

MENTAL HEALTH DEPARTMENT
UOC Psychiatry of Treviso
UOS Nutrition and Eating Disorders – Treviso

PROTOCOL

NON-PHARMACOLOGICAL INTERVENTIONAL STUDY

Study Title:	<i>Parallel randomised controlled pilot study on the efficacy of Hatha Yoga and From Feeling to Seeing the Body – Embodied Experience Intervention for body image (FSB) in the treatment of body image in patients with eating disorders.</i>
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Protocol Version:	Version No. 2.1
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Date:	14/03/2025
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Funding:	<i>No funding is planned</i>
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Sponsor:	AULSS 2 Marca Trevigiana
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Coordinating Centre:	U.O.S. Eating Disorders, U.O.C. Psychiatry – Treviso District
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Principal Investigator:	Fuligno Chiara, TNPEE, U.O.S. Eating Disorders TV AULSS 2.
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Other Investigators at the Coordinating Centre:	Fontana Francesca, Psychiatrist, U.O.S. Eating Disorders TV AULSS 2.
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PROTOCOL APPROVAL

The Investigators:

- approve the present Protocol;
- declare that the study will be conducted in accordance with what is reported in the present protocol.

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25/11/2024

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Background and Rationale

In Eating Disorders (ED) the body and its representation is the field in which the individual's distress is expressed. The DSM-5 (APA, 2013) identifies as a diagnostic criterion for Anorexia Nervosa (AN) and Bulimia Nervosa (BN) a *"disturbance in the way in which one's body weight or shape is experienced, and undue influence of body weight or shape on self-evaluation"*.¹

Body image, which refers to the mental representation people have of their own body, therefore plays a central role in the development and maintenance of EDs. To date, research in this area has primarily focused on negative body image, finding evidence of an association between perceptual distortion of body image and the long-term outcome of AN, both in adolescence² and in adulthood. A systematic review of the literature on body image disturbance in adolescents with AN and BN found that, compared to individuals without EDs, those with AN show lower accuracy in estimating their own body dimensions, higher levels of body dissatisfaction, greater negative emotions and more negative thoughts towards their own body, as well as greater body checking behaviours (i.e., checking the shape and dimensions of their own body).³ Building on these studies, recent research is investigating the different levels of bodily experience in this population, making evident the strong interconnection between the sensory, motor, cognitive and emotional components.

In addition to studies investigating the concept of negative body image, a line of research on positive body image is developing. Positive body image is a multidimensional construct involving multiple aspects, including body and functionality appreciation, body acceptance, a broad conceptualisation of beauty, inner positivity and awareness of body needs.⁴ Recent studies suggest a close association between positive body image and remission from EDs. The recent study by Torres, Vieira et al.⁵ examined the main indices of positive body image in AN, exploring their association with emotion regulation and well-being, finding that positive body image significantly predicted emotion regulation and psychological well-being in people with AN. Consequently, therapeutic pathways that promote a positive body image are fundamental to the treatment of AN.

A systematic review of the literature⁶ revealed that body-oriented therapeutic programmes promoting a positive body image are effective in reducing risk factors and strengthening protective factors in patients with EDs, and that the inclusion of body-oriented therapy in standard therapeutic practice could substantially

¹ Diagnostic and statistical manual of mental disorders. Milan: Raffaello Cortina, 2014.

² Boehm, I., Finke, B., Tam, F.I. et al. Effects of perceptual body image distortion and early weight gain on long-term outcome of adolescent anorexia nervosa. *Eur Child Adolesc Psychiatry* 25, 1319–1326 (2016)

³ Sattler, F.A., Eickmeyer, S. & Eisenkolb, J. Body image disturbance in children and adolescents with anorexia nervosa and bulimia nervosa: a systematic review. *Eat Weight Disord* 25, 857–865 (2020)

⁴ Tylka, T.L.; Wood-Barcalow, N.L. What is and what is not positive body image? Conceptual foundations and construct definition. *Body Image* 2015, 14, 118–129.

⁵ Torres S, Vieira AI, Vieira FM, Miller KM, Guerra MP, Lencastre L, Reis AC, Timóteo S, Nunes P, Barbosa MR. A Comprehensive Study of Positive Body Image as a Predictor of Psychological Well-Being in Anorexia Nervosa. *Nutrients*. 2024 Jun 6;16(11):1787. doi: 10.3390/nu16111787.

⁶ Korsak, Emilia. (2022). Body-oriented therapy in the prevention of eating disorders. A systematic review. *Przegląd Psychologiczny*. 65. 177-195.

reduce ED symptoms. The studies analysed involved the following methods and therapeutic protocols: body awareness, yoga, dance movement therapy, Feldenkrais method, body perception treatment protocol, basic body awareness therapy, relaxation techniques and aerobic exercise. The studies examined indicate that the integration of body-oriented methods into standard therapeutic programmes (cognitive-behavioural therapy and/or pharmacotherapy) or the use of body-oriented therapy as an autonomous therapeutic method can substantially reduce ED symptoms.

In line with this direction is research based on the Embodied Self Model⁷. The Embodied Self Model provides a comprehensive framework supporting positive body image and its associated characteristics (e.g., intuitive eating) as protective factors for EDs and related symptoms. According to this model, at the centre of ED symptoms is the relationship an individual has with their own body, reflected in the way the body is experienced, nourished, cared for and accepted. EDs therefore involve the loss of an embodied sense of self (i.e., embodiment),⁸ which leads to a lack of attunement and a disconnection from the signals of one's own body. The model offers strategies for reconnecting with oneself, through the development of Body Appreciation, Body Functionality, Body Image Flexibility, Mindful Attunement, Self-Compassion, and Intuitive Eating.

Body Appreciation – acceptance, a favourable attitude and respect towards one's own body – is the most widely studied aspect of positive body image. Several meta-analyses have shown that body appreciation is inversely associated with numerous indices of dysfunctional eating (dietary restriction) and body image disturbance (internalisation of the thinness ideal, body surveillance, sociocultural pressures) and general psychopathology (depression, anxiety). Body appreciation has been positively associated with several well-being constructs (self-esteem, self-compassion, sexual satisfaction). In particular, the associations found remained significant even after controlling for the influence of negative body image.⁹

Body Functionality describes everything the body is capable of doing, across different domains (e.g., physical activities, physical sensations, creative activities). Research has demonstrated that Body Functionality is a key component of positive body image and well-being, especially when individuals appreciate their body's abilities and view their body's functionality in a holistic and integrated manner.¹⁰

Body Image Flexibility is the ability to accept positive and negative bodily experiences, to openly experience thoughts or feelings about the body without acting on them or seeking to change them. Body image flexibility has been positively associated with constructs of positive psychology and is linked to mental health indices.¹¹

Mindful Attunement is the integration of awareness and healthy, sustainable connection with internal and external experiences of the self, guiding intentional thinking and behaviours in support of well-being.¹²

⁷ Cook-Cottone, C. (2006), The attuned representation model for the primary prevention of eating disorders: An overview for school psychologists. *Psychol. Schs.*, 43: 223-230.

⁸ Catherine P. Cook-Cottone, Incorporating positive body image into the treatment of eating disorders: A model for attunement and mindful self-care, *Body Image*, Volume 14, 2015, Pages 158-167, ISSN 1740-1445.

⁹ Linardon J, McClure Z, Tylka TL, Fuller-Tyszkiewicz M. Body appreciation and its psychological correlates: A systematic review and meta-analysis. *Body Image*. 2022 Sep;42:287-296.

¹⁰ Alleva JM, Tylka TL. Body functionality: A review of the literature. *Body Image*. 2021 Mar;36:149-171.

¹¹ Linardon J, Anderson C, Messer M, Rodgers RF, Fuller-Tyszkiewicz M. Body image flexibility and its correlates: A meta-analysis. *Body Image*. 2021 Jun;37:188-203.

¹² Tylka, Tracy L., Niva Piran, and Catherine P. Cook-Cottone, 'Mindful Attunement', in Tracy L. Tylka (ed.), *Handbook of Positive Body Image and Embodiment* (New York, 2019).

Self-Compassion is kindness and understanding towards oneself, rather than using harsh self-criticism and severe judgment; considering one's own experience as part of a broader human experience rather than as a separate and isolated one; holding one's painful thoughts and feelings in balanced awareness rather than over-identifying with them. Self-compassion is linked to positive mental health outcomes such as lower depression and anxiety and greater life satisfaction.¹³

Intuitive Eating is eating based on physiological hunger and satiety signals rather than situational and emotional cues, and is associated with psychological well-being.¹⁴

A recent network analysis study (Cerea et al., 2024) considered both the dimensions of ED symptoms (e.g., drive for thinness, bulimic symptoms and body dissatisfaction) and protective factors linked to positive body image (e.g., body and functionality appreciation, intuitive eating and self-esteem), to shed light on how these factors are correlated. The network analysis showed that some dimensions of positive body image (e.g., body and functionality appreciation and specific dimensions of intuitive eating) are relevant protective factors with respect to ED symptoms.¹⁵

Therefore, the literature suggests incorporating the promotion of a positive body image into psychological interventions for EDs, and making psychological interventions more 'embodied'.

In the field of research on interventions following the embodiment model, studies exist on yoga practice in the treatment of EDs. The results of a meta-analysis conducted by Borden and Cook-Cottone in 2020 indicated that yoga interventions can be an effective approach to support the prevention and treatment of EDs.¹⁶ Yoga practice has been associated with various indices of positive embodiment in correlational and intervention studies. However, systematic and theoretically grounded models are lacking that describe in detail the specific mechanisms by which yoga supports positive embodiment.

Results regarding the efficacy of yoga in the treatment of EDs and body image are still limited, albeit with promising findings, and are generally characterised by a not always clear articulation of the theoretical concepts guiding the design of the intervention programme. Another aspect highlighted by O'Brien, Evans et al. is the need to clarify which component of the intervention (yoga with or without psychological approaches) contributes to the outcomes.¹⁷

Also following the embodiment model, the treatment "From Feeling to Seeing the Body" (FSB) was developed – a body image intervention based on the embodied experience of the body. FSB comprises experiences aimed at fostering greater body awareness at the sensory, motor, cognitive and emotional levels. The pathway was developed starting from the experimentation of the body through mindful listening to bodily sensations (interoceptive, proprioceptive and tactile) to arrive at "re-seeing" the body by reconstructing an

¹³ Neff, Kristin. (2003). The Development and Validation of a Scale to Measure Self-Compassion. *Self and Identity*. 2. 223-250.

¹⁴ Tylka, TL (2006). Development and psychometric evaluation of a measure of intuitive eating. *Journal of Counseling Psychology*, 53(2), 226–240.

¹⁵ Silvia Cerea, Sara Iannattone, Paolo Mancin, Gioia Bottesi, Igor Marchetti, Eating disorder symptom dimensions and protective factors: A structural network analysis study, *Appetite*, Volume 197, 2024.

¹⁶ Ashlye Borden & Catherine Cook-Cottone (2020) Yoga and eating disorder prevention and treatment: A comprehensive review and meta-analysis, *Eating Disorders*, 28:4,400-437.

¹⁷ O'Brien J, Evans S, McIver S, O'Shea M. A scoping review of integrated yoga and psychological approaches for the treatment of eating disorders. *J Eat Disord*. 2023 Sep 8;11(1):152.

image based on the embodied experience. In this pathway, the experience of touch and shadow are very important steps, structured on the basis of studies conducted in this area. Recent research indeed suggests that anomalies in the perception of touch may contribute to the pathological mechanisms of AN. A 2018 study by Davidovic, Starck et al. investigated through fMRI possible cortical anomalies in patients with AN in the presence of gentle touch. The results suggest that abnormal functioning of the dorsal striatum could influence the evaluation of pleasurable tactile stimuli and that abnormal functioning of the lateral occipital cortex could be correlated with a distorted perception of body image.¹⁸

Another study investigated the ability to distinguish between self-generated and other-generated touch, and how this contributes to the perception of body boundaries and, more generally, to the distinction between self and other. Both of these abilities are found to be altered in AN. The inability to attenuate self-touch could be correlated with altered predictions about one's own body and a reduced perception of body boundaries.¹⁹ The perceptual component of body image has also been investigated through studies related to shadows. Pavani and Galfano demonstrate that self-attributed body shadows draw attention to the part of the body they refer to, rather than to the position they occupy; therefore, recognising oneself as the owner of a shadow influences the distribution of tactile attention. Body shadows orient attention towards the body part that projects the shadow itself.²⁰ Being able to orient attention to one's own body through touch and the mediation of the shadow exposes patients to a new way of coming into contact with their own body, which allows them to approach their own image in a more embodied manner – an important step for these patients in helping them to expose themselves to the sight of their own body (e.g., in the mirror).

Study Objectives

Primary Objective

To investigate the efficacy of two psychological interventions for body image and eating behaviours in patients with EDs. The two intervention groups are: 1) yoga practice and 2) From Feeling to Seeing the Body (FSB); these interventions will be compared with a control group (i.e., treatment as usual).

Specifically, we are interested in investigating the efficacy of the interventions on two primary outcomes: 1) eating behaviours and 2) body dissatisfaction.

The three groups (i.e., yoga practice, FSB, control) will share a common integrated multidisciplinary baseline treatment – SSCM (Specialist Supportive Clinical Management) at the same level of intensity, comprising periodic psychiatric, psychotherapeutic, nutritional and dietetic visits.

¹⁸ Davidovic M, Karjalainen L, Starck G, Wentz E, Björnsdotter M, Olausson H. Abnormal brain processing of gentle touch in anorexia nervosa. *Psychiatry Res Neuroimaging*. 2018 Nov 30;281:53-60.

¹⁹ Frost-Karlsson M, Capusan AJ, Perini I, Olausson H, Zetterqvist M, Gustafsson PA, Boehme R. Neural processing of self-touch and other-touch in anorexia nervosa and autism spectrum condition. *Neuroimage Clin*. 2022;36:103264.

²⁰ Pavani F, Galfano G. Self-attributed body-shadows modulate tactile attention. *Cognition*. 2007 Jul;104(1):73-88.

Secondary Objective

To investigate the psychological mechanisms underlying the efficacy of the two psychological interventions (i.e., Yoga and FSB) for body image and eating behaviours. The possible psychological mechanisms involved, in accordance with the Embodied Self Model, which we consider to be at the basis of the interventions' efficacy, are: embodiment, interoceptive awareness, body and functionality appreciation, mindfulness/awareness and self-compassion.

Study Design

Experimental non-pharmacological interventional study, single-centre randomised controlled, with non-profit purposes.

The study will involve patients attending the Provincial Centre for Nutrition and Eating Disorders of Treviso (Aulss2) on an outpatient basis, who meet the inclusion criteria.

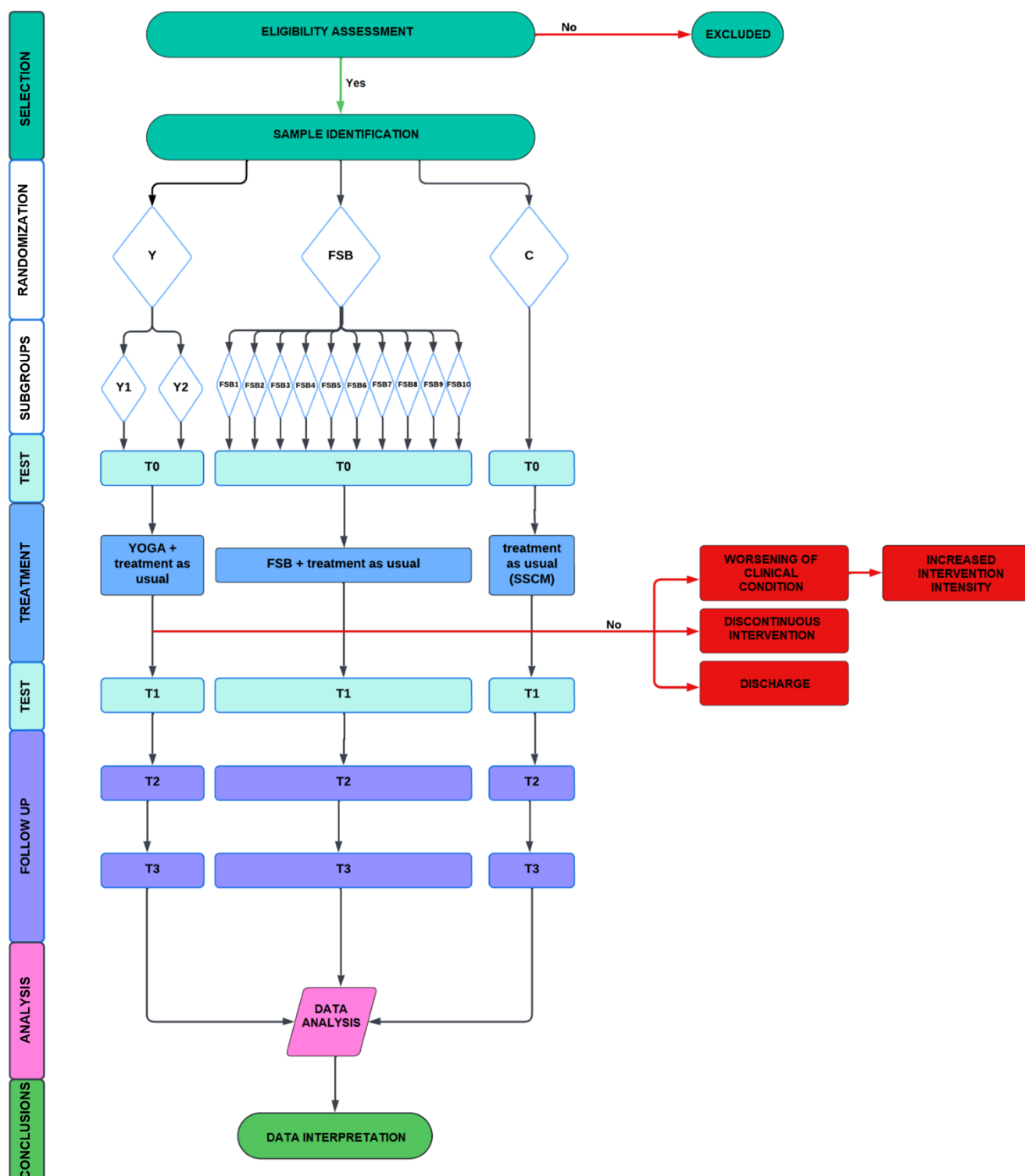
Three groups are planned:

- Control Group (C), which will follow the treatment-as-usual (Specialist Supportive Clinical Management; SSCM) comprising periodic psychiatric, psychotherapeutic, nutritional and dietetic visits.
- Yoga Group (Y), which will participate in treatment-as-usual (SSCM) + a weekly group Hatha Yoga session.
- From Feeling to Seeing the Body Group (FSB), which will follow treatment-as-usual (SSCM) + a weekly paired FSB session.

Patients will be randomly assigned to the groups (C, Y, FSB) using the Research Randomizer software.

Each group/pair will participate in the same number of sessions and will follow the same type of intervention as the other groups: the session structure will remain identical across the different subgroups.

Questionnaire administration (described in the Instruments section) will take place for all 3 groups (CG, Y, FSB) at four time-points: T0 (before the start of treatment), T1 (at the end of treatment), T2 (one month after the end of treatment), T3 (three months after the end of treatment).



Study Duration

The study includes the following phases with indicative implementation periods:

- Selection, enrolment and questionnaire administration at T0 (December 2024 – February 2025);
- Implementation of Yoga and FSB interventions and questionnaire administration at T1 (March – June 2025);
- Follow-up including questionnaire administration at T2 (July 2025) and T3 (September 2025);
- Data analysis and completion (October – November 2025).

Study Population

Setting: U.O.S. Provincial Centre for Nutrition and Eating Disorders AULSS2 Treviso, U.O.C. CSM Treviso.

Sample size: A sample of 60 patients has been defined based on the number of users attending the Provincial Centre for Nutrition and Eating Disorders AULSS2 Treviso.

Eligibility Criteria

Inclusion Criteria

- Female gender
- Patients under outpatient care at the CPD DNA of Treviso;
- Diagnosis of Anorexia Nervosa (AN) and/or Bulimia Nervosa (BN);
- Age between 16 and 25 years;
- Body Mass Index (BMI) ≥ 17 kg/m²;
- Clinically stable condition in the past month (i.e., stable weight, absence of worsening in clinical symptoms);
- No hospitalisations or discharges planned within 3 months of enrolment.

Exclusion Criteria

- Sudden worsening of the clinical condition;
- Transition to a higher intensity intervention (semi-residential, residential, hospitalisation) during the treatment phase;
- Discontinuous treatment attendance (participation in less than 80% of total sessions);
- Discharge during the treatment phase;
- Pregnancy: Pregnant women are excluded because pregnancy alters body weight and body shape and may exacerbate body dissatisfaction during the pre- and postpartum periods.²¹ The exclusion of pregnant women is therefore related to the objectives of the study.

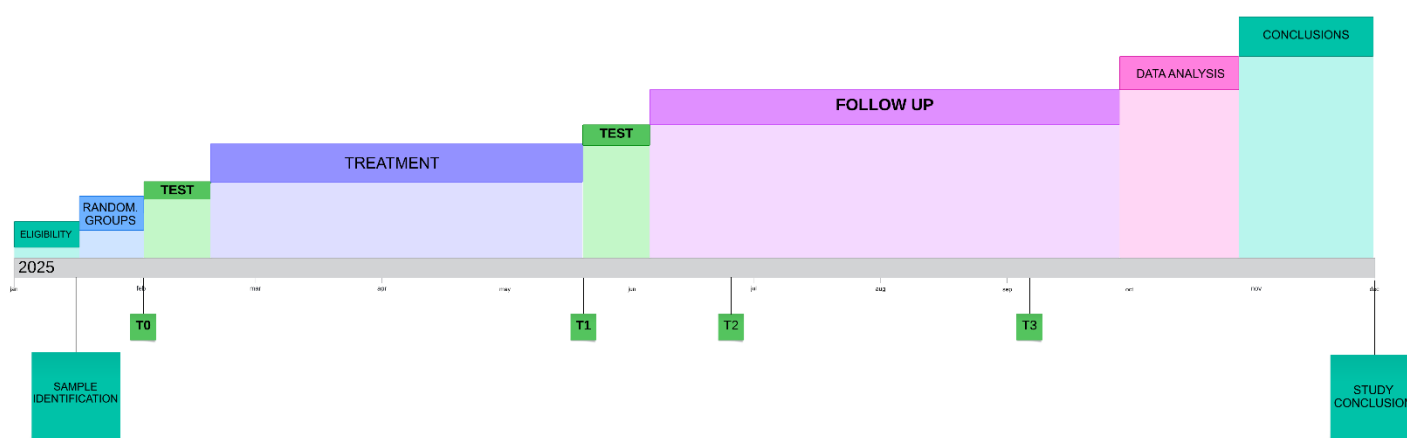
²¹ Skouteris H, Carr R, Wertheim EH, Paxton SJ, Duncombe D. A prospective study of factors that lead to body dissatisfaction during pregnancy. *Body Image*. 2005; 2:347–61.

- Previous continuous yoga practice (i.e., for more than 6 months).

Study Procedures

Study Timeline

The study timeline proceeds from initial identification of the sample, through T0 baseline assessment, treatment phases for all groups, T1 post-treatment assessment, T2 (1-month follow-up) and T3 (3-month follow-up) assessments, culminating in data analysis and study conclusions.



Sample Size

Sample composed of 60 patients (sample size defined based on the available user population attending the Provincial Centre for Nutrition and Eating Disorders AULSS2 Treviso).

Screening Phase

Before enrolment, eligibility for participation is assessed based on the inclusion/exclusion criteria for the study.

Eligibility and Randomisation

Enrolment Procedure

Participation in the study will be proposed to patients who:

- Have been followed by the Provincial DNA Centre of Treviso for at least one month and have therefore completed the diagnostic-evaluative pathway;

- Have already started the integrated multidisciplinary baseline SSCM (Specialist Supportive Clinical Management) intervention, which includes periodic psychiatric, psychotherapeutic, nutritional and dietetic visits;
- Meet the eligibility criteria (inclusion and exclusion).

Patients deemed eligible for enrolment will be offered participation in the study and the informed consent form will be shared.

Intervention Assignment

Block randomisation will be used to assign participants to the groups, to ensure that the experimental groups (the two intervention groups) and the control group have a similar number of participants.

The allocation sequence will be generated using randomisation software (i.e., Research Randomizer). The allocation ratio will be 1:1:1, ensuring that the two experimental groups and the control group have the same number of participants.

The study has been organised in a manner that maintains independence between the different phases of the process.

Participants will be recruited by staff of the U.O.S. Provincial Centre for Nutrition and Eating Disorders AULSS2 Treviso, U.O.C. CSM Treviso.

Treatment

Due to the different characteristics of the two interventions and the implementation methods, it will be necessary to divide patients into subgroups:

- Group Y will subsequently be divided into 2 groups of 10 patients.
- Group FSB will subsequently be divided into 10 pairs of patients.

YOGA Intervention

13 sessions (one per week) of group Hatha Yoga, each lasting 60 minutes.

The groups will be led by the principal investigator, Dr. Chiara Fuligno, a certified Hatha Yoga teacher for beginners.

Hatha Yoga is an ancient Indian doctrine that aims at the person's psychophysical well-being and integrates body movement with the flow of breath and awareness through different types of practice. Hatha Yoga is suitable for people of all ages, fitness levels and experience. It provides a wide range of movements (Asana) and breathing techniques (Pranayama) adaptable to any clinical condition.

Each session will have the following structure: 5 minutes of mindfulness practice and Mantra²², 25 minutes

²² Mantra is a Sanskrit word derived from two roots: man, meaning 'mind' or 'to think', and trai, meaning 'to protect', 'to liberate from' or 'instrument'. Therefore, mantras are instruments for liberating the mind. It is one of the most commonly used aids in meditation.

of Asana²³, 10 minutes of Pranayama²⁴, 18 minutes of Yoga Nidrā²⁵, 2 minutes of final mantra.

The sessions involve different practices over the course of the weeks according to progressive familiarisation with yoga. For the purposes of the research, the sessions of the two groups will be identical.

FSB Intervention

13 sessions (one per week) of 60 minutes of FSB (From Feeling to Seeing the Body – Embodied experience intervention for body image). Session 0 will be individual, while the subsequent 12 will be conducted in pairs.

The groups will be led by the principal investigator, Dr. Chiara Fuligno, TNPEE, who designed and structured the FSB intervention based on bodily experimentation.

SESSION 0 (individual)

The intervention includes an individual preparatory session for the contents of the intervention, in which the body outline activity will be experienced (drawing of the body figure) with a subsequent mindful-oriented reflection to introduce the complexity of the concept of embodied experience of body image according to the Embodied Self Model⁶.

FEELING/SENSING

SESSION 1 (beginning of the paired pathway) – Mutual experimentation of passive contact with balls of different sizes, weights and textures, with the use of music. Brief listening and mindfulness practice. Graphic representation. Mindful-Oriented reflection on the experience.

SESSION 2 – Mutual experimentation of passive contact with fabrics of different sizes, weights and textures, with the use of music. Brief listening and mindfulness practice. Graphic representation. Mindful-Oriented reflection on the experience.

SESSION 3 – Active tactile and proprioceptive experimentation through movement with elastic fabrics of different sizes, weights and textures, with the use of music. Brief listening and mindfulness practice. Graphic representation. Mindful-Oriented reflection on the experience.

SESSION 4 – Experimentation of one's own muscle tone and contact with the other through voluntary contraction/relaxation exercises, bodily experimentations of pushing, falling and wrestling on the ground. Brief listening and mindfulness practice. Graphic representation. Mindful-Oriented reflection on the experience.

SESSION 5 – Active motor and proprioceptive experimentation through spontaneous movement in space with the use of music and a blindfold/eyes closed. Brief listening and mindfulness practice. Graphic representation. Mindful-Oriented reflection on the experience.

SESSION 6 – Active motor and proprioceptive experimentation through spontaneous movement in space

²³ Postures used in Yoga practice that aim to trigger specific beneficial physiological processes.

²⁴ 'Prana' means breath, 'Ayama' means extension, control. The word Pranayama therefore means the extension of breath and its control. Pranayama comprises various techniques to make the respiratory organs move and expand intentionally, rhythmically, and to regulate the flow of energy in the body

²⁵ Yoga Nidrā is a meditation practised lying down. In Sanskrit, the word 'nidra' means 'sleep'. During the practice a state of deep relaxation is reached during which, even though relaxed, one is totally awake, receptive and aware of one's own sensations, emotions and thoughts.

with the use of music and a blindfold/eyes closed. Interaction with the other is encouraged. Brief listening and mindfulness practice. Graphic representation. Mindful-Oriented reflection on the experience.

SEEING/VIEWING

SESSION 7 – Bodily experimentation of the shadow through the projection of images and music inspired by the following contrasts (light/heavy, rigid/flexible). Brief listening and mindfulness practice. Graphic representation. Mindful-Oriented reflection on the experience.

SESSION 8 – Bodily experimentation of one's own shadow through the projection of slides with progressively wider spaces of light, with the use of music. Brief listening and mindfulness practice. Graphic representation. Mindful-Oriented reflection on the experience.

SESSION 9 – Bodily experimentation of one's own image reflected in progressively more numerous distorting mirrors that the patient will decide where to position. Brief listening and mindfulness practice. Graphic representation. Mindful-Oriented reflection on the experience.

SESSION 10 – Bodily experimentation, with the use of music, of one's own image in movement reflected in a large flexible mirror moved by both the patient and their partner. Brief listening and mindfulness practice. Graphic representation. Mindful-Oriented reflection on the experience.

SESSION 11 – Guided mirror exposure with spontaneous and non-judgmental description. Brief listening and mindfulness practice. Graphic representation. Mindful-Oriented reflection on the experience.

SESSION 12 – Guided mirror exposure focused on body functionality and cognitive dissonance. Brief listening and mindfulness practice. Graphic representation. Mindful-Oriented reflection on the experience.

As-usual Intervention (SSCM)

The integrated multidisciplinary baseline SSCM (Specialist Supportive Clinical Management) intervention includes periodic psychiatric, psychotherapeutic, nutritional and dietetic visits.

Specialist Supportive Clinical Management (SSCM) combines clinical management and supportive psychotherapy within individual sessions, focusing on normalising eating and on weight restoration. It provides specialist psychoeducation on the key characteristics of the eating disorder and addresses other personal problems identified by the patient.

The treatment-as-usual, present in the other two intervention groups (Y and FSB) as well, includes periodic individual sessions personalised according to the patient's clinical needs. Each patient will have access to outpatient specialist visits with the following professionals:

- Psychiatrist: psycho-clinical consultation, monitoring of any pharmacological therapy. Frequency: from once a month to once every two months.
- Nutritionist: monitoring of clinical condition, any prescription of instrumental tests and medications. Frequency: once every two months.
- Psychologist-psychotherapist: individual psychotherapeutic consultation. Frequency: from once a week to once every two weeks.
- Dietitian: personalised dietary guidance, any management of oral nutritional supplements, monitoring of the dietary plan, nutritional education. Frequency: from once a week to once every two weeks.

Tests

Below are the questionnaires used and the administration time-points planned by the project timeline.

INSTRUMENTS:

Negative body image and eating behaviours: Drive for Thinness, Bulimia and Body Dissatisfaction subscales of the Eating Disorder Inventory-3 (EDI-3; Garner, 2004; Italian version by Giannini, Pannocchia, Dalla Grave, Muratori & Viglione, 2008): subscales investigating the presence of dietary restriction behaviours, binge eating and the presence of dissatisfaction with one's body shape and weight.

Reference: *Giannini, M., Pannocchia, L., Dalla Grave, R., & Muratori, F. (2008). Italian adaptation of the EDI-3. Eating Disorder Inventory-3. Giunti OS: Organizzazioni Speciali*

Embodiment: Experience of Embodiment Scale (EES; Piran, Teall, & Counsell, 2020; Italian version by Cerea et al., in preparation): questionnaire investigating the experience of living in one's own body.

Reference: *Piran N, Teall TL, Counsell A. The experience of embodiment scale: Development and psychometric evaluation. Body Image. 2020 Sep;34:117-134.*

Interoceptive awareness: Multidimensional Assessment of Interoceptive Awareness (MAIA; Mehling et al., 2012; Italian version by Calì et al., 2015): instrument investigating interoceptive awareness.

Reference: *Calì, G., Ambrosini, E., Picconi, L., Mehling, W. E., & Committeri, G. (2015). Investigating the relationship between interoceptive accuracy, interoceptive awareness, and emotional susceptibility. Frontiers in psychology, 6, 1202.*

Body Appreciation: Body Appreciation Scale-2 (BAS-2; Tylka & Wood-Barcalow, 2015): self-report questionnaire investigating love towards one's own body.

Reference: *Casale, S., Probst, A., Giovannetti, S., & Fioravanti, G. (2021). Translation and validation of an Italian version of the Body Appreciation Scale-2. Body Image, 37, 1–5.*

Functionality Appreciation: Functionality Appreciation Scale (FAS; Alleva, Tylka & Van Diest, 2017): self-report questionnaire investigating the individual's appreciation of their body's functionality.

Reference: *Cerea, S., Todd, J., Ghisi, M., Mancin, P., & Swami, V. (2021). Psychometric properties of an Italian translation of the Functionality Appreciation Scale (FAS). Body Image, 38, 210–218.*

Mindfulness: Five Facet Mindfulness Questionnaire (FFMQ; Baer et al. 2006): self-report questionnaire investigating mindfulness across five dimensions (Observing, Describing, Acting with Awareness, Non-judging and Non-reacting).

Reference: *Giovannini, C., Giromini, L., Bonalume, L., Tagini, A., Lang, M., Amadei, G. (2014). The Italian Five Facet Mindfulness Questionnaire: A Contribution to its Validity and Reliability. Journal Of Psychopathology And Behavioral Assessment, 36(3), 415-423.*

Self-compassion: Self-Compassion Scale (SCS; Neff, K. D. 2003): self-report questionnaire investigating the concept of self-compassion across five dimensions (self-kindness, self-criticism, common humanity, isolation, awareness, over-identification).

Reference: *Veneziani, C. A., Fuochi, G., & Voci, A. (2017). Self-compassion as a healthy attitude toward the self: Factorial and construct validity in an Italian sample. Personality and Individual Differences, 119, 60-68.*

Body image: Mi disegno (Confalonieri E. 2011): instrument for the evaluation of body image in adolescence

through graphic representation of one's own body.

Reference: Confalonieri, Emanuela. (2011). *"MI DISEGNO" A tool for the evaluation of body image in adolescence.*

TIME-POINTS:

All questionnaires will be administered at the 4 time-points. The "MI DISEGNO" instrument will be administered only at T0 and T1.

T0: after enrolment and before the start of the intervention

T1: at the conclusion of the intervention

T2: 1 month after the conclusion of the intervention

T3: 3 months after the conclusion of the intervention

Expected time for administration of the questionnaire battery: maximum 60 minutes.

Follow-up

The Follow-up involves the administration of questionnaires 1 month after the conclusion of treatment (T2) and 3 months after the conclusion of treatment (T3) for all 3 groups.

Benefit/Risk Assessment for the Population

No risks are anticipated for the population. The Hatha Yoga and FSB interventions do not entail specific risks.

Presumed direct benefits: improved perception of body image and relationship with one's own body, and improved eating behaviours.

Possible indirect benefits: improvement of the constructs of embodiment, interoceptive awareness, body and functionality appreciation, mindfulness/awareness and self-compassion.

Subject Withdrawal and Intervention Modifications

The intervention will be suspended in the event of worsening of the clinical condition and/or the need for an increase in the intensity of the intervention (semi-residential, residential, hospital admission).

Withdrawal of participant consent from the study involves suspension of treatment.

A possible withdrawal of 10 out of 60 patients is anticipated.

Early Termination or Study Suspension

In the event of unforeseen circumstances that may prevent the intervention from being carried out as described above, the sponsor may interrupt the study at any time and promptly notify the investigators and the ethics committee. Patients will continue to be followed according to normal clinical practice.

Definition of Study Completion

The study will be concluded for the individual patient following the 3-month follow-up after the conclusion of treatment (T3), with the final completion of the self-report questionnaires.

Study Endpoints

To demonstrate that bottom-up interventions improve body image and eating behaviours in patients with Eating Disorder.

Primary Endpoint

Investigation of the efficacy of the Hatha Yoga and FSB interventions.

MEASURED VARIABLES: negative body image and dysfunctional eating behaviours

ANALYSIS METHOD: Measurement of the constructs with the following self-report instruments, collected at 4 different time-points of the study (T0, T1, T2 and T3).

AGGREGATION METHODS: Data will be processed in an aggregate manner, considering means and standard deviations.

Secondary Endpoint

Investigation of the psychological mechanisms involved in the efficacy of the Hatha Yoga and FSB interventions.

MEASURED VARIABLES: embodiment, body and functionality appreciation, interoceptive awareness, mindfulness/awareness and self-compassion.

ANALYSIS: Measurement of the constructs with the following self-report instruments, collected at 4 different time-points of the study (T0, T1, T2 and T3). The "MI DISEGNO" instrument will be administered only at T0 and T1.

Blinding (Masking)

The person responsible for randomisation and data analysis will use an automated system (i.e., Research Randomizer) to generate the group allocation sequence. Once the allocation sequence has been created, it will be concealed through anonymous codes that associate participants with intervention groups without revealing their assignment. During the data analysis phase, the person responsible for data analysis will not have direct access to group allocation information, so as to maintain blinding.

Only at the end of the main analyses will the codes be decrypted in order to conduct any post hoc analyses.

To maintain blinding during the analysis phase, participant data will be coded and stripped of information relating to group allocation. Access to the randomisation sequence will be restricted exclusively until the point when all data have been collected and prepared for analysis.

During the course of the study, the operators involved in the intervention will not be blinded with respect to the assignment of participants to groups, nor will the patients, as they will be aware of the type of intervention.

Blinding will be maintained until the completion of the main statistical analyses.

Other Study Procedures

None.

Data Management

Data Collection

Demographic data, data related to clinical history, and self-report questionnaire scores will be collected. Demographic and clinical history data will be collected only at T0, while data from paper-based self-report questionnaires will be collected at all time-points of the study (T0, T1, T2 and T3).

The self-report questionnaires used are validated instruments currently in widespread use in psychological research. The paper version bearing the user's ID code will be stored at the Coordinating Centre (U.O.S. Provincial Centre for Nutrition and Eating Disorders AULSS2 Treviso, U.O.C. CSM Treviso).

Data Management

Self-report questionnaire data will be entered into an Excel database. The database will be password-protected and accessible only to authorised members of the research team. Furthermore, IT security measures such as data encryption and regular backups will be implemented to prevent loss of information.

Data Storage

Data will be stored by the Coordinating Centre (U.O.S. Provincial Centre for Nutrition and Eating Disorders AULSS2 Treviso, U.O.C. CSM Treviso) and kept in dedicated folders within the company computer to be subsequently entered into a protected database.

Protocol Deviations

There may be protocol deviations on an individual basis in the presence of a worsening of the clinical condition (as per the inclusion/exclusion criteria) and/or the need for an increase in the intensity of the intervention (semi-residential, residential, hospital admission). Patients will continue to be followed according to normal clinical practice.

Statistical Plan

Statistical analyses will be conducted using the Statistical Package for Social Science (SPSS) software for Windows (version 28.0).

First, descriptive analyses of the sample will be conducted (variables of interest: age, level of education, Body Mass Index). Following the descriptive analyses of the sample, a one-way ANOVA will be used to evaluate any significant differences between the three groups (experimental groups and control group) with respect to age, BMI and scores obtained in the self-report questionnaire battery at T0 (pre-intervention), to verify the presence of differences between the three groups pre-intervention, which could affect the results obtained at T1 (post-intervention). Based on the results of the one-way ANOVA (i.e., absence or presence of differences between the two groups), mixed-model repeated measures ANOVA (Analysis of Variance) 3 (Group) × 4 (Time) (in the absence of differences between the two groups) or mixed-model repeated measures ANCOVA (Analysis of Covariance) 3 (Group) × 4 (Time) (in the presence of differences between the two groups in the variables investigated) will be conducted.

Description of the mixed-model repeated measures ANOVA/ANCOVA 3 (Group) × 4 (Time):

The "Group" factor consists of 3 levels. The "Group" factor refers to the two experimental groups (yoga and FSB) and the control group; the "Time" factor corresponds to T0 (measures obtained before the start of the intervention from the experimental groups and the control group, which undergoes only the standard treatment), T1 (represented by the measures reported at the end of the intervention for the experimental groups and by the measures obtained at the end of 13 weeks for the control group), T2 (1-month follow-up) and T3 (3-month follow-up).

The repeated measures ANOVA will be conducted in order to verify, in the different evaluation phases (T0, T1, T2 and T3), the presence of statistically significant variations in scores obtained from the self-report questionnaires relating to the psychological variables of interest (i.e., body image and eating behaviours) between the experimental groups and the control group.

Additional Analyses

If the yoga and FSB interventions emerge as effective in improving body image and eating behaviours, mediation analyses will also be conducted to understand the psychological mechanisms underlying the efficacy of the two interventions. It will therefore be investigated whether the improvement in body image and eating behaviours is mediated by the psychological variables hypothesised as mediators (i.e., embodiment, interoceptive awareness, body and functionality appreciation, mindfulness/awareness and self-compassion).

Administrative Aspects

Study Funding

No funding is planned for the study. For the procedures planned in the groups, an application will be made to the non-profit Fund.

Insurance Coverage

Low-level intervention study; the insurance coverage of the promoting institution will be used.

Protocol Amendments

This study will be conducted in accordance with the current version of the protocol. Any modification to the document, the study design, patient safety, or that may influence the willingness of participating subjects to continue their participation in the study is considered an amendment and must therefore be described and submitted as an amendment to the protocol and/or the informed consent. All amendments will be submitted for approval before becoming operative.

Ethical Considerations

Informed Consent

All patients eligible for the study and/or their parents will be provided with an appropriate information sheet, written in simple language, explaining the aims of the study and its methods of conduct. Enrolled subjects and their parents will be asked to sign the informed consent form, after having had time to read the information sheet and to clarify any doubts.

Confidentiality

Data will be collected in a confidential manner (with ID code).

Conflict of Interests

There are no conflicts of interests.

Responsibilities and Publication Policies

Role of the Sponsor and Investigators

Study design: Coordinating Centre

Data collection and management: Coordinating Centre

Data analysis and interpretation: Coordinating Centre

Report writing: Coordinating Centre

Authorship: Coordinating Centre

Data Ownership

Data ownership belongs to the sponsor.

Publication Policies

At the conclusion of the study, a period of approximately 8/12 months is anticipated to make the study results available through participation in conferences or through scientific publications. Anonymous data may be the subject of publication and presentation at conferences.

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