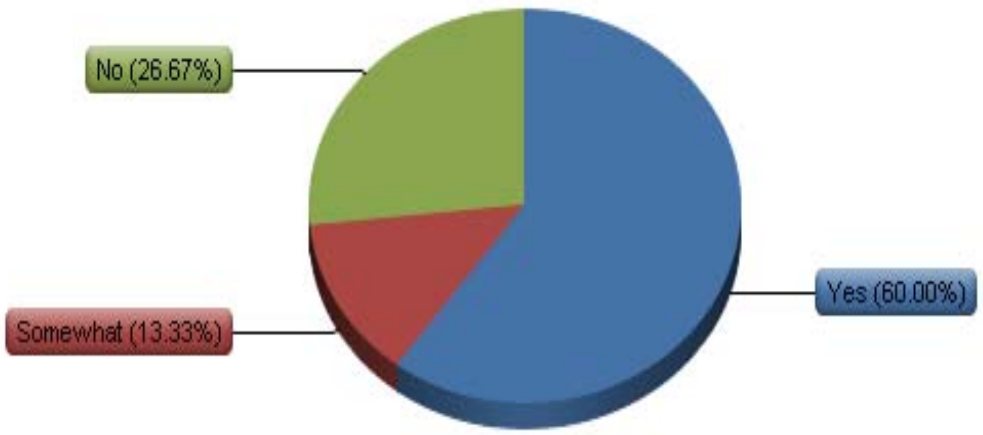

Figure 18. The percentage of participants whose ADL improved, somewhat improved, or did not improve while taking Alli®.

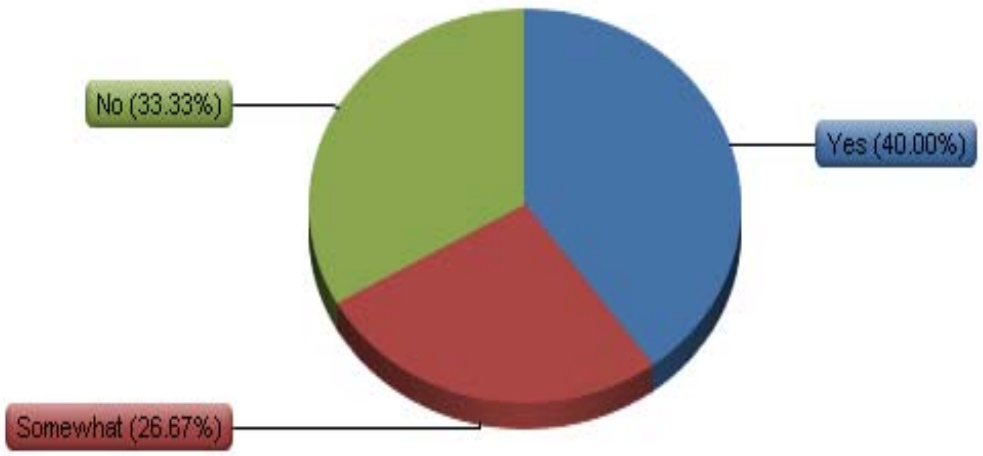

Figure 19. The percentage of participants who felt the discrimination against them improved, somewhat improved, or did not improve while taking Alli®.

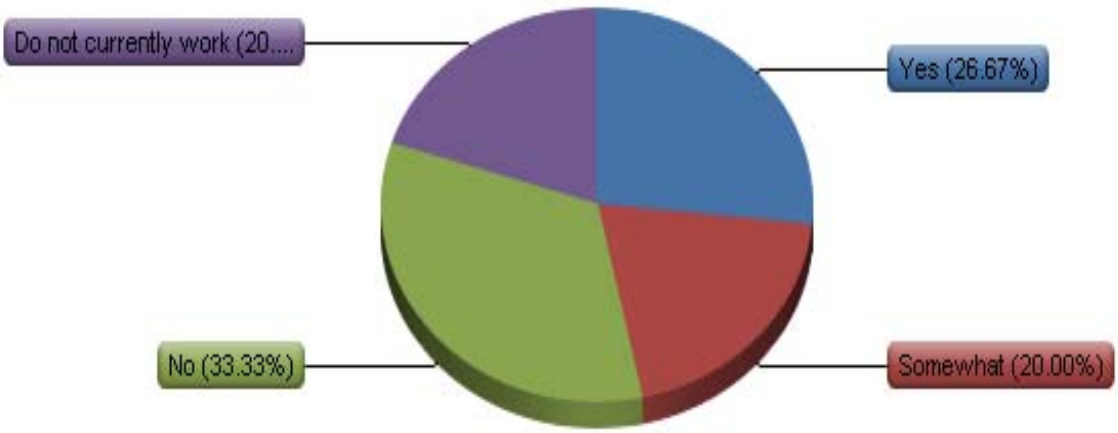

Figure 20. The percentage of participants whose work life improved, somewhat improved, or did not improve while taking Alli®.

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APPENDIX A

Promotional Flyer

ARE YOU CURRENTLY TAKING OVER-THE-COUNTER ALLI®?

My name is Kendall DiLorenzo and I am a graduate student at the University of Delaware. I am completing a thesis with my advisor Dr. Nancy Cotugna on the over-the-counter weight-loss drug Alli®. I am looking for volunteers to complete a short web-based survey. To participate you must have the following criteria:

18 years or older
Overweight
Currently taking the over-the-counter drug Alli® for at least 1 month

The survey will ask basic questions about your experience with the drug Alli® and should take no longer than 10 minutes. If you would like to participate in my study please go to the following web address (www.udel.edu/00677) to complete the short online survey. All of your information will remain anonymous. Upon completion of the survey you will be asked if you would like to participate in a drawing for a **$50 gift certificate**.

If you have any questions or concerns please contact:

Kendall DiLorenzo, graduate student
kendalld@udel.edu
302-521-5846

Dr. Nancy Cotugna, advisor
ncotugna@udel.edu
302-831-1006

Chair, Institutional Review Board
302-831-2137

Thank you for your time.

APPENDIX B

Survey Instrument

Q1 Alli® User Survey

This research study is designed to examine how the over-the-counter weight-loss drug Alli® affects individuals. Kendall DiLorenzo, a graduate student at the University of Delaware, and Dr. Nancy Cotugna, an advisor and professor at the University of Delaware are conducting this study to learn more about how weight-loss drugs affect different people. Participation in the study involves completion of a web-based survey which will take approximately take 10 minutes to complete. You must be 18 years or older to complete this survey. Upon completion, you will be asked if you would like your name entered into a drawing for a $50 gift card to Barnes and Noble. Your personal information will remain anonymous to the investigator and advisor and will not be connected to your responses in any way. Participation is voluntary and you may withdraw at anytime. Thank you for your time.

Q2 Gender

- ❍ Male (1)
- ❍ Female (2)

Q3 Race

- ❍ African American or Black (1)
- ❍ Asian (2)
- ❍ Hispanic (6)
- ❍ Native American or Alaska Native (3)
- ❍ Native Hawaiian or Pacific Islander (4)
- ❍ White/Caucasian, not Hispanic (5)
- ❍ Other (7)

Q4 Age

- ❍ 18-24 (1)
- ❍ 25-34 (2)
- ❍ 35-44 (3)
- ❍ 45-54 (4)
- ❍ 55-64 (5)
- ❍ 65+ (6)

Q5 Educational Status

- ❍ Less than High School (1)
- ❍ High School/GED (2)

- ❍ Some College (3)
- ❍ 2-Year College Degree (4)
- ❍ 4-Year College Degree (5)
- ❍ Masters Degree (6)
- ❍ Doctoral Degree (7)
- ❍ Professional Degree (MD, JD) (8)

Q6 In which state do you currently reside?

- ❍ Alabama (1)
- ❍ Alaska (2)
- ❍ Arizona (3)
- ❍ Arkansas (4)
- ❍ California (5)
- ❍ Colorado (6)
- ❍ Connecticut (7)
- ❍ Delaware (8)
- ❍ District of Columbia (9)
- ❍ Florida (10)
- ❍ Georgia (11)
- ❍ Hawaii (12)
- ❍ Idaho (13)
- ❍ Illinois (14)
- ❍ Indiana (15)
- ❍ Iowa (16)
- ❍ Kansas (17)
- ❍ Kentucky (18)
- ❍ Louisiana (19)
- ❍ Maine (20)
- ❍ Maryland (21)
- ❍ Massachusetts (22)
- ❍ Michigan (23)
- ❍ Minnesota (24)
- ❍ Mississippi (25)
- ❍ Missouri (26)
- ❍ Montana (27)
- ❍ Nebraska (28)
- ❍ Nevada (29)
- ❍ New Hampshire (30)
- ❍ New Jersey (31)

- ❍ New Mexico (32)
- ❍ New York (33)
- ❍ North Carolina (34)
- ❍ North Dakota (35)
- ❍ Ohio (36)
- ❍ Oklahoma (37)
- ❍ Oregon (38)
- ❍ Pennsylvania (39)
- ❍ Puerto Rico (40)
- ❍ Rhode Island (41)
- ❍ South Carolina (42)
- ❍ South Dakota (43)
- ❍ Tennessee (44)
- ❍ Texas (45)
- ❍ Utah (46)
- ❍ Vermont (47)
- ❍ Virginia (48)
- ❍ Washington (49)
- ❍ West Virginia (50)
- ❍ Wisconsin (51)
- ❍ Wyoming (52)
- ❍ I do not reside in the United States (53)

Q7 Where did you see a flyer for the study?

Q8 Please answer the following questions about yourself. There are no right or wrong answers.

Q9 What was your body weight before starting Alli®? (please record in pounds)

Q10 What is your body weight today? (please record in pounds)

Q11 What is your height?

Q12 How long have you been taking Alli®?

Q13 How much weight have you lost while taking Alli®? (please record in pounds)

Q14 How long do you plan to continue taking Alli®?

Q15 On average, how many Alli® pills do you take daily? (Please enter a numerical value)

Sunday (1)
Monday (2)
Tuesday (3)
Wednesday (4)
Thursday (5)
Friday (6)
Saturday (7)

Q16 How satisfied are you with your weight loss?

- ❍ Very Satisfied (1)
- ❍ Somewhat Satisfied (2)
- ❍ Not Satisfied (3)

Q17 Are you a first time user of Alli®?

- ❍ Yes (1)
- ❍ No (2)

Q18 Who did you consult before taking Alli®? (Choose all that apply)

- ❑ No one (1)
- ❑ Doctor (2)
- ❑ Friend / Family Member (6)
- ❑ Nurse (4)
- ❑ Pharmacist (5)
- ❑ Registered Dietitian (3)

Q19 Which educational materials do you use from the Alli® starter kit ? (Choose all that apply)

- ❑ None (1)
- ❑ Read Me First Guide (2)
- ❑ Welcome Guide (3)
- ❑ Quick Facts Cards (4)
- ❑ Companion Guide (5)
- ❑ Healthy Eating Guide (6)
- ❑ Calorie & Fat Counter (7)
- ❑ Daily Journal (8)

Q20 Which fat-soluble vitamins (A, D, E, K) do you take as a separate pill daily? (Choose all that apply)

- ❑ None (1)
- ❑ A (2)
- ❑ D (3)
- ❑ E (4)
- ❑ K (5)

Q21 Do you take a multivitamin daily?

- ❍ Always (1)
- ❍ Sometimes (2)
- ❍ Never (3)

Q22 Do you take Alli® with meals?

- ❍ Always (1)
- ❍ Sometimes (2)
- ❍ Never (3)

Q23 Are you following a low-fat diet while taking Alli®?

- ❍ Always (1)
- ❍ Sometimes (2)
- ❍ Never (3)

Q24 Do you experience stool leakage?

- ❍ Always (1)

- ❍ Sometimes (2)
- ❍ Never (3)

Q25 Do you experience cramping?

- ❍ Always (1)
- ❍ Somtimes (2)
- ❍ Never (3)

Q26 Do you experience flatulence (gas)?

- ❍ Always (1)
- ❍ Sometimes (2)
- ❍ Never (3)

Q27 Do you experience an urgency to use the restroom?

- ❍ Always (1)
- ❍ Sometimes (2)
- ❍ Never (3)

Q28 Do you experience nausea and/or vomiting?

- ❍ Always (1)
- ❍ Sometimes (2)
- ❍ Never (3)

Q29 Do you experience fatigue?

- ❍ Always (1)
- ❍ Sometimes (2)
- ❍ Never (3)

Q30 Do you experience diarrhea?

- ❍ Always (1)
- ❍ Sometimes (2)
- ❍ Never (3)

Q31 Did any of the side effects mentioned above stop over time?

- ❍ Yes (1)
- ❍ No (2)

Answer: If Did any of the side effects mentioned above stop over time? Yes Is Selected

Q32 Which side effects stopped over time? Choose all that apply

- ❑ Stool leakage (1)
- ❑ Cramping (2)
- ❑ Flatulence (3)
- ❑ Urgency to use the restroom (4)
- ❑ Nausea and/or vomiting (5)
- ❑ Fatigue (6)
- ❑ Diarrhea (7)

Q33 Answer the following questions based on how you feel now after taking Alli®

Q34 Since taking Alli®, has your self-esteem improved?

- ❍ Yes (1)
- ❍ Somewhat (2)
- ❍ No (3)

Q35 Since taking Alli®, has your physical health improved?

- ❍ Yes (1)
- ❍ Somewhat (2)
- ❍ No (3)

Q36 Since taking Alli®, do you feel less discrimination against you?

- ❍ Yes (1)
- ❍ Somewhat (2)
- ❍ No (3)

Q37 Since taking Alli®, has your life at work improved?

- ❍ Yes (1)
- ❍ Somewhat (2)

- ❍ No (3)
- ❍ Do not currently work (4)

Q38 Since taking Alli®, have your activities of daily living (ADLs) become easier? (ADLs consist of self-care tasks, such as personal hygiene and grooming, dressing and undressing, walking, functional transfer e.g. getting out of bed.)

- ❍ Yes (1)
- ❍ Somewhat (2)
- ❍ No (3)

APPENDIX C

Institutional Review Board Exempt Document

RESEARCH OFFICE

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DATE: March 18, 2011

TO: Kendall DiLorenzo
FROM: University of Delaware IRB

STUDY TITLE: [227716-1] The Impact of Orlistat on Quality of Life

SUBMISSION TYPE: New Project

ACTION: DETERMINATION OF EXEMPT STATUS
DECISION DATE: March 18, 2011

REVIEW CATEGORY: Exemption category # 2

Thank you for your submission of New Project materials for this research study. The University of Delaware IRB has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

We will put a copy of this correspondence on file in our office. Please remember to notify us if you make any substantial changes to the project.

If you have any questions, please contact Jody-Lynn Berg at (302) 831-1119 or jlberg@udel.edu. Please include your study title and reference number in all correspondence with this office.