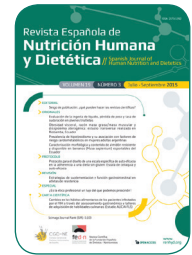# Revista Española de
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PROTOCOL

Protocol development for a scale to assess self-efficacy in adherence to a gluten free diet: Self-Efficacy and Celiac Disease Scale

Ricardo Fueyo-Díaz[a,*]**, Rosa Magallón-Botaya**[b]**, María Antonia Sánchez-Calavera**[c]**, Angela Asensio-Martínez**[d]**, Santiago Gascón-Santos**[d]

[a] Department of Medicine, Universidad de Zaragoza, Spain.

[b] Institute of Health Research Aragón, Spain.

[c] Department of Health Science, Universidad de Zaragoza, Spain.

[d] Department of Psychology and Sociology, Universidad de Zaragoza, Spain.

* rfueyo@ricardofueyo.com

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ABSTRACT

Background: Celiac disease is a chronic autoimmune disorder consisting of a permanent intolerance for gluten, with a prevalence of 1%, for which the only treatment to date is to follow a strict gluten free diet for life. Lack of adherence to this treatment is related to severe health problems while compliance leads to normalization. Recently, self-efficacy has been associated with self-management behaviors in chronic disease and health status in many fields.

Aims: To construct and validate a self-administered scale to measure self-efficacy in adherence to gluten free diet in the different areas a patient with celiac disease must face everyday.

Material and Methods: For the validation phase, the research team aims to recruit 500 celiac individuals over 12 years of age from primary care services and patient associations.

The scale will be designed to explore specific self efficacy to adhere to a gluten free diet in the following areas: purchases, eating out, eating at home with others, travelling and at work or school. An expert panel will be conducted to assure quality of the items and utility of the scale. The preliminary form will be tested in as many pilot studies as necessary. An exploratory factor analysis will be applied to study construct validity while concurrent validity will be measured with the correlation coefficient between the new instrument and the Baessler and Schwarzer General Self Efficacy Scale. The reliability of the instrument as well as that of each of the factors extracted from the prior analysis will be analyzed using Cronbach's alpha internal consistency coefficient. Two weeks later, the scale will be administered to, at least, one third of the sample as a retest in the validation process and to allow for confirmatory factor analysis.

Results: This research will design, develop and validate a questionnaire for two types of measures: A score for Self-Efficacy for the management of celiac disease, and a score of self-efficacy for each of the identified key areas. This research will result in the first scale to assess specific self efficacy while following a strict gluten free diet and will allow further research in the role that this expectation may play in patient´s adherence to the unique treatment developed to date and it may be useful in both clinical and research settings. The new scale will be easy to apply and it is expected to have a higher predictive value than instruments assessing general self-efficacy.

Conclusions: This questionnaire will be the first of its kind to determine levels of self-efficacy for adherence to gluten free diet and will help to the design of self-management interventions for celiac patients.

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> **Protocolo para el diseño de una escala específica de auto-eficacia en la adherencia a una dieta sin gluten: Escala de celiaquía y auto-eficacia**

RESUMEN

Antecedentes: La enfermedad celíaca es un trastorno autoinmune crónico, caracterizado por una intolerancia permanente al gluten, con una prevalencia del 1%, y para la que el único tratamiento hasta la fecha consiste en seguir una dieta estricta libre de gluten de por vida. La falta de adherencia a este tratamiento está relacionada con problemas de salud graves, mientras que el cumplimiento conduce a la normalización. Recientemente, la auto-eficacia se ha asociado con comportamientos de autogestión de las enfermedades crónicas y el estado de salud en muchos campos.

Objetivos: Diseñar y validar una escala para medir la auto-eficacia en la adherencia a una dieta libre de gluten en los diferentes ámbitos a los que se enfrentan todos los días los pacientes con enfermedad celíaca.

Material y Métodos: Para el proceso de validación, el equipo de investigación reclutará a 500 personas diagnosticadas de enfermedad celíaca, de más de 12 años de edad, a partir de los servicios de atención primaria y las asociaciones de pacientes. Se diseñará una escala para explorar la autoeficacia específica en la adherencia a una dieta sin gluten en las siguientes áreas: compras, comer fuera de casa, comer en casa con otros, viajar y comer en el trabajo o en el colegio. Se llevará a acabo un panel de expertos para asegurar la calidad de los ítems y la utilidad de la escala. Se realizarán los estudios piloto que sean necesarios para su mejora y se analizará su validez de constructo mediante un análisis factorial exploratorio mientras que la validez concurrente será medida mediante su correlación con la adaptación española del General Self Efficacy Scale de Baessler y Schwarzer. La fiabilidad del instrumento, así como de cada uno de los factores, será determinada utilizando el coeficiente alfa de Cronbach de consistencia interna. Dos semanas más tarde, la escala será administrada a, al menos, un tercio de la muestra para obtener una fiabilidad test-retest y para permitir un análisis factorial confirmatorio.

Resultados: Se espera diseñar, construir y validar un cuestionario que permita producir dos tipos de medidas: una valoración especifica la auto-eficacia percibida en el manejo de la enfermedad celíaca, y una valoración de la auto-eficacia para cada una de las áreas clave identificadas. Esta investigación proporcionará la primera escala para evaluar la autoeficacia específica para la adherencia a la dieta sin gluten de importante utilidad en entornos tanto clínicos como de investigación. Se prevé que su valor predictivo sea superior a medidas generales de la expectativa de autoeficacia.

Conclusiones: Este cuestionario será el primero capaz de determinar los niveles de auto-eficacia en la adherencia a la dieta libre de gluten y ayudará en el diseño de intervenciones de auto-cuidado para pacientes celíacos.

INTRODUCTION

Celiac disease is a chronic autoimmune disorder consisting of a permanent intolerance for gluten, the protein found in cereals like wheat, barley, and rye and, most likely, some varieties of oats. It occurs in genetically pre-disposed individuals and causes a serious enteropathy of the mucous membrane of the upper small intestine, so hindering the proper absorption of nutrients[1]. It is considered to be the most common of the chronic inflammatory intestinal illnesses. Many studies report a prevalence for celiac disease in the United States and Europe of between 1:67 and 1:250[2], with a prevalence of 1% being widely accepted[3]. However, due to a lack of awareness regarding the wide variety of clinical symptoms, its diagnosis is considered to be undervalued by a ratio of 1:7 of diagnosed to undiagnosed cases[4]. The female-male proportion is 2:1[5].

Today, celiac disease is considered to be a systemic illness and, therefore, if it is not treated, it may result in a spectrum of gastrointestinal and nutritional problems, osteoporosis, infertility, in both men and women, or malignancy[2]. Currently, the only valid treatment is to maintain a strict gluten free diet for life.

The clinical characteristics of celiac disease differ considerably based on the age of onset of the illness. These characteristics are much more evident when onset occurs in children. At other life stages, such as adolescence or adulthood, extra-intestinal symptoms tend to predominate, leading the patient to search for a diagnosis[1].

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Few studies have sought to determine the safety threshold for gluten consumption that may be tolerated by individuals suffering from celiac disease; so further research is needed on this issue. Catassi established the maximum tolerable daily dose for celiac patients at 50mg/day[3]. This and other studies have led the European Union, under Commission Regulation (EC) Nº 41/2009, to restrict "gluten free" products labeling to products with less than 20mg/kg[6]. This shows the scope of the problem for individuals suffering from celiac disease in the management of their daily lives; it is not only a medical problem but also a social problem, as celiac patients need to be always on the alert to adhere to their gluten free diet. Despite the benefits of a gluten free diet, strict adherence is estimated to be only 45-80% in adults[2]. Therefore, further research to investigate the underlying factors for effective adherence is essential.

In a study conducted via critical incident interviews with individuals suffering from celiac disease, Sverker[7] determined that these patients face problems mainly in the following five areas:
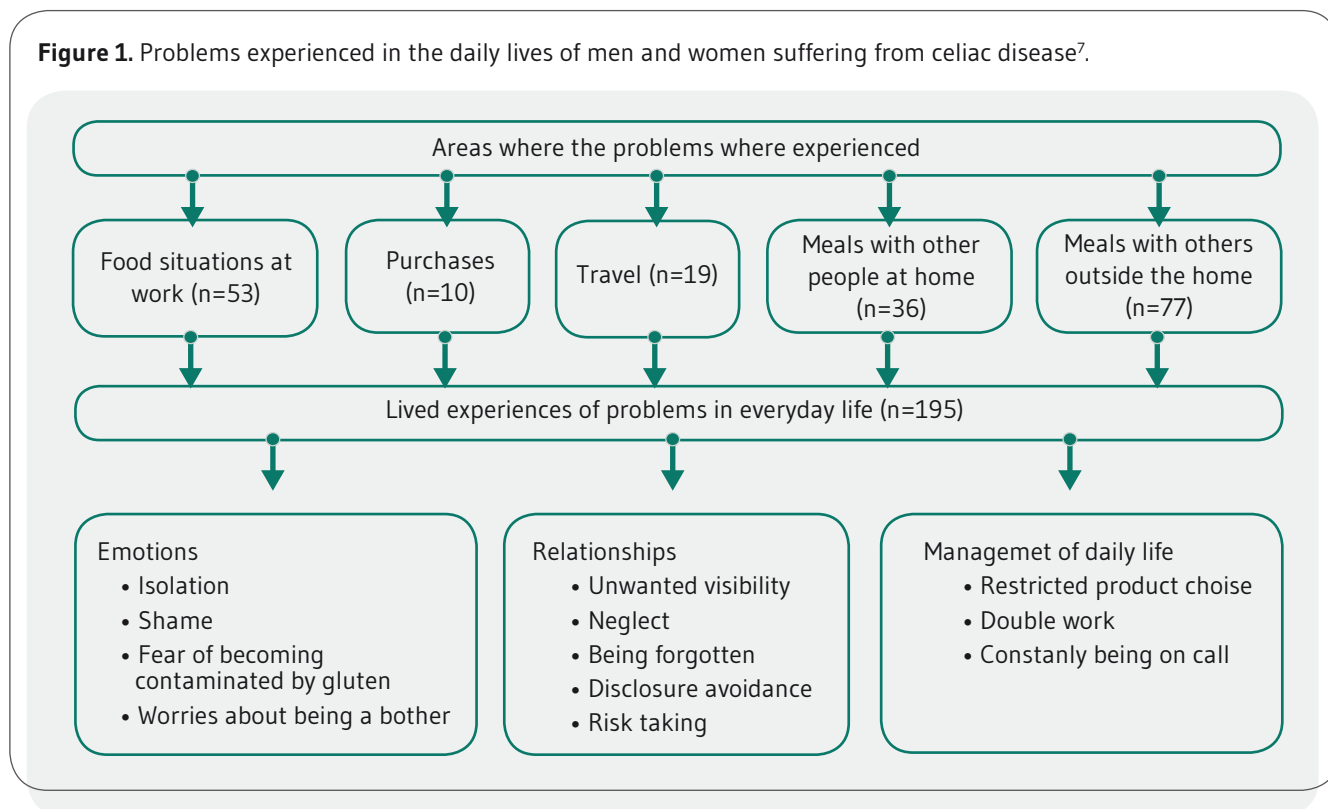
1- Purchases: the celiac patient frequently faces uncertainty regarding labeling issues, whether or not some ingredients may contain gluten, changes in product composition, etc.

2- Traveling: celiacs may find difficulties when traveling, eating in trains or airplanes, handling their diet in a different language or with different cultural customs.

3- Eating with others at home: this area deals with correcting risky behavior partaken by others, identifying oneself as a celiac, avoiding seeming rude when refusing food offered by others, etc.

4- Eating outside the home: eating outside home is one of the major challenges for individuals suffering from celiac disease. In this case, along with self-efficacy for identifying oneself as a celiac, other aspects are relevant, including how to reject unsafe dishes, eating food brought from home at the restaurant, etc.

5- Eating at work or at school: in this area, levels of self-efficacy for participating in social situations at work such as company celebrations or events at school may play an important role.

These problems lead to negative emotions, affect relationships and lead to difficulties in daily life (Figure 1).

Figure 1. Problems experienced in the daily lives of men and women suffering from celiac disease[7].

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In the frame of the Social Cognitive Theory, Bandura defines self-efficacy as the judgment of one's ability to organize and execute given types of performances[8]. Self-efficacy has been associated with self-management behaviors[9], and health status in many fields, such as arthritis[10], physical activity[11], multiple sclerosis[12], or tobacco dependence[13], and in many countries[14].

Recently self-efficacy questionnaires and scales have been developed for many chronic disorders such as alcoholism[15], multiple sclerosis[16] or those developed by Bandura for eating habits, pain management or regulating exercise[17]. Even though Bandura suggests that self-efficacy beliefs tend to be specific and deeply influenced by the situation, Schwarzer[18] has developed the General Self-Efficacy Scale (GSE), a 10-item scale to assess general self-efficacy rapidly. As this scale has good validity and reliability it may be useful for research purposes but lack predictive value in certain situations where a more specific self-efficacy needs to be assessed.

To date, no scale has been developed for determining self-efficacy levels in celiac patients as an important factor in following a gluten free diet while facing the challenges arising during the daily management of their illness.

The main objective of this study is to design and validate a scale that permits the determination of levels of self-efficacy in individuals suffering from celiac disease in the maintenance of a strict gluten free diet by examining the five relevant problem areas identified by Sverker.

The ultimate goal is the easy detection of patients that may benefit from educational interventions to increase their perceived self-efficacy levels for adherence to a gluten free diet and, therefore, to improve, not only their health, but also their quality of life by empowering them to participate, due to their feeling lower anxiety, in new activities.

It is hypothesized that the new scale, once validated, will predict adherence to a gluten free diet and quality of life in celiac patients better than the GSE.

MATERIAL AND METHODS

Participants and sample size

The study population will consist of individuals affected by celiac disease who must follow a strict gluten free diet for life, based on physician's instructions. When considering the appropriate age range for which the scale was designed, a minimum was established at 12 years of age, when primary education is completed and the student enters high school institutions.

During the validation study, the scale will be administered to 500 participants from various Spanish Autonomous Communities. As the total diagnosed celiac population in Spain remains unknown, this sample size is estimated sufficient according to the objective and methodology of this research. Participants will be presented with an informative sheet on the project as well as an informed consent form. The questionnaire will be answered anonymously, using a six digit code, and sent back to the research team.

Validation process and statistical analysis methods

Scale design: A preliminary questionnaire will be created based on the Spanish adaptation of Baessler and Schwarzer of the GSE[19] on the adherence to a strict gluten-free diet for each of the areas identified by Sverker following, Bandura´s recommendations for the creation of self-efficacy scales.

A validation process for this self-administered questionnaire has been designed through a series of phases (Figure 2).

The pre-validation questionnaire (based on the Spanish adaptation of Baessler and Schwarzer of the GSE)[19] will contain less than 80 questions, divided into the five different areas identified by Sverker and a section of demographic questions.

The scale will give a score for Self-Efficacy for the management of celiac disease consisting of the average of the scores from all of the questions; and a score of self-efficacy for each of the identified areas.

Preliminary testing: To assess face and content validity, the draft will be analyzed and improved by an expert panel made up of university lecturers, physicians, psychologists, and association dietitians for their comments. Next, it will be trialed in as many pilot studies as necessary in order to create a pre-validation draft.
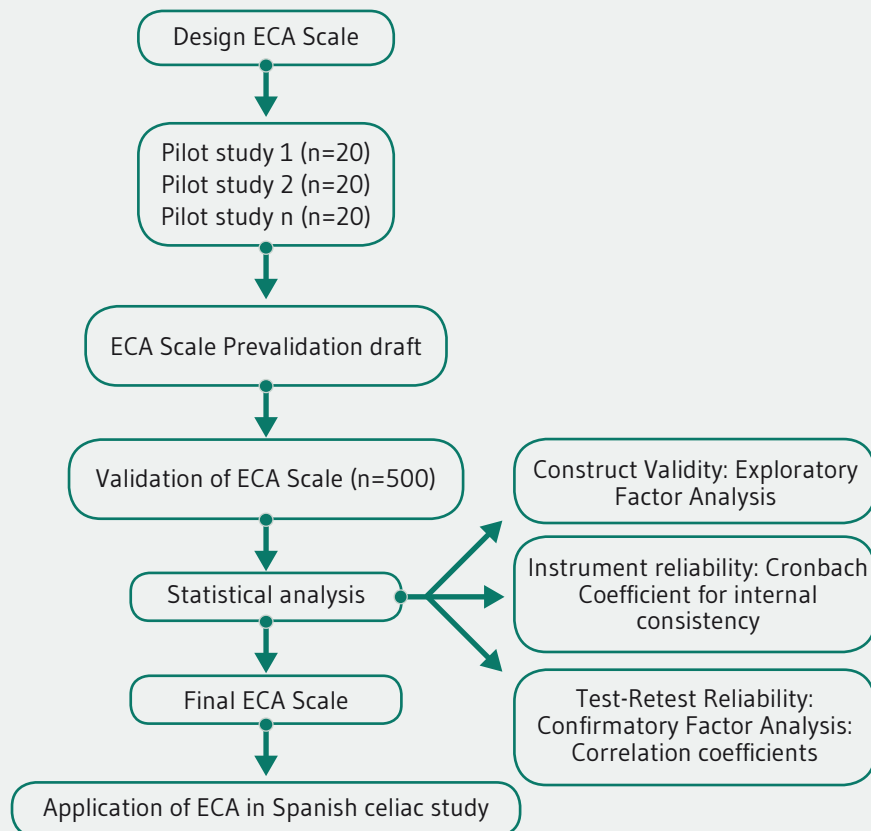
It will be applied to an initial pilot group of 20 patients. The scale will be modified based on this initial pilot study and it will be tested in a second pilot until consensus about the quality of the questionnaire is reached.

During expert panel and the pilot studies participants will be asked to answer, after examining the draft, a series of questions on the quality of the designed scale, grouped into five dimensions: appropriateness, attempting to determine whether or not the scale complies with the pursued objectives; ease: concerns the difficulty of questionnaire completion; applicability: whether or not the questionnaire reflects and evaluates the subject's personal circumstances;

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Figure 2. Self-Efficacy and Celiac Disease Scale validation process.

amplitude: referring to the degree to which all of the important aspects are covered; universality: referring to the degree to which the questionnaire can be generalized to different subjects and to similar issues.

These questions will be answered using a scale from 1 (completely disagree) to 5 (totally agree). Three additional questions are added: one regarding a general evaluation of the quality of the questionnaire, a second question on the time needed for completion and a last one catering for comments. Comments from experts will help to add, eliminate or clarify items for the validation study.

After reaching consensus, the research team will start with the validation study of the scale. This final version is expected be reduced to the 40-50 most significant items distributed in the five areas identified by Sverker.

Validation process: Participants will fill out the scale, in digital or paper format, in which they will have to answer

using a scale ranging from 0 to 10, evaluating the degree of self-efficacy that they experience in each of the proposed situations. These questions should be answered on a scale ranging from 0 (cannot do at all) to 10 (highly certain can do).

In order to analyze concurrent validity, this questionnaire will be applied along with the Spanish adaptation of the General Self-Efficacy Scale, which will be used for correlation analysis during the validation process. In this case, a Likert scale of 4 original points will be presented for 1=not at all true, 2=hardly true, 3=moderately true, 4=exactly true. This scale has already been validated in Spanish[19].

In addition to these questions and in order to explore differences in specific self efficacy when following a gluten free diet, other socio-demographic variables will be incorporated, including: place of residence, date of completion, if the participant should follow a gluten free

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diet for life based on physician's prescription, reasons for the diet, year of diagnosis, current age, gender, and patient association membership (if any).

Statistical analysis methods: Construct validity will be analyzed with exploratory factorial analysis using the main components method for factor extraction and varimax rotation to generate the final solution and to associate each of the questions in the questionnaire to its corresponding factor. The appropriateness of the factorial model will be evaluated using the KMO (Kaiser-Meyer-Olkin index of sampling adequacy) and Bartlett's sphericity test[20]. KMO values above 0.75 will be expected.

The internal consistency of the instrument, as well as that of each of the factors extracted from the prior analysis, will be analyzed using Cronbach's alpha coefficient. Similarly, the test-retest reliability will be examined using the non-parametric correlation coefficients of Spearman's rho for numeric variables or with Kendall's Tau-b coefficient for qualitative or ordinal variables. Likewise, the questionnaire's coefficient of intraclass correlation will be extracted[21]. Values above 0.65 will be accepted. Concurrent validity will be measured using Spearman´s rho coeficient with the General Self Efficacy Scale and positive and significant values are expected .

Two weeks later, the scale will be administered to at least one third of the sample as a retest in the validation process and to allow for confirmatory factor analysis.

Version 21 of the SPSS statistics program will be used and 0.05 will be considered to be statistically significant for all analysis.

RESULTS

This research will result in the first scale to assess specific self efficacy while following a strict gluten free diet and will allow further research in the role that this expectation may play in patient´s adherence to the unique treatment developed to date.

The research team intends to develop an easily applicable instrument, which can be completed in less than 15 minutes, which will give the degree of confidence of an individual diagnosed with celiac disease to follow a gluten free diet for life. The new specific scale is expected to have a higher predictive value than instruments assessing general self-efficacy.

This questionnaire will allow the fast assessment of the celiac patient´s self-efficacy for each of the areas identified: purchases, eating with others at home, eating out with others, traveling and eating at work or school.

DISCUSSION AND CONCLUSIONS

The aim of this study is the design and validation of a scale that will serve to determine the levels of self-efficacy perceived by individuals suffering from celiac disease who have been prescribed a strict gluten free diet in the main areas of their life where they may face problems.

Bandura defines the expectation of self-efficacy as the "*belief in one´s capability to organize and execute the courses of action required to produce given attainments*"[22], clearly distinguishing between the perceived self-efficacy and other types of expectations, such as outcome expectations. Therefore, this scale will not seek to examine the feelings or motivations for following a gluten free diet, but the individual's confidence in following a gluten free diet. Elsewhere, Bandura defined the self-efficacy belief as a specific expectation as opposed to a general expectation and therefore, this scale does not only aim to offer a measure of self-efficacy in following a gluten free diet, but also to explore its level for the different areas.

Theoretically speaking, this study is based on the Bandura´s Social Cognitive Theory and Schwarzer´s HAPA model[23] to serve as an initial step in the future design of educational self-management programs for the illness similar to those developed by Kate Lorig[24] of Stanford University or van Puffelen of the Netherlands Institute for Health Services Research[25].

This scale (Self-Efficacy and Celiac Disease Scale), therefore, will seek to examine the levels of self-efficacy of the celiac patients with regard to the areas determined by Sverker, which include: eating at work, purchases, traveling, eating out with others and eating at home with others.

This instrument will allow for future exploration of self-efficacy expectation and its relationship with these variables and the perceived quality of life and so facilitate the design of self-management programs for celiac patients. This final scale will be applied to the celiac population of Spain as part of subsequent research.

Finally, it is also expected that this scale will be easily adaptable to other individuals suffering from illnesses with dietary restrictions and will foster the development of

programs for self-management of their health in order to improve their quality of life.

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COMPETING INTERESTS

The authors declare that there are no conflicts of interest to draft the manuscript.

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