ÖZGÜN ARAŞTIRMA ORIGINAL RESEARCH

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MICROBIOTA AWARENESS SCALE VALIDITY AND RELIABILITY STUDY

MİKROBİYOTA FARKINDALIK ÖLÇEĞİ GEÇERLİLİK VE GÜVENİLİRLİK ÇALIŞMASI

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Öz

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Amaç

Bu çalışmada kişilerin mikrobiyota farkındalık düzeylerini belirlemeye yönelik geçerli ve güvenilir bir ölçme aracı geliştirmek amaçlanmıştır.

Gereç ve Yöntem

Metadolojik türde yürütülen bu araştırma Eylül 2019-Eylül 2020 tarihleri arasında Isparta ili Eğirdir ilçesi aile sağlığı merkezine başvuran kişilerde yapılmıştır. Çalışmaya 301 kişi katılmış olup çoğunluğu (%61,5) kadındır. Literatür taranarak oluşturulan taslak ölçek formu daha sonra kapsam geçerliliği amacıyla konuyla ilgili uzman görüşüne sunulmuştur. Kapsam geçerliliği sonucunda katılımıcılara uygulanan ölçeğe ait verilere açıklayıcı ve doğrulayıcı faktör analizi uygulanmıştır.

Bulgular

Yapılan açıklayıcı faktör analizi sonucu 4 faktörlü 20 maddeli bir yapı elde edilmiştir. Ölçeğe daha sonra doğrulayıcı faktör analizi yapılmış ve ölçeğin iyi uyum değerleri gösterdiği belirlenmiştir. Ölçeğin güvenirlik için hesaplanan Cronbach Alpha katsayısı 0,852 saptanmış olup iyi düzeydedir.

Sonuç

Çalışma sonucunda mikrobiyota farkındalık ölçeği'nin kapsamı ölçmeyle ilgili geçerli ve uygulanma metadolojisi açısından güvenilir bir ölçme aracı olduğu saptanmıştır. Ölçeğin faktörlere ayrılmadan toplanarak kullanılması tavsiye edilmektedir.

Anahtar Kelimeler: Mikrobiyota farkındalığı, probiyotik, prebiyotik, faktör analizi

Abstract

Objective

This study aimed to develop a valid and reliable measurement tool to determine the microbiota awareness levels of individuals.

Materials and Methods

This methodological study was conducted on people who applied to the family health center of Egirdir District of Isparta Province between September 2019 and September 2020. Three hundred one people participated in the research, and the majority (61.5%) were women. The draft scale form, created by scanning the literature, was then presented to the expert opinion on the subject for content validity. As a result of the content validity, explanatory and confirmatory factor analysis was applied to the data of the scale applied to the participants.

Results

As a result of the explanatory factor analysis, a structure with 4 factors and 20 items was obtained. Afterward, confirmatory factor analysis was

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performed on the scale, and it was determined that the scale showed good fit values. The Cronbach Alpha coefficient calculated for the scale's reliability was found to be 0.852 and is at a reasonable level.

Conclusion

As a result of the study, it has been determined that the microbiota awareness scale is a valid measurement

tool for measuring the scope and a reliable measurement tool in terms of application methodology. It is recommended to use the scale without separating it into factors.

Keywords: Microbiota awareness, probiotic, prebiotic, factor analysis

Introduction

The human body is an ecosystem that supports trillions of living microorganisms (1). All of the microorganisms that can be found in different regions of the human are called the microbiota, and the genome of these microorganisms is called the microbiome (2). The gastrointestinal tract (GIS) is very suitable for colonization because it has a large surface area and contains rich nutrients (3). This ecosystem, which consists of these microorganisms colonized in the GIS and functions like an organ, is called the intestinal microbiota (4). The composition of the microbiota is region dependent and also highly dynamic. Changes in this composition can affect host physiology and health. Evidence shows that the etiology and persistence of both metabolic and behavioral disorders are related to the microbiota (5). Studies have shown that the intestinal microbiota is as unique as a fingerprint and creates a different pattern in each person (6). The genetic richness of the intestinal microbiota enables the microbiota to be considered an organ on its own. It can affect the intestines, brain, liver and other organs at the molecular level (7, 8).

When the national and international literature on this subject is examined, it has been observed that there is a lack of an up-to-date scale that has a holistic perspective, which has completed validity and reliability studies, therefore within the scope of the current study, it is aimed to develop a valid and reliable scale that measures the microbiota awareness levels of individuals.

Materials and Methods

This study was conducted methodologically in order to develop a measurement tool for assessing individual microbiota awareness levels and to evaluate the assessment tool's reliability and validity. The research sample consists of patients and their relatives aged 18 and above who have no communication problems and who applied to the Family Health Center in the

Egirdir district of Isparta province at the time of the research. No sample selection method was used in the study. The data collection tool consists of two parts. In the first part, some questions investigate the participants' sociodemographic characteristics (age, gender, educational status, occupation, etc.). The other part consists of the draft form of the Microbiota Awareness Scale, in which the researchers by review the literature prepared. The draft form of the scale was developed in a five-point Likert type (1=strongly disagree, 2=disagree, 3=undecided, 4=agree, 5=strongly agree) and includes 27 positive and 2 negative statements. Two of the questions in the scale are information questions with five options, and marking each correct one in these questions was evaluated as 1 point, and not marking any incorrect one was assessed as 1 point. The last two questions of the scale were designed as open-ended questions, and evaluations were made in such a way that those who wrote no answer received 1 point, one answer 2 points, two answers 3 points, three answers 4 points, and those who answered four and above received 5 points. In order to enable people to understand the questions more easily, definitions of scientific words in the scale are given at the beginning of the scale form. The research was carried out with the approval of the Ethics Committee of the Faculty of Health Sciences of Süleyman Demirel University, dated 29.11.2019, and numbered 326. The data used in the research were collected between January 28 and February 11, 2020. In scale development studies, it is necessary to reach a sample size of 10 times the number of scale items (9). For this reason, a total of 301 people, 185 females and 116 males, who met the criteria and agreed to participate in the research, were reached.

Frequency, percentile, and mean tests were used to define the participants' sociodemographic characteristics. To perform validity and reliability analyses, the content validity of the draft scale was first checked, and then factor analysis was performed to evaluate the construct validity. For the validity and reliability studies of the scale, Keiser-Meyer-Olkin Sample Adequacy Scale was used, Bartlett's Test of Sphericity was used for the suitability of the sample for analysis, Cronbach Alpha (α) was used for item analysis and item-whole correlations, followed by the Split-Half Test method and explanatory factor analysis method. The floor-to-ceiling effect and item distinctiveness index of the scale were also evaluated. The T-Test in independent groups and oneway ANOVA tests examined the relationship between the independent variables and the average scores obtained from the sub-factors and the whole scale. IBM SPSS 25 package program was used for the explanatory factor analysis to analyze the research data, and the AMOS 23 package program was used for the confirmatory factor analysis.

Results

The study determined that 61.5% of the participants were female, and 38.5% were male. The mean age of the individuals participating in the survey is 38.50±14.88, 22% are primary school graduates, and below, 10.6% are secondary school graduates, 38.5% are high school graduates, 10.3% are associate degree students, and 18.6% of them have undergraduate and postgraduate education. When we look at the distribution by occupational groups, it was determined that 36.9% of the participants do not work in any paid job, 14.6% are students, 3.3% are farmers, 4.3% are tradesmen, 20.3% are whitecollar workers, 13% are blue-collar workers, 4.3% are health workers, and 3% were members of highqualification occupational groups. In the study, 23.9% of the participants have at least one chronic disease, 62.1% have never smoked before, 13% have guit smoking, and 24.9% are still smoking. Looking at the family type, 87% of the participants had a nuclear family, 9.6% had an extended family, and 3.3% lived alone.

Content Validity

An expert primarily evaluated the Microbiota Awareness Scale consisting of 29 items in terms of grammar, and necessary revisions were made. Then, the Lawshe technique was used for content validity. Since the opinion of at least 5 and maximum 40 experts should be sought in this technique, the views of 11 experts were obtained (10).

Experts evaluated items in three categories as "Appropriate/ items can be used as such; partially appropriate/Item can be used with suggested corrections; "Not at all suitable/ Item should be removed." In addition, experts were asked to suggest additional item suggestions and indicate corrections

for items that were thought to be changed. The qualitative data obtained from the expert opinion were converted into quantitative data by calculating the content validity ratio (CVR) and content validity index (CVI) (11). As a result of the evaluations, no item with a negative or zero content validity ratio (CVR) was found on our scale. Eleven experts evaluated the scale, and the equivalent of CVRs in the minimum value table was specified as 0.59 at the α =0.05 significance level (12). It was decided to exclude items with a CVR value less than 0.59 from the scale. As a result of the calculations, no item with CVR<0.59 was found. An item similar to the other questions in the scale was removed from the scale upon suggestions. In the calculation made with the remaining items, the content validity index (CGI) was 0.81. After the necessary arrangements were made, the draft version of the scale consisting of 26 positive and 2 negative propositions was determined.

Construct Validity and Reliability

For construct validity and reliability, item-whole correlations of the items, the change in the Cronbach's alpha coefficient when the item was removed, the common variance values in the items, and the item distinctiveness power indices were examined. If the item-whole correlation coefficient of an item is low, the contribution of that item to the scale is also low. The item-total correlation coefficient should be positive and greater than 0.25 (13). Five items with an item-whole correlation coefficient below +0.25 (m7, m11, m12, m22, m24) were identified in the scale.

These items were not included in the scale and were removed from the scale.

In determining the distinctiveness (item validity) of the items, the method of comparing the item averages of the lower and upper 27% groups was used, and the item distinctiveness power index was calculated. As a result of the analysis, it was determined that the t value for each item was positive and significant at the p<0.001 level (13).

In order to test the structural validity of the scale, the principal components method from explanatory factor analysis methods and direct oblimin method from oblique rotation methods were used. The load distributions formed according to the analysis were examined, and three items (6, 10, 15) with a load value difference of less than 0.1 in at least two factors were removed from the scale (14). Kaiser-Meyer Olkin (KMO), Bartlett Sphericity tests were performed, and anti-image correlation values were examined to examine the data's suitability for the principal component analysis of the sample. The KMO coefficient of the Microbiota Awareness Scale was 0.834, and the chi-square value of the Bartlett test was found to be 1923.84 and was found to be significant (p<0.001). The anti-image correlation values of the questions in the scale were found above 0.50. Accordingly, due to the factor analysis with the remaining items, 20 items were grouped under four factors with an eigenvalue greater than 1.0 (Kaiser's Criterion). It is considered significant if the eigenvalue of the factors is greater than 1 (15). The resulting scree plot also supports the four-factor structure (Fig 1).

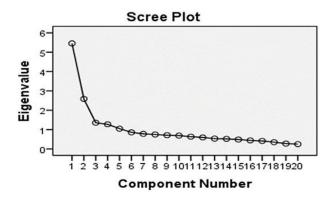


Figure 1 Factor number eigenvalue slope graph

According to the analysis results, the rate of total variance explained by the four-factor structure was 53,331%, and the eigenvalue was 1,273. The mean, standard deviation, item-total correlation, item distinctiveness index, factor analysis, and rotated factor analysis results of the items in each factor are shown in Table 1.

As a result of the factor analysis, it was seen that the Microbiota Awareness Scale, consisting of 20 positive statements, was distributed over four factors. Factors to reflect the content;

Factor 1: General Information (m1, m2, m4, m5, m6, m13),

Factor 2: Product Information (m17, m18, m19, m20),

Factor 3: Chronic Disease (m8, m10, m12, m14, m16), Factor 4: It was named as Probiotic and Prebiotic (m3, m7, m9, m11, m15).

Reliability analysis of the scale consists of 20 items and 4 factors. According to the factors and as a whole, Cronbach's alpha reliability coefficient was calculated using the Spearman-Brown inter-half reliability formula and the Guttman inter-half reliability formula. The results regarding the reliability of the scale are shown in Table 2. The Spearman Brown reliability coefficient for the entire Microbiota Awareness Scale was 0.789; Guttman Split Half reliability value was found to be 0.782. The Cronbach Alpha reliability coefficient was found to be 0.852. If the scale is deleted in its final form, no item increases the alpha coefficient. In the study, Spearman-Brown, Guttman Split Half, Cronbach Alpha coefficient were also used to measure the reliability of the subgroups of the scale (Table 2).

Confirmatory factor analysis was applied on the sample in which explanatory factor analysis was performed, and fit indices related to the model were examined. Covariance in modification indices M.I. Covariance was created between 4 values e9-e10 and e16-e17 with a value above 50, and the fit values were improved. Confirmatory factor analysis compatibility values of the scale are shown in Table 3, and the path diagram for confirmatory factor analysis is shown in Fig 2.

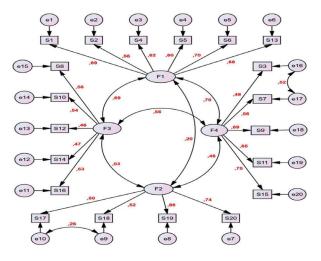


Figure 2 Confirmatory factor analysis diagram of the Microbiota Awareness Scale.

Discussion

Since there are no physical tools for measuring individuals' attitudes, behaviors, and similar characteristics, different measurement tools (scales) are developed to obtain indirect measurements. There are two requirements for a newly developed scale to fulfill. These are validity and reliability (13). Validity means that a test can accurately measure the feature it wants to measure without confusing it with other features (16).

Table 1

Mean, Standard Deviation, Item Total Correlation, Factor Analysis, Rotated Factor Analysis, and Item Distinctiveness Index Results of Microbiota Awareness Scale Items

	ltem Number	Average	Standard Deviation	Item Total Correlation	Factor Load	Rotated Factor Load	Item Distinctiveness Index
	1	3,86	1,33	0,506	0,607	0,856	9101
,	2	3,52	1,11	0,446	0,540	0,669	7526
0R	4	3,66	1,19	0,507	0,602	0,594	10331
FACTOR	5	3,63	1,12	0,470	0,563	0,685	8334
ш	6	3,97	1,12	0,572	0,656	0,709	10454
	13	3,86	1,25	0,579	0,670	0,477	11348
2	17	3,03	1,21	0,295	0,566	0,629	8140
0R	18	1,98	1,27	0,345	0,517	0,770	7150
FACTOR	19	1,67	0,96	0,376	0,679	0,764	7142
Ē	20	1,48	0,96	0,295	0,596	0,849	5348
	8	3,41	1,05	0,355	0,355	0,504	6246
R 3	10	3,42	1,04	0,288	0,323	0,663	5337
FACTOR	12	3,47	1,05	0,277	0,259	0,527	4727
FA	14	3,26	0,96	0,329	0,389	0,670	5864
	16	3,08	1,03	0,410	0,037	0,583	7514
	3	3,06	1,29	0,454	0,186	0,717	9547
R 4	7	3,05	1,29	0,467	0,234	0,821	10551
FACTOR	9	3,58	1,12	0,594	0,192	0,473	11957
FAC	11	3,40	1,04	0,522	0,225	0,543	9821
	15	3,47	1,05	0,603	0,145	0,556	12534

Table 2

Results Regarding the Reliability of the Scale

Factors	Item Number	Spearman Brown coefficient	Guttman Split Half	Cronbach Alfa		
Factor 1	6	0.804	0.803	0.806		
Factor 2	4	0.692	0.684	0.758		
Factor 3	5	0.641	0.606	0.639		
Factor 4	5	0.723	0.665	0.786		
Microbiota Awareness Scale	20	0.789	0.782	0.852		

Table 3

Confirmatory factor analysis compatibility values of the scale.

Model fit indices	Good Fit	Acceptable fit	Scale Values
NPAR			48
Chi-square(χ2)			326,797
p value	0,05 <p£1< td=""><td>0,001<p£0,05< td=""><td>0,000</td></p£0,05<></td></p£1<>	0,001 <p£0,05< td=""><td>0,000</td></p£0,05<>	0,000
Degrees of Freedom(df)			162
Chi-square / Degrees of Freedom (χ 2/df)	0£ χ2/sd £2	2< χ2/sd £3	2,017
The Root Mean Square Error of Approximation (RMESA)	0£ RMSEA£0,05	0,05< RMSEA£1	0,058
Standardized Root Mean Squared Residual (SRMR)	0£ SRMR£0,05	0,05< SRMR£1	0,061
Comparative Fit Index (CFI)	0,95£ CFI £1	0,90£ CFI <0,95	0,908
The Goodness of Fit Index (GFI)	0,95£ GFI £1	0,90£ GFI <0,95	0,904
Adjusted Goodness of Fit Index (AGFI)	0,90£ AGFI £1	0,80£ AGFI<0,90	0,876
Incremental Fit Index (IFI)	0,95£ IFI £1	0,90£ IFI <0,95	0,909
Tucker-Lewis Index (TLI)	0,95£ TLI £1	0,90£ TLI <0,95 (veya TLI>0,80)	0,892

Reliability, on the other hand, means that the expected results from the test are similar when a test is applied to the same individual more than once (13).

If the developed scale includes all the essential subheadings of the subject to be examined, it is concluded that the scale has content/content validity (13). In this study, the opinions of eleven experts were consulted for content validity, and the CVR and CGI values of the scale were calculated accordingly. Questions with negative or zero CVR values are removed from the scale with priority. At α =0.05 significance level, the smallest CVR value required for eleven experts is 0.59. CGI is the average of the CVR values of the items. The CGI value found is required to be greater than 0.67 (13). There was no question for the microbiota awareness scale with a negative CVR value, zero or less than 0.59, and the total CGI value of the scale was found to be 0.81. Since this value is greater than 0.67, the scale was evaluated as statistically significant.

The structure can be defined as the whole or the pattern formed by the items related to each other. Factor analysis is often used to determine to construct validity. Factor analysis is basically of two types as explanatory factor analysis and confirmatory factor analysis (13). While the factor structure in the data is tried to be determined in explanatory factor analysis, confirmatory factor analysis aims to test the statistical significance of the structure with a certain number of items. In other words, we can check with confirmatory factor analysis that the sample data confirms the proposed structure (13, 17). KMO, Bartlett Sphericity test, and antiimage correlation values were calculated to evaluate the scale's suitability for factor analysis. It is used to determine the adequacy of the sample size for KMO factor analysis and the Bartlett sphericity test to assess the adequacy of the correlation ratio between the variables (18). The suitability of each question for factor analysis is determined by the anti-image correlation (19). KMO takes a value between 0-1, and it is required to be more than 0.80 for good factor analysis. A Bartlett Test p value less than 0.05 indicates a sufficient level of correlation for factor analysis (18). If the anti-image correlation value is less than 0.50, exclude the relevant item from the analysis (20). The KMO coefficient of the Microbiota Awareness Scale was 0.834, and the chi-square value of the Bartlett test was found to be 1923.84 and was found to be significant (p<0.001). The anti-image correlation values of the questions in the scale were found above 0.50. The results obtained showed that factor analysis could be performed on the scale.

After these stages, the confirmatory factor analysis stage is started to test the predetermined structure's accuracy. Accordingly, how well the model created explains the obtained data is determined through fit indices (22). The fit values of the scale were found as $x^2/$ sd=2.017, RMSEA=0.058, SRMR=0.061, CFI=0.908, GFI=0.904, AGFI=0.876, IFI=0.909, and TLI=0.892. In line with the found fit indices, it was seen that the Microbiota Awareness Scale had good fit values, and the study was at an acceptable level.

The reliability of the scale includes internal consistency and stability. The Cronbach Alpha coefficient is frequently used to calculate the internal consistency of the Likert-type scale. The Cronbach Alpha coefficient for the whole scale was found to be 0.852. According to the literature, if the alpha coefficient is between 0.60-0.79, the scale is highly reliable, and if it is between 0.80-1, the scale is highly reliable (13). In this case, it can be said that the Microbiota Awareness Scale is highly reliable. Considering the sub-dimensions of the scale, it was found that general information subdimension (Cronbach Alpha value 0.806) was highly reliable, product knowledge (Cronbach Alpha value 0.758), chronic disease (Cronbach Alpha value 0.639), probiotic and prebiotic (Cronbach Alpha value 0.786) sub-dimensions were quite reliable. The scale's stability

Appendix

Microbiota Awareness Scale TR-Form- Mikrobiyota Farkındalık Ölçeği

Mikroorganizma: Gözle görülemeyen küçük canlı. Mikrobiyota: İnsanda farklı bölgelerde bulunabilen mikroorganizmaların tamamı. Probiyotik: Probiyotikler insanlarda çeşitli organların mikrobiyotasında yer alabilen mikroorganizmalardır. Prebiyotik: İnsan vücudunda bulunan probiyotiklerin gelişmesini teşvik eden bileşenlerdir.		Kesinlikle	katiimiyorum	Katılmıyorum	Kararsızım	Katılıyorum	Kesinlikle katılıyorum	
1.	İnsan vücudu çok sayıda mikroorganizma içermektedir.		_					
2.	Bağırsak mikrobiyotası bebek anne karnındayken oluşmaya başlamaktadır.							
3.	<u>Pre</u> biyotik ürünlerin neler olduğu hakkında bilgim var.							
4.	Antibiyotik kullanımı bağırsak mikrobiyotasını olumsuz yönde etkiler.							
5.	Bağırsak mikrobiyotasında meydana gelen bozulmalar obeziteye neden olur.							
6.	Beslenme şekli bağırsak mikrobiyotasını etkileyen önemli faktörlerden biridir.							
7.	Probiyotik ürünlerin neler olduğu hakkında bilgim var.							
8.	Mikrobiyotada meydana gelen değişiklikler bağırsak kanseri ile ilişkilidir.							
9.	Probiyotikler düzenli olarak tüketilmelidir.							
10.	Bağırsak mikrobiyotasında meydana gelen bozulmalar diyabete (şeker hastalığı) neden olur.							
11.	Probiyotik kullanımının ishal sorununu çözebileceğini düşünüyorum.							
12.	Bağırsaklarda zararlı bakteri sayısında meydana gelen artış alkole bağlı olmayan karaciğer yağlanmasına neden olabilir.							
13.	Anne sütü ile beslenme bebeğin bağırsak mikrobiyotasını olumlu yönde etkiler.							
14.	Bağırsak mikrobiyotasında meydana gelen değişiklikler çölyak hastalığıyla ilişkilidir.							
15.	Probiyotik kullanımının kabızlık sorununu çözebileceğini düşünüyorum.							
16.	Bağırsak mikrobiyotası ile depresyon ve alzheimer hastalıkları arasında ilişki vardır.							
17.	Aşağıdaki besinlerden probiyotik olanları kutucuk içine alınız. Kefir Çay Sirke Boza Yumurta		**					
18.	Aşağıdaki besinlerden prebiyotik olanları kutucuk içine alınız. Badem Muz Yulaf Soğan Kırmızı et		**					
19.	Probiyotik özelliğinden dolayı özellikle tükettiğiniz ürünleri yazınız.		***					
20.	Prebiyotik özelliğinden dolayı özellikle tükettiğiniz ürünleri yazınız.		***					

*1-16 arasındaki sorular kesinlikle katılmıyorum:1.....kesinlikle katılıyorum: 5 olacak şekilde 1-5 arası puanlanmalıdır.

**17 ve 18 sorular:

(Doğru yanıt; 17: Kefir, sirke, boza- 18: Badem, muz, yulaf, soğan)

***19 ve 20 sorular: Her 1 doğru yanıta 1 eklenecektir, 4 ve üzeri doğru yapan 5 puan, hiç doğru yanıtı olmayan da 1 puan alacaktır.

^{(&}lt;u>işaretlenen doğru sayısı</u> Gerçek doğru sayısı – <u>işaretlenen yanlış sayısı</u>) *5 olarak hesaplanacak ve en yakın olduğu 1,2,3,4,5 rakamlarına yuvarlanacaktır.

was calculated by dividing the test into two halves. In this method, the test is divided into two halves. Spearman-Brown or Guttman approaches calculating the reliability coefficient between the two variables obtained from the sum of the items in each half. The Spearman-Brown coefficient of the scale was 0.789, and the Guttman coefficient was 0.782. According to the literature, if these coefficients are between 0.70-0.89, the scale is highly reliable, and if it is between 0.90-1, the scale is highly reliable (13). Accordingly, the scale is highly reliable in terms of stability.

Conclusion

As a result, the scale was constructed within the scope of this research to measure individual microbiota awareness. The Microbiota Awareness Scale was created due to the research and included 20 items and 4 sub. The scale's lowest score is 18, and highest score is 100. The high score obtained from the scale was evaluated as a high level of microbiota awareness. Explanatory and confirmatory factor analyzes obtained provided reliability and validity. Accordingly, it was determined that the Microbiota Awareness Scale could be used as a reliable and valid scale. It is thought that the developed scale will contribute to the literature within the scope of determining the microbiota awareness levels of individuals and taking the necessary precautions with the results obtained. The Microbiota Awareness Scale and TR-form are shown in Appendix.

Acknowledgment

This study, carried out within the framework of the Suleyman Demirel University Health Sciences Institute Public Health Department Master's Program, was approved by the Council of Higher Education as the thesis study numbered 641344.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Ethical Approval

Ethical approval was obtained from Suleyman Demirel University Faculty of Medicine Clinical Research Ethics Committee (Number: 326, Date: 29.11.2019).

Consent to Participate and Publish

Written informed consent to participate and publish was obtained from all individual participants included in the study.

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