FOOD AND NUTRITION IN COLLECTIVE HEALTH
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DEMETRA Alimentação, Nutrição & Saúde

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Identifying elements of empowerment and autonomy in food choices in Food and Nutrition Education groups: A qualitative research

Identificando elementos de empoderamento e autonomia nas escolhas alimentares em grupos de Educação Alimentar e Nutricional: uma pesquisa qualitativa

Abstract

Introduction: Public health policies have reinforced the importance of empowerment and autonomy of individuals, but these aspects are unfamiliar in the Nutrition field. ***Aim***: To identify elements that contribute to the strengthening of empowerment and autonomy in food choices of Food and Nutrition Education Groups participants. ***Methods***: A qualitative research from the perspective of social representations was carried out in the Primary Health Care in São Paulo city, Brazil. Two groups containing patients with chronic diseases were developed. These patients, between 47 and 78 years old, attended an average of 6 group meetings, within a three-month period. To explore the experiment patients, in order to understand how they attribute senses and meanings to their food choices, a semi-structured interview was conducted with 15 patients, post-intervention. To analyze the data, thematic content analysis was applied. ***Results***: Five themes were identified: self-perception, information and knowledge, personal ability, attitude and active adaptation towards choices. The first four were identified as elements of empowerment, because they evidenced the expansion of individuals' capacity to think and act critically towards food choices. The last theme was formed by the confrontation of meanings from determinants, accountability and internal negotiation, which proved to be elements of autonomy, since they have configured transformations constructed by the participants themselves, post-intervention. ***Conclusions***: The identified elements demonstrated to compose the evaluation of autonomy in individuals' food choices, being able to constitute rating indicators of Food and Nutrition Education, as well as to evaluate and monitor care practices recommended in health promotion.

Keywords: Food and Nutrition Education. Health Promotion. Healthy Diet. Primary Health Care. Qualitative Research.

Resumo

Introdução: As políticas públicas de saúde têm reforçado a importância do empoderamento e da autonomia dos indivíduos, mas esses aspectos são desconhecidos na área da Nutrição. ***Objetivo:*** Identificar elementos que contribuem para o fortalecimento do empoderamento e autonomia nas escolhas alimentares de participantes de grupos de Educação Alimentar e Nutricional. ***Métodos:*** Pesquisa qualitativa na perspectiva das representações sociais realizada na Atenção Primária à Saúde da cidade de São Paulo, Brasil. Foram desenvolvidos dois grupos contendo

usuários com doenças crônicas. Esses usuários, com idade de 47 a 78 anos, compareceram em média a seis encontros grupais, em um período de três meses. Para explorar a vivência dos participantes, a fim de compreender como eles atribuem sentidos e significados a suas escolhas alimentares, realizou-se entrevista semiestruturada com 15 usuários, pós-intervenção. Para a análise dos dados, aplicou-se a análise de conteúdo temática. ***Resultados:*** Cinco temas emergiram: autopercepção, informação e conhecimento, capacidade pessoal, atitude e adaptação ativa às escolhas. Os quatro primeiros foram identificados como elementos de empoderamento, pois evidenciaram a ampliação da capacidade dos indivíduos de pensar e agir criticamente frente às escolhas alimentares. O último foi formado pelo confronto de determinantes, responsabilização e negociação interna, que se revelaram elementos da autonomia, uma vez que configuraram transformações construídas pelos próprios participantes, pós-intervenção. ***Conclusão:*** Os elementos identificados mostraram compor a avaliação da autonomia nas escolhas alimentares dos indivíduos, podendo constituir indicadores de avaliação da Educação Alimentar e Nutricional, bem como avaliar e monitorar as práticas de cuidado preconizadas na promoção da saúde.

Palavras-chave: Educação Alimentar e Nutricional. Promoção da Saúde. Alimentação Saudável. Atenção Primária à Saúde. Pesquisa qualitativa.

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INTRODUCTION

Chronic diseases are a major public health issue, being considered the cause of life quality loss with high limitation level in individuals.[1] In Brazil, these diseases, especially those related to food and nutrition, are present in Primary Health Care (PHC) services, where multiprofessional teams develop care practices. To prevent such diseases and promote health in individuals through the improvement of their food choices, these professionals develop Food and Nutrition Education (FNE) actions.[2,3]

FNE studies demonstrate that actions are more effective when they are based on theories and have defined objectives[4] and when they are carried out in groups.[5,6] In order to measure the results of these groups in individuals' health status, researchers used of anthropometric indicators. At the same time, it is conceived that these should be complemented with other indicators, which expand the understanding of the process of individuals' food choices.[2,7] Therefore, other researchers have stressed the importance of assessments with qualitative and participatory approaches.[8,9]

These approaches can be instigated by the pursuit of autonomy in health, that is defined as the individual's ability to evaluate health options, to decide among the options, to feel confident about their decisions, to define solutions to reach their decisions and to act on health determinants, taking responsibility in caring.[10-13] This is strengthened by an empowerment process, in which individuals expand their ability to think and act critically on their care.[14]

The autonomy strengthening and empowerment in individuals are promoted by public policies in several countries, especially in the context of PHC and related to the care of individuals with chronic diseases.[15] However, these aspects are unfamiliar in the Nutrition field and there is no evidence of elements that constitute autonomy in food choices.[15,16] Brandstetter et al.[16] confirm this in a systematic review on empowerment for healthy nutrition, in which authors revealed that researchers and practitioners use generalizable health concepts and indicators, due to insufficient debate on these issues.

The construction of new knowledge about these elements can facilitate the consolidation of FNE groups, so this study aimed to identify elements that contribute to the strengthening of empowerment and autonomy in food choices of FNE groups participants.

METHODS

Setting

In Brazil, FNE actions, mainly in health promotion, have been stimulated, recognized and financed by public policies, which recommend for professional practice the incorporation of active and problematizing approaches and resources, relying on evaluation within a participatory planning process.[17,18]

Based on these recommendations, the present study performed two FNE groups, in 2015 and 2016, with the objective of promoting participants' autonomy in food choices. The construction of the educational method was based on theoretical references: FNE,[18] health promotion,[19] healthy diet,[17] and Operative Group (OG).[20]

The FNE groups, hereinafter referred to as "groups", were coordinated by a nutritionist, principal author of the study, with the support of an observer. For the implementation, a work plan, composed of meetings task, moments of reception, of integration/reflection and of closure, was used as guide. In all meetings, weekly and fortnights, active and problematizing approaches and strategies were included. The groups were evaluated post-intervention through a results assessment of the participants' autonomy in food choices.

Design

A qualitative research was carried out in the perspective of social representations[21] and, for the construction of the empirical universe, a reflective interview was applied.

Participants and Recruitment

The study was conducted in the city of São Paulo (Brazil), in a Basic Health Unit (BHU) which is responsible for the care of 110,000 individuals. From these, the Nutrition team attended 455 during the period of the survey, the majority being women and over 40 years old. To represent those and with the intention of achieving homogeneity among patients the inclusion criteria were established: to be at least 40 years old, to seek care due to some chronic disease related to food and nutrition and to attend at least three group meetings.

The selection was for convenience, carried out by the Nutrition team through nutritional screening for two months. When patients met the criteria, they were invited to voluntarily participate in the study. So 32 patients were invited, 22 of whom attended the first meetings and 15 remained until the end of the intervention.

The 15 participants attended 4 to 8 meetings, with an average of six, within a three-month period. Regarding the presence in the meetings, the number of participants varied from 2 to 9, with an average of 7 per meeting. Of these participants, 13 were female and 2 were male, between 47 and 78 years old, with educational level from incomplete elementary school up to bachelor's degree. The most frequent occupations were homemaker, house cleaner and caregiver. As for chronic diseases, they had either alone or in combination obesity, systemic arterial hypertension, dyslipidemia, diabetes mellitus, osteoporosis and gastritis.

This research was performed in accordance with the standards of research involving human beings, and was approved by the School of Public Health Ethics Committee, University of São Paulo, under opinion number 1.035.608/2015. Written informed consent was obtained from all participants.

Semi-structured interviews

A month after the end of the groups, an individual interview was conducted with the 15 participants by the main author, previously trained, at the BHU. The reflexive interview technique was used, in which the interviewer reflected upon the participants' speech and expressed her understanding, providing the possibility for another reflexive movement.[22]

The interviewer used a questionnaire that was elaborated, tested and improved before the selection of participants. Three roadmap questions were related to food choices, for example: "thinking about your routine at home and / or work, did you notice any changes in your diet and health?". In one of the questions, their thoughts on a case of a BHU patient with similar characteristics and health needs to theirs were inquired.

The interviews, on an average of 34 minutes long each, were sound recorded in audio and transcribed in its totality to Portuguese by the first two authors. Excerpts from the interviews, which are presented in this study, were translated into English by a language-fluent researcher.

Data analysis

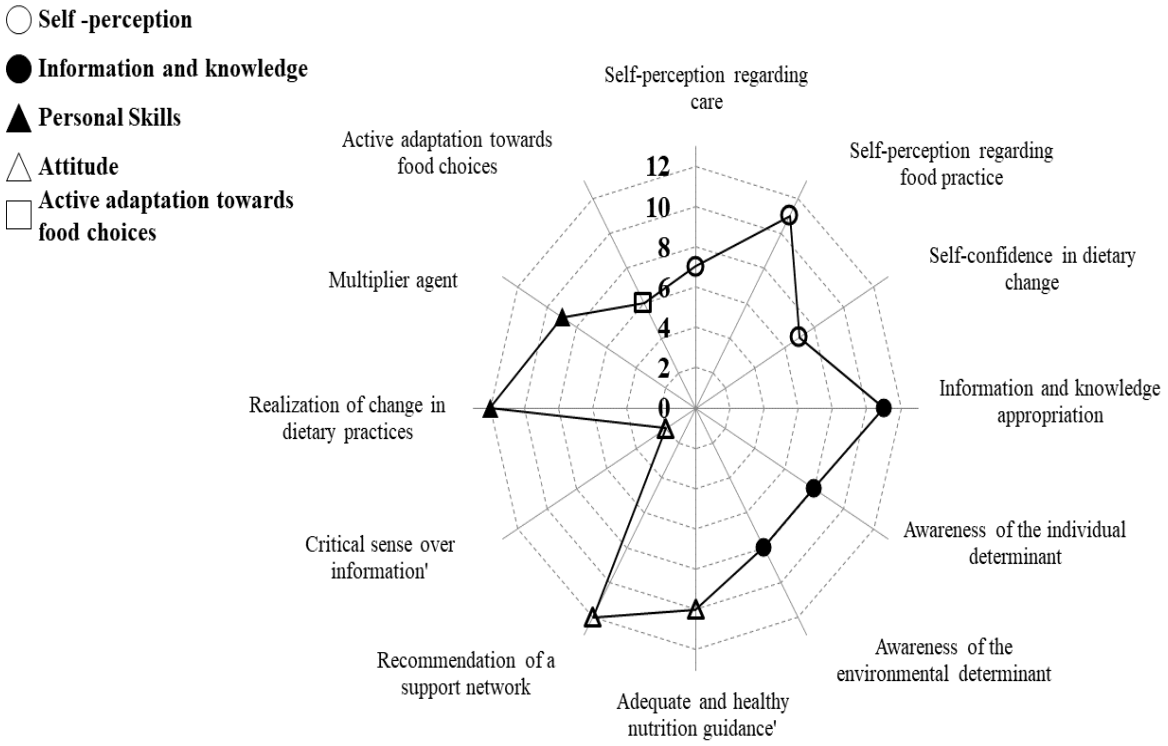
In order to analyze the data, thematic content analysis was applied through deductive and inductive approaches, and the stages of exploration, coding, category development and interpretation were followed.[23] In

exploration and coding, the first two authors organized the data in Microsoft® Word 2010, and, by reading line by line, edited to benefit reading and analysis of the texts, codifying them. In category development, the software NVivo 11® (QSR International) was used, which facilitated the process of shortening the texts to significant expressions, as well as for data classification and aggregation through formulation of categories. In this, there was a content validation among all authors.

RESULTS

Regarding participants' autonomy in food choices, five themes were identified: self-perception, information and knowledge, personal ability, attitude and active adaptation towards choices. The themes, including their subthemes and participants frequency in them, are presented in figure 1 and described in the following, with examples of excerpts from participants' speeches, indicated by number, gender and age in years.

Figure 1. Themes and subthemes about autonomy in food choices of Food Nutrition and Education group



Self-perception

In "self-perception regarding care", the participants' way of thinking and/or acting on health care was revealed, since they reported the association between diet and care, either to prevent diseases, either to question their illness and to take care of their health or nutritional status. In "self-perception regarding food practice", it was found that participants were able to compare food practices among them thanks to the group experience, since the majority mentioned that from this experience they perceived their own practice, confirming it or noticing the need for

changes. With this, some participants identified difficulties, especially when related to out-of-home eating and over the weekends. Still, they were looking for improvements:

> There was a word that was said there that weighed in my mind, in such a way, a person, I do not remember who it was, that he / she spoke thus, "I was born to live I was not born to eat", I said "I thought I was born to eat" and that word stayed in my mind making an effect. I was acting in a wrong way, really I have to understand that I was born to live and not to eat [...] (Participant 15, female, 47 years).

In "self-confidence in dietary change", it was noticed the presence of a confidence feeling in maintaining the conquered changes and/or to acquire new ones, even after the dismantlement of the groups. This confidence was attributed, by the participants, to the feeling of being capable, to the group recollection, to body weight reduction and to the expectation of demonstrating progress to the professional:

> Funny, it seems like when you go to a place that has a really technical thing, because when a professional in the field alerts you, like, you watch television you see magazine, everything, but it seems like when you are being directed, someone is guiding you, it seems things are clearer in our minds, we become happier, able to perform what we want to, that is how I feel (Participant 10, female, 54 years).

Information and knowledge

Regarding "information and knowledge appropriation", the participants' acquisition of information stands out, since the majority claimed to obtain information on topics discussed at the meetings, on healthy diet and on diet related to chronic diseases care. They also reported a knowledge construction from the nutritionist or other participants' speeches, by strengthening an existing knowledge, updating health status and finding the need for change:

> After I joined the group, it changed a lot, that there were things I was eating without knowing anything, then after I joined the group, I became aware of the things I could eat, the things that were bad [for control of diabetes] and things that weren't bad [...] (Participant 5, female, 63 years).

Concerning "awareness of the individual determinant", it was found that the groups aroused the association between food practices and individual components among participants, since they stated that the realization of these is influenced by personal desire and by physiological, psychological and emotional factors:

> I think I've been making myself aware, I cannot keep eating pork fat at this point, even more that I have a mobile prosthesis, in the upper part does not feel anything, anyway, are no longer important for me (Participant 12, male, 78 years).

As for the "awareness of the environmental determinant", it was identified the association between food practices and social and economic factors. However, participants reported them as aggravating factors of a healthy diet, emphasizing the work environment and food acquisition as obstacles for dietary changes.

Personal Skills

The ability to give support to other individuals through "healthy diet guidance" emerged in response to the presented case, in which participants reported guidance to chronic disease and diet care, as well as to self-

perception. In addition, the majority recommended, given the situation, the group in which they participated and nutritional advice from the nutritionist, creating the "recommendation of a support network":

> I'd recommend the group for her because what would I do? Give her a diet? No, no, I would say "you're going to the group", because I could even say "oh there it's done in this and this way", she would not understand because to understand she would have to participate, be a part of it. [...] Because if I told her to be part of the group, she would already learn what I learned, and then she definitely would be able to reach her goal (Participant 1, female, 52 years).

The "Critical sense over information" appeared due to participants criticality in relation to food and nutrition information found in their daily lives, given that they brought into question other people's use of weight-loss medication and food lists to guide food choices, in addition to claims in some products as "whole foods" or "organic foods", and the information released by the media:

> A very cool thing I learned from you: I do not believe what's in the magazines, or in the big news, "do not eat the egg, look at cholesterol, look at vitamin C", all these confusions, I go by common sense. There is one thing: I believe in rice, beans and vegetables, in real food. I do not believe in these little pockets of food, these magics that replace a meal, I do not even know the names anymore (Participant 8, female, 64 years).

Attitude

In this theme, it is highlighted the "realization of change in food practices", since most participants mentioned dietary changes, such as: increasing the distribution of meals throughout the day; reduction of fatty foods, fried foods and sugar; increased consumption of fruits and vegetables, whole foods and water intake. Participants were able to find solutions for the implementation, the motivation from the culinary preparations worked at the meetings and the decision to eliminate specific foods:

> [...] I added three things that were: do not eat that bread full of thing, I started to make that whole bread, that I not wide, I adored it and even my daughters liked. [...] I added the water, I drink a lot of water. And eat something in the morning. It's my bread that I eat with coffee or a glass of milk with chocolate. I learned to make that water with flavors, apple or lemon in the water, very good [...] that helped and it was that I took the group because I spent the day and did not remember to drink water (Participant 9, female, 56 years).

In the attitude of "multiplier agent", the act of sharing information/knowledge and/or dietary changes to other social groups was identified, since participants declared sharing information or knowledge with their relatives and friends and, especially, the expansion of these changes with their families:

> Even my husband has also changed, my daughter has changed too. I think it helped a lot for me, because that way we did not have the habit of eating lots of vegetables, and now everyone, even my husband, has already gotten used to it (Participant 4, female, 54 years).

Active adaptation towards food choices

Despite the dismantlement of the groups, "active adaptation towards food choices" was identified by the participants' transformation, on their own account, of the environment in which they live and/or take daily actions to improve their food practices. This was visualized by the act of confronting the determinants that influence their decisions in nutritional care. It was found that the participants confronted their beliefs about eating and dieting, provoking an adjustment in the way of thinking, caused by the recollection of life experiences related to this care:

> [...] It helped me a lot there in the group to talk about the effects over a lifetime, over time, so there's no point in hurrying now, not that I'm not going to do anything because there's no point in hurrying, but I don't feel so distressed by it. [...] Like, my sister, we were together this weekend and we talked about this and that, and she said, "Oh, but there's no way for us to lose weight, we need to reduce our food, we need a diet." Then I said: "Look, I'm no longer in favor of dieting, my whole life I've done it and it did not work, which is a sign that it's wrong if it did not work out." So I told her, "I do not feel like doing it anymore, it makes me angry, makes me tired, makes me nervous, stressed out." [...] (Participant 14, female, 53 years).

Adaptation was also identified in the way participants perceived care, recognizing that it is a consequence of their decisions and attitudes and those food choices can be managed by a constant self-perception:

> I think that the one thing that struck me the most was that we have to take care of ourselves, that every person in the group will live each one in each house and if each one does not follow and talk like this' ah I went there and I did it, but now I do not want to do it anymore ", it did not help anything, like it was three months that came, but it was like making one of these miracle diets. So, I think what has struck me the most was the learning, learning that a follow up is: either you will do it for your whole life or you will learn and practice because otherwise you will not solve anything (Participant 1, female, 52 years).

Furthermore, it was verified that transformation was a product of continuous reflections carried out by the participants themselves, who went through an internal negotiation and caused changes in the way they deal with food choices, including social events and cooking:

> Nowadays it has changed, if I'm at a party and there's cake I eat it, anyway, I see now that I can eat everything, but I do not have to eat everything. I used to eat everything, the party was only mine, just for me ((laughs)). I liked the way of seasoning, I liked the way to mix white rice with black rice or with grains, with seeds, all these mixes it's so easy. In the salad, my God, I've done each one [...] (Participant 15, female, 47 years).

DISCUSSION

The findings in this study indicate that the participants have achieved changes in self-perception, information and knowledge, personal ability and attitude, and that they have actively adapted towards their choices, shaping the elements.

It was observed that changes in self-perception, regarding health and nutritional care, were consequences of an internal dialogue between participants and the objects, health and diet, in which they established a new bond with these objects.[20,24] In this dialogue, the discovery of difficulties related to changes and their reasons, promoted by the democratic communication, intrinsic to OG, was found[20] and fostered self-perception from the comparison between food practices. In the self-confidence change, the found sense of ability relates to self-efficacy, which is established as the individual's opinion about his/her own ability to take care or strength to maintain changes in food practices and/or to achieve new ones. The trust attributed to group recollection, weight loss and the professional is implicated in the belief for change.[25,26]. Given that self-confidence is not inherent,[25] it is said that it was provided by the groups, in which participants elaborated new meanings for their abilities and aspirations, enabling nutritional adherence.[26,27]

The change in self-perception belongs to empowerment,[24] since the sense of control over health and food choices is conditioned by the individual's perception of care, difficulties, capacities and the sense of change for these aspects. This perception is linked to beliefs and values that are influenced by affective and cognitive dimensions.[28]

Therefore, it is pointed out that empowerment for food issues starts with self-perception, given that individuals make their choices according to what they think and feel about their health care and diet.

The change found in information and knowledge appropriation is in agreement with evaluations of nutritional interventions, as verified in the review by Perry et al.[25] and of FNE groups,[29] which show that appropriation interferes in the decision for food acquisition and cooking. In this study, it is highlighted the knowledge production made by participants from the reflection of their realities, triggered by possibilities of constructions emerged in the groups, which enabled the transformation of existing knowledge into dietary changes.

Findings linked with determinant awareness, both individual and environmental, are related to personal expectations, experiences and preferences, as well as social norms, purchasing power and food supply status.[30,31] The barrier in relation to acquiring healthy foods, such as fruits and vegetables, has also been found in studies in the USA, the UK and Australia.[31] Lindemann et al.[32] suggest that this is a consequence of nutritional recommendations of PHC professionals, which are generally restrictive. However, it is argued that participants formed their knowledge not only through the FNE groups, but also by living in other social environments, which may have different references. It is assumed that the awareness promoted discoveries in motivations of previously unconscious food choices in participants, invigorating their decisions and strengths related to control.[33] It is understood that changes in information and knowledge belongs to empowerment, because it produces more informed and conscious decisions,[15] amplifying the individual's capacity to deal with the determinants network.[33]

Regarding change in personal ability, it was verified the deconstruction of diets with food restrictions representation and the construction of capacity for recommendation of a support network, according to needs. This change implies empowerment, since the ability to identify and analyze needs and direct care is the result of a capacity building process.[34] The critical sense of information, although not very noticeable, is important since the current existence of circulating information on nutrition can induce food choices and keep individuals away from healthy diets.[30,31]

In attitude change related to food practices, it was found that the groups increased participants' interest in learning how to prepare food and in developing culinary skills and the pleasure for cooking, preparing and sharing meals.[25] Increased consumption of fruits and vegetables is reinforced by other FNE experience,[35] indicating a salient change in individuals exposed to actions. It was observed that the approach of routine dietary practices, especially related to culinary aspects, was propitious because it caused an increase in the consumption of shared foods in the groups. This was a consequence of the food experimentation with the valorization of positive aspects, which intervened in the participants' dietary memory and generated changes, as explained by Robinson et al.[36] Moreover, the conception of a multiplier agent, also found in others intervention studies,[24,29] reinforces the importance of groups promoting empowerment, since the sense of expansion from the individual to the community was clear.

Nevertheless, it is revealed that the connection between positive change in attitude and empowerment is not unidirectional, reciprocal or even existent.[16] Researchers argue that perceptions of healthy diet vary considerably because they relate to individual experiences, and that, therefore, results of empowerment may differ from the recommendations advocated in the action.[14,16] Consequently, the finding of food deprivation can be interpreted as an informed and conscious choice, even though it has not been encouraged in the groups. However, understanding food as an element of care humanization assumes that its improvement is related to the individual capacity and feeling of freedom of choice as an essential element of life, that is, with empowerment.

Thus, the elements that contribute to empowerment in food choices have been identified: self-perception, information and knowledge, personal ability and attitude - as they demonstrated, within a network, the expansion of individuals' capacity to think and act critically[14] towards food choices. These have shown that empowerment fortifies

personal identity as an autonomous subject of food choices, reinforcing it as a special ingredient of the autonomy in question.

With regard to active adaptation towards food choices, it was verified that the findings related to the confrontation of choice determinants and accountability for care are in line with evidence of empowerment and autonomy in health.[10,14,15,33,37] The first, directed to the individual determinants, shows that by transforming the environment participants also modify it, and by doing so, modify themselves.[20] The second, points out that once they understood the responsibility involved with their choices, they took an active attitude in care, paying attention to consequences of their decisions. It is shown that when individuals take responsibility for their care, they become more capable of acting critically and decisively, in addition to developing preventive health practices.[28,38]

It is worth noting the internal negotiation, since there was a continuous internal dialogue between participants and objects, in which they conquer and adjust forms to organize their food practices. In OG theory, this negotiation is established with active learning within an adaptation to reality.[20] In the participants' reality, there are social events, which are known to offer differentiated meals from daily meals, which are seen, by individuals with chronic diseases, as obstacles to a healthy diet.[39] It was inquired that participants, from the internal dialogue, learned that social events are part of this healthy diet given thoughtful and responsible choices, which were constructed according to their experiences, judgments and involvement.[11] Individuals, in thinking, feeling and practicing their food choices, are supposed to develop as human beings, by actively adapting to their means and improving their perceptions, knowledge, skills and attitudes towards food choices. Thus, the elements that contribute to the autonomy in food choices, identified by active adaptation, were: confrontation of determinants, accountability and internal negotiation.

Given that changes occurred at different intensities and were influenced by participants and groups singularities it is pointed out that the identified elements are neither linear nor consistent, but indicate possibilities of evaluation and, consequently, of consolidation of FNE groups. Thus, it is congruent to suggest the use of these elements when planning and implementing groups that aim at this goal, especially for those with chronic diseases related to food and nutrition because, according to Entwistle et al.[11] the autonomy in health in the existence of disease is impaired by social norms and practices.

It is claimed that the theoretical references adopted for the groups were complementary to the achievement of its goal, through the attribution of qualitative, participatory, active and problematizing approaches to educational and evaluation methods, corroborating the recommendations of Brazilian public policies and with the statement by Murimi et al.[4] on the effectiveness of actions based on theories and with a defined objective. It is emphasized the insertion of the appreciation of the act of eating, interpersonal relations and lifestyles of healthy diet, which has been used in the Brazilian and international context to health promotion.[1,2]

From the perspective of social representations, it was expressed that the experience in the groups enabled the participants to produce new senses and meanings about health care, capacity for change, as well as their relationship with diet, eating and food choices. This production took place in scenarios where thinking, feeling and practicing food choices existed, by recalling past food experiences, collectively discussed in the present and projected to a future of well-being and personal fulfillment, generating more thoughtful, responsible and shared choices.

Some limitations need to be considered. The groups and the interviews were conducted by the same researcher, which could cause interference in findings, however, the minimization of this effect was sought. And the time of the study due to the continuation of the groups was not considered in the design of the study, weakening the understanding of the phenomenon in the long term.

CONCLUSION

The elements of empowerment were identified, which signal individual actions to think and act critically towards their food choices. The autonomy in food choices was evidenced by the confrontation of the determinants, by the accountability for care and by internal negotiation, which demonstrate the continuation, post-nutritional intervention, of the reflecting act of individuals about their realities and possibilities of dietary changes. It was verified that autonomy in food choices causes negotiations, adjustments, decisions and actions in individuals, reinforcing the empowerment. The elements can compose the evaluation of FNE actions that seek the promotion of autonomy, direct the planning and implementation of FNE groups in the PHC and support the monitoring of participatory, humanized and comprehensive forms of care, as advocated by the health promotion.

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Contributors

Vincha KRR participated in the conception and design of the study, in the production, analysis and interpretation of data and in the writing of the manuscript; Santos BZB and Vivi Vieira VL contributed to the analysis and interpretation of the data; Cervato-Mancuso AM participated in the conception and design of the study, in the critical review and in the approval of the final version to be published.

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