Secondary study protocol focusing on the BIS, with rudimentary statistical analysis plan

This secondary study protocol was finalized on September 3rd 2026.

Internet-Delivered Psychological Treatment for Cancer Survivors (IN-FACT-1)

ClinicalTrials.gov identifier: NCT06046586

Study protocol: Psychometric evaluation of the Body Image Scale (BIS) as administered in Swedish

Main author (first draft): Hana Fotoohi

Background

Body image concerns are a common problem in cancer survivors and have been found to negatively affect health-related quality of life (HRQOL) in these patients. The 10-item Body Image Scale (BIS) is a widely used self-report scale designed to measure the cognitive, behavioral and emotional aspects of body image [1]. The scale measures body image concerns, regardless of the respondent's cancer type or treatment modality. Each item is rated on a 4-point Likert scale (0–3), and the total score ranges from 0 to 30.

In the current study the scale was administered in the context of a psychological intervention for cancer survivors with psychiatric symptoms. To date, no psychometric evaluation of a Swedish translation of the BIS has been published. Furthermore, a systematic review evaluating the measurement properties of the BIS has identified the need for future high-quality psychometric studies across different cancer types and treatment modalities [2].

Validating the BIS is essential for understanding the trajectory, predictors, and consequences of body image concerns.

The IN-FACT research program

The IN-FACT-0 (pilot) [3] and IN-FACT-1 are randomized factorial trials designed to evaluate an internet-based, 10-week support program for Swedish cancer survivors suffering from psychological distress. Participants conduct a battery of instruments, in which the BIS is included, at pre- and post-treatment. The instrument was translated to Swedish by the research group preceding the trial.

Aim of this study

This study aims to evaluate the measurement properties of the Swedish translation of the Body Image Scale (BIS) using data from the IN-FACT-0 and IN-FACT-1 clinical trials. We aim to evaluate specific psychometric indices as listed in Table 1 below.

Methods

This secondary psychometric study will utilize a pooled sample of 350 participants, comprising 40 individuals from the IN-FACT-0 feasibility trial and 310 participants from the IN-FACT-1 randomized factorial trial (ClinicalTrials.gov NCT06046586). Analysis will commence in the autumn of 2026.

Table 1. Psychometric indices

Domain / outcome	**Hypothesis / target**
Distributions	In the original article, the mean score for a heterogenous cancer survivor sample 1-2 years after curative treatment was 7.78-9.46[4]. Based on this, we expect a sample selected on psychiatric symptoms to score similarly or slightly higher, tentatively with a mean in the range of 6-11.
Factor analysis	We hypothesize that confirmatory factor analysis (CFA) of the BIS will show a unifactorial structure [2]; acceptable model fit in terms of a Comparative Fit Index (CFI) ≥0.90 or ideally 0.95, Tucker-Lewis Index (TLI) ≥0.90 or ideally 0.95, and a Root Mean Square Error of Approximation (RMSEA) <0.08 or ideally <0.06 [5]. Some studies report a two-factor structure for the BIS [2]. Therefore, we will evaluate a two-factor model and compare it to the standard one-factor structure (significance test of difference in chi2 values). We hypothesize that the one-factor model will demonstrate superior fit across the previously mentioned indices (CFI, TLI, and RMSEA). If neither model exhibits acceptable fit, we will conduct an Exploratory Factor Analysis (EFA) to identify an appropriate factor structure for this sample.
Internal consistency	We hypothesize that the BIS will exhibit good internal consistency as indicated by an alpha and omega of ca 0.86-0.96 [2]. An alpha and omega of ≥0.70 will be considered acceptable.
Construct validity	To assess construct validity, Spearman correlations with other key scales will be calculated. Based on the existing literature, we hypothesize that the BIS will show Spearman correlations with other constructs in the following ranges: • Psychosocial disability (WD2-12-psychosocial): approx. -0.35-0.60 • Health-related quality of life (EQ-5D): approx. -0.65--0.40 [2] • Depression symptoms (PHQ-9): approx. 0.40-0.60 [2, 6] • General anxiety (GAD-7): approx. 0.40-0.60 [2, 6] In the original article, younger age (<55 years) was significantly associated with higher body image concerns [2]. Therefore, we hypothesize that a significant association between age (continuous variable) and body image concerns will be found in our sample, with younger participants scoring significantly higher on the BIS. We will also evaluate whether gender is associated with body image concerns. We hypothesize that the women in our sample will have a significantly higher mean score on the BIS.
Sensitivity to change	We are aware of one study indicating that the BIS is sensitive to change, as this studied after different types of breast surgery (mastectomy vs. conservative surgery, n=56) [1]. However, in a meta-analysis, the sensitivity to change of the BIS was deemed indeterminate because of a lack of studies [2]. To date, no study has investigated the sensitivity to change of the scale in the context of psychological interventions. A study evaluating the properties of the WD2-12 in a sample undergoing psychological treatment for stress- and anxiety, found the scale to be sensitive to change [8]. That study also proposed a psychosocial subscale in the factor

	structure of the WD2-12. To estimate the sensitivity to change of the BIS, we will calculate Spearman's correlations between change in the BIS and the WD2-12 psychosocial subscale, provided the two measures show a baseline correlation of at least 0.50. Under this scenario, a correlation of ≥0.50 between the change trajectories will be considered indicative of sensitivity to change.

References

1. Hopwood, P., et al., *A body image scale for use with cancer patients.* European Journal of Cancer, 2001. **37**(2): p. 189-197.
2. Melissant, H.C., et al., *A systematic review of the measurement properties of the Body Image Scale (BIS) in cancer patients.* Support Care Cancer, 2018. **26**(6): p. 1715-1726.
3. Winter, J., et al., *Proof-of-concept for a randomized factorial design strategy to build a complex online support program for cancer survivors with psychiatric symptoms: the IN-FACT-0 feasibility trial.* Journal of cancer survivorship, 2025: p. 1.
4. Hopwood, P., et al., *A body image scale for use with cancer patients.* European journal of cancer (1990), 2001. **37**(2): p. 189-197.
5. Hu, L.t. and P.M. Bentler, *Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives.* Structural Equation Modeling: A Multidisciplinary Journal, 1999. **6**(1): p. 1-55.
6. Hartung, T.J., et al., *The German version of the body image scale: Validation and item response analysis in cancer patients.* J Psychosom Res, 2023. **165**: p. 111129.
7. Swami, V., et al., *German translation and psychometric evaluation of the Body Appreciation Scale.* Body Image, 2008. **5**(1): p. 122-7.
8. Axelsson, E., et al., *The 12-item Self-Report World Health Organization Disability Assessment Schedule (WHODAS) 2.0 Administered Via the Internet to Individuals With Anxiety and Stress Disorders: A Psychometric Investigation Based on Data From Two Clinical Trials.* JMIR Ment Health, 2017. **4**(4): p. e58.