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ORIGINAL ARTICLE

An Analysis of the Relationship between a Novel Weight Loss Contract, Weight Loss Protocols, and Actual Weight Loss

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Abstract

Aims: In this study, we aim to determine the impact that compliance with weight loss protocols can have on weight management for patients after initial staging of metabolic dysfunction–associated steatohepatitis (MASH) and metabolic dysfunction-associated steatotic liver disease (MASLD).

Methods: We retrospectively evaluated medical records for patients seen between 2020 and 2022 for a FibroScan exam, application of a weight loss protocol, and recording of their weight change from the date of their first appointment through August 2023.

Results: We analyzed the data for a cohort of 871 patients who were 65% female and whose mean age was 50.91 years. These 871 patients were all seen by La Maestra Community Health Center's Liver Clinic for a Fibroscan and were advised weight loss. Five hundred sixty of these patients complied with at least 1 weight loss protocol step (signing weight loss contract, receiving health education, meeting with a dietician and/or following up regarding weight loss) and lost significantly more weight than the 311 patients who did not (-3.39 lbs v -0.90 lbs; P < 0.01, 95% CI, 1.11-1.97).

Conclusion: Taken together, our data demonstrate that patients who are more compliant with weight management protocols are shown to have substantially more weight loss.

Keywords

Weight loss, Weight loss contract, Dietician, Provider

Introduction

Steatotic liver diseases (previously known as fatty liver disease) - such as metabolic dysfunction-associated steatotic liver disease (MASLD), metabolic dysfunction-associated fatty liver disease (MAFLD), or metabolic dysfunction-associated steatohepatitis (MASH) - are diseases that are characterized by an excess of fat in the liver and in many patients, fibrosis [1].

MASLD is the leading cause of liver disease and liver-related morbidity and mortality in the world with an estimated prevalence of 47 cases per 1,000 individuals [2]. For adults, it is estimated that the global prevalence of MASLD, previously known as nonalcoholic fatty liver disease (NAFLD), is 32% [3]. This number has been slowly increasing in time: studies in 2005 estimated the prevalence of MASLD to be 26% and studies in 2016 predicted the prevalence to be 38% [4]. FibroScan® (Echosens: 6 rue Ferrus, 75014 Paris France) is a device that helps healthcare providers check a patient's liver "health" in a non-invasive manner to diagnose, stage fibrosis, stage the level of fat,and monitor patients for progression, stability, or regression of steatotic liver diseases [5].

Although MASLD is the most common cause of liver disease worldwide, there was no FDA-approved

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medication to help treat individuals with the disease before 2024. Because fat accumulating in the liver can progress to advanced fibrosis and cirrhosis, the recommended treatment for MASLD was sustained weight loss of at least 3-5% of the patient's weight coupled with a variety of behavior modifications [6,7].

Due to the complicated challenges of weight loss, providers are constantly searching for ways to help motivate and encourage patients to lose weight. Discovering effective ways to improve weight management for patients has not only been a goal for researchers and healthcare professionals, but it has been a topic of debate among the general public [8]. With the additions of GLP-1s, there have been some recent breakthroughs for medication regarding weight loss. However, the affordability and coverage of GLP-1s is a main concern for patients. In a KFF poll conducted in May 2024, which studied the public opinion regarding GLP-1s, 54% of individuals receiving GLP-1 agonists showed difficulty in covering the cost of GLP-1sagonists [9]. We wish to discover ways apart from using GLP-1 agonists to help with weight loss.

We aim, in this article, to determine the impact that signing a weight loss contract, receiving health education, following up with a naturopath/dietician, following up with a general provider, or the combination of these actions can have on weight management for patients after initial staging of their fatty liver disease. The goal is to offer strategies to providers that want to help their patients lose weight.

Subjects, Materials and Methods

This study is a retrospective chart review that is exempted from Institutional Review Board approval under 45 CFR § 46.104(d)(4)(ii). Although the research conducted for this paper involves the use of identifiable private information about biospecimens, information about biospecimens is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects. The investigator does not contact the subjects, and the investigator will not re-identify subjects. This study complied with both the Helsinki Declaration and the ethical standards at La Maestra Community Health Centers.

This paper is a retrospective study of patients who were seen at La Maestra Community Health Centers in San Diego, California for a FibroScan and were advisedweight loss from 2020 to 2022. We recorded their weight change from the date of their first appointment through August 2023 using their patient records at La Maestra Community Health Centers. To determine the impact of signing Weight Loss contracts (WLC) s on managing weight, we recorded the number of patients who signed a WLC and calculated the percentage of those patients who lost weight, gained weight, or had no weight change. The threshold for weight loss was characterized by a negative change in weight over 0.1 lbs, and the threshold for weight gain was a positive weight change of over 0.1 lbs. We then calculated an average/median of how much weight was changed. We then compared these patients' weight changes to patients who did not sign the WLC.

We repeated this analysis for patients who did and did not follow up with health education, a naturopath/dietician, and a general provider for weight management. To determine the effect of provider consults on weight loss, we categorized patients by the number of providers they met with and compared the weight changes in patients by group (Provider 1 *vs.* Provider 2 *vs.* Both Providers). To discover if the effects of following the weight loss protocol steps is cumulative, we also evaluated the weight change of those who followed 1, 2, 3, or all 4 weight loss protocol steps. Figure 1 shows the steps of the weight loss protocol. Although the weight loss protocol is intended to be followed in the order given by the figure, patients are allowed to continue alongside the protocol in the order in which they desire.

We excluded patients who did not get their weight recorded at a La Maestra Community Health Center after their initial FibroScan and diagnosis of weight loss.

The individual patient records from the NextGen® electronic health records (EHR) were used to collect information such as the confirmation of the FibroScan, weight loss diagnosis, provider appointments, WLC records, weight loss follow-up appointments, and health education records.

The weight loss protocol described in this paper is aproposed method from La Maestra Community Health Center's Liver clinic designed to help engage patients and provide accountability for their weight management. The weight loss contract (WLC) is a physical agreement between the patient and the physician to commit to a long-term goal of attaining a healthy weight; an example is in the appendix. Signing the WLC alongside other forms of weight loss interventions such as receiving health education, following up with a general healthcare provider, and following up with a naturopath/dietician may best incentivize individuals to continue on their path of weight loss and better overall health.

The meeting with a dietician/naturopath is a much more personalized experience, wherein the dietician/naturopath considers the specific problems and diet that the patient faces and makes specific recommendations based upon them. The dietician/naturopath also considers patient goals, such as increased energy and better health. The patient is also informed about the etiology of MASH and the consequences regarding it during the meetings.

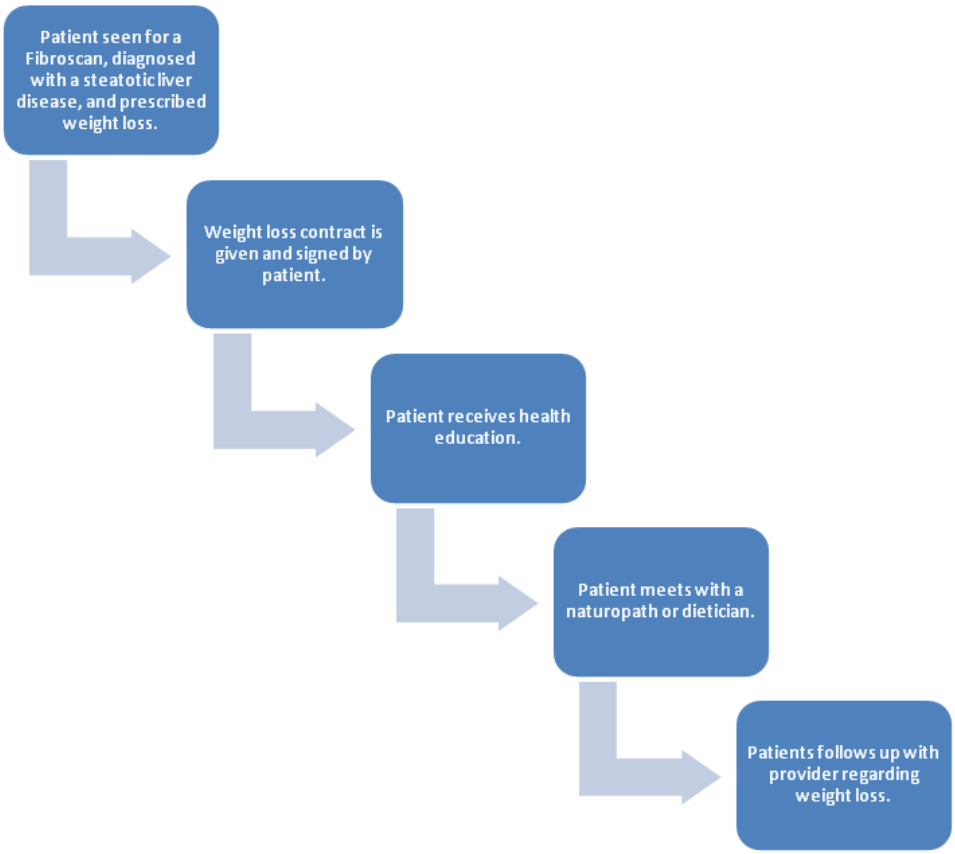

Figure 1: Weight loss protocol.

The health education is provided by a different team (not the dietician/naturopath) and is equally important but very different. The topics discussed are related to being able to read a nutrition facts label, the consequences of being overweight, and how to properly create a diet. It is much less specific; however, it gives much more information about why certain foods are recommended for patients who hope to lose weight.

The weight loss follow-up conducted with the providers describes an appointment in which the provider follows up with a patient regarding their journey with weight management. In these appointments the doctor and patient discuss the patient's weight loss journey and ensure that the patient continues working on their weight management.

We used R to perform statistical analyses of the data. The statistical significance was determined as having a *P*-value < 0.05. Comparisons of patients and their respective weight loss were categorized by the weight loss protocol followed, such as whether a patient was seen by both providers or just one, and whether or not the WLCwas signed.Two-tailed unpaired independentt-tests were used to compare continuous variables between 2 groups (ie, comparing weight loss for persons who signed the WLC *vs.* persons who did not sign the WLC). Comparisons between continuous variables among multiple groups were performed using analysis of variance (ANOVA) (ie, comparisons made between the patient weight loss data depending on length of time between initial and most recent weight loss date.)

Results

Included in the study were 871 patients who visited for a FibroScan and were advised weight loss from 2020 to 2022. Table 1 describes the characteristics of the study population.

Table 2 represents whether or not a patient was compliant in at least 1 of the 4 weight loss protocol steps (signing a WLC, receiving health education, following up with a naturopath/dietician, orfollowing up with a general provider) and compares it with patients who did not comply with any weight loss protocol steps. Of these 871 patients who were seen for a FibroScan and were referred for weight loss, 560 complied with at least 1 of 4 weight loss protocol steps while 311 did not comply with any weight loss protocol steps. Of the 560 patients who complied with 1 step, 336 (60%) showed a decrease in weight while 225 (40%) gained weight. Of the 311 patients that did not comply with any steps, 161 (51.77%) lost weight and 150 (48.23%) gained weight. The patients who complied with 1 step collectively had a median weight change of -1.6 lbs, whereas the patients who did not comply with any steps had a median weight change of -0.4 lbs (P < 0.01; 95% CI, 1.11-1.97).

Table 3 represents how each of the specific weight loss protocol steps affected weight loss. Of these 871 patients, 249 signed a WLCbut 622 did not due to a

Table 1: Patient characteristics.

Characteristics	**(N = 871)**
Age, Years ± SD	
Average Age	50.91 ± 13.31
Sex, N (%)	
Female	567 (65)
Male	304 (35)
Race, N (%)	
American Indian	7 (0.8)
Asian	52 (5.93)
Black/African American	48 (5.5)
Multiracial	1 (0.11)
Other Pacific Islander	4 (0.46)
White	759 (87.14)
Ethnicity, N (%)	
Hispanic Or Latino	607 (69.74)
Not Hispanic Or Latino	264 (30.26)

Table 2: Weight change in patients compliant in 1 of the 4 weight loss protocol steps.

	Complied	**Did Not Comply**	**P-value**
Number of individuals	560	311	0.02
Percentage who lost weight (total)	60.0 (336)	51.68 (161)	
Average weight change, lbs	-3.40 ± 15.8	-0.90 ± 12.3	
Median weight change, lbs	-1.6	-0.4	

Table 3: Weight change in patients who participated in each of the weight loss protocol steps (N = 871)*.

Weight Loss Protocols	**Participated**	**Did Not Participate**	**P-value**
Signed weight loss contract	**n = 249**	**n = 622**	0.80
Percentage who lost weight (total)	59.83 (149)	55.95 (348)	
Average weight change, lbs	-2.32 ± 13.6	-2.58 ± 15.2	
Median weight change, lbs	-1.3	-1.1	
Received health education	**n = 278**	**n = 593**	
Percentage who lost weight (total)	59.0 (164)	56.15 (333)	0.56
Average weight change, lbs	-2.08 ± 14.2	-2.71 ± 14.9	
Median weight change, lbs	-1.4	-1	
Standard error	0.85	0.61	
Met with naturopath /dietician?	**n = 180**	**n = 691**	
Percentage who lost weight (total)	60.9 (109)	55.9 (388)	0.02
Average weight change, lbs	-4.77 ± 18.8	-1.92 ± 13.4	
Median weight change, lbs	-2.2	-1	
Followed up with provider?	**n = 285**	**n = 586**	
Percentage who lost weight (total)	65.20 (186)	52.98 (311)	
Average weight change, lbs	-4.62 ± 16.9	-1.48 ± 13.4	0.003
Median weight change, lbs	-2.4	-0.6	

* Of the 871patients, 311 did not participate in any weight loss steps.

combination of not being offered and/or refusing to sign the WLC. There was no significant difference in weight change between patients who signed the WLC and patients who did not sign the WLC (-2.3 v -2.58 lbs, P = 0.395). There was also no significant difference in weight change between patients who signed the WLC and patients who did not participate in any weight loss protocol steps (-2.3 v -0.90 lbs, P = 0.20). There was also no significant difference inweight change between patients who received health education and patients who did not participate in any weight loss protocol steps (-2.1 v -0.90 lbs, P = 0.28).

Of the 180 patients that met with a naturopath/ dietician, there was a significant difference in weight change between patients who met with a naturopath/ dietician and those who did not meet with a naturopath/ dietician (-4.77 v -1.91, P < 0.05). Those who had a follow-up appointment with their general provider regarding weight had significantly more weight change than those who did not followup with their general provider (-4.62 v -1.48lbs, P = 0.03).

Of the 285 patients that followed up with a general provider,therewas also a significant difference in weight change between patients who followed up with a general provider for weight loss management and patients who did not participate in any weight loss protocol steps (-4.62 v -0.90 lbs, *P* = 0.002).

Table 1 of the supplementary data represents how each of the specific weight loss protocol steps affected weight loss; however, it also divides the patients up by how much time elapsed between their weight at the date they were prescribed weight loss and the date that their weight was most recently recorded. Running an ANOVA test to compare every group produces a *P*-value of 0.17, which signifies that there was no significant difference between the weight loss of the patients basedon the time that elapsed between initial weight loss prescription and their most recent recorded weight.

Table 2 of the Supplementary data explores how increased compliance with 1 or more of the weight loss protocol steps affected total weight loss. Of the 264 patients who were compliant with 1 step, they showed an average weight change of -3.29 pounds, and 148 (56.0%) of these patients lost weight. Of the 184 patients who were compliant with 2 steps, they showed an average weight change of -3.35 pounds, and 114 (62.0%) of the patients lost weight. Of the 91 patients who were compliant with 3 steps, they showed an average weight change of -4.85 pounds, and 64 (70.3%) of the patients lost weight. Surprisingly, of the 22 patients who were compliant with 4 steps, they showed an average weight change of +1.14 pounds, and 10 (45.5%) of the patients lost weight.

Table 4 represents data that was collected to compare the following:

- Patients who signed the WLC and followup with another weight loss protocol step.
- Patients who signed the WLC but did not follow up with another weight loss protocol step.
- Patients who did not sign the WLC but did follow up with another weight loss protocol step.
- Patients who did not sign the WLCor followupwith another weight loss protocol step.

Of the 252 patients who signed the WLC, 194 (77.0%) followed up with at least 1 other weight loss protocol step while 56 (23.0%) did not follow up with any other stepof the weight loss protocol. Of the 194 patients who did follow up, they had an average weight change of -2.94 pounds; 121 (62.4%) of these patients lost weight while 73 (37.6%) gained weight (> 0.2 lbs). Of the patients who signed the WLCand did not follow up with another weight loss protocol step (n = 56), they lost an average of 0.08 pounds. Twenty-eight (50%) of these patients lost weight and 28 (50%) gained weight (P = 0.03, 95% CI, 0.911-3.018).

Of the 622 patients who did not sign the WLC, 311 (50%) followed up with another weight loss protocol step while 311 (50.%) did not. Of the patients who did follow up with a provider regarding weight loss, they had an average weight change of -4.26 pounds; 187 (60.1%) lost weight and 124 (39.9%) gained weight. Of the 311 patients who signed the WLCand did not follow up with another weight loss protocol step, they had an average weight change of -0.90 pounds; 161 (51.7%) lost weight while 150 (48.3%) gained weight.

Table 5 shows the differences in howa hepatologist, an internist, or both providers were able to care for patients in the study. Of the 871 patients seen for a FibroScan and referred for weight loss from 2020 to 2022, 152 (17.4%) saw Dr. Gish only, 307 (35.2%) saw Dr. Tessier only, and 412 (47.3%) followed up with both Dr. Gish and Dr. Tessier. There was no significant difference between the patients who saw Dr. Gish, Dr. Tessier, or both of them (9.86 *vs.* 9.28 *vs.* 10.77 lbs, P = 0.62).

We also wanted to determine the effects that glucagon-like peptide-1 (GLP-1) agonists and alcohol use disorders (AUD) had on weight loss. Using Table 3 of the supplementary data, we compared the populations of individuals who were receiving GLP-1 agonists during the study and those who were not. We also compared the patients with and without AUDs during the study. We found that the weight loss of patients with no history of AUD were not statistically different than patients with

Table 4: Weight change in patients who signed weight loss contract and complied with another weight loss protocol step.

	Signed WLC		**Did Not Sign WLC**	
	Participated in other weight loss protocol steps	**Did not participate in other weight loss protocol steps**	**Participated in other weight loss protocol steps**	**Did not participate in other weight loss protocol steps**
Number of individuals	194	55	311	311
Percentage who lost weight (total)	62.37 (121)	50.90 (28)	60.13 (187)	51.77 (161)
Average weight change, lbs	-2.90 ± 14.7	-0.12 ± 8.2	-4.26 ± 17.04	-0.90 ± 12.3
Median weight change, lbs	-1.7	0	-1.8	-0.4

Table 5: Weight change in patients who saw one or both providers.

Differences in Provider Consult	**Hepatologist**	**Internist**	**Both Providers**	**P-value**
Number of individuals	152	307	412	Between hepatologist and internist: 0.86
Percentage who lost weight (total)	54.60 (83)	55.1 (169)	59.32 (413)	Between hepatologist and both: 0.61
Average weight change, lbs	-2.21 ± 16.8	-1.97 ± 11.7	-3.00 ± 15.9	Between internist and both: 0.34
Median weight change, lbs	-0.9	-1	-1.4	**Between all groups: 0.629**

a history of AUD (-2.73 *vs.* 0.03 lbs; P = 0.13).We found that the weight loss of patients who were receiving GLP-1 agonists during our study had weight loss that was not statistically different than patients who did not receive GLP-1 agonists during the study (-7.25 *vs.* -2.4 lbs; P = 0.28).For these reasons we did not exclude these patients from our study.

Discussion and Limitations

In our study, we were able to find a significant difference between the weight loss of patients who complied with at least 1 of the weight loss protocol stepscompared to the patients who did not comply with any of the 4 weight loss protocol steps. These steps included signing a WLC, receiving health education, visiting a naturopath/dietician, and following up with their general provider regarding weight loss. This significant difference helps show us that the steps of the weight loss protocol may have been important in helping patients lose weight.

In this paper, we discussed the effect of patients being presented with and signing a WLC. There was an increase in the percentage of patients who lost weight among those who signed the WLC. Although the difference between those who signed the WLC and those who did not was statistically significant, we can see that there is a much higher percentage of individuals who followed up with another weight loss protocol step after signing the WLC relative to those who did not sign the WLC.

So, although signing the WLC alone may not be the sole reason that an individual loses weight, presenting the WLC for the patients to sign and handing it to them to take home provides more incentive to get health education, visit with the naturopath/dietician, or followup with their general provider about weight loss. One possible explanation is that patients who have the WLC and keep it at home will see it more often and are more likely to remember to book appointments for the other weight loss protocol steps.The WLC is a simple and inclusive form of weight loss responsibility for a patient.

We also looked at the differences in weight loss and the percentage of individuals who lost weight when they met with a single provider compared to when they met with 2 different providers discussing their weight loss. There is some evidence showing that meeting with both providers is important and leads to both a higher amount of weight loss and a higher percentage of patient weight loss; however, the differences are not statistically significant in our data set. This was surprising to us as we predicted that individuals who met with both providers would have significantly increased weight loss compared to those who did not. Thebasis for this assumption was the belief that those who meet with 2 providers have the opportunity to obtain opinions and recommendations from 2 different healthcare specialists while those who only meet with 1 provider would only receive a single opinion. Although our data presents some evidence that meeting with 2 separate providers when discussing weight loss instead of a single one has improvements for their weight, more research will have to be done regarding this theory and seeing if getting multiple opinions regarding weight loss will have a significant effect on an individual's weight loss journey.

Although not statistically significant, there is a trendthat showed that when patients increased compliance with the weight loss protocol steps, there was increased weight loss (albeit with the exception that following all 4 of the weight loss protocol steps may be associated with weight gain). For those who follow more of the weight loss protocol steps become more educated regarding their health, which may lead to the increased amounts of weight loss and higher percentage of patients who lost weight as we increase compliance with weight loss protocol steps.

Focusing on the other minor steps of the weight loss protocol, more research will have to be conducted on why there is a significant weight loss for those who meet with a naturopath/dietician and follow up with the doctor but not for those who receive health education.

As mentioned previously, somewhat unexpected were the results of those who complied with all 4 types of weight loss protocol steps: the average patient gained weight as opposed to losing weight. This leads us to believe that 1 limitation of this study is the lack of sample size for the individuals who complied with all 4 weight loss protocol steps relative to the sample size for all the other levels of compliance that were compared [10].

Other limitations to our study may be the use of only a single health clinic when implementing our weight loss protocol and conducting our analysis. Having multiple health clinics across the United States or the World implement our weight loss protocol in order for us to analyze their weight loss protocol will help us with the generalizability of our data.

In conclusion, our study shows thatcompliance with at least than 1 of the 4 steps of the weight loss protocol, more specifically meeting with a naturopath/dietician and following up with their provider regarding weight loss, is correlated to an increased amount of weight loss and a higher percentage of patients who experience weight loss. Through our research of the WLC, we see that although those who sign the WLCalone do not lose significantly more weight than those who do not sign, interestingly they are more likely to follow up with other steps of the weight loss protocol which in turn can lead to higher weight loss relative to those who do not follow any of the weight loss protocol steps. The WLC is a good tool to allow patients to be more accountable during their weight loss journey.

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Author Contributions

JT was responsible for investigation, visualization, data curation, and preparing the original draft of the paper. RGG was responsible for the conceptualization of the study, project administration, supervision, and review and editing of the abstract and paper. RW was responsible for reviewing and editing the abstract and paper. VL was responsible for data curation. AT and YZ were responsible for project administration and supervision.

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Conflict of Interest

The authors have declared that there are no known conflicts of interest associated with this publication and also that there has been no significant financial support for this work that could have influenced its outcome.

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Appendix

Weight Loss Contract

LA MAESTRA COMMUNITY HEALTH CENTERS
City Heights · El Cajon · National City · Lemon Grove

Weight Loss Commitment

I understand that I am, by calculated Body Mass Index (BMI) obese ____ BMI

Check www.heart.org and search for BMI Calculator for BMI number

I understand that I am at high risk of dying from: liver failure, liver cancer, heart disease, kidney failure and or stroke. Patient's Initials: _____

I hereby am committed to a weight loss program that works: Patient's Initials: _____

1. Nutrition consult, treat high cholesterol if present, treat diabetes if present
2. Log book with within a paper folder or using http://www.myfooddiary.com/
    a. Record daily weight
    b. Record daily calorie intake
3. Three hours of exercise per week
    a. Heart rate goal over 100 for three hours
    b. Buy a Fitbit or Fitbit alternative to monitor heart rate
    c. Learn to take heart rate manually or using a heart rate monitor
4. Initiate an immediate 40% calorie restriction
5. Six small snacks daily
6. Use tea cup saucers for all meals, no second servings
    a. High Protein
    b. Moderate Carbohydrate
    c. Low Fat
7. No liquids from plastic bottle. Use only glass storage containers (see information on bisphenol (BPA) at http://www.pbs.org/wgbh/nova/body/jirtle-epigenetics.html
8. No alcohol
9. Utilize "Hungry is healthy" motto
10. Take fiber supplements three times per day with meals
11. Post the weight loss contact in three places
    a. Kitchen
    b. Bedroom
    c. Bathroom

Target Weight ___ Target BMI _____

Print Name _ Date ___

Patient Signature ___