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ORIGINAL RESEARCH

Development and Pilot-Testing of a Patient Decision-Making Aid for Nutrition in Age-Related Macular Degeneration

Wenmei Guo[1,2], Junli Wan[1,2], Feng Zhang[1,2], Mingqiong Liu[1,2], Mingqiong Tan[1,2], Wei Bian [1,2]

[1]Southwest Hospital/Southwest Eye Hospital, Third Military Medical University (Army Medical University), Chongqing, People's Republic of China; [2]Key Lab of Visual Damage and Regeneration & Restoration of Chongqing, Chongqing, People's Republic of China

Correspondence: Wei Bian, Southwest Hospital/Southwest Eye Hospital, Third Military Medical University (Army Medical University), Chongqing, 400038, People's Republic of China, Tel +8615922933012, Email bianwei@Tmmu.edu.cn

Objective: We described the development and pilot-testing of an application based patient decision-making aid (PDA) for nutrition in age-related macular degeneration (AMD). Alpha-testing and beta-testing were performed to explore the PDA's usability, acceptability, and comprehensibility in the design stage and in "real-life" conditions.

Methods: A nutrition PDA was developed in this study by a multidisciplinary steering committee that consisted of ophthalmologists, nurses, nutritionists, and methodologists using a systematic development process. The PDA was based on a smartphone native installation and a free-to-use app. First, based on information from literature reviews and focus group interviews for needs assessment, we developed a decision aid prototype. Second, we conducted the alpha testing to explore the acceptability, usability, and comprehensibility of the PDA prototype among 18 AMD patients. Third, a before/after study was conducted to assess changes in the attitudes, risk perceptions, intentions, knowledge, decisional conflicts, and decision self-efficacy of 33 AMD patients.

Results: The alpha test proved that the nutrition PDA is acceptable and usable. In the beta test, after the AMD participants used the PDA, their scores for knowledge [mean = 13.3, standard deviation (SD) = 2.92], attitude (mean = 18.97, SD = 2.19), decision self-efficacy (mean = 23.94, SD = 6.04), and preparation significantly increased (mean = 26.30, SD = 4.90), and their score for decisional conflict significantly decreased (mean = 10.15, SD = 3.66). There was no significant difference in anxiety (mean = 2.64, SD = 1.08) before and after the use of the PDA. The mean score in the system usability scale was above 70 (mean = 72.61; SD = 5.38), which indicates the good usability of the PDA. With regard to the PDA acceptability, the scores for satisfaction with its comprehensibility, satisfaction with its attractiveness, and satisfaction with its emotional support were 5.49 (SD = 1.03), 5.30 (SD = 1.40), and 4.91(SD = 1.07), respectively, which show its adequate acceptability.

Conclusion: Our study showed that the nutrition PDA was an acceptable and suitable instrument for AMD patients and fit the values of all its stakeholders. This study is an important step in supporting shared decision-making, which has the potential to provide a more patient-centered and value-based nutrition health system for individuals with different types of AMD.

Keywords: age-related macular degeneration, nutrition, decision-making aid

Introduction

Age-related macular degeneration (AMD) is a neurodegenerative and late-onset multifactorial disease that affects the central region of the retina, resulting in blindness of the central vision. The prevalence of early and late AMD among Chinese populations older than 50 years is 5.6%; and with further population aging, the number of AMD patients is expected to increase.[1]

AMD can be clinically divided into dry and wet categories. Therapeutic interventions such as intravitreal injection of the antivascular endothelial growth factor are the main treatment modalities for wet AMD, which represents a small proportion of all types of AMD.[2,3] However, 65% of the patients did not show significant improvement in visual acuity after the treatment.[4] Recently, other interventions, such as nutrition interventions, including antioxidant supplementation and dietary modifications, were reported to have benefited both wet and dry AMD patients.[5–8] Evidence suggests[5,6,9–12]

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that all AMD patients, regardless of their disease severity, should be given dietary advice. Additionally, 25% of the intermediate- and late-AMD patients showed reduced progression to more advanced AMD when they took Age-Related Eye Disease Study (AREDS) type antioxidant vitamins (such as vitamin C or vitamin E), lutein, zeaxanthin, and zinc within five years.[13] Therefore, nutrition intervention has become the key modifiable factor of the reduced incidence of AMD and one of the main tools for preventing and slowing down both dry and wet AMD.[5,14]

However, there is still some confusion about decision-making on nutrition interventions among patients and medical staff. Patients comply poorly with nutrition interventions because they lack nutrition knowledge and have different dietary attitudes.[15,16] Medical staff could not provide patients enough information and have no effective instruments for guiding patients in dietary adjustment.[17] Furthermore, a large number of studies have reported contradictory results on nutritional supplementation for AMD patients, which makes it very difficult for medical staff to educate patients on nutrition.[18] Consequently, patients are uncertain about whether they should modify their nutrition sources and what foods and supplements they should take.[19]

Shared decision-making (SDM) is a patient-centered approach in which patients and medical staff work together to make better and more reasonable decisions based on the patient's preferences and values.[20] An important tool for promoting SDM is the patient decision aid (PDA). It helps patients make specific and prudent choices based on evidence-based medicine by providing treatment options and information on related outcomes, including benefits and risks.[21] Recently, some PDAs have been developed and applied in the field of ophthalmological medicine, including for cataract surgery[22] and primary open-angle glaucoma treatment.[23] Although a PDA for nutrition advice for AMD is already available, it needs to be standardized and made more reliable.[24] This is because first, its development process was not based on the International Patient Decision Aid Standards (IPDAS), and only patients who met the eligibility criteria for the Age-Related Eye Disease Study 2 (AREDS 2) could use it. Second, it uses flowcharts to assist with nutrition advice, whereas other forms of PDAs, such as apps, might provide better options. Finally, due to dietary and cultural differences, its suitability for Chinese patients must be determined.

This study developed and pilot-tested an app-based PDA for nutrition in AMD. The app was intended to provide AMD patients general advice and personalized interventions. We used alpha testing and beta testing to explore the PDA's usability, acceptability, and comprehensibility in the design stage and in "real-life" conditions.

Methods

The PDA was developed in accordance with the IPDAS development process model for decision aids[25] and its quality criteria.[26,27] The nutrition PDA developed in this study is based on smartphone native installation and a free-to-use app.

Steering Group

A multidisciplinary expert team that included ophthalmologists, nurses, nutritionists, and methodologists acted as the multidisciplinary steering group for the development of the PDA and its evaluation in different phases of this study.

The expert inclusion criteria were as follows: (1) has work experience in the field of ophthalmology, nursing, or nutrition for 5 years or more; (2) has a master's or higher degree or an associate senior or higher rank in any of the fields stated in; (3) has a high academic level in a related field; and (4) has given their informed consent to participate in the full conduct of this study.

Prototype Development

The development of the PDA prototype was based on information from literature reviews and two focus group interviews (FGIs). One interview was with AMD patients, and the other, with health professionals. The steering group was required to create a standard PDA format for future writing and development.

Literature Review

A review of literature from major databases was conducted based on current international guidelines to obtain information on the general management of AMD, specifically on nutrition interventions and PDA content design. Then, a standardized approach was used to assess options and to formulate recommendations.

The information on the background of the nutrition PDA and the clinical evidence that informed its development were based on a needs assessment among health professionals and patients, as well as on an assessment of the quality and content of all kinds of evidence. We searched for original studies and systematic literature reviews on the Cochrane Library, JBI, Pubmed, EMBASE, Web of Science, CNKI, and Wanfang databases using the keywords ("age-related maculopathies" OR "age-related macular degeneration" OR "macular degeneration, age-related" OR" macular dystrophy") AND ("nutritional support" OR "dietary intervention" OR "nutritional supplement" OR "dietary adjustment" OR "dietary supplement" OR "food supplement" OR "nutraceutical" OR "antioxidant" OR "lutein" OR "zeaxanthin" OR "fatty acids" OR "meso-zeaxanthin" OR "vitamin"). Current international guidelines on AMD interventions and nutrition were also reviewed from the National Institute for Health and Care Excellence, National Guideline Clearinghouse, Scottish Intercollegiate Guidelines Network, Guidelines International Network, Canadian Medical Association, Registered Nurses' Association of Ontario (RNAO), New Zealand Guidelines Group, and Australia's National Health and Medical Research Council (Clinical Practice Guidelines).

High-quality tools were used to evaluate the evidence and to obtain accurate PDA information. The Chinese version of the Appraisal of Guidelines for Research and EvaluationII(AGREE II[28]) tool was used to evaluate the quality of the included clinical guidelines. The quality standards for the systematic reviews were adopted from the quality evaluation of the Systematic Evaluation project of the Centre for Evidence-Based Medicine of the University of Oxford.[29] The quality of the original studies was evaluated using the quality evaluation criteria of the JBI Evidence-based Health Care Australia (2016) for randomized controlled trials, class trials, cross-sectional studies, and case control studies.[30] The quality evaluation standards for the evidence summary were adopted for the quality evaluation and evidence recommendation of the included studies using the Evidence Classification and Evidence Recommendation Level system of the JBI Evidence-based Health Care Center in Australia (2014).[31]

The methods of these reviews are presented in the electronic Supplementary Material 1.

Performance of Needs Assessments for the PDA

The needs of the patients and health professionals (ophthalmologists and nurses) had to be assessed once the evidence was established. Two in-depth semi-structured FGIs, one with patients and the other, with health professionals, were conducted based on the user-centered design model.[32]

The FGI with the patients was recorded and had two parts. The first part explored the worries and considerations of the patients and investigated the physical, emotional, and social influences on them to determine the information they needed in the PDA. The second part figured out the patients' needs related to the design, content, and functionalities of the PDA.

In the FGI with the health professionals, they were asked what information they believed AMD patients should know in their decision-making process and how the PDA should present such information. To determine how to disseminate and best apply the PDA in clinical practice, they were also asked to discuss the timing and ways of applying the PDA to patients.

Finally, the data from both FGIs were analyzed, summarized, and synthesized to determine the main content of the PDA prototype.

Prototype Alpha Testing

Alpha testing was performed to explore the PDA prototype's acceptability (ie, the evaluation of its comprehensibility), usability (ie, the quality of its user's experience with it), and comprehensibility (ie, the degree of understandability of its content).[33,34]

Participants

The participants in this prototype alpha testing phase were recruited from the Eye Clinic of Southwest Hospital. The inclusion criteria for all three stages of this study were as follows: (1) surgically diagnosed with AMD by an ophthalmologist; (2) older than 45 years; (3) has no history of any other eye disease that affects the vision such as retinal detachment and diabetic retinopathy; and (4) does not have any other systematic disease.

Data Collection

Purposive sampling was used to recruit patients from the Eye Clinic, and the recruitment was stopped when the data were saturated. The semi-structured interviews were conducted in a meeting room of the clinic after the patients used the PDA. First, they were asked to answer a questionnaire on their demographic and clinical characteristics. Second, they were asked to individually use the PDA through an iPad. Third, the external facilitators asked them questions to assess the acceptability, usability, and comprehensibility of the PDA. Among the questions were: "How do you feel about the PDA?" "Do you think the PDA helps you make decisions? Please give examples." "Did you have any difficulty in using the PDA?" "How did you navigate through the PDA, and what barriers did you encounter?" "Do you believe the outputs of the PDA?" "What do you want to achieve by using the PDA?" An audio recording of the entire interview was made, and field notes were taken by JW and WB.

Data Analysis

The audio recording was transcribed verbatim and listened to several times to ensure the accuracy of the transcription. All the transcriptions and field notes were summarized and thematically analyzed. The data analysis went hand in hand with the data collection and helped with the iterative development of the PDA. This procedure resulted in a list of positive remarks on the PDA, which informed its needed main improvements and those of each of its parts. Finally, the draft was approved by the steering group and the patients.

Prototype Beta Testing

After the draft was accepted, beta testing was conducted to analyze the effectiveness of the PDA in "real-life" conditions among AMD patients who did not participate in the PDA's development.[25,35] Then, the pre- and post-test results were compared to assess differences in the attitudes, risk perceptions, intentions, knowledge, decisional conflicts, and decision self-efficacy between the first and second groups of AMD patients.

For this beta testing phase, the sociodemographic characteristics (age, gender, level of education, and time from diagnosis) of the second group of AMD patients were collected, and the Preparation for Decision-Making (PrepDM), Decisional Conflict Scale (DCS), Decision-Making Self-Efficacy Scale (DM-SES), and Hospital Anxiety and Depression Scale (HADS) were administered to them. PrepDM was used to evaluate the strength of a decision support in the process of decision communication. There were 11 items in the source scale, and the 5-point Likert scale was used to evaluate each item from 1 ("totally useless") to 5 ("very useful"). The higher the score was, the higher the readiness of the patient was for decision-making. DCS was used to assess the patients' uncertainty about the treatment options and their effectiveness. There are 16 items in the scale, including three dimensions of leading uncertainty, leading factors, and effective decisions. DM-SES was used to assess the confidence of the patients in making informed choices in the process of receiving medical care. The scale consists of 11 items. HADS was used to assess the anxiety status of the patients. The scale has two dimensions—anxiety and depression—with a total of 14 items.

Data Collection

AMD patients who met the inclusion criteria in the in alpha testing phase were recruited from the Eye Clinic for this beta testing phase. For the pre-test study, the participants were asked to complete a series of questionnaires before using the PDA. Their sociodemographic characteristics, including their age, gender, educational level, and marriage status, were collected as the baseline data. In the before/after study, the measures of the outcomes (ie, knowledge,[38] attitude, decisional conflict,[39] decision self-efficacy,[40] preparation for decision-making,[41] and anxiety[42]) were selected based on the Ottawa Decision Support Framework[36] and IPDAS[37] and are presented and explained in Table 1. The additional outcome measures in the post-test (after the patients used the PDA) were acceptability[43] and usability.[44] The entire process lasted approximately 30 min.

Sample Size Calculation

According to a study[45] on the acceptable sample size for usability testing, 12 research objects can test 80% of general usability problems. Also, a sample size higher than 30 was determined as appropriate for intervention pilot studies.[46] Therefore, considering dropouts, we decided on a sample size of 33.

Table 1 Outcome Measures in the Pre- and Post-Tests

Outcome Indicator	Measurement	Number of Items and Scoring	Pre-Test	Post-Test
Knowledge	Knowledge of risks and benefits of nutrition intervention in AMD	15 items scored as to whether they were true/ false/ unsure	√	√
Attitude	Attitude scale	4 items scored on a 5-point scale	√	√
Decisional conflict	Decisional conflict scale	16 items scored on a 5-point scale, with higher scores indicating higher decision conflict	√	√
Decision self-efficacy	Decision self-efficacy scale	11 items scored on a 5-point scale, with higher scores indicating higher decision self-efficacy	√	√
Preparation for decision-making	Preparation for decision-making scale	10 items scored on a 5-point scale, with higher scores indicating higher decision preparation	√	√
Anxiety	Hospital anxiety and depression scale	7 items scored on a 4-point scale, with higher scores indicating a higher anxiety level	√	√
Acceptability	Acceptability testing scale	12 items and 3 subscales (satisfaction with comprehensibility, satisfaction with attractiveness, and satisfaction with emotional support) scored on a 7-point scale, with higher scores indicating better acceptability		√
Usability	Systems usability scale	10 items scored above 70 indicating "good" or "acceptable"		√

Data Analysis

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS, Version 20.0). Descriptive statistics were generated for all outcome measures (in the pre- and post-tests). The Wilcoxon signed-rank test was used to assess the differences between the outcomes of the pre- and post-tests in terms of the continuous outcome measures (knowledge, attitude, decisional conflict, decision self-efficacy, preparation for decision-making, and anxiety). Only the acceptability and usability of the PDA were measured in the post-test using frequency statistics calculations.

Ethics Approval

The verbal and written consent of the patients to participate in this study were obtained before their interview. This study was registered at clinicaltrials.gov with Identification Number ChiCTR2000031853, was approved by the Ethics Committee of the First Affiliated Hospital of Army Medical University (NO. KY2019100), and was conducted in accordance with the Declaration of Helsinki. The participants were informed that they had the right to withdraw from the study at any time. All of them were assured that their names, interview transcripts, and other personal data would be kept confidential.

Results
Steering Group

The steering group was composed of two ophthalmologists and two nurses (with expertise in the management and long-term care of AMD patients), one nutritionist, one methodologist (with expertise in evidence-based medicine and PDA development), and three patients (with adequate knowledge of AMD).

Prototype Development
Performance of Needs Assessments for the PDA

Six health professionals (two ophthalmologists and four nurses) and four AMD patients participated in the two FGIs.

The patients pointed out that the information provided by the PDA should be simple, big, clear, and pictorial so that they could be seen and understood easily. They added that more information should be included in the PDA, such as the concept and meaning of nutrition for AMD, the kinds of foods to take, and the methods of food preparation to maximize nutrient absorption. They further said that the PDA should also offer information on the potential benefits and risks of nutrition interventions and the duration of their effects. They also stated that the PDA should stress that nutrition intervention is a supple mental treatment but not the only way to slow down the progression of AMD.

The health professionals indicated that the PDA should include information on the disease and on the interventions to improve the knowledge of the patients. They added that the benefits and risks of the interventions should also be presented in a balanced way. Additionally, they pointed out that items to test patients' knowledge of their current situation and their preferences should be included to help health professionals to fully understand patients' fears, worries, and willingness to accept the interventions.

The patients and the health professionals agreed that too many words in the PDA would burden the patients and thus, should be simplified by adding pictures to help improve understanding. How to present the benefits and risks of the interventions in a balanced way was a challenge. Additionally, all the patients and health professionals believed that the PDA was a useful tool for improving patients' knowledge of AMD and its treatment, for evaluating patients' preferences, for enhancing the relationship between patients and health professionals, for improving patients' treatment compliance, and ultimately, for improving health outcomes. However, how to utilize the PDA in a more useful and time-saving way in a clinical setting presents a problem.

The details of focus group interviews are presented in the electronic [Supplementary Material 2](#).

Prototype Alpha Testing
Usability Test Among the Patients
Eight (44.44%) men and 10 (55.55%) women were recruited for the alpha testing, with an average age of 70.56 years (range: 56–79 years, SD = 7.63). Three subjects (16.67%) received primary or lower education; 11 (61.11%), intermediate education; and 4 (22.22%), college or higher education. All the patients were diagnosed with AMD 2 to 60 months earlier. Nine patients (50.0%) had bilateral AMD, and the other nine (50.0%) had unilateral AMD. Five patients (28%) were in the early stages of AMD, and 13 patients (72%) were in the intermediate and late stages.

Most of the patients, after visiting the homepage of the PDA, agreed that the structure was very convenient to use and the parts were closely connected. The PDA demonstrated full knowledge of the disease and of the benefits and risks of different options. It could also test the patients' preferences and provide suggestions based on their conditions. Additionally, the PDA had plenty of graphics and texts, and the information provided was simple and easy to understand. The detailed comments are as follows.

"This tool is much better than ordinary propaganda materials. It is rich in content and pictures for us to understand."

"It helps me understand deeply and think systematically about the options."

> I think the decision aid tool is very useful. It not only provides disease-related knowledge but also explains the advantages and disadvantages of different interventions in detail. It is very practical for us to use to make decisions.

However, there still were some obstacles to the PDA's usability. First, because it displayed only one font size, some patients with poor visual acuity took a long time to read it. Many patients said it would have been better had we added the font size selection function or the voice broadcasting function. Two participants mentioned the need for more pictures and suggested that adding some animation would be more helpful. Second, six patients hoped to get more details on the treatment and complained that some words were not professional. They hoped those words would be revised and that the new words would be easier to understood. Third, three participants had difficulty understanding the benefits and risks provided by the PDA and were surprised about some related information. All the information was provided in the same way, and the sources of evidence were not mentioned. Fourth, when the patients chose the option "Patients' preferences", they did not know what to do and stopped to ask for help. They commented that the display of this part is not clear enough to understand.

Redraft and Redesign of the PDA

The steering group discussed the PDA adjustments based on the results of the usability tests among the patients. We set three font sizes for the patients with different degrees of visual acuity to choose from—that is, large, medium, and small—and added the function of voice broadcasting, which made the PDA user-friendly. The benefits and risks of all the options were adjusted and presented on only one side of the PDA to show a clear overview of all treatment options, details of the procedures, and recommendations of the ophthalmologists. In the part on the instructions for the disease and related nutrition modification, unnecessary words were removed and more pictures were added. On the options for the patients' preferences, chart selection and arrows were added to facilitate patients' better understanding.

The general structure of the APP-based PDA for nutrition in AMD (in Chinese) are presented in the electronic Supplementary Figure 1.

Prototype Beta Testing
Characteristics of the Participants

Of all the patients (n = 33) who had an average age of 56.76 years (SD = 6.84) in the beta-testing stage, 25 (75.76%) were women, 29 (87.88%) were married, 12 (36.36%) had a middle or high education level, and 16 (48.48%) had a low education level. The duration of the disease was 17.85 (SD = 7.19) years, and 11 patients (33.33%) were affected in bilateral eyes. Eleven patients (33%) were in the early stages of AMD, and 22 patients (67%) were in the middle and late stages of AMD.

Before/After Study Findings

The changes in the outcome variables after the patients used the PDA are shown in Table 2. After they used the PDA, their scores for knowledge, attitude, decision self-efficacy, and preparation significantly increased, and their score for decisional conflict significantly decreased. There was no significant difference in anxiety before and after the use of the PDA.

Acceptability and Usability of the PDA

The mean score in the system usability scale was above 70 (mean = 72.61; SD = 5.38), which indicated good usability of the PDA. As for the PDA's acceptability, the scores for satisfaction with the PDA's comprehensibility, attractiveness, and emotional support were 5.49 (SD = 1.03), 5.30 (SD = 1.40), and 4.91(SD = 1.07), respectively, which show adequate acceptability.

Discussion

We used a mixed-methods design (alpha and beta testing) to develop and pilot-test a PDA for AMD patients that would help them choose a nutrition intervention. Based on the needs assessments among health professionals and patients and on the quality of all kinds of evidence, we developed a PDA that consisted of the following: (1) general information on the PDA, AMD, and nutrition modification for AMD; (2) comparison of benefits and risks of nutrition interventions; (3) questions to explain the patient's preferences and worries; and (4) patients' understanding of the information provided by the PDA and of the final decision according to their preferences after discussion with their health professionals. The PDA

Table 2 Pre-Test and Post-Test Findings on the Use of the PDA (mean±SD, n = 33)

Outcome	Pre-Test	Post-Test	t	p value
Knowledge	4.27±1.44	13.33±2.92	−17.663	0.000
Attitude	17.75±2.48	18.97±2.19	−2.803	0.009
Decisional conflict	17.03±7.67	10.15±3.66	5.184	0.000
Decision self-efficacy	18.27±6.73	23.94±6.04	−4.746	0.000
Preparation for decision-making	20.12±5.39	26.30±4.90	−4.679	0.000
Anxiety	3.39±2.65	2.64±1.08	1.922	0.064

was an acceptable and useful instrument for helping with SDM by improving patients' knowledge, attitude, decision self-efficacy, and preparation, and by reducing their decisional conflicts.

In the prototype development stage, the patients' and health professionals' needs for information and decision support were assessed based on the IPDAS development process model. A larger font size, clarity, and sufficient information on the PDA were the basic requirements of the patients. The patients stressed their need for more information on the disease and the interventions, such as on the concept and content, potential risks and benefits, and side effects of the intervention, and the post-treatment care. Like the patients, the health professionals believed that it was essential to provide sufficient information about the disease and the nutrition modification. However, the patients and the health professionals evaluated the intervention options differently: the health professionals tended to focus on the disease, the intervention, and the patients' knowledge and preferences, whereas the patients cared more about whether the intervention would have side effects and would affect their quality of life in the short and long terms. Therefore, a common app for making informed decisions from different viewpoints is needed based on these two perspectives.

In the alpha testing, the patients gave a positive response that confirmed that the PDA was an acceptable, usable, and comprehensive instrument. Most of them preferred a simple and clear PDA interface, and the voice-broadcasting function was particularly important for patients with poor vision. Some patients admitted that they did not fully understand the benefits and risks of the PDA. Therefore, we used plenty of pictures to make the PDA more vivid and thus, easier to understand. However, a few patients mentioned that the information on the potential harms of the nutrition modification should be excluded because it would increase the anxiety of the patients and inhibit them from participating in the intervention. However, in line with a study[10,11] on the willingness of AMD patients to undergo a dietary intervention, most of the participants in this study had preventive beliefs and positive attitudes towards dietary intervention, so they were more inclined towards the potential benefits rather than the risks. Therefore, it would be better for patients to fully understand the advantages and disadvantages of various options and make the best decision according to their own situation. Further research should focus on optimizing the PDA according to different levels of the patients' basic knowledge, attitudes, and beliefs in nutrition interventions to promote the application of the PDA in clinical practice. Additionally, most of the patients preferred chart selection and arrows in choosing their preference rather than a single Likert option. Therefore, we made some modifications of the PDA to improve its comprehensibility and communicability.

In the beta-testing stage, significant improvements were found in the patients' knowledge, attitude, preparation for the SDM, and decision-making self-efficacy. The results showed that this tool can achieve efficient knowledge transmission, and then, promote the patients' mastery of AMD nutrition-related information.[47] The PDA can also significantly improve patients' ability to analyze the advantages and disadvantages of nutritional interventions, reduce their blindness and uncertainty, increase their participation in the decision-making process, and help them prepare for decision-making.[48] The decision conflict was significantly reduced because the patients felt informed about the pros and cons of nutrition modification, felt uncertain about the options, felt supported in making decisions, and had clear values of their own. However, we did not find any difference in anxiety after the use of the PDA in our study, which is consistent with the finding of Cox.[49] However, there was no clear certainty about the effect of the PDA on patients' anxiety, which may be due to the small sample size of the beta test and the short tracking time. Therefore, a large sample size and a longer research time would be needed in a future study to clarify the impact of the PDA application on patients' anxiety.

Although the results were satisfactory, some limitations should be mentioned. First, we tried to include all stakeholders in the development of our PDA, but only small groups of patients and health professionals were recruited from only one hospital. Therefore, the generalizability of our study results was limited, although the number of participants reached the recommended number.[50] Consequently, more participants should be involved in further research on the PDA. Second, the PDA did not present the probabilities of the outcomes because there was no sufficient evidence on the interventions and their security. Otherwise, the PDA presented benefits and risks based on evidence as well as specific intervention options and their possible impacts on the patients' daily life in a structured way. The patients regarded this way of presenting results as useful. Third, the knowledge questionnaire might have made the participants unresponsive because of anxiety over the publicizing of the results. Hence, we encouraged the patients to express all their positive and negative opinions anonymously, as our purpose for this study was to make the PDA suitable and acceptable for all the patients. Fourth, the sample size for the beta testing was small. A larger sample size is needed in a future study to test the effectiveness of the PDA.

In further studies, we will combine other influencing factors with interventions to further improve the quality of life of AMD patients.

Conclusion

Our study showed that the PDA for nutrition is an acceptable and suitable instrument for AMD patients and fits the values of all stake-holders. It could provide evidence-based information on the condition and on the benefits, risks, and probabilities of different care options, which would help the patients to make decisions consistent with their values and preferences. Besides, the PDA could be easily integrated into the patient pathway and the daily workflow of medical professionals. Although the results were encouraging, they also suggested some improvements, especially in terms of availability. In future research, we will optimize the performance of the PDA and develop diversified display forms and functions to make it usable for more patients. In conclusion, this study is an important step in supporting SDM, which has the potential to provide a more patient-centered and value-based healthcare system involving nutrition for individuals with different types of AMD.[20]

Abbreviations

AMD, Age related macular degeneration; PDA, Patient decision-making aid; SDM, Shared decision making; IPDAS, International Patient Decision Aid Standards; AREDS 2, Age-Related Eye Disease Study 2; ODSF, Ottawa Decision Support Framework; SPSS, Statistical Package for the Social Sciences; NICE, National Institute for Health and Care Excellence; NGC, National Guideline Clearinghouse; CMA. Canadian Medical Association; SIGN, Scottish Intercollegiate Guidelines Network; GIN, Guideline International Network; RNAO, Registered Nurses' Association of Ontario; NZGG, New Zeal and Guidelines Group.

Data Sharing Statement

All data generated or analysed during this study are included in this published article.

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study. The person(s) providing consent have been shown the article contents to be published.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

The authors declare no conflicts of interest in this work.

References

1. Jin G, Zou M, Chen A, et al. Prevalence of age-related macular degeneration in Chinese populations worldwide: a systematic review and meta-analysis. *Clin Exper Ophthalmol*. 2019;47(8):1019–1027.
2. Balaratnasingam C, Dhrami-Gavazi E, McCann JT, Ghadiali Q. Aflibercept: a review of its use in the treatment of choroidal neovascularization due to age-related macular degeneration. *Clin Ophthalmol*. 2015;9:2355. doi:10.2147/OPTH.S80040
3. Martin DF, Maguire MG, Ying G-S. Ranibizumab and bevacizumab for neovascular age-related macular degeneration. *N Engl J Med*. 2011;364:1897–1908.
4. Rosenfeld PJ, Brown DM, Heier JS, et al.; MARINA Study Group. Ranibizumab for neovascular age-related macular degeneration. *N Engl J Med*. 2006;355:1419–1431.
5. Age-Related Eye Disease Study Research Group. A randomized, placebo-controlled, clinical trial of high-dose supplementation with vitamins C and E, beta carotene, and zinc for age-related macular degeneration and vision loss: AREDS report no. 8. *Arch Ophthalmol*. 2001;119 (10):1417–1436. doi:10.1001/archopht.119.10.1417
6. Age-Related Eye Disease Study 2 Research Group. Lutein + zeaxanthin and omega-3 fatty acids for agerelated macular degeneration: the age-related eye disease study 2 (AREDS2) randomized clinical trial. *JAMA*. 2013;309(19):2005–2015. doi:10.1001/jama.2013.4997
7. Downie LE, Keller PR. Nutrition and age-related macular degeneration: research evidence in practice. *Optom Vis Sci*. 2014;91(8):821–831. doi:10.1097/OPX.0000000000000285
8. Carneiro A, Andrade JP. Nutritional and lifestyle interventions for age-related macular degeneration: a review. *Oxid Med Cell Longev*. 2017;2017:6469138. doi:10.1155/2017/6469138
9. Broadhead GK, Grigg JR, Chang AA, et al. Dietary modification and supplementation for the treatment of age-related macular degeneration. *Nutr Rev*. 2015;73(7):448–462. doi:10.1093/nutrit/nuv005
10. Davis MD, Gangnon RE, Lee LY, et al. Age-related eye disease study group. the age-related eye disease study severity scale for age-related macular degeneration: AREDS Report No. 17. *Arch Ophthalmol*. 2005;123:1484–1498.
11. Chew EY, Clemons TE, Sangiovanni JP, et al.; Age-Related Eye Disease Study 2 (AREDS2) Research Group. Secondary analyses of the effects of lutein/zeaxanthin on age-related macular degeneration progression: AREDS2 report No. 3. *JAMA Ophthalmol*. 2014;132(2):142–149. doi:10.1001/jamaophthalmol.2013.7376.
12. Shah SU, Pilli S, Telander DG, et al. Survey of patients with age-related macular degeneration: knowledge and adherence to recommendations. *Can J Ophthalmol*. 2013;48(3):204–209. doi:10.1016/j.jcjo.2013.01.013
13. Evans JR, Lawrenson JG. Antioxidant vitamin and mineral supplements for preventing age-related macular degeneration. *Cochrane Database Syst Rev*. 2017;7:1.
14. Thornton J, Edwards R, Mitchell P, Harrison RA, Buchan I, Kelly SP. Smoking and age related macular degeneration: a review of association. *Eye*. 2005;19(9):935–944. doi:10.1038/sj.eye.6701978
15. Stevens R, Bartlett H, Cooke R. Dietary analysis and nutritional behaviour in people with and without age-related macular disease. *Clin Nutr ESPEN*. 2015;10(3):e112–e117. doi:10.1016/j.clnesp.2015.03.080
16. Stevens R, Bartlett HE, Walsh R, Cooke R. Age-related macular degeneration patients'awareness of nutritional factors. *Br J Vis Impair*. 2014;32 (2):77–93. doi:10.1177/0264619613519341
17. Bian W, Wan J, Tan M, et al. Patient experience of treatment decision making for wet age-related macular degeneration disease: a qualitative study in China. *BMJ Open*. 2019;9(9):e031020. doi:10.1136/bmjopen-2019-031020
18. Chapman NA, Jacobs RJ, Braakhuis AJ. Role of diet and food intake in age-related macular degeneration: a systematic review. *Clin Experiment Ophthalmol*. 2019;47(1):106–127.
19. Kent C. AMD and nutrition: the missing message. *Rev Ophthalmol*. 2007;14(8):31–37.
20. Spatz ES, Krumholz HM, Moulton BW. Prime time for shared decision making. *JAMA*. 2017;317. doi:10.1001/jama.2016.19268
21. Oshima Lee E, Emanuel EJ. Shared decision making to improve care and reduce costs. *N Engl J Med*. 2013;368(1):6–8. doi:10.1056/NEJMp1209500
22. Swanson MW. Medical decision-making capacity and cataract surgery. *Optom Vis Sci*. 2012;89(10):e23–6. doi:10.1097/OPX.0b013e31826a3d85
23. Shum JWH, Lam WWT, Choy BNK, et al. Development and pilottesting of patient decision aid for use among Chinese patients with primary open-angle glaucoma. *BMJ Open*. 2017;2(1):e000100.
24. Stevens R, Bartlett H, Cooke R. Evaluation of a clinical decisionmaking aid for nutrition advice in age-related macular degeneration. *Br J Vis Impair*. 2017;35(3):185–196. doi:10.1177/0264619616683989
25. Coulter A, Stilwell D, Kryworuchko J, Mullen PD, Ng CJ. A systematic development process for patient decision aids. *BMC Med Inform Decis Mak*. 2013;13(Suppl2):S2. doi:10.1186/1472-6947-13-S2-S2
26. Elwyn G, Connor AMO, Bennett C, et al. Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi). *PLoS One*. 2009;4(3):e4705. doi:10.1371/journal.pone.0004705
27. Elwyn G, Connor AO, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ Open*. 2006;333(7565):417.
28. Brouwers MC, Kho ME, Browman GP, et al.; AGREE Next Steps Consortium. AGREE II: advancing guideline development, reporting and evaluation in health care. *Prev Med*. 2010;51(5):421–424. doi:10.1016/j.ypmed.2010.08.005.
29. Howick J, Chalmers I, Glasziou P, et al. The Oxford levels of evidence 2. Oxford Centre for Evidence-Based Medicine; 2016. Available from: https://www.cebm.net/index.aspx?o=5653. Accessed September 1, 2022.
30. The Joanna Briggs Institute (JBI).Joanna Briggs Institute review-ers'manual:2016 edition [EB/OL] (2017-07-15); 2020. Available from: http://joannabriggs.org/research/critical-appraisal-tools.html. Accessed September 1, 2022.
31. The Joanna Briggs Institute Levels of Evidence and Grades of Recommendation Working Party. Supporting document for the Joanna Briggs Institute levels of evi-dence and grades of recommendation. The Joanna Briggs Institute; 2014. Available from: http://joannabriggs.org/jbi-approach.html#tabbed-nav=Lev-els-of-Evidence. Accessed September 1, 2022.
32. Nota I, Drossaert HC, Melissant HC. Development of a web-based patient decision aid for initiating disease modifying anti-rheumatic drugs using user-centred design methods. *BMC Med Inform Decis Mak*. 2017;17(1):1. doi:10.1186/s12911-017-0433-5

33. US Department of Health and Human Services. The research-based web design& usability guidelines. Washington, DC; 2006. Available from: http://guidelines.usability.gov/. Accessed September 1, 2022.

34. Turner S. The HEP test for grading web site usability. *Comput Libr.* 2002;22(10):37–39.

35. Schonberg MA, Hamel MB, Davis RB, et al. Development and evaluation of a decision aid on mammography screening for women 75 years and older. *JAMA Intern Med.* 2014;174(3):417–424. doi:10.1001/jamainternmed.2013.13639

36. O'Connor AM. Ottawa decision support framework to address decisional conflict; 2006.

37. Elwyn G, O'Connor A, Stacey D, et al.; International Patient Decision Aids Standards. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ.* 2006;333(7565):417. doi:10.1136/bmj.38926.629329.AE

38. Essink-Bot ML, Dekker E, Timmermans DRM, Uiters E, Fransen MP. Knowledge and informed decision-making about population-based colorectal cancer screening participation in groups with low and adequate health literacy. *Gastroenterol Res Pract.* 2016;(2016):8.

39. O'Connor AM. User manual—decisional conflict scale (16 item statement format); 1993: 1–16. Available from: https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_decisionalconflict.pdf. Accessed February, 2018.

40. O'connor AM. User manual—decision self-efficacy scale; 1995. Available from: https://decisionaid.ohri.ca/docs/develop/user_manuals/UM_decision_selfefficacy.pdf. Accessed February, 2018.

41. Graham I, O'connor AM. User manual—preparation for decision making scale; 1995. Available from: https://decisionaid.ohri.ca/docs/develop/user_manuals/UM_prepdm.pdf. Accessed February, 2018.

42. van der Bij AK, De Weerd S, Cikot RJ, Steegers EA, Braspenning JC. Validation of the Dutch short form of the state scale of the Spielberger State-Trait Anxiety Inventory: considerations for usage in screening outcomes. *Commun Genet.* 2003;6(2):84–87.

43. Bol N, van Weert JCM, de Haes HCJM, et al. Using cognitive and affective illustrations to enhance older adults' website satisfaction and recall of online cancer-related information. *Health Commun.* 2014;29(7):678–688. doi:10.1080/10410236.2013.771560

44. Brooke J. SUS - A quick and dirty usability scale. *Usabil Eval Ind.* 1996;189(194):4–7.

45. Kushniruk AW, Patel VL. Cognitive and usability engineering methods for the evaluation of clinical information systems. *J Biomed Inform.* 2004;37(1):56–76. doi:10.1016/j.jbi.2004.01.003

46. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract.* 2004;10 (2):307–312. doi:10.1111/j.2002.384.doc.x

47. Zdenkowski N, Butow P, Tesson S, et al. A systematic review of decision aids for patients making a decision about treatment for early breast cancer. *Breast.* 2016;26:31–45. doi:10.1016/j.breast.2015.12.007

48. Fung CH, Martin JL, Liang LJ, et al. Efficacy of a patient decision aid for improving person-centered decision-making by older adults with obstructive sleep apnea. *J Clin Sleep Med.* 2021;17(2):121–128. doi:10.5664/jcsm.8798

49. Cox CE, White DB, Hough CL, et al. Effects of a personalized web-based decision aid for surro-gate decision makers of patients with prolonged mechanical ventilation: a randomized clinical trial. *Ann Intern Med.* 2019;170(5):285–297. doi:10.7326/M18-2335

50. Jaspers MW. A comparison of usability methods for testing interactive health technologies: methodological aspects and empirical evidence. *Int J Med Inform.* 2009;78(5):340–353. doi:10.1016/j.ijmedinf.2008.10.002