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The Polish version of the Body Image Avoidance Questionnaire: an exploratory structural equation modeling approach

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Abstract The objective of the study was to validate a Polish version of the Body Image Avoidance Questionnaire (BIAQ). The study included 115 participants with no diagnosis (control group) (Mage = 20.53, SD = 1.80) on which we have based factor analyses, 48 participants anorexia nervosa (Mage = 18.69, diagnosed with SD = 3.52) and 39 participants diagnosed with bulimia nervosa (Mage = 22.28, SD = 3.80). In the current study, we have run confirmatory factor analysis; however, the analysis did not fit the data (CFI = 0.81, RMSEA = 0.09). Three-factor solution (number of factors were chosen basing on parallel analysis and MAP) was assessed using exploratory structural equation modeling approach (extraction: Maximum Likelihood; rotation: Geomin) which appeared fit the data well (CFI = 0.90.RMSEA = 0.07). Validation with the clinical sample was performed using multi-group ESEM. Since the models achieved only configural level of invariance, we have examined the structure of clinical group with next ESEM model (CFI = 0.95, RMSEA = 0.05). To evaluate internal consistency, we have employed Omega (ω) and Cronbach's α with bootstrapped 95 % confidence interval (95 % CI). The first factor (food and weight preoccupation) was 0.79 (95 % CI = 0.74-0.83), for second factor (social activities) was 0.86 (95 % CI = 0.81-0.90), and for third factor (clothing) was 0.84 (95 % CI = 0.79-0.87). Convergent validity was assessed by correlating the Eating Disorder Inventory and the Body Attitude Test scores. The results have shown that the Polish version of the BIAQ fulfilled basic psychometric criteria and may be used for evaluation of body image avoidance behaviors among Polish women.

Keywords Body image disturbance · Avoidance behavior · Validation · Women

Introduction

Body image disturbance has been conceptualized as a construct, which includes perceptual and behavioral dimensions. Perceptual component of body image disturbance refers to body size estimation, whereas behavioral component of body image disturbance encompasses body checking and body avoidance. Body checking involves selective attention to one's body shape, size and weight, whereas body avoidance describes a range of behaviors aimed at to avoid seeing one's weight and/or shape (e.g., refusing to look at oneself in the mirror, wearing loose-fitting clothing) [1]. Body avoidance behaviors serve to maintain dysfunctional attitudes about the body and may be associated with increased importance being placed on shape and weight [2].

Although a lot of body image research has focused on the measurement of attitudinal and perceptual aspects of body image, behavioral measures have received limited analyses in the body image literature [3]. Furthermore, Polish research lacks an instrument to measure body image avoidance behaviors. Thus, the purpose of the present study was to validate the Polish version of the Body Image Avoidance Questionnaire (BIAQ) among non-clinical female undergraduate sample and assess its reliability and validity.



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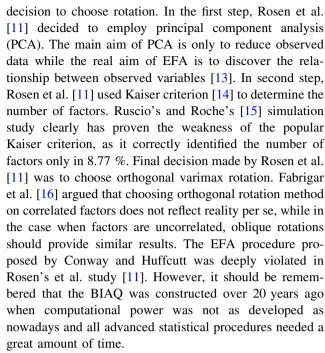
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Despite the fact that the BIAQ was developed over 20 years ago, there is still no clear answer about its factor structure. Some of the previous studies relied on exploratory approach; however, due to the violation of assumptions of exploratory factor analysis, results varied in 11-item three-factor model [4] and 13-item three- and four-factor solution [5]. Other studies relied on confirmatory approach; however, alongside with looking for well fitted model, authors relied on modification indices and extraction of items [6]. Due to the lack of the factorial structure clarity of the BIAQ, we have decided to use exploratory structural equation modeling (ESEM) approach.

Confirmatory factor analysis (CFA) and structural equation modeling (SEM) are often employed methods of data analysis and model testing; however, they both have several limitations. Measurement model in CFA specifies a number of loadings fixed at zero; there are no cross loadings, producing inflated factor correlations. Such restrictions rarely reflect reality and often lead to model misspecification [7]. On the other hand, they allow to test for measurement invariance and to compare alternative models, provide model fit indices and give the opportunity to test for method factors, bifactor models, correlated uniqueness or latent mean structures [8]. Because exploratory factor analysis (EFA) is found by many researchers as inappropriate and "old-fashioned" method of analysis [7], the confirmatory tools are often used for exploratory purposes. Browne [9] argues that exploring modification indices in CFA just toimprove the model fit, it denies the confirmatory character of the analysis. In such case, discovery of misspecified loadings is more direct through rotation of the data. Recently introduced ESEM integrates benefits of CFA/SEM (e.g., testing measurement invariance, model fit indices) with less restrictive character of EFA (e.g., estimation of cross loadings, rotation of the data). On the basis of a priori knowledge, ESEM could be more exploratory or confirmatory, which depends on used rotation method. The geomin rotation reflects exploratory approach, while in target rotation one specifies the items which are pure measures of the factor [7]. Using target rotation reflects confirmatory approach, but allows to compute cross loadings of other items and to prevent inflated inter-correlations. The ESEM approach is especially useful when measured constructs are multidimensional and when a priori knowledge about the structure is limited [7, 10].

Rosen et al. [11] proposed a four-factor solution of the BIAQ; however, their study had three major limitations. According to Conway and Huffcutt [12], there are three major decisions that could greatly influence obtained results while conducting exploratory factor analysis: firstly, a decision to choose extraction method; secondly, a decision to determine the number of factors and thirdly, a



The natural consequence of described steps is the difficulty with a replication of the original model in ours as well as other adaptation studies [4–6, 17]. In the Italian version of the BIAQ [5], exploratory factor analysis resulted in a 13-item three-factor model for high school students and four-factor model for university students and patients with obesity. However, in the German version of the BIAQ [4], exploratory factor analysis resulted in an 11-item three-factor model for female university students and women with eating disorders.

The main goal of our study is to organize the psychometric issues that are associated with the BIAQ and answer following questions: (1) what is the factorial structure of the BIAQ?; (2) does the BIAQ results differentiate between healthy and clinical group?; and (3) is the Polish adaptation of the BIAQ a valid and reliable measure?

Methods

Participants and procedure

The sample comprised 115 healthy female participants, 48 females with anorexia nervosa and 39 females with bulimia nervosa diagnosis, according to the DSM-IV-TR classification [18].

The average participants' age in control group (no eating disorders diagnosis) was 20.53 years (SD = 1.80), in bulimia nervosa 22.28 years (SD = 3.80), and in anorexia nervosa 18.69 years (SD = 3.52), respectively. The average body mass index (BMI) in control group was 20.88 kg/ m^2 (SD = 2.53) and in bulimia nervosa group was



22.46 kg/m² (SD = 4.08), which fits the standards set by the World Health Organization [19] of a normal weight (18.50–24.99 kg/m²) in both groups. Individuals with anorexia nervosa reached the average BMI of 17.35 kg/m² (SD = 2.41), which indicates underweight (17.00–18.49 kg/m²) according to the norms set by the WHO [19].

Participants were selected among non-clinical female undergraduate sample and outpatients with eating disorders. Inclusion criteria for the healthy group were the following: no current or past full or partial eating disorder symptoms, body mass index (BMI) no greater than 25 kg/m² as this principal cut-off points to overweight (according to the WHO's classification) and at least 18 years of age (adult participants).

In the clinical groups, diagnoses were made using a structured interview based on DSM-IV-TR criteria. The mean duration of disease was 3.31 years (SD = 2.71) in women diagnosed with anorexia nervosa and 5.10 years (SD = 2.92) in women diagnosed with bulimia nervosa, respectively. A random selection was made among adult outpatients (the present study includes women aged at least 18 years) in several psychotherapy center (e.g., the Polish Milton H Erickson Institute). All outpatients were tested in the starting phase of their treatment. The response rate was 100 % of those contacted.

All participants were informed that obtained results are anonymous and provided conscious consent to take part in the study. The research was approved by the Bioethics Commission at the University of Medical Sciences in Poznan (Poland).

Material

The BIAQ [11] is a 19-item self-report questionnaire designed to assess behavioral dimension that frequently accompanies body image disturbances. In particular, the instrument includes the avoidance of situations that provoke concern about physical appearance. Rosen et al. [11] postulated a four-factor structure composed of clothing (the tendency to disguise or cover-up appearance by wearing baggy, non-revealing clothes; e.g., "I avoid going clothes shopping"), social activities (avoiding social situations in which food, weight, or appearance could become a focus of attention; e.g., "I do not go out socially if the people I am with are thinner than me"), eating restraint (e.g., "I only eat fruits, vegetables and other low calorie foods") as well as grooming and weighing (e.g., "I weight myself"). Responses are scored on a 6-point Likert scale from never (0) to always (5).

The BIAQ has proven psychometric properties in clinical and non-clinical populations of female subjects [11].

The BIAQ has shown excellent internal consistency, with Cronbach's alpha of 0.89, and strong stability over a 2-week interval, the test–retest reliability coefficient of 0.87; p < .0001. The BIAQ shows modest associations with body size estimation tasks (r = .22, p < .01) and strong correlation with negative body attitudes (The Body Shape Questionnaire; r = .78, p < .0001).

The BIAQ has been translated into German [4], Portuguese [6], Italian [5] and French [17]; no Polish version existed. In the present study, translations followed a forward–backward procedure, independently carried out by two native speakers of the target language. Polish and English versions of the 19-item BIAQ are presented in Table 1.

The Body Attitude Test (BAT) [20] is a 20-item questionnaire developed to assess the subjective body experience and the attitudes toward one's body. Despite the fact that the instrument was originally developed to assess eating disorders in patients, it can also be used in healthy population [20]. Responses are scored on a 6-point Likert scale ranging from never to always. The BAT is composed of a stable four-factor structure: negative appreciation of body size, lack of familiarity with one's own body, general dissatisfaction, and a rest factor. Reliability measured by internal consistency demonstrated satisfactory levels of internal reliability ($\alpha = 0.93$). The factor-total correlation for the subscales ranges from 0.88 to 0.90 [20]. The shortterm test-retest reliability (interval 1 week) in female high school and university students and patients with eating disorder ranged from r = .87-.92 for the total score and from r = .72-.95 (all p < .01) for the subscales. The Polish adaptation of the BAT [21] has demonstrated satisfactory levels of internal reliability ($\alpha = 0.89$).

The Eating Disorder Inventory (EDI) [22] is one of the most widely used measures to assess various aspects of eating disorders pathology. The EDI contains eight scales: drive for thinness, bulimia, body dissatisfaction, ineffectiveness, perfectionism, interpersonal distrust, interoceptive awareness and maturity fears. Respondents are asked to indicate whether each item applies to them on a 6-point Likert scale ranging from *always* to *never*.

The EDI has shown excellent internal consistency coefficients ranging from 0.83 to 0.93. Test–retest reliability coefficients ranging from 0.85 to 0.95 have been reported for the eight scales. The Polish adaptation of the EDI [23] is a stable and reliable instrument with Cronbach's α ranging from 0.61 to 0.92.

Statistical analyses

All the analyses were performed using Mplus version 7.2 [24]. To answer formulated research questions, firstly we examined the factorial structure of the BIAQ. For this



Item	Content
1	Noszę luźne ubrania
	I wear baggy clothes
2	Noszę ubrania, których nie lubię
	I wear clothes I do not like
3	Noszę ubrania w ciemnych kolorach
	I wear darker color clothing
4	Noszę specjalny zestaw ubrań (np. tzw. "szerokie ubrania")
	I wear a special set of clothing, e.g., my "fat clothes"
5	Ograniczam ilość spożywanego jedzenia
	I restrict the amount of food I eat
6	Jem jedynie owoce, warzywa i inne potrawy niskokaloryczn
	I only eat fruits, vegetables and other low calorie foods
7	Poszczę dzień lub dłużej
	I fast for a day or longer
8	Nie wychodzę z domu, jeśli przypuszczam, że będą obserwowana
	I do not go out socially if I will be "checked out"
9	Nie wychodzę z domu, jeśli wiem, że osoby, z którymi mar się spotkać będą rozmawiać o wadze
	I do not go out socially if the people I am with will discuss weight
10	Nie wychodzę z domu, jeśli osoby, z którymi spotykam się s ode mnie szczuplejsze
	I do not go out socially if the people I am with are thinner the

I do not go out socially if the people I am with are thinner than

11 Nie wychodzę z domu, jeśli związane jest to ze zjedzeniem posiłku

I do not go out socially if it involves eating

12 Sama się ważę I weigh myself

13 Nie jestem aktywna

I am inactive

Patrzę się na siebie/przeglądam się w lustrze I look at myself in the mirror

15 Unikam fizycznej bliskości I avoid physical intimacy

16 Noszę ubrania, które odwrócą uwagę od mojej wagi I wear clothes that will divert attention from my weight

Unikam robienia zakupów-kupowania ubrań 17 I avoid going clothes shopping

Nie noszę "odkrytych" ubrań (np. kostiumów kąpielowych, 18 szortów, bluzek na ramiączkach)

I don't wear "revealing" clothes (e.g., bathing suits, tank tops, or shorts)

Ubieram się ładnie, dbam o makijaż

I get dressed up or made up

purpose, we analyzed series of competing ESEM models with geomin rotation (E value was left to vary as recommended [10]). In spite of the fact that the BIAQ has six response categories, some items (e.g., "I do not go out socially if the people I am with are thinner than me") are not typical for healthy group; therefore, cited item had only two categories, while some of the other had four and five categories. For this purpose, we treated items with less than 6 categories as categorical [25] and used WLSMV estimator. Secondly to answer whether BIAQ results differentiate between healthy and clinical group, we performed multi-group ESEM. To test measurement invariance, we followed the procedure proposed by Meredith [26] and assessed configural, weak and strong invariance and used maximum likelihood estimation with robust standard errors. Because we have proven that both groups are not invariant, we have assessed the factorial structure of eating disorders group using ESEM independently [10]. Unlike in healthy group, the data were approximately normally distributed; therefore, we used maximum likelihood estimation. Finally, the reliability of the Polish version of the BIAQ was assessed using Cronbach's α formula and convergent validity was assessed using two-tailed Pearson's r correlation coefficient with two other measures—the Eating Disorder Inventory and the Body Attitude Test.

Results

We have distinguished and addressed three important issues: (1) the factorial structure of the Polish version of the BIAQ; (2) the validation of the BIAQ with the clinical group; and (3) the validity and reliability of the measure.

In the current study, we compared competing ESEM models in the healthy group comprising from one to five latent factors. Table 2 presents fit indices for all models.

To positively define the covariance matrix in five factor model, we needed to delete four items; however, this resulted in uninterpretable model fit indices. Therefore, model with four latent factors in healthy group is best fitted to the data. Results of the four-factor structure with residuals and standardized factor loadings values are presented in Table 3.

In healthy group, original clothing factor is divided into two: (Factor 1) items that concern clothing and appearance and (Factor 4) items that concern preoccupation with physical appearance. Factor 2 corresponds to social activities while remaining Factor 3 corresponds to food and weight preoccupation. It is worth noting that item 19 from the first factor had negative loading; therefore, it is recommended to score it reversely.

Validation with clinical population

The general definition of measurement invariance if whether scored from the operationalization of a construct has



Table 2 Model fit indices of competing exploratory structural equation models in healthy group

Number of latent factors	χ^2	df	p	CFI	TLI	RMSEA [90 % CI]
1	312.00	152	0.0000	0.667	0.625	0.096 [0.081–0.111]
2	207.30	134	0.0001	0.847	0.805	0.069 [0.050-0.087]
3	165.33	117	0.0022	0.899	0.863	0.060 [0.037-0.080]
4	132.17	101	0.0203	0.935	0.890	0.052 [0.022-0.075]
5 ^a	36.25	0.40	0.1065	1.000	1.036	0.041 [0.000-0.068]

^a Model with deleted four items due to difficulties with identification

Table 3 Exploratory structural equation modeling results for the Polish version of the BIAQ

Item	Clothing and appearance	Social activities	Food and weight preoccupation	Preoccupation with physical appearance	Residual variances
1	0.37*	0.01	0.03	0.30*	0.69*
2	0.48*	0.14	-0.27	0.10	0.58.*
3	0.01	-0.10	0.13	0.45*	0.81*
4	0.82*	0.03	0.21	0.02	0.28
5	-0.17	0.57	0.49*	0.05	0.37*
6	-0.05	0.25	0.63*	0.06	0.50*
7	0.03	0.55	0.56*	-0.03	0.34*
8	0.16	0.43*	-0.14	0.19	0.61*
9	-0.05	0.92*	0.02	0.03	0.14
10	0.33	0.87*	0.04	-0.07	0.06
11	0.06	0.80*	-0.12	0.12	0.23
12	-0.22	0.18	0.23*	0.05	0.87*
13	-0.14	0.15	-0.43*	0.49*	0.56*
14	-0.21	0.12	0.21*	-0.05	0.89*
15	-0.02	-0.33	0.02	0.81*	0.49*
16	0.07	0.00	0.44*	0.71*	0.24
17	0.14	0.17	0.00	0.43*	0.64*
18	0.21	0.04	-0.02	0.68*	0.35*
19	-0.53*	0.06	0.05	-0.13	0.66*

^{*} p < .01

the same meaning under different conditions [27]. For the purpose of our study, we have tested if the model distinguished in healthy sample is invariant with equivalent model in clinical population using the multi-group exploratory structural equation model. There are three most basic degrees of invariance: the configural, metric and scalar. The configural invariance is the most basic level, which can be tested without any assumptions. Therefore, results provided by this level do not allow to assume equivalence of compared structure but only confirm that compared groups have the same number of latent variables formed by the same number of indicators. The metrical invariance (also referred as weak invariance) allows to compare comparison of the latent variances and covariances and the scalar invariance (also referred as strong invariance) allows to compare groups between themselves on all levels, since compared group factor structures are equivalent.

The interpretation of the multi-group analysis proceeds hierarchically by comparing differences in fit indicators. If compared groups are ideally equivalent, all the indices should be equal. Chen [28] provides the guidelines for assessment of the small (less than 300) groups. The configural level should be interpreted like general structural equation model (CFI >0.90; RMSEA <0.08; [29]). The metrical level of invariance assumes differences between other levels of no greater than <-0.005 in CFI, >-0.010 in RMSEA and ≥0.025 in SRMR. The scalar level of invariance assumes differences between other levels of no greater than <-0.005 in CFI >0.010 in RMSEA and >0.005 in SRMR. Due to the difficulties with models' identification, we were not able to estimate model fit indices; therefore, the clinical and healthy groups are not invariant even on the configural level. Because of this fact, we decided to examine the factorial structure of the BIAQ in clinical group using



Table 4 Model fit indices of competing exploratory structural equation models in clinical group

Number of latent factors	χ^2	df	p	CFI	TLI	RMSEA [90 % CI]
1	290.54	152	0.0000	0.740	0.707	0.102 [0.084–0.120]
2	216.02	134	0.0000	0.846	0.803	0.084 [0.063-0.104]
3	146.40	117	0.0341	0.945	0.919	0.054 [0.016-0.080]
4	Model not identified					
5	Model not identified					

exploratory structural equation modeling approach (ESEM). To determine the number of factors, we have followed the same procedure as in healthy group and the model fit indices of competing models are presented in Table 4.

A three-factor solution was the best fitted to the data. Four and five factor models were not identified due to non-positive covariance matrix. Results of the three factors ESEM model for the clinical group are presented in Table 5.

In clinical group, Factor 1 corresponds to merged clothing and social activity scales and Factor 2 corresponds to eating restraint and weighing scales. Factor 3 is not corresponding to any factor; however, its structure inversely reflects the social activities factor. However, those results should be interpreted with carefulness because small sample size could result in low power of the model.

Reliability and validity

Due to structural differences, we have assessed reliability in clinical and healthy groups independently. Results are presented in Table 6.

Results suggest that the Polish version of the BIAQ is a reliable measure that can be used both in healthy and clinical groups.

To assess convergent validity of the Polish version of the BIAQ, we have correlated distinguished factors with the BAT and the EDI subscales. A summarized correlation matrix is presented in Table 7.

All the correlations were found significant which confirm the convergent validity of the Polish adaptation of the BIAQ.

Discussion

We are proposing a new model for the healthy population based on exploratory structural equation modeling approach. In the current study, in healthy group we have distinguished a well fit four-factor model: clothing and appearance (items 1, 2, 4, and 19), social activities (items 8, 9, 10, and 11), food and weight preoccupation (items 5, 6, 7, 12, and 14), and preoccupation with physical appearance (items 3, 13, 15, 16, 17, and 18). With the

 Table 5
 Exploratory structural equation modeling results for the clinical group of the BIAO

Item	Factor 1 Clothing and social activities	Factor 2 Eating restraint and grooming and weighing	Factor 3 Social withdrawal	Residual variances
1	0.67*	0.00	0.31*	0.41*
2	0.48*	-0.16	0.10	0.74*
3	0.57*	-0.02	0.37*	0.50*
4	0.71*	0.01	-0.04	0.50*
5	0.00	0.82*	0.17	0.35
6	-0.02	0.62*	-0.05	0.61*
7	0.36*	0.49*	0.02	0.63*
8	0.78*	-0.01	-0.67*	0.05
9	0.64*	-0.01	-0.34*	0.51*
10	0.65*	0.08	-0.20	0.53*
11	0.57*	0.18	-0.21	0.58*
12	0.03	0.37*	0.28*	0.81*
13	0.46*	-0.05	0.11	0.77*
14	-0.03	0.34*	0.16	0.88*
15	0.63*	0.11	-0.03	0.58*
16	0.59*	0.11	0.17	0.59*
17	0.72*	-0.11	0.00	0.49*
18	0.68*	0.04	-0.07	0.54*
19	-0.45*	0.36*	-0.05	0.70*

^{*} p < .01

exception of the negatively keyed item (19), items are scored ranging from *never* (0) to *always* (5). Contrary to other BIAQ adaptations, we have followed the rigorous methodological guidelines.

In the current study, we have proven that the BIAQ has capabilities to distinguish healthy group from patients with anorexia and bulimia nervosa, which is in line with other studies (e.g., [11]). The Polish adaptation of the BIAQ could be administered for screening purposes of eating disorders psychopathology alongside with specific measures as its content is a valuable complement of information. We have examined the structure of the BIAQ in clinical sample; however, the results were obtained from small sample size and, therefore, should be interpreted only as guidelines for future studies.



Table 6 Reliability of the Polish version of the BIAQ

	Cronbach's α
Healthy group	
Clothing and appearance	0.67
Social activities	0.71
Food and weight preoccupation	0.68
Preoccupation with physical appearance	0.75
Clinical group	
Clothing and social activities	0.89
Eating restraint and grooming and weighing	0.63
Social withdrawal	0.72

Table 7 Pearson's correlation matrix between three-factor model and measured variables

Scale	Food and weight preoccupation	Social activities	Clothing
BAT negative appreciation of body size	0.41*	0.35*	0.38*
BAT lack of familiarity with one's own body	0.48*	0.42*	0.42*
BAT general body dissatisfaction	0.35*	0.35*	0.36*
EDI drive for thinness	0.50*	0.45*	0.42*
EDI bulimia	0.34*	0.38*	0.37*
EDI body dissatisfaction	0.42*	0.34*	0.34*
EDI ineffectiveness	0.45*	0.32*	0.34*
EDI perfectionism	0.32*	0.19*	0.23*
EDI interpersonal distrust	0.39*	0.22*	0.28*
EDI interoceptive awareness	0.47*	0.38*	0.38*
EDI maturity fears	0.39*	0.21*	0.20*

^{*} p < .01

In measurement invariance analysis, we provided evidence that healthy and clinical groups are not invariant, which supports the hypothesis about differentiative power of the BIAQ. Contrary to healthy group, we have found a well-fitted three-factor structure in clinical group representing: (1) clothing and social activities; (2) eating restraint and grooming and weighing; and (3) social withdrawal. The structural differences between healthy and clinical group could be possibly caused by specificity of eating disorders. Individuals with eating disorders are excessively focused on own appearance and have disordered body image. Therefore, eating disorder patients engage in body image avoidance behaviors.

Some limitations of the study should be mentioned. The main limitation was the relatively small sample size. Despite the fact that the BIAQ is a very short measure, a greater sample size could greatly affect and underpin our

results and, therefore, a further examination of distinguishing the BIAQ structure is required. Secondly, our sample was limited to women; consequently, the Polish version of the BIAQ has to be used with females only. Further research is needed to explore possible gender differences in the field of body image avoidance behaviors. Thirdly, a four-factor solution was determined to be the most appropriate for the group of healthy women. Another aspect which needs to be considered in future studies is the assessment of sensitivity to change.

In conclusion, the examination of the psychometric properties of the Polish version of the BIAQ has provided evidence of its validity among women with and without eating disorders. The Polish version of the BIAQ could be a useful tool for assessing body image avoidance behaviors among Polish women.

Compliance with ethics standards

Conflict of interest The authors declare they have no conflict of interest.

Ethical approval The research was approved by the Bioethics Commission at the University of Medical Sciences in Poznan (Poland). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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