EDUCATIONAL PROTOCOL FOR PATIENTS ON ORAL ANTICOAGULANT THERAPY: CONSTRUCTION AND VALIDATION

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ABSTRACT: This is a report of experience on the construction and validation of an educational protocol for patients on oral anticoagulant therapy. Based on Bandura’s Social Cognitive Theory, three phases were identified to construct the educational protocol. The literature review on oral anticoagulants was used to prepare the content of each phase of the protocol. As a result, verbal and written orientation in the phases of attention and retention were developed. In the reproduction and motivation phase, support through contact by telephone was provided. And finally, an improvement in the evaluation of the outcomes related to oral anticoagulant is expected in the performance phase. Once the educational protocol was defined, we proceeded with the face and content validity process, which allowed adaptations to the final version of the educational protocol constructed.

INTRODUCTION

Oral anticoagulant therapy (OAT) comprises vitamin K antagonist drugs, which act by increasing the blood clotting time of the individual (assessed by the INR - International Normalized Ratio). They are generally prescribed in the presence of diseases that lead to the formation of intravascular thrombi, such as the presence of venous thrombosis, stroke or cardiac arrhythmia. Their use requires constant and strict control of blood levels so that the patient benefits from safe treatment. Patients who start using OAT remain hospitalized until the dose adjustment to their clinical condition, and, even after discharge, frequent tracking is needed to monitor the treatment.1

Numerous factors influence blood coagulation and may lead the patient to a higher risk of bleeding or thrombi. These factors are related to individual aspects (e.g., genetic influence and comorbidities), food (e.g., excessive intake of foods rich in vitamin K) and use of other drugs (e.g., anti-inflammatories).2 To minimize the risk of complications due to OAT use, specialized clinics in the management of such treatment have become common on the world stage. Specialized health professionals (physicians, pharmacists, nurses) develop actions for the realization of educational programs with verbal and written guidance, and the use of instructional videos;3-6 support groups, home visits, follow-up by telephone and quality indicators for the service provided.7

Studies suggest that patient education promotes better clinical outcomes, such as greater compliance, better INR control with values within the expected therapeutic range,8 better understanding of the signs and symptoms of complications,9-10 significant reduction in readmissions11-12 and decreased health costs.13 Such an education process should begin even during the patient’s hospitalization and continue throughout the outpatient follow-up of the patient.14 This practice also supports greater involvement of professionals working with this population.15

In this paper, we report the experience of building an educational protocol for the self-care of patients using OAT, and carrying out the face and content validity by a board of experts.

BUILDING THE EDUCATIONAL PROTOCOL

The construction of the protocol is one of the development stages of two randomized clinical trials in progress, aiming to test whether participation in the educational program, focused on the self-care of patients using OAT, improves the impact of treatment on the quality of life and satisfaction with the drug product. Both studies, which included the construction stage of the educational protocol, were performed in a public hospital in the state of São Paulo, after approval by the Research Ethics Committee responsible for the hospital referred to.

Theoretical foundation

An American study is an example in which proposing changes to human behavior in health care is a challenge. This study, researching the various existing theories on human behavior, defined five stages in the change process: 1) gaining attention, 2) having stimulating material, 3) identifying performance and providing feedback, 4) providing guidance for learning and 5) increasing retention and transfer. However, this process involves numerous factors (the individual, the health system, the geographic, social and political environment) that interact in complex ways to influence the behavior in question.16

Another scholar17 in the area adds that the behavior comes from the perspective of the human agency for self-development, adaptation and change. Being an agent means influencing the function itself and the circumstances of life intentionally, in other words, it is mediated by a self-awareness that enables them to adopt personal standards, monitor their actions to reflections on their personal effectiveness, making adjustments whenever necessary.17 The Social Cognitive Theory of the Personality may be called the Social Cognitive Theory or simply Bandura’s Theory. It assumes that human functioning is associated with a wide network of influences mediated by cognitive processes in the adaptation to human changes. As if thoughts and actions were products of a dynamic interplay between personal, behavioral and environmental influences, enabling therapeutic interventions.17

In short, “that which people think, believe and feel affects how they behave”.17:99 These
Educational protocol for patients on oral anticoagulant therapy…

capabilities provide a cognitive means to these individuals. Perhaps, among these cognitive aspects, the belief in self-efficacy is what most affects human functioning. Self-efficacy is a “judgment of people in their capabilities to organize and execute actions required to achieve certain performance”. These beliefs provide the foundation for human motivation, for well-being and for social achievements.

The assumption of this theory helps us to understand why people’s behaviors are sometimes not related to their actual capabilities and why they differ from each other, even if they have similar knowledge and skills. Thus, we elected this theory to build the educational protocol.

**Definition of the protocol**

In an attempt to combine the theoretical precepts to the construction of an educational protocol for OAT patients, we adapted Table 1 from the book “The Nurse as Educator: Principles of Teaching and Learning for Nursing Practice”, which represents the foundation of Bandura’s theory.

**Table 1 - Processing of information according to Bandura’s Theoretical Model of Social Learning adapted to patients who will use OAT**

<table>
<thead>
<tr>
<th>External processes</th>
<th>Internal processes</th>
<th>External processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral anticoagu-lant use</td>
<td><strong>Self-Regulation and Control</strong></td>
<td>Performance</td>
</tr>
<tr>
<td></td>
<td>Attention</td>
<td>Retention</td>
</tr>
<tr>
<td>Presentation about the treatment:</td>
<td>The use of figures and texts with a focus on the guidance provided, aimed at the patient’s memorizing of the content.</td>
<td>Reinforcement by telephone contact:</td>
</tr>
<tr>
<td>-verbal (slides)</td>
<td></td>
<td>- 1 week and 1 month after discharge</td>
</tr>
<tr>
<td>-written (leaflet)</td>
<td></td>
<td>Verbalization of the content learned by the patient faced with the nurse’s questions.</td>
</tr>
</tbody>
</table>

Table 1 shows that, initially, the attention phase takes place, a condition necessary for any learning to happen. Next, there is the retentive phase, which involves the storage and retrieval of what has been observed. The reproduction phase is in third place, wherein the mental training and corrective feedback strengthen the reproduction of the behavior. Finally, there is the motivation stage, in which the learner is motivated to perform a certain type of behavior.

One of the foundations of this theory that stands out is the vicarious reinforcement. A person can acquire skills from a certain behavior, but learning will rarely be activated if it is received in a negative or unfavorable manner. When they go through experiences of reinforcement, individuals observe the progression they are making and tend to set goals of progressive improvement for themselves. Hence, the learning situation and the appropriateness of subsequent situations will make the behavior become adopted.

**Verbal and written guidance (attention and retention phase)**

For the preparation of the content to compose the verbal (slides) and writing (pamphlet) guidance, a bibliographical survey of studies relevant to the themes of oral anticoagulation and Bandura’s Theory was conducted. The databases used were: the Medical Literature Analysis and Retrieval System Online (MEDLINE) and the Latin American and Caribbean Literature on Health Sciences (LILACS).

Of the studies on OAT, two studies stood out. One of them on the systematic review of OAT education strategies and another methodological study of building an instrument of knowledge about OAT.

The main information brought by these authors relates to: 1) physiological aspects of the drug, such as mechanisms of action; 2) risk-benefit in indicating this treatment with a view to safe treatment; 3) adherence to schedule, dose and
failure in intake; 4) balanced diet rich in vitamin K and fatty foods; 5) strict laboratory monitoring; 6) the science of drug interactions; 7) the need for self-care; 8) alert for surgeries, dental care, pregnancy and travel; 9) specialized health professionals; and 10) guidance on the need for the emergency service.

There are still few studies on the behavior of individuals who make use of OAT considering Bandura’s Theory. However, studies that applied this theory in other populations\textsuperscript{24-27} assisted in the analysis of the educational strategies used. We have the use of leaflets and telephone contact to reinforce the behavior of patients to maintain control of blood pressure.\textsuperscript{24} In Korea, psychiatric patients were helped to cope with treatment through videos of vicarious experiences, group discussions and follow-up by telephone.\textsuperscript{25} Telephone contact was also the reinforcement method adopted by American nurses for the modification of risk factors in patients with acute myocardial infarction.\textsuperscript{26} Internet use was another feature used to enhance the behavior of mothers in maintaining breastfeeding.\textsuperscript{27}

A presentation for verbal guidance was developed in 26 slides from the PowerPoint\textsuperscript{®} for Windows program, 2007 version, containing illustrations to address topics related to the use of OAT (Table 2). The use of figures allows the researcher to retain the attention and stimulate the participant to report their experiences as the information is given. For example, the figure of the normal blood vessel and its occlusion due to thrombus illustrates the action of the OAT. Written guidance was given with the delivery of an information leaflet on treatment with OAT.

### Table 2 - Topics addressed for teaching patients about oral anticoagulation

<table>
<thead>
<tr>
<th>Topics</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physiology</td>
<td>Definition of oral anticoagulants, mechanisms of action and clinical indication.</td>
</tr>
<tr>
<td>Medication</td>
<td>Dose, schedule, storage and duration of treatment.</td>
</tr>
<tr>
<td>Monitoring of anticoagulation</td>
<td>Meaning of INR and normal value expected for each indication, collection period and consultations.</td>
</tr>
<tr>
<td>Using other drugs</td>
<td>Interaction with allopathic medicines and those considered “natural”.</td>
</tr>
<tr>
<td>Meals</td>
<td>Intake of foods rich in vitamin K and fats.</td>
</tr>
<tr>
<td>Alcoholic beverages</td>
<td>Avoid drinking alcohol, if it occurs, do not stop taking the oral anticoagulant.</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>Need to start oral anticoagulant for injection.</td>
</tr>
<tr>
<td>Activities</td>
<td>In physical, domestic or labor activities use protective measures.</td>
</tr>
<tr>
<td>Health care</td>
<td>Alert about oral anticoagulant to another professional and take the INR value card.</td>
</tr>
<tr>
<td>Traveling</td>
<td>Take the oral anticoagulant and plan to perform the INR outside of your healthcare facility.</td>
</tr>
<tr>
<td>Signs and symptoms of complications related to treatment with oral anticoagulant</td>
<td>Information on the possibility of complications related to underdosing (thrombus formation) and overdose (bleeding), as well as the need to seek health care in cases such as: bleeding in the gums, in the urine, among others.</td>
</tr>
</tbody>
</table>

**Telephone reinforcement (reproduction and motivation phase)**

Resuming the precept of Bandura’s Theory,\textsuperscript{17} individuals may or may not choose to perform the behavior about which they learned. This decision is determined by the consequences that such action may cause. The use of positive reinforcement and encouragement is important for that individual’s decision making.

In our study, reinforcement for OAT patients was done using telephone contact. At this time, the nurse/researcher performed the positive stimulus for the participant so that they could recall the relevant information on the use of the OAT, encouraging them positively. For the telephone contact, a script was used, which was developed by the researchers and composed of questions and conducts guided by the theoretical framework and the bibliographical survey conducted for this study (Table 3).
Table 3 - Script for telephone contact

<table>
<thead>
<tr>
<th>Questions</th>
<th>Answers</th>
<th>Conduct</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) After being discharged from the hospital, did you feel able to carry out the guidance given during their hospitalization?</td>
<td>( ) yes</td>
<td>If yes: positive stimulus (“very good, now let’s remember some important information”). If no: positive reinforcement (“okay then, now let’s remember some important information”).</td>
</tr>
<tr>
<td>2) Are you having difficulties taking the oral anticoagulant as per guidance during discharge?</td>
<td>( ) yes</td>
<td>If yes: inquire about the difficulty and then guide them how to properly take oral anticoagulants, according to medical prescription. If no: positive stimulus (“very good”).</td>
</tr>
<tr>
<td>3) Do you remember what you should do/how you should act when realizing that you have forgotten to take your medicine?</td>
<td>( ) yes</td>
<td>If yes: if remembered on the same day, take the medicine right away at the prescribed dose. If remembered only the next day, do not take the dose from the previous day, only the dose for that day (“very good”). If no: guide them according to the expected response.</td>
</tr>
<tr>
<td>4) If you experience any disease, for example, flu or infection, can you tell me what kind of care you should have?</td>
<td>( ) yes</td>
<td>If yes: do not take any medication without medical advice (“very good”). If no: remind them about the medications that should be taken with caution (e.g., antibiotics, analgesics, anti-inflammatories and medicinal herbs).</td>
</tr>
<tr>
<td>5) Another caution is about food, can you tell me with which foods this caution should be taken?</td>
<td>( ) yes</td>
<td>If yes: caution with foods rich in fat, dark leafy greens, beets, etc. (“very good”). If no: remind them about diet and ask questions about other foods.</td>
</tr>
<tr>
<td>6) If you go to the dentist or another doctor, what is important to remind them?</td>
<td>( ) yes</td>
<td>If yes: making use of oral anticoagulants (“very good”). If no: remind them about the importance of such information. If they are women of childbearing age, reinforce the importance of going to the gynecologist especially in the 1st trimester to alter the oral anticoagulant to the injectable type.</td>
</tr>
<tr>
<td>7) If you travel, what kind of care should you take?</td>
<td>( ) yes</td>
<td>If yes: you need to take an oral anticoagulant for every day of the trip (“very good”). If no: remind them about the importance of such information.</td>
</tr>
<tr>
<td>8) So, it is important to take the oral anticoagulant correctly. Can you tell me, how you are currently taking oral anticoagulants this week?</td>
<td>( ) yes</td>
<td>If yes: Monday ( ); Tuesday ( ); Wednesday ( ); Thursday ( ); Friday ( ); Saturday ( ) and Sunday ( ) (“very good”). If no: remind them about the importance of this information and if the participant reports another dose, ask about the reason for this change.</td>
</tr>
<tr>
<td>9) If the anticoagulant dose is inadequate, can you recall what signs/symptoms you may present?</td>
<td>( ) yes</td>
<td>If yes: bleeding gums, blood in urine, cuts that does not stop bleeding, dark or red stools, purple spots, severe headache, leg pain, swelling, throbbing, dizziness, malaise. If no: remind them about the signs and symptoms of treatment complications and emphasize the importance of their observations.</td>
</tr>
<tr>
<td>10) If they have any of these signs/symptoms, it is necessary to seek a health service and remember the INR value. Can you tell me what this value was on your last visit?</td>
<td>( ) yes</td>
<td>If yes: value ( ) (“very good”). If no: remind them about the importance of this information and if the participant reports another INR value, ask whether there was the need to perform the examination at another health service.</td>
</tr>
<tr>
<td>Closure: Would you like to ask me anything? Would you like me to pass some of this information on to your family?</td>
<td>( ) yes</td>
<td>If yes: name of the family member ( ). If no: thanks for your time.</td>
</tr>
</tbody>
</table>
VALIDATION OF THE EDUCATIONAL PROTOCOL

The face and content validity of the material (slides and leaflet) designed for the educational protocol was performed by a board of experts composed of a multidisciplinary team of two nurses, a physician, a nutritionist, a psychologist, two pharmacists, a social worker and a patient using OAT. Professionals worked in the hospital where the study was conducted and they were elected to contribute with their practical experience. The patient was male and used OAT, due to atrial fibrillation, for four years. In a meeting held between researchers and the staff, the material (slides and leaflet) was submitted to face and content assessment. Suggestions were made for the addition of a suitable place for the storage of the OAT, replacement of words to facilitate the understanding of the patients and reformulating some information so that it was objective and so the terms stood out to refer to the key information on each slide.

The script for telephone contact was subjected to face and content validity by five research nurses, elected for their knowledge regarding Bandura’s Theory. Suggestions were made for the reformulation of sentences using verbs that address stimulus to action. For instance, “if you forget to take the anticoagulant, would you remember what to do?”. All suggestions were accepted and incorporated into the material.

Next, in order to implement the educational protocol, the researchers conducted interviews with patients admitted to the hospital for a month. A convenience sample was composed of seven patients using OAT. After verbal and written guidance, participants were asked about the need for changes in the material constructed for the educational protocol. Four of the participants considered the presentation of long slides, and the adjustments made, the presentation time was reduced from 45 to 30 minutes. The script for telephone contact was also evaluated by the participants and the application time of 15 minutes was considered adequate.

Expected results (performance phase)

Provided with the material defined for the educational protocol to patients using OAT, figure 1 outlines the proposed implementation.

![Figure 1 - Educational protocol according to the follow-up time](image_url)

When the patient starts using the OAT, they remain hospitalized for a period until the OAT dose is adjusted. It is during this period that the nurse will approach the OAT patient with a laptop and perform the verbal guidance and deliver the information leaflet. After discharge from the hospital, we propose conducting a follow-up telephone call during the first and fourth week. The definition of this period is based on the feature of adjusting the OAT. It is necessary to perform weekly blood tests at the start of the OAT. After adjusting the OAT dose, blood tests may be performed monthly.

Determining the period for assessing the expected results, i.e., the performance of the patient when participating in an educational intervention focused on self-care with the OAT will be linked to the reality of each health service. As regards our reality, it was suggested that this review was conducted two months after the participant’s discharge.
Thus, it is expected that with the use of an educational protocol, the knowledge and motivation for the self-care of patients using OAT would result in better control of blood clotting, better quality of life, greater treatment adherence and decreased emotional impact on them. The assessment of such outcomes can be performed with instruments and/or validated questionnaires, which already exist in literature.31-33

FINAL CONSIDERATIONS

Protocols to guide the conduct of health professionals in search of better results related to various treatments have been developed and successfully applied in different contexts. Therefore, it is essential to know the reality of the target population that the development and implementation of a protocol will be dedicated to.

In our reality, OAT patients are mostly elderly people who have difficulty reading and understanding. Considering these aspects was the basis for directing the researchers in choosing the best strategies to prioritize the educational content.

This experience proved important for us to identify that the potential for the use of this protocol is related to the use of resources accessible to health services, facilitating their implementation and reflecting the best care for patients using OAT. The motivation, availability and knowledge of health professionals in using this protocol may be some of the barriers to their effective implementation in daily practice.

Even in the face of obstacles, we suggest that the implementation of the educational protocol be carried out and, in the long term, we should consider possibilities for application in larger groups of patients, different cultures and in public and private health institutions.

When we decided to report the experience of constructing and validating an educational protocol, we also collaborated to point out the difficulties involved in this task. We observed that the patient’s emotional state is an ambiguous factor, which may be both limiting and impulsive, by providing patient involvement in the explanations of the researchers on the disease and its treatment. Even with the health terminology adjustments to the content of the educational protocol, the cognitive status of some patients makes them more susceptible to longer explanations. Finally, the very fact of change - starting to use oral anticoagulants - imposes the decision of a behavior on a patient, which may be expected or not. Intervention studies conducted by the authors are being concluded and will confirm that the use of this educational protocol with incentives by telephone has helped patients in the adherence to treatment with oral anticoagulants.

REFERENCES


