

Test-retest Repeatability; Integrated assessment of adherence to treatment questionnaire for Cardiometabolic Diseases

Vasiliki Belitsi¹, Thomas Tsiampalis^{1,2}, Vasiliki Kalantzi¹, Odysseas Androutsos¹, Fotini Bonoti¹, Demosthenes B. Panagiotakos^{2,3}, Rena I. Kosti¹

¹Department of Nutrition and Dietetics, School of Physical Education, Sports and Dietetics, University of Thessaly, Trikala, Greece

²Department of Nutrition and Dietetics, School of Health Science and Education, Harokopio University, Athens, Greece

³Faculty of Health, University of Canberra, Canberra, Australia

ABSTRACT

Aim: Low adherence to health-related behaviors to treatment is still a major public health challenge in primary healthcare settings. Our aim was to assess the repeatability of a tool that can be used by health care professionals in the primary health care sector, as a means to evaluate the degree of adherence to medication and recommended lifestyle changes of patients with cardiometabolic diseases while simultaneously identifying potential treatment obstacles.

Material: The Integrated Assessment of Adherence to Treatment Questionnaire for Cardio Metabolic Diseases (IAATQ-CMD) tool includes 126 questions concerning the following domains: (i) socio-demographic characteristics, (ii) medical history, (iii) dietary and lifestyle habits, (iv) healthcare system, (v) patients' disease/treatment/health status awareness, (vi) adherence to medication (vii) self-efficacy to medication and lifestyle changes, and (viii) therapeutic treatment views/perceptions. In order to evaluate the repeatability of the IAATQ-CMD tool, Cohen's kappa statistic was calculated for qualitative questions, while Kendall's tau-b and the Bland & Altman methods were applied for quantitative questions.

Results: Fifty individuals (Mean (Standard Deviation (SD)): (66 (14) years old; 68% females) were recruited for the repeatability process. The repeatability of all parts of the IAATQ-CMD questionnaire was found to be adequate, as the relevant statistics (Cohen's kappa, Kendall's tau-b and the Bland & Altman method) ranged in acceptable limits.

Corresponding author:

Associate Professor Rena I. Kosti
Department of Nutrition and Dietetics
School of Physical Education, Sports and Dietetics,
University of Thessaly, Trikala, Greece
Argonafton 1Γ, Trikala 421 32
Tel. +30 2431 023602
E-mail: renakosti@uth.gr

Submission: 20.12.2022, Acceptance: 22.01.2023

Conclusions: The IAATQ-CMD questionnaire was found to be a substantially repeatable tool that can assess patients' adherence to medication and lifestyle changes while simultaneously identifying potential treatment barriers in need of actionable interventions.

KEY WORDS: *Diet, medication, adherence, questionnaire, health behavior*

INTRODUCTION

According to the European Society of Preventive Medicine (ESPReVMed), it is projected that by 2030 the deaths from cardiovascular diseases (CVDs) will reach the tremendous number of 23.3 million, keeping CVDs as the leading cause of death globally.¹ Medication adherence, which according to the World Health Organization (WHO) is defined as "the degree to which the person's behavior corresponds with the agreed recommendations from a health care provider",² still remains a crucial problem for CVD patients.³ Poor medication adherence leads to poor clinical outcomes, such as re-hospitalization, increased mortality,^{3,4} and subsequent serious public health implications.⁵ According to the literature almost half of CVD patients are poor adherers to prescribed medications,^{6,7} and therefore healthcare professionals need to utilize multiple approaches, design effective health interventions and identify simple solutions, in order to improve and maintain their patients' short and long-term medication adherence levels.^{8,9}

On top of that, the majority of CVDs could be preventable through the adoption of healthy behavioral habits (i.e., tobacco cessation, healthy dietary habits, loss of weight, physical activity, and moderate use of alcohol). According to a recently conducted microsimulation study in Greece, it was shown that improving the adherence level to the Mediterranean diet in at least 10% of the population, could lead to a significant reduction in 10-year CVD onset, recurrence, and mortality.¹⁰ However, on a global level the overall "ideal cardiovascular health" through the adoption of healthy lifestyle remains well below optimal levels.¹¹ It is therefore obvious that the combined synergistic effect of adherence to both medication and healthy lifestyle habits is a one-way approach to combat the burden of CVD in primary health care settings in an efficient and effective manner. However, there is scarce evidence regarding the development of tools encompassing all related to adherence axes using the WHO conceptual framework accounting for their interaction in a rather multi-dimensional and integrated approach.^{12,13}

Therefore, the present study aims to develop for the first time and test the repeatability of the Integrated Assess-

ment of Adherence to Treatment Questionnaire in Cardio Metabolic Diseases (IAATQ-CMD), a new patient-based tool that can be used in primary health care settings, and can evaluate the degree of adherence to medication and healthy lifestyle habits in patients with cardiometabolic risk factors while concomitantly identifying the key treatment obstacles, taking into consideration the reported cultural diversity among different populations.¹⁴

MATERIAL

Questionnaire development

The development of the IAATQ-CMD was based on the following five pylons: (I) the multidimensional conceptual model developed by WHO¹² referring to the five-dimensional domains affecting medication adherence; (II) the American Heart Association's (AHA) recommended rapid diet screener tools¹⁵; (III) existing validated scales estimating the level of medication adherence and/ or medication self-efficacy¹⁶⁻²⁴; (IV) the clinical practice guidelines on the primary prevention of CVDs^{25,26}; and (V) the published literature concerning the beliefs, perceptions, and self-efficacy related to adherence both to medication and to recommended health behavior modifications.²⁷⁻³⁰

On the basis of this information, we developed a conceptual draft to guide the development of the preliminary versions of the IAATQ-CMD consisting of five core content domains: (i) sociodemographic factors, (ii) disease-related factors, (iii) treatment-related factors including medication and lifestyle habits, (iv) health care system factors, as well as (v) self-efficacy/perceptions/awareness/social factors. We then generated questionnaire items for all content domains guided by: literature findings per domain as regards the potential reasons for non-adherence to treatment in cardiometabolic diseases^{27,29}; literature findings relevant to recommended healthy lifestyle habits and behaviors^{25,26}; borrowed specific items and/or validated scales from existing questionnaires^{16,24} following the approval of the corresponding authors. Some items were specifically customized to cardiometabolic patients, cultural characteristics as well as the culinary habits of the Mediterranean region.

We pre-tested the preliminary version of the IAATQ-CMD through face-to-face interviews with 10 health care professionals in primary care settings (health visitors, general practitioners, internal medicine doctors, cardiologists, sociologists and psychologists) in order to evaluate content validity, clarity and appropriateness of wording, item sequence as well as completeness and integrity of items. Minor modifications were made to the pre-test questionnaires to produce field test versions of the IAATQ-CMD as regards questionnaire format in Google forms, instructions of use and consent in accordance to General Data Protection Regulation (GDPR).

Ethic approval and consent to participate

The study was implemented in accordance with the ethical standards of the University of Thessaly Ethics Committee (Ethics 11-14/07/2022) and with the Declaration of Helsinki (1989). All patients were informed on the confidentiality, aims and procedures of the study.

Structure and content of the Questionnaire

Elements of seven (7) questionnaires were included in the final version of the IAATQ-CMD. These include the r-MEDAS questionnaire^{21,23} (12 questions), the MedDiet Score¹⁸ (8 questions), the Morisky Medication Adherence Scale MMAS-4 and MMAS-8^{16,20} (5 questions), the Self-Efficacy for Appropriate Medication Use Scale SEAMS¹⁹ (6 questions), MASES-R²⁴ (7 questions) and the Hill-Bone Scale¹⁷ (4 questions). It is noted that several questions were common in the above-mentioned questionnaires, while the remaining questions were formulated based on literature findings. Nevertheless, permission was requested and granted by all authors whose questionnaires are used in a solid, partial or modified way for the purposes of our research. The questionnaire consists of total 126 questions spread in eight (8) subsections having different type of response formats as follows:

Socio-Demographic Characteristics (9 questions)

Age, weight and height were self-reported. This section also includes questions related to educational level, professional and marital status, as well as family/ personal income.

Medical history (17 questions)

The medical history, count and frequency of patients' pills intake per disease and total years of suffering since the diagnosis are also included. The diseases investigated are hypertension, type II diabetes, type I diabetes, hypercholesterolemia, elevated triglycerides, obesity, coronary heart disease, stroke, fatty liver (non-alcoholic fatty liver

disease). There also exists a question on whether patients suffer from any other diseases (comorbidities) with the form of YES/NO. If YES the principle investigator records the answer in the last section.

Dietary and Lifestyle Assessment (56 questions)

This section incorporates questions related to dietary by including all major food groups and lifestyle habits. The frequency of consumption ranged from "Never", " ≤ 1 ", "1-2", "2-3", "3-4", "5-6", " > 6 ", or "Never", "1", "2", "3", "4", " > 4 ", "Daily", and "Yes/No" depending on whether the question measures serving frequency or habits of consumption. New questions were also created in order to incorporate consumption habits of Greek traditional dishes as well as lifestyle habits such as physical activity (frequency, duration, type of exercise), smoking habits (yes/no, duration), sedentary behavior, sleep (hours), weight control (yes/no) and social life (dinning out with friends).

Dietary habits in terms of the overall consumption of fruits, vegetables, lean and red meat, fish, dairy, legumes, salt, sugar and alcohol among others are being recorded. More specific questions regarding alcohol consumption are included (type of alcoholic beverage and drinking pattern). Pictures from the Greek "National Dietary Guidelines for Adults" were used as reference portion guide in order to best describe food portions, ensuring comprehension and avoid discrepancies.

Health care system (3 questions)

Likert scale questions in the form of "Satisfactory", "Moderate", "Inadequate" are used in order for the participants to be able to rate the Primary Health Care System in Greece based on their experience in terms of the availability of healthcare professionals, time devoted during the visit and ease of access.

Adherence to medication (11 questions)

Likert scale questions in the form of "Never", "Sometimes", "Most times", "Always" or (Yes/No) are used in order for the participants to be able to express the reasons of non-adherence to medication.

Awareness of disease, therapeutic treatment and health status (5 questions)

Patients' awareness as regards to the severity of their symptoms, the long term life implications of their disease, the clarity of the recommendations (both in terms of medication and lifestyle changes) received by the healthcare professionals relevant to their treatment, are asked with the form of YES/NO as well for their health status in the

form of Likert scale questions (“Excellent”, “Very Good”, “Good”, “Medium”, “Poor”).

Evaluation of Self-efficacy to Medication and Lifestyle Adherence (15 questions)

Self-efficacy is evaluated through questions by the use of Likert Scale. Questions in the form of “I am not confident”, “I am confident”, “I am very confident” are used to evaluate participants’ confidence in their ability to take their medications. Questions in the form of “Not at all”, “A little bit”, “Moderately”, “Enough”, “Very” are used for the evaluation of patients’ self-efficacy to healthy life style changes (i.e. alcohol consumption, physical activity, smoking habits and diet).

Therapeutic treatment Views/Perceptions (10 questions)

Likert scale questions in the form of “Agree”, “I am not sure”, “Disagree” are used to assess patients views, and perceptions on drugs (polypharmacy, toxicity, necessity, importance, substitution with other traditional “remedies”), as well as the significance of lifestyle changes for the management of their disease.

Test and Re-test repeatability

Patient Selection and Recruitment

Patients who visit Primary Health Care settings were recruited from the primary health care units of the metropolitan area of Athens. Inclusion criteria were Greek nationality, being at least 18 years of age, suffering from at least one of the following diseases: hypertension, type II diabetes, type I diabetes, hypercholesterolemia, elevated triglycerides, obesity, coronary heart disease, stroke, fatty liver (non-alcoholic fatty liver disease) and taking medication for their relevant condition for at least a year. Patients with psychiatric disorders such as schizophrenia, bipolar disease or dementia were excluded.

Following the approval from the ethics committee of the University of Thessaly, patients were sent informed consent forms, information sheets, and questionnaires by e-mail. More specifically, the IAATQ-CMD questionnaire was sent via e-mail and was completed on line. A trained investigator was virtually present throughout the whole procedure of completing the questionnaire to address any potential misconceptions. The completion of the questionnaire lasted on average 16 min. Fifty participants, who were randomly selected through the medical registry of the central metropolitan primary health care unit (aged Mean (Standard Deviation (SD)): 66 (14) years) completed

the IAATQ-CMD twice with an interval of 2 weeks, for test-retest reliability.

Statistical Analysis

Demographic and clinical characteristics are presented in terms of Mean (Standard Deviation (SD)) values and absolute (N) and relative (%) frequencies, in case of continuous and categorical characteristics respectively. To evaluate the repeatability of the questionnaire related to the participants’ nutritional habits, Spearman’s rho and the Kendall’s tau-b coefficients^{31,32} were calculated from the information provided by the two administrations. Furthermore, to further evaluate the results for the agreement between the two administrations the Wilcoxon signed-rank test for the difference (bias) in intake, as well as the Bland & Altman method of agreement,³³ were also applied. With respect to the Bland & Altman method the limits of agreement were calculated as mean(difference) \pm 1.96 standard deviation(difference), assuming normal distribution of the differences. Normality was tested using Q-Q plots. As for the rest aspects of the questionnaire, due to their categorical nature, the Cohen’s kappa coefficient of agreement was calculated, the interpretation of which is³⁴: values \leq 0 as indicating no agreement and 0.01–0.20 as none to slight, 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1.00 as almost perfect agreement. All statistical analyses were performed in STATA version 17.

RESULTS

Sample characteristics

Regarding the sample characteristics, as depicted in Table 1, all participants were Greek, the majority of whom were females (68%) and their mean (SD) age was equal to 66 (14) years old. As for their educational level, 34% of the participants were at least of undergraduate level, while as regards their occupational status, 64% of the participants were retired and 30% of them were working either as state/ private employees, or as freelancers. Finally, the yearly personal/ family income of the 48% of the participants was at least equal to 18,000€. As for their clinical characteristics, the most frequently diagnosed disease was hypertension (68%), followed by hypercholesterolemia (56%) and diabetes mellitus II (44%), while only 2 participants were diagnosed with diabetes mellitus I, kidney disease and stroke.

Repeatability of the questionnaire related to nutrition

Food groups’ comparison suggested that the sub-

TABLE 1. Demographic and clinical characteristics of the 50 participants who participated in the repeatability study.

Demographic characteristics		Demographic characteristics	
Nationality [Greek]	50 (100)	Married	29 (58)
Sex [Female]	34 (68)	Widowed	13 (26)
Age [Mean (SD); years]	66.1 (14.5)	Divorced	4 (8)
Body Mass Index [BMI; Mean (SD); kg/m ²]	29.5 (6.3)	Cohabitation	2 (4)
Educational level		Single without cohabitation	0 (0)
Graduate of Primary school	16 (32)	Other	0 (0)
Graduate of High school	4 (8)	Personal/ Family income	
Graduate of Lyceum	11 (22)	<12000 €/ year	10 (20)
Graduate of Technical Lyceum	2 (4)	12 – 18000 €/ year	16 (32)
Undergraduate level	6 (12)	18 – 24000 €/ year	13 (26)
Postgraduate level	5 (10)	24- 30000 €/year	6 (12)
PhD level	1 (2)	>30000 €/ year	5 (10)
Other	5 (10)	Clinical characteristics	
Occupation		Hypertension	34 (68)
State employee	5 (10)	Diabetes Mellitus II	22 (44)
Private employee	8 (16)	Diabetes Mellitus I	2 (4)
Freelancer	2 (4)	Hypercholesterolaemia	28 (56)
Retired	32 (64)	Increased levels of triglycerides	12 (24)
Unemployed	0 (0)	Obesity	7 (14)
Undergraduate student	0 (0)	Coronary heart disease	8 (16)
Other	3 (6)	Stroke	2 (4)
Marital status		Kidney Disease	2 (4)
Single	2 (4)	Fatty liver (non-alcoholic fatty liver disease)	10 (20)

Notes: Results are presented in the form N (%), except otherwise mentioned

questionnaire related to nutrition was repeatable for all of them, as there were no significant differences in the consumption of the food groups between the two phases. Moreover, Kendall’s tau-b ranged from 0.807 for “potatoes” to 0.993 for “soft drinks”. Similar results were found using the Spearman’s rho coefficient, with its values being a little bit higher compared to the respective values of the Kendall’s tau- b. The Bland & Altman method revealed acceptable mean differences and limits of agreement (Table 2).

Repeatability of the questionnaire related to lifestyle

As regards to the agreement in the questions related to the lifestyle characteristics of the participants, depicted in Table 3, Cohen’s kappa ranged between 0.802 and 1 for all the questions, except for beer consumption, suggesting that the agreement between the two phases was perfect.

Regarding beer consumption, Cohen’s kappa was found to be equal to 0.769, suggesting a substantial agreement between the two recordings.

Repeatability of the questionnaire related to primary healthcare system, treatment of patients and factors related to their disease status and treatment

As depicted in Table 4, the agreement between the two phases was perfect in all cases (Cohen’s kappa> 0.8), except for the questions: “Do you consider the ability to access primary care centers to be satisfactory?” (Cohen’s kappa= 0.775), “Physician’s guidelines for lifestyle changes due to health status” (Cohen’s kappa= 0.658) and “How often do you miss scheduled appointments?” (Cohen’s kappa= 0.697), where the Cohen’s kappa statistic revealed a substantial agreement, as well.

TABLE 2. Results regarding the repeatability of the FFQ in terms of food groups intake (N= 50).

Servings [Median (Q1-Q3)]:	Phase I	Phase II	p-value*	Kendall's tau-b	Bland & Altman method		Spearman's rho
					Mean difference	Limits of agreement	
<i>Daily consumption of:</i>							
Vegetables	1.5 (0.5- 1.5)	1.5 (0.5- 1.5)	0.276	0.951***	-0.03(0.21)	-0.45, 0.39	0.964***
Fruits	2 (1- 2)	2 (0.5- 2)	0.168	0.839***	-0.15(0.76)	-1.63, 1.33	0.859***
Bread	0.5 (0.5- 1.5)	0.5 (0.5- 1.5)	0.334	0.852***	0.06(0.47)	-0.86, 0.98	0.885***
Dairy products	1.5 (1.5- 2)	1.5 (1.5- 2)	0.516	0.927***	0.06(0.42)	-0.77, 0.89	0.948***
<i>Weekly consumption of:</i>							
Potatoes	2 (2- 2)	2 (2- 2)	0.157	0.807***	0.08(0.40)	-0.70, 0.86	0.808***
Red meat	1 (1- 1.5)	1 (1- 1.5)	0.458	0.931***	-0.02(0.22)	-0.46, 0.42	0.947***
Processed meat	1 (0- 2.5)	1 (0- 2.5)	>0.999	0.959***	0.01(0.38)	-0.74, 0.76	0.974***
White meat	1.5 (1- 1.5)	1.5 (1- 1.5)	0.763	0.920***	0.02(0.47)	-0.91, 0.95	0.947***
Legumes	1.5 (1- 1.5)	1.5 (1- 1.5)	0.655	0.941***	-0.03(0.29)	-0.60, 0.54	0.949***
Fish/ Seafood	1 (1- 1.5)	1 (1- 1.5)	0.102	0.934***	0.05(0.21)	-0.36, 0.46	0.945***
Eggs	2 (1- 3)	2 (1- 3)	0.655	0.938***	0.02(0.32)	-0.60, 0.64	0.959***
Nuts	0.25 (0- 0.5)	0.5 (0- 0.5)	0.888	0.942***	0.01(0.29)	-0.57, 0.59	0.963***
Butter, Margarine, etc.	0 (0- 0.5)	0 (0- 0.5)	0.317	0.986***	-0.01(0.07)	-0.15, 0.13	0.993***
Soft drinks	0 (0- 0.5)	0 (0- 0.5)	0.317	0.993***	-0.03(0.21)	-0.45, 0.39	0.999***
Sweets	2 (1- 3)	2 (1- 3)	0.257	0.934***	-0.06(0.37)	-0.79, 0.67	0.958***

Notes: Q1: 25-th percentile; Q3: 75-th percentile; *Wilcoxon signed rank test in case of continuous variables;***p< 0.001

Repeatability of the questionnaire related to the participants' abilities to take their medication and to keep up with the changes in their lifestyle habits, as well as their views/ perceptions for the therapeutic treatment

As regards to the participants' abilities to take their medication (Table 5), the vast majority stated that they have the ability to take their medication even in cases when they feel frustrated, or no one reminds them. As for the agreement between the two phases, based on the Cohen's kappa statistic (all values > 0.625), there was a substantial level of agreement between the two phases of the study. Regarding their ability to keep up with the changes in their lifestyle habits, in all cases at least 68% of the participants stated that they can keep up with these changes, while the agreement between the two phases was substantial in all questions (all Cohen's kappa statistics > 0.723). Finally, when it comes to the participants' opinion about their medication, the vast majority of them supported the medication's usefulness, as just 1 participant agreed that the negative effects of drugs outweigh the positive ones, while

at least 9 out of 10 participants supported that both the use of drugs and lifestyle changes are necessary for the effective treatment of a disease. Finally, the agreement between the two phases, was perfect in all questions, as the Cohen's kappa statistic ranged between 0.732 and 1.

DISCUSSION

Data analysis revealed good repeatability of all parts of the IAATQ-CMD questionnaire. In particular, Kendall's tau-b, in case of the questions related to the nutritional habits of the patients, as well as the Cohen's kappa coefficient in all other cases, demonstrated excellent degree of agreement, for the repeatability of the IAATQ-CMD questionnaire. Furthermore, the Bland & Altman method also revealed acceptable mean differences and limits of agreement between the two phases of the questionnaire administration. It should also be noted that based on the Wilcoxon signed-rank test, a method that has been already used in various validation studies,³⁵ there were no significant differences in the median intake of the various food groups.

TABLE 3. Results regarding the repeatability of the questionnaire related to the lifestyle habits of the participants (N= 50).

	Phase I	Phase II	k- Measure of agreement	p-value
<i>Type of alcohol consumption [N (%) Yes]:</i>				
All types of alcohol	18 (36)	20 (40)	0.915	<0.001
Wine	12 (24)	12 (24)	1.000	<0.001
Whiskey	5 (10)	5 (10)	1.000	<0.001
Ouzo/ Tsipouro	7 (14)	7 (14)	0.926	<0.001
Beer	15 (30)	16 (32)	0.769	<0.001
Beer without alcohol	3 (6)	3 (6)	1.000	<0.001
Other preference	3 (6)	3 (6)	1.000	<0.001
<i>Do you only drink alcohol during your meals? [N (%) Yes]</i>	28 (56)	29 (58)	0.959	<0.001
<i>Do you add sugar to your coffee or tea? [N (%) Yes]</i>	28 (56)	29 (58)	0.959	<0.001
<i>Do you tend to remove the visible fats from your food? [N (%) Yes]</i>	31 (62)	31 (62)	0.957	<0.001
<i>Do you tend to add salt to your meal/ salad? [N (%) Yes]</i>	23 (46)	28 (56)	0.802	<0.001
<i>Do you prefer grilled instead of fried food? [N (%) Yes]</i>	42 (84)	43 (86)	0.834	<0.001
<i>Do you prefer home-cooked food instead of delivery food? [N (%) Yes]</i>	46 (92)	47 (94)	0.847	<0.001
<i>Do you prefer to consume a variety of vegetables and fruits? [N (%) Yes]</i>	40 (80)	40 (80)	1.000	<0.001
<i>Questions regarding the participants' lifestyle habits</i>				
<i>Physical activity [N (%) Yes]</i>	19 (38)	20 (40)	0.917	<0.001
<i>Frequency of physical activity for at least 30 minutes [N (%) 3-4 times/ week]</i>	7 (37)	7 (35)	1.000	<0.001
<i>Type of physical activity [N (%) Walking]</i>	18 (95)	18 (90)	1.000	<0.001
<i>Smoking habits [N (%) Smoker]</i>	9 (18)	9 (18)	1.000	<0.001
<i>Sleeping hours [N (%) 6-8 hours/ day]</i>	27 (54)	30 (60)	0.897	<0.001
<i>Elimination of sedentary lifestyle after being diagnosed with your disease [N (%) Yes]</i>	25 (50)	25 (50)	0.960	<0.001
<i>Do you sleep at noon? [N (%) Yes]</i>	30 (60)	30 (60)	1.000	<0.001
<i>Going out with friends [N (%) At least 2 times/ week]</i>	12 (24)	12 (24)	1.000	<0.001
<i>Do you control your weight frequently? [N (%) Yes]</i>	34 (68)	33 (66)	0.864	<0.001

According to the relevant literature, the level of adherence to CVD medication has been proposed to be assessed using self-report tools such as MMAS-4 MMAS-8, SEAMS, HBCS which are practical in daily routine examinations, have low cost, and are easy to administrate.³⁶ However, AHA suggests the use of rapid diet screener tools in the primary care sector, designed to facilitate clinical decision-making for actionable health behavior modifications, such as the Mediterranean Diet Adherence Screener although new tools (MEDAS).¹⁵

The lack of consistent treatment adherence of patients is an additional cause of frustration in health care providers due to the time constraints that they face.³ Moreover literature findings suggest that unintentional non-adherence such as forgetfulness or carelessness may

be rooted on medication perceptions, sociodemographic characteristics and type of chronic disease.³⁷

Thus, given that adherence has been proven to be associated beyond disease and therapy factors, with healthcare, patient and social factors (in accordance to the Multidimensional Model proposed by the World Health Organization¹² the simultaneous identification of patients' views/perceptions for the therapeutic treatment as well as their self-efficacy toward healthy lifestyle behaviors is equally important for actionable interventions.

CONCLUSIONS

The IAATQ-CMD questionnaire is the first of its kind that incorporates all elements necessary for the overall

TABLE 4. Results regarding the repeatability of the questionnaire related to primary healthcare system, treatment of patients and factors related to their disease status and treatment (N= 50).

Questions regarding the primary healthcare system	Phase I	Phase II	k- Measure of agreement	p-value
The availability of physicians for managing the diseases is satisfactory [N (%) Yes]	41 (82)	40 (80)	0.872	<0.001
The time the physicians devote to you in order to inform you about your disease status is satisfactory [N (%) Yes]	38 (76)	40 (80)	0.884	<0.001
Do you consider the ability to access primary care centres to be satisfactory? [N (%) Yes]	30 (60)	32 (64)	0.775	<0.001
Questions regarding the treatment of patients:				
Physician's guidelines for lifestyle changes due to health status [N (%) Yes]	48 (96)	48 (96)	0.658	<0.001
Physician's guidelines regarding the way of taking medicine* [N (%) Yes]	50 (100)	49 (98)	-	-
Evaluation of health status [N (%) At least good]	34 (68)	38 (76)	0.879	<0.001
Questions regarding the factors related to the disease status				
Do you think the symptoms of your disease are serious? [N (%) Yes]	28 (56)	28 (56)	0.959	<0.001
Do you know the effects/risks of your disease on your life in the long term? [N (%) Yes]	49 (98)	49 (98)	1.000	<0.001
Questions regarding the factors related to treatment				
Have you ever forgotten to take your medicine? [N (%) Yes]	28 (56)	30 (60)	0.836	<0.001
Have you ever faced any problem of remembering to take your medicine? [N (%) Yes]	19 (38)	20 (40)	0.874	<0.001
Do you stop your medicine, when you feel that your health status is good? [N (%) Yes]	9 (18)	9 (18)	0.864	<0.001
Are there times when you stopped taking your medication because you felt worse when you took it? [N (%) Yes]	11 (22)	9 (18)	0.875	<0.001
How often do you stop/ change the dose of your medicine without informing your doctor? [N (%) Most of the time/ Always]	7 (14)	5 (10)	0.811	<0.001
How often do you run out of medication? [N (%) Most of the time/ Always]	0 (0)	0 (0)	0.811	<0.001
How often do you plan ahead and refill your prescription medications before they run out? [N (%) Most of the time/ Always]	47 (94)	47 (94)	0.858	<0.001
How often do you make your next appointment before leaving the doctor's office? [N (%) Most of the time/ Always]	19 (38)	19 (38)	0.937	<0.001
How often do you miss scheduled appointments? [N (%) Most of the time/ Always]	0 (0)	0 (0)	0.697	<0.001
How often do you put off buying your medicines because they are expensive, and you cannot afford them? [N (%) Most of the time/ Always]	0 (0)	0 (0)	1.000	<0.001
How often do you have people around to take care of you? [N (%) Most of the time/ Always]	42 (84)	43 (86)	0.863	<0.001

Notes: k- statistic could not be computed as all the answers at phase I were constant (Yes)

evaluation of adherence to medication and necessary lifestyle behaviours of patients with cardiometabolic diseases in primary health care settings, while simultaneously allowing the health care professional to identify potential treatment barriers for actionable interventions. Overall, the IAATQ-CMD tool could be

considered a quick screening tool taking on average 16 min for completion and can be used both for assessing patients' adherence to medication and lifestyle changes for actionable interventions in clinical practice as well as for research purposes. The early identification of potential barriers to treatment by health care

TABLE 5. Results regarding the repeatability of the questionnaire related to the participants' abilities to take their medication and to keep up with the changes in their lifestyle habits, as well as their opinions for the medication's prescription (N= 50).

Participants' ability to take their medicine in the right way when:	Phase I	Phase II	k- Measure of agreement	p-value
You take many different medications and in different dosages every day? [N (%) Quite/ Much]	47 (94)	47 (94)	0.782	<0.001
You are away from home for travel or business? [N (%) Quite/ Much]	46 (92)	46 (92)	0.696	<0.001
No one reminds you to take the medicine? [N (%) Quite/ Much]	45 (90)	45 (90)	0.808	<0.001
You are with others in a public place and you don't want to be seen taking your medication? [N (%) Quite/ Much]	48 (96)	47 (94)	0.625	<0.001
You feel frustrated, sad and lonely? [N (%) Quite/ Much]	45 (90)	47 (94)	0.728	<0.001
You have no symptoms? [N (%) Quite/ Much]	46 (92)	46 (92)	0.717	<0.001
Participants' ability to keep up with the changes in their lifestyle habits when:				
Others eat foods in the house that are not part of your diet? [N (%) At least Moderate]	39 (78)	40 (80)	0.839	<0.001
Others drink alcohol excessively? [N (%) At least Moderate]	43 (86)	43 (86)	0.874	<0.001
You have anxiety/stress and negative emotions? [N (%) At least Moderate]	39 (78)	40 (80)	0.791	<0.001
You are out of the house (being invited to a social gathering/table/etc)? [N (%) At least Moderate]	34 (68)	34 (68)	0.723	<0.001
Your partner/friend smokes? [N (%) At least Moderate]	42 (84)	42 (84)	0.866	<0.001
Your life is burdened with many obligations and you don't have time for yourself to exercise? [N (%) At least Moderate]	37 (74)	38 (76)	0.756	<0.001
You will deprive yourself of taste and the ability to eat freely to improve your health for the rest of your life? [N (%) At least Moderate]	40 (80)	39 (78)	0.844	<0.001
N (%) of agreement with the following statements:				
Doctors prescribe more drugs than what is necessary	10 (20)	10 (20)	0.937	<0.001
The occasional cessation of drug intake is necessary for better "response to drugs"	1 (2)	1 (2)	0.941	<0.001
The negative effects of drugs outweigh the positive ones	1 (2)	1 (2)	1.000	<0.001
Taking drugs routinely forms a "dependency"	6 (12)	6 (12)	0.850	<0.001
Alternative traditional "remedies" are better than drugs for my disease	3 (6)	6 (12)	0.827	<0.001
I'd rather take medication than restrict my diet and lifestyle	12 (24)	11 (22)	0.905	<0.001
I am willing to change my habits rather than take medications	23 (46)	22 (44)	0.906	<0.001
Both the use of drugs and lifestyle changes are necessary for effective treatment	47 (94)	46 (92)	0.848	<0.001
I believe that changes in my lifestyle portray an important role in the course of my health	47 (94)	45 (90)	0.732	<0.001
I use alternative treatments (herbal medicines or supplements) without informing my doctor	4 (8)	4 (8)	0.816	<0.001

providers could shed light on the distinction between patients' intentional and unintentional non-adherence to treatment related behaviors. The proactive identification and corresponding management of patients' unhealthy unintentional behaviours resulting from their wrong views and perceptions before they become

an intentional pattern, could decrease the burden of cardiometabolic diseases.

Funding

Non declared

Conflicts of Interest

Non declared

ΠΕΡΙΛΗΨΗ

Έλεγχος της Επαναληψιμότητας του Εργαλείου για την Ολιστική Αξιολόγηση του Βαθμού Συμμόρφωσης στη Θεραπεία Ασθενών με Καρδιομεταβολικά Νοσήματα

Βασιλική Μπελίτση¹, Θωμάς Τσιάμπαλης^{1,2}, Βασιλική Καλαντζή¹, Οδυσσέας Ανδρούτσος¹, Φωτεινή Μπονώτη¹, Δημοσθένης Β. Παναγιωτάκος^{2,3}, Ρένα Ι. Κωστή¹

¹Τμήμα Διαιτολογίας και Διατροφολογίας, Σχολή Επιστημών Φυσικής Αγωγής, Αθλητισμού και Διαιτολογίας, Πανεπιστήμιο Θεσσαλίας, Τρίκαλα, Ελλάδα, ²Τμήμα Επιστήμης Διαιτολογίας - Διατροφής, Σχολή Επιστημών Υγείας και Αγωγής, Χαροκόπειο Πανεπιστήμιο, Αθήνα, Ελλάδα, ³Σχολή Υγείας, Πανεπιστήμιο της Καμπέρα, Καμπέρα, Αυστραλία

Σκοπός: Σκοπός της μελέτης ήταν ο έλεγχος της επαναληψιμότητας ενός εργαλείου που μπορεί να χρησιμοποιηθεί από τους επαγγελματίες υγείας στον τομέα της πρωτοβάθμιας φροντίδας υγείας, ως μέσο αξιολόγησης του βαθμού συμμόρφωσης στη φαρμακευτική αγωγή και τις συνιστώμενες αλλαγές στον τρόπο ζωής ασθενών με καρδιομεταβολικά νοσήματα, εντοπίζοντας ταυτόχρονα πιθανά εμπόδια θεραπείας.

Υλικό: Το εργαλείο ολοκληρωμένης αξιολόγησης της συμμόρφωσης στη θεραπεία για καρδιομεταβολικά νοσήματα (IAATQ-CMD) περιελάμβανε 126 ερωτήσεις σχετικές με: (i) κοινωνικοδημογραφικά χαρακτηριστικά, (ii) ιατρικό ιστορικό, (iii) συνήθειες διατροφής και τρόπου ζωής, (iv) σύστημα υγειονομικής περίθαλψης, (v) κατάσταση υγείας ασθενών, (vi) βαθμό συμμόρφωσης (vii) αυτο-αποτελεσματικότητα (viii) απόψεις που αφορούν την θεραπεία. Για την αξιολόγηση της επαναληψιμότητας του εργαλείου IAATQ-CMD, χρησιμοποιήθηκαν ο συντελεστής kappa του Cohen για τις ποιοτικές μεταβλητές καθώς και ο συντελεστής tau-b του Kendall και η μέθοδος Bland & Altman για τις ποσοτικές μεταβλητές.

Αποτελέσματα: Πενήντα άτομα ηλικίας 66±14 ετών (68% γυναίκες) συμμετείχαν στη διαδικασία ελέγχου της επαναληψιμότητας του ερωτηματολογίου. Η επαναληψιμότητα όλων των συνιστωσών του εργαλείου IAATQ-CMD βρέθηκε επαρκής, καθώς οι στατιστικοί συντελεστές κυμαίνονταν σε αποδεκτά όρια (kappa του Cohen > 0.625 σε όλες τις μετρήσεις, tau-b του Kendall: 0.807 -0.993), ενώ παράλληλα στην περίπτωση των ποσοτικών μεταβλητών, η μέθοδος Bland & Altman υπέδειξε πως η μέση τιμή της διαφοράς μεταξύ των δύο μετρήσεων βρισκόταν στα αποδεκτά όρια συμφωνίας.

Συμπεράσματα: Το ερωτηματολόγιο IAATQ-CMD βρέθηκε να είναι ένα εργαλείο με επαρκή επαναληψιμότητα ώστε να μπορεί να αξιολογήσει τη συμμόρφωση των ασθενών στη φαρμακευτική αγωγή και τις αλλαγές στον τρόπο ζωής, ενώ ταυτόχρονα εντοπίζει πιθανά θεραπευτικά εμπόδια που χρειάζονται δραστικές παρεμβάσεις.

ΛΕΞΕΙΣ ΚΛΕΙΔΙΑ: Διατροφή, φαρμακευτική αγωγή, συμμόρφωση, ερωτηματολόγιο, συμπεριφορά υγείας

REFERENCES

- Mathers CD, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. Samet J, ed. PLoS Med [Internet]. 2006 Nov [cited 2022 Dec 2];3(11):e442. Available from: <https://doi.org/10.1371/journal.pmed.0030442> Doi:10.1371/journal.pmed.0030442
- Dobbels F, Damme-Lombaert RV, Vanhaecke J, Geest SD. Growing pains: Non-adherence with the immunosuppressive regimen in adolescent transplant recipients. *Pediatr Transplant*. 2005 Jun;9(3):381-90 Doi:10.1111/j.1399-3046.2005.00356.x
- Piña IL, Di Palo KE, Brown MT, Choudhry NK, Cvengros J, Whalen D, et al. Medication adherence: Importance, issues and policy: A policy statement from the American Heart Association. *Prog Cardiovasc Dis*. 2021 Jan-Feb;64:111-20 Doi:10.1016/j.pcad.2020.08.003
- Leslie KH, McCowan C, Pell JP. Adherence to cardiovascular medication: A review of systematic reviews. *J Public Health (Oxf)*. 2019 Mar;41(1):e84-e94 Doi:10.1093/pubmed/fdy088
- Simon ST, Kini V, Levy AE, Ho PM. Medication adherence in cardiovascular medicine. *BMJ [Internet]*. 2021 Aug [cited 2022 Nov 28]; n1493. Available from: <https://doi.org/10.1136/bmj.n1493> Doi:10.1136/bmj.n1493
- Kronish IM, Ye S. Adherence to cardiovascular medications: lessons learned and future directions. *Prog Cardiovasc Dis*. 2013 May;55(6):590-600. Doi:10.1016/j.pcad.2013.02.001

7. Naderi SH, Bestwick JP, Wald DS. Adherence to drugs that prevent cardiovascular disease: Meta-analysis on 376,162 patients. *Am J Med.* 2012 Sep;125(9):882-7.e1. Doi:10.1016/j.amjmed.2011.12.013
8. Cutler RL, Fernandez-Llimos F, Frommer M, Benrimoj C, Garcia-Cardenas V. Economic impact of medication non-adherence by disease groups: A systematic review. *BMJ Open [Internet].* 2018 Jan [cited 2022 Nov 28];8(1):e016982. Available from: <https://bmjopen.bmj.com/content/8/1/e016982> Doi:10.1136/bmjopen-2017-016982
9. Kwan YH, Weng SD, Loh DHF, Phang JK, Oo LJY, Blalock DV, et al. Measurement properties of existing patient-reported outcome measures on medication adherence: Systematic Review. *J Med Internet Res [Internet].* 2020 Oct [cited 2022 Nov 20];22(10):e19179. Available from: <https://pubmed.ncbi.nlm.nih.gov/33034566/> Doi:10.2196/19179
10. Kouvari M, Tsiampalis T, Chrysohoou C, Georgousopoulou E, Notara V, Souliotis K, et al. A Mediterranean diet micro-simulation modeling in relation to cardiovascular disease burden: The ATTICA and GREECS epidemiological studies. *Eur J Clin Nutr.* 2022 Mar;76(3):434-41. Doi:10.1038/s41430-021-00967-6
11. Younus A, Aneni EC, Spatz ES, Osondu CU, Roberson L, Ogunmoroti O, et al. A Systematic Review of the prevalence and outcomes of ideal cardiovascular health in US and Non-US populations. *Mayo Clin Proc.* 2016 May;91(5):649-70. Doi:10.1016/j.mayocp.2016.01.019
12. Sabate, E. (1970). World Health Organization [Accessed: 2022 Nov 6]. Adherence to long-term therapies: Evidence for action. Available from: <https://apps.who.int/iris/handle/10665/42682>.
13. Fernandez-Lazaro CI, García-González JM, Adams DP, Fernandez-Lazaro D, Mielgo-Ayuso J, Caballero-García A, et al. Adherence to treatment and related factors among patients with chronic conditions in primary care: a cross-sectional study. *BMC Fam Pract [Internet].* 2019 Sep [cited 2022 Nov 20];20(1):132. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6744672/> Doi:10.1186/s12875-019-1019-3
14. McQuaid EL, Landier W. Cultural issues in medication adherence: Disparities and Directions. *J Gen Intern Med.* 2018 Feb;33(2):200-6. Available from: <https://doi.org/10.1007/s11606-017-4199-3>
15. Vadiveloo M, Lichtenstein AH, Anderson C, Aspry K, Foraker R, Griggs S, et al. Rapid diet assessment screening tools for cardiovascular disease risk reduction across healthcare settings: A scientific statement from the American Heart Association. *Circ Cardiovasc Qual Outcomes [Internet].* 2020 Sep [cited 2022 Nov 22];13(9):e000094. Available from: <https://pubmed.ncbi.nlm.nih.gov/32762254/> Doi:10.1161/HCQ.0000000000000094
16. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care.* 1986 Jan;24(1):67-74. Doi:10.1097/00005650-198601000-00007
17. Kim MT, Hill MN, Bone LR, Levine DM. Development and testing of the hill-bone compliance to high blood pressure therapy scale. *Prog Cardiovasc Nurs.* 2000 Jun;15(3):90-6. Doi:10.1111/j.1751-7117.2000.tb00211.x
18. Panagiotakos DB, Pitsavos C, Arvaniti F, Stefanadis C. Adherence to the mediterranean food pattern predicts the prevalence of hypertension, hypercholesterolemia, diabetes and obesity, among healthy adults; the accuracy of the MedDietScore. *Prev Med.* 2007 Apr;44(4):335-40. Doi:10.1016/j.ypmed.2006.12.009
19. Risser J, Jacobson TA, Kripalani S. Development and psychometric evaluation of the Self-efficacy for Appropriate Medication Use Scale (SEAMS) in low-literacy patients with chronic disease. *J Nurs Meas.* 2007;15(3):203-19. Doi:10.1891/106137407783095757
20. Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive validity of a medication adherence measure in an outpatient setting. *J Clin Hypertens (Greenwich).* 2008 May;10(5):348-54. Doi:10.1111/j.1751-7176.2008.07572.x
21. Schröder H, Fitó M, Estruch R, Martínez-González MA, Corella D, Salas-Salvadó J, et al. A short screener is valid for assessing Mediterranean diet adherence among older Spanish men and women. *J Nutr.* 2011 Jun;141(6):1140-5. Doi:10.3945/jn.110.135566
22. Martínez-González MÁ, Corella D, Salas-Salvadó J, Ros E, Covas MI, Fiol M, et al. Cohort profile: Design and methods of the PREDIMED study. *Int J Epidemiol.* 2012 Apr;41(2):377-85. Doi:10.1093/ije/dyq250
23. Investigators tools. *Predimed.es.* [Accessed 2022 Nov 6]. Available from: <http://www.predimed.es/investigators-tools.html>
24. Ogedegbe G, Mancuso CA, Allegrante JP, Charlson ME. Development and evaluation of a medication adherence self-efficacy scale in hypertensive African-American patients. *J Clin Epidemiol.* 2003 Jun;56(6):520-29. Doi:10.1016/s0895-4356(03)00053-2
25. Arnett DK, Blumenthal RS, Albert MA, Buroker AB, Goldberger ZD, Hahn EJ, et al. 2019 ACC/AHA Guideline on the primary prevention of cardiovascular disease: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation.* 2019 Sep;140(11):e596-e646. Doi:10.1161/CIR.0000000000000678
26. Michos ED, Khan SS. Further understanding of ideal cardiovascular health score metrics and cardiovascular disease. *Expert Rev Cardiovasc Ther.* 2021 Jun;19(7):607-17. Doi:10.1080/14779072.2021.1937127
27. Castillo-Mayén R, Cano-Espejo C, Luque B, Cuadrado E, Gutiérrez-Domingo T, Arenas A, et al. Influence of self-efficacy and motivation to follow a healthy diet on life satisfaction of patients with cardiovascular disease: A Longitudinal Study. *Nutrients.* 2020 Jun;12(7):1903. Doi:10.3390/nu12071903
28. Cuadrado E, Gutiérrez-Domingo T, Castillo-Mayen R, Luque B, Arenas A, Tabernero C. The Self-Efficacy Scale for Adherence to the Mediterranean Diet (SESAMeD): A scale construction and validation. *Appetite.* 2018 Jan;120:6-15. Doi:10.1016/j.appet.2017.08.015
29. Kumar K, Greenfield S, Raza K, Gill P, Stack R. Understanding adherence-related beliefs about medicine amongst patients of South Asian origin with diabetes and cardiovascular disease patients: A qualitative synthesis. *BMC Endocr Disord.* 2016 May;16(1):24. Doi:10.1186/s12902-016-0103-0
30. White ND, Lenz TL, Smith K. Tool guide for lifestyle behavior change in a cardiovascular risk reduction program.

- Psychol Res Behav Manag. 2013 Aug;6:55-63. Doi:10.2147/PRBM.S40490
31. Spearman C. The proof and measurement of association between two things. *Am J Psychol*. 1987 Fall-Winter;100(3/4):441. Doi:10.2307/1422689
 32. Kendall MG. A new measure of rank correlation. *Biometrika*. 1938 Jun;30(1-2):81-93. Doi:10.1093/biomet/30.1-2.81.
 33. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet*. 1986 Feb;1(8476):307-10.
 34. McHugh ML. Interrater reliability: the kappa statistic. *Biochem Med (Zagreb)*. 2012;22(3):276-282.
 35. Cade J, Thompson R, Burley V, Warm D. Development, validation and utilisation of food-frequency questionnaires - a review. *Public Health Nutr*. 2002 Aug;5(4):567-87. Doi:10.1079/PHN2001318
 36. Kubica A, Kosobucka A, Michalski P, Fabiszak T, Felsmann M. Self-reported questionnaires for assessment adherence to treatment in patients with cardiovascular diseases. *Med Res J*. 2017;2:115-22.
 37. Gadkari AS, McHorney CA. Unintentional non-adherence to chronic prescription medications: how unintentional is it really?. *BMC Health Serv Res*. 2012 Jun;12:98. Doi:10.1186/1472-6963-12-98.