

Conceptual model: Predictors of entrepreneurial motivation among students – the role of entrepreneurship education

“Active measures to increase the participation in entrepreneurship in tertiary education of disadvantaged students Antre_S”, POCU project / 379/6/21/124388

Abstract

This study proposes a model in which the entrepreneurial knowledge base and skills are antecedents of entrepreneurial motivation among students. In addition, it is proposed that entrepreneurship education have a moderating effect on the relationships described in the model. That is, the effect of entrepreneurial knowledge bases and skills on entrepreneurial motivation is greater for students with an entrepreneurial education.

Keywords: Predictors, entrepreneurial motivation, entrepreneurship education

1. Introduction

In order to prepare students for entrepreneurship, it is necessary to evaluate the factors that give rise to entrepreneurial behavior. According to Locke (2000) [33], "entrepreneurship is the result of integrating cognitive factors (knowledge and skills) with motivational factors". Thus, if entrepreneurship education aims to contribute to the growth of entrepreneurship, it should promote the acquisition and / or strengthening of students' knowledge and skills and motivate them to take entrepreneurial action [1,2, 33].

Entrepreneurship education should stimulate the development of the knowledge base (ie knowledge in business management) and entrepreneurial skills (ie behavioral traits and skills), thus creating value for students and encouraging more competent entrepreneurs who are able to cope with complexity, disruption and uncertainty of entrepreneurial environments [34]. Mitchelmore and Rowley (2010) [35] also state that competent entrepreneurs “have a good chance of choosing the best business opportunities; they can better manage their business

strategically; have the capacity to undertake high quality actions”. However, in the preparation of students it is also necessary to motivate them to participate in entrepreneurial actions [2, 3, 34, 35].

Understanding the factors that motivate individuals to take entrepreneurial action is a prerequisite for a comprehensive understanding of the entrepreneurial process. Motivation helps to describe the process that drives individuals to engage in entrepreneurship. Moreover, it is vital to discover the motivational factors of entrepreneurial behavior so that, in their sphere of influence, decision makers can propose more effective programs to support and promote successful entrepreneurship [2, 9, 36].

An approach focused solely on the acquisition of knowledge is not enough to provide the attributes needed for long-term success. This involves educating / learning students beyond conventional boundaries; that is, at the same time as the transfer of knowledge, it is imperative that we provide students with entrepreneurial skills [2, 3, 7, 9, 23, 30, 35, 39, 40, 41].

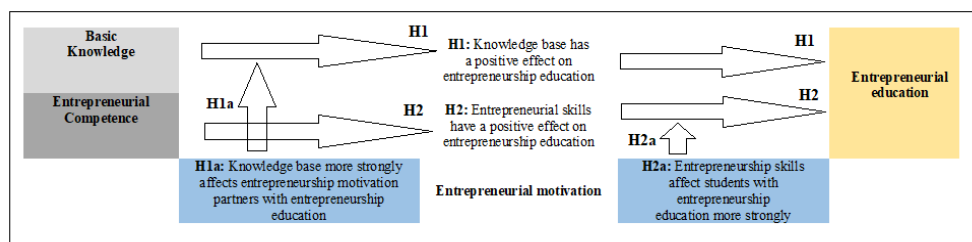


Figure 1. Predictors of entrepreneurial motivation among students: the role of entrepreneurial education (adapted from [2])

2. Research method

Entrepreneurship education is relevant because it stimulates economic and social development. In this sense, the three universities involved in the project try to highlight the role of entrepreneurship education by presenting themselves as active agents that contribute to the economic and social development of the three regions they represent (North-East, South-East and West). In contrast, entrepreneurship education is also important because the complexity of the entrepreneurial phenomenon requires specific skills on the part of the entrepreneur. Entrepreneurs often face many extremely demanding challenges and therefore need to have certain skills that will enable them to succeed in entrepreneurial activities. Entrepreneurship has a different profile than other professional activities and therefore entrepreneurs need specific traits for this particular type of activity [2, 3, 4, 30].

Questionnaires related to this study "Proposal, development and evaluation of a complementary entrepreneurial program at three universities with objectives and topics specific to undergraduate specializations developed with innovative methods such as tutoring, coaching, occupational simulation, online communities, etc." within the POCU project / 379/6/21/124388 entitled "Active measures to increase the participation in entrepreneurship in tertiary education of disadvantaged students *Antre_S*", focused on three main phases, corresponding to quantitative (phase 1) and qualitative approaches (phases 2 and 3). The questionnaires were applied to a sample of 35 students from four different universities, located in the western part of Romania, namely:

- Banat's University of Agricultural Sciences and Veterinary Medicine "*King Michael I of Romania*" from Timișoara
- Polytechnic University of Timișoara (UPT);
- "*Victor Babeș*" University of Medicine and Pharmacy from Timișoara (UMFT);
- West University of Timișoara (UVT).

The questionnaires were anonymous, requesting only useful data in processing (level of education, scientific field, etc.). The questionnaire was then divided into three parts with the questions below.

Empirical research involves a combination of quantitative (phase 1) and qualitative (phase 2 and phase 3) approaches.

In the first part, it was set out to identify on a larger scale the impact of knowledge base and entrepreneurship skills on the motivation to become an entrepreneur. This phase involves the development of a survey questionnaire, to be applied to university students taking level 5 courses (year IV) in the academic year 2020-2021. The analysis of the obtained data was performed on the basis of 35 surveyed subjects. For a more realistic assessment with a high truth index, the questionnaire was anonymous.

Sample profile: Respondents are undergraduate students (level 5), but there is a 6% percentage of level 6 students. Respondents are from various fields of study: science and engineering, life sciences, health, natural and environmental sciences.

Evaluation. The evaluations in the questionnaire were based on previous research and used the five-point Likert scale, ranging from 1 - "very poor" to 5 - "very good" and from 1 - "strongly disagree" to 5 - "strongly agree". Also, the knowledge base was measured on a five-point Likert scale (from 1 - "very poor" to 5 - "very good"), and the scale of 1 was used to measure entrepreneurial motivation. Moreover, the questionnaire included questions on entrepreneurship education courses.

The qualitative approach developed in phases 2 and 3 aimed at achieving a better understanding of the quantitative results obtained in phase 1, in order to establish how the results obtained in phase 1 can be corroborated with the proposed interviews. The interviews were applied to small groups, and the selection of interviewees was based on the following criteria:

- students must be from the three universities in the undergraduate courses (level 5);
- students who already have a business;
- students with ongoing projects or business ideas;
- students who participated in phase 1 of the study.

Phase 1. A. General sample profile

For the first phase of the evaluation of the complementary entrepreneurial program, developed with innovative methods such as tutoring, coaching, operational simulation and online communities, the data of the respondents related to gender, age, level of education, scientific field followed, which represented the general profile of the sample, in compliance with GDPR rules. Also in this phase

were assessed the general basic knowledge, entrepreneurial skills, entrepreneurial motivation, entrepreneurial knowledge base, entrepreneurial motivation for personal development, establishing the level of entrepreneurial competence, and the construction of the "item" in the part of measuring characteristics of the entrepreneurial level, respectively the business area pursued, the current situation, the previous experience, the area of residence and the geographical location, including here the possibility of the existence of disadvantaged people, who were grouped in the profile of the interviewed persons.

In the sample used for this assessment, about a quarter were males (23%) and three quarters were females (77%), most of them under the age of 24 (97%).

The level of education is largely correlated with the age of the respondents, only 6% of the respondents being from the second cycle of studies (master), while 94% were students from the first cycle of undergraduate.

In terms of science, there is a relatively balanced distribution between the fields of life and health sciences (46%), natural and environmental sciences (28%) and exact sciences and engineering (26%), while economics and management have no were represented.

B. Measurement characteristics

Most respondents indicated average and good basic knowledge (34% and 37%), but there is also a proportion of 14% who say they have poor basic knowledge, while 6% have very good basic knowledge. In the area of entrepreneurial skills and entrepreneurial motivation, the distribution of answers was similar, with percentages of 37/29% and, respectively, 46/26% for agreement / strong agreement.

The knowledge base by entrepreneurial areas presented a varied distribution depending on the entrepreneurial field in question, these being mainly the following: Corporate strategy; 2. Marketing; 3. Finance; 4. Human resources; 5. Specific legislation; 6. Accounting; 7. Business ethics

Respondents had the opportunity to choose an answer on the importance of these areas, a response quantified by "NI" -not-important, "PI" -little important, "MI" -middle important, "I" -important and "FI" -very important.

Regarding the corporate strategy, most respondents considered it to be unimportant (36% and 37%), while the marketing part was rated as important (37%) and very important (17%). Finance and human resources were considered by respondents to be of medium importance (40% and 46%, respectively), although 34% of respondents considered human resources to be important and 37% of respondents considered finance as being of lesser importance. On the other hand, the specific legislation is of great importance for the respondents (57%), but also the aspects related to accounting (48% important and 17% very important). The last aspect of this question, related to business ethics, is of less importance for respondents (37%).

To the question related to the entrepreneurial motivation (in personal development), evaluated at the five levels, the following aspects were followed: 1. It allows my personal growth; 2. It allows me to prove that I can succeed; 3. Allow my personal fulfillment; 4. It allows me to face challenges; 5. Allows me to obtain monetary compensation on the basis of merit; 6. It allows me to gain economic wealth; 7. It allows to increase the profit opportunities; 8. It allows me to live a comfortable life; 9. It helps me increase my personal income; 10. Allows me to obtain public recognition; 11. It allows me to be free; 12. It allows me to have independence; 13. Allow me to be my own boss; 14. It allows me to have the power to make decisions; 15. It allows me to have authority; 16. Allows me to choose my own tasks; 17. Allows me to participate in the whole decision-making process; 18. It allows me to ensure a secure future for the family; 19. It allows me to be close to family; 20. Allows increased funding for retirement.

Very important in terms of answering this question were the aspects of being able to demonstrate that you can be successful, to meet the challenges, to help increase your personal income and to be your own boss, with the following proportions: 63%, 63%, 66%, 57% and 80%, respectively. It was also considered important to allow personal fulfillment, to gain economic wealth, to increase profit opportunities, to lead a comfortable life, to have the power to make decisions, to allow to have authority and to ensure a secure future for the family, with the following proportions of answers: 60%, 68%, 54%, 77%, 54%, 71% and 68%, respectively.

On the other hand, the aspects of allowing monetary compensation to be obtained on the basis of merit,

allowing it to obtain public recognition, allowing it to be free, allowing it to be independent, allowing it to choose its own tasks, allowing to participate in the whole decision-making process, to allow to be close to the family and to allow an increased financing for retirement were considered as insignificant or at most of medium importance, with percentages for the evaluation “MI”/“I” of 54/6%, 23/46%, 40/17%, 49/23%, 54/14%, 71/3%, 40/40% and 20/43%, respectively.

Another question in this phase was to establish the level of entrepreneurial competence, being evaluated at the mentioned levels the following aspects: 1. Identify the goods or services that customers want; 2. Unmet consumer needs; 3. Actively look for products or services that offer real benefits to customers; 4. Take advantage of high quality business opportunities; 5. Develop long-term trusting relationships with others; 6. Negotiate with others / Interact with others; 7. Maintain a personal network of work contacts; 8. Understand what others mean by their words and actions; 9. Communicate effectively with others; 10. Apply ideas, problems, and observations in alternative contexts (integrate ideas, problems, and observations into more general contexts); 11. Reasonable risks related to the workplace; 12. Monitor progress towards goals in risky actions; 13. Look at old issues in new ways; 14. Explore new ideas; 15. Treat new issues as opportunities; 16 Plan your business operations; 17. Plan the organization of different resources; 18. Keep your organization running.

Maximum percentages for “very important” and “important” responses were obtained for most aspects analyzed, such as identifying goods or services that customers want, unmet consumer needs, actively searching for products or services that provide real benefits to customers, take advantage of high quality business opportunities, develop long-term trusting relationships with others, negotiate / interact with others, maintain a personal network of work contacts, understand what others mean by words and actions communicate effectively with others, apply ideas, problems, and observations in alternative contexts (integrate ideas, problems, and observations into more general contexts), look at old problems in new ways, plan business operations, maintain functional organization, which “FI” / “I” percentages were 34/46%, 26/46%, 9/71%, 34/40%, 11/60%, 29/60%, 54/37%, 66/20 %, 17/63%, 0/60%, 14/46% , 9/48% and 26/48%, respectively. The following aspects related to assessing reasonable

occupational risks, monitoring progress towards goals in risky actions, exploring new ideas, treating new issues as opportunities, planning the organization of various resources were considered to be of medium or even minor importance, for which the percentages “MI” / “PI” were 57/11%, 40/20%, 43/26%, 37/23% and, respectively, 63/14%.

The question related to the construction of the personal “item” was evaluated on the aspects mentioned below on the same scale of answers: 1. Task coordination; 2. Supervise subordinates; 3. Organize people; 4. Motivate people; 5. Delegate effectively; 6. Determine long-term issues or opportunities; 7. Be aware of the projected directions of the industry and how the changes could affect the company; 8. Prioritize work in accordance with business objectives; 9. Redesign the department and/or organization to better meet long-term goals and changes; 10. Align current actions with strategic objectives; 11. Assessing and linking short-term, day-to-day tasks in the context of long-term direction; 12. Monitor progress towards strategic objectives; 13. Evaluate the results according to the strategic objectives; 14. Determine strategic actions by weighing costs and benefits; 15. Dedicate yourself to making the operation work whenever possible; 16. Refuses to fail the operation whenever necessary; 17. Put an extremely strong indoor unit; 18. Commit to long-term business goals.

Most of the issues discussed in this question, which were considered important (“I”) and very important (“FI”) by the respondents were task coordination, supervising subordinates, organizing people, motivating people, determining problems or opportunities on long-term, awareness of the projected directions of the industry and how changes could affect the company, monitoring progress towards strategic objectives, evaluating results according to strategic objectives, determining strategic actions by weighing costs and benefits, refusing to let go succeed the operation whenever necessary, extremely strong internal unity and commitment to long-term business objectives, with percentages of answers “FI” / “I” of 3/51%, 20/57%, 29/51% , 46/46%, 11/57%, 37/20%, 17/40%, 0/54%, 8/46%, 11/31% (but also 23/29% for “MI” and “PI”), 40/34% and 17/46%, respectively. Less favorable responses were recorded only to issues related to effective delegation, prioritization of work in line with business objectives, redesign of the department and / or organization to better meet long-term goals and changes, alignment of current actions with

strategic objectives, evaluation and short-term, day-to-day tasks, in the context of long-term direction, dedication to making the operation work whenever possible, with 46/8% percentages for “MI” / “PI” responses, 57/6%, 40/20%, 40/34%, 57/23% and 63/6%, respectively.

C. Profile of interviewees

The profile of the interviewees was divided into six directions related to the expected business area, the current situation regarding entrepreneurship, previous experience, area of residence / entrepreneurship, geographical location, but also belonging to a group of disadvantaged people. The answers were varied, so that 53% of the respondents chose the business area related to communication and only 34% that of engineering and technology. On the other hand, the majority of respondents answered that they would present a project in development (94%), but the previous experience would be based more on engineering and technology (78%), only 16% on communication sciences. There is a fairly balanced distribution in terms of area of residence / entrepreneurship area (54% urban and 46% rural), and the chosen geographical location is in the west (57%) or southwest (34%). Regarding the existence of disadvantaged people in the sample that responded to the request to complete the questionnaire, only 6% were part of the group of national minorities.

Phase 2. D. Selection of interviewees

For the set of questions related to the selection of the interviewees, with which they entered the second phase of the evaluation, the selection criteria were considered - students must be from universities undergraduate / master courses (USAMVBT, UPT, UMFT and UVT), those who already have a business, or are with ongoing projects / business ideas, if they have participated in phase 1 of the study, respectively questions if certain traditional courses from various fields are decisive in motivating students to develop an entrepreneurship, the intentions of entrepreneurship may be influenced by exogenous factors such as traits and situational variables, the entrepreneurial intentions of students depend on the field in certain crises focus on developing the entrepreneurial skills and competencies needed to run a business successful entrepreneurship, if entrepreneurship education should not stimulate certain aspects related to

entrepreneurship, if entrepreneurship programs implemented in universities involve the achievement of differences between entrepreneurship learning or entrepreneurship education, respectively if it would be necessary to introduce psychological disciplines.

For the selection criteria of the interviewed persons, a significant share was represented by the respondents of the Banat's University of Agricultural Sciences and Veterinary Medicine “*King Michael I of Romania*” from Timișoara (USAMVBT, 57%), followed by the Polytechnic University of Timișoara (UPT, 23 %), respectively with a lower share of the West University of Timișoara (11%), respectively the “*Victor Babeș*” University of Medicine and Pharmacy of Timișoara (9%).

The following traditional courses were considered decisive in motivating students to develop an entrepreneurial action: corporate strategy (54%), marketing (94%), finance (66%), human resources (60%), business ethics (69%), online communication platforms (91%), but also other business courses (80%), while commercial law and accounting were rather unimportant to respondents (74% and 66%, respectively, negative answer).

As to whether the intentions of entrepreneurial actions can be influenced by exogenous factors such as traits and situational variables, the answers were mostly affirmative only for the risk of entrepreneurial actions and discussions that make students think "twice" before to start a business (63% and 91%, respectively). In all other cases, the answers were negative: insisting on understanding entrepreneurial barriers, such as the personality traits of potential entrepreneurs - students.

For the question related to the entrepreneurial intentions of students - depending on the field in certain crises, the answers were mostly affirmative only for health (pandemics, eg COVID-19) and food security / safety (food crisis), where it would be necessary with laboratories testing and research, respectively control of compositions and additives (54% and 74%, respectively, [Figures 1b](#) and [1c](#)). In all other cases, the answers were mostly negative: global economic crises, energy crises (eg oil crisis), or climate change - an increasing risk factor for ecosystems, human health, with mostly negative responses of 89%, 63% and 74%, respectively ([Figures 1a](#), [1d](#) and [1e](#)).

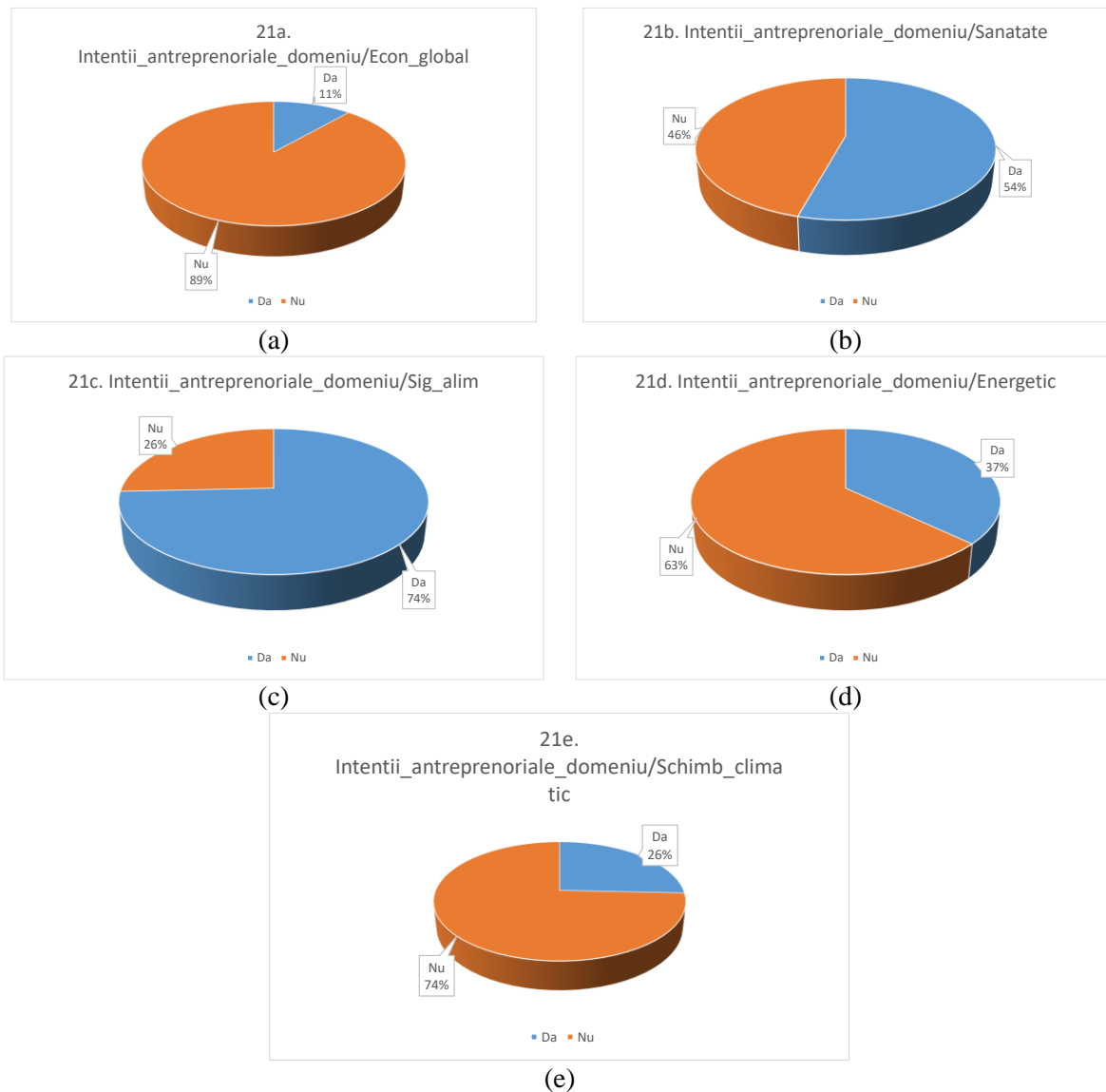


Figure 1. Distribution of responsibility for students' entrepreneurial intentions - field function in certain crises such as: global economic (a), health (pandemics, eg COVID-19, with Laboratory testing and research) (b), food security / safety (food crisis) (Control of compositions and additives) (c), energy (eg oil crisis) (development of green energy - solar, wind) (d), or climate change - an increasing risk factor for ecosystems, human health

As a current model of entrepreneurship education, it should have in particular an approach focused on creating business projects (business plan, etc.) (77%), but not a model of a taught / learned approach - a convenient approach, both for teachers and students or focused on self-management of business/career courses (negative response rates of 91% and 69%, respectively).

In terms of entrepreneurship education, which should focus on developing the entrepreneurial skills and competencies needed to carry out a successful entrepreneurial activity, leadership, identifying

opportunities, creativity, negotiating and creating new business and entrepreneurship in organizations were the most with positive response rates of 51%, 95%, 63%, 74% and 62%, respectively, while analytical skills and the creation of new individual businesses and entrepreneurship were rather negatively answers of 66% and 63%, respectively.

The last three questions in this second phase of the evaluation based on the questionnaire were related to entrepreneurship education, entrepreneurial programs implemented in universities, and the need to introduce psychological disciplines.

Entrepreneurial education was considered not to stimulate the development of “new” business projects (simple business plans, non-functional) - 63%, but should be relevant in the daily activity in the “entrepreneurial reality” - 86% positive answers. On the other hand, entrepreneurship programs implemented in universities should not involve the difference between learning through entrepreneurship - 74%, but rather through education through entrepreneurship (focuses on developing entrepreneurial skills and encouraging students' entrepreneurial intent) - 77% “Yes” response rate. Finally, the profile of the answers regarding the need to introduce some psychological disciplines is quite balanced, with 57% answers “Yes” and 43% answers “No”.

Phase 3.

The third phase of the evaluation included three main questions, all addressing several issues regarding the importance of objectives for the development of entrepreneurial skills for Antre_S students, topics considered relevant for the development of entrepreneurial skills for Antre_S students, and innovative methods considered to help develop entrepreneurial skills.

Thus, the importance of the objectives for the development of entrepreneurial skills for Antre_S students was assessed for the following aspects, using the same levels of appreciation: developing entrepreneurial skills for students who intend to start a business; developing the skills to transform business ideas into concrete actions; providing all the information related to the business environment and the existing opportunities; elaboration of a business plan and its implementation; running and developing a successful business; acquiring entrepreneurial skills; leadership attitudes and awareness of the ethical values that underpin leadership behaviors; authentic management style.

Positive responses were obtained especially for the development of entrepreneurial skills for students intending to start a business, the development of skills to turn business ideas into concrete actions, the provision of all information about the business environment and existing opportunities, the acquisition of entrepreneurial skills, attitudes leadership and awareness of ethical values that support leadership behaviors, respectively authentic management style, with percentages of “FI” / “I” of 71/23%, 17/51%, 77/23%, 26/54%, 37/43% and 40/34%, respectively, while mostly “MI” or “PI”

answers (medium or minor importance) were obtained for the elaboration of a business plan and its implementation or the development and development of a business, successful, with percentages for “MI” / “PI” answers of 60/6% and 37/23%.

The question on the topics considered relevant for the development of entrepreneurial skills for Antre_S students had several directions of evaluation, namely: starting a business, business documentation, business ethics; consumer behavior, marketing planning; sales techniques, efficient negotiation techniques; financial indicators, management accounting and cost calculation; life cycle of the organization, organizational culture, quality management systems; human resources planning, selection and recruitment; drawing up, signing and terminating the employment contract; the reward system and the evaluation of the employees' performance; investment management; methods and techniques in project management; creativity and innovation; time management; efficient meeting management; effective decision-making techniques, personal style and marketing.

The most favorable aspects were consumer behavior, marketing planning, sales techniques, efficient negotiation techniques, financial indicators, management accounting and costing, life cycle of the organization, planning, selection and recruitment of human resources, preparation, signing and termination of the employment contract, reward system and evaluation of employee performance, investment management, methods and techniques in project management, creativity and innovation, time management, efficient meeting management, efficient decision-making techniques, respectively personal style and marketing, with percentages for the answers “FI” / “I” of 34/37%, 28/40%, 74/14%, 43/31%, 20/66%, 46/40%, 40/40%, 28/43%, 74/17%, 86/14%, 60/31%, 31/23% and 40/51%, respectively, and the least favorable aspects were starting a business, business documentation, business ethics and organizational culture, quality management systems with percentages of “MI” / “PI” answers of 43/9% and 46/14%.

The question regarding the innovative methods considered to help the development of entrepreneurial skills was followed by several aspects: lecture; the type of tutoring; project-based teaching; practical / computer work; trips to specialized companies; coaching; occupational simulation; online communities.

Figures 2a-2h show the distribution of affirmative or negative answers for each of the aspects mentioned above. The most appreciated such aspects were those of practical or laboratory works, with a share of the answers “FI” and “I” of 43% and 46%, of trips to specialized companies (51% and 29%), of coaching (26% and 54%), respectively online communities

(29% and 28%) (Figures 2d, 2e, 2f and 2h). On the other hand, there were aspects less appreciated by the respondents, such as lecture, tutoring, project-based teaching or occupational stimulation, with weights of “MI” / “PI” answers of 37/37%, 43/3%, 40/40% and 54/31%, respectively (Figures 2a, 2b, 2c and 2g).

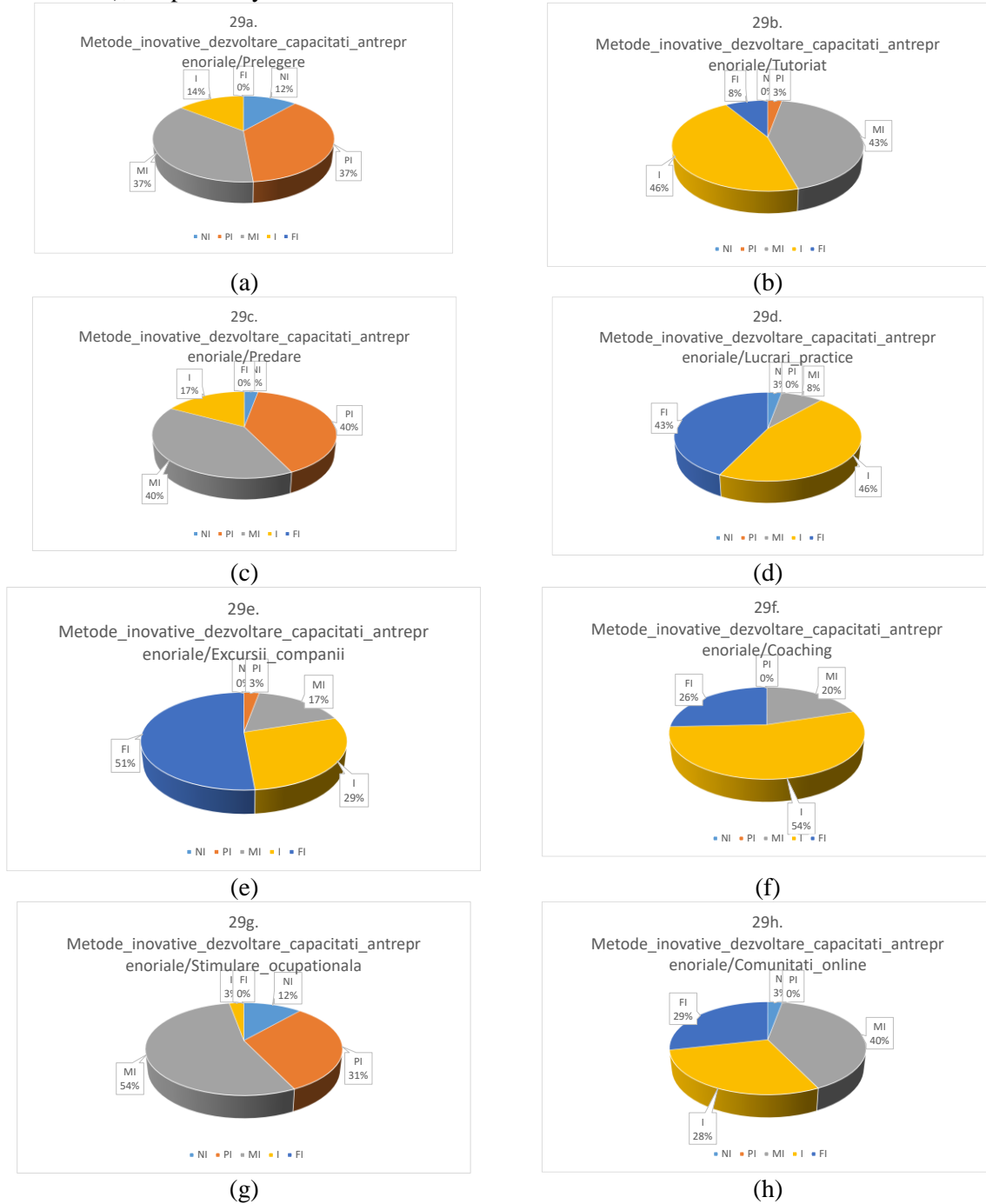


Figure 2. Distribution of response on innovative methods considered to help develop entrepreneurial skills, after: lecture (a), type of tutoring (b), project-based teaching (c), practical / computer work (d), trips to companies in profile companies (e), such as coaching (f), through occupational stimulation (g) and through online communities (h)

Conclusions

Following the analysis of the data obtained on the basis of a questionnaire regarding the development and evaluation of a complementary entrepreneurial program with objectives and themes specific to undergraduate specializations, developed with innovative methods such as tutoring, coaching, occupational simulation, online communities, and other specific methods, the following main conclusions can be drawn:

- The data obtained after completing the questionnaires regarding the development and evaluation of a complementary entrepreneurial program were analyzed for a number of 35 respondents with a distribution of about half from USAMVBT, a quarter from UPT and the other quarter from UVT and UMFT, with a balanced distribution in terms of gender, respectively a significant percentage of respondents from the undergraduate cycle in various fields specific to the universities involved;
- Most respondents specified that they have entrepreneurial knowledge, entrepreneurial motivation, the most important aspects in this regard being the specific legislation and accounting;
- Entrepreneurial motivation is mainly related to personal growth, success, challenges, income, or the ability to be your own boss, while the level of entrepreneurial competence is mainly determined by maintaining a personal network of work contacts or understanding what others mean by their words and actions, and for the construction of the personal “item” the most important aspects are related to the motivation of the people and an extremely strong internal unity;
- Traditional courses in marketing, finance or online platforms are considered crucial in motivating students to develop an entrepreneurial action, and the entrepreneurial intentions of students depending on the field in certain crises have been most indicated for health (pandemics) and food security / safety;
- Entrepreneurship education should focus on developing the entrepreneurial skills and competencies needed to carry out a successful entrepreneurial activity, leadership, identifying opportunities, creativity, negotiation and creating

new business and entrepreneurship in organizations;

- The aspects regarding the importance of the objectives for the development of entrepreneurial capacities, of the topics considered relevant for the development of entrepreneurial capacities for Antre_S students, respectively of the innovative methods considered to help the development of entrepreneurial capacities, were significantly pointed in the direction of business, providing all the information about the business environment and existing opportunities, financial indicators, management accounting and costing, creativity and innovation, time management, or trips to companies.

Compliance with Ethics Requirements. Authors declare that they respect the journal’s ethics requirements. Authors declare that they have no conflict of interest and all procedures involving human or animal subjects (if exist) respect the specific regulation and standards.

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