CLINICAL PROTOCOL COVER PAGE

Protocol Title:	A proof-of-concept study to evaluate the efficacy of Salmon Protein Hydrolysate Powder on energy increase and anti-inflammatory modulation in healthy males and females.
Protocol Number:	18PEHH
Protocol Date:	May 3, 2018
Version:	2
Study Phase:	Phase I
Study Design:	Open-Label
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Qualified Investigator:	David Crowley, MD KGK Science Inc. Telephone: 519-438-9374

PROTOCOL SIGNATURE SHEET

The sponsor and the investigator agree to conduct the study in compliance with the clinical study protocol (and amendments), International Conference on Harmonization (ICH) guidelines for current Good Clinical Practice (cGCP) and applicable regulatory requirements.

Name	Signature	Date
Sponsor: Dr. Bomi Framroze Hofseth Biocare ASA Havnegata 11 6005 Aalesund Norway		
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1 LIST OF ABBREVIATIONS

AE	Adverse Event
BMI	Body Mass Index
BP	Blood Pressure
CRF	Case Report Form
CRO	Contract Research Organization
EDTA	Ethylene Diamine Tetra Acetic Acid
etc.	*"and so forth"*
e.g.	*"for example"*
et al	*"and others"*
g	Gram
g	gravity
GCP	Good Clinical Practice
Hb	Hemoglobin
HbA1c	Glycated hemoglobin
HR	Heart Rate
lbs.	Pounds
ICF	Informed Consent Form
ICH	International Conference of Harmonization
IRB	Institutional Review Board
kg	Kilogram
LOCF	Last Observation Carried Forward
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
MCV	Mean Corpuscular Volume
QI	Qualified Investigator
RBC	Red Blood Cells
RDW	Red Cell Distribution Width
ROS	Reactive Oxygen Species
RNS	Reactive Nitrogen Species
SAE	Serious Adverse Event
SPH	Salmon Protein Hydrolysate
SST	Serum Separating Tube
WBC	White Blood Cell
WHO	World Health Organization

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2 INTRODUCTION

In the United States. 38% of Americans report waking up and feeling tired for more than four days a week (Moore, 2015). During 2010-2011, 15.3% of women and 10.1% of men reported feelings of fatigue and exhaustion on most days or every day for 3 months (Blackwell, 2013). Increased lethargy and fatigue and decreased time and energy for nonwork-related activities may be contributed by a decreased amount of physiological energy to complete work-related tasks (Haas and Brownlie, 2001). This may ultimately lead to lower perceived overall quality of life.

Red blood cells are essential in oxygen transport thus making them an important part of health. Hemoglobin, the protein in red blood cells, is responsible for oxygen transport and plays an important role in oxygen transport and energy production. Iron is the essential element found in hemoglobin (Haas and Brownlie, 2001). Poor levels of red blood red cells, hemoglobin, and iron in the bloodstream has been implicated in sub-optimal oxygen transport and increased lethargy (Billett, 1990). In a placebo-controlled clinical trial, eight weeks of Salmon Protein Hydrolysate supplementation was shown to significantly increase red blood cells and hemoglobin enhance alertness, and energy in anemic individuals (Bomi et al., 2015).

Fatigue refers to a reduction of effort that may be caused by an imbalance in energy costs and expected reward of actions. It is one of the most common symptoms associated with immune system activation. Pro- and anti-inflammatory cytokines are released during an immune response. Cytokines induce behavioral alterations in the central nervous system through inducing modifications of neurotransmitters and brain functions. (Karshikoff et al., 2017). Salmon hydrolysate has been shown to augment cytotoxic activity of natural killer cells through enhancing T-helper cells and increasing the number of cytokines, implicating its immunomodulating effect (Kim, 2013).

The investigative product, Salmon Protein Hydrolysate (SPH), is produced by the solubilization of salmon flesh and enzymatic hydrolyzation of the protein. This process is done at very low temperatures to fully separate fat from protein and to prevent oxidation. SPH contains 620 bioactive peptides and 21 amino acids. The oil ingredient is readily absorbed without the action of pancreatic proteases due to its high concentration of short peptides and free amino acids (Nørgaard et al., 2012). The low molecular weight of short peptides also allows for greater solubility in water and fast uptake of nitrogen with over 98% digestibility.

The following open-label, proof-of-concept study will evaluate the effect of a 128-day salmon protein hydrolysate (ProGo®) supplementation on energy and anti-inflammatory modulation in healthy adults.

3 STUDY OBJECTIVES

The objective of this study is to evaluate the efficacy of Salmon Protein Hydrolysate Powder (ProGo®) on energy increase and anti-inflammatory modulation in healthy males and females

Primary outcome:

The change from baseline (Day 0) to end-of-study (Day 128) in energy level as assessed by a Vitality and Quality of Life Questionnaire after a 128-day supplementation with Salmon Protein Hydrolysate Powder (ProGo®)

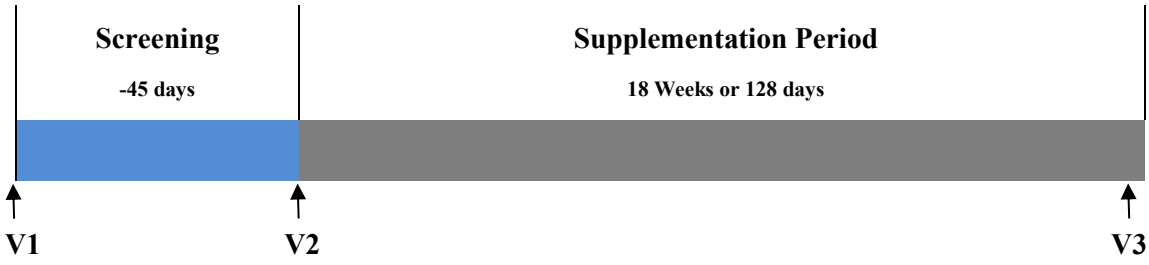
Secondary outcomes:

1. Change from baseline to Day 128 in Red Blood Cell (RBC) count, RBC indices (MCV, MCH, MCHC), hematocrit, and Red Cell Distribution Width (RDW) after supplementation with Salmon Protein Hydrolysate Powder (ProGo®)
2. Change from baseline to Day 128 in Hemoglobin (Hb) after supplementation with Salmon Protein Hydrolysate Powder (ProGo®)
3. Change from baseline to Day 128 in relative expression of 84 stress genes (Section 14.5) as evaluated by oxidative stress-related gene RT Profiler PCR array after supplementation with Salmon Protein Hydrolysate Powder (ProGo®)
4. Change from baseline to Day 128 in total Reactive Oxygen Species/Reactive Nitrogen Species free radical activity assessed by ROS/RNS assay after supplementation with Salmon Protein Hydrolysate Powder (ProGo®)
5. Change from baseline to Day 128 in levels of human inflammatory cytokines (IL-1RA, IL-4, IL-6, IL-10, IL-11, IL-13 and TGF-β) as measured by the Multi-Analyte ELISArray after supplementation with Salmon Protein Hydrolysate Powder (ProGo®)
6. Change from baseline to Day 128 in glycated hemoglobin (HbA1c) and fasting glucose after supplementation with Salmon Protein Hydrolysate Powder (ProGo®)
7. Change in score of the Hair, Nails, and Skin Self-Assessment Questionnaire after 128-day supplementation with Salmon Protein Hydrolysate Powder (ProGo®)

Safety outcomes:

1. The incidence of pre-emergent and post-emergent adverse events following a 128-day supplementation
2. The effect of a 128-day supplementation on complete blood count which includes: hematology (WBC) count with differential (neutrophils, lymphocytes, monocytes, eosinophils, basophils) and platelet count
3. The effect of a 128-day supplementation on vital signs: weight, blood pressure (BP) and heart rate (HR), and waist and hip circumference

4 STUDY DESIGN



= Screening Period

= Intervention Period

This will be an open label study conducted at the KGK clinic in London, ON.

The planned sample size for this study is 20 participants (includes 20% attrition).

Study Arm	**Number of Participants**
Salmon Protein Hydrolysate (ProGo®)	N = 20

In order to evaluate primary, secondary, and safety outcomes, study assessments will be conducted at baseline and at Day 128.

5 SELECTION OF STUDY POPULATION

This study will enroll 20 healthy males and females. Each participant must fulfill the inclusion criteria and not meet any of the exclusion criteria as described in sections 5.1 and 5.2, respectively.

5.1 Inclusion Criteria

1. Healthy male or female, 30-60 years of age
2. Female participant is not of child bearing potential, defined as females who have had a hysterectomy or oophorectomy, bilateral tubal ligation or are post-menopausal (natural or surgically with > 1 year since last menstruation)

or,

Females of childbearing potential must agree to use a medically approved method of birth control and have a negative urine pregnancy test result. All hormonal birth control must have been in use for a minimum of three months. Acceptable methods of birth control include:

- Hormonal contraceptives including oral contraceptives, hormone birth control patch (Ortho Evra), vaginal contraceptive ring (NuvaRing), injectable contraceptives (Depo-Provera, Lunelle), or hormone implant (Norplant System)
- Double-barrier method
- Intrauterine devices
- Non-heterosexual lifestyle or agrees to use contraception if planning on changing to heterosexual partner(s)
- Vasectomy of partner (shown successful as per appropriate follow-up)

3. BMI of 18.5 kg/m²-32.5 kg/m²
4. Agrees to comply with study procedures
5. Willing to commit to taking product for 128 days (See questionnaire in 14.2)
6. Agrees to provide voluntary, written, informed consent to participate in the study
7. Agrees to maintain normal diet and exercise routine throughout the study
8. Healthy as determined by medical history, medical physical test for good health, and laboratory results

5.2 Exclusion Criteria

1. Women who are pregnant, breastfeeding, or planning to become pregnant during the trial
2. Blood donation during or within 30 days of the last study visit
3. Taking any specific energy supplements or vitamins at least 1 month prior to and during the trial as assessed by the QI
4. Unstable weight for the last 2 months prior to the study assessed case by case by QI
5. Individuals on a low protein diet
6. Excessive consumption of alcohol equivalent to >2 alcoholic drinks/day
7. Use of marijuana assessed case by case by QI
8. Known allergy to the test material's active or inactive ingredients
9. Clinically significant abnormal Physical Examination results at screening

10. Participation in clinical trials in the past 30 days
11. Cognitively impaired and/or unable to give informed consent
12. current cardiovascular disorders or uncontrolled blood pressure will be assessed by QI)
13. Verbal confirmation of history of or current diagnosis of bleeding/blood disorder
14. Verbal confirmation of Type I or Type II diabetes
15. Verbal confirmation of kidney disease
16. Verbal confirmation of history of liver disease
17. Anemia based on hemoglobin and hematocrit at screening
18. Thyroid disease assessed case by case by QI (5.3.1)
19. Iron Supplementation (5.3.1)
20. Mood stabilizers assessed case by case by QI (5.3.1)
21. Energy boosting supplements (5.3.2)
22. Individuals on workout supplements (5.3.2)
23. Habitual users of energy drinks
24. Melatonin supplementation assessed case by case by QI (5.3.2)
25. Autoimmune disease or if immune-compromised (i.e. HIV positive, use of anti-rejection medication, rheumatoid arthritis, Hepatitis B/C positive)
26. Surgical procedures which may impact the study outcomes within the past 3 months to be assessed by the QI
27. Cancer, except skin cancers completely excised with no chemotherapy or radiation with a follow up that is negative. Volunteers with cancer in full remission will be assessed by the QI for inclusion.
28. Presence or history of neurological disorders or significant psychiatric illness as assessed by QI
29. Any other condition, in the QI's opinion, which may adversely affect the participant's ability to complete the study or its measures or which may pose significant risk to the participant

5.3 Concomitant Medications and Washout Periods

Participants who are currently taking any prescribed medications must agree to maintain their current method and dosing regimen during the course of the study unless recommended by their physician.

5.3.1 Prescribed Medications

Participants on the following concurrent prescribed medications/treatments will be assessed by the QI:

1. Thyroid medications to be evaluated case by case by QI
2. Mood stabilizes to be evaluated case by case by QI
3. Iron supplementation

5.3.2 Over-the-counter Medications, Supplements, and Foods/Drinks

Volunteers who are currently consuming the following supplements will not be allowed to participate unless willing to undergo a 2-week washout:

1. Energy boosting supplements
2. Workout supplements
3. Melatonin supplements to be evaluated case by case by QI

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5.3.3 Rescue Medications

Not applicable.

5.4 Premature/Discontinuation Criteria

Personal reasons

As stated in the Informed Consent Form, a participant may withdraw from the study for any reason at any time.

Removal by Qualified Investigator

Participant discontinuation should be considered at the discretion of the qualified investigator. The circumstances of any discontinuation have to be documented in detail in the participant file and final report. If possible, the evaluations planned for the end of treatment will be carried out at the time when the participant is withdrawn from the study. A participant leaving the study prematurely will NOT be replaced by another. It is understood by all concerned that an excessive rate of withdrawals can render the study un-interpretable; therefore, unnecessary withdrawal of participants should be avoided.

Criteria for removal of participants from the study will include:

Clinical reasons

A participant may be withdrawn from the study if, in the opinion of the qualified investigator, it is not in the participant's best interest to continue. Any participant who experiences a serious adverse event (SAE) may be withdrawn from the trial at the discretion of the qualified investigator. A participant will also be withdrawn due to adverse events causing clinically significant illness or the need for prohibited medication(s) during the trial.

Protocol violation

Any participant found to have entered this study in violation of the protocol will be discontinued from the study at the discretion of the qualified investigator. This will include any participant found to have been inappropriately enrolled (did not meet eligibility criteria). Participant non-compliance includes not showing up for study visits, not taking the investigational product as directed, or refusing to undergo study visit procedures. Participants who are found to be taking prohibited medications or supplements without the knowledge of the qualified investigator will also be withdrawn. Any major protocol deviations (i.e., those that increase the risk to participants and/or compromise the integrity of the study or its results) will result in participant discontinuation.

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6 INVESTIGATIONAL PRODUCT

6.1 Manufacturing and Storage

The investigational product will be provided to KGK by the Sponsor. The investigational product will be carefully stored at the study site in a lockable, limited access area, accessible only to study team personnel in compliance with pertinent regulations. Only authorized persons will have access to the investigational product. The products will be stored at room temperature and will not be exposed to direct sunlight or heat. The investigational products will be kept in a locked investigational product storage room at KGK Science Inc. on receipt. An accountability log will be kept for the investigational products.

All unused investigational product will be returned to the study sponsor by KGK (at the sponsor's expense) or destroyed on receipt of written confirmation from the sponsor at study closeout (within one month of last participant visit).

Manufactured by: Hofseth Biocare ASA
Havnegata 11
6005 Aalesund
Norway

6.2 Labeling and Coding

The investigational product will be labeled according to the requirements of ICH-GCP guidelines and applicable local regulatory guidelines.

6.3 Investigational Product

Dietary Ingredient	Quantity (Qty)
Salmon protein hydrolysate (ProGo®)	4000 mg

Non-medical ingredients: 750 mg Forest Fruit Flavoring (made up of Malic acid, Sucralose, Forest Fruit SY653533, Beetroot Powder, and Lecithin)

6.4 Directions

Participants will be instructed to take 4.75 g powder in individual sachets (4 g Salmon Protein Hydrolysate (ProGo®) + 750 mg Forest Fruit Flavoring) mixed in 100-300 mL of water daily at breakfast for 128 days. Participants will be instructed to consume the product within 5-10 minutes of mixing with water. Clinic staff will instruct participants to save all unused and open packages and return them to KGK for a determination of compliance. If a morning dose is missed participants are instructed to take the dose as soon as possible after breakfast at any time during the same day. Participants will be advised not to exceed 2 sachets daily.

7 STUDY ASSESSMENTS

See 14.1 for the schedule of assessments.

7.1 Visit 1; Screening (Day -45 to Day -1) *

** At the discretion of the Qualified Investigator, any participants falling outside of the screening window (Day -45 to Day -1) due to scheduling issues may be asked to repeat eligibility/screening procedures prior to enrolment.*

At screening, an informed consent form will be given to the potential volunteer. They will be required to read the information and will be given the opportunity to seek more information if needed, or provided with the option of taking the consent form home to review prior to making their decision. If agreeable, the volunteer will sign the consent form and receive a duplicate of the signed copy. Once consent has been obtained, the screening visit will proceed. Each volunteer will be sequentially assigned a screening number to be entered in the screening and enrollment log. No fasting is required for this visit.

Screening assessments include:

1. Obtain informed consent
2. Review inclusion and exclusion criteria
3. Review medical history and capture recurring conditions
4. Review concomitant therapies and current health status
5. Weight and height measurements for BMI calculation (Section 7.5.2)
6. Waist and hip circumference measurements (Sections 7.5.3 and 7.5.4)
7. Seated resting blood pressure and heart rate measurements (Section 7.5.5)
8. Urine pregnancy test for female participants of child bearing potential
9. Physical Examination (excludes genital and rectal examination)
10. Collect blood sample for CBC
11. Administer Product Tolerance Questionnaire to assess participants' response to product (see 14.2)

The next visit will be scheduled for potentially eligible participants in ≤45 days.

Reminders for participants prior to their next in-clinic visit:

1. Refrain from consumption of supplements as per Section 5.3.2.
2. Maintain current dietary and exercise habits
3. 8-hour fast prior to next visit

7.2 Visit 2; Baseline (Day 0)

Eligible participants will return to the clinic for baseline assessments. An 8-hour fasting period is required for this visit.

Baseline (Day 0) assessments include:

1. Review inclusion and exclusion criteria
2. Review concomitant therapies and current health status and identify pre-emergent adverse events

3. Weight measurement (BMI calculation)
4. Waist and hip circumference measurements
5. Seated resting blood pressure and heart rate measurements
6. Urine pregnancy test for female participants of child bearing potential
7. Two buccal cell swabs will be collected for DNA analysis (Section 7.5.6)
8. Collect blood samples for future analysis (Section 7.5.8):
    - Oxidative stress-related gene expression (Sections 7.5.8.1 and 14.5)
    - Total ROS/RNS free radical activity (Section 7.5.8.2)
    - Human inflammatory cytokine levels (Section 7.5.8.3)
9. Collect blood samples for HbA1c and fasting glucose
10. Complete Vitality and Quality of Life Questionnaire (Section 14.2)
11. Complete Hair, Nails, and Skin Self-Assessment Questionnaire (Section 14.4)
12. Dispense investigational product and instruct participants on use
13. Dispense study diary instructions for participants (record daily product use, changes in concomitant therapies, and any adverse events throughout the study).

The next visit will be scheduled for Week 18 (Day 128 ± 3).

Reminders for participants prior to their next in-clinic visit:

1. Follow instructions on consumption of the investigational product and log any irregularities or missed doses in the subject diary
2. Refrain from consumption of supplements as per Section 5.3.2.
3. Complete and bring subject diaries on the next visit if diary is not completed using the app
4. Maintain current dietary and exercise habits.
5. Bring unused investigational product in the original packaging to next visit.
6. 8-hour fast prior to next visit

7.3 Compliance Phone Calls

Participants will be contacted via telephone at Week 6 and Week 12 to ensure compliance to study product and study processes.

7.4 Visit 3; End-of-Study; Week 18 (Day 128 ± 3)

Participants will return to the clinic for Visit 3 assessments with any unused investigational product and completed study diaries if any. An 8-hour fasting period is required for this visit.

Visit 3 assessments include:

1. Return unused investigational product in the original packaging and remnants and calculation of compliance by counting the returned unused investigational product
2. Ensure that study apps have been reviewed
3. Collect and review study diaries if applicable
4. Weight measurement (BMI calculation)
5. Waist and hip circumference measurements

6. Seated resting blood pressure and heart rate measurements
7. Collect blood sample for CBC
8. Collect blood samples for future analysis (Section 7.5.8):
    - Oxidative stress-related gene expression (Sections 7.5.8.1 and 14.5)
    - Total ROS/RNS free radical activity (Section 7.5.8.2)
    - Human inflammatory cytokine levels (Section 7.5.8.3)
9. Collect blood samples for HbA1c and fasting glucose
10. Complete Vitality and Quality of Life Questionnaire (Section 14.2)
11. Complete Hair, Nails, and Skin Self-Assessment Questionnaire (Section 14.4)
12. Physical Examination (excludes genital and rectal examination)
13. Review concomitant therapies and adverse events

7.5 Clinical Assessments and Procedures

Calculations or measurements of specific parameters are required as indicated in the schedule of assessments. Instructions for determining these parameters are provided in the following sections.

7.5.1 Questionnaires

Product Tolerance Questionnaire will be completed at Visit 1 for screening (see Section 14.2).

Vitality and Quality of Life Questionnaire for energy levels will be completed at Visit 2 and Visit 3 (see Section 14.3)

Hair, Nails, and Skin Self-Assessment Questionnaire will be completed at Visit 2 and Visit 3 (see Section 14.4)

7.5.2 Height, Weight

Weight measurements will be performed with shoes removed, and bladder empty. Participants will be weighed on the same scale at all visits.

At least two separate measurements will be taken at each visit. If the two measurements are more than 0.5 kg (1.1 lbs.) apart, a third measurement will be taken. Then the two closest values will be selected and entered in the database.

Measurement of height will be performed with the participant's shoes removed. The participant's knees will be straightened, and head held upright.

7.5.3 Waist Circumference

The waist circumference is measured at the part of the trunk located midway between the lower costal margin (bottom of lower rib) and the iliac crest (top of pelvic bone) while the participant is standing. The measurer should stand beside the participant and fit the tape tightly against the skin but without compressing any underlying soft tissues. The circumference should be measured at the end of a normal expiration. At least two separate measurements should be taken at each visit. If the two measurements differ by more than 10%, a third measurement should be taken. Then the two closest values will be selected and entered into

the database. The method of measurement for waist circumference is from the Waist Circumference and Waist-Hip Ratio report of a WHO Expert Consultation, Geneva 8-11 December 2008.

7.5.4 Hip Circumference

While participant is standing upright, place a measuring tape around the greater trochanteric prominence (the widest part of the hips). Hold tape firmly but do not press the tape into the skin. Make sure the tape is parallel to the floor. Record the reading. At least two separate measurements should be taken at each visit. If the two measurements differ by more than 10% a third measurement should be taken. Then the two closest values will be selected and entered into the database. The method of measurement for hip circumference is from the Waist Circumference and Waist-Hip Ratio report of a WHO Expert Consultation, Geneva 8-11 December 2008.

7.5.5 Blood Pressure

In office, seated resting blood pressure and heart rate will be determined from 3 measurements obtained at least 1 minute apart. One arm will be chosen and used consistently throughout the study. Blood pressure will be checked in both arms at the first examination. If a consistent inter-arm difference exists, the arm with the higher pressure will be used throughout the study. The arm selected for use at the initial visit will be documented in the study file.

The participant should be seated comfortably with the back supported and the upper arm bared without restrictive clothing. Feet should be flat on the floor, legs will not be crossed. The participant will rest in this position for at least 5 minutes prior to the first reading.

As per the QI a high office blood pressure should be rechecked after participant is given a glass of water and is seated for 15 min. Also, participant should be queried about their usual blood pressure.

The same recording method and the same equipment will be used for each participant throughout the study.

7.5.6 Buccal Cell Swab Collection

Buccal cell swabs will be collected at baseline (visit 2) at the KGK Science clinic site to analyze single-nucleotide polymorphisms (SNPs) to identify responders vs. non-responders. The clinic coordinator will verify that the participant's mouth is empty and that the participant is still fasting. The clinic coordinator will sanitize their hands and don a mask and gloves. A sterile brush will be carefully removed from the collection package. Caution is exercised not to touch the swab tip with gloves or against any surface. The participant will be asked to open his or her mouth and the inside of the mouth will be scraped 10 times using the Buccal Collection brush against the inside of the cheek. The brush will be removed immediately without touching the brush against teeth, lips or other surfaces. The collection brush will then be removed from its handle using sterile scissors or a razor blade and placed into a microcentrifuge tube containing 300 µL of cell lysis solution. This process will then be repeated using a fresh brush to generate a second buccal swab sample. The samples will be sent to Stanford for DNA analysis.

7.5.7 Sample Preparation for RNA

One EDTA blood tube will be used for stabilization of whole blood RNA. The whole blood will be aliquoted into 6 cryovials- each containing 500 µL of whole blood. 1.3 mL of RNA*later* will then be added to each cryovial to stabilize the whole blood RNA. The tubes will then be gently mixed 5 times and the samples will be stored at -40˚C for future analysis (see Section 7.5.8.1).

7.5.8 Future Analyses

7.5.8.1 Oxidative Stress-Related Gene Expression

Previous *in vitro* experiments using PCR gene-array to evaluate the efficacy of SPH on oxidative stress, showed up- and down-regulation of multiple human oxidative stress-related genes. The present study will evaluate the same effects of the investigational product *in vivo* (Section 14.5).

The PCR array is a highly sensitive and reliable method for the analysis of multiple genes. It will be used to analyze expression levels of 84 genes related to oxidative stress by determining which, if any, oxidative stress genes will be impacted by supplementation with the investigational product.

RNA samples will be prepared for this analysis (Section 7.5.7) and stored at -80 C.

7.5.8.2 Total ROS/RNS free radical activity

Measuring the effect of antioxidant interventions and ROS/RNS activity is crucial to suppressing or managing oxidative stress reducers. Previous studies have shown that fish protein hydrolysate has antioxidant properties (Girgih et al., 2013).

An ROS/RNS Assay kit will be used for measuring total ROS/RNS free radical activity to evaluate the efficacy of the investigational product on the presence of free radicals. The kit will measure the total free radical presence of a sample using green fluorescence techniques. Fluorescence intensity is proportional to the total ROS/RNS levels within the sample. Free radical molecules are representative of both ROS, and RNS, which allows for the measurement of total free radical population within a sample.

Serum samples will be centrifuged at 10,000 x *g* for 5 minutes and stored at -80°C.

7.5.8.3 Human Inflammatory Cytokine Levels

In a previous study, supplementation with the investigational product showed significantly lower IL-6 levels in comparison to a control (Framroze et al., 2016). The current study will evaluate the efficacy of the investigational product on levels of inflammatory cytokines, which includes IL-1RA, IL-4, IL-6, IL-10, IL-11, IL-13 and TGF-β.

Inflammatory cytokine levels will be measured using a multi-analyte ELISArray kit. This kit enables the analysis of protein expression for multiple protein targets.

Serum samples will be centrifuged for 15 minutes at 1000 x *g* within 30 minutes of collection and then stored at ≤-20°C.

7.5.9 Compliance

Compliance will be assessed by counting the returned unused study product at each visit. Compliance is calculated by determining the number of dosage units taken divided by the number of dosage units expected to have been taken multiplied by 100.

$$\frac{number\ of\ dosage\ units\ taken}{number\ of\ dosage\ units\ expected\ to\ have\ been\ taken} \times 100\%$$

In the event of a discrepancy between the information in the treatment diary and the amount of study product returned, use will be based on the product returned unless an explanation for loss of product has been provided. Participants found to have a compliance of <80% or >120% will be counseled.

7.6 Laboratory Analyses

Blood samples will be drawn from the participants at screening (Visit 1), baseline (visit 2), and the end of Study (Visit 3) as indicated in the schedule of assessments. Blood draws will be performed from a participant's arm via venipuncture. See Section 11.3 for potential risks associated with venipuncture.

Protection of participant confidentiality will extend to all data generated from the assaying of these samples. These samples will be alphanumerically coded and the persons performing the analysis will not be aware of the subject's identity.

At screening (Visit 1), 4 mL of whole blood will be collected in:

1. 1 x 4 mL EDTA vacutainer tube to generate plasma for:
    a. CBC (1 tube)

At baseline (Visit 2), 23 mL of 8 hour fasting whole blood will be collected in:

1. 1 x 4 mL EDTA vacutainer tube to generate plasma for:
    a. HbA1c (1 tube)
2. 1 x 4 mL EDTA vacutainer tube for whole blood for:
    a. Future analysis - Gene expression analysis (1 tube)
3. 3 x 5 mL SST vacutainer tube to generate serum for:
    a. Future Analysis - ROS/RNS and Inflammatory Cytokines (2 tubes)
    b. Fasting Glucose (1 tube)

At the end of the study (Visit 3), 27 mL of 8 hour fasting whole blood will be collected in:

1. 2 x 4 mL EDTA vacutainer tube to generate plasma for:
    a. CBC (1 tube)
    b. HbA1c (1 tube)
2. 1 x 4 mL EDTA vacutainer tube for whole blood for:
    a. Future analysis - Gene expression analysis (1 tube)
3. 3 x 5 mL SST vacutainer tube to generate serum for:
    a. Future Analysis - ROS/RNS and Inflammatory Cytokines (2 tubes)
    b. Fasting Glucose (1 tube)

The total blood volume collection for the laboratory assessments listed above will be approximately 54 mL, over the period from screening to end of study (approximately 128 days). At any study visit, blood loss per volunteer is not expected to exceed 27 mL. Additional blood samples may be collected during the course of the study in order to perform or repeat laboratory tests outlined in the Schedule of Assessments if needed.

The central laboratory, Life Labs, London Ontario, will be used in this study to measure CBC, HbA1c, and fasting glucose.

Blood collected for future analysis will be shipped to the sponsor.

Urine pregnancy test will be performed at the KGK Science clinic site.

7.7 Termination of the Trial

In the case of premature termination of the trial, participating investigators/participants, and the Institutional Review Board must be promptly informed of the termination.

7.8 Protocol Amendments

If amendments to the study protocol are required after approval such changes will be captured in writing the reasons for the change documented and signed and dated by the sponsor. Any such amendments may be subject to IRB and Health Canada review/approval prior to implementation. Exception: if it becomes necessary to alter the protocol to eliminate an immediate hazard to participants, an amendment may be implemented prior to IRB approval. In this circumstance, the Investigator must notify IRB and Health Canada in writing within five (5) working days of the implementation.

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8 SAFETY INSTRUCTIONS AND GUIDANCE

8.1 Adverse Events and Laboratory Abnormalities

8.1.1 Adverse Events

An adverse event (AE) is any untoward medical occurrence in a clinical investigation participant who has been administered an investigational product and which does not necessarily have a causal relationship with this treatment. An AE can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a product, whether or not it is considered related to that product. Pre-existing conditions which worsen during a study are to be reported as AEs.

During the study, participants should record any adverse effects in their diary. At each visit the participant will be asked "Have you experienced any difficulties or problems since I saw you last"? Any adverse events (AEs) will be documented and in the study record and will be classified according to the description, duration, intensity, frequency, and outcome. The qualified investigator will assess any AEs and decide causality.

Intensity of AEs will be graded on a three-point scale (mild, moderate, severe) and reported in detail in the study record.

Mild: Awareness of event but easily tolerated

Moderate: Discomfort enough to cause some interference with usual activity

Severe: Inability to carry out usual activity

The causality relationship of investigational product to the adverse event will be assessed by the qualified investigator as either:

Most probable: There is a reasonable relationship between the investigational product and AEs. The event responds to withdrawal of investigational product (dechallenge) and recurs with rechallenge when clinically feasible.

Probable: There is a reasonable relationship between the investigational product and AEs. The event responds to dechallenge.

Possible: There is a reasonable relationship between the investigational product and AEs. Dechallenge information is lacking or unclear.

Unlikely: There is a temporal relationship to the investigational product administration but there is no reasonable causal relationship between the investigational product and the AEs.

Not related: No temporal relationship to the investigational product administration or there is a reasonable causal relationship between non-investigational product, concurrent disease or circumstance and the AEs.

8.1.2 Serious Adverse Event

A serious adverse event (SAE) is any experience that suggests a significant hazard, contraindication, side effect or precaution. It is any AE that results in any of the following outcomes:

1. Death
2. A life-threatening adverse event
3. Inpatient hospitalization or prolongation of existing hospitalization
4. A persistent or significant disability or incapacity
5. A congenital anomaly/birth defect in the offspring of a participant who received the study treatment

Important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the participant or may require intervention to prevent one of the outcomes listed above. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalization; or the development of drug dependency or drug abuse.

8.1.3 Unexpected Adverse Reaction

An unexpected adverse reaction is an adverse reaction, the nature and severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product).

8.1.4 Laboratory Test Abnormalities

The investigator must assess the clinical significance of all abnormal laboratory values as defined by the compendium of normal values for the reference laboratory.

Any treatment emergent abnormal laboratory result which is clinically significant, i.e., meeting one or more of the following conditions, should be recorded as a single diagnosis on the AEs form in the study record:

1. Accompanied by clinical symptoms
2. Leading to interruption or discontinuation of the investigational product
3. Requiring a change in concomitant therapy

This applies to any protocol and non-protocol specified laboratory result from tests performed after the first dose of the investigational product, which falls outside the laboratory reference range and meets the clinical significance criteria for liver and kidney tests as well as for hematology and clinical chemistry.

This does not apply to any abnormal laboratory result which falls outside the laboratory reference range but which does not meet the clinical significance criteria or those which are a result of an AE which has already been reported.

Any laboratory result abnormality fulfilling the criteria for a serious adverse event (SAE) should be reported as such, in addition to being reported as an AE in the study record.

8.2 Treatment and Follow-up of AEs and Laboratory Abnormalities

8.2.1 Treatment and Follow-up of AEs

AEs, especially those for which the relationship to the investigational product is suspected, should be followed up until they have returned to baseline status or stabilized.

If after follow-up, return to baseline status or stabilization cannot be established, an explanation should be recorded in the study record.

8.2.2 Treatment and Follow-up of Laboratory Abnormalities

In the event of participant-initiated withdrawal or clinically significant unexplained abnormal laboratory test values, the participant will be withdrawn from the treatment and will remain in the study and be required to attend all remaining study visits as part of a safety arm.

8.3 Reporting of SAEs and Unexpected Adverse Reactions

The qualified investigator will be responsible for classification of an AE as an SAE within 24 hours of notification. Causality should be signed off by the qualified investigator prior to reporting to ethics and regulatory bodies. Notification of any serious adverse events must be made in writing to the study sponsor. The IRB will be notified of all product related SAEs and unexpected adverse reactions.

KGK Science must notify the TPD of all serious adverse events and reactions as follows:

If it is neither fatal or life threatening, within 15 calendar days after the day on which the sponsor becomes aware of the information; and

If it is fatal or life threatening, must be reported as soon as possible, but not later than seven (7) days after the day on which the sponsor becomes aware of the information.

9 STATISTICAL EVALUATION

9.1 Determination of sample size

A Sample size of 16 completers are required for this study. A total of 20 participants will be enrolled in the study accounting for a 20% attrition rate. A formal sample size calculation was not conducted for this study as it is an open-label study.

9.2 Analysis Plan

1. The **Safety Population** will consist of all participants who received any amount of product, and whom any safety information is available.
2. The **Intent-to-Treat (ITT) Population** consists of all participants who received product and whom any efficacy information is available.
3. The **Per Protocol (PP) Population** consists of all participants who consumed at least 80% of treatment doses, do not have any major protocol violations, and complete all study visits and procedures connected with measurement of the primary variable.

9.3 Statistical Analysis Plan

An efficacy analysis based on the intent-to-treat population will be performed and an efficacy analysis based on the per-protocol population will be performed. Variables will be tested for normality and log-normality. Log-normally distributed variables will be analyzed in the logarithmic domain. Non-normal variables will be analyzed by appropriate non-parametric tests.

Appropriate missing values will be imputed with the most recent previously-available value (LOCF, or "last-observation-carried-forward" imputation). No imputation will be performed for missing values of safety variables.

Data will be summarized in tabular form by visit. Numerical variables will be summarized as mean, standard deviation, standard error of the mean, median, and range (minimum and maximum). Changes from baseline to each subsequent visit will be summarized in the same way, along with a p value indicating whether the mean change is significantly different from zero (based on the paired Student *t*-test, or the non-parametric Wilcoxon Signed-Ranks test). Sensitivity analysis may be conducted as judged by statisticians.

9.3.1 Premature Discontinuation Description

For each premature discontinuation, the following parameters will be listed: participant number, dates of start and end of treatment, and the reason of premature discontinuation.

9.3.2 Safety

For adverse events, a descriptive analysis will be given. Adverse events will be presented in a frequency table by category and treatment. Furthermore, description, frequency, severity and causality will be reported for each adverse event.

Protocol 18PEHH: A proof-of-concept study to evaluate the efficacy of Salmon Protein Hydrolysate Powder on energy increase and anti-inflammatory modulation in healthy males and females.

Continuous safety parameters (e.g. weight, heart rate and blood pressure) will be summarized using a table including mean, standard deviation, median, minimum value, and maximum value for each measurement point. The changes from baseline will also be summarized similarly.

9.4 Protocol Deviation Description

Protocol deviations will be listed in the final study report.

9.5 Protocol Amendments

Once the protocol has been approved by the IRB and Health Canada, any changes to the protocol must be documented in the form of an amendment. All amendments will be documented in the final study report.

10 DATA COLLECTION AND STORAGE

All data collection and record storage will be done in compliance with ICH GCP Guidelines and applicable local regulatory guidelines.

11 ETHICAL ASPECTS OF THE STUDY

This study will be conducted with the highest respect for the individual participants (i.e., participants) according to the protocol, the ethical principles that have their origin in the Declaration of Helsinki, and the ICH Harmonised Tripartite Guideline for GCP.

11.1 IRB Approval

KGK Science Inc. will supply relevant documents for submission to an IRB for the protocol's review and approval. The following must be submitted to the IRB: This protocol, a copy of the informed consent form, and, if applicable, volunteer recruitment materials and/or advertisements and other documents required by all applicable laws and regulations. The IRB's written approval of the protocol and volunteer informed consent must be obtained before commencement of the study. The IRB approval must refer to the study by exact protocol title, number, and version date; identify versions of other documents (e.g., informed consent form) reviewed; and state the approval date.

KGK must adhere to all requirements stipulated by the IRB. This may include notification to the IRB regarding protocol amendments, updates to the informed consent form, recruitment materials intended for viewing by volunteers, local safety reporting requirements and submission of the investigator's annual/final status report to the IRB.

11.2 Volunteer Information and Informed Consent

Written consent documents will embody the elements of informed consent as described in the declaration of Helsinki and the ICH Guidelines for GCP and will be in accordance with all applicable laws and regulations. The informed consent form describes the planned and permitted uses, transfers, and disclosures of the volunteer's personal and personal health information for purposes of conducting the study. The informed consent form further explains the nature of the study, its objectives, and potential risks and benefits, as well as the date informed consent is obtained. The informed consent form will detail the requirements of the volunteer and the fact that he or she is free to withdraw at any time without giving a reason and without prejudice to his or her further medical care.

11.3 Potential Risks and Procedures to Minimize Risk

All potential risks are disclosed to study participants prior to their participation. The potential risks associated with this study include venipuncture. Risks associated with venipuncture include pain, bruising, and infection at the site. Alcohol swabs and proper venipuncture procedure will be followed to minimize the risk of infection.

12 QUALITY ASSURANCE AND QUALITY CONTROL

12.1 Auditing

All material used in clinical studies are subjected to quality control. Quality assurance audits may be performed by the sponsor or any health authority during the course of the study or after its completion. The Investigator agrees to comply with the sponsor and regulatory requirements in terms of auditing of the study. This includes access to the source documents for source data verification.

12.2 Monitoring

An initiation meeting will be conducted by the sponsor or an approved representative (CRO). At this meeting, the protocol and logistical aspects of the study will be reviewed with the Investigator and all study staff.

Source documents will be reviewed to ensure that all items have been completed and that the data provided are accurate and obtained in the manner specified in the protocol. The participant files will be reviewed to confirm that:

1. Informed consent was obtained and documented
2. Enrolled participants fulfilled all inclusion criteria and did not meet any exclusion criteria;
3. AE/SAE reporting has been performed as applicable
4. Study visits have been conducted as per protocol and information has been recorded in the appropriate place in the source document
5. The study product is being stored correctly and an accurate record of its dispensation to the study participants is being maintained (accountability)

Incorrect, inappropriate, or illegible entries in the participant files will be returned to the Investigator or designee for correction. No data disclosing the identity of participants will leave the study center. The Investigator and any designees will maintain confidentiality of all participant records.

The Investigator will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspections and will allow direct access to source data and documents for these purposes.

12.3 Data Management

Data required for the analysis will be acquired from source documentation (including laboratory reports) and entered into *OpenClinica Enterprise Version* study instance designed specifically for this study. The two instances for the database would be created, test instance and production instance. The database would be test verified in the test instance and then moved to the production instance. A password protected user id's will be created which would give access to the limited authorized personnel.

The standard data validation and validation checks would be performed on the production instance of the study by designing study specific rules. Data tables will be created, queried and exported during and at the end of study using *PostgreSQL tool (pgadminIII 9.5)* and *MS Access*.

For Statistical analysis, the validated soft lock copy of the database will be sent to the Statistician to perform the analysis. The study database would be a read only file to ascertain changes in the data are not made during or after the analysis.

High safety standards for the transfer and storage of study data are guaranteed by the use of technologies such as password protection, firewalls and periodic backup to protect stored data.

All study data is archived for a period not less than 25 years from the date of completion of the study in accordance with Health Canada regulatory requirements.

13 REFERENCE LIST

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14 APPENDICES

14.1 Appendix I - Schedule of Assessments

Schedule of Assessments (N=20)

	Visit 1 Screening	**Visit 2 Baseline Day 0**	**Visit 3 Week 18 Day 128**
Informed consent	X		
Review inclusion/exclusion criteria	X	X	
Review medical history	X		
Review concomitant therapies	X	X	X
Height*, weight, heart rate, blood pressure, waist & hip circumference	X	X	X
Urine pregnancy test	X	X	
Physical examination	X		X
Complete Blood Count	X		X
Product Tolerance Questionnaire	X		
DNA – buccal cells**		X	
Future analysis blood draws** (oxidative stress-related gene expression, total ROS/RNS free radical activity, human inflammatory cytokine levels)		X	X
HbA1c and Fasting plasma glucose		X	X
Quality of Life Questionnaire		X	X
Hair, Nails, and Skin Self-Assessment Questionnaire		X	X
IP dispensed		X	
IP returned			X
Study diary dispensed		X	
Study diary returned			X
Compliance calculated			X
Adverse events pre-and post-emergent		X	X

** only measured at Visit 1*

***KGK to draw, process and store blood for shipment to lab. Lab costs and shipment costs to be covered by Sponsor.*

14.2 Appendix II – Product Tolerance Questionnaire

Product Tolerance Questionnaire	**YES**	**NO**
1. Do you like the smell and taste of this product?	☐	☐
2. If not, will you still take this product for 128 days?	☐	☐

14.3 Appendix III – Vitality and Quality of Life Questionnaire

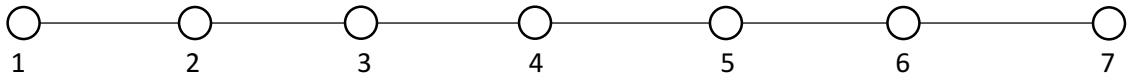
This self-assessment questionnaire has been developed to be administered to a healthy population.

Subject Initials: _____ Subject Number: _____ Visit Date: _____

Vitality and Quality of Life Questionnaire

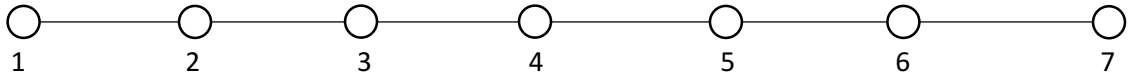
Please respond to each of the following statements by indicating the degree to which the statement is true for you in general in your life.

1. **I feel alive and vital**



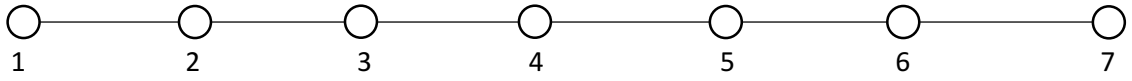
Never Sometimes Always

2. **I don't feel very energetic**



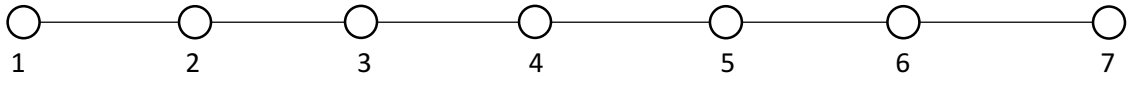
Never Sometimes Always

3. **Sometimes I feel so alive I just want to burst**



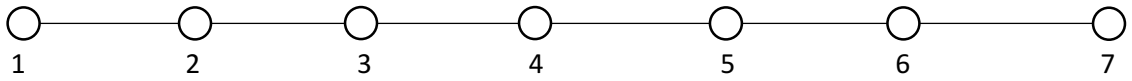
Not at all true Somewhat true Very true

4. **I have energy and spirit**



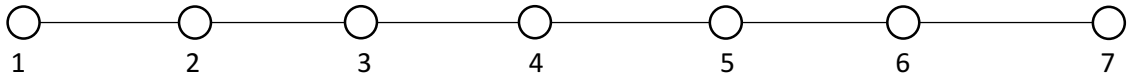
Never Sometimes Always

5. I look forward to each new day



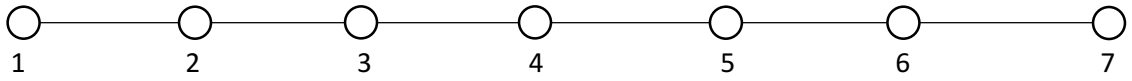
Never Sometimes Always

6. I always feel alert and awake



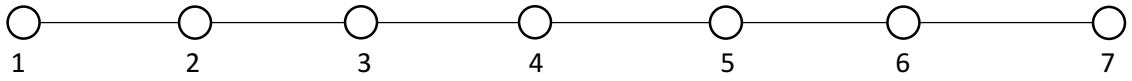
Not at all true Somewhat true Very true

7. I feel energized when I wake up



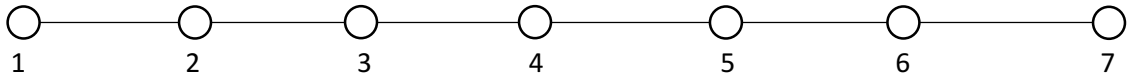
Never Sometimes Always

8. I feel energy and vitality throughout the day



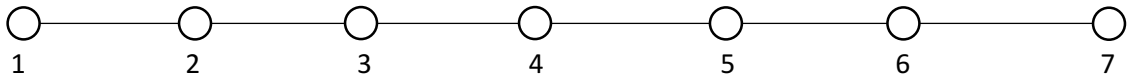
Never Sometimes Always

9. I have a midday slump in energy



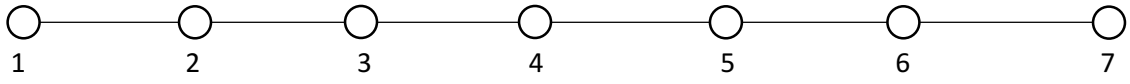
Never Sometimes Always

10. I feel engaged and enthusiastic in my personal relationships (friends and family)



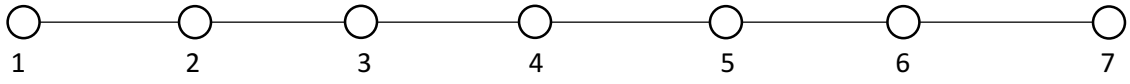
Never Sometimes Always

11. I have good mental clarity and focus



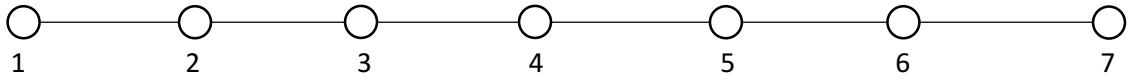
Never Sometimes Always

12. I feel I have a good sense of purpose and meaning in my life



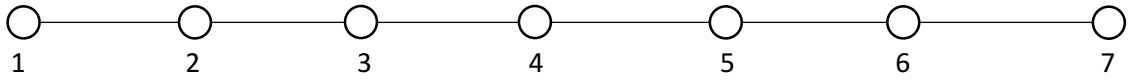
Never Sometimes Always

13. It takes a great effort to start things. This applies to everyday activates such as getting out of bed, washing myself, and eating



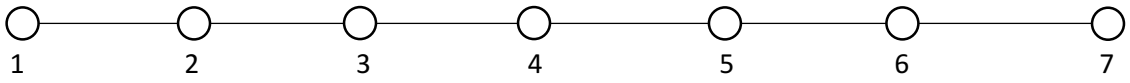
Never Sometimes Always

14. I forget things slightly more often than I should, but I am able to manage by making notes



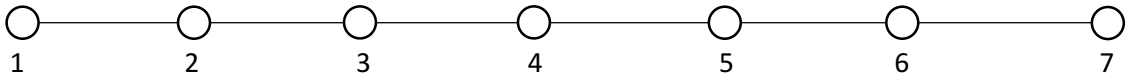
Not at all true Somewhat true Very true

15. My thoughts are neither slow nor sluggish when it comes to work involving mental effort



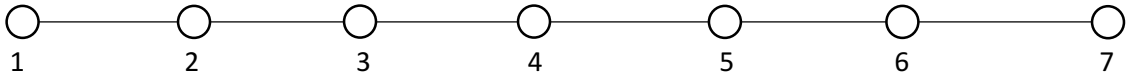
Never Sometimes Always

16. My thoughts often feel slow and sluggish, even when carrying out every day activities, for example, a conversation with a person or when reading the newspaper



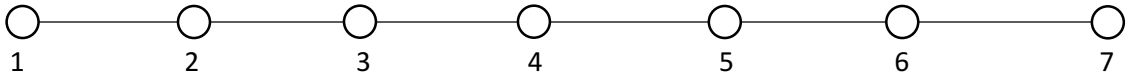
Not at all true Somewhat true Very true

17. I become stressed easily



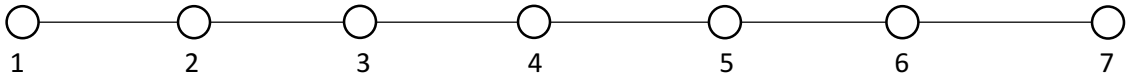
Never Sometimes Always

18. I am often short-tempered or irritable



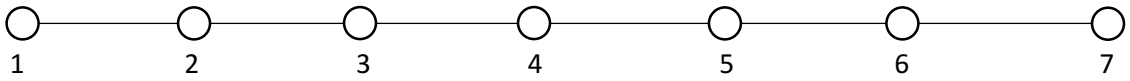
Not at all true Somewhat true Very true

19. I become irritated very quickly about small things or things that do not bother other people



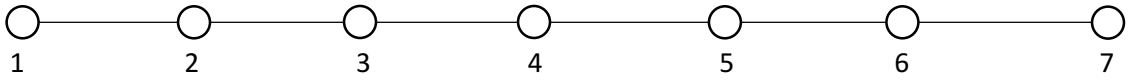
Never Sometimes Always

20. I do not get enough sleep



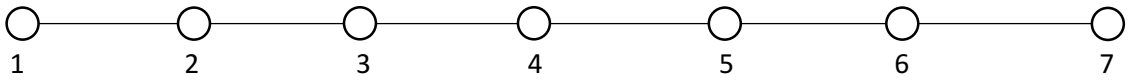
Never Sometimes Always

21. I have slight problems falling asleep or my sleep is shorter, lighter, or more restless



Never Sometimes Always

22. My energy level fluctuates throughout the day. I can predict that I will feel better at certain times and worse at other times

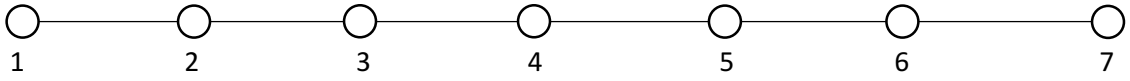


Not at all true Somewhat true Very true

What time of day do you feel at your best?

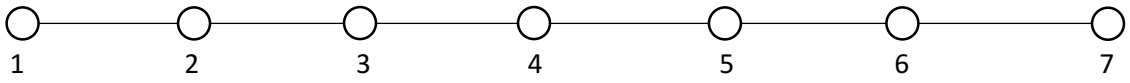
Morning Afternoon Evening Night

23. I feel unwell at all times of the day and night



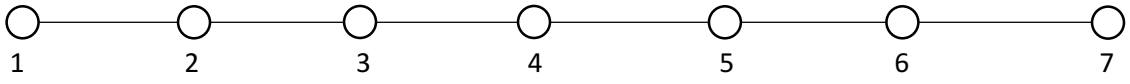
Never Sometimes Always

24. I wake up feeling tired



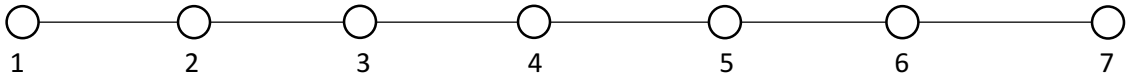
Never Sometimes Always

25. I have a hard time participating in vigorous activity



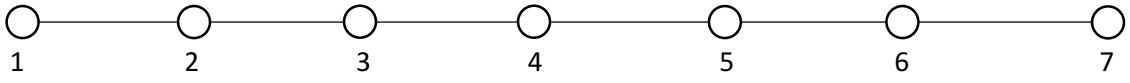
Never Sometimes Always

26. I don't do much during the day



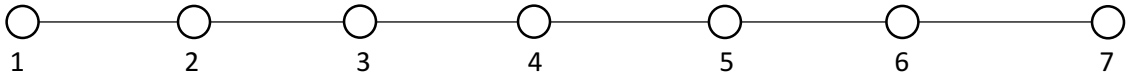
Never Sometimes Always

27. I have enough energy for everyday life



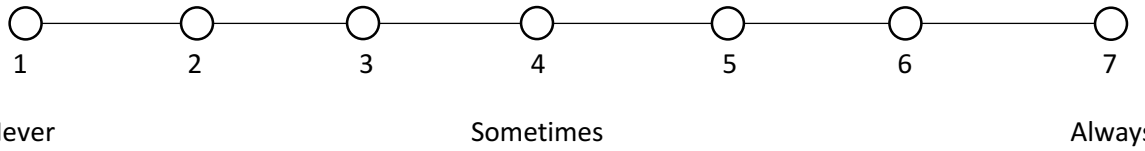
Never Sometimes Always

28. I have problems starting things

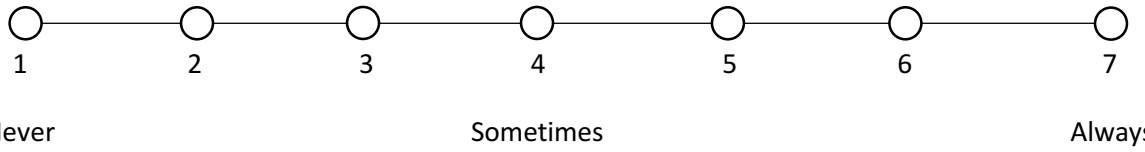


Never Sometimes Always

29. I feel no desire to do anything



30. When I am doing something, I can concentrate quite well



14.4 Appendix IV – Hair, Nails, and Skin Self-Assessment Questionnaire

This Self-Assessment Questionnaire was modified from (Glynis, 2012), and will be administered at baseline and end-of-study.

Please review each of the parameters below and select the most appropriate answer.						
	GREATLY SATISFIED	**MODERATELY SATISFIED**	**SLIGHTLY SATISFIED**	**SLIGHTLY DISSATISFIED**	**MODERATELY DISSATISFIED**	**GREATLY DISSATISFIED**
1. Hair Volume	1 □	2 □	3 □	4 □	5 □	6 □
2. Softness of Hair	1 □	2 □	3 □	4 □	5 □	6 □
3. Hair Shine	1 □	2 □	3 □	4 □	5 □	6 □
4. Hair Strength	1 □	2 □	3 □	4 □	5 □	6 □
5. Nail Strength	1 □	2 □	3 □	4 □	5 □	6 □
6. Skin Hydration	1 □	2 □	3 □	4 □	5 □	6 □
7. Overall Skin Health	1 □	2 □	3 □	4 □	5 □	6 □

14.5 Appendix V – Gene table - RT² Profiler PCR Array

Position	UniGene	GenBank	Symbol	Description
A01	Hs.418167	NM_000477	ALB	Albumin
A02	Hs.654431	NM_000697	ALOX12	Arachidonate 12-lipoxygenase
A03	Hs.406238	NM_001159	AOX1	Aldehyde oxidase 1
A04	Hs.654439	NM_000041	APOE	Apolipoprotein E
A05	Hs.125213	NM_004045	ATOX1	ATX1 antioxidant protein 1 homolog (yeast)
A06	Hs.144873	NM_004052	BNIP3	BCL2/adenovirus E1B 19kDa interacting protein 3
A07	Hs.502302	NM_001752	CAT	Catalase
A08	Hs.514821	NM_002985	CCL5	Chemokine (C-C motif) ligand 5
A09	Hs.502917	NM_005125	CCS	Copper chaperone for superoxide dismutase
A10	Hs.292356	NM_000397	CYBB	Cytochrome b-245, beta polypeptide
A11	Hs.95120	NM_134268	CYGB	Cytoglobin
A12	Hs.498727	NM_014762	DHCR24	24-dehydrocholesterol reductase
B01	Hs.272813	NM_175940	DUOX1	Dual oxidase 1
B02	Hs.71377	NM_014080	DUOX2	Dual oxidase 2
B03	Hs.171695	NM_004417	DUSP1	Dual specificity phosphatase 1
B04	Hs.212088	NM_001979	EPHX2	Epoxide hydrolase 2, cytoplasmic
B05	Hs.279259	NM_000502	EPX	Eosinophil peroxidase
B06	Hs.239	NM_021953	FOXM1	Forkhead box M1
B07	Hs.645360	NM_002032	FTH1	Ferritin, heavy polypeptide 1
B08	Hs.654465	NM_001498	GCLC	Glutamate-cysteine ligase, catalytic subunit
B09	Hs.315562	NM_002061	GCLM	Glutamate-cysteine ligase, modifier subunit
B10	Hs.76686	NM_000581	GPX1	Glutathione peroxidase 1
B11	Hs.2704	NM_002083	GPX2	Glutathione peroxidase 2 (gastrointestinal)
B12	Hs.386793	NM_002084	GPX3	Glutathione peroxidase 3 (plasma)
C01	Hs.433951	NM_002085	GPX4	Glutathione peroxidase 4 (phospholipid hydroperoxidase)
C02	Hs.248129	NM_001509	GPX5	Glutathione peroxidase 5 (epididymal androgen-related protein)
C03	Hs.448570	NM_182701	GPX6	Glutathione peroxidase 6 (olfactory)
C04	Hs.43728	NM_015696	GPX7	Glutathione peroxidase 7
C05	Hs.271510	NM_000637	GSR	Glutathione reductase
C06	Hs.82327	NM_000178	GSS	Glutathione synthetase
C07	Hs.523836	NM_000852	GSTP1	Glutathione S-transferase pi 1
C08	Hs.655292	NM_001513	GSTZ1	Glutathione transferase zeta 1
C09	Hs.520459	NM_001518	GTF2I	General transcription factor IIi
C10	Hs.517581	NM_002133	HMOX1	Heme oxygenase (decyding) 1
C11	Hs.728810	NM_005345	HSPA1A	Heat shock 70kDa protein 1A
C12	Hs.80828	NM_006121	KRT1	Keratin 1
D01	Hs.234742	NM_006151	LPO	Lactoperoxidase
D02	Hs.517586	NM_005368	MB	Myoglobin
D03	Hs.499674	NM_000242	MBL2	Mannose-binding lectin (protein C) 2, soluble
D04	Hs.191734	NM_004528	MGST3	Microsomal glutathione S-transferase 3
D05	Hs.458272	NM_000250	MPO	Myeloperoxidase
D06	Hs.75659	NM_002437	MPV17	MpV17 mitochondrial inner membrane protein
D07	Hs.490981	NM_012331	MSRA	Methionine sulfoxide reductase A
D08	Hs.73133	NM_005954	MT3	Metallothionein 3
D09	Hs.647047	NM_000265	NCF1	Neutrophil cytosolic factor 1

Position	UniGene	GenBank	Symbol	Description
D10	Hs.587558	NM_000433	NCF2	Neutrophil cytosolic factor 2
D11	Hs.709191	NM_000625	NOS2	Nitric oxide synthase 2, inducible
D12	Hs.371036	NM_016931	NOX4	NADPH oxidase 4
E01	Hs.657932	NM_024505	NOX5	NADPH oxidase, EF-hand calcium binding domain 5
E02	Hs.406515	NM_000903	NQO1	NAD(P)H dehydrogenase, quinone 1
E03	Hs.534331	NM_002452	NUDT1	Nudix (nucleoside diphosphate linked moiety X)-type motif 1
E04	Hs.148778	NM_181354	OXR1	Oxidation resistance 1
E05	Hs.475970	NM_005109	OXSR1	Oxidative-stress responsive 1
E06	Hs.368525	NM_020992	PDLIM1	PDZ and LIM domain 1
E07	Hs.78016	NM_007254	PNKP	Polynucleotide kinase 3'-phosphatase
E08	Hs.180909	NM_002574	PRDX1	Peroxiredoxin 1
E09	Hs.432121	NM_005809	PRDX2	Peroxiredoxin 2
E10	Hs.523302	NM_006793	PRDX3	Peroxiredoxin 3
E11	Hs.83383	NM_006406	PRDX4	Peroxiredoxin 4
E12	Hs.502823	NM_181652	PRDX5	Peroxiredoxin 5
F01	Hs.120	NM_004905	PRDX6	Peroxiredoxin 6
F02	Hs.153310	NM_020820	PREX1	Phosphatidylinositol-3,4,5-trisphosphate-dependent Rac exchange factor 1
F03	Hs.472010	NM_183079	PRNP	Prion protein
F04	Hs.201978	NM_000962	PTGS1	Prostaglandin-endoperoxide synthase 1 (prostaglandin G/H synthase and cyclooxygenase)
F05	Hs.196384	NM_000963	PTGS2	Prostaglandin-endoperoxide synthase 2 (prostaglandin G/H synthase and cyclooxygenase)
F06	Hs.332197	NM_012293	PXDN	Peroxidasin homolog (Drosophila)
F07	Hs.134623	NM_014245	RNF7	Ring finger protein 7
F08	Hs.128856	NM_182826	SCARA3	Scavenger receptor class A, member 3
F09	Hs.32148	NM_203472	SELS	Selenoprotein S
F10	Hs.275775	NM_005410	SEPP1	Selenoprotein P, plasma, 1
F11	Hs.253495	NM_003019	SFTPD	Surfactant protein D
F12	Hs.466693	NM_012237	SIRT2	Sirtuin 2
G01	Hs.443914	NM_000454	SOD1	Superoxide dismutase 1, soluble
G02	Hs.487046	NM_000636	SOD2	Superoxide dismutase 2, mitochondrial
G03	Hs.2420	NM_003102	SOD3	Superoxide dismutase 3, extracellular
G04	Hs.437277	NM_003900	SQSTM1	Sequestosome 1
G05	Hs.516830	NM_080725	SRXN1	Sulfiredoxin 1
G06	Hs.516807	NM_006374	STK25	Serine/threonine kinase 25
G07	Hs.467554	NM_000547	TPO	Thyroid peroxidase
G08	Hs.134602	NM_003319	TTN	Titin
G09	Hs.435136	NM_003329	TXN	Thioredoxin
G10	Hs.728817	NM_003330	TXNRD1	Thioredoxin reductase 1
G11	Hs.443430	NM_006440	TXNRD2	Thioredoxin reductase 2
G12	Hs.80658	NM_003355	UCP2	Uncoupling protein 2 (mitochondrial, proton carrier)
H01	Hs.520640	NM_001101	ACTB	Actin, beta
H02	Hs.534255	NM_004048	B2M	Beta-2-microglobulin
H03	Hs.592355	NM_002046	GAPDH	Glyceraldehyde-3-phosphate dehydrogenase
H04	Hs.412707	NM_000194	HPRT1	Hypoxanthine phosphoribosyltransferase 1
H05	Hs.546285	NM_001002	RPLP0	Ribosomal protein, large, P0
H06	N/A	SA_00105	HGDC	Human Genomic DNA Contamination
H07	N/A	SA_00104	RTC	Reverse Transcription Control
H08	N/A	SA_00104	RTC	Reverse Transcription Control
H09	N/A	SA_00104	RTC	Reverse Transcription Control
H10	N/A	SA_00103	PPC	Positive PCR Control
H11	N/A	SA_00103	PPC	Positive PCR Control
H12	N/A	SA_00103	PPC	Positive PCR Control