

RESEARCH INFORMED CONSENT FORM—BATTLE READY WEIGHT LOSS AND HEALTH STUDY

TITLE: THE EFFECTS OF A STRUCTURED, VOLUME-BASED WEIGHT LOSS AND HEALTH PROGRAM COMBINED WITH RESPIRATORY MUSCLE TRAINING OVER 2 MONTHS

PROTOCOL NO.: None
WCG IRB Protocol #20233119

SPONSOR: PN Medical

CO-INVESTIGATORS: Nicholas J. Meyer, MD
Stillwater, Minnesota 55082
United States

Nina Bausek, PhD
Human Integrative and Environmental Physiology Lab
200 First St. SW
Rochester, Minnesota 55905
United States

STUDY-RELATED

PHONE NUMBER(S): 651-351-2639
763-242-2822 (24 hours)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

This Consent Form describes research conducted by **BATTLE READY RESEARCH GROUP ("Researchers")** and you, the participant ("**Participant**"), in the **BATTLE READY WEIGHT LOSS AND HEALTH STUDY**.

Purpose of the Study

The purpose of the study is to investigate the effectiveness of a new, investigational weight loss program that combines healthy eating habits with regular exercise, The Breather, and the ProportionFit App. As a participant in this study, you will be asked to complete weekly online surveys and perform simple health measures at the start of the study and at the two-month end date. Our primary goal is to measure weight loss and other health measures throughout the two-month period, with online surveys completed also at 3-, 6-, and 12-months. Participants may continue to utilize the tools beyond the two-month primary study period. Your participation in the study will last approximately two months (we will send surveys at 3-, 6-, and 12-months via email and appreciate your assistance in completing these surveys).

Participant Responsibilities

As a **Participant**, you are asked to provide honest and accurate information in all surveys and health measures conducted throughout the study. You are asked to follow the weight loss program guidelines as provided by the **Researchers**.

Specific responsibilities:

1. Complete online enrollment survey screening for participation in the Battle Ready Study and gain approval
2. Present to the St. Louis Park office to complete your health screening and to receive your Battle Ready Health Kit and instruction. (in-person only; remote participants need not present to Health Quotient). You will have a finger-stick blood test to evaluate blood glucose levels as part of this screening.
3. Follow the plan as outlined (individualized plans provided)
4. Complete weekly online surveys (will be provided via email)
5. Use the ProportionFit/Four Pillar Health App for tracking and information, coaching from **Researchers**
6. Present to the St. Louis Park office to complete your end of study health evaluation (at the end of 2 months). (in-person only; remote participants need not present to Health Quotient) You will have another finger-stick blood test at this visit.
7. Receive \$100 remuneration for time and energy spent upon completion of the study—keep all of the tools provided!

Risks

Participation in this research may involve some risk. There is a minor risk of pain, bleeding, and infection related to the finger-stick blood tests. You may find following the health plan exercises to be challenging and it may make you feel uncomfortable. You may find completing the health surveys to be boring.

There is also a risk of breach of confidentiality; however, the study team will take precautions to minimize this risk and secure the data.

Alternatives

You do not have to participate in this research to receive weight loss treatment. There are other available options that you can discuss with your primary care doctor.

Compensation

You will be paid \$100 compensation at the end of the program for participation in the in-person study.

Additional Participant Compensation (greater than \$560 value to participants)

1. Receive a Battle Ready Health Kit (value \$100+)
2. Receive a custom health and weight loss plan through the **ProportionFit/Four Pillar Health App** (greater than \$20 value)
3. Receive individual and group coaching through the **ProportionFit/Four Pillar Health App** (greater than \$60 value)
4. Receive a phone or virtual consultation with Dr. Nick Meyer at the beginning of the program (greater than \$30 value)

5. Receive a health evaluation/screening through Health Quotient at the beginning and end (two months) of the study to include a finger stick blood sample to measure a cholesterol panel and blood glucose. Non-invasive screening would include blood pressure, resting heart rate, weight, body fat percentage, waist to height measurement, 60-second sit-to-stand test, resting pulse oximetry, skin-fold caliper measurement, and spirometry (greater than \$100 value each)*
6. Access to ProportionFit Secrets and the ProportionFit Video Book Series (\$30 value)
7. Access to the ProportionFit Community on the **ProportionFit/Four Pillar Health App** (\$20 value)

Benefits

It is hoped that your participation in this research may improve your health and result in weight loss, but this cannot be guaranteed. It is hoped that the information learned will help future patients.

Confidentiality

All information collected during the study will be kept confidential and will only be used for research purposes. Any personal information obtained from you during the study will not be disclosed to anyone outside of the study group without your express written consent.

The study records may be accessed by the FDA and IRB as part of their oversight responsibilities.

Treatment for Injury

If you are injured while participating in this research, please notify the study team and obtain treatment from your primary care doctor. The sponsor does not plan to provide additional compensation in the event of injury. If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

Use of Data

By signing this Consent Form, you consent to the use of your non-identifying data in the study, which may include but is not limited to, publication of research results in scientific journals and presentations at scientific conferences.

Termination of Participation

You have the right to terminate your participation in the study at any time without penalty but will not receive the \$100 payment if you do not complete the study. You can still keep the items provided to you in the Battle Ready Kit if you withdraw from the research before the end of the program. The **Researchers** may terminate your participation in the study at any time for any reason.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Documentation of Consent

By signing this Consent Form, you acknowledge that you have read and understand the terms in this Consent Form.

Signature of subject

Date

Signature of person obtaining consent

Date