

# Saxenda Medical History & Consent Form



Consultation Date & Time: \_\_\_\_\_

Date of birth: \_\_\_\_\_

First name: \_\_\_\_\_

Last name: \_\_\_\_\_

Gender:  Male  Female

Occupation: \_\_\_\_\_

Phone: \_\_\_\_\_

Mobile: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## Emergency Contact

Name: \_\_\_\_\_

Phone: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## GP/Consultant

Name: \_\_\_\_\_

Phone: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

I **give/do not give** my permission to inform my GP about the Saxenda treatment that I am about to receive (please circle).

 Patient signature: \_\_\_\_\_ Date: \_\_\_\_\_

What is your purpose for having Saxenda treatment? \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

What is the reason you want to lose weight? \_\_\_\_\_

\_\_\_\_\_

How long has your weight been a problem? \_\_\_\_\_

\_\_\_\_\_

Are you currently at your heaviest weight (if no, how much did you weight at your heaviest weight ever)?

\_\_\_\_\_

\_\_\_\_\_

What methods have you previously tried to lose weight? \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Are you scared of needles/needle phobic/faint easily when you have blood taken? \_\_\_\_\_

**Women only answer the following:**

*Check those questions to which you answer yes (leave the others blank).*

Are you trying for pregnancy or planning pregnancy in the near future?

Are you or could you be pregnant?

Are you breastfeeding?

Are you on any type of hormone replacement therapy?

Are you on any contraceptive methods?

Comments: \_\_\_\_\_

\_\_\_\_\_



Patient Signature: \_\_\_\_\_

**Men and women answer the following:**

List any prescription medications you are now taking: \_\_\_\_\_

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List any self-prescribed medications, dietary supplements, or vitamins you are now taking:

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Date of last complete physical examination: \_\_\_\_\_

Normal     Abnormal     Never     Can't remember

List any other medical or diagnostic test you have had in the past two years: \_\_\_\_\_

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List hospitalisations, including dates of and reasons for hospitalisation (including surgeries): \_\_\_\_\_

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List any drug or other causes of allergies including...: \_\_\_\_\_

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Are you on any blood thinners? \_\_\_\_\_

Weekly alcohol intake? \_\_\_\_\_

Do you or have you ever smoked? \_\_\_\_\_

## Past or current medical history

Check those questions to which you answer yes (leave the others blank).

- Heart disease (such as heart attack, rheumatic fever, irregular heart beat, angina, heart murmur)
- Diseases of the arteries
- High blood cholesterol
- Anaemia or other blood disorders i.e. Sickle Cell disease, Thalassemia
- Stroke
- Medullary thyroid cancer
- Any thyroid disease/problems
- Parathyroid problems or Adrenal gland problems
- Diabetes or abnormal blood-sugar tests
- Phlebitis (inflammation of a vein)
- Deep vein thrombosis/blood clot in the leg (DVT) or PE (pulmonary embolism)
- Gallstones or any gallbladder disease (including jaundice)
- High blood pressure (Hypertension)
- Severe reflux
- Any breathing problems (such as asthma, COPD, bronchitis)
- Infective endocarditis
- Kidney problems including Chronic Kidney disease (CKD)
- Pancreas/digestion problems (including acute or chronic pancreatitis)
- Stomach/duodenum/gastric ulcer
- Liver problems (including hepatitis, liver failure, fatty liver, alcoholic liver disease)
- Any neurological problems (including Parkinson Disease)
- Severe stomach/gut problems (incl. Inflammatory bowel disease: Crohn's disease or Ulcerative colitis)
- Irritable bowel syndrome (IBS)
- Jaundice or gall bladder problems
- Skin conditions
- Eating disorder (such as anorexia or bulimia)
- Mental health problems (including personality disorder, psychosis, diagnosis of depression)
- Self-diagnosis of depression, low mood, nervous or emotional problems
- Substance abuse (including alcohol or drugs)
- Any allergies (including food or drugs)
- Do any of the discussed contraindications apply to you (refer to last page)

Comments: \_\_\_\_\_

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Patient Signature: \_\_\_\_\_

## **Familial Diseases (Family history)**

*Have you or your blood relatives had any of the following (include grandparents, aunts and uncles, but exclude cousins, relatives by marriage and half-relatives)?*

*Check those questions to which you answer yes (leave the others blank).*

- Heart attacks under age 50
- Strokes under age 50
- High blood pressure
- Elevated cholesterol
- Diabetes
- Asthma or hay fever
- Skin allergies
- Congenital heart disease (existing at birth but not hereditary)
- Heart operations
- Red blood cell disorders i.e. Sickle Cell, Thalassaemia, Anaemia
- Glaucoma
- Kidney disease
- Obesity (20 or more pounds overweight)
- Leukemia or cancer under age 60

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_



Patient Signature: \_\_\_\_\_

# Consent to Saxenda (Liraglutide 3mg) Treatment

Before you choose to use the services of practitioner: please read the following information

**FULLY AND CAREFULLY:**

Why Saxenda (liraglutide 3mg) injections?

The main benefits may include:

1. Saxenda (Liraglutide) is 97% similar to natural human GLP-1 and therefore acts as a physiological regulator of appetite and thereby reducing food intake by reducing feelings of hunger and increasing feelings of fullness/satiety. The exact underlying mechanism of action is not entirely clear.
2. Saxenda (Liraglutide 3mg injection) is a newly licensed medication indicated for reduction in appetite as an adjunct to a reduced-calorie diet and increased physical activity for weight management of patients with an increased Body Mass Index (BMI).
3. For long term success the treatment needs to be combined with lifestyle changes including nutritional, exercise and behavioural habits. Access to support modules are given through the WeightJourney online service.
4. Weight loss can lead to secondary benefits by improving weight loss related health problems such as cardiovascular risk factors (including hypertension, blood glucose levels and waist circumference) and physical health-related Quality of Life.

I understand that I have the right to be informed of the procedure, any feasible alternative options, and the risks and benefits. Except in emergencies, procedures are not performed until I have had an opportunity to receive such information and to give my informed consent.

Since every human being is unique, we cannot guarantee any specific result from Saxenda treatment. Medication and or medical conditions may have a negative impact on the outcomes as well as lifestyle factors. Treatment should be discontinued after 12 weeks on the full 3mg/day dose if the patient has not lost at least 5% of their initial body weight. The minimum recommended duration of therapy is 4 weeks of dose escalation followed by 12 weeks of full dose therapy in cases with no contraindications or side-effects of ongoing treatment. If escalation to the next dose step is not tolerated for 2 consecutive weeks, discontinuation of treatment should be considered. Daily doses higher than 3.0 mg are not recommended

Patients need to follow the instructions carefully as provided separately in the patient instruction sheet. Patients must agree to notify their practitioner of any contraindications or side effects of the treatment.

We will write to your GP to notify them of details of the program and any blood results (if completed).

It is essential to engage with the 2 weekly telephone review and monthly face-to-face reviews with your doctor throughout the treatment program.

**HEALTH CONCERNS:** If you suffer from a medical or pathological condition, you need to consult with an appropriate healthcare provider such as your GP or Consultant. If you are under the care of another healthcare provider, it is important that you inform your other healthcare providers of your use of Saxenda (Liraglutide). If you are using medications of any kind, you are required to alert us of.

**Note:** *If you have any physical or emotional reaction to Saxenda treatment, discontinue use immediately, and contact your PRACTITIONER to ascertain if the reaction is adverse or an indication of the natural course of the body's adjustment to the treatment.*

Laboratory testing may be done to any patient identified at risk to determine areas of dysfunction, not to diagnose or treat. Potential blood tests:

1. Full blood count
2. Liver function test
3. Kidney Function Tests
4. Cholesterol levels, HbA1c, Glucose

Patient groups who may require blood test monitoring at additional cost:

- Age 50 or above
- High blood pressure
- Pre-Diabetics
- Any significant medical problem

I confirm that I accept the extra blood tests with further monitoring as above if required with an additional cost as specified in the Patient price list.

Patient Name: \_\_\_\_\_

 Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**COMMUNICATION:** Every client is an individual, and it is not possible to determine in advance how your system will react to the treatment. It is sometimes necessary to adjust your program as we proceed.. It is your responsibility to do your part by following healthy dietary guidelines, exercise your body and make necessary behavioral modifications.

***I understand that:***

1. Alternatives to Saxenda therapy are surgical procedures, oral medical treatments (including Orlistat) and / or dietary and lifestyle changes alone.
2. Several weeks to months of treatment may be required depending on your individual response.
3. If a missed dose is more than 12 hours late, the missed dose should not be taken and the next dose should be taken at the normal time.
4. It is essential to combine eating, exercise and behavioral modifications with Saxenda.
5. Saxenda should not be used in combination with another GLP-1 receptor agonist, insulin or insulin secretagogues (such as sulfonylureas) due to the risk of hypoglycaemia.
6. Upon initiation of liraglutide treatment in patients on warfarin or other coumarin derivatives more frequent monitoring of International Normalised Ratio (INR) is recommended.
7. Saxenda® causes a delay of gastric emptying, and has the potential to impact the absorption of concomitantly administered oral medications. Monitor for potential consequences of delayed absorption of oral medications concomitantly administered with Saxenda®
8. There are several special warnings and precautions for use of Saxenda including warnings on pancreatitis, cholelithiasis and cholecystitis, thyroid disease, heart rate, dehydration and hypoglycaemia in people with type 2 diabetes.
9. Thyroid adverse events, such as goitre have been reported in particular in patients with pre-existing thyroid disease. Saxenda should therefore be used with caution in patients with thyroid disease.
10. A higher rate of cholelithiasis and cholecystitis (gallstone and gallbladder disease) has been observed in patients treated with liraglutide. Cholelithiasis and cholecystitis may lead to hospitalisation and cholecystectomy (surgery to remove the gallbladder). Patients should be aware of the characteristic symptoms of cholelithiasis and cholecystitis.
11. Signs and symptoms of dehydration, including renal impairment and acute renal failure, have been reported in patients treated with Liraglutide. Patients treated with liraglutide should be advised of the potential risk of dehydration in relation to gastrointestinal side effects and take precautions to avoid fluid depletion. Patients should also be aware of the symptoms of increased heart rate.
12. Acute pancreatitis has been observed with the use of Liraglutide. Patients and their carers should be told how to recognise signs and symptoms of acute pancreatitis and advised to seek immediate medical attention if symptoms develop. If pancreatitis is suspected, liraglutide should be discontinued; if acute pancreatitis is confirmed, liraglutide should not be restarted.
13. Liraglutide may cause dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Saxenda® causes thyroid C-cell tumors, including medullary thyroid carcinoma (cancer, MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined. Patients should be aware of symptoms of thyroid tumours (such as a mass in the neck, difficulty swallowing, difficulty breathing or shortness of breath, persistent hoarseness).

## The most common Saxenda® side effects are:

- nausea
- hypoglycemia
- diarrhea
- constipation
- vomiting
- headache
- decreased appetite
- dyspepsia
- fatigue
- dizziness
- abdominal pain
- increased lipase

Nausea is the most common side effect when first starting Saxenda®, but decreases over time for most people as their body gets used to the medicine. The **dosing schedule** is designed to reduce the likelihood of gastrointestinal symptoms. Tell your health care professional if you have any side effect that bothers you or that does not go away.

## Risks of Saxenda treatment include but not limited to:

- a. Common or very common, reported in  $\geq 5\%$ : Dysgeusia (altered sense of taste), dry mouth, insomnia, asthenia; burping; constipation; diarrhoea; dizziness; dry mouth; gallbladder disorders; gastrointestinal discomfort; gastrointestinal disorders; insomnia; nausea; vomiting, hypoglycaemia, dyspepsia, gastritis, gastro-oesophageal reflux disease, flatulence, eructation, upper abdomen pain, abdomen distension, cholelithiasis, injection site reactions, fatigue, increased lipase and increased amylase.
- b. Uncommon: Malaise; pancreatitis; tachycardia; urticaria
- c. Rare: Renal impairment, allergic reaction, anaphylaxis

## Summary of Saxenda Side effects:

<i>Organ classes</i>	<b>Very common (<math>\geq 5\%</math>)</b>	<b>Common</b>	<b>Uncommon</b>	<b>Rare</b>
<i>Immune system</i>				Anaphylactic reaction
<i>Metabolism/nutrition</i>		Hypoglycaemia	Dehydration	
<i>Psychiatric</i>		Insomnia (3 months)		
<i>Nervous system</i>		Dizziness Dysgeusia (altered sense of taste)		
<i>Cardiac</i>			Tachycardia	
<i>Gastrointestinal</i>	Nausea Vomiting Diarrhoea Constipation	Dry mouth Dyspepsia Gastritis Gastro-oesophageal reflux disease Abdominal pain upper Flatulence/Burping Eructation Abdominal distension	Pancreatitis	
<i>Hepatobiliary</i>		Cholelithiasis	Cholecystitis	
<i>Skin &amp; subcutaneous</i>			Urticaria	
<i>Renal &amp; Urinary</i>				Acute renal failure Renal impairment
<i>General &amp; admin sites</i>		Injection site reactions Asthenia Fatigue	Malaise	
<i>Investigations</i>		Increased lipase Increased amylase		

**Do not take Saxenda if any of the below contraindications apply to you:**

- a. Aged under 18 or above 75
- b. Severe renal/kidney impairment (with eGFR of 30 or below) or a history of renal disease
- c. Severe hepatic/liver impairment
- d. Personal or family history of medullary thyroid cancer (MTC)
- e. Hypersensitivity to Saxenda (Liraglutide) or to any of the excipients: disodium phosphate dihydrate, propylene glycol, phenol and water for injection.
- f. Concurrent treatment with any other products for weight management
- g. Weight problems related to endocrinological or eating disorders
- h. Concurrent insulin or sulfonylurea
- i. Patients on warfarin (more frequent INR monitoring required)
- j. Concurrent use of any medicinal products with may cause weight gain
- k. Pregnancy, breastfeeding or trying to/planning to become pregnant.
- l. Congestive heart failure
- m. History of pancreatitis, gallbladder disease, inflammatory bowel disease, diabetic gastroparesis.
- n. Patients with a personal or family history of MEN 2 (Multiple Endocrine Neoplasia syndrome).

**The below drugs interact with Saxenda and treatment of Saxenda should not be used concurrently.**

**Drug interactions:**

Acarbose	Exenatide	Linagliptin
Alogliptin	Glibenclamide	Lixisenatide
Biphasic insulin aspart	Gliclazide	Metformin
Biphasic insulin lispro	Glimepiride	Nateglinide
Biphasic isophane insulin	Glipizide	Pioglitazone
Canagliflozin	Any insulin including aspart,	Repaglinide
Dapagliflozin	degludec, detemir, glargine,	Saxagliptin, Sitagliptin, Vildagliptin
Dulaglutide	glulisine, lispro, isophane, zinc	Tolbutamide
Empagliflozin	suspension	

I am aware that other unforeseeable complications could occur. I do not expect the clinic to anticipate and or explain all risk and possible complications. I rely on them to exercise judgment during the course of treatment. I understand the risks and benefits of the treatment and have had the opportunity to have all of my questions answered.

Patient Name: \_\_\_\_\_

 Signature: \_\_\_\_\_ Date: \_\_\_\_\_

I understand that I have the right to consent to or refuse any proposed treatment at any time prior to its performance. ***At any stage during the treatment, I have the right to request that the procedure is terminated, however I accept that I will not be reimbursed once supply has commenced.***

***I am clear about the risks of using the medication***

***I am clear about the expected weight loss outcomes of this program***

***I am clear about the diet, exercise and behavioral changes I need to make***

My signature on this form affirms that I have given my consent to a ***Saxenda (Liraglutide)*** protocol as specified below:

### 4 weeks dose escalation schedule

Week 1	Week 2	Week 3	Week 4	Week 5 Full Dose
0.6 mg	1.2 mg	1.8 mg	2.4 mg	3.0 mg

Maintenance dose: 3.0 mg

#### Cost of program:

- Initial Consultation
- First treatment session
- Fortnightly telephone reviews
- Monthly reviews
- Blood test (if required)
- Monthly supply (5 pens)
- WeightJourney support programme

Patient Name: \_\_\_\_\_



Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Practitioner Name:

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

# Adult Eating Behaviour Questionnaire

Please read each statement and tick the box most appropriate to you

		Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
EF	I love food	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF	I often decide that I don't like a food, before tasting it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EF	I enjoy eating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EF	I look forward to mealtimes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EOE	I eat more when I'm annoyed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H	I often notice my stomach rumbling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF	I refuse new foods at first	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EOE	I eat more when I'm worried	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H	If I miss a meal I get irritable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EOE	I eat more when I'm upset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SR	I often leave food on my plate at the end of a meal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF*	I enjoy tasting new foods	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FR	I often feel hungry when I am with someone who is eating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SE*	I often finish my meals quickly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EUE	I eat less when I'm worried	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EOE	I eat more when I'm anxious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FR	Given the choice, I would eat most of the time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EUE	I eat less when I'm angry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF*	I am interested in tasting new food I haven't tasted before	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EUE	I eat less when I'm upset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EOE	I eat more when I'm angry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FR	I am always thinking about food	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SR	I often get full before my meal is finished	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF*	I enjoy a wide variety of foods	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SE	I am often last at finishing a meal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SE	I eat more and more slowly during the course of a meal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
EUE	I eat less when I'm annoyed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H	I often feel so hungry that I have to eat something right away	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SE	I eat slowly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SR	I cannot eat a meal if I have had a snack just before	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SR	I get full up easily	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H	I often feel hungry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FR	When I see or smell food that I like, it makes me want to eat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H	If my meals are delayed I get light-headed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EUE	I eat less when I'm anxious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Do you feel you would benefit from cognitive behavioral therapy (CBT) input?      Yes       No

Patient Name: \_\_\_\_\_



Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## For Practitioner use only:

Enjoyment of food = item mean EF  
 Emotional over-eating = item mean EOE  
 Emotional under-eating = item mean EUE  
 Food fussiness = item mean FF  
 Food responsiveness = item mean FR  
 Slowness in eating = item mean SE  
 Hunger = item mean H  
 Satiety responsiveness = item mean SR

Strongly disagree =1, Disagree = 2, Neither agree nor disagree = 3, Agree =4, Strongly agree =5

\* Reversed items