Experiment outlining the effects of anti-appetite drug essay

In recent years, a variety of new methods of appetite control have been marketed to consumers, both in America and around the globe.

There are a variety of different methods, as well, ranging from pure diet and exercise to extreme options like the roux-en-y gastric bypass, meant to prevent absorption of many nutrients by our system. Recently, however, a breakthrough drug has been discovered that mimics the effects of gastric bypass in the sense that it practically reduces the size of the stomach without the risks and dangers of surgery and the potential for complications from the gastric bypass procedure. This new drug has been found effective in small research studies to work with the body to reduce the amount of food eaten, rather than by limiting the absorption of food in the digestive tract. With the successes that have been seen in preliminary research, a grant was given to commission this study, which will examine on a far larger scale whether the relationships that were found in preliminary research will stand up when the drug is given to a much larger sample group. Methodology.

The methodology for this experiment is relatively simple, although for the sake of thoroughness, does need to explained in order to fully understand the scope of the proposed study. The first thing that needs to be discussed is the selection of our participants. While it is possible to gather information by randomly selecting people to participate in this study, the results need to be as accurate as possible. As such, the conclusions that are to be drawn at the end of the study need to be based on data gathered from people who would likely be real-world users of this drug. As such, the participant group needs to be modified to include only participants who are morbidly obese. For the purposes of this study, the definition of morbid obesity from the National

Center for Biotechnology Information (abb. NCBI, a sub-division of the National Institute for Health, abb.

NIH) will be used. The NCBI defines morbid obesity as being 100 pounds or more over the target weight for a given age & height, or having a BMI greater than 40kg/m2 (Obesity, n. d.). With a participant group defined, the next step is to look at the actual methodology for conducting the study. There are two options for how we can conduct this study. The first is to use a fully laboratory-like setting, hospitalizing patients while they participate to ensure that food quantity and quality are the same among all participants.

Now, while this is a fundamentally sound idea in theory, it cannot be implemented without compromising the data that would otherwise be collected. The chances are that the participants in our study did not become obese while eating food from a hospital. Therefore, this study must leave the control of deciding where to eat, what to eat and how much to eat directly in the hands of participants. This way, they can maintain their current lifestyle and see if the drug will work for them to decrease their appetite in their natural setting, rather than being held in some sort of proverbial mouse cage with the inability to behave naturally. In order to accurately measure the effects of the drug that is on trial, there must be a form of control group. Even though this study cannot be performed in a purely laboratory setting, there should be as much done as possible to ensure the legitimacy of this experiment. Therefore, this study will equally divide participants into two groups, a control group who will receive a placebo, and a test group who will receive the real drug. Many people will also agree, as well, that losing weight is not a process that happens overnight.

Therefore, this study must be a longitudinal study, tracking the results of participants with a repeated measures design. Participants will be scheduled bi-weekly appointments to assess them on a variety of functions, including both physical measures (measuring height, weight, as well as other physical measurements including waist, chest and hip size) and psychological measures (effect of treatment on personal/social lives, self-esteem changes related to appearance changes noticed (or not noticed) by others. While the length of the study is somewhat open to question, a reasonable goal would be anywhere between six months to a year from the beginning of the study. This time-frame would allow researchers to gather a large amount of data from both the test and control groups that will enable them to answer questions about the drugs real effectiveness when applied in real-world situations. Sampling When considering the sample that will be used for this study, there are a variety of concerns. The first thing to recognize is that the study demands a population that may actually benefit from the drug being tested.

The research team should not be looking for anyone just walking down the street and invite them to the study. Rather, there are a lot of characteristics that need to be identified in potential participants. As mentioned earlier, the key characteristic is that they are morbidly obese. This is not to embarrass them or ridicule them, it is so that they study can determine the efficacy of the drug by using people who would benefit from it the most. Additionally, it is already known that obesity happens across both gender and ethnic lines. What would be important, however, is to find out at what rate does obesity happen across those gender and ethnic lines, and then select participants to

fill out those slots. If the study calls for 100 participants, and the research record finds that 5% of all cases of obesity happens in African-American females, the research time should strive to find five morbidly obese African-American females to take part in the study. The reason for this is that external validity (which will be covered later) can often rely heavily on the characteristics of the sample population and how well they match up with the real world (Zechmeister, Zechmeister, & Shaughnessy, 2001, p.

24) As far as how to reach people who fall into the desired demographic for this study, there are a variety of ways that researchers could find participants. First, many gastric bypass procedures are performed by larger hospitals. Researchers could sit down and talk with the surgeons who perform these operations and give them the information about the study, and see if they would be willing to ask their patients to consider taking part in the study of the drug instead of jumping right into surgery. It is possible that many patients, when informed of the risks of surgery – and especially with the risks associated with a gastric bypass – may want to try a non-surgical route before going under the knife in order to correct their obesity. Also, contacting organizers of events like Overeaters Anonymous (OA) may prove to be beneficial in gathering participants.

If permitted, researchers could meet with an OA group to see if any of those members would be willing to consider taking part. Once all of the participants are gathered, the process of splitting them into groups can begin. These groups should be randomly decided, as the group of participants that is involved all fall in our desired demographic. Other categorical distinctions that would provide us with more divisional categories

begin to matter less and less as more people join the study. The truth of the matter is that the study wants to prove or disprove the efficacy of this new medical breakthrough, and there is no good way to divide up participants without simply doing it randomly. Ethics With every potential study, there must be a review conducted to ensure that the study meets certain ethical standards. In this case, there are few overt ethics violations that we need to be concerned about.

This study is made to help people by empirically proving a drug that may one day be used to prevent obesity before it even starts. However, even the best-laid plans come sometimes be brought to a dead stop by certain actions or behaviors. Even though our intention here is to find a way to help the morbidly obese, there may be unknown side effects or unknown drug interactions that could open the potential for an ethics violation.

As a research team, there must be a contingency plan in place in case one of the participants has a severe, negative reaction to the drug that would allow us to move quickly in case action needed to be taken to save the patient’s life. Additionally, there should also be therapists and other mental health professionals on duty to help answer questions that may arise about self-esteem, self-efficacy and the struggle that many obese people find themselves struggling with, day after day. These services should be available to participants at no charge to help them work out issues related to their struggle so that they can achieve the best results that they possibly can. Expected Results Based on the preliminary research on the drug, the research team should expect to see a slow, but steady decline in the measures taken through the life of the survey.

Participants in the test group should also be able to see these results, as they will be the ones having to deal with the results. There are several key pieces of information that need to be discovered through this trial. The first piece of data that needs to be established when reviewing the results is the percentage of people in each of the two groups (test and control) who experienced weight loss, as well as the average amount of weight that was lost. When we have these pieces of data, the research team can begin drawing conclusions about the efficacy of the drug.

If the placebo group and test group both show similar rates of weight loss, then there has been a low correlation established between the use of the drug and rates of weight loss. Should the results show that one group has a significantly different rate of weight loss, than the study has shown that there is a strong positive correlation between use of the drug and losing weight. Internal and External Validity Because this study would like to show a potential causal relationship between the use of the drug and weight loss, internal validity must be addressed. With any weight-loss scheme, there are a variety of factors that play into the end result, least among them being diet and exercise. It could very well be said at the end of the study that one group lost a statistically significant amount of weight, while the other did not. Hopefully that is what the data will lead to.

However, there are other considerations that must be taken into effect. Thus, in order to help control for internal validity, a long series of questions must be asked of each participant to try and determine if and why they are losing/gaining weight. Indeed, internal validity consists of three parts: a covariant relationship, a time-order relationship and a lack of plausible

alternatives that could explain the relationships observed. Zechmeister, Zechmeister, & Shaughnessy, 2001, p. 161) As to the first part of internal validity, the research team should expect to see a covariant relationship develop during the course of the study. That is, as time moves forward during the study, a connection should observably form between the people taking the weight-loss drug (the independent variable) and their reaction to it (the dependent variable).

For the second part, the weight loss that we are basing any conclusions on must happen after the participants are given the drugs to ake. The efficacy of our new wonder weight-loss drug cannot be inferred from weight loss the participants report before the beginning of the study. Since this is relatively easy to overcome, all the research team needs to do is ensure that the data being applied to the conclusions is reflective of the time period during which the study takes place. The final part of internal validity is a little harder to resolve, especially considering that there are many variables are not being controlled for in the course of this study. Chief among the questions that need to be asked are questions meant to determine the role of other factors (diet, exercise, tobacco use, etc…) in the weight loss or gain of a patient. Researchers need to know exactly how a person eats, moves, sleeps and basically everything else about their lifestyle in order to try to come up with conclusions that are not marked by otherwise unseen factors that would affect the validity of the study. Similarly, what has the patient’s health been like? Were they recently or are they currently pregnant? What types of food do the participants consume? Does the participant work out or otherwise lead an active lifestyle? The answer to that last question is found along with

many others by simply talking with the patient about the lives they lead, and finding out where the similarities lay.

For external validity, the researchers must look at how the small sample can be transferred to larger groups. For instance, if the study finds that 40% or more of patients in the test group lose a statistically significant amount of weight during the study compared with only 10% of the control group, we may be able to draw the conclusion that the drug is helpful in aiding patients to lose weight. However, in order to make sure that that conclusion will still be applicable to a larger group than what is the study, external validity must be established. The easiest way to do this will be to show that the sample that we used for our study is representative of the target population that will be using the drug. Since the sample population that was selected for this study consists of morbidly obese individuals (the people who would stand to benefit the most from the drug if it is successful), it should be fair to say that since the sample is representative of the overall target population, there is sufficient ethodological evidence to prove external validity for the conclusions drawn at the end of the study. Limitations on Conclusions The first big limitation that needs to be addressed is that the study is not performed entirely in a laboratory environment.

Since it is a longitudinal study, it is hard to sequester the entire population of the study in order to completely eliminate other behaviors that may contribute to weight loss. Therefore, in order to make the most accurate conclusions possible, the research team needs to ask the participants about other habits that may contribute to weight loss. What types of food are they eating, and how much? Are they exercising? Are they using other weight loss

medications in conjunction with the experimental drug? Do they smoke (or have they started/quit)? In order to make an accurate conclusion, researchers must have all of the available data. If the research team can rule out variables in uncontrolled habits (or at least factor them in while processing the data), the conclusions that will be drawn at the end of the study have a higher likelihood of being accurate. In addition, it must be acknowledged that with all of the uncontrolled variables, it is going to be exceedingly difficult to make an accurate case for causality. As before, the more information the researchers have about these uncontrolled variables and how they interact with the experimental drug, the better our conclusions will be, and the easier it will be to make a case for a causal connection between the drug and subsequent weight loss.

What can be easily done, however, is to review the data in search of any correlations. If there is strong evidence that people in the control group did not lose as much weight as people in the test group, than it can be said that there is a strong correlation between taking the drug and losing weight. With this strong correlation based on statistical data, the drug can be moved into the next phase for clinical acceptance. Recommendations for Future Study If this study were to find a strong correlation, but was unable to determine causality due to other conflicting factors, the next logical step would be to commission a new study along the same guidelines and find a way to put he study into a laboratory-type environment. While it would be hard to physically maintain this many people in a laboratory, one possible way would be to use houses that are rented out by the research team to give the participants a place to reside while in the survey.

For this survey, food would be brought in by the researchers, other pharmacological concerns can be eliminated and experimenters can monitor levels of exercise. This would allow us not to only validate the results of the first study, but would also help us expand on it by delivering new evidence that can help prove causality instead of a simple but strong correlation.