Official study title: Does Focusing on Body Functionality Improve Body Image Among Women Who Have Undergone Bariatric Surgery?

Study title for participants: Positief Lichaamsbeeld (Positive Body Image)

Ethics approval number: ERCPN-167_03_05_2016 (approved June 2nd, 2016)

Document: Ethics application form (including description of study protocol)

Study Protocol Application

I Use of this Form

1. This form should be used for an individual study or line of research. A line of research is a coherent set of studies in which the same types of questions are tested and the same types of experiments are performed with an equal amount of subjects.

If possible, researchers are encouraged to submit lines of research. To this end, one experiment needs to be fully worked out and an overview needs to be provided of the other intended experiments.
In principle, a line of research is not possible for studies including children younger than 18 years of age and studies that involve the presentation of emotional stimuli.
Individual projects within an approved line of research should be submitted to the secretariat of ERCPN (ercpn-fpn@maastrichtuniversity.nl) using the designated form or by submitting the study to the fMRI and EEG proposal boards.

2. Ethical approval of a project or research line will remain valid for a period of 5 years or until changes are made to the information below.
Researchers should report to the ERCPN whether the submitted protocol is still actively in use on an annual basis, for both projects and lines of research. If a project or line of research has been terminated, the ERCPN should be notified immediately.

3. By signing below, the undersigned declares that he or she has described the study truthfully, with particular attention to the ethical aspects of the subjects' participation, the handling of personal details and the involvement of and execution by scientists.

For approval (Name of the PRINCIPAL RESEARCHER in capital letters)

JESSICA ALLEVA
CAROLIEN MARTIJN

Only PhD students and scientists appointed to the Faculty of Psychology and Neuroscience of Maastricht University or elsewhere at the UM for the purpose of supervising students of FPN bachelor's and master's programmes, as well as the mental health care direction of the FHML bachelor's programme Health Sciences and the FHML master's programme Mental Health are allowed to submit a protocol as principal researcher. This requires the use of the Maastricht University email address.
Bachelor's and master's students need to seek ethical approval through the principal researcher.

II General Information

1. **What is the name of the study**

   Leidt het focussen op de functionaliteit van het lichaam tot meer lichaamstevredenheid bij vrouwen die bariatrische chirurgie hebben ondergaan?

   [Does focusing on body functionality improve body image among women who have undergone bariatric surgery?

2. **What is the name of the study used for the participants (if applicable)**

   Positief Lichaamsbeeld

   [Positive Body Image]

3. **In general terms, what is the subject of the study?**

   This study investigates improving body image among women who have undergone bariatric surgery approximately 6 months ago, by having them focus on their *body functionality* (i.e., everything the body can *do*).

4. **It concerns a:**
   - ☐ Line of research
   - X Study project

5. **In case of students:**
   NA

6. **Are any grant providers involved in the study?**

   No

7. **What is the name of the PRINCIPAL researcher?**

Jessica Alleva and Carolien Martijn

8. **What is the email address of the PRINCIPAL researcher?**

   jessica.alleva@maastrichtuniversity.nl and c.martijn@maastrichtuniversity.nl

9. **Which faculty initiated this study?**

   Faculty of Psychology and Neuroscience

10. **Which department or section instigated the study?**

    Department of Clinical Psychological Science

11. **At which organisation will the study be carried out?**

    Nederlands Obesitas Kliniek (NOK)

12. **Are there any protocols related to and approved by the ERCPN (formerly named ECP – Ethical Committee Psychology) regarding the procedures, interventions and measurements described in this application? If so, then please provide the reference number(s) of these protocols so that the committee can take this into account (for your benefit).**
    No

III Description of the Study (please keep to 500 words maximum)

1. **What is the background of the study?**
   In this research we make a distinction between two perspectives toward the body: how the body looks, and what the body can do. Often the focus lays on the appearance-related aspects of the body, and there is less focus on what the body can do and how it enables us to do the things that we enjoy and find important in life. This last perspective focuses on body functionality, and refers to everything the body is able to do, in contrast to how the body looks. Body functionality comprises physical capacities and movement (e.g., strength, stamina, walking, biking). It also comprises aspects such as health (e.g., healing from a cold), creativity (e.g., drawing), social contact and communication (e.g., body language), and bodily senses (e.g., smell). In prior experimental research, women with a negative body image were instructed to focus on their body functionality with the help of three structured writing exercises. This led to an improvement in body satisfaction and body appreciation.

   Based on these positive results, the Nederlandse Obesitas Kliniek (NOK; Dutch Obesity Clinic) decided to offer this intervention to women with obesity who have undergone a bariatric surgery approximately 6 months ago. After bariatric surgery, the NOK offers standard aftercare involving psychological support to help clients adjust in the period after surgery, and to achieve and

maintain a healthy weight. The NOK has asked us to deliver and evaluate the present intervention among their clients who have undergone bariatric surgery.

We would like to evaluate whether focusing on body functionality has a positive impact on the body image of women who have undergone bariatric surgery. Improving body image is important because a negative body image is related to (further) weight gain, physical inactivity, unhealthy eating behaviour, negative mood, and low self-esteem. Recent research has also shown that positive body image is the most important predictor of weight loss and maintenance.

2. What are the hypothesis and study question (in layman's terms)?

Research questions: Does focusing on body functionality lead to (1) a more *positive body image* and (2) a more *positive self-image* among women who have undergone bariatric surgery approximately 6 months ago?

Hypotheses: In comparison to NOK clients in the waitlist comparison group, NOK clients in the experimental group will experience improvements in (1) *positive body image* and (2) *positive self-image*, at posttest, follow-up 1, and follow-up 2.

3. What measurements and outcome measures (depended variables) are used?

- Body Appreciation Scale
- Physical Condition Subscale
- Body Areas Satisfaction Subscale
- Self-Objectification Questionnaire
- Body Responsiveness Scale
- Rosenberg Self-Esteem Scale
- Self-Kindness Subscale

NOK clients will also complete questions assessing their self-reported age, sex, height, and weight.

4. **What is the statistical approach?**

Statistical design: - What are the independent and dependent variables? - Is it a correlational or (quasi-)experimental design? - Are human subjects randomly assigned to the conditions? - For each independent variable, what design is used: within-groups or between-groups?

The study will take place entirely online, and comprises three writing exercises and four measurement points, spread over a period of 95 days.

- Day 1: Informed consent + Pretest (15 minutes) + Writing Exercise 1 (15 minutes)

- Day 3: Writing Exercise 2 (15 minutes)
- Day 5: Writing Exercise 3 (15 minutes) + Posttest (15 minutes)
- Day 12: Follow-up 1 (15 minutes)
- Day 95: Follow-up 2 (15 minutes)

We aim to test 100 female clients from the NOK: 50 clients will be randomised to the experimental group (intervention) and 50 clients will be randomised to the waitlist comparison group.

Clients in the experimental group will complete all aspects of the study, described above. Clients in the comparison group will only complete the assessments at pretest, posttest, and follow-ups. At the end of Follow-up 2, they can decide to receive the writing exercises.

5. **How many subjects are measured based on a statistical power analysis?**

We will need 82 clients. This is based on a power analysis with a (f = 0.25), α = 0.05, and an 80% likelihood of detecting a true effect. We aim to test 100 clients to compensate for potential drop-out.

6. **Why should this study be done?**
Improving body image is important because a negative body image is related to (further) weight gain, physical inactivity, unhealthy eating behaviour, negative mood, and low self-esteem. Positive body image is the most important predictor of weight loss and maintenance.

7. Is there any additional relevant information?
The NOK declares that they would like to use this intervention with their clients, and has asked us to evaluate its effectiveness. The participants are clients who have undergone bariatric surgery approximately 6 months ago at the NOK. The NOK plans to use the present intervention to foster the (further) psychological well-being of its clients.

As described (page 3), we have already tested this intervention among a group of women with a negative body image. We will be using the same intervention material for the present research (see ethics application with approval number: ECP-137 13_02_2014).

The clients will complete the informed consent sheet online, at the beginning of the first session (Day 1, page 4).

8. What documents are enclosed in the application?

- ☐ Advertisement
- X Statement of consent of the external organisation where the study takes place
- X Information letter for subjects
- X Statement of consent form for subjects
- ☐ Cover story for subjects
- X Debriefing form for subjects

☐ Other documents,
namely:……

9. **Only for adult subjects:**
Participants are asked to be added to the test subject database (FPN-wide database with subjects who have previously indicated their willingness to participate in scientific research).
No

This concerns a database for and by FPN researchers, which is managed by the Research Support Department (RSD) of the FPN and contains details of subjects over the age of 18 years who are willing to participate in scientific research. The persons involved have expressly given their consent. For more information visit: www.maastrichtuniversity.nl/fpn/proefpersonen

IV Ethically Sensitive Aspects of the Study

Please explain below the method of dealing with ethically sensitive aspects of the planned study:

1. **Please mark the relevant age and categories (multiple entries possible):**

☐ Students
X >17 years, with legal and mental capacity
☐ <12 years
X Patients
☐ 12-17 years, with legal and mental capacity
☐ 12-17 years, without legal and mental capacity
☐ >17 years with legal and mental capacity with cover story

2. **How will informed consent be obtained and recorded? Please mark the relevant form(s)**

Form 1

Forms • Form 1: For studies with persons of age and with legal and mental capacity, consent must be given by the person involved.

- Form 2: For studies with persons under the age of 12 years, consent must be given by at least one parent or guardian.
- Form 3: For studies with persons under the age of 18 years but over 11 years of age with legal and mental capacity, consent must be given by the child in addition to at least one parent or guardian.
- Form 3: For studies with persons (including children over 11 years of age) lacking legal and/or mental capacity, consent must be given by at least one parent or guardian or other (legal) representative.
  Note: In case the absence of legal and/or mental capacity is temporary, renewed informed consent should be obtained from the subject directly once the capacity/capacities has/ve been re-established.
- Form 4: For studies with persons of age and with legal and mental capacity involving a cover story, consent must be given by the person involved.

3. What are the inclusion criteria?

Inclusion criteria: De NOK clients who are (1) women between 18 and 65 years old, (2) have undergone bariatric surgery approximately 6 months prior, and (3) qualify for NOK standard aftercare.

4. What are the <u>specific</u> exclusion criteria?

NA

5. Please describe in plain language what actions are required of the subjects or what behaviour will be observed:

Clients of the NOK (who meet the inclusion criteria) will receive information about the study from their treatment provider at the NOK, and can apply for the study via email. Clients can decide whether they would like to send us an email or not. If the client sends us an email, they will receive extended information about the study. Afterward they can decide themselves whether they would like to take part in the study or not. This decision has no consequences for the clients' further treatment at the NOK. If the client would like to take part in the study, she will be randomised to the intervention or comparison group. Afterward, the client will follow the research procedure (page 4). Clients may withdraw from the study at any moment, without needing to provide a reason. This also has no consequence for their treatment at the NOK.

6. **What is the maximum load per subject per experiment? Please provide the following:**
   - Maximum number of hours per session = 0.5
   - Maximum number of sessions per day = 1
   - Maximum number of days per experiment = 5
   - Total number of hours per participant per experiment = 1 hour and 45 minutes

7. **Does the study include the use of equipment and measuring instruments?**

   No

8. **Are there any risks of damage and discomfort involved for the participants of the study?**

   No

9. **Does the study involve video and audio recordings of subjects?**

   No

10. **Are the subjects provided with all the information about the study beforehand?**

    Yes

11. **Does the study involve deception?**

    Deception is when participants are not informed beforehand of the true nature of the study and what is expected of them. For research purposes, deception is vital to avoid socially desirable answers and demand characteristics, but it also goes against the principle of active, informed consent. In other words, it is a serious measure that should only be used if sufficiently motivated and surrounded with appropriate safeguards, including adequate debriefing after participation. Deception is not allowed in studies involving minors (< 18 years).

    No

12. **How much time are the subjects given to decide on participation?**

    Clients from the NOK who have undergone bariatric surgery approximately 6 months ago may take part in the study. Because we would like to keep this relatively consistent, clients will have approximately 2 weeks to decide whether they would like to take part or not.

13. What is the reward per participant per experiment:

Compensation per subject cannot be too great, as that would interfere with reasonable consideration and as such voluntary participation.
The FPN generally awards a maximum of EUR 7.50 per hour in cash or gift vouchers or (for students) 1 research participation credit with the possibility of a raffle for a predetermined gift amount at the end of the study among subjects who participated for the entire duration of the study. In case of a raffle, the content of the prize and chances of winning should be announced in advance.
In case of early termination of participation in the study, the participant will still receive the promised amount of compensation. If multiple compensations are used for repeated measurements, these will be awarded in proportion to the number of participations.
Participation credits are registered via the Research Participation System (also called SONA) https://maastricht-fpn.sona-systems.com. Researchers (and students) need to comply with the rules and regulations of SONA.

X Compensation (maximum of EUR 7.50 per hour); for higher rates, please explain why:

Every client will receive 15 Euro (VVV gift voucher).

14. Are the subjects debriefed after their participation in the study?

☐ Yes, both in oral and written form (please provide written form with this application)

X No, please explain: Clients will receive a debriefing letter via email. They will also receive our contact information (email and telephone number) should they have any questions.

In case of deception, there is always a debriefing (in oral and written form) immediately after having participated in the study. A debriefing is also required if the purpose of the study has not been explained beforehand or if the provided information was incomplete. The explanation should be given in plain language, with emphasis on the actions of the participants and/or what was asked of them and why.

15. Does the subject participate in other related experiments alongside this one?

No

16. Please indicate in which way the personal and study data are stored.

X All data is stored confidentially
☐ All data is stored confidentially and encrypted
☐ All data is stored anonymously

The subjects' privacy should be respected and protected at all times. Personal data (all data that can be traced back to individuals directly or indirectly) should be stored in encrypted form separately from obtained study data and be treated confidentially by researchers. This personal data may not be kept longer than necessary to the ongoing study. An exception is when subjects have given their approval to retain their personal data longer for a clearly defined purpose, such as follow-up studies. Raw study data (completed questionnaires and other scoring lists) must be kept for at least 10 years after publication.

The difference between confidential and anonymous data storage; storage of personal data:

- **Anonymous** storage means that study data can in no way be traced back to the subject. That means there are no links (through numbers or other forms of encryption) to the personal data of subjects and the data cannot be used to identify the subject that it relates to. Anonymous storage is preferable to confidential storage.
- **Confidential** storage includes traceability. That means that study data can be traced back to the subject.

17. Do the subjects receive feedback regarding the provided data on an individual basis?

No